Patient Reported Outcomes Study  
System Intelligence and Analytics  
Department of Health and Human Services.  
50 Lonsdale Street  

To whom it may concern

**Patient Reported Outcome Measures (PROMs) Consultation - VRCN Submission 2016**

We wish to lodge the following submission in response to the PROMs Consultation Paper, on behalf of the Victorian Renal Clinical Network Leadership Group (VRCN-LG).

1 **How can PROMs be used?**

In addition to the possible uses of PROMs identified in the *Consultation Paper*, we recommend that PROMs are integrated into our routinely collected clinical data, risk adjusted and that the focus of their use is for clinical monitoring and management and quality of care improvement. We believe that this will facilitate clinical engagement, support patient centred care, shared decision making between the patient and the provider, and help to inform/promote patient preferences and self-management.

However, at this stage we recommend against the premature linking of improvements in PROMs to funding of health policy. We feel that this should be delayed until data demonstrate measurable quality improvement from defined interventions that are clinically plausible, otherwise we risk clinical disengagement.

The rationale to support this recommendation is that renal KPIs were unsuccessfully implemented in Queensland as they were linked to funding e.g. funding was recalled in response to unrealistic targets that were not achieved, resulting in clinical disengagement and dissatisfaction. In contrast, all Victorian public renal units are fully supportive of the Victorian renal KPIs used to identify and improve variation in practice by simply bench-marking units and publishing the identified data without negative consequences, and with proven changes in outcome measures. The VRCN actively collaborates with renal units to facilitate improvements in clinical practice, so the KPIs are seen to be ‘owned’ by both the renal sector and the DHHS and appear a good model for working collaboratively.

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2 What diseases and conditions are to be included in the pilot?

We recommend that Chronic Kidney Disease (CKD) 4/5 and dialysis patients should be included in a pilot PROMs program. The rationale for this recommendation is that PROMs has scope to inform improvement in all three domains of renal clinical practice, and health outcomes and resource allocation. Victorian renal services are well-positioned to capture PROMs along the patient journey which can span years. Some renal services already capturing PROMs metrics and others have aspiration to do so. In addition the national registry is very interested in capturing this data in order to make it available nationally.

Improvement in clinical practice, health outcomes and resource allocation.

CKD and End Stage Renal Disease (ESRD) are chronic conditions characterised by high mortality, poor quality of life, significant symptom burden (SB) and considerable variability in disease trajectories and treatment options. Of significance, 30 symptoms have been associated with CKD, with many of these going frequently unrecognised. Symptom burden is considered the most important predictor of reduced health-related quality of life (HRQoL). QoL is significantly lower for haemodialysis patients when compared to patients with chronic angina, diabetes, chronic lung disease, hypertension, cancer and depression, but is improved by transplantation.

PROMs could assist with identifying: those in whom Renal Replacement Therapy ((RRT – dialysis, transplantation or conservative care) has positive or negative impacts on health care outcomes; how services and symptoms can be improved; and to support direct patient recognition and self-management of symptoms.

Although dialysis requirement is <0.1% of the population, it accounts for disproportionately high health care costs. In Australia, the demographics of ESRD is changing as noted at the end of 2014, a total of 22,234 patients received RRT with a significant number of these patients over 64 years of age and its prevalence is significantly overrepresented in Aboriginal and Torres Strait Islanders. Additionally, the incidence of ESKD has increased rapidly with age, with the incidence highest among those aged 75 and over. Accordingly there is increasing emphasis on conservative management to improve quality of life rather than aggressive disease management and extending life. Currently in Victoria there is no specific resource allocation for conservative care and given the changing demographics of ESRD there is opportunity for reform in resource allocation. PROMs has scope to inform resource allocation in renal care to ensure resources are directed to improving quality of life, and not merely aiming to improve quantity of life.

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**Victorian Renal Services in Victoria are well-positioned to capture PROMs routinely.**

The Victorian renal services are in the fortunate position of having a framework and number of existing infrastructure options available at state and national level for collecting and reporting PROMs.

The Victorian renal services have a long history of collaborating with an established framework for collecting, reporting and using renal data to drive improvement. All public adult renal services have contributed to the Australia New Zealand Transplant and Dialysis Registry (ANZDATA) since 1971. Additionally they contribute to the Victorian Renal KPI Registry that informs state-wide project improvement efforts.

The renal care community recognise the importance of PROMs, and supports the routine capture of PROMs and by invitation contribute to an International Consortium for Health Outcomes Measurement (ICHOM). The VRCN plan to contribute to the ICHOM CKD standard, due in March 2017. Collectively this will strengthen the capacity to standardise and benchmark PROMs.

