CLINICAL PROFILES AND OUTCOMES OF END-STAGE KIDNEY DISEASE ADULT PATIENTS TREATED WITH HEMODIALYSIS AT THE KENYATTA NATIONAL HOSPITAL DURING OUT-OF-POCKET PAYMENT AND NATIONAL HEALTH INSURANCE REIMBURSEMENT FOR HEMODIALYSIS SERVICES

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DECLARATIONS

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

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LIST OF ABBREVIATIONS

AVF - Arteriovenous fistula

AVG - Arteriovenous graft

CAPD - Continuous ambulatory peritoneal dialysis

CGN - Chronic glomerulonephritis

CKD - Chronic kidney disease

DKD - Diabetes kidney disease

DM - Diabetes mellitus

ESAs – Erythropoiesis stimulating agents

ESKD - End stage kidney disease

FSGS - Focal segmental glomerulosclerosis

Hb - Hemoglobin

HD - Hemodialysis

HIC - High income country

HIV - Human immunodeficiency virus

Int$ - International dollars

KNH - Kenyatta National Hospital

KRT - Kidney replacement therapy

LMIC - Low- middle- income country

MCD - Minimal change disease

MN - Membranous nephropathy

MPGN - Membranoproliferative glomerulonephritis

MRSA - Methicillin resistant Staphylococcus aureus

NHIF - National Health Insurance Fund

PD - Peritoneal dialysis

pmp - per million population

SD - Standard deviation

SPSS - Statistical package for the social sciences

UHC - Universal healthcare coverage

URR - Urea reduction ratio

USA - United States of America

USRDS - United States Renal Data System

UK - United Kingdom

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OPERATIONAL DEFINITIONS

End stage kidney disease- patients who have been on hemodialysis for more than 90 days

Clinical profiles- age at initiation of hemodialysis, sex, cause of end stage kidney disease, comorbidities, hemodialysis vintage (duration on hemodialysis)

Clinical outcomes - whether the patient is alive on hemodialysis, alive having transplanted, deceased while on hemodialysis, deceased after kidney transplantation

Hemodialysis services - encompasses a variety of services including vascular access creation, laboratory tests like kidney function tests, drugs, vascular access creation and dialysis itself

Out-of-pocket payment - refers to paying for hemodialysis services in cash (before NHIF was launched in July 2015)

National health insurance reimbursement for hemodialysis services - refers to National Health Insurance Fund (NHIF) catering for the hemodialysis services from July 2015

Hemodialysis vintage - length of time on dialysis in months

ABSTRACT

Background: The demand for hemodialysis has grown briskly especially in low- and middle-income countries. Sadly, availability of kidney replacement therapy in developing countries is scarce and may be unavailable in very-low-resource regions. As a result, a compelling number of patients have finite access to KRT resulting in premature deaths. In July 2015, NHIF launched a renal dialysis package which caters for hemodialysis two sessions per week.

Objective: To describe and compare selected clinical profiles and clinical outcomes amongst ESKD patients treated with HD in KNH between June 2013 - June 2015 and July 2015 - May 2018 i.e., during the out-of-pocket payment period (pre-NHIF) and the national health insurance reimbursement period (post-NHIF).

Methods: This was an ambispective observational study among ESKD patients treated with HD in KNH between June 2013 - June 2015 and July 2015 - May 2018. The medical records of the 338 randomly selected patients were retrieved from the health records and information department in KNH. Data on the patients' sociodemographic characteristics, clinical profiles and outcomes was collected and analysed.

Results: Comparing the two groups (pre- and post-NHIF), the mean age at HD initiation did not differ significantly (46.76 vs 46.96 years). Males outnumbered females in both groups, at 64% and 60% respectively. Diabetes and hypertension remained the most common documented causes of ESKD in both groups. Following the introduction of NHIF reimbursement, there was a significant rise in HD sessions (1.94 ± 0.7 vs 2.12 ± 0.4, p value 0.04), however, the HD vintage decreased (36.3 vs 30.5 months). Our mortality rate was high at 85% (pre-NHIF) and 76% (post-NHIF) with no statistical significance across all the clinical outcomes assessed.

Conclusion: The mortality rate remained quite high during both time periods. In as much as NHIF reimbursement increased access to hemodialysis, it did not have any impact on clinical outcomes including survival. This suggests that there could be other factors like quality of hemodialysis offered, complications associated with hemodialysis that play a crucial role in the clinical outcomes as well.

Chapter 1 INTRODUCTION

1.1 Background information

Chronic kidney disease (CKD) is becoming a common disease in the general population and a major public health problem world over (1). There is a rising incidence and prevalence of CKD globally which poses an important challenge to many health systems. It is an important contributor to morbidity and mortality among the non-communicable diseases (NCD). Patients with CKD have a higher mortality rate in comparison to the general population (2).

According to the Global Burden of Disease Study in 2017, the global prevalence of CKD was 9.1% across 195 countries, this translated to 697.5 million cases globally. Chronic kidney disease resulted in 1.2 million deaths in 2017 and it was ranked as the 12th leading cause of death worldwide. In a systemic review assessing the burden of CKD in Africa, the prevalence of CKD was found to range from 2% to 14% in sub-Saharan Africa (3).

1.2 Kidney replacement therapy

Kidney replacement therapy (KRT) broadly encompasses dialytic modalities and kidney transplantation. Dialytic modalities include hemodialysis (HD) and peritoneal dialysis (PD). In the last two decenniums, great advances in treatment of CKD have emerged. Dialysis treatment ameliorates most of the clinical manifestations of end stage kidney disease (ESKD); this helps improve the survival of hemodialysis patients. The population of patients in need of KRT is growing rapidly particularly in low- and middle- income countries (LMIC). Currently, there are about two million people on KRT worldwide. This represents only 10% of the people who need it. The demand for HD has grown tremendously in the recent years and it has become an important issue in healthcare. Unfortunately, the availability of KRT in developing countries is scarce and may be unavailable in very-low-resource regions. As a result, a sizeable number of patients lack

access to KRT and large numbers of people die of kidney failure annually, often without any form of supportive care (4).

1.3 National health insurance reimbursement for treatment of kidney diseases in Kenya

Health is a basic human right as enshrined in the 2010 Kenya constitution. However, health care cost limits the attainment of this constitutional right. This therefore is bound to select for those who have resources to receive the care. National Health Insurance Fund (NHIF) is the primary health insurance provider in Kenya; its mandate is to enable all Kenyans to access quality and affordable health care services.

The NHIF has evolved over the years and in July 2015, NHIF launched its out-patient services. This included renal dialysis and kidney transplant packages which cater for two hemodialysis sessions per week and support for kidney transplantation surgical costs respectively. Before July 2015, patients used to meet all the costs by themselves. The influence of national insurance reimbursement for hemodialysis services has not been studied.

1.4 Study questions

The study endeavored to put to light some aspects in treatment of end stage kidney disease with hemodialysis during an era when patients used to foot all the costs and when the national health insurance undertook to reimburse for the hemodialysis services. The study aimed to answer the following questions: -

i. What are the clinical profiles (age at initiation of hemodialysis, sex, cause of ESKD and hemodialysis vintage) of ESKD patients treated with HD in KNH between June 2013 - June 2015 and July 2015 - May 2018?

ii. What are the clinical outcomes i.e., alive on HD, alive having transplanted, deceased while on HD, deceased after kidney transplantation of ESKD patients treated with HD in KNH between June 2013 - June 2015 and July 2015 - May 2018?

iii. What are the differences and similarities in the selected clinical profiles and clinical outcomes amongst ESKD patients treated with HD in KNH between June 2013 - June 2015 and July 2015 - May 2018?

1.5 Study objectives

1.5.1 Broad objective

Broadly, the study endeavored: -

i. To describe and compare selected clinical profiles amongst ESKD patients treated with HD in KNH between June 2013 - June 2015 and July 2015 - May 2018

ii. To document and compare selected clinical outcomes amongst ESKD patients treated with HD in KNH between June 2013 - June 2015 and July 2015 - May 2018.

1.5.2 Specific objectives

Specifically, the study sought: -

i. To describe and compare the clinical profiles i.e., age at initiation of hemodialysis, sex, cause of ESKD and hemodialysis vintage of ESKD patients treated with HD in KNH between June 2013 - June 2015 and July 2015 - May 2018.

ii. To document and compare the clinical outcomes i.e., alive on HD, alive having transplanted, deceased while on HD, deceased after kidney transplantation, of ESKD

patients treated with HD in KNH between June 2013 - June 2015 and July 2015 - May 2018.

1.6 Study justification

Chronic kidney disease has a major impact on global health given the associated significant morbidity and mortality. Notably, there has been an increasing incidence and prevalence of HD due to advanced age and comorbid conditions like diabetes mellitus (DM), hypertension and malignancies. The outlay of HD care is high and are prone to rise. The effect of national health insurance reimbursement on HD remains largely unknown. A few sets of data suggest that decreased reimbursement may increase morbidity and mortality directly or indirectly. Health system planning requires careful assessment of the epidemiology, morbidity and mortality associated with disease.

