AN ASSESSMENT OF ADHERENCE TO MANAGEMENT MODALITIES BY AMBULANT END STAGE RENAL DISEASE PATIENTS UNDERGOING HAEMODIALYSIS AT THE KENYATTA NATIONAL HOSPITAL

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DECLARATION

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ABBREVIATIONS

ACR	Albumin Creatinine Ratio
CBT	Cognitive Behavioural Therapy
CKD	Chronic Kidney Disease
CKD-EPI	Chronic Kidney Disease Epidemiology collaboration
DDFQ	Dialysis Diet and Fluid Non adherence Questionnaire
ESRD	End Stage Renal Disease
ESRD-AQ	End Stage Renal Disease Adherence Questionnaire
GFR	Glomerular Filtration Rate
HIV	Human Immunodefiency Virus
ICU	Intensive Care Unit
IDWG	Inter Dialytic Weight Gain
KDIGO	Kidney Disease Improving Global Outcomes
KDOQI	Kidney Disease Outcomes Quality Initiative
KNH	Kenyatta National Hospital
MEMS	Medication Event Monitoring System
MDRD	Modification of Diet in Renal Disease
NHIF	National Hospital Insurance Fund
WHO	World Health Organisation

ABSTRACT

Background: Treatment of patients with End Stage Renal Disease (ESRD), entails regular dialysis sessions and medical management of complications of kidney failure. Globally, rates of non-adherence to treatment amongst ESRD patients are high. Implications of non-adherence include an increase in hospitalisations, Intensive Care Unit admissions, mortality, and financial burden to the healthcare system. It is vital to study the level of adherence to ESRD care, as a basis to evaluate whether or not patients will be subjected to the dire consequences of non-adherence. No such study has been conducted in Kenya.

Objective: To determine patient's adherence to their ESRD care, by utilising the ESRD Adherence Questionnaire (ESRD-AQ).

Study Design: Descriptive Cross Sectional Study.

Setting: Renal Unit of Kenyatta National Hospital.

Subjects: Adult ESRD patients undergoing haemodialysis at KNH Renal Unit.

Methodology: Adherence to ESRD care was assessed by utilising the ESRD-AQ, which utilises an alphanumerical approach to score patients level of adherence to treatment. Predialytic serum potassium level & mean Interdialytic weight gain,(IDWG) were obtained from patient's Haemodialysis Flow Sheet. Serum potassium, and IDWG are routine measures of effective management in ESRD care. The association between adherence to dietary restrictions and serum potassium levels, and association between adherence to fluid restriction and patient's IDWG was determined.

Data Analysis: Demographic & clinical characteristics were summarised. Utilising data from ESRD-AQ, the level of adherence to ESRD care, as an aggregate, was computed . Correlations between adherence to dietary recommendations and serum potassium level, & between adherence to fluid restrictions & IDWG were computed. P values of<0.05 were considered significant. Confidence Intervals were calculated.

Results: During the 2 month study period between 2^{nd} october-29^{th} november 2019, 87 patients undergoing chronic haemodialysis at the Renal Unit of Kenyatta National Hospital were studied. All patients were black Africans; 51 (59%) were male, with a male: female ratio of 1:0.7. Ages ranged from 18 to 79 years, with 62% of patients aged 50 years or below. Prevalent comorbidities included Hypertension in 97% , Diabetes Mellitus in 26%, polycystic kidney disease in 1.14%,whilst 24.13% had both Diabetes Mellitus and Hypertension.

The overall adherence to ESRD Care was Good in 48% (95% CI 38-59) of patients, Moderate in 43% (95% CI 33-53) and Poor in 9 % (95% CI 5-17).

A total of 70% (95% CI 60-79) of the ESRD population studied, were adherent to their twice weekly haemodialysis sessions in the month preceding the study period. The magnitude of non-adherence was, such that, among the 26 non-adherent patients, 16 (61.5%) patients missed a single haemodialysis session of the total possible 8 sessions in a month; 7 (27%) patients missed 2 sessions, whilst 3(11.5%) patients missed 3 sessions. A total of 72(83%; 95%CI 73-89) patients reported adherence to their medications, whilst 59(68% ; 95% CI 57-78) patients were adherent to their fluid restrictions and,61(70%;95% CI 60-79) patients were adherent to their dietary restrictions. IDWG was significantly higher amongst the patients who were non-adherent to their fluid restrictions as compared to those who were adherent to fluid restrictions.

Conclusion: Overall adherence to ESRD care amongst patients undergoing haemodialysis at KNH Renal Unit is suboptimum; with 52% of patients having overall Moderate or Poor adherence. Amongst the four parameters contributing to ESRD care, adherence to fluid restrictions was poorest , followed by adherence to haemodialysis. IDWG was significantly higher amongst patients who were non-adherent to fluid restrictions.

The implications of non-adherence, to a twice weekly schedule, is longer interdialytic intervals, which puts patients at increased risk of all-cause mortality (62). Secondly, high IDWGs above 3Kg, implies the patients are constantly in a hypervolemic state, and apart from risks of predialysis hypertension, uncontrolled intradialytic blood pressures, pulmonary oedema and even death, there are also the risks of hemodynamic instability in subsequent haemodialysis sessions when ultrafiltration is being performed.

1.0 CHAPTER ONE: BACKGROUND

Chronic Kidney disease (CKD) is defined by KDIGO as, a heterogeneous group of disorders, characterised by abnormal kidney structure or function, present for more than 3 months. (1)

CKD has a high global prevalence, estimated at between 11-13% of the world population. This is attributed to the increased incidence worldwide of the non-communicable diseases, Diabetes and Hypertension, which accelerate kidney dysfunction. In Kenya, HIV and post infectious glomerulonephritis further contribute to the burden of CKD. The burden of CKD in Africa was studied in 2018,and the overall CKD prevalence was 15.8%.(2)

CKD is categorised, according to estimated glomerular function, into Stages 1 to 5. Patients at Stage 5 CKD are considered to have End Stage Renal Disease(ESRD). Treatment of patients with ESRD is complex, and requires the engagement of a multidisciplinary team. Patients are burdened with complex medical regimens, as well as lifestyle modifications with strict dietary recommendations and fluid restrictions. These are in addition to the regular scheduled haemodialysis sessions that a patient is expected to diligently attend.

Despite the importance of adhering to this complex treatment regimen, it is understandably challenging for patients with ESRD. It is critical to assess whether or not patients with ESRD are adhering to their treatment modalities, because of the numerous complications associated with non-adherence. Implications of non-adherence to ESRD management include increased hospitalisations, increased Intensive Care Unit admissions, increased mortality, as well as a reduced possibility of future renal transplantation. (3)

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Definition of CKD & ESRD

Chronic Kidney disease (CKD) is defined by KDIGO as a heterogeneous group of disorders, characterised by an abnormality and alteration of kidney structure or function that have persisted for more than 3 months. (1) End Stage Renal Disease (ESRD) is the last stage of Chronic Kidney Disease, and it refers to kidney failure necessitating Renal Replacement Therapy (RRT).The options available for RRT include haemodialysis, peritoneal dialysis or renal transplantation. ESRD remains an ambiguous entity with no universally accepted cut-off, however a GFR of <15ml/min/1.73m^2 is the most accepted.(4)

CKD is differentiated from Acute Kidney Injury(AKI), in that, the alteration or deterioration of kidney function in CKD, must be present for more than 3 months. Structural or functional renal abnormalities that resolve within the period of 3 months are therefore considered AKI, and not CKD. The kidney structural damage can be confirmed by a renal biopsy or can be detected by imaging modalities such as an ultrasonography. Abnormalities of kidney function, on the other hand, can be detected by a declining glomerular filtration rate (GFR) or by the evidence of proteinuria in sampled urine. Glomerular filtration is the initial step in urine formation, and it is a passive process of ultra-filtration of the plasma into the Bowman's space through the glomerulus.(5)

As a patient progresses through the stages of CKD, from stage 1 to 5, their GFR declines. The normal GFR varies according to body size, gender, age and other variables. However, the normal range is from 90-130ml/min/1.73m^2.Several equations are used to determine the estimated GFR, (eGFR) and hence the degree of kidney impairment. Cockcroft-Gault, MDRD (Modification of Diet in Renal Disease) and CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration), are examples of such equations; however they are all only estimates of actual glomerular function. KDIGO utilises a cut off of GFR < 60ml/min/1.73m^2 for more than 3 months as criteria for decreased GFR defining CKD.(6)

Proteinuria indicates abnormal excretion by the kidney, but is non-specific. However, albuminuria is more specific and can be categorised as microalbuminuria or macro albuminuria. Microalbuminuria indicates renal endothelial dysfunction, and is a risk for cardiovascular events especially in Diabetics and Hypertensives.(7) The Albumin to Creatinine ratio (ACR) is calculated by dividing albumin concentration (in mg) by creatinine (in g), and the ACR can be used to define micro and macro albuminuria. (8) Micro

albuminuria refers to ACR 30-300mg/g while macro albuminuria is >300mg/g. On the basis of GFR and albuminuria, the KDIGO classifies CKD into 5 categories for GFR(G1-G5) and 3 categories for albuminuria,(A1-A3), as reflected in the tables below (1)

Table 1: GFR Category

GFR Stage	Terms	GFR (ml/min/1.73m^2)
G1	Normal or High	>90
G2	Mildly decreased	60-89
G3a	Mild to Moderately decreased	45-59
G3b	Moderately to Severely decreased	30-44
G4	Severely decreased	15-29
G5	Kidney failure	<15

Table 2 : Albuminuria Categories

A1	A2	A3
Normal to Mildly increased	Moderately increased	Severely increased
<30mg/g or <3mg/mmol	30-300mg/g or 30/300mg/mmol	>300mg/g or >30mg/mmol

Patients in G4-G5 are commenced on Renal Replacement Therapy, whereas patients in G1-3 are managed conservatively, with the aim to preserve as much residual renal function as possible.

2.2 Aetiology & Epidemiology of CKD

Diabetes and Hypertension are responsible for up to two thirds of CKD cases worldwide, while the remaining are attributable to Glomerulonephritis, Polycystic kidney disease, nephrolithiasis and obstructive uropathies.(9) CKD has a high global prevalence, estimated at between 11-14% of the world population. As part of the Global Burden of Disease Project published in 2015, which utilised data from 44 country prevalence studies, found the

worldwide prevalence of CKD to be 13.4%.The Global Burden of Disease Project further projected an estimated 19.6% increase in CKD prevalence from 2005 to 2015, based upon a complex Bayesian model that integrated multiple sources of data globally.(10)

There is a paucity of data on the prevalence of CKD & ESRD in Kenya. A study of the Epidemiology of CKD in Sub Saharan Africa done in 2014, which included Kenya, established an overall prevalence of 13.9%. The burden of CKD in Africa was studied in 2018,and the overall CKD prevalence had risen to 15.8%.(2) The only study done in Kenya to determine prevalence of CKD was conducted in Kericho county, located west of the Kenyan Rift valley, and found that the prevalence of CKD in 2014 was 0.41%. (13)

2.3 Treatment Modalities in ESRD Patients

ESRD is the final stage in CKD, and is characterised by permanent kidney failure necessitating implementation of renal replacement therapy(RRT). Currently, an estimated 2.6million patients worldwide undergo dialysis for ESRD, and this value is expected to double by 2030(16). The KDOQI Guidelines 2015 recommend patients with ESRD with low residual kidney function of less than 2ml/min should undergo thrice weekly sessions of haemodialysis, as prescribed for a minimum of 3 hours per session. This can be increased in patients with larger interdialytic weight gain, poorly controlled blood pressures, poor metabolic control with metabolic acidosis, hyperphosphatemia and hyperkalaemia. (41)

Most public facilities providing haemodialysis in Kenya, dialyse ESRD patients twice weekly, instead of the KDOQI recommended thrice weekly, due to cost implications. The National Hospital Insurance Fund (NHIF) only caters for the expenses of 2 haemodialysis sessions per patient per week. Any additional haemodialysis sessions required, are then paid for directly by the patient themselves.

Haemodialysis can be a cumbersome treatment, restricting a patient to the haemodialysis machine for almost 6-8 hours per session, and as such their health related quality of life is reduced. This was confirmed in a study by E Kamau et al.,(17) in Kenya, which confirmed that the health related quality of life was reduced in patients on maintenance haemodialysis.

In Kenya, haemodialysis is the preferred modality for initiation of RRT in ESRD patients, rather than peritoneal dialysis. There are very few studies on the global distribution of patients on haemodialysis and peritoneal dialysis. A study done in 2008,(20) found that globally only 11% of the dialysis population was on peritoneal dialysis, representing approximately 196,000 patients, with the remainder 89% on haemodialysis.

Renal transplantation is an invaluable method of RRT, but requires suitable donors and adequate finances to cover the cost of the surgical procedure. Patients recruited into the Kenyan Renal Transplant Programs, are initially started on haemodialysis as various preparations are made for eventual renal transplantation. Post renal transplant, patients must adhere to costly immunosuppressive drugs. Patients who have a failed renal transplant can be reverted back to haemodialysis.

Apart from the regular dialysis sessions, patients with ESRD also require strict lifestyle changes including restriction of their fluid intake, restriction of potassium and phosphate containing foods, restriction of salt intake, as well as adherence to their various medications. Patients with ESRD are at risk of developing multiple complications as a result of their kidney failure. Such complications include Mineral Bone Disorders (with imbalances in calcium, phosphate and parathyroid hormone levels,) hyperlipidaemia, hyperkalaemia, metabolic acidosis, and anaemia. ESRD patients therefore are prescribed multiple drugs, with a large pill burden. Medications such as oral and injectable haematinics/iron supplementations, Erythropoietin, antihypertensives, phosphate binders, calcimimetics, and glycaemic control agents are common prescriptions. Hence treatment, is complex and requires a multidisciplinary team effort as well as patient adherence to their prepared regimens.

