Territory Kidney Care

Data Participation Agreement Guide



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Purpose

This document is to be read in conjunction with the Territory Kidney Care Data Participation Agreement. It provides some background to the development of Territory Kidney Care (TKC) and can be used by readers as a guide to the Agreement.
The Data Participation Agreement ('Agreement') is a legal document and is not intended to be the only source of information regarding TKC. Stakeholders including Health Boards are encouraged to seek presentations, feedback from Clinical Reference Group members and Steering Committee members and to review other documentation (Frequently Asked Questions, Quarterly updates, Project Plan, Clinical Risk Management Plan and the Business Rules and Data Dictionary) to gain a better understanding of the processes completed in the collaborative development of the system.

This information is readily available on the TKC website and also from the Project Team. It is anticipated that each Health Service, through the development of their Implementation Plan, will gain a deeper understanding of the functionalities and outputs of TKC and how the system may be used to support them, which can then be shared more broadly with other stakeholders.

Guiding principle and purpose

The Agreement recognises, supports and promotes the collaborative partnerships developed between TKC organisations across the government and non-government sectors. It acknowledges the common goal and intent of partners to work to improve the health and wellbeing of Territorians and the good will demonstrated in the collaborative development of TKC. TKC partners will actively support each other in the delivery of culturally secure care. An agreed approach to safeguard the rights, views and values of health service clients will underpin TKC.

By participating, each organisation demonstrates its priority for, and commitment to preventive, early intervention and evidence-based practice in the treatment, management and planning of chronic kidney disease care. This is reflected in the patient focus of this agreement and scope of the data contribution. This agreement refers specifically to patients attending participant primary health services who have a chronic disease that confers a high risk for developing CKD (ie hypertension, cardiovascular disease or diabetes) or have chronic kidney disease (see Table 3 TKC Inclusion Criteria).

The scope of the data components collected is based on national and local CKD screening guidelines, legal advice and the input and advice of stakeholders, primary health clinicians and the steering committee. It will enable the TKC system to meet its objectives. Detail regarding the patient inclusion, exclusion criteria and identifying information collected can be found in the TKC Business Rules and Data Dictionary. A summary of key TKC processes is provided in Table 3.

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Background

Chronic disease is a common and serious health problem in Australia and a significant resource burden on the Australian Health Care system (Chadban et al., 2010). While chronic diseases can affect all Australians, Aboriginal people are particularly affected experiencing high rates of chronic kidney disease (CKD), diabetes and cardiovascular disease (CVD). These diseases require intensive management and generally persist over a long time.

CKD, diabetes and CVD are strongly associated with each other. The interrelated nature and complex causal relationships of the chronic conditions means they have shared risk factors, which often results in these diseases occurring as comorbid conditions in an individual (Australian Institute of Health and Welfare, 2014).

Managing one condition well increases the appropriate management of the other conditions. Evidence supports the significant gains made from the establishment of shared prevention, management and treatment strategies (Howard et al., 2010; Komenda et al., 2014).

CKD refers to all kidney conditions where a person has kidney damage and/or reduced kidney function. In the Northern Territory (NT), kidney disease rates are particularly high for Aboriginal people who present for dialysis 20 years younger than non-Aboriginal people(ANZDATA Registry, 2017). In regional areas and remote communities, where 70% of Aboriginal people live in the NT, the impact on families and communities is devastating. However, the true number of people with CKD in the NT is unknown, thus making projections of the numbers progressing to end stage and the requirement for dialysis difficult and unreliable.

CKD is categorised into five stages according to the level of kidney function with stage 5 CKD, also known as End Stage Kidney Disease (ESKD), requiring renal replacement therapy (RRT) in the form of dialysis or a kidney transplant to stay alive. The need for dialysis has a major impact on health, lifestyle and social and emotional wellbeing, especially among Indigenous Australians living in rural and remote areas who are usually required to relocate for treatment.

