

**ASSESSMENT OF CARE FOR AMBULANT ADULT
PATIENTS ON MAINTENANCE CHRONIC
HAEMODIALYSIS AT THE KENYATTA NATIONAL
HOSPITAL**

PRINCIPAL INVESTIGATOR

DR. SAMUEL K. KABINGA

REGISTRATION NUMBER: H114/10156/2018

INSTITUTION: EAST AFRICAN KIDNEY INSTITUTE

UNIVERSITY OF NAIROBI, KENYA

**A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE
REQUIREMENTS FOR THE AWARD OF THE FELLOWSHIP IN CLINICAL
NEPHROLOGY OF THE UNIVERSITY OF NAIROBI**

MARH, 2018

DECLARATIONS

This dissertation is my original work and has not been presented for any award in any other university.

Signed Date

Dr. S.K. Kabinga M.B.Ch. B., M.MED (Internal Medicine)

University of Nairobi

This dissertation has been presented with my full approval as supervisor.

Signed Date

Prof. S.O. McLigeyo M.B.Ch.B., M.MED (Internal Medicine)

Professor of Medicine

Department of Clinical Medicine and Therapeutics, University of Nairobi

Consultant Physician & Nephrologist

This dissertation has been presented with my full approval as supervisor.

Signed Date

Prof. J. K. Kayima M.B.Ch.B., M.MED (Internal Medicine)

Associate professor

Department of Clinical Medicine and Therapeutics, University of Nairobi

Consultant Physician & Nephrologist

.

This dissertation has been presented with my full approval as supervisor.

Signed Date

Dr. J.N. Ngigi M.B.Ch.B., M.MED (Internal Medicine)

Fellow of International Society of Nephrology

Head of Unit-Renal

Department of Medicine, Kenyatta National Hospital

Consultant Physician & Nephrologist

TABLE OF CONTENTS

DECLARATIONS	ii
ACKNOWLEDGEMENT	viii
LIST OF ABBREVIATIONS AND ACRONYMS.....	ix
LIST OF FIGURES	x
LIST OF TABLES.....	xi
ABSTRACT.....	xii
CHAPTER ONE.....	1
1 INTRODUCTION	1
1.1 Background information	1
1.2 Haemodialysis.....	1
1.3 Problem statement.....	1
1.4 Study question.....	2
1.5 Study objectives	2
1.5.1 Main objective.....	2
1.5.2 Specific objectives	2
1.6 Rationale/ study justification	3
1.7 Significance of the study.....	3
CHAPTER TWO	4
2 LITERATURE REVIEW	4
2.1 Chronic kidney disease	4
2.2 Common underlying conditions leading to chronic kidney disease.....	4
2.3 Chronic care model in chronic kidney disease.....	5
2.3.1 The chronic kidney disease care collaborative team.....	5
2.3.2 Referral to specialist services and initiation of kidney replacement therapy	6
2.4 Renal replacement therapies	6
2.5 Kidney replacement therapy by haemodialysis.....	6

2.5.1	Morbidity and mortality among haemodialysis patients	7
2.6	Prevalence of dialysis population	7
2.7	Complications of chronic kidney disease.....	7
2.7.1	Anaemia	8
2.7.2	Chronic kidney disease mineral and bone disorder.....	8
2.7.3	Cardiac and vascular complications.....	8
2.8	Management of some conditions resulting from chronic kidney disease	9
2.8.1	Anaemia management in patients on haemodialysis.....	9
2.8.2	Mineral and bone disorder in patients on haemodialysis	10
2.9	Theoretical framework of haemodialysis care	10
CHAPTER THREE		12
3	METHODOLOGY	12
3.1	The study design	12
3.1	Area of the study	12
3.2	Study population	12
3.3	Sampling	12
3.4	Inclusion criteria	13
3.5	Exclusion criteria	13
3.6	Instrument /tool (See appendix 1).....	13
3.7	Study procedures.....	13
3.8	Laboratory methods	13
3.8.1	Specimens collection, handling, transportation and storage	13
3.9	Quality control and quality assurance	14
3.10	Data management.....	15
3.10.1	Data collection, storage and cleaning.....	15
3.10.2	Data analysis	15
3.10.3	Data presentation.....	15

3.11	Ethical considerations	15
3.11.1	Approvals.....	15
3.11.2	Privacy and confidentiality	16
3.12	Benefits to the patients.....	16
CHAPTER FOUR.....		17
4	RESULTS	17
4.1	Study recruitment.....	17
4.2	Sociodemographic and clinical characteristics	17
4.3	Duration of medical follow up and initiation of haemodialysis.....	18
4.4	Preparedness for kidney replacement therapy.....	20
4.5	Initial and current haemodialysis vascular access.....	22
4.6	Counseling and enrolment into renal transplantation evaluation	23
4.7	Haemoglobin level, serum calcium and phosphate.....	24
4.8	Serum calcium, albumin and phosphate laboratory evaluation.....	25
4.9	Haematologic parameters.....	25
4.10	Blood pressure, body weight and ultrafiltration volumes during the last 4 haemodialysis treatment sessions	25
CHAPTER FIVE		26
5.	DISCUSSION	26
RECOMMENDATIONS		29
STUDY LIMITATIONS		30
REFERENCES		31
APPENDICES		38
Appendix 1: Ambulant adult patients on chronic maintenance haemodialysis in KNH questionnaire		38
Appendix 2. Kenyatta national hospital renal unit haemodialysis flow sheet		43
Appendix 3. Patient consent explanation form		44
Appendix 4. Fomu ya maelezo kuhusu utafiti huu		46

Appendix 5. Patient consent form.....	48
Appendix 6: Karatasi ya makubaliano ya watu wazima	49
Appendix 7. Timeframe	50
Appendix 8. Budget	51
Appendix 9. Ethics and Research Committee clearance.....	52
Appendix 10. KNH Study Registration Certificate.....	54

ACKNOWLEDGEMENT

I am grateful to the Almighty God from whom comes all providence. I wish to thank all the patients on haemodialysis in Kenyatta National Hospital who graciously agreed take part in the study. I am indebted to the staff of the renal unit who gave enormous support to the study.

I would like to specifically thank my supervisors Prof. S. O. McLigeyo, Prof. J. K. Kayima and Dr. J. Ngigi for their support and guidance during the study. I wish to profoundly thank the KNH department of Research and Programs who came in handy and settled the costs incurred in study. Finally I wish to thank everyone who in any way assisted in making the study a reality. To you all, God bless you in excess of your giving.

LIST OF ABBREVIATIONS AND ACRONYMS

AIDS	-	Acquired Immune Deficiency Syndrome
AKI	-	Acute Kidney Injury
CAD	-	Coronary Arterial Disease
CBC	-	Complete Blood Count
CERA	-	Continuous Erythropoietin Receptor Activator
CKD	-	Chronic Kidney Disease
CKD-EPI	-	Chronic Kidney Disease Epidemiology Collaboration
CKD-MBD	-	Chronic Kidney Disease-Mineral and Bone Disorder
CVD	-	Cardiovascular Disease
DM	-	Diabetes Mellitus
EDTA	-	Ethylenediaminetetraacetic acid
eGFR	-	estimated Glomerular Filtration Rate
ESA	-	Erythropoiesis Stimulating Agent
ESKD	-	End Stage Kidney Disease
GFR	-	Glomerular Filtration Rate
HB	-	Haemoglobin
HD	-	Haemodialysis
HIV	-	Human Immunodeficiency Virus
IDWG	-	Interdialytic Weight Gain
IV	-	Intravenous
KDIGO	-	Kidney Disease: Improving Global Outcomes
KDOQI	-	Kidney Disease Outcome Quality Initiative
KNH	-	Kenyatta National Hospital
LVH	-	Left Ventricular Hypertrophy
MDRD	-	Modification of Diet in Renal Disease
NSAID	-	Non-Steroidal Anti-Inflammatory Drugs
PAD	-	Peripheral Arterial Disease
KRT	-	Kidney Replacement Therapy
SC	-	Subcutaneous

LIST OF FIGURES

Figure 2.1. Theoretical framework	11
Figure 4.1. Recruitment flow diagram	17
Figure 4.2. Composition of subset of patients aged 40years and below without diabetes mellitus	19
Figure 4.3 Initial and current haemodialysis vascular access	23
Figure 4.4 Leading reasons for failure to enroll in the kidney transplant evaluation programme	23
Figure 4.5. Haemoglobin testing frequency.....	24
Figure 4.6 Anaemia, calcium and phosphate management.....	24

LIST OF TABLES

Table 4-1. Age of the patients and first out-patient clinics attendance	18
Table 4-2 Follow up duration before initiation of haemodialysis	19
Table 4-3 Medical follow up and haemodialysis durations	20
Table 4-4. Diagnosis and circumstance around haemodialysis initiation	20
Table 4-5. Sex, HD duration and circumstances around initiation of HD of non-diabetic ESRD patients aged 40 years and below	20
Table 4-6. Knowledge about the modalities of kidney replacement	21
Table 4-7 Knowledge and information about disease progression during pre-dialysis clinic visits	21
Table 4-8 State of preparedness for haemodialysis	22
Table 4-9 Serum albumin, calcium and phosphate	25
Table 4-10 Haematologic parameters of patients on chronic maintenance haemodialysis	25

ABSTRACT

Background information

The burden of chronic kidney disease (CKD) is on the rise locally and globally. The care for patients with CKD is multifaceted and multidisciplinary. The aim of the study was to explore the actual extent of care given to the patients on chronic maintenance haemodialysis (HD) at Kenyatta National Hospital (KNH).

Study methodology

The study design was cross-sectional descriptive carried out between June and July 2018 among the patients on chronic maintenance HD at KNH. Primarily, the study was to establish the actual extent of care for these patients. Specific objectives were to document the morbidities as the underlying cause(s) of CKD and the level of preparedness for kidney replacement therapy (KRT) by the time the patients were initiated on HD. In addition, the study was to establish the duration the patients had been on chronic HD. Finally, the study was to establish the status of management of the documented underlying conditions which resulted in end stage kidney disease (ESKD) and assess the status of management of anaemia, mineral and bone disorder among these patients.

Results

There were 91 patients on chronic maintenance HD in KNH between June and July 2018. Among the eligible patients, 82 were enrolled. Males were 50% (41) males. The mean age was 45.39 ± 15.96 years (p value <0.001 , 95%, CI 41.80-48.90). Hypertension and diabetes mellitus (DM) were the leading co-morbidities at 62.2% and 23.2% respectively (p value <0.001). Majority of the patients were referred from these clinics. The followed up duration had median of 11 months, maximum duration of 552 months and minimum duration of less than 1 month (p value <0.001 , 95%, CI 23.57-59.60). Despite the contact with health providers prior to development of ESKD, 74.4% of the patients were initiated on HD as emergency (p value 0.001) and 29.3% knew of HD as the only modality of KRT (p value <0.001). Acute central venous catheters were used by 85.30% of the patients as the vascular access for initiation of HD. Long stay cuffed tunneled catheters were used in 13.40% while arteriovenous fistulae (AVF) use was in 1.2% of the patients (p value <0.001). Counseling and other supportive services such as health education and nutritional counseling were not optimal. At least 20% of patients gave responses indicating deficiency of information or knowledge in these domains. More than 40% of the patients had not been counseled about

kidney transplantation. More than 80% of the patients were on intravenous (IV) iron supplementation, 82.90% on erythropoiesis stimulating agents (ESA) and 75.6% had been transfused with blood since they initiated on HD (p value <0.001). Despite the use of ESA and IV iron, anemia was common. The average haemoglobin (HB) was 8.60 ± 1.92 g/dL (p value < 0.001, 95%, CI 8.23-9.07). Mean serum calcium was 2.14 ± 0.37 mmol/L and phosphate of 1.40 ± 0.55 mmol/L. Only 24.0% of the patients were on calcium supplementation and none was on phosphate lowering therapies. Eighty eight percent of the patients were on twice weekly intermittent HD. The mean interdialytic weight gain (IDWG) was between $3.09-3.92\% \pm 2.48-3.03\%$ during the 4 HD sessions preceding the study. (p value <0.001, 95%, CI 2.48-4.46). The mean systolic blood pressure (SBP) during four HD sessions preceding the study were $140 - 148 \pm 24.39-26.61$ mmHg (p value <0.001, 95%, CI 138-151).

Conclusion

In conclusion, the study shows our HD patients are young with the commonest causes of CKD being hypertension and DM. Due to development of ESKD in non-diabetic patients at young age, it is plausible to suspect glomerulonephritides as the underlying cause of hypertension and subsequent ESKD. Diabetes mellitus is also contributing a sizeable burden of ESKD in our population. Even patients with long duration of follow up in outpatients' clinics are not well prepared for KRT. Majority initiate HD as emergency with acute vascular accesses. Management of anaemia, mineral and bone disorder are suboptimal. Counseling, nutrition education and transplantation uptake are low.

CHAPTER ONE

1 INTRODUCTION

1.1 Background information

Chronic kidney disease (CKD) has emerged as public health issue globally with rising burden more profound in low-income and middle-income nations [1-3]. The aetiologies of CKD are varied spanning from hereditary to acquired causes. Hypertension and diabetes mellitus (DM) are among the commonest causes of CKD. Progression to end-stage kidney disease (ESKD) is varied, and at ESKD, kidney replacement therapy (KRT) is necessary for sustenance of life. Modalities of KRT are peritoneal dialysis (PD), haemodialysis (HD) as well as kidney transplant.

1.2 Haemodialysis

Haemodialysis is the most popular modality of KRT world over. There is a tendency to concentrate efforts on HD and failure to address the underlying conditions once chronic HD has been initiated. In Kenya, there are in-centre HD units with no documented home HD. For chronic maintenance intermittent HD, the patients have twice or thrice weekly sessions each session lasting for about 4 hours. The study explored the follow up for the primary health conditions, the attention given to management of anemia, mineral and bone disorder for the patients who were on chronic maintenance HD programme at Kenyatta national hospital (KNH). The study documented the extent of the patient knowledge about the modalities of KRT and some aspects of multidisciplinary approach to care delivery in CKD. The standards of care against which the actual care delivered was measured against were as set in the international guidelines for various aspects of kidney diseases by Kidney Disease Quality Initiative (KDOQI) and Kidney Disease: Improving Global Outcomes (KDIGO).

1.3 Problem statement

The prevalence rates of CKD is approximately 10%-14% among the general population [4]. Among the people with CKD, 35.4% are in stage 2. About 5% are in stage 3a, while less than 2% are in stage 3b and advanced CKD in about 0.5% of this population [5]. The leading cause of death among patients on KRT is cardiovascular disease (CVD) [6]. This could be due to suboptimal management of the primary disease and progression of CKD with profound target organs damage.

In Kenya, unpublished data from the Kenya Renal Association show a massive increase in the number of facilities offering HD services across the country. The HD units have risen from 10 to 102 and patients on HD have increased from 300 to 2400 in the period between 2006 and 2018. This translates in 920% increase in HD units and 700% rise in the patients' population. By the year 2006, there were 16 nephrologists in Kenya, and 30 by March 2018, a rise of 87.5%. The increase in HD units and the patients' population is far much higher than the increase in the trained kidney specialists. Kenyatta national hospital is the first public renal unit with the largest population of patients on HD in Kenya. Assessing the care given at KNH chronic maintenance HD population is likely to represent the care offered by other public HD units spread across the country.

1.4 Study question

The study question was: - What is the actual extent of care offered to patients on chronic maintenance haemodialysis at Kenyatta national hospital?

1.5 Study objectives

1.5.1 Main objective

To establish the actual extent of care for patients on chronic maintenance haemodialysis at Kenyatta national hospital

1.5.2 Specific objectives

- i. To document the morbidities documented as the underlying cause(s) of chronic kidney disease among ambulant patients attending chronic maintenance haemodialysis at KNH
- ii. To establish the status of management of the documented underlying conditions which resulted in end stage kidney disease among ambulant patients attending chronic maintenance haemodialysis at KNH
- iii. To document the level of preparedness for kidney replacement therapy by patient on maintenance haemodialysis at KNH by the time they were initiated on haemodialysis
- iv. To establish the duration for chronic maintenance haemodialysis among ambulant patients attending chronic maintenance haemodialysis at KNH
- v. To assess the status of management of selected complications of chronic kidney disease i.e. anaemia, mineral and bone disorder among ambulant patients attending chronic maintenance haemodialysis at KNH

1.6 Rationale/ study justification

The study documented the care to patients on chronic maintenance haemodialysis. This entailed the primary conditions, the follow up duration, the frequency of haemodialysis and the recent fluid removal as per the ultrafiltration volume. The study established the haematologic parameters, serum calcium, phosphate and albumin levels among these patients. The level of preparedness and some aspects of multidisciplinary approach to care were assessed as perceived by the patients. This information is utilized in the management of CKD in areas of care delivery.

1.7 Significance of the study

The information from the study will be utilized to better the care of patients who are currently enrolled in the haemodialysis programme and in can inform peripheral haemodialysis units too. The findings can be used in future programming of healthcare delivery for CKD population. The study has generated questions which require further studies to be carried out to answer them so as to inform practice.