Another vital element in the treatment regimen in ESRD undergoing haemodialysis is fluid and dietary regimen adjustments. Whilst the KDIGO Guidelines are very clear on sodium and protein restrictions, fluid restrictions tend to be more individualised. KDIGO recommends avoiding high protein intake, and to restrict it to 0.8g/kg/day in adults with or without Diabetes once their GFR is below 30ml/min/1.73m.(6) The basis for this recommendation was that excessive dietary protein leads to accumulation of uremic toxins. Furthermore these uremic toxins can further suppress appetite, and worsen muscle protein wasting, which is already increased due to muscle catabolism associated with ESRD as a proinflammatory state. KDIGO recommends that salt intake must be lowered to 90mmol(less than 2g) per day corresponding to 5g of sodium chloride, unless contraindicated(for example in hyponatremic patients).(6)

2.4 Definition & Components of Adherence

WHO currently defines adherence as the extent to which a person's behaviour of taking medications, executing lifestyle changes, and following a diet, corresponds to the agreed recommendations from a healthcare provider(22). The term compliance is no longer utilised, as it was noted to suggest a patient simply follows treatment instructions given by a health provider, with no active role in their management(22).

Adherence incorporates the patient's agreement to the recommendations given by the healthcare provider, without simply submitting to instructions.Adherence is a dynamic process that requires regular follow-up and patient readiness to cooperate at any given point. Interventions to improve patient adherence are individualised and patient-tailored to their specific disease. A multi-disciplinary approach with engagement of patient's family, caregivers, community and patient based organisations are implemented to improve adherence.(23) The minimum percentage of adherence that is vital in order to have the complete benefit of any known drug is not known. However most institutions arbitrarily use 80%.(24)

An important aspect when evaluating adherence and non-adherence, is to differentiate between intentional or unintentional non-adherence. Intentional non-adherence occurs when the patient deliberately decides to disregard their treatment recommendations. Unintentional non-adherence on the other hand occurs due to passive processes beyond the patients control, like age, lack of knowledge about the disease process, and illiteracy.(25)

2.5 Factors Influencing Adherence to Treatment

The World Health Organisation (WHO) recognises that the degree of adherence to any form of therapy is a primary determinant of treatment success and that poor adherence results in reduced clinical benefit and reduced efficacy of the health system. (23)

As per the WHO 2003 Adherence to long term therapies, evidence for action report, there are 5 main factors that affect adherence, namely; Health system/healthcare team factors, Socioeconomic factors, Therapy related factors, Patient related factors, and Condition related factors.(23)

Socio-economic Factors : Low level of income, unemployment, low literacy level and cultural beliefs with regards to treatment hinder adherence.(23) Good social support from immediate family is associated with higher adherence. (26)

Healthcare Team/Health System Related Factors: Good patient-provider relationships with shared decision making improves adherence, whilst lack of knowledge by healthcare providers and poorly developed health services with weak capacity to educate patients hinder adherence. (26)

Condition Related Factors: This refers to the illness related demands on the patients and their level of disability (physical or psychological). Severity of the disease and its rate of progression, are determinants of adherence. Depression, cognitive impairment, Alcoholism and drug abuse are known to reduce levels of adherence. (23)

Therapy Related Factors: Side effects of medicines, longer duration of treatment, frequent changes in medication regimens, previous treatment failures experienced by the patient and complexity of medical regimens, contribute to reduced levels of adherence. (23)

2.6 Assessment of Adherence to Care

It is essential to assess adherence to treatment regimens, however there is currently no Gold Standard to measure adherence. Various strategies are frequently utilised in studies, to measure adherence to care.(27) Options currently available include; patient and provider subjective rating of adherence, standardised patient administered questionnaires, directly observed therapy, remaining dosage units (counted each clinic visit) and pharmacy databases (to check date prescriptions are filled, refilled or prematurely discontinued). Other less frequently utilised methods to assess adherence to care, include electronic devices such as the Medication Event Monitoring System (MEMS) that records the time and date the container was opened and number of pills taken out, biochemical measures to assess drug levels (or drug metabolite levels) in urine/blood specimens and measurements of physiologic response to medications (e.g. heart rate in patients on beta-blockers).

Assessment of adherence can be divided into two categories; direct and indirect. Direct measures of adherence are objective and most accurate. Measurements of blood levels of drugs or drug metabolites, and Directly Observed Therapy (DOT) are the only direct measures of adherence. The other methods are considered indirect methods, and so are only estimates of the patient's actual adherence.

Several factors limit the use of each of these assessment modalities. Financial implications and costs limit the use of MEMS in several studies. In attempts to assess drug levels in patient's specimens, factors such as diet, absorption, rate of excretion, underlying co-morbities, can all alter the drug levels, and therefore drug levels may not be accurate direct

indicators of adherence. Pharmacy databases require costly software that is not widely available in most pharmacies in Kenya, and also prescription refill does not necessarily indicate ingestion of medication. Questionnaires are susceptible to distortion by patient. (27)
Therefore with the shortcomings of most modalities, and with no single measurement strategy deemed optimum, then, it is important to choose the strategy that most fits the situation. A multi-method approach that combines the self-reporting and a reasonable objective measure is currently most widely used.(16)

2.7 Adherence to ESRD Care & Factors Contributing to Non-adherence

Patients with ESRD have complex drug regimens, lifestyle modifications, dietary and fluid restrictions, that they must adhere to. The complex medical regimens involve combinations of haematinics, anti-hypertensives, phosphate binders, calcium supplements and glycaemic controlling agents. Rates of adherence to ESRD care is not widely studied globally, and there has been no study to date, conducted in Kenya, to assess adherence to ESRD care. There is also paucity of data on factors that could be contributing to non-adherence to ESRD care. Studies done amongst CKD patients, have proven that medication adherence represents an independent predictor for CKD progression. (29) This highlights the importance of adherence to medication amongst CKD patients.
Adherence to treatment is key to effective management. A meta-analysis done in 2006 involving 46,847 patients, concluded that good adherence to treatment regimens in general, was associated with lower mortality and positive health outcomes.(31)
A literature review published in 2008 in the American Journal of Critical Care, on the prevalence of non-adherence to immunosuppressive drugs amongst ESRD patients, post renal transplant, found the weighted mean prevalence of non-adherence was 28%. (32).Adherence to treatment modalities amongst ESRD patients, both pre transplant and post-transplant, are crucial to reducing morbidity and mortality.
In 2008, a systematic review of the prevalence and determinants of non-adherence to phosphate binders in ESRD patients, concluded that there was a mean reported rate of non-adherence of 51%. (33)The use of phosphate binders is an essential component of the ESRD treatment regimen because of the large cardiovascular risk associated with hyperphosphatemia. Hyperphosphatemia contributes to the increased risk of death from vascular calcification, due to the regulating role phosphorous has in vascular smooth muscle cell calcification(34). If 51% of the ESRD population are non-adherent to phosphate binders,

then there is an increased risk of hyperphosphatemia, which would translate to an increased cardiovascular risk.

In another retrospective cohort study performed in 2005, from 8 medical centres across North America, it was concluded that hyperphosphatemia was independently associated with an increased mortality risk in CKD patients regardless of whether or not they were undergoing haemodialysis. Serum phosphate levels above 3.5mg/dl were associated with a significantly increased risk of death, with this mortality risk increasing linearly with each subsequent 0.5mg/dl increase in serum phosphorous levels.(35) Hence compliance to phosphate binders is a crucial element to the regimen to maintain serum phosphorous levels within normal range in ESRD patients. Despite the importance of maintaining normal phosphate haemostasis, it remains a challenge to clinicians because, it involves not only adherence to phosphate binders as medication, but to dietary phosphate restriction and adequate removal of phosphate intradialysis.(36)

In a systematic review in 2009, the mean non-adherence rate to prescribed oral medications amongst ESRD patients was 67%. This was noted to be life threatening behaviour.(44). In another study from 54 haemodialysis centres across Italy it was noted that amongst patients undergoing haemodialysis only 48% of patients were adherent to medication prescriptions.(45)

Another aspect of treatment in ESRD care includes dietary and fluid restrictions. Fluids are limited due to minimal or absent urine output at ESRD, whilst dietary restrictions mainly target potassium, phosphate and sodium containing foods. A systematic review conducted by Suetonia et al., concluded that dietary and fluid restrictions are an intense burden for patients undergoing haemodialysis whilst Safdar N et al., noted a 64% noncompliance rate to fluid or dietary restrictions(38) In a cross sectional survey done in 2018 in India, there was a reported 69% non-adherence to dietary restrictions and a 21% non-adherence to fluid restrictions amongst CKD patients. There was also an association between non-adherence to treatment and illiteracy, $p<0.05$. This affirms the challenge of encouraging adherence to treatment amongst patients who are not literate, and who may therefore have a challenge in understanding the nature of their disease and the often fatal implications of non-adherence.(39)

In 2018, in Rwanda, the assessment of adherence to ESRD care was conducted by utilising the ESRD-AQ, and found that 51% of patients had Good adherence, while 42% moderate and 7% had low levels of adherence to ESRD care. This study incorporated adherence to all four aspects of ESRD care (53)

A cross sectional study done in Palestine in 2016, also utilising the ESRD-AQ, reported 55.5% patients had good adherence overall. A correlation was also noted between poor dietary adherence and serum elevated pre-dialysis serum potassium levels.(55) A similar study replicated in Saudia Arabia, also utilising the ESRD-AQ as its primary tool, noted adherence to haemodialysis was only 55.96%.However their dietary restrictions adherence was noted to be 88.37%.(56)

Apart from determining the prevalence of adherence to treatment amongst ESRD patients, it is also important to evaluate what factors contribute to non-adherence. To date very few review articles address, what factors contribute to non-adherence to treatment amongst ESRD patients. A study done in the USA in 2015,noted that patients with CKD have one of the highest daily pill intake, and that amongst patients on haemodialysis, the median number of pills taken daily was 19; while a quarter of them were taking more than 25 pills. This high pill burden can therefore contribute to non-adherence. Furthermore the study noted that the higher the pill burden the lower was the health related quality of life.(24)(42)

A systematic review conducted utilising databases from 1970 up to 2014 found that the prevalence of non-adherence to medications in ESRD patients on haemodialysis, varied from 12.5%- 98.6%.(37) The factors contributing to non-adherence were broadly classified into patient related factors, disease related factors, and medication related factors.

The most common patient related factors associated with non-adherence were smoking, being divorced/widowed, younger age, and being of non-Caucasian ethnicity.

The disease related factors that most contributed to non-adherence was, longevity of the haemodialysis sessions, recurrent hospitalisations, having concomitant Diabetes, Hypertension or other concomitant illnesses.

The medication related factors contributing to non-adherence were the total pill burden, number of phosphate binders prescribed, and complexity of medication regimens prescribed.(37)

The above mentioned factors contributing to non-adherence to treatment amongst ESRD patients, are similar to the 5 factors listed in the WHO 2003 Adherence to long term therapies, evidence for action report; namely Health system/healthcare team factors, Socioeconomic factors, Therapy related factors, Patient related factors, and Condition related factors.(23)

2.8 Interventions Aimed At Improving Adherence to Treatment amongst ESRD Patients

Several strategies have been implemented in an attempt to improve adherence to treatment amongst the ESRD population. Such strategies have varying success rates. Firstly, the number of pills taken as well as the frequency of administration of the pills and the complexity of the dosing regimen all contribute to an increased pill burden; which is a factor that reduces adherence to treatment. A study published in the American Journal of Kidney Disease in 2006, found that when the phosphate lowering drug Sevelamer, was given as a once daily dosing, it was as effective in lowering phosphate levels, as compared to a thrice dosing regimen. This was the basis of reducing pill frequency of such phosphate lowering drugs, and this has been shown to improve adherence to medications. (43)

The psychological aspect to adherence to treatment regimens is also important. Cukor et al., in 2014 tested the efficacy of cognitive behavioural therapy (CBT) intervention to improve quality of life and fluid regimen adherence amongst ESRD patients. CBT lead to significant improvements in quality of life and prescription adherence.(46)

In another study on psychodynamic interventions, it was found that amongst ESRD patients who underwent psychodynamic psychotherapy, there was reduction in non-adherence (reflected by a reduction in the number of skipped haemodialysis sessions).(47) This study was formed on the basic principle of the Ego Psychology theory which is a concept that non-adherence stems from a maladaptive strategy the patient develops to give themselves a sense of control or independence in their treatment. The psychodynamic psychotherapy intervention therefore was administered to reverse this maladaptive thinking and in turn it proved to improve patient adherence to their scheduled haemodialysis regimen.

The EPIC trial education programme evaluated the impact of a nutritional education program on serum phosphate levels amongst 179 ESRD patients. It was a prospective interventional study utilising a 4 month educational intervention during each dialysis session. At the end of the 4 month period 132 patients had significant reduction in their serum phosphate levels, having gained knowledge on the importance of adhering to dietary restrictions limiting phosphate intake.

