ADEQUACY OF MONITORING OF INTRAVENOUS FLUIDS IN ELDERLY PATIENTS IN KENYATTA NATIONAL HOSPITAL

by

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DECLARATION

I, hereby, declare that the work contained herein is my original idea and has not been presented at any other university.

Signature .... Date.... 12-11-2010

APPROVAL BY SUPERVISORS

This dissertation has been submitted with my approval as a University supervisor.

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DEDICATION

With absolute humility, I am most grateful to Almighty God, without whom nothing is possible and for all the blessings in my life, which are unquantifiable.

I dedicate this dissertation to my family who are my pillars of strength. I draw immeasurable inspiration from my parents, Mr Ben Kenyatta and Mrs Christine Kenyatta for their unwavering support. They have always ensured that I pursue my dreams to get quality education and a healthy balance in all aspects of life.

I also dedicate this dissertation to my brothers, Ken, Steve and Alex who in moments of fatigue reminded me "that life was never meant to be that serious". To all my friends who make life beautiful and memorable, I will forever be indebted.

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ABBREVIATIONS

ADR – Adverse drug reaction

BUN - Blood Urea Nitrogen

Hrs - hours

IV – Intravenous

K.N.H - Kenyatta National Hospital

ml/Kg/day - millilitre per kilogram per day

mmHg - millimetres of mercury

mmol/Kg - millimole per kilogram

mmol/L - milli moles per litre

Mol Wt kD - molecular weight kilo dalton

mOsm/L - milli osmoles per litre

Na – Sodium

NBM - Nil by Mouth

NCEPOD - National Centre of Enquiry into Peri-operative Deaths

NPSA- National Patient Safety Agency

SID - Strong Ion Difference

SPSS - Statistical Package for the Social Sciences

UEC- Urea Electrolytes Creatinine

U.K - United Kingdom

$<$ - less than

$>$ - greater than

$\geq$ - equal or greater than

DEFINITION OF TERMS

Elderly- For purposes of this study, elderly refers to adults 50 years and above.

IV fluids - This refers to fluids introduced directly to the vein via an intravenous access device to correct fluid and electrolyte imbalance. It does not include solutions for total parenteral nutrition.

Dilutional hyponatremia – A lower than normal concentration of sodium in the blood (< 135mmol/ L) caused by inadequate excretion of water or by excessive water in the circulating bloodstream.

ABSTRACT

Background

Iatrogenic problems arising from inappropriate IV fluid therapy can increase morbidity and prolong hospital stay. Among those at risk, are the elderly patients as they have a high burden of cardio respiratory and renal diseases. Volumes and types of IV fluids will vary depending on the clinical scenario. Therefore, monitoring of fluid balance parameters is crucial and should remain consistent regardless of the clinical indications for IV fluids. Research has revealed gaps in the monitoring of fluid balance among the elderly patients.

Objective

The study thus aimed to establish if IV fluids were prescribed rationally and to determine if fluid balance was adequately monitored in elderly patients.

Methodology

This was a longitudinal descriptive study. All elderly patients who met the inclusion criteria, between March and July 2010 in Kenyatta National Hospital, were followed up until the day of discharge or death. A universal sample of 150 patients was obtained. The data obtained were entered into a structured data collection form. The data were analyzed using SPSS 12.0 software. Descriptive data analysis was performed on all variables. Exploratory data analysis was done to assess variables for associations and correlations. Multivariate logistic regression was done to control for confounding.

Results

A good majority of the patients (87.3 %) had IV fluids rationally prescribed. About 79.3 % had their baseline UEC determined. The most commonly prescribed IV fluid was Normal saline. The IV fluid most prone to administration errors was Normal saline alternating with 5 % dextrose. About 25 % of the patients either had no prescriptions for IV fluids or had incomplete prescriptions, though they received IV fluids. Weight and fluid charting were the least frequently monitored parameters. In contrast, vital signs and clinical signs and symptoms were the most frequently monitored (98 %). Determination of baseline UEC, duration of hospital stay and duration of IV fluid administration were found to be significantly associated with adequate monitoring. ($P<0.05$)

Conclusion and recommendations

The study found that only 50% of the patients were noted to have had their fluid balance parameters adequately monitored. Lack of clarity of some of the prescriptions may have contributed to errors observed. Redesigning of the IV fluid prescription segment of the treatment sheet will go a long way in ensuring clarity of the prescription. Continuous Medical Education should be encouraged so as to stress the need to give IV fluid prescriptions just as much importance as is given to other medication.

CHAPTER ONE

1.0 INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

Intravenous fluids are broadly classified as crystalloids and colloids. Crystalloids are solutions of small molecules that dissolve completely in water whereas colloids are dispersions of large organic molecules.[1] Based on their mechanism of distribution, crystalloids pass freely between the intravascular and interstitial compartments. Examples include sodium chloride, glucose and Hartmann's solutions. Colloid solutions, depending on their molecular size, structure and permeability of the capillaries, remain in the intravascular compartment and for longer periods than crystalloids.[2]

Colloid solutions used in clinical practice for fluid therapy are divided into the semi synthetic colloids and the naturally occurring human plasma derivatives. Examples of synthetic colloids include gelatin, dextrans, and hydroxyethyl starches (HES). The naturally occurring colloids are human albumin solutions, plasma protein fraction, fresh frozen plasma and immunoglobulin solutions.[3]

IV fluids are used to replace or maintain fluid and electrolytes which can be lost in a wide variety of situations. These include maintaining homeostasis when enteral intake is insufficient and replacing gastrointestinal losses occur due to diarrhoea, vomiting or fistula. Other losses arise from urinary tract (for example diabetes insipidus) or from blood loss due to trauma or surgery. After suffering burns or in episodes of fever, IV fluids are given to match increased insensible losses. IV fluids are used during anaesthesia, surgery or in inflammatory conditions such as sepsis, where there is loss of circulating volume due to vasodilation and leakage of vascular epithelial walls.[1, 4]

Fluid and electrolyte balance is often poorly understood. Iatrogenic problems arising from inappropriate fluid therapy can increase morbidity and prolong hospital stay.[5] When it comes to IV fluids, one size definitely does not fit all. Volumes and types of IV fluids will vary depending on the clinical scenario. It is for this reason that monitoring of fluid balance

parameters is crucial and should remain consistent regardless of the clinical indications for IV fluids.[6] This study focuses on adult patients.

1.2 Literature Review

1.2.1 Basic fluid physiology

Total body water in a 70 kg individual is approximately 42 L (60 % of total body weight). Two thirds of this (28 L) is intracellular water. The remaining third in the extracellular compartment is divided between the intravascular (3 L) and interstitial (11 L) compartments. The cell wall separates the intracellular from extracellular compartments. The intravascular and interstitial compartments are separated by the capillary endothelium and walls of arteries and veins. Water moves freely across membranes that separate the compartments to maintain osmotic equilibrium.[3]

Normally, fluid is gained from a person's food and drink intake while it is lost via urine, sweat and faeces as well as insensible losses via lung and skin. In healthy individuals, volume homeostasis is regulated largely by antidiuretic hormone (ADH) which is released when osmoreceptors and baroreceptors detect small decreases in osmolality and blood pressure. It then elicits a sensation of thirst and reduces renal excretion of water. Renal mechanisms also play a role whereby renin-angiotensin mechanism is activated by falling renal perfusion pressure. However, after injury or during episodes of sepsis or other critical illness, normal homeostatic mechanisms may not work well.

