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Impact of hospital-based early detection on management in chronic kidney disease: the CKD Stewardship study (CKD-S) – protocol for a prospective, multicentre, observational cohort study

Lucinda Alix Wynter ,[1,2] Brendan Smyth,[3,4] John Saunders,[5] Carmen Moroney ,[1] Lilijana Gorringe,[2] Kylie Turner,[3] Sreeram Venugopal,[3] Lisa Tienstra,[6] Rowena Monteverde,[5] Amy Kang,[7,8] Sarah Norris ,[9] Leyla Aouad,[5] Shaundeep Sen,[2,6] George Mangos,[10,11] Steven Chadban[5,12]

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For numbered affiliations see end of article.

Correspondence to
Dr Lucinda Alix Wynter; lucy.wynter@sydney.edu.au

ABSTRACT

Introduction Chronic kidney disease (CKD) causes significant morbidity and mortality. Medical therapies can reduce the progression of disease by up to 50%. CKD is undiagnosed in the majority of people who have it, resulting in undertreatment. CKD Stewardship (CKD-S) aims to identify hospital inpatients with undiagnosed mid-stage to late-stage CKD with the goal of facilitating diagnosis and initiating guideline-based therapies.

Methods and analysis This prospective, multicentre, cohort study compares two models of care, CKD-S and standard care, for identification and management of CKD, across six public hospitals in metropolitan Sydney, Australia. CKD-S entails active case finding using the electronic medical record, with nephrologist outreach to admitting teams and kidney nurse provided patient education. Adult inpatients with an admission estimated glomerular filtration rate (eGFR)<45 mL/min/1.73 m^2 and not known to a nephrologist will be eligible, excluding those with short life expectancy or advanced age (>80 years). Participants will be enrolled between 1 March 2024 and 1 March 2025. Baseline and demographic data will be collected after discharge from the hospital. Participants will be followed up 12 months after discharge using Pharmaceutical Benefits Schedule and Medical Benefits Schedule data, linked via the Australian Institute of Health and Welfare Hub. We will report the proportion of all adults admitted to the hospital who are not already known to a nephrologist, in which a diagnosis of stage 3b–5 CKD is recognised by the CKD-S intervention team, compared with standard care. We will then compare the proportion in each cohort who have an eGFR or urine albumin:creatinine ratio measured, are referred to a nephrologist, and are prescribed guideline-directed therapies over the 12 months following discharge from the hospital.

Ethics and dissemination The study has ethics approval from the Sydney Local Health District's Ethics Committee (Concord Hospital Zone). The results of the CKD-S study will be published in peer-reviewed journals and presented at academic conferences.

Trial registration number ACTRN12624000452594.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Chronic kidney disease Stewardship (CKD-S) is simple, opportunistic and is readily reproducible at other hospitals using existing technologies.
⇒ The inclusion and exclusion criteria are pragmatic and real-world.
⇒ Direct nephrologist involvement reduces 'alert fatigue'.
⇒ Collection of contemporaneous data in a comparator health district permits inferences to be made about the impact of CKD-S on healthcare utilisation and prescribing.
⇒ Inclusion of patients with acute kidney injury rather than true CKD may result in an overestimate of CKD burden and reduce the impact of CKD-S.

INTRODUCTION

In Australia, 11% of the adult population and 25% of those over 65 years of age have chronic kidney disease (CKD).[1 2] CKD is associated with significant morbidity and mortality. Studies have consistently shown an independent and graded association between reduced estimated glomerular filtration rate (eGFR) and albuminuria and risk of death, cardiovascular events and all-cause hospitalisations.[3 4] CKD is substantially more common than diabetes and is a stronger risk factor for coronary events and all-cause mortality.[5] In Australia, an estimated 50% of patients with CKD die from cardiovascular disease.[6] Quality of life is significantly lower for patients across all stages of CKD compared with the general population.[7] CKD and kidney replacement therapies cost the Australian health system approximately $A3.48 billion (converted from US dollars) in 2022, which is predicted to rise 13% by 2027.[8]