CHAPTER TWO

2 LITERATURE REVIEW

2.1 Chronic kidney disease

The Kidney Disease: Improving Global Outcomes (KDIGO) defines CKD in terms of abnormalities in structure and function. To qualify to be CKD, these must be present for more than twelve weeks and must be negatively affecting health. The CKD should be classified based on glomerular filtration rate (GFR), cause and albuminuria categories. Inclusion of the presence or absence of systemic disease is also advocated for. Duration and consistency of abnormalities are key in the definition of CKD [1]. According to KDIGO, there are six categories of CKD based on GFR [5].

The increase in the incidence of CKD is now a recognized problem to the healthcare systems globally [7, 8]. Kenya is not an exception as unpublished data by the Kenya Renal Association has shown > 920% increase in the HD units and >700% in the patients population between 2006 and 2018. By the year 2006, there were 16 nephrologists in Kenya, and 30 by March 2018, a rise of 87.5%. The increase in HD units and increase in the number of patients on HD is far much higher than the increase in the trained kidney specialists. Chronic kidney diseases carry a high morbidity and mortality, and colossal economic social, physical and psychological burdens.

2.2 Common underlying conditions leading to chronic kidney disease

Hypertension and diabetes mellitus (DM) are the global leaders in causation of CKD. Obesity predisposes an individual to hypertension and DM and is also directly linked to CKD [9-11]. Communicable diseases for example human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) have direct effects, immune response effects as well as the effects linked to the treatment of the HIV [12] which are known causes of CKD. Obstetrics and gynaecological, obstructive uropathy as well as autoimmune conditions and malignancies contribute to CKD too.

In India [13], Nigeria [14] and Ghana [15], the commonest conditions documented as the underlying causes of CKD and resultant ESKD were hypertension and DM. In Japan [16], Spain [17], United States of America [18], China [19] and Brazil [20], DM is the leading

cause CKD. Some patients, especially the young ones who suffer from glomerulonephritides present with phenotype of hypertension. Chronic glomerulonephritides as underlying causes of CKD leading to ESKD has been reported in Japan [16] and Ghana [15] in about a third of patients. Nigeria [14] and Cameroon [21] have also reported high number of chronic glomerulonephritides. Locally the burden of chronic glomerulonephritides is unknown because kidney biopsies are rarely performed. Development of hypertension and subsequent ESKD at young age may suggest glomerulonephritides as the underlying causes.

2.3 Chronic care model in chronic kidney disease

Like any other chronic disease, CKD management can employ the chronic care model design to improve outcomes. Patients identification, improvement of continuity of care, multidisciplinary teams, patient self-management support and provider collaboration [22] are key in chronic care model. There is often inconsistency between the CKD patients care and published guidelines [23-25]. Chronic kidney disease and its associated complications are often unrecognized and untreated because CKD is asymptomatic in early stages, inappropriate screening and misinterpretation of results [26]. Monitoring of metabolic complications among CKD patients is not satisfactory [27]. More than half of CKD patients do not attain current recommended blood pressure targets [24, 25]. More than 7 in every 10 patients are initiated on HD with central venous catheters which are well known to be plagued by higher mortality and morbidity [28].

2.3.1 The chronic kidney disease care collaborative team

Chronic kidney disease is a sentinel disease, punctuated by cardiovascular complications, hospitalization and death [29]. There are other players which drive the relationship between CKD and CVD other than age and sex [30, 31]. Due to the strong causal relationship between CKD and CVD, prevention of CKD progression can translate into prevention of CVD [32]. The mortality from CVD is about double as high CKD stage 3, and thrice higher at CKD stage 4 than that in individuals with normally functioning kidneys [33, 34]. Risk of heart failure is twice GFR less than 60 mL/min/1.73 m² when compared with that people whose kidney function is normal [35]. There is heightened risk for stroke, coronary arterial disease, atrial fibrillation and peripheral arterial disease (PAD) [36-39]. Multidisciplinary team members require reliable and timely information to be able to formulate appropriate care plan including co-ordinated transition to RRT if necessary [22, 40]. The KDIGO guidelines

recommends that the CKD multidisciplinary team should comprise of or have access to dietary, education services and counseling about different options for KRT. The dialysis accesses surgery, ethical and psychosocial care should be provided in a multidisciplinary approach [41].

2.3.2 Referral to specialist services and initiation of kidney replacement therapy

According to KDIGO [41], referral for specialist kidney care services for people with CKD is recommended for acute kidney injury (AKI) or abrupt sustained fall in kidney function, patients with a consistent finding of significant albuminuria, rapidly progressive CKD, CKD and high blood pressure unresponsive to treatment with ≥ 4 antihypertensive drugs. Indications for KRT include uremic syndromes, acid-base or electrolytes disorders, and volume overload which often manifests at GFR of 5-10 ml/min/1.73 m². For the patients initiated on HD, defining targets indicators for care, identification of weaknesses and prompting the establishment of corrective measures can better clinical practice [42].

2.4 Renal replacement therapies

Advancement of CKD to ESKD renders the kidney unable to support bodily functions sufficiently, thus, KRT is indicated. The KRT include dialytic and kidney transplantation with latter being superior to the former. Pre-emptive kidney transplantation should be considered when GFR is less than 20mL/min with evidence of chronicity [41]. Despite kidney transplantation being the best treatment modality for ESKD, this service is out of reach to many patients. This is partly due to cost and scarcity of donors. Dialytic therapies HD and peritoneal dialysis (PD). Haemodialysis is the most popular among adult patients world over. Anecdotal data from the Kenya Renal Association show low uptake of kidney transplantation with most patients opting to remain in HD and is thought to be due to the national insurance support for HD and lack of support for post kidney transplant care support.

2.5 Kidney replacement therapy by haemodialysis

Haemodialysis utilizes an extracorporeal circuit where the blood circulates and waste products are removed. There are blood and dialysate circuits in HD. The dialyzer is the meeting point for the blood and the dialysate solution. The blood is pumped from the patient through the arterial circuit to the dialyzer and returned through venous circuit to the patient. There are several monitors, ports and chambers appended to the venous and arterial circuits.

There are checks for temperature, concentrations of various electrolytes within the dialysate circuit [43].

2.5.1 Morbidity and mortality among haemodialysis patients

There is documented poor survival among ESRD patients who are on HD. The survival is 82% at the first year and 47% by the fifth year in Europe and mortality is mainly driven by cardiovascular disease and other co-morbidities [44, 45]. In Korea the, the survival of HD patient is 67.8% which comparable to survival among patients with colon and gastric carcinomas. Various HD targets have been used. These include serum albumin, haemoglobin, calcium–phosphate products, dialysis dose and type of vascular access against the outcomes like hospital admissions, hospitalization days, hospital costs and mortality. These outcome measures have a strong association regardless of which target are being considered [46]. Establishing of quality-of-care indicators based on scientific evidence can improve the outcomes in patients on HD [47].

2.6 Prevalence of dialysis population

The prevalence of CKD in the general population ranges between 10% and 14% [4]. Among the people with various stages of CKD, 35.4% are in stage 2. About 5% are in stage 3a, while less than 2% are in stage 3b. Advanced CKD accounts for about 0.5% of this population [5]. The decrease in burden as the CKD stage advances is largely due to high mortality associated with the disease progression. Management of the underlying conditions that resulted ESKD and the complications of long standing CKD are often managed sub-optimally once patients are initiated on HD. This might be one of the reasons why the cause of mortality in patients on HD is predominantly from cardiovascular disease [6]. Chronic kidney disease carry a high morbidity and mortality, and colossal economic, social, physical and psychological burdens. In Kenya, the population patients on HD has grown exponentially in the recent years.

2.7 Complications of chronic kidney disease

Chronic kidney disease is plagued by various complications. The complications become severer as the disease advances. Therapy-related complications are also recognized. Below are some of the complications of CKD.

2.7.1 Anaemia

Anaemia is very prevalent among CKD patients. The burden increases as the disease progresses though very little is known about the exact mechanisms of development of anaemia in CKD [48]. In addition to the usual possibilities of iron loss, HD patients have repeated blood sampling and retention of blood in the extracorporeal circuit, and this augments the anaemia and iron deficiency. Surgical procedures, interference with iron absorption by medications such as antacids and phosphate binders and inflammatory milieu associated with CKD lead to the deficiency [49]. Erythropoietin (EPO) deficiency, reduction in available iron and chronic inflammation contribute to the development of anaemia in CKD stages 3 to 5 [50].

2.7.2 Chronic kidney disease mineral and bone disorder

This is common in CKD. Hyperphosphatemia and deficiency of active vitamin D3 lead to secondary hyperparathyroidism which ultimately results in bone disease. Kidney bone disease, is characterized by abnormal calcifications in bones and soft tissues. This condition is termed as CKD-mineral and bone disorder (CKD-MBD) [51].

2.7.3 Cardiac and vascular complications

There is a wide range of cardiac and vascular complications related to CKD.

2.7.3.1 Peripheral arterial disease

The burden of peripheral arterial disease (PAD) is largest among the diabetic or atherosclerotic patients who are on dialysis. This is compounded by hypoalbuminemia in patients on dialysis.

2.7.3.2 Cerebrovascular disease

More than 1 in every 3 patients on dialysis have been reported to suffer from severe cognitive impairment [52]. In the United States of America, incident dialysis patients have a six-fold age-adjusted relative risk of stroke when adjusted for age compared with the general population [53, 54].

2.7.3.3 Left ventricular hypertrophy

Chronic kidney disease patients commonly have left ventricular hypertrophy (LVH), which is a risk factor for death in ESKD. Left ventricular hypertrophy increases the risks for stroke and sudden death [55].

2.7.3.4 Extracellular volume overload

Due to resultant loss of sodium excretory capacity in CKD, extracellular volume is the major cause of high blood pressure in patients on dialysis. Interdialytic weight gain (IDWG) is a strong predictor for mortality even after adjustment for age and co-morbidities. The IDWG is calculated by subtracting the weight at the end of the previous HD session from the weight at the beginning of the current session. The IDWG can be expressed as a percentage of the dry weight of the patient. Left ventricular hypertrophy and dilatation may result from recurrent hypervolemia. Hypervolemia may present as pulmonary or peripheral oedema. Ability to tolerate large ultrafiltration (UF) volume indicate that the target weight has not been attained [56].

2.8 Management of some conditions resulting from chronic kidney disease

2.8.1 Anaemia management in patients on haemodialysis

Evaluation of anemia in CKD includes full haemogram. Full haemogram can assist in assessment of the severity of anemia and bone marrow function [48]. Optimal haemoglobin level in CKD patients on HD is unknown, but guidelines suggest HB of 11-13g/dl [57]. Correction of anaemia in CKD does not slow the decline in kidney function but may precipitate hypertension [58]. For the CKD stage 5 on HD or PD, testing for anaemia should be performed at least every 3 months [48].

2.8.1.1 Treatment with iron agents

Patients with CKD 5 on HD lose between 1 and 2 grams of iron yearly. This is in part from the HD itself and related CKD circumstances [59-61]. Correction of iron deficiency orally or intravenously (IV) can reduce the degree of anaemia in CKD [62, 63]. Iron deficiency is a known cause of ESA hyporesponsiveness [64]. The IV iron administration in CKD 5 on dialysis is supported by studies over the oral route [64-66]. The approaches employed are periodic iron repletion and maintenance treatment, consisting of smaller doses administered at regular intervals to keep the iron level within pre-specified ranges [48].

2.8.1.2 Erythropoiesis-Stimulating Agents (ESA)

In absence of use of ESA, gradual decrease in HB concentration is witnessed as kidney function declines [67], a fact that supports regular surveillance of HB in CKD population.

Epoetin therapy

Alpha- and beta-epoetins, darbepoetin as well as continuous erythropoietin receptor activator (CERA) [methoxy polyethylene glycol-epoetin-beta] have been used in anaemia management

among the CKD patients. Erythropoiesis stimulating agents should be used for adult patients with CKD 5 on dialysis to maintain HB above 9.0 g/ dl [48].

Dosing of epoetin in haemodialysis patients

The dosing of alpha- and beta-epoetins is initiated at a dose of 20-50 IU/kg thrice weekly. Darbepoetin-alfa is initiated at 0.45 mg/kg subcutaneously or intravenously weekly. The same darbepoetin-alfa can be given at 0.75 mg/kg fortnightly by subcutaneous route. Continuous erythropoietin receptor activator (CERA) dosing is started at 0.6 mg/kg fortnightly by IV route [48].

2.8.2 Mineral and bone disorder in patients on haemodialysis

Restriction of phosphates in the diet and use of phosphate binders are measures employed to curb secondary hyperparathyroidism [68]. Vitamin D analogues are also utilized in management of bone and mineral disorder of CKD [69].

According to KDIGO, CKD-MBD treatments should be guided by assessments of calcium, parathyroid hormone and phosphate serially. In adult CKD patients with CKD 3a to CKD5 on HD, avoidance of hypercalcemia is suggested [70]. Treatment entails reduction of phosphate absorption from the gastrointestinal system by reduction of phosphate containing diet as well as administration of oral phosphate binders [71]. Management of CKD-MBD is complex with a lot of grey areas to the extent that even KDIGO guidelines on this subject have less than 20% recommendations (level 1) with the rest being suggestions (level 2). More than a third being suggestions of low grade (2C) and less than 5% being recommendations of high grade (1A)[72].

2.9 Theoretical framework of haemodialysis care

The preferred treatment in patients with ESKD is kidney transplantation. Dialytic therapies are stop gap measures especially for patients who are transplantable. The underlying condition and the resultant morbidities from the underlying disease and the progression of CKD should be addressed. From observation of the care given to the CKD patients, once HD is initiated, a vicious cycle ensues and the care for the underlying conditions is often forgotten. (Figure 2-1).

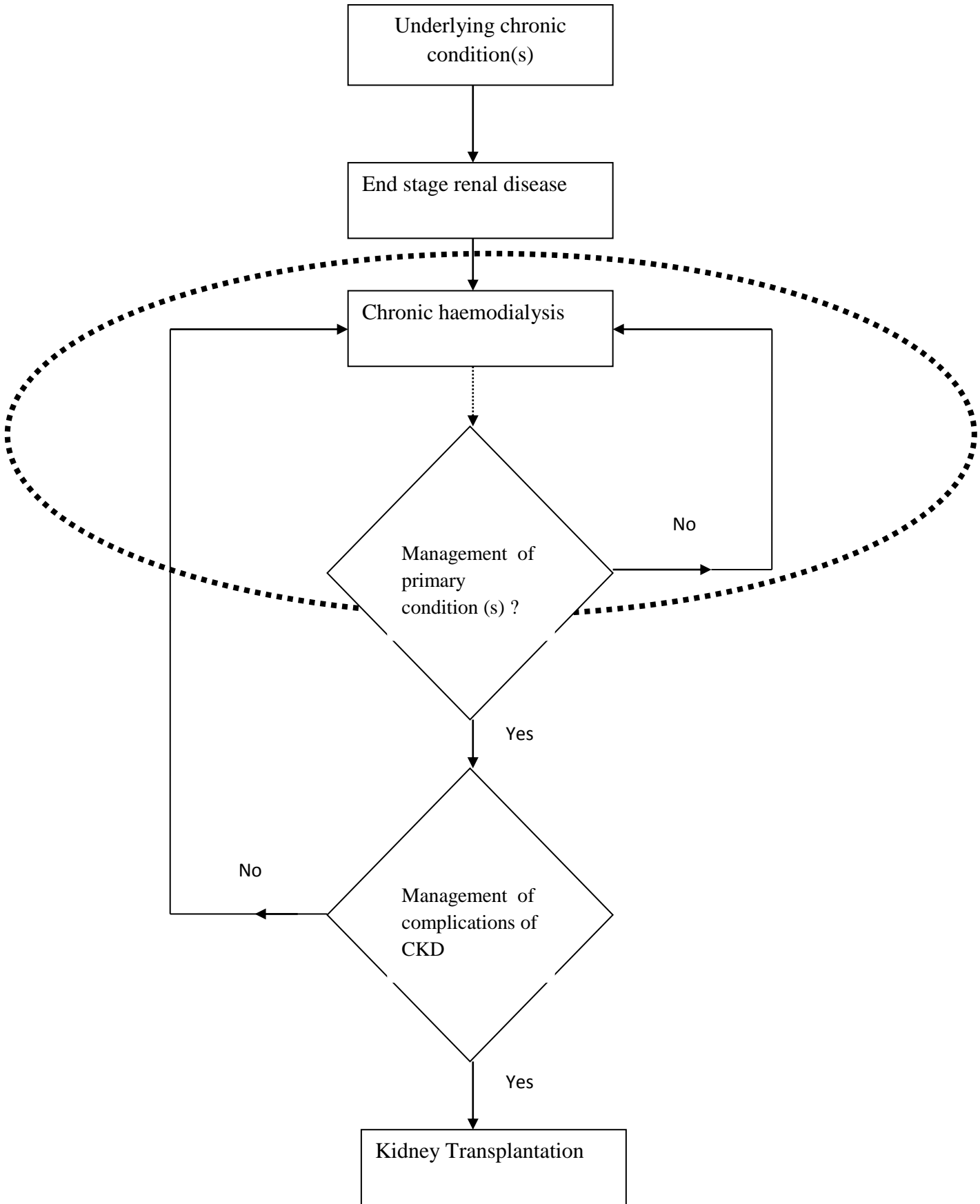


Figure 2.1. Theoretical framework

Dotted oval represents a repetitive cycle when all effort is concentrated on haemodialysis only. CKD, chronic kidney injury

CHAPTER THREE

3 METHODOLOGY

3.1 The study design

This was a descriptive cross sectional study.

