CONSERVATIVE KIDNEY MANAGEMENT PROGRAM COMPONENTS IN A RESOURCE LIMITED SETTING: SOUTH AFRICA

BY

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DEDICATION

Behind my success there are three powerful women that I would like to dedicate this mini dissertation to. To the mother of my three children, the love of my life, Joy Nkateko Zungu, thank you so much for your love, your patience, wisdom and support throughout this research journey.

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ABSTRACT

Background: End Stage Kidney Disease (ESKD) is emerging as one of the most challenging diseases on the rise and unfortunately very expensive to manage. Countries, including South Africa (SA), have a challenge in equitably providing resources to meet the needs of patients with ESKD. In some SA tertiary institutions, more than half of patients who apply for enrolment into Renal Replacement Therapy (RRT) program are not selected due to resource limitation in the dialysis program. Many patients with ESKD are managed in Primary Health Care (PHC) settings with either no access to Palliative Care (PC) and/or prompt referral. There is a need for a standardised program that is well informed by policy to improve the delivery of care for patients with ESKD, especially those who fall under the choice restricted Conservative Kidney Management (CKM) pathway of Kidney Supportive Care (KSC).

Aim: This study aimed to determine the perceived standards or components of care in providing CKM services in low resourced countries like SA.

Objectives: To describe standards or components of a CKM program; to identify available CKM documents in SA; and to analyse SA CKM documents according to perceived standards or components of a CKM program.

Methodology: This was a qualitative study with semi-structured expert interviews, in-depth interviews and document analysis of SA ESKD documents. Participants were selected purposefully and through snowballing. Of the participants, seven (7) were in SA, one (1) in Australia and one (1) in Uganda. Secondary data collections were conducted through desktop analysis of SA ESKD documents. Data were analysed through thematic analysis coded using inductive, and some aspects of deductive analysis guided by the health systems building blocks. The NVivo version 12 software data analysis tool was utilised. A data extraction template was used to extract data from documents that met inclusion criteria for the study.

Findings: While dialysis and kidney transplantation are highly technical elements of KSC and generally need the technical leadership of a nephrologist, the comprehensiveness of KSC requires other stakeholders who specialise in preventative and palliative care medicine for its full delivery. A more integrated interdisciplinary response is needed for a successful CKM program. Furthermore, it is not only CKM patients that must move from tertiary facilities to primary care centres, but information, resources and skills must also move and be available in primary care centres for continuity of care. Choice restricted CKM without a proper CKM program leads to patient presenting in acute settings without Advance Care Planning (ACP) leading to an increase in health care cost with repeated extensive workups costing countries more in both direct and indirect costs. Poor organ transplantation policy framework does not only require support with funding but also relies on a good organ transplant policy framework and increased public awareness on organ donation. Most analysed documents where silent on transplant policy framework involvement, leadership and financing of CKM programs. The confusion in KSC terminology was also noted on analysed documents. It is important that policies and documents in

Low- and Middle-Income Countries (LMIC) align themselves with the new core curriculum as led by the International Society of Nephrology (ISN) to avoid confusion of terms and definitions of KSC and CKM.

Conclusion: This study has identified the need for and proposed an essential package of service for CKM in a low resourced setting like SA. This study proposes that such a package should be founded on the health systems building blocks and all components should be integrated, coherent and coordinated. This study will serve as a baseline study for more in-depth studies and possible a CKM program framework. CKM program needs to be funded as per commitment by SA, a co-sponsor of World Health Assemble (WHA) 67.19 resolution which states that all clinicians working in areas with a high burden of patients (such as nephrology) in need of PC need intermediate level training in PC as a matter of urgency.

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LIST OF ABBREVIATIONS

ESKD	End Stage Kidney Disease
WBOT	Ward Based Outreach Teams
CBO	Community Based Organisations
KSC	Kidney Supportive Care
CKM	Conservative Kidney Management
CCI	Charlson Comorbidity Index
RRT	Renal Replacement Therapy
PHC	Primary Health Care
PC	Palliative Care
UHC	Universal Health Coverage
LMIC	Low- and Middle-Income Countries
WHO	World Health Organisation
SA	South Africa
WHA	World Health Assembly
ACP	Advance Care Planning
AKD	Acute Kidney Disease
CKD	Chronic Kidney Disease
HD	Haemodialysis
PD	Peritoneal dialysis
IHD	Ischaemic Heart Disease
KT	Kidney Transplant
USA	United States of America
PS	Performance Status
DoH	Department of Health
ISN	International Society of Nephrologists
NGO	Non-Governmental Organisation

CHAPTER 1: INTRODUCTION AND BACKGROUND

With diseases of lifestyle crippling the whole world, it is not a surprise that End Stage Kidney Disease (ESKD) is emerging as one of the challenging diseases on the rise and, unfortunately, very expensive to manage.[1] Countries, including South Africa(SA), have a challenge in equitably providing resources to meet the needs of patients with ESKD.[2] In some SA tertiary institutions more than half of patients who apply for enrolment into Renal Replacement Therapy(RRT) program are not selected because of resources limitation in the dialysis program.[3] A large number of patients with ESKD are managed in Primary Health Care(PHC) settings with either no access to Palliative Care(PC) and/or prompt referral.[4] The problem of access to PC is not a problem that is unique to SA but one that affects many ESKD patients around the globe especially in Low and Middle Income Countries(LMIC).[2]

Out of the 54 countries in Africa, SA is one of only 12 countries that offer Renal Replacement Therapy (RRT) to citizens with ESKD.[5] This emphasises the fact that many patients in LMIC do not have access to RRT. Current RRT options in SA include haemodialysis (HD), peritoneal dialysis (PD) and kidney transplantation (KT). Despite many challenges, the development of nephrology in SA has been fortunate to develop in a similar way as higher-income countries (especially in private setting), albeit in a much smaller scale and with differences in primary insults causing ESKD.[5]

The true prevalence and numbers of patients of ESKD in SA remains largely unknown especially in the public sector due to under-reporting.[6] According to the SA Renal Registry Annual Report 2016 the Western Cape has the highest prevalence followed by Gauteng province and there is a huge backlog of patients in need of accessing RRT in these provinces. This necessitates the need for a well thought of and implementable country wide Package of Nephrology Services (PNS) allowing patients with ESKD to access the standardised and comprehensive services that include best practices for CKM. This model of care of care or PNS should be the most minimum care acceptable and implementable in both public and private care. There currently are no known published prescripts for CKM in SA unlike in high income countries like Australia and the United States of America (USA) leading to heterogeneity in available nephrology services in different SA provinces.

A challenging concern from nephrologists has been that providing PC or a robust CKM pathway may excuse the government from investing in adequate renal care services including the support of renal transplantation programs.[3] Given the resource scarcity, the SA Constitutional Court has ruled that rationing of dialysis is appropriate by applying the ethical principle of utilitarianism.[3] What is most unfortunate regarding the poor access to PC is the fact that it continues despite SA having a robust PC policy and other formal documents seeking to protect and address the PC needs of patients.

The causes of ESKD, needs and care for patients with ESKD are complex thus documents seeking to deliver the package of care for ESKD must be complex and comprehensive enough to address the ethical complexities associated with the implementation of CKM services.

Policies and documents that seek to address the needs of patients with ESKD must have a strong stance and plan for the addressing of the PC needs of patients with ESKD. This contributes to the avoidance of abandonment when patients with ESKD are deemed not to qualify for RRT. Abandonment exists when patients with ESKD in need of PC find themselves in a health system that is not geared up to look after them when diagnosed with ESKD and facing distressing symptoms. Policies and documents that seek to address this problem must be implementable, have a clear understanding of the role of PC in ESKD, relevant and appropriate to the context of the country of implementation.

Not all patients with ESKD require PC, some have very minimal comorbidity and /or are eligible for KT, which if obtained, would substantially change their health related quality of life and mortality risk.[7] However, at some point most patients will move onto a trajectory of progressive functional decline associated with a cluster of physical and psychological symptoms obviating the need to introduce most patients with ESKD requiring RRT to PC concurrently with dialysis and initial RRT education.[7]

The need for PC is often obvious when patients decline in Performance Status(PS), thus unable to attend dialysis, these patients often die in acute care facilities with aggressive biomedical approach to treatment even when physicians and nephrologists are aware of treatment futility.[7] Withdrawal from dialysis (voluntary and involuntary) is another common reason that requires the need for a PC approach. Because of the severe resource constrains in SA, only patients who are considered transplantable and willing to undergo transplantation are accepted onto the public sector dialysis program.[8] The Western Cape is the only province that has an official policy approved by the Human Rights Commission which guides the selection of patients for RRT in the public sector.[8]

Patients with ESKD experience physical, psychological, socio economic and spiritual symptoms which are amiable to the PC approach using validated assessment tools. Hydromorphone, buprenorphine, methadone and fentanyl are the best drugs to use for physical pain and shortness of breath in patients with ESKD as concurred by well renown international authors in renal PC medicine.[7] Authors like Davison(2011) and Murtagh(2010) advocate for the use of these drugs since they are mostly not renal excreted.[7, 9] There is a need to integrate pain scales and opioid risk assessment scores in the management of pain for patients with ESKD.[7]

Low- and middle-income countries like SA may not have these renal friendly drugs easily available or accessible in the public sector and often ESKD patients are left with no choice but to use morphine even though it may linger in the blood system longer and cause toxic side effects like myogenic jerks and over-sedation. Other common symptoms in patients with ESKD including depressed mood, pruritus, restless legs syndrome, sleep disturbance and fatigue and are all amiable to the PC approach.[9]

There is growing understanding that initiating CKM pathway in patients with ESKD does not signal imminent death , conservatively managed ESKD patients can remain stable for long periods.[10] CKM pathway of ESKD does entail active management in the form of actively managing anaemia, metabolic bone disease, electrolyte

abnormalities and aggressive PC to manage distressing symptoms in patients who opt not to start dialysis or not deemed to qualify for dialysis for reasons mentioned earlier. It is important to note that PC in ESKD patients and in general can be an active process and can keep a PC practitioner busy with implacable assessment and treatment of distressing symptoms experienced by patients and families.

ESKD patients often experience existential distress and a high burden of physical and psychological symptoms.[7] PC practitioners are well trained in screening for spiritual distress/existential crisis and management or appropriate referral to other members of the interdisciplinary team making them a valuable assert in management of patients with ESKD and skills transfer to staff working in RRT units. Prognostication in patients with ESKD is inherently difficult with a huge number of patients with heterogeneous outcomes.[7]

A PC approach may assist in ensuring that all patients with ESKD receive patient-specific estimates of their prognosis as recommended the Renal Physicians Association of the America.[11] An increase in age, low serum albumin, poor functional status and comorbidity have been identified (though not proven) clinically useful in prognosticating individual patients at high risk of mortality within the next year.[7] A modified Charlson Comorbidity Index (CCI) that takes age into account has been applied to ESKD patients and often used to identify patients who may be appropriate for PC assessment.[7] The simplest clinical tool in use to identify dialysis patient at high risk of mortality is the Surprise Question (SQ): “Would you be surprised if this patient were to die in the next twelve months?” Unfortunately, neither the CCI or SQ alone are sufficiently sensitive or specific in identifying individuals at high risk of early mortality.[7]

The disparity between LMIC and low resourced countries in accessing CKM is further complicated by the complex needs of patients with ESKD. There is a gap of a CKM package of care or program that should be accessed by all patients in the CKM pathway especially in low resourced countries like SA. This program or package of care for CKM patients should be applicable in the South African setting and other low resourced countries and must identify and address all components needed for the management of CKM patients and their families.

CHAPTER 2: LITERATURE REVIEW

2.1 LITERATURE SEARCH PROCESS

The narrative literature search process was conducted on PubMed through the University of Cape Town library. The literature was conducted from 1st of March 2021 to 31st of August 2023. On PubMed in the University of Cape Town library and Google Scholar, articles from 1st January 2005 to 31st December 2022 we selected specifically looking for full text articles, free full text articles and abstracts. Further filters included that articles that could be meta-analysis, randomised control trials, reviews, systemic reviews, books and documents. The disease "End Stage Kidney Disease" OR "Conservative Kidney Management AND "health policy analysis OR review" AND "palliative care" were the initial keywords and Mesh terms used on advance search. A total of 102 articles were found, 53 full-text articles had abstracts that were found to be relevant were selected transferred to a reference manager EndNote 20 as separate files. Eight of the 53 full-text were found to be not eligible for the study and were excluded. A total of 38 articles used in this review remained after the merging of files from reference manager after duplicates were identified and removed. Two additional articles were provided by a Nephrologist in Limpopo province.

The documents search process followed the same process using the same filters, but the keyword "document" was added. Out of 19 articles found only 4 were found to be relevant and further two documents were provided by a Nephrologist in Limpopo province.

2.2 BURDEN OF END STAGE KIDNEY DISEASE (ESKD)

With diseases of lifestyle crippling the whole world, it is not a surprise that ESKD is emerging as one of the costly and challenging diseases on the rise.[5, 12] ESKD poses a global public health concern with more than 750 million people affected worldwide.[5] The true prevalence and numbers of patients of ESKD in SA remains largely unknown especially in the public sector due to under-reporting.[6] According to the SA Renal Registry Annual Report 2016, there were 10 257 patients with ESKD in SA by end of December 2016, only 1472 (14%) of these patients were reported to be on RRT.[6] This implies that 86% of patients with ESKD were not put on RRT program or dialysis despite them qualifying to be on dialysis.

According to SA Renal Registry Annual Report 2016, the Western Cape was leading with 328 patients on RRT followed by Gauteng Province with 241 patients on RRT.[6] According to the guideline review: priority setting approach in the selection of patients in the public sector with ESKD for RRT in the Western Cape Province in 2015, there were 1220 new ESKD patients by December 2015.[8] The total number of patients who were receiving RRT then was 300, an annual mortality of about 10% and approximately only 60 patients who are successfully transplanted annually.[8] This meant that only 90 new ESKD patients could be accommodated in the program, leaving most patients defaulting by circumstances to PC or CKM pathway.[8] Although these registries are often limited by underreporting and lack of updates, they do give a snapshot of the high burden of ESKD patients in need of CKM in LMIC like SA.

Furthermore, these registries are outdated and do not always include those patients who are not referred to renal units.

The burden of ESKD requiring CKM pathway also remains largely unmet especially in LMIC including SA where there is limited awareness of the pathway, limited staff training for the pathway and poor documentation of its utilisation which may lead to exclusion of CKM from nephrology policies.[12]

The quadruple burden of disease that affects SA is reflected in the aetiology of kidney insults that eventually lead to a need of RRT and thus the need for the involvement of all stakeholders for proactive awareness and preventative measures.[4] Common causes of Acute Kidney Disease (AKD), Chronic Kidney Disease (CKD) and ESKD in SA include: diabetic nephropathy, glomerulonephritis, kidney disease associated with HIV infection, glomerular disease associated with hepatitis B virus, hypertensive renal disease and genetic disorders.[5] AKD is often caused by toxins and trauma since more than 80 percent of the population often use traditional medicines as their principle form of healthcare and trauma together with violent injuries form part of the quadruple burden of disease in the country.[5] HIV and pregnancy related kidney insults are other common causes of AKI often leading to CKD and ESKD contributing to spiral clinical presentations of ESKD symptoms requiring RRT in the resource limited SA.[5] There is however still a big gap in identifying aetiology of kidney disease in SA since many patient are never referred to facilities with the resource for a definitive diagnosis like kidney biopsy and renal ultrasound.[4]

Until recently, patients with HIV were excluded from any form of RRT due to several studies suggesting that outcomes were very poor in patients with HIV and ESKD.[13] The introduction of highly active antiretroviral therapy (HAART) has changed the landscape of RRT in HIV positive patients allowing them to qualify for RRT in SA when their CD4 count is more than 200 cell per micro litre and virally suppressed.[8] Fabian (2015) studied black HIV positive South Africans in the private sector and demonstrated improved survival in HIV positive patients with ESKD on haemodialysis.[13] This study was limited by the fact that it could not necessarily be generalised to the rest of HIV positive patients in the public sector who mostly were from poor socioeconomic status and would not necessarily qualify for dialysis in the public sector due to poverty related factors like ill-health, lack of resources and means to get to dialysis units and other institutional barriers leading to missed dialysis sessions in the public sector.[8] The study also alludes to poor quality of life in HIV positive ESKD patients on haemodialysis associated with higher hospital admissions, higher symptom burden and morbidity related to vascular access infections compared to HIV negative ESKD patients in the cohort.[13]

2.3 TREATMENT OPTIONS IN ESKD

Current RRT options in SA include haemodialysis, peritoneal dialysis and kidney transplantation.[5] RRT focuses on the technical treatment (haemodialysis, peritoneal dialysis and kidney transplant) modalities of ESKD and is only available for the minority of patients with ESKD.