Demand for dialysis treatment and the associated expenditure has increased relentlessly over recent decades in the NT and has surpassed all projections(You JQ et al., 2015) . Recurrent expenditure by the NT Department of Health (DoH) was estimated to be over $74 million in 2017 and growing by more than $4 million annually. The net growth in people requiring dialysis is equivalent to three eight chair dialysis facilities every two years – an infrastructure cost estimated at $11 million.

Evidence suggests that patients who have intense monitoring, follow-up and treatment according to evidence-based protocols have better health outcomes, reduced health service utilisation and make timely and more informed choices about treatment options (Reilly et al., 2016).

Additionally, there is extensive evidence on strategies to facilitate the earlier identification of people with CKD which include the regular screening of people with hypertension, cardiovascular disease and diabetes. These strategies are enshrined in local, national and international guidelines (KDIGO, 2013; Kidney Health Australia, 2013; Remote Primary Health Care Manuals, 2017)

In early 2016 Menzies School of Health Research (Menzies) commenced discussions with stakeholders to develop a business case and seek support for a CKD Registry and Clinical Support Unit. Later that year the NT Minister for Health provided in-principle support and committed to be an active partner in the project. In March 2017, Menzies received philanthropic funding for up to three years to develop and implement a clinical decision support system for kidney disease. This has since been renamed Territory Kidney Care (TKC).

TKC is not a research project. It is the operational application of research findings to the real world – evidence translation. Menzies, through its unique position and ability to attract philanthropic funding, is leading this important initiative in partnership with government and non-government service providers including Aboriginal community-controlled health services, NT PHN and AMSANT. Menzies' role is to ensure that the:

- system is built to meet stakeholder expectations
- milestones and deliverables agreed to with the Funder are met
- system is evaluated for impact and sustainability and
- system is transitioned to the DoH seamlessly.

Objectives of Territory Kidney Care project

Territory Kidney Care is an integrated clinical decision support system for the early identification and management of chronic kidney disease. The aim of TKC is to support primary health clinicians improve the identification and management of people with kidney disease, delay the progression to dialysis and support forward planning. TKC meets these objectives by:

I. Developing partnerships with health services to enable data sharing to close the clinical information gap between primary and tertiary, government and non-government health services.

II. Supporting evidence based best practice in the delivery of recommendations to close the gap between optimal practice and actual clinical care for CKD management.

III. Providing timely clinical decision support for the management of CKD to primary health services via the Clinical Support Unit.

IV. Working with primary health services to fully utilise the supports and outputs of TKC to enhance service delivery.

V. Improving clinical support unit workflow through streamlined classification and prioritisation processes with a focus on mapping the patient journey and CKD models of care.

VI. Providing regular and user defined reports to support patient care, service delivery planning and evaluation.

VII. Establishing an appropriate and sustainable governance model.

VIII. Supporting primary health services CQI processes including data quality and performance measures.

IX. Evaluate the impact of TKC to:

1. improve the care and management of people with kidney disease
2. smooth the patient journey between primary and tertiary care
3. better understand demand to assist with forward planning and advocacy for resourcing
4. provide a cost benefit to individuals and health services.

Governance and oversight – 2 phases

Development phase

The TKC Development Steering Committee is the advisory body of the TKC initiative during the development and testing phase providing advice and direction to the project team. It comprises representatives from stakeholder and interested organisations and in recognition of the collaborative nature of the initiative, aims for consensus on decisions to meet stakeholder and Funder expectations. A Clinical Reference Group and Technical Working Group report to the Development Steering Committee. The Development Steering Committee endorses key documents during this phase including:

- Terms of Reference for all reference groups
- Territory Kidney Care Business Rules and Data Dictionary (ongoing)
- Territory Kidney Care Data Participation Agreement and Data Participation Agreement Guide
- TKC Participant Health Service Implementation Plan Template.