In summary, all Victorian renal services are in the position to implement the collection of PROMs by 1 July 2017.

### 3 Which PROMs questionnaires to use?

There are a number of PROMs tools available that have been validated for use in renal care. These include generic tools such as SF-36 and kidney disease specific tools such as: KDQOL; Dialysis symptom index; the POS-S (Renal) available at Appendix 1, and the Australian modified Karnofsky Performance Status (AKPS).

The VRCN recommend the use of both the POS-S (Renal) and the AKPS because these are currently used by the majority of Victorian adult renal services, they have been translated to a number of languages, they would permit benchmarking across Australia and internationally and can be implemented with minimum training by 1 July 2017.

A number of hospitals have built their own data capture POS-S solutions e.g. a large Melbourne hospital have a data capture solution built and tested in house that records data within their renal electronic patient record (Nephworks). This instrument could be modified and rolled out across other units at relatively low cost. The majority of renal units are using paper based forms and manually entry data into their local databases.

### 4 Who will collect the data?

The specific roles for PROMs data collection in CKD will depend on the option selected for data collection as identified in section 5.

The main role for the VRCN will be to establish the framework for data collection to include questionnaire selection, frequency of completion, and patient inclusion criteria (transplant, haemodialysis in centre, peritoneal dialysis and conservative care patients). In addition, the VRCN will provide expert advice on analysis, data linkage with clinical and administrative data and oversight of report development.

The main role for renal health services will be to obtain patient consent, administer the PROMs questionnaires to patients through various mediums, to nominate a key contact person for queries and to ensure that the data is representative of their local population. As questionnaires are completed
they will be submitted to either the DHHS administrative dataset, the ANZDATA Registry or the KPI Registry.

The main role of the ANZDATA registry, if they are to be nominated as the preferred collecting method, will be to monitor, collate and report data and to make it available to DHHS for linkage with administrative data.

5 What will be the collection method?

There are a number of options for collecting PROMs for renal care in Victoria.

**Option 1:** Provide financial support to develop a state-wide eSolution from which renal services, DHHS, and ANZDATA could receive the data

The advantage of this method is that the data could be exported and integrated within a renal hub EMR or local IT solution where it exists, or stand-alone analyses were it does not. It would allow reporting of the data to DHHS and integration with administrative data.

Indicative costs from the following two providers (Provider A and B) are available on request only as these estimates are commercial in confidence.

**Provider A eSolution**

Provider A has designed a digital tool to enhance engagement and support adherence in patients with chronic disease. Founded in evidence based practice, and developed with a multidisciplinary approach, Provider A eSolution utilises an interactive, online application to provide a conduit between clinicians and the patient. It enhances the communication between healthcare provider and recipient, improves workflows for the clinicians and, provides tailored information for consumers to achieve better outcomes. Provider A eSolution captures PROM’s that are customised to specific disease states or procedures, simplifying analytics.

**Provider B eSolution**

Provider B eSolution has a history of delivering eSolutions within a healthcare context and has won a number of awards for innovation in IT and has an ISO9001 Quality System implementation within its design builds. The eSolution from this provider would involve designing and developing a web based platform based on architecture from its previous software solutions. This would involve undertaking a dedicated requirements scoping phase engaging all users and creating a global set of requirements, then selecting the key requirements to be included in the first phase. This would incorporate specific user requirements, an assessment of requirements for data storage and movement, and system interoperability requirements based on treating hospital/unit requirements including inclusion of relevant data in the patient’s electronic record. This model allows for continual improvement, changes, refinement and enhancements to the platform and is not restricted by numbers of patients. This model also allows for even spread of ongoing costs across key users in the longer term after it has been established within an appropriate framework.

**Option 2:** Provide all participating renal services with financial support to develop their local IT solution to collect the PROMs data and report in the KPI Renal Data Registry.
The advantage of this method is that the data could be, reported along with the KPI clinical data, collected and stored locally, could be integrated with administrative data, be secure and reported transparently in the KPI Quarterly Reports though would need identifiers.

The disadvantage of this method is the potential costs and heterogeneity of data captured at different sites and delay involved with installing the software.

**Option 3:** Provide all participating renal services with financial support to develop a single renal IT solution across the state to collect the PROMs data and other metrics that would interface with all systems and report to the ANZDATA Registry.

The advantage of this method is that the data could be, reported along with the ANZDATA clinical data, be integrated with administrative data through data linkage, be secure and reported transparently in the KPI Quarterly Reports. It also has the potential to vastly improve data flows within renal services and centrally to DHHS and to ANZDATA. Many renal services do not have an electronic renal unit solution or are using a generic EMR without the functionality or granularity of such a renal system.

