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# Developing a Canadian research strategy in pre-dialysis Chronic Kidney Disease

## Planning document

February, 2014

*This report is based on the invaluable contributions of the stakeholders who came together in Atlanta in November 2013, to start transforming chronic kidney disease research and care across Canada. Our gratitude to our workshop supporters: the Canadian Institutes for Health Research, the Canadian Society of Nephrology, The Kidney Foundation of Canada and CANN-NET*

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# Introduction

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The incidence of chronic kidney disease (CKD) is increasing as our population ages and major CKD risk factors such as diabetes and obesity increase.<sup>1,2</sup> It is estimated that 3.6 million Canadians have CKD, challenging both health care decision making and system resources.<sup>3</sup> Research efforts have mirrored health care funding, focusing primarily on dialysis and transplantation for the 2% of patients who experience kidney failure. However, a predominant research focus on these extreme and late-stage interventions is both unacceptable to patients and unsustainable to the health system. We have an urgent need to prevent the onset of chronic kidney disease in the first place, and where it exists, to slow and control its progression to reverse the growth of kidney failure. The best way to improve health outcomes – and reduce the \$100,000 annual per patient cost of dialysis<sup>4,5</sup> - is to avoid needing dialysis or transplantation in the first place.

To achieve better chronic kidney disease outcomes, the focus of this emerging research strategy, and the intent of this planning document, is to specifically address the pre-dialysis stages of CKD.

## Why do we need this strategy?

To achieve major improvements in health outcomes, researchers and health leaders are increasingly faced with complex questions and translational requirements which are well beyond the capacity of any single researcher or team to address. Globally, research funding is rapidly evolving to respond to the changing nature of science, as well as the increasingly-urgent need to ensure that the potential benefits of scientific discovery are realized in the real world. In Canada, for example, the Canadian Institutes of Health Research (CIHR) is shifting emphasis to cross-Institute “Signature Initiatives” and the Strategy for Patient-Oriented Research (SPOR); both approaches assume that research and health breakthroughs will increasingly result from large-scale, multi-disciplinary, multi-pillar, multi-professional, cross-jurisdictional approaches to science. We also need strong biomedical research effectively connected to our investigations of clinical diagnostics and therapeutics in order to succeed.

If the Canadian chronic kidney disease (CKD) research community wants to tackle the most exciting opportunities in science, change the most intractable health outcomes, and participate in the new research funding opportunities, we need to change. We need to respond to funders’ demands for integrative, translational approaches by better connecting our small and fragmented resources to create the needed critical mass of expertise, patients, data, funding, and partners. We need to participate and help lead larger efforts to better address chronic disease in Canada. We need to support and build on the wide range of major infrastructure and emerging initiatives which could all hugely benefit CKD research – but which currently do not have CKD on their radar. We need to create a visible, demonstrably-effective focal point that attracts partners and investment. Recognizing that over 90% of CKD patients are managed solely by family physicians,<sup>6</sup> innovative partnerships with primary care and with provincial kidney care programs will be top priority to improve care and patient outcomes.

But first and foremost, we need to recognize that we can actually achieve our individual research aspirations - as well as address our provincial goals and meet our national needs - faster and better by connecting our efforts and resources, rather than by continuing to go it alone.

## Why focus on pre-dialysis CKD?

Over the last fifteen years, the *Horizons* meetings have been connecting researchers to develop a Canadian strategic kidney research agenda. A major result of *Horizons 2000* was the creation of KRESCENT - the Kidney Research Scientist Core Education and National Training Program. *Horizons 2015* focused on creating a broader network, with the large gaps in chronic kidney research and care topping the priorities list. Two of the priorities coming out of *Horizons 2015* were to: (1) strengthen links among kidney researchers and knowledge users; and (2) create a kidney research network.

CANN-NET – the CANadian Kidney KNowledge TraNslation and GEneration NeTwork – was created to translate knowledge and support knowledge users in dialysis-dependent CKD, providing infrastructure that connects researchers to develop multicentre clinical trials. In addition, a CIHR/ KFOC-supported Canadian Transplant Research Program (CNTRP) has also been successfully launched. A focus on pre-dialysis CKD complements other research and health initiatives, and was therefore supported by the Canadian Society of Nephrology (CSN) Scientific Committee, medical leads of provincial kidney care programs; the CANN-NET Knowledge Users committee, and The Kidney Foundation of Canada.

## What has been done so far?

Emerging CIHR and other funding initiatives may offer opportunities to support a collaborative national approach to CKD research. However, much remains to be done before our community is adequately organized and ready to develop compelling proposals. In consequence, the CSN Scientific Committee and the KFOC proposed a national stakeholder workshop, and funded it together with CIHR's INMD; a working group with all partners developed the workshop plan and preparatory materials (see workshop presentations in Annex B for planning group as well as details of the pre-workshop materials).

