Territory Kidney Care

Frequently Asked Questions

Menzies School of Health Research

Version control

Version	Date	Author	Detail
3.0	2/8/2018	Gillian Gorham	Information regarding opt-out technical functionality included and 'Draft' removed
3.1	5/11/2018	Gillian Gorham	Updated to include latest developments
3.2	16/11/2018	Gillian Gorham	Update to include clarification of Opt-out and staged releases.
3.3	29/01/2019	Gillian Gorham June Fairless	Update to include outcomes of Clinical Working Group, Technical Group meetings and Steering Committee
3.4	2702/2019	Gillian Gorham	Review of Governance Structure based on Steering Committee and health service advice
3.5	18/07/2019	Gillian Gorham	Updated participation, implementation and governance structure information
4.0	11/08/2020	Gillian Gorham	Updated according to stage of development

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General Questions

1. *What is Territory Kidney Care?*

Territory Kidney Care (TKC) is an integrated clinical decision support system for the management of chronic kidney disease. It has been developed in partnership with the Department of Health and Aboriginal health services. The aim of TKC is to improve the identification and management of people with kidney disease across the Territory, to slow the progression to dialysis. This will be done by closing the clinical information gap between health services and increasing timely expert clinical decision support to the services that work closely with patients and their families.

2. *What is the purpose of collecting the data and will it be used for research?*

TKC is not a research project. The principle focus is for clinical care and improving the patient journey. The clinical information is not accessible to researchers or Menzies staff. The data is stored within the DoH data warehouse and is subject to the NT Governments data security and privacy legislation. Data access protocols apply as per any other request for clinical information. While TKC is not a clinical registry it will be able to provide reports to participating health services for quality improvement.

3. *Who funds Territory Kidney Care?*

Menzies School of Health Research received philanthropic funding for up to three years to develop and implement TKC in partnership with health services across the NT. The NT Minister for Health provided in-principle support for the system. This included determining on-going funding mechanisms to ensure the sustainability of the program if it proved to be beneficial in the care and management of people with kidney disease.

4. *How do we ask questions and provide feedback?*

Contact the project director Gillian Gorham, (gillian.gorham@menzies.edu.au); the TKC Health Informatics RN Paul Kamler (Paul.Kamler@nt.gov.au) (89468514) or the Clinical Lead Dr Asanga Abeyaratne (Asanga.Abeyaratne@nt.gov.au).

Health Service Questions

5. *What are the inclusion criteria?*

The aim of the TKC is to support primary health services with the management of people with CKD according to national and Territory guidelines. Therefore, only patients who are at high risk of developing CKD (excluding Indigenous status) and those with CKD (including end stage kidney disease) are included.

Table 1 describes the inclusion criteria and the reporting formats to health services. A more detailed overview of the inclusion criteria is available in the TKC Business Rules and Data Dictionary.

Table 1: Patient inclusion criteria

Patient Group: Implied Consent – Opt-out	Proposed reporting	Point of de-identification
1 **(a) Patient with a recorded diagnosis for CKD or renal failure** **(b) Patient with a recorded eGFR or ACR indicating CKD or renal failure regardless of diagnosis** **2** **Patients with a recorded diagnosis that is a well-established risk factor for CKD (diabetes, cardiovascular disease, hypertension)** ***Note: We are not suggesting case-management of these patients. No individual patient reviews.***	Individual patient reviews completed by the health professionals in the Clinical Support Unit if a flag is raised. HL7 document sent via ARGUS.	Patient information is identifiable
	Health service reports will be determined by health services.	Patient information can be identifiable or de-identified. If services want to be able to drill down to the identified data then it will need to remain identifiable. This could only be accessed by a secure login given to each health service.
	De-identified aggregate reports will be determined by health services and overseen by the governance structure. Selection of reports will be standardised for regular reporting. Ad hoc and additional reports will require health service approval.	Patient information is de-identified in the 'TKC Database' before it reaches the 'TKC Aggregated Business Objects Reporting'.