2.9 Implications of Non -adherence to Treatment Amongst ESRD Patients

Studies conducted around the world on ESRD patients have found dire consequences of non-adherence to treatment, including increased hospitalisations, Intensive Care Unit admissions, mortality, and financial burden to the healthcare system. A study conducted across the USA, reviewed whether non-adherence caused an increased risk of hospitalisations, emergency room visits, or Intensive Care Unit (ICU) admissions in the immediate 2 days after a missed dialysis session. It was an observational cohort analysis that covered over 1500 clinics and 182,536 patients over a 5year period. Notable findings in this study were that there was significant risk of hospitalisation and Emergency Room visit with missed dialysis sessions. After a single missed haemodialysis session the probability of hospitalisation was 5%, and risk of ICU admission was 2% after missed treatment. Conditions necessitating admission were those requiring urgent haemodialysis like hyperkalemia and pulmonary oedema. Reasons for the missed dialysis commonly included transportation, weather changes, pain, diarrhoea, vomiting and underlying psychiatric disease.(3) Poor adherence to haemodialysis is an obstacle to achieving good patient outcomes.

A prospective observational study of 8501 patients participating in the Dialysis Outcomes and Practice Patterns Study (DOPPS) who were on haemodialysis concluded that missed treatments were positively associated with all-cause mortality(HR,1.68;95%CI 1.37-2.05), cardiovascular mortality, and hospitalisation.(48)

The implications of non-adherence was studied in ESRD patients in 2005, and concluded that patients who skipped their haemodialysis sessions, and who did not comply to phosphate and potassium restrictions had a higher risk of death (hazard ratio 1.69, 95%CI 1.24-2.31).

Furthermore, skipping dialysis sessions was also associated with a lower likelihood of renal transplantation in patients less than 65 years(OR 0.41,95% CI 0.18-0.93) (49).

Another relevant study conducted in the United States of America in 2014, found that there was an increased risk of hospitalisation of 5%, and ICU admission of 2%, if a patient missed one single haemodialysis session.(3) These studies show how important strict adherence to management is amongst the ESRD population, such that even a single skipped session will increase their morbidity and mortality risk.

There are several financial implications of non-adherence to treatment. These consequences of non-adherence affect the individual patients, as well as the healthcare system as a whole. The financial implications maybe directly due to non-adherence to treatment, or maybe due to secondary consequences of non-adherence.

The WHO adherence report 2003 states that adherence itself is a modifier of health system effectiveness such that the desired population health outcomes cannot be achieved unless there is adequate adherence rates to then allow for projects evaluation and planning. There is a great economic burden as well as a result of non-adherence. Sources of funding maybe withdrawn if there is inadequate proof of proper adherence to treatment regimens being supplied; and this would be a challenge for developing nations like Kenya that depend heavily on donor funding for several health projects. The report also recognised the improved economic benefit of adherence to the patient in the form of reduced hospitalisations for exacerbations of their conditions, as well as the indirect savings attributed to the improved quality of life noted in them, and hence their overall productivity.(14)

In 2005, in the United States of America, it was noted that, of all medication related hospital admissions, 33-69% were attributed to poor medication adherence. This resulted in costs exceeding $100 billion a year. (27).If such financial losses, as a result of non-adherence to treatment, are burdening the healthcare system of a developed nation like the USA, then a resource poor developing nation like Kenya would be unable to withstand such a burden.

2.10 Assessment of Adherence amongst ESRD Patients Utilising the ESRD-AQ

There is no gold standard method to assess adherence to treatment amongst the ESRD population, however several studies utilise questionnaires as the main study tool. The Dialysis Diet and Fluid Non adherence Questionnaire (DDFQ), developed in 2001, has been frequently utilised in the past, to assess adherence to ESRD care. However the DDFQ only assessed 2 out of the 4 arms of treatment (namely fluid restriction and dietary modification).It did not however address adherence to haemodialysis or adherence to prescribed medications. Hence even though it was a valid and reliable tool, it was noted to be over simplified.(51)

One of the more recent questionnaires introduced, for the purposes of assessing adherence to treatment amongst ESRD patients, is the End Stage Renal Disease Adherence Questionnaire (ESRD-AQ). The ESRD-AQ was developed in 2010 by Kim et al, in Los Angeles USA, as a validated and reliable tool, to determine adherence rates amongst ESRD patients, to the various components of ESRD care. The instrument was the first tool that could reliably assess for treatment adherence to haemodialysis, medications, fluid restrictions, and dietary recommendations. It consists of a 46 item questionnaire with a total score possible score of 1200.The lower the score the lower the level of adherence.

The need to develop this tool was due to the limited number of reliable measurement tools that could assess the all 4 of the classic components of treatment in ESRD patients.

Furthermore, this tool, apart from directly measuring adherence, also assesses patients knowledge and perceptions about their treatment.(50)

The main advantage of this ESRDA-AQ tool lies in the fact that it incorporates all aspects of the ESRD care, and hence adherence can be measured as an aggregate of all the components. It is self-administered and comprises 46 questions, that are grouped into 5 main categories(General Information, Haemodialysis Treatment, Medication, Fluid, and Diet).

The ESRD-AQ tool classifies patients as Good, Moderate or Poor Adherence based on their aggregate score from each of the 4 sections, assessing adherence to haemodialysis schedules, to medications, to fluid restrictions, and to dietary recommendations. The ESRD-AQ utilises an alphanumerical approach to then score patients level of adherence to ESRD care.

Scores of less than 700 indicate Poor adherence, 700-999 is Moderate, while 1000-1200 indicates Good adherence to ESRD care.

Furthermore, the tool also provides information with regard to patient's beliefs on importance of adherence to each modality, information with regard to adequacy of information provided to the patient by their healthcare provider, as well as exploring reasons for non-adherence.

The tool has even been translated into various languages including Portuguese, Arabic and Spanish (52). Across the world countries such as India, Saudia Arabia, Spain, Palestine, and Portugal have utilised the ESRD-AQ to assess adherence to ESRD care.

The first African country to utilise the ESRDAQ to assess adherence to treatment amongst the ESRD population was Rwanda, in 2018. (53) Considering this study has been conducted amongst an African population it would be informative to determine whether the Kenyan ESRD population has similar adherence to their Rwandese counterparts. Despite both countries being in Africa, there are vast differences in their healthcare systems, as well as their Renal Programs catering for growing numbers of ESRD patients, in both countries. Kenya had its first haemodialysis in 1962-1963, the maintenance haemodialysis program was initiated in 1984,has an active renal transplantation program, and as at July 2014 had 17 nephrologists (translating to 0.4 per million population).Rwanda on the other hand has no official data on date of initiation of first haemodialysis sessions or their maintenance program, but as at 2014 had only 2 registered nephrologists.(54)

The studies, utilising the ESRD-AQ as their main study tool, have been able to quantify adherence to all the components of treatment involved in ESRD care. The data obtained from the ESRD-AQ has been utilised to provide quantitative data, in terms of the rate of adherence to ESRD care, as well as provide qualitative data, in terms of the factors contributing to non-adherence to ESRD care. To date no such study has been conducted in Kenya.

2.11 Research Question

What is the level of adherence to haemodialysis schedules, to medication use, to fluid restriction and to dietary modification, amongst ambulant End Stage Renal Disease patients on haemodialysis at the Kenyatta National Hospital Renal Unit?

2.12 Study Justification

Chronic Kidney Disease, as defined by KDOQI (Kidney Disease Outcomes Quality Initiative) & KDIGO guidelines is the presence of kidney damage **or** decreased kidney function for three or more months, irrespective of the cause. Chronic kidney disease (CKD) is a worldwide public health problem, with adverse outcomes of kidney failure, cardiovascular disease (CVD), and premature death. CKD causes at least 2.4million deaths annually, whilst it affects more than 13 million people worldwide. A large population of CKD patients occurs in low and middle income countries like Kenya. The prevalence of CKD is expected to rise within our Kenyan population, as more cases of Hypertension and Diabetes are being detected, as well as post infectious glomerulonephritis and HIV associated nephropathies.

The treatment of stage-five CKD (End Stage Renal Disease/ESRD) requires a complex therapeutic regimen, which can be divided into the dialysis component and the non-dialytic components. The non-dialytic components involve a strict regimen of medication, dietary limitations and fluid restrictions. These four treatment aspects are inseparable and constitute the pillars of treatment, directly influencing the morbidity and mortality rates.

Adherence is defined as the extent to which patients are able to follow the recommendations for prescribed treatments. It can be described as the extent to which a person’s behaviour corresponds to the prescribed medical advice of a healthcare provider. It is essential not only to the prescribed medication dose, form and frequency but also to attendance of haemodialysis sessions as prescribed, follow up in clinics, dietary modifications and fluid restrictions.

Hence, non-adherence to any of these variables negatively affects the patient's quality of life and increases the health costs. In addition to this, non-adherence to the components of their management, is known to increase mortality, hospitalisation, Intensive Care Unit (ICU) admission, as well as reduce the likelihood of future kidney transplantation, amongst patients with ESRD.

Most studies done around the world have used patient self-reporting questionnaires & have highly variable rates of non-adherence amongst CKD patients with ranges of 43-78%.

There is paucity of data regarding adherence in our population, of patients undergoing this essential modality of treatment. This study will provide an insight into which aspects of treatment are not being adhered to, amongst our own population, and more importantly, determine associations between their non-adherence and clinical parameters such as serum potassium and interdialytic weight gain. The results will help to form a basis for future studies to be performed to then determine reasons for non-adherence to treatment; & this would help develop strategies to improve adherence, hence reducing health costs, improving morbidity & mortality.

2.13 Broad Objective

To determine patient's adherence to their End Stage Renal Disease care, by utilising the End Stage Renal Disease Adherence Questionnaire (ESRD-AQ).

2.14 Specific Objectives

2.14.1 Primary Objective

To determine the level of adherence to ESRD care, as an aggregate, incorporating adherence to haemodialysis schedules, to medications, to fluid restrictions, and to dietary recommendations, amongst ESRD patients undergoing haemodialysis at the Kenyatta National Hospital.

2.14.2 Secondary Objectives

a) To determine the proportional individual contribution of the 4 components of ESRD care to non-adherence.

b) To determine the association between adherence to dietary recommendations and mean pre dialytic serum potassium levels.

c) To determine the association between adherence to fluid restrictions and mean Inter Dialytic Weight Gain.

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study Design

Descriptive cross sectional study

3.2 Setting

The study was undertaken at the Renal Unit of the Kenyatta National Hospital, which is Kenya's major teaching and referral Centre. It is the largest referral hospital in Sub Saharan Africa with an approximately 1800 bed capacity. Over 6000 staff are employed at this facility which also serves as the teaching hospital for the University of Nairobi, College of Health Sciences. The Renal Unit is run by several pioneer nephrologists in Kenya, and apart from Haemodialysis, the Renal Unit is incorporated in Renal Transplantation, Renal Biopsy and outpatient renal clinics. There are approximately 110 patients undergoing chronic haemodialysis at the Kenyatta National Hospital Renal Unit, and they dialyse in groups daily between 5am-11pm.The Renal Unit itself functions 24 hours a day.

3.3 Study Population

The study population comprised all the patients with CKD 5(ESRD) undergoing haemodialysis at the renal unit in KNH for at least 3 months, and who were above 18years of age.

3.4 Inclusion Criteria

- -Age above 18years.
- -Receiving haemodialysis for at least 3 months.
- -Conscious and oriented in time place and person.

3.5 Exclusion Criteria

- -Patients who decline participation.
- -Patients who have had a failed renal transplant in the past 3 months.

3.6 Sampling Procedure & Sample Size

This was a population study. An estimated number of 110 patients undergo haemodialysis at the Renal Unit at Kenyatta National Hospital. A representative sample size is determined, for a finite population of less than 10,000, using the Fisher formula.

Thus the calculation is

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

where

n = sample size

N = size of the target population =110

Z= the standard normal deviation, set at 1.96, which corresponds to 95% confidence level

P = The proportion in the target population estimated to have the outcome of interest (estimated adherence of 52% by Karam et al., (55) in Palestine) hence 0.52

d= margin of error =5 %(0.05)

hence

$$n = \frac{110 \times (1.96)^2 \times 0.52(1-0.52)}{0.05^2(110-10) + 1.96^2 \times 0.52 \times (1-0.52)}$$

Therefore n =85.6 indicating a minimum of 86 patients were sampled to estimate levels of adherence within 5% level of precision.

3.7 Recruitment and Consenting Procedure

Eligible ambulatory patients undergoing chronic haemodialysis at the Renal Unit of Kenyatta National Hospital were recruited into the study after duly completing the written informed consent form. A thorough verbal explanation of the purpose of this study was given to the patient prior to gaining consent to participate. Furthermore, any queries with regard to the study were addressed fully prior to participants appending their signatures onto a written informed consent form. Recruitment for the study was done before, during or even after the patient's haemodialysis session. The Principal Investigator recruited patients daily, over the stipulated study period, until the desired sample size was attained. Patients who declined participation were excluded from the study, and reassured of no prejudice to their further treatment in the unit. Furthermore, the medical records and clinical details available in the patients file were reviewed thoroughly to ensure that no patient meeting the exclusion criteria was recruited.

3.8 Study Tool & Methodology:

In this study, two tools, namely the Haemodialysis Flow Sheet (HFS) and a reliable, validated instrument called the ESRD-AQ (End Stage Renal Disease – Adherence Questionnaire) were utilised. The questionnaire served as a tool to:

(1) Assess the overall level of adherence to ESRD care.

(2) Compute proportions of adherence to each of the 4 subcategories involved in ESRD care. Namely adherence to haemodialysis schedules, to fluid restrictions, to dietary recommendations and to medications.