It is plausible to think that national insurance reimbursement for the HD services is likely to result in improved access to this care. It is not clear whether the patients' demographics and clinical profiles have changed. The outcomes of patients on HD during the out-of-pocket payment of HD services costs and during the national health insurance reimbursement in our setting has not been studied.

The findings of this study will highlight the clinical profiles and outcomes of our ESKD patients treated with hemodialysis as well as the differences and similarities observed with implementation of the national health insurance. These findings can inform programming for funding for HD services by the national health insurance.

Chapter 2 LITERATURE REVIEW

2.1 Chronic kidney disease

Kidney disease has an immense effect on global public health. It is a sizeable threat to the world's health but in some African countries it is a death sentence. It causes gross morbidity and mortality and is an important risk factor for cardiovascular disease. Kidney disease is largely preventable and treatable and as such it deserves greater attention in global health policy decision making especially in low- and middle-income countries. There is a great need to improve management of CKD risk factors at primary care level.

In 2017, 697.5 million cases of all-stage chronic kidney disease were recorded globally, giving a 9.1% global prevalence. In the same year, 1.2 million people died from CKD; and is projected to rise to 4.0 million by the year 2040 in the worst-case scenario. More than one million cardiovascular disease-related deaths and 25.3 million cardiovascular disease disability-adjusted life-years were attributed to impaired kidney function (5). The prevalence of kidney failure globally is unknown but was approximated to be 0.07% which translated to around 5.3 million people in 2017 (6).ESKD is projected to increase at a rate of 6-8% in Africa (7).

Chronic kidney disease is approximately 3-4 times more frequent in Africa than in developed countries (8). It is estimated that by 2030, more than 70% of patients with ESKD will be living in developing countries (5). This is alarming bearing in mind that the global prevalence of maintenance hemodialysis has doubled since 1990. Kidney replacement therapy was accessed by only 1.8 million people globally in 2004; less than 5% of this population came from sub-Saharan Africa (9).

In sub-Saharan Africa, CKD is a substantial health burden, it affects the economically productive young adults aged between 20-50 years while in the developed world it affects the middle aged and elderly people. In the US, prevalence of CKD increased dramatically with age, 4% at age 29-39 years and 47% at age more than 70 years. Utmost rapid growth was observed in those aged 60 years or older (10). In 2017, 20 million cases of CKD and 37,332 deaths were reported in Eastern sub-Saharan Africa; with 2.6 million cases and 4,687 deaths occurring in Kenya. It is estimated that by 2030, 4.8 million Kenyans will be suffering from kidney disease (6).

Gender disparities have been found to exist with a higher prevalence of CKD stages 1-3 in females and higher mortality in males suggesting that males progress to ESKD more rapidly (11).In the United States Renal Data System (USRDS) 2011 Annual Data Report, it was found that incident rate of ESKD cases at the initiation of hemodialysis in 2009 was higher in males than females at 415.1 p.m.p compared with 256.6 females respectively(10).

The lack of appropriate renal records implies that there are no reliable statistics regarding the incidence and prevalence rates of CKD in majority of the countries in Africa. In addition, poor renal registry systems also restrict the understanding of cost effectiveness and outcomes of KRT in African settings. There are numerous challenges facing renal care in Africa; these include equity, accessibility, financial constraints, lack of the necessary facilities, inadequate workforce. It is therefore paramount for Africa countries to prioritise renal care and incorporate it in the health agenda. Preventive measures which are key in the management of CKD are still in their infancy stage in Africa due to lack of personnel and resources.

2.2 Causal attribution / Etiology of CKD/ ESKD

There is a looming global strain and threat of NCDs. This is as a result of ageing, lifestyle changes and rapid urbanisation. Over the years, there has been a change in the world's disease profile with

chronic diseases now becoming the leading cause of morbidity and mortality. Whilst infections remain the leading cause of death in Africa, NCDs seem to be featuring in the forefront. Africa is now experiencing a rapid increase in diabetes and hypertension which are known underlying causes of CKD (7).

A systematic review of 42 studies run specifically to clarify the underlying cause of CKD in the entire African continent revealed that vascular/ hypertensive sclerosis was the main cause of CKD (16%). This was followed by diabetic nephropathy (15%), chronic glomerulonephritis (13%), tubulointerstitial/ obstructive disease (8%), systemic lupus erythematosus (3%), polycystic kidney disease (3%) and undetermined cause in 20% (3).

In sub-Saharan Africa, CKD is a significant health strain with risk factors that include both communicable and noncommunicable diseases. It affects mainly the young adults aged between 20 and 50 years and is primarily due to glomerular diseases and hypertension. As stated earlier, hypertension is a leading cause of CKD in Africa, with prevalence rates ranging from 25% in Senegal, 29% in Ghana, 45% in South Africa and 48% in Ghana(8).

Glomerular disease is quite rampant in Africa and is a leading cause of ESKD in sub-Saharan Africa; unfortunately, there is sparsity of epidemiologic data from most areas. It has been noted that glomerular disease is more prevalent in Africa than in the Western countries. It is outlined by poor response to treatment and eventually progresses to kidney failure (8).Glomerular diseases remain poorly characterized in sub-Saharan Africa. Muthui et al in a cross-sectional descriptive survey done in KNH in 2010 revealed that FSGS accounted for 30.1% of the glomerular diseases, MN 18.1%, MPGN 15.4% and MCD 14.5%.

Currently, according to the International Diabetes Federation 2017, approximately 500 million people are affected by diabetes globally, this number is expected to rise to 693 million by 2045. Type 2 diabetes mellitus is a major cause of kidney failure, stroke, heart attacks, lower limb amputation and blindness. About 30 - 40% of patients with diabetes develop chronic kidney disease during their lifetime and end up requiring kidney replacement therapy (12).

HIV is epidemic in Africa; however, the number of new infections seems to be declining with increasing number of patients on anti-retroviral therapy. Kidney disease associated with HIV is becoming more conspicuous as patients live longer especially in the era of antiretroviral therapy; it often presents late in ESKD requiring dialysis (13). An escalating disease burden is anticipated with this expected increase in the life expectancy and ageing of the HIV-infected populations as well as the nephrotoxicity associated with the disparate drugs used in this population (8).

2.3 Kidney replacement therapy

If CKD progresses to ESKD, survival and quality of life are maintained by kidney replacement therapy (KRT). KRT encompasses hemodialysis, peritoneal dialysis and kidney transplantation (14, 15). Generally, the need for kidney replacement therapy and renal health care is increasing. Kidney replacement therapy is a life-saving but expensive form of treatment; very few countries can afford to meet the needs of all the patients.

Development of dialysis set in motion several striking changes in the management of kidney failure. Although hemodialysis is costly, it is the most regularly offered form of KRT in LMICs as well as in HICs (16). Globally, ~89% of patients receiving dialysis are on hemodialysis with the majority (>90%) living in the HICs or upper middle-income countries like South Africa and Brazil. The uptake of hemodialysis is expected to continue increasing worldwide, in the coming

decades (16). The prevalence of chronic dialysis correlates strongly with the national income hence it varies widely by region (17).

There has been a rapid increase in dialysis use in the last two decades. The frequency of dialysis initiation in many HICs reached its peak in the early 2000s and has remained stable or slightly decreased since then (22,26,27). There is lack of reporting in LMICs hence it is difficult to ascertain the true demand for KRT in these countries. Incidence data in LMICs is less robust than prevalence data. By extrapolation of the prevalence data from LMICs, the incidence of dialysis initiation in these countries seems to be steadily increasing. Further increases are expected over the coming decades (10, 28,29,30).

The population of patients on dialysis treatment is increasing at an annual global average of 7% (18). The main contributors to this trend include the availability of dialysis, universal ageing of populations, multi-morbidity and increased prevalence of hypertension and diabetes, toxic environmental exposures, higher expectancy of treated ESKD patients and increasing access of a generally younger patient population to dialysis treatment in countries which previously had limited access (9, 19, 20).

Notwithstanding the global expansion, there are notable regional discrepancies in the availability and accessibility of the different dialysis modalities (20). In Africa, in-center hemodialysis is the most common modality that is used. Peritoneal dialysis is seldom used, except in Sudan and South Africa, because of the cost of importing fluids (8). In excess of 2.5 million people are currently receiving kidney replacement therapy globally and this is projected to double to 5.4 million by 2030 (21).

The prevalence of patients on KRT is lower in most developing countries due to low availability of dialysis and transplantation, lower diagnostic yield and the presence of infectious and cardiovascular illnesses which cause competitive mortality hence limiting the number of patients who live long enough to reach end stage kidney disease (22). Kidney transplantation is favourable due to its clinical and economic benefits; it offers improved quality of life, longer survival and lowest costs compared to dialysis. However not all patients qualify for kidney transplantation(14).

