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    School of Medicine, University of Queensland
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    Royal Brisbane & Women’s Hospital
    Professor, University of Queensland School of Medicine & Human Movement Studies

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    Head, Kidney Research Laboratory, Bancroft Centre, QIMR
Assoc. Prof Glenda Gobe, Co-Director Centre for Kidney Disease Research, SOM UQ
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Prof Geoff Mitchell, Professor of General Practice & Palliative Care, UQ, & Head of MBBS program, Ipswich
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Assoc. Prof Thomas Titus, Gold Coast Hospital
Dr Helen Healy, RBWH
Dr Ken-Soon Tan, Logan Hospital
Dr Govindarajulu, Toowoomba Hospital
Dr Thin Han, Rockhampton Hospital
Dr Peter Miach, Bundaberg Hospital
Dr Murty Mantha, Cairns Hospital
Dr Krishan Madhan, Hervey Bay & Maryborough Hospitals
Dr George Kan, Townsville Hospital
Dr Nicholas Gray, Nambour Hospital
Ms Chris Banney, Mackay Hospital
Summary:
We have established a program for surveillance, practice improvement and research for chronic kidney disease (CKD) across the entire renal practice network in the public health system in Queensland, in an entity called CKD.QLD. It is unique within Australia, and one of few comprehensive CKD surveillance entities globally. With its beginnings in June 2009, the program is now into its third year. The administrative, organizational, structural and ethical foundations are now established and the program is in its roll-out and execution stage.

Background:
CKD represents the vast continuum between kidney health and end stage kidney disease (ESKD). It is the most common chronic disease in Australia, with an estimate from the AUSDIAB study that 13.5% of Australian adults have CKD: this translates to 1,623,579 Australians. It is more common with increasing age, hypertension, diabetes, obesity and socioeconomic disadvantage, and in certain ethnic groups, including Indigenous Australians. Its rates of co-morbidities are very high. CKD predicts progression to ESKD and thus renal replacement therapy (RRT); it also carries a greatly increased cardiovascular (CV) risk, with CV deaths outnumbering ESKD 10-fold or more. There is a great disproportion between early and advanced stages of CKD, suggesting that many earlier stages do not progress, are misdiagnosed or succumb to inter-current non-renal deaths. It is estimated that CKD accounts directly or indirectly for more than 10% of deaths in Australia.

CKD is often silent until well advanced. Current CKD staging systems are imperfect; they result in under- and over-diagnosis, with distinctions between disease and age-related loss of renal function sometimes unclear. Knowledge of predictors of course, outcomes and responses to treatment is likewise incomplete. All these issues have implications for disease labeling, health outcomes and service inefficiencies.

Recognition of the nature and prevalence of CKD has forced a paradigm shift in nephrology, which previously concentrated on ESKD and provision of renal replacement therapy (RRT). RRT is a largely hospital based life-prolonging therapy, without potential for disease mitigation or prevention. Awareness of CKD allows possibilities of stabilizing and improving health profiles before renal failure or non-renal endpoints are reached. Healthcare provision has expanded beyond hospitals, and beyond doctor-led specialty practices towards nurse-practitioner-run community CKD clinics and into primary care. However, the range of patient trajectories and optimal models of care have not been defined, and no formal CKD training streams or courses exist.

Outline of CKD.QLD:
Queensland is well positioned to pioneer, and to benefit from, better knowledge of, and practice improvement in, CKD. Health care is largely delivered through a single system, Queensland Health. Queensland’s population is 4.6 million and growing rapidly at a rate of 1.2% per year. As elsewhere, RRT dominates hospital separations. With a large retiree population, Queensland has 493,525 people aged over 65 years, who are at high risk for CKD, and this figure is expected to almost quadruple by 2056. Queensland’s multiethnic mix includes large numbers of Chinese, other Asian and Indian people, Pacific Islanders, Maori and more recently, Africans. It also includes more than 140,000 Indigenous Australians, the second largest number in any State. The aggregate Queensland Indigenous incidence rate of treated ESKD in 2007 (ANZDATA) was 440 per million, which, with age adjustment, is 6–times the non-Indigenous rate, and, with an RRT prevalence of 2130 pm, is a serious financial burden for Queensland’s health care budget. The Indigenous population itself, however, is heterogeneous, spread across the urban to very remote geographic gradient, has variable genetic admixture, variable access to services and, although generally disadvantaged, a broad spectrum of socioeconomic status.
This highlights the importance of determining rates and characteristics in each setting and customizing approaches accordingly. We have therefore established a CKD Registry, research and practice collaboration with all public renal practices in Queensland. The goals of that entity, CKD.QLD, are:

- To set up and maintain a registry of CKD in Queensland
- To characterize CKD patients within that registry
- To evaluate population trends in CKD by longitudinal study within that registry
- To document the course and outcomes of CKD patients, and ultimately develop predictors
- To identify treatment gaps and support and promote best practice of CKD
- To evaluate various models of health service delivery for CKD patients
- To support an ongoing stream of well-conceived clinical trials in CKD
- To develop a platform and a repository of biological samples for CKD biomarker research
- To develop educational streams to improve knowledge and management of CKD
- To develop a research capability in healthcare workers: scientific, medical, nursing and allied health