In the past few years, there has been a paradigm shift in the management of CKD driven by a series of new therapies proven to significantly slow CKD progression, delay or prevent kidney failure and reduce the risk of cardiovascular disease. It has long been accepted that the use of ACE inhibitors (ACEis) and angiotensin receptor blockers (ARBs) significantly reduce the progression of diabetic kidney disease (DKD)[9–11] and other forms of proteinuric CKD.[12] Sodium-glucose cotransporter-2 inhibitors (SGLT2i) have been shown to significantly reduce the progression of CKD and cardiovascular events in patients with diabetes[13] and non-diabetes[14] with CKD. Non-steroidal mineralocorticoid receptor antagonists (MRAs) have also been demonstrated to reduce the progression of CKD and cardiovascular events when used in combination with ACE or ARB with or without SGLT2i for patients with diabetes.[15] Most recently, semaglutide use was found to be associated with kidney protection (significant eGFR preservation and less albuminuria) and a 20% lower risk of death from any cause in patients with diabetes with CKD, as compared with placebo.[16] In people with DKD, combination therapy with these agents likely provides additive benefits in reducing cardiovascular events and CKD progression.[17] Guidelines currently recommend ACE or ARB and SGLT2i for most patients with albuminuric CKD and finerenone in those with DKD.[18 19] Studies into the benefits of finerenone in non-diabetics,[20] endothelin antagonists[21] and IL-6 inhibitors[22] are ongoing, so there are likely to be further advances in CKD and DKD management.

CKD is under-recognised. The REVEAL-CKD study, a large multinational (USA, France, Germany, Italy and Japan) observational study found that among 144 827 patients with stage 3 CKD, between 61.6% and 95.5% did not have a diagnosis of CKD in their medical record.[23] Late diagnosis also remains common. Approximately one in five patients who start dialysis are referred too late for adequate dialysis planning.[24 25] To improve CKD detection, Kidney Health Australia recommends the 'kidney health check' which involves targeted screening comprised of eGFR, urine albumin:creatinine ratio (UACR) and blood pressure check every year for patients with diabetes or hypertension; or every 2 years for those with other risk factors. Uptake of the Kidney Health Check, however, is low. From Australian General Practice data, only 25% of patients known to have stage 3 CKD have a UACR, eGFR and blood pressure check at guideline-recommended frequency, and less than 20% of non-diabetics have a UACR completed.[26] In 2020, a large observational study of general practice patients found only 3.8% of all patients with CKD had a UACR that year.[27] Globally, efforts to improve early identification of CKD have focused on primary care,[28] but diagnosis and appropriate surveillance of CKD in Australia is still clearly lacking.

Despite the therapeutic advances, the uptake of kidney protective therapies remains low. Analysis of the CURE-CKD registry in the USA demonstrated that despite their long-established efficacy, only one in five patients with CKD are prescribed an ACEi or ARB.[29] In Australia, only 65% of patients with stage 3–5 CKD are prescribed an ACEi or ARB and uptake of SGLT2i among eligible patients is just 4.1%.[30] Increasing uptake to 75% is predicted to prevent over 3600 cardiovascular and kidney failure events per year.[30] Unrecognised CKD and lack of awareness of guideline-based therapy among primary care physicians are both likely to contribute to suboptimal CKD care.

The importance of case detection of CKD cannot be overstated considering the availability of therapies for CKD and their potential to reduce cost through the prevention of end-stage kidney disease and cardiovascular events. A second benefit of early detection is timely referral to nephrology care, which is associated with better outcomes.[31] Local and international guidelines[24 25 31 32] recommend patients with an eGFR of less than 30 mL/min/1.73 m^2 (stage 4 CKD), or persistent albuminuria, be referred to a nephrologist for best practice management. There is also a strong economic case to be made for the timely detection of CKD.