3.1 Area of the study

The study was executed at Kenyatta National Hospital renal department. Kenyatta National Hospital (KNH) is a teaching and referral centre located in the capital city of Kenya, Nairobi. The hospital was established in 1900. It has a capacity of about 1800 beds. The KNH is the teaching hospital for the University of Nairobi, for the health-related courses for undergraduate and the post graduate programmes. It serves as a referral hospital for Kenya and Eastern Africa region. It runs general and specialized clinics and in-patients services in surgical, medical, obstetrics and gynaecology, ophthalmology and paediatrics. Renal unit is one of the specialized units in the hospital. The main services offered in the unit are HD and kidney transplantation.

3.2 Study population

The study population included the ambulatory adult patients on chronic maintenance HD. There were about 91 patients on chronic HD programme for at least 3 months at KNH renal unit during June-July 2018.

3.3 Sampling

Ambulant patients on chronic maintenance HD were informed about the study. All consenting patients were enrolled into the study.

Formula with finite population correction

$$n' = \frac{NZ^2P(1-P)}{d^2(N-1) + Z^2P(1-P)}$$

where n' = Sample size with finite population correction,

N = Population size,

Z = Z statistic for a level of confidence,

P = Expected proportion (If the prevalence is 20%, $P = 0.2$), and

d = Precision (If the precision is 5%, then $d = 0.05$)

Where, $N = 91$, $Z = 1.96$, and $P = 50\%$,

At least 74 (n') patients on chronic HD, was the minimum number of the patients required for this population study.

3.4 Inclusion criteria

Ambulant consenting adult patients aged 18 years and above on chronic maintenance HD for at least three months prior to the study commencement.

3.5 Exclusion criteria

Very sick patients, non-consenting patients and those aged under 18 years were excluded from the study.

3.6 Instrument /tool (See appendix 1)

3.7 Study procedures

Medical records for the ambulant patients on chronic maintenance HD were retrieved from health records and information office. Sociodemographic, medical history, duration of follow-up and state of preparedness parameters were obtained through interview and entered into the questionnaire. Data from HD flow sheet for the last 4 sessions preceding the interview were extracted. These included average systolic and diastolic blood pressure, pre-dialysis and post-dialysis body weight, ultrafiltration volumes. Treatment history was taken through interview. Data on the primary diagnosis and the date of initiation of dialysis were collaborated from the patients' verbal reports. These were extracted and filled into a data collection proforma. (Appendix 1).

3.8 Laboratory methods

3.8.1 Specimens collection, handling, transportation and storage

A qualified medical laboratory technologist who works in the KNH renal laboratory was engaged to draw the blood samples from the study participants.

Blood samples

A sample of venous blood (about 4.0ml) was collected from each participant. This sample was divided into two. Two millilitres (2ml) was put in a plain vacutainer for assay for serum

calcium, phosphate and albumin, while the other 2ml were put in an ethylenediaminetetraacetic (EDTA) anticoagulant vacutainer for assay for full blood count (FBC). The vacutainers were labelled with the study number of the participant to conceal obvious patients' identity. They were delivered to the laboratory within an hour from the time of collection for processing in batch for biochemical parameters.

Equipment used

The machines that were used for the sample analysis were the BioLis® clinical chemistry analyser for calcium, phosphate and albumin. Full blood count was performed using the Sysmex® blood cell counter from Hass Scientific™.

Blood cell count principles

Full blood count was performed by an automated analyzer that counts the numbers and types of different cells in the blood. It aspirates a very small amount of the sample through the narrow tubing. Within this tubing, there are sensors that count the number of cells going through it. Flow cytometry principles are utilized to differentiate and measure the cells in the blood sample. For detection, light detectors are used as well as the measurement of electrical impedance. One way the instrument can tell what type of blood cell is present is by size. The parameters which were measured were the erythrocytes, leucocytes and thrombocytes counts, haematocrit, and haemoglobin concentration. Absolute and differential counts for neutrophils, lymphocytes, eosinophils, monocytes and basophils were performed. The red blood cells indices were measured too.

Serum calcium, phosphate and albumin analysis method

Two millilitres of blood in a plain vacutainer were let to stand for 20 minutes, after which the blood was centrifuged at 2500 rounds/minute for 3 minutes. The serum was then transferred into the analysis cup, and placed in the respective sample position in the biochemical multianalyser machine. Respective parameters of calcium, phosphate and albumin were ordered. The results were then printed out.

3.9 Quality control and quality assurance

Renal laboratory actively runs quality control (QC) materials every day to ensure the quality of results is guaranteed at all times. The laboratory runs calibration materials parallel with the

samples. Renal laboratory also is involved in external quality control (EQC) programme facilitated by Riqas[®]. Standard operating procedures for specimen collection were followed; labelling was done after sample collection to minimize pre-analytical errors. To ensure quality, the renal laboratory biochemical machines were calibrated daily. Standards and controls were run with each batch of tests. Every 15th sample was taken to laboratory 16 in KNH for quality control. Verification of results was done together with the medical laboratory technologist and accurate transcription of results to the case report forms was ensured. A print out of the results was also availed in the patient's medical file.

3.10 Data management

3.10.1 Data collection, storage and cleaning

Completion of the questionnaire/study proforma was verified before the investigator/research assistant releases the patient. The questionnaires were identified by unique codes which were also be used to identify the blood specimens for the patients. The filled forms were kept under lock and key by the investigator. Data cleaning was done before analyses. Back up for the data was done in an external hard drive and written on a compact disk (CD), and versatile compact disk (DVD). Access to these back-ups was limited to the investigators only. The hard copies of the filled proforma/questionnaires were to be destroyed by burning six months after completion of the study.

3.10.2 Data analysis

Data analyses utilized the Statistical Package for Social Sciences (SPSS) ver. 20.0. Continuous variables e.g. age, mean, mode, median, range, and standard deviations were calculated. Frequencies of categorical variables e.g. sex were calculated. Significance testing was performed with chi square testing and student t-test.

3.10.3 Data presentation

The presentation of data used graphs (bars, line and histograms), tables and pie-charts.

3.11 Ethical considerations

3.11.1 Approvals

The proposal was submitted for approval to the University of Nairobi/Kenyatta National Hospital Ethics and Research Committee before the commencement of the study. After Ethics Committee approval, authority to use the medical records in Kenyatta National

Hospital was sought from the health information and medical records in-charge in Kenyatta national hospital. The study was also registered by KNH Research and Programs department.

3.11.2 Privacy and confidentiality

Coding of patients information was done to protect privacy. Information gathered was held in confidence by the investigators, and was only used for the study.

3.12 Benefits to the patients

Enrollment into the study was voluntary and after having signed informed consent. Refusal to participate did not by any way affect the services offered to the patients in the clinic. If there were abnormal results from the analyses of blood, these results were communicated to the primary clinician and treatment prescribed if necessary. A copy of the study results was availed in the patient's file for future reference and follow up.

CHAPTER FOUR

4 RESULTS

4.1 Study recruitment

There were 91 patients on chronic haemodialysis in Kenyatta National Hospital renal unit for ≥ 3 months between June and July 2018. Three of the patients were aged below 18 years, thus not eligible for enrolment into the study. There were therefore 88 eligible patients. Six of the patients were not included. Eighty two (93.2%) of the eligible patients were enrolled into the study (Figure 4-1).

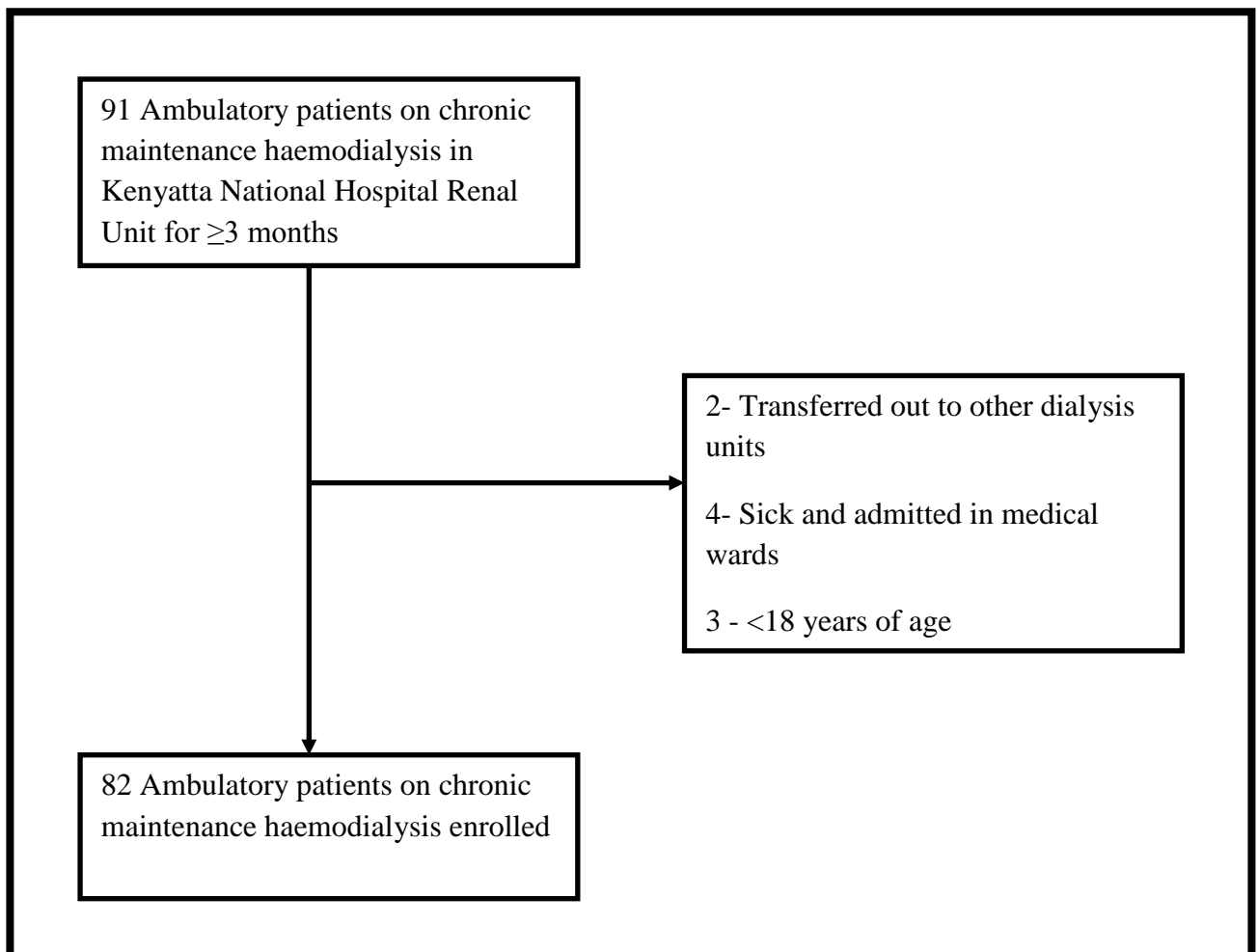


Figure 4.1. Recruitment flow diagram

4.2 Sociodemographic and clinical characteristics

Among the patients on chronic maintenance haemodialysis in KNH in June-July 2018, the males and females were equal in number. About two in every three (65.9%) of the patients were aged 50 years and below. Almost half (47.60%) of the patients on haemodialysis were

enrolled from the hypertension clinic. About 1 in every 5 patients (19.50%) was from diabetes clinic. More than 3 in every 10 patients (31.70%) were enrolled from the renal clinic while almost 15% of the patients had no regular clinics prior to enrollment into haemodialysis programme. For the patients who enrolled in the haemodialysis from regular out-patient clinics, only 53.70% reported to still attend the clinics. Majority of those who reported to attend the clinic regularly had not attended the said clinic even once in the last six months preceding the study (Table 4-1).

Table 4-1. Age of the patients and first out-patient clinics attendance

Description	Male	Female	All	P-value
Sex n (%)	41(50)	41(50)	82(100)	1.000 [‡]
Age[‡] (year)				
Mean±SD	50.76 ±17.05	40.02 ±12.90	45.39 ±15.96	
Mode	50	35	50	
Median	50	39	46	
Minimum	18	18	18	
Maximum	87	70	87	
Clinic Attended (%)				
Diabetes clinic	22.00	17.10	19.50	<0.001 [‡]
Hypertension clinic	51.20	43.90	47.60	0.659 [‡]
Renal clinic	14.60	48.80	31.70	0.001 [‡]
Others clinic	12.20	7.30	9.80	<0.001 [‡]
No clinic	17.10	12.20	14.60	<0.001 [‡]
Current clinic attendance	43.90	63.40	53.70	0.508 [‡]
Number of times of clinic attendance in the last 6 months^λ				
Mean ±SD	1.27±2.01	1.76±2.11	1.51±2.06	
Median	0	2	1	
Mode (%)	0 (50.0)	0 (40.5)	0 (45.1)	
Minimum (%)	0 (50.0)	0 (40.5)	0 (45.1)	
Maximum (%)	8 (2.9)	10 (2.7)	10 (1.4)	

[‡]age statistics p-value<0.001 (95% CI 41.80-48.90)

^λclinic visits statistics p-value <0.001* (*95% CI, 1.35-1.57)

CI-confidence interval, SD Standard deviation, [‡]Chi-square test, *student-t test

4.3 Duration of medical follow up and initiation of haemodialysis

The follow up duration before initiation of haemodialysis ranged from zero (0) months to 552 months (46 years). Almost 55% of the studied patients had duration of follow up of one year or less before initiation of haemodialysis (Table 4-2). The duration of follow up mean, mode

and median were 41, 0 and 0 months respectively. The duration which the patients were on haemodialysis ranged from 3 months to 138 months (11.5 years). (Table 4-3). Almost 3 in every 4 patients were started on haemodialysis as emergency (p value <0.001). At the initiation of haemodialysis, 62.2% of patients were hypertensive, 31.7% were diabetic alone or in combination with hypertension. (p value <0.001) (Table 4-4). Those who were aged 40 years and below and were not diabetic were 31.7% of the patients studied. Females predominated this subset of the subjects. (Figure 4-2). Individuals in this subset were likely to have suffered from glomerulonephritides. (Figure 4-2).