CKM in ESKD has had many names over the past years. It is important to define and understand CKM to avoid confusion since it is often used interchangeable with other

terms in ESKD management. While RRT refers to dialysis and kidney transplant, CKM in patients with ESKD excludes dialysis and kidney transplant.[14] CKM is a comprehensive and holistic pathway for patients with ESKD and has components which include shared decision making, active symptom management, detailed communication which includes ACP, psychological support, social support and spiritual domains of care with some well documented benefits.[14, 15] A systemic review of cohort studies from 1976 to 2014 by Foote (2016) revealed no significant survival benefit at one year for the elderly who either took the dialysis or CKM option.[16] Most of the studies are single centred and there may have been a selection bias in local practices and the fact that most patients who are put on the conservative pathway often have a poor performance status.

Patients over the age of 75 appear to gain no survival benefit over initiating dialysis in the place of managing these patients conservatively, especially among those with high comorbidity scores like Ischaemic Heart Disease (IHD) with some studies reporting severe functional loss within six months of initiating dialysis.[4] In a retrospective analysis study, Fliss et al. demonstrated improved survival in patients over the age of 75 when they chose the dialysis pathway, however increased comorbidity especially IHD was associated with the loss of survival benefit in this age group.[15] The study was limited by its small sample size (n=129), retrospective nature leading to the inability to determine the quality of life of elderly patients who survived on dialysis and the fact that it cannot be generalizable to low resourced countries like SA where the elderly do not qualify for dialysis.

Survival appears to be an important outcome, however, there are other important factors to consider before initiation of dialysis including patient functional status, quality of life, time spent in dialysis units, time spent in hospital and other social inconveniences associated with being in a dialysis program. There generally appears to be a need to move away from dialysis being the default modality for the management of ESKD to a model incorporating patient values, preferences, accessibility of dialysis units and individualised prognosis of ESKD.

2.4 THE COST OF DIALYSIS

Countries including SA have a challenge in equitably providing resources to meet the needs of patients with ESKD.[2] A systemic review by Mushi(2015) attempted to quantify the annual cost (direct and indirect) of dialysis per patient in LMIC the study was largely limited by the lack of data in LMIC.[1] This systematic review included SA data and found an estimated dialysis cost of up to 43 000 British Pounds per patient annually for direct and indirect cost. Even though there was lack of data in the field of dialysis in LMIC, the study found the cost of dialysis to be beyond what individuals can afford and thus the need for dialysis to be included in the package for Universal Health Coverage (UHC).[1] However, UHC also recommends that care should not leave patients nor health systems in poverty.

While CKM pathway costs less than the RRT pathway it is very important to be cognisant of the fact that when indicated it is a non-inferior program that applies evidence based medicine and a viable option for patients with socio-economic problems like transportation to dialysis units, those whom dialysis is not in line with

their values or preferences and the elderly patients with multiple comorbidities especially IHD.[12, 16]

2.5 ACCESS TO RENAL REPLACEMENT THERAPY (RRT) AND PALLIATIVE CARE (PC)

In some SA tertiary institutions more than half of patients who apply for enrolment into RRT program are not selected because of resources limitation in the dialysis program.[3] RRT focuses on the technical treatment (haemodialysis, peritoneal dialysis and kidney transplant) modalities of ESKD and is only available for the minority of patients with ESKD.[8]

A large number of patients with ESKD are managed in primary care facilities with either no access to PC and/or prompt referral to PC services.[4] The problem of access to PC is not a problem that is unique to SA but a problem that affects many ESKD patients around the globe especially in LMIC.[2] Many patients who qualify for ESKD PC in SA continue to suffer due to lack of access or referral to PC services.[3]

It was initially believed that the unaddressed PC needs were due to the lack of a national policy in PC. This belief cannot be true anymore since the release of the SA National Policy Framework and Strategy on PC 2017 to 2022 in 2017.[17] Similar challenges seen in patients with ESKD are seen in patients TB/HIV, cancer and other non-communicable diseases in that many patients in need of PC in rural areas and even prisons continue to have no access to basic PC services.[18,17] The quadruple burden of disease in SA makes it a country in great need of a health system that is responsive to the PC needs of its citizen. Many patients with ESKD are managed in primary care facilities, this exposes the need for such facilities and other levels of care facilities to be able to diagnose ESKD, refer accordingly and appropriately handle data of ESKD patients.[4] PHC facilities should be able to offer PC services to patients with ESKD as an oblique program and contribute to decentralisation and strengthening of CKM program due to the high burden of ESKD.

Because of the severe resource constrains in SA, only patients who are considered transplantable and willing to undergo transplantation are accepted onto the public sector dialysis programmes.[19] As stated, the Western Cape is the only province that has an official policy approved by the Human Rights Commission (HRC) which guides the selection of patients for RRT in the public sector.[8] Category 1 patients are those who are excellent candidates for transplantation (often younger with no comorbidities) and are all accepted into the dialysis programme even if it means they will be in a queue of this competitive program. Category 2 and 3 patients are the most of patients with ESKD and are considered less than ideal for the RRT programme, often due to high comorbidities and challenging social factors that will prevent them from regularly attending dialysis sessions.

The heterogeneity in RRT and CKM access in the SA is also evidenced by the provincial disparities of services and human resource availability.[6] Until March 2022, there had been no public sector nephrologist practising in Mpumalanga Province (MP) of SA and there is currently no available provincial document that informs RRT and CKM. RRT services in MP have been outsourced (from private companies) for many years guided by the SA guideline for renal dialysis for selection of patients for

the dialysis program. Since March 2022 two nephrologist have been made available through a partnership with MP Department of Health (DoH) and Wits Heath Consortium, this marked the beginning of availability of public service driven RRT services in MP starting with acute dialysis availability in Witbank and Rob Ferreira hospitals i.e., the tertiary hospitals in MP (personal communication with Witbank Clinical Manager June 2022). This is an opportunity for the province to begin the process of collecting data for nephrology patients since there currently in no data available regarding RRT and CKM in the province (personal communication with Witbank hospital Clinical Manager, June 2022).

Disparities become apparent when one compares MP with the WC province which is known to have started implementing PC, has a working group and a document on ESKD that has been accepted by the HRC of SA.[4, 8] Limpopo, North West and Northern Cape provinces are facing similar challenges to MP.[6]

2.6 NEPHROLOGY PACKAGE OF SERVICE IN SA

The heterogeneity of RRT and CKM programs in SA necessitates the need for a well thought of and implementable Package of Nephrology Services (PNS) countrywide allowing patients with ESKD to access standardised and comprehensive services that include best practices for CKM and data handling countrywide.[6] This model of care should be the most minimum care acceptable and implementable in both public and private care. There currently are no known published basic standards for CKM or structured KSC programmes in SA unlike in high income countries like Australia, Canada and the USA, this seems to have led to heterogeneity in available nephrology services in SA provinces.[12, 20]

There generally appears to be a high number of patients who do not qualify for any form of RRT when diagnosed with ESKD thus making a robust CKM pathway worthwhile and beneficial to patients with ESKD in LMIC like SA.[3, 4, 20, 21] Palliative Care in ESKD should be provided alongside with curative medical care.[4] As stated, a challenging concern from nephrologists has been that providing PC may excuse governments from investing in adequate renal care services including the support of renal transplantation programs.[3] It is well understood that a country is only obliged to provide health care for its citizens within the available resources thus very few patients make it to the RRT programme and given the resource scarcity in SA, the SA constitutional court has ruled that rationing of dialysis is appropriate by applying the ethical principle of utilitarianism.[3] On the other hand, patients who do not qualify for RRT have the right to CKM and in this case happen to be a great majority of patients with ESKD but have their PC needs not addressed by the health system that has largely not implemented its PC policy.[17]

Programmatically, the care of patients with ESKD can be divided into various components according to Hole (2020) depending on the resources available in the country.[20] Preventative component of care is available in most countries, while the management of kidney disease (RRT) is limited in most LMIC and CKM is minimally available in most LMIC like SA.[20] There are key elements, that are recommended internationally, that are involved in a CKM program. These include the fact that it is an active program governed by principles of nephrology and PC, it is evidence based

in symptom management, shared decision making in the form of skilled communication and provision of prognostic information. Furthermore, it is a patient centred program (biopsychosocial approach) incorporating Advance Care Planning (ACP) and end of life care (EOLC).[20] However, the applicability in our setting has not been reviewed.

Davison(2015) emphasises the importance of family and spiritual care, further Davison emphasises the goal to delay the progress of ESKD and its associated distressing symptoms as the most important in CKM programs.[14] Perhaps the most important aspect or goal for palliative care physicians should be to improve the quality of life with the aim to neither hasten nor prolong life in accordance with the PC principles.[22]

Physical pain is the most common symptom in patients with ESKD and its management forms an integral part in providing PC for patients with ESKD.[9] In a systematic review by Davison(2021) moderate to severe chronic pain appears to be common across diverse ESKD populations.[23] Davison (2021) also found that 60.5% of patients with ESKD on haemodialysis have pain of which 43.6% was moderate to severe pain. Pain was much less in the peritoneal dialysis group (35.9%) and was significant in the CMK group (59.8%).[23] This study was limited by a lack of a consistent approach to defining the chronicity and nature of pain but does give an insight into the prevalence of pain in patients with ESKD. Another limitation of this study was that it focused on ESKD patients on HD and not patients on CKM pathway. High income countries also follow the WHO Three-Step Analgesic Ladder, the use of non-pharmacological pain management modalities and can provide the best care in terms of analgesia and shortness of breath with regards to opioids availability.[23] The WHO ladder does not specify the type of opioid, a factor that is very important in ESKD. Weak opioids are generally not recommended due to complex liver induction processes leading to under and overdosing, this leaves patients with ESKD with the option of WHO step one and three when analgesia is needed.[23]

Hydromorphone, buprenorphine, methadone and fentanyl are the best drugs to use for pain and shortness of breath in patients with ESKD, as concurred by well renown international authors in renal PC medicine, authors like Davison (2011) and Murtagh (2010) advocate for the use of these drugs since they are mostly not renal excreted.[7],[9],[23] There is a need to integrate pain scales and opioid risk assessment scores in the management of pain for patients with ESKD to ensure that issues of opioid abuse are prevented.[23] However, although these are excellent recommendations, low and middle income countries like SA do not have these renal friendly drugs available in the public sector. Therefore, ESKD patients are left with no choice but to use morphine even though it may linger in the blood system longer and cause toxic side effects like myogenic jerks and over-sedation.[22]

Other common physical symptoms amiable to the PC or conservative approach in patients with ESKD include pruritus, restless leg syndrome, sleep disturbance and fatigue.[9] Persistent itchiness related to ESKD can be debilitating and reduce quality of life and is increasingly associated with poor outcomes including mortality in patients with ESKD.[24] The pathogenesis of uraemic pruritis remains unknown and is

not related to urea levels. Skin moisturisers and topical anaesthetics improve localised pruritis while gabapentinoids (strong evidence) are supported by randomised control trials and meta-analysis for systemic itch.[25] However, these drugs are not available at primary care setting nor at most hospital settings.[26]

Restless leg syndrome (RLS) is a clinical diagnosis and is a common symptom in patients with ESKD and is associated with an urge to move legs accompanied by an unpleasant sensation during rest. Up to 50% of patients with ESKD experience RSL and is often associated with progressive disease, peripheral neuropathy and iron deficiency.[9] Management of RLS involves correction of contributing factors, gabapentinoids and dopamine agonists.[9] The relevance of these recommendations can again be pointless because of the lack of access to these drugs at primary care level in SA.

Anxiety and depression are the commonest psychiatric symptoms in patients with ESKD.[7] Antidepressants are used in ESKD patients with anxiety and depression while benzodiazepines are used for patients with poor prognosis and less risk for dependence. Sertraline has been found to be of no benefit in patients with ESKD and ongoing dialysis and was associated with nausea, vomiting and diarrhoea.[27, 28] Marginal benefits of sertraline compared to cognitive behavioural therapy was demonstrated by Mehnotra (2019) and is the reason the drug is often used in ESKD since it is not renally excreted and needs no dose adjustment as seen with mirtazapine (helpful for sedation), duloxetine (helpful for neuropathy) and venlafaxine where there is a need for dose adjustments if used in patients with ESKD.[29] There generally appear to be poor evidence on the use of antidepressants in patients with ESKD.

There is growing understanding that initiating CKM in patients with ESKD does not signal imminent death and that conservatively managed patients can remain stable for long periods.[10] CKM does entail active management as well in the form of actively managing anaemia, metabolic bone disease, electrolyte abnormalities and aggressive PC to manage distressing symptoms in patients who opt not to start dialysis or not deemed to qualify for dialysis for reasons mentioned earlier.[7]

Dialysis patients as well often experience existential distress and a high burden of physical and psychological symptoms.[23] We can argue that the distress of patients who do not qualify is unknown and may be even worse. PC practitioners are well trained in screening for spiritual distress/existential crisis, impeccable assessment and management of physical symptoms making them a valuable assert in management of patients with ESKD and skills transfer to staff working in dialysis units. Prognostication in patients with ESKD is inherently difficult with a huge number of patients with heterogeneous outcomes.[7]

Although dialysis is life sustaining therapy and extends life, it may also create, increase or prolong suffering while not restoring or maintain well-being, function or cognition.[30] The dialysis pathway is not immune to challenges for patient with ESKD, hence there is an urgent need for early PC introduction in patients with ESKD along with curative treatment plans.[3] Early PC introduction allows for early ACP. The purpose of ACP is to help the patient understand his/her condition, identify his/her

goals of care, and prepare for the decisions that may have to be made as the condition progresses over time.[11] Physicians generally avoid ACP and prognosis discussion until it is too late and often prompted by a deterioration in the patient status.[11] This even more complex in the South African setting with cultural differences and limited choices of resources.[31] Numerous studies show that patients and families expect their physicians to discuss ACP with them.[11] Even though patients and families expect their physicians to raise the issues involved in ACP, other dialysis unit personnel such as social workers, nurses or peer counsellors, may be integral to the process.[11] There is a great need for teamwork that will direct patients and their families towards the mode of care, be it to dialysis or CKM pathway depending on resource availability in a country.