Through the CKD registry we will define the distribution of CKD in Queensland, by region, remoteness, ethnicity and socioeconomic status. We will define its characteristics, associations, stages, co-morbidities and its current management, as well as outcomes in individuals and population trends over time. A database will be maintained for epidemiological purposes as well as clinical use, and will incorporate best practice support. Documentation of CKD patient outcomes will allow assessment of predictors from parameters documented at baseline, and data from additional testing, such as biomarkers. Such predictors in turn can be incorporated into evaluations of models of care of CKD, intensity of surveillance and interventions, and customisation of individual therapy. The CKD.QLD registry will be the first to inform the official monitoring process of CKD across Australia, a priority articulated in Oct 2007 by the Australian Institute of Health and Welfare. Given that all patients who receive RRT pass through renal practices, ours will also be the first delineation of the stream of pre-terminal disease in the public health system that feeds into RRT. Description of that pre-terminal CKD pool by demographic groupings can then allow group-specific extrapolations to estimate CKD burdens in other states and territories in Australia. Development of direct links to the ANZDATA registry is a natural anticipated further step.

With increasing interest from the private sector, we will soon begin inviting private renal practices to participate, optionally, in CKD.QLD. As many of those practices move to Audit 4 for data entry and patient management, the coordination and collation of those data will be increasingly easier. Ultimately that information will supplement the CKD data in the public health stream, with caution exerted, however, to avoid double-documentation of patients who move between the private and public systems.

CKD.QLD is committed to evaluate and promote models of best care for CKD patients. Practices are variably establishing community-based models of care, systems led by nurses and nurse practitioners (NPs), and with multidisciplinary allied health involvement. Some practices are also establishing CKD patient advocacy groups. However, there is very little evaluation of these systems. CKD.QLD will evaluate and, as appropriate, promote models of nurse-led CKD practice in Queensland and nationwide, by working closely with the CKD nurses’ coalition and leaders in nursing research, as well as other bodies. Education and capacity building in palliative care as an option for certain CKD patients will be an additional high priority. For the Indigenous population, there is need for better communications, improved access, better models of care, empowerment and training of the Indigenous workforce and much more outreach, education, prevention and screening. Through CKD.QLD we will develop CKD educational materials and training opportunities for practitioners, trainees and investigators in a variety of disciplines.
Substantial investment of personnel and resources has led to impressive progress, as follows:

**Development of our Website:** [www.ckdqld.org](http://www.ckdqld.org). This is a key resource for communicating activities & network outcomes for both patients & professionals, with exponential growth in site access nationally and internationally.

**Surveys:** We have completed two state-wide baseline surveys of all the public renal practices in QLD. Survey 1, completed in March 2010, involved a cross-sectional profile of CKD activity and provided an estimate of more than 11,000 CKD patients in the QH system. Site Survey 2, completed in March 2011 & with a 100% response rate, profiled CKD management using a web-based questionnaire, completed by Senior Renal Medical and Nursing Staff.

**Ethics and Governance:** Extensive consultation has resulted in a sound Ethical Framework across three Queensland institutions: Queensland Health, the University of Queensland & the Queensland University of Technology, as well as with the 12 Queensland Health renal practices. The ethical structure and logistics for a Registry were developed in collaboration with network members from inception and further developed with a Database Workshop held in mid 2010. The workshop helped define ethical issues, Governance structure, roles and responsibilities and Terms of Reference. State wide Ethical approval of the Registry research protocol was obtained in November 2010, allowing applications for Site Specific Governance Approvals (SSGAs) for each renal practice site to proceed. 11 of these 12 SSGAs have been received with the final pending (see table below).