Implementation Phase

During the Implementation and Evaluation phase (Phase 3 and 4) the Governance Structure and Steering Committee membership will change to reflect the requirements of the initiative, including ensuring the objectives of TKC are met and being more representative of participating health services.

The role of the Steering Committee is to support the TKC initiative, monitor time frames, endorse the Evaluation Framework, oversee the evaluation and review the evaluation outcome. The Steering Committee will oversee and authorise public releases of de-identified aggregated data.

On advice from health services, consumer engagement will be through each health services' existing mechanisms for community and patient feedback rather than establishing a TKC specific consumer reference group.

Consumer Reference Group and Cultural Security

The importance of culture is enshrined in NT and Commonwealth legislation. The NT's Anti-Discrimination Act promotes 'recognition and acceptance within community of the principle of the right to equality of opportunity of persons'. Commonwealth legislation (Racial Discrimination Act 19754) also upholds the enjoyment, recognition or exercise of fundamental rights and freedoms in cultural, social and public life.

"Culture is central to how Aboriginal people view individual, family and community health and wellbeing. Culture can influence decisions about when and why Aboriginal people seek health services, acceptance or rejection of treatment, the likelihood of adherence to treatment and follow up, as well as the likely success of prevention and health promotion strategies. Culture also shapes assessments of the quality of care and views about the service and staff. Recognising the centrality of culture to health and respecting Aboriginal people and cultures is necessary to enhance service access, equity and effectiveness."(Department of Health, 2018)

The Consumer Reference Groups will play a key role in providing advice to the Steering Committee regarding the outputs of TKC particularly reporting Frameworks and data

sovereignty. Feedback from recent work with patient and consumers identified the following themes:

I. Clinical care for kidney health is so strongly linked with kidney information and data
II. Information about kidney illness, the people and families impacted by kidney disease are very important knowledge that should be used and made available to patients, families, communities and health services.
III. Partnering in health should also include Aboriginal and Torres Strait Islander patients and communities, to create the best kidney health policy, health services design and support best use of data.
https://www.menzies.edu.au/page/Research/Projects/Kidney/Catching_Some_Air-_Asserting_Indigenous_Information_Rights_in_Renal_Disease