Unfortunately, there is a shortage of kidney replacement services in many countries and an estimated 2.3 -7.1 million people have died from lack of access to this treatment(21). The great disparities in mortality by world region are mainly due to differences in access to kidney replacement therapy - initiating and maintaining dialysis - combined with increased prevalence of hypertension and diabetes. Up to 85% of incident dialysis patients in sub-Saharan Africa are unable to pay for ongoing dialysis forcing them to withdraw from treatment (23).

2.4 Global dialysis perspective

The prevalence of hemodialysis is increasing more rapidly in Latin America (4% annually) compared to 2% in Europe and the USA (24, 25). The prevalence of hemodialysis diverges widely across South Asia. A high prevalence and rapid growth has been reported in India and a lower prevalence in Afghanistan and Bangladesh (26). There is limited data available on the prevalence of dialysis therapies in sub-Saharan Africa; however, a 2017 report suggests that hemodialysis services were available in 34 African countries (27, 28).

In Beijing, the incidence of dialysis-treated ESKD increased from 94 p.m.p in 2007 to 147.3 p.m.p in 2010. The root of ESKD in incident patients on maintenance HD was CGN (32.1%), second was DKD (29.3%) and third was hypertension 14.3%. The percent of patients with CGN decreased

to 24% in 2010 while the percent of patients with DKD increased to 40.1%. As such, DKD became the leading cause of ESKD in incident cases in 2010 (29).

The point prevalence of patients on maintenance HD at the end of 2006 was 269 p.m.p and this gradually increased to 509 p.m.p by 2010. The number of maintenance HD patients with CGN decreased from 37.2% in 2007 to 33.9% in 2010; while those with DKD increased from 21.4% in 2007 to 29.4% in 2010. CGN was still the leading cause of ESKD in prevalent maintenance HD patients at 33.9% followed by DKD (29.5%) and hypertension (29). This growth in incidence and prevalence of maintenance HD was attributed to availability of a government-operated medical insurance and growth in the incidence and prevalence of diabetes.

The annual mortality rate varied from 7.4% to 9.0% within the period 2007-2010. It was noted that old or diabetic patients suffered a higher mortality. The annual mortality rate was <5% for patients less than 60 years old, 19% for those more than 70 years old and 36% for those older than 80 years of age. Cardiovascular disease (congestive heart failure, myocardial infarction, arrythmia) was the leading cause of death at 27.8%, while stroke and infection accounted for 11.5% each (29).

In South Africa, KRT in the community is strictly rationed; with 'transplantability' a prerequisite for access to treatment. This implies that patients with severe comorbidities and those above 60 years of age are seldom admitted to the public-sector KRT programs. According to 2017 data, there are 278 dialysis treatment centers, 29 public and 249 (89%) private. In the private dialysis treatment centers the cost is fully covered by medical insurance schemes. On the other hand, in the public dialysis treatment centers the government caters fully for indigent patients and partially for the other patients (based on the income). The approximate cost of dialysis session is US $ 100 in the public dialysis centers and US $ 150 in the private centers. The average length of a dialysis

session is 4 hours thrice weekly. In terms of vascular access; 51% patients had an AVF, 33% tunneled catheter, 7% AVG, 6% temporary HD catheter(30).

Hemodialysis is the predominant KRT in South Africa within the public and private sector with a prevalence of 41% and 84% respectively. 87% of all the patients on chronic dialysis are on hemodialysis. Most of the patients in the public sector are younger than those in the private sector. This is a result of the rationing criteria applied in the public sector. From the 2017 data, 35% of the dialysis-treated ESKD patients had hypertensive kidney disease, the etiology was unknown in 32%, while 15% had diabetic nephropathy, 10% had glomerular disease and 3% had cystic kidney disease. In terms of the viral seropositivity, 10% of the patients had HIV, 2% had Hepatitis B and 0.8% had Hepatitis C(30).

The survival rate of South African patients on KRT is comparable to that in better-resourced countries. The reported 1-year survival rate in incident patients was 90%, there was no difference in survival rate between patients treated in the public and private healthcare sector. Higher mortality rate was associated with old age, the primary kidney disease, and the province of residence. Neither the first KRT modality, diabetes, ethnicity nor the healthcare sector were independently associated with survival; the effect of HIV infection on survival was unclear (31).

2.5 Predictors of clinical outcomes/ mortality in ESKD patients on dialysis

Kidney replacement therapy is not without adverse effects especially on the patient's quality of life. The negative effects are more profound in the elderly and in patients with multiple comorbidities resulting in lower survival rates. In such patients palliative or conservative therapy is preferred (32).

Mortality is relatively high among patients on dialysis treatment, especially in the first 3 months following initiation of hemodialysis treatment. In HICs, almost one-quarter of patients on hemodialysis die within the first year of initiating therapy; this proportion is even higher in LMICs (33-35). There have been contractions in the relative and absolute risk of mortality in the past two decades. Factors responsible for this downward trend could include better management of comorbidities, improvements in the prevention and treatment of dialysis-related complications like infections, and better care prior to initiation of dialysis translating into better health after dialysis initiation (36, 37).

Despite these great and promising improvements, mortality among dialysis patients remains unacceptably high. The main drivers of these are infection and cardiovascular events, due to the high burden of cardiovascular risk factors. Hence, strategies to reduce the risk of infection associated with dialysis access (both hemodialysis and peritoneal dialysis) should continue to be a major clinical priority (38-40).

Many traditional risk factors such as age, sex, socioeconomic status, history of diabetes mellitus, history of cardiovascular disease, mineral bone disorder, nutrition status, type of vascular access, inadequate dialysis; have been implicated in the outcomes of ESKD patients. Socioeconomic characteristics such as low education level, low income, living in remote or rural areas, lack of social and family support, have been associated with poor survival rate and quality of life in ESKD patients on hemodialysis (41, 42).There is inconsistent evidence that exists to suggest that mortality varies significantly by sex among incident adult dialysis patients (43, 44).

In Africa, many patients receive inadequate dialysis due to the great financial constraints. Hardly any can sustain chronic dialysis beyond 6 months, most are forced to cease dialysis when funds

get depleted. Bamgboye et al noted that only 20% of the patients in a Nigerian dialysis center could afford thrice-weekly dialysis while 70% could only afford once-weekly dialysis. Since majority were self-funded, only a few were able to sustain chronic dialysis beyond 6 months due to limited funds (45).

2.6 Cost of dialysis in low- and middle-income countries

Chronic kidney disease and dialysis are both a medical and economic problem. There is limited data on the economics of dialysis in low- and middle- income countries. There has been a rise in the treatment costs for CKD with the availability of kidney replacement therapy (20). Dialysis is an expensive treatment making financing dialysis services an economic burden in low- and middle-income countries. The current costs are not sustainable even for high income countries. Globally, most ESKD patients forego treatment resulting in millions of deaths annually (20).

The costs incurred during dialysis treatment are generally described into four categories: namely, direct medical costs, direct non-medical costs, indirect costs and intangible costs (46, 47). Direct costs include staffing costs, salaries, costs of dialyzers and tubing in HD, costs of fluids and tubing in PD, capital costs of HD machines and PD cyclers, radiology, laboratory and medications costs, costs of outpatient consultations and hospitalization costs. Direct non-medical costs include facility costs, building costs and other overhead costs.

Indirect costs encompass the productivity losses for both the patients and their families and caretakers. These costs have neither been assessed nor incorporated in dialysis economic evaluations. Intangible costs are costs associated with impairment of quality of life, pain and suffering as well as the value of extending life. Unfortunately, these costs are usually omitted

during the economic evaluation since they are difficult to quantify and may actually appear irrelevant to providers (48).

The economic burden may be in the form of direct loss of gross domestic product or financial cost of managing the disease. In countries where dialysis is available without restrictions, it consumes between 2% and 5% of the overall healthcare expenditure. In low- and middle-income countries, reimbursement of dialysis is insufficient to treat all ESKD patients. It has a disproportionately high effect on public health expenditure (49).

The rate of patients receiving dialysis treatment is on the rise, at an annual global average of 7% (18). The main reasons for this trend are the multi-morbidity, universal ageing of populations and the higher-expectancy of treated ESKD patients(9). Hence, ESKD is an important disease that burdens the financial health of many nations and threatens the public health as well (50).

In a systemic review, Lawrencia Mushi et al found that the annual cost per patient for hemodialysis in low- and middle-income countries ranged from international dollars (Int$) 3,424 to Int$ 42,785 and Int$ 7,974 to Int$ 47,971 for peritoneal dialysis. The main cost drivers were direct medical cost especially drugs and consumables for hemodialysis and dialysis solutions and tubing for peritoneal dialysis (51). Based on this, dialysis might only be cost-effective in upper-middle income countries where it can be included in the socially protected basic healthcare package.

In countries where the government offers limited or no reimbursement for dialysis, patients must contribute a substantial amount of their own resources for dialysis care. In some dire situations, patients end up refraining from dialysis treatment due to financial reasons. As a result, many dialysis candidates globally remain untreated and some even die prematurely (21, 52). It has been

reported that 59% of people in sub-Saharan Africa stop dialysis while it is still indicated due to the heavy medical and non-medical financial burden (23).

