RECORD REVIEW OF POST-HAEMODIALYSIS BLOOD RESULTS TO ASSESS ADHERENCE TO GUIDELINES FOR END STAGE RENAL DISEASE

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DECLARATION

I, Yolinda Louise van der Nest, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and I have used the American Psychological Association (APA) system of referencing. I declare that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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DEDICATION

All thanks and praise to my heavenly Father for guidance upon this journey. Your word as recorded in Philippians 4:13 I Can Do All Things Through Christ Who Strengthens Me is my daily prayer.

It is with deep gratitude that I dedicate this dissertation to my children Robin Nathan and Dominique Louise, who have been a pillar of support and the source of great joy as we traversed life together.

In addition, I dedicate this dissertation to the memory of my beloved aunt Hazel Marlene Williams the only Mom I knew, whose many sacrifices and perseverance provided me with the opportunity of an excellent education and a strong sense of self. I trust I've made you proud.

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To my family and Dylan, thank you for your support and patience as I raced to complete this dissertation. Your love and encouragement remained my source of strength to persevere.

ABSTRACT

Background: End Stage Renal Disease is an irreversible decline in kidney function and fatal in the absence of renal replacement therapy. Resource constraints in the South African public healthcare sector limits patients' access to renal replacement therapy: here 14.8% are on haemodialysis compared to 85.2% in private dialysis units. Quality indicators in internationally accepted guidelines address complications of End Stage Renal Disease for patients on haemodialysis to reduce mortality and morbidity. Monitoring clinical outcomes for patients on haemodialysis is essential for good quality of life.

Aim: To design and validate a record review template for monitoring and describing target and actual outcomes for each clinical indicator to assess adherence to established guidelines.

Methods
Design: Retrospective chart review.

Participants: Patient records were accessed from an electronic database in 8 private units between 01 January and 31 December 2018.

Data instruments: Data were captured and analysed in SPSS. DAG Stat was used for the Kappa statistic for interrater reliability (test-retest). A *P*-value of <0.05 was taken as significant.

Results: Of the dialysis population (N=412) for the study period n=243 (58.98%) records were excluded. The median age of the convenience sample (169/412, 41.01%) was 60 years (IQR: 21-86), comprising 100/169 (59.17%) males and 69/169 (40.8%) classified as Coloured. Most patients (55/169, 32.54%) had Diabetic Nephropathy. Suboptimal dialysis adequacy (Kt/V levels) was present in 86/133 (64.6%) of the patients, similarly 102/166 (62.5%) for serum phosphate. Arterio-venous fistula or graft is recommended for vascular access for HD and 112/169 (66.27%) patients had either. While all patients should receive erythropoiesis stimulating agents and iron therapy, 110/169 (65.08%) and 104/169 (61.53%) respectively did. For the required phosphate binders and Vitamin D supplements there were recordings for 57/169 (33.72%) and 54/169 (32.72%) patients respectively.

Conclusion: Adherence to clinical guidelines for 3/5 quality indicators was considered unsatisfactory which has implications for patients' quality of life.

Keywords: Anemia, Arteriovenous Fistula, Chronic Kidney Disease, Guideline Adherence, Health Personnel, Kidney Failure-Chronic, Mineral Bone Disorder, Serum Albumin, Treatment Outcome and Treatment Practice Guidelines.[MESH] checked (September 2019)

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ABBREVIATIONS

AVF – Arteriovenous Fistula

AVG – Arteriovenous Graft

BP - blood pressure

Ca – Calcium

CKD – Chronic Kidney Disease

CPG – Clinical Practice Guidelines

CVD – Cardiovascular Disease

ESRD – End Stage Renal Disease

EuCliD® – European Clinical Database

FMC – Fresenius Medical Care

GFR - Glomerular Filtration Rate

Hb – Haemoglobin

HD – Haemodialysis

KDOQI – Kidney Disease Outcomes Quality Initiative

KDIGO – Kidney Disease Improving Global Outcomes

Ml - Millilitre

NKF – National Kidney Foundation

P – Phosphates

RRT – Renal Replacement Therapy

SARS – South African Renal Society

SPSS 26 - Statistical Package for Social Sciences version 26

TSAT – Transferrin Saturation

WHO – World Health Organisation

OPERATIONAL DEFINITIONS

Accuracy (percent correctness) of transcribing - recording parameters on the EuCliD® form accurately onto the Record Review Template (Polit & Beck, 2004).

Anaemia – Anaemia is a common complication of chronic kidney disease (CKD) (Strippoli, Navaneethan, & Craig, 2006)

Clinical guidelines – Guidelines developed internationally for patients on dialysis(Hoy et al., 2007; NKF-KDOQI, 2002). The guidelines provide benchmarks for improvement of various aspects of the medical treatment and care of patients on dialysis who have End Stage Renal Disease (ESRD) (Wikstrom et al., 2010).

End stage renal disease (ESRD) – An irreversible decline in kidney function, which is severe enough to be fatal in the absence of dialysis or transplantation. ESRD is included under stage 5 of the National Kidney Foundation Kidney Disease Outcomes Quality Initiative classification of chronic kidney disease (CKD), where it refers to individuals with an estimated glomerular filtration rate of less than 15 ml per minute per 1.73 m^2 body surface area, or those requiring dialysis irrespective of glomerular filtration rate (Abbasi, Chertow, & Hall, 2010).

Haemodialysis – Blood purification treatment for patients without kidney function (Davids, Marais, & Jacobs, 2017)

Kt/V - is a dimensionless ratio representing fractional clearance where ***K*** represents the dialyser clearance of urea (expressed in litres per hour), ***t*** is time on dialysis (expressed in hours) and ***V*** is the volume of distributed urea (expressed in litres) (Malekmakan et al., 2010).

Quality indicators – recommendations of care to improve quality of life and reduce mortality and morbidity in patients affected with ESRD (Wikstrom et al., 2010).

Renal replacement therapy – Renal Replacement Therapy (RRT) is therapy that replaces the normal blood filtering function of the kidneys. RRT includes dialysis (haemodialysis or peritoneal dialysis), haemofiltration and haemodiafiltration, which are various ways of filtration of blood with or without machines(Tamura, Tan, & O'Hare, 2012)

CHAPTER ONE INTRODUCTION

Chronic kidney disease (CKD), also known as the uremic syndrome (Vanholder, Pletinck, Schepers, & Glorieux, 2018), can lead to end stage renal disease (ESRD) (Kalantar-Zadeh, Mehrotra, Fouque, & Kopple, 2004). ESRD is an irreversible decline in kidney function, which is severe enough to be fatal in the absence of dialysis or transplantation (Allsopp, 2011). ESRD is a worldwide phenomenon (Abbasi, Chertow, & Hall, 2010). CKD affects people of all ages but more so the older (>70 years) population (Power & Brown, 2013) where the prevalence is almost 50% (Hallan, Coresh, Astor, & al., 2006) and the risk of death is high. Treatment is renal replacement therapy (RRT) either by peritoneal dialysis (PD) or haemodialysis (HD). The ultimate option is a kidney transplant. RRT and kidney transplantation are fraught with ethical implications.

Do all patients have a right to access PD, HD or a kidney transplant, in other words, a right to life (Sidley, 1997)? What if patients cannot afford the costs involved in the provision of RRT? The South African Durban High court ruling against the provision of free dialysis treatment for Soobramoney was upheld by the Constitutional Court on the grounds that the state would not be able to fulfil its other constitutional health obligations (Sidley, 1997). Soobramoney died two days later, reportedly from a stroke. This situation raises questions about the ethical principle of justice (fairness). How are decisions made about apportioning a limited public sector health budget to primary preventative health care activities versus expensive interventions such as HD or kidney transplantation for life-threatening illnesses?

The outcomes of kidney transplantation in human immunodeficiency virus (HIV)-positive patients in South Africa have been successful (Muller & Barday, 2018). Peritoneal dialysis may be accessible to more patients needing RRT because of the relative ease of access, particularly in resource constrained public sector healthcare settings because of the lower costs involved compared to HD which is prohibitively expensive and more available in private healthcare settings. Ethical principles such as beneficence (doing good) and non-maleficence (doing no harm) may be in conflict (Beauchamp & Childress, 2001) particularly when organs become a commodity that can be purchased (Bass, 2005; Scheper-Hughes, 2003) albeit illegally. Considerations such as the greatest good for the greatest number (utilitarian ethics) by withholding HD or transplantation for patients unable to afford this treatment and allocating funds elsewhere, may also be in conflict with deontological ethics (strict adherence to a moral code) by considerations of intervention at all costs

(Beauchamp & Childress, 2001). Due to the costs involved in RRT particularly kidney transplantation and the unavailability of donor kidneys, strict criteria for access to HD are applied in the public health sector. When patients meet these criteria and are willing to progress to transplantation, they are eligible to enter the HD programme.

1.1 Background

CKD has been classified into 5 stages by an international organization, the National Kidney Foundation (NKF). ESRD is stage 5 of this classification of CKD where individuals have an estimated glomerular filtration rate (GFR) of less than 15 ml per minute per 1.73 m^2 body surface area or require dialysis irrespective of GFR (Abbasi et al., 2010). Patients in stage 5 present with uremic symptoms that are eventually incompatible with life if left untreated. The NKF has developed clinical practice guidelines known as NKF-Kidney Disease Outcomes Quality Initiative (NKF-KDOQI) guidelines set out as quality indicators that address complications of ESRD.

In South Africa, the numbers of newly diagnosed patients requiring RRT continues to increase at an alarming rate (Davids, Singh, Marais & Jacobs, 2014). From data recorded in the South African Renal Register (SARS, 2015), the Western Cape Province has a prevalence rate of 327 per million population, with 856 (public sector) and 1172 (private sector) patients on RRT.

Mortality and morbidity amongst patients with ESRD are very high and providing care comes at a great financial cost (Clark, Farrington, & Chilcot, 2014). Because of the marked increase in patients requiring HD and the chance of receiving a kidney transplant in South Africa is minimal, patients are destined to spend many years on HD (Davids et al., 2014).

1.1.1 Primary predictors of successful HD outcomes

HD is one of the treatment modalities of RRT available to patients with ESRD. HD is required at least three times a week for sessions that last four hours. Patent vascular access is required in the form of an arterio-venous fistula, arteriovenous graft or temporary or permanent central venous catheter to access the patient's blood for distribution from the patient to the dialyser on the dialysis machine. The main aim of HD is to eliminate waste products and fluid from the patient in the same way that the kidneys normally operate. Patients are prone to anaemia due to heparinisation used in the treatment which may cause prolonged bleeding post-dialysis, blood loss due to decreased blood clotting and bleeding tendencies due to high levels of urea to mention but a few examples.

Permanent and temporary catheters predispose patients to a risk of infection leading to increased mortality and morbidity in this patient population (Dutka & Brickel, 2010).

Dialysis adequacy is closely related to frequency and duration of dialysis, and the quality of the access used for the session. Ineffective dialysis leads to complications for example anaemia as discussed previously, bone disease that leads to vascular calcifications and malnutrition that causes patients with renal disease to have a lowered resistance to infections that are detrimental to patients on dialysis. The clinical guidelines referred to previously, address these complications in order to deliver quality care and reduce mortality and morbidity.

Research shows that the primary predictors of successful HD outcomes are: 1) type of HD vascular access used, 2) dialysis adequacy, 3) management of anaemia associated with CKD and cardiovascular problems, 4) management of bone disease, 5) patients' nutritional status and 6) HD associated infections (Abdelwahab, Shigidi, El-Tohami, & Ibrahim, 2013; NKF-KDOQI, 2002). Vascular access management has always been one of the critically important components in the care of haemodialysis patients. An arteriovenous fistula therefore is the gold standard of care for patients on HD, followed by an arteriovenous graft if patients have vascular problems (NKF-KDOQI, 2015) for example, patients with diabetic nephropathy.

1.1.2 Guidelines for patients with End Stage Renal Disease on Haemodialysis

Since 1997 the National Kidney Foundation has produced evidence-based guidelines such as the NKF KDOQI for all stages of CKD and related complications. The guidelines are recognized worldwide and have been instrumental in improving the diagnosis and treatment of patients with renal disease (NKF-KDOQI, 2002).

1.1.3 Profile of government *versus* private health sector renal units in the Western Cape

In South Africa, where a rationing system in state hospitals is applied in selecting patients for HD, socio-demographic factors (excluding race) associated with inadequate housing and sanitation that might compromise good clinical outcomes, will limit the chances of a patient receiving dialysis. HD requires meticulous care of vascular access sites if the patient is accepted (Moosa & Kidd, 2006). If patients are not accepted for the HD programme, PD becomes the next option. The annual per-patient cost for PD is about 50% of that for HD, without considering the number of HD dialyser reuses. However, PD costs less than HD only if the fluids are manufactured and distributed locally (Okpechi, Rayner, & Swanepoel, 2012).

In Sub-Saharan Africa, CKD affects mainly young adults aged between 20-50 years and is primarily due to hypertension and glomerular disease (Jha et al., 2013). Hypertensive renal disease accounts for 33.7% of reported causes of ESRD in South Africa (SARS, 2015).

Monitoring clinical outcomes for patients on HD is essential to ensure a good quality of life. Non-adherence or non-compliance from a patient perspective is well documented in numerous research articles (Clark et al., 2014; Ibrahim, Hossam, & Belal, 2015; Saran et al., 2003). There is, however, a paucity of publications on the impact of clinician adherence to clinical guidelines and its importance for the provision of quality care.

The focus of this study is to monitor anonymised patients' blood results by retrospective record review to assess adherence to guidelines for ESRD. Adherence to guidelines should result in a patient who has ESRD and is on HD, having achieved blood results for parameters as set out in the guidelines. Such a study from a South African perspective has not been located in the published literature. The South African Renal Society (SARS) is concerned about quality outcomes following HD and it publishes an annual report on HD quality initiatives (SARS, 2015). This study will use the NKF-KDOQI (2002) and the NKF-Kidney Disease Improving Global Outcomes (NKF-KDIGO) guidelines (2009) to measure outcomes.

1.2 Problem statement

Monitoring clinical outcomes for patients on HD is essential for good quality of life. The NKF-KDOQI (2002) has established guidelines for improving the management of kidney disease. These guidelines have been developed as clinical indicators with parameters to measure patient outcomes and serve as a blueprint for all renal units in South Africa and internationally. The SARS annual report does not provide specific data that addresses measurement of quality indicators by record review to assess adherence to the guidelines and no such South African published study was located which is the focus of the present study.

1.3 Research question

What proportion of patients with ESRD on chronic haemodialysis in selected private dialysis units in the Western Cape Province reached target levels for each clinical indicator outlined in the NKF-KDOQI (2002) guidelines between 1 January 2018 and 31 December 2018?

1.4 Aim

The aim of the study was to design and validate a record review template to be used for record review to describe target and actual outcomes for each clinical indicator to assess adherence to established guidelines.

1.5 Objectives

The objectives of this study were to:

1.5.1 design a prototype record review template (Appendix 1);

1.5.2 validate the prototype record review template by a) ascertaining the index of content validity (CVI) and b); to establish accuracy (percent correctness) of the prototype record review template by inter-rater reliability testing.

1.5.3 describe haemodialysed patients' demographic and clinical characteristics (Appendix 1, Section A), prescribed medications (Appendix 1, Section B) and biochemical results (Appendix 1, Section C) at the completion of a dialysis session; and

1.5.4 compare recorded clinical data against the Kidney Disease Quality Outcomes Initiative (KDQOI) guidelines and where applicable, the Kidney Disease Improving Global Outcomes (KDIGO) guidelines as the gold standard for management of clinical outcomes (Appendix 1, Section C).

1.6 Significance of the study

What is known about the treatment of patients who have ESRD and receive HD is that internationally accepted guidelines for improving the management of kidney disease have been developed. These guidelines serve as clinical indicators with parameters to measure patient outcomes and serve as a blueprint for all renal units in South Africa and internationally. The SARS annual report does not provide specific data that addresses measurement of quality indicators by record review to assess adherence to the guidelines and no such South African published study was located. Nephrology nursing is a scarce skill in South Africa (Moosa, Meyers, Gottlich, & Naicker, 2016). The University of Cape Town (UCT) Division of Nursing and Midwifery introduced the Postgraduate Diploma in Nephrology Nursing in 2010, one of only three Higher Education Institutions (HEIs) in South Africa to do so and should provide data for evidence-based practice.

This study will add to the existing body of renal knowledge in two ways, by: 1) providing data on adherence to the gold standard for HD practice as set out in the practice guidelines on a validated record review form for a sample of adult patients in selected local private HD units to determine whether a standardised protocol is fit for purpose for these patients (Saunders, MacLeod, Salyers, MacMillan, & Ogborn, 2013); and 2) drawing conclusions about best practice and making recommendations for the private healthcare sector in the Western Cape

1.7 Summary

In this chapter the outline of this study was described: the background to record review of haemodialysis blood results to assess adherence to guidelines for End Stage Renal Disease. The aim of the study was to design and validate a record review template to be used to describe target and actual outcomes for each clinical indicator to assess adherence to established guidelines which will also give an indication of clinicians' compliance with the guidelines. The study objectives describe how the aim of the study will be achieved.

CHAPTER TWO LITERATURE REVIEW

2.1 Introduction

This chapter provides a narrative review of published literature on specific aspects of haemodialysis (HD) to achieve the aim of the study: adherence to established guidelines and clinical indicators relevant to the care of patients with end stage renal disease (ESRD) on HD to reduce morbidity and mortality. The literature review is presented to give a fuller understanding of the context in which HD is provided and criteria for selection of candidates for RRT and kidney transplantation. Gaps in the existing published literature on clinical indicators for good outcomes for patients on HD for ESRD and clinician compliance with these indicators are highlighted. In addition, the literature review included a search for validation studies referencing Content Validity Index (CVI) and inter-rater reliability specifically for accuracy of transcription and record review studies.

2.2 Search strategy

Multiple bibliographic databases were searched by platform (PubMed, EBSCOHost CINAHL, Africa Wide and Medline) and Health Source: Nursing/Academic Edition for relevant publications using key words, Boolean operators (AND, OR) and truncations (*) covering the years 2000–2019 and filtered for English language publications. MESH terms were searched in PubMed. The search was expanded by a manual search for references cited in useful sources. A summary of the search strategy is shown in Table 2.1. The full search strategy and results are presented in Appendix 2. Published studies were reviewed critically for clinician adherence to best practice international renal guidelines and the impact thereof on clinical outcome parameters for patients in ESRD on HD and to review factors such as anaemia, bone disease, nutrition, dialysis access and dialysis adequacy in these patients.

Table 2. 1: Sample of search strategy for keywords

Databases	Keywords	Results	No. of relevant papers	No. used
PubMed	A combination of keywords using Boolean operators [AND] [OR] and truncations [*] guided the search: Kidney Failure-Chronic, Guideline Adherence, Treatment Practice Guidelines, Treatment Outcome, Anemia, Serum Albumin, Chronic Kidney Disease-Mineral Bone Disorder Arteriovenous Fistula and Health Personnel [MESH checked (September 2019)	877	80	57
EBSCOHost CINAHL		549	74	16
Africa Wide and		8	3	0
Medline		218	58	7
Health Source: Nursing/Academic Edition		47	7	0
TOTAL RESULTS OF THE SEARCH STRATEGY FOR ALL DATABASES		1699	222	80

2.3 Hierarchy of evidence and evidence strength rating scale

Clinical research studies originate from anecdotal findings that may be a catalyst for various types of studies. The hierarchy of evidence (Figure 2.1) (Andrade, 2016) represents the types of studies on different levels. Meta-analysis and systematic reviews are considered the most robust evidence, followed by randomized controlled trials (RCTs), cohort studies, case control and then cross-sectional studies.

Figure 2. 1: Hierarchy of Evidence Retrieved from http://guides.lib.uchicago.edu/nursing

However, traditional hierarchies of evidence (Figure 2.1) have been challenged in favour of a more nuanced typology (Petticrew & Roberts, 2003; Miller & Jones-Harris, 2005). When applied to the present study, for example, observational studies (cohort, case control, cross-sectional) would have the same level of evidence as RCTs in informing the research question.

Levels of Clinical Research Evidence

An explanation of the strength of evidence for nursing practice from levels 1 to 1V and high to low from the Johns Hopkins guide are shown in Tables 2.2 and 2.3 respectively.

Table 2. 2: JHNEBP Evidence Strength Rating Scale

Strength of Evidence	
Level I	Experimental study/randomized controlled trial (RCT) or meta-analysis of RCT
Level II	Level II Quasi-experimental study
Level III	Non-experimental study, qualitative study, or meta-synthesis.
Level IV	Opinion of nationally recognized experts based on research evidence or expert consensus panel (systematic review, clinical practice guidelines)

Level V	Opinion of individual expert based on non-research evidence. (Includes case studies; literature review; organizational experience e.g., quality improvement and financial data; clinical expertise, or personal experience)

(Adapted from Poe and White (2010). Johns Hopkins nursing evidence-based practice Implementation and translation: Sigma Theta Tau)

The strength of evidence is explained in detail in Table 2.3.

Table 2. 3: STRENGTH of the Evidence

a. High	Scientific	Consistent results with sufficient sample size, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific evidence.
	Summative reviews	Well-defined, reproducible search strategies; consistent results with sufficient numbers of well-defined studies; criteria-based evaluation of overall scientific strength and quality of included studies; definitive conclusions
	Experiential	Expertise is clearly evident
b. Good	Scientific	Reasonably consistent results, sufficient sample size, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence.
	Summative review	Reasonably thorough and appropriate search; reasonably consistent results with sufficient numbers of well-defined studies; evaluation of strengths and limitations of included studies; fairly definitive conclusions.
	Experiential	Expertise appears to be credible
c. Low quality or major flaws	Scientific	Little evidence with inconsistent results, insufficient sample size; conclusions cannot be drawn.
	Summative reviews	Undefined, poorly defined, or limited search strategies; insufficient evidence with inconsistent results; conclusions cannot be drawn.
	Experiential	Expertise is not discernible or is dubious

(Adapted from Poe and White (2010). Johns Hopkins nursing evidence-based practice Implementation and translation: Sigma Theta Tau)

The literature that was reviewed was analysed for rigour by hierarchy of evidence (Andrade, 2016) and level of evidence as shown in Table 2.4.

Table 2. 4: Analysis of reviewed literature for rigour by hierarchy of evidence (type of study) and level of evidence for five themes that emerged from a literature review (vascular access for haemodialysis, assessment of haemodialysis adequacy, nutritional management during haemodialysis, management of anaemia, prevention of bone disease during haemodialysis)

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
SYSTEMATIC REVIEWS AND META ANALYSES					
Aiyegbusi et al. (2017)	Comprehensive evaluation of studies that assessed the measurement properties of PROMs in adults with CKD.	Four databases were searched; reference list and citation searching of included studies was also conducted. The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist was used to appraise the methodological quality of the included studies and to inform a best evidence synthesis for each PROM.	The search strategy retrieved 3,702 titles/abstracts. After 288 duplicates were removed, 3,414 abstracts were screened, and 71 full-text articles were retrieved for further review. Of these, 24 full-text articles were excluded as they did not meet the eligibility criteria. Following reference list and citation searching, 19 articles were retrieved bringing the total number of papers included in the final analysis to 66. There was strong evidence supporting internal consistency and moderate evidence supporting construct validity for the Kidney Disease Quality of Life-36 (KDQOL-36) in pre-dialysis patients. In the dialysis population, the KDQOL-Short Form (KDQOL-SF) had strong evidence for internal consistency and structural validity and moderate evidence for test-retest reliability and construct validity while the KDQOL-36 had moderate evidence of internal consistency, test-retest reliability and construct validity. The End Stage Renal Disease-Symptom Checklist	We suggest considering the KDQOL-36 for use in pre-dialysis patients; the KDQOL-SF or KDQOL-36 for dialysis patients and the ESRD-SCLTM for use in transplant recipients. However, further research is required to evaluate the measurement error, structural validity, responsiveness and patient acceptability of PROMs used in CKD	IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
			Transplantation Module (ESRD-SCLTM) demonstrated strong evidence for internal consistency and moderate evidence for test-retest reliability, structural and construct validity in renal transplant recipients.		
Casey et al, (2008)	In this review, the available evidence was synthesized to determine to what extent proactive vascular access monitoring affects the incidence of AV access thrombosis and abandonment compared with clinical monitoring.	Nine studies (1363 patients) compared a strategy of surveillance vs clinical monitoring. A vascular intervention to maintain or restore patency was provided to both groups if needed. Surveillance followed by intervention led to a nonsignificant reduction of the risk of access thrombosis (RR, 0.82; 95% CI, 0.58-1.16; I2 β 37%) and access abandonment (RR, 0.80; 95% CI, 0.51-1.25; I2 β 60%). Three studies (207 patients) compared the effect of vascular interventions vs observation in patients with abnormal surveillance result. Vascular interventions after an abnormal AV access surveillance led to a significant reduction of the risk of access thrombosis (RR, 0.53; 95% CI, 0.36-0.76) and a nonsignificant reduction of the risk of access	Very low quality evidence yielding imprecise results suggests a potentially beneficial effect of AV access surveillance followed by interventions to restore patency. This inference, however, is weak and will require randomized trials of AV access surveillance vs clinical monitoring for rejection or confirmation. (J Vasc Surg 2008;48:48S-54S.)		IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
		abandonment (RR, 0.76; 95% CI, 0.43-1.37)			
Chen, et al. (2016)	The focus of the meta-analysis was to evaluate the efficacy of nurse-led disease management programs in improving the quality of life for patients with chronic kidney disease.	Literature survey was performed to identify the eligible studies from PubMed, Current Nursing and Allied Health Literature, and Cochrane Central Register of Controlled Trials with predefined terms. The outcome measured was quality of life. This meta-analysis was conducted in line with recommendations from the preferred reporting items for systematic reviews and meta-analyses.	Eight studies comprising a total of 1520 patients were included in this meta-analysis, with 766 patients assigned to the nurse-led disease management program. Nurse-led disease management improved the quality of life in terms of symptoms, sleep, staff encouragement, pain, general health perception, energy/fatigue, overall health and mental component summary when evaluated 6 weeks after the beginning of intervention. When evaluated 12 weeks later, the quality of life in terms of symptoms, sleep, staff encouragement, energy/ fatigue, and physical component summary was improved. Stratified by the modalities of dialysis, similar results of pooled analyses were observed for patients with peritoneal dialysis or haemodialysis, compared with the overall analyses. The results of sensitivity analyses were the same as the primary analyses. The symmetric funnel plot suggested that the possibility of potential publication bias was relatively low.	Nurse-led disease management program seems effective to improve some parameters of quality of life for patients with chronic kidney disease. However, the seemingly promising results should be cautiously interpreted and generalized and still need to be confirmed through well-designed large-scale prospective randomized controlled trials.	IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
Chironda G., & Bhengu B. (2016)	To highlight the factors contributing to nonadherence in patients with CKD.	Six categories of factors contributing to nonadherence were identified. These were patient related, socioeconomic factors, psychological factors, therapy related factors, pathophysiological related factors and health care system related factors.	Articles were identified from online data bases namely Medline, PubMed, Cinahl, Google scholar and Grey literature. A comprehensive search was done to identify articles which highlight the factors contributing to non-adherence in patients with CKD. The following words were used for this search: Adherence & non-adherence, factors contributing to non-adherence to dialysis, medication, diet and fluid, patients with CKD. 96 of them were identified.	Non adherence remains a major obstacle in the effective management of CKD population. There is need for collaborative approach to devise measures that eliminate relevant contributing factors to non-adherence in patients with CKD.	IV
Coronado et al., (2015)	To assess the clinical benefits and harms of early versus delayed EPO for anaemia in patients with ESKD undergoing haemodialysis or peritoneal dialysis	The Cochrane Kidney and Transplant Specialised Register to 8 July 2015 was searched through contact with the Trials' Search Coordinator using search terms relevant to this review.	Literature searches yielded 1910 records, of these 1534 were screened after duplicates removed, of which 1376 were excluded following title and abstract assessment. We assessed 158 full text records and identified 18 studies (66 records) that were potentially eligible for inclusion. However, none matched our inclusion criteria and were excluded.	It was planned that two authors would independently extract data from included studies and assess risk of bias using the Cochrane risk of bias tool. For dichotomous outcomes (all-cause mortality, cardiovascular mortality, overall myocardial infarction, overall stroke, vascular access thrombosis, adverse effects of treatment, transfusion), we planned to use the risk ratio (RR) with 95% confidence intervals (CI). We planned to calculate the mean difference (MD) and CI 95% for continuous data (haemoglobin level) and the standardised mean difference (SMD) with CI	IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
				95% for quality of life if different scales had been used.	
Douvris et al., (2018)	To evaluate the effectiveness of RRT-related interventions for reducing HIRRT in such patients across RRT modalities.	A systematic review of publications was undertaken using MEDLINE, MEDLINE in Process, EMBASE, and Cochrane's Central Registry for Randomized Controlled Trials (RCTs). Studies that assessed any intervention's effect on HIRRT (the primary outcome) in critically ill patients with AKI were included. HIRRT was variably defined according to each study's definition. Two reviewers independently screened abstracts, identified articles for inclusion, extracted data, and evaluated study quality using validated assessment tools.	Five RCTs and four observational studies were included (n = 9; 623 patients in total). Studies were small, and the quality was mostly low. Interventions included dialysate sodium modeling (n = 3), ultrafiltration profiling (n =2), blood volume (n = 2) and temperature control (n =3), duration of RRT(n =1), and slow blood flow rate at initiation (n = 1). Some studies applied more than one strategy simultaneously (n = 5). Interventions shown to reduce HIRRT from three studies (two RCTs and one observational study) included higher dialysate sodium concentration, lower dialysate temperature, variable ultrafiltration rates, or a combination of strategies. Interventions not found to have an effect included blood volume and temperature control, extended duration of intermittent RRT, and slower blood flow rates during continuous RRT initiation. How HIRRT was defined and its frequency of occurrence varied widely across studies, including those involving the same RRT modality. Pooled analysis was not possible due to study heterogeneity.	Small clinical studies suggest that higher dialysate sodium, lower temperature, individualized ultrafiltration rates, or a combination of these strategies may reduce the risk of HIRRT. Overall, for all RRT modalities, there is a paucity of high-quality data regarding interventions to reduce the occurrence of HIRRT in critically ill patients.	IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
Flythe et al (2015)	Patients with end-stage renal disease (ESRD) receiving dialysis have poor health related quality of life (HRQoL). Physical symptoms are highly prevalent among dialysis dependent patients and play important roles in HRQoL. A range of symptom assessment tools have been used in dialysis-dependent patients, but there has been no previous systematic assessment of the existing symptom measures' content, validity, and reliability.	patient-reported physical symptom assessment instrument	From 3,148 screened abstracts, 89 full-text articles were eligible for review. After article exclusion and further article identification via reference reviews, 58 articles on 23 symptom assessment instruments with documented reliability or validity testing were identified. Of the assessment instruments, 43.5% were generic and 56.5% were ESRD-specific. Symptoms most frequently assessed were fatigue, shortness of breath, insomnia, nausea and vomiting, and appetite. The instruments varied widely in respondent time burden, recall period, and symptom attributes. Few instruments considered recall periods less than 2 weeks and few assessed a range of symptom attributes. Psychometric testing was completed for congruent validity (70%), known group validity (25%), responsiveness (30%), internal consistency (78%), and test-retest reliability (65%). Content validity was assessed in dialysis populations in 57% of the 23 instruments.	The number of available instruments focused exclusively on physical symptoms in dialysis patients is limited. Few symptom-containing instruments have short recall periods, assess diverse symptom attributes, and have undergone comprehensive psychometric testing. Improved symptom-focused assessment tools are needed to improve symptom evaluation and symptom responsiveness to intervention among dialysis-dependent patients.	IV
Ghimire S., Castelino R. L., Lioufas N. M., Peterson G. M., & Zaidi S. T. (2015)	This review summarizes existing literature on nonadherence and identifies factors associated with nonadherence to medication	A comprehensive search of PubMed, Embase, CINAHL, PsycInfo, and Cochrane Database of Systematic Reviews covering the period from 1970	Of 920 relevant publications, 44 were included. The prevalence of medication nonadherence varied from 12.5% to 98.6%, with widespread heterogeneity in measures and	A number of patient-, disease-, and medication-related factors are associated with medication nonadherence in haemodialysis patients. Clinicians should be	IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
	therapy in patients undergoing haemodialysis.	through November 2014 was performed following a predefined inclusion and exclusion criteria. Reference lists from relevant materials were reviewed. Data on study characteristics, measures of nonadherence, prevalence rates and factors associated with nonadherence were collected. The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines was followed in conducting this systematic review.	definitions employed. Most common patient-related factors significantly associated with nonadherence were younger age, non-Caucasian ethnicity, illness interfering family life, being a smoker, and living single and being divorced or widowed. Similarly, disease-related factors include longevity of haemodialysis, recurrent hospitalization, depressive symptoms and having concomitant illness like diabetes and hypertension. Medication-related factors such as daily tablet count, total pill burden, number of phosphate binders prescribed, and complexity of medication regimen were also associated with poor adherence.	aware of such factors so that adherence to medications can be optimised in haemodialysis patients. Future research should be directed towards well-designed prospective longitudinal studies developing standard definitions and validating available measurement tools, while focusing on the role of additional factors such as psychosocial and behavioural factors in predicting nonadherence to medications.	
Landreneau K., Lee K., & Landreneau M. D. (2010)	The purpose of this review was to determine the magnitude of effect of renal transplant on quality of life measures when compared with haemodialysis.	Sixteen studies were analysed, and the summary effect sizes were as follows: general quality of life was 0.98, physical functioning was 0.77, and psychosocial functioning was 0.39. Compared to haemodialysis, renal transplantation was significantly more effective in improving all three domains, particularly general overall quality of life and physical functioning.	a key finding in the study is the lack of adequate clinical trials using dialysis therapy with that of RT, even when methodologies other than randomized clinical trials were considered. More trials comparing dialysis with RT are needed.	Patients who remain on either type of dialysis continue to have increased risks as time progresses due to the renal failure that remains. Although RT may not provide quality of life equal to what the patient had prior to renal failure, convergent evidence suggests that quality of life benefits are distinctly better over that of HD after the immediate reduction in immunosuppression. Lastly, general quality of life and	IV