CKD Stewardship (CKD-S) is a new model of care which was implemented at three hospitals in metropolitan Sydney, Australia, in 2024. It aims to identify and manage patients with mid-stage to late-stage CKD who are admitted to the hospital for any reason. Run by nephrologists and kidney nurses, in consultation with the primary health network (general practitioners (GPs)), it is separate from, and in addition to standard care, which consists of referral for nephrology consultation only if initiated by the admitting team. This programme is similar in concept to antimicrobial stewardship, now an accepted part of routine hospital practice.[33]

Here, we describe the protocol for an observational study of the CKD-S model of care, including contemporaneous comparator data from a health service that has not implemented CKD-S. The study aims to assess differences in case identification, uptake of kidney-protective medications and follow-up for patients with mid-late stage CKD.

METHODS AND ANALYSIS

Study aim and hypothesis

The primary aim of this study is to describe the prevalence of unrecognised CKD in hospital inpatients. Second, we aim to assess the process outcomes of a CKD-S model of care by comparing the uptake of guideline-recommended therapies, regular kidney testing and referral to nephrology care between centres using CKD-S compared with those using standard care. We hypothesise that a substantial minority of hospital inpatients will have undetected CKD stage 3b–5 and that the CKD-S programme will increase recognition of CKD during admission, with a corresponding increase in appropriate healthcare utilisation and patient management over the ensuing year.

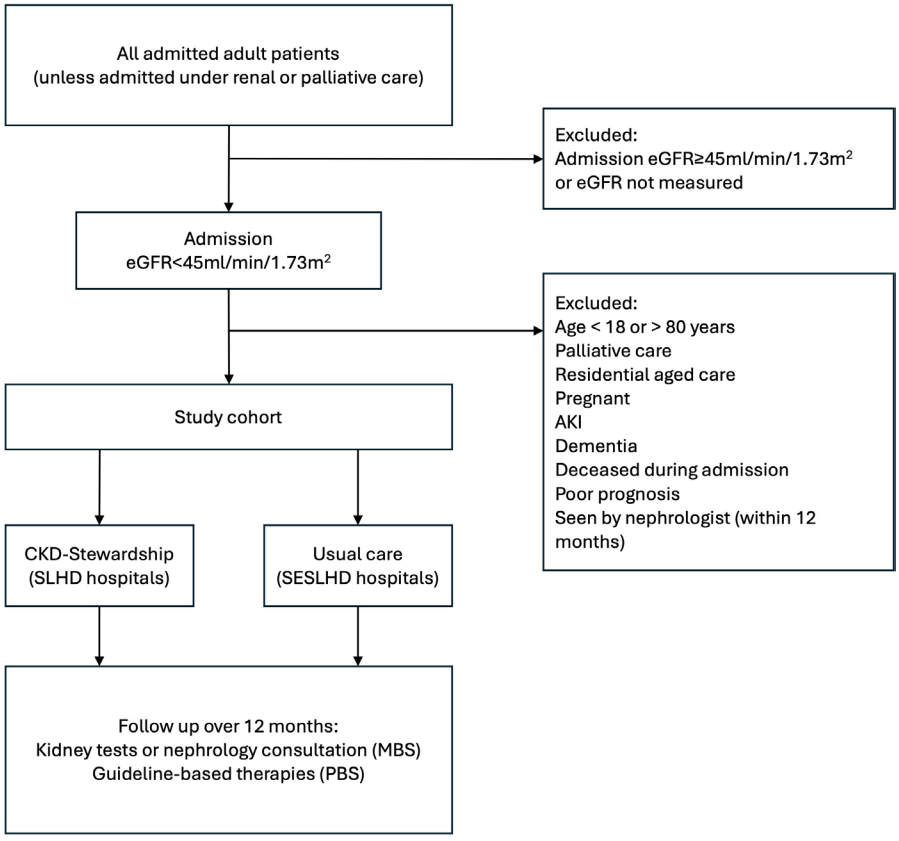

Figure 1 Study flow chart for the CKD Stewardship study, assessing outcomes of an in-hospital intervention for early identification of mid to late-stage CKD, compared with standard care. AKI, acute kidney injury; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; MBS, Medical Benefits Schedule; PBS, Pharmaceutical Benefits Schedule; SESLHD, South East Sydney Local Health District (St George, Prince of Wales, Sutherland Hospitals); SLHD, Sydney Local Health District (Royal Prince Alfred, Concord, Canterbury Hospitals).