In Kenya, all kidney replacement therapy modalities are available including transplantation. However, this is not the case in other countries with a similar level of socio-economic development. Unfortunately, the costs of hemodialysis and peritoneal dialysis are prohibitive at Int$ 16,845 for hemodialysis and Int$ 12,633 for peritoneal dialysis; as reported by Abu-Aisha et al. The cost in Sudan was found to be equivalent to Int$ 11,054 for hemodialysis and Int$ 12,107 for peritoneal dialysis (53).

With these exorbitant costs, dialysis is either limited to the richest minority or must be financed within the public health system. Dialysis might not be the top priority in least developed countries due to the cost implications. This indicates that there is need for policy makers and governments in low and middle-income countries to ensure that the costs of drugs and consumables of dialysis are not higher than necessary.

In 2015, the Kenya national government in collaboration with the various county governments installed dialysis units across the country with an aim of enhancing renal care services. According to the current statistics from Kenya Renal Association; there are around 212 dialysis units in the country,54 (public), 141 (private) and 17 (faith-based organisations). Unfortunately, like many other developing nations, Kenya lacks a national registry for patients undergoing maintenance hemodialysis especially in the public facilities. However, it is estimated that there are at least 4,800 patients on maintenance dialysis across the country.

2.7 Dialysis remuneration: per patient, per session, per bundle

There has been an exponential growth in ESKD patients in the recent years. Consequently, the dialysis costs have kept increasing, causing a great financial burden on families and the society. Reimbursement for dialysis consumes a substantial portion of the healthcare expenditure. There are three main methods of calculating the cost of dialysis and establishing how dialysis should be reimbursed.

The first involves dividing dialysis into a series of different elements and reimbursing each one separately; for example, dialysis itself, hospitalization, consultations, laboratory tests, imaging, medication, transportation. The capitation system/ method entails merging these elements in a per capita reimbursement. The bundles system/ method involves identifying procedures that are intrinsically linked to treatment, for example, dialysis sessions, intradialytic drugs, tests and transportation.

Each of the systems has its pros and cons and impacts differently on the delivery of dialysis care. Payment per session may favour fragmentation making global appraisal difficult. The capitation system requires a careful correction for comorbidity and may increase competition between public and private centers with the latter preferring the least complex cases. On the other hand, a bundle system in which the main elements linked to dialysis sessions are considered together may be a better option but risks penalizing complex patients. It also requires a rapid adaptation to treatment changes.

2.8 Global dialysis remuneration

Remuneration for chronic dialysis takes up a significant share of the healthcare expenditure to cater for a relatively small proportion of the total population. Each country has a specific

remuneration system which attempts to cushion the increasing costs incurred during dialysis treatment. Major differences exist across countries resulting in as much as a 3.3-fold difference between the highest and lowest reimbursement rates for chronic dialysis. These differences persist even after adjusting for per capita gross domestic product (54). There has been continual evolution of remuneration policies world over. This indicates that all governments are struggling to achieve the optimal balance of cost containment with high-quality care for all patients regardless of the socioeconomic status.

Remuneration for peritoneal dialysis is lower in most countries apart from the United States and Germany. Reimbursement for home hemodialysis has only been incentivized in the Netherlands; whereas the United Kingdom is the only country that has implemented an incentive if patients use an arteriovenous fistula (54-57). Generally, the US provides the lowest remuneration except for CAPD reimbursement; the UK offers the lowest reimbursement for CAPD. Peritoneal dialysis is generally reimbursed at a lower level than hemodialysis except in the US where reimbursement is similar for all dialysis modalities, and in Germany where it is reimbursed at a higher rate than all hemodialysis strategies (46, 54).

Payments for hospital hemodialysis are generally higher except in the US, UK and The Netherlands. The US and UK both provide a single flat rate for hemodialysis regardless of the site of care. However, in The Netherlands, home dialysis is reimbursed at the highest level if performed by a nursing assistant, if performed without an assistant it is reimbursed lower than hospital hemodialysis (54).

The Netherlands and the US have an expanded bundled reimbursement package which includes all the intravenous drugs namely, erythropoiesis-stimulating agents, vitamin D and iron. On the

other hand, France and Ontario have bundled payment systems which include everything apart from ESAs. The reimbursement package in the US and Ontario also encompasses laboratory tests. However, there are restrictions on the number of tests performed in some countries; for example, in Belgium there is a restriction on the number of tests performed per collected blood sample whereas in Germany the restriction is on the number of tests performed per month. In France the biochemical analyses are only included in the package for public hospitals (54).

In the US, UK, Canada and Germany, the nephrologist's fee is paid separately hence it is not included in the bundled fee. Germany offers additional reimbursement for patients with HIV, hepatitis B and C infections as well as carriers of MRSA, patients with diabetes and patients over 59 years of age. UK offers extra reimbursement for patients with hepatitis B, C and HIV infection but reduces reimbursement for patients with central venous catheter for dialysis access. Most countries reimburse for a maximum of three sessions per week, and longer dialysis in excess of the standard 4 hours is not reimbursed. Achieving targets for clinical measures (Kt/V or its surrogate, URR, and hemoglobin) affect reimbursement only in Germany and the US; if these targets are not met (Kt/V 1.2, URR >65%, Hb >10g/dl), the reimbursement is decreased (54).

It is difficult to make definite conclusions on the overall financial cost of dialysis across countries because of various reasons. First, there are substantial differences in patient mix, comorbidities, transplantation rates and policy and number of available in-center dialysis units (58). Secondly, the average age of dialysis patients is higher in some countries and it is well known that health expenditures are higher in older dialysis patients (59). Thirdly, the number of patients receiving the various modalities differs by country and even within these countries there are regional differences. Lastly some countries offer additional reimbursement for specific conditions like HIV,

hepatitis, and diabetes. Some countries include specific dialysis-related drugs within the payment bundle.

Kenya implemented healthcare reforms in July 2015 to ensure universal healthcare provision. National Health Insurance Fund (NHIF) is the primary health insurance provider in Kenya; its mandate is to enable all Kenyans to access quality and affordable health care services. In the last couple of years, NHIF has developed and rolled out new benefit packages with the intention of increasing health care access to all citizens. It has also continued to implement social health strategies with an aim to achieve Universal Health Coverage (UHC) for the benefit of all Kenyans.

The NHIF Supacover is a comprehensive and affordable health insurance scheme which caters for renal dialysis. This is applicable for both inpatient and outpatient care for pre-dialysis, intra-dialysis, and dialysis care. It offers a maximum of KSh 9,500 per session twice weekly. This has widened access to medical service amongst Kenyans.

2.9 Effects of dialysis reimbursement on the growth of ESKD

ESKD has a great impact on public health and health care economics; it burdens the financial health of many nations globally (50, 60). It is a significant issue in medical care considering that the cases of ESKD requiring dialysis have been increasing progressively over the last decade (18, 61). Dialysis reimbursement influences multiple factors including but not limited to dialysis patient mortality, hospitalisation, quality of treatment, dialysis unit staffing and innovation.

Incidence data is useful when considering issues of access to treatment, the patterns of referral to treatment and disease prevention. On the other hand, prevalence data is useful for evaluating the health effects of disease on the society, estimating the cost of providing healthcare services and determining which resources and manpower are necessary to provide these health care services.

Based on international comparisons, there are great differences in ESKD incidence and prevalence among the reported countries in Europe. These differences in ESKD parameters between countries are multifactorial and are attributable to variations in methods of data collection, use of different analytic tools, patient characteristics, socioeconomic status and most importantly the system of health insurance (62-64). Unfortunately, studies in this area are limited as is the case with kidney transplantation. The prevalence of patients per million population being treated with maintenance HD in low- and middle-income countries increases linearly with the gross domestic per capita (49).

Yang et al in Taiwan noted an abrupt increase in the incident and prevalent dialysis ESKD case numbers and rates following the launch of the national health insurance (NHI) system in 1995. The increase in ESKD case numbers was most pronounced in the elderly subgroups aged 65 and above. There was a sharp increase in the mean age of both the incident and prevalent ESKD cases. This could be attributed to the improvements in public health and medical care resulting in a prolonged life expectancy and an ageing society. The average age at initiation of dialysis was also noted to have increased from 50.8 years to 57.9 years. This implied that some elderly ESKD patients only enrolled into dialysis treatment once they were covered by the national health insurance (65).

The percent of female dialysis patients also increased progressively from 1990 to 2001. A change in the percentages of primary diseases was also noted; before dialysis reimbursement, chronic glomerulonephritis was the main cause of ESKD. However, with NHI coverage, there was a crossover point when diabetes became the leading cause of ESKD (35.3%). This could be due to the increasing prevalence of diabetes in Taiwan resulting in an increase in the number of patients at risk of diabetic nephropathy and those that progress to ESKD. In addition, more diabetic patients were able to access better healthcare and this increased the chances of developing end-stage

diabetic nephropathy as opposed to dying from other acute or chronic diabetes-related complications (65, 66).