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				physical functioning are better with RT as the method of renal replacement therapy as seen in the last several decades of ESRD research.	
Muchayi et al. (2015)	The National Kidney Foundation Kidney Disease Outcomes Quality Initiative recommends the routine use of haemodialysis arteriovenous (AV) access surveillance to detect hemodynamically significant stenoses and appropriately correct them to reduce the incidence of thrombosis and to improve accesses patency rates. Access blood flow monitoring is considered as one of the preferred surveillance method for both AV fistulas (AVF) and AV grafts (AVG); however, published studies have reported conflicting results of its utility that led healthcare professionals to doubt the benefits of this surveillance method.	We performed a meta-analysis of the published randomized controlled trials (RCTs) of AV access surveillance using access blood flow monitoring. Our hypothesis was that access blood flow monitoring lowers the risk of AV access thrombosis and that the outcome differs between AVF and AVG.	The estimated overall pooled risk ratio (RR) of thrombosis was 0.87 (95% confidence interval [CI], 0.67 to 1.13) favoring access blood flow monitoring. The pooled RR of thrombosis were 0.64 (95% CI, 0.41 to 1.01) and 1.06 (95% CI, 0.77 to 1.46) in the subgroups of only AVF and only AVG, respectively	Results added to the uncertainty of access blood flow monitoring as a surveillance method of haemodialysis accesses	IV
Palmer, et al. (2017)	This review evaluated the benefits and harms of dietary interventions among adults with CKD including people with end-stage kidney disease (ESKD) treated with dialysis or kidney transplantation.	All studies were combined to look at dietary changes for people who kidney disease including people treated with dialysis or who have a kidney transplant.	Included 17 studies involving 1639 people with CKD. Three studies enrolled 341 people treated with dialysis, four studies enrolled 168 kidney transplant recipients, and 10 studies enrolled 1130 people with CKD stages 1 to 5. Eleven studies (900 people) evaluated dietary counselling	Dietary interventions have uncertain effects on mortality, cardiovascular events and ESKD among people with CKD as these outcomes were rarely measured or reported. Dietary interventions may increase health-related quality of life,	IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
			with or without lifestyle advice and six evaluated dietary patterns (739 people), including one study (191 people) of a carbohydrate-restricted low-iron, polyphenol enriched diet, two studies (181 people) of increased fruit and vegetable intake, two studies (355 people) of a Mediterranean diet and one study (12 people) of a high protein/low carbohydrate diet. Risks of bias in the included studies were generally high or unclear, lowering confidence in the results. Participants were followed up for a median of 12 months (range 1 to 46.8 months).	eGFR, and serum albumin, and lower blood pressure and serum cholesterol levels. Based on stakeholder prioritisation of dietary research in the setting of CKD and preliminary evidence of beneficial effects on risks factors for clinical outcomes, large-scale pragmatic RCTs to test the effects of dietary interventions on patient outcomes are required	
Yan et al. (2018)	This review evaluates the current evidence concerning the correlation of diabetes and AVF failure.	A search was conducted using MEDLINE, SCIENCE DIRECT, SPRINGER, WILEYBLACKWELL, KARGER, EMbase, CNKI and WanFang Data from the establishment time of databases to January 2016. The analysis involved studies that contained subgroups of diabetic patients and compared their outcomes with those of non-diabetic adults. In total, 23 articles were retrieved and included in the review.	The meta-analysis revealed a statistically significantly higher rate of AVF failure in diabetic patients compared with non-diabetic patients (OR¼1.682; 95% CI, 1.429–1.981, Test of OR¼1: z¼6.25, p<.001).	This review found an increased risk of AVF failure in diabetes patients. If confirmed by further prospective studies, preventive measure should be considered when planning AVF in diabetic patients.	IV
Zazzeroni L., Pasquinelli G., Nanni E., Cremonini	To determine whether haemodialysis or peritoneal dialysis	Searched databases: Cinahl, Medline, PubMed, Scopus and Proquest, including articles	Only some of the seven articles found significant differences between the two treatments. One of the studies	The analysis has not led to a unanimous conclusion. Quantitative analysis showed	IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
V., & Rubbi I. (2017)	provide a better QoL, a systematic meta-analysis was performed.	published from 2011 until June 2016; selected articles that compared, through KDQOL-SF 1.3 or 36 questionnaires, QoL among patients undergoing haemodialysis and peritoneal dialysis. The data was collected using Excel Office, and t-test has been performed on independent samples to identify significant differences.	showed a better QoL for peritoneal dialysis patients, while, on the contrary, two other studies support that the best QoL is in patients receiving haemodialysis. Another article displayed significant difference only for satisfaction in relation to care, better in patients on peritoneal dialysis, and for physical health, better in haemodialysis.	that the only statistically significant difference between the QoL of patients on haemodialysis and peritoneal dialysis regards the effect of kidney disease, which happens to be better in patients undergoing peritoneal dialysis.	
Matteson M. L., & Russel C. (2010)	To systematically review randomized-controlled trial intervention studies designed to increase treatment, medication, fluid, and diet adherence in adult haemodialysis patients	A search of Cumulative Index of Nursing and Allied Health Literature (CINAHL) (1982 to May 2008), MEDLINE (1950 to May 2008), PsycINFO (1806 to May 2008), and all Evidence-Based Medicine (EBM) Reviews (Cochran DSR, ACP Journal Club, DARE, and CCTR) was conducted to identify randomized-controlled studies that tested the efficacy of interventions to improve adherence in adult haemodialysis patients.	Eight randomized-controlled trials met criteria for inclusion. Six of the 8 studies found statistically significant improvement in adherence with the intervention. Of these 6 intervention studies, all studies had a cognitive component, with 3 studies utilizing cognitive/behavioral intervention strategies.	Based on this systematic review, interventions utilizing a cognitive or cognitive/behavioral component appear to show the most promise for future study.	IV
Philipneri et al., (2008)	Clinical practice guidelines for management of chronic kidney disease (CKD) have been developed within the Kidney Disease Outcomes Quality Initiative (K/ DOQI). Adherence patterns may	We retrospectively studied contemporary CKD care patterns within a private health system in the United States, and systematically reviewed literature of reported	KDOQI-consistent measurements of parathyroid hormone (7.1 vs. 0.6%, P = 0.0002), phosphorus (38.2 vs. 1.9%, P\0.0001) and quantified urinary protein (23.8 vs. 9.4%, P = 0.008) were more common among patients with	Delivery of CKD care may be monitored by administrative data. There is opportunity for improvement in CKD guideline adherence in practice.	IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
	identify focus areas for quality improvement.	practices internationally. Five hundred and nineteen patients with moderate CKD (estimated GFR 30–59 ml/ min) using healthcare benefits in 2002–2005 were identified from administrative insurance records. Thirty-three relevant publications in 2000–2006 describing care in 77,588 patients with CKD were reviewed. Baseline demographic traits and provider specialty were considered as correlates of delivered care. Testing consistent with K/DOQI guidelines and prevalence of angiotensin converting enzyme inhibitor/ angiotensin receptor blocker (ACEi/ARB) medication prescriptions were ascertained from billing claims. Care descriptions in the literature sample were based on medical charts, electronic records and/or claims.	CKD versus without nephrology referral in the administrative data. Nephrology referral correlated with increased likelihood of testing for parathyroid hormone and phosphorus after adjustment for baseline patient factors. Use of ACEi/ARB medications was more common among patients with nephrology contact (50.0 vs. 30.0%; P = 0.008) but appeared largely driven by higher comorbidity burden. The literature review demonstrated similar practice patterns.		
Rao et al. (2016)	The Strengthening the Reporting of OBservational studies in Epidemiology (STROBE) statement was published in October 2007 to improve quality of reporting of	Systematic literature review.	37 papers (11 Pre & 26 Post STROBE) were identified from 3621 potential articles. Only four of the 22 STROBE items and their sub-criteria (objectives reporting, choice of quantitative	This study highlights continuing deficiencies in the reporting of STROBE items and their sub-criteria in cohort studies in nephrology. There was weak	IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
	observational studies. The aim of this review was to assess the impact of the STROBE statement on observational study reporting and study design quality in the nephrology literature.		groups and description of and carrying out sensitivity analysis) showed improvements, with the majority of items showing little change between the period before and after publication of the STROBE statement. Pre- and post-period analysis revealed a Manuscript STROBE score increase (median score 77.8% (Inter-quartile range [IQR], 64.7–82.0) vs 83% (IQR, 78.4–84.9, p = 0.05). There was no change in quality of study design with identical median scores in the two periods for NOS (Manuscript NOS score 88.9), SIGN (Manuscript SIGN score 83.3) and CASP (Manuscript CASP score 91.7) tools.	evidence of improvement in the overall reporting quality, with no improvement in methodological quality of CKD cohort studies between the period before and after publication of the STROBE statement.	
Sinclair P. M., Kable A., Levett-Jones T., & Booth D. (2016)	To identify, appraise and synthesise the best available evidence for the effectiveness of e-learning programmes on health care professional behaviour and patient outcomes.	A systematic review of randomised controlled trials was conducted to assess the effectiveness of e-learning programmes on clinician behaviour and patient outcomes. Electronic databases including CINAHL, Embase, ERIC, MEDLINE, Mosby's Index, Scopus and Cochrane – CENTRAL were searched in July 2014 and again in July 2015.	The results suggest that e-learning was at least as effective as traditional learning approaches, and superior to no instruction at all in improving health care professional behaviour. There was variation in behavioural outcomes depending on the skill being taught, and the learning approach utilised. No papers were identified that reported the effectiveness of an e-learning programme on patient outcomes.	This review found insufficient evidence regarding the effectiveness of elearning on healthcare professional behaviour or patient outcomes, consequently further research in this area is warranted. Future randomised controlled trials should adhere to the CONSORT reporting guidelines in order to improve the quality of reporting, to allow evaluation of the effectiveness of e-learning programmes on healthcare professional	IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
				behaviour and patient outcomes.	
Strippoli G. F. M., Navaneethan S. D., Craig J. C., & Palmer S. C. (2006)	To assess the benefits and harms of different Hb or HCT targets in patients with CKD with CKD receiving any treatment for anaemia.	Randomised controlled trials (RCTs) and quasi-RCTs comparing different Hb/HCT targets in patients with the anaemia of CKD. Two reviewers independently assessed trial quality and extracted data. Statistical analyses were performed using the random effects model and results expressed as risk ratio (RR) for dichotomous outcomes and mean difference (MD) for continuous outcomes, with 95% confidence intervals (CI).	Twenty-two trials (3707 patients) were included. Hb ≥ 133 g/L was not associated with a reduction in the risk of all-cause mortality compared with 120 g/L in dialysis and pre-dialysis patients. In pre-dialysis patients, there was a significantly lower end of treatment creatinine clearance with Hb < 120 g/L compared to > 130 g/L (MD -4.17, 95% CI -6.33 to -2.02) but no significant difference in the risk of end-stage kidney disease (ESKD) (RR 1.05, 95% CI 0.50 to 2.22). Lower Hb targets resulted in an increased risk for seizures (RR 5.25, 95% CI 1.13 to 24.34) and a reduced risk of hypertensive episodes (RR 0.50, 95% CI 0.33 to 0.76). There were no significant differences in the risk of vascular access thrombosis.	There was no significant difference in the risk of death for low (< 120 g/L) versus higher Hb targets (>133 g/L). Lower Hb targets were significantly associated with an increased risk for seizures but a reduced risk of hypertension. In general study quality was poor. There is a need for more adequately powered, well-designed and reported trials. Trials should be pragmatic, focusing on hard endpoints (mortality, ESKD, major side effects) or outcomes which were previously not studied adequately (e.g. seizures, quality of life).	IV
van der Veer et al (2011)	Recent studies showed wide variation in the extent to which guidelines and other types of best practice have been implemented as part of routine health care. This is also true for the delivery of renal replacement therapy (RRT) for ESRD patients. Increasing uptake of best practice within such complex care systems requires an	Systematic review of over 5000 titles published since 1990 including papers describing planned attempts to accelerate uptake of best RRT practice into daily care.	Results tend to support previous findings that multifaceted strategies are more effective than single strategies. Improving our understanding of how to successfully implement best practice can inform system-level change and is the only way to close the gap between knowledge on what works and the actual care delivered to ESRD patients.	Research into implementation, using specific QI techniques, should therefore be given priority in future.	IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
	understanding of implementation strategies and specific quality improvement (QI) techniques.		Research into implementation, using specific QI techniques, should therefore be given priority in future.		
Wyczesany B., & Steefel L. (2015)	The objective of this project was to provide an education module to increase the knowledge of care of patients with ESRD on dialysis regarding albumin as a quality indicator among team members in an outpatient, private haemodialysis clinic.	Methods: A convenience sample of team members (n=24) in an outpatient haemodialysis unit participated in an education program of four 25-minute sessions for four days. A10-question pre-test initiated the program, followed by a PowerPoint presentation and a 10-question post-test.	The test questions, which were analysed using a paired sample t-test, showed a significant increase in nephrology team members' knowledge from pre-test to post-test (p= .000).	The education program was successful in improving team members' knowledge regarding albumin as a quality indicator, which can result in improved patient care.	IV
Yong K., & Kairaitis L. (2010)	This manuscript describes the effect of implementing proactive protocol-driven adjustments for iron and ESA in maintenance haemodialysis patients.	This was a cohort study of 46 satellite haemodialysis patients examined from 2004 to 2006 with protocol implementation in 2005. Baseline haemoglobin, transferrin saturations (TSAT), ferritin values and ESA administration were obtained during 2004. Follow-up data was collected in 2006 and compared to baseline values in reference to specified targets in the 2004 Caring for Australasians with Renal Impairment (CARI) guidelines.	Fifty-four percent of patients achieved haemoglobin targets during follow up versus 43% patients during baseline. Seventy-nine percent of patients achieved TSAT targets during follow up versus 67% patients during baseline. Ninety percent of patients achieved ferritin targets during follow up versus 75% patients during baseline. Odds ratios for values falling within target ranges during follow up compared to baseline were 1.63 (Hb: P = 0.037; 95% confidence interval (CI), 1.03–2.57), 1.90 (TSAT: P = 0.006; 95% CI, 1.20–3.01) and 3.72 (ferritin: P = 0.003; 95% CI, 1.57–8.83). There was a trend toward lower average ESA dose (P = 0.07)	This study demonstrates the successful implementation and efficacy of a proactive protocol for iron and ESA treatment in haemodialysis patients. Benefits include increased concordance with historical guideline targets and decreased haemoglobin variability. Improved iron status and optimizing ESA response allows for lower ESA doses, limiting both potential side-effects of ESA (hypertension) and the burgeoning costs of anaemia management.	IV

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
RANDOMISED CLINICAL TRIALS					
Coiera E., Choong M. K., Tsafnat G., Hibbert P., & Runciman W. B. (2017)	This study tests a novel method for automatically linking indicators to clinical trial registrations.	A set of 522 quality of care indicators for 22 common conditions drawn from the CareTrack study were automatically mapped to outcome measures reported in 13 971 trials from ClinicalTrials.gov. Intervention: Text mining methods extracted phrases mentioning indicators and outcome phrases, and these were compared using the Levenshtein edit distance ratio to measure similarity. Main Outcome Measure: Number of care indicators that mapped to outcome measures in clinical trials.	While only 13% of the 522 CareTrack indicators were thought to have Level I or II evidence behind them, 353 (68%) could be directly linked to randomized controlled trials. Within these 522, 50 of 70 (71%) Level I and II evidence-based indicators, and 268 of 370 (72%) Level V (consensus-based) indicators could be linked to evidence. Of the indicators known to have evidence behind them, only 5.7% (4 of 70) were mentioned in the trial reports but were missed by our method.	Number of care indicators that mapped to outcome measures in clinical trials were automatically linked indicators to clinical trial registrations with high precision. Whilst the majority of quality indicators studied could be directly linked to research evidence, a small portion could not and these require closer scrutiny. It is feasible to support the process of indicator development using automated methods to identify research evidence.	1
Shi Y. X., Fan X. Y., Han H. J., Wu Q. X., Di H. J., Hou Y. H., & Zhao Y. (2013)	To prospectively evaluate the effects of a nurse-led educational intervention on the management of hyperphosphataemia as well as knowledge of phosphate among patients with end-stage renal disease.	This prospective randomised controlled trial was conducted during the period from June 2009–March 2011 at the HD units of two hospitals in Tianjin, China. Methods. A total of 80 participants were randomly assigned to experimental group (n = 40) and control group (n = 40). Participants in the	There were statistically significant differences between the study groups in decline in serum phosphorus and calcium– phosphorus product levels and improvement in patients' general knowledge three months postintervention, and these differences sustained until the end of the study. Increased serum calcium level was observed both in the	Nurse-led intensive educational programme plays an important role in the control of hyperphosphataemia among patients with end-stage renal disease. Relevance to clinical practice. Chronic kidney failure patients with hyperphosphataemia are	1

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
		experimental group received the nurse-led intensive educational programme, including individualised education and educational session about diet and medicine regimes, etc., while participants in the control group received the routine guidance.	experimental group and in the control group, but there was no significant difference between groups. No statistical significance was found regarding serum albumin level between the groups. No significant difference in the serum parathyroid hormone level was found between the groups by month 6.	more likely to benefit from nurse-led intensive educational programmes.	
Williams A., Manias E., Walker R., & Gorelik A. (2012)	The aim of this study was to test the feasibility and impact of an intervention consisting of self-monitored blood pressure, medicine review, a Digital Versatile Disc, and motivational interviewing telephone calls to help people with diabetes and kidney disease improve their blood pressure control and adherence to prescribed medications.	Patients aged ‡18 years with diabetes, chronic kidney disease and systolic hypertension were recruited from nephrology and diabetes outpatients' clinics of an Australian metropolitan hospital between 2008–2009. Participants were randomly allocated on a 1:1 basis to one of two groups in a randomized controlled trial: the intervention delivered over 3 months (n = 39) and usual care (n = 41), with follow up at 3, 6 and 9 months postintervention. People collecting data and assessing outcomes were blinded to group assignment.	Seventy-five participants completed the study. The intervention was acceptable and feasible for this cohort. There were no statistically significant differences between groups, although the mean systolic blood pressure reduction in the intervention group (n = 36) was 6Æ9 mmHg 95% CI (13Æ8, 0Æ02) at 9 months postintervention.	The study was feasible and statistically significant differences may be determinable in a larger sample to overcome the variability between groups, paying attention to recommendations for further research.	1
OBSERVATIONAL STUDIES					
Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
Cicolini G., Palma E., Simonetta C., & Di Nicola M. (2012)	To determine the influence of a family carer on haemodialyzed patients' 'adherence'.	A total of 72 subjects with end-stage renal disease participated in the study. The subjects assisted by a family carer were identified as cases (n = 36), whereas those who did not have a family carer, as controls (n = 36). All subjects were followed up (4 months) and checked up regarding interdialytic weight gain, and serum levels of potassium and phosphate. Important differences in potassium and phosphate serum level and interdialytic weight gain between the two groups were evaluated separately using a repeated measures ANOVAOVA test.	Participants in the case group showed significantly lower phosphate and potassium serum levels and a lower interdialytic weight gain during follow-up when compared to controls	The presence of a family carer improves patients' adherence, particularly as far as phosphate levels are concerned, since phosphate intake plays a fundamental role in avoiding long-term complications in end-stage renal disease patients.	3
Ogawa C., Tsuchiya K., Tomosugi N., Kanda F., Maeda K., & Maeda T. (2017)	To Investigate the relationship between hemoglobin (Hb) level and iron status in hemodialysis patients to identify the optimal iron levels for patients undergoing hemodialysis.	A total of 208 outpatients on maintenance hemodialysis were followed up between July 2006 and June 2007. Men accounted for 64.9% cases [mean age, 59.3 ± 13.1 years and median dialysis history, 7.7 (3.6–13.2) years], and diabetic nephropathy accounted for 25.0% cases. Hemoglobin level was measured twice a month and serum ferritin, serum iron,	By receiver operating characteristic curve, the cutoff point of serum ferritin and transferrin saturation levels with a hemoglobin 10 g/dL showed <90 ng/mL (sensitivity: 69.1%, specificity: 72.1%, $p < 0.001$) and 20% (sensitivity: 77.6%, specificity: 48.8%, $p = 0.302$). Upon logistic regression model analysis with a hemoglobin 10 g/dL as the endpoint, the analysis of odds ratios relative to a group with serum ferritin 90 ng/mL	In this study, the iron status of serum ferritin <90 ng/mL and transferrin saturation 20% was optimal in hemodialysis patients receiving recombinant human erythropoietin for anemia therapy. This result indicates that the threshold values for the optimal iron status may be lower than those currently recommended in iron-level management guideline.	3

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
		and total iron-binding capacity were measured once a month. The doses of recombinant human erythropoietin and low-dose iron supplement were adjusted to maintain a hemoglobin level of 10–11 g/dL, according to the guidelines of the Japanese Society for Dialysis Therapy. Hepcidin was measured at baseline. Using the mean values for 1-year period, the relationships among hemoglobin, serum ferritin levels, and transferrin saturation levels were investigated based on a receiver operating characteristic curve and a logistic regression model. In addition, the correlations among serum ferritin, transferrin saturation, and hepcidin levels were analyzed by Pearson product—moment correlation coefficient and linear regression model.	and transferrin saturation <20% revealed that the group with serum ferritin <90 ng/mL and transferrin saturation 20% had the highest ratio: 46.75 (95% confidence interval: 10.89–200.70, p < 0.001). In Pearson product—moment correlation coefficient, hepcidin showed a strong positive correlation with serum ferritin [r = 0.78 (95% confidence interval: 0.72–0.83, p < 0.001)] and a weak positive correlation with transferrin saturation [r = 0.18 (95% confidence interval: 0.04–0.31, p = 0.010)]. In the multivariable analyses of the linear regression model, a positive relationship was shown between hepcidin and serum ferritin [βcoefficient of 0.30 (95% confidence interval: 0.27–0.34, p < 0.001)]; however, no relationship was shown with transferrin saturation [β-coefficient of 0.09 (95% confidence interval: −0.31–0.49, p = 0.660)].		
Pronai et al. (2017)	This study was conducted to identify treatment combinations used in clinical practice in Austria and Switzerland and the potential to control this disorder.	A total of 333 adult hemodialysis and peritoneal dialysis patients were analysed. All patients received conventional care prior to	Overall, the mean intact parathyroid hormone (iPTH) increased from 64.2 pmol/l to 79.6 pmol/l under conventional therapy and decreased after cinacalcet initiation to 44.0	In conclusion, cinacalcet appears to be a necessary treatment component to achieve recommended targets. The detailed composition of the	3

Authors	Study Aims/objectives	Method and sample size	Findings/results	Outcome measures/conclusion	Level of Evidence
		initiation of a cinacalcet-based regimen. During the study, treatment components, e.g. cinacalcet, active vitamin D analogues and phosphate binders, were adapted to individual patient requirements and treatment dynamics were documented.	pmol/l after 12 months (mean decrease between baseline and 12 months –45%). Calcium remained within the normal range throughout the study and phosphorus ranged around the upper limit of normal. The Kidney Disease: Improving Global Outcomes (KDIGO) target achievement for iPTH increased from 44.5% of patients at baseline to 65.7% at 12 months, corrected calcium from 58.9% to 51.9% and phosphorus from 18.4% to 24.4%. On average, approximately 30% of patients adapted their regimen from one observation period to the next. The reasons for changing a given regimen were to attain or maintain any of the bone mineral markers within recommended targets and to avoid developments to extreme values. Some regional differences in practice patterns were identified. No new safety signals emerged.	treatment mix should be adapted to patient requirements and reassessed on a regular basis.	

2.4 Introduction and main themes

Implementation and achievement of the clinical indicators in patients with ESRD have improved patient outcomes and decreased hospitalisations (Plantinga et al., 2007). Patient outcomes are also determined by adherence to the guidelines. Patient adherence to renal guidelines is well described in the literature, for example clinical studies from Europe on hyperphosphatemia in patients with ESRD (Covic & Rastogi, 2013). Diet and fluid non-adherence are described in a study undertaken in Belgium (Vlaminck, Maes, Jacobs, Reyntjens, & Evers, 2001), and the prevalence and psychological determinants of non-adherence in dialysis patients in the United Kingdom (Clark et al., 2014).

The (NKF-KDOQI, 2002) has established guidelines for improvement in the process of kidney disease care from pre-dialysis and dialysis (haemodialysis and peritoneal dialysis) to transplantation. The guidelines were further developed into clinical indicators with parameters to measure patient outcomes. Moosa (SARS, 2015, p. 2) reports that "Extensive use was made of the European Best Practice Guidelines (EBPG) and the Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines in drawing up" the SARS Guidelines.

KDIGO (2012) guidelines focus on topics related to the prevention of complications and management of individuals with kidney disease. Adherence to guidelines to achieve recommended outcomes assists in decision-making that contributes to the total care of patients on RRT. The desired outcomes that underpin adherence to best practice guidelines seek to reduce disease-related morbidity in patients. Previous studies relating to adherence to the guidelines report improved quality of life and decreased morbidity and mortality in patients presenting with ESRD (Leggat, 2005; Miranda et al., 2016). Compliance with the guidelines largely depends on adherence by both clinicians and patients (Djukanovic et al., 2015; Plantinga et al., 2007). The focus in this study is not on patient compliance (that is, adherence to dietary or fluid restrictions for example) but on compliance in achieving the recommended blood result parameters as set out in the guidelines, which implies clinician compliance with the guidelines. The implementation of the clinical practice guidelines seeks to improve the results of haemodialysis treatment and outcomes of patients with ESRD.

In addition to five relevant topics related to adherence to clinical guidelines in haemodialysis for patients in ESRD (presented in Table 2.4), the decision to provide HD is based on set criteria as outlined in this table (Okpechi et al., 2012).

Table 2. 5: Renal assessment tool for the provision of renal replacement therapy (Okpechi *et al.*, 2012).