**Collaborators and Sites: Nephrologists & CKD nurses in Queensland** (as of 25.11.11):

<table>
<thead>
<tr>
<th>Sites (12)</th>
<th>Investigator</th>
<th>Governance Status</th>
<th>Nursing</th>
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<tr>
<td>RBWH</td>
<td>Dr Helen Healy</td>
<td>Approved 11.02.11</td>
<td>Sonya Coleman NP</td>
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<td>Toowoomba</td>
<td>Dr Govindarajulu</td>
<td>Approved 25.03.11</td>
<td>John Fanning ACNC CKD</td>
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<td>Mackay</td>
<td>Ms Chris Banney</td>
<td>Approved 12.04.11</td>
<td>Chris Banney CNC CKD</td>
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<td>Rockhampton</td>
<td>Dr Thin Han</td>
<td>Approved 31.03.11</td>
<td>Katrina Duff NP</td>
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<td>Bundaberg</td>
<td>Dr Peter Miach</td>
<td>Approved 07.04.11</td>
<td>Barb Harvie NP</td>
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<tr>
<td>Cairns</td>
<td>Dr Murty Mantha</td>
<td>Approved 20.04.11</td>
<td>Lois Berlund NP</td>
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<td>Hervey Bay &amp; Maryborough</td>
<td>Dr Krishan Madhan</td>
<td>Approved 01.06.11</td>
<td>Leanne Brown NP</td>
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<td>Gold Coast</td>
<td>Dr Thomas Titus</td>
<td>Approved 26.07.11</td>
<td>Michele Harvey NP</td>
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<td>PAH</td>
<td>Dr David Johnson</td>
<td>Approved 06.10.11</td>
<td>Bettina Douglas NP</td>
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<td>Logan</td>
<td>Dr Ken-Soon Tan</td>
<td>Approved 17.10.11</td>
<td>Cassandra Stone NP</td>
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<td>Townsville</td>
<td>Dr George Kan</td>
<td>Approved 19.10.11</td>
<td>Anne Blong NP</td>
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<tr>
<td>Sunshine Coast</td>
<td>Dr Nick Gray</td>
<td>Awaiting approval</td>
<td>Andrea Pollock, Trials Coordinator</td>
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**Patient Consenting:** Sites with completed SSGA’s can now inform CKD patients of the opportunity to participate in the registry and gain formal consent from those who agree. Consenting of the accrued number of existing patients (the resource-intensive component) has begun in the CKD practices at RBWH, Mackay, Toowoomba, Gold Coast and the PAH, with other sites being phased in. More than 750 patients have been recruited to date (fig.1), with a negligible refusal rate. Our target is to have gained consent from 1,000 CKD patients by the end of December 2011, 5,000 by mid 2012, and 11,000 by the end of 2012. Informing and consenting of new CKD patients as they are referred to clinics will be a less labour intensive process and performed by the renal service provider seeing them for their first consultation as a proposed part of standard care. Our targets for the first descriptions of each CKD patient cohort are within three months of reaching each of the recruitment goals.

**Data collection:** CKD.QLD facilitates resources at each site in regards to patient information, consenting and data capture. With a flexible Central Data system housed within Q.Health, data accrual is affiliated to each site’s current data system, from excel spreadsheets through to Audit 4, a software program with specific CKD worksheets.
Additional achievements: Two major additional projects have been funded in line with the vision of our Network – the first is a study on CKD Nursing Models of Care (cKiDNAP), led by Prof Glenn Gardner, Prof Ann Bonner and NP Barbara Harvie. The second project is a study on the influence of nutritional status on clinical outcomes of CKD patients, led by Dr Katrina Campbell, a Senior Research Fellow in the Department of Nutrition & Dietetics, PAH.

Clinical Trials: The CKD patient platform provides excellent potential opportunities for large-scale clinical trials. Our close collaboration and shared investigators with the Australian Kidney Trials Network (AKTN) are a major benefit. Current and planned studies include that of fish oil and of allopurinol in mitigating the course of CKD.

Biomarker research: Integration with the CKD clinical practices will support applied biomarker research, and post-marketing evaluation, such as those under discussion with Alere Biomedical. Novel biomarker discovery and validation is planned with our collaborator and co-investigator Prof Matthew Cooper, at the Institute for Molecular Bioscience (IMB), University for Queensland. In addition, a critical link has been achieved via a formal MOU towards International Biomarker Research Collaboration and Validation, between the Proof Centre of Excellence, Canada, and CKD.QLD, headed by our co-investigator Prof Glenda Gobe.

Collaborations: State – CKD.QLD is affiliated with the two State Renal Patient Advocacy agencies – Kidney Support Network (KSN) & Kidney Health Australia (KHA). National – CKD.QLD is in discussion with Western Australia, the Northern Territory, Victoria and New South Wales in progressing a National Network in CKD research, a concept that is supported by key renal bodies, including Kidney Health Australia and ANZDATA. International - The Memorandum of Understanding with the Proof Centre of Excellence, Canada, for an International Collaboration in CKD Biomarker research as noted previously.

Education & Training: CKD.QLD has well articulated strategies for research workforce development and sponsoring PhDs and other higher degrees. These include recruitment of a CKD Nurse Practitioner to a PhD, funded in collaboration with QUT School of Nursing.

Presentations, Publications & Conferences: We have presented at multiple national and international conferences including ANZSN, RSA and ASN. In 2011, five conference abstracts and papers have been submitted and accepted; two presentations as Invited Speaker, and one publication “Biomarkers in Chronic Kidney Disease: a review” in Kidney International. Another paper is in preparation for Nephrology Dialysis Transplantation’s 2012 issue dedicated to “Clinical Kidney Disease: a Research and Public Health Priority.” Regular dissemination of Registry outcomes is a key objective for the future.

Significance: End-users who will benefit from the activities and products of CKD.QLD are:
- CKD patients, through better outcomes.
- Practitioners, from structured and efficient support systems and models of care.
- Health systems, from more efficient models of care.
- The taxpayer, from cost containment achieved through more efficient services
- The general population, through better health awareness
- Commercial interests, through increased identification of CKD and its better management, a clinical trials platform, new diagnostic agents and opportunities for private insurance.
- Teaching and training institutions, through the proposed new tools and training curricula, and improving their relevance in addressing present day health needs.

It is anticipated that the activity and products of CKD.QLD will prove so useful that they will be incorporated into routine health care delivery and education streams within 5-years. We expect other States to join, with a National CKD registry and network being a long-term aim.
Figure 1: CKD.QLD patient consent and recruitment progress to date.