To provide a starting point for workshop discussion, a web-based consultation on research priorities was undertaken with stakeholders, including provincial renal agencies and academic and health system leaders. A pilot study exploring what patients and caregivers felt were the most important research uncertainties in nondialysis CKD was also undertaken.

In addition, a review of major research databases and key funder datasets provided an overview of the types of clinical research currently being conducted in non-dialysis CKD; and identified gaps in patient care, as well as additional studies needed to improve outcomes generally, and in Canada specifically.

The goal of the workshop, held November 5, 2013 in Atlanta, was to agree on top priorities and a plan for a Canadian research strategy in pre-dialysis chronic kidney disease. The objectives were to:

1. Identify the most urgent Canadian health needs, research gaps and opportunities
2. Identify the most appropriate research priorities for a Canadian CKD initiative, and how they could be best addressed
3. Plan next steps to develop a Canadian CKD strategy compelling to researchers, patients, partners and funders

Building on the pre-workshop work, discussion addressed three major challenges; how research could:

1. most improve **identification/screening and risk stratification**?
2. best slow **progression** of chronic kidney disease?
3. most improve **management and outcomes** of people with CKD?

# Situation analysis

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## Most urgent health needs

### Identification/screening and risk stratification

- Predicting who is at risk/ who needs screening
- Improving access – ensuring those most in need get the right services
- Connecting screening to appropriate next steps

### Slowing progression

- Understanding who progresses, why and when
- Finding better ways to intervene, earlier
- Improving treatment safety and effectiveness, especially with co-morbidities
- Increasing uptake of known best practice care

### Improving management and outcomes

- Identifying and increasing the use of optimal models of care
- Reducing the symptoms which most affect patient quality of life
- Innovative approaches to improving care (from self-management to telehealth)
- Addressing CKD in real-life contexts – e.g. growth (pediatric), comorbidities, etc

## Major research strengths and enablers

- Universal health care and strong primary care - increase research feasibility
- Large administrative databases, widespread use of EMR
- Strong research capacity and key skills (e.g. methodological, health services, epidemiology)
- Collaborative environment, connected clinical researchers, CANN-NET<sup>1</sup> and KRESCENT<sup>2</sup>
- Growing clinical trials capacity, including pragmatic trials
- Culture of research; CKD clinics well-connected
- CNODES<sup>3</sup> – connecting provincial drug databases

## Key research gaps

- No national data system, such as registries (like CORR<sup>4</sup>), for nondialysis CKD
- Limited collaboration with primary care
- Limited national guidelines, best practices, implementation of existing evidence

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<sup>1</sup> CANN-NET : Canadian Kidney Knowledge Translation and Generation Network, linking Canadian kidney disease guideline producers, knowledge translation specialists and knowledge users to improve knowledge dissemination and care of patients with kidney disease: [www.cann-net.ca](http://www.cann-net.ca)

<sup>2</sup> KRESCENT is a training initiative focused on the prevention of end-stage renal disease and new treatments for kidney disease; funded by KFOC, CSN and CIHR: [www.krescent.ca](http://www.krescent.ca)

<sup>3</sup> CNODES uses population-based approaches to provide rapid answers to questions about drug safety and effectiveness, using multiple healthcare databases: [www.cnodes.ca](http://www.cnodes.ca)

<sup>4</sup> CORR - The Canadian Organ Replacement Register (CORR) contains data and tracks long-term trends in organ transplants, donations and dialysis: [www.cihi.ca/cihi-ext-portal/internet/en/tabbedcontent/types-of-care/specialized-services/organ-replacements/cihi021362](http://www.cihi.ca/cihi-ext-portal/internet/en/tabbedcontent/types-of-care/specialized-services/organ-replacements/cihi021362)

- Limited multidisciplinary research experience, collaboration with other specialties/ disciplines (e.g. cardiology, diabetologists, urology, pediatrics, imaging/ clinical care, research education)
- Diverse provincial priorities, systems, data, models of care; no data connects these to outcomes
- No national trials infrastructure/ approaches – lack critical mass for recruitment, trials expertise
- Lack of national coordination/ coherence in research – from identification of priorities for new investigational interventions to common REB review
- Little research on health-related quality of life/ symptoms/ patient priorities
- No mechanism to facilitate patient engagement
- Need innovative strategies for both new interventions and for care approaches