Category 1 • Patients must be accepted	**Category 2** • Patients will be accepted depending on availability of space on the program and number of factors in this category	**Category 3** • Patients will be excluded
• Age: <50 years • Body mass index: <30 kg/m^2 • Gainfully employed • HIV negative • Hepatitis B negative • South African Citizen	• Age: 50 – 60 years • Body mass index: 30 – 35 kg/m^2 • Hypertension with target organ damage • Diabetes Mellitus • Smoking • Hepatitis B or Hepatitis C (no cirrhosis) • HIV positive (CD4 count >200, undetectable viral load, on HAART) • Late presentation needing urgent dialysis • Co-morbid disease • Previous renal transplant • Poor home circumstances • Convicted criminal for serious offence • Not gainfully employed • Poor social network/support • No proximity to dialysis unit	• Age: >50 years • Body mass index: >30 kg/m^2 • Transplantation contraindicated or associated with unacceptable risk • HIV infection other than described in Category 2 • Active substance abuse • Hepatitis B positive with cirrhosis • Diabetes Mellitus and Age >50 years • Active uncontrolled malignancy with short life expectancy • Non-South African citizen • Advanced irreversible progressive vital organ disease • Mental Illness resulting in diminished capacity to take responsibility for actions • Habitual non- adherence with any medical treatment

As patients from category 1 undergo transplantation, space is opened for other ESRD patients to be accepted for HD. If, however, the program is full, patients with ESRD needing HD cannot be accepted. South Africa, a middle-income developing country, has limited resources and the government healthcare sector does not provide equal access to all patients with ESRD. Only patients who can pay privately or who have medical aid are offered dialysis in private clinics (Davids et al., 2014). Space for dialysis in the private sector is therefore unlimited; anyone who can pay is accommodated (Okpechi et al., 2012).

The five main themes related to adherence to clinical guidelines in haemodialysis for patients in ESRD and presented in Table 2.3 are:

- Vascular access for haemodialysis
- Assessment of haemodialysis adequacy
- Nutritional management during haemodialysis
- Management of anaemia
- Prevention of bone disease during haemodialysis

Each theme and the relevant literature are discussed next.

2.4.1 Vascular access for haemodialysis

The National Kidney Foundation (NKF) has published the Dialysis Outcomes Quality Initiative (KDOQI) clinical practice guidelines for vascular access with regular updates (NKF-KDOQI, 2002). The guidelines provide clinicians the framework to optimize vascular access care of haemodialysis patients. The guidelines are based on available data from published literature and the opinion of the leaders in the vascular access field. Vascular access issues impose a major financial burden to health care and can be associated with increased hospitalisations among haemodialysis patients and the rise in morbidity and mortality (Jackson & Litchfield, 2006). The rope-ladder cannulation technique involves the cannulation of the vein/graft that moves progressively up the vein/graft in a systematic manner at each cannulation, to ensure uniform use of the vein/graft (Levey, 2012). This should be used for to prevent complications such as aneurysm, stenosis and infections (Deaver, 2010). For dialysis dose management, frequent and long dialysis sessions are recommended. This improves quality of life, controls hyperphosphatemia and reduces hypertension (Locatelli & Canaud, 2012).

Vascular access is referred to as the Achilles heel of dialysis treatment. A patent vascular access yielding a good blood flow is of fundamental importance to ensure adequate dialysis. Access refers to a surgically created Arterio-Venous Fistula (AVF) for the specific use of dialysis recommended in the KDOQI Guidelines as the first choice of access for patients receiving HD. The preferred vascular access type for patients on HD is indicated as an AVF. A synthetic arteriovenous graft (AVG) would be an alternative option for patients with diabetic nephropathy or problematic vasculature (SARS, 2015). There is evidence that clinical outcomes play a crucial role in regulating the overall treatment plan for patients afflicted with ESRD. Allsopp (2011) suggests that staff in an emergency department should know how to take care of a dialysis access point when such patients present

themselves to emergency departments. For example, no blood samples should be taken from a fistula or blood pressure measurements taken on that arm.

Other forms of vascular access include placement of a central venous catheter or a permanent catheter. Catheters pose numerous potential complications for example such as infections and stenosis of vessels. Appropriate placement of vascular access (for example AVF or graft) at an early stage, ensures that patients do not succumb to the potential complications of emergency insertion of any catheter. Furthermore, patients in ESRD are uremic and prone to infections (Dinwiddie & Bhola, 2010).

Frequency and duration of HD sessions should be 4 to 5 hours, three times a week (Leggat, 2005). Clinical studies have shown that the use of AV fistulas results in lower rates of infection, thrombosis, and hospitalizations (Jackson & Litchfield, 2006) compared to the use of grafts and catheters (Dutka & Brickel, 2010).

2.4.2 Assessment of haemodialysis adequacy

Adequacy of dialysis refers to the amount of dialysis needed for a patient to remain asymptomatic. Adequacy of haemodialysis improves patient survival, quality of life and biochemical outcomes and minimizes disease complications and hospitalisation (Adas, Al-Ramahi, Jaradat, & Badran, 2014). Dialysis adequacy is therefore an important determinant of patient outcome and thus an important clinical performance indicator. Dialysis adequacy refers to how well a patient is dialysed after measurement of urea clearance, expressed as Kt/V. Kt/V refers to a value (for example 1.2) used in medicine to quantify haemodialysis treatment adequacy: K, dialyzer clearance of urea; t, dialysis time divided by V, volume of distribution of urea, approximately equal to a patient's total body water. The guidelines recommend a Dialysis Adequacy of Kt/V of 1.2 for patients receiving dialysis three times a week and 1.6 for patients being dialyzed twice a week (Malekmakan et al., 2010; NKF-KDOQI, 2015).

Dialysis adequacy relies on removal of accumulated solutes achieved during the HD with the ultimate objective of each dialysis session being to restore the patient’s homeostasis and realizing a zero sodium and water balance. ‘Dialysis dose’, defined as the net product of ‘solute clearance’ (K) and ‘treatment time’ (t), is a useful index for assessing treatment delivery (Locatelli & Canaud, 2012). Inadequate dialysis increases mortality and morbidity among dialysis patients therefore evaluation of HD adequacy using various biochemical tests is recommended (Sehgal, 2002).

According to NKF-KDOQI guidelines, to achieve adequate HD, the urea reduction ratio must be above 65%, with a target Kt/V of 1.4 and a minimum of 1.2 (NKF-KDOQI, 2015). Every 0.1 fall in Kt/V leads to a 7% increase in relative risk of death and an 11% rise in annual hospitalization levels (Sehgal, 2002).

2.4.3 Nutritional Management during haemodialysis

Nutritional management in ESRD is important to assess patient's nutritional status by evaluating serum albumin and body weight. A pre dialysis albumin level of ≥-4.0 g/dl is the outcome goal, and patients with serum albumin levels lower than 3.5 g/dl should be evaluated for protein-energy malnutrition (Combe et al., 2004).

Nutrition is an important factor in maintaining good health of patients on HD, affecting their morbidity and mortality (Al-Ali et al., 2016). Albumin is one of the many nutritional indicators to evaluate nutritional status in patients on HD that correlates with morbidity and mortality. Protein-energy wasting, sodium and water retention, vitamin D deficiency, and phosphate retention are some of the nutritional abnormalities commonly encountered in patients with CKD (Ameh, Cilliers, & Okpechi, 2016). Taking measures to ensure good nutrition (or lack thereof) perhaps represents the strongest predictors of clinical outcomes in patients in ESRD (Ibrahim, Hossam, & Belal, 2015; Kovesdy, 2016).

Poverty is a problem in South Africa and yet patients are expected to follow strict treatment and dietary regimes. This often results in non-adherence to treatment leading to poor outcomes but there is a paucity of published research on the association between patient outcomes and patient adherence to dietary regimes.

Nutritional management is important to ensure that patients have an adequate level of serum albumin to create a physiologically desirable blood oncotic pressure ('pull' of interstitial fluid into the vessel) to prevent hypoalbuminaemia. Furthermore, a low serum albumin level would result is low production of immunoglobulins and increase the risk of infection. The guidelines recommend a serum Albumin of >35 mmol as a nutritional marker.

Serum plasma albumin, an important measurement for ESRD, predicts quality outcomes. Clinicians need to be aware of deviations in albumin levels and acceptable nutritional goals in order to ensure patients are as healthy as possible. Team members' knowledge of the ill-effects of hypoalbuminemia is essential for the provision of quality care (Wyczesany & Steefel, 2015a).

In ESRD, chronic inflammation is independently associated with malnutrition and anaemia, leading to accelerated atherosclerosis, cardiovascular complications and death (Kalantar-Zadeh et al., 2005). Other causes of infection and/or inflammation are, for example, related to the dialysis treatment itself such as microbial dialysate contamination or oxidative stress and uraemia in CKD (Vanholder et al., 2018).

2.4.4 Management of anaemia

In ESRD anaemia refers to a HB level of <10 g/dL. The management of anaemia during HD includes measurement of parameters such as serum HB, Transferrin Saturation and Ferritin. The burden of anaemia in patients with ESRD is substantial, resulting in considerable morbidity that dramatically reduces their quality of life (Locatelli et al., 2008).

Anaemia can be defined as having a lower-than-normal number of red blood cells or quantity of HB and in ESRD anaemia refers to an HB level of <10 g/dL. Anaemia is caused by: 1) an inability of the kidneys to produce the hormone erythropoietin to stimulate bone marrow to produce red blood cells which contain Hb; 2) blood loss; and 3) high rates of red blood cell destruction during the haemodialysis process.

The management of anaemia during haemodialysis includes measurement of parameters such as serum HB, Transferrin Saturation and Ferritin. The guidelines recommend maintaining the levels for these parameters at 10 – 12 g/dL for serum HB, 20% for Transferrin Saturation (TSAT) and 200 ng/L for Ferritin. Transferrin saturation (TSAT) and ferritin are measures of iron status, used to detect abnormalities relating to iron status for diagnosing iron deficiency and to guide therapy (Besarab & Szczech, 2014). Transferrin levels are measured as total iron building capacity (TIBC).

Ibrahim (2010) found that the KDOQI target of 11 to 12 g/dL for Hb after the administration of erythropoietin to prevent anaemia was achievable only in 18% of prevalent dialysis cases in Egypt. The mean value of Hb in this study (9.23 ± 7.18 g/dL) is lower than that reported by the Dialysis Outcomes and Practice Patterns Study (Locatelli et al., 2004).

The burden of anaemia in patients with ESRD is substantial, resulting in considerable morbidity that dramatically reduces their quality of life (Locatelli et al., 2004). The inability of the bone marrow to form red blood cells due to decreased levels of erythropoietin, the shorter than normal lifespan of red blood cells and blood loss during HD are some of the factors that may influence the maintenance of Hb levels in the target range of 11 – 12g/dl (NKF-KDOQI, 2007).

Current Kidney Disease Improving Global Outcomes (KDIGO) guidelines recommend iron supplementation to maintain TSAT >20% in patients with CKD to compensate for the reduced TIBC and the reduction in metabolic cycling of iron (KDIGO, 2012). A ferritin >200 ng/ml is recommended in ESRD patients, but irrespective of TSAT, an upper ferritin limit of 500 ng/ml is also recommended (KDIGO, 2012).

Individualised treatment of anemia requires the use of erythropoiesis-stimulating agents (ESAs) (Messana, 2006), the parenteral administration of iron (Besarab & Szczech, 2014) and frequent monitoring of Hb levels. It has been well documented that patients at the start of dialysis present with low HB/haematocrit levels, malnourishment, elevated parathyroid hormone levels, elevated phosphorus levels, low calcium levels, acidosis, elevated blood pressure, and congestive heart failure (Levin et al., 2008).

The KDIGO Clinical practice guideline (CPG) (2012) for the management of anaemia in chronic kidney disease (CKD) is based upon systematic literature searches last conducted in October 2010, supplemented with additional evidence up to March 2012. It is designed to provide information and assist decision making. CPGs can improve the quality of clinical decisions. Evidence-based guidelines support interventions that are of proven benefit while documenting the quality of the supporting data (Drüeke & Parfrey, 2012). Complications of anaemia in ESRD result in left ventricular hypertrophy and or dilatation, decreased exercise capability, increased intradialytic hypotension, decreased quality of life, decreased cognitive function and increased sexual dysfunction (Weisbord et al., 2004).

The kidney produces approximately 90% of circulating erythropoietin in the body, therefore the level of anaemia that develops is directly related to the amount of residual renal function present. As the kidney disease progresses, the iron carrying capacity of the Hb is limited as a result of decreased erythropoiesis as transferrin, a carrier protein that transports absorbed and stored iron, is also decreased (Kanbay, Perazella, Kasapoglu, Koroglu, & Covic, 2010).

The KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anaemia in Chronic Kidney Disease define iron deficiency as a serum ferritin concentration of <200 ng/ml in haemodialysis patients. A transferrin saturation of <20% indicates iron deficiency in patients with CKD and may be corrected with intravenous iron which will decrease the need for blood transfusions in the presence of anaemia. The KDIGO guidelines, released in 2012, recommend that

intravenous iron should be routinely administered to patients on haemodialysis. Erythropoietin Stimulating Agents (ESA) are routinely prescribed for the production of red blood cells.

Anaemia management is the first of the evidence based quality of care indicators: Hb levels of patients on HD should be maintained at between 10 and 12 g/dl, transferrin saturation (TSAT) at ≥20% and ferritin at ≥200 ng/dl (NKF-KDOQI, 2007). ESA therapy should be initiated when Hb levels are ≤9 g/dl, and iron supplement therapy should be commenced if TSAT is ≤20% and ferritin is ≤200 ng/dl (KDIGO, 2012).

2.4.5 Prevention of bone disease during haemodialysis

Monitoring of phosphate, calcium and parathyroid hormone (PTH) is important for the prevention of bone disease, vascular calcification and uncontrollable increased levels of PTH (Bazydlo, Needham, & Harris, 2014). Progressive loss of kidney function in CKD leads to reduced production of 1.25-(OH)2vitamin-D3 (1,25-dihydroxyvitamin D; calcitriol) and abnormal mineral homeostasis reflected mainly by an imbalance in both serum calcium (Ca) and phosphorus (P) levels, as well as increasing levels of parathyroid hormone (PTH) (KDIGO, 2009) Phosphate Binders are routinely prescribed to treat hyperphosphatemia. Calcium levels are regulated by the dialysate used in the process of dialysis. Abnormal serum calcium levels are regulated by prescribed calcium supplements. Clinicians need to have an awareness and understanding of desirable serum calcium and serum phosphate levels following dialysis. Adequate dietary advice needs to be given to patients to maintain acceptable levels of calcium and phosphate.

Bone disease management ensures that patients' calcium and phosphate levels remain within acceptable limits to prevent bone disease and an overactive parathyroid. The four parathyroid glands are situated on the thyroid gland, one at the upper pole and another at the lower pole of each of the two lobes of the thyroid gland. The parathyroid glands secrete parathyroid hormone to regulate serum calcium and phosphate.

The secretory function of the kidney cannot be substituted by the dialysis process therefore, the patient will have to receive erythropoietin as a subcutaneous injection for the stimulation of bone marrow to form red blood cells. One Alpha is a tablet administered orally as a vitamin D supplement essential to maintain bone formation and prevent osteoporosis (Levy, Morgan, & Brown, 2004). A Calcium x Phosphate (Calcium-Phosphate Product) of >4 indicates that bone is demineralising, and the patient is at risk of developing osteoporosis. Bone disease management is where the calcium

(Ca) and phosphate (Phos) product will be considered as the indicator for bone disease, the target of Ca x Phos product of less than 4 (Hoy et al., 2007).

Abnormalities in calcium and phosphorus metabolism are common among patients regularly treated with dialysis, and observational studies suggest that elevated serum calcium and phosphorus levels are associated with increases in all-cause and cardiovascular mortality (Hoy et al., 2007; KDIGO, 2009b). The KDOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease provide recommendations for the frequency of biochemical testing to determine plasma parathormone (PTH) levels and the serum levels of calcium (Ca) and phosphorus (P) and also includes calculated values for the calcium-phosphorus ion product in serum (Ca × P). Acceptable target ranges for these biochemical parameters also are delineated. In previous studies hyperphosphatemia has emerged as an important clinical issue in dialysis patients because higher levels of serum phosphorus (P) and calcium–phosphorus (Ca x P) product have now been associated with increased vascular calcification and cardiovascular mortality (Block et al., 2004; Hoy et al., 2007; Uribarri, 2004b; Wei et al., 2006).

In summary, target outcomes for clinical indicators (dialysis access, anaemia management, dialysis adequacy, mineral bone disease and nutritional management) are well documented (AlYousef et al., 2016; Kimata et al., 2014; Miranda et al., 2016; Uribarri, 2004b; Wyczesany & Steefel, 2015b). Increased morbidity and mortality are associated with inadequate dialysis, poor dietary protein intake, hyperphosphatemia, low Hb levels and co-morbid conditions (NKF-KDOQI, 2002) in dialysed patients.

2.5 Validation studies

Validation studies are referred to as works consisting of research using processes by which the reliability and relevance of a procedure for a specific purpose are established (Kimberlin & Winterstein, 2008). Confirmation of the validity and reliability of tools are a prerequisite for assuring the integrity of study findings (DeVon et al., 2007). For rigorous research, instruments and profiles should be psychometrically sound, valid and reliable (DeVon et al., 2007).

The process of developing and validating an instrument is in large part focused on reducing error in the measurement process ((Kimberlin & Winterstein, 2008). Validity is the extent to which the interpretations of the results of a test are warranted, which depends on the particular use the test is intended to serve (Rodrigues, Adachi, Beattie, & MacDermid, 2017). The responsiveness of

the measure to change is of interest in many of the applications in health care where improvement in outcomes as a result of treatment is a primary goal of research (Kimberlin & Winterstein, 2008).

2.5.1 Content Validity Index and face validity

Content validity (CV) has become one of the most important validation processes in instrument development due to confusion with face validity and unavailability of standardised ways of conducting validation (Lynn, 1986). Lynn (1986), therefore proposed the quantification of content development in two stages: 1) the development stage that consists of activities such as domain identification, item generation and instrument formation and 2) the judgment stage which includes the quantification of CV items (Lynn, 1986). Measuring content validity of research instruments is important (Yaghmaie, 2003). According to Rusticus (2014) validity refers to the degree to which an instrument measures what it is designed to measure, while content validation provides evidence about the validity of the instrument and how well it measures the targeted construct to make meaningful and appropriate inferences. Content validity is a subjective judgement of experts about the degree of relevant construct in an assessment instrument (Yaghmaie, 2003). Content validity can be quantified by using an index of validity, referred to as the content validity index (CVI) (Lynn, 1986; Waltz & Bausell, 1983). In addition to assessing experts' judgement of the relevance of each item in a research instrument (Lynn, 1986), Yaghmaie (2003) added clarity, simplicity and ambiguity. The concepts clarity, simplicity and ambiguity were implied in the assessment of face validity of Kyriacos' (2011) research instrument. Assessment of face validity is a subjective form of validation (Yaghmaie, 2003).

2.5.2 Accuracy

Reliability estimates the stability of measures, internal consistency of measurement instruments and interrater reliability of instrument scores (Burns, 2014). Internal consistency is a measure of how consistently each item measures the same underlying construct by correlating performance on each item with overall performance across participants which can be represented by Cronbach's alpha reliability coefficient. Interrater reliability refers to the degree of agreement determined by having two or more observers watching the same event and independently recording the variables according to a predetermined coding system represented as a percentage of agreement or Cohens Kappa (Wagner, Healy & Johnson, 1999).

Several issues may affect the accuracy of data collected, such as those related to self-report and secondary data sources (Atkinson, 2012). Self-report of patients or subjects is required for many of the measurements conducted in health care, but self-reports of behaviour are particularly subject to problems with social desirability biases (Kimberlin & Winterstein, 2008). Interrater reliability is the agreement of the same data obtained by different raters, using the same scale, classification, instrument, or procedure, when assessing the same subjects or objects (Kottner et al., 2011). Inter-rater reliability testing for accuracy of transcription amongst raters was appropriate for this study.

2.6 Record review

According to Vassar and Holzman (2013), the most common strategy for Record Chart Reviews (RCR) was convenience sampling because researcher could use medical data that was available. While this method presents limitations with respect to the generalizability of results, it proved to be a practical method and particularly useful when dealing with small sample sizes, as observed in this study.

2.7 Summary

The available published literature on search terms from databases between 2000 and 2019 yielded major subject areas, particularly relating to adherence from the point of view of patients. Numerous studies have been published relating to the different quality indicators this was used to inform the foundation and background of the different quality indicators however, this study was specifically aimed at the adherence of clinicians to quality indicators.

The National Kidney Foundation (NKF) has published the Dialysis Outcomes Quality Initiative (DOQI) clinical practice guidelines based on numerous Randomised Controlled Trials. These guidelines are further divided into clinical quality indicators that acts as a framework in delivering care to the patient with ESRD on haemodialysis for the purpose of this study. Guidelines recommend that

- AVF/AVG should be the first choice of access to deliver haemodialysis to patients in ESRD and it is referred to as the gold standard.
- Anaemia profile Hb 10 -12g/dl, TSAT above 20% and Ferritin 200 – 500ng/dl
- Adequacy reflected in a Kt/V 1.2 – 1.4
- Bone disease management Calcium Phosphate product of < 4
- Nutritional Albumin > 35mmol/l

Literature reveals patients have invasive catheters in place for the purpose of dialysis which predisposes them to blood stream infections (Dutka & Brickel, 2010). There is also a difficulty in limiting anaemia and bone management profiles in patients with ESRD. Furthermore, adequacy and nutritional aspects also pose problems for these patients. Numerous studies on patients and non-compliance have been published while it is not known how well clinicians adhere to guidelines due to the paucity in research. Literature reveals the greater percentage of patients that reach each of these targets results in a decrease in morbidity and mortality in patients with ESRD and thereby improving the quality of life of these patients.

CHAPTER THREE METHODS

3.1 Introduction

In this chapter the methods employed to answer the research question are described. The research question was "What proportion of patients with ESRD on chronic haemodialysis (HD) in selected private dialysis units in the Western Cape reached target levels for each clinical indicator outlined in the NKF-KDOQI (2002) guidelines between 1 January 2018 and 31 December 2018?". The primary aim of this multi-phase study was to design (Phase 1) and validate a prototype record review template to ensure that the results of the study are valid (Phase 2) and reliable (Phase 3) (DeVon et al., 2007; Lynn, 1986; van Melle et al., 2018). Construction of the template was based on the Quality Indicators outlined in the KDOQI/KDIGO Guidelines for patients on HD. This was followed by record review (Phase 4) using the validated record review template to describe target and actual levels outcomes for each clinical indicator to assess adherence to established guidelines (KDIGO, 2009a, 2012; NKF-KDOQI, 2002, 2007; Uribarri, 2004a).

3.2 Research design

Retrospective record review using a multi-phase descriptive design was employed to achieve the aim of the study. The advantages of conducting chart review include the following: it is inexpensive, existing records are used and it allows for the study of rare occurrences (Gearing, Mian, Barber, & Ickowicz, 2006; Vassar & Holzmann, 2013). However, the limitations of this design are that it relies on accuracy and recall of individuals, important data may not be available and records might not be accessible (Hess, 2004). An outline of the 4-phase study design is presented in Figure 3. 1.

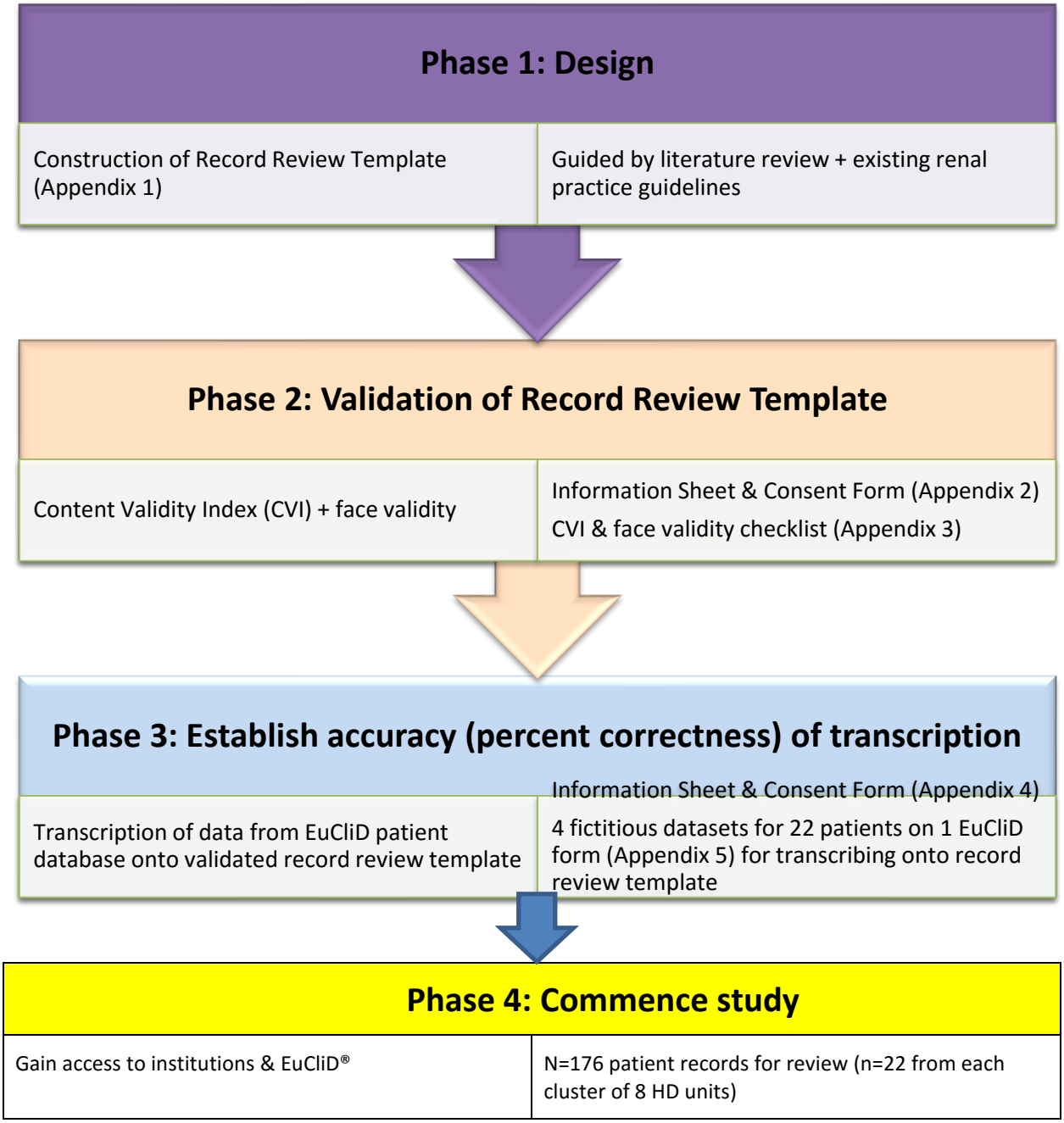


Figure 3. 1: Diagram of the four research phases

3.3 Research sites

The head nurse of the national Fresenius Medical Care (FMC) company allocated eight of 11 HD units within the Western Cape Province, South Africa which used the European Clinical Database (EuCliD®) for patient records, as research sites for this study. The eight HD units in the private healthcare sector where patients received Renal Replacement Therapy (RRT) were situated in various geographical areas within Cape Town. The clinical records of patients who received RRT

between 1 January 2018 and 31 December 2018 were considered for review. Patients in the public healthcare sector do not comply with all the inclusion criteria, therefore the study was conducted in the private healthcare sector where older patients needing HD who can afford the treatment are accepted onto the programme. In public sector units younger patients have a better chance of accessing HD. In addition, more patients are on HD in private units (85.2%) than in public sector units (14.8%). Patients in public sector renal units reportedly receive predominantly peritoneal dialysis (PD) (South African Renal Registry Report, 2016). It was anticipated that a larger sample would therefore be available in the private sector.

3.4 Phase 1: Construction of Prototype Record Review Template

The first objective of the study was to design a prototype record review template for data extraction to describe target and actual levels for each identified clinical indicator to assess adherence to established guidelines. The variables in the prototype were constructed using the KDOQI/KDIGO guidelines for biochemical targets as the gold standard. A 3-part prototype record review template comprising 58 variables (Appendix 1) was constructed in a Statistical Package for the Social Sciences (SPSS) version 26 (IBM, 2013) data file.

The FMC EuCliD® contains clinical data of large numbers of patients in various international dialysis units including South Africa. Gregory and Radovinsky (2012) report that the organisation and structure of the data collection tool are important and ideally, the tool should correspond to the data as these appear in the patient's record. Grouping the relevant data facilitates reliable data collection and ease of use by the data abstractor (Gregory & Radovinsky, 2012).

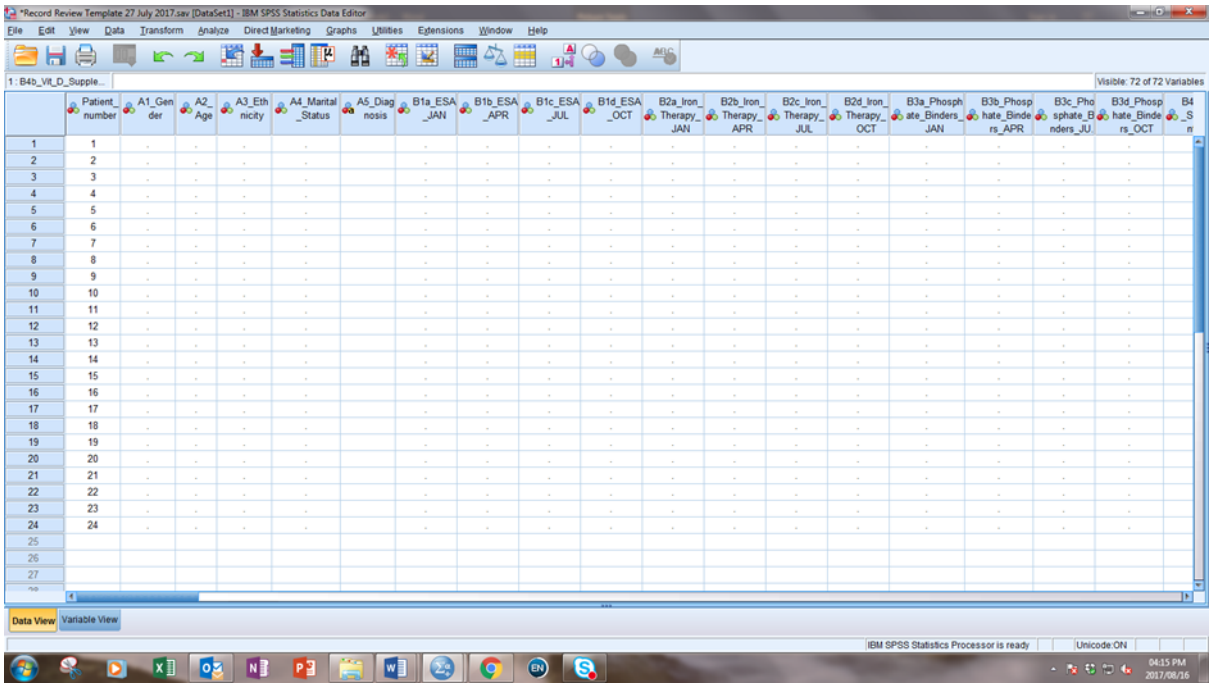
Demographic data such as gender and age and clinical characteristics are entered into the EuCliD® and maintained by FMC staff on an ongoing basis to ensure quality outcomes. Demographic data such as marital status and ethnicity are located in other parts of the EuCliD® not easily accessible to renal nurse practitioners. The 3-part prototype record review template (Sections A, B and C, each with sub-divisions) (Appendix 1) comprised of:

- Demographic data: gender, age, ethnicity (for disease-linked patterns), marital status (to assess social support systems) and clinical data such as diagnosis (Section A1-5);
- medications taken (Section B1-4);
- selected laboratory results: Hb, Transferrin Saturation (TSAT) and Ferritin (quality indicator of anaemia) (Section C1-3);

- type of access (Section C4);
- Kt/V which indicates adequacy of dialysis (Section C5);
- serum phosphorus (Section C6);
- serum calcium (Section C7);
- Calcium and Phosphate (including Ca x Phos product) (for bone disease management) (Section C8); and
- Albumin (quality indicator of nutritional status) (Section C9).