The Haemodialysis Flow Sheet (HFS) is an essential part of the haemodialysis regimen individualised to every patient. It is the property of Kenyatta National Hospital Renal Unit and it contains crucial information required for each haemodialysis session. The information captured in this flowsheet includes –the Access site –the dialysis orders (treatment time, dialysis solution, dialyser, bath potassium, membrane type and heparin dose) -pre dialytic weight, -post dialytic weight, -laboratory results, -blood group, -HIV/HBsAg screening date -patients vital signs intradialysis ,-post dialysis observations and other crucial information required during the dialysis session. For purpose of this study, the crucial elements in this HFS that were scrutinised were the Pre dialysis Weight and the Post Dialysis weight.

The ESRD-AQ has 46 questions that are distributed into sections: the first section has general and history related information while the remaining four sections measure adherence to Haemodialysis sessions, adherence to medications, adherence to fluid restriction, and adherence to diet recommendations. These questions were scored and responses of patients to these questions were aggregated to calculate the overall adherence score. According to ESRD-AQ, higher scores represents higher adherence to the measured behaviour.

The questionnaire uses multiple choices and Yes/No answers .The total points are 1200.The questionnaire utilises an alphanumerical approach to reduce subjectivity.

Scores for questions 14, 17, 18,26,31,46 are then added up to give a total ESRD-AQ score. This sums up the adherence to all the four components of care (haemodialysis, fluid restrictions, dietary recommendations and medications).

Table 3: ESRDAQ Score

Adherence category	Total score
Poor	<700
Moderate	700-999
Good	1000-1200

The weighting system for the scores is determined based on the degree of importance relevant to the clinical outcome. For example missing a scheduled haemodialysis session is reported to have a stronger association with increased mortality than the other components and therefore it is computed higher when scoring. The tool also summarizes important information about the patient's clinical history related to their ESRD, as well as their perception and level of understanding of their medical recommendations.

Each component of adherence that is being assessed (haemodialysis, fluid restrictions, dietary recommendations and medications) is addressed in separate sections of the questionnaire. Section 2 has 14 questions that focus on haemodialysis, Section 3 has 9 questions on Medication adherence, Section 4 has 10 questions on adherence to fluid restrictions, and Section 5 has 8 questions with regard to adherence to dietary restrictions. Within each section, there are questions that shall generate a response that were graded with a numerical value.

Section 2, (Haemodialysis) explores the frequency of missing planned haemodialysis sessions and reasons for this, and is then quantified using numerical scores, with 5 response categories and each response giving a different score. The higher the score, the higher the level of adherence. Section 3(Medication), explores the frequency of missing medications in one month and is scored numerically giving an addition numerical component to final adherence score. Section 4(Fluid), obtains data from the questions involving the frequency of not adhering to fluid restrictions. These will also be scored according to the response category the patient selects. Finally, Section 5(Diet) revolves around questions involving frequency of self-monitored dietary restriction. These shall also be given a numerical value which shall then contribute to the final score.

Each section of the questionnaire also includes questions with regard to adequacy of information provided to the patient by a healthcare worker. The number of times a patient is counselled on adherence, its importance and results of non-adherence. The tool is a self-administered questionnaire. It was investigator assisted for patients unable to read. The tool takes approximately 20-40 minutes to administer.

For the vital clinical aspect of the study, Pre dialytic serum levels of potassium were obtained from the patients latest laboratory results. The mean/median values of their pre dialytic serum potassium readings over the last 3 months were obtained. Dialysing patients with ESRD have a minimum of twice monthly serum electrolytes done, and they report to their respective facilities with their lab results, prior to the haemodialysis, so that any adjustments to dialysis instructions are made. Therefore, we utilised the most recent readings to compute the data.

In addition, inter dialytic body weight gain (IDWG) was obtained from the patients Haemodialysis Flow Sheet. Prior to dialysing a patient, the renal nurse fills in a haemodialysis flow sheet for every patient. IDWG was calculated by the principal investigator by, subtracting the post-HD weight from the pre-HD weight.

Further information was gathered from medical records in patient files including Socio-demographic data as well as patient comorbidities.

3.9 Data Management & Analysis

The data was coded, entered and managed in the Microsoft Access 2013 database. Data cleaning and verification continued throughout the data collection and at the end of data entry, in order to ensure accuracy of the information obtained. The database was exported to SPSS version 21.0 software for the statistical analysis. The patients Demographic characteristics and clinical characteristics were summarised and presented into means, medians, standard deviations, interquartile range, and percentages for continuous and categorical data respectively.

Furthermore, our data management was targeted to each objective of the study specifically.

In relation to the Primary Objective, the level of adherence to ESRD care, as an aggregate incorporating adherence to haemodialysis schedules, to medications, to fluid restrictions, and to dietary recommendations, was analysed as an aggregated score. This score was then categorised into Good, Moderate or Poor adherence, and presented with the respective frequencies and proportions; where from a possible total of 1200, Good adherence was reflected by 1000-1200, Moderate 700-999, and Poor <700.

Hence the study variable was the aggregate score, and it was derived from the ESRD-AQ.

In relation to Secondary Objective 1), in order to determine the proportion of patients having poor adherence in the 4 categories of ESRD care, specific questions addressing each category individually, were utilised from the ESRD-AQ.

Firstly, the proportion of patients having difficulty complying with their haemodialysis schedule was determined by Question 14 of the ESRD-AQ.

The proportion of patients having difficulty complying with their medications was determined by utilising Question 24 of the ESRD-AQ.

The proportion of patients having difficulty with complying with their fluid restrictions was determined by utilising Question 34 of the ESRD-AQ.

Finally, the proportion of patients have difficulty complying with their dietary recommendations, was determined, utilising Question 43 of the ESRD-AQ.

These questions (14, 24, 34 and 43) were analysed in order to categorise patients as

a) Having difficulty with adherence (hence non-adherent) or

b) Having no difficulty with adherence(hence adherent).Proportions were computed for each subcategory of care to determine adherence in each; whereby for example for adherence to haemodialysis the numerator is number of patients adherent to haemodialysis schedules, (as answered in question 14), and the denominator is total number of patients assessed.

$$\frac{\text{Number of patients non adherent to specific category}}{\text{Total number of patients assessed}}$$

Therefore we were able to determine, if a patient had an overall Poor aggregate score of adherence, was the patient non adherent to all 4 categories or to 2 or 3 only. This enabled us to determine what proportion of patients are adherent to each specific individual component of the overall ESRD care.

For Secondary objectives 2 and 3,

- **a)** The correlation between adherence to dietary restrictions and pre dialytic serum potassium levels and
- **b)** The correlation between adherence to fluid restriction and Inter dialytic weight gain, (IDWG) were both analysed using the independent sample t-test. P values of less than 0.05 were considered significant. Confidence intervals were also computed.

3.10 Ethical Considerations

The study only proceeded after approval from the Department of Clinical Medicine and Therapeutics, University of Nairobi and the Ethics and Research Committee. All information gathered during the study was kept confidential. The information did not bias or influence in any way a patient's further treatment. Patients were briefed on the nature and purpose of the study and allowed to ask any questions or raise concerns prior to consenting to participate in the answering of the questionnaire, as well as allow access to their medical file for the Clinical information.

4.0 CHAPTER FOUR: RESULTS

4.1 Patient Socio-Demographic Characteristics & Comorbidities

There were 104 patients on chronic haemodialysis at the time of the study at the Renal Unit at Kenyatta National Hospital. Initially 4 were excluded as they were below 18years of age. A further 9 declined consent for personal reasons, whilst 3 were excluded as they were prisoners under watchful guard. There was 1 patient who was excluded on the basis that he had been admitted in the Kenyatta National Hospital for over 1 month duration, and was still an inpatient by the time of the study. Therefore a total of 87 patients undergoing chronic haemodialysis at the Renal Unit at Kenyatta National Hospital were studied. All the patients were black Africans, 51 (59%) were male, with a male: female ratio of 1 : 0.7. Ages ranged from 18 years to 79 years, with a median age of 43 years, and a mean of 44.4 years (SD + 15.57) ; 62% of patients were aged 50 years or below. With regard to employment status, 62% were unemployed, 23% of the patients were in formal employment, 9% were retired whilst 6% were students (in Secondary Schools or Universities. All the study subjects were residents of Nairobi County and its environs. The mode of transport utilised to access their dialysis sessions was 83% Public transport, 10% personal vehicles and 7 % taxi service. Escorts accompanying patients to the dialysis centre included immediate relatives in 48% while 52% were unaccompanied. All the patients had active NHIF membership that was catering for the entire cost of their twice weekly dialysis sessions.

Prevalent comorbidities amongst study subjects included Hypertension in 97% , Diabetes Mellitus in 26%, polycystic kidney disease in 1.14% (one patient) whilst 24.13% had both Diabetes Mellitus and Hypertension.

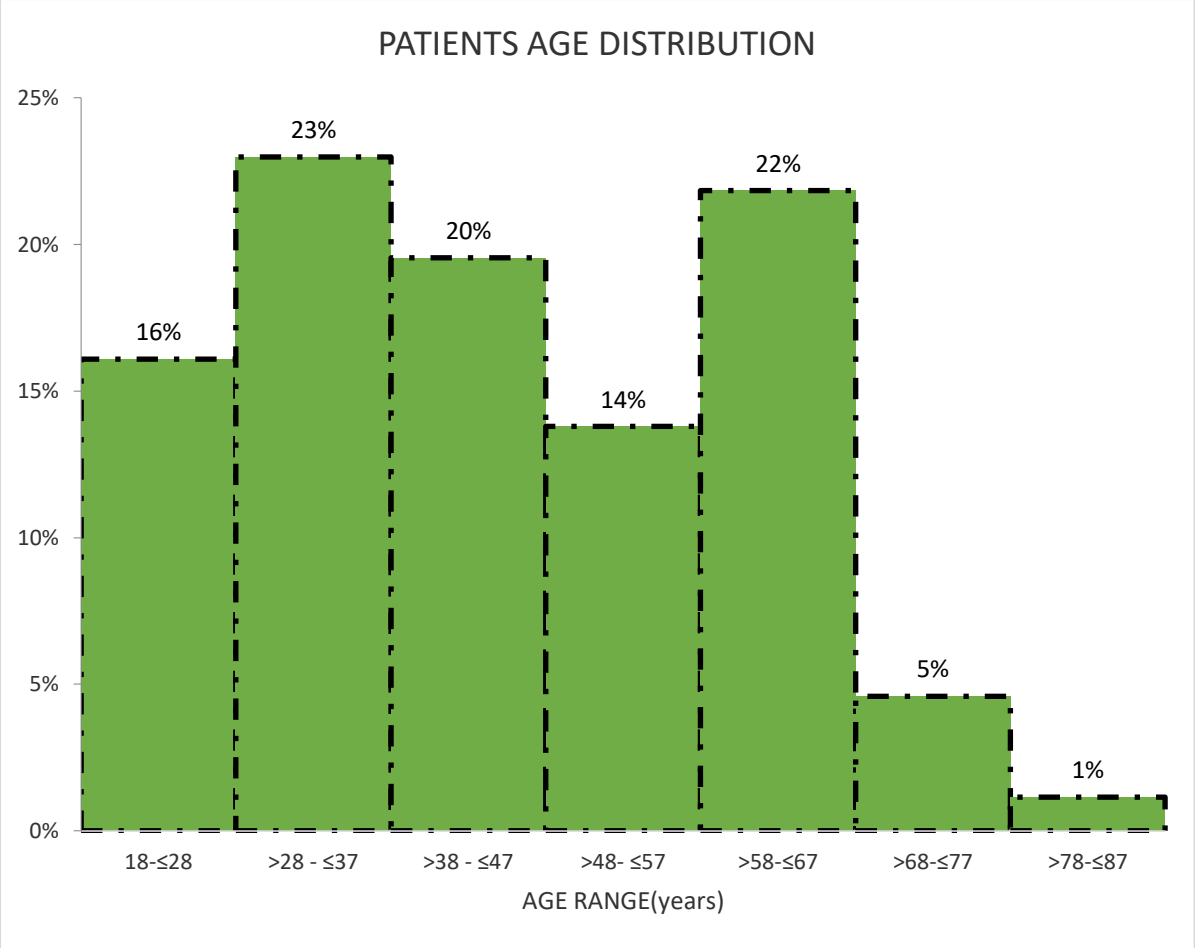

Figure 1: Age Distribution of patients with ESRD attending chronic haemodialysis at KNH Renal Unit.

4.2 Overall Adherence to ESRD Care Scores

Patients overall adherence scores to their ESRD care, were categorically grouped into Good, Moderate or Poor according to the numerical score obtained from their responses in the ESRD-AQ. Good adherence included scores of between 1000-1200, moderate included 700-999 and poor was any score less than 700. The overall adherence to ESRD Care was good in 48% (95% CI 38-59) of patients, with scores of between 1000-1200. The remaining 52% had suboptimal adherence; with 43% (95% CI 33-53) categorised as having Moderate adherence to ESRD care (scores of between 700-999) , and 9 % (95% CI 5-17) categorised as Poor adherence to ESRD care (scores of less than 700).

4.3 Adherence to Haemodialysis Schedules

Adherence to the twice weekly scheduled haemodialysis sessions, which is the standard of practice in the KNH Renal Unit, was assessed, with adherence requiring 100% attendance. There were 61 patients, representing 70%, (95% CI 60-79) who were adherent to these haemodialysis sessions. A total of 26 patients were non adherent to their twice weekly haemodialysis sessions, representing 30% (95%CI 21-40).