1.2.2 Components of IV fluids

The main solute of crystalloid IV fluids is either glucose or sodium chloride. The solutions may be isotonic, hypotonic or hypertonic with respect to plasma. Potassium, calcium and lactate may be added to more closely replicate the ionic makeup of plasma. The osmolality of blood plasma is about 290 mOsm/litre and this sets the standard. Fluids in the range of 240 to 340 mOsm/litre are considered isotonic. Examples include 0.9 % w/v Sodium chloride, 5 % w/v dextrose and Hartmann's solution. Those with tonicity above 340 mOsm/litre are hypertonic while those below 240 mOsm/litre are hypotonic. Crystalloids with an ionic composition close to that of plasma may be referred to as "balanced" or "physiological" fluid.[3, 7]

Most colloid solutions have the colloidal molecules dissolved in isotonic saline but isotonic glucose, hypertonic saline and isotonic balanced electrolyte solutions are also used. Their molecular size can be highly variable. Many modern colloidal solutions are based on hydroxyethyl starches which have high molecular weights and can provide volume expansion for 6-24 hrs. There are well recognized and documented differences in the pharmacokinetic properties of colloids.[8] However, a 2007 meta-analysis failed to show any difference in clinical outcome between different types of colloids.[9] Table 1.1 summarizes the various types and composition of IV fluids.

This study focuses on crystalloid IV fluids. A recently updated Cochrane meta-analysis and a subsequent SAFE study showed no difference in mortality between patients treated with colloids and those treated with crystalloids for fluid resuscitation.[10, 11]

Table 1.1: Typical properties of commonly used intravenous fluids

Type of fluid	Sodium mmol/L	Potassium mmol/L	Chloride mmol/L	Osmolality mOsm/L	Weight average Mol Wt Kd	Plasma volume expansion duration Hrs
Plasma	136-145	3.5-5.0	98-105	280-300	-	-
Dextrose 5 % w/v	0	0	0	278	-	-
Dextrose (4 % w/v) and saline (0.18 % w/v)	30	0	30	283	-	-
0.9 % w/v "normal saline"	154	0	154	308	-	0.2
0.45 % w/v "half normal saline"	77	0	77	154	-	-
Ringer's lactate	130	4	109	273	-	0.2
Hartmann's solution	131	5	111	275	-	0.2
4 % gelatine	145	0	145	290	30,000	1-2
5 % albumin	150	0	150	300	68,000	2-4
HES 6 % 130/0.4	154	0	154	308	130,000	4-8
HES 6% 450/0.6	154	0	154	308	450,000	24-36

1.2.3 Selection of an IV fluid

Deciding which fluids are appropriate for each patient depends on the type of fluid lost and the body compartment(s) that require additional volume. IV fluids are prescribed either for resuscitation or for maintenance.

Fluid resuscitation is required in situations where there is acute circulatory shock or intravascular volume depletion. The objective is to restore circulating volume and increase cardiac output thus restoring tissue perfusion and oxygen delivery. Usually large volumes of fluid are required in the short term. Sodium or colloid based solutions can be used to achieve this. Fluids that distribute throughout total body water such as glucose do not restore intravascular volume and can worsen interstitial oedema in those with inflammatory conditions. Where large volumes of fluid are required for longer periods, a crystalloid of a more physiological composition such as Hartmann's solution is preferred.[12-15, 20]

For a patient requiring fluid maintenance with healthy kidneys and no co-morbidities that affect fluid homeostasis, a suitable regimen aims to provide 1 - 1.5 mmol/Kg sodium,
1 mmol/Kg potassium per day and 30 ml/kg/day of water. Calcium and magnesium supplementation is considered where oral intake is interrupted for a few days. Often a combination of a glucose based and second fluid to boost intravascular volume (usually a sodium based fluid) will suffice.

Isotonic glucose solution is prescribed to treat simple dehydration and provide water replacement. The small amount of glucose in the isotonic solution is rapidly metabolized, thus allowing the solvent water to freely distribute throughout total body water. The hypertonic glucose solutions are given to provide glucose as a metabolic substrate in hypoglycaemia or in combination with insulin therapy.[15-20]

After identifying the type of fluid that will best treat the deficit or maintain euvolumia, the appropriate rate of fluid administration guided by clinical assessment and safety limits of each fluid is determined.

1.2.4 Guidelines for assessing IV fluid requirements

On admission, patients' medical histories give an indication of their expected fluid status. Patients' conditions suggestive of a fluid deficit include haemorrhage, vasodilation, diarrhoea, and vomiting, insensible or renal losses. In addition, signs such as thirst, reduced skin turgor, dry mucous membranes, increased capillary refill time and altered levels of consciousness, are strong indicators for institution of IV fluid therapy.

When a patient has volume depletion, heart rate increases so as to maintain tissue perfusion. Blood pressure only begins to fall when the intravascular volume drops by 20-30 %.[1-3, 7] Urine becomes more concentrated and in more severe cases of volume depletion, a fall in urine output will be noted. Thus hypotension and acute renal failure are strong indicators for IV fluid therapy.

Checking lab values is vital for clues of fluid imbalance. Elevated plasma sodium (> 145 mmol/L), hematocrit and urea (> 6 mmol/L) indicate dehydration as does acidosis from a blood gas analysis.

1.2.5 Guidelines for monitoring of IV fluid therapy

IV fluid administration requires monitoring the clinical response and for signs of adverse effects to ensure safety and efficacy. To evaluate the desired endpoint, the hydration status is monitored by checking urine output, heart rate, capillary filling time and blood pressure. A patient's subjective report of feeling better and absence of thirst can indicate successful therapy as well as a return of sodium, urea and creatinine levels to normal.

Since fluid overload is common to all IV fluids, one needs to monitor for this. This is indicated by neck vein distension, adventitious lung sounds and respiratory distress as well as vital signs showing increased blood pressure, heart or respiratory rate. Weighing and documenting initial and daily weight is the simplest and most reliable means of monitoring fluid status.

For immobile patients and the high risk patients, accurate monitoring of overall intake and output is vital to tailor fluid administration. This includes losses via urine drains, stoma or nasogastric aspirates. In addition insensible losses via respiratory tract and skin are estimated

and compared with patients normal physiological requirements. The normal daily water intake and output for an adult is 2500 to 3000 ml. Invasive techniques for monitoring, such as measurement of central venous pressure and use of techniques like oesophageal Doppler or thermodilution are usually restricted to critical care areas.

In a study done in a London hospital, it was found that the most frequently monitored parameters of fluid balance are daily serum urea, creatinine and sodium levels. Initial weight and daily weight is not frequently monitored yet they are non-invasive procedures.[21]

It is important to note that all signs and symptoms need to be evaluated as a whole since their specificity in isolation is limited. All observations should be interpreted in the context of a patient's clinical diagnosis. Prescribers also need to be aware of any concurrent conditions or medication that can predispose the patient to adverse effects from fluid therapy or alter fluid distribution.[1, 4, 5, 22-24]

1.2.6 Complications of IV fluid therapy

These can broadly be classified as those due to excessive fluid administration, electrolyte imbalance and those due to inadequate fluid replacement. Insufficient fluid administration leads to a reduced effective circulating volume. Diversion of blood away from non vital organs towards the vital organs results in pre-renal renal failure and inadequate tissue perfusion.[3, 25-27]

Fluid overload as a result of excessive fluid has no precise definition but complications arise in the context of pre-existing cardiorespiratory disease and severe acute illness. This results when the heart fails to pump the expanded circulatory volume effectively. Over distension of the left ventricle causes heart failure and hence pulmonary oedema. This presents as a cough with pink frothy sputum and respiratory distress that worsens when lying down. Abdominal compartment syndrome (ACS) is also a recognized consequence. It arises as a result of an acute rise in intra-abdominal pressure usually > 20 mmHg. It is characterized by difficulty in breathing and decreased urine output due to compression of renal arteries and veins. The bowel develops severe oedema reducing visceral perfusion and leading to bowel ischemia.[1, 25]

Electrolyte imbalance is often a result of administering the wrong type of fluid. This causes a derangement of serum sodium concentration which can cause serious neurological injury.[3, 25] These and other biochemical disturbances have been summarized in Table 1.2.