An excerpt from the SPSS data record review template (data extraction form) (Appendix 1) is presented in Table 3.1.

Table 3. 1: Excerpt from the Prototype Record Review Template (Appendix 1)



The organisation and structure of the record review template corresponded with the actual patient data recorded on the EuCliD®. According to Gearing et al. (2006), logical organisation of data and a user-friendly structure is a good strategy for optimal data collection. Each variable was allocated a numerical code. Internal validity and reproducibility of any retrospective study is significantly enhanced by the standardisation of data (Gregory & Radovinsky, 2012).

To achieve coherence, the validation processes (Phases 2 and 3) for the record review template are described separately as a whole in this chapter: study population (inclusion and exclusion criteria

for participants), research activities and followed by the results. For Phase 4 (record review), the study population and estimation of sample size, data collection procedure including gaining access to the research sites are described but the results are presented in Chapter 4 .

3.5 Phase 2: Instrument Validation

The second objective of the study was to validate the prototype record review template (Appendix 1) by ascertaining the content validity index (CVI) (Phase 2) and to establish accuracy (percent correctness) of transcription of the prototype record review template by inter-rater reliability (Phase 3). Although the CVI was conducted, validation was actually an assessment of renal healthcare professionals' perceptions of the relevance of the quality indicators on the EuCliD® reflected on the prototype record review template. Therefore, even if not considered content valid at the conclusion of the validation process, the items could not be changed before the actual clinical record review (Phase 4 of the study).

3.5.1 Validation of the record review template

It must be kept in mind that this validation process was actually an assessment of renal healthcare professionals' perceptions of the relevance of the items on the prototype record review template that reflect the quality indicators on the EuCliD®. Although content and face validity of the template were measured, the items, even if not content valid at the conclusion of the validation process, could not be removed before the actual clinical record review (Phase 4 of the study).

3.5.1 Validation of the CVI and face validity checklist for the record review template

An Information Sheet and Consent form (Appendix 3) and a checklist (Appendix 4) for determining the CVI and face validity of the prototype Record Review Template (Appendix 1) were designed. The organisation and structure of the CVI/face validity checklist corresponded with the variables on the record review template (Appendix 1) in SPSS and therefore with the actual patient data recorded in the same order on the EuCliD® (except for Section A which is explained later). The checklist (Appendix 4) comprised Section A – Demographic and clinical characteristics with 18 variables, Section B – Treatment details with 16 variables and Section C – Quality Indicator Outcomes with 24 variables (total n=58 variables), as indicated in Tables 3.1 and 3.3. However, 8 items not appearing on the EuCliD® and relating to demographic characteristics were added. Ratings on the CVI checklist (Appendix 4) were indicated as 1 = not relevant, 2 = somewhat relevant,

3 = relevant or 4 very relevant. A separate column for comments was available. An excerpt of the CVI checklist is shown in Table 3.2.

Table 3. 2: Excerpt from the Index of Content Validity checklist for the record review template

Item Code	Item	1 not relevant	2 somewhat relevant	3 relevant	4 very relevant	Comments
	Section A – Demographic Details					
A1	**Gender**					
A1.1	Male					
A1.2	Female					
A2	**Age**					

A panel of experts was purposively sampled and invited to validate the tool.

3.5.1.1 Participants for CVI and face validity

It has been established that a minimum of five experts can produce a sufficient level of control for chance agreement (Lynn, 1986:383).

Inclusion criteria for five experts purposively selected for index of content validity (CVI) and numerical face validity of the research instrument:

- 1 Nephrologist in Private Practice
- 1 nurse lecturer with a Postgraduate Diploma in Nephrology Nursing at a University in South Africa
- 1 clinical facilitator with a Postgraduate Diploma in Nephrology Nursing in a private renal unit
- 2 qualified nephrology nurse practitioners working in two different private renal units.

Exclusion criteria:

- Students in training.

3.5.1.2 Data management and analysis for CVI and face validity

The CVI for each item (ratings at 1 = not relevant, 2 = somewhat relevant; 3 = relevant or 4 = very relevant) was determined by the proportion of experts who rated it as content valid (a rating of 3 or 4) (Yaghmaie, 2003; (Lynn, 1986). As Likert score values are ordinal level data, a median was calculated (Jamieson, 2004)(Jamieson, 2004) for each item. The items that had CVI of 0.80 (4/5 experts rating 1 item) amongst raters of a rating of 3 or were regarded as valid whereas Yaghmaie's (2003) study reported content validity of 0.75 and Gutmann, Hunter-Schaedle and Shannon, (2006) regarded a preset >70% agreement as acceptable. The CVI for the entire instrument was the

proportion of total items judged content valid (Lynn, 1986) for example for 77/80 items deemed content valid, the CVI would be .96 (DeVon, 2007). For a count of the total scores for each of the ratings (1, 2, 3, 4) a median and interquartile range (IQR) and mean and standard deviation (SD) were calculated. The intended method of data analysis is shown in Table 3.3.

Table 3. 3: Intended method of analysis of data for CVI of the record review template (n=5 experts)

Item Code	**Item**	1 **not relevant**	2 **somewhat relevant**	3 **relevant**	4 **very relevant**	Median	Changes made
Section A – Demographic Details							
A1	**Gender**						
A1.1	Male						
A1.2	Female						
A2	**Age**						
Total numbers of this score amongst 290 ratings of 58 items							
Median (IQR) of items with this score							
Mean (SD) of items with this score							
Count: scores of 3 and 4 of 58 items							

The intended method of data analysis for face validity of the record review template (adapted from Kyriacos, 2011) is shown in an excerpt from the template in Table 3.4.

Table 3. 4: Intended method of analysis of data for face validity of the record review template (n=5 experts)

	Very skilful 1	Satisfactory 2	Needs Improvement 3	Unacceptable 4
Layout				
Format				
Length of the record review template				
Total number of items with this score amongst 5 raters of 58 items				
Median (IQR) of items with this score				
Mean (SD) of items with this score				
Total numbers with this score				
All participants with 1 and 2= xx/7 items (xx%)				

3.5.1.3 Data collection for CVI and face validity process

The researcher met with potential participants individually in the units during day working hours (there are no night shifts although there are late shifts up until 21h00). Potential participants were purposively selected and considered as a result of their knowledge and competency in the renal field, they were also active mentors in the clinical setting, training nephrology students or skilful in research aspects of evidence practice within the renal field respectively. Each expert was given a printed Information Sheet and Consent Form (Appendix 3). After indicating their understanding by questioning and clarifying aspects of the contents of the study, they signed the consent form (Appendix 3) to participate voluntarily in the study.

A printed copy of the content and face validity checklist (Appendix 4) was given to each expert on which to rate the relevance of each item on the prototype record review template (Appendix 1) in SPSS on the researcher's laptop not yet populated for fictitious patient data (needed for Phase 4). Participants were requested to scroll across the SPSS file in '*data view*' to see all the variables that were on the checklist. The experts rated the relevance of each item on a 4-point Likert scale on the checklist (Appendix 4) that corresponded with variables on the template in the SPSS file. The researcher was sitting at a distance from the participants and therefore available for answering any questions that might have arisen.

3.5.1.4 Results for CVI and face validity

Results for the CVI from the checklist are shown in Table 3.5.

Table 3. 5: Results (number and percent for ratings 1-4) for CVI of the record review template (n=5 experts)

Item Code	Item	1 not relevant	2 somewhat relevant	3 relevant	4 very relevant	Number of experts rating 3 + 4	Median ratings of 3 + 4	Comments
Section A – Demographic Details								
A1	**Gender**							
A1.1	Male	0	1 (20%)	1(20%)	3 (60%)	4 (80%)	2	None
A1.2	Female	0	1 (20%)	1 (20%)	3 (60%)	4 (80%)	2	None
A2.1	**Age**	0	0	2 (40%)	3 (60%)	5 (100%)	2,5	None
A3	***Ethnicity:**							
A3.1	Asian	0	1 (20%)	3 (60%)	1 (20%)	4 (80%)	2,5	None
A3.2	Black	0	1 (20%)	2 (40%)	2 (40%)	4 (80%)	2	None
A3.3	Coloured	0	1 (20%)	2 (40%)	2 (40%)	4 (80%)	2	None
A3.4	White	0	1 (20%)	3 (60%)	1 (20%)	4 (80%)	2	None
A4	***Marital Status**							
A4.1	Single	1 (20%)	1 (20%)	3 (60%)	0	3 (60%)	1,5	None
A4.2	Married	1 (20%)	1 (20%)	2 (40%)	1 (20%)	3 (60%)	1,5	None
A4.3	Separated	1 (20%)	1 (20%)	2 (40%)	1 (20%)	3 (60%)	1,5	None
A4.4	Divorced	1 (20%)	1 (20%)	3 (60%)	0	3 (60%)	1,5	None
A5	**Diagnosis**							
A5.1	Hypertension	0	1 (20%)	0	4 (80%)	4 (80%)	2	None
A5.2	Diabetes	0	1 (20%)	0	4 (80%)	4 (80%)	2	None
A5.3	Glomerulonephritis	0	1 (20%)	0	4 (80%)	4 (80%)	2	None
A5.4	Systemic Lupus Erythematosus	0	1 (20%)	0	4 (80%)	4 (80%)	2	None
A5.5	Polycystic Kidney Disease	0	1 (20%)	0	4 (80%)	4 (80%)	2	None
A5.6	Other	0	1 (20%)	1 (20%)	3 (60%)	4 (80%)	2	None
A5.7	Unknown	0	1 (20%)	1 (20%)	3 (60%)	4 (80%)	2	None

Item Code	Item	1 not relevant	2 somewhat relevant	3 relevant	4 very relevant	Number of experts rating 3 + 4	Median ratings of 3 + 4	Comments
Section B – Treatment Details								
B1	**Erythropoietin Stimulating Agent (ESA)**							
B1.1	Eprex	0	1 (20%)	1 (20%)	3 (60%)	4 (80%)	2	**1-**Omit Product Names ADD: ESA Therapy (Y/N)
B1.2	Micera	0	1 (20%)	1 (20%)	3 (60%)	4 (80%)	2	**1-**Omit Product Names ADD: ESA Therapy (Y/N)
B1.3	Rocormen	0	1 (20%)	1 (20%)	3 (60%)	4 (80%)	2	**1-**Omit Product Names ADD: ESA Therapy (Y/N)
B1.4	Aranesp	0	1 (20%)	1 (20%)	3 (60%)	4 (80%)	2	**1-**Omit Product Names ADD: ESA Therapy (Y/N)
B1.5	Not prescribed	0	0	0	5 (100%)	5 (100%)	2,5	None
B1.6	Treatment on hold	0	0	0	5 (100%)	5 (100%)	2,5	None
B2	**Iron Therapy**							
B2.1	Venofer	0	2 (40%)	0	3 (60%)	3 (60%)	1,5	1-Omit Product Names ADD: ESA Therapy (Y/N)
B2.2	Cosmofer	0	2 (40%)	0	3 (60%)	3 (60%)	1,5	1-Omit Product Names ADD: ESA Therapy (Y/N)
B2.3	Other	0	2 (40%)	1 (20%)	2 (40%)	3 (60%)	1,5	None
B2.4	Not prescribed	0	0	0	5 (100%)	5 (100%)	2,5	None
B3	**Phosphate binders**							
B3.1	Titralac	0	0	2 (40%)	3 (60%)	5 (100%)	2,5	1-Omit Product Names ADD: ESA Therapy (Y/N)
B3.2	ENO tums	0	0	2 (40%)	3 (60%)	5 (100%)	2,5	1-Omit Product Names ADD: ESA Therapy (Y/N)
B3.3	Phosphosorb	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	1-Omit Product Names ADD: ESA Therapy (Y/N)
B3.4	Not prescribed	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
B4	**Vitamin D supplements**							
B4.1	One Alpha	0	0	0	5 (100%)	5 (100%)	2,5	None
B4.2	Not prescribed	0	0	0	5 (100%)	5 (100%)	2,5	None
								1-ADD: Calcimemetics
	Section C Quality Indicator Outcomes							
C1	**Haemoglobin, g/dl**							
C1.1	<10	0	0	0	5 (100%)	5 (100%)	2,5	None
C1.2	10 – 12	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C1.3	>12.1	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None

Item Code	Item	1 not relevant	2 somewhat relevant	3 relevant	4 very relevant	Number of experts rating 3 + 4	Median ratings of 3 + 4	Comments
C2	**Transferrin Saturation, %**							
C2.1	<20	0	0	0	5 (100%)	5 (100%)	2,5	None
C2.2	>20	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C3	**Ferritin, ng/dl**							
C3.1	<200	0	0	0	5 (100%)	5 (100%)	2,5	None
C3.2	200 – 500	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C3.3	>501	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C4	**Dialysis Access**							
C4.1	Temporary Catheter	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C4.2	Permanent Catheter	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C4.3	AVF	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C4.4	AVG	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C5	**Single pool Kt/V**							
C5.1	<1.2	0	0	0	5 (100%)	5 (100%)	2,5	None
C5.2	1.2 – 1.4	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C5.3	>1.4	0	0	2 (40%)	3 (60%)	5 (100%)	2,5	None
C6	**Serum Phosphorus, mmol/L**							
C6.1	<0.8	0	0	0	5 (100%)	5 (100%)	2,5	None
C6.2	0.8 – 1.4	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C6.3	>1.41	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C7	**Serum Calcium, mmol/L**							
C7.1	<2.15	0	0	0	5 (100%)	5 (100%)	2,5	None
C7.2	2.15 – 2.5	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C7.3	>2.51	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None
C8	**Serum Calcium x Phosphorus, $mmol^2/L^2$**							
C8.1	>4.4	1 (20%)	0	1 (20%)	3 (60%)	4 (80%)	2	None
C9	**Serum Albumin, mmol/L**							
C9.1	<35	0	0	0	5 (100%)	5 (100%)	2,5	None
C9.2	>35	0	0	1 (20%)	4 (80%)	5 (100%)	2,5	None

Total numbers (%) of this score amongst 290 ratings of 58 items	5 (1.72)	27 (9.32)	55 (18.96)	203 (70.0)	258 (88.96)
Median (IQR) of items with this score	0 (0)	0 (1)	1 (1)	4 (1)	5 (1)
Mean (SD) of items with this score	.09 (.283)	.47 (.599)	.95 (.867)	3.50 (1.274)	4.45 (.705)

Count: scores of 3 and 4 of 58 items	37/58 (63.79%)

Note to table: A total of five raters each scored 58 items.
*Items are not on the EuCliD® form but were added for the purpose of this study.

As described in Section 3.5.2.2, a rating of 3 or 4 was accepted as valid. For 51/58 (87.93%) items there was between 80-100% agreement by the experts for a rating of these items at 3 (relevant) or 4 (very relevant) which exceeded the predetermined CVI of 0.80 (4/5 experts rating 1 item) for this study. The CVI for the entire instrument was the proportion of total items judged content valid (Lynn, 1986). For this study a count of scores of 3 and 4 of 58 items achieved CVI of 63.79% (37/58).

Results from the validation processes would have warranted changes to the items in the prototype Record Review Template (Appendix 1) that did not achieve CVI in preparation for the main study. However, as the CVI was an assessment of clinician's perceptions of the relevance of the EuCliD® form these changes could not be effected.

Results for face validity and shown in Table 3.6.

Table 3. 6: Results for face validity of the record review template from the checklist (n=5 participants)

	Very skillful 1	Satisfactory 2	Needs Improvement 3	Unacceptable 4
Layout	3 (60%)	2 (40%)	0	0
Format	3 (60%)	2 (40%)	0	0
Quality of printing	3 (60%)	2 (40%)	0	0
Length of the questionnaire	3 (60%)	2 (40%)	0	0
If visually easy to read	4 (80%)	1 (20%)	0	0
If visually easy to comprehend	3 (60%)	2 (40%)	0	0
If instructions at the beginning of the questionnaire are clear and easy to understand	4 (80%)	1 (20%)	0	0
Total number of items with this score amongst 5 raters of 58 items	23	12	0	0
Median (IQR) of items with this score	3 (1)	2 (1)		
Mean (SD) of items with this score	3.29 (.488)	1.71 (.488)		

Results for face validity indicated that all the experts rated the prototype record review template as either very skillful (23/35, 65.7%) or satisfactory (12/35, 34.2%) and no improvements were required.

Results for the CVI of the prototype record review template show that of the n=8 items not on the current EuCliD®, 4 /58 (6.89%) and 8/58 (13.79%) of the variables were rated as not relevant (1) and somewhat relevant (2) respectively and refer to ethnicity and marital status that might be useful for further research. For example, ethnicity might be linked to disease patterns and marital status might be useful to assess social support systems.

Results from the CVI showed that the items on the record review template (Appendix 1) were content valid (63.79%, 37/58). The prototype template was used unchanged for Phase 3: inter-rater reliability testing for accuracy of transcription.

3.6 Phase 3: Inter-rater reliability testing for accuracy of transcription

Inter-rater reliability testing for accuracy of transcription was conducted to measure agreement amongst raters. In this study reliability refers to the accuracy (percent correctness) of transcribing data from the EuCliD® form onto the Record Review Template. Protocols (KDOQI/KDIGO guidelines)

with explicit criteria (NKF-KDOQI, 2002) should increase inter-rater reliability of data extraction and transcription as these guidelines are used for each HD session. An instrument cannot be valid unless it is reliable, yet the reliability of an instrument does not depend on its validity (Takavol & Dennick, 2011) and needs to be measured independently. Construct validity for internal consistency of a research instrument should be assessed for example by using the Cronbach alpha coefficient (Takavol & Dennick, 2011), but in this study, record review template constructs were taken from clinical records and from established guidelines and therefore not assessed.

3.6.1 Participants for Inter-rater Reliability testing for accuracy of transcription

There are a number of statistics that have been used to measure interrater and intrarater reliability. Two of the most common measures includes percent agreement (agreement amongst raters) and Cohen's kappa specifically for two raters, Cohen specifically discussed two raters in his papers (McHugh, 2012). The best advice for researchers is to calculate both percent agreement and kappa. Cohen's Kappa is the most used agreement statistic in literature (Zec, Soriani, Comoretto, & Baldi, 2017). The greater the expected chance agreement, the lower the resulting value of the kappa.

Inclusion criteria for record review

- 1 nurse lecturer with a Postgraduate Diploma in Nephrology Nursing at a University in South Africa.
- 1 qualified nephrology nurse practitioner in a private renal unit.

Exclusion criteria for record review

- Participants for the Index of content validity process
- Students in training.

3.6.2 Process for establishing accuracy (percent correctness) of transcription

Two expert renal health practitioners who did not participate in the CVI validation process were purposively selected and invited to participate in the interrater reliability testing of the validated record review template (Appendix 1). Each expert was given an Information Sheet and Consent Form (Appendix 5). After indicating their understanding of the contents of the study and willingness to participate voluntarily in the study, they signed the consent form (Appendix 5). When consent had been obtained, a prototype Record Review Template populated with 22 study subject code numbers and one EuCliD® form populated with 22 sets of fictitious patient data (Appendix 6) was

given to each expert. An excerpt of the EuCliD® form populated with 22 sets of fictitious patient data is shown in Table 3.7.

Table 3. 7: Excerpt from one EuCliD® form populated with 22 sets of fictitious patient data (Appendix 6)

	ACCESS				HAEMOGLOBIN				TRANSFERRIN SATURATION				FERRITIN				Kt/V			
No.	Mth 1	Mth 2	Mth 3	Mth 4	Mth 1	Mth 2	Mth 3	Mth 4	Mth 1	Mth 2	Mth 3	Mth 4	Mth 1	Mth 2	Mth 3	Mth 4	Mth 1	Mth 2	Mth 3	Mth 4
					g/dl	g/dl	g/dl	g/dl	%	%	%	%	ng/dl	ng/dl	ng/dl	ng/dl				
1	TC	TC	PC	PC	7,6	9,7	8,6	8,7	12	28	34	34	614	712	1200	1200	1,12	1,16	1,11	1,3
2	AVF	AVF	AVF	AVF	10,7	11,2	10,9	9,0	28	19	37	37	170	171	217	217	1,09	1,16	1,12	1,2
3	PC	AVF	AVF	AVF	12,8	12,5	13,0	13,1	13	13	17	17	247	247	539	539	0,9	0,8	0,9	0,8
4	AVG	AVG	AVG	AVG	11,7	15,0	14,1	9,4	104	14	37	37	104	133	206	206	1,11	1,04	1,17	0,94
5	TC	TC	PC	PC	9,6	10,3	9,6	11,3	28	19	16	16	100	188	550	550	0,7	0,8	1,1	1,6
6	PC	PC	PC	PC	9,9	10,4	10,0	11,3	21	21	15	15	645	645	517	517	1,13	1,00	0,90	1,45
7	AVF	TC	PC	PC	12,2	10,4	10,7	13,5	31	31	35	35	509	509	1058	1058	1,3	1,36	1,22	1,45
22	PC	PC	PC	PC	9,8	10,0	9,8	10,4	27	52	65	65	620	542	614	895	1,06	1,11	0,94	0,99

Research participants transcribed data directly from the paper EuCliD® (Marcelli et al., 2001) form populated with 4 fictitious datasets for Month 1, 2, 3, 4 for each of 22 fictitious patients (Appendix 6) onto a blank Record Review Template (Appendix 1) to estimate accuracy (percent correctness) of transcriptions. After giving each expert Appendices 1 and 6 on days at their convenience, they were also given one paper SPSS code guide in Word (Appendix 7) as a guide for transcribing the fictitious data onto the SPSS template on the researcher's password protected laptop. During the transcription the researcher was available to clarify question participants may have had. The transcription process took approximately 2 hours as indicated on the consent form.

Testing the degree of inter-rater reliability (IRR), in this context, relates to an estimation of consistency and accuracy in transcribing fictitious clinical data onto the prototype record review template. The Cohen's kappa statistical test which measures interrater reliability (sometimes called

interobserver agreement) was conducted using Dag Stat and a 95% level of accuracy between the two raters was accepted for reliability. Interrater reliability, or precision, refers to the two raters giving the same score for the same data item (Gearing et al., 2006).

Sim and Wright's (2005) classification of Cohen's kappa was employed as shown in Table 3.8.

Table 3. 8: Classification of Cohen's kappa

0	Agreement equivalent to chance
0.1 – 0.20	Slight agreement
0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-0.99	Near perfect agreement
1.0	Perfect agreement

This should be sufficient to detect Cohen's kappa of 0.61-0.80 (substantial agreement or better) (Sim & Wright, 2005:264).

3.6.3 IRR results

There was perfect agreement (100% accuracy of transcription) between the two raters for 42 items. Only results where there is a difference are presented in Table 3.9.

Table 3. 9: Differences in inter-rater reliability (IRR) results for 16 items between two raters for accuracy of transcription

Template item	Correct = 1/ Incorrect = 0 recording			Kappa	Standard error	95% confidence interval (CI) of agreement amongst two raters	Chi-square *P* value	Percent agreement (95% CI)
Gender (n=22)		Rater 1 Correct	Rater 1 Incorrect	0.955	0.045	0.867-1.043	40.17 <0.003	0.98 (0.88-0.99)
	Rater 2 Correct	21	1					
	Rater 2 Incorrect	0	22					
ESA 1 (n=22)		Rater 1 Correct	Rater 1 Incorrect	0.955	0.045	0.867-1.042	40.17 <0.003	0.98 (0.88-0.99)
	Rater 2 Correct	22	0					
	Rater 2 Incorrect	1	21					
ESA 3 (n=22)		Rater 1 Correct	Rater 1 Incorrect	0.727	0.099	0.532-0.922	25.14 <0.003	0.86 (0.73-0.95)
	Rater 2 Correct	22	0					
	Rater 2 Incorrect	6	16					
ESA 4 (n=22)		Rater 1 Correct	Rater 1 Incorrect	0.909	0.063	0.786-1.03	36.67 <0.003	0.95 (0.85-0.99)
	Rater 2 Correct	22	0					
	Rater 2 Incorrect	2	20					
Phosphate Binders 4 (n=22)		Rater 1 Correct	Rater 1 Incorrect	0.01	0.063	0.786-1.032	40.17 <0.003	0.95 (0.85-0.99)
	Rater 2 Correct	22	0					
	Rater 2 Incorrect	1	21					
Vitamin D 2 (n=22)		Rater 1 Correct	Rater 1 Incorrect	0.955	0.045	0.866-1.043	40.17 <0.003	0.98 (0.88-0.99)
	Rater 2 correct	22	0					
	Rater 2 Incorrect	1	21					
Vitamin D 4 (n=22)		Rater 1 Correct	Rater 1 Incorrect	0.955	0.045	0.866-1.043	40.17 <0.003	0.98 (0.88-0.99)
	Rater 2 correct	22	0					
	Rater 2 Incorrect	1	21					
Haemoglobin 4 (n=22)		Rater 1 Correct	Rater 1 Incorrect	0.955	0.045	0.867-1.043	40.17 <0.003	0.98 (0.88-0.99)
	Rater 2 correct	21	1					
	Rater 2 Incorrect	0	22					

		Rater 1 Correct	Rater 1 Incorrect					
Ferritin 4 (n=22)	Rater 2 correct	20	2	0.909	0.063	0.786-1.032	36.67 <0.003	0.95 (0.85-0.99)
	Rater 2 Incorrect	0	22					
		Rater 1 Correct	Rater 1 Incorrect					
Dialysis Access 3 (n=22)	Rater 2 correct	22	0	0.955	0.045	0.867-1.042	40.17 <0.003	0.98 (0.88-0.99)
	Rater 2 Incorrect	1	21					
		Rater 1 Correct	Rater 1 Incorrect					
Kt/V 2 (n=22)	Rater 2 correct	21	1	0.955	0.045	0.867-1.043	40.17 <0.003	0.98 (0.88-0.99)
	Rater 2 Incorrect	0	22					
		Rater 1 Correct	Rater 1 Incorrect					
Serum Phosphorus 2 (n=22)	Rater 2 correct	21	1	0.955	0.045	0.867-1.043	40.17 <0.003	0.98 (0.88-0.99)
	Rater 2 Incorrect	0	22					
		Rater 1 Correct	Rater 1 Incorrect					
Serum Phosphorus 4 (n=22)	Rater 2 correct	21	1	0.909	0.063	0.786-1.032	36.36 <0.003	0.95 (0.85-0.99)
	Rater 2 Incorrect	1	21					
		Rater 1 Correct	Rater 1 Incorrect					
Serum Calcium 3 (n=22)	Rater 2 correct	22	0	0.682	0.105	0.477-0.887	22.76 <0.003	0.84 (0.69-0.93)
	Rater 2 Incorrect	7	15					
		Rater 1 Correct	Rater 1 Incorrect					
Serum Albumin 2 (n=22)	Rater 2 correct	22	0	0.955	0.045	0.866-1.043	40.17 <0.003	0.98 (0.88-0.99)
	Rater 2 Incorrect	1	21					

		Rater 1 Correct	Rater 1 Incorrect					
Albumin 3 (n=22)	Rater 2 correct	21	1	0.955	0.045	0.867-1.043	40.17 <0.003	0.98 (0.88-0.99)
	Rater 2 Incorrect	0	22					

The *P*-value for the difference between correct and incorrect transcriptions for all 16 items achieved statistical significance (<0.003). Data in Table 3.11 show IRR agreement results in terms of Sim and Wrights's (2005) classification.

Table 3. 10: Agreement for IRR results

Item statement		
0	Agreement equivalent to chance	0
0.1 – 0.20	Slight agreement	0
0.21-0.40	Fair agreement	0
0.41-0.60	Moderate agreement	0
0.61-0.80	Substantial agreement	ESA Month 3, Calcium Month 3 (2 items)
0.81-0.99	Near perfect agreement	Gender, ESA Month 1 & Month 4, Phosphate Binder Month 4, Vitamin D Supplement Month 2&Month 4, Hb Month 4, Ferritin Month 4, Vascular Access Month 3, Kt/V Month 2, Serum Phosphate Month 2 & Month 4, Albumin Month 2 & Month 3 (14 items)
1.0	Perfect agreement	42 items not included in Table 3.9

(Sim & Wright, 2005)

There were no ratings for slight, fair or moderate agreement. There was substantial agreement (0.61-0.80) for 2 items (ESA Month 3, Calcium Month 3); near perfect agreement (0.81-0.99) for 14 items (Gender, ESA Month 1 & 4, Phosphate Binder Month 4, Vitamin D Supplement Month 2 & 4, Hb Month 4, Ferritin Month 4, Vascular Access Month 3, Kt/V Month 2, Serum Phosphate Month 2 & 4, Albumin Month 2 & 3) and perfect agreement (1.0) (100% accuracy) for 42 items which could not be computed.

Validation processes yielded the results above regarding the record review prototype. It is evident that the validated record review instrument was reliable. The measurement scale therefore had stability. All items on the template were content valid (Polit & Beck, 2012) and retained for data collection for record review for Phase 4.

3.7 Phase 4: Record review

Vassar and Holzman (2013) posit that the most common strategy for record chart review (RCR) is convenience sampling because researchers can use medical records that are available. While convenience sampling limits external validity of study results and therefore the generalizability of results, it is practical and particularly useful when dealing with small sample sizes. Methodology guidelines (Gearing et al., 2006) enhance the planning and process of the record review process and adherence to these guidelines adds rigour to a study (Vassar & Holzmann, 2013). The record review process for the present study was carefully planned.