A twice weekly haemodialysis schedule provides for a total of 8 possible haemodialysis sessions per month. Patients who were non-adherent to their haemodialysis schedules missed 1 or more of the total 8 sessions in the previous month. The magnitude of non-adherence was identified, such that, out of the 26 non-adherent patients, 16 (61.5%) patients missed a single session in the previous month; 7 (27%) patients missed 2 haemodialysis sessions, whilst 3(11.5%) patients missed a total of 3 haemodialysis sessions in the month preceding the study.

4.4 Adherence to Medications

Adherence to medications amongst these patients with ESRD was assessed on the basis of their responses to questions on medication adherence in the ESRD-AQ. The ESRD-AQ tool does not assess for adherence to these individual pharmacologic drug categories, rather it assesses adherence to ESRD medications as a whole. A total of 72(83%; 95%CI 73-89) patients reported adherence to their medications, whilst only 15 (17%,;95% CI 11-27)were non adherent.

4.5 Adherence to Fluid Restrictions

The assessment of adherence to Fluid restrictions revealed 59(68% ; 95% CI 57-78) patients were adherent, whilst 28(32%; 95% C.I 23-43) patients were not adherent to their fluid restriction recommendation.

4.6 Adherence to Dietary Restrictions

A total of 61(70%; 95% CI 60-79) patients were adherent to their dietary restrictions, while 26 (30%; 95%C.I 21-40) patients were found to be non-adherent to these dietary restrictions.

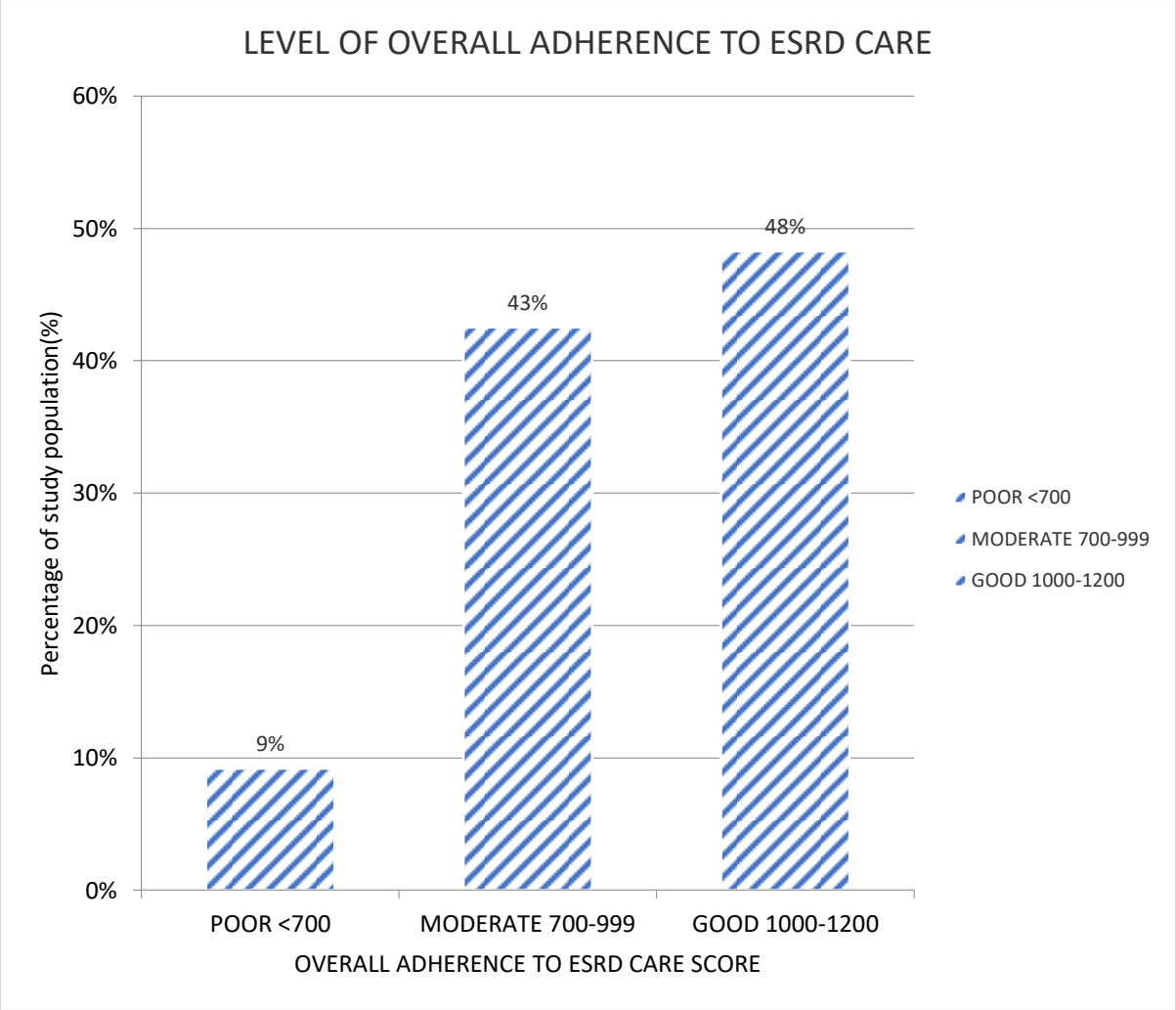

Figure 2 : Level of overall adherence to ESRD care amongst patients with ESRD on chronic haemodialysis at the KNH Renal Unit.

4.7 Serum Potassium (K+)

The serum potassium levels over the month prior to the study, were obtained from the information in the individual patients Haemodialysis flow sheet. The mean serum potassium was 4.84mmol/L,(SD 0.74) and the range was from 3.5mmol/L - 6.5mmol/L. The median potassium was 4.8mmol/L. A total of 54 (62%) patients had normal serum potassium, within the range of 3.5-5.0mmol/L, whilst 25(29%) patients had mild hyperkalaemia (serum potassium 5.1-6.0mmol/L) and 8(9%) patients had a moderate hyperkalaemia (serum potassium 6.1-6.5mmol/L). No patient had severe hyperkalaemia (serum potassium>6.5mmol/L), neither was any patient hypokalaemic (serum potassium < 3.5mmol/L).

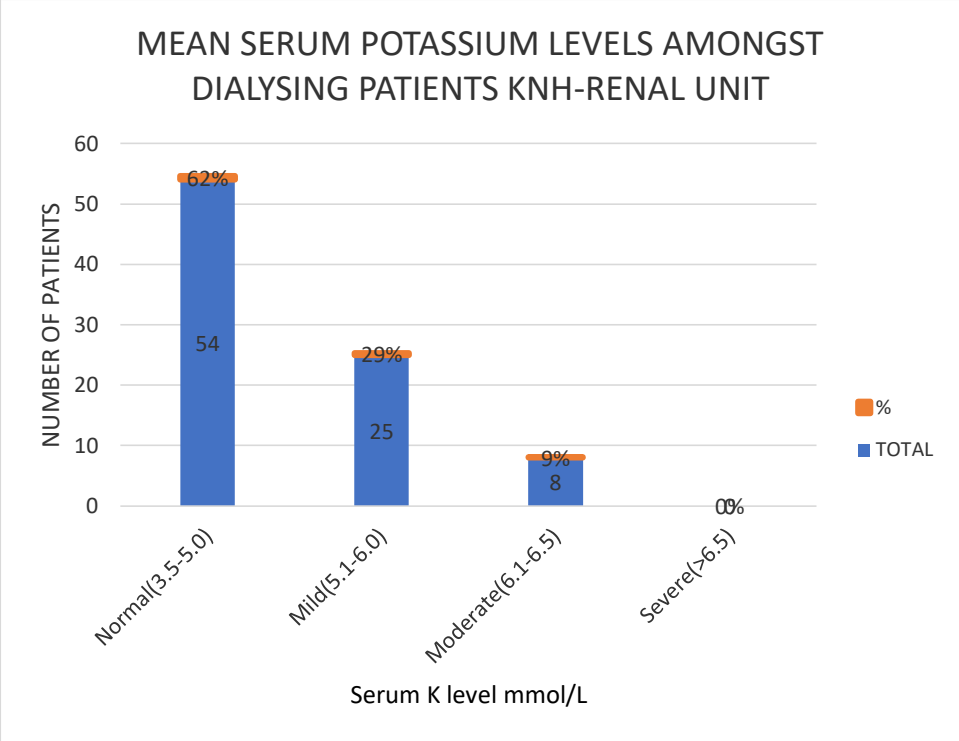

Figure 3: Mean serum potassium level(mmol/L) amongst patients with ESRD on chronic haemodialysis at the KNH Renal Unit.

4.8 Interdialytic Weight Gain

The mean Interdialytic weight gain (IDWG) was calculated for each individual patient, utilising their Haemodialysis Flow sheet data. The IDWG was derived by subtracting the post dialysis weight,(from their last haemodialysis session) from the pre dialysis weight. Without universally acceptable guidelines and cut offs for IDWG, most dialysis units formulate their own acceptable ranges. At KNH Renal Unit, a 3kg upper limit for IDWG was deemed acceptable, based on an approximation of 1kg/day increase in bodyweight, and considering maximum target ultrafiltration of 10-13ml/kg per session. Our study found that the IDWG ranged from 0.75kg to 4.13kg, with a mean IDWG of 2.51kg (SD 0.76, 95% C.I 2.35-2.67), and median of 2.6kg; 26 (30%) patients had an IDWG of more than 3kg.

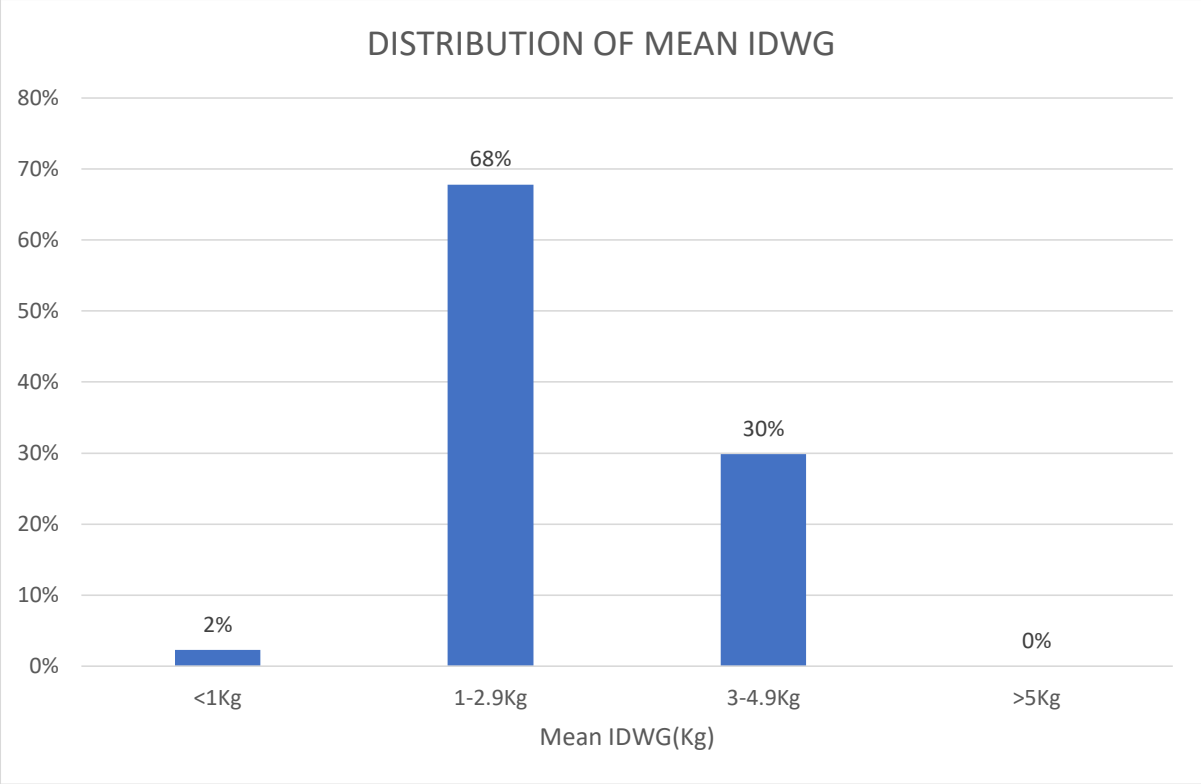

Figure 4: The Mean IDWG amongst patients with ESRD on chronic haemodialysis at the KNH Renal Unit.

4.9 Association between Adherence to Dietary Restrictions & Mean Serum Potassium Level

In evaluating the association between adherence to dietary restrictions and mean serum potassium level, our study found that, amongst patients who were adherent, the mean serum potassium was 4.84mmol/L(SD 0.7), whilst amongst those who were non-adherent the mean serum potassium was 4.85mmol/L(SD 0.8).The difference between the means was therefore 0.01mmol/L(0.3-0.4) and p value of 0.955.A statistically significant association between adherence to dietary restrictions and mean serum potassium level therefore did not exist.

We further investigated, as a subgroup analysis, that amongst those 61 patients who were adherent to dietary restrictions, 43 were also adherent to haemodialysis, whilst 18 were non-adherent. The mean serum potassium were noted to be 4.80mmol/l (SD 0.76) amongst those adherent to both dietary restrictions and haemodialysis, whilst the mean serum potassium was 4.93mmol/L (SD 0.63) amongst those adherent to dietary restrictions but not adherent to haemodialysis. The difference between the means was 0.13mmol/L and p value 0.53.

Table 4:Mean serum potassium and adherence to dietary restrictions amongst ESRD patients undergoing chronic haemodialysis at the KNH Renal unit.