6. What is the model of 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 TKC Steering Committee.

The patient consent model is Opt-out on the basis of:

1. Patient consent may be implied given that appropriate privacy notices are provided to patients;
2. the patient can reasonably be taken to have consented in the circumstances;
3. the risks associated with implied consent are regarded as acceptable and the patient has the choice to opt-out.

Menzies has and will continue to work with participating health services to ensure the necessary information and suitable communication mechanisms are in place to enable patients to make informed decisions regarding participating in TKC. This support has taken the form of creating specific communication materials (posters and pamphlets) and amending existing patient privacy notices, attending patient forums and community meetings (educational BBQs), and presenting at clinician meetings. Health services have also determined their own mechanisms such as sending SMS messages to patients. Other options such as presenting to Board meetings or assisting with the creation of audio or video messages are also possible.

In addition we suggest that primary health service clinicians, conducting an Adult health check or completing a chronic disease care plan (where the 'consent to the health assessment must be noted in the patient's records' in order to conform to Medicare Benefit Scheme (MBS) requirements[1]), use this juncture to discuss participation in TKC. In the case of Aboriginal health services this includes the automated sharing of their clinical information with the DoH to facilitate earlier specialist advice and support from renal physicians.

[1] Australian Government. (2018, 13 December 2018). Medicare Benefits Schedule. Retrieved from http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Home

As TKC sits within the DoH warehouse and clinical information is only visible and available to DoH clinical staff, there is no change to the consent model for patients attending DoH primary health services. If an individual patient attending an ACCHO health service chooses to not participate they can "Opt-Out". Health Services and individual patients can choose to "Opt-out" at any time.

A two-stage process has been designed for individual patient Opt-out. Menzies has worked with Telstra Health to create a 'TKC Opt-out' Group functionality in Communicare. Clinical information for patients in this group will not be extracted. However, the demographic identifiers of patients in this group will be sent securely to TKC, where it will be 'run' against information from all source systems - government and non-government health services. In this way patients who may have opted-out at one health service but not at another, will be identified and their extracted clinical data purged.

7. What will it look like in PCIS, Communicare or CareSys?

There will be no change to PCIS, Communicare or CareSys. Decision support (at time of writing) is sent to PCIS and Communicare as a HL7 document attached to a patient record. This is the same format used to send pathology results. Patient recommendations will not constitute an episode of care but will require the recommendation to be witnessed by the primary health service clinician. Health services can determine how to embed this into their model of service delivery so that it is appropriate for their context and patients. Documents for an individual patient can be sent to multiple health services if required.

8. Where do the decision support/patient recommendations come from?

The clinical support unit (CSU) is made up of NT Renal Services health professionals (CKD nurses and nephrologists as a minimum) reviewing patient information. Access to the system is in-line with the DoH policies for access to clinical information systems and is monitored by the TKC System Administrator. An audit log tracks all access to patient information, including user identification of the person accessing the record, the record accessed, the date/time it was accessed and the type of data access (view, edit, delete or other actions). Menzies is not part of the CSU.

9. What is the turnaround time for decision support/patient recommendations?

Turnaround time is dependent on the individual health services' requirements. TKC receives data weekly from participating Aboriginal health services and nightly from the DoH Datawarehouse. Algorithms have been used to create efficiencies such as identifying clinically significant events and stratifying patients by those most at risk. The CSU will not be reviewing each record received and feedback to health services will be based on their needs as identified in their "Health Service Implementation plan".

10. Will this be another alert? We already receive many alerts.

Alerts will be used sparingly and only for those patients considered at significant risk and would benefit from an immediate change in their treatment regime. We discuss the content and format of individual patient advice with each primary health service in order to develop processes that are acceptable to the service. The alert will be accompanied by a recommendation and plan of action and services will determine where and to whom the information will be sent for witnessing and action. Several "Alerts" have already been developed by health services.