2.7 THE NEED FOR PALLIATIVE CARE INTEGRATION (PCI) IN ESKD

The focus on cure and life prolonging treatments like RRT and less focus on alleviation of Serious Health-related Suffering (SHS) associated with ESKD forms part of moral failure in the global community as pointed out by the Lancet commission report of 2017.[18] ESKD related SHS forms part of the more that 61 million people living with unaddressed SHS especially in LMIC due to barriers that include lack of political commitment in addressing the costs associated with integrating PC in UHC.[18]

PC has now been included in the WHO's definition of UHC together with promotive, preventative, curative and rehabilitative health services.[18] Access to PC and pain relief is a health, equity, and human rights imperative that has been largely ignored in the UHC goal to achieve.[18] The WHA made a major PC resolution on strengthening PC as a component of comprehensive care throughout the life course in 2014, known as the Palliative Care Resolution 67.19 of 2014.[32] This was further brought home to Africa by the consensus statement for strengthening PC as a component of comprehensive care throughout the life course in Africa- "The Kampala Declaration 2016".[33] South Africa played an important role as a co-sponsor of the PC Resolution 67.19 of 2014 thus committing itself as a country to the strengthening and delivery of PC services to its citizens.

Unfortunately, most parts of the world have not seen the above definition of PC being translated into practice due to slow progress in implementation of the PC approach.[18] Patients with ESKD and their families face distressing physical, emotional, social and spiritual symptoms that need a PC approach and are unfortunately affected by the slow progress in implementation of the PC approach as part of UHC.

The PC approach is well established in oncology units and services thus more oncologists are becoming aware of the PC needs of patients with cancer. There is an increase trend of mandatory PC training for oncologists as part of a requirement to obtain the oncology qualification.[34] However, nephrologists in training are not obliged to rotate in PC as a requirement to become nephrologists in most LMIC.[3] A significant barrier to combining renal medicine and PC is that the vast majority of nephrologists throughout most parts of the world have never received PC training.[35] An Expert Consensus Group for patients dying with renal failure found that those dying from ESKD had similar symptoms to those dying with terminal cancer hence the Renal Liverpool Care Pathway prescribing guidelines were developed with the aim of

controlling those symptoms.[10] This emphasises the need for RRT staff members to be orientated in PC, know who to and when to refer for PC in ESKD patients.

Not all patients with ESKD require PC: some have very minimal comorbidity and /or are eligible for kidney transplantation, which if obtained, would substantially change their health-related quality of life and mortality risk.[7] It is often for this reason that patients with ESKD are often divided into a dialysis group and CKM group. However, at some point most patients will move onto a trajectory of progressive functional decline associated with a cluster of physical and psychological symptoms exposing the need to introduce most patients with ESKD requiring RRT to PC concurrently with dialysis as part of initial RRT education.[7] In this review article Davison (2011) as an expert (lowest form of evidence) in the field acknowledges the inherent difficulty in prognosticating ESKD but controversially suggests the use of the “surprise question” and a modified Charlson Comorbidity Index (CCI) as tools that can be used for prognosticating ESKD.[7] Both these tools are known to be controversial in accuracy and reliability but are useful in the clinical environment.[7]

The need for PC is often obvious when patients decline in performance status, thus unable to attend dialysis, these patients often die in acute facilities with aggressive biomedical approach to treatment even when physicians and nephrologist are aware of treatment futility.[7] Withdrawal from dialysis (voluntary and involuntary) is another common reason that obviates the need for PC, unfortunately this is often too late for ACP and patients are more often in acute settings in the hands of health professionals who are not PC trained when faced with distressing symptoms associated with end of life.[7] Many nephrologists feel unequipped with the knowledge and skills to ensure excellent care for patients when dialysis is not an option since PC is currently not a component of the nephrology curriculum in SA.[3]

There is a great need for PC integration and training in nephrology curriculum since a vast majority of nephrologist need support in recommending the non-dialysis pathway even when indicated. In a survey by Shah (2014), only 35 percent of nephrology fellows in USA felt comfortable with recommending non-dialysis pathway for patients with multiple organ failure and futile prognosis in an ICU setting.[36] The response rate of 11 percent in the survey was low but the results are important since they are consistent with most surveys. Training in PC seems to improve PC perception and skill in nephrology fellows as seen in a study by Combs (2015) which demonstrated improvement of perception of nephrology fellows in providing end of life care for their ESKD patients ten years following a baseline study.[37] In a human and equipment/consumables resource constraint country like SA where there is a very limited number of nephrologists and lack of PC training in the nephrology fellowship curriculum, a consultative hospital-based PC model may be implementable to sensitize nephrology fellows and registrars to PC, a model that appears to be cost-effective.[38]

2.8 THE ROLE OF POLICY IN PALLIATIVE CARE INTEGRATION (PCI)

The burden of ESKD requiring CKM pathway remains largely unmet especially in LMIC including SA where there is limited awareness of the pathway, limited staff training for the pathway and poor documentation of its utilization which may lead to exclusion of CKM from nephrology policies.[12]

The structure, management and functioning of a health system is shaped and guided by health policies.[39] Health policies go through various stages before becoming official documents for implementation and can be influenced at any stage provided there is awareness of the problem that they address.[39] The PC policy in SA is at its implementation phase, while there is no formal CKM policy in the country, there are pockets of documents published and unpublished making the CKM policy to be at agenda setting stage.[3, 4, 22] Policy development is well known to be often messy, complex, iterative and emergent rather than linear and sequential.[39]

Policies and documents that seek to address the needs of patients with ESKD must have a strong stance and plan for the addressing of the PC needs of patients with ESKD. Abandonment exists when patients with ESKD in need of PC find themselves in a health system that is not geared up to look after them when diagnosed with ESKD and facing distressing symptoms.[18] Policies and documents that seek to address this problem must be implementable and have a clear understanding of the role of PC in ESKD.

A model of care or integration of PC and nephrology must be relevant to the unique challenges and resource constraints faced by a country. A consensus statement to assist with PC in nephrology was taken by multiple stakeholders across SA including nephrologists, primary-level care, PC providers, patient family members affected by ESKD, and hospital management in Cape Town.[4] In SA morphine (used for pain control and improvement of shortness of breath) also not recommended in ESKD but careful dose reduction can be considered since it is very often the only option available for state patients.[4]

Generally, there has been a very slow progress in PC policy implementation and thus achievement of PC outcomes in SA.[17] This is not a phenomenon that is only seen in PC or SA but a world-wide phenomenon that is also seen other fields of medicine.[5] Well known reasons for slow progress in health outcomes are mostly attributed to lack of investment in health systems of low- and middle-income countries, insufficient or poorly coordinated donor resources, lack of agreement on effective technical strategies and limited scale up of effective interventions. Many policies and documents may be perfect in content and may appear Specific, Measurable, Attainable, Relevant, & Time based (SMART) at face value, but often these policies are found to be not implemented few years down the line due to non-technical factors (complex rules shaping how decisions are made in institutions, interest from groups or individuals, public administration processes, politics and political commitment) that become major barriers or enablers in the implementation of policy.[40]

It is important for health care workers to understand conceptual frameworks and theories that focus on policy analysis, and they often use document analysis as a methodology policy analysis. Michael Lipsky's Street Level Bureaucrats model

focuses on policy implementation, examining what happens at the point where policy is translated into practice.[40] This model focuses on the factors that enable or inhibit policy implementation by street level bureaucrats as actors or implementers that directly affect policy outcomes, it does not look at policy factors outside implementation and focuses on the actors within policy implementation.[40]

The Kingdon model of Agenda Setting helps make sense of how certain health issues get into government policy agenda.[40] This model suggests that policy and policy change are made through several independent processes: the problem stream, the politics stream and the policies stream. A combination of factors coming together at the same time to create a window of opportunity to shift an issue onto the agenda. Often these opportunities are accompanied by long standing problems (problem stream) within a country without any action being taken and a politician or prominent leader (political stream) works with a small group of policy actors in the form of individuals or communities (policy stream) who have been concerned about the issues being addressed in the policy. These three streams come together, implement the policies and resulting in radical policy change or implementation.[40]

The Policy Analysis Triangle model by Gill Walt and Lucy Gilson is a comprehensive conceptual framework available for a more systematic policy analysis.[40] It takes into consideration a multitude of factors affecting policy and the interrelations among these factors.[40] It is applicable during all phases of the policy journey and it takes into consideration factors involved in both Michael Lipsky's Street Level Bureaucrats model and the Kingdon model of Agenda setting.[40] The Policy Analysis Triangle focuses on factors such as policy content, process, context and actors that influence policy in all phases of policy, it is a deductive framework.[40]

The understanding of these frameworks may help health workers to see how they can influence policy at different stages as needed for the implementation of CKM and other PC programs, herein lies the knowledge of the power that consultant nephrologists and palliative care physician have when it comes to advocacy and policy influence.

2.9 CONCLUSION

Both communicable and noncommunicable diseases have had a spiralling effect on the burden of ESKD with resultant inability of LMIC to equitably provide dialysis for most ESKD even when indicated. ESKD patients who are not for dialysis automatically fall into the CKM pathway, a basic human right imperative to alleviate multifaceted symptoms and needs associated with ESKD. Nephrology as a speciality and its services (mainly dialysis) are based in tertiary institutions, while most patients who are on the CKM are concentrated in primary care facilities. PC integration can be brought about through different models of care and there is an urgency to integrate CKM along the care continuum since it has been included as part of UHC. The structure, management and functioning of health systems are shaped and guided by health policy and documents that have a strong stance on specific subject matters. Document analysis can be used to interrogate and improve the stance of health policies and documents in structure, management and functioning of health systems.

CHAPTER 3: STUDY RATIONALE

3.1 AIMS AND OBJECTIVES

3.1.1 Aim

To determine the perceived standards or components of care in providing CKM services in low resourced countries like South Africa.

3.1.2 Research Question

What are the perceived standards of care in providing CKM services in low resourced countries like South Africa?

3.1.3 Objectives

1. To describe standards or components of a CKM program.
2. To identify available CKM documents in SA.
3. To analyse SA CKM documents according to perceived standards or components of a CKM program.

CHAPTER 4: METHODOLOGY

4.1 STUDY DESIGN

An exploratory sequential mixed method study with sub-studies consisting of qualitative, semi-structured, in-depth interviews and document analysis.

4.2 STUDY SITES

Data were collected through the use of an interview guide with semi structured expert interviews conducted via Microsoft Teams. Of the participants, seven were in South Africa (n=7), one in Australia (n=1) and one in Uganda (n=1). Secondary data collections were done through desktop DA of ESKD documents from SA.

4.3 STUDY POPULATION

International and SA experts in the field of ESKD were identified through a snowball sampling technique (expert were asked to identify further experts and documents in the field) as indicated in table 1 and interviewed to determine the standard of care for CKM services both intonationally and local.[41] Expert were asked to identify further experts and documents in the field. SA documents on ESKD were analysed.

Table 1: List of Research Participants

Participant	**Purpose**	**Method of Data Collection**
International experts	To describe good practice in providing CKM.	Observer administered questionnaire.
Local experts	To appropriate international standards to local context within available resources.	Observer administered questionnaire.

Selection criteria

Expert interviews

Table 2: Participants Selection Criteria

Inclusion criteria	Exclusion criteria
1. Nephrologist or Palliative Care Physician. 2. Published at least two ESKD papers in reputable journal. 3. Currently working in the field of ESKD or retired while working in the field.	1. Non-PC or nephrology trained Physicians. 2. No publications in ESKD. 3. No experience in ESKD.

Documents

Table 3: Inclusion and Exclusion Criteria of Documents

Inclusion criteria	Exclusion criteria
1. SA CKM documents within past 15 years. 2. CKM documents in English.	1. Unofficial documents and those not meeting the inclusion criteria. 2. Paediatric documents. 3. International documents.

Librarians, peer reviewed databases and grey literature were consulted and searched for SA documents on CKM or ESKD management. Librarians were requested to find documents since the initial search yielded an unexpected, limited number of SA CKM documents. International documents on ESKD were not analysed since the study aimed to analyse only SA documents. International experts were only interviewed to gain insight into international standards of care in CKM. Documents that met the inclusion criteria were assessed for appropriateness and quality using the CASP. Only SA documents on CKM were included in data extraction.

4.4 SAMPLING: SAMPLE SIZE AND METHOD

Purposive sampling is a non-probability sampling technique used when a researcher has something in mind and then chooses participants that suits the purpose of the study to be included in the study.[42] Purposive sampling technique is relevant for researchers with limited resources, time, workforce, for a research field that still requires data collection to understand theoretical frameworks in the field of study.[43] Purposive sampling was the sampling technique employed in the study. Expert sampling was the applied purposive sampling method for the study and included both local and international experts in the field of CKM.

Snowball sampling is another non-probability sampling technique that is frequently used in qualitative research albeit its criticism of limitations. In snowball sampling a researcher usually starts with a few suitable participants who are then requested to recommend other suitable participants for the study.[41] The process whereby participants who fit the criteria for participation in the study repetitively recommend participants that have already been included in the study is referred to as data saturation.[41] Data saturation as a process in research is not without controversy due to many factors that have an effect on it and thus its effect on validity of a study through the introduction of bias.[44] Nephrology, CKM and PC in SA generally have limited number of professionals in the fields which makes early achievement of data saturation probably a true indication that there is high probability that information from further interviews or documents will not significantly contribute towards an improvement in the validity of the study.

Both local and international experts were interviewed and rolled the snowball until data saturation (n=9). Local experts were further requested to roll the snowball by recommending documents that guide the standards of care in ESKD in SA and specifically in Mpumalanga and Western Cape provinces. This process was followed until document data saturation was reached.

4.5 DATA COLLECTION TOOLS

Data were collected using a semi structured interview guide (Appendix 9.1) conducted via Microsoft Teams. The interview guide covered deductive biopsychosocial and spiritual themes as all are known to be vital components of comprehensive RRT and CKM programs.[14] Secondary data collections were done through desktop DA of ESKD documents from SA whereby initially documents were collected and put together in one folder. The second step in DA was as according to Kayesa and Shung-King and entailed the recording, labelling and archiving

documents on password protected computer (n=6).[39] Documents on password protected computer were thoroughly read then data extraction was done through Microsoft office table where the first column was a document followed by CKM program components that were search for in each document for analysis.

4.5.1 Development of tool

Initial deductive themes in five areas of biopsychosocial model were derived from literature on ESKD PC services or models. Semi-structured interview questions were developed based on the research question and literature themes as discussed with supervisors (Appendix 9.1).

4.5.2 Study trustworthiness validity and reliability

No validated instrument for measuring the standards of CKM services were found from a preliminary literature review. However, a questionnaire was developed using common literature themes, Principal Investigators (PI) knowledge of the field and through inductive themes from expert interviews.

For document analysis, the steps for DA as described by Kayesa and Shung-King were followed, the researchers also drew from Critical Appraisal Skill Programme criteria (CASP).[39] Critical Appraisal Skill Programme criteria (CASP) refers to a qualitative checklist tool for quality appraisal in qualitative evidence synthesis, it has been approved by the WHO and is recommended for novice qualitative researchers.[45]

Furthermore, trustworthiness was ensured for the study through the framework by Lincoln and Guba (1985) who relied on four general criteria in their approach to trustworthiness. [46]

Credibility

Due to time constraints, member checking for study interviews was omitted in this study, a factor which could have boosted the credibility of the study results should participants have been given an opportunity to check for accuracy and resonance of study transcripts. Debriefing and constant comparison of findings and with study supervisors was done throughout the study to further ensure credibility. Furthermore, the exploratory sequential mixed method nature of the study was implemented to triangulate findings from study interviews.