Study design

The CKD-S study is a prospective, multicentre observational cohort study, enrolling patients admitted to the hospital for any cause who are subsequently found to have unrecognised CKD 3b–5. The study will compare outcomes between three centres conducting the CKD-S model of care and three centres conducting the standard model of care for patients with CKD. Participant outcomes, including medical management and healthcare utilisation relevant to CKD, will be assessed 12 months after hospital discharge by linkage to administrative data sets. The study design flow chart is illustrated in figure 1. This study will follow the Strengthening the Reporting of Observational Studies in Epidemiology guidelines for reporting cohort studies.[34]

Target population and eligibility criteria

The target population for this study is adult patients between the ages of 18 and 80 years, admitted to one of six hospitals in metropolitan Sydney, Australia, between 1 March 2024 and 1 March 2025, who are, or would be eligible to be included in the CKD-S model of care, as defined in the below inclusion and exclusion criteria. Three of these hospitals (Royal Prince Alfred (RPA), Concord Repatriation Hospital and The Canterbury Hospital from the Sydney Local Health District (SLHD)) implemented CKD-S from 1 March 2024, and three of these hospitals (St George Hospital, The Sutherland Hospital and Prince of Wales Hospital from the South East Sydney Local Health District (SESLHD)) did not.

Inclusion criteria

The CKD-S model of care includes any adult patient between the ages of 18 and 80 years, with an admission eGFR<45 mL/min/1.73 m^2 who has been admitted to a medical, surgical or psychiatric service. See box 1.

Exclusion criteria

The full exclusion criteria are listed in box 1. Patients admitted to day stay, infusion centres or admitted for day-only procedures will be excluded. Participants who are already under nephrology care or who are seen by a nephrologist during their admission through the renal consultation service will be excluded. Patients with shorter life expectancy who are unlikely to benefit from CKD-S will be excluded (advanced age (>80 years), poor prognosis, receiving palliative care or who are in residential aged care). Patients with acute kidney injury (AKI) will be excluded wherever information permits this diagnosis to be reasonably made (see box 1). Patients admitted to the intensive care unit, who are acutely delirious or mentally disordered (as per treating team notes),

Box 1 Inclusion and exclusion criteria

Inclusion criteria

⇒ Any patient admitted to hospital under a medical, psychiatry or surgical team between 1 March 2024 and 1 March 2025.
⇒ Aged between 18 and 80 years of age.
⇒ Patients who have an estimated glomerular filtration rate (eGFR)<45 mL/min/1.73 m^2 on first available bloods during the incident admission.

Exclusion criteria

⇒ Patients who are pregnant.
⇒ Patients who have been seen by a nephrologist as an outpatient in the previous 12 months, as documented or referred to in the electronic medical record (eMR).
⇒ Patients admitted under a nephrologist, or who will be seen by a nephrologist as an inpatient during the incident admission (renal consult) as per the eMR (not as a result of chronic kidney disease (CKD) Stewardship (CKD-S)).
⇒ Individuals who have acute kidney injury, defined as at least one eGFR>60 mL/min in the past 3 months or>90 mL/min in the past 6 months, or if eGFR recovers>60 mL/min during admission.
⇒ Are from or being discharged to a high-level care residential aged care facility.
⇒ Have advanced dementia documented in the eMR at any time.
⇒ Are admitted under or being seen by a palliative care team.
⇒ Patients with a poor prognosis.
⇒ Patients who have died during the admission.
⇒ Patients already been identified by CKD-S twice.

will be re-assessed through their admission until the CKD-S nephrologist deems them well enough to receive the intervention. Patients may be excluded during this 'watch-only' period if they meet any exclusion criteria. Patients who are included in CKD-S in one district but are subsequently readmitted to a hospital in the other district during the 12-month study period will be censored.