Figure 1: Implementation Phase Governance Structure

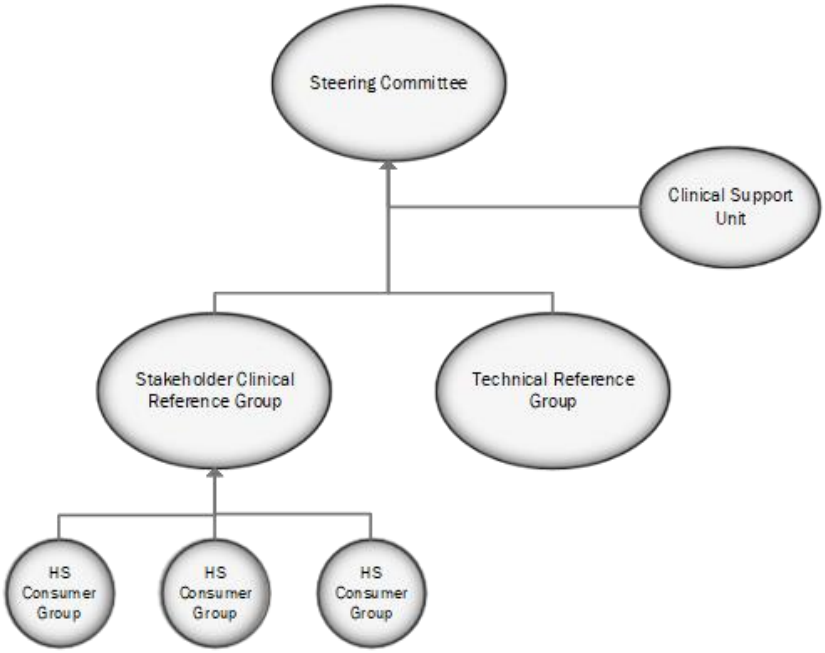


Table 1: Implementation Phase Governance Structure - roles and responsibilities

Group	Purpose	Meeting Frequency	Suggested Membership
Steering Committee	To represent stakeholder interests and support the TKC initiative. The Steering Committee will also assist in setting priorities, defining outcomes and endorsing the evaluation framework.	Annual face to face Quarterly teleconferences	Reflective of participating health services (10-14 members)
Clinical Reference Group	To provide expert advice and direction to the Steering Committee and Clinical Support Unit to support quality improvements for clinical care. This may include clinical advice regarding	Bi-annual	Clinicians (approx. 10 – 14 members)

	models of care to improve integration, clinical policies and recommending changes in scope or data variables to improve clinical services. Diversity across regions, disciplines and sectors is required.		
Technical Working Group	To provide expert technical advice on health information systems, digital health and the support required for health services. This may include reviewing system modifications, system interoperability and future technical challenges or opportunities for Territory Kidney Care.	Bi-annual	Technical experts (5 – 10 members)
Consumer engagement	To provide advice to the Steering Committee and Clinical Support Unit to ensure that Territory Kidney Care reflects the needs of communities. Existing mechanisms in participating health services for community engagement and patient feedback will be utilised to ensure input is individualised and reflective of the patient group.	As per each health service	Unlimited

TKC Model for Patient Consent

The patient consent model was developed based on legal advice from two separate legal teams and endorsed at health service workshops and by the Steering Committee. Patient consent may be implied given that appropriate privacy notices are provided to patients; the patient can reasonably be taken to have consented in the circumstances; the risks associated with implied consent are regarded as acceptable and the patient has the choice to opt-out.

TKC Project team are assisting health services refine and implement processes to inform patients regarding TKC and provide a mechanism for opting out. Mechanisms already exist within primary health services for patient consent to a 'health assessment' or commencement of a 'chronic disease care plan' and these processes will be built upon to include discussion of TKC. Patients choosing not to participate in TKC will have *TKC Opt-out* ticked in the electronic health record - a functionality created for Communicare sites. Patient identifiers of those opting out will be retained to identify and remove clinical information for these patients from all other source systems (govt and non-govt). Primary health services will be supported in their core business of informing patients regarding the care and management they receive when attending the health service. TKC Project team can assist with the development of this communication - content and format – which should be devised with individual health services to ensure it is appropriate for the local context.

Information to assist primary health services advise patients of their rights will be developed in accordance with the health services requirements. Health services can cease to participate in TKC by terminating the Agreement at any time.

Greater detail of the Opt-Out functionality can be found in the appendices.

Appendix 1

Summary of Key TKC processes

TKC Inclusion Criteria	The core function of the TKC is to identify, provide clinical support for and report to Health Services on patients who have, or are at risk of CKD, and/or undertaking Renal Replacement Therapy (RRT). To meet this objective patient records that meet the following criteria are included in the TKC reporting data base: 1. Diagnosis (recorded or derived) of Diabetes, Cardio-vascular disease, Acute Kidney injury, Obesity, Cardio-Vascular Risk 2. Currently undergoing RRT 3. Diagnosis (recorded or derived) of CKD It is from this cohort that all TKC outputs (see below) are derived.
TKC Patient Identifiers/ Demographics	TKC collects the following identifiers as recorded within each source system (Health Service): • Source system patient identifier • Individual Healthcare Identifier (IHI) • Medicare Number • Hospital Record Number (HRN) This information along with the following demographic information: • Date of Birth • Sex is used to apply the TKC patient linking process Further Demographics: • First Name and Family Name • Residential address These additional identifiers enable final patient ID checks.
TKC Patient Linking Process	The TKC system presents a single view of an individual's medical history from across multiple source systems. TKC relies on existing Patient Identity Management processes within source systems, and uses identifiers already allocated to patients from the source platforms to link records. The TKC system does not alter existing identifiers. Patient names are not used in the identity matching process. Matching follows deterministic matching protocols based on a hierarchical process of • **HRN:** The NT Patient Identifier, all patients who interact with the NT health service are allocated HRN. • **IHI:** The National Patient Identifier. • **Medicare Number:** Allocated to all Australian citizens. Use of the number is strictly controlled. (*Note the checksum and issue numbers are not used when comparing Medicare numbers) However, caveats are applied to ensure linking does not occur where date of birth and gender do not match. Error reports identify records likely to be the same person (based on a process similar to probabilistic matching ie two out of four identifiers match) and provide reports to the individual health service so that they may investigate possible data entry errors eg transposed numbers in the HRN. The patient matching protocol is described in greater detail in the TKC Business Rule and Data Dictionary. Regular audit reports of matching accuracy are built into the system.