Yang et al also noted a decrease in the first-year mortality, in all age groups, before NHI reimbursement. This could be explained by the fewer incoming patients without medical insurance before the NHI system especially elderly ESKD or diabetic patients who might have already given up on dialysis because of the huge financial burden. However, the first-year mortality increased sharply, in all patients, following the launch of the NHI system but was more obvious in the elderly age groups aged over 65 years. This could reflect the effect of an increase in the number of elderly ESKD patients on dialysis having worse prognosis and high first-year mortality.

The cumulative survival rates were found to be worse in the groups aged over 65 years compared to the all-patient group. The survival rates among the elderly patients were better in the pre-reimbursement cohort compared to the post-reimbursement cohort (65). These increasing trends of ESKD incidence and prevalence noted in Taiwan were closely related to implementation of the national health insurance in 1995.

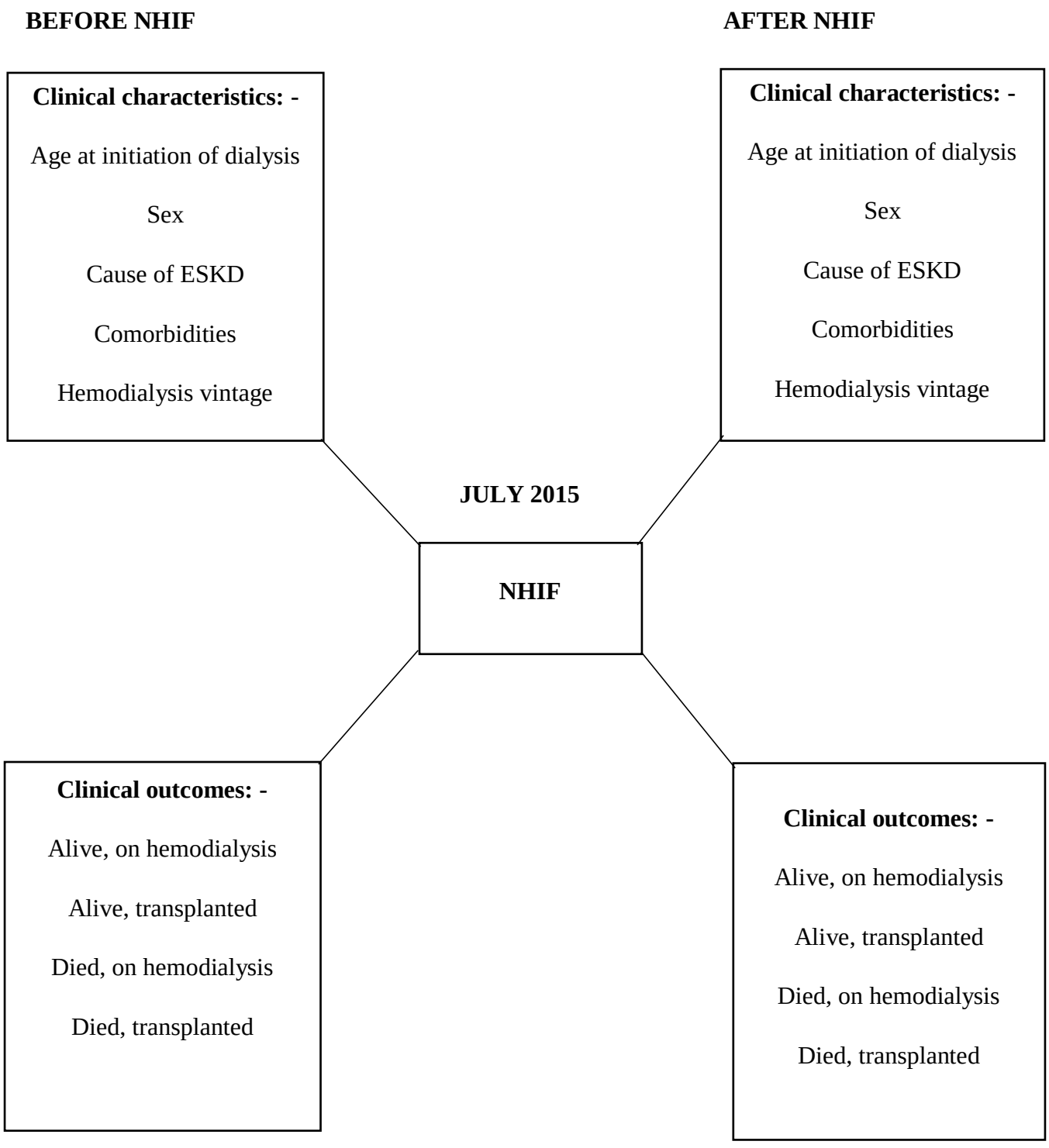

Figure 2.1 Theoretical framework

Chapter 3 METHODOLOGY

In this chapter, I discuss the research design, area of study, study population, sample of the population, sampling technique, instrument for data collection, validation of the questionnaire, administration of the instrument and method of data analysis.

3.1 Study design

This was an ambispective observational study among ESKD patients who had been treated with HD in Kenyatta National Hospital between June 2013- June 2015 and July 2015 - May 2018.

3.2 Study area

The study was conducted at the records department in Kenyatta National Hospital. KNH is a teaching, research and referral hospital located in Upper Hill area in Nairobi, Kenya. It also serves the greater East and Central African region. It has a capacity of about 2,000 beds and offers general and specialized clinics and in-patient services. Renal unit is one of the specialized units in the hospital offering dialysis and kidney transplantation services.

Kenyatta National Hospital was the first public hospital to offer hemodialysis services in Kenya in 1979. Through the years, it has been serving close to 300 patients on a regular basis but with the opening of dialysis units in the county hospitals, the numbers have gone down to around 120 patients. However, most patients still come to KNH for vascular access creation and initiation of hemodialysis then thereafter transfer to the county hospitals to continue with hemodialysis

3.3 Study population

Patients who had ESKD treated with HD between June 2013 - June 2015 and July 2015 - May 2018 as documented in the medical records. The patients' medical records kept by the health

records and information office were retrieved and perused for eligibility. The telephone numbers of all the eligible patients and the next of kin were noted and used to contact the patient or next of kin to ascertain the current status of the patient.

3.3.1 Case definition

Medical records of adult patients aged 18 years and above who had ESKD treated with HD between June 2013 - June2015 and July 2015 - May 2018 as documented in the medical records.

3.3.2 Inclusion criteria

Medical records of adult patients aged 18 years and above who had ESKD treated with HD between June 2013 - June 2015 and July 2015 - May 2018 as documented in the medical records.

3.3.3 Exclusion criteria

Missing or incomplete data and those who themselves or their next of kin were not be traceable by telephone.

3.4 Sample size determination

This was an ambispective observational study among ESKD patients on HD in KNH between June 2013 - June 2015 & July 2015 - May 2018. A total of 3135 patient records were captured in the patient's registry book in Renal Unit between 2013 and 2018. Filtering was done and out of the remaining 1676 files, only 660 medical records were available for review. The sample size was calculated and random sampling done, 141 medical records in the pre-NHIF group and 197 in the post-NHIF group were reviewed. The equation below was used to calculate sample size, with a confidence interval of 95% and a margin of error of 5%.

Sample size calculation (Equation):

$$Sample\ size = \frac{\frac{z^2 \times p(1-p)}{e^2}}{1 + \left(\frac{z^2 \times p(1-p)}{e^2 N}\right)}$$

where N = population size; e = margin of error; z = z score; p = sample proportion

3.5 Screening and recruitment

The principal investigator (PI) obtained the patients' records from the patients register book in Renal Unit Health Records and Information Department. The medical records for ESKD patients treated with HD between June 2013 - June 2015 and July 2015 - May 2018 were retrieved. The medical records were perused for eligibility. For all the eligible patients, their telephone numbers and that of the next of kin were noted. The patients or their next of kin were contacted through telephone to confirm the current status of the patient. The other relevant data was extracted and filled into the study proforma. The proformas were identified by unique numbers for anonymity.

3.6 Study variables

- **Dependent variables -** clinical outcome (dead or alive, on hemodialysis or transplanted)
- **Independent variables -** age, sex, documented cause of ESKD, hemodialysis vintage

3.7 Research instruments

The data was extracted from the medical records and filled into the study proforma which captured the relevant data (Appendix 1).

3.8 Data management

<u>Data collection procedure</u>

The principal investigator perused through the medical records to obtain the relevant information. The earliest records of sociodemographic and clinical data such as age, sex, county of residence, marital status, education level, employment status, NHIF status, documented cause of ESKD, viral seropositivity, type of vascular access at initiation of HD, transplant status was recorded. The PI called the patient or the next of kin to establish the clinical outcome/ current clinical status of the patient i.e., whether the patient is alive or deceased, if still on hemodialysis or has transitioned to transplantation. If deceased, the month, and the year of death was documented. The study proformas were identified by unique codes to conceal the patients' identity. The filled forms were kept under lock and key by the principal investigator.