3.7.1 Study Population

The clinical records of patients who received RRT between 1 January 2018 and 31 December 2018 in the eight HD units in the Western Cape Province that had been allocated for the purpose of this study were considered for review.

3.7.7.1 Sampling method and estimation of sample size

It was estimated that for eight HD units at the research sites approximately N=370 patient records will be required for record review. The sample size was estimated as follows using Stat Calc (Epi info7, CDC):

- Population of N=370 records (based on 2015 data);
- 95% confidence interval (CI);
- 5% confidence limit;
- 8 clusters (dialysis units); and
- In the absence of published data on all the parameters to be measured in this study, an expected frequency of 30% adherence to the guidelines for clinical indicators (acceptable blood results) was taken, therefore a sample size of n=22 per cluster will be required; a total sample size of n=176.

At the commencement of Phase 4 simple random sampling of anonymised records for the study period was done for each of the eight units using the Randbetween function in Microsoft Excel (2013).

3.7.1.2 Eligibility criteria

Inclusion criteria

- Patients must be 18 years and older
- Have End Stage Renal Disease
- Receive haemodialysis three times a week for four hours per session
- 4 available datasets from each patients' records for record review.

Exclusion criteria

- Acutely ill patients
- Haemodialysis units in the public sector as patient records are not on the EuCliD®.

3.7.1.3 Recruitment for participation

At the commencement of the planning stage for this study (2018), 8 units within the Western Cape region assigned to the researcher used the EuCliD® Database System; other units only started using the database at a later stage. Records of all patients over 18 years who received haemodialysis during the period under review (01 January 2018 to 31 December 2018) were selected and screened to ascertain whether records met the inclusion criteria: patients who had had HD three times a week for four hours; and assessment of clinical parameters Hb, Ferritin, SATS, Albumin, Calcium, Phosphate and Kt/V every three months (therefore for the 12-month period under review each record would have four available datasets for record review).

Of the total eligible population of records (N=412) (Figure 3.2) the estimated sample size of 176 records (22 for each of 8 clusters) was not achieved because the return rate was 169 (94.0%), therefore no datasets with missing data were excluded and all n=169 records were included in the review for eligibility. There were few records in some units and records reviewed from the 8 participating units ranged from n=9 (5.3%) to n=51 (30.2%). Reasons for excluding records are illustrated in Figure 3.2, a diagrammatic representation of the record selection process.

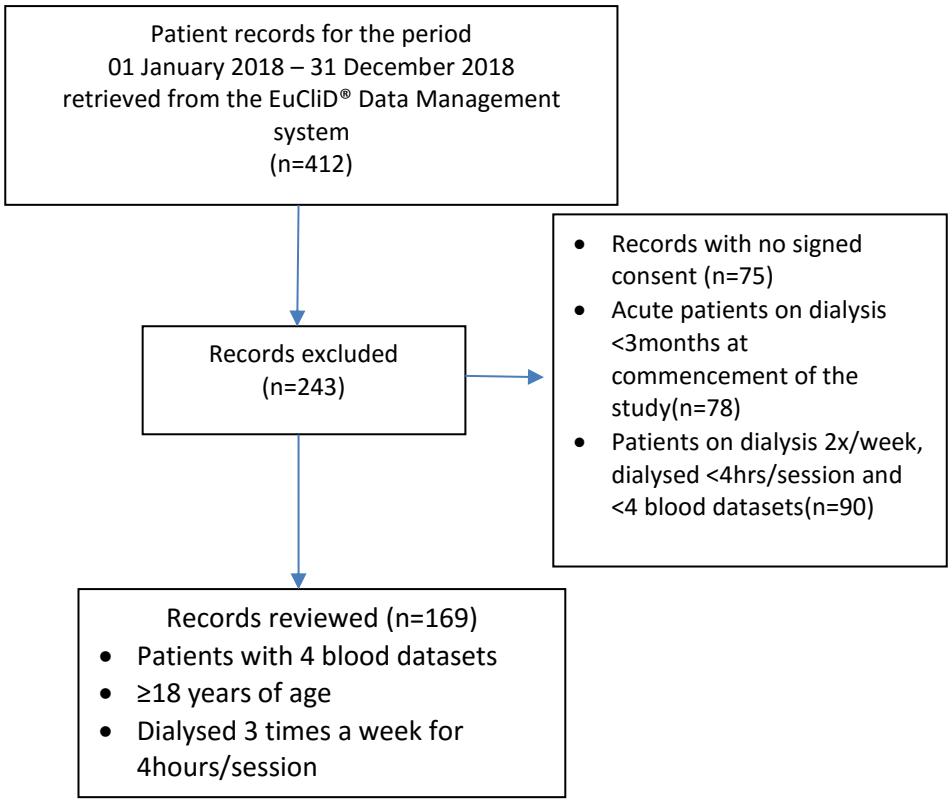


Figure 3. 2: Diagrammatic representation of the record selection process for Phase 4

Simple random sampling for 22 records per unit could not be realised for this study as all the units had different numbers of patients on dialysis. Furthermore, only a few patients in small units fulfilled the inclusion criteria. This resulted in a final sample size of n=169.

3.8 Data collection procedure

The rigour of the data collection method correlates with the reliability of the data and, ultimately, the analytical outcome of the study (Gregory & Radovinsky, 2012).

3.8.1 Gaining access

Formal permission-seeking letters were written to the FMC Research Committee (Appendix 8a and 8b), national Head Nurse of the private dialysis provider and the unit managers and the Appendix 9 requesting permission to access patient data and invite selected personnel to participate voluntarily in the validation processes (CVI and IRR). The letters (Appendices 8 and 9) outlined the

study purpose, ethical principles to be upheld, the University of Cape Town (UCT) Faculty of Health Sciences Human Research Ethics Committee approval and ethics clearance number (Appendix 10), details of the researcher and supervisor, the process for data collection and the timeframe for returning the completed questionnaires. Upon receiving ethics clearance and written permission from the relevant authorising bodies, the researcher made telephonic contact with the Unit Managers to arrange a face to face meeting, to provide them with copies of the ethics clearance and the permission letters that allowed the researcher access to the dialysis centres to retrieve data from EuCliD® (Appendix 11).

The data collection process was discussed in the office of each unit manager and they had an opportunity to deal with any uncertainty. The unit managers identified a physical space for the researcher to occupy during working hours for the data collection process. This meeting was also used to request the unit managers to identify, approach and recruit experts in the unit to participate in the validation processes at a later stage of the study.

Written patient consent is obtained by Fresenius Medical Care staff from all haemodialysed patients upon commencement of treatment which allows all patient data to be placed on the Fresenius EuCliD® (Appendix 12). A signed consent form confirms that all patients have been informed that their results will be placed on the database anonymously and that the data may be used for research purposes. This however was not the case therefore, many records needed to be excluded from the study. Entered patient data receive an automatic pin code, which is only identifiable by dialysis centre. To ensure patient privacy rights, information on the system is password protected and only accessible to a designated unit manager and is sent to the Clinical Management Europe (CME) part of the Fresenius Medical Care organisation. The researcher was given the same access for record review during Phase 4 of the study as the national Head Nurse of the private dialysis provider.

3.9 Data management and analysis

Patient data from the EuCliD® system for the actual study were entered into the validated template file in SPSS (version 25) on a password protected personal computer, cleaned and analysed using SPSS software. Anonymised data for the 1-year period were analysed using KDOQI /KDIGO guidelines as the gold standard. Statistical tests used for analysis of data on the Record Review Template (Appendix 1) are presented in Table 3. Data will be stored securely for 5 years on a

password protected encrypted flash drive to which only the researcher has access and then deleted permanently.

3.9.1 Data analysis

The 3-part prototype record review template (Appendix 1) comprised 58 variables. Descriptive and inferential statistics will be used as outlined in Table 3.13 to compare data against international guidelines for number, proportion and percentage as the gold standard.

To enhance the rigour of the study and transparency in reporting, an extension of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist, the REporting of studies Conducted using Observational Routinely collected health Data (RECORD) Statement (RECORD) (Benchimol et al., 2015) was used (Appendix 14).

Table 3. 11: Data analysis and statistical tests

Socio-demographic Parameters			
Variables	**Indicator Variables**	**Data**	**Statistical Analysis**
Gender	F (= 0) M (= 1)	Categorical	Number, Proportion, percentage
Age	Actual Age	Categorical	If data are normally distributed: Mean, min -max, Standard Deviation Median if data are not normally distributed
Ethnicity	Asian (= 0) Black (= 1) Coloured (= 2) White (= 3) Not specified (=4)	Categorical	Number, Proportion, percentage
Marital Status	Single (= 0) Married (= 1) Separated, Divorced or Widowed (= 2)	Categorical	Number, Proportion, percentage
Diagnosis	Hypertension (= 0) Diabetes (= 1) Glomerulonephritis (= 2) SLE (= 3) Polycystic Kidney (= 4) Other (= 5) Unknown (= 6)	Categorical	Number, Proportion, percentage
Medication	ESA Iron Therapy Phosphate Binders Calcium Supplementation	Binary Yes = 0 No =1 Binary Yes = 0 No = 1 Binary Yes = 0 No = 1 Binary Yes = 0 No = 1	Number, Proportion, percentage
Physiological Parameters			
Physiological Variables	**Indicator Variables**	**Data**	**Statistical Analysis**
Dialysis Access	Temporary Catheter (= 0) Permanent Catheter (= 1) *Arteriovenous Fistula (= 2)* Arteriovenous Graft (= 3)	Numerical	Number, Proportion, percentage
Single Pool Kt/V	<1.2 (=0) *1.2 - 1.4 (=1)* >1.4 (=2)	Numerical	Number, Proportion, percentage

Biochemical Parameters			
Biochemical Variables	**Value Labels**	**Data**	**Statistical Analysis**
Anaemia Management			
Haemoglobin	<10g/dl (= 0)	Numerical	Number, Proportion, percentage, Mean
	10 - 12g/dl (= 1)		
	>12g/dl (=2)		
	<20% (= 0)		Number, Proportion, percentage, Mean
TSAT	*>20% (= 1)*	Numerical	Number, Proportion, percentage, Mean
	>200ng/l (= 0)		
Ferritin	*200 - 500ng/l (= 1*)	Numerical	
	>500ng/l (= 2)		
Bone Disease Management			
Serum Phosphate	0 = < 1.1	Numerical	Number, Proportion, percentage, Mean
	1 = 1.2 – 1.79		
	2 = > 1.8		Number, Proportion, percentage, Mean
Serum Calcium	0 = < 2.10	Numerical	
	1 = 2.11 – 2.39		Number, Proportion, percentage, Mean
	2 = > 2.4		
Serum Calcium x Phosphate	*0 = < 5.49*	Numerical	
(Ca x P) Product	1 = > 5.5		
Nutritional Management			
Serum Albumin	0 = < 35	Numerical	Number, Proportion, percentage, Mean
	1 = > 35		

Note to table: Gold standards for relevant parameters are in italics.

3.10 Ethical considerations

The study received ethical clearance in June 2019 HREC Ref 306/2019 from the University of Cape Town, Faculty of Health Sciences' Human Research Ethics Committee (Appendix 10).

3.10.1 General Principles

According to the Declaration of Helsinki (2013) the principles of autonomy, beneficence and non-maleficence were considered and privacy and confidentiality were adhered to (World Medical Association, 2013), including the protection of personal information.

The nature of the study was a retrospective record review therefore the researcher had no personal contact with any of the patients represented by anonymised data in clinical records. There was no risk of personal or psychological harm. Although the researcher is an employee at FMC all efforts were made to ensure that there was no conflict of interest: code numbers were allocated to participants for the validation processes of the prototype record review sheet and fictitious data were used for inter-rater reliability processes. In addition, the final dataset for the actual study were anonymised by the FMC country head nurse before the researcher was issued with a username and password to access to the data. The study was partially funded by my supervisor, A/Prof U Kyriacos (R10,000 from NRF CSUR Grant No. 90295).

3.10.2 Risks, Burdens and Benefits

The risk-benefit ratio of the study was carefully considered (Lott, 2005). There was no risk or burden to patients in the actual study as a result of the record review design. Participants might have experienced the process of assessing content validity and inter-rater reliability potentially burdensome. However, the benefits of this retrospective study outweigh the risks by a great margin as it provided data that can reduce morbidity and mortality of patients receiving haemodialysis. Data about guideline adherence will have the potential to raise the level of awareness amongst renal healthcare practitioners and this should improve patient outcomes. The principles of privacy, confidentiality, anonymity, autonomy and justice were upheld before, during and after the study.

3.10.3 Vulnerable Groups and Individuals

The patients are a vulnerable group having been diagnosed with a chronic life-threatening disease and their rights and dignity would be respected. Patients' physical, psychological or social wellbeing will not be affected in any way as no information will be linked to them to change their treatment regime in any way (Richter, Groft, & Prinsloo, 2007). This retrospective record review seeks to improve practice where possible to improve patients' quality of life and decrease morbidity and mortality.

3.10.4 Privacy and Confidentiality

The Fresenius Medical Care database EuCliD® (European Clinical Database) stores patient data and replaces patient names with a code number that ensured their anonymity (Appendix 12 - EuCliD® consent form). A researcher confidentiality and non-disclosure agreement (Appendix 13) is enclosed. Precautions was taken to protect the privacy of participants and the confidentiality of their personal information by using code numbers. No personal, identifiable data were recorded. Responses were not of a personal nature.

3.10.5 Informed Consent

The process of informed consent involved information provision to and understanding of the information by renal health professionals invited to validate the record review template (Appendix 1). It also involves verification of whether the subject understands the information at his level of education, an overall ability to reason with the information, and the expression of choice about participation in the validation process. Participants who voluntarily agreed to assist with the

content validation (Appendix 3) and inter-rater reliability testing (Appendix 5) were informed of the aims, methods, sources of funding, institutional affiliations of the researcher as well as anticipated benefits and possible burdens of the study. Participants were informed of their right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal after which all voluntarily gave written informed consent for inter-rater reliability testing (Appendix 5). Participants returning a completed CVI provided implicit informed consent to participate in the study in addition to the written consent.

3.11 Summary

The primary aim of this multi-phase study was achieved. In Phase 1 a prototype record review template was designed and validated. Construction of the template was based on the Quality Indicators outlined in the KDOQI/KDIGO Guidelines for patients on HD. The template was content valid following Phase 2: for 51/58 (87.93%) items there was between 80-100% agreement by the experts for a rating of these items at 3 (relevant) or 4 (very relevant) which exceeded the predetermined CVI of 0.80 (4/5 experts rating 1 item) for this study. Results for face validity indicated that all the experts rated the prototype record review template as either very skillful (23/35, 65.7%) or satisfactory (12/35, 34.2%) and no improvements were required. The template was reliable as there were no ratings for slight, fair or moderate agreement and substantial agreement (0.61-0.80) for 2 items; near perfect agreement (0.81-0.99) for 14 items3) and perfect agreement (1.0) (100% accuracy of transcription) for 42 items. The next chapter describes results for the record review (Phase 4) using the validated template to describe target and actual levels outcomes for each clinical indicator to assess adherence to established guidelines.

CHAPTER FOUR RESULTS

4.1 Introduction

This chapter presents the results of Phase 4 of the study guided by the research question, aim and objectives 1.5.3 and 1.5.4 (Chapter 1): to describe target and actual outcomes for each clinical indicator to assess adherence to established guidelines (KDIGO, 2009a, 2012; NKF-KDOQI, 2002, 2007; Uribarri, 2004a) for patients receiving haemodialysis (HD). The head nurse for the national Fresenius company allocated eight HD units within the Western Cape Province as research sites for this study because they used the EuCliD® for patient records.

The research question investigated the proportion of patients with ESRD on chronic haemodialysis in selected private dialysis units in the Western Cape Province that reached target levels for each clinical indicator outlined in the NKF-KDOQI (2002) guidelines between 1 January 2018 and 31 December 2018

4.2 Objectives for Phase 4

The objective of the final phase of the study was to undertake record review to:

- describe haemodialysed patients' demographic and clinical characteristics, prescribed medications and biochemical results at the completion of a dialysis session; and
- compare recorded clinical data against the Kidney Disease Quality Outcomes Initiative (KDQOI) guidelines and where applicable, the Kidney Disease Improving Global Outcomes (KDIGO) guidelines as the gold standard for management of clinical outcomes.

4.3 Response rate

As outlined in section 3.9.2 and summarized in Table 4.1, the estimated sample size was 176 records and the return rate were 169 (96.02 %).

Table 4. 1: Number of records that met inclusion criteria (n=169) from N=412 records from 8 dialysis centres

UNITS	(n)	NOT ELIGIBLE (on dialysis <3 months)	NO CONSENT	EXCLUSION CRITERIA (x2/week, <4 hrs/session and <4 datasets	INCLUSION CRITERIA MET	%
1	65	13	7	15	30	46.15
2	25	2	2	10	11	44
3	18	1	4	4	9	50
4	111	20	20	20	51	45.94
5	60	8	16	10	16	26.66
6	27	4	10	3	10	37.03
7	31	8	6	7	10	32.25
8	85	22	10	21	32	37.64
(n)	**412**	**78**	**75**	**90**	**169**	

4.4 Description of Demographic and Clinical Characteristics

Patients' age, gender, ethnicity, marital status and diagnosis are summarised in Table 4.2.

Table 4. 2: Demographic and clinical characteristics (n=169 patient records)

Demographic characteristics	Number	Percent
Age in years		
21 – 35	10	5.91
36-52	32	18.93
53 – 70	99	58.57
71 +	28	16.56
Gender		
Females	69	40.82
Males	100	59.17
Ethnicity (South African classification) (n=113; missing data n=56)		
Asian	0	0
Black	22	13.00
Coloured	69	40.80
White	22	13.00
Marital Status (n=119; missing data n=50)		
Single	29	24.37
Married	81	68.07
Separated	7	5.89
Divorced	2	1.68
Widowed	0	0
Diagnosis		
Hypertension	42	24.85
Diabetic Nephropathy	55	32.54
Glomerulonephritis	16	9.46
Systemic Lupus Erythematosus	3	1.77

Polycystic Kidney Disease	9	5.32
Other	13	7.76
Unknown (not recorded)	31	18.34

Missing data were recoded -1 in the SPSS database for analysis. Data for age in years (range: minimum 21 – 86 maximum) were not normally distributed (Shapiro-Wilk *P*=0.055) although only marginally so therefore the median (60.0) and interquartile range (IQR) 17 were accepted. The data for age in Table 4.2 are categorised for grouping purposes comprising mostly those between 53-70 years 99/169 (58.57%) with the least number of patients in the youngest age category 10/169 (5.91%). The largest proportion of the cohort was male 100/169 (59.17%), classified as Coloured 69/169 (40.8%) missing data for ethnicity 56/169 (33.1%), married 81/169 (47.93%) and had a diagnosis of diabetic nephropathy 55/169 (32.54%). The other causes noted were Hypertension 42/169 (24.85%), Glomerulonephritis 16/169 (9.46%), unknown 31/169 (18.3%), Systemic Lupus Erythematosus 3/169 (1.8%) and Polycystic Kidney Disease 9/169 (5.3%).

4.5 Results for Medications as prescribed

The secretion of Erythropoietin (EPO) stimulates the bone marrow to form red blood cells (RBC). The failing kidneys are unable to secrete EPO and therefore Erythropoietin Stimulating Agents (ESA) are prescribed for the majority of patients in ESRD. Iron Therapy is prescribed in conjunction with EPO to assist in the formation of haemoglobin (Hb) so that oxygenated blood can be distributed throughout the body and to compensate for blood loss during dialysis sessions resulting in a low Hb level.

Patients diagnosed with ESRD experience loss of bone minerals in the form of Calcium and Phosphorus which can also combine and form calcification of vessels. An imbalance of these two elements can cause complications such as mineral bone disease by stimulating the secretion of parathyroid hormone (PTH) and creating a negative feedback system leading to bone disease. Active Vitamin D is therefore prescribed to control the balance of calcium, phosphorus and PTH.

Phosphate binders are prescribed to reduce the amount of phosphate in the blood that increases due to failing kidney function and the bound phosphate is then excreted by the bowel. Some of the phosphate will be removed by dialysis depending on the properties of the dialyser clearance and time on dialysis. Phosphorus is difficult to control as it is contained in the patients' dietary intake. Data in Table 4.3 represent the number and percentage of patients on various prescribed medicines and the mean recordings for four HD sessions.

Table 4. 3: Prescribed medication for 4 HD sessions

	Month 1	Month 2	Month 3	Month 4	*Mean for the 4 periods*
No. of patients	**169**	**169**	**169**	**169**	**169**
Medication					
ESA n=, (%)	103 (61)	110 (65)	115 (68)	110 (65)	110 (65.08)
Iron Therapy n=, (%)	102 (60)	104 (62)	107 (63)	107 (63)	104 (61.53)
Phosphate Binders n=, (%)	41 (24)	60 (36)	67 (40)	60 (36)	57 (33.72)
Vit D Supplements n=, (%)	56 (33)	56 (33)	54 (32)	52 (31)	54 (31.95)

Data in Table 4.3 show the mean number of recordings for each of the prescribed medicines for the four HD sessions: 110/169 (65.08%) for ESA, 104/169 (61.53%) for Iron Therapy, 57/169 (33.72%) for Phosphate Binders and 54/169 (31.95%) for Vitamin D supplementation.

4.6 Results for Quality Indicators

Results for the quality indicators are presented in the order outlined in the literature review Chapter 2: dialysis access, dialysis adequacy, management of nutrition, management of anaemia and management of bone disease.

4.6.1 Results for Dialysis Access

Well-functioning vascular access (VA) sites, recommended in the guidelines as quality indicators, are essential for efficient dialysis therapy. Access refers to a surgically created Arterio-Venous Fistula (AVF) for the specific use of dialysis recommended in the KDOQI Guidelines as the first choice of access for patients receiving HD. A synthetic arteriovenous graft (AVG) is an alternative option for patients with diabetic nephropathy or problematic vasculature (SARS, 2015). Results for VA from the record review for the four HD sessions showing levels of adherence to the guidelines are presented in Table 4.4.

Table 4. 4: Quality indicator: dialysis vascular access for HD 4 sessions (mean values and levels of adherence)

	Month 1	Month 2	Month 3	Month 4	*Mean for the 4 periods*
Dialysis Access					
No. of patients n=, (%)	**169 (100)**	**169 (100)**	**169 (100)**	**169 (100)**	**169 (100)**
TC n=, (%)	6 (3.55)	3 (1.77)	3 (1.77)	6 (3.55)	5 (2.95)
PC n=, (%)	56 (33.13)	56 (33.13)	51 (30.17)	48 (28.40)	52 (30.76)
AVF/AVG n=, (%)	107 (63.31)	110 (65.08)	115 (68.04)	115 (68.04)	112 (66.27)
Dialysis Access					
Dialysis Access: Target not Attained n=, (%)	62 (36.68)	60 (35.50)	56 (33.13)	54 (31.95)	**57 (33.72)**
Dialysis Access: Target Attained n=, (%)	107 (63.31)	110 (65.08)	115 (68.04)	115 (68.04)	**112 (66.27)**

Note to table: TC = Temporary Catheter, PC = Permanent Catheter AVF/AVG = Arteriovenous Catheter/Arteriovenous Graft;

Data in Table 4.4 show that overall, recordings of dialysis access attained a mean level of 112/169 (66.27%) with no missing data for the four HD sessions. AVF and AVG were used the most frequently as recommended and collectively yielded a mean number of 112/169 (62.27%) recordings. Temporary catheters were used the least 5/169 (2.95%) and the mean number of recordings for the use of permanent catheters was 52/169 (30.76%). This means that 57/169 (33.72%) of the patient recordings indicated that dialysis access did not meet targets set in the guidelines.

4.6.2 Results for Dialysis Adequacy

Adequacy of dialysis refers to the amount of dialysis needed for a patient to remain asymptomatic and improves patient survival, quality of life and biochemical outcomes and minimizes disease complications and hospitalisation (Adas, Al-Ramahi, Jaradat, & Badran, 2014). Dialysis adequacy is therefore an important determinant of patient outcome and thus an important clinical performance indicator. Dialysis adequacy refers to how well a patient is dialysed after measurement of urea clearance, expressed as Kt/V: a value (for example 1.2) used in medicine to quantify haemodialysis treatment adequacy: K, dialyzer clearance of urea; t, dialysis time divided by V, volume of distribution of urea, approximately equal to a patient's total body water. The guidelines recommend a Dialysis Adequacy of Kt/V of 1.2 for patients receiving dialysis three times a week and 1.6 for patients being dialyzed twice a week (Malekmakan et al., 2010; NKF-KDOQI, 2015). Data in Table 4.5 show recordings for dialysis adequacy (Single Pool Kt/V of 1.2 – 1.4) for the four HD sessions for the study period under review.

Table 4. 5: Quality indicator: dialysis adequacy for 4 HD sessions (mean values and levels of adherence)

	Month 1	Month 2	Month 3	Month 4	*Mean for the 4 periods*
Single Pool Kt/V					
No. of patients n=, (%)	134 (79.28)	139 (82.24)	143 (84.6)	114 (67.45)	133 (78.69)
<1.2 n=, (%)	51 (38.05)	48(34.53)	41 (28.67)	35 (30.70)	44 (33.08)
***1.2 – 1.4 n=, (%)**	**47 (35.07)**	**40 (28.77)**	**55 (34.46)**	**45 (39.47)**	**47 (35.33)**
>1.4 n=, (%)	36 (26.86)	51.(36.69)	47 (32.86)	34 (29.82)	42 (31.57)
Single Pool Kt/V Target not Attained n=, (%)	71.(52.98)	80 (57.55)	74 (51.74)	47.(41.22	86 (64.66)
Single Pool Kt/V Target Attained n=, (%)	47 (35.07)	40 (29.86)	55 (38.46)	45 (39.47)	47 (35.33)

Note to table: * Target for dialysis adequacy

Data in Table 4.5 show that a mean of 47/169 (35.33%) of the recordings for dialysis adequacy (Single Pool Kt/V of 1.2 – 1.4) for the four HD sessions attained the target level stipulated in the guideline. The mean number of recordings for dialysis adequacy was 133/169 (78.69%) of which missing data accounted for 36/169 (21.30%) of the recordings, results below the target (<1.2) were found in 44/169 (33.08%) of the recordings and recordings above the target (> 1.4) accounted for 42/169 (31.57%) of the recordings. This means that 86/169 (64.66%) of the patient records indicated that target levels for dialysis adequacy were not attained.

4.6.3 Results for Management of Nutrition

Assessing patients' nutritional status in ESRD is important by evaluating serum albumin and body weight. A pre-dialysis albumin level of ≥4.0 g/dl is the outcome goal, and patients with serum albumin levels lower than 3.5 g/dl should be evaluated for protein-energy malnutrition (Combe et al., 2004). Data in Table 4.6 show mean values for recordings of the management of nutrition for four HD sessions.

Table 4. 6: Quality indicator: Management of nutrition for 4 HD sessions (mean values and levels of adherence)

	Month 1	Month 2	Month 3	Month 4	*Mean for the 4 periods*
Serum Albumin in mmol/L (N)					
No. of patients n=, (%)	**167 (98.8)**	**169 (100)**	**167 (98.8)**	**169 (100)**	**168 (99.40)**
<35mmol/L n=, (%)	49 (29.34)	49 (28.99)	26 (15.56)	26 (15.38)	38 (22.61)
>35mmol/L n=, (%)	118 (70.65)	120 (71.00)	141 (84.43)	143 (84.61)	130 (77.38)
Serum Albumin in mmol/L Target not Attained n=, (%)	49 (29.34)	49 (28.999)	26 (15.56)	26 (15.38)	38 (22.61)
Serum Albumin in mmol/L Target Attained n=, (%)	118 (70.65)	120 (71.00)	141 (84.43)	143 (84.61)	130 (77.38)

For Nutritional Management a mean of 130/168 (77.38%) records attained the guidelines, while 38/168 (22.61) records failed to meet the prescribed guidelines and missing data accounted for a mean of 1/169 (0.6%) of the study data for this parameter.

4.6.4 Results for Management of Anaemia

In ESRD anaemia refers to a HB level of <10 g/dL. The management of anaemia during HD includes measurement of parameters such as serum HB, Transferrin Saturation and Ferritin. The guidelines recommend maintaining the levels for these parameters at 10 – 12 g/dL for serum HB, 20% for Transferrin Saturation (TSAT) and 200 ng/L for Ferritin. Data in Table 4.6 show mean values for recordings for the management of nutrition for four HD sessions. Anaemia levels lower or higher than the targets as set out in the guidelines as indicated below can lead to adverse effects that can negatively affect quality of life. Data in Table 4.7 show mean values and levels of adherence for recordings of management of anaemia for four HD sessions.

Table 4. 7: Quality Indicator: Management of anaemia (mean values and levels of adherence) for 4 HD sessions

	Month 1	Month 2	Month 3	Month 4	*Mean for the 4 periods*
Hb in g/dl					
No. of patients n=, (%)	**162 (95.8)**	**169 (100)**	**168 (99.4)**	**169 (100)**	**167 (98.8)**
<10 g/dl n=, (%)	47 (29.01)	23 (13.60)	25 (14.88)	36 (21.30)	33 (19.76)
10 – 12g/dl n=, (%)	80 (49.38)	106 (62.72)	101 (60.11)	88 (52.07)	93 (55.68)
>12g/dl n=, (%)	35 (21.60)	40 (23.66)	42 (25.0)	45 (26.62)	41 (24.55)
Transferrin Saturation in%					
No. of patients n=, (%)	**163 (96.4)**	**162 (95.8)**	**159 (94.0)**	**160 (94.6)**	**161 (95.2)**
<20 % n=, (%)	58 (35.58)	59 (36.41)	49 (30.81)	46 (28.75)	53 (32.91)
>20 % n=, (%)	105 (64.41)	103 (63.58)	110 (69.18)	114 (71.25)	108 (67.08)
Ferritin in ng/dl					
No. of patients n=, (%)	**163 (96.4)**	**164 (97)**	**162 (95.8)**	**163 (96.4)**	**163 (96.4)**
<200 ng/dl n=, (%)	41 (25.15)	39 (23.78)	28 (17.28)	28 (17.17)	34 (20.85)
200 – 500 ng/dL n=, (%)	50 (30.67)	50 (30.48)	54 (33.33)	52 (31.9)	52(31.90)
>500 ng/dL n=, (%)	72 (44.17)	75.(44.4)	80 (49.38)	83 (50.92)	77 (47.23)
Hb in g/dl					
Target not Attained n=, (%)	82 (50.61)	63 (37.27)	67 (39.88)	81(47.92)	**74 (44.31)**
Target Attained n=, (%)	80 (49.38)	106 (62.72)	101 (60.11)	88 (52.07)	**93 (55.68)**
Transferrin Saturation in %					
Target not Attained n=, (%)	58 (35.58)	59 (36.41)	49 (30.81)	46 (28.75)	**53 (32.91)**
Target Attained n=, (%)	105 (64.41)	103 (63.58)	110 (69.18)	114 (71.25)	**108 (67.08)**
Ferritin in ng/dl					
Target not Attained n=, (%)	113 (69.32)	114 (69.51)	108 (66.66)	111 (68.09)	**111 (68.09)**
Target Attained n=, (%)	50 (30.67)	50 (30.48)	54 (33.33)	52 (31.90)	**52 (31.90)**

Note to table: Hb = Haemoglobin; g/dL Ferritin; ng/dL SATS=Transferrin Saturation %

Data in Table 4.7 show that 93/167 (55.68%) recordings for management of anaemia revealed an Hb of 10 – 12g/dl, therefore that the mean target level had been attained. Records that yielded a

result Hb <10 g/dl was 33/167 (19.76%) and Hb >12g/dl was 41/167 (24.55%), therefore 74/167 (44.31%) failed to meet the required guidelines for Hb. Suboptimal Hb levels were present in 44.31% of the patient recordings. For Transferrin Saturation a mean of 108/161 (67.08%) recordings attained the prescribed target and 53/161 (32.91%) failed to reach the desired outcomes. For ferritin levels 34/163 (20.8%) reported levels below the desired target level, while, 77/163 (47.2%) represented levels above the desired target level. Collectively 111/163 (68.09%) of the records failed to attain target levels. Furthermore, 52/163 (31.09%) of the records attained the desired targets for Ferritin as required by the guidelines.