11. Who can access the patient information?

Only authorised health professionals working within the DoH will have access to patient information for clinical care. This data within TKC is only accessible to clinicians. Authorised DoH non-clinical staff may have access to de-identified information for aggregated reporting. Menzies is not part of the CSU.

12. Can primary health service staff view the patient information in TKC?

At time of writing non DoH staff do not have access to TKC. Primary health services have indicated that a web portal would be useful but also recognised that previous systems offering web access were used infrequently and security regarding the control of user access and sharing of logins was an issue.

As this is a DoH system and the DoH is in the middle of a significant clinical system replacement program (ACACIA), the issue will be revisited once the transition has been completed.

13. Will patients be contacted by staff from TKC?

Your patients will not be directly contacted by any team members attached to TKC.

14. How will Territory Kidney Care promote patient centered care?

TKC is intended to provide support for care which is tailored to individual patients and we believe primary health services are best placed to do this. We are keen to ensure patients have opportunities to have input and provide feedback into TKC. As health services have existing relationships with their patients, we would welcome feedback regarding the best way to start the conversation and establish membership of a Consumer Reference Group. Existing staff within health services might be more suitable to provide information to patients on TKC and we are keen to work with them.

15. How will TKC add value to what we already have and do?

The project team has been reviewing existing reports including the NT KPI's, CKD reports in Communicare, PenCat reports and the Traffic Light Report for PCIS. The support will be different and feedback we have received from stakeholders see value in the following:

- Improve the patient journey by increasing the identification of undiagnosed CKD, closing the information gap between different health services and providing a more complete picture of patient care including results and treatment delivered across health services.
- Improve the timeliness of specialist support and provide risk stratification for disease progression so that patients are prioritised and those patients who may be progressing to dialysis at a faster rate are identified. This would allow staff to focus on patients who will benefit most.
- Reduce the burden on reviewing patients with CKD 4-5 (as the system would provide additional support) which will allow health services to focus on CKD 1-3 to promote prevention and health promotion strategies.
- Streamline the specialist referral process and facilitate timely advice, reducing the need for face to face appointments and patient travel. This will allow clinicians who have a better

rapport and relationship with patients and their families, to discuss management options, and develop a more planned approach to end stage treatment.

- With the high rates of staff turnover, it can support new staff, directing them to best practice guidelines, providing assistance with education and advice on tailoring care to individual patients.
- Provide a mechanism for quality improvement using clinical and administrative data for service improvements.
- Promote and facilitate integration, particularly between primary and specialist clinicians, through sharing CQI data and coming together to discuss reports, identify gaps and determine solutions together.
- Provide information for service planning and enable greater advocacy for resourcing.

16. What do health services need to do to participate?

Participation for Aboriginal Health Services is voluntary however the success of TKC to close the gaps in the patient journey and provide a complete clinical record will be dependent upon the majority of health services participating. A TKC Data Participation Agreement formalises the partnership and involvement in TKC. The Data Participation Agreement was developed by a legal team of AMSANT's choosing and endorsed by the Steering Committee. The project team will work with each health service to develop implementation and communication plans that specifically meet their needs.

The TKC V1 was released into the DoH production environment in early April 2019 and since then the Project Team have worked closely with a select number of clinicians and health services in the testing, validation and modification of the application. TKC V1.5 is expected to be released in September 2020. Development will continue while funds are available. Menzies expects the philanthropic funds they secured to be expended by the end of 2020.

Data Questions

17. What data governance measures will be in place?

TKC data management protocols will be governed by the TKC Data Participation Agreement which includes DoH data guidelines and legislation for privacy, confidentiality and security.

18. Where will the data sit?

TKC is hosted within the DoH data warehouse. Participants who attended our workshop on the 1st of August 2017 in Darwin felt that this was the most appropriate location. Any databases within the DoH system cannot be accessed by third parties without authorised credentials including the Menzies project team.

19. Who owns the data?

Data is owned by the health service that generated the data. Any requests for access to data and reports will need to be in accordance with the agreed use cases as set out in the Data Participation

Agreement. It is a priority to work with health services to ensure that data ownership and governance is in accordance with expectations.

20. How will the data transfer from PCIS or Communicare to TKC?

A secure and automated data extract delivery mechanism has been developed for Communicare. The functionality of this secure transfer is incorporated in Communicare 18.3 and implementation of TKC is dependent on participating health services upgrading to Version 18.3 or higher. Data transfer occurs via a scheduled extract, transform, load (ETL) process which automatically delivers the data weekly from the participating health service via Argus (secure messaging) through the DoH firewall to the Health Integration Platform (HIP) and to TKC. The ETL is automated and health services will not be required to manually submit data to the system.

Information from PCIS and Caresys is already in the data warehouse and extracts to TKC occur securely.

21. What is the process of de-identifying the patient information?

Patient identifiers are required to ensure that patient information from multiple health services can be consolidated, and that clinical decision support from the CSU is attached to the correct patient record. TKC has the capability to provide de-identified aggregated reports to participant health services which may be used for annual reporting, planning and advocacy purposes. Reporting of any clinical information will be in accordance with the agreed use cases as detailed in the Data Participation Agreement and governed by DoH privacy and confidentiality protocols eg reporting of small numbers.

22. Besides patient recommendations, what other reports are available?

Additional reports are currently under design in consultation with primary health services. These will be refined as primary health services gain a better understanding of the information that would be useful for clinical management, monitoring and quality assurance. The functionality within TKC will facilitate reports across three levels:

Level One: information will focus on clinical decision support for patients that require 'immediate' attention (patient recommendations). These reports are likely to be based on a sentinel event such as an acute decline in renal function; undiagnosed CKD which is rapidly progressing or evidence of contraindicated medications or treatment. These messages are authorised by a nephrologist and are sent via secure messaging to the patient record and delegated clinician within the primary health service.

Level Two Reports are, in general terms, lists of patients that meet pre-defined criteria. These lists are intended to support operational aspects of care and allow prioritisation of workload. It is an alternative/complimentary form of outpatient management for the CKD patient cohort. The reports generated by TKC are intended to value-add to current reports and use longitudinal information as well as more than one risk factor component to identify patients e.g. a patient with poorly managed diabetes and previous admission for AKI.

Level Three Reports are aggregated, de-identified patient data reports provided to participant health services. These reports could be used by the health service to understand the burden of disease in a

region, the type of factors influencing disease rates and provide reliable data for advocacy of resourcing and service planning. Health services will determine the content, format and frequency of reports made available to them.

Sustainability Questions

23. What happens when the philanthropic funding is expended?

Once the funding Menzies secured is expended, further development of TKC is unlikely. Menzies has secured a small amount of funding to enable a five year evaluation of the impact and outcomes of TKC. TKC will be managed and supported by the DoH and the aim is for it to be embedded into health service delivery models. Participating health services entering into the Participation Agreement should be confident that data ownership and security is in accordance with their expectations.

24. How will the system pay for itself – is there a license or commercial value?

A cost benefit evaluation over five years will commence at the end of 2020. We are confident TKC will deliver efficiencies, but our evaluation will be much broader and consider financial as well as health outcomes to demonstrate value for money. The commercial value of the application has not been investigated.

25. What happens if health services move to new health information system?

We are working with the Core Clinical System Renewal Program (now called Acacia) to keep abreast of developments and to ensure TKC will integrate with the final system. The design of TKC is sufficiently flexible to enable, with minimal effort and cost, to write the ETL for new systems. If a health service is planning to change their health information system, we are keen to talk with them now, so that we can anticipate any additional developments that might be required.

26. Will the system be evaluated?

Monitoring and evaluation are part of good governance and an evaluation framework has been developed in collaboration with stakeholders and approved by the Steering Committee. The scope and components will be refined in the coming months (August to November2020) and endorsement attained from participating health services before submission for ethics approval.

It is important to understand whether the system has been successful in achieving the desired goals and the barriers and facilitators to uptake. These are normal quality assurance processes and assessment will be at both the individual health service level and system level.

Governance Questions

27. What governance arrangements are in place?

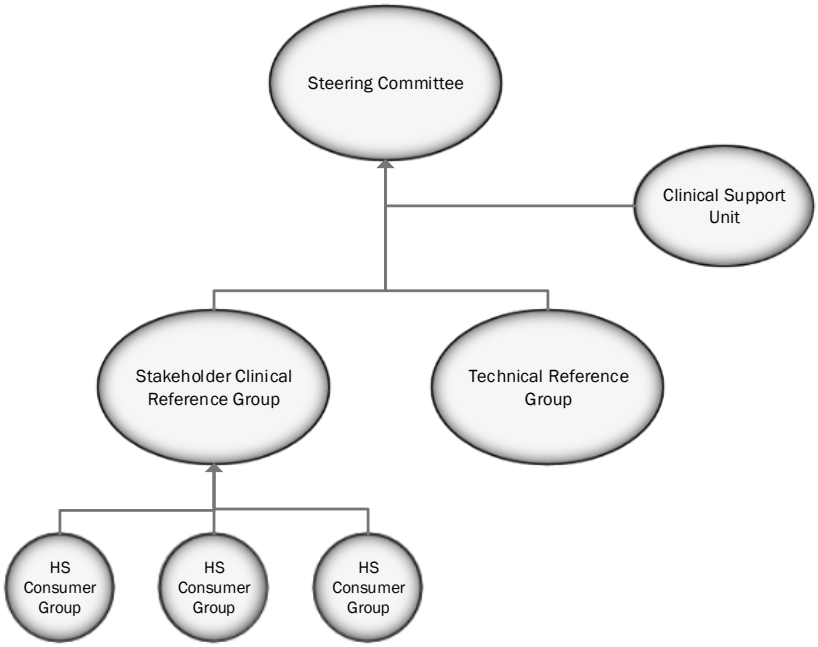
Implementation Phase

The Governance structure in the implementation phase includes an Executive Steering Committee, Clinical Reference Group and a Technical Reference Group. The Terms of Reference and membership fir the Executive Steering Committee ensure the focus of this group is directed towards evaluation and sustainability. The TKC Clinical Reference Group meet frequently to provide feedback on usability, and test and validate outputs.

Collaboration with Health services has identified that their preference for consumer engagement is via existing consumer reference groups and processes, rather than establishing a Consumer Reference group specifically for this initiative. Health services are best placed to advise us regarding local community and consumer engagement. We recognise that each health service and region will have specific values, needs and priorities and these cannot be generalized to a single group. It is expected consumer input will come from a variety of people and regions, determined by the expert advice required at that time.

The project team will focus on supporting services to bed down processes and conducting the evaluation.

Figure 1 Implementation Phase Governance Structure



The Terms of Reference for the revised structure have been developed and approved by the Steering Committee.

Table 2: Purpose of Implementation Phase Governance

Group	Purpose	Meeting Frequency	Suggested Membership
Executive Steering Committee	To provide advice and support the project team during the implementation and evaluation phase to meet Funder deliverables. Diversity across regions, disciplines and sectors is required.	Annual face to face Bi-Monthly teleconferences	Reflect participant health services and interested stakeholders (approx. 10 – 14 members)
Clinical Reference Group	To provide expert advice to the project team and development team on health service requirements. This may include advice and information regarding specific clinical models of care and processes required to improve service integration. Diversity across regions, disciplines and sectors is required.	As required Face to face, email and teleconferences	Clinicians (approx. 10 – 14 members)
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 TKC.	As required Face to face, email and teleconferences	Technical experts (approx. 5 – 10 members)
Project and Development Team	The project and development team are responsible for the collaborative design of the system, development according to stakeholder needs and implementation to meet Funder requirements. Facilitate information between all interested parties and establish the parameters of the evaluation framework.	Meet daily	Menzies Project team, DoH clinicians and Contracted IT Development team,