Data management and analysis

Data was entered into preprogrammed Statistical Package for the Social Sciences (SPSS®) version 20. Continuous variables were expressed as mean ± standard deviation for normally distributed data or as median for skewed data. Categorical data was presented using counts and percentages. The differences and similarities in the clinical profiles and outcomes between the two groups (out-of-pocket payment and national health insurance reimbursement) were analysed using the t-test for normally distributed continuous data and the chi-square test for categorical measures.

Dissemination of study findings

The findings of this study will be communicated to KNH in order to improve patient care. The study findings will also be published in a scientific journal.

3.9Ethical considerations

The study was carried out following approval by the University of Nairobi/ Kenyatta National Hospital Ethics and Research Committee, Research Approval number P325/05/2021. Authority to

use the medical records was sought from the in-charge of Health Information and Records Department. Consent was sought from the patient or their next of kin through a telephone call (Appendix 2). Coding of patients' information was done to maintain patient privacy. Information gathered was considered private and confidential, and was only used for the purpose of this study.

3.10 Quality assurance

The data collection tool was pre-tested by randomly selecting ten files i.e., two files from each year. The medical records were retrieved from the records department, the PI then perused through the medical file and established whether the data of interest was available in the medical records. Each study proforma had a serial number linking it to the patients' medical record. All study proformas were reviewed to ensure completeness of data after which the data was transferred to an SPSS data base. Cleaning and verification of the data was done before data analysis. Back up for the extracted data was done by storing the data on email. This was accessible to the principal investigator only. The hard copies of the study proformas shall be destroyed six months after successful completion of the study.

Chapter 4 RESULTS

4.1 Introduction

The goal of this study was to describe and compare selected clinical profiles and outcomes of ESKD patients treated with HD at KNH between June 2013 and June 2015 (pre-NHIF), as well as July 2015 and May 2018 (post-NHIF). The study sought to shed light on some aspects of the treatment of ESKD with hemodialysis during a time when patients borne all costs (pre-NHIF) and national health insurance agreed to reimburse for hemodialysis services (post-NHIF). The research was carried out at the KNH Health Records and Information department between September and October 2021.

4.2 Flow chart

A total of 3135 patient records were captured in the patient's registry book in Renal Unit between 2013 and 2018. Filtering was done and out of the remaining 1676 files, only 660 medical records were available for review. The sample size was calculated and random sampling done, 141 medical records in the pre-NHIF group and 197 in the post-NHIF group were reviewed.

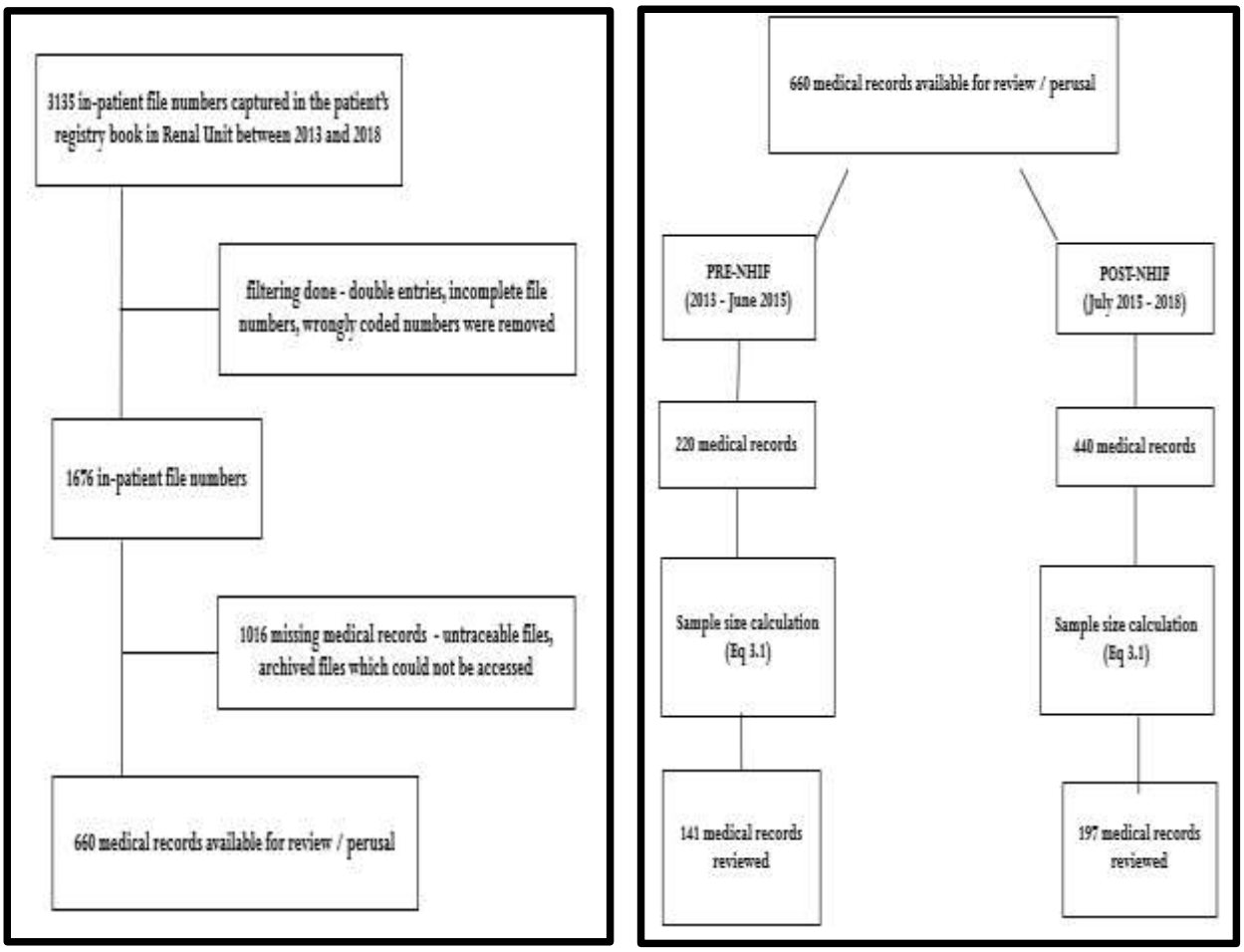

Figure 1: Recruitment process

A total of 338 files, 141 in the pre-NHIF group and 197 in the post-NHIF group were reviewed. The mean age at onset of HD did not differ significantly between the two groups during the study interval, with a reported mean age of 46.76 years in the pre-NHIF group and 46.96 years in the post-NHIF group. Males constituted a larger proportion of study participants in both groups, accounting for 64% (pre-NHIF) and 60% (post-NHIF). As shown in Table 4.1, majority of the study participants in both groups were married.

Table 4.1: Demographics				
Characteristic	**Pre-NHIF (N = 141)**	**Post-NHIF (N = 197)**	**All (N = 338)**	**p value**
Age at HD initiation (year)				
Mean ± SD	46.76 ± 15.55	46.96 ± 15.54	46.88 ± 15.52	0.91
Sex				
Male n (%)	90 (63.8)	119 (60.4)	209 (61.8)	0.52
Female n (%)	51 (36.2)	78 (39.6)	129 (38.2)	
Marital status				
Married n (%)	112 (79.4)	152 (77.2)	264 (78.1)	0.82
Separated n (%)	2 (1.4)	1 (0.5)	3 (0.9)	
Single n (%)	24 (17.0)	38 (19.3)	62 (18.3)	
Widowed n (%)	3 (2.1)	6 (3.0)	9 (2.7)	

Table 4.2: Clinical characteristics				
Characteristic	**Pre-NHIF (N = 141)**	**Post-NHIF (N = 197)**	**All (N = 338)**	**p value**
Causes of ESKD				
Diabetes n (%)	43 (30.5)	76 (38.6)	119 (35.2)	0.12
Hypertension n (%)	78 (55.3)	120 (60.9)	198 (58.6)	0.31
Glomerulonephritis n (%)	53 (37.6)	47 (23.9)	100 (29.6)	0.08
Obstructive uropathy n (%)	13 (9.2)	19 (9.6)	32 (9.5)	0.90
Polycystic kidney disease n (%)	3 (2.1)	6 (3.0)	9 (2.7)	0.53
Chronic graft dysfunction n (%)	2 (1.4)	1 (0.5)	3 (0.9)	0.42
Pregnancy related n (%)	3 (2.1)	8 (4.1)	11 (3.3)	0.30
Retroviral disease n (%)	7 (5.0)	16 (8.1)	23 (6.8)	0.40

Table 4.2 summarises the documented causes of ESKD. Hypertension, diabetes, chronic glomerulonephritis and obstructive uropathy were the leading causes of ESKD in both groups. Overall, the number of cases for the various causes of ESKD increased over the years. Diabetes and hypertension saw the greatest percentage increases, at 8% and 6%, respectively.

During the study, the number of hepatitis B positive patients increased from 5 to 13. Similarly, the number of HIV-positive patients increased from 7 to 16. None of our patients were found to have hepatitis C. However, none of these increases in the number of cases were found to be statistically significant as depicted in Table 4.3 below.

Table 4.3: Clinical characteristics

Characteristic	**Pre-NHIF (N = 141)**	**Post-NHIF (N = 197)**	**All (N = 338)**	**p value**
HBsAg status				
Negative n (%)	136 (96.5)	184 (93.4)	320 (94.7)	0.20
Positive n (%)	5 (3.5)	13 (6.6)	18 (5.3)	
HIV status				
Negative n (%)	134 (95.0)	181 (91.9)	315 (93.2)	0.40
Positive n (%)	7 (5.0)	16 (8.1)	23 (6.8)	
HCV status				
Negative n (%)	141 (100)	197 (100)	338 (100)	0.28

Looking at number of hemodialysis sessions per week, patients in the pre-NHIF group had a lower mean (1.94 ± 0.6 months) compared to patients in the post-NHIF (2.12 ± 0.35). This was also found to be statistically significant (p value 0.04). Similarly, the number of patients on once-weekly hemodialysis decreased significantly in the post-NHIF group while the number on twice-weekly hemodialysis almost doubled (p value 0.04). The average HD vintage in our study was

32.9 months overall, but we noted a decrease in HD vintage after introduction of NHIF (36.3 vs 30.5 months) as shown in Table 4.4 below.

Table 4.4: Clinical characteristics				
Characteristic	**Pre-NHIF (N = 141)**	**Post-NHIF (N = 197)**	**All (N = 338)**	**p value**
HD sessions **1 session n (%)** **2 sessions n (%)** **Unknown n (%)**	 35 (24.8) 79 (56.0) 27 (19.1)	 2 (1.0) 169 (85.8) 26 (13.2)	 37 (10.9) 247 (73.1) 54 (16.0)	0.04
HD sessions **Mean ± SD**	1.94 ± 0.663	2.12 ± 0.358	2.05 ± 0.515	0.04
HD vintage (month) **Mean ± SD**	36.28 ± 34.09	30.48 ± 18.99	32.90 ± 26.47	0.07

Most patients had an acute vascular access at initiation of HD. There was a decline in the use of nontunneled subclavian catheters; 87% in the pre-NHIF group and 62% in the post-NHIF group. Use of the internal jugular vein increased to 30% in the post-NHIF group compared to 5% in the pre-NHIF group. Uptake of AVF remained low in both groups at 1% and 2% respectively.

Table 4.5: Clinical characteristics				
Characteristic	**Pre-NHIF (N = 141)**	**Post-NHIF (N = 197)**	**All (N = 338)**	**p value**
Vascular access **AVF n (%)** **ntfemoral n (%)** **ntIJ n (%)** **ntSubclavian n (%)** **tunfemoral n (%)** **tunIJ n (%)**	 2 (1.4) 7 (5.0) 5 (3.5) 123 (87.2) 2 (1.4) 2 (1.4)	 4 (2.0) 10 (5.1) 32 (16.2) 122 (61.9) 1 (0.5) 28 (14.2)	 6 (1.8) 17 (5.0) 37 (10.9) 245 (72.5) 3 (0.9) 30 (8.9)	0.16

Table 4.6: Clinical outcomes				
Characteristic	**Pre-NHIF (N = 141)**	**Post-NHIF (N = 197)**	**All (N = 338)**	**p value**
Outcomes				
Alive n (%)	20 (14.2)	47 (23.9)	67 (19.8)	0.47
Dead n (%)	121 (85.8)	150 (76.1)	271 (80.2)	
Alive on HD n (%)	9 (6.4)	33 (16.8)	42 (12.4)	0.12
Alive on KTx n (%)	6 (4.3)	3 (1.5)	9 (2.7)	0.13
Deceased on HD n (%)	120 (85.1)	149 (75.6)	269 (79.6)	0.10
Deceased after KTx n (%)	1 (0.7)	1 (0.5)	2 (0.6)	0.76
Alive not on HD or KTx n (%)	5 (3.5)	11 (5.6)	16 (4.7)	0.50

The mortality rate for ESKD patients receiving hemodialysis was 79.6%. Of the 67 patients who survived, 42 were on HD, 9 had a functioning kidney graft, and 16 had recovered kidney function. As summarised in Table 4.6, 269 patients (79.6 %) died while on dialysis, and only two (0.6%) died with a functioning graft. Our mortality rate was high at 80% with more deaths being reported in the pre-NHIF group (85%) but the mortality rate remained high in the post-NHIF group at 76%. Patients on hemodialysis continued to die at a higher rate than patients who had undergone kidney transplantation in both groups.

Chapter 5: DISCUSSION

The ever-increasing prevalence of ESKD places a huge burden on healthcare systems, as well as patients and caregivers. This presents a significant challenge in the delivery and management of ESKD services, particularly in resource-constrained settings. Unfortunately, CKD is still underappreciated, and early diagnosis is frequently missed due to the nature of its nonspecific symptoms. The clinical profiles and clinical outcomes of 338 patients on maintenance hemodialysis at KNH were examined in this study.

When compared to reports from developed countries where ESKD affects the elderly, 60 years and above, the participants in this study were relatively young (10). However, our findings are consistent with many reports from developing countries (8, 45, 67). According to a systematic review of studies conducted in Sub-Saharan Africa, the mean age ranged from 35.6 years (SD 13.2) to 58.2 years (SD 15.0) (68).

The mean age at HD initiation did not differ between the two groups (pre-NHIF & post-NHIF), indicating that even with NHIF reimbursement, there was no increase in the number of elderly patients on hemodialysis. Similarly, no difference in gender was found between the two groups. Males outnumbered females in both groups, this is consistent with studies from most other countries (10, 69). Male gender is a known risk factor for CKD, hence male predominance among the ESKD population is a worldwide phenomenon (70).

In our study, the leading causes of ESKD were hypertension, diabetes, glomerulonephritis, and obstructive uropathy. Glomerulonephritis and HIV infection decreased with age, whereas diabetes alone or in combination with hypertension increased. This aetiologic profile is consistent with previous African studies (8, 67, 71-73). Diabetes and high blood pressure remained the most

common documented causes of ESKD in both groups. Overall, the number of cases for the various documented causes of ESKD was noted to have increased in the post-NHIF group. However, none of these increases in number of cases were found to be statistically significant. It is well known that blacks are more likely to develop hypertension and glomerulonephritis, which may explain the aetiologic pattern of ESKD in our study. Sedentary lifestyles, obesity, and an ageing population may also contribute to the increase in the number of cases reported in this study. In addition, low levels of awareness, detection, treatment, and control of blood pressure and blood sugar are also possible contributing factors, like what has been found in other studies (74-76).

A third of the participants in our study had chronic glomerulonephritis, there was no statistically significant difference between the two groups. In a Nigerian retrospective study, 34.5% of the study population had CGN (77). In our study, CGN was presumed based on either a history of documented glomerular disease or the presence of a glomerular syndrome (proteinuria and/or hematuria, hypertension in the absence of identifiable secondary causes). Only about 6% of patients had a confirmatory kidney biopsy report, indicating a scarcity of facilities capable of performing kidney biopsies and histology at reasonable rates.

ESKD caused by HIV nephropathy was common among young people and women, mirroring the demographics of HIV infection in Africa (78). Only 6.8% of our study participants were infected with HIV, which is comparable to the 6.6% reported in Cameroon but slightly lower than the 10.4% reported in Tanzania (67) (73). We noted a rise in the number of HIV cases in the post-NHIF group, though it was not statistically significant. This trend may be due to improved comprehensive care for patients with retroviral disease, as well as easy access to kidney-friendly regimens when indicated. It was difficult to ascertain how many of our patients had secondary hypertension due to a primary renal disease. Unfortunately, many of our patients did not undergo

a diagnostic kidney biopsy as part of their evaluation mainly due to the cost implications, availability of the service as well as late presentation.

Financial constraints are a well-known reason for developing countries' lack of access to KRT (79, 80). Prior to the implementation of NHIF reimbursement in July 2015, nearly one-fourth (25%) of our study participants were on once-weekly hemodialysis. However, since the implementation of NHIF reimbursement, this figure significantly dropped to 1% (p value 0.04, 95%). Unfortunately, none of our patients were on thrice weekly dialysis. Failure to meet the international recommendation of thrice weekly dialysis despite NHIF reimbursement, may have contributed to the poor outcomes observed in this study. This reflects a lack of hemodialysis service sustainability, which has been observed in other countries as well (81, 82). Hemodialysis is the most widely used form of kidney replacement therapy in the world (9). Inadequate infrastructure and high out-of-pocket costs limit ESKD patients' access to hemodialysis services. As a result, most patients go undiagnosed, untreated, and die prematurely.