4.6.5 Results for Management of Bone Disease

Bone disease management in patients with ESRD requires careful monitoring of serum Calcium and serum phosphate levels to maintain these within target levels. Limiting dietary intake of phosphates and adequate dialysis can keep the levels within required limits. Data in Table 4.8 show mean values and levels of adherence for the quality indicator, management of bone disease.

Table 4. 8: Quality Indicator: Management of Bone Disease (mean values and levels of adherence) for 4 HD sessions

	Month 1	Month 2	Month 3	Month 4	*Mean for the 4 periods*
Serum Phosphorus in mmol/L (N)					
No. of patients n=, (%)	**163**	**168**	**167**	**166**	**166**
< 0.8mmol/L n=, (%)	8 (4.90)	5 (2.97)	5 (2.99)	7 (4.21)	6 (3.61)
0.8 – 1.4mmol/L n=, (%)	61 (37.42)	60 (35.71)	72 (43.11)	64 (38.55)	64 (38.55)
>1.4mmol/L n=, (%)	94 (57.66)	103 (61.30)	90 (53.89)	95 (57.22)	96 (57.83)
Serum Calcium in mmol/L (N)					
No. of patients n=, (%)	**165**	**133**	**162**	**132**	**148**
< 2.1mmol/L n=, (%)	49 (29.69)	33 (24.81)	44 (27.16)	46 (34.84.)	43(29.05)
2.1 – 2.5mmol/L n=, (%)	96 (58.18)	79 (59.39)	95 (58.64)	63 (47.72)	83(56.08)
>2.5mmol/L n=, (%)	20 (12.12)	21 (15.78)	23 (14.19)	23 (17.42)	22(14.86)
Serum Calcium x Phosphorus in mmol2/L2 n=, (%)					
No. of patients n=, (%)	**164**	**133**	**162**	**131**	**148**
<4.4mmol²/L² n=, (%)	133 (81.09)	84.(63.15)	122(75.30)	83 (63.35)	106 (71.62)

	Month 1	Month 2	Month 3	Month 4	*Mean for the 4 periods*
>4.4mmol²/L² n=, (%)	31 (18.90)	49 (36.84)	40 (24.69)	48 (36.64)	42(28.37)
No. of patients n=, (%)	163 (94.44)	168 (99.41	167 (98.81)	166 (98.22)	166 (98.22)
Serum Phosphorus in mmol/L Target not Attained n=, (%)	102 (62.57)	108 (64.28)	95 (56.88)	102 (61.44)	102 (61.44)
Serum Phosphorus in mmol/L Target Attained n=, (%)	61 (37.42)	60 (35.57)	72 (43.11)	64 (38.55)	64 (38.55)
No. of patients n=, (%)	165	133	162	132	148
Serum Calcium in mmol/L Target not Attained n=, (%)	69 (41.81)	54 (40.60)	67(41.35)	69 (52.27)	65 (43.91)
Serum Calcium in mmol/L Target Attained n=, (%)	96 (58.18)	79 (59.39)	95 (58.64.)	63 (47.72)	83 (56.08)
No. of patients n=, (%)	164 (97.04)	133 (78.69)	162 (95.85)	131 (77.51)	148 87.57
Serum Calcium x Phosphorus in mmol2/L2 Target not Attained n=, (%)	31 (18.90)	49 (36.84)	40 (24.69)	48 (36.64)	42 (28.37)
Serum Calcium x Phosphorus in mmol2/L2 Target Attained n=, (%)	133 (81.09)	84 (63.15)	122 (75.30)	83 (63.35)	106 (71.62)

Records reflecting serum Phosphorus levels revealed that 102/166 (61.44%) failed to meet the required guidelines, while 64/166 (38.55%) of the records attained the required levels. Serum Calcium levels reflected that 65/148 (43.91%) did not meet the guidelines and 83/148 (56.08%) did. Calcium Phosphate Product was not attained by 42/148 (28.37%) of the records while 106/148 (71.62%) reached the required guidelines for Bone disease management.

4.7 Summary

The estimated sample size was 176 records (return rate of 169/176, 96.0%). The typical patient with ESRD having HD was 60 years of age, male, classified as Coloured, married and had a diagnosis of diabetic nephropathy. Of the prescribed medicines for the four HD sessions, patients received: ESA 110/169 (65.08%), Iron Therapy 104/169 (61.53%), Phosphate Binders 57/169 (33.72%) and Vitamin D supplementation 54/169 (31/95%). For dialysis access, AVF and AVG were used the most frequently as recommended but 57/169 (33.72%) of the patient recordings indicated that dialysis access did not meet targets set in the guidelines. A mean of 47/169 (35.33%) of the recordings for dialysis adequacy (Single Pool Kt/V of 1.2 – 1.4) for the four HD sessions attained the target level stipulated in the guideline and 86/169 (64.66%) of the patient records indicated that target levels

for dialysis adequacy were not attained. For management of nutrition a mean of 130/168 (77.38%) records attained the guidelines for this parameter. For management of anaemia the mean target level for Hb of 10 – 12g/dl had been attained and 74/167 (44.31%) failed to meet the required guidelines for Hb; for Transferrin Saturation a mean of 108/161 (67.08%) recordings attained the prescribed target and 53/161 (32.91%) failed to reach the desired outcomes; and for ferritin levels 34/163 (20.8%) reported levels below the desired target level, while, 77/163 (47.2%) represented levels above the desired target level. Collectively 111/163 (68.09%) of the records failed to attain target levels. Furthermore, 52/163 (31.09%) of the records attained the desired targets for Ferritin as required by the guidelines. For management of bone disease, records reflecting serum Phosphorus levels revealed that 102/166 (61.44%) failed to meet the required guidelines, while 64/166 (38.55%) of the records attained the required levels; serum calcium levels reflected that 65/148 (43.91%) did not meet the guidelines and 83/148 (56.08%) did; and calcium phosphate product was not attained by 42/148 (28.37%) of the records while 106/148 (71.62%) reached the required guidelines for this parameter.

CHAPTER FIVE DISCUSSION, IMPLICATIONS, RECOMMENDATIONS AND CONCLUSION

5.1 Introduction

Quality indicators for patients on haemodialysis (HD) as defined by international guidelines for dialysis access, dialysis adequacy, nutritional management of the dialysis patient, anaemia management and bone disease management have a solid scientific basis with clear clinical outcomes. Patients on HD are susceptible to many complications associated with this form of renal replacement therapy (RRT) and the guidelines aim to minimise these and to improve patients' quality of life. The goals for nephrology in the next decade are: to reduce the burden of preventable causes of acute kidney injury in low-income countries and promote affordable renal replacement therapies; to make worldwide interventions available that help combat the burden of chronic kidney diseases with selective screening, prevention and treatment of curable diseases; to develop new drugs for kidney diseases; and to create new methods for diagnosis and treatments for inherited kidney disease (Remuzzi et al., 2013).

Monitoring clinical outcomes for patients on HD is essential for good quality of life. The NKF-KDOQI (2002) has established guidelines that serve as clinical indicators with parameters to measure patient outcomes and serve as a blueprint for all renal units in South Africa and internationally for improving the management of kidney disease. At the start of the study it was not known what proportion of patients with (ESRD) on chronic haemodialysis (HD) in selected private dialysis units in the Western Cape Province reached target levels for each clinical indicator outlined in the guidelines. The aim of the present study was to design and validate a record review template for record review to describe target and actual outcomes for each clinical indicator to assess adherence to established guidelines.

In the first three phases of the study a record review template was constructed and validated for content, ease of use (quality of instrument) and accuracy of transcription (inter-rater reliability). In phase 4 of the study the validated template was used for record review of patient data in selected private HD units in the Western Cape Province to assess adherence to established guidelines and the results were described in Chapter 4. The aim of the study was achieved.

In this chapter the principal findings and implications for nursing education institutions, clinicians, healthcare management teams and further research are discussed, and recommendations made.

5.2 Principal findings

5.2.1 Patients' (n=169) demographic and clinical data

Results showed that in general, the demographic and clinical characteristics of the study sample are different to those receiving treatment for HD units in the public healthcare sector. The median age of the 169 patients with ESRD and receiving HD was 60 years, ranging between 21 and 86 with most 99/169, (58.57%) patients between being between 53-70 years of age. According to the 2015 South African Renal Registry Annual Report (SARS, 2015), the mean age for patients treated in 2015 was 51.3% (± 15.0) years and the majority were male 59.3%. The population in the present study was older and more males were represented in the sample of patient records. The average age of patients undergoing dialysis in the United States of America (USA) has been increasing progressively over the last several decades and in 2000 the average age was approximately 62 years (Dimkovic et al., 2015; Power & Brown, 2013; Rao et al., 2016).

South Africa's population is currently estimated at more than 54 million, according to the 2015 South African Renal Registry Annual Report. The majority of the country's population (84%) are dependent on the public sector for the provision of health care and 16% have access to private health care. In South Africa rationing and selection criteria for renal replacement therapy results in younger patients 43.4 (±13.5) years of age being accepted into HD programmes in the public healthcare sector versus 55.0 (±14.3) years of age for the private sector (Davids et al., 2017).

From an ethnicity perspective, Black persons constitute 80.5% of the South African population; Coloureds make up 8.8%; Whites 8.8% and Indians/Asians 2.5%. The present study was undertaken in private sector HD units in the Western Cape Province. An analysis of ethnicity of the study sample revealed that the majority of patients represented Coloureds 69/169 (40.8%) whereas Blacks and Whites respectively represented 22/169 (13%). These figures differ significantly from the distribution by ethnicity contained within the 2014 South African Renal Registry Annual Report for patients receiving HD, with black patients reported to make up 51.2%, Whites 22.1%, Coloureds 14.5% and Indians/Asian 12.2% (Davids, Singh, Marias & Jacobs, 2014). The paucity of data on the provision of dialysis in developing countries is largely attributable to a deficiency of renal registries, thereby limiting the ability to compare our data to other similar settings.

The majority 55/169 (32.54%) of the records in the present study reflected a diagnosis of diabetic nephropathy (32.5%) similar to results of 22% in Europe. The foremost causes of chronic kidney

disease (CKD) in both developed and many developing countries are attributable to chronic conditions such as diabetes and hypertension, whereas glomerulonephritis and unknown causes are more common in developing countries (Naicker, 2013). The most common causes of ESRD in the present study in descending order were Diabetes, Hypertension, Glomerulonephritis, Unknown Polycystic Kidney Disease and SLE. This list differs from the most commonly reported causes in ESRD in the 2012 South African Renal Registry Annual Report. In a 2013 publication, Naicker stated that hypertension affects about 25% of the adult population and is the cause of ESRD in approximately 20% of patients on RRT in South Africa (Naicker, 2013). In the present study hypertension as the primary cause of CKD accounts for 24.9% of recordings.

5.2.2 Results for medication

Results for prescribed medications show that the majority of patients received Erythropoiesis Stimulating Agent (ESA) therapy and intravenous iron therapy. Very low levels of phosphate binders and calcium supplementation were reported. Calcium can be corrected by the type of dialysate used during the dialysis session but phosphate binders with low levels of calcium are important. Records reported elevated levels of serum phosphate and this correlates with the low prescription of phosphate binders. Anaemia management with prescription of ESA and intravenous iron replacement in haemodialysis patients poses several clinical challenges, including the maintenance of stable Hb levels within narrow target ranges, balancing iron and ESA dosage and optimizing response to ESA to achieve the lowest possible effective ESA dose (Yong & Kairaitis, 2010).

5.2.3 Results for Quality Indicators

The results of this study confirm that patients receiving HD are vulnerable to many complications. Guidelines have been implemented to improve care, yet use of access sites varies greatly across countries and VA complications remain a problem (Ethier et al., 2008).

5.2.3.1 Results of Dialysis Access

Dialysis access via arteriovenous fistula (AVF) and arteriovenous graft AVG combined showed that a target level of 112/169 (66.27%) had been attained and there were no missing data. Temporary catheters were used the least 5/169 (2.95%) and the use of permanent catheters remained constant between 52-55/169 (30.76-32.54%) for the duration of the study period.

Local and international guidelines indicate that the AVF route is the vascular access of choice in haemodialysis patients (Yan et al., 2018). In terms of these guidelines, if it is not possible to

establish an AVF, the next access route of choice is an AV graft. Generally, access via a cuffed tunnelled venous catheter is not advocated as a permanent means of vascular access. In the present study 66% of the patients had vascular access via an AVF or AVG comparable to countries like Japan according to the Dialysis Outcomes and Practice Patterns Study (DOPPS) (Rayner et al., 2004). Native arteriovenous fistula (AVF) was used by 67–91% of patients in Japan, Italy, Germany, France, Spain. The AVF use rose from 24% to 47% and the use of AVG's decreased by 50% in the USA (Ethier et al., 2008). .

Although 66% of the patients in the present study had vascular access via an AVF or AVG thereby complying with the recommended guidelines, surprisingly, this result was in contrast to the Dialysis Adequacy target that was not met in 51% of the records reviewed, as it would be expected that more patients would have reached the target guidelines because access parameters had met the guideline target. This could be due to 21% missing data. The dialysis adequacy outcome for the present study was 28% which is not optimal in terms of the KDOQI Guidelines (NKF-KDOQI, 2015).

5.2.3.2 Results for Dialysis Adequacy

Results for this quality indicator did not satisfy target levels. A mean of 47/169 (35.33%) of the recordings for dialysis adequacy (Single Pool Kt/V of 1.2 – 1.4) for the four HD sessions attained the target level stipulated in the guideline. The mean number of recordings for dialysis adequacy was 133/169 (78.69%) with 36/169 (21.30%) missing data. Results below the target (<1.2) were found in 44/169 (33.08%) of the recordings and recordings above the target (>1.4) accounted for 42/169 (31.57%) of the recordings. This means that 86/169 (64.66%) of the patient records indicated that target levels for dialysis adequacy were not attained. This is in contrast with the high percentage of AVF/AVG access sites. The dialyser size and blood flow per treatment will be useful in further investigations but were beyond the scope of this study. The result could be as a direct result of the missing data that accounted for 36 (21.3%) records. Similarly, in Palestine only 25 (39.1%) patients achieved the Kt/V goal, and in a study from Sri Lanka, it was shown that only 39 (28.2%)achieved the guideline target (Adas et al., 2014).

In Europe (2004), the mean delivered dose of haemodialysis as measured by normalized urea clearance (Kt/V) varied from 1.28 to 1.50 (Goodkin, Mapes, & Held, 2001). Japan exhibits one of the lowest mortality rates in the world for HD patients, and receives dialysis doses below the current KDOQI guideline recommendations of spKt/V 1.2 or higher (Kimata et al., 2014).

5.2.3.3 Results for Nutritional Management

A mean of 130/168 (77.38%) records attained the guidelines for management of nutrition while 38/168 (22.61%) records failed to meet the prescribed guidelines for this parameter. According to Usvyat et al., (2013) serum albumin levels dropped between 0.33 (Asia) and 0.52 (North America) g/dl in the 2 years preceding death in female patients and these results were comparable in Europe and South and North America, and less pronounced in Asia. The rate of serum albumin decline accelerated before death (Usvyat et al., 2013). Although there was no reported correlation with anaemia, a low serum albumin is thought to fairly accurately reflect an inflammatory state of moderate severity, and a low serum albumin is more likely to be associated with greater rates and worse levels of anaemia (Kliger et al., 2013).

In End Stage Renal Disease (ESRD), serum plasma albumin is a predictor of patients' future health outcomes for these patients. The multidisciplinary team must be knowledgeable about serum albumin and the ill-effects of hypoalbuminemia in the provision of quality care. Vigilance in maintaining albumin levels and nutritional goals is very important (Wyczesany & Steefel, 2015). Patients with ESRD have to adhere to and maintain lifestyle changes such as nutrition to improve health and well-being and a chance to 'self-manage' care of their kidney disease (Palmer et al., 2017).

5.2.3.4 Results for Anaemia Management

Suboptimal Hb levels were present in 44.31% of the patient recordings and therefore target levels for this quality indicator were not reached. For Transferrin Saturation a mean of 108/161 (67.08%) recordings attained the prescribed target and 53/161 (32.91%) failed to reach the desired outcomes. For ferritin levels 34/163 (20.8%) reported levels below the desired target level, while, 77/163 (47.2%) represented levels above the desired target level. Collectively 111/163 (68.09%) of the records failed to attain target levels. Furthermore, 52/163 (31.09%) of the records attained the desired targets for Ferritin as required by the guidelines. In patients receiving HD it is more difficult to achieve Hb targets because of comorbidities, including numerous inflammatory diseases responsible for ESA resistance.

Forty-nine percent of the study cohort reached the target Hb level 10g/d – 12g/dl. This may be due to the increase in prescription of erythropoietin and the optimization of the iron status as prescribed however, this is not in accordance with the recommendations set out in the guidelines

that "at least 75% of a cohort of patients should have haemoglobin levels of 11g/dl and that no patient should have a haemoglobin level of less than 8g/dl (SARS, 2015).

In terms of mortality, meta-analyses did not show any statistically significant difference between higher and lower Hb levels in haemodialysis patients (Zazzeroni, Pasquinelli, Nanni, Cremonini, & Rubbi, 2017). The target allows for relative flexibility in medical decision making and considers variability between patients' comorbidities, prognosis, functional status, and responsiveness to ESA therapy.

5.2.3.5 Results for management of Bone Disease

Results for this quality indicator did not satisfy target levels as 60% of the records did not attain the target for Phosphorus; Calcium revealed that a 49% target had been reached for 148 records and the calcium Phosphate Product results achieved a 70.5% target level.

5.3 Limitations and strengths of the study methods

5.3.1 Limitations of the study methods

Record Review of blood results of patients receiving HD to assess adherence to established guidelines for End Stage Renal Disease was limited by the small sample size that it yielded. While a randomized sample was intended and an appropriate sample size was calculated, due to lack of consent and other factors, all available records for patients who met the inclusion criteria were included, resulting in a convenience sample which limits external validity of the results. Convenience sampling has the potential for sampling bias (Higgins et al., 2011). Participants for the validation processes were selected by convenience sampling, which also poses a risk for selection bias (Higgins et al., 2011). The two participants in Phase 3 of the study who were requested to transcribe fictitious patient datasets onto the SPSS file in the presence of the researcher, may have felt under pressure to please the latter, thereby the potential for performance bias (Higgins, 2011). Furthermore, the study was conducted in the private sector thereby further reducing the generalisability of the study findings to other research sites.

The design of the record review chart restricted any corrective measures that could be of benefit to further research as the chart was modelled on the quality indicators in established guidelines. The actual patient care measures therefore cannot be assessed from this data.

5.3.2 Strengths of the study methods

Strength of this study were the standardised outcomes measures of adherence compared to the KDOQI guidelines. The KDOQI guidelines have been established since 1997, leading to standardisation of adherence outcome measures. Standardisation allows for future research across haemodialysis centres nationally and internationally (Matteson & Russel, 2010).

5.4 Implications of the study and recommendations

There are implications for nursing education institutions, healthcare institutions/management, research and, by implication for policy makers. Nephrology nurses should be familiar with current guidelines and work towards integrating standards of care into clinical practice (Dutka & Brickel, 2010).

Recommendations

The benefit of clinical practice guidelines can only be useful if implemented into daily practice. The clear benefit will be better outcomes for patients and a reduction in the mortality and morbidity rates of patients in End Stage Renal Disease (ESRD) firstly by creating awareness of the importance and prioritization of access sites and dissemination of the results of this study amongst clinicians. Informed clinicians should feel more confident to assist patients to understand their pathology and the consequent lifestyle changes needed to improve adherence to their treatment plan and therefore an improved quality of life.

Constant evaluation of patients' blood results pre- and post-dialysis against quality indicators will alert clinicians to any deviation and to take corrective action immediately. Clinical Practice Guidelines (CPG) with its rigorous methodology based on scientifically sound systematic reviews, are effective for improving patient outcomes. As the focus on providing the best-quality health care increases, we can expect an increasing role of CPG adherence in the assessment of clinical care quality (Ryan, 2017).

5.4.1 Nursing education institutions

Curricula should include adequate content relating to kidney disease and prevention of avoidable conditions starting in undergraduate programmes. These factors need to be considered from a primary healthcare perspective given the fact that non-communicable lifestyle diseases are the major causes of ESRD evidenced by this study and supported in the reviewed literature. This should

be a collaborative effort between educators and clinicians including multidisciplinary team members and case studies need to inform teaching and learning in the classroom. Nephrology nursing students need to be made aware of their scope of practice and expected competencies.

Nephrology nursing students should gain in-depth knowledge about the importance of clinical guidelines and should share this information with patients to encourage shared decision making in the treatment and care delivered (Ryan, 2017). This is particularly important because of the many co-morbidities experienced by patients with ESRD and therefore sharing information in clinical practice guidelines with patients and their families should improve adherence. Clinicians need regular structured educational sessions and clinical practice guidelines should be easily accessible to all clinicians caring for patients (Ryan, 2017).

5.4.2 Health care institutions

A question in the reviewed literature (Bennett & Simmonds, 2008) was: Is a Change in Adequacy Standards Necessary?. This might mean different times of the day and/or night for dialysis units to operate to accommodate more patients requiring HD. These suggestions carry financial and ethical costs. Results in the present study show the need for change in order to improve practice. However, this change can only occur when clinicians adhere to clinical practice guidelines to improve patient outcomes.

Clinician adherence is of paramount importance to decrease morbidity and mortality rates, and to increase the quality of life of patients on dialysis. Awareness of the importance of the quality indicators must therefore be highlighted amongst clinicians. This will assist with the identification of associations that exist amongst the indicators for early detection and treatment of sub optimal outcomes. Nephrology practitioners need to be made more aware of their scope of practice as they function autonomously in the units due to the shortage of medical nephrologists in South Africa.

The EuCliD® is a useful tool for identification of any variance from normal targets. The enhanced awareness, understanding, and implementation of the guidelines should ensure that patients receive immediate attention before complications occur. Data from the present study show that many patients presented with elevated serum phosphate levels, but few patients had phosphate binders prescribed. Knowledge of clinical practice guidelines could present a completely different result, as the blood results could be accessed and together with the multidisciplinary team an appropriate care plan could be developed for patients.

Interpretation of blood results form the basis of decision making in the management of patients with CKD from pre dialysis to transplant, irrespective of the type of renal replacement therapy. The quality indicators therefore inform individualised care based on the blood results.

Knowledge of the requirements and recommendations for Vascular Access as a quality indicator should help nurses to be vigilant about access sites and to ask questions such as: is there recirculation, are there problems with cannulation and should the patient be referred to a vascular surgeon? Questions nurses can ask when target levels are not met for Haemodialysis Adequacy (Kt/V) relate to: access adequacy/appropriateness, dialysis prescription, being dialysed for the prescribed time, appropriate size of the dialyser, time pump speed, reasons for patients not turning up for dialysis. Nurses can refer patients to a nutritionist for nutritional management where indicated or to a social worker or psychologist if there are there specific issues that impact on the treatment plan.

It is suggested that there is a lack of accountability on the part of patients to their treatment regimen and that education is the key to personal accountability (Cahill, 2007). Healthcare institutions should offer regular in-service education for renal practitioners on patient education and on changes to clinical guidelines and these practitioners should be empowered to contribute to change in practice by employing consensus research methods.

5.4.3 Research

Unanswered questions and future research

- What educational strategies can healthcare institutions employ to encourage staff to adhere to established clinical guidelines for renal replacement therapy?
- How can compliant patients who have ESRD be encouraged to participate in motivating other such patients to adhere to their treatment plan?
- What ethical issues surrounding renal replacement therapy should be addressed?

5.7 Conclusion

This appears to be the only South African study that reports adherence levels to quality indicators for patients receiving HD: vascular access, haemodialysis adequacy, nutritional management, management of anaemia and prevention of bone disease in one study. Target levels for three of the five quality indicators were not met. These pertain to dialysis adequacy, management of bone

disease and of anaemia. Results have implications for the quality of life on patients on HD and renal personnel need to be informed about the importance of meeting target levels for all quality indicators.

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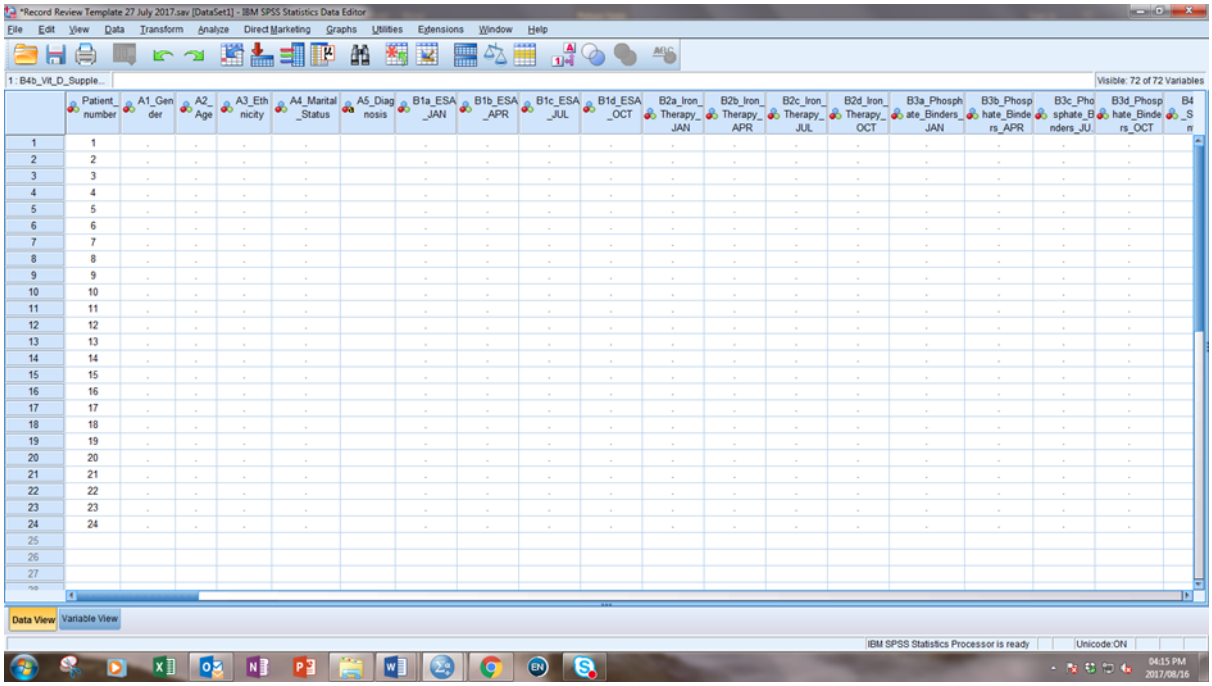
Zec, S., Soriani, N., Comoretto, R., & Baldi, I. (2017). High Agreement and High Prevalence: The Paradox of Cohen's Kappa. The Open Nursing Journal, 2017(11), 211-218.