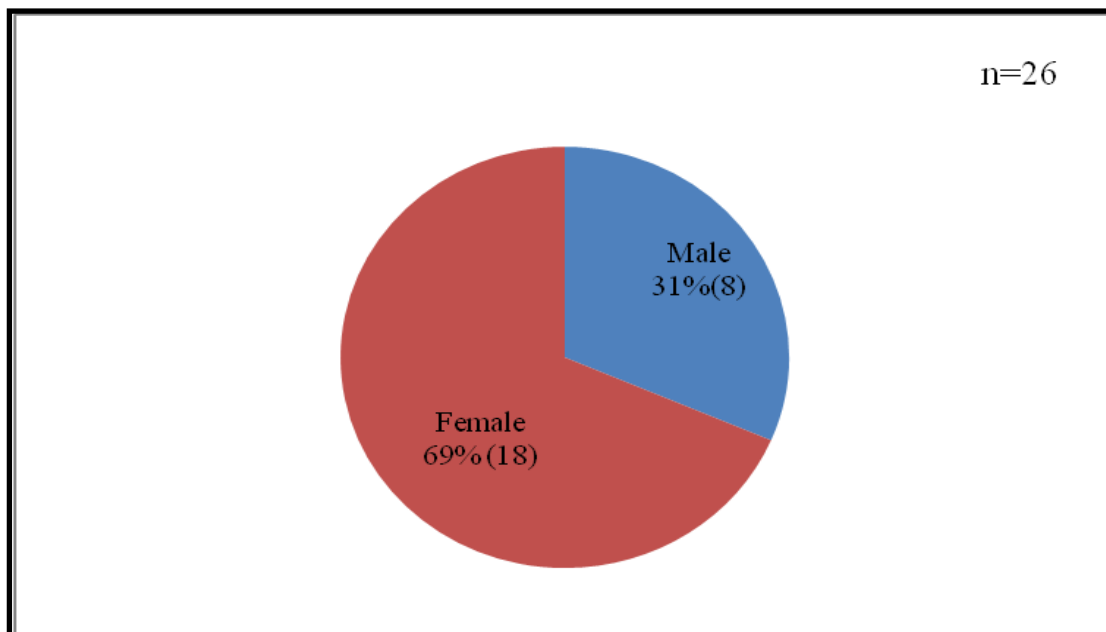


Figure 4.2. Composition of subset of patients aged 40years and below without diabetes mellitus

Table 4-2 Follow up duration before initiation of haemodialysis

Duration of follow up before the start of haemodialysis (month)	Number (%) (n=82)
0	16 (19.5)
1-6	19 (23.2)
7-12	10 (12.2)
13-24	10(12.2)
25-36	6(7.2)
37-48	3 (3.6)
49-60	3(3.6)
61-120	7(8.4)
>120	8(9.8)

Table 4-3 Medical follow up and haemodialysis durations

Statistic	Follow up duration before starting haemodialysis (month) ^β	Duration of haemodialysis (month) ^α
Mean±SD	41.59±81.97	15.35±23.91
Median	11	9
Mode (%)	0(19.5)	5(12.2)
Minimum (%)	0(19.5)	3(11.0)
Maximum (%)	552(1.4)	138(1.2)

^βt-test p value<0.001 (95% CI, 23.57-59.60), ^αpvalue<0.001 (95% CI, 11.66-22.17) **SD standard deviation, CI confidence interval**

Table 4-4. Diagnosis and circumstance around haemodialysis initiation

Circumstance around HD initiation	Number (%)	P –value Chi-square
Emergency HD initiation	61 (74.4)	<0.001
Elective HD initiation	21(25.6)	
Diagnosis at start of haemodialysis		
Hypertension	51(62.2)	<0.001
Diabetes mellitus and hypertension	14(17.1)	
Others	12(14.6)	
Diabetes mellitus	5(6.1)	

HD haemodialysis,

Table 4-5. Sex, HD duration and circumstances around initiation of HD of non-diabetic ESRD patients aged 40 years and below

n=26	Characteristic/statistics	Frequency	Percent
Sex	Male	8	30.77
	Female	18	69.23
Circumstances around HD initiation	Elective	9	34.62
	Emergency	17	65.38
Haemodialysis duration (month)	Mean ± SD	18.40±19.84	
	Mode	5	
	Median	11.50	
	Minimum	3	
	Maximum	94	

4.4 Preparedness for kidney replacement therapy

Eighty eight percent of patients on chronic maintenance HD were twice weekly intermittent HD, while 6% were on weekly and 6% on thrice weekly intermittent HD for at least 3 months

preceding the study. By the time of the study, 70.7% of the patients on HD knew two modalities of kidney replacement therapy. Thirty percent (30.5%) of the patients on HD did not know about kidney transplantation as a modality of kidney replacement therapy. In the chronic maintenance HD patients, 52.4% had been counseled about kidney transplantation (Table 4-6). Among the 43 patients who had been counseled for kidney transplantation, 42 of them had not started evaluation process for kidney transplantation.

Table 4-6. Knowledge about the modalities of kidney replacement

	Number (%)	P-Value (Chi-square)
Number of modalities of kidney replacement		
Dialysis only	24(29.3)	<0.001
Dialysis and kidney transplant	58(70.7)	
Know about kidney transplantation		
Yes	57 (69.5)	<0.001
No	25(30.5)	
Counseled about kidney transplantation		
Yes	43 (52.4)	0.659
No	39(47.6)	

About 19.5 % to 30.5% of the patients felt that they were never informed about the deterioration of the kidney disease and the results of the tests performed in the clinics. They never had health education during the course of their follow up in the out-patient clinics. (Table 4-7).

Table 4-7 Knowledge and information about disease progression during pre-dialysis clinic visits

	Before I was initiated on dialysis, the clinicians informed me about my illness and progression every time I attended the clinic (%)	The clinicians informed me about the test results every time I brought them during the clinic visits (%)	The clinicians referred me for health education during my clinic visits (%)
Never	30.5	19.5	28.0
Sometimes	28.0	18.3	37.8
Most of the times	17.1	22.0	9.8
Every time	24.4	40.2	24.4

In a Likert scale with never, sometimes, most of the times and every time, 13.2% of the patients felt strongly that they were not well informed about their health, with only 44.7%

reporting to have been well informed about their health conditions by the time they were initiated on HD. In another Likert scale spanning from strongly disagree, disagree, somehow agree and strongly agree, 42% of the patients reported that they were not informed about the risks of kidney failure due to the underlying medical conditions. More than 1 in every five (22.4%) had no counseling sessions by the time they were initiated on HD (Table 4-7).

4.5 Initial and current haemodialysis vascular access

Majority of the patients were initiated on HD as a matter of emergency. Almost 80% were initiated HD via acute vascular access placed in the jugular or subclavian veins. At least 3 months later, 40% still had acute catheters on the same veins. In-dwelling acute venous catheters on the femoral veins were in 9.2% at initiation and 6.6% of the patients at least 3 months later. Less than 2% of the patients had arteriovenous fistulae (AVF) at the incident HD, which rose to 14.5% at least three months later. Tunneled catheter were placed at 11.8% of incident HD and at least 3 months, were almost 40% (Figure 4-3).

Table 4-8 State of preparedness for haemodialysis

	I felt well informed about my health condition by the time I was initiated on haemodialysis (%)	I felt adequately informed to cope with complications of the kidney disease by the time I was initiated on dialysis (%)	I had been informed about the risks of kidney failure due to the primary illness during the clinic visits (%)	I had adequate nutritional counseling in respect to the kidney disease (%)	I had sessions with the renal counsellor before initiation of dialysis (%)
Strongly disagree	13.2	13.2	17.1	5.3	22.4
Disagree	14.5	25.0	25.0	19.7	21.1
Somehow agree	27.6	28.9	13.2	17.1	13.2
Strongly agree	44.7	32.9	44.7	57.9	43.4
P-value	<0.001	<0.001	0.007	<0.001	0.001
Chi-square					

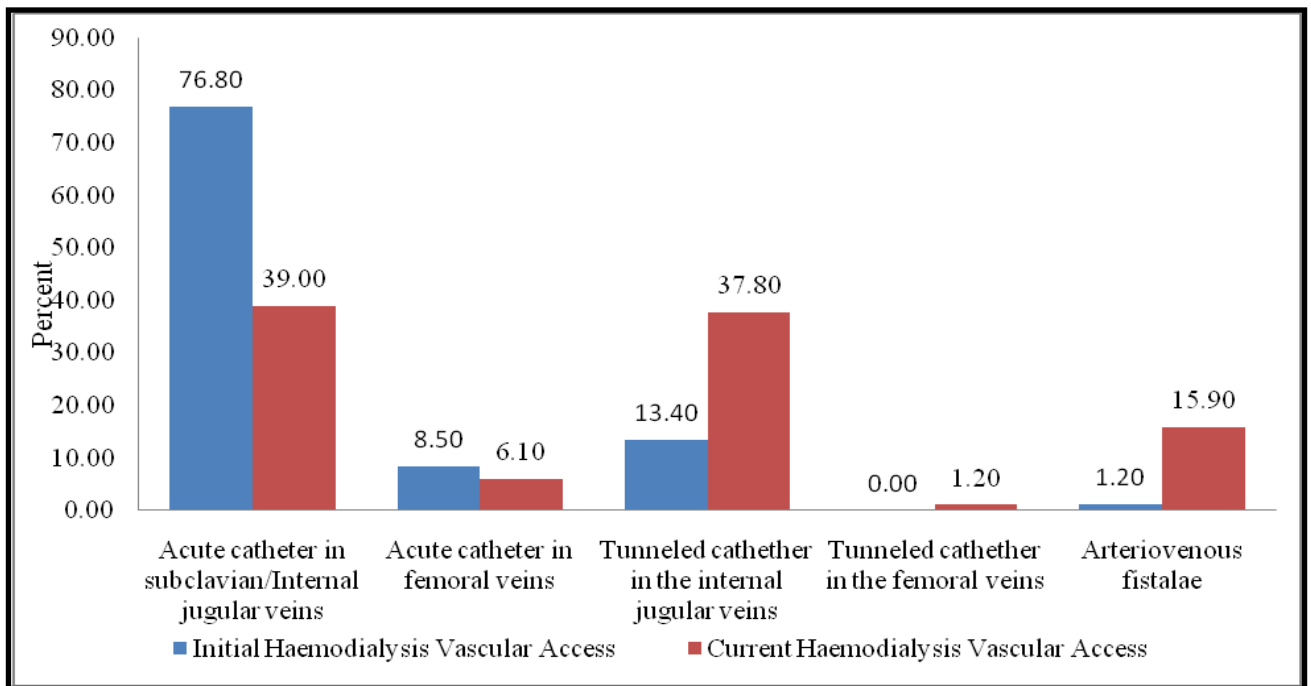


Figure 4.3 Initial and current haemodialysis vascular access

4.6 Counseling and enrolment into renal transplantation evaluation

Forty three patients (52.4%) of the patients on chronic maintenance HD had been counseled about kidney transplantation as a modality of renal replacement, but only 18.6% of them had started evaluation for transplantation. (Table 4-5). When asked about the single most pressing reason why they had not enrolled in transplant evaluation programme, lack of donors and lack of finances were the commonest reported reasons for not enrolling into the programme. (Figure 4-4).

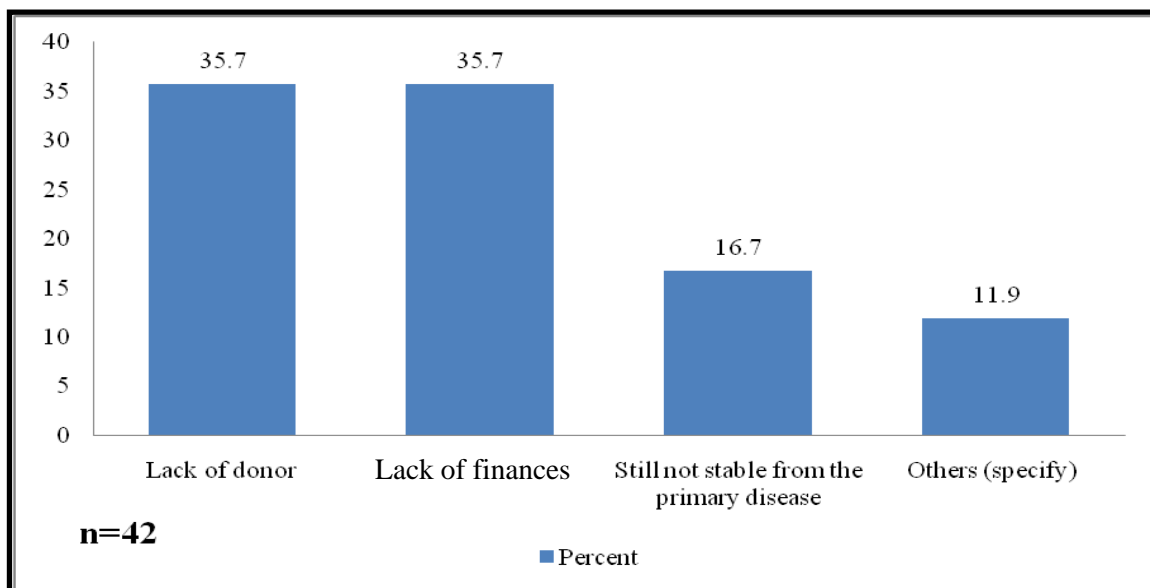


Figure 4.4 Leading reasons for failure to enroll in the kidney transplant evaluation programme

4.7 Haemoglobin level, serum calcium and phosphate

Two in every 3 patients had no monthly haemoglobin monitoring (Figure 4-5). Six percent had not tested for HB for three months. However, 84% of the patients were on iron supplementation and 82.9% were on erythropoietin injections for management of anaemia. Seventy five percent had had blood transfusion at least once since they were initiated on HD. Forty five percent of the patients had received blood transfusion within three months prior to the study. Less than a quarter (24.4%) of the patients were on calcium supplementation with none of the patients on phosphate lowering therapies (Figure 4-6).

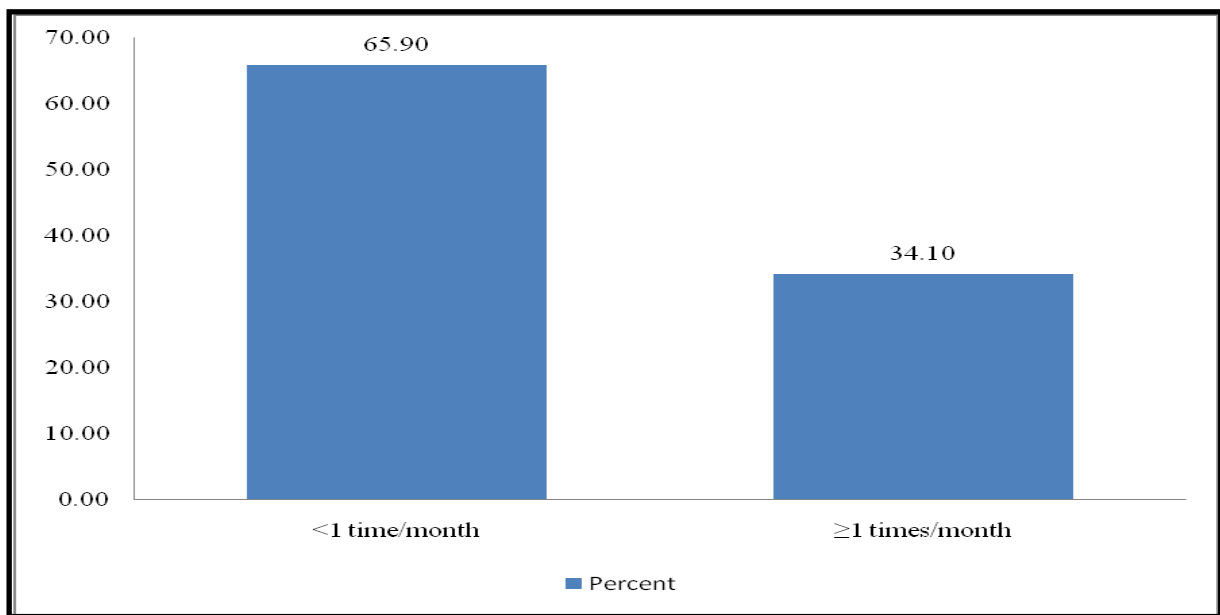


Figure 4.5. Haemoglobin testing frequency

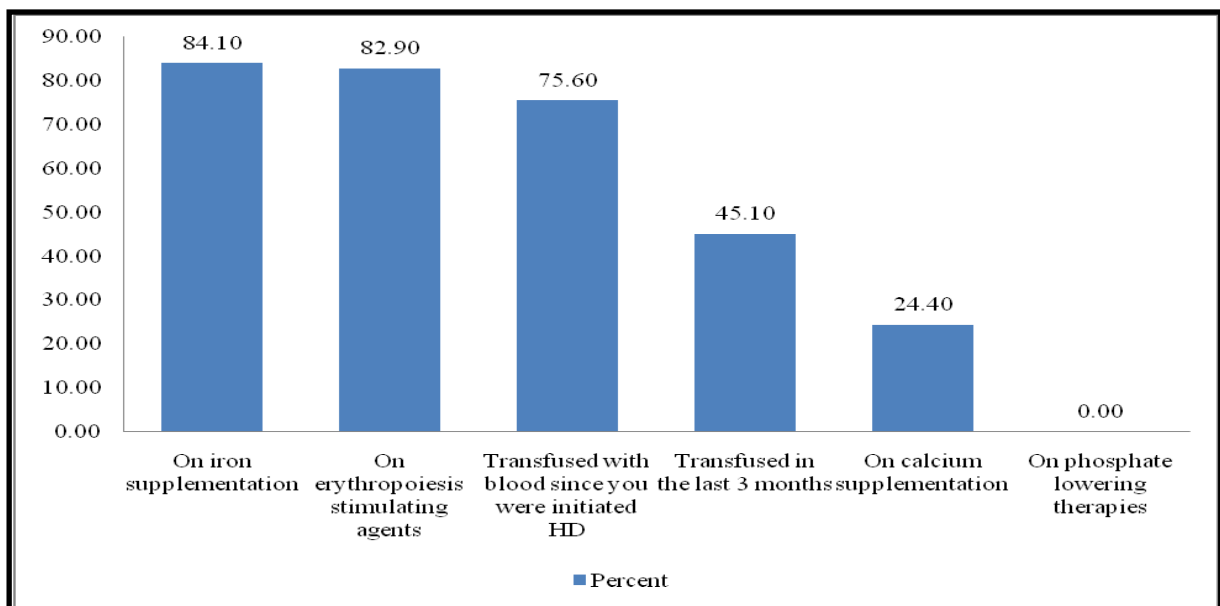


Figure 4.6 Anaemia, calcium and phosphate management

4.8 Serum calcium, albumin and phosphate laboratory evaluation

The mean serum albumin was 37.13 g/L and the mean corrected calcium was 2.14 mmol/L while the mean phosphate was 1.40 mmol/L (Table 4-9).