Patient identification

Patients will be identified using the electronic medical record (eMR) at each of the participating hospitals. Lists of eligible patients will be generated using prespecified criteria, all admissions to the hospital excluding those under palliative care, renal medicine, obstetrics or paediatrics. The 'worklist' function in the eMR application Powerchart (Oracle Cerner) has been used to then filter those lists by eGFR. A member of the research team, which consists of two nephrologists, a nephrology fellow and two kidney clinical nurse consultants (CNCs), will then remotely access these lists at a set time on Monday, Wednesday and Friday mornings, with a look-back period of 2–3 days to ensure all admitted patients are reviewed. Separate lists for those who have already been discharged at the time of review have also been created using the same criteria. All patients who meet the inclusion criteria and none of the exclusion criteria, including those who have already been discharged, will be shortlisted for review by a nephrologist who will then confirm eligibility for the study. One of the principal investigators, a nephrologist, will review all patients deemed eligible in both districts, to ensure consistency.

CKD-S model of care (SLHD)

Eligible patients admitted to a hospital within the SLHD will undergo CKD-S in addition to standard care. CKD-S is a new model of care for identification and management of CKD that runs only in the SLHD and consists of three distinct components: a nephrologist eMR note, a patient visit by a CKD CNC and a letter to the GP. First, the CKD-S team identifies eligible patients as described above, and details are sent to a nephrologist and a CKD CNC at the corresponding hospital via a secure messaging service. The nephrologist undertakes a file review of the patients' admission and writes a 'CKD Stewardship' file note in the patient's medical record, under 'documents' in the eMR. The note suggests that the admitting team review medication doses as per eGFR, request a urine ACR (if judged clinically appropriate), document the likely stage of CKD in the discharge summary, and advise if the patient should have follow-up with their GP or in some cases, a direct referral to a nephrologist, in line with the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines.[18] The CKD-S nephrologist may also on occasion recommend an inpatient renal consult or contact the team directly if they have a clinical concern that needs to be addressed during the incident admission. A kidney CNC then sees the patient during their admission to inform them that they may have CKD and suggest they see their GP on discharge to retest and discuss further. The CNC then provides the patient with general information about CKD, but does not offer any specific, individually tailored advice. The patient is given a one-page handout developed by the CKD-S team in consultation with an experienced consumer review committee, who provide feedback on all patient-facing material for use in the SLHD. The handout includes a QR code linking to the Kidney Health Australia (KHA) patient with CKD education resources,[35] as well as an email address that is monitored by a CKD CNC and a nephrologist. Finally, a discharge letter addressed to the GP (where known), which was developed in consultation with GP editors from the local primary health network is given to the patient as well as sent electronically via the same secure messaging service as the standard hospital discharge summary. The letter specifically identifies the patient as likely to have CKD, requests that the GP record this diagnosis and where possible, code it in their practice software. It also contains specific guidance stratified by eGFR, on the frequency of kidney health testing, commencement of kidney protective medications and when to refer to nephrology, as per the KDIGO guidelines. This resource was developed by the CKD-S team in consultation with a focus group of local GPs.

Standard model of care (SESLHD)

Eligible patients admitted to a hospital within the SESLHD will be identified by eMR screening and nephrologist data review to determine eligibility, but will receive standard

care and not undergo the interventions employed by the CKD-S model of care. Standard care across participating hospitals involves patients being admitted under an admitting medical officer (AMO) who leads a team of doctors responsible for patient care. The AMO can consult subspecialty services, for example, nephrology, when they feel it is clinically indicated. Nephrology services do not currently conduct active case finding for patients with reduced kidney function admitted under other medical services.

Data collection

Baseline data will be collected for each participant at or after the discharge date directly from the hospital records. Follow-up data will be collected at 12 months post the discharge date from the incident admission. Data will be obtained through linkage to the Australian Institute of Health and Welfare (AIHW) National Health Data Hub (NHDH) which holds Pharmaceutical Benefits Schedule and Medical Benefits Schedule data. Patients who have more than one admission in the recruitment period will be followed up at 12 months after their first discharge date and only included once.

Primary outcome

Determine the proportion of all adult patients admitted to the hospital who are not already known to a nephrologist, in which a diagnosis of stage 3b–5 CKD is recognised by the CKD-S team, compared with standard care.