Adherence to dietary restrictions	Number of patients	Mean serum Potassium (mmol/L)	Standard Deviation
Adherent	61	4.84	0.7
Non-adherent	26	4.85	0.8
p VALUE		0.955	

Table 5 : Mean serum potassium amongst patients adherent to both haemodialysis and dietary restrictions

Adherence to both Haemodialysis & Dietary restrictions	Number of patients	Mean Serum Potassium(mmol/L)	Standard Deviation	p value
Adherent	43	4.8	0.76	
Non-adherent	18	4.93	0.63	
				0.53

4.10 Association between Adherence to Fluid Restrictions and Mean Interdialytic Weight Gain

The mean IDWG amongst patients adherent to fluid restrictions was compared to the mean IDWG amongst those that were non-adherent to fluid restrictions. Amongst the patients who were adherent to fluid restrictions, the mean IDWG was 2.37kg(SD0.8), while amongst those who were non-adherent, the mean IDWG was 2.81kg(SD 0.6).The difference in the means was 0.44kg with a p value of 0.005. Therefore this meant that the IDWG was significantly higher amongst the patients who were non-adherent to their fluid restrictions as compared to those who were adherent to fluid restrictions.

Table 6 : Association between adherence to fluid restrictions and Mean IDWG amongst ESRD patients undergoing chronic haemodialysis at the KNH Renal unit

Adherence to fluid restrictions	N	Mean IDWG(Kg)	Standard Deviation
Adherent	59	2.37	0.8
Non-adherent	28	2.81	0.6
p VALUE		0.005	

5.0 CHAPTER FIVE: DISCUSSION, IMPLICATIONS, CONCLUSION & RECOMMENDATIONS

5.1 Discussion

This study primarily set out to determine the level of adherence to ESRD care, amongst ESRD patients undergoing chronic haemodialysis at the KNH Renal Unit, by utilising the validated ESRD-AQ tool. The ESRD care incorporates the prescribed twice weekly haemodialysis sessions, medications, as well as dietary and fluid restrictions that patients are expected to adhere to. In relation to the primary objective, to determine the overall adherence score, amongst our patients, to their ESRD care, our study revealed a very important finding that, only 48% of the ESRD patients undergoing haemodialysis at the KNH Renal Unit had good overall adherence to ESRD care. The remainder 52% who had suboptimum levels of adherence were further categorised; and 43% had moderate adherence, while 9% had poor adherence to ESRD care.

In 2017, Karam et al conducted a study similar to ours in Palestine, utilising the same ESRD-AQ instrument, and similar methodology, and found that amongst their ESRD adult patients, 55.5% had good adherence. This is comparatively higher than our level of good adherence. Palestine, being a developing nation, ravaged by war and with limitations to their infrastructure, reports greater adherence to ESRD care as compared to our results. Another study by Couvert et al (55) conducted across 7 study centres in the United States and involving 3939 ESRD patients from 2003-2008, found that 68% patients had good adherence, 17% moderate adherence and 15% poor adherence.

The tool however utilised was not the ESRD-AQ that our study utilised. However, this emphasises the fact that suboptimal adherence to ESRD care is not limited to only developing countries. Our study revealed 9% of the ESRD population studied have poor adherence to ESRD care, and this would indicate that almost 1 in 10 patients that are dialysed at the KNH-Renal Unit are not adhering to any of the 4 components of ESRD care. In order for a patient to have been categorised as having poor adherence to ESRD care, they would have to have been non-adherent to all of the four components of ESRD care, namely to haemodialysis, to medications, to fluid restrictions as well as dietary restrictions. Since the ESRD care plan is implemented by a multidisciplinary team of nephrologists, nurses, dieticians and nutritionists, if patients are non-adherent to even a single component of ESRD care, it reflects the need for each of the team members to address and investigate further what barriers are impeding

adherence to ESRD care, and what can then be changed in order to achieve optimum adherence.

We further determined the proportional individual contribution of the 4 components of ESRD care to non-adherence. The first component of the ESRDAQ was adherence to haemodialysis sessions. We found that 70% of patients were adherent to their recommended twice weekly haemodialysis sessions. In Brazil in 2016, Nakao et al, (59) noted adherence to haemodialysis to be at 54%, however the methodology involved in this study utilised clinical parameters like serum phosphate and IDWG as well as attendance records to determine adherence. In the state of Chenai in India, in 2019, Suganthi et al (60) utilised the same study instrument as our study, the ESRDAQ, and found that amongst their population, adherence to haemodialysis sessions was 83.3%.In Rwanda in 2018, Mukaranga et al (53) found 51% of their patients had good adherence to haemodialysis and the ESRDAQ tool was utilised as the study instrument. These results show that there are large variations in adherence to haemodialysis amongst ESRD patients, regardless of geographic location.

The current hospital policy at the Renal Unit of KNH involves a twice weekly haemodialysis for a four hour duration. The cost of the haemodialysis session, including cost of the dialysate fluids, blood lines, and haemodialysis catheters, is fully catered for by the Health Insurance program in Kenya called the National Health Insurance Fund (NHIF). Additional haemodialysis sessions, for patients who require more frequent haemodialysis, are then only performed at an additional direct cost to the patient. All patients in our study, were on the twice weekly haemodialysis program. Different countries around the world implement different frequency of dialysis schedules, however our twice weekly schedule is based primarily on finances required to cover the costs of dialysis, amongst a population that would ordinarily be unable to fund the sessions themselves.

Each session is worth 9500 kenyan shillings and therefore produces a large burden on the NHIF as an insurer, and would not be affordable or sustainable to an average Kenyan if they were not under the NHIF cover. Considering that 77% of the ESRD patients we studied were unemployed, had they not been insured by NHIF, they would probably be unable to sustain these costs independently, and adherence to haemodialysis sessions may have been lower than the 70% that our study found. The NHIF spent 1.76billion Kenyan shillings in the year 2017/2018 catering for dialysis expenses alone, and at any given point if almost one in three patients is not adhering to their haemodialysis schedules as catered for, then this leads to wastage of allocated large sums of public funds. This is because allocation of funds toward Haemodialysis in subsequent financial years depends on the usage and uptake in the

preceding year; thus as patients do not turn up for their haemodialysis, the allocated money is thus not utilised and therefore a false assumption is made of a lower than necessary budgetary allotment for this essential treatment modality. Apart from financial burden of non-adherence, the most important implication of non-adherence to haemodialysis schedules is the increased morbidity and mortality associated with it. Chan et al(3) in the their study conducted in the United States, from 2009-2013 found that, over the 5-year study period, the risk of hospitalization (OR, 3.98; 95% CI 3.93 to 4.04), or ICU admission (OR, 3.89; 95% CI, 3.81 to 3.96) increased significantly after a single missed haemodialysis session. The study further noted that ICU admissions were due to pulmonary oedema necessitating ventilatory support as well as electrolyte imbalance induced arrhythmias, especially hyperkalemia.

With such detrimental effects of missing haemodialysis sessions, it would be of utmost importance to determine methods that can be implemented to improve adherence amongst the 30% of patients, who our study has shown, are non-adherent to their haemodialysis sessions at the KNH Renal Unit. Furthermore, the 30% who are non-adherent to haemodialysis may actually be an underrepresentation of the magnitude of non-adherence. This is because our study is based on a twice weekly haemodialysis schedule, however a thrice weekly schedule may be even more cumbersome for patients to adhere to, and therefore our 30% may be an underestimate of the probable reality. Our study also found that amongst the 30% of patients who were non-adherent to haemodialysis, 38.5% had actually missed 2 or more haemodialysis sessions completely, out of the possible 8 sessions a month. The more sessions a patient misses, the longer their interdialytic interval would be. The longer the interdialytic interval, the higher the mortality risks. This was confirmed by the Dialysis Outcomes and Practice Patterns Study (DOPPS) on patients on haemodialysis, which found that missed treatments were positively associated with all-cause mortality. It was noted in the European cohort, that when 1 or more haemodialysis sessions were missed in the 4 month period, then it was associated with increased risk of death of 16.3deaths/ 100 patient years, of hospitalisation and poorer patient associated outcomes.(48) This study emphasises the risks associated with missing only a single haemodialysis session in a four month period, yet our study has revealed that 38.5% of the non-adherent patients, actually missed more than 2 haemodialysis sessions in a month.

Other studies done in Africa, for example, in Rwanda, it was found that 61% of patients were adherent to their haemodialysis schedules, however the study utilised a mix of twice, thrice and even four times a week haemodiaysis schedules when assessing adherence. In

Saudia Arabia, in 2014, Al khattabi et al (61) reported adherence to haemodialysis sessions at 55.9%, while in 2017 in Palestine Naalweh et al (55), reported adherence to haemodialysis sessions was 52%.These studies all utilised the ESRDAQ as a tool to assess adherence to ESRD care, however the haemodialysis schedules varied from twice to thrice or rarely four times a week haemodialysis. We utilised the KNH Renal Unit/ NHIF protocol (of 2 haemodialysis sessions per week) as a basis to conclude that 70% of our patients are adherent to haemodialysis schedules. This may not be reflective of the situation if we were actually using the global recommendations of thrice weekly haemodialysis. Our study may therefore be an underestimate of the actual non-adherence to haemodialysis.

The second component investigated was adherence to medications. Patients with End Stage Renal Disease are at risk of several complications as a result of their kidney disease. These complications include Bone Mineral Disease, anaemia, hypertension, altered glycemic control, as well as the CKD being an independent risk factor for cardiovascular disease. Therefore these patients are prescribed a variety of medications to control and modulate the risk of such complications. Our study found that 83% (95%C.I 73-89) of patients were adherent to their medications. In Palestine, in 2017, Naalweh et al (55) reported adherence to medication was 81%, whilst in 2014,in Saudia Arabia, Al-Khattabi et al (56) reported amongst their ESRD population adherence to medication stood at 88%. Both these studies utilised the ESRDAQ tool to assess adherence to medication amongst ESRD patients. In Chicago, Couvert et al (58) in 2017, found that amongst their ESRD population, 68% had good adherence to medications, utilising a self-reported, but unvalidated, questionnaire. This confirms that amongst the studies that have utilised the ESRDAQ tool to assess adherence, the adherence to medications amongst the ESRD population, regardless of region, is good.

The third component addressed was adherence to fluid restrictions. Our study found that 32% of patients were non-adherent to restrictions on their daily fluid consumption. The implications of excessive fluid consumption in patients who are anuric or oliguric include immediate life threatening complications of a fluid overloaded state such as Pulmonary Oedema. Therefore a 32% non-adherence to fluid restrictions has a significant impact and should stand out as an alarming figure. In Saudia Arabia Al-Khattabi et al reported an adherence to fluid restrictions of 87.78% which is higher than our proportion.

The fourth component assessed was adherence to dietary restrictions. Patients with ESRD are often advised to limit their potassium and phosphate containing foods and are therefore given their own dietary plans charted by specialised Renal Nutritionists. Our study found that 30% of the patients were non-adherent to their dietary recommendations. Beerendrakumar et al.,

(39) in India, in 2018 reported a 69% non-adherence amongst their ESRD population to dietary restrictions. Direct comparisons cannot be made, since methodology used in studies varies, however we can conclude that non-adherence does remain a problem amongst ESRD patients that is not limited to only a specific region.

Our secondary objective was to determine if there was an association between adherences to fluid restrictions and mean IDWG. Our study found IDWG was significantly higher amongst the patients who were non-adherent to their fluid restrictions as compared to those who were adherent to fluid restrictions. Furthermore, we found that 30% of the ESRD patients had an IDWG of above 3Kg. In patients with ESRD an excessive IDWG implies the patient is being maintained in a hypervolemic state, and this could cause hemodynamic instability if a rapid Ultra Filtration is performed at their next haemodialysis session. This has the dangers of leading to uncontrolled and fluctuating intradialytic blood pressures as well as the risk of hemodynamic collapse and mortality. IDWG is however often confounded by variables such as salt intake and sodium in the dialysate bath that can spuriously elevate the IDWG. Patients therefore may have higher IDWG than expected, due to a noncompliance to sodium restriction as opposed to being solely due to non-adherence to fluid restrictions. Furthermore, the target ultrafiltration in each dialysis session generally doesn't exceed 10-13ml/kg. Therefore a maximum total of 3.5-4Litres can be ultrafiltrated in a 70kg man in a single dialysis session. The fluid gained above this threshold cannot be ultrafiltrated and it is a risk for increased morbidity. When an increment of 1kg per day is allowed, considering a thrice weekly schedule with shorter interdialytic intervals, the IDWG would be expected to be lower in comparison to our twice weekly haemodialysis sessions with longer interdialytic intervals. An IDWG therefore above 3Kg is not recommended. This should be highlighted for interventions to be sought to lower the IDWG or shorten the interdialytic interval.

Our final secondary objective was to determine if there was an association between adherence to diet and mean serum potassium levels. Our study did not find a statistically significant association between non-adherence to dietary restrictions and mean serum potassium levels. This finding could be explained by the various confounders to serum potassium level, including use of medications(such as ACE-inhibitor/ARB, loop diuretics, beta blockers, digitalis, insulin etc), exercise, red cell transfusion intradialysis, to name a few. Furthermore, the potassium used in the dialysate bath during the previous dialysis could also contribute to the potassium level. These multiple confounders were not controlled for in our study. This may explain why we found no positive association between adherence to dietary restrictions and mean serum potassium levels. In Palestine Naalweh et al., utilised the same

ESRD-AQ study instrument as our study did, and they reported a significant correlation between adherence to fluid restriction and mean IDWG, as well as a significant correlation between adherence to dietary restrictions and mean serum potassium levels, which our study did not.