Table 1.2: Electrolyte imbalance induced by IV fluid therapy

Type of fluid	Electrolyte imbalance	Mechanism	Signs and symptoms
Isotonic NaCl	Hyperchloraemic acidosis Metabolic acidosis	Excessive Cl ions, being a strong anion tends to reduce the strong ion difference (SID), with the net effect of acidosis[5, 15, 32]	-
Hypotonic NaCl, Dextrose solutions	Hyponatremia; serum Na < 135 mmol/L	Surplus of electrolyte free water thus dilution of Na. This causes the brain cells to swell	Headache, lethargy, decreasing levels of consciousness and seizures. Death due to cerebral oedema. Serum levels < 125 mmol/L can cause permanent neurological abnormalities.[4, 25-29]
Hypertonic NaCl, Excessive isotonic saline	Hypernatremia; serum Na >145 mmol/L	Due to rapid rise in extracellular osmolality, brain cells shrink	Lethargy, weakness, irritability, seizures, obtundation and death in severe cases. Severe permanent neurological dysfunction is more likely to occur with acute increase in serum Na > 160mmol/L [30,31]

1.2.7 Patient groups at risk for complication

This includes patients at extremes of age and those with pre-existing medical conditions that predispose them to adverse effects of IV fluid administration. Indeed, in paediatrics, it has long been established that children are susceptible to complications of inappropriate IV fluid therapy. [33] Strict guidelines have therefore been developed by the NPSA for paediatrics departments.[16]

Those with cardiac diseases, tissue perfusion may be reduced and there is a risk of fluid retention and overload. For patients with renal diseases, it may be difficult to remove excess fluid such that there is a risk of fluid overload. In cerebrovascular diseases, patients are likely to have complex requirements and it may be difficult to maintain electrolyte and fluid balance.[1]

Amongst the elderly, age related changes and chronic diseases mentioned above impair fluid and electrolyte homeostasis. These factors act in concert to increase susceptibility of elderly patients to such complications.[4, 34] In fact, it is estimated that 20 % of the elderly have poorly

documented fluid balance or have fluid imbalance that is unrecognized or untreated. [35] Therefore, fluid administration has to be particularly balanced in these groups of people.

1.3 Study problem

Research has shown that IV fluids are often administered with little regard for actual fluid and electrolyte needs. It has also shown that prescribers are often not aware of sodium and potassium contents of common IV fluids.[36] In addition, the review and monitoring of IV fluids is less consistent compared to that of other injectable drugs.

Iatrogenic problems arising from inappropriate fluid therapy can increase morbidity and prolong hospital stay. This is especially seen in patients with coexisting cardiac, renal, cerebral and respiratory diseases or those at risk of hemodynamic instability. Irrational use of IV fluids arises as a result of inappropriate prescribing, lack of monitoring as well as lack of guidelines and knowledge on the practical aspects of IV fluids.

A report by the NCEPOD criticized the fluid management of the elderly patients. [35] This may reflect inadequate training of junior hospital doctors who are responsible for most of the prescriptions of IV fluids. For instance an evaluation of the level of training and the clinical practice of pre-registration house officers and senior house officers in south Wales showed that 58 % had never received any formal training on the subject and that 36 % did not check either the clinical details or the blood results before prescribing IV fluids.[36]

A study done in a university hospital, Nottingham UK, found that training on the subject of IV fluids in both undergraduate and postgraduate does not prepare prescribers for the task. [37] In Kenya, no studies have been done on the practical aspects of fluid and electrolytes therapy.

Traditionally "elderly" is defined as age over 65. However, chronological age is only one of the determinants of factors pertinent to drug therapy. The onset of renal, cardiovascular and most chronic diseases often begin at age 45 years in the Kenyan context. Thus patients' aged 45 to 64 years, though not elderly are prone to adverse drug reactions due to declining body functions. Given that the life expectancy at birth in Kenya is 52 and 55 years for men and women respectively, arbitrarily assigning persons above 50 years as elderly may apply.[35, 38-40]

1.4. Justification

In absence of guidelines for monitoring IV fluids for the elderly or those with chronic conditions, the study aimed to establish baseline data on the prescribing and monitoring of IV fluids in K.N.H.

With regard to prescribing of IV fluids, this study showed whether clinical details or biochemical results were checked prior to their administration. Thus revealed any shortfalls or cases where there was no rationale for giving IV fluids.

The study was done in a resource constrained setting. Its findings on parameters of fluid balance that were routinely assessed and monitored were used to draw comparison with findings of other studies done in well resourced settings. That was done in view of parameters that should have been more keenly and feasibly followed in our setting.

The study also drew conclusions on the incidence of IV fluid induced adverse effects. That was not a primary objective however that information provided evidence for the need to closely monitor IV fluid therapy in the elderly patients.

Where gaps were identified, findings of the study would help initiate dialogue on strategies that can inform, guide and regulate decisions of prescribers on the use of IV fluids. Elderly patients are selected because they had an increased risk for iatrogenic complications of inappropriate fluid therapy.

1.5 Research questions

1) What baseline assessments were done prior to prescribing IV fluids?

2) What are the most commonly prescribed IV fluids?

3) What are the deficiencies in prescriptions for IV fluids?

4) How frequently are measures of fluid balance monitored?

5) What is the prevalence of fluid overload as an adverse effect of IV fluid therapy?

1.6 Objectives

1.6.1 Main objective
The main objective of the study was to assess adequacy of monitoring of intravenous fluids in patients aged 50 years and above in K.N.H

1.6.2 Specific Objectives
The specific objectives of the study were to:

1) Find out what baseline clinical and laboratory assessment was done prior to prescribing IV fluids and conditions for which IV fluids are prescribed.
2) Identify types of IV fluids prescribed.
3) Establish how frequently measures of fluid balance were monitored once IV fluid therapy was initiated.
4) Assess the prevalence of fluid overload as an adverse effect of inappropriate IV fluids administration.

CHAPTER TWO

2.0 METHODOLOGY

2.1 Study area

The study was carried out in internal medical wards of Kenyatta National Hospital, which is the main teaching and referral hospital in Eastern Africa.

2.2 Study population

The study population was elderly patients aged 50 years and above admitted to K.N.H medical wards between March to July 2010.

2.3 Study design

This was a longitudinal descriptive study carried out between March to July 2010 on patients admitted during that time interval.

2.4 Sample size

Prevalence of poorly documented fluid balance or fluid imbalance that is unrecognised or untreated in the elderly is 10-20 %. [21]

Sample size was therefore calculated using the formulae:

$N = [p(1-p)] / (S.E)^2$ ....Equation [1]

Where;

S.E was the standard error or accepted level of precision set at ±5 %

P was the hypothesised prevalence of poorly documented fluid balance 10 %.

Using equation [1], the minimal study population was 144 subjects however 150 patients were recruited.

2.5 Sampling method

Sampling of the patients was carried out on post admission days. All patients who met the inclusion criteria were recruited from the admitting wards over a period of 3 days every fortnight from March to July 2010. On the sampling days, a universal sample was obtained.

2.6 Inclusion criteria

The inclusion criteria were as follows: Patients 50 yrs and above, receiving IV fluids within the preceding 24 hrs of the survey days and who consented to the study

2.7 Exclusion criteria

The exclusion criterion was patients with non medical condition such as surgical patients.

2.8 Data collection and materials

A pre-designed data collection instrument was pre-tested and modified. The data collection form is appended (Appendix D). Data collection took place during a twelve week period between March and July 2010.

Data was collected from the following sources: patient medical records, drug charts, observation charts and laboratory reports which are all contained in the patients' file, as well as the patient. Where there was need to verify information, patients were interviewed. Data was collected daily until the day of discharge or death.

2.9 Data analysis

Data collected were entered into and analyzed using SPSS 12.0 software. Accuracy of the data entered was counterchecked daily by the investigator. Descriptive data analysis was performed on all variables. The medians and range were reported for variables that showed skewed distribution. Exploratory data analysis was performed to examine the variables for associations and correlations. A bivariate analysis using chi-squared test was done to determine the association between categorical variables.

Odds ratios (OR) and 95 % confidence intervals (CI) associated with adequate monitoring were calculated. Logistic regression modelling was done with only variables that had p-value < 0.06 in the bivariate analysis. Model building was done by a forward stepwise combination of the predictive variables to successfully determine Akaike Information Criterion (AIC). Those that were then found to be significantly associated with the outcome were retained in the final model. All p-values were two tailed at a significance of 5 %.