Table 4-9 Serum albumin, calcium and phosphate

Statistic	Serum albumin(g/L)	Corrected serum calcium (mmol/L)	Serum phosphate (mmol/L)
Mean±SD	37.13±7.10	2.14±0.37	1.40±0.55
Median	37.30	2.14	1.38
Mode	36.50	1.91	1.60
Minimum	15.50	1.00	0.36
Maximum	56.50	2.91	3.01
p-value	<0.001	<0.001	<0.001
(95% CI)	(35.57-38.68)	(2.06-2.22)	(1.28-1.52)

4.9 Haematologic parameters

The mean leucocyte count was 6.53X10⁹/L while mean erythrocyte count was 3.11 X10¹²/L. The mean HB concentration was 8.65 g/dL, mean corpuscular volume of 90.88 fL and mean platelets count of 252 X10⁹/L (Table 4-10).

Table 4-10 Haematologic parameters of patients on chronic maintenance haemodialysis

	White blood cells (X10 ⁹ /L)	Relative neutrophils count (%)	Relative lymphocytes count (%)	Red blood cells (X10 ¹² /L)	Haemoglobin (g/dL)	Mean corpuscular volume (fL)	Platelets (10 ⁹ /L)
Mean ±SD	6.53±2.99	64.44±12.46	22.53±9.71	3.11±0.76	8.65±1.92	90.88±6.96	252.72±88.31
Median	6.015	65	21.3	2.98	8.3	90.65	249.5
Mode	4	65	10.7	2.58	8	87.8	252
Minimum	2.48	35.4	4.9	1.71	4.6	75.6	45
Maximum	21.69	89.8	52.3	5.37	14.6	104.1	505

4.10 Blood pressure, body weight and ultrafiltration volumes during the last 4 haemodialysis treatment sessions

The average pre-dialysis weight in the 4 treatment sessions ranged 61.43-61.85 kg, and post HD weight of 59.48-59.71 kg. The average ultrafiltration volume was 2litres. Minimum ultrafiltration volume was 0.2 litres while the maximum volume was 5.0 litres. The interdialytic weight gain ranged between 0 and 13% with average of 3.09-3.92% (p value <0.001 CI 95%, 2.48-4.46) during the last four HD treatment sessions preceding the study.

CHAPTER FIVE

5. DISCUSSION

Among the 82 patients who were on chronic maintenance HD in KNH renal unit in June-July 2018 the number of males and females were equal. The average age was 45.39 years for both males and females but males were slightly older than females. Almost 2 in every 3 patients were aged ≤ 50 years. This compares with HD populations from Nigeria [14], Côte d'Ivoire [73] and Cameroon [21] [74] and India [13], but differs from the HD populations from Iran [75], Japan [16], Spain [76], Brazil [20] and Sweden [73] where the age is 60 years and above. The commonest conditions documented as the underlying causes of CKD and resultant ESKD were hypertension (62.2%), diabetes mellitus (DM) (6.1%) and combination of hypertension and DM (17.1%) (p value <0.001 , 95%). This mirrors the report from India [13], Nigeria [14] and Ghana [15] but different from Japan [16], Spain [17], United States of America [18], China [19] and Brazil [20] where DM was leading cause ESKD. Similarly, the patients reported to have been attending diabetes and hypertension out-patient clinics before they were initiated on HD. Once the patients were initiated on HD, the out-patients clinics attendance for DM and hypertension was low, as mean, median and mode number of times of clinics attendance in the 6 months preceding our study was 1.51, 0 and 0 times respectively (p-value <0.001 , 95%, CI 1.35-1.57). In our study, we could not ascertain from medical history the magnitude of glomerulonephritides as none of our cohort had a renal biopsy performed. However, there is possibility that some patients, especially the young ones suffered from glomerulonephritides and presented with phenotype of hypertension. Chronic glomerulonephritides as an underlying cause of CKD leading to ESKD has been reported in HD in Japan [16] and Ghana [15] in about a third of patients. Nigeria [14] and Cameroon [21] have also reported high number of chronic glomerulonephritides.

Despite significant follow up in the specialized clinics before starting HD, three-quarters of the patients were initiated HD as emergency. Almost 80% were initiated HD via acute central venous catheters. Only 1.3% incident HD were using arteriovenous fistulae (AVF) initially. This is different elsewhere. In Spain [77], more than 50% of incident HD are initiated HD electively with only 3 in 10 of the patients using acute central venous catheters and more than 50% have functional AVF at the start of HD [17]. However, similar low AVF use and

high prevalence of acute central venous catheters use at start of HD have been seen in the USA [78] [79].

Patient education is important in management of chronic medical conditions to win participation of the patients in delivery of their health care. Information to the patient about disease progression, laboratory tests results and referral for health education was low among clinic attendees. Subjectively, significant proportion of the patients felt inadequately informed about their health conditions and inadequate to cope with complications of kidney disease. Information about the risks of kidney failure resulting from the primary diseases was also inadequate. Nutritional management is necessary in CKD. More than 20% of the patients reported inadequate nutritional counseling. Dietary and fluid restrictions compliance have been shown to reduce symptoms and improvement of quality of life and increase in life expectancy [80] in patients who are on dialysis. This can be shown in the interdialytic weight gain (mean 3.09 – 3.92%, p value <0.001, 95%, CI 2.49-4.46) and blood pressure control (median SBP 144 -147 mmHg, p value <0.001, 95%, CI 138- 151), (median DBP 82-88mmHg, p value <0.001, 95%, CI 81-92).

Among the patients on chronic maintenance HD, the median duration was 9 months, mode of 5 months and mean of 15.35 months (p value <0.001, 95%, CI 11.66-22.17). The longest duration was 138 month (11.5 years). This is shorter than duration reported in Cameroon [74], dialysis median duration of 25 months, Iran [75] where the average duration of dialysis was 4.16 years, with longest duration of 25 years and Sweden [81] where Lindberg *et al* reported mean dialysis vintage duration of 5.7 years and a range of 0-38 years.

Chronic kidney disease has phenotypes of anaemia, mineral and bone disorder. The mechanisms by which CKD causes these disorders are complex and still under investigations. In our study, the mean HB concentration was 8.65g/dl (p value <0.001, 95%, CI 8.23-9.07). The use of intravenous iron (84.10% p value <0.001) and erythropoiesis stimulating agents (ESA) (82.90% p value <0.001) were high. Despite frequent use of the iron and ESA, anaemia was still managed with blood transfusion in 75.60% (p value < 0.001) which is not the international standard of care especially for potential transplantable candidates who are at risk of allosensitization [82-84]. There is no consensus regarding when blood transfusion is indicated, the rate of blood transfusion rises significantly when the HB concentration drops to

less than 10g/dl [85, 86]. Volume overload, transfusion errors, hypothermia, hyperkalemia, coagulopathy, citrate toxicity, immunologically-mediated transfusion reactions, transfusion-transmitted infections, iron overload and transfusion-related acute lung injury are uncommon risks associated with blood transfusion [87-92].

The routine testing for haematological parameters was low, as more than 65% of the patients had no monthly HB monitoring as recommended by international guidelines [93]. The HB level, the ESA and dose of iron with maximal clinical benefit with risk minimization is unknown for any individual patient. Erythropoiesis stimulating agents treatment is unlikely to fully effectively raise HB until other attendant complications are treated appropriately [93]. High HB concentration in CKD is linked with heightened risk for cerebrovascular events, high blood pressure and vascular access thrombosis [94]. For patients on HD, KDIGO suggests initiation of ESA when the HB concentration is 9.0-10.0 g/dl. The rate of rise in HB concentration initially is by 1-2g/dl per month and rise by more than 2g/dl per month should be avoided [93].

Chronic kidney disease increases the risk for mineral and bone disorder [95]. This is due to disturbances in handling of hormonal and local systems regulating calcium and phosphate metabolism. This results in abnormal mineralization of bones and ectopic calcifications. In our HD patients and the average serum calcium concentration was 2.14 mmol/l (p value <0.001, 95%, CI 2.05-2.22) and phosphate of 1.40 mmol/l (p value <0.001, 95%, CI 1.28-1.52). About 61% of our patients had serum calcium lower than the lower normal of the laboratory reference range of 2.20 mmol/l, while 12.2% of the studied population has serum calcium above the upper normal reference range of 2.60 mmol/l. About a quarter of our patients were on calcium supplementation despite majority of the patient having hypocalcaemia. Graciolli *et al.* reported lower serum albumin, and calcium levels among patients on conventional HD [96]. High serum phosphate in CKD has been thought to increase cardiovascular mortality in epidemiological studies [97, 98]. In several cohort studies, the analyses suggested that patients on dialysis who used phosphate-binders therapy had improved survival [99-101]. Majority of patients had normal serum phosphate and none was on phosphate-lowering therapies. The CKD-MBD[72] disorder is plagued by a lot of grey areas as shown in international guidelines and well-designed researches are required to answer many questions in this area.

Majority of our patients (88%) were on twice weekly intermittent HD. The internationally recommended is thrice weekly [5]. This has a role in interdialytic weight gain. The mean percentage interdialytic weight gain 3.58%, 3.28% and 3.81% respectively in the last 3 sessions of HDs prior to our study. This compares with interdialytic weight changes reported in Sweden [81]. Fluid restriction is key in HD population especially in anuric patients. Compliance with fluid restriction is not easy as shown in other studies [75]. This might be the cause of poor control of blood pressure in our study.

In conclusion, the study shows our HD patients are young with the commonest causes of CKD being hypertension and DM. Due to development of ESKD in non-diabetic patients at young age, it is plausible to suspect glomerulonephritides as the underlying cause of hypertension and subsequent ESKD. Diabetes mellitus is also contributing a sizeable burden of ESKD in our population. Even patients with long duration of follow up in out-patients clinics are not well prepared for kidney replacement therapy. Majority initiate HD as emergency with acute vascular accesses. Management of anaemia, mineral and bone disorder are suboptimal. Counseling, nutrition education and transplantation uptake are low.

RECOMMENDATIONS

1. The population of patients on haemodialysis in our setting is young. Hypertension and diabetes mellitus are the leading underlying morbidities. More effort in assessment and stratification of risks for development and progression of CKD in patients attending diabetes and hypertension clinics is required.
2. This being a young population, majority of individuals are likely to qualify as candidates for kidney transplantation, which is a superior modality of treatment than haemodialysis. Assessment patients on haemodialysis for suitability of transplantation should be done regularly and documentation of findings done.
3. Continual of follow up out-patient clinics and regular medical reviews for the patients on haemodialysis is required for the patients on haemodialysis
4. Establishment of structured follow up of CKD patients with multidisciplinary team approach with the psychologists, counselors, clinicians, pharmacists and vascular surgeons might help in patients preparations for kidney replacement therapy
5. Management of anaemia should be made more objective. This can be achieved by:-

- i. Formulation of guidelines with explicit information on dosages, frequencies and durations of ESA and intravenous iron supplementation and measures of response to treatment in patients on chronic haemodialysis
- ii. Formulation of explicit guidelines on indications for blood transfusion in patients on chronic haemodialysis

STUDY LIMITATIONS

Some data were missing from the medical records. This included some investigations like urinalysis and imaging reports which are important in ascertaining diagnosis like chronic glomerulonephritis. Due to this, glomerulonephritides as causes of ESRD could only be inferred. The inference was guided by young age picked arbitrarily at age of 40 years and below. Some patients might had diagnoses which were new, and which could confound their current health status. Majority of the information was retrospective and depended on the patients' memory.

REFERENCES

1. Eckardt, K.U., et al., *Evolving importance of kidney disease: from subspecialty to global health burden*. Lancet, 2013. **382**: p. 158-169.
2. *GBD 2015 Disease and Injury Incidence and Prevalence Collaborators*. *Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015*. Lancet, 2016. **388**: p. 1545-1602.
3. Couse, W.G., et al., *The contribution of chronic kidney disease to the global burden of major non-communicable diseases*. Kidney Int, 2011. **80**: p. 1258-1270.
4. Coresh, J., et al., *Prevalence of chronic kidney disease and decreased kidney function in the adult US population: Third National Health and Nutrition Examination Survey*. Am J Kidney Dis, 2003. **41**(1): p. 1-12.
5. *KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease* Kidney International Supplements, 2013. **3**(1): p. 1-150.
6. Keith, D.S., et al., *Longitudinal follow-up and outcomes among a population with chronic kidney disease in a large managed care organization*. Arch Intern Med, 2004. **164**(6): p. 659-663.
7. Fishbane, S., et al., *Challenges and opportunities in late-stage chronic kidney disease*. Clin Kidney J, 2015. **8**: p. 54-60.
8. Garcia-Garcia, G. and V. Jha, *Chronic kidney disease (CKD) in disadvantaged populations*. Clin Kidney J, 2015. **8**: p. 3-6.
9. Tuttle, K.R., et al., *Diabetic kidney disease: a report from an ADA Consensus Conference*. Am J Kidney Dis, 2014. **64**: p. 510-533.
10. Stenvinkel, P., C. Zoccali, and T.A. Ikizler, *Obesity in CKD—what should nephrologists know?* J Am Soc Nephrol, 2013. **24**: p. 1727-1736.
11. Jun, M. and B.R. Hemmelgarn, *Strategies for BP control in developing countries and effects on kidney function*. Clin J Am Soc Nephrol, 2016. **11**: p. 932-934.
12. Kimmel, P.L., L. Barisoni, and J.b. Kopp, *Pathogenesis and treatment of HIV-associated renal diseases: lessons from clinical and animal studies, molecular pathologic correlations, and genetic investigations*. Ann Intern Med, 2003. **139**: p. 214-226.
13. Kulkarni, M.J., et al., *A Cross-Sectional Study of Dialysis Practice-Patterns in Patients with Chronic Kidney Disease on Maintenance Hemodialysis* Saudi J Kidney Dis Transpl, 2015. **26**(5): p. 1050-1056.
14. EnajiteOkaka, I. and E.I. Unuigbo, *Eight year review of hemodialysis: Treated patients in a tertiary center in Southern Nigeria*. Annals of African Medicine, 2014. **13**(4): p. 221-226.
15. Amoako, Y.A., et al., *Clinical and demographic characteristics of chronic kidney disease patients in a tertiary facility in Ghana*. Pan African Medical Journal, 2014. **18**: p. 274.
16. Nakai, S., et al., *An Overview of Regular Dialysis Treatment in Japan (as of 31 December 2012)*. Therapeutic Apheresis and Dialysis, 2014. **18**(6): p. 535-602.