Transferability

The study interviewed SA expert (n=7), African expert outside SA (N=1) and an Australian expert (n=1) with extensive experience in CKM program. More SA experts were intentionally included in the study to get a deep contextual understanding of the SA context. Only SA documents were included in document analysis part of this study to further ensure that the study findings are interpretive of a SA context.

Dependability

To ensure that study findings reflected current reality, the findings were discussed with research supervisors, an audit trail with detailed steps of data handling was kept, and document analysis was added over and above study interviews.

Confirmability

Multiple data sources were used to ensure confirmability of the study, furthermore both local (n=7) and international (n=2) family physician were included in the study and the study was supervised by a local family physician and an international co-supervisor.

4.5.3 Piloting

Expert interviews

A pilot study was conducted to test the developed structured interview questionnaire to ascertain its adequacy, assessment if it was realistic or workable, assessment of later data analysis techniques and to uncover potential problems that may have aroused during the actual research. The expert interview questions were piloted on both local and international experts in the field of CKM.

Documents

The DA tool with a scoring system developed from inductive themes derived from expert interviews and was piloted on ESKD documents.

4.5.4 Translation

Both expert interviews and documents were in English. There was no need to translate tools into other languages since the PI conducted the study and clarified questions that needed clarification, moreover, the study participant's education level allowed English to be the only language for the study.

4.6 DATA COLLECTION PROCESS

After University of Cape Town HREC ethics (161/2022) approval was received data was collected and processed.

Expert interviews

The purpose of the in-depth interviews with the experts was to describe good practice in providing CKM. Experts were contacted via email. The PI conducted the study interviews through MS teams, an online platform that allowed recording, saving and transcription of interviews. There was no need for research assistants and training thereof since only the PI conducted the expert interviews. Vulnerability and protection of intellectual property was one of the risks that experts were envisaged to be prone to. All interviewed experts were asked to sign written informed consent for participation in the study and for recording of the interviews as a prerequisite to be included in the study (Appendix 9.2 and 9.3). Each expert was allocated a separate participant code which they utilized to join MS teams. The recordings of the interviews bared no name identifiers and were saved in a secured password-controlled password protected computer storage.

Documents

The steps for DA according to Kayesa and Shung-King entailed firstly the search and retrieval process with the understanding that most of the documents would be in grey literature. This required that librarians, non-peer reviewed databases and websites be visited. Searches in government and other websites were conducted. Key informants and experts interviewed played a critical role in DA process in that they pointed out South African CKM documents that they believed to be important. A strict inclusion and exclusion criteria of documents was followed as depicted in table 3 above. Information from primary data analysis from expert interviews was used to inform the formation of a data extraction template for good practice or essential components of CKM for CKM document analysis. The purpose of this document analysis was to compare how existing South African documents on CKM aligned with the proposed good practice or essential components of a CKM program in MLICs according to expert interviews.

Documents that met the inclusion criteria were assessed for appropriateness and quality using the CASP. Only SA documents on CKM were included in data extraction. The second step in DA was as according to Kayesa and Shung-King and entailed the recording, labelling and archiving documents.[39]

4.7 DATA EXTRACTION AND ANALYSIS

Expert interviews

Transcripts from Microsoft Teams were downloaded into Microsoft Word and saved on password protected computer for review and correction of transcript errors that occurred through auto-transcription by Microsoft Teams. Microsoft Word transcripts were individually imported into NVivo version 12 and were coded using inductive, thematic analysis and some aspects of deductive analysis guided by the health systems building blocks.

Inductive analysis is a process of coding data without trying to fit it into a pre-existing coding frame, or the researcher's analytic preconceptions.[47] The coding approach in this research was inductive in nature because the themes identified were strongly linked to the data themselves and the data was collected specifically for the research and themes identified were not driven by the researcher's theoretical interest in the topic.[47] The deductive aspect guided by the health systems building blocks is not uncommon in qualitative research as noted by Braun and Clark that often researchers cannot free themselves of their theoretical and epistemological commitments, and data is not coded in an epistemological vacuum.[47] Themes were analysed at latent level i.e. beyond the semantic content (purely descriptive) of the data, the themes were analysed with an intention to identify or examine the underlying ideas, assumptions, conceptualisations and ideologies that are theorised as shaping or informing the semantic content of the data (latent thematic analysis).[47] Six themes were derived, with a total of 22 sub-themes.

Documents

Six SA documents in the form of journal articles or treatment guidelines on CKM and ESKD in South Africa were analysed. The READ approach as outline by Dalglish and Khalid and McMahon was employed.[48] This refers to a stepwise process in DA whereby: (1) Ready your materials, (2) Extract data, (3) Analyse data and (4) Distil your findings.[48] All selected documents were read thoroughly, data were extracted from documents using a data extraction template for further analysis using deductive themes derived from expert interviews.

Merging of findings was done through the use of a data extraction template containing essential elements or components of a CKM program as informed by expert interviews. These elements or components also informed the document search process.

4.8 ETHICAL CONSIDERATIONS

This study complied with the declaration of Helsinki.[49] The study was not a clinical trial, thus the risk of harm to participants was negligible (non-maleficence). All expert interviewed were asked to sign written informed consent (approved by Research Ethics Committee of the health sciences faculty of the University of Cape Town before implementation) that clearly stipulated the voluntary nature of their participation in the study (autonomy) and for recording of the interviews as a prerequisite to be included in the study. Each expert was allocated a participant code which they utilized to join teams, an online platform for interviews. The recordings of the interviews bared no name identifiers and were saved in a secured password protected computer cloud storage.

There was no need for a distress protocol for the study since interviews were conducted on experts and not patients. Study participants signed an informed consent (Appendix 9.2 and 9.3) informing them on the nature of the research, their role and right to terminate the interview when they wished to do so. Interviews were conducted online thus no COVID protocols applied. All protocol was observed in institutions and individuals interacted with during the process of document requests.

A protocol was written, and approval was granted by the scientific committee in the University to ensure scientific soundness of the study. The protocol was also approved by the University's Research Ethics Committee (161/2022) (Appendix 9.4) to ensure that ethical processes in the research were followed.

Expert participants were envisaged to be at risk of exposure to vulnerability in their opinions in relation to the state CKM services DoH, a risk that was acknowledged. Since private and personal documents were included, it is further acknowledged that policy stakeholders may have also been vulnerable, subsequent results may be applied to influence policy and implementation processes. Findings from this research may be appalling to the provincial DoH, politicians, and street-level bureaucrats and may lead to a breach of confidentiality in the form of institutional information, internal documents and agreements with service providers and other involved stakeholders. This may cause harm to healthy relationships formed by stakeholders and investigators. The reason for conducting this kind of research is to

remove potential barriers to CKM program and RRT (justice). This research has value and can benefit in that it can add value to the body of knowledge in CKM and KSC in general an area that has not been explored enough in the country which will ultimately improve the quality of patient care.

4.9 TIME FRAME

The study was conducted from the 1st of March 2021 to the 31st of January 2023.

4.10 BUDGET

The study was self-funded with no major financial implication.

4.11 DISSEMINATION OF FINDINGS

Feedback will be provided to all the participants through a written summary of the findings. We plan to disseminate findings of this study though a journal article to be published in a scientific journal and through conference presentation.

CHAPTER 5: RESULTS

5.1 CONTEXT AND PARTICIPANTS' BASIC CHARACTERISTICS

Nine in-depth interviews (n=9) which lasted an average of 25 minutes were undertaken. Of these participants, seven were in SA (n=7), one in Australia (n=1) and one in Uganda (n=1).

Three of the participants were female; six were nephrologists and three were palliative care physicians. Participants' experience in nephrology and/or palliative care for nephrology patients ranged from 4 to 17 years. Table 4 summarises participants' basic characteristics.

Table 4: Participants' Demographic Characteristics

Country	**Province/state/region**	**Designation**	**Years of experience in nephrology and/or palliative medicine**
Australia	New South Wales	Internal Medicine, Palliative Physician based in Nephrology unit	16
South Africa	Eastern Cape	Nephrologist	12
South Africa	Western Cape	Internal Medicine, Palliative Physician	4
South Africa	Limpopo	Nephrologist	7
Uganda	Central	Nephrologist	9
South Africa	Mpumalanga	Nephrologist	4
South Africa	Western Cape	Family Medicine, Palliative Physician	9
South Africa	Western Cape	Nephrologist	14
South Africa	Western Cape	Nephrologist	17

5.2 THEMES AND SUB-THEMES IDENTIFIED

1. *Kidney Supportive Care (KSC) curriculum.*

2. *Challenges for patients with chronic kidney disease.*
   2.1 Cost of dialysis.
   2.2 Poor organ transplant policy framework.

3. *Defining Conservative Kidney Management.*
   3.1 Profile of patients who are on the CKM program.
   3.2 Common symptoms experienced by patients on the CKM program.
   3.3 Principles of management of patients on conservative kidney management programme.

4. *Needs and Challenges of CKM program.*
   4.1 Lack of a dedicated service and lack of funding.
   4.2 Weak referral pathways and lack of continuity of care.
   4.3 Poor communication between the different levels of care and specialists.
   4.4 Lack of standardisation of the conservative kidney management program.

5. *Advances and possible care model.*
   5.1 Hallmarks of a successful program.
   5.2 Possible care model for CKM in South Africa.
      5.2.1 Leadership and Governance.
      5.2.2 Health Workforce.

         a. Human Resource Development.
         b. Health workforce planning – Health workforce cadres.
         c. Health workforce planning- Complimentary health care management.

      5.2.3 Health Financing.
      5.2.4 Medicines, Technologies and Infrastructure.
      5.2.5 Service delivery platform.
      5.2.6 Community participation.
      5.2.7 Health Information Systems.

5.3 KIDNEY SUPPORTIVE CARE (KSC) CURRICULUM

Most participants had a similar understanding on the approach to management of a patient who has been diagnosed with CKD. They expressed that, once a patient has been diagnosed with CKD there are generally three options, dialysis, kidney transplant and conservative kidney management (Figure 1).

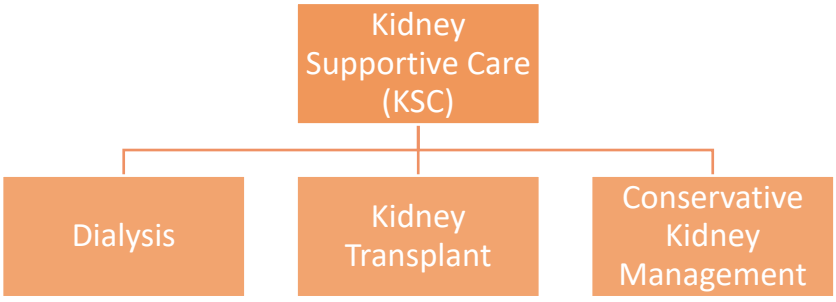

Figure 1: Options for chronic kidney disease management

Principles of chronic kidney disease management are currently receiving high level attention from the International Society of Nephrologist (ISN) on CKM to ensure that nephrology fellows can offer the full package of services for patients with ESKD as noted by one participant.

> *"…often people get the terms a bit confused. … kidney supportive care is essentially the holistic care of patients with kidney failure or chronic kidney disease, who were either on dialysis or on conservative kidney management……they may be transplant patients……..including good communication, good symptom management, advance care planning, care of the dying into that group. So sometimes people think that kidney supportive care equals conservative kidney management, in fact kidney supportive care is a broad umbrella term for all these patients, dialysis, conservative, transplant and the conservative group is the one that are non-dialysis". Participant 4*

5.4 CHALLENGES FOR PATIENTS WITH CHRONIC KIDNEY DISEASE

The late presentation of patients ESKD patients in both SA and Uganda may be attributed to patients having difficulties being enrolled on either the dialysis or organ transplant programs even when they qualify due to direct and indirect costs, health systems' capacities and organ transplant challenges.

5.4.1 Cost of dialysis

In Uganda, dialysis is a paid for service that is partially covered by the National Health Insurance (NHI) for two sessions per week. Because a third session in a week is a paid-for service, it's therefore difficult for most patients to access it since most patients do not have the resources to pay for a long-term service. All SA participants mentioned that the government in SA pays for three sessions in a week, but very few patients qualify to be enrolled on the dialysis program, often because of social factors, including the lack of transport to get to dialysis units. The backlog of getting into a dialysis program even if qualified is also affected by slow progress and funding of kidney transplantation program. In high-income countries, the non-dialysis population tends to be older and high comorbidity patients, while it is not uncommon to find younger patients in LMIC due to the high cost of dialysis.

> *"So, it means that if you are to do it three times a week, then the third one you must end up paying for it….. because it's a paid-for service, it's a bit difficult for most patients to access…", Participant 8*

> *"…someone on a conservative pathway in South Africa may well be younger, fitter…, but they're just not fitting into the criteria, and they can't afford insurance. Versus in Australia, which it is usually the older highly comorbid frailer patient." Participant 7*

At times patients who do not qualify for dialysis in the state sector are encouraged to join medical insurances and wait for a year before they can move into medical insurance covered dialysis programs. Those patients who come to the public sector

for dialysis while they have private medical insurance are encouraged to access dialysis through the private sector.

> *"…if there's a family member that could possibly assist and get the patient onto a medical aid because if you can get the patient onto a medical aid then they can survive a year then there's an opportunity for them to get dialysis."* Participant 4

5.4.2 Poor organ transplant policy framework

There is poor organ transplantation policy in SA, the funding for organ transplant is also poor and there is associated poor public awareness on organ donation. As narrated by a participant:

> *"… they do fund transplantation, but unfortunately it is a lot of riddles to why transplantation isn't happening like it should, many of them is the inability for us to procure donors. South Africa has got an extremely low organ donation rate (sic) and many rights for deceased donors compared to other countries around the world and that is due to the inefficiencies and the lack of space in our system…"* Participant 3

5.5 DEFINING CONSERVATIVE KIDNEY MANAGEMENT

Participants' description of CKM was similar. Most participants understood CKM to be the main option of care for ESKD patients, mainly stage 5 where dialysis and kidney transplant were not options, either because of a limitation of those resources or because the patient is predicted to have a short life. In some cases, the assessment would have, for instance, been that the quality of life would worsen or the patient's prognosis would worsen should they be on dialysis. Participants understand the program as aiming to make the patient comfortable by providing holistic and supportive care and delaying further progression of kidney disease.

In high income countries like Australia and USA patients have the luxury to opt in or out of dialysis, a phenomenon unknown in LMIC countries like SA hence the coining of a new term, choice restrictive conservative kidney management since patients on CKM in LMIC are largely due to lack of choice and poor financial circumstances.