2.10 Definition of cases

The following criteria were used to define adequacy of monitoring parameters of fluid balance and adverse effects of IV fluid therapy.

Adequacy of monitoring; At least one UEC determined every three days of a patient been on IV fluid other than the baseline, daily recording of vitals, daily observation of clinical signs and symptoms with regard to evidence of dehydration or oedema, taking weight measurements every two days (besides the baseline measurement) and at least one hemogram every 3 days, charting of input and output for catheterized patients

For each patient, the total number of adequately monitored parameters was computed and this was then used as an index of the adequacy of monitoring.

Adverse effects of IV fluid therapy; Signs of fluid overload after institution of IV fluids therapy included, patients who developed or had worsening of pre-existing oedema, respiratory distress characterised by dyspnoea, cough with pink frothy sputum and crackles, worsening of hypertension within 24 hrs of instituting IV fluids characterised by a rise in diastolic blood pressure by $\geq$ 10 mmHg and dilutional hyponatremia defined by serum Na levels < 135 mmol/L

2.11 Variables, confounders and outcomes of interest

The **main outcome of interest** was adequacy of monitoring measures of fluid balance.

The **independent variables/ confounders** were patients' demographics, NBM status, immobility, consciousness, pre-existing medical conditions that predispose to fluid overload, determination of UEC within 24 hrs of initiating IV fluid therapy, length of hospital stay, duration of IV fluid therapy, adverse effects attributable to IV fluid therapy and concurrent medication.

2.12 Ethical considerations

Ethical approval for this study was granted by K. N. H Research and Ethics Committee as per the attached letter of approval (Appendix A). Consent from the patients or their relatives were also sought as per attached consent form (Appendix B).

Review of information from the patient and their files was done within the wards to ensure confidentiality. Patients' names were not included in the data collection form. Patients were assigned study numbers in place of actual hospital numbers. In the case that a clinically important issue was discovered by the investigator, it was followed up according to KNH procedures

CHAPTER THREE

3.0 RESULTS AND DISCUSSION

3.1 Baseline characteristics

The baseline characteristics are presented in Table 3.1. The median age of the participants was 60 years (range of 50-95 years) with those 65 years and above forming 33.3 % of the patients.

Table 3.1: Baseline characteristics of the study population

Characteristics	Proportion of the study population [n=150] % age [95 % CI]
Age in years:	60 (50 - 95)[a]
>=65	33.3 (25.2 – 40.9)%
Gender:	
Male	51.3 (43.3 – 59.3)%
Female	48.7 (40.7 – 56.7)%
Marital status:	
Married	63.3 (55.6 – 71.0)%
Single	3.3 (0.5 – 6.2)%
Widowed	26.7 (19.6 – 33.8)%
Divorced/separate	6.7 (2.7 – 10.7)%
Residence:	
Rural	49.3 (41.3 – 57.3)%
Semi urban	28.0 (20.8 – 35.2)%
Urban (poor)	5.3 (1.7 – 8.9)%
Urban	17.3 (11.3 – 23.4)%
Occupation:	
Unemployed	38.7 (30.9 – 46.5)%
Employed (Casual)	14.0 (8.5 – 19.6)%
Employed (Self)	35.3 (27.7 – 43.0)%
Employed (Permanent)	12.0 (6.8 – 17.2)%
Parity:	5 (0 - 18)[a]
Parity one or more	96.7 (93.8 – 99.5)%
Religion:	
Christian	87.3 (82.0 – 92.7)%
Muslim	2.0 (0 – 4.2)%
Other	10.7 (5.7 – 15.6)%
Highest level of education:	
No formal education	32.7 (25.2 – 40.2)%
Primary School	18.7 (12.4 – 24.9)%
Secondary School	29.3 (22.0 – 36.6)%
College/University	19.3 (13.0 - 25.7)%

[a] median and range presented

Slightly more males (51.3 %) than females were recruited. At the time of the study, 63.3% were married and a cumulative 96.7% were noted to have been at least once married.

The majority of the participants (87.3 %) were Christians by religion and 49.3 % resided in the rural areas. Almost all, 96.7 % had children and the median number of children was 5 (range of 0-18). Just over half the population (51.4%), either had no formal education or stopped at primary school. About 36% were unemployed while 35.3 % were self employed, most of who were subsistence farmers.

3.2. Clinical and laboratory assessments at admission.

At admission, 93.3 % were conscious. About 21 % of the patients could not feed orally (NBM) while 43 % were immobile. It was found that, the majority of the patients 87.3 % had indications for IV fluids. The most prevalent indications for IV fluids were clinical signs of dehydration which is rather subjective. (Table 3.2)

Table 3.2: Presentation at admission

Characteristics	Proportion of the study population (n=150) % (95% CI)
Patients characteristics:	
Inability to feed orally (NBM)	20.7 (14.2 – 27.2)%
Conscious	93.3 (89.3 – 97.3)%
Immobile	43.3 (35.4 – 51.3)%
Prevalence of conditions that are indications for IV fluids:	
Signs & symptoms of dehydration	59.3 (51.5 – 67.2)%
Dizziness, hypotension, loss of consciousness	12.0 (6.8 – 17.2)%
Decreased renal function/renal failure	4.0 (0.9 – 7.1)%
Inadequate dietary intake	12.0 (6.8 – 17.2)%
None	12.7 (7.4 – 18.0)%
Baseline measurements:	
Initial UEC done	79.3 (72.9 – 85.8)%
Initial body weight taken	6.0 (2.2 – 9.8)%
Co-morbidities that predisposes to fluid overload:	30.7 (23.3 – 38.1)%

Baseline UEC results were checked in 79.3 % of the patients whereas initial body weight was only taken for a paltry 6 %. This was in line with guidelines that require UEC determination before initiation of therapy. The findings also compare well with a survey done at a London hospital which showed that 65% of the patients had their initial UEC checked. In the same

survey, 85% of doctors claimed that they were likely to check initial UEC prior to prescribing IV fluids.

Only a quarter of the doctors claimed to check initial weight. Indeed only 46.8 % of patients had their initial weight determined in the same London survey, which is eight times higher than that observed in our own setting. [21] It was however noted that 12.7 % of the patients did not have any indications for IV fluids. These patients may actually have had indications for IV fluids but this information may have been missing from the records.

3.3 Prescribing patterns for IV fluids

As shown in Table 3.3, the most commonly prescribed intravenous fluid was normal saline 36.7 %, followed by normal saline alternating with dextrose solutions (30.7 %). The least prescribed IV fluid was hypertonic saline and it was noted to always be unavailable.

Table 3.3: Prescribing patterns of IV fluids

Procedure	Proportion of the study population (n=150), % (95 %CI)
Type of IV fluid prescribed:	
Normal saline	36.7 (29.0 – 44.4)%
IVF	14.0 (8.5 – 19.6)%
Normal saline alternating with dextrose	30.7 (23.3 – 38.1)%
Hartmann	4.7 (1.3 – 8.1)%
Hartmann alternating with 5% dextrose	6.0 (2.2 – 9.8)%
10%/50% dextrose infusion	2.7 (0.1 – 5.3)%
Hypertonic saline	1.3 (0 – 3.2)%
None	4.0 (0.9 – 7.1)%
Content of prescription:	
Type	81.3 (79.7 – 91.0)%
Volume	85.3 (74.4 – 87.0)%
Duration	80.7 (75.1 – 87.6)%
*Completeness of prescription:	73.3 (63.3 – 80.4)%

It was worrying that for some of the patients' prescriptions, the term "IVF" had been written thus leaving prescription open to interpretation by nurses as regards choice of fluid.