17. P´erez-García, R., et al., *Baseline characteristics of an incident haemodialysis population in Spain: results from ANSWER—a multicentre, prospective, observational cohort study*. *Nephrol Dial Transplant*, 2009. **24**: p. 578-588.
18. Slinin, Y., et al., *Hemodialysis Patient Outcomes: Provider Characteristics*. *Am J Nephrol*, 2014. **39**: p. 367-376.
19. Wang, K., et al., *Epidemiology of haemodialysis catheter complications: a survey of 865 dialysis patients from 14 haemodialysis centres in Henan province in China*. *BMJ Open*, 2015. **5**: p. e007136.
20. Cordeiro, A.C., et al., *Study of the incidence of dialysis in São Paulo, the largest Brazilian city*. *Clinics*, 2013. **68**(6): p. 760-765.
21. Halle, M.P., et al., *Epidemiological profile of patients with end stage renal disease in a referral hospital in Cameroon*. *BMC Nephrology*, 2015. **16**: p. 59.
22. Drawz, P.E., et al., *CKD as a Model for Improving Chronic Disease Care through Electronic Health Records*. *Clin J Am Soc Nephrol*, 2015 August. **10**: p. 1488-1499.
23. Patwardhan, M.B., et al., *Advanced chronic kidney disease practice patterns among nephrologists and non-nephrologists: A database analysis*. *Clin J Am Soc Nephrol*, 2007. **2**: p. 277-293.
24. Muntner, P., et al., *Chronic Renal Insufficiency Cohort (CRIC) Study Investigators: Hypertension awareness, treatment, and control in adults with CKD: Results from the Chronic Renal Insufficiency Cohort (CRIC) Study*. *Am J Kidney Dis*, 2010. **55**: p. 441-451.
25. Wasse, H., S.D. Hopson, and W. McClellan, *Racial and gender differences in arteriovenous fistula use among incident hemodialysis patients*. *Am J Nephrol*, 2010. **32**: p. 234-241.
26. Kern, E.F., et al., *Failure of ICD-9-CM codes to identify patients with comorbid chronic kidney disease in diabetes*. *Health Serv Res*, 2006. **41**: p. 564-580.
27. Hoy, T., et al., *Adherence to K/DOQI practice guidelines for bone metabolism and disease*. *Am J Manag Care*, 2007. **13**: p. 620-625.
28. Astor, B.C., et al., *CHOICE Study: Type of vascular access and survival among incident hemodialysis patients: The Choices for Healthy Outcomes in Caring for ESRD (CHOICE) Study*. *J Am Soc Nephrol*, 2005. **16**: p. 1449-1455.
29. Go, A.S., et al., *Chronic kidney disease and the risks of death, cardiovascular events, and hospitalization*. *N Engl J Med*, 2004. **351**: p. 1296-1305.
30. Hallan, S.I., et al., *Chronic Kidney Disease Prognosis Consortium. Age and association of kidney measures with mortality and end-stage renal disease*. *JAMA*, 2012. **308**: p. 2349-2360.
31. Nitsch, D., et al., *Chronic Kidney Disease Prognosis Consortium. Associations of estimated glomerular filtration rate and albuminuria with mortality and renal failure by sex: a meta-analysis*. *BMJ*, 2013. **346**: p. 324.
32. Gansevoort, R.T., et al., *Chronic kidney disease and cardiovascular risk: epidemiology, mechanisms, and prevention*. *Lancet*, 2013. **382**: p. 339-352.
33. Matsushita, K., et al., *CKD Prognosis Consortium. Association of estimated glomerular filtration rate and albuminuria with all-cause and cardiovascular*

- mortality in general population cohorts: a collaborative meta-analysis. *Lancet*, 2010. **375**: p. 2073-2081.
34. Velde, M.V., et al., *Chronic Kidney Disease Prognosis Consortium. Lower estimated glomerular filtration rate and higher albuminuria are associated with all-cause and cardiovascular mortality. A collaborative meta-analysis of high-risk population cohorts.* *Kidney Int*, 2011. **79**: p. 1341-1352.
 35. Kottgen, A., et al., *Reduced kidney function as a risk factor for incident heart failure: the Atherosclerosis Risk In Communities (ARIC) study.* *J Am Soc Nephrol*, 2007. **18**: p. 1307-1315.
 36. Abramson, J.L., et al., *Chronic kidney disease, anemia, and incident stroke in a middle-aged, community-based population: the ARIC study.* *Kidney Int*, 2003. **64**: p. 610-615.
 37. Wattanakit, K., et al., *Kidney function and risk of peripheral arterial disease: results from the Atherosclerosis Risk In Communities (ARIC) study.* *J Am Soc Nephrol*, 2007. **18**: p. 629-636.
 38. Astor, B.C., et al., *Kidney function and anemia as risk factors for coronary heart disease and mortality: the Atherosclerosis Risk In Communities (ARIC) study.* *Am Heart J*, 2006. **151**: p. 492-500.
 39. Alonso, A., et al., *Chronic kidney disease is associated with the incidence of atrial fibrillation: the Atherosclerosis Risk In Communities (ARIC) study.* *Circulation*, 2011. **123**: p. 2946-2953.
 40. Lee, B.J. and K. Forbes, *The role of specialists in managing the health of populations with chronic illness: The example of chronic kidney disease.* *BMJ*, 2009. **339**: p. b2395.
 41. *Kidney Disease: Improving Global Outcomes (KDIGO) Work Group. KDIGO clinical practice guideline for evaluation and management of chronic kidney disease.* *Kidney Int Suppl*, 2013. **3**: p. 1-163.
 42. Grangé, S., et al., *Monitoring of hemodialysis quality-of-care indicators: why is it important?* *BMC Nephrology*, 2013. **14**(109): p. 1-10.
 43. Daugirdas, J.T., P.G. Blake, and T.S. Ing, *Handbook of Dialysis*. 4th ed. Hemodialysis Apparatus ed. S. Ahmad, et al. 2007, Philadelphia: Lippincott Williams & Wilkins.
 44. *Registry E-E. ERA-EDTA Registry 2002. Annual Report.* Amsterdam The Netherlands: Academic Medical Centre, 2004.
 45. *NKF-DOQI (National Kidney Foundation). Clinical practice guidelines for hemodialysis adequacy.* *Am J Kidney Dis*, 1997. **30**(2): p. s15-s66.
 46. Plantinga, L.C., et al., *Attainment of clinical performance targets and improvement in clinical outcomes and resource use in hemodialysis care: a prospective cohort study.* *BMC Health Services Research*, 2007. **7**(5): p. 13.
 47. Grangé, S., et al., *Monitoring of hemodialysis quality-of-care indicators: why is it important?* *Nephrology*, 2013. **14**: p. 109.
 48. *KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease.* *Kidney International Supplements*, 2012. **2**.

49. Fishbane, S. and J.K. Maesaka, *Iron management in end-stage renal disease*. Am J Kidney Dis, 1997. **29**: p. 319-333.
50. Obrador, G.T. and B.J. Pereira, *Anaemia of chronic kidney disease: an underrecognized and under-treated problem*. Nephrol Dial Transplant, 2002. **17**(suppl 11): p. 44-46.
51. Moe, S., et al., *Definition, evaluation, and classification of renal osteodystrophy; a position statement from Kidney Disease: Improving Global Outcomes (KDIGO)*. Kidney Int. **69**: p. 1945-1953.
52. Murray, A.M., et al., *Cognitive impairment in hemodialysis patients is common*. Neurology, 2006. **67**: p. 216-223.
53. Seliger, S.L., et al., *Elevated risk of stroke among patients with end-stage renal disease*. Kidney Int, 2003. **64**: p. 603-609.
54. *U.S. Renal Data System. USRDS 2008 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*. 2008, Bethesda: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases.
55. Krane, V., et al., *Electrocardiography and outcome in patients with diabetes mellitus on maintenance hemodialysis*. Clin J Am Soc Nephrol, 2009. **4**: p. 394-400.
56. Kalantar-Zadeh, K., et al., *Fluid retention is associated with cardiovascular mortality in patients undergoing long-term hemodialysis*. Circulation, 2009. **119**: p. 671-679.
57. Locatelli, F., et al., *European Best Practice Guidelines Working Group. Revised European best practice guidelines for the management of anaemia in patients with chronic renal failure*. Nephrol Dial Transplant, 2004. **19**(suppl 2): p. ii1-ii47.
58. Jungers, P., et al., *Beneficial influence of recombinant human erythropoietin therapy on the rate of progression of chronic renal failure in predialysis patients*. Nephrol Dial Transplant, 2001. **16**: p. 307-312.
59. Eschbach, J.W., et al., *Iron balance in hemodialysis patients*. Ann Intern Med, 1977. **87**: p. 710-713.
60. Sargent, J.A. and S.R. Acchiardo, *Iron requirements in hemodialysis*. Blood Purif, 2004. **22**: p. 112-123.
61. Schaefer, R.M. and L. Schaefer, *Iron monitoring and supplementation: how do we achieve the best results?*. Nephrol Dial Transplant, 1998. **13**(Suppl 2): p. 9-12.
62. Mircescu, G., et al., *Intravenous iron supplementation for the treatment of anaemia in pre-dialyzed chronic renal failure patients*. Nephrol Dial Transplant, 2006. **21**: p. 120-124.
63. Silverberg, D.S., et al., *Intravenous iron supplementation for the treatment of the anemia of moderate to severe chronic renal failure patients not receiving dialysis*. Am J Kidney Dis, 1996. **27**: p. 234-238.
64. Fishbane, S., G.L. Frei, and J. Maesaka, *Reduction in recombinant human erythropoietin doses by the use of chronic intravenous iron supplementation*. Am J Kidney Dis, 1995. **26**: p. 41-46.
65. Macdougall, I.C., et al., *A randomized controlled study of iron supplementation in patients treated with erythropoietin*. Kidney Int, 1996. **50**(1694-1699).

66. Allegra, V., G. Mengozzi, and A. Vasile, *Iron deficiency in maintenance hemodialysis patients: assessment of diagnosis criteria and of three different iron treatments*. *Nephron*, 1991. **57**: p. 175-182.
67. Astor, B.C., et al., *Association of kidney function with anemia: the Third National Health and Nutrition Examination Survey (1988-1994)*. *Arch Intern Med*, 2002. **162**: p. 1401-1408.
68. Locatelli, F., et al., *Management of disturbances of calcium and phosphate metabolism in chronic renal insufficiency, with emphasis on the control of hyperphosphataemia*. *Nephrol Dial Transplant*, 2002. **17**: p. 723-731.
69. Martin, K.J. and E.A. Gonzalez, *Vitamin D analogues for the management of secondary hyperparathyroidism*. *Am J Kidney Dis*, 2001. **38**(suppl 5): p. S34-S40.
70. *KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD)*. *Kidney International Supplements*, 2017. **7**(1): p. 1-59.
71. Laouari, D., et al., *Subtotal nephrectomy alters tubular function: effect of phosphorus restriction*. *Kidney Int*, 1997. **52**: p. 1550-1560.
72. *KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD)*. *Kidney International Supplements*, 2017. **7**: p. 1-59.
73. Ouattara, B., et al., *Particularities of chronic renal failure in black adult patients hospitalized in internal medicine of Treichville university hospital*. *Néphrologie & Thérapeutique*, 2011. **7**: p. 531-534.
74. Halle, M.P., et al., *Nutritional status of patients on maintenance hemodialysis in urban sub-Saharan Africa: evidence from Cameroon*. *J Nephrol*, 2014. **10.1007/s40620-014-0047-2**: p. 1-9.
75. Rambod, M., et al., *Dietary and Fluid Adherence in Iranian Hemodialysis Patients*. *The Health Care Manager*, 2010. **29**(4): p. 359-364.
76. García, A.I.M., et al., *Dispositional optimism in patients on chronic haemodialysis and its possible influence on their clinical course*. *Nefrologia*, 2011. **31**(2): p. 199-205.
77. Couto, A.G., et al., *Causes of unscheduled haemodialysis initiation*. *Nefrologia*, 2011. **31**(6): p. 733-737.
78. Foley, R.N. and A.J. Collins, *The USRDS: what you need to know about what it can and can't tell us about ESRD*. *Clin J Am Soc Nephrol*, 2013. **8**: p. 845-851.
79. Arce, C.M., et al., *Hispanic Ethnicity and Vascular Access Use in Patients Initiating Hemodialysis in the United States*. *Clin J Am Soc Nephrol*, 2012. **7**: p. 289-296.
80. Durose, O.C., et al., *Knowledge of dietary restrictions and the medical consequences of non-compliance by patients on hemodialysis are not predictive of dietary compliance*. *J Am Diet Assoc*, 2004. **104**: p. 35-41.
81. Lindberg, M., B.r. Wikström, and P. Lindberg, *Subgroups of haemodialysis patients in relation to fluid intake restrictions: a cluster analytical approach*. *Journal of Clinical Nursing*, 2010. **19**: p. 2997-3005.

82. *USRDS System. USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. National Institutes of Health 2010. National Institute of Diabetes and Digestive and Kidney Diseases, 2010.*
83. Linman, J.W., *Physiologic and pathophysiologic effects of anemia.* N Engl J Med, 1968. **279**: p. 812-818.
84. I Terasaki, P. and M. Ozawa, *Predicting kidney graft failure by HLA antibodies.* Am J Transplant, 2004. **4**: p. 438-443.
85. *Canadian Erythropoietin Study Group. Association between recombinant human erythropoietin and quality of life and exercise capacity of patients receiving haemodialysis.* BMJ, 1990. **300**: p. 573-578.
86. Pfeffer, M.A., E.A. Burdmann, and C.Y. Chen, *A trial of darbepoetin alfa in type 2 diabetes and chronic kidney disease.* N Engl J Med, 2009. **361**: p. 2019-2032.
87. Cid, J., et al., *Efficacy in reducing potassium load in irradiated red cell bags with a potassium adsorption filter.* Transfusion, 2008. **48**: p. 1966-1970.
88. Dodd, R., *Managing the microbiological safety of blood for transfusion: a US perspective.* Future Microbiol 2009. **4**: p. 807-818.
89. Goodnough, L.T., A. Shander, and M.E. Brecher, *Transfusion medicine: looking to the future.* Lancet, 2003. **361**: p. 161-169.
90. Jacobs, M.R., E. Palavecino, and R. Yomtovian., *Don't bug me: the problem of bacterial contamination of blood components—challenges and solutions.* Transfusion, 2001. **41**: p. 1331-1334.
91. Kleinman, S., et al., *Toward an understanding of transfusion-related acute lung injury: statement of a consensus panel.* Transfusion, 2004. **44**(44): p. 1774-1789.
92. Looney, M.R., M.A. Gropper, and M.A. Matthay, *Transfusion-related acute lung injury: a review.* Chest, 2004. **126**: p. 249-258.
93. *KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease.* Kidney International Supplements, 2012. **2**(4 Suppl): p. 288-291.
94. Palmer, S.C., et al., *Meta-analysis: erythropoiesis stimulating agents in patients with chronic kidney disease.* Ann Intern Med, 2010. **153**: p. 23-33.
95. *Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD).* Kidney Int Suppl, 2009. **113**: p. s1-s130.
96. Graciolli, F.G., et al., *The complexity of chronic kidney disease—mineral and bone disorder across stages of chronic kidney disease.* Kidney International, 2017. **91**: p. 1436-1446.
97. Block, G., et al., *CKD-mineral and bone disorder and risk of death and cardiovascular hospitalization in patients on hemodialysis.* Clin J Am Soc Nephrol, 2013. **8**: p. 2132-2140.
98. Chartsrisak, K., et al., *Mineral metabolism and outcomes in chronic kidney disease stage 2-4 patients.* BMC Nephrology, 2013. **14**: p. 14.
99. Cannata-Andia, J.B., et al., *Use of phosphate-binding agents is associated with a lower risk of mortality.* Kidney Int, 2013. **84**: p. 998-1008.

100. Isakova, T., et al., *Phosphorus binders and survival on hemodialysis*. J Am Soc Nephrol, 2009. **20**: p. 388-396.
101. Lopes, A.A., et al., *Phosphate binder use and mortality among hemodialysis patients in the Dialysis Outcomes and Practice Patterns Study (DOPPS): evaluation of possible confounding by nutritional status*. Am J Kidney Dis, 2012. **60**: p. 90-101.

APPENDICES

Appendix 1: Ambulant adult patients on chronic maintenance haemodialysis in KNH questionnaire

A. Sociodemographics section

A1. Date of interview (dd/mm/yyyy) /...../.....

A2. Serial number:

A3. File Number:

A4. Sex: [1] Male [2] Female

A5. Year of birth: Current age (yr)

A6. 1. Which clinic(s) did you use to attend? [1] Diabetes [2] Hypertension [3] Renal clinic
[4] None

[99] Others (specify)

A6.2 Do you still attend the clinic? [1] Yes [2] No

A6.2.1. In the last 6 months, how many times have you attended the clinic? times

A6.2. 2. Month and year of enrolment into the earliest clinic (mm/yyyy)...../.....

A6.3. When did you start dialysis (mm/yyyy)/.....

A6.4. How was the initiation? [1] Elective [2] Emergency

B. Clinical characteristics section

B1. Diagnosis at enrolment: [1] Diabetes [2] Hypertension [3] Both

[99] Others (specify)

B2. When were you first diagnosed with the condition(s) which made you attend clinic before starting on dialysis (YYYY)

B3. How many modalities of renal replacement therapy does the patient know?

B3.1 Which are they?

.....

B4. How many times per week do you attend dialysis in the last 3 months? times/week

C. Health Education, nutrition and psychological

C1. By the time you initiated dialysis,

Kindly read the following statements and respond as per the responses given. Mark your response in the respective box

		<i>Never</i>	<i>Sometimes</i>	<i>Most of the times</i>	<i>Every time</i>
C1.1	The clinicians informed me about my illness and its progression every time I attend the clinic				
C1.2	The clinicians informed me about the tests results every time I brought the results during the clinic visits				
C1.3	The clinicians referred me for health education during my clinic visits				
		<i>Strongly disagree</i>	<i>Disagree</i>	<i>Somehow agree</i>	<i>Strongly agree</i>
C1.4	I feel well informed about my health condition by the time I was initiated on dialysis				
C1.5	I had been informed about the risks of kidney failure due to the primary illness during the clinic visits				
C1.6	I felt adequately informed to cope with kidney complications of by the time I was initiated on dialysis				
C1.7	I had adequate nutritional counseling in respect to kidney disease				
C1.8	I had sessions with the renal counselor before initiation of dialysis				

C2. What was your first vascular access?

- [1] Acute catheter in subclavian/jugular veins
- [2] Acute catheter in the lower limbs
- [3] Tunneled catheter in the internal jugular

- [4] Tunneled catheter in the lower limbs
- [5] Arteriovenous fistula
- [99] Others (specify)

C3. What is your current vascular access?

- [1] Acute catheter in subclavian/jugular veins
- [2] Acute catheter in the lower limbs
- [3] Tunneled catheter in the internal jugular
- [4] Tunneled catheter in the lower limbs
- [5] Arteriovenous fistula
- [99] Others (specify)

C4. Have you been counseled about kidney transplantation? [1] Yes [2] No

If yes,

C5. Have you started on kidney transplant evaluations? [1] Yes [2] No

If no, why?