Secondary outcomes

The following activities of care will be compared at 12 months after discharge between patients with probable stage 3b–5 CKD in the CKD-S and standard care cohorts: (1) the proportion who have a nephrology consultation, (2) the proportion who have a measurement of urine ACR and eGFR, (3) the proportion prescribed a statin, ARB, SGLT2i, MRA or GLP-1 agonist where indicated by guidelines. In addition, we will compare the proportion of patients with probable stage 3b–5 CKD who have the diagnosis recorded in the discharge summary.

Patient and public involvement

The SLHD consumer feedback committee reviewed the design and content of the patient handout. Three rounds of consumer feedback were undertaken, and appropriate changes were made.

Data management and access

A Research Data Management Plan has been approved by the RPA ethics committee. All patient demographic information will be collected in an SLHD Research Electronic Data Capture (REDCap) database, accessible only to the research team. A separate linked SLHD REDCap database will hold all clinical information. The researchers will also create a project-specific person number for each study participant, which will be provided to the AIHW in two separate files, the study cohort identifier and the study content clinical data. AIHW will link the study cohort file to the NHDH and upload the data to an approved AIHW Secure Remote Access Environment (SRAE), accessible only to the research team with AIHW supervision. All data analysis will take place in the SRAE. All file transfers are via an encrypted messenger service.

Data analysis plan

To our knowledge, no other study of this kind has been carried out in Australia, and so we are unable to accurately perform a statistical power calculation based on the effect size of anticipated SE rates. From a 12-month pilot performed in 2021 at Canterbury Hospital, we estimate that there will be approximately 600 participants recruited for each arm of the cohort. This study will use descriptive statistics for all outcome variables and χ^2 testing comparing proportions in the intervention and standard care cohorts. Exploratory analysis will assess the effect of the intervention on secondary outcomes using multilevel logistic regression.

ETHICS AND DISSEMINATION

This study has been approved by the SLHD's Ethics Committee (RPA Hospital Zone), with a waiver of consent, under project ID 2023/ETH02357. The linkage analysis has been approved by the AIHW Ethics Committee under project ID EO2024/6/1477. Data will be kept in the SLHD REDCap secure environment and the AIHW SRAE for a period of 5 years. We anticipate publishing the results of this study in peer-reviewed scientific journals and presenting the findings at national and international scientific meetings. The rapidly increasing global burden of CKD and the associated costs, particularly of kidney replacement therapy,[8] have reignited interest in programmes that identify CKD in its early stages, and so we anticipate that the findings of this study will be of global importance.

DISCUSSION

The present study provides a real-world test of the efficacy of a novel, opportunistic CKD detection strategy. Better ways to bridge the enormous gap between the number of patients with CKD and the number of patients receiving evidence-based therapies that slow progression to kidney failure is a current area of need in medicine.[36 37] To date, strategies to improve early detection of CKD have mainly focused on primary care.[32 38] Okpechi *et al* published a scoping review in 2022 which reported 290 early identification programmes for CKD across 83 countries and found 210 were based in primary care settings.[28] Hospital-based screening strategies were rare. Six programmes offered 'one-off' general CKD screening to patients and/or their relatives in a tertiary hospital on World Kidney Day. One programme in Kenya screened general patients in an inpatient hospital setting, but again only at a single time point and no interventions were undertaken.[39] Against this background, we propose to assess a new model of

care which couples opportunistic detection of CKD with patient and provider education in best practice, evidence-based care. CKD-S represents a novel, low-cost strategy to improve rates of CKD detection and management.

In contrast to CKD, hospital-based screening for AKI has been widely studied. Initial enthusiasm for eMR-embedded AKI alerts has been tempered by mixed clinical trial outcomes. A recent meta-analysis concluded that such automated eMR-based alert systems may reduce the progression of AKI, increase nephrology consultations and AKI documentation, but also increase the use of dialysis with no impact on mortality, length of stay or cost.[40] The failure of automated alerts for AKI to deliver clear benefits to patients or health systems remains incompletely understood; however, one hypothesis is that the automated, impersonal nature of the alert promotes a one-size-fits-all approach to an often complex clinical problem.[41] In contrast, the CKD-S programme is only semiautomated, requiring a decision to insert an entry into eMR with content specific to each patient, at the discretion of a nephrologist. The programme therefore has similarities with antibiotic stewardship, where rules-based case finding and prescribing restrictions are overseen by clinicians providing individualised support to hospital teams.[42] We hypothesise that the direct involvement of a nephrologist will result in clinically appropriate treatment recommendations and minimise the risk of 'alert fatigue'.