> *"… So conservative kidney management is when dialysis isn't necessarily the best option, so for the patient, so for a variety of reasons so either, they can't tolerate dialysis they've got disease process that actually makes them unable to attend dialysis… But a new term that's been jolted around is called choice restrictive conservative kidney management…. deals with patients like in the state sector of South Africa who unfortunately have no access*". Participant 1

> *"…when you read the literature from overseas, it's a choice that patients make. They choose conservative management and it's very different in South Africa where the patients are not given the choice… most of them…, should receive dialysis therapy in most majority countries around the world, they would receive treatment with dialysis, ……, but unfortunately the conservative kidney management is forced on them* (sic)*…"* Participant 3

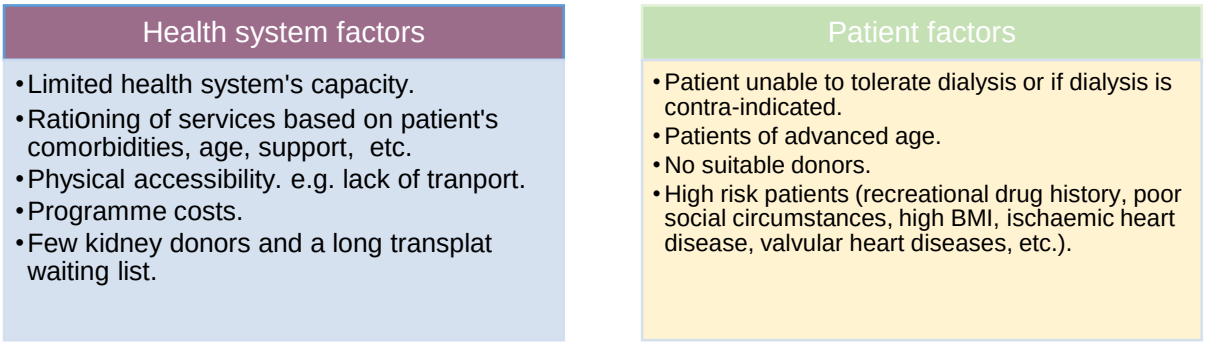

Figure 2:Common patient and health system factors that result in patients being in a choice restrictive CKM pathway according to study participants

According to some participants, not all patients consent to dialysis as it's not mandatory, some patients choose CKM even when they qualify and have access dialysis. As explained by a participant:

> *"Some patients go into the dialysis unit, look at it or they've heard of relatives who have been on it or other friends and say, look, I don't want to do that. So, it's a choice that is given" Participant 7*

Participants further expressed that dialysis and renal transplant are to a certain extent a form of PC, bringing into light the complexities of the term conservative management since dialysis is a form of making a patient have an improved quality of life as the patient faces distressing symptoms of ESKD:

> *"…not to forget that just because you are under dialysis does not mean you are not going to die. I also believe that every patient who has had a kidney transplant or under dialysis needs to be on a conservative care service and that's why palliative care needs to be hand in hand with organ transplant units and organ failure units* (sic)*… " Participant 4*

5.5.1 Profile of patients who are on the CKM program

Whereas patients who have been enrolled in the conservative kidney management programme in high income countries are generally older, South African and Ugandan patients tend to be younger, often between 45 and 50. These patients would ordinarily be transplantable in high income countries.

> *"…if you look at the tons of patients that we are treating with conservative kidney management is very different from what you're reading in Australia* (sic)*. We've got a bunch of young people here". Participant 3*

5.5.2 Common symptoms experienced by patients on the CKM program

Clinicians noted a diverse range of symptoms but mostly reported similar symptoms. It was appreciated that as the kidney disease progressed and, as the patients lost kidney function and got closer to end-stage, the symptom burden increased as well. Symptoms can range from neuropathic pain, nausea to severe dyspnoea, oedema, restless legs, pruritis and inability to swallow.

" …you are looking at the complications of renal failure. … nausea, vomiting from uraemic gastritis, itching, insomnia and seizures… at the end of stage, maybe they can come with the pericarditis (sic). …depression is represented about 40% and associated with mortality in end stage kidney disease patients (sic)*. Participant 9*

5.5.3 Principles of management of patients on CKM

All interviewed participants both in SA and outside SA seemed to be familiar with the SA palliative care consensus document written by SA palliative care physicians supported by the Australian palliative care physician, SA nephrologists, medical managers and other disciplines. When managing a patient enrolled in the CKM program, this document was referred to by most participants during interviews. The document advocates for a biopsychosocial approach to care for patients with ESKD and their families. The document emphasises that even though there is medication that aims to treat the patient's immediate symptoms, management also relies on optimal treatment of comorbid conditions, reduction of the patient's fluid volume, prophylactic treatment (e.g., Vitamin D and Calcium) to prevent possible complications of ESKD and mental health care of the patient and their families.

"…the first thing is to appropriately offer counselling to these patients and the family so that they can actually understand what the disease means and also, the best medical treatment requiring management of all the symptoms as well as management of the diabetes, hypertension, cholesterol, ischemic heart disease and all the risk factors that would shorten their life (sic)*..." Participant 4*

5.6 NEEDS AND CHALLENGES OF CKM PROGRAM

5.6.1 Lack of a dedicated service and lack of funding

Participants reported that most parts of SA, like Limpopo and Mpumalanga province, do not have dedicated palliative care units. The Eastern Cape province's program is hindered by the limited funding available for the service. For instance, the government withdrew funding that they used to give to Hospice. The impact of this has been the failure to down-refer patients who can no longer be accepted by the hospice that they previously used.

"… The government withdrew their funding, and we have tried to use Hospice services, and they were initially happy to help but when they saw the numbers of patients, we were sending to them, they said sorry, we can't assist you at all. So, we can't make use of Hospice anymore (sic)". Participant 3

5.6.2 Weak referral pathways and lack of continuity of care

Clinicians who are based in teaching hospitals admit that at some stage after diagnoses with ESKD, patients who are on the CKM pathway are discharged and down referred to their local primary care facilities or local hospitals (i.e., district or regional hospital).

" …a lot of time we make the decision that… patient is not accepted for dialysis and then we send them back to regional and district hospitals where unfortunately we don't have much control of that process". Participant 5

"..the typical clinician (nephrology) *is overburdened almost just dealing with emergencies and you know overwhelmed….the usual strategy is just to send them home with some medication and just vague information." Participant 5*

"I think if they (nephrologists) *can lead……. instead of saying well you are discharged I can't help you anymore…….. where is the follow up that says please do x,y for the person?…when the nephrologist says you been denied dialysis ,even if its ok copy and paste please do this for the person…, here must they we go to when they denied it, they don't refer…" Participant 6*

5.6.3 Poor communication between the different levels of care and specialists

Clinicians feel that sometimes communication between different levels of care is lacking. One clinician even felt that nephrology merely discharges the patient to get rid of them from their care in the central (teaching) hospitals and does not share a care plan or a follow-up date when down-referred.

"…the nephrologists don't seems to care, …then it's our problem and… if they can actually lead that, instead of saying: 'well you are discharged I can't help you anymore', so even the letter that says they are not for dialysis, ….if this person doesn't qualify for this but do this and this and this but has a lovely letter, telling you what to do …explain why and that's it. Where must we go to when they have denied it?..a primary health care to be linked with a nephrologist would be amazing.. I think it's a long way to go". Participant 6

5.6.4 Lack of standardisation of the CKM program

Participants overwhelmingly decried the lack of standardisation of the CKM program. One nephrologist admitted to being overwhelmed, with the focus mainly on those patients whom they could do something for in terms of dialysis and transplantation, they tended to not put consideration on the other patients. Their feelings were that, with contextually and clinically appropriate standardisation of the basics or core of the basic principles the situation would improve, as emphasised by a participant:

"…I think the problem I see and what made me sad is that without it [standardisation of the CKM programme], we tend to have a lot of abandonment and people are left to go through this process without having any support". Participant 1

"..because we are a tertiary hospital in the only renal unit for the province, a lot of time we make the decision that no dialysis available or patient is not accepted for dialysis and then we send them back to regional and district hospitals where unfortunately we don't have much control of that process.." Participant

5.7 ADVANCES AND POSSIBLE CARE MODEL

5.7.1 Hallmarks of a successful program

Palliative care skills and palliative care integration are needed in all organ failures and renal failure is not excluded according to participants.

> *" It is bringing those great palliative care skills to bear for these patients including good communication, good symptom management, advance care planning, care of the dying…" Participant 7*

5.7.2 Possible care model for CKM in South Africa

Using the WHO's six health systems building blocks and added the population, seven sub-themes were derived for the required packages of care:

5.7.2.1 Leadership and Governance

Most participants point towards government as the one to provide leadership in CKM program feasibility.

> *"…it does require leadership because it may require a shifting from the status quo…" Participant 7*

> *"….and then the next thing is you need to have buy in from the nephrologist especially, because they are the ones who talks to the patient and tell them you need the dialysis or don't need the dialysis so if you don't have buy in from the nephrologists, then your program may not really succeed because most of them realise that and some may not realise that patients are dropping out at the higher rate and is good to have buy in from a nephrology community….." Participant 8*

5.7.2.2 Health Workforce

a. Human Resource Development

Part of the challenges noted is that other disciplines and other health workers, do not understand what palliative care is or what it seeks to achieve.

> *"There is still the understanding the palliative care to mean the patient is not for life support or the patient is not for intubation, the patient is not for dialysis, and this is the way they understand it* (sic). *So, they forget that the palliative care is a part of the management of the CKD* [chronic kidney disease] *patients that are either getting dialysis or not." Participant 9*

Participants believed that the program could benefit from the mandatory training of all nephology trainees in palliative care, mandatory training of palliative care physicians on kidney failure management, and further train health professionals who are in lower levels of the health system. One participant went further to propose palliative care as a possible essential nursing career path for those nurses who have ambitions of specialising. As alluded by a participant:

> *"So, if you could train and support people to just sort of starting to manage it so it doesn't come into the tertiary level* (sic)*, I think that can be done in certain satellite areas….." Participant 1*

Other perspectives were that undergraduate medical and nursing students also needed to have some basic training in palliative care and kidney supportive care.

b. Health workforce planning – Health workforce cadres

Participants overwhelmingly thought that care would require a multidisciplinary effort.

> *"Social worker will make sure the patient gets a disability grant… tries to help with financial aspects and so forth and then with a little bit of the psychology as well, but must be definitely helpful to have somebody with more psychology training* (sic)…" *Participant 2*

c. Health workforce planning- Complimentary health care management

Even though most participants felt that the programme could benefit from the integration of non-religious pastoral care teams or spiritual carers, this view was not unanimous. Those who advocated for such a service admitted that such a massive step would require innovation and thinking out of the box, if such integration were to have a chance of being successful. Below are a few of the diverse participants' expressions on this subject:

> *"No,no,no, I'm not in support of that. So, I don't know what the situation is at the small hospitals because I've never really worked there or at the clinics but in the bigger hospitals there's always somebody available for Christian patients and often for Muslim patients, I'm not sure what would happen if it was a Hindu patient… I'm not sure what range of faith would be covered by those practitioners." Participant 2*

> *"So, in terms of counselling, I've got what I call spiritual or bedside counsellors because these patients have enormous spiritual needs. There are always issues, you know…was it their fault, you know, should they have taken their medication better or should they have been the better diabetic over the years, there's anger issues. There's, you know many, many issues related to this that require spiritual counselling." Participant 4*

5.7.2.3 Medicines, Technologies and Infrastructure

Because pain is one of the most common symptoms experienced, fentanyl is thought to be better than morphine for CKD patients. However, most participants mentioned that it's not readily available in most public care platforms, when it is available it is usually in tertiary hospital.

> *Participant 1: "…we don't have access in our setting to fentanyl, other forms of gabapentin…fentanyl probably is a better option than morphine and we don't have that available to us".*

Table 5 summarises some of the commonly mentioned medication and symptoms. In some instances, participants only mentioned the symptom that would need to be treated but not the drug.

Table 5: Summary of symptoms and medication commonly preferred by participants

Symptom	Drugs/class
Pain	• Fentanyl • Morphine/Mist morphine • Tramadol • Methadone • Amitriptyline • High dose pyridoxine • Gabapentin • Pregabalin
Generalised oedema	Diuretics
Nausea and vomiting	Antiemetics, e.g., • Metoclopramide • Ondansetron Antipsychotic, e.g., • Haloperidol
Pruritis	• Camphor cream • Calamine lotion • Antihistamines • Gabapentin • Pregabalin
Gastritis	H2 blockers Proton Pump Inhibitors (PPIs)

Over and above the medication, according to participants the CKM program needs to be supported with adequate infrastructure, consumables and medical technologies. Such are said to be as small as a glucometer, blood pressure meters, weight scale, more sophisticated technologies such as blood gas machines. Another service reported to be important for CKM program according to participants (n=2) is access to a laboratory because the clinicians will need to have access to HBA1c, potassium (in the case where there is no blood gas machine or point of care HBA1c), etc. If patients are becoming bedbound, then often, they have got very swollen limbs, they start leaking through the skin, therefore, one needs to ensure that families have access to linen savers, to reduce the wetting of the bedding, which is a major concern for patients and their families. Patients who can afford, should also be advised to buy a wedge or hire a hospital bed and oxygenator to help with fluid overload in the lungs and associated symptoms. Similarly, an eggbox mattress, can also be purchased which helps with the prevention of bed sores.

5.7.2.4 Service delivery platform

Three participants felt that CKM should be decentralised from teaching hospitals to primary care facilities and the patient's communities. This reorientation of services could have the teaching hospital as a hub and have the peripheral facilities as outreach sites which they support. The service delivery platform should be expanded to include digital health interventions such as telemedicine where teaching hospitals can support low resourced and/or lower levels of the health system delivery pathway.

"..if you could train and support people to..manage it so it doesn't come to tertiary level (sic)*,..can be done in certain satellite areas. If a nurse at a clinic knew that….a patient that has got chronic kidney disease, I need to look out for the …because then the patient will not have to travel for such a long time to get those supplements, that kind of a thing."* Participant 1

5.7.2.5 Community participation

Participants thought that it would be essential to involve patients and the community members in palliative care teams at the primary care level. Home based care teams could be community members who undertake home visits. A further opinion was that when the government is not actually providing funding for dialysis treatment or transplant treatment, they should at least be funding an alternative which is community-based organisations involved in conservative kidney management programs.

"…families don't know what to do, they don't know how to manage. That's where I think community-based organisations are really the way forward because we don't want to have all these patients bouncing in and out of hospital..." Participant 3

Three participants felt that patients and communities also needed to be empowered with the correct information because they can be very good advocates and sources of support. Communities can also organise to mobilise resources from governments and private funders for the support of patients with ESKD. They can also provide direct support to individual patients, such as helping to clean the patient or wash the patient, etc. Patient representatives can form part of advisory boards, such as the South African renal registry.

"… another community I think I've talked to you about it already, is that of the dialysis community. So, our dialysis unit, what we noticed is that the patients really supported each other a lot." Participant 8

Patients in RRT or CKM program form and become a supportive community to each other since they know the needs of the program and other patients in the program.

5.7.2.6 Health Information Systems

Basic Information Communication Technology (ICT) equipment and connectivity can help as a link between nephrologists and primary care facilities in remote areas, this was thought to be important by one participant based in a tertiary facility:

"… I mean there are other things that I've been thinking of recently, like maybe, you know, chatting to someone who is very peripheral through skype or something, who does need that support…." Participant 1

5.8 DOCUMENT ANALYSIS

From the document search process, six documents were included in the analysis. Three of the documents were journal articles while the other three were treatment guidelines that were expected to have a section on CKM. Challenges associated with identifying or accessing documents included the fact that CKM is often referred to under a different terminology often as renal palliative care since it is only recently that the subject and its curriculum is receiving international attention by ISN. Furthermore, SA as a country does not have a formal CKM program.

Four of the six documents stated the purpose of the documents and included exploration of CKM referral pathways, renal preservation, health systems interventions, improvement of symptom management skills by HCP, integration of nephrology and palliative care, creating CKM awareness and general improvement of care given to patients with ESKD irrespective of whether they are on dialysis on not.[3, 4, 19, 22, 50, 51] Only one document out of six mentioned involvements in organ and transplant policy framework specifically pre-transplant assessment with particular attention to indications and contra-indications for kidney transplantation.

KSC core curriculum and CKM definitions were discussed in three out of six documents and of note was the fact that Essential Medicines List and the guideline for optimal care of patients on chronic dialysis did not have KSC curriculum mention nor definition or discussion on CKM. All documents went into great depts on symptom management and renal preservation including basic drugs that are often needed in the CKM program.