Appendices

Appendix 1: Excerpt from Prototype Record Review Template not populated with fictitious patient data



Appendix 2: Full literature search strategy

Database	Keywords	Overall Results	Specific Results	No. of relevant papers	No. used
PubMed	FINAL TOTAL FOR STUDY		877	537	57
	Set 1 (Population)	239568			
	Kidney Failure, Chronic [MeSH]				
	OR End stage kidney disease OR end stage renal disease OR chronic kidney failure OR chronic renal failure OR ESRD				
	AND				
	Renal Replacement Therapy [MeSH]				
	OR Renal dialysis OR hemodialysis OR haemodialysis OR renal replacement therapy				
	Set 2 (Guidelines)	2565365		52127	
	Practice Guidelines as Topic [MeSH]				
	OR Kidney Disease Outcomes Quality Initiative OR KDOQI OR KDIGO OR Kidney Disease Improving Global Outcomes OR Policy OR policies OR guideline OR guidelines OR recommendations OR consensus OR statement OR standard OR standards				
	Set 3 (Compliance)	366815		98	
	Guideline Adherence [MeSH]				
	OR Compliance OR Adherence OR Practice Patterns				
	Set 4	6042926		25643	
	Treatment Outcome [MeSH]				
	OR efficacy OR effectiveness OR outcome OR outcomes OR measure OR measures OR target OR indicators OR parameters OR adequacy				
	Set 5 (measures)	2728		1623	
	Anemia [MeSH]				
	OR Anaemia OR anemia OR haemoglobin OR hemaglobin				
	Serum Albumin [MeSH]				
	OR Albumin OR protein levels				

	Chronic Kidney Disease-Mineral and Bone Disorder [MeSH] OR Bone mineral Arteriovenous Fistula [MeSH] OR Vascular access OR arteriovenous fistula OR arteriovenous grafts Dialysis Adequacy OR Dialysis Dose Set 6 (Personnel) Health Personnel [MeSH] OR Clinicians OR doctors OR health personnel OR medical personnel OR technologists OR nurses Set 7 Validation Studies (terms) Reproducibility of Results [MeSH] OR Validation Studies [Publication Type] *instead of MeSH field choose publication type* OR Validation OR validity OR validated OR reliability OR relevance OR evaluation Set 8 Record review Retrospective Studies [MeSH] OR Record review Set 9 Reliability Inter-rater Agreement OR Inter-rater Reliability	121047 2572433 841750 9137		877 537 10808 366	
	Combinations of: Set 1 AND Set 2 AND Set 3 AND Set 6 Set 2 AND Set 3 AND Set 6 Set 2 AND Set 3 and Set 5 Set 1 AND Set 2 Set 1 AND Set 2 AND Set 3 Set 1 AND Set 2 AND Set 5 Set 1 AND Set 2 AND Set 3 AND Set 6 Set 1 AND Set 2 AND Set 7 Set 1 AND Set 2 AND Set 5 AND Set 7 Set 1 AND Set 2 AND Set 8 Set 1 AND Set 2 AND Set 5 AND Set 8 Set 1 AND Set 2 AND Set 9 Set 1 AND Set 2 AND Set 5 AND Set 9	 537 52127 98 25643 1653 877 537 10808 366 2886 77 7 0			
	Set 1 (Population)	65728			

Medline via EBSCOHOST CINAHL Health Source Academic Africa Wide	Kidney Failure, Chronic [MeSH] OR End stage kidney disease OR end stage renal disease OR chronic kidney failure OR chronic renal failure OR ESRD AND Renal Replacement Therapy [MeSH] OR Renal dialysis OR hemodialysis OR haemodialysis OR renal replacement therapy Set 2 (Guidelines) Practice Guidelines as Topic [MeSH] OR Kidney Disease Outcomes Quality Initiative OR KDOQI OR KDIGO OR Kidney Disease Improving Global Outcomes OR Policy OR policies OR guideline OR guidelines OR recommendations OR consensus OR statement OR standard OR standards Set 3 (Compliance) Guideline Adherence [MeSH] OR Compliance OR Adherence OR Practice Patterns Set 4 Treatment Outcome [MeSH] OR efficacy OR effectiveness OR outcome OR outcomes OR measure OR measures OR target OR indicators OR parameters OR adequacy Set 5 (measures) Anemia [MeSH] OR Anaemia OR anemia OR haemoglobin OR hemaglobin Serum Albumin [MeSH] OR	4365749 8552132 9816044 362482			

	Albumin OR protein levels Chronic Kidney Disease-Mineral and Bone Disorder [MeSH] OR Bone mineral Arteriovenous Fistula [MeSH] OR Vascular access OR arteriovenous fistula OR arteriovenous grafts Set 6 (Personnel) Health Personnel [MeSH] OR Clinicians OR doctors OR health personnel OR medical personnel OR technologists OR nurses	2787692			
	Combinations of: Set 1 AND Set 2 AND Set 4 Set 2 AND Set 4 AND Set 7 Set 3 AND Set 4 and Set 5 Set 2 AND Set 3 Set 2 AND Set 3 AND Set 5 AND Set 6 Set 1 AND Set 2 AND Set 6 AND Set 8 Set 2 AND Set 3 AND Set 6 AND Set 9	 549 153565 519684 9118 1221 202 133			
	CINAHL Medline Africa Wide Health Source: Nursing/Academic Edition **FINAL TOTAL FOR STUDY**		549 218 8 47 1699	74 58 3 7 222	16 7 0 0 80

Appendix 3 – Information Sheet and Consent Form for Index of Content Validity (CVI) and face validity of the Record Review Template

Participant Code:

INFORMATION SHEET

Dear colleague

My name is Yolinda L van der Nest and I am a Master of Science (Nursing) degree student at the University of Cape Town. I am undertaking a study entitled **RECORD REVIEW OF POST-HAEMODIALYSIS BLOOD RESULTS TO ASSESS ADHERENCE TO GUIDELINES FOR END STAGE RENAL DISEASE.**

Patients in End Stage Renal Disease on dialysis need to adhere to guidelines that will improve their quality of life. Renal patient morbidity and mortality can be decreased by improving clinical outcomes with effective management of Anaemia, Nutrition and Bone Disease and Adequacy of Dialysis and Vascular Access as set out in the KDQOI/KDIGO guidelines. Adherence to the guidelines ensures reduced morbidity and mortality and thereby improving quality of life in renal patients.

In this study, I undertake to gain deeper insight into the extent in which, these aspects will be described and compared against the KDQOI/KDIGO guidelines and whether haemodialysis patients adhere to best practice guidelines. The study will measure patient outcomes retrospectively against pre-determined clinical outcome parameters.

Why is this study being done?

This study will add to the existing body of renal nursing knowledge in three ways by:

1) providing data on haemodialysis best practice and recommendations from a local Western Cape perspective;

2) creating knowledge about clinical outcomes for a sample of South African adult haemodialysis patients to determine whether a standardised protocol is fit for purpose for all patients in selected local private units (Saunders, MacLeod, Salyers, MacMillan, & Ogborn, 2013); and

3) forming the basis for further study to ascertain whether care providers have the relevant knowledge, skill and attitude to maintain the gold standard for haemodialysis practice as set out in the guidelines.

Does the study have ethics approval?

Ethics approval (HREC REF: 305/2019) has been obtained from the UCT Faculty of Health Sciences' Human Research Ethics Committee and is available upon request.

Why am I being asked to take part?

You have been invited to participate because you are a nephrology nurse/ medical doctor with expert knowledge in caring for patients on dialysis. The guidelines for dialysis form the basis of the care rendered to patients and application of these guidelines will improve patient outcomes. Your expert knowledge can provide valuable information on the validity of the Record Review Template (Appendix 1) designed for this study. Any information provided by you will remain confidential and anonymous. Your name will not be used at any stage during the study and a code number will be assigned instead. Only I will have access to the code number assigned to your name and this information will be stored on a password protected computer.

What will happen if you decide to take part in the study?

If you agree to participate in this study, you will be provided with the self-designed Record Review Template (Appendix 1) and the checklist (Appendix 4) on which you will rate (1-4) the template. The data on the template are based on the

KDOQI/KDIGO guidelines and when I do the record review, I will compare the patient data to the KDOQI/KDIGO guidelines. There is also a section on the checklist for your rating of the face validity of the template such as layout, length, etc., A date, time and location will be agreed upon by yourself. Your rating will assist with any changes that will have to be made to the template before the actual study.

It should take you about 30 minutes to complete the checklist.

What are the risks and discomforts of this study?

This study does not have any foreseeable adverse effects, risks or hazards for participants. The questions asked of you are intended to obtain assistance in validating the data extraction form (data review template, Appendix 1) that captures clinical variables from best practice renal guidelines to determine the level of guideline adherence from patient documentation.

What if I decide not to take part?

You have a choice to participate in or to exit the study at any time without penalty or obligation.

Are there any benefits to you for being in this study?

There may be no direct benefits to you for participating in this study other than an understanding of validating a data extraction form for review of patients receiving haemodialysis, which could improve future practice and improve patient outcomes. No financial benefits are payable for participating in the study.

Who do I speak to (or contact) if I have any questions about the study?

Researcher: Yolinda Louise van der Nest (3 Balfour Mansions, 7 Church Street Muizenberg 7945.
Telephone Number: 079 492 9358 e-mail: Yolinda.vandernest@uct.ac.za

Supervisor: Associate Professor Una Kyriacos, Division of Nursing & Midwifery, Department of Health & Rehabilitation Sciences, Faculty of Health Sciences, University of Cape Town, OBSERVATORY 7925.
Telephone Number: 0761422676 e-mail: una.kyriacos@uct.ac.za

HUMAN RESEARCH ETHICS COMMITTEE DETAILS:
Professor Marc Blockman (Chairman)
Faculty of Health Sciences Human Research Ethics Committee, Room E52-24, Groote Schuur Hospital Old Main Building, OBSERVATORY 7925,
Telephone number: 021 406 6338 e-mail: marc.blockman@uct.ac.za

Appendix 3 continued)

Participant consent form

For expert opinion on the Record Review Template

Researcher: Yolinda van der Nest R/N, Supervisor: Una Kyriacos PhD

	Initial
1. I (the participant) confirm that I have read and understand the information sheet for the above study (dated 2018) and have had the opportunity to ask questions and have them answered to my satisfaction.	
2. I am aware that I can withdraw from the study at any time without penalty.	
3. I am aware that all my details on this consent form and the validation process are confidential.	
4. I am aware that there are no physical risks involved. Information offered by me is confidential and protected. There are no known or anticipated risks.	
5. I am aware that benefits to me include knowledge about validating a data extraction form for review of patients receiving haemodialysis and the benefits to the health care industry include the potential to improve future practice and patient outcomes.	
6. I consent to take part in the above study and have reached this decision without coercion or undue pressure.	

Print name of participant Signature Date

This study is being conducted by the University of Cape Town. Funding for this work is supported in part from my supervisor, Emeritus A/Prof Una Kyriacos from the National Research Foundation of South Africa, Grant No. 90295.
Any opinion, finding and conclusion or recommendation expressed in this material is that of the author(s) and the NRF does not accept any liability in this regard.

When complete: original copy to be kept with transcript documents with a second copy for the researcher. Please offer a third copy to the participant for own records.

Appendix 4 – Checklist for Content and Face Validity of the data review template

RESEARCHER'S DETAILS:
Student: Master of Science in Nursing:
Ms. Yolinda L van der Nest
UNIVERSITY OF CAPE TOWN
Division of Nursing and Midwifery
TEL: 021-4066173
Yolinda.vandernest@uct.ac.za

SUPERVISOR'S DETAILS:
Assoc/Prof. Una Kyriacos
UNIVERSITY OF CAPE TOWN
Division of Nursing and Midwifery
TEL: 0761422676

HUMAN RESEARCH ETHICS COMMITTEE DETAILS:
Chairperson: Professor Mark Blockman
Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
OBSERVATORY
7925
TEL: 021-406 6626

Title of Study: **RECORD REVIEW OF POST-HAEMODIALYSIS BLOOD RESULTS TO ASSESS ADHERENCE TO GUIDELINES FOR END STAGE RENAL DISEASE**

Thank you for agreeing to evaluate the content and face validity of the self-designed Record Review Template (Appendix 1). Please e-mail or post the completed checklist to the researcher at the above address.

The purpose of this checklist is to ensure uniform evaluation by all experts using a structured procedure.

You, the expert, will establish index of content validity (CVI) for each item on the template using a 4-point ordinal rating scale and this will be taken as the proportion of items that received a rating of 3 or 4 (Polit & Beck, 2004).

If, in your opinion, there are omissions, these can be listed separately (Polit & Beck, 2004).

For evaluation of face validity, the checklist includes a rating scale for quantification of layout, format, quality of printing, the length of the questionnaire, the response scale of 1-4, if visually easy to read and comprehend and if instructions at the beginning of the questionnaire are clear and easy to understand (Polit & Beck, 2004).

Index of Content Validity checklist

Item Code	Item	1 not relevant	2 somewhat relevant	3 relevant	4 very relevant	Comments
Section A – Demographic Details						
A1	**Gender**					
A1.1	Male					
A1.2	Female					
A2	**Age**					
	Age					
A3	**Ethnicity:**					
A3.1	Asian					
A3.2	Black					
A3.3	Coloured					
A3.4	White					
A4	**Marital Status**					
A4.1	Single					
A4.2	Married					
A4.3	Separated					
A4.4	Divorced					
A5	**Diagnosis**					
A5.1	Hypertension					
A5.2	Diabetes					
A5.3	Glomerulonephritis					
A5.4	Systemic Lupus Erythematosus					
A5.5	Polycystic Kidney Disease					
A5.6	Other					
A5.7	Unknown					
Section B – Treatment Details						
Item Codes	**Item**	1 not relevant	2 somewhat relevant	3 relevant	4 very relevant	Comments
B1	**Erythropoiesis Stimulating Agents**					
B1.1	Eprex					
B1.2	Micera					
B1.3	Rocormen					
B1.4	Aranesp					
B1.5	Not prescribed					
B1.6	Treatment on hold					
B2	**Iron Therapy**					
B2.1	Venofer					
B2.2	Cosmofer					
B2.3	Other					
B2.4	Not prescribed					
B3	**Phosphate Binders**					
B3.1	Titralac					
B3.2	ENO tums					
B3.3	Phosphosorb					
B3.4	Not prescribed					
B4	**Vitamin D supplements**					
B4.1	One Alpha					
B4.2	Not prescribed					
Section C Quality Indicator Outcomes						
C1	**Haemoglobin, g/dl**					
C1.1	<10					
C1.2	10 – 12					
C1.3	>12.1					
C2	**Transferrin Saturation, %**					
C2.1	<20					
C2.2	>20					

Item Code	Item	1 not relevant	2 somewhat relevant	3 relevant	4 very relevant	Comments
C3	**Ferritin, ng/Dl**					
C3.1	<200					
C3.2	200 – 500					
C3.3	>501					
C4	**Dialysis Access**					
C4.1	Temporary Catheter					
C4.2	Permanent Catheter					
C4.3	AVF					
C4.4	AVG					
C5	**Single pool Kt/V**					
C5.1	<1.2					
C5.2	1.2 – 1.4					
C5.3	>1.4					
C6	**Serum Phosphorus, mmol/L**					
C6.1	<0.8					
C6.2	0.8 – 1.4					
C6.3	>1.41					
C7	**Serum Calcium, mmol/L**					
C7.1	<2.15					
C7.2	2.15 – 2.5					
C7.3	>2.51					
C8	**Serum Calcium x Phosphorus, $mmol^2/L^2$**					
C8.1	>4.4					
C9	**Serum Albumin, mmol/L**					
C9.1	<35					
C9.2	>35					

Evaluation of FACE VALIDITY

Please check one box for each statement relating to the questionnaire.

	Very skillful 1	Satisfactory 2	Needs Improvement 3	Unacceptable 4
Layout				
Format				
Quality of printing				
Length of the questionnaire				
If visually easy to read				
If visually easy to comprehend				
If instructions at the beginning of the questionnaire are clear and easy to understand				

Omissions:

Comments: THANK YOU VERY MUCH

References

1. Lynn, M. R. Determination and quantification of content validity. Nursing Research 1986;35(6), November/December):382-85.

2. Adapted with permission from: Kyriacos, U. 2011. The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients. PhD thesis. Cape Town: University of Cape Town.

Appendix 5 - Information Sheet and Consent Form for reliability testing (percent accuracy of transcription) of the Record Review Template

Participant Code:

INFORMATION SHEET

Dear colleague

My name is Yolinda L van der Nest and I am a Master of Science (Nursing) degree student at the University of Cape Town. I am undertaking a study entitled **RECORD REVIEW OF POST-HAEMODIALYSIS BLOOD RESULTS TO ASSESS ADHERENCE TO GUIDELINES FOR END STAGE RENAL DISEASE**.

Patients in End Stage Renal Disease on dialysis need to adhere to guidelines that will improve their quality of life. Renal patient morbidity and mortality can be decreased by improving clinical outcomes with effective management of Anaemia, Nutrition and Bone Disease and Adequacy of Dialysis and Vascular Access as set out in the KDQOI/KDIGO guidelines. Adherence to the guidelines ensures reduced morbidity and mortality and thereby improving quality of life in renal patients.

In this study, I undertake to gain deeper insight into the extent in which, these aspects will be described and compared against the KDQOI/KDIGO guidelines and whether haemodialysis patients adhere to best practice guidelines. The study will measure patient outcomes retrospectively against pre-determined clinical outcome parameters.

Why is this study being done?

This study will add to the existing limited body of renal nursing knowledge in three ways by:

1) providing data on haemodialysis best practice and recommendations from a local Western Cape perspective;

2) creating knowledge about clinical outcomes for a sample of South African adult haemodialysis patients to determine whether a standardised protocol is fit for purpose for all patients in selected local private uniits (Saunders, MacLeod, Salyers, MacMillan, & Ogborn, 2013); and

3) forming the basis for further study to ascertain whether care providers have the relevant knowledge, skills and attitude to maintain the gold standard for haemodialysis practice as set out in the guidelines if appropriate.

Does the study have ethics approval?

Ethics approval (HREC REF: 305/2019) has been obtained from the UCT Faculty of Health Sciences' Human Research Ethics Committee and is available upon request.

Why am I being asked to take part?

You have been invited to participate because you are a nephrology nurse/ medical doctor with expert knowledge in caring for patients on dialysis. The guidelines for dialysis form the basis of the care rendered to patients and application of these guidelines will improve patient outcomes. Your expert knowledge can provide valuable information for reliability testing (percent accuracy of transcription) of the Record Review Template (Appendix 1) designed for this study. Any information provided by you will remain confidential and anonymous. Your name will not be used at any stage during the study and a code number will be assigned instead. Only I will have access to the code number assigned to your name and this information will be stored on a password protected computer.

What will happen if you decide to take part in the study?

If you agree to participate in this study, you will be provided with 1 EuCliD® form with 22 sets of fictitious data from fictitious patient records (Appendix 6) and 1 blank paper data extraction form (Appendix 1). The data extraction form

will be based on the KDOQI/KDIGO guidelines. You will be asked to transcribe the data from the EuCliD® form onto the data extraction form. You can do this in your own time but are requested to return the completed forms within 14 days. *What are the risks and discomforts of this study?*

This study does not have any foreseeable adverse effects, risks or hazards for participants. The questions asked are intended to provide us with valuable information on the level of guideline adherence as presented in patient documentation.

What if I decide not to take part?

You have a choice to participate in or to exit the study at any time without penalty or obligation.

Are there any benefits to you for being in this study?

There may be no direct benefits to you for participating in this study other than an understanding of validation by interrater reliability testing of a data extraction form which could improve future practice and improve patient outcomes. No financial benefits are payable for participating in the study.

What will happen when the study is over?

Following completion of this study, information gained from the experts will be analysed and improvements made to the Record Review Template that will be used for data collection.

Who do I speak to (or contact) if I have any questions about the study?

Researcher: Yolinda Louise van der Nest (MSc candidate, Division of Nursing & Midwifery, University of Cape Town) 3 Balfour Mansions, 7 Church Street Muizenberg 7945

Telephone Number: 079 492 9358 e-mail: Yolinda.vandernest@uct.ac.za

Supervisor: Dr Una Kyriacos Division of Nursing & Midwifery Department of Health & Rehabilitation Sciences Faculty of Health Sciences University of Cape Town OBSERVATORY 7925

Telephone Number: 0761422676 e-mail: una.kyriacos@uct.ac.za

HUMAN RESEARCH ETHICS COMMITTEE DETAILS:

Faculty of Health Sciences Human Research Ethics Committee Room E52-24 Groote Schuur Hospital Old Main Building OBSERVATORY 7925 Professor Marc Blockman (Chairman)

Telephone number: 021 406 6338 e-mail: marc.blockman@uct.ac.za

(Appendix 5 continued)

Participant consent form

For expert opinion: Reliability testing

Research team: Yolinda van der Nest R/N, Supervisor: Una Kyriacos PhD

	Initial
1. I (the participant) confirm that I have read and understand the information sheet for the above study (dated 2018) and have had the opportunity to ask questions and have them answered to my satisfaction.	
2. I am aware that I can withdraw from the study at any time without penalty.	
3. I am aware that all my details on this consent form and the validation process are confidential.	
4. I am aware that there are no physical risks involved. Information offered by me is confidential and protected. There are no known or anticipated risks.	
5. I am aware that benefits to me include knowledge about interrater reliability testing.	
6. I consent to take part in the above study and have reached this decision without coercion or undue pressure.	

Print name of participant Signature Date

Print name of researcher Signature Date

This study is being conducted by the University of Cape Town. This work is based on the research supported in part by the National Research Foundation of South Africa for the Grant, Unique Grant No. 90295.
Any opinion, finding and conclusion or recommendation expressed in this material is that of the author(s) and the NRF does not accept any liability in this regard.

When complete: original copy to be kept with transcript documents with a second copy for the researcher. Please offer a third copy to the participant for own records.

Appendix 6: Example of 1 EuCliD® form populated with 4 fictitious datasets for Month 1, 2, 3,4 for 1 of 22 fictitious patients for transcription onto a blank SPSS Record Review Template (Appendix 1) to estimate accuracy (percent correctness) of transcriptions

	ACCESS				HAEMOGLOBIN				TRANSFERRIN SATURATION				FERRITIN				Kt/V			
No.	Mth 1	Mth 2	Mth 3	Mth 4	Mth 1	Mth 2	Mth 3	Mth 4	Mth 1	Mth 2	Mth 3	Mth 4	Mth 1	Mth 2	Mth 3	Mth 4	Mth 1	Mth 2	Mth 3	Mth 4
					g/dl	g/dl	g/dl	g/dl	%	%	%	%	ng/dl	ng/dl	ng/dl	ng/dl				
1	TC	TC	PC	PC	7,6	9,7	8,6	8,7	12	28	34	34	614	712	1200	1200	1,12	1,16	1,11	1,3
2	AVF	AVF	AVF	AVF	10,7	11,2	10,9	9,0	28	19	37	37	170	171	217	217	1,09	1,16	1,12	1,2
3	PC	AVF	AVF	AVF	12,6	12,5	13,0	13,1	13	13	17	17	247	247	539	539	0,9	0,8	0,9	0,8
4	AVG	AVG	AVG	AVG	11,7	15,0	14,1	9,4	104	14	37	37	104	133	206	206	1,11	1,04	1,17	0,94
5	TC	TC	PC	PC	9,6	10,3	9,6	11,3	28	19	16	16	100	188	550	550	0,7	0,8	1,1	1,6
6	PC	PC	PC	PC	9,9	10,4	10,0	11,3	21	21	15	15	645	645	517	517	1,13	1,00	0,90	1,45
7	AVF	TC	PC	PC	12,2	10,4	10,7	13,5	31	31	35	35	509	509	1058	1058	1,3	1,36	1,22	1,45
8	PC	PC	PC	PC	9,8	10,0	9,8	10,4	27	52	65	65	620	542	614	895	1,06	1,11	0,94	0,99
9	PC	PC	PC	PC	13,7	13,9	14,2	15,1	38	38	26	38	234	234	234	234	0,53	0,81	1,00	1,2
10	AVF	AVF	AVF	PC	12,2	9,4	11,6	11,8	53	38	12	12	947	1188	1606	895	1,40	1,39	1,24	1,19
11	PC	PC	PC	PC	8,8	12,9	11,0	11,3	50	18	45	45	499	464	348	670	1,11	0,86	1,21	1,20
12	PC	PC	PC	AVF	10,0	11,2	10,8	10,2	36	32	20	20	661	681	514	514	0,95	1,31	1,39	1,22
13	AVF	AVF	AVF	PC	10,9	10,5	10,7	11,5	86	70	20	20	1048	753	564	564	1,34	1,41	0,98	1,40
14	PC	PC	PC	PC	10,6	11,1	11,2	9,6	31	23	30	30	411	475	737	679	1,17	0,97	1,20	1,29
15	AVF	AVF	AVF	AVF	12,4	10,4	11,0	9,5	27	23	32	32	675	1164	1002	881	1,25	1,07	0,82	1,00
16	AVF	AVF	AVF	AVF	8,8	9,9	10,2	12,1	13	29	52	52	345	369	1648	1648	1,22	1,12	1,27	1,24
17	AVF	AVF	AVF	AVF	10,4	10,1	11,3	13,3	11	20	18	19	257	231	188	202	1,13	1,46	1,30	0,86
18	PC	PC	PC	PC	10,9	12,1	12,9	10,1	26	26	28	28	608	551	565	565	1,08	1,13	1,18	1,15
19	PC	PC	PC	PC	13,2	13,7	13,7	9,8	23	22	12	20	2176	710	178	627	1,11	0,75	0,87	1,34
20	TC	TC	PC	PC	10,4	11,7	11,5	12,4	27	13	36	51	1615	1233	1421	2026	1,32	1,08	1,09	1,13

Appendix 7: Code guide

A. Demographic Details		
Patient Number		**Codes**
A1_Gender	Female Male	**(0)** **(1)**
A2_Age	18 – 35 36-52 53 – 70 71 +	**(0)** **(1)** **(2)** **(3)**
A3_Ethnicity	Asian Black Coloured White	**(0)** **(1)** **(2)** **(3)**
A4_Marital_Status	Single Married Separated, Divorced or Widowed	**(0)** **(1)** **(2)**
A5_Diagnosis	Hypertension Diabetic Nephropathy Glomerulonephritis Systemic Lupus Erythematosus Polycystic Kidney Disease Other Unknown	**(0)** **(1)** **(2)** **(3)** **(4)** **(5)** **(6)**
B. Medication Details		
B1a_ESA_Month_1	Yes No	**(0)** **(1)**

B1b_ESA_Month_2	Yes No	**(0)** **(1)**
B1c_ESA_Month_3	Yes No	**(0)** **(1)**
B1d_ESA_Month_4	Yes No	**(0)** **(1)**
B2a_Iron_Therapy_Month_1	Yes No	**(0)** **(1)**
B2b_Iron_Therapy_Month_2	Yes No	**(0)** **(1)**
B2c_Iron_Therapy_Month_3	Yes No	**(0)** **(1)**
B2d_Iron_Therapy_Month_4	Yes No	**(0)** **(1)**
B3a_Phosphate_Binders_Month_1	Yes No	**(0)** **(1)**
B3b_Phosphate_Binders_Month_2	Yes No	**(0)** **(1)**
B3c_Phosphate_Binders_Month_3	Yes No	**(0)** **(1)**
B3d_Phosphate_Binders_Month_4	Yes No	**(0)** **(1)**
B4a_Vit_D_Supplements_Month_1	Yes No	**(0)** **(1)**
B4b_Vit_D_Supplements_Month_2	Yes No	**(0)** **(1)**
B4c_Vit_D_Supplements_Month_3	Yes No	**(0)** **(1)**
B4d_Vit_D_Supplements_Month_4	Yes	**(0)**

	No	**(1)**
C. Quality Indicator Details		
C1a_Haemoglobin_Month_1	< 10 g/dl 10 – 12g/dl >12g/dl	**(0)** **(1)** **(2)**
C1a_Hb_Month_1_KDOQI_Guidelines	< 10 g/dl 10 – 12g/dl >12g/dl	**(0)** **(1)** **(2)**
C1b_Haemoglobin_Month_2	< 10 g/dl 10 – 12g/dl >12g/dl	**(0)** **(1)** **(2)**
C1b_Hb_Month_2_KDOQI_Guidelines	< 10 g/dl 10 – 12g/dl >12g/dl	**(0)** **(1)** **(2)**
C1c_Haemoglobin_Month_3	< 10 g/dl 10 – 12g/dl >12g/dl	**(0)** **(1)** **(2)**
C1c_Hb_Month_3_KDOQI_Guidelines	< 10 g/dl 10 – 12g/dl >12g/dl	**(0)** **(1)** **(2)**
C1d_Haemoglobin_Month_4	< 10 g/dl 10 – 12g/dl >12g/dl	**(0)** **(1)** **(2)**
C1d_Hb_Month_4_KDOQI_Guidelines	< 10 g/dl 10 – 12g/dl >12g/dl	**(0)** **(1)** **(2)**
C2a_Transferrin_Saturation_Month_1	< 20 % > 20 %	**(0)** **(1)**
C2a_Transferrin_Saturation_Month_1_KDOQI_Guidelines	< 20 %	**(0)**

	> 20 %	**(1)**
C2b_Transferrin_Saturation_Month_2	< 20 %	**(0)**
	> 20 %	**(1)**
C2b_Transferrin_Saturation_Month_2_KDOQI_Guidelines	< 20 %	**(0)**
	> 20 %	**(1)**
C2c_Transferrin_Saturation_JUL	< 20 %	**(0)**
	> 20 %	**(1)**
C2c_Transferrin_Saturation_Month_3_KDOQI_Guidelines	< 20 %	**(0)**
	> 20 %	**(1)**
C2d_Transferrin_Saturation_OCT	< 20 %	**(0)**
	> 20 %	**(1)**
C2d_Transferrin_Saturation_Month_4_KDOQI_Guidelines	< 20 %	**(0)**
	> 20 %	**(1)**
C3a_Ferritin_Month_1	<200ng/dl	**(0)**
	200 – 500ng/dl	**(1)**
	>500ng/dl	**(2)**
C3a_Ferritin_Month_1_KDOQI_Guidelines	<200ng/dl	**(0)**
	200 – 500ng/dl	**(1)**
	>500ng/dl	**(2)**
C3b_Ferritin_Month_2	<200ng/dl	**(0)**
	200 – 500ng/dl	**(1)**
	>500ng/dl	**(2)**
C3b_Ferritin_Month_2_KDOQI_Guidelines	<200ng/dl	**(0)**
	200 – 500ng/dl	**(1)**
	>500ng/dl	**(2)**
C3c_Ferritin_Month_3	<200ng/dl	**(0)**
	200 – 500ng/dl	**(1)**
	>500ng/dl	**(2)**
C3c_Ferritin_Month_3_KDOQI_Guidelines	<200ng/dl	**(0)**

	200 – 500ng/dl >500ng/dl	**(1)** **(2)**
C3d_Ferritin_Month_4	<200ng/dl 200 – 500ng/dl >500ng/dl	**(0)** **(1)** **(2)**
C3d_Ferritin_Month_4_KDOQI_Guidelines	<200ng/dl 200 – 500ng/dl >500ng/dl	**(0)** **(1)** **(2)**
C4a_Dialysis_Access_Month_1	TC PC AVF/AVG	**(0)** **(1)** **(2)**
C4a_Dialysis_Access_Month_1_KDOQI_Guidelines	TC PC AVF/AVG	**(0)** **(1)** **(2)**
C4b_Dialysis_Access_Month_2	TC PC AVF/AVG	**(0)** **(1)** **(2)**
C4b_Dialysis_Access_Month_2_KDOQI_Guidelines	TC PC AVF/AVG	**(0)** **(1)** **(2)**
C5c_Dialysis_Access_Month_3	TC PC AVF/AVG	**(0)** **(1)** **(2)**
C4c_Dialysis_Access_Month_3_KDOQI_Guidelines	TC PC AVF/AVG	**(0)** **(1)** **(2)**
C5d_Dialysis_Access_Month_4	TC PC AVF/AVG	**(0)** **(1)** **(2)**