5.2 Implications

Our study has provided crucial information as to whether or not patients on ESRD care are adhering to the 4 core aspects of their management. With an overall 52% of patients with suboptimum level of adherence to ESRD care, it implies that, overall our population still has to be studied and reasons for non-adherence explored. Approximately 2billion Kenyan shillings and resources are injected into the Kenyan dialysis program annually, therefore, justifiably patients should benefit from each and every hemodialysis session that is being catered for them. Any degree of non-adherence should not be accepted, and therefore, gaps need to be identified as to where improvements can be made to increase adherence. With regard to adherence to haemodialysis sessions specifically, 30% of patients are not adhering to their twice weekly sessions, this implies far reaching consequences. Firstly, by scheduling only two haemodialysis sessions per week, already this is below the thrice weekly KDOQI recommendations, and therefore patients are already being subjected to a longer interdialytic interval. If patients further are not adhering, even to a twice weekly schedule, then their interdialytic intervals are even longer, and thus putting them at increased risk of all-cause mortality (62). Secondly, only 68% of our ESRD patients were adherent to their fluid restrictions while,30% had high IDWGs above 3Kg.This implies the patients are constantly in a hypervolemic state, and apart from risks of predialysis hypertension, uncontrolled intradialytic blood pressures, pulmonary oedema and even death, there are also the risks of hemodynamic instability in subsequent haemodialysis sessions when ultrafiltration is being performed.

5.3 Conclusion

Our study showed that overall adherence to the 4 components of ESRD care amongst ESRD patients undergoing haemodialysis at KNH Renal Unit are suboptimum, with 52% of patients having overall Moderate or Poor adherence. Amongst the 4 parameters contributing to ESRD care, adherence to fluid restrictions was poorest, followed by adherence to haemodialysis. Our study also found that IDWG was significantly higher amongst patients who were non-

adherent to fluid restrictions. However serum potassium levels were not significantly higher amongst patients who were non-adherent to their dietary restrictions.

5.4 Limitations

Our study has a limitation of recall bias with regard to answering questions in the ESRD-AQ. Questions in the questionnaire referred to events in the one month prior to administration of the questionnaire. Therefore patients may not clearly recall and may concoct as a result or approximate their responses. Patients also maybe mentally affected by their chronic condition and ill health and may therefore have recall bias. This bias can either exaggerate or underestimate an event, and it would be difficult to control for such. Secondly our study is a single centre study, based in Nairobi in the largest tertiary referral Hospital in East Africa, and the adherence proportion maybe an under or overestimate of the National figure, so we may be unable to generalise our findings. Private dialysis units or smaller public hospitals may have different levels of adherence to ESRD care.

5.5 Recommendations

Further studies need to be conducted to determine causes of non-adherence to ESRD care and procedures implemented to overcome the barriers to adherence. Attempts should be made to convince the NHIF to fully cater for a thrice weekly haemodialysis schedule, in order to reduce interdialytic intervals and reduce the large IDWG and fluid overloaded state that our patients are being exposed to. A multidisciplinary team approach needs to be implemented to educate patients on importance of adherence to ESRD care and the consequences of non-adherence

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APPENDICES

Appendix I: 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 OBSEVATION	LAB RESULTS
ADDITIONAL ORDERS LABORATORY REQUESTS	
ADDITIONAL ORDERS	
COMMENTS	

Appendix II: ESRD-AQ

I. General Information

1. When did you begin or restart your hemodialysis treatment?

Date:

2. Have you ever had chronic peritoneal dialysis treatment? No (1) Yes (2) (Please answer below)I had peritoneal dialysis from …….(date)

3. Have you had a kidney transplant? No (1) Yes (2) (Please answer below)

4.What type of transportation do you use to go to the dialysis center?□Personal transportation(1)□Bus(2)□Taxi(3)□Medical transportation van(4)□Other (Specify)(5): _____

5.Who accompanies you to the dialysis center?□Myself(1)□Parent(2)□Spouse (Husband or wife)(3)□Child(4)□Friend(5)□Other (Specify the person)(6): _____

II. Hemodialysis Treatment

6.How many days a week do you receive hemodialysis treatment?□2 days or less(1)□3 days(2)□4 days(3)□More than 4 days(4)□More than 5 days(5)

7.How many hours are you treated for each hemodialysis?□Less than 3 hours(1)□3 hours(2)□3 hours and 15 minutes(3)□3 hours and 30 minutes(4)□3 hours and 45 minutes(5)□4 hours(6)□More than 4 hours(7)□Other (Specify the hours)(8): _____

8. Is your dialysis schedule convenient for you? (Please choose one best answer that applies to you.)□Yes$_{(1)}$□No, because I have to come to the dialysis center too early$_{(2)}$□No, because I have to come to the dialysis center too late$_{(3)}$□No, because of my work schedule$_{(4)}$□No, because it is my meal time and I get hungry during dialysis treatment$_{(5)}$□No, because it is my medication time and I have to take medicines/insulin$_{(6)}$□No, because of (Other)$_{(7)}$: _____

9.When was the last time a medical professional (your doctor, nurse, dietician, or other medical staff) talked to you about the importance of not missing your dialysis treatment?□This week$_{(1)}$□Last week$_{(2)}$□One month ago$_{(3)}$□More than a month ago$_{(4)}$□When I first began dialysis treatment$_{(5)}$□Never$_{(6)}$□Other (Specify)$_{(7)}$: _____

10.How often does a medical professional (your doctor, nurse, dietician, or other medical staff) talk to you about the importance of staying for the entire dialysis time during your dialysis treatment?□Every dialysis treatment$_{(1)}$□Every week$_{(2)}$□Every month$_{(3)}$□Every 2 to 3 months$_{(4)}$□Every 4 to 6 months$_{(5)}$□When I have abnormal blood or other test results$_{(6)}$□Rarely$_{(7)}$□Irregularly$_{(8)}$□Never$_{(9)}$□Other (Specify)$_{(10)}$: _____

11.How important do you think it is to follow your dialysis schedule?□Highly important$_{(1)}$□Very important$_{(2)}$□Moderately important$_{(3)}$□A little important$_{(4)}$□Not important$_{(5)}$

---

12. Why do you think it is important to follow your dialysis schedule? (Please choose one best answer that applies to you.)□Because I fully understand that my kidney condition requires dialysis as scheduled$_{(1)}$□Because following the dialysis schedule is important to keep my body healthy$_{(2)}$□Because medical professional (my doctor, nurse, or dietitian) told me to do so$_{(3)}$□Because I had an experience that I was sick after I missed dialysis$_{(4)}$□Because I had an experience that I was hospitalized after I missed dialysis$_{(5)}$□I don't think following the dialysis schedule is very important to me$_{(6)}$□Other (Specify)$_{(7)}$: _____

13.How much difficulty have you had staying for your entire dialysis treatment as ordered by your doctor?□No difficulty$_{(1)}$□A little difficulty$_{(2)}$□Moderate difficulty$_{(3)}$□A lot of difficulty$_{(4)}$□Extreme difficulty$_{(5)}$

14.During the *last month,* how many dialysis treatments did you miss completely?□None (I did not miss any treatments)$_{(1)}$□Missed one dialysis treatment$_{(2)}$□Missed two dialysis treatments$_{(3)}$□Missed three dialysis treatments$_{(4)}$□Missed four or more dialysis treatments$_{(5)}$

15.What was the main reason you missed your dialysis treatment *last month*?□Not applicable: I did not miss any treatment$_{(1)}$□Transportation problems$_{(2)}$□I had other things to do (Please explain)$_{(3)}$:□Hemodialysis access (graft, fistula, or catheter) clotted$_{(4)}$□Physician (medical or surgical) appointment$_{(5)}$□I had to go to the emergency room$_{(6)}$□I was hospitalized$_{(7)}$□Forgot$_{(8)}$□"Didn't want to go" or "Couldn't go" *(Go to the next question: Question #16)*$_{(9)}$□Other (Please specify)$_{(10)}$: _____

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16. (Answer this question when you marked the above question as *"Didn't want to go Couldn't go."*)
Why didn't you want to go to the dialysis center? (Please choose one best answer that applies to you)□Because dialysis treatment makes me anxious$_{(1)}$□Because I had vomiting/diarrhea$_{(2)}$□Because I had cramping$_{(3)}$□Because I often get hungry during dialysis treatment$_{(4)}$□Because I was physically uncomfortable (Specify the condition)$_{(5)}$□Because I was sick due to other conditions (Specify the conditions)$_{(6)}$□Because I was emotionally depressed$_{(7)}$□Other$_{(8)}$: _____

17.During the *last month*, ***how many times*** have you ***shortened*** your dialysis time?□Not applicable: I have not shortened my dialysis time$_{(1)}$□Once$_{(2)}$□Twice$_{(3)}$□Three times$_{(4)}$□Four to five times$_{(5)}$□Other (Specify frequency)$_{(6)}$: _____

18.During the *last month*, when your dialysis treatment was shortened, what was the ***average number of minutes?***□Not applicable: I have not shortened my dialysis time$_{(1)}$□Less than 10 minutes or 10 minutes$_{(2)}$□11 to 20 minutes$_{(3)}$□21 to 30 minutes$_{(4)}$□More than 31 minutes$_{(5)}$□Other (Specify)$_{(6)}$
(If you need to write two or more different time because you shortened dialysis more than once, please use this space): _____

19.What was the main reason you have shortened your dialysis treatment?□Not applicable: I have not shortened my dialysis time$_{(1)}$□Cramping$_{(2)}$□Bathroom use$_{(3)}$□Restlessness$_{(4)}$□Low blood pressure$_{(5)}$□Access (graft, fistula, or catheter) clotted$_{(6)}$□Physician (medical or surgical)

appointment(7)□Personal business or emergency(8)□Work schedule(9)□Transportation problems(10)□Staff decision (**Why? Please explain:** For example, poor blood flow, clotting dialyzer, machine malfunction, etc.)(11): _____□Did not feel like staying (12)□Other (Please specify)(13): _____

III. Medication

20.When was the last time a medical professional (your doctor, nurse, dietician or other medical staff) spoke to you about your medicines?□This week(1)□Last week(2)□One month ago(3)□More than a month ago(4)□When I first began dialysis treatment(5)□Never(6)□Other (Specify)(7): _____

21.How often does a medical professional (your doctor, nurse, dietician or other medical staff) talk to you about the importance of taking medicines as ordered?□Every dialysis treatment(1)□Every week(2)□Every month(3)□Every 2 to 3 months(4)□Every 4 to 6 months(5)□When I have abnormal blood or other (for example, blood pressure) test results(6)□Rarely(7)□Irregularly(8)□Never(9)□Other (Specify)(10): _____

22.How important do you think it is to take your medicines as scheduled?□Highly important(1)□Very important(2)□Moderately important(3)□A little important(4)□Not important(5)

---

23. Why do you think it is important to take your medicines as scheduled? (Please choose one best answer that applies to you.)□Because I fully understand that my kidney condition requires to take medicines as scheduled(1)□Because taking medicines is important to keep my body healthy(2)□Because a medical professional (my doctor, nurse, dietician, or other medical staff) told me to do so(3)□Because I had an experience that I was sick after I missed medicines(4)□Because I had an experience that I was hospitalized after I missed medicines(5)□I don't think taking medicines is very important to me(6)□Other (Specify)(7): _____

---

24. Have you had any difficulty with taking your medicines? □No (1) □Yes (2)

25.How much difficulty have you had with taking your prescribed medicines?□No difficulty$_{(1)}$□A little difficulty$_{(2)}$□Moderate difficulty$_{(3)}$□A lot of difficulty$_{(4)}$□Extreme difficulty$_{(5)}$

26.During the *past week*, ***how often*** have you missed your prescribed medicines?□None of the time: I did not miss my medicines$_{(1)}$□Very seldom$_{(2)}$□About half of the time$_{(3)}$□Most of the time$_{(4)}$□All of the time$_{(5)}$

27.What was the main reason for not taking your prescribed medicines this *past week*?□Not applicable: I did not miss medicines$_{(1)}$□Forgot to take medicines$_{(2)}$□Forgot to order medicines$_{(3)}$□Medicine cost$_{(4)}$□Inconvenience$_{(5)}$□I was hospitalized$_{(6)}$□Side effects$_{(7)}$ *(Go to question #28)*□Other$_{(8)}$: _____

---

28. (Answer this question when you have marked the above question as *"Side effects."*) What kind of side effect(s) to the medication(s) did you have? (Please choose one best answer that applies to you.)□Loss of appetite$_{(1)}$□Nausea/vomiting/diarrhea/constipation$_{(2)}$□Stomach pain$_{(3)}$□Dizziness$_{(4)}$□Headache$_{(5)}$□Itching/skin problems$_{(6)}$□Other (Specify symptoms)$_{(7)}$: _____

IV. Fluid

29.When was the last time a medical professional (your doctor, nurse or dietician or other medical staff) spoke to you about your fluid restrictions?□This week$_{(1)}$□Last week$_{(2)}$□One month ago$_{(3)}$□More than a month ago$_{(4)}$□When I began dialysis treatment$_{(5)}$□Never$_{(6)}$□Other (Specify)$_{(7)}$: _____

30.How often does a medical professional (your doctor, nurse, dietician or other medical staff) talk to you about the importance of fluid restriction?□Every dialysis treatment$_{(1)}$□Every week$_{(2)}$□Every month$_{(3)}$□Every 2 to 3 months$_{(4)}$□Every 4 to 6 months$_{(5)}$□When I have abnormal blood or other (for example, blood pressure) test results$_{(6)}$□Rarely$_{(7)}$□Irregularly$_{(8)}$□Never$_{(9)}$□Other (Specify)$_{(10)}$: _____