Overall, only 73.3% were noted to have a complete prescription as defined by type, volume and duration of administration of IV fluids. Duration was defined by the volume of fluid given over a specified period of time as opposed to the number of days the fluid was to be given. (Figure 3.1)
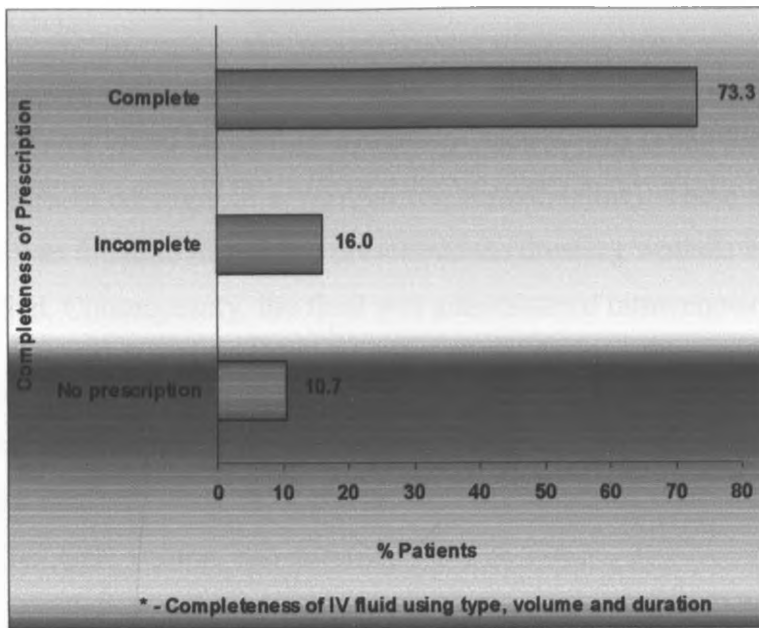
Figure 3.1: Completeness of prescription

3.4 Compliance to prescribed IV fluid

As shown in Figure 3.2, slightly over half the population 51.3%, either did not receive IV fluid as prescribed, received a mixture of fluids or received IV fluids though not prescribed. On enquiry, various reasons were advanced. Whenever normal saline was prescribed to alternate with dextrose, there were often numerous errors in the administration of IV fluids. This may have been due to failure to keenly record or follow up the order by which the fluids were administered. In addition, where the type had not been specified, it was not easy to establish the criteria by which the fluids were chosen and subsequently given.
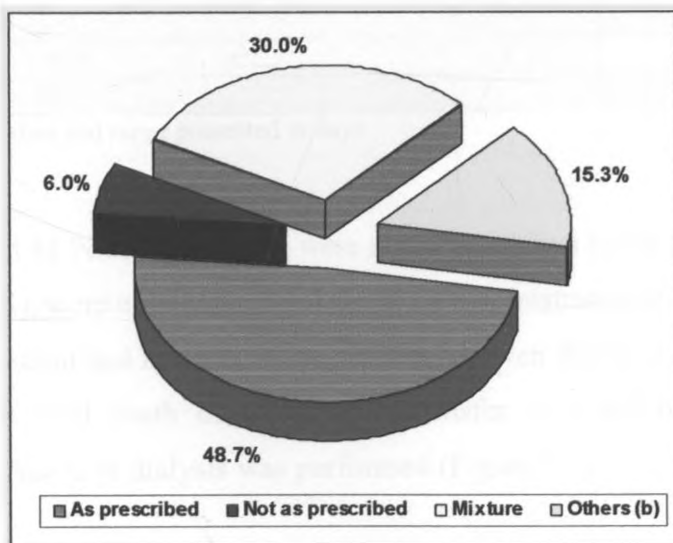
(b) – Received IV fluid though not prescribed
Figure 3.2: Compliance to treatment

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About 15 % of the patients received IV fluids even though they had not been prescribed. For some, it was found out that abbreviations such as V/S (vital signs 4 hourly) were confused to mean N/S (a common abbreviation for normal saline). There are a few cases where normal saline was found to have been prescribed for dressing wounds but this had not been expressly specified. Consequently, the fluid was administered intravenously.

In others, it was simply an error as there were no clear reasons given, however, administration of the fluid was subsequently stopped. All these errors may have resulted from the fact that only 73.3 % of the patients prescriptions were found to have clarity as regards specified type, volume and duration.

3.5 Duration of treatment and reasons for stoppage of IV fluid administration

The median length of hospital stay was 6 days (range of 1-21 days)   while the median duration of intravenous fluid therapy was 3 days (range of 1-16days). Almost two thirds were on IV fluids for 3 days. (Table 3.4)

Table 3.4: Duration of IV fluid administration

Characteristics	Proportion of the study population (n=150), % (95 % CI)
Length of stay in hospital:	6 (1 - 21)^c
Median of days patient was on IV fluid:	3 (1 – 16)^c
Duration of IV fluid therapy:	
1 -3	56.7 (48.7 – 64.6)%
4- 6	24.0 (17.2 – 30.8)%
>6	19.3 (13.0 – 25.7)%

^{c} – Median and range presented in days

About 41 % of the patients were noted to achieve better hydration status. Some of the patients (28 %), were either noted to have fluid administration stopped due to adverse effects or where the patient had no clear reasons for been given the fluids. The rest of the patients received the fluids until death of the patient, transfer to a different ward or hospital or until when transfusion or dialysis was performed (Figure 3.3).
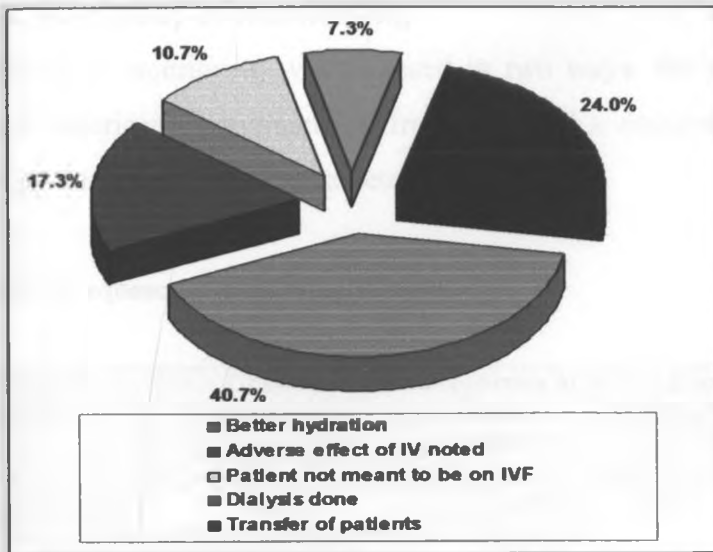
Figure 3.3: Reasons for stoppage

3.6. Monitoring of IV fluid therapy

3.6.1. Parameters of fluid balance monitored

Six parameters namely UEC, daily weight, vitals, clinical signs and symptoms, fluid charting and hemogram were followed up. While determination of blood glucose levels is not an indicator of fluid balance, it was also followed up. This was because it sometimes was the reason for initiating IV fluid therapy or determining the end point for giving the fluids. The latter however was noted to only be keenly followed up in the diabetic population as expected.

Amongst the non invasive parameters, clinical signs and symptoms as well as vitals were the easiest and most frequently monitored parameters. These were monitored daily in about 98% of the patients as shown in Table 3.5. In contrast, daily weight was the most unpopular and was only checked in two patients (1.3 %). For the invasive parameters, a cumulative 84 % of the patients had their UEC determined at least once besides the baseline UEC results. At least one hemogram was obtained in 82.7 % of the patients while 26.6% had their fluid charting well done.

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3.6.2. Adequacy of monitoring

Adequacy of monitoring was assessed in two ways: the observed frequency vis a vis the defined criteria of recommended frequency and a composite measure for adequacy which took into consideration all parameters.