Opt-Out process	Patients can choose to not be involved and an 'Opt-out' option is available for services using Communicare. The TKC opt-out is a two-stage process. **Opt-Out Stage One**: occurs within the source system by placing a check in the opt-out group box. This means that when the TKC extraction routine is run the opt-out is recorded and only the patient identifier data is extracted – no clinical data for that patient is accepted into the TKC system. **Opt-Out Stage Two**: occurs within the TKC – the patient identifiers are run through the TKC patient linking routine. Records from other source systems - government and non-government health services - currently within the TKC system, which would have been linked will be identified. All clinical results and measures for these records will also be deleted from the system. The TKC Registration Table will remain and will record the opt-out. Any TKC reports sent prior to the opt-out being recorded will remain – no new reports generated after the opt-out was recorded in TKC will contain any reference to this record.
TKC Clinical Data Components	TKC does not collect all the clinical data contained in a Health Service patient record. Only those data components identified by renal specialists, based on evidence-based best practice clinical guidelines, that are necessary to: • to apply those guidelines, defined as rules or algorithms and mapped within TKC, to support the functions of the CSU • provide clinical support based on individual clinical characteristics of a patient The TKC Business Rules and Data Dictionary documents in detail the processes, rules and applications of the following system attributes: • Data Conformity to TKC data model • Application of clinical algorithms • TKC Inferential Data Elements.
TKC Outputs/ Agreed use Cases	Outputs from the TKC Clinical Support Unit to participant Health Services consist of three types of reports that meet the Agreed use cases. **A. Treatment: for the provision, coordination, or management of health care and related services.** Patient cohort which may receive this type of report includes: a) diagnosis for CKD or renal failure b) eGFR or ACR indicating CKD or renal failure regardless of diagnosis The TKC reports used in this case are: 1. TKC Level 1 reports that provide individual patient advice from the CSU Nephrologist, directly to a clinician or the clinic manager. They contain identified patient information. 2. TKC Level 2 reports provide lists of patients who are at high risk of progressing to CKD. These patients are not individually case managed by TKC CSU. Reports are designed to support health service patient management and may be used to improve operational aspects of care, for example a prioritisation of workload. Reports contain identified patient information and are provided by the CSU clinicians to health services in accordance with their established protocols (eg may be provided to the chronic disease coordinator, clinic manager). They can be customised to each health service, although it is intended that a suite of standardised reports will be developed to be delivered at pre-determined intervals.

	B. Health Care Operations – analysing data for better understanding of patient population / evaluate impact of clinical interventions 3. TKC Level 3 reports are intended for use by participant health services to support their own service planning projections, advocacy and annual reporting. They can be customised to each health service, although it is intended that a suite of standardised reports will be developed to be delivered at pre-determined intervals. The development of each Health Services Implementation Plan will identify to what level aggregated reports may be developed and shared among participant health services given that by joining TKC each health service becomes a provider and recipient of data in TKC. Aggregate reports below Top End and Central Australia level will require health service approval.

Appendix 2

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