Half of the documents analysed explore the issue of finance in CKM program with mentions of the need for more public hospital to be funded by government since most of PC is currently being offered by non-government organisations (NGOs) at community level.[3, 4, 22] Limited data on cost effectiveness of Renal Supportive Care frameworks was noted by these documents but equally so was the high usage of heath resources as patients recirculated into services once the decision for no dialysis has been made both in private and public healthcare facilities.

Both primary care and hospital level standard treatment guidelines and essential drug list together with the guideline for optimal management of patients on dialysis have no mention of the importance of leadership and communication in looking after patients with ESKD. The importance and improvement of referral pathway, a better care model and improvement of health workforce is cited by five of six documents reviewed. The basic model generally proposed is that of nephrologists and palliative care physicians being based at academic hospitals while primary care staff rotate in academic hospitals for skills transfer and continuous support using technology and ICT infrastructure that enables such.

Only one document recognised the importance of community participation and intersectoral collaboration to improve the care of all patients with ESKD by involving community members in drafting the document.[4] This document had the most

components of CKM mentioned according to inductive themes compared to all other five documents included in the analysis.

Table 6: Components of CKM program according to study participants depicting essential elements of an ideal CKM program

Component	Description
KSC core curriculum and CKM definition understanding	According to ISN with KSC being the umbrella that covers HD, Peritoneal Dialysis (PD), KT and CKM
Medicines, technology and infrastructure	Fentanyl, morphine, tramadol, methadone, gabapentin, pregabalin, ondansetron, aqueous cream, furosemide, metoclopramide, haloperidol, calamine lotion and proton pump inhibitors availability in all levels of care Consumables include glucometer, BP meter, weight scale, laboratory access, linen savers, eggbox mattress, syringe driver Basic ICT equipment and connectivity to link nephrologists and primary care facilities in remote areas
Symptom management and renal preservation	Meticulous assessment and management of pain, nausea, vomiting, dyspnoea, oedema, restless legs, pruritic, depression and anxiety Knowledge of drugs to stop or start in patients with ESKD
Health workforce	PC skills transfer and PC integration in all care levels Interdisciplinary team including a Social Worker Mandatory training in PC for all nephrology trainees
Referral pathway and care model	Centres of excellence for rotational training of lower care level staff Comprehensive discharge plans from tertiary institutions and linkage to primary care facilities
Communication and leadership	Nephrologists buy in a key to a successful CKM program Communication of dialysis application outcomes by tertiary institutions to patients and lower levels of care when patients are referred back
Community participation	Community involvement and intersectoral collaboration in KSC awareness and support
Financing of CKM program	Government funding for hospices Funding for CKM infrastructure, staff, equipment and consumables in facilities
Involvement in organ and transplant policy framework	CKM program involvement in implementation of organ and transplant policy framework through public awareness and donor procurement to allow more patients to access HD as more patients on HD receive KT.

Table 7: Data extraction template and document analysis of CKM Essentials in SA according to information from study interviews

Article, authors and publication year	Aim or Purpose of document	Involvement in organ and transplant policy framework	KSC core curriculum and CKM definition understanding	Symptom management and renal preservation	Financing of CKM program	Communication and leadership	Referral pathway and care model	Health workforce	Medicines, technology and infrastructure	Community participation
Radically rethinking renal supportive and palliative care in South Africa, Wearne et al. 2020.	Not stated	None stated	The term CKM is not mentioned. RSC/PC are defined in a similar fashion to CKM and is said to be currently not a component of the nephrology curriculum. (RSC/PC may decrease hospitalizations intensive care, and emergency department admissions). The importance of upskilling staff from all health care levels through education and exposure is mentioned as essential. The guidelines focus on prognostication,	Essential medicine for symptom control and lobbying for restricted medications accessible at all levels of care (i.e., morphine, gabapentin, and fentanyl patches).	More state hospitals need to be funded for PC services since currently PC services are mainly found in community nongovernment nonprofit organizations. Trajectories of CKD are often difficult to predict. Compounding this is a high use of health resources as patients recirculate into services once the decision for PC has been made. There are limited data on the cost effectiveness of RSC/PC frameworks. however, there is a well-established	Although the national government is responsible for national health policy, the provincial governments are responsible for provincial policy development and health service delivery. Perceived barriers reported by primary care physicians to collaborate with nephrologists include (i) a lack of adequate information exchange, (ii) unclear roles and responsibilities, and (iii) limited access to nephrologists. Family physicians expressed a desire for better communication tools and clear CKD care plans.	Nephrologists mainly work within a tertiary health care setting and predominantly see patients who have been referred from primary and secondary levels of care. There is also a huge problem of late referral for nephrology care, with most patients entering tertiary or quaternary-level care at the point of ESKD. There is a lack of integration of care between primary, secondary, and tertiary state facilities in the country. High use of health resources	Multidisciplinary approach that identifies and tackles common problems using shared skill sets across the care continuum is imperative to ensure that all patients receive adequate care at the right place and at the right time. Many nephrologists feel unequipped with the knowledge and skills to ensure excellent renal care for patients when dialysis is not an option. Currently, in the primary care setting, there is a lack of trained PC providers and limited PC	Electronic health platforms are also becoming increasingly used. Technology (e.g., Zoom/Skype) can link off-site health professionals to the expertise of the RSC/PC multidisciplinary team. The effectiveness of using a Web-based approach to deliver health care interventions has been demonstrated and recommended as a medium to help increase awareness and improve capacity regarding the provision of PC.	None stated

Article, authors and publication year	Aim or Purpose of document	Involvement in organ and transplant policy framework	KSC core curriculum and CKM definition understanding	Symptom management and renal preservation	Financing of CKM program	Communication and leadership	Referral pathway and care model	Health workforce	Medicines, technology and infrastructure	Community participation
			communication strategies, advance care planning, and treatment noted as important aspect of CKM program.		Cost benefit in oncology. There have been policies developed to integrate PC into the government health system, but, to date, minimal funding has been available to start this process.	Improved communication is essential between all health care levels. This can be achieved with a simple patient booklet(roadmap), which would detail advanced care planning and current treatments. For RSC/PC to flourish in SA, there needs to be commitment from the government, hospital management, pharmacy, and medical insurance companies to support this fundamental aspect of patient care	as patients recirculate into services once the decision for PC has been made and the underuse of home-based care and community-oriented primary care workers. Models of RSC/PC also need to coordinate care for patients with multiple comorbidities who are treated across different health care settings by numerous care providers. Renal PC clinic could be established at a tertiary centre, with primary health care physicians rotating through the service and nephrologists	resources, expertise, and guidelines to palliate ESKD in the South African setting. Before the initiation of an RSC/PC consensus workshop, there was a lack of any guidelines to assist primary care physicians working in a South African context to assist with patients with ESKD. Moral injury experienced by medical teams in which the feeling of abandonment of their patients within the system. In a resource-limited setting, upskilling staff from all health		

Article, authors and publication year	Aim or Purpose of document	Involvement in organ and transplant policy framework	KSC core curriculum and CKM definition understanding	Symptom management and renal preservation	Financing of CKM program	Communication and leadership	Referral pathway and care model	Health workforce	Medicines, technology and infrastructure	Community participation
							supporting community physicians with outreach. Once a care plan is formulated, then it could be continued at primary-level care including home-based services.	care levels through education and exposure is essential. Multidisciplinary RSC/PC service could serve as a platform to expand training and would be ideal for the team to include a nephrologist, primary caregiver (general practitioner/family physician), PC physician, social worker, and nursing staff, homebased care and community nurses and may involve trained volunteers.		
The primary care provider's role in providing	This article explores the referral pathways, renal preservation,	None stated	PC training for staff members at primary care; system adjustments to ensure	Although some patients are not candidates for chronic dialysis programmes,	None stated	Communication around the disease, education on renal preservation, reasons no	Referral to the nephrologist should occur when renal function declines	Following a community-oriented primary care (COPC) model, each team would be	Further health system adjustments that can assist in the improvement of care include	None stated

Article, authors and publication year	Aim or Purpose of document	Involvement in organ and transplant policy framework	KSC core curriculum and CKM definition understanding	Symptom management and renal preservation	Financing of CKM program	Communication and leadership	Referral pathway and care model	Health workforce	Medicines, technology and infrastructure	Community participation
supportive and palliative care for patients in chronic renal failure. Krause et al. 2020.	supportive and palliative care and, finally, health system interventions that can improve comprehensive care.		supportive care and PC is integrated into all care pathways. No mention of CKM but conservative pathway seems to be referred to as PC.	renal preservation must continue focussing on the following prevention of further damage and renal preservation through avoidance of nephrotoxic drugs and regular blood monitoring. Specific guidance on the pharmacological and non-pharmacological management of the symptoms and pain.		dialysis and advance care planning should be initiated early. Discussions should preferably include family members and carers. Numerous ways to measure the impact of PC interventions. Many of these can be used as clinical governance quality assurance tools to assist specialist family physicians to support CHC teams using quality improvement cycles.	to an eGFR of < 30. However, referral to tertiary level care for CKD should only occur if the patient is a potential candidate for the dialysis and transplant programme. Discussions must be documented and, if the patient wishes, should be shared with family members and closer collaboration between the tertiary, secondary and primary care healthcare providers.	supported by a clinical nurse practitioner or professional nurse and medical officer with PC modular training, at a minimum, and access to more specialised kidney and palliative services if more complex situations arise. Community occupational therapy and physiotherapy are all required to ensure comprehensive care is provided to the patients.	embedded stationery prompts and supportive standards of practice that are aligned to the guidelines.	
Renal palliative and supportive care in South Africa - a consensus	The aim of this consensus statement is to assist healthcare providers to improve the		The term CKM is spoken about as an alternative to dialysis. Article mentions that in a	Routine screening of physical and emotional symptoms is recommended at each	Cost benefit also needs to be analysed in terms of personal cost. The burden experienced	The ability to prognosticate and communicate prognosis is essential. This may be a long process and require	There is lack of integration of care between primary, secondary and tertiary facilities	Limited palliative care teams and beds in both the private and public sectors	Resources need to be appropriately allocated at primary, secondary and tertiary care levels. This will require	None stated (while patients and community members formed part of the consensus statement, the

Article, authors and publication year	Aim or Purpose of document	Involvement in organ and transplant policy framework	KSC core curriculum and CKM definition understanding	Symptom management and renal preservation	Financing of CKM program	Communication and leadership	Referral pathway and care model	Health workforce	Medicines, technology and infrastructure	Community participation
statement. Wearne et al. 2020.	management of symptoms and biopsychosocial factors of patients with ESKD in a South African context. TO improve the care of all patients with ESKD whether receiving renal replacement therapy (RRT) or not, by integrating nephrology care, palliative care and family practice. It aims to align with the fundamental principles of UHC and has the secondary goal of creating awareness regarding an alternative conservative management pathway, where appropriate.		resource-limited setting, upskilling staff at all healthcare levels through PC education and exposure is essential. Multidisciplinary RSC/PC clinic would serve as a platform to expand training, create awareness and upskill across the care continuum. Establishment of this clinic could be done at a tertiary centre, with primary healthcare physicians rotating through this service and nephrologists supporting community health centres with outreach.	consultation using a validated tool. Recommended tools include: 1) Integrated Palliative Care Renal Outcome Scale–Renal (IPOS–Renal) 2) ESAS-r (Edmonton Symptom Assessment System revised: Renal) 3) Brief Pain Inventory. Ethical and compassionate care is the main goal when managing a patient at the end of life.	by families include physical, emotional, social, and economic dimensions. In view of the limited access to RRT, we advocate that renal supportive care should be supported by government. Fund renal supportive care nurses and their training. Establish the role of medical insurance societies in Palliative and supportive care in ESKD. Hidden costs of dialysis that are not included by some medical insurers AND explore better arrangements	frequent repeating. Patient-centred decision making should be implemented by a multidisciplinary team and should be a family orientated and culturally appropriate process where the team and patient agree on a specific course of action based on a common understanding of the patient's treatment goals. It should consider the benefits and harms of the treatment and the likely outcomes. All the possible options should be discussed openly and should include all dialysis modalities, withholding or withdrawing	Multidisciplinary RSC/PC clinic would serve as a platform to expand training, create awareness and upskill across the care continuum. Establishment of this clinic could be done at a tertiary centre, with primary healthcare physicians rotating through this service and nephrologists supporting community health centres with outreach. Once a care plan is formulated, it should be continued at primary level care and community-based services (home-based carers) should be involved.	Under-utilisation of home-based care and community orientated primary care workers. There needs to be strong collaboration between multiple disciplines, including the nephrologist, primary caregiver (GP), palliative care physician, social worker and nursing staff.	discussions with government, hospital management and medical insurance companies. Technology needs to be used by health professionals to link peripheral teams to the expertise of the multidisciplinary team. A call-in/Skype system could be used during the multidisciplinary clinic to support primary carers with advice on clinical management and symptoms. Web-based information is a cost-effective tool to assist families in providing care. Motivate for all the required medication at primary healthcare level.	paper itself does not say how the community can be involved or play a role in CKM)

Article, authors and publication year	Aim or Purpose of document	Involvement in organ and transplant policy framework	KSC core curriculum and CKM definition understanding	Symptom management and renal preservation	Financing of CKM program	Communication and leadership	Referral pathway and care model	Health workforce	Medicines, technology and infrastructure	Community participation
			Governments to fund renal supportive care nurses training.		for the provision of hidden costs, such as packaged care models.	dialysis and an "opt-out" option for the patient in the future after a trial of dialysis. Access to private medical insurance should also be discussed. Periodic review of the proposed decision should be included in the plan. Protocols such as SPIKES (breaking bad news) and the "Serious Illness Conversations" should be taught to team members and conversations clearly documented in patient files. Regular reflections, debriefing and collegial support from management of staff members to alleviate moral distress of doctors	Improved communication is essential between all healthcare levels. This can be achieved with a simple booklet for patients (a roadmap), which would detail the advanced care plan (ACP) and current treatments.		Extend the Essential Drugs List to include renal friendly drugs.	