Table 3.5: Frequency of monitoring IV fluids

Parameter monitored	Observed frequency *	Proportion of patients N=150	Recommended frequency of monitoring **	Proportion of adequately monitored patients N=150, % (95% CI)
Vitals	Daily	98.0 %	Daily	98.0 (95.8 - 100) %
	Not done	2.0 %		
Clinical signs & symptoms	Daily	98.7 %	Daily	98.7 (96.8 – 100) %
	Not done	1.3 %		
Daily weight	Once	1.3 %	Once every 2 days	0.0 %
	Not done	98.7 %		
UEC	Once	48.7 %	Once every 3 days	62.7 (54.9 – 70.4) %
	2 – 4 times	31.3 %		
	> 4 times	4.0 %		
	Not done	16.0 %		
Fluid charting	Not done	73.4 %	Daily charting for catheterized patients	12.7 (7.4 – 18.0) %
	Well charted	26.6 %		
Hemogram	Once	74.7 %	Once every 3 days	63.3 (55.6 – 71.0) %
	Twice	5.3 %		
	Thrice	2.7 %		
	Not done	17.3 %		

*- This excludes baseline measurements   **- Criteria as defined in case definition

3.6.2.1 Frequency of monitoring each parameter;

The only two parameters that were adequately monitored were vital signs and clinical signs and symptoms. These were monitored daily as required in almost 100 % of the patients as shown in Table 3.5. Vitals give a measure of intravascular fluid balance while clinical evidence of oedema and dehydration are indices of extracellular volume as is daily weight.

Daily weight, which was determined only once in two patients, was the most inadequately monitored parameter. Indeed for those two patients, weight may have been taken for other reasons. This compares with resource enabled centres where only 9.4 % of patients were found to have their daily weight monitored.[21]

Admittedly, daily weight monitoring is more cumbersome in an adult or geriatric patient particularly where there are few or no bedside weighing machines. Even when the machines

are availed, the healthcare team may be too few and overburdened thus not motivated to take these measurements. However, despite all that, weight alone has been long established to provide an accurate guide to assessment of fluid requirements and status. It also is non invasive and provides just as useful information in comparison to the more invasive parameters such as UEC and catheterization associated with higher costs, bleeding and risk of infection.

For the invasive parameters, of the 84 % and 26.6 % of the patients' who had their UEC and fluid charting routinely monitored respectively, only 62.7 % and 12.7 % of these patients respectively were noted have the above parameters adequately monitored. The high percentage of UEC monitoring maybe explained by a general perception that laboratory results provide more accurate information on hydration status and end organ function. In addition, it is easy to check UEC even in the bed bound or critically ill (immobile patients).

For immobile patients the odds of having been adequately monitored by fluid charting were 1.3 times more than the non-immobile patients. Similarly, the odds of having been adequately monitored by UEC were 1.7 times more in the immobile than in the non-immobile. This however was not found to be significant (p=0.535 and p=0.073 respectively).

A strict and accurate fluid charting of input and output provides a potential surrogate marker for daily weight where a millilitre fluid discrepancy is equivalent to 1 milligram change in body weight. [1,16,21,30] In our setting, fluid output was found not to be recorded consistently yet it was a crucial index of end organ perfusion for the immobile patients that enables comparison with fluid intake. This may be explained by the delay in time taken to catheterize these patients and the laborious nature of recording on the chart by an over stretched team of nurses.

3.6.2.2 Composite measure of adequacy of monitoring;

The total number of parameters monitored in a single patient was used as a composite measure of adequacy. Among the seven parameters followed up, daily weight was left out as it was 100% inadequately measured in all the patients. Glucose was also left out as it was both not a measure of fluid balance and noted to have been only keenly followed in the diabetic population.

For the remaining five parameters, those judged to be adequately monitored had a combination of 4 or more parameters monitored. Therefore as shown in Figure 3.4, only 50% of the patients had parameters of fluid balance adequately monitored.
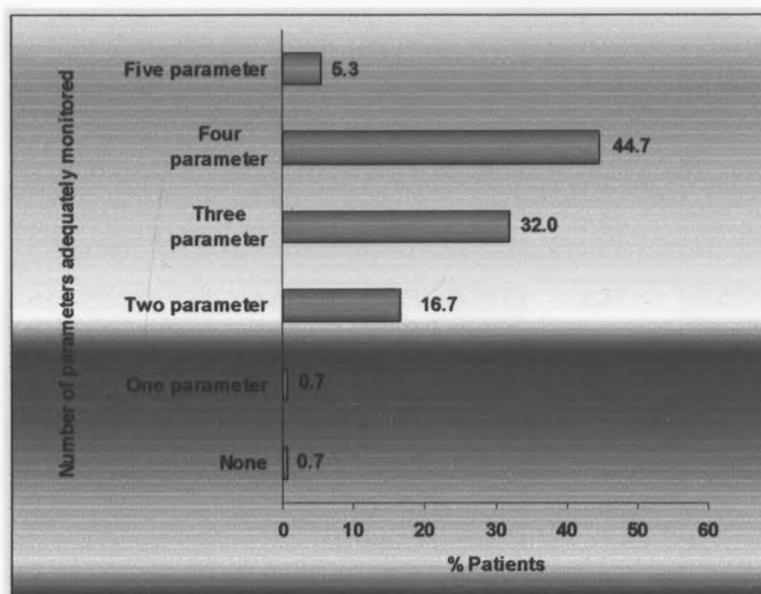
Figure 3.4: Combination of adequately monitored parameters

3.7. Factors associated with adequacy of monitoring

As shown in table 3.6, there was no significant association between age of the patients and adequacy of monitoring of IV fluids (P=0.299). Patients aged ≥ 65 years (56.0%) were 1.44 [95% CI= 0.73 – 2.84] times more likely to be adequately monitored compared to those aged < 65 years (47.0%). A similar pattern was observed for gender, residence, religion and marital status

Male patients (53.2%) were monitored 1.31 [95% CI= 0.69 – 2.48] times more compared to females (46.6%). Patients from rural residence (49.1%) were 1.61 [95% CI= 0.31 – 8.99] times more likely to be monitored adequately compared to those categorized as urban poor (37.5%). The likelihood increased upwards to 2.27 [95% CI= 0.35 – 15.71] times for urban middle class compared to urban poor.

3.6: Association between adequacy of monitoring and socio demographic characteristics of the patients

Variables	>= 4 par. (n=75)	< 4 par. (n=75)	Crude OR	95% CI		P value
	n (%)	n (%)		Lower	Upper	
Age of the patient (yrs)						
>= 65	28 (56.0)	22 (44.0)	1.44	0.73	2.84	0.299
< 65	47 (47.0)	53 (53.0	1.00			
Sex						
Male	41(53.2)	36 (46.8)	1.31	0.69	2.48	0.414
Female	34 (46.6)	39 (53.4)	1.00			
Residence						
Urban (middle class)	15 (57.7)	11 (42.3)	2.27	0.35	15.71	0.429
Rural	57 (49.1)	59 (50.9)	1.61	0.31	8.99	0.719
Urban (poor)	3 (37.5)	5 (62.5)	1.00			
Religion						
Christian	66 (50.4)	65 (49.6)	1.13	0.43	2.96	0.806
Others	9 (47.4)	10 (52.6)	1.00			
Marital status						
Married/widowed	68 (50.4)	67 (49.6)	1.16	0.40	3.38	0.785
Others	7 (46.7)	8 (53.3)	1.00			

Binary logistic regression was run using a forward stepwise model building approach. The most important predictors for adequacy of monitoring IV fluids were length of hospital stay; duration of treatment with IV fluids and determination of baseline UEC. This is as shown in Table 3.7

Adjusting for duration of hospital stay and duration of IV fluid administration, determination of baseline UEC was significantly associated with adequate monitoring of IV fluids (P<0.001). A patient whose UEC was assessed within 24hrs of starting IV fluids was 20 [95% CI= 5.75 – 71.38] times more likely to be adequately monitored compared to those who did not. This may have been because; when an abnormality in the biochemical markers was noted early enough it was likely to motivate monitoring of the patient more keenly.

There was a significant association between adequacy of monitoring and duration of hospital stay, with patients admitted for 5 – 9 days being 4 [95% CI= 1.11 – 12.96] times more likely to be adequately monitored (P=0.034). The likelihood decreases slightly to 3 [95% CI= 0.51 – 20.29] times for patients admitted for 10 or more days. Patients whose hospital stay is < 3

days may have had blood samples taken but results may not have been back by the time of discharge.