The disadvantage of this method is the cost and delay involved with installing the IT software, nevertheless this is an aspirational solution.

**Nephworks**

Nephworks is a secure SQL database developed for a large renal unit in Melbourne. It incorporates advanced functionality including prescribing, letters/discharge summaries, dialysis prescriptions, patient tracking, integrates pathology from multiple pathology providers, pathology tracking, results audit and exception reporting. It incorporates data management with ability to collect and analyse PROMs. It also permits electronic submission of data to ANZDATA (one of the very few systems across Australia to have successfully completed this). Nephworks can collect and store PROMs, pass this data to DHHS and if required link it with ANZDATA. Only one Melbourne hospital has this renal IT solution currently, but discussions were undertaken to rollout this software state-wide to all renal units. This is a potential state-wide solution for all renal data collection, analysis and data provision to both DHHS and ANZDATA.

Detailed costing for a state-wide rollout of Nephworks has not been performed.

**6 What resources will be needed?**

ANZDATA is the Australia and New Zealand Dialysis and Transplant registry. The registry records the incidence, prevalence and outcome of dialysis and transplant treatment for patients with ESRF. ANZDATA is located at the Royal Adelaide Hospital, South Australia. The database is a secure SQL database. The aims of the registry are to collate and disseminate the *Report of Renal Failure Management*, provide reports of individual hospital activity and treatment outcome, provide a database for collaboration with research studies and to support health care planning.

ANZDATA is currently funded by the Commonwealth through the Organ and Tissue Authority, the New Zealand Government and Kidney Health Australia (KHA). The registry is responsible jointly to the Australia and New Zealand Society of Nephrology and to KHA.
Data is usually collected by web based data entry and by circulation of printed survey forms for each patient annually to all dialysis and transplant units in Australia and New Zealand. Participation is voluntary by all physicians/surgeons involved in dialysis/transplant treatment in both countries. A list of the participating units is available from the most recent ANZDATA Report Contents file and is published with a wide national and international circulation.

ANZDATA is currently negotiating via the VRCN for increased data linkage and is keen to be involved in the collection and analysis of PROMS data from participating units.

Nephworks is a secure SQL server based renal IT programme hosted at a large Melbourne Hospital, with secure daily backup. It can supply data electronically to ANZDATA and to the DHHS.

7 Who will use and have access to the data?

We recommend that all the data is stored securely centrally and distributed to appropriately credentialed clinicians electronically or otherwise as specified by individual units. Data should then be stored within the patient’s own hospital record accessible only to appropriately credentialed clinicians. Ideally patients would also have ready access to their own data. In practice this means that units will have different methods to retain and store the information. All renal units should have access to de-identified data pertaining to appropriate groups and through each hub unit this data is available to ANZDATA as an electronic download. Renal units, DHHS, VRCN and the ANZDATA registry should also have access to aggregated and de-identified data. Such data could also be available to interested clinicians on request for publications or research after appropriate ethical review.

Thank you for the opportunity to submit this application.

Yours sincerely

Professor Steve Holt
Clinical Lead and Chair
Victorian Renal Clinical Network.

Alice Gleeson
Acting Manager
Victorian Renal Clinical Network

28/10/2016
## APPENDIX 1 – POS-S Renal

**POS-S RENAL – PATIENT COMPLETION**

Below is a list of symptoms, which you may or may not have experienced. Please put a tick in the box to show how you feel each of these symptoms has affected you and how you have been feeling over the past week.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Severely</th>
<th>Overwhelmingly</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Weakness or lack of energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>Nausea (feeling like you are going to be sick)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>Vomiting (being sick)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>Poor appetite</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>Constipation</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>Mouth problems</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>Drowsiness</td>
<td>0</td>
<td>1</td>
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<td>Poor mobility</td>
<td>0</td>
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<tr>
<td>Itching</td>
<td>0</td>
<td>1</td>
<td>2</td>
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<tr>
<td>Difficulty sleeping</td>
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<td>1</td>
<td>2</td>
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<td>Restless legs or difficulty keeping legs still</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
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<tr>
<td>Feeling anxious</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>Feeling depressed</td>
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<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>Changes in skin</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>Diarrhoea</td>
<td>0</td>
<td>1</td>
<td>2</td>
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Any other symptoms:

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Which symptom has affected you the most?

Which symptom has improved the most?

POS-S v1_Renal_P_fill_16052011