- C5.1.1** [1] Lack of donor
- [2] Lack of money
- [3] Still not stable from the primary disease
- [99] Others (specify)

D. Miscellaneous

D1. How many times in three months do you test for haemoglobin? times/3months

D1.1 Are you on iron supplementation? [1] Yes [2] No

If answer to D1.1 is Yes,

D1.1.1 How many times/week? times/week

D2. Are you on erythropoiesis stimulating agents? [1] Yes [2] No

If answer to D2 is Yes,

D2.1 How many times per week? times/week

D3. Have you ever been transfused with blood since you were initiated in chronic maintenance haemodialysis? [1] Yes [2] No

If answer to D3 is Yes,

D3.1 How many times? times

D3.2 Have you been transfused in the last 3 months? [1] Yes [2] No

D4. Are you on calcium supplementation? [1] Yes [2] No

D5. Are you on phosphate lowering therapies? [1] Yes [2] No

If answer to D5 is Yes, list them.

D5.1
.....

D6. Biochemical Laboratory parameters

D6.1 Calcium mmol/l

D6.2 Albumin g/l

D6.3 phosphatemmol/l

D7. Haematological parameters

D7.1 White blood cellsX10⁹/L **D.7.1.1** Neutrophils %

D7.1.2 Lymphocytes% **D7.2.** Red blood cells X10¹²/L

D7.3 Haemoglobin g/dL **D7.4.** Haematocrit %

D7.5 Mean corpuscular volume fL

D7.6 Mean corpuscular haemoglobinpg

D7.7 Mean corpuscular haemoglobin concentration g/dL

D.7.9 Platelets X10⁹/L

D8. Clinical parameters during the last 4 sessions of haemodiaaaysis as per haemodialysis flow sheet

		Average systolic BP (mmHg)	Average diastolic BP (mmHg)	Pre-dialysis weight (kg)	Post dialysis weight (kg)	Ultrafiltration volume (l)
D8.1	4 th last session					
D8.2	3 rd last session					
D8.3	2 nd last session					
D8.4	Last session					

Appendix 2. Kenyatta national hospital renal unit haemodialysis flow sheet

KENYATTA NATIONAL HOSPITAL – RENAL UN IT



HAEMODIALYSIS FLOW SHEET

Date Age: Sex: Treatment Number

Name OP/IP NO:..... Physician:

Access	HIV/HBsAg screening Date		Result	Blood Group	
Predialysis Weight	Target Weight		Post dialysis Weight		
DIALYSIS ORDERS					
Treatment Time/Hrs	Prime	Dialysis solution	Dialyzer	Bath K+	Heparinization Loading dose Units/Hrs
			Membrane type		
MACHINE CHECKS					

Blood leak Tested on	Air Detect Tested on	Temp	Conductivity	Dialysis P.	TMP On	Rej Rate
----------------------------	----------------------------	------	--------------	-------------	--------	----------

Staff setting machine

Time Due On Nurse commencing dialysis No clamps

Time Off Nurse discontinuing dialysis No clamps

Time	BP	Pulse	Temp	BFR	TMP	UF	VP	DR	Dial Temp	Heparin	Prot. Sulp	Fluids	Coag. Time	Comment

POST-DIALYSIS OBSERVATION	LAB RESULTS
ADDITIONAL ORDERS	
LABORATORY REQUESTS	
ADDITIONAL ORDERS	
COMMENTS	

Appendix 3. Patient consent explanation form

Information sheet

Research Title: Assessment of care for ambulant adult patients on maintenance chronic haemodialysis at the Kenyatta national hospital

I am Dr Samuel Kabinga currently undertaking a course in fellowship in nephrology the East African Kidney Institute of the University of Nairobi. I am conducting a research project entitled ‘**assessment of care for ambulant adult patients on maintenance chronic haemodialysis at the Kenyatta national hospital**’ for which I request your participation.

Why have I been invited to take part?

Chronic kidney disease has become more common in our setting. Subsequently, the number of patients with end-stage kidney disease on dialysis is also on the increase. The study aims to find out the extent of care accorded to the patients on chronic maintenance haemodialysis at Kenyatta national hospital renal unit. This information will help us put in place measures that would help us better the care given to patients with end stage renal disease on chronic maintenance haemodialysis.

How do I benefit from the study?

There will be immediate benefit from the study. You will get to know the status of your blood calcium, phosphate, and albumin, as well as the haemoglobin. These findings will assist in management of your current condition. The immediate benefits of this study will be to give information about kidney disease. However, there will be no compensation with money. The information got from the study will also assist in betterment of care given to the patients on haemodialysis in the hospital.

Risks of participation

There are minimal risks involved in clinical assessment and laboratory tests done in this study. Blood samples will be drawn from the veins in upper limbs. Only a total of one teaspoon of blood will be drawn from you. You will also be requested to give a sample of

your urine in a bottle for testing too. The results of these tests will be utilized in management of your condition.

Do I have to take part?

It is up to you to decide whether or not to take part, taking part is voluntary. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. You will still receive all treatment that you should get even without participating in the study.

What would I have to do?

If you consent for the study, you will be expected to give information about yourself and the illness you have. Your medical records will be reviewed and more information extracted. You will have blood sample drawn for investigations, for measurement of blood count, blood calcium, phosphate and albumin levels.

Confidentiality

The medical records and data collected for this study will only be accessible to authorized persons. This will minimize accidental disclosure to any unauthorized personnel. Results will only be made available to the patient and his/her primary care provider.

What happens to the information that is collected?

All details that can identify you will be removed before storing the data. The data will then be analysed to help us understand the care in kidney disease. The filled up data collection tool will be destroyed by burning within three months after successful completion of the study.

Thank you for taking the time to read this information sheet.

Appendix 4. Fomu ya maelezo kuhusu utafiti huu

Mada: “Uchunguzi wa huduma kwa watu wazima wenye ugonjwa wa figo wanaooshwa damu kwa mashine katika hospitali kuu ya Kenyatta”

Mimi ninaitwa Daktari Samuel Kabinga kutoka Chuo Kikuu Cha Nairobi. Ninafanya utafiti kuhusu magonjwa ya figo kati ya watu waliyo wagonjwa waliyo na ugonjwa wa figo wanaoshwa damu kwa mashine.

Je, nimealikwa kwa nini?

Mimi na watafiti wenzangu tunataka kuangalia maelezo na huduma ya afya kuhusu figo kwa wale tayari wameshaanza kuoshwa damu kwa mashine baada ya figo zao kushindwa kufanya kazi. Habari hizi zitatusaidia kuweka mikakati ya mapema kutambua wagonjwa figo na kuwetayirisha wagonjwa kupokea matibabu mapema.

Je, nitanufaika kivipi kwa kujiunga na utafiti huu?

Manufaa ya kuingia utafiti huu yanaanzia kupata mawaidha kuhusu magonjwa ya figo. Damu yako pasipo malipo. Matokeo ya vipimo hivi yatasaidia kukuhudumia vyema. Wanaojiunga na utafiti huu hawatapewa pesa.

Je, kuna athari za kujiunga na utafiti?

Athari zilizopo ni kidogo sana na zinatokana na vipimo vya damu vitakavyofanywa kwenye utafiti huu. Damu itakayotumiwa kufanya vipimo itatolewa kwenye mshipa wa mkono.

Je, ni lazima kujiunga na utafiti huu?

La! Umuzi kuingia utafiti huu ni wako, unaingia kwa hiari yako. Ukiamua kujiunga na utafiti huu, utapewa fomu hii ya maelezo na kusaini kartasi ya makubaliano. Ukiingia utafiti huu, una uhuru wa kutoka wakati wowote bila ya kutupatia sababu zako za kutoka. Baado utaendelea kupata matibabu yako yote ya kawaida hata bila kuendelea na utafiti huu.

Nikitaka kujiunga na utafiti huu, nitahitajika kufanya nini?

Mwanzo, utatupa maelezo kidogo kukuhusu wewe binafsi pamoja na maelezo zaidi kuhusu ugonjwa wako wa figo.

Je, rekodi zangu binafsi na matokeo ya vipimo vyangu yatawekwa siri?

Rekodi zako za matibabu na matokeo yote yatakayojulikana kutoka utafiti huu yataangaliwa na watafiti walioidhinishwa pekee yao. Tunatumaini kwamba kufanya hivi itapunguza uwezekano ya watu nje ya utafiti huu kutambua mambo yako binafsi. Matokeo yatapeanwa kwa mgonjwa binafsi ama kwa mtu yule wa karibu aliyeidhinishwa kupokea matokeo ya matibabu yake.

Habari yote itakayotambuliwa kunihusu mimi na wagonjwa wengine itafanywaje?

Vitambulishi vyako vyote (nambari ya rekodi yako, nambari ya simu na vinginevyo) vitaondolewa kabla ya ripoti yako kuhifadhiwa. Ripoti yako, pamoja na ya wagonjwa wengine, itaangaliwa kwa undani ili kupata habari kuhusu huduma ya magonjwa ya figo wanaopata wagonja katika hospitali kuu ya Kenyatta. Fomu zote zilizojazwa zitaharibiwa kwa kuchomwa miezi mitatu baada ya kukamilisha utafiti huu.

Asanta kwa kuchukua muda wako kusoma maelezo haya.

Appendix 5. Patient consent form

I,, have read and fully understood the explanation given to me regarding this study. All my questions have been answered satisfactorily by the investigators. I hereby consent to participation in this study.

Signed: (Patient)

Witness: (Principal Investigator/Research assistant) Date:

CONTACTS

For further information, you may contact any of the following:

1. Dr. Samuel Kabinga (Principal investigator)

P.O Box 30197

Nairobi

Tel: 020-4915067

2. Professor A. N. Guantai,

Chairman of Kenyatta National Hospital/University of Nairobi Ethics and Research Committee,

P.O Box 20723, Nairobi.

Tel 020-2726300, extension 44102.

Appendix 6: Karatasi ya makubaliano ya watu wazima

Mimi,..... ,nimesoma na kukubaliana na maelezo nimepewa kuhusu utafiti huu.Maswali yangu yote yamejibiwa kwa ukamilifu na Daktari Ndinya na watafiti wenzake. Nimekubali kuingia utafiti huu.

Sahihi (mgonjwa)

Shahidi (mtafiti mkuu ama msaidizi wake) Tarehe

Wanaohusika:

Kwa maelezo zaidi ,unaombwa uwasiliane na watu wafuatao

1. Daktari Samuel kabinga (mtafiti mkuu)

Sanduku la posta (S.L.P.) 30197

Nairobi

Simu: 020-4915067

2. Profesa A.N. Guantai

Mkurugenzi wa Idhaa ya Uadilifu kwenye utafiti,

Hospitali Kuu ya Kenyatta,

S.L.P. 20723,Nairobi

Simu ya ofisi:020-2726300-ugani 44102

Appendix 7. Timeframe

s/no	Activity	Timeline									
		Mar '18	Apr '18	May '18	Jun '18	Jul '18	Aug '18	Sept '18	Oct '18	Nov '18	
1	Protocol presentation and corrections	■									
2	Submission of protocol for ethics for approval	■	■	■	■						
3	Data collection				■	■					
4	Data analysis						■	■			
5	Results presentation								■	■	
6	Corrections and write up submission								■	■	
7	Final write up submission										■

Appendix 8. Budget

The study cost will be footed by the principal investigator.

s/no	Description	Unit Cost (Ksh)	Number	Cost estimate (Ksh)
1	Stationary	5,000.00	1	5,000.00
2	Research assistants	20,000.00	2	40,000.00
3	Laboratory analysis	1,000.00	110	110,000.00
4	Data entry and cleaning	15,000.00	1	15,000.00
5	Communication	5,000.00	1	5,000.00
6	Data Analysis	10,000.00	1	10,000.00
7	Reports printing and binding	12,000.00	1	12,000.00
8	Dissemination and publishing results	20,000.00	1	20,000.00
9	Contingency	32,700.00	1	32,700.00
	TOTAL			249,700.00

Appendix 9. Ethics and Research Committee clearance



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355



KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: <http://www.erc.uonbi.ac.ke>
Facebook: <https://www.facebook.com/uonknh.erc>
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC



KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/191

May 25, 2018

Dr. Samuel K. Kabinga
Reg. No.H114/10156/2018
East African Kidney Institute
University of Nairobi

Dear Dr.Kabinga

RESEARCH PROPOSAL – ASSESSMENT OF CARE FOR AMBULANT ADULT PATIENTS ON CHRONIC MAINTENANCE HAEMODIALYSIS AT THE KENYATTA NATIONAL HOSPITAL (P226/04/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is from 25th May 2018 – 24th May 2019.


This approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
- c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- f) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

For more details consult the KNH- UoN ERC website <http://www.erc.uonbi.ac.ke>

Yours sincerely,



PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

- c.c. The Principal, College of Health Sciences, UoN
 The Deputy Director, CS, KNH
 The Chairperson, KNH-UON ERC
 The Assistant Director, Health Information, KNH
 Supervisors: Prof. S.O. McLigeyo, Prof. J.K. Kayima, Dr. J.N. Ndungu

Protect to discover

Appendix 10. KNH Study Registration Certificate

KNH/R&P/FORM/01



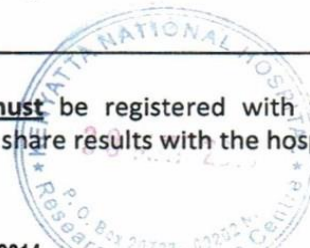
KENYATTA NATIONAL HOSPITAL
P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
DR. SAMUEL K. KABINGA
2. Email address: kabingas@yahoo.com Tel No. +254723494755
3. Contact person (if different from PI) N/A
4. Email address: N/A Tel No. _____
5. Study Title
ASSESSMENT OF CARE FOR AMBULANT PATIENTS ON MAINTENANCE CHRONIC HAEMODIALYSIS AT THE KENYATTA NATIONAL HOSPITAL
6. Department where the study will be conducted RENAL DEPARTMENT
(Please attach copy of Abstract)
7. Endorsed by Research Coordinator of the Department where the study will be conducted.
Name: DR. MAMBUWA, B.M. Signature [Signature] Date 30/5/2018
8. Endorsed by KNH Head of Department where study will be conducted.
Name: DR. JOHN MUKH Signature [Signature] Date 30/5/18
9. KNH UoN Ethics Research Committee approved study number P226/04/2018
(Please attach copy of ERC approval)
10. I DR. SAMUEL K. KABINGA commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Research and Programs.
Signature [Signature] Date 29.05.2018
11. Study Registration number (Dept/Number/Year) Renal / 49 / 2018
(To be completed by Research and Programs Department)
12. Research and Program Stamp _____

All studies conducted at Kenyatta National Hospital **must** be registered with the Department of Research and Programs and investigators **must commit** to share results with the hospital.



1. Eckardt, K.U., et al., *Evolving importance of kidney disease: from subspecialty to global health burden*. Lancet, 2013. **382**: p. 158-169.
2. GBD 2015 Disease and Injury Incidence and Prevalence Collaborators. *Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015*. Lancet, 2016. **388**: p. 1545-1602.
3. Couse, W.G., et al., *The contribution of chronic kidney disease to the global burden of major non-communicable diseases*. Kidney Int, 2011. **80**: p. 1258-1270.
4. Coresh, J., et al., *Prevalence of chronic kidney disease and decreased kidney function in the adult US population: Third National Health and Nutrition Examination Survey*. Am J Kidney Dis, 2003. **41**(1): p. 1-12.
5. *KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease* Kidney International Supplements, 2013. **3**(1): p. 1-150.
6. Keith, D.S., et al., *Longitudinal follow-up and outcomes among a population with chronic kidney disease in a large managed care organization*. Arch Intern Med, 2004. **164**(6): p. 659-663.
7. Fishbane, S., et al., *Challenges and opportunities in late-stage chronic kidney disease*. Clin Kidney J, 2015. **8**: p. 54-60.
8. Garcia-Garcia, G. and V. Jha, *Chronic kidney disease (CKD) in disadvantaged populations*. Clin Kidney J, 2015. **8**: p. 3-6.
9. Tuttle, K.R., et al., *Diabetic kidney disease: a report from an ADA Consensus Conference*. Am J Kidney Dis, 2014. **64**: p. 510-533.
10. Stenvinkel, P., C. Zoccali, and T.A. Ikizler, *Obesity in CKD—what should nephrologists know?* J Am Soc Nephrol, 2013. **24**: p. 1727-1736.
11. Jun, M. and B.R. Hemmelgarn, *Strategies for BP control in developing countries and effects on kidney function*. Clin J Am Soc Nephrol, 2016. **11**: p. 932-934.
12. Kimmel, P.L., L. Barisoni, and J.b. Kopp, *Pathogenesis and treatment of HIV-associated renal diseases: lessons from clinical and animal studies, molecular pathologic correlations, and genetic investigations*. Ann Intern Med, 2003. **139**: p. 214-226.
13. Kulkarni, M.J., et al., *A Cross-Sectional Study of Dialysis Practice-Patterns in Patients with Chronic Kidney Disease on Maintenance Hemodialysis* Saudi J Kidney Dis Transpl, 2015. **26**(5): p. 1050-1056.
14. EnajiteOkaka, I. and E.I. Unuigbo, *Eight year review of hemodialysis: Treated patients in a tertiary center in Southern Nigeria*. Annals of African Medicine, 2014. **13**(4): p. 221-226.
15. Amoako, Y.A., et al., *Clinical and demographic characteristics of chronic kidney disease patients in a tertiary facility in Ghana*. Pan African Medical Journal, 2014. **18**: p. 274.
16. Nakai, S., et al., *An Overview of Regular Dialysis Treatment in Japan (as of 31 December 2012)*. Therapeutic Apheresis and Dialysis, 2014. **18**(6): p. 535-602.
17. P´erez-García, R., et al., *Baseline characteristics of an incident haemodialysis population in Spain: results from ANSWER—a multicentre, prospective, observational cohort study*. Nephrol Dial Transplant, 2009. **24**: p. 578-588.
18. Slinin, Y., et al., *Hemodialysis Patient Outcomes: Provider Characteristics*. Am J Nephrol, 2014. **39**: p. 367-376.
19. Wang, K., et al., *Epidemiology of haemodialysis catheter complications: a survey of 865 dialysis patients from 14 haemodialysis centres in Henan province in China*. BMJ Open, 2015. **5**: p. e007136.