Table 3.7: Association between adequacy of monitoring and various variables

Variables	>= 4 par. (n=75) n(%)	< 4 par. (n=75) n (%)	Crude OR (95% CI)	P value	Adjusted OR (95% CI)	P value
Patients characteristics						
NBM	16 (51.6)	15 (48.4)	1.08 (0.49 – 2.39)	0.840	-	
Unconscious	6 (60.0)	4 (40.0)	1.54 (0.42 – 5.71)	0.513	-	
Immobile	36 (55.4)	29 (44.6)	1.46 (0.77 – 2.80)	0.249	-	
Absence of conditions that predisposes to fluid overload	54 (51.9)	50(48.1)	1.29 (0.64 – 2.58)	0.479	-	
Determination of baseline UEC	69 (58.0)	50 (42.0)	5.75 (2.20 – 5.05)	<0.001	20.3 (5.75 – 71.38)	<0.001
***Duration of hospital stay**						
> 10 and more	6 (24.0)	19 (76.0)	0.27 (0.07 – 0.94)	**0.020**	**3.22 (0.51 – 20.29)**	**0.213**
5 – 9	50 (55.6)	40 (44.4)	1.05 (0.45– 2.48)	**0.898**	**3.79 (1.11 – 12.96)**	**0.034**
****Duration of IV fluid administration**						
1 – 3	63 (74.1)	22 (25.9)	17.9 (5.11 – 8.91)	<0.001	**74.5 (14.65 – 9.18)**	<0.001
4 – 6	8 (22.2)	28 (77.8)	1.79 (0.41 – 8.15)	0.388	1.9 (0.46 – 7.93)	0.374
Medication that influence fluid homeostasis	23 (51.1)	22 (48.9)	1.07 (0.53 – 2.14)	0.859	-	
Presence of Adverse effects attributable to IV fluid therapy	24 (63.2)	14 (36.8)	2.05 (0.96 – 4.37)	**0.060**	-	
Incomplete IV fluid prescription	22 (55.0)	18 (45.0)	1.31 (0.64 – 2.72)	0.460	-	

*reference group is 1 – 4 days in hospital   **reference group is > 6 days of IV fluid administration

On the other hand, patients whose duration if hospital stay is 5 – 9 days had their laboratory results back in time. Patients in the hospital for > 10 days were inadequately monitored. A longer hospital stay may inadvertently invite laxity and assumption by the health team toward the patient or diversion of attention to other incoming newer patients.

Similarly, adjusting for duration of hospital stay and determination of baseline UEC, duration of IV fluid administration was significantly associated with adequacy of monitoring (P<0.001). Patients receiving IV fluids for 1 – 3 days were 75 [95%CI= 14.65 – 379.18] times more likely to be adequately monitored compared to those admitted for more than 6 days. The likelihood dropped to 2 [95% CI= 0.46 – 7.93] times for those on IV fluids for 4 - 6

25

days. The shortest duration of IV fluid therapy is consistent with one week (5 – 9 days) of hospital stay. This may be explained by the drive to ensure drastic recovery in those severely dehydrated presenting with pre-renal renal failure to prevent the more serious and difficult to reverse parenchymal renal failure.

3.8. Prevalence of fluid overload.

The prevalence was found to be 25.3 % [95% CI=18.4 – 32.9] % as assessed by an earlier defined criteria as shown in Table 3.8. The most utilized criteria were patient reported as well as observed development or worsening of clinical signs and symptoms of respiratory distress, oedema and worsening of hypertension. Due to non specificity of the mentioned criteria, information on diagnosis and concurrent illnesses that predispose patients to symptoms of fluid overload was also obtained. Those with co morbidities predisposing to fluid overload at admission were 30.7 % of the patients. (Refer to Table 3.2)

Table 3.8.: prevalence of fluid overload

Characteristics	Proportion of the study population (n=150)
Adverse effects attributable to IV fluid therapy;	
None	60.0 (52.2 – 67.8) %
Unlikely	14.7 (9.0 – 20.3) %
Possible	12.0 (6.8 – 17.2) %
Probable	13.3 (7.9 – 18.8) %
On medication that influence fluid homeostasis;	30.0 (22.7 – 37.3) %

Based on this, 14.7% of patients were found to have their symptoms unlikely to be attributable to IV fluid administration. Most studies have not been done on this topic in the Kenyan setting, however the findings compare well with the estimation by NCEPOD that 20% of elderly patients have fluid imbalance that is unrecognized or untreated. [35]

3.9 Limitations

Recruitment was done from the internal medical wards thus information obtained as regards observations made in casualty room was that which was recorded by clinicians. This may have been prone to omission or inaccuracies.

The range of patients selected, while followed up until the day of discharge or death, had differing requirements in terms of intensity of fluid balance monitoring. This is because no

exclusion was made on the basis of different fluid requirements as regards resuscitation or maintenance regimens thus this may have affected the precision of observations made.

Lack of local and national guidelines on administration and monitoring of IV fluids among the adults and elderly patients thus this study borrowed from NPSA guidelines for paediatrics, recommendations of NCEPOD as well those of an audit done in London District General Hospital.

CHAPTER FOUR

4.0 CONCLUSION AND RECOMMENDATIONS

While there were various indications for IV fluids for a good majority of the patients, only half the patients were noted to be adequately monitored.

The intravenous fluid prescription section on the treatment sheet should be redesigned to enhance clarity of the prescription and improve the ease with which it is reviewed on a daily basis. It should thus include sections for the date, type of IV fluid, additives and dose of additives, rate and route of administration. (Appendix E)

If possible, an already pre- mixed dextrose saline solution should be purchased to replace the practice of prescribing normal saline alternating with 5 % dextrose. The latter was quite prone to errors as regards the order with which fluids were given.

The health care team should use as many parameters to accurately assess patients IV fluid needs and thus monitor thereon for clinical response and adverse effects. The various parameters should then be interpreted as a whole and not in isolation as well as in context of a patients' clinical diagnosis. In a resource constrained setting, the following are recommended.

As is already been done, all elderly patients should have their vitals checked daily as these are indices of intravascular volume. There should be daily observation for signs and symptoms reflective of fluid status. This includes checking for clinical evidence of edema or dehydration as these are indices of extracellular fluid balance. Thirdly, where possible all elderly patients should be weighed in the casualty department and prior to initiation of IV fluids. Thereafter weight measurements should be taken every 2 days throughout the period of IV fluid administration.

For the immobile patients, strict input and output charts should be maintained. Daily fluid balance should be documented consistently and accurately. These are indices of end organ perfusion. Both weight and fluid balance should be documented adjacent to the IV fluid prescription section of the treatment sheet. Initial UEC should be determined prior to or within 24 hrs of initiating IV fluids. Thereafter measurements should be repeated every 48 hrs of initiation of IV fluid therapy. However, where plasma electrolytes are found to be

abnormal, then repeated measurements every 24 hrs whilst the patient is on IV fluids should be done.

Continuous medical education sessions should be held on the need to give just as much importance to IV fluid prescriptions as is given to other medications. In addition, knowledge on both judicious selection of a fluid regimen and adequate monitoring will reduce costs and morbidity associated with inappropriate fluid administration.

Further exploration with a smaller more selective patient sample can be done prospectively to establish with more precision the rate of complications of IV fluid administration as regards both fluid overload and insufficient hydration. The information obtained from this and other studies done in future can be used to initiate dialogue on local standards and protocols of administering and monitoring IV fluids in adults and elderly patients. This is in view of age related changes and high burden of cardio-respiratory, renal and cerebral vascular diseases amongst this age bracket that predispose to adverse effects of IV fluids.