31.During the *past week*, how often have you followed the ***fluid restriction*** recommendations?□All of the time$_{(1)}$□Most of the time$_{(2)}$□About half of the time$_{(3)}$□Very seldom$_{(4)}$□None of the time$_{(5)}$

32.How important do you think it is to limit your fluid intake?□Highly important$_{(1)}$□Very important$_{(2)}$□Moderately important$_{(3)}$□A little important$_{(4)}$□Not important$_{(5)}$

---

33. Why do you think it is important for you to limit your fluid intake? (Please choose one best answer that applies to you.)□Because I fully understand that my kidney condition requires limiting fluid intake$_{(1)}$□Because limiting fluid intake is important to keep my body healthy$_{(2)}$□Because a medical professional (my doctor, nurse, dietician, or other medical staff) told me to do so$_{(3)}$□Because I got sick after I drank lots of fluid$_{(4)}$□Because I was hospitalized after I drank lots of fluid$_{(5)}$□I don't think limiting fluid is very important to me$_{(6)}$□Other (Specify)$_{(7)}$: _____

---

34. Have you had any difficulty with limiting your fluid intake? □No $_{(1)}$ □Yes $_{(2)}$

35.How much difficulty have you had following your fluid restriction recommendations?□No difficulty$_{(1)}$□A little difficulty$_{(2)}$□Moderate difficulty$_{(3)}$□A lot of difficulty$_{(4)}$□I was unable to follow any recommendations at all$_{(5)}$

36.If you had difficulty following your fluid restriction recommendations, ***what type of difficulty*** have you had?□No difficulty$_{(1)}$□Not interested$_{(2)}$□I was unable to control fluid intake$_{(3)}$□I don't understand how to follow the fluid restriction$_{(4)}$□Other$_{(5)}$: _____

37.During the past week, how many times have you weighed yourself ***at home*** (outside dialysis center)?□More than 3 times$_{(1)}$□3 times$_{(2)}$□Twice$_{(3)}$□Once$_{(4)}$□None of the time$_{(5)}$□Other$_{(6)}$: _____

38.How important do you think it is to weigh yourself daily?□Highly important$_{(1)}$□Very important$_{(2)}$□Moderately important$_{(3)}$□A little important$_{(4)}$□Not important$_{(5)}$

V. Diet

39.When was last time a medical professional (your doctor, nurse, dietician, or other medical staff) talked to you about your diet?□This week$_{(1)}$□Last week$_{(2)}$□One month ago$_{(3)}$□More than a month ago$_{(4)}$□When I first began dialysis treatment$_{(5)}$□Never$_{(6)}$□Other (Specify)$_{(7)}$: _____

40.How often does a medical professional (your doctor, nurse, dietician or other medical staff) talk to you about the importance of following a proper diet?□Every dialysis treatment$_{(1)}$□Every week$_{(2)}$□Every month$_{(3)}$□Every 2 to 3 months$_{(4)}$□Every 4 to 6 months$_{(5)}$□When I have abnormal blood or other (for example, blood pressure) test results$_{(6)}$□Rarely$_{(7)}$□Irregularly$_{(8)}$□Never$_{(9)}$□Other (Specify)$_{(10)}$: _____

41.How important do you think it is to watch the types of food you eat each day?□Highly important$_{(1)}$□Very important$_{(2)}$□Moderately important$_{(3)}$□A little important$_{(4)}$□Not important$_{(5)}$

42 Why do you think it is important for you to watch your diet daily? (Please choose one best answer that applies to you.)□Because I fully understand that my kidney condition requires to watch my diet$_{(1)}$□Because watching my diet is important to keep my body healthy$_{(2)}$□Because a medical professional (my doctor, nurse, or dietician) told me to do so$_{(3)}$□Because I got sick after eating certain food that I was not supposed to eat$_{(4)}$□Because I was hospitalized after eating certain food that I was not supposed to eat$_{(5)}$□I don't think watching my diet is important to me$_{(6)}$□Other (Specify)$_{(7)}$: _____

43 Have you had any difficulty following your dietary recommendations? □No $_{(1)}$ □Yes $_{(2)}$

44.How much difficulty have you had following your dietary recommendations?□No difficulty$_{(1)}$□A little difficulty$_{(2)}$□Moderate difficulty$_{(3)}$□A lot of difficulty$_{(4)}$□I was unable to follow any recommendations at all$_{(5)}$

45.What type of difficulty have you had keeping your dietary recommendations?□Not applicable: No difficulty$_{(1)}$□I was not willing to control what I want to eat$_{(2)}$□I was unable to avoid certain unrecommended food$_{(3)}$□I don't understand what type of diet to follow$_{(4)}$□Other (Specify)$_{(5)}$: _____

46.During the *past week*, how many times have you followed the diet recommendations?□All of the time$_{(1)}$□Most of the time$_{(2)}$□About half of the time$_{(3)}$□Very seldom$_{(4)}$□None of the time$_{(5)}$

Appendix III: Consent Form

I have been explained to the purpose and nature of this study.

I have had an opportunity to ask any questions I may have had with regards to this study.

I am satisfied with the information I have been given in regard to my rights as a participant.

I understand that there are no monetary benefits to me, and neither shall I be required to incur any costs whatsoever with regard to this study.

I have also been assured that my responses to the questionnaire utilised in this study, shall remain confidential, and shall in not any way affect my further treatment.

I understand that I will not benefit directly from this research.

I understand that I have the right to withdraw at any point from the study.

I understand that I am free to contact the Principal Investigator for any clarification during or after the study.

I consent to participate in this study voluntarily, and confirm that I have not been coerced into so doing.

I confirm that I have not been forced, in any manner or form, into participating in this study.

Name of Participant ----------

Signature of Patient ----------

Date ----------

Appendix IV: Patient Information Form

Introduction: My name is Dr Mehreen Adam, and I am pursuing my Masters Degree in Internal Medicine at the University of Nairobi. I am currently conducting research to study the levels of adherence to treatment amongst patients with kidney failure at Kenyatta National Hospital.

Procedures: Participation in this study is voluntary. If you agree to participate we shall obtain information such as your age, gender, demographic data, and data with regards to your weight and electrolyte levels after which you will be requested to fill out a questionnaire provided to you. The questionnaire will ask questions with regard to your adherence to your treatment as a patient with kidney disease.

Your Rights: Your participation is entirely voluntary, and if you wish to decline participation, your further treatment will not be affected in any way. You are entitled to ask any questions or concerns with regards to the study. All your responses shall remain confidential, and shall only be seen by myself and the statistician. You have the right to withdraw at any time of the study.

Benefit to you: You shall not have any direct benefit as a participant in this study. However as a result of the information you provide, we may be able to identify gaps in treatment of kidney failure patients that need to be addressed. In the long term this shall benefit the patients like yourself, undergoing dialysis.

Compensation: You will not receive any monetary compensation for participation in this study.

Contact: In case of any query or clarification at any time do not hesitate to contact;

Dr Mehreen Adam 0720225070 or Email: mehreen_adam@msn.com

Secretary KNH-UoN Ethics and Review Committee 2726300 Ext 4410 or email uonknh_erc@uonbi.ac.ke

Appendix V: Kiswahili Consent Form

Nimeelezewa kusudi na maumbile ya utafiti huu. Nimepata nafasi ya kuuliza maswali yoyote ambayo ningekuwa nayo kuhusu utafiti huu. Nimeridhika na habari ambayo nimepewa kuhusu haki yangu kama mshiriki. Ninaelewa kuwa hakuna faida yoyote ya kifedha kwangu, na hata mimi sitatakiwa kulipia gharama yoyote juu ya utafiti huu. Pia nimehakikishiwa kuwa majibu yangu kwa dodoso linalotumiwa katika utafiti huu, yatabaki kuwa ya siri, na kwa njia yoyote hayataathiri matibabu yangu zaidi. Ninaelewa kuwa sitafaidika moja kwa moja na utafiti huu. Ninaelewa kuwa nina haki ya kujiondoa wakati wowote kutoka kwa masomo. Ninaelewa kuwa niko huru kuwasiliana na Mpelelezi Mkuu kwa ufafanuzi wowote wakati wa masomo au baada ya masomo. Ninakubali kushiriki katika utafiti huu kwa hiari, na ninathibitisha kwamba sijalazimishwa kufanya hivyo. Ninathibitisha kwamba sijalazimishwa, kwa namna yoyote au fomu, kushiriki katika utafiti huu.

Jina la Mgonjwa ----------

Saini ya Mgonjwa ---------- ---

Tarehe ----------

Appendix VI: Scoring ESRD-AQ

Scoring Individual Items of the End-Stage Renal Disease Adherence Questionnaire

Section Name	Question Numbers	Targeted Area in the Item	To Recorded Value of (Points)
Section 1: General Information (5 items)	1, 2, and 3	Fact related to previous RRT history	No value
	4 and 5	Fact related to transportation situation to get HD	No value
Section 2: HD Treatment (14 items)	6 and 7	Fact related to HD schedule	No value
	8	Perception of patients on HD schedule	No value
	9 and 10	Information about counseling on HD	No value
	11	Perception on importance of HD adherence	No value Analyze responses using descriptive statistics
	12	Understanding level on importance of HD	No value Analyze responses using descriptive statistics
	13	Perception of patients on HD	No value
	14	Frequency of missing HD during last month	Response category 1→300 Response category 2→200 Response category 3→100 Response category 4→50 Response category 5→0
	15	Reason for missing HD	No value (Note: If patients missed HD due to medical reasons (if the answer is 4, 6, or 7), adjust scores from question number 14 and give a full credit (300 points)
	16	Supplementary question for Question 15 (psychophysical symptoms)	No value
	17	Frequency of shortening HD during last month	Response category 1→200 Response category 2→150 Response category 3→100 Response category 4→50

Section Name	Question Numbers	Targeted Area in the Item	To Recorded Value of (Points)
			Response category 5→0
	18	Duration of shortening HD during last month	Response category 1→100 Response category 2→75 Response category 3→50 Response category 4→25 Response category 5→0
	19	Reason for shortening HD treatment	No value (Note: If patients shortened HD due to medical reasons (if the answer is 2, 5, 6 or 11), adjust scores from question number 17 & 18 and give a full credit (200 and 100 points)
Section 3: Medication (9 items)	20 and 21	Information about counseling on medication	No value
	22	Perception on importance of medication adherence	No value Analyze responses using descriptive statistics
	23	Understanding level on importance of medication	No value. Analyze responses using descriptive statistics
	24 and 25	Fact related to difficulty with taking medicines	No value
	26	Frequency of missing medication during last month	Response category 1→200 Response category 2→150 Response category 3→100 Response category 4→50 Response category 5→0
	27	Reason for missing medication	No value (Note: If patients missed medication due to medical reasons (if the answer is 6 or 7) adjust scores from the question number 26 and give a full credit (200 points).
	28	Supplementary question for Question 27 (psychophysical symptoms)	No value
Section 4: Fluid Restriction (10 items)	29 and 30	Information about counseling on fluid restriction	No value
	31	Fluid restriction: Self-monitoring (Frequency)	Response category 1→200 Response category 2→150

Section Name	Question Numbers	Targeted Area in the Item	To Recorded Value of (Points)
			Response category 3→100 Response category 4→50 Response category 5→0
	32	Perception on importance of fluid restriction	No value Analyze responses using descriptive statistics
	33	Understanding level on importance of fluid restriction	No value Analyze responses using descriptive statistics
	34 and 35	Fact related difficulty with limiting fluid intake	No value
	36	Types of difficulty following fluid restriction (additional question to #35)	No value
	37 and 38	Information on weighing at home (not mandatory requirements for all ESRD patients)	No value
Section 5: Dietary Restriction (8 items)	39 and 40	Information about counseling on dietary recommendations	No value
	41	Perception on importance of dietary recommendations	No value Analyze responses using descriptive statistics
	42	Understanding level on importance of dietary recommendations	No value Analyze responses using descriptive statistics
	43 and 44	Fact related to difficulty with following dietary recommendations	No value
	45	Types of difficulty following fluid restriction (Additional question to #44)	No value
	46	Dietary restriction: Self-monitoring (Frequency)	Response category 1→200 Response category 2→150 Response category 3→100 Response category 4→50 Response category 5→0

Appendix VII: KNH/UON-ERC Letter of Approval

UNIVERSITY OF NAIROBI
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KENYATTA NATIONAL HOSPITAL APPROVED 02 SEP 2019 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI

Ref: KNH-ERC/A/328

2nd September, 2019

Dr. Mehreen Adam
Reg. No.H58/87682/2016
Dept.of Clinical Med. & Therapeutics
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Adam

RESEARCH PROPOSAL: AN ASSESSMENT OF ADHERENCE TO MANAGEMENT MODALITIES BY AMBULANT END STAGE RENAL DISEASE PATIENTS UNDERGOING HAEMODIALYSIS AT THE KENYATTA NATIONAL HOSPITAL (P543/07/2019)

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 2nd September 2019 – 1st September 2020.

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. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. 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*).
g. 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 Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept.of Clinical Medicine & Therapeutics, UoN
Supervisors: Prof. Mark Joshi, Dept.of Clinical Medicine & Therapeutics, UON
Prof. Joshua Kayima, Dept.of Clinical Medicine & Therapeutics, UoN
Dr. Anthony Were, Dept.of Clinical Medicine & Therapeutics,UON