20. Cordeiro, A.C., et al., *Study of the incidence of dialysis in Saõ Paulo, the largest Brazilian city*. Clinics, 2013. **68**(6): p. 760-765.
21. Halle, M.P., et al., *Epidemiological profile of patients with end stage renal disease in a referral hospital in Cameroon*. BMC Nephrology, 2015. **16**: p. 59.
22. Drawz, P.E., et al., *CKD as a Model for Improving Chronic Disease Care through Electronic Health Records*. Clin J Am Soc Nephrol, 2015 August. **10**: p. 1488-1499.
23. Patwardhan, M.B., et al., *Advanced chronic kidney disease practice patterns among nephrologists and non-nephrologists: A database analysis*. Clin J Am Soc Nephrol, 2007. **2**: p. 277-293.
24. Muntner, P., et al., *Chronic Renal Insufficiency Cohort (CRIC) Study Investigators: Hypertension awareness, treatment, and control in adults with CKD: Results from the Chronic Renal Insufficiency Cohort (CRIC) Study*. Am J Kidney Dis, 2010. **55**: p. 441-451.
25. Wasse, H., S.D. Hopson, and W. McClellan, *Racial and gender differences in arteriovenous fistula use among incident hemodialysis patients*. Am J Nephrol, 2010. **32**: p. 234-241.
26. Kern, E.F., et al., *Failure of ICD-9-CM codes to identify patients with comorbid chronic kidney disease in diabetes*. Health Serv Res, 2006. **41**: p. 564-580.
27. Hoy, T., et al., *Adherence to K/DOQI practice guidelines for bone metabolism and disease*. Am J Manag Care, 2007. **13**: p. 620-625.
28. Astor, B.C., et al., *CHOICE Study: Type of vascular access and survival among incident hemodialysis patients: The Choices for Healthy Outcomes in Caring for ESRD (CHOICE) Study*. J Am Soc Nephrol, 2005. **16**: p. 1449-1455.
29. Go, A.S., et al., *Chronic kidney disease and the risks of death, cardiovascular events, and hospitalization*. N Engl J Med, 2004. **351**: p. 1296-1305.
30. Hallan, S.I., et al., *Chronic Kidney Disease Prognosis Consortium. Age and association of kidney measures with mortality and end-stage renal disease*. JAMA, 2012. **308**: p. 2349-2360.
31. Nitsch, D., et al., *Chronic Kidney Disease Prognosis Consortium. Associations of estimated glomerular filtration rate and albuminuria with mortality and renal failure by sex: a meta-analysis*. BMJ, 2013. **346**: p. 324.
32. Gansevoort, R.T., et al., *Chronic kidney disease and cardiovascular risk: epidemiology, mechanisms, and prevention*. Lancet, 2013. **382**: p. 339-352.
33. Matsushita, K., et al., *CKD Prognosis Consortium. Association of estimated glomerular filtration rate and albuminuria with all-cause and cardiovascular mortality in general population cohorts: a collaborative meta-analysis*. Lancet, 2010. **375**: p. 2073-2081.
34. Velde, M.V., et al., *Chronic Kidney Disease Prognosis Consortium. Lower estimated glomerular filtration rate and higher albuminuria are associated with all-cause and cardiovascular mortality. A collaborative meta-analysis of high-risk population cohorts*. Kidney Int, 2011. **79**: p. 1341-1352.
35. Kottgen, A., et al., *Reduced kidney function as a risk factor for incident heart failure: the Atherosclerosis Risk In Communities (ARIC) study*. J Am Soc Nephrol, 2007. **18**: p. 1307-1315.
36. Abramson, J.L., et al., *Chronic kidney disease, anemia, and incident stroke in a middle-aged, community-based population: the ARIC study*. Kidney Int, 2003. **64**: p. 610-615.
37. Wattanakit, K., et al., *Kidney function and risk of peripheral arterial disease: results from the Atherosclerosis Risk In Communities (ARIC) study*. J Am Soc Nephrol, 2007. **18**: p. 629-636.
38. Astor, B.C., et al., *Kidney function and anemia as risk factors for coronary heart disease and mortality: the Atherosclerosis Risk In Communities (ARIC) study*. Am Heart J, 2006. **151**: p. 492-500.
39. Alonso, A., et al., *Chronic kidney disease is associated with the incidence of atrial fibrillation: the Atherosclerosis Risk In Communities (ARIC) study*. Circulation, 2011. **123**: p. 2946-2953.
40. Lee, B.J. and K. Forbes, *The role of specialists in managing the health of populations with chronic illness: The example of chronic kidney disease*. BMJ, 2009. **339**: p. b2395.

41. *Kidney Disease: Improving Global Outcomes (KDIGO) Work Group. KDIGO clinical practice guideline for evaluation and management of chronic kidney disease.* *Kidney Int Suppl*, 2013. **3**: p. 1-163.
42. Grangé, S., et al., *Monitoring of hemodialysis quality-of-care indicators: why is it important?* *BMC Nephrology*, 2013. **14**(109): p. 1-10.
43. Daugirdas, J.T., P.G. Blake, and T.S. Ing, *Handbook of Dialysis*. 4th ed. Hemodialysis Apparatus ed. S. Ahmad, et al. 2007, Philadelphia: Lippincott Williams & Wilkins.
44. *Registry E-E. ERA-EDTA Registry 2002. Annual Report.* Amsterdam The Netherlands: Academic Medical Centre, 2004.
45. *NKF-DOQI (National Kidney Foundation). Clinical practice guidelines for hemodialysis adequacy.* *Am J Kidney Dis*, 1997. **30**(2): p. s15-s66.
46. Plantinga, L.C., et al., *Attainment of clinical performance targets and improvement in clinical outcomes and resource use in hemodialysis care: a prospective cohort study.* *BMC Health Services Research*, 2007. **7**(5): p. 13.
47. Grangé, S., et al., *Monitoring of hemodialysis quality-of-care indicators: why is it important?* *Nephrology*, 2013. **14**: p. 109.
48. *KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease.* *Kidney International Supplements*, 2012. **2**.
49. Fishbane, S. and J.K. Maesaka, *Iron management in end-stage renal disease.* *Am J Kidney Dis*, 1997. **29**: p. 319-333.
50. Obrador, G.T. and B.J. Pereira, *Anaemia of chronic kidney disease: an underrecognized and under-treated problem.* *Nephrol Dial Transplant*, 2002. **17**(suppl 11): p. 44-46.
51. Moe, S., et al., *Definition, evaluation, and classification of renal osteodystrophy; a position statement from Kidney Disease: Improving Global Outcomes (KDIGO).* *Kidney Int.* **69**: p. 1945-1953.
52. Murray, A.M., et al., *Cognitive impairment in hemodialysis patients is common.* *Neurology*, 2006. **67**: p. 216-223.
53. Seliger, S.L., et al., *Elevated risk of stroke among patients with end-stage renal disease.* *Kidney Int*, 2003. **64**: p. 603-609.
54. *U.S. Renal Data System. USRDS 2008 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States.* 2008, Bethesda: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases.
55. Krane, V., et al., *Electrocardiography and outcome in patients with diabetes mellitus on maintenance hemodialysis.* *Clin J Am Soc Nephrol*, 2009. **4**: p. 394-400.
56. Kalantar-Zadeh, K., et al., *Fluid retention is associated with cardiovascular mortality in patients undergoing longterm hemodialysis.* *Circulation*, 2009. **119**: p. 671-679.
57. Locatelli, F., et al., *European Best Practice Guidelines Working Group. Revised European best practice guidelines for the management of anaemia in patients with chronic renal failure.* *Nephrol Dial Transplant*, 2004. **19**(suppl 2): p. ii1-ii47.
58. Jungers, P., et al., *Beneficial influence of recombinant human erythropoietin therapy on the rate of progression of chronic renal failure in predialysis patients.* *Nephrol Dial Transplant*, 2001. **16**: p. 307-312.
59. Eschbach, J.W., et al., *Iron balance in hemodialysis patients.* *Ann Intern Med*, 1977. **87**: p. 710-713.
60. Sargent, J.A. and S.R. Acchiardo, *Iron requirements in hemodialysis.* *Blood Purif*, 2004. **22**: p. 112-123.
61. Schaefer, R.M. and L. Schaefer, *Iron monitoring and supplementation: how do we achieve the best results?* *Nephrol Dial Transplant*, 1998. **13**(Suppl 2): p. 9-12.
62. Mircescu, G., et al., *Intravenous iron supplementation for the treatment of anaemia in predialyzed chronic renal failure patients.* *Nephrol Dial Transplant*, 2006. **21**: p. 120-124.

63. Silverberg, D.S., et al., *Intravenous iron supplementation for the treatment of the anemia of moderate to severe chronic renal failure patients not receiving dialysis*. Am J Kidney Dis, 1996. **27**: p. 234-238.
64. Fishbane, S., G.L. Frei, and J. Maesaka, *Reduction in recombinant human erythropoietin doses by the use of chronic intravenous iron supplementation*. Am J Kidney Dis, 1995. **26**: p. 41-46.
65. Macdougall, I.C., et al., *A randomized controlled study of iron supplementation in patients treated with erythropoietin*. Kidney Int, 1996. **50**(1694-1699).
66. Allegra, V., G. Mengozzi, and A. Vasile, *Iron deficiency in maintenance hemodialysis patients: assessment of diagnosis criteria and of three different iron treatments*. Nephron, 1991. **57**: p. 175-182.
67. Astor, B.C., et al., *Association of kidney function with anemia: the Third National Health and Nutrition Examination Survey (1988-1994)*. Arch Intern Med, 2002. **162**: p. 1401-1408.
68. Locatelli, F., et al., *Management of disturbances of calcium and phosphate metabolism in chronic renal insufficiency, with emphasis on the control of hyperphosphataemia*. Nephrol Dial Transplant, 2002. **17**: p. 723-731.
69. Martin, K.J. and E.A. Gonzalez, *Vitamin D analogues for the management of secondary hyperparathyroidism*. Am J Kidney Dis, 2001. **38**(suppl 5): p. S34-S40.
70. *KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD)*. Kidney International Supplements, 2017. **7**(1): p. 1-59.
71. Laouari, D., et al., *Subtotal nephrectomy alters tubular function: effect of phosphorus restriction*. Kidney Int, 1997. **52**: p. 1550-1560.
72. *KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD)*. Kidney International Supplements, 2017. **7**: p. 1-59.
73. Ouattara, B., et al., *Particularities of chronic renal failure in black adult patients hospitalized in internal medicine of Treichville university hospital*. Ne´ phrologie & The´rapeutique, 2011. **7**: p. 531-534.
74. Halle, M.P., et al., *Nutritional status of patients on maintenance hemodialysis in urban sub-Saharan Africa: evidence from Cameroon*. J Nephrol, 2014. **10.1007/s40620-014-0047-2**: p. 1-9.
75. Rambod, M., et al., *Dietary and Fluid Adherence in Iranian Hemodialysis Patients*. The Health Care Manager, 2010. **29**(4): p. 359-364.
76. Garcıa, A.I.M., et al., *Dispositional optimism in patients on chronic haemodialysis and its possible influence on their clinical course*. Nefrologia, 2011. **31**(2): p. 199-205.
77. Couto, A.G., et al., *Causes of unscheduled haemodialysis initiation*. Nefrologia, 2011. **31**(6): p. 733-737.
78. Foley, R.N. and A.J. Collins, *The USRDS: what you need to know about what it can and can't tell us about ESRD*. Clin J Am Soc Nephrol, 2013. **8**: p. 845-851.
79. Arce, C.M., et al., *Hispanic Ethnicity and Vascular Access Use in Patients Initiating Hemodialysis in the United States*. Clin J Am Soc Nephrol, 2012. **7**: p. 289-296.
80. Durose, O.C., et al., *Knowledge of dietary restrictions and the medical consequences of non-compliance by patients on hemodialysis are not predictive of dietary compliance*. J Am Diet Assoc, 2004. **104**: p. 35-41.
81. Lindberg, M., B.r. Wikstro¨m, and P. Lindberg, *Subgroups of haemodialysis patients in relation to fluid intake restrictions: a cluster analytical approach*. Journal of Clinical Nursing, 2010. **19**: p. 2997-3005.

82. *USRDS System. USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. National Institutes of Health 2010. National Institute of Diabetes and Digestive and Kidney Diseases, 2010.*
83. Linman, J.W., *Physiologic and pathophysiologic effects of anemia.* N Engl J Med, 1968. **279**: p. 812-818.
84. I Terasaki, P. and M. Ozawa, *Predicting kidney graft failure by HLA antibodies.* Am J Transplant, 2004. **4**: p. 438-443.
85. *Canadian Erythropoietin Study Group. Association between recombinant human erythropoietin and quality of life and exercise capacity of patients receiving haemodialysis.* BMJ, 1990. **300**: p. 573-578.
86. Pfeffer, M.A., E.A. Burdmann, and C.Y. Chen, *A trial of darbepoetin alfa in type 2 diabetes and chronic kidney disease.* N Engl J Med, 2009. **361**: p. 2019-2032.
87. Cid, J., et al., *Efficacy in reducing potassium load in irradiated red cell bags with a potassium adsorption filter.* Transfusion, 2008. **48**: p. 1966-1970.
88. Dodd, R., *Managing the microbiological safety of blood for transfusion: a US perspective.* Future Microbiol 2009. **4**: p. 807-818.
89. Goodnough, L.T., A. Shander, and M.E. Brecher, *Transfusion medicine: looking to the future.* Lancet, 2003. **361**: p. 161-169.
90. Jacobs, M.R., E. Palavecino, and R. Yomtovian., *Don't bug me: the problem of bacterial contamination of blood components—challenges and solutions.* Transfusion, 2001. **41**: p. 1331-1334.
91. Kleinman, S., et al., *Toward an understanding of transfusion-related acute lung injury: statement of a consensus panel.* Transfusion, 2004. **44**(44): p. 1774-1789.
92. Looney, M.R., M.A. Gropper, and M.A. Matthay, *Transfusion-related acute lung injury: a review.* Chest, 2004. **126**: p. 249-258.
93. *KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease.* Kidney International Supplements, 2012. **2**(4 Suppl): p. 288-291.
94. Palmer, S.C., et al., *Meta-analysis: erythropoiesis stimulating agents in patients with chronic kidney disease.* Ann Intern Med, 2010. **153**: p. 23-33.
95. *Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD).* Kidney Int Suppl, 2009. **113**: p. s1-s130.
96. Graciolli, F.G., et al., *The complexity of chronic kidney disease—mineral and bone disorder across stages of chronic kidney disease.* Kidney International, 2017. **91**: p. 1436-1446.
97. Block, G., et al., *CKD-mineral and bone disorder and risk of death and cardiovascular hospitalization in patients on hemodialysis.* Clin J Am Soc Nephrol, 2013. **8**: p. 2132-2140.
98. Chartsrisak, K., et al., *Mineral metabolism and outcomes in chronic kidney disease stage 2-4 patients.* BMC Nephrology, 2013. **14**: p. 14.
99. Cannata-Andia, J.B., et al., *Use of phosphate-binding agents is associated with a lower risk of mortality.* Kidney Int, 2013. **84**: p. 998-1008.
100. Isakova, T., et al., *Phosphorus binders and survival on hemodialysis.* J Am Soc Nephrol, 2009. **20**: p. 388-396.
101. Lopes, A.A., et al., *Phosphate binder use and mortality among hemodialysis patients in the Dialysis Outcomes and Practice Patterns Study (DOPPS): evaluation of possible confounding by nutritional status.* Am J Kidney Dis, 2012. **60**: p. 90-101.