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APPENDICES

Appendix A: Letter of approval

Ref: KNH-ERC/ A/430

17th March 2010

Kenyatta Gloria Kavutha
Dept. of Clinical Pharmacy
School of Pharmacy
University of Nairobi

Dear Gloria

RESEARCH PROPOSAL "EVALUATION OF FACTORS INFLUENCING PRESCRBING OF INTRAVENOUS FLUIDS AND ADEQUACY OF MONITORING IN ELDERLY PATIENTS IN KENYATTA NATIONAL HOSPITAL" (P305/11/2009)

This is to inform you that the KNH/UON-Ethics & Research Committee has reviewed and **approved** your above revised research proposal for the period 17th March 2010 16th March 2011.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimens must also be obtained from KNH/UON-Ethics & Research Committee for each batch.

On behalf of the Committee, I wish you a fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of the data base that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

DR. L. MUCHIRI
AG. SECRETARY, KNH/UON-ERC
c.c.   Prof. K. M. Bhatt, Chairperson, KNH/UON-ERC
          The Deputy Director CS, KNH
          The Dean, School of Pharmacy, UON
          The Chairman, Dept. of Human Pathology, UON
          The HOD, Records, KNH
          Supervisors: Dr. F. A. Okalebo
                        Dr. K. O. Bosire
                        Dr. P. M. Maturi

Appendix B: Informed Consent explanation and Consent form

To be read in a language that the respondent is fluent.

TITLE OF THE STUDY: EVALUATION OF FACTORS INFLUENCING PRESCRIBING OF IV FLUIDS AND ADEQUACY OF MONITORING IN THE ELDERLY PATIENTS IN KNH

Institution: Department of Pharmaceutics and Pharmacy practice, School of Pharmacy,
        University of Nairobi
        P. O. Box 30197 – 00400

Investigator: Gloria Kenyatta
        P. O. Box 4526-01002 Thika Tel. 0721687629

Supervisors:

        Dr. Faith A. Okalebo, Lecturer, Dept. of Pharmacology and   Pharmacognosy

        Dr. Kepha O. Bosire, Lecturer, Dept. of Pharmacology and Pharmacognosy

        Dr Peter M. Maturi   Lecturer, Dept. of Hematology and Blood Transfusions

Ethical Approval

Kenyatta National Hospital/ University of Nairobi Ethics and Research committee
P. O. Box 20723 – 00100, Nairobi Tel: 2726300/2726450 Ext. 44102
Located at the School of Pharmacy buildings, University of Nairobi

Permission is requested from you to enrol in this medical research study. You should understand the following general principles, which apply to all in medical research participants whether normal or patient volunteers.

Your agreement to enrol in this study is entirely voluntary. You may withdraw from the study at any time without necessarily giving any reason for such withdrawal. After you read the

explanation, please feel free to ask any questions that will enable you to understand clearly the nature of this study.

Introduction

In this study, I am assessing factors influencing prescribing of IV fluids and parameters routinely monitored during their use in elderly patients admitted in KNH internal medical wards.

Purpose

The purpose of the study is to reduce complications of inappropriate IV fluid therapy and shorten hospital stay and costs for admitted patients.

Procedures

I intend to refer to your file including treatment sheet and lab reports daily for a minimum of five days. The information obtained will then be filled into a data collection form by me in confidence. Occasionally and with your permission, I will request you to provide answers to questions on information that is not available from the file or that which needs to be verified.

Risks

I wish to inform you that in this study, I will not carry out any invasive procedures such as insertion of needles or physical examination of the patient. It also does not involve any cost to the patient. No risks are therefore foreseen to result from this study.

Benefits

No monetary rewards or other material awards will be gained from this study. However, it is hoped that your participation will improve healthcare management of elderly patients.

Assurance of confidentiality

Any information /data obtained about patients will remain confidential and will not be accessed by any unauthorized individuals or groups. Your names will not be used during data handling or any publication. Your participation is voluntary and any refusal to participate will not interfere with your treatment and management in KNH.

Contacts

In case you need to contact me, my supervisors, my academic department or KNH/ University of Nairobi Ethics and Research Committee with any queries, please feel free to use the contacts provided in the first page.

Informed consent form

I, the undersigned, willingly agree to participate in this study, the nature and purpose of which have been fully explained to me by the investigator/ translator. I understand that the information gathered will be used for the purposes of this study only and strict confidentiality will be maintained.

_____   ___/_____/___

Signature of respondent   Date: day month year

Investigator (witness)...

_____   ___/_____/___

Signature   Date: day month year

Appendix C: Study eligibility checklist

Date...........................

Data collector's initials........

Patient code no................

Inclusion criteria (If any inclusion criteria is marked "NO", the patient is not eligible for enrolment)

Yes   No

[ ]   [ ]   1. Patient is above 50 yrs old

[ ]   [ ]   2. Patient has been started on IV fluids within 24hrs

[ ]   [ ]   3. Patient has signed consent form

Exclusion criteria (If any exclusion criteria is marked "YES", the patient is not eligible for enrolment)

Yes   No

[ ]   [ ]   1. Patient has a non medical condition (surgical patient)

Is the patient eligible for the study?

Yes   [ ]

No   [ ]

Appendix D: Data collection form

Patient demographics

Date............................

Data collector's initials......

Patient code no..............

Age [   ]   Sex [M] / [F]   Marital status; Single/Married/Divorced or separated/Other

Residence.....................   Occupation; Unemployed/employed[self/casual/permanent]

No. of children..............   Religion..............

Highest level of education; No formal education/Primary/secondary/University or college

Date of admission............   Ward of admission.........   Date of discharge or death............

Patient medical history on the day of admission

1. Presence of the following signs and symptoms of dehydration. (Tick appropriately)

[ ] Thirst   [ ] Dry mucous membranes   [ ] Diarrhoea

[ ] Decreased skin turgor   [ ] Hypotension   [ ] other specified

[ ] Dizziness   [ ] Concentrated/ little/no urine

[ ] Decreased capillary filling time   [ ] Vomiting

2. Condition that led to admission? ....

3. Is the condition an indication for IV fluids? (Tick appropriately)

[ ] Yes

[ ] No

Tick appropriately for the following;

4. Is the patient Nil by Mouth (NBM)   Yes [ ]   No [ ]

5. Is the patient conscious   Yes [ ]   No [ ]

6. Is the patient immobile   Yes [ ]   No [ ]

7. Any concurrent ailments/ conditions? ....

Were the following assessed at or within 24 hrs of admission? (Tick appropriately)

Yes   No

8. [ ]   [ ]   Urea and electrolytes

9. [ ]   [ ]   Initial body weight

IV fluids

10. Which IV fluid was prescribed? ....

Specify Date...................................

11. Were the following specified?

[ ] Volume   [Yes]   [No]

[ ] duration over which fluid is to be administered [Yes]   [No]

12. Why was it stopped?

   Specify Date............................

Medication

13. Medication that patient has been taking?

....

....

....

....

....

14. Medication that patient is prescribed on admission?

....

....

....

....

Determination of various parameters

Parameter	Days on which parameters are monitored						
	Day1 (admission day)	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
UEC							
Urea (mmol/L)							
Ref range							
Creatinine (mmol/L)							
Ref range							
Na (mmol/L)							
Ref range							
k (mmol/L							
Ref range							
VITALS							
BP							
HR							
RR							
BODY WEIGHT (KG)							
HEMOGRAM							
Hb (g/dl)							
Hct (%)							
FLUID CHARTING							
Fluid input (L)							
Fluid output (L)							
Fluid balance (L)							
GLUCOSE (mmol/l)							
Ref range							
CLINICAL SIGNS AND SYMPTOMS							
Dyspnoea							
Crackles							
productive /pink frothy cough							
neck vein distension							
Pulmonary oedema							
Generalized oedema							

BP- blood pressure   RR - respiratory rate   HR – heart rate

Day refers to the date sample was taken

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Appendix E: Redesigned IV fluid section of treatment sheet

Date	Infusion solution	Additives and dose	Volume	Rate	Route
03/08/2010	Hartmann's	·	1000 ml	6hours	IV
07/08/2010	10 % dextrose	·	250 ml	stat	IV