Article, authors and publication year	Aim or Purpose of document	Involvement in organ and transplant policy framework	KSC core curriculum and CKM definition understanding	Symptom management and renal preservation	Financing of CKM program	Communication and leadership	Referral pathway and care model	Health workforce	Medicines, technology and infrastructure	Community participation
						involved in withdrawing or withholding dialysis. Advance Healthcare Planning. Awareness of all available palliative care options and support structures in both the private, public and NGO sectors.				
PHC-Standard Treatment Guidelines and Essential. Medicines List. Department of Health, SA. 2020.	To provide clear guidance to support equitable access to essential health care services at the primary level of care to enable the prevention and treatment of a wide range of acute and chronic conditions, with appropriate referral to higher levels of care.	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated

Article, authors and publication year	Aim or Purpose of document	Involvement in organ and transplant policy framework	KSC core curriculum and CKM definition understanding	Symptom management and renal preservation	Financing of CKM program	Communication and leadership	Referral pathway and care model	Health workforce	Medicines, technology and infrastructure	Community participation
Standard Treatment Guidelines and Essential Medicines List for South Africa Hospital Level, Adults. Dept of Health SA. 2019	To provide clear guidance to support equitable access to safe, effective and affordable treatment options at hospital level.	Not stated	Not stated	Fluid overload, calcium, phosphate, anaemia and hyperparathyroidism management.	Not stated	Not stated	Stage 1 to 3 should be managed in PHC. Stage 3 to 5 should be seen by specialist. Only transplantable patients should be referred to nephrologists. Consult specialist for rapid deterioration, cause unknown, proteinuria.	Not stated	EPO, Lasix, calcium, calciferol, EPO.	Not stated
Guideline for the optimal care of patients on chronic dialysis in South Africa. South African Nephrology Society. 2015.	Not stated	Pre-transplant assessment should be carried out before the patient is entered on the transplant waiting list. Indications and contra-indications mentioned.	Not stated	Several actions and precautions are recommended to preserve residual renal function (RRF), which is a strong predictor of mortality for dialysis patients: Angiotensin-converting enzyme (ACE) inhibitors and/ or angiotensin receptor blockers (ARBs) are the agents of choice. Monitor	Not stated	Not stated	When to refer to nephrologist: 1) Abnormal renal imaging e.g. cystic kidney disease, at any GFR 2) Persistent proteinuria and/or haematuria 3) eGFR <60 ml/min (recommended) 4) eGFR <30 ml/min (mandatory)	Nephrologist, nephrology nurse, nephrology technicians.	Not stated	Not stated

Article, authors and publication year	Aim or Purpose of document	Involvement in organ and transplant policy framework	KSC core curriculum and CKM definition understanding	Symptom management and renal preservation	Financing of CKM program	Communication and leadership	Referral pathway and care model	Health workforce	Medicines, technology and infrastructure	Community participation
				for hyperkalaemia and use with caution in vasculopathies, avoid potential nephrotoxins and aggressive lowering of blood pressure.						

CHAPTER 6: DISCUSSION

This is a study which aimed to determine the components of CKM program in a SA context. Through the triangulation of qualitative data and documents analysis, this study has proposed an essential package of service for CKM in a low resourced setting like SA. This study proposes that such a package should be founded on the health systems building blocks and all components should be integrated, coherent and coordinated.

This study was conducted at a crucial time when CKM was receiving international attention at the level of the ISN. The study participants were well experienced, relevant and represented in low-resourced countries (SA and Uganda) and a well-resourced lens (Australia) to compare and contrast good practices between well and poorly-resourced settings. Most of the participants (n=6) were nephrologists with a high total shared experience in years in the field of Nephrology and CKM. One of the participants had more than 10 years of experience in the field of CKM as a PC Physician further giving credibility to their opinions and knowledge shared during the CKM study period.

While participants had a similar understanding of CKM as indicated during study interviews, there appears to be some level of confusion about how it differs from KSC. Often, SA literature uses Kidney Supportive Care to refer to CKM.[4] This is understandable because CKM under the umbrella of KSC has only recently received international attention, with the ISN paying particular attention to standardised terminology that will apply to both poorly and well-resourced settings.

Under the umbrella topic of KSC there is CKM, KT and dialysis. While dialysis and KT are highly technical elements of KSC and generally need the technical leadership of nephrologist, the comprehensiveness of KSC requires other stakeholders who specialise in preventative and palliative care medicine for its full delivery.[20] This study finding is consistent with an observation made by Hole(2020) that programmatically, the care of patients with ESKD is divided into various components and requires the skills of skilled nephrologists working with other disciplines like palliative care and preventative medicine and primary care physcians.[20] A more integrated interdisciplinary response is needed for a successful CKM program.

There is, therefore, a need for some form of integration of skills, knowledge and resource availability along the continuum of care for health professionals to be able to support ESKD patients as they navigate the health system, including CKM patients as they move between tertiary and primary care settings. This is especially important since many nephrologists feel unequipped to deal with complex conversations, including treatment withholding, withdrawal and ACP.[3] Furthermore, it is not only CKM patients that must move from tertiary facilities to primary care centres, but information, resources and skills must also move and be available in primary care centres, including, Ward Based Outreach Teams (WBOT) for continuity of care. Primary care providers, therefore, have a big role to play in looking after patients on the CKM pathway and can assist to a greater extent with decongesting tertiary

facilities and with the management of patients on the CKM pathway at primary care level.[22] This may assist in improving access to CKM and general care of Kidney Supportive Care patients in settings other than teaching hospitals, especially in LMIC.

From the study interviews finding we can confirm that there is serious inequity in accessing dialysis between high income countries and LMIC. Participants in this study suggested that LMIC governments simple cannot afford to provide everyone with dialysis and either have very stringent criteria for accessing the dialysis program or only partially subsidise RRT. For instance, in Uganda, dialysis is a paid-for service that the NHI partially covers. Because it is a paid-for service, it's, therefore, difficult for most of the population to access it because most patients do not have the resources to pay for a long-term service since the twice-weekly dialysis regimen is known to be largely ineffective.[50]

Whilst dialysis is catered for in SA's public health sector, the health system is fragmented, with different criteria in the private and public health sector.[1, 2, 52] This may lead to the overtreatment of patients who are well funded in private health care and high-resourced countries, while those with public health care as the only option and low-resource countries face the risk of undertreatment and abandonment even when dialysis is indicated.[18] One participant voiced their disappointment with the lack of government funding for RRT and CKM:

> *"Especially when the government is not actually providing enough funding for dialysis treatment or transplant treatment, the government should at least be funding an alternative which is community-based organisations involved in conservative kidney management programs."* ***Participant 3***

The above is consistent with findings of a systemic review by Mushi(2015) that quantifies the direct and indirect costs of dialysis in LMIC including SA and found an estimated annual dialysis cost of up to 43 000 British Pounds per patient.[1] A patient who doesn't qualify for dialysis in the public health sector might go to the private sector for dialysis if they can afford and survive the one-year waiting period given by most private medical insurance before they can fund dialysis for new members. A challenge will, however, arise once the funds run dry to pay for medical insurance or direct private dialysis unit payments. This is consistent with findings of access abys as reported by Lancet despite studies having proven the feasibility and affordability of a consultative model for the delivery of PC services across all levels of care.[18] With palliative care forming part of UHC, a good CKM program is an absolute human imperative resource for any country.[53]

Such a program needs to be well budgeted for and supported financially, which is a big problem in poor countries, as alluded by Buse(2009).[40] Such funding may not be limited to the funding of mainstream hospitals but community organisations like hospices may also be subsidised for the care they can render to public sector patients. Based on the study interviews, currently attempts to decongest the already overwhelmed public sector includes patients who can afford being encouraged to join medical aids/health insurance to privately access dialysis when they become eligible

which is usually after a one year waiting period from the time of joining the health insurance.

According to literature and study participants, dialysis should be available for everybody when indicated, however most LMIC simple cannot afford to put everyone on dialysis when indicated hence the coining of the term choice-restricted CKM which without a proper CKM program leads to patients presenting more in acute settings without ACP and thus an increase in health care costs with repeated extensive workups costing the country even more in both direct and indirect costs.[4, 7] The need for a comprehensive program that incorporates all aspects of KSC including kidney transplantation as noted by some of the study participants is an important study finding and implies that staff members on a CKM program must also promote organ transplantation policy frameworks.

Poor organ transplantation policy framework as a study finding does not only require support with funding, but also relies on a good organ transplant policy framework and increased public awareness on organ donation.[54] The decision by ISN to put dialysis, transplant and CKM pathways under the umbrella term KSC appears to be a great move and would benefit low resourced settings like SA.[3, 55] Low-resourced settings would benefit because this concept of KSC allows for the best of palliative care to meet the best of nephrology and the best of transplant, meaning that all parties involved in KSC, including dialysis, will be supportive and familiar with all KSC pathways.[55]

Dialysis is technically a form of palliative care as agreed by most participants, thus, the need for nephrologist to also be conversant with activities in CKM pathway and not only in dialysis and transplantation. Further, people involved in the CKM pathway may benefit from supporting the transplant pathway by being actively involved in campaigns to improve organ donation rate, which if successful, will mean that there will be improvement and increase in the number of kidney transplants in SA thus allowing more patients in choice restricted CKM pathway to enter dialysis and transplant pathways. However, the latter will not be achieved unless there is improvement in the transplant policy framework to involve district and primary care communities to take and play a significant role in KSC. Considering poor prognostication in KSC, there appears to be a need for palliative care integration in the KSC program regardless of whether a patient is for dialysis or not because, at some point, most patients in the KSC program undergo functional decline and are in need of PC.[7]

Participants mostly defined CKM as a non-dialysis pathway. However, the fact that some clinicians offer palliative dialysis with the intent of trying to alleviate the initial symptoms and allay the patient's anxiety about death remains controversial.[56] In this instance, clinicians would know fully well that the patient is not being optimised for renal transplant or will not be on dialysis for long. This approach questions the legitimacy of the CKM pathway. In LMICs like SA, it may be difficult initially to know whether kidney injury is acute or chronic with first presentation, but once clinicians know that it is chronic, a decision should be taken immediately to put patients on the CKM pathway following a well-documented patient centred consultation and a family

meeting where indicated.[56] The researcher observes palliative dialysis as a symptom of a moral injury experienced by nephrologists and specialist physicians and points to the need for a supportive interdisciplinary teamwork KSC environment where specialists can be supported ethically and emotionally by psychosocial team members.

Younger patients are seen in the CKM pathway of LMIC than in high-income countries, as reported by participants. The reason for these differences is said to be mainly due to resource limitations. Notwithstanding, the inaccessibility of dialysis in younger qualifying patients in low-resourced settings appears to be causing moral injury to most nephrologists. An improved public health awareness on kidney disease if put high on the list just like hypertension and diabetes during awareness campaigns due to its morbidity, mortality and economic burden especially in younger people may reduce the number of young people in need of dialysis.[52] Prevention, early detection and management of kidney disease through a comprehensive KSC program along the continuum of care with more emphasis on empowering, supporting and incorporating primary care into the program may improve the number of young patients in need of RRT.[38]

As alluded by all SA expert (n=7) the biggest challenge is that most patients are down referred to PC facilities upon rejection from dialysis program, primary care facilities need to be equipped with a basic technological transformation process to allow improved service delivery and linkage to support structures and human resources for mentorship and skills transfer from tertiary institutions.[20] This service requires a supportive system for information management and dedicated appointments for clinic times since very sick patients may not be able to wait for too long in the primary care platform. An effective booking system may be shared and accessed at all levels of care and may not only improve efficiency but also provide data that may be used for research purposes.[57] These systems can assist with continuous education and support between nephrologists in tertiary centres and health workers who are based remote locations in poorly resourced settings.

According to participants, pain and shortness of breath appear to be the main distressing symptoms experienced by patients on CKM pathway both in poor and well-resourced countries and are both amiable to palliative care approach and common drugs like morphine and furosemide. Furosemide appears to be easily available in all levels of care in SA. For CKM program there will need to be work done to make sure that morphine is available in primary care facilities especially in rural provinces like the Mpumalanga province where morphine is not available at all in primary care facilities and appears to be a challenge to access in primary care. Morphine stockouts and access barriers are a common problem in SA.[58] South African clinicians are supposed to be guided by the palliative care consensus document when managing a patient enrolled in the CKM program.[4] Participants based in primary care strongly felt that it would be important that drugs that are renal friendly are equally available in both tertiary and primary care centres where most of CKM patients are found.

Hinderances of CKM include the fact that some parts of SA like the Mpumalanga province do not have dedicated palliative care units while the Eastern Cape province's programme is hindered by the limited funding available for the PC service as stated by a participant based in the Eastern Cape province of SA. For instance, according to study participant, the government withdrew funding that they used to give to Hospice in the Eastern Cape province of SA. The impact of this has been the difficulty of down referrals of patients who can no longer be accepted by Hospice as stated by the participant. This study finding is consistent with literature findings that well known reasons for slow progress in health outcomes are mostly attributed to lack of investment in health systems of LMICs, insufficient or poorly coordinated donor resources, lack of agreement on effective technical strategies and limited scale up of interventions that work.[40] The researcher believes that programmatically and ethically speaking, there may never be oncology, nephrology or neurology services provided by health managers without the support of palliative care yet provinces like Mpumalanga province have got these programs with no provincial palliative care policy or palliative care program in the province. PC advocacy and lobbying may assist in bringing about change in policy implementation when a factor is changed as described by a policy analysis triangle coined by Buse(2009). [40]

According to research findings there appears to be a disconnect in low resource settings where nephrologists are based in specialised hospitals and mainly focus on dialysis and kidney transplant but little or no involvement in CKM because patients for CKM are stepped down to district hospitals and primary care facilities with no clear plan of management or follow-up. As established in this study, some respondents complained about poor continuity of care plans when patients were down referred from teaching hospitals to the primary care platform. This is said to be a source of frustration for both the doctors who would be taking over the management and the patients as they felt helpless. This is consistent prior mentions in literature that many patients with ESKD are managed in primary care with either no access or late referrals to PC.[4] A poorly resourced country like SA, the concept of collusion of anonymity (abandonment) applies because the important decision of allocating patients to a CKM pathway is not followed by the taking of responsibility for what happens to them after the allocation and step down to lower levels of care with health workers often experiencing moral injury and only focusing on one aspect of KSC.[59]

There is a great need for a well communicated and supported interdisciplinary management plan that will support CKM patients as they navigate between the levels of care. Internal physicians, nephrologists, family and PC physicians can play a critical role in skills transfer in the management of CKM patients to regional, district and primary care facilities to strengthen CKM program in PC. This finding is consistent with the concerns that Wearne and Krause(2020) addressed on the SA guideline for CKM and the role of a primary care provider in a CKM program respectively.[4],[22] The SA guidelines for CKM addresses the biopsychosocial needs of both paediatric and adult patients including resources that are needed in such a program, it also proposes a basic model of a CKM program in a low-resource country like SA.[4] Participants in this study seemed to be well versed with this guideline and most referred to it during the study interviews.[4]

Clinicians who are centred in teaching hospitals admit that at some stage after diagnoses with ESKD, patients who are on the CKM pathway are discharged and down referred to their local primary care facilities and/or local hospitals (i.e., district or regional hospital). These clinicians find themselves with a dilemma on trying to retain them in their care for long but limited by their capacity and the growing numbers of patients who are for “active” nephrology interventions. The recommendation is that a clear management plan before referral is documented, and means are made to ascertain that it is received by health professional who will be taking over the management at lower levels of care through a digital health platform.

From this study findings, the referring clinicians across the continuum of care are themselves often aware that the health facilities that they are referring patients to are also overburdened and cannot maintain the relationship with these patients. Specialised hospitals often also end up referring them further to the nearest district health facility. This process is even more haphazard in provinces where there is limited nephrology care. In other centres, priority is given to patients who reside closest to the tertiary hospital as stated by one study participant.

Leadership, decentralisation of KSC and formal implementation of a standardised CKM program like the HIV program can empower a PHC based and a well-supported CKM program. Therefore, the non-standardisation of care as indicated by the participants and the limitation of guidance of standard care in local documents leaves many patients receiving suboptimal care.

This is further complicated by global CKM guidelines being driven from high-income countries.[12, 20] The move for an international KSC curriculum by the International Society Nephrology is noted and appreciated, but the complexities and heterogenicity of resource availability between poor resourced and well resources countries and the heterogenicity among poor resourced countries themselves makes one standardised international CKM program unfeasible. Standardizing CKM programmes will need flexibility since countries are different in terms of resources and health systems; each country will need something suitable for its setting but draw from international standards. It is important though that the international community thinks of poorly resourced countries as well when formulation guidelines without compromising care for countries that have the resources to provide RRT for their population.