The average duration of hemodialysis in our study was 32 months overall, but we noticed a significant decrease in HD vintage after introduction of NHIF (p value 0.04, 95%). This could partly be because frail patients and patients thought to have a poor prognosis were now able to access hemodialysis services through the NHIF system. Furthermore, NHIF does not cover the entire cost of hemodialysis, so patients must pay out of pocket for investigations and medications. This in effect means that some patients are unable to cater for the other demands that come with ESKD as documented by Yang et al (80). Third, NHIF only covers two hemodialysis sessions, which is insufficient for the majority of our ESKD patients, this translates to higher mortality and shorter hemodialysis vintage. According to a Tanzanian retrospective study, patients who were not enrolled in the NHIF scheme had a higher risk of poor outcomes (67). Many patients in Nigeria

and Sub-Saharan Africa were unable to pay for the recommended adequate dialysis sessions due to high costs, with only 6.8% of patients able to afford hemodialysis services beyond 3 months, according to studies from Nigeria and Sub-Saharan Africa (77, 82).

The mortality observed in our study was high (80%), this was double what was reported by McLigeyo et al in 1985. More deaths were reported in the pre-NHIF group (85%) but the mortality rate remained high in the post-NHIF group (76%). This could be attributed to an increase in the number of critically ill patients being initiated on hemodialysis as well as late presentation resulting in unavoidable deaths. NHIF usually caters for two sessions per week meaning that most patients are on suboptimal treatment. Although we did not investigate the causes of death, most of our patients had diabetes and hypertension, which would invariably increase their cardiovascular risk, resulting in poor outcomes. This is consistent with the findings of a two-year retrospective study conducted in a tertiary hospital in southern Nigeria, where only 27% of patients were still alive at the end of the two years (77). Dialysis duration and number of sessions were strong predictors of survival among dialysis patients in Ghana and Lithuania (83, 84). Even in resource-rich environments, the same has been reported (85).

Patients had to travel long distances to access hemodialysis services before county hospitals in Kenya began offering the services in 2015. This had a significant impact on adherence to hemodialysis appointments, resulting in premature dialysis discontinuation and hence poor outcomes (80). A systematic review conducted to investigate the outcomes of dialysis in ESKD in Sub-Saharan Africa discovered that the majority of ESKD patients starting dialysis in Sub-Saharan Africa discontinue treatment and die (68). The mortality rate among hemodialysis patients varies by country, ranging from 6% in Morocco, 10.4% in Tunisia, 12% in Algeria (86).

Other KRT options (peritoneal dialysis and kidney transplantation) are less common due to the high costs and lack of facilities (8). Only 3% of patients in our study went on to receive a kidney transplant. This could be because NHIF does not cater for post-transplant costs (medication, clinic visits, laboratory, and imaging costs), so most patients choose to stay on hemodialysis since it is already covered by NHIF. Given the high mortality rate reported in this study, we should endeavour to better support the kidney transplant program which is clearly associated with better outcomes.

Conclusion

The mortality rate remained quite high during both time periods. In as much as NHIF reimbursement increased access to hemodialysis, it did not have any impact on clinical outcomes including survival. This suggests that there could be other factors like quality of hemodialysis offered, complications associated with hemodialysis that play a crucial role in the clinical outcomes as well.

Recommendations

1. The causes of death in our hemodialysis patients should be investigated in order to identify any preventable measures that can be implemented to reduce mortality in our HD patients.
2. Timely kidney biopsies will aid in more accurate diagnosis, especially in our young patient population.
3. Poor vascular access may have contributed to poor outcomes; therefore, we should advocate for early and planned vascular access in our patients.

4. Investigate the reasons for dialysis discontinuation and the factors that contribute to dialysis discontinuation. As well as the difficulties/ challenges faced by hemodialysis patients, this may aid in improving outcomes.
5. Implement electronic medical records, and create renal registries that include all CKD patients. Using such registries, it will be easier to plan for better care and ensure that patients are not lost to follow up only to reappear when they require urgent dialysis.

Study strength

The study center continues to house the country's largest hemodialysis unit. As a result, the population described in this study is very likely to be representative of the people with ESKD in the country.

Study limitations

1. Because this was a chart review, some data was missing or was poorly documented. Record keeping can be quite poor in the absence of electronic records. As a result, the amount and quality of data extracted may be suboptimal.
2. Many of our study participants did not have a histology report to confirm the cause of ESKD.
3. There was recall bias because some patients and their next of kin were unable to recall all the required details.
4. Because some of the potential participants were not reachable by phone, information on the patients' current clinical status was not easily accessible.

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APPENDICES

Appendix 1: Data collection tool

Study serial number: ….……..

A. Sociodemographic characteristics

A1. Unique identifier - …….

A2. When was the patient initiated on hemodialysis? (mm/yyyy) ……/20……

A3. What was the age of the patient at initiation of hemodialysis? (years) ……

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

A5. County of residence - …….

A6. Marital status -[1] single [2] married [3] separated [4] widowed

A7. Highest level of education attained -[1] primary [2] secondary [3] tertiary

A8. Employment status-[1] unemployed [2] employed

A9. Does the patient have medical insurance other than NHIF - [1] Yes [2] No

B. Clinical characteristics

B1. Is the cause of ESKD documented? [1] Yes [2] No

B1.1. Diabetes: ….……..……[1] Yes [2] No

B1.2. Hypertensive: ……..[1] Yes [2] No

B1.3. Glomerulonephritis ……....**.**[1] Yes [2] No

B1.4. Obstructive uropathy……[1] Yes [2] No

B1.5. Lupus nephritis: …..…… [1] Yes [2] No

B1.6. ADPKD: ……[1] Yes [2] No

B1.7. Chronic allograft dysfunction ….[1] Yes [2] No

B1.8. Pregnancy-related diseases…….[1] Yes [2] No

B1.9 Others: (specify)……..……. [1] Yes [2] No

B2. What was the viral seropositivity at initiation of hemodialysis?

B2.1.Hepatitis B: …….…….....[1] Positive [2] Negative

B3. What was the vascular access at initiation of hemodialysis?

[1] non-tunneled internal jugular catheter

[2] non-tunneled femoral catheter

[3] non-tunneled subclavian catheter

[4] tunneled internal jugular catheter

[5] tunneled femoral catheter

[6] arteriovenous fistula

B4. How many dialysis sessions per week was the patient receiving? ……

B5. Has the patient transferred to another dialysis center? [1] Yes [2] No

If yes, to…… [1] another public dialysis unit [2] a private dialysis unit

C. Clinical outcomes section

C1. How is the patient currently?

[1] Alive on HD

[2] Alive having transplanted **C1.1** If transplanted, which year (mm/yyyy) …./20…….

[3] Deceased while on HD **C1.2** If deceased while on HD, which year (mm/yyyy) ……/20……

[4] Deceased after kidney transplantation **C1.3**If deceased after kidney transplantation, which year (mm/yyyy) ……/20……

C5. What is the patients' hemodialysis vintage? State the duration in months …….

Appendix 2: Verbal consent form

TITLE OF STUDY: CLINICAL PROFILES AND OUTCOMES OF END-STAGE KIDNEY DISEASE ADULT PATIENTS TREATED WITH HEMODIALYSIS AT THE KENYATTA NATIONAL HOSPITAL DURING OUT-OF-POCKET PAYMENT AND NATIONAL HEALTH INSURANCE REIMBURSEMENT FOR HEMODIALYSIS SERVICES

Hello, my name is Dr. Wanjiru Kibe, I am studying to become a kidney specialist at the East African Kidney Institute, University of Nairobi. I am attached to the Kenyatta National Hospital Renal Department.

You have been randomly chosen to participate in a study that aims to look at the clinical profiles and outcomes of patients treated with hemodialysis before and after national health insurance reimbursement for hemodialysis. In this study, we shall document the year you were initiated on hemodialysis, your age at initiation of dialysis, the cause of your kidney disease and whether you are still on hemodialysis or have transitioned to kidney transplant.

This will take approximately fifteen minutes of your time. If you choose to participate in the study, I will proceed to ask you a few questions whose answers I shall fill in a study form. There are no foreseeable risks or benefits for participating in this study; neither is there a cost or payment to you. You are free to ask any questions and seek clarification at any time. We shall keep your information private and confidential but we cannot guarantee absolute anonymity. We will link your answers to you initially by assigning a unique code to your study form but this link will be removed later so as to protect you.

If you have any questions or concerns regarding this research, you can contact Dr. Wanjiru Kibe on 0723486685. If you have any questions regarding your rights as a research participant you can call the secretary/ chairperson KNH-UoN ERC on Tel. No 2726300 Ext 44102.

Your participation in this study is voluntary hence you will not be penalized or lose any benefits if you refuse to participate. May I continue? YES/ NO

I certify that I have consented the participant (code no.) …….

Researcher's name: ……..……...

Signature: ……..

Date: ……..

This study has approval by the Kenyatta National Hospital – University of Nairobi Ethics and Research Committee protocol number P325/05/2021