C4d_Dialysis_Access_Month_4_KDOQI_Guidelines	TC PC AVF/AVG	**(0)** **(1)** **(2)**
C6a_Single_Pool_KTV_Month_1	<1.2 1.2 – 1.4 >1.4	**(0)** **(1)** **(2)**
C6a_Single_Pool_KTV_Month_1_KDOQI_Guidelines	<1.2 1.2 – 1.4 >1.4	**(0)** **(1)** **(2)**
C6b_Single_Pool_KTV_Month_2	<1.2 1.2 – 1.4 >1.4	**(0)** **(1)** **(2)**
C6b_Single_Pool_KTV_Month_2_KDOQI_Guidelines	<1.2 1.2 – 1.4 >1.4	**(0)** **(1)** **(2)**
C6c_Single_Pool_KTV_Month_3	<1.2 1.2 – 1.4 >1.4	**(0)** **(1)** **(2)**
C6c_Single_Pool_KTV_Month_3_KDOQI_Guidelines	<1.2 1.2 – 1.4 >1.4	**(0)** **(1)** **(2)**
C6d_Single_Pool_KTV_Month_4	<1.2 1.2 – 1.4 >1.4	**(0)** **(1)** **(2)**
C6dSingle_Pool_KTV_Month_4_KDOQI_Guidelines	<1.2 1.2 – 1.4 >1.4	**(0)** **(1)** **(2)**
C7a_Serum_Phosphorus_Month_1	< 0.8mmol/L 0.8 – 1.4mmol/L	**(0)** **(1)**

	>1.4mmol/L	**(2)**
C7a_Serum_Phosphorus_Month_1_KDOQI_Guidelines	< 0.8mmol/L 0.8 – 1.4mmol/L >1.4mmol/L	**(0)** **(1)** **(2)**
C7b_Serum_Phosphorus_Month_2	< 0.8mmol/L 0.8 – 1.4mmol/L >1.4mmol/L	**(0)** **(1)** **(2)**
C7b_Serum_Phosphorus_Month_2_KDOQI_Guidelines	< 0.8mmol/L 0.8 – 1.4mmol/L >1.4mmol/L	**(0)** **(1)** **(2)**
C7c_Serum_Phosphorus_Month_3	< 0.8mmol/L 0.8 – 1.4mmol/L >1.4mmol/L	**(0)** **(1)** **(2)**
C7c_Serum_Phosphorus_Month_3_KDOQI_Guidelines	< 0.8mmol/L 0.8 – 1.4mmol/L >1.4mmol/L	**(0)** **(1)** **(2)**
C7d_Serum_Phosphorus_Month_4	< 0.8mmol/L 0.8 – 1.4mmol/L >1.4mmol/L	**(0)** **(1)** **(2)**
C7d_Serum_Phosphorus_Month_4_KDOQI_Guidelines	< 0.8mmol/L 0.8 – 1.4mmol/L >1.4mmol/L	**(0)** **(1)** **(2)**
C8a_Serum_Calcium_Month_1	< 2.1mmol/L 2.1 – 2.5mmol/L >2.5mmol/L	**(0)** **(1)** **(2)**
C8a_Serum_Calcium_Month_1_KDOQI_Guidelines	< 2.1mmol/L 2.1 – 2.5mmol/L >2.5mmol/L	**(0)** **(1)** **(2)**
C8b_Serum_Calcium_Month_2	< 2.1mmol/L	**(0)**

	2.1 – 2.5mmol/L >2.5mmol/L	**(1)** **(2)**
C8b_Serum_Calcium_Month_2_KDOQI_Guidelines	< 2.1mmol/L 2.1 – 2.5mmol/L >2.5mmol/L	**(0)** **(1)** **(2)**
C8c_Serum_Calcium_Month_3	< 2.1mmol/L 2.1 – 2.5mmol/L >2.5mmol/L	**(0)** **(1)** **(2)**
C8c_Serum_Calcium_Month_3_KDOQI_Guidelines	< 2.1mmol/L 2.1 – 2.5mmol/L >2.5mmol/L	**(0)** **(1)** **(2)**
C8d_Serum_Calcium_Month_4	< 2.1mmol/L 2.1 – 2.5mmol/L >2.5mmol/L	**(0)** **(1)** **(2)**
C8d_Serum_Calcium_Month_4_KDOQI_Guidelines	< 2.1mmol/L 2.1 – 2.5mmol/L >2.5mmol/L	**(0)** **(1)** **(2)**
C9a_Serum_Calcium_Phosphate_Product_Month_1	<4.4mmol²/L² >4.4mmol²/L²	**(0)** **(1)**
C9a_Serum_Calcium_Phosphate_Product_Month_1_KDOQI_Guidelines	<4.4mmol²/L² >4.4mmol²/L²	**(0)** **(1)**
C9b_Serum_Calcium_Phosphate_Product_Month_2	<4.4mmol²/L² >4.4mmol²/L²	**(0)** **(1)**
C9b_Serum_Calcium_Phosphate_Product_Month_2_KDOQI_Guidelines	<4.4mmol²/L² >4.4mmol²/L²	**(0)** **(1)**
C9c_Serum_Calcium_Phosphate_Product_Month_3	<4.4mmol²/L² >4.4mmol²/L²	**(0)** **(1)**
C9c_Serum_Calcium_Phosphate_Product_Month_3_KDOQI_Guidelines	<4.4mmol²/L² >4.4mmol²/L²	**(0)** **(1)**

C9d_Serum_Calcium_Phosphate_Product_Month_4	<4.4mmol²/L²	**(0)**
	>4.4mmol²/L²	**(1)**
C9d_Serum_Calcium_Phosphate_Product_Month_4_KDOQI_Guidelines	<4.4mmol²/L²	**(0)**
	>4.4mmol²/L²	**(1)**
C10a_Serum_Albumin_Month_1	<35mmol/L	**(0)**
	>35mmol/L	**(1)**
C10a_Serum_Albumin_Month_1_KDOQI_Guidelines	<35mmol/L	**(0)**
	>35mmol/L	**(1)**
C10b_Serum_Albumin_Month_2	<35mmol/L	**(0)**
	>35mmol/L	**(1)**
C10b_Serum_Albumin_Month_2_KDOQI_Guidelines	<35mmol/L	**(0)**
	>35mmol/L	**(1)**
C10c_Serum_Albumin_Month_3	<35mmol/L	**(0)**
	>35mmol/L	**(1)**
C10c_Serum_Albumin_Month_3_KDOQI_Guidelines	<35mmol/L	**(0)**
	>35mmol/L	**(1)**
C10d_Serum_Albumin_Month_4	<35mmol/L	**(0)**
	>35mmol/L	**(1)**
C10d_Serum_Albumin_Month_4_KDOQI_Guidelines	<35mmol/L	**(0)**
	>35mmol/L	**(1)**

Appendix 8a: Research Committee Fresenius Medical Care

3 Balfour Mansions
7 Church Street
Muizenberg
Cape Town
8001

5th March 2019

To: The Research Committee Fresenius Medical Care

REQUEST FOR APPROVAL TO CONDUCT RESEARCH IN SELECTED FRESENIUS MEDICAL CARE UNITS IN CAPE TOWN TO FULFIL REQUIREMENTS FOR A MASTER'S DEGREE IN NURSING SCIENCE: van der Nest Y. L. (VNSYOL001)

My name is Yolinda L van der Nest and I am a Master of Science (Nursing) degree student at the University of Cape Town. The study has ethics approval from the Faculty of Health Sciences Human Research Ethics Committee (HREC REF:305/2019).

Included, please find a copy of my research proposal. The aim of this study is to design and validate a record review template and to describe target and actual levels for each clinical indicator to assess adherence to established guidelines. This study will measure the patient outcomes retrospectively against the clinical outcome parameters.

I hereby request permission to conduct my research within Fresenius Medical Care. I believe that the findings and recommendations thereof will form a platform for future studies that will involve transfer of knowledge to nursing staff to improve quality improvement initiatives.

Authorisation is requested to conduct a research project **RECORD REVIEW OF POST-HAEMODIALYSIS BLOOD RESULTS TO ASSESS ADHERENCE TO GUIDELINES FOR END STAGE RENAL DISEASE** in selected Fresenius Medical Care units in Cape Town

Your approval will be greatly appreciated.

Thank you in anticipation

Y. L. van der Nest

Student Number: VNSYOL001

Appendix 8b: University of Stellenbosch HREC approval for use of Euclid® database

UNIVERSITEIT
STELLENBOSCH
UNIVERSITY

Progress Report Approval Letter

10/07/2018

Project Reference #: 3997

Ethics Reference #: N11/01/028

Title: South African Renal Registry

Dear Prof Mogamat Davids ,

Your request for extension/annual renewal of ethics approval dated 21/06/2018 07:24 refers.

The Health Research Ethics Committee reviewed and approved the annual progress report you submitted through an expedited review process.

The approval of this project is extended for a further year.

Approval date: 10 July 2018

Expiry date: 09 July 2019

THIS APPROVAL IS SUBJECT TO THE FOLLOWING PROVISOS:

- that the approval includes a waiver so that individual consent does not have to be obtained
- that the approval includes adults and children
- that it includes country-wide data collection, in both public and private sectors
- that it includes approval to make the Web-based platform available to other African countries as part of the African Renal Registry initiative
- that various data sources may be tapped (to enable cross-checking for accuracy and completeness of data), including (but not limited to) records available through doctors' practices, dialysis and transplant centres, provider companies, medical aid funds and entities that capture data on mortality (e.g., Home Affairs, Medical research Council).

Kindly be reminded to submit progress reports two (2) months before expiry date.

Where to submit any documentation

Kindly note that the HREC uses an electronic ethics review management system, *Infonetica*, to manage ethics applications and ethics review process. To submit any documentation to HREC, please click on the following link: https://applyethics.sun.ac.za.

Please remember to use your **Project ID [3997]** and Ethics Reference Number on any documents or correspondence with the HREC concerning your research protocol.

National Health Research Ethics Council (NHREC) Registration Numbers: REC-130408-012 for HREC1 and REC-230208-010 for HREC2

Federal Wide Assurance Number: 00001372

Institutional Review Board (IRB) Number: IRB0005240 for HREC1

Institutional Review Board (IRB) Number: IRB0005239 for HREC2

The Health Research Ethics Committee complies with the SA National Health Act No. 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki and the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles, Structures and Processes 2015 (Department of Health).

Yours sincerely,

Mr. Franklin Weber

Health Research Ethics Committee 1

APPENDIX 9: Example of permission requesting letter

3 Balfour Mansions
7 Church Street
Muizenberg
7945

5th March 2019

Fresenius Medical Care South Africa (Pty) Ltd
Private Bag X10039
Edenvale
1610

Dear Sir / Madam

REQUEST FOR PERMISSION TO CONDUCT RESEARCH IN FRESENIUS MEDICAL CARE

RESEARCH TOPIC: RECORD REVIEW OF POST-HAEMODIALYSIS BLOOD RESULTS TO ASSESS ADHERENCE TO GUIDELINES FOR END STAGE RENAL DISEASE

My name is Yolinda L van der Nest and I am a Master of Science (Nursing) degree student at the University of Cape Town. Your written approval is requested to conduct research at the Fresenius Medical Care South Africa (Pty) Ltd.

Approval has been granted by University of Cape Town Faculty of Health Sciences Human Research Ethics Committee. My ethical clearance number is:

HREC REF: 305/2019.

Included, please find a copy of my research proposal. The aim of this study is to design and validate a record review template and to describe target and actual levels for each clinical indicator to assess adherence to established guidelines.

This study will measure the patient outcomes retrospectively against the clinical outcome parameters.

If permission is granted, I will ensure that all information will be treated confidentially. Data sent to me from the Fresenius EuCliD database will be anonymized by using code numbers and therefore patient names will not be disclosed to me. Anonymity of dialysis centres will be ensured. As the employing body, I will ensure that you will receive a copy of the Executive Summary of the completed research. I will comply with legal requirements regarding the data that I will retrieve from the database.

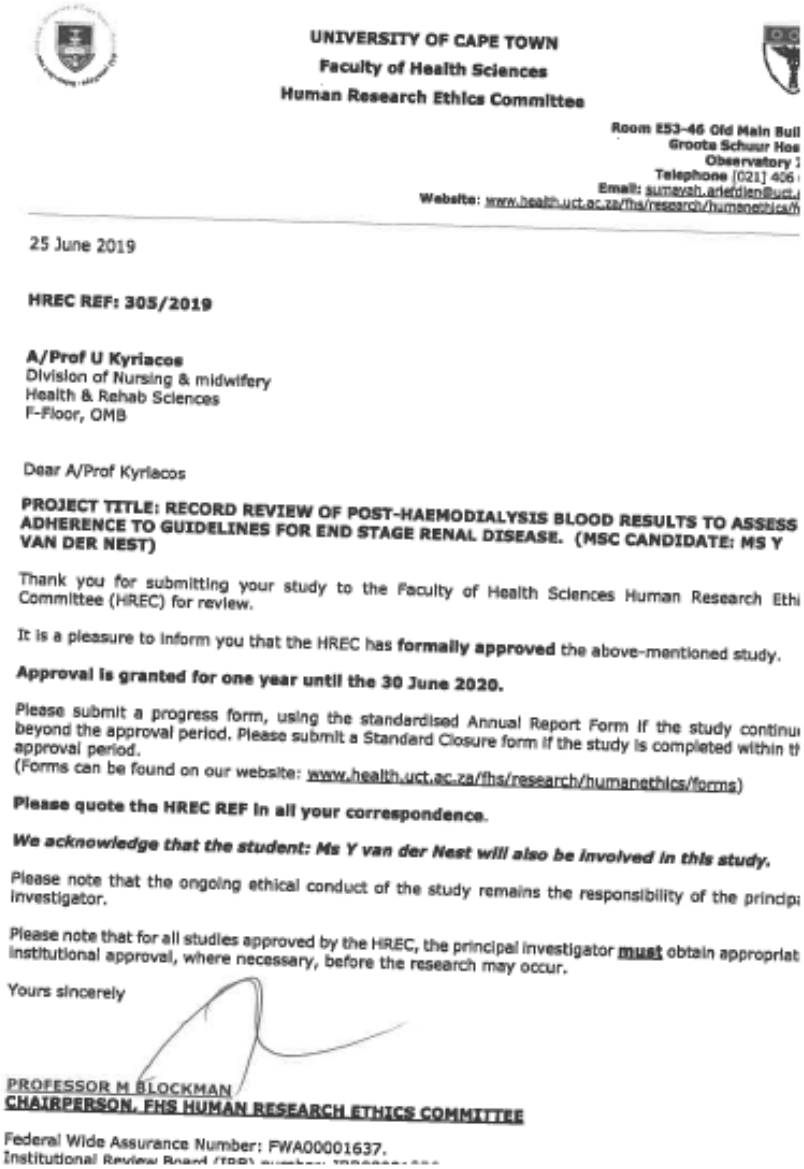
Your consideration of my request to conduct this study at your dialysis centres is greatly appreciated.

Thank you

Ms. Yolinda L van der Nest

Student No.: VNSYOL001

Appendix 10: UCT Faculty of Health Sciences Human Research Ethics Committee approval



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

Room E53-46 Old Main Bui
Groote Schuur Hos
Observatory 7
Telephone [021] 406
Email: sumaiyah.arieff
Website: www.health.uct.ac.za/fhs/research/humanethics/h

25 June 2019

HREC REF: 305/2019

A/Prof U Kyriacos
Division of Nursing & midwifery
Health & Rehab Sciences
F-Floor, OMB

Dear A/Prof Kyriacos

PROJECT TITLE: RECORD REVIEW OF POST-HAEMODIALYSIS BLOOD RESULTS TO ASSESS ADHERENCE TO GUIDELINES FOR END STAGE RENAL DISEASE. (MSC CANDIDATE: MS Y VAN DER NEST)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethi Committee (HREC) for review.

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

Approval is granted for one year until the 30 June 2020.

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

Please quote the HREC REF in all your correspondence.

We acknowledge that the student: Ms Y van der Nest will also be involved in this study.

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

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

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number:

Appendix 11: Permission letter from FMC

Appendix 12: Patient information Leaflet and consent for EuCliD® Database

FRESENIUS MEDICAL CARE

What does EuCliD® stand for?

Euclid® stands for the European Clinical Database.

What is the EuCliD® Database?

EuCliD® is a clinical database designed to monitor the key aspects of your haemodialysis treatment. At the present moment in time EuCliD® is in operation in approximately 233centres in 11European countries and has collected the results of more than 30,000 patients.

What aspects are monitored?

The data within EuCliD® are divided into 5 main areas or modules:

1. Centre Module
   This collects information about the dialysis centre
2. Patient Module
   This collects information about your medical and basic social history. For example your date of birth, gender, race, marital status, height, dry weight, diagnosis, blood group, medication, allergies, type of access etc.
3. Lab Test Module
   This collects your blood results, your treatment prescription and your dietary status.
4. Follow Up Module
   This module collects information on your transplant status (blood pressure, drug prescription, dialysis therapy, type and strength of EPO etc.)
5. Outcome Module

This module collects information about any periods of hospital admission and infections that you have.

Why do we want to collect all this information about you and your haemodialysis treatment?

Fresenius Medical Care strives to continuously improve your dialysis treatment. This database allows us to review your treatment and compare it with other dialysis centres in the UK and Europe. This allows us to measure the effectiveness of the treatment we offer against the UK and European Standards.

Where does your information go to?

When you grant consent, your details are entered onto the database. Your name is automatically given a pin code, which is only identifiable by your dialysis centre. To ensure your privacy rights, information on the database is only sent to Clinical Management Europe (CME), part of Fresenius Medical Care headquarters in Germany. Fresenius is certified by an independent notified body and has implemented the Good Dialysis Practice concept in all its European clinics. CME is committed to the continuous improvement of treatment quality and patient safety in the European Dialysis Network.

What does CME do with the Information?

They review all the information and send regular reports to your clinic manager. This allows your clinic manager to compare the quality of treatment in his/her unit against other units in the UK and Europe.

DATA PROTECTION / CONSENT

I, the undersigned _____

_____ (full name)

Agree / Disagree to Grant consent to Fresenius Medical Care that would record and monitor my clinical results on the EuCLid system. This information would then be released to relevant parties.

I fully understand the reasons given to me and that this form was explained to me by interpreter _____

Signed at dialysis centre:

_____

Date: _____

_____

Signature (patient, parent, guardian)

_____

Signature (witness)

FRESENIUS MEDICAL CARE

This section should be filled in whether you agree or disagree!

Complaints:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Suggestions:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Can anyone else access my Information?

Fresenius Medical Care places great emphasis in the need for strictest confidentiality in respect of your personal health data. This applies to paper and computer records. Everyone working in the dialysis unit has a legal duty to keep your information confidential.
This legal duty is defined in the Data Protection Act (1998) and the Caldecott Guidelines (1997).

Will my treatment change if I don't give my consent?

No. Your treatment will be provided to the same high standards with which Fresenius Medical Care prides itself. You are not obliged to consent to your information being held on the database. However, your data is very important in order to help improve the quality of life all dialysis patients.

Will my information be shared with anyone else?

Sometimes we need to share your information with other health care professionals. We will only do this if people have a genuine need for it, as the law strictly controls the sharing of sensitive and personal information.
Whenever we can we shall remove details, which identify you. Anyone we give information to also have a duty to keep it confidential.

Euclid® Database
Patient Information Leaflet

This leaflet explains why we would like to collect personal and clinical information about you and what the information is used for.

Appendix 13: Researcher confidentiality and non-disclosure agreement

CONFIDENTIALITY AND NON-DISCLOSURE AGREEMENT

By

Yolinda Louise van der Nest
7002070060081
3 Balfour Mansions
7 Church Road
Muizenberg, 7945
("Receiving Party")

AND

FRESENIUS MEDICAL CARE SOUTH AFRICA (PTY) LTD
(Registration number 1969/014163/07)

31A Lake Road, Longmeadow Business Estate, Edenvale, Johannesburg,
South Africa
("Disclosing Party")

1 BACKGROUND

1.1 The Disclosing Party has agreed to allow the Receiving Party to become privy to certain sensitive and Confidential Information of the Disclosing Party in order for the Receiving Party to carry out the Purpose.

1.2 The Disclosing Party wishes to protect such Confidential Information in the manner set out in this Agreement.

1.3 The Confidential Information represents substantial monetary, competitive, economic and strategic value to the Disclosing Party and could be have interest or benefit to its competitors.

1.4 The Disclosing Party may suffer irreparable financial or other harm if the Confidential Information is divulged to other parties.

1.5 The Disclosing Party wishes to ensure that the Confidential Information is held confidential and seeks to do so by means of this Agreement.

1.6 The confidentiality undertakings contained herein are in addition to and not in lieu of any other confidentiality undertakings given by the Receiving Party to the Disclosing Party and shall survive termination of the pursuit by the Receiving Party of the Purpose.

INTERPRETATION

In this Agreement, unless inconsistent with or otherwise indicated by the context–

"**Agreement**" means the agreement as set out herein and all the appendixes hereto;

"**Confidential Information**" means any information, documentation, record or report and all other information of the Disclosing Party, whether recorded orally, in writing, in print or electronic media, disclosed to or received by the Receiving Party pursuant to this Agreement including, but not limited to:

the existence and contents of this Agreement;
the Purpose and any information related to the Purpose;

patient's information, including patients medical related information and personal information; information concerning any of the Disclosing Party's subsidiaries or associated companies; and Personal Information which is disclosed by the Disclosing Party to the Receiving in terms of this Agreement.

"**Parties**" means the parties to this Agreement and "Party" means any one of them; and

"**The Purpose**" means the data, documentation, patient's personal information and medical related information that the Disclosing Party will provide and/or make available to the Receiving Party through EuCliD. The Receiving Party shall strictly use the data or information for conducting his/her clinical studies or research with an academic institution and will use such data, information and/or documentation in a general manner without any reference or link to the Disclosing Party or the Disclosing Party's patients.

COMMENCEMENT AND DURATION

This Agreement will be effective as at the date of signature of the last party signing and shall continue for an indefinite period.

UNDERTAKINGS

The Receiving Party hereby undertakes in favour of the Disclosing Party, in order to protect the proprietary interests of the Disclosing Party in respect of its Confidential Information, that it shall maintain the Disclosing Party's Confidential Information in secrecy and strictest confidence and will exercise in relation thereto no lesser security measures and degree of care than those which the Receiving Party applies to its own confidential information, which the Receiving Party warrants as providing adequate protection against unauthorized disclosure, copying or use.

EXCLUSIONS

The obligations of the Receiving Party pursuant to the provisions of this Agreement shall not apply to any Confidential Information that is or becomes publicly known, otherwise than pursuant to a breach of this Agreement; or

The Receiving Party will be entitled to disclose any Confidential Information if and to the extent that the Receiving Party is required or requested to do so by any law or by any court or regulatory agency or authority in any jurisdiction provided that, the Receiving Party will, if permitted by such law, court, regulatory agency or authority to do so, notify the Disclosing Party as soon as possible upon becoming aware of any such requirement.

DOCUMENTATION AND RECORDS

Documentation or records, whether written, electronic or otherwise, relating to or arising from the Confidential Information which comes into the possession of the Receiving Party as part of records or documentation that are supplied to it pursuant to this Agreement -

shall be deemed to form part of the Confidential Information; and

shall be surrendered to the Disclosing Party on demand.

LIABILITY FOR DAMAGES

To the extent that the Disclosing Party suffers any damage as a result of any disclosure to any unauthorised person of the Confidential Information by the Receiving Party -

the onus shall be on the Receiving Party to show that the disclosure was not in breach of the provisions of this Agreement; and

the Receiving Party shall be liable for any damages, including direct, indirect, special and consequential damages, suffered by the Disclosing Party as a result of such disclosure, as determined by a court of competent jurisdiction.

INDEMNITY

The Receiving Party indemnifies the Disclosing Party and agrees to hold the Disclosing Party (including any of its Affiliates) harmless against any claims, penalties, fines, damages (whether direct or indirect, in contract or otherwise), losses, liabilities, costs (including costs on an attorney and client basis), expenses of any nature that may be imposed upon, incurred by, or awarded against the Disclosing Party by a third party in relation to a failure by the Receiving Party to comply with its obligations in terms of this Agreement.

DISCLAIMER

The Disclosing Party does not make any representation or give any warranties, express or implied or assume responsibility for the accuracy, reliability or completeness of any of the Confidential Information.

RETURN OF CONFIDENTIAL INFORMATION

The Receiving Party shall, on written demand by the Disclosing Party and in any event if the Purpose is no longer being pursued, cease the use of all Confidential Information furnished by the Disclosing Party pursuant to this Agreement, promptly return to the Disclosing Party all of the Confidential Information which is in physical form (including all copies) or destroy or expunge (to the extent reasonably practicable and legally permissible) any other records (including, without limitation, those in electronic, machine readable and hard copy form) as far as they contain Confidential Information.

OWNERSHIP

The Receiving Party hereby agrees and undertakes that any documentation of whatsoever nature or description relating to the Confidential Information which it has acquired or may acquire or which may come into its possession pursuant to this Agreement, shall remain the property of the Disclosing Party and shall be surrendered to the Disclosing Party forthwith on demand.

ANNOUNCEMENTS

The Receiving Party shall not make any public announcement or otherwise publish the existence of this Agreement nor use the name of the Disclosing Party for promotional purposes or any other purpose.

GENERAL

Whole Agreement

This Agreement constitutes the whole agreement between the Parties as to the subject matter hereof and no agreements, representations or warranties between the Parties regarding the subject matter hereof other than those set out in this Agreement are binding on the Parties.

Variation

No addition to or variation, consensual cancellation or novation of this Agreement and no waiver of any right arising from this Agreement or its breach or termination shall be of any force or effect unless reduced to writing and signed by all the parties or their duly authorised representatives.

Cession

Neither Party shall be entitled to cede, assign or otherwise transfer any of its rights or obligations in terms of this Agreement without the prior written consent of the other Party.

Severability

In the event any one or more of the provisions of this Agreement shall for any reason be held to be invalid, illegal or unenforceable, the remaining provisions shall remain valid and enforceable. Furthermore, the unenforceable provision(s) shall be modified to carry out to the full extent possible the intent of the provision deemed unenforceable.

IN WITNESS WHEREOF, the Parties hereto execute this agreement:
THUS DONE AND SIGNED in Cape Town by ***Yolinda Louise van der Nest*** *on this*
20th day of July 2019 in the presence of the undersigned
Witness:
Witness:
1) ..... *2).....*
Name: *NAME:*

FRESENIUS MEDICAL CARE SOUTH AFRICA (PTY) LTD

THUS, DONE AND SIGNED in ..... by ***FRESENIUS MEDICAL CARE South Africa (PTY) LTD*** *on this …….day of ……..20……. in the presence of the undersigned witness:*
Witness:
1) ..... *.....*
Name: *AUTHORISED REPRESENTATIVE*

DESIGNATION:

NAME:
.....
AUTHORISED REPRESENTATIVE

DESIGNATION:

NAME:

Appendix 14: REporting of studies Conducted using Observational Routinely collected health Data (RECORD) guide

The RECORD statement – checklist of items, extended from the STROBE statement, that should be reported in observational studies using routinely collected health data.

	Item No.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Title and abstract					
	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	Title Cover Page i Conclusion in Abstract Page iv	RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included. RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract. RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract.	Cover and Abstract Page I & iv Abstract Page iv Abstract Page iv
Introduction					
Background rationale	2	Explain the scientific background and rationale for the investigation being reported			Page 16

Objectives	3	State specific objectives, including any prespecified hypotheses			Page 19
Methods					
Study Design	4	Present key elements of study design early in the paper			Page 39
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection			Page 38 Introduction (3.1)
Participants	6	***(a) Cohort study* - Give the eligibility criteria, and the sources and methods of selection of participants.** Describe methods of follow-up *Case-control study* - Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study* - Give the eligibility criteria,		RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided. RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and	Page 42 CVI Page 48 IRR (3.6.1) Eligibility Criteria (Page 54) 3.7.1.2

		and the sources and methods of selection of participants *(b) Cohort study* - For matched studies, give matching criteria and number of exposed and unexposed *Case-control study* - For matched studies, give matching criteria and the number of controls per case		results should be provided. RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage.	Page 38 Diagram of the four research phases
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.		RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided.	page 39
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is			

		more than one group			
Bias	9	Describe any efforts to address potential sources of bias			
Study size	10	Explain how the study size was arrived at			Page 54
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why			Page 73
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) *Cohort study* - If applicable, explain how loss to follow-up was addressed *Case-control study* - If applicable, explain how matching of cases			Page 74 Not applicable Page 80

		and controls was addressed *Cross-sectional study* - If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses			
Data access and cleaning methods		..		RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population. RECORD 12.2: Authors should provide information on the data cleaning methods used in the study.	give the page numbers where discussed Page 73
Linkage		..		RECORD 12.3: State whether the study included person-level, institutional-level, or other data linkage across two or more databases. The methods of linkage and methods of linkage quality evaluation should be provided.	Institution level (Phase 2 & 3) and person-level (Phase 4) Page 53
Results					
Participants	13	(a) Report the numbers of individuals at each		RECORD 13.1: Describe in detail the selection of the persons included	Diagram included explaining this Page 56

		stage of the study (*e.g.*, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed) (b) Give reasons for non-participation at each stage. (c) Consider use of a flow diagram		in the study (*i.e.,* study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram.	
Descriptive data	14	(a) Give characteristics of study participants (*e.g.*, demographic, clinical, social) and information on exposures and potential confounders (b) Indicate the number of participants with missing data for each variable of interest (c) *Cohort study* - summarise follow-up time (*e.g.*, average and total amount)			Table 3. 5: Results (number and percent for ratings 1-4) for CVI of the record review template (n=5 experts) Page 44 Table 3. 6: Results for face validity of the record review template from the checklist (n=5 participants)Page 47 Table 3.9: Differences in inter-rater reliability (IRR) results for 16 items between two raters for accuracy of transcription Page 50 -52
Outcome data	15	*Cohort study* - Report numbers of outcome events or summary			As outlined in section 3.9.2 and summarized in Table 4.1, the estimated sample size was 176

		measures over time *Case-control study* - Report numbers in each exposure category, or summary measures of exposure *Cross-sectional study* - Report numbers of outcome events or summary measures			records and the return rate were 169 (96.02 %)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a			

		meaningful time period			
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses			
Discussion					
Key results	18	Summarise key results with reference to study objectives			Page 88
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias		RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported.	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence			

Generalisability	21	Discuss the generalisability (external validity) of the study results			
Other Information					
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based			Page xx
Accessibility of protocol, raw data, and programming code		..		RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code.	

*Reference: Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM, the RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. *PLoS Medicine* 2015; in press.