Comprehensive, contextually and clinically appropriate standardisation of the basics or core of the basic principles may improve the delivery of CKM services to patients whether in poor or well-resourced setting.[12] A functional program with a strong health system with a dedicated service for CKM, good communication between the different levels of care and specialties, adequate funding, coherent referral pathways, maintenance of continuity of care for all patients, and a standardised care model that is contextually and clinically relevant may form the basic or core principles of CKM pathway.

Most participants appeared to have no awareness of the leadership influence or leverages that consultant nephrologists or palliative care physicians can have on governments regarding any chance or implementation of health policy, including CKM policies. Leadership has always appeared to be seen as something that needs to be done by the district, provincial, and national governments or by someone external from the working environment of consultants. There is a great need to sensitise health professionals in KSC and CKM on the role that they can play in policy change or implementation and factors that lead to policy change as stated by Buse et. al.[40] CKM is reliant upon good leadership at all levels of the care pathway. Furthermore, an Advisory Board formed by multiple stakeholders, including patients and academics could strengthen the governance of this program. Leadership is a strong element of successful health systems, its education and practice may be improved and strengthened by undergraduate curriculum development and mentorship programmes in hospital and medical school academic environments.[60]

The CKM program would benefit from a palliative care trained nurse, social workers with psychology competencies at all levels of care, primary care doctors who are trained in palliative care, competent nephrologist who will refer patients to the program, and a palliative care physician who would oversee the care across all levels of care.[34] Psychologists could be of great value to CKM programs, however, due to scarcity of resources, social workers are often favoured because of their dual role in terms of psychotherapy and management of the associated social factors are the chief cornerstones of CKM programs as stated by most study participants.

A successful programme requires adequate human resources development, health workforce planning and competent health workforce management.[61] Part of the challenges noted is that other disciplines and other health workers, do not understand what palliative care is or what it seeks to achieve.[36] KSC and CKM program may benefit from the mandatory training of all nephology trainees in palliative care, mandatory training of palliative care physicians on kidney failure, and further training health professionals who are in lower levels of the health system in palliative care as recommended by the WHA 67.19 resolution which states that all clinicians working in areas with a high burden of patients in need of PC need intermediate level training.[62] The program may be a nurse-run service as an essential nursing career path for those nurses who have ambitions of specialising since it is well known and documented that driven programs often do well in improving health outcomes in HIV and other chronic diseases.[63-65]

A noted by one participant, the community in a CKM program can be a patient community whereby patients on the CKM program get to know each other as they attend CKM care. This arrangement can also be formalised into patient support groups in communities where patients live. The community can be a source of support as well as source of stigma for some patients, scaling up of social interventions and awareness may assist in removing stigma associated with changes in physical appearance in patients with ESKD, awareness campaigns may also assist in harvesting support and advocacy for patients with ESKD. It would be essential to involve patients and community members in palliative care teams at the primary care level. Home-based care teams could be community members who undertake home

visits. In line with WBOT and CBOs, a well-structured CKM program can be a form of government providing funding for alternative to dialysis treatment or transplant treatment since most poorly resourced countries cannot afford enrol everybody who needs RRT on dialysis.

Patients and communities also needed to be empowered with the correct information because they can be important and effective advocates and sources of support and policy change of implementation agents.[40] Communities can also organise to mobilise resources from governments and private funders for the support of patients with CKD as noted by one of the study participants who is also very passionate about keeping good renal registers and community participation in KSC. Communities can also provide direct support to individual patients, such as helping to clean the patient or wash the patient, etc. Patient representatives can form part of advisory boards, such as the South African renal registry. Patients in RRT or CKM program form and become a supportive community to each other since they know the needs of the program and other patients in the program.

With only 14 percent of patients with ESKD allocated to the dialysis pathway and over 80 per cent of ESKD patients on the conservative pathway in SA[8], one would expect to have more documents addressing the needs of patients on the CKM pathway. The opposite was found after an extensive search for SA CKM documents with literature flooded with RRT documents, which are helpful but unfortunately only address the minority of this vulnerable population. Only one SA document out of the six analysed and comprises of a few individuals who came together in Cape Town had most of the suggested components of an ideal CKM program. There is a great need to shift the focus to the program that will be addressing most patients with ESKD in LMICs since most of these countries cannot afford to put all deserving patients on dialysis. A good CKM program and policy will not be an excuse for governments not to provide RRT but would be a fair and just response to the current abandonment of patients in need of the program. This needs to be clearly reflected in ESKD policies and documents.

Most analysed documents where silent on transplant policy framework involvement, leadership and financing of CKM programs. Documents are well known to play a major role in policy change.[40, 66] Comprehensiveness of CKM documents with all important components is a necessary change in addressing perpetual poor referral system, programs under KSC working parallel to each other, ESKD patients recirculating in acute care facilities and back log of patients awaiting RRT and KT.

Leadership roles need to be reflected in documents to propel policy implementers to the direction of harbouring community participation, intersectoral collaboration and decentralised comprehensive nephrology services to empower all levels of care on the needs of patients on the CKM pathway to allow them to receive CKM through vertical programs between tertiary and primary care level of care without the need to congest tertiary centres.

The confusion in terminology was also noted during DA. It is important that policies and documents in LMICs align themselves with the new core curriculum as led by the ISN to avoid confusion of terms and definitions of KSC and CKM even though

programmatically LMICs might adapt their policies to fit their local circumstances and unique challenges.

LIMITATIONS OF THE STUDY AND FUTURE RESEACH

Even though rigour was undertaken to conclude this study, there are limitations that could not be avoided. Snowballing and data saturation as techniques employed in this study may have introduced bias into the study. However, nephrology in South Africa is a small field with fewer nephrologists in general and even fewer that are interested in CKM. Documents that were not published during the conduction of the study could have also given more insight into CKM advancement in the country but were excluded from the study leading to fewer documents being reviewed. Moreover, due to CKM curriculum development being in its infancy stage, finding literature and documents could have been limited by terminology used in different countries and setting.

Whatever the setting may be, it is apparent that there is a need for future research and improvement in the development of a policy framework for CKM in both well-resourced and resource limited setting. Due to many health systems challenges in the referral pathways and poor feedback mentioned by most study participants, an important area of research would be an investigation into how leadership and ICT can play a role in HCW skill transfer, digitalisation of patient records and management plans as patients move across the levels of care for the effective and efficient delivery of healthcare services in CKM.

CHAPTER 7: CONCLUSION AND RECOMMENDATIONS

This study aimed to determine the standards or components of care in providing CKM services in low resourced countries like SA. This study achieved its objective by proposing the components of a CKM program in a SA context, identifying and analysing SA CKM documents according to the proposed components of a CKM program. This study has proposed an essential package of service for CKM in a low resourced setting like SA (table 6). This study proposes that such a package should be founded on the health systems building blocks and all components should be integrated, coherent and coordinated. The recommendations are:

1. SA clinicians should be guided by the PC consensus document when managing a patient enrolled in the CKM program
2. The standards on the CKM program in SA must be updated to include vital components as prescribed by experts during study interviews. (Table 6)
3. CKM documents reviewed, and future documents should consider their bases to include the WHO building blocks to ensure successful and sustainable service delivery and should be aligned with the organ and transplant policy framework since they are interdependent streams of KSC.
4. CKM program should align its curriculum in KSC as led by the ISN with a bit of flexibility or consideration in LMIC with resource limitations.
5. A possible model of CKM care may be that of an oblique program with teaching hospitals being centres of excellence allowing primary care providers to rotate in centres of excellence and the use of technology for experts in teaching hospitals to support primary care provides.
6. There is a need for leadership in CKM with improved discharge summaries from teaching hospitals and linkage to care in lower levels of care for continuity of care.
7. Resources needed by CKM patients; especially renal friendly medicines will benefit many patients on CKM pathway if made easily accessible in primary care since most are looked after in primary care facilities.

The needs of patient on CKM in SA and LMIC are complex and require a comprehensive CKM program that considers the context and available resource within a country.[3, 4, 22]. This study will serve as a baseline study for more in-depth studies and possible a CKM program framework. CKM program needs to be funded as per commitment by SA, a co-sponsor of WHA 67.19 resolution which states that all clinicians working in areas with a high burden of patients in need of palliative care need intermediate level training as a matter of urgency. Nephrology, especially choice restricted CKM is a high burden speciality for patients in need of PC and forms part of UHC which aims to leave no one behind.

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APPENDICES

Data Collection Tool

INTERVIEW SCHEDULE FOR ESKD EXPERTS

Participant Code: _____

Date of Interview: _____

Interview instructions:

- For Section A insert an X in the appropriate box.
- For Section B answer the questions as accurately as possible.
- Please note that the information provided during this interview is confidential.

Section A: Demographic Information

A1. Expert speciality

Nephrologist	
Palliative Care Physician	
Dual Trained	

A2. Year of experience in ESKD PC (CKM)

0 – 5 years	
6 – 10 years	
11 - 15 years	
More than 15 years	

A3. Country of practice

A4. Institution of practice

Section B: Prescripts of ESKD PC service

Objective: To determine the prescripts of ESKD PC service internationally and in South Africa.

B1: Understanding the Term End Stage Kidney Palliative Care (ESKD PC) or Conservative Kidney Management (CKM)

B1: Defining ESKD PC or CKM

In your own understanding, how would you define the term ESKD PC or CKM, please elaborate?

……

……

B2: Biological Prescripts

Question B2. In terms of meeting the physical needs of patients with ESKD patients for PC or CKM, what are the prescripts that such a program should meet?

……

……

B3: Psychological Prescripts

Question B3. In terms of meeting the psychological needs of patients with ESKD patients for PC or CKM, what are the prescripts that such a program should meet?

……

……

B4: Social Prescripts

Question B4. In terms of meeting the social needs of patients with ESKD patients for PC or CKM, what are the prescripts that such a program should meet?

……

……

B5: Spiritual Prescripts

Question B5. In terms of meeting the spiritual needs of patients with ESKD patients for PC or CKM, what are the prescripts that such a program should meet?

……

……

B6: Importance of standardized Prescripts

Question B5. Why is it important that countries should have standardised ESKD PC or CKM programs?

……

……

Information Sheet

PARTICIPANTS'S INFORMATION SHEET FOR SEMISTRUCTURED INTERVIEWS

NAME OF RESEARCHER: Dr. Christopher Menzi Zungu

PHONE NUMBER AND EMAIL: Dr. C Zungu 072 181 4260 menzizu@yahoo.com

Prof. S Prasad 612 626 2935 shailey@umn.edu

Dr. R Krause 021 650 1475 rene.krause@uct.ac.za

INSTITUTION: University of Cape Town

DEPARTMENT: School of Public Health and Family Medicine

Dear Participant

AN ANALYSIS OF END STAGE KIDNEY DISEASE PALLIATIVE CARE SERVICES DOCUMENTS IN SOUTH AFRICA: A CASE STUDY OF WESTERN CAPE AND MPUMALANGA PROVINCE

I am a post graduate student in Palliative Medicine in the School of Public Health and Family Medicine, University of Cape Town. I am inviting you to participate in our research project on Analysis of End Stage Kidney Disease Palliative Care (ESKD PC) Documents in South Africa: A Case Study of Western Cape and Mpumalanga Province.

This letter gives information to help you to decide if you want to take part in this study. Before you agree you should understand what is involved. If you do not understand the information or have any questions, do not hesitate to ask. You should not agree to take part in this study unless you understand are completely happy about what we expect of you.

The purpose of the study is to understand the basic needs to be put in place and gaps in policy providing ESKD PC services in the Western Cape and Mpumalanga Provinces of South Africa. This kind of research is needed because of an increase in the number of people who are in need of ESKD PC services because they cannot be accepted for dialysis. Experts in the field of ESKD will be interviewed of their opinion of what should constitute ESKD PC service and documents on ESKD in the provinces of study will be reviewed to determine if they do cover the expected basic needs of ESKD PC services. This information will assist in strengthening ESKD PC services in the country where weaknesses are identified and reinforcing good practices or existing policies.

I will interview you and will be asking both closed and open-ended questions. This will take about 30 minutes. The interview will be recorded to assist with the transcription of information provided during the interview in a later stage of the research process. The audios recorded during the interview will be kept in a safe place to ensure confidentiality. Before the interview is analysed you will be able to review the transcription. You will not be penalized for refusing to participate in the study. Findings of this study will be shared with you in the form of a report and a presentation upon completion of the study.

The Health Research Ethics Committee (HREC) of the University of Cape Town, Faculty of Health Sciences has granted written approval for this study. Your participation in this study is voluntary. You can refuse to participate or stop at any time without giving a reason. Once the interview is completed, you cannot recall your consent.

NOTE: The implication of proceeding with the interview and signature below is that informed consent has been obtained from you. Thus, any information derived from the interview may be used for e.g. publication, by the researcher.

The committee approving the collection of data is the Faculty of Health Sciences Human Research Ethics Committee of the University of Cape Town. You can contact Dr C Zungu on 072 181 4260 or menzizu@yahoo.com, alternatively you can contact Dr R Krause on 021 650 1475 or rene.krause@uct.ac.za. You can also contact the Ethics Committee directly at 021 4066492 or by email: lamees.emjedi@uct.ac.za.

Consent Form

PARTICIPANTS'S INFORMED CONSENT FOR SEMISTRUCTURED INTERVIEWS

NAME OF RESEARCHER: Dr. Christopher Menzi Zungu

PHONE NUMBER AND EMAIL: Dr. C Zungu 072 181 4260 menzizu@yahoo.com

Prof. S Prasad 612 626 2935 shailey@umn.edu

Assoc. Prof. R Krause 021 650 1475 rene.krause@uct.ac.za

INSTITUTION: University of Cape Town

DEPARTMENT: School of Public Health and Family Medicine

Dear Participant

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I _____ (Name and Surname) agree to take part in the above study. I confirm that I have read and understand the participant information sheet. I understand that my participation is voluntary, and I am free to withdraw at any time without giving any reason.

_____ _____

PARTICIPANT SIGNATURE **DATE**

_____ _____

INTERVIEWER NAME AND SIGNATURE **DATE**

Ethical Clearance Letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room 45 E-52-E-Floor- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-submissions@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

13 June 2022

HREC REF: 161/2022

Dr R Krause
Division of Interdisciplinary palliative Care
Public Health & Family Medicine-FHS
Email: Rene.krause@uct.ac.za
Student: menzizu@yahoo.com

Dear Dr Krause

PROJECT TITLE: AN ANALYSIS OF END STAGE KIDNEY DISEASE PALLIATIVE CARE SERVICES DOCUMENTS IN SOUTH AFRICA: A CASE STUDY OF WESTERN CAPE AND MPUMALANGA PROVINCES-
(MPHIL CANDIDATE-DR CHRISTOPHER ZUNGU)

Thank you for your response letter, addressing the issues raised by the Faculty of Health Sciences Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19. Please refer to guidance letter dated 02 February 2022 on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

Approval is granted for one year until the 30 June 2023.

Please submit a progress form, using the standardised Annual Report Form (FHS016) if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: - Dr Christopher Zungu will also be involved in this study.

Please quote the HREC REF 161/2022 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

HREC/ref 161.2022

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.9.2025
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	6/9/2024

Note: Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.

Please use the latest form found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

Comments to PI from the HREC
Thank you for your Study Deviation 161/2022 HREC Chair Signature Date: 10/9/2024

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	09 September 2024		
HREC REF Number	161/2022	Current Ethics Approval was granted until	30 July 2024
Protocol title	Conservative Kidney Management Program Components In Resource-limited setting: South Africa		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes	☒ No	
If yes, could you please provide the HREC Reference number for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Ass. Prof. Rene Krause		

HUMAN RESEARCH ETHICS COMMITTEE
10 SEP 2024
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN