

# **Territory Kidney Care Project Progress Report**

**April 2019**



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# 1. Background

In 2017 Menzies School of Health Research negotiated with a philanthropic organisation to fund the establishment of an integrated clinical information system to support early identification and improved management of people with kidney disease.

Menzies proposed a strategy to stakeholders: evidence translation in the form of an integrated clinical information system that included a clinical decision support tool. The system, incorporating a secure and automated extract from participating health services (to limit impact on health services), consolidates a patient's record across multiple government and non-government health services, thereby closing the information gap and facilitating integrated care. Risk stratification identifies patients at various stages of disease progression and clinical decision support, based on evidence based best practice guidelines from renal specialists, ensures primary health clinicians are provided with timely and relevant specialist support.

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. Funding for the development of TKC has been allocated in stages over 4 years, with each funding allocation dependent on the successful attainment of pre-determined milestones and deliverables.

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.

This report covers the completion of project phase two and commencement of phase three.

# 2. Overview

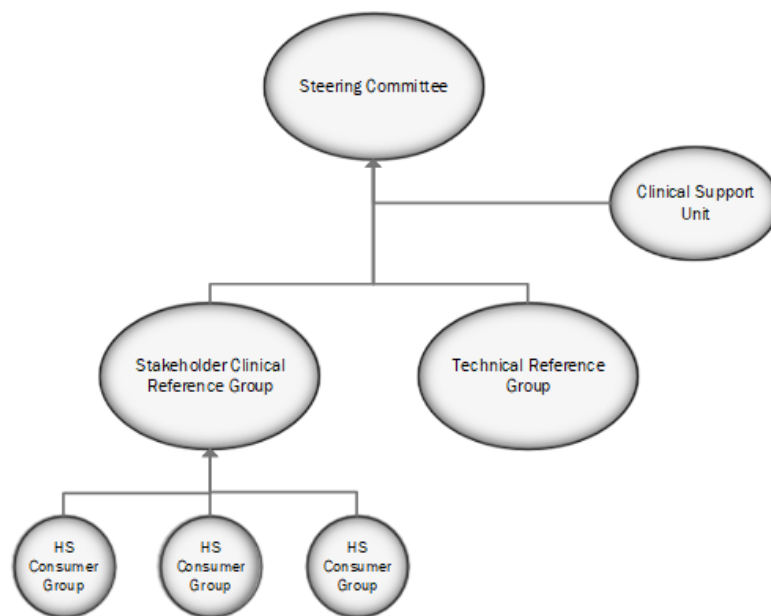
With the completion of all test phases and finalisation of all documentation required by the DoH, the system has been declared stable and fit for purpose and released into the DoH production environment. This process demonstrated the TKC Version 1 met requirements for release but also provided the opportunity – through the execution of the various test phases (specifically the UAT) – to identify future minor development which could streamline and enhance the user experience

The project has now entered phase three: Implementation. The planned staged rollout of TKC Version 1 will permit extensive validation of TKC outputs, including TKC generated patient recommendations and reports, using real-time clinical information. The project team will be working to support Health Services to execute their individual implementation plans, refine TKC outputs and embed these into the workflows of both primary health care and renal services to efficiently manage their patient's needs.

### 3. Governance

With the progression to project phase three, the governance structure will have a more operational focus. 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. Supporting the Steering Committee will be the Stakeholder Clinical Reference Group and the Technical Reference Group.

Figure 1: Implementation Phase Governance Structure



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.

The roles and responsibilities of each group are broadly described in Table 1.

**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 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.	Bi-annual	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 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

## 4. Project Progress

Since the November 2018 Progress Report, there has been considerable development. All phase two deliverables have now been met and we have entered phase three. The TKC Project Management Plan for phases three and four has been updated to more accurately reflect the planned activity for these next

phases. A project schedule detailing completed activity for phase two and an outline of the plan for phase 3 is available at Appendix A. Specific areas of focus over this report period are described under the following points.

## 4.1. System Development

The TKC Version 1 has now been developed and is in the production environment within DoH. This work was completed following the quality cycle adopted for the build and deployment of the TKC system and the focus areas were:

### 4.1.1. Validation and Testing

The TKC initial product release testing was completed with the system meeting all requirements as defined by the TKC Master Test Plan. For the TKC System Owner (Department of Health) to accept the TKC release and allow deployment into the production environment, a number of criteria had to be met. The acceptable values and the outcomes of TKC testing for the System Integration Test (SIT), User Acceptance Test (UAT) and Product Verification Test (PVT) are outlined in Table 2:

**Table 2: Testing criterion for TKC release**

Criterion	Acceptable values for release	TKC Results
Test coverage – execution	All agreed to test cases have been executed	100% of all agreed test cases have been executed
Test coverage – success	90% of test cases passed (based on results of last test run)	97.5% of test cases passed
Severity 1 defects open	0 (zero)	0 defects open
Severity 2 defects open	2 (two)	0 defects open
Severity 3 & 4 defects open	A Resolution Plan is in place for any outstanding defects	2 defects identified and resolution plan in place.

The following activities and requirements were also completed:

- TKC System documentation: Business Requirements; Functional, Technical and Design Specifications; Data Governance, Security and Access Protocols; Updated Project Management Plan for Phases Three and Four.
- Execute and Report Testing: SIT, UAT and PVT.
- The independent data specialist report on TKC patient matching processes was completed. It provided validation of the patient record matching and linking approach adopted by TKC to effectively manage the clinical risk associated with the use of the TKC system for clinical decision support.
- The TKC Clinical Risk Management Plan identifies the controls and mitigation strategies that have been implemented during the design and development phase of TKC. This in turn has informed the deployment strategy and the development of localised implementation plans with each health service to effectively manage the clinical risks.

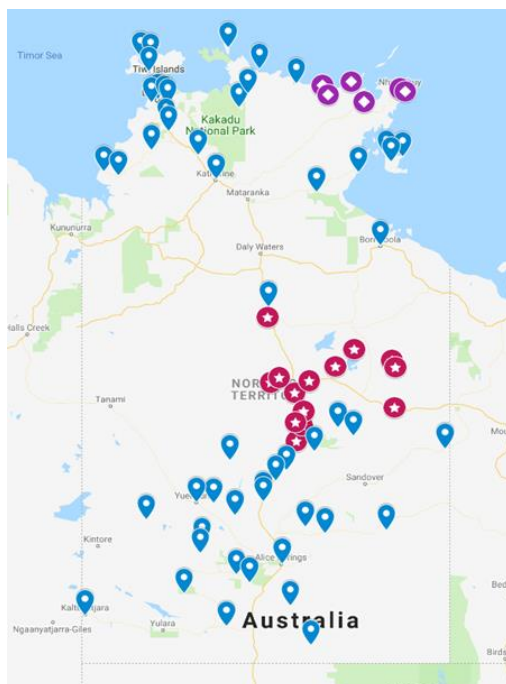
#### 4.1.2. Deployment

TKC was released into the production environment at the beginning of April. Implementation of the system across the Territory is via a staged rollout. The initial phase is underway and will involve a Soft Launch using production data (real-time clinical information) from the Department of Health (DoH) and our partner aboriginal health services. TKC system access has been limited to specific clinical users of the Clinical Support Unit. This approach is supported by our clinical risk management plan and will provide the opportunity to validate TKC outputs using live production data. It will also enable the project team to finalise the mapping of NT Renal Services current processes to identify and define further opportunities to integrate the TKC system into usual practice to realise efficiencies.

During this stage, the project team will work closely with our partner health services. The objectives are to:

- validate TKC outputs (with the use of real time production data)
- refine processes to embed TKC outputs into primary health workflows and
- execute and evaluate the implementation process before commencing further rollout.

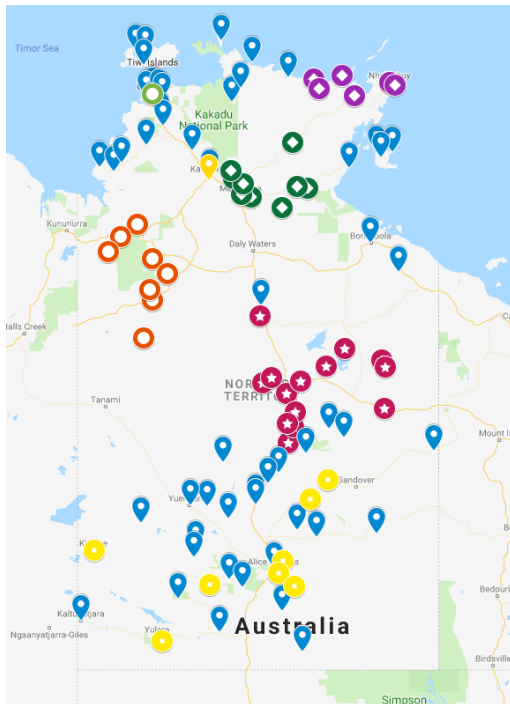
In the production environment for the initial launch, TKC has a relatively broad and even spread across the Territory. The maps below provide an overall view of the initial and potential coverage of TKC during the rollout stages.



#### Initial TKC Coverage April to June

This map shows the current Northern Territory coverage of TKC with our development partner health services as indicated by Primary Health Care Center location (to indicate catchment areas).

This coverage includes primary health clinics under the DoH, including two services in the process of transitioning to Aboriginal Controlled Health Services and the DoH tertiary services (all blue icons). The three Aboriginal Controlled Health Services that are participating in the “Soft Launch” for TKC are represented in purple (two HS) and red.



### Potential Coverage of TKC at Completion of Rollout

This map indicates the potential additional coverage at the completion of stage two of TKC implementation should all additional Health Services choose to participate. This will involve implementation across the:

- Katherine region – three Aboriginal controlled health services (orange, green and dark yellow).
- Central Australia region – additional Aboriginal controlled health services (yellow circles)
- Darwin Urban region – one Aboriginal controlled health service (Green Circle).

## 4.2. TKC Current State

Table 3 below gives a broad summary of patient numbers currently in TKC, categorised according to their status of 'At Risk' for CKD, CKD Stage 1-5, and end stage kidney disease receiving renal replacement therapy (RRT) (Table 3). *\*NB: These are our first real time data and these numbers will need to be validated to ensure there is no duplication/calculation errors, they are listed here as an example of the TKC information and should not be used for any other purpose.*



**Table 3: Individual patients by cohort status**

Category	Count*	% Total*
Total Linked Records in Reporting Database	38,485	
Total in At Risk Cohort*	9,403	24.4
• Diabetes:	2,813	
• Cardiovascular:	6,266	
• CVD Hypertension:	5,222	
Total in CKD Cohort*:	14,229	37.0
• CKD Stage 1:	8,652	
• CKD Stage 2:	3,548	
• CKD Stage 3	967	
• CKD Stage 3a:	334	
• CKD Stage 3b:	186	
• CKD Stage 4:	373	
• CKD Stage 5:	150	
• CKD Stage NS:	19	
Total in RRT Cohort*:	1,127	2.9
• RRT 1: Hemodialysis	872	
• RRT 2: Peritoneal	69	
• RRT 3: Transplant	144	
• RRT 4: Home Dialysis	42	

While the overall total number of linked registrations in TKC may not increase significantly once fully implemented, as it is likely the majority of the TKC targetted cohort will already have a DoH record, the matching of records across participant health services should provide clinicians of the Clinical Support Unit a consolidated and enhanced patient clinical history. It is important to note TKC only collects **renal related clinical data elements for patients who meet the TKC inclusion criteria.**

## 5. Risk management

A TKC risk register is maintained and reviewed by the Steering Committee at each meeting.

A Clinical Safety Management Plan and Clinical Hazard log, in line with the UK's NHS Digital Clinical Risk Management Policies for the manufacture and deployment of health systems has been developed. Of the nine clinical risks identified, additional control measures and mitigation strategies reduced the residual risk to one (acceptable) in eight cases. The remaining risk – related to patient linking of records – which attained a residual risk level of 3 out of 5, was subject to a risk benefit analysis. A risk benefit analysis considers the local context in terms of social, health and economic outcomes of the activity, the additional external controls that can be deployed to reduce the risk and whether the benefits of the activity outweigh the clinical risk. This risk was considered acceptable given the low likelihood of it occurring, usual business processes and external sources of information available to clinicians that would override TKC outputs. This Clinical Risk Case Report is provided as Appendix B.

## 6. Communication Strategy

The TKC project team maintains a Stakeholder Engagement Database which is continuously added to. Quarterly updates on project progress are provided in summary to all stakeholders via email lists and the Menzies TKC Project webpage. Detailed updates are provided to key stakeholders on a regular basis. The TKC Frequently Asked Questions (FAQs) was produced to provide clear information in response to concerns/issues raised during engagement sessions. It is reviewed and updated regularly as the project progresses and new information comes to hand. This has proved an essential communication tool to build trust and a shared vision among stakeholders.

In this quarter the TKC Project team has continued to engage with stakeholders and has been invited to present at:

- Hot North (Health Outcomes in the Tropical North) workshop in Katherine
- Chronic Disease Steering Committee.

In addition to these presentations, there has been targeted collaboration with our pilot Aboriginal health services. The key focus has been to develop, plan and implement their transition to TKC in the production environment. It has included:

- Development, via consensus, of the participation and data sharing agreement.
- Developing plans and resources for culturally appropriate communication strategies to inform communities of their health services' participation in the TKC and data sharing.
- The project team has also supported these organisations to meet accreditation standards for project governance, implementation and evaluation.
- Participation in renal program planning sessions to identify areas of integration and “value add” through TKC outputs.

## 7. Issues

In order for Aboriginal health services to participate in TKC, an upgrade of their Communicare clinical information system to v18.3 is required. The roll out of Version 18.3 has been delayed due to technical issues but several sites upgraded their system in the last month and were feeling more confident with the new release. It is expected that most other Aboriginal health services will upgrade in the coming year.

The Data Participation Agreement has been reviewed and refined by a legal firm of AMSANT's choosing and is currently being circulated for endorsement. The DoH and at least two Aboriginal health service sites have indicated that they will continue with implementation under the MOU.

## 8. Lessons Learned - Phase Two.

Execution of phase two took longer than first anticipated. Additional time was required in the initial stages of the project to build trust, develop a shared vision and forge strong collaborative relationships. In particular, key Aboriginal health services and the DoH clinical and ICT departments are now strong champions of TKC. Our time investment here will translate to greater coverage and uptake of TKC and we envisage gains in terms of

- eventual reach (number of aboriginal health services that choose to participate)
- sustainability (transition and embedding within DoH processes)
- positive impact and expansion of the clinical decision support tool (applications beyond the renal specific to include chronic disease management).

## Appendix A – Project Schedule

Task Name	Start	Finish	% Comp	Qtr 2, 2018			Qtr 3, 2018			Qtr 4, 2018			Qtr 1, 2019			Qtr 2, 2019
				Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
1 Phase 1	Thu 1/12/16	Sat 31/03/18	100%													
2 Phase 2	Mon 2/04/18	Fri 29/03/19	100%													
2.1 IT Build Contract Awarded	Mon 2/04/18	Wed 15/08/18	100%													
2.2 Operational Governance	Thu 26/04/18	Fri 1/03/19	100%													
2.3 Machine Learning - TKC Access	Sat 1/09/18	Fri 1/02/19	100%													
2.4 HL7 Messaging	Mon 2/04/18	Fri 29/03/19	100%													
2.5 Establish Clinical Support Unit	Wed 1/08/18	Fri 1/02/19	100%													
2.6 Develop and Build TKC system	Mon 20/08/18	Fri 29/03/19	100%													
2.7 Documentation Developed	Mon 20/08/18	Fri 22/03/19	100%													
3 Phase 3	Mon 1/04/19	Fri 27/09/19	32%													
3.1 TKC Version 1 Release to PROD Environment	Mon 1/04/19	Mon 15/04/19	100%													
3.2 Staged Rollout - Phase 1 Soft Launch (Min 4 Health Services)	Mon 1/04/19	Fri 28/06/19	31%													
3.3 Staged Rollout - Phase 2	Mon 1/07/19	Fri 27/09/19	0%													
3.4 TKC Version 2 Development	Mon 1/04/19	Mon 26/08/19	0%													
3.5 Version 2 Deployed into PROD	Tue 27/08/19	Mon 2/09/19	0%													
3.6 Evaluation Framework Developed	Mon 1/04/19	Fri 28/06/19	0%													
4 Phase 4	Mon 30/09/19	Fri 18/12/20	0%													

## Appendix B – Patient Linking Risk Benefit and Clinical Risk Safety Report

Clinical Risk	Cause	Mitigation	Clinical Risk Rating
<p>Failure to link records of same patient from different source systems (false negative)</p>	<ul style="list-style-type: none"> <li>Lack of consistent identifier across source systems</li> <li>Incorrect identifier data provided by source systems</li> <li>TKC linking protocol weighted too heavily to not match same patient if there are inconsistencies</li> </ul>	<ul style="list-style-type: none"> <li>Source systems remain available to all clinicians</li> <li>TKC Interface displays source ID and demographic</li> <li>Independent validation determined false negatives of 1.7%</li> <li>Regular audit reports of potentially same patients unmatched sent to health services for checking and updating system data</li> </ul>	<p>1</p> <p>Likelihood is Low</p> <p>Impact if it was to occur is Minor</p>
<p><b>Risk Benefit Analysis</b></p>		<p><b>Acceptable.</b> Impact is no different to current situation as current clinical systems do not match patient records from different source systems</p>	
<p>Incorrect linking of records from different patients (false positive)</p>	<ul style="list-style-type: none"> <li>Incorrect identifier data provided by source systems</li> <li>TKC linking protocol insufficiently robust</li> </ul>	<ul style="list-style-type: none"> <li>Source systems remain available to all clinicians</li> <li>TKC Interface displays source ID and demographic</li> <li>Independent validation determined false positives of 0.0%</li> <li>System administrator has ability to over-ride linking protocol and retain over-ride information</li> <li>Continuous validation exercise implemented for ongoing checking</li> <li>Routine error logs reviewed by system administrator.</li> </ul>	<p>3</p> <p>Likelihood is Low</p> <p>Impact if it was to occur is Major</p>
<p><b>Risk Benefit Analysis</b></p>		<p><b>Acceptable.</b> Given the low likelihood of it occurring and the alternative, of not linking records, defeats the purpose of TKC. Additional future mitigation measures include increase in use of IHI identifier by all health services and the completion of the DoH EMPI project which is likely to improve patient data quality, integrity and linking.</p>	