CKD-S has other strengths. The inclusion and exclusion criteria are pragmatic, focusing on patients at higher risk of adverse outcomes. The programme is also simple and inexpensive to implement. Importantly, CKD-S offers a multistep intervention that targets the hospital team, the community GP and the patient. The inclusion of the latter, with contact by a skilled CKD CNC, is an important element which may promote health literacy and self-efficacy. CKD-S has also been designed to complement existing CKD detection strategies and leverage existing resources for patients and health practitioners.

A recent cluster randomised trial of a primary care intervention similar to CKD-S demonstrated the challenges of generating this evidence. Vazquez *et al* randomised 11 182 patients at 141 primary care clinics between 2016 and 2019 to a personalised kidney care programme or standard care but found no reduction in hospitalisation at 12 months. The CKD-S programme differs in that it targets those with more advanced CKD (who are at higher risk of adverse outcomes) and is operating in an era where multiple new therapies are available in addition to ACEi/ARB and statins. Future assessments of CKD-S are also likely to require follow-up beyond 12 months in order to detect a difference in clinical outcomes.

This study has a number of limitations. It is likely that some people with AKI (rather than true CKD) will be included, which will reduce the potential impact of CKD-S. AKI is, however, a strong risk factor for subsequent CKD, and so it is possible that these patients may also benefit from the intervention. For pragmatic reasons, the CKD-S model of care does not include people with earlier stages of CKD with or without albuminuria. As a result, there will be patients at risk of progression of CKD who are not included in this study. Finally, while the inclusion of CKD-S eligible patients contemporaneously identified at SESLHD, a similarly sized hospital network in the same metropolitan area which otherwise continues to provide standard care, is a major strength, the study remains observational and we are unable to control for confounding factors.

In conclusion, the present study will assess the novel CKD-S model of care and gather crucial information on the impact of this programme on health-service utilisation and treatment after discharge from the hospital. If successful, CKD-S could emerge as a critical node in the translation of evidence into practice and play an important role in reducing the burden of kidney and cardiovascular disease worldwide.

Author affiliations
[1]Department of Medicine, Canterbury Hospital, Campsie, New South Wales, Australia
[2]Concord Clinical School, The University of Sydney Faculty of Medicine and Health, Concord, New South Wales, Australia
[3]Department of Renal Medicine, St George Hospital, Sydney, New South Wales, Australia
[4]NHMRC Clinical Trials Centre, University of Sydney, Sydney, New South Wales, Australia
[5]Department of Renal Medicine, Royal Prince Alfred Hospital, Camperdown, New South Wales, Australia
[6]Department of Renal Medicine, Concord Repatriation General Hospital, Concord, New South Wales, Australia
[7]Department of Nephrology, Prince of Wales Hospital, Randwick, New South Wales, Australia
[8]The George Institute, Sydney, New South Wales, Australia
[9]Leeder Centre for Health Policy, Economics and Data, The University of Sydney Faculty of Medicine and Health, Sydney, New South Wales, Australia
[10]St George and Sutherland Clinical School, University of New South Wales, Sydney, New South Wales, Australia
[11]Department of Renal Medicine, St George Hospital, Kogarah, New South Wales, Australia
[12]Kidney Node, Charles Perkins Centre, The University of Sydney Faculty of Medicine and Health, Sydney, New South Wales, Australia

X Sreeram Venugopal @Kidneylad

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ORCID iDs
Lucinda Alix Wynter http://orcid.org/0000-0003-2466-0727
Carmen Moroney http://orcid.org/0009-0004-7360-5980
Sarah Norris http://orcid.org/0000-0002-4733-6906

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