## Key opportunities for collaboration

- Multidisciplinary and multi-centre approaches to study complex interventions
- Connecting family medicine and specialists, for education and innovation strategies
- CANN-NET (national kidney KT initiative)
- Partnering with Canada’s unique Aboriginal population
- Building on existing systems to connect data / create a common CKD registry across Canada
- Expand collaborations with informatics specialists to use large administrative-based datasets
- DOPPS<sup>5</sup> - The Dialysis Outcomes and Practice Patterns Study
- DSEN<sup>6</sup> - Drug Safety and Effectiveness Network
- SPOR infrastructure – SUPPORT Units
- CIHR community-based primary care initiative – now integrated health care<sup>7</sup>
- CNTRP<sup>8</sup> - Canadian National Transplant Research Program
- Genome Canada
- Societies and organizations with related interested (e. diabetes); integrating CKD researchers and recruiting pre-dialysis CKD patients into related trials and initiatives
- Connect to researchers, initiatives and networks in UK and Australia

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<sup>5</sup> DOPP: A prospective cohort study of hemodialysis practices in a random sample of units in more than 20 countries, to describe and compare practices and outcomes in each facility, and in each geographic area. <http://www.dopps.org>

<sup>6</sup> DSEN: CIHR-led initiative to increase evidence on drug safety and effectiveness, and the capacity to produce it: [www.cihr-irsc.gc.ca/e/40269.html](http://www.cihr-irsc.gc.ca/e/40269.html)

<sup>7</sup> <http://www.cihr-irsc.gc.ca/e/44079.html>

<sup>8</sup> CNRTP: a national CIHR-funded research initiative designed to increase organ and tissue donation in Canada and enhance the survival and quality of life of Canadians who receive transplants: <http://www.cntrp.ca>

# Elements of a pre-dialysis CKD strategy

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## What do we want to change?

**Vision: we will improve outcomes for people with or at risk of chronic kidney disease**

We aim to improve outcomes by preventing the onset and slowing the progression of chronic kidney disease, in order to avoid the need for dialysis and transplantation. We seek to reduce complications and improve symptoms associated with pre-dialysis chronic kidney disease.

## Objectives of a pre-dialysis CKD strategy

1. Create a platform that connects and deploys Canadian experts, knowledge, infrastructure to rapidly identify needs, and to implement research inventions and best practices
2. Identify and assess available evidence, current practices and their associated outcomes
3. Develop innovative interventions to prevent onset or slow progression
4. Identify high-risk subpopulations and match them with effective interventions
5. Improve quality of life for CKD patients
6. Assess and enhance models of care

## How could these objectives be achieved?

### 1. Create a platform that connects and deploys Canadian experts, knowledge, and infrastructure to rapidly identify needs, and to implement research inventions and best practices

- Build a national research network of CKD stakeholders with shared leadership including patients, health care professionals, policy makers and researchers
- Develop shared national standards, approaches and infrastructure which make it possible to connect people, data, resources, findings and implementation efforts across Canada
- Create a collaborative process, which includes patients, to identify and prioritize interventions and models of care for research
- Create a common pipeline to identify and prioritize potential therapeutics for clinical studies
- Create a shared trial and data analysis infrastructure to link smaller study centres to facilitate urgently-needed larger studies

### 2. Identify and assess available evidence, current practices and their associated outcomes

- Identify known best practice in CKD, and describe major evidence gaps – e.g. develop a filter and process to identify, assess and annotate the literature related to CKD identification, progression, management and outcomes
- Identify and validate a set of critical outcomes and indicators for quality of care and patient-relevant outcomes, and describe current care across Canada to inform evidence practice gaps
- Establish linked data sources and the described quality indicators to measure system and patient quality of care, as well as current outcomes in CKD, across Canada

### 3. Develop innovative interventions to prevent onset or slow progression

- Basic and translational investigations of major gaps in our understanding of the diverse etiology of CKD onset and progression, disease mechanisms
- Basic and translational investigations to identify and target factors which cause some patients to progress and others not
- Develop robust experimental designs to deal with complex interventions and multidisciplinary approaches
- Catalog potential interventions for slowing CKD progression, across all phases of development, and agree on the most promising intervention to test using rigorous clinical trials

### 4. Identify high-risk subpopulations and match them with effective interventions

- Identify outcomes associated with variations in CKD etiology
- Develop evidence-based risk-stratification approaches targeting both prevention and slowing of progression (addressing both populations and phenotypes)
- Connect and link available datasets which could be used to describe disease and drug outcomes, including provincial administrative databases and electronic medical records, e.g. like CNODES<sup>9</sup>
- Assess which interventions are most effectively, efficiently and consistently delivered, by whom – for example, primary care approaches should be cheap, simple, linked to reimbursement, and aligned with provider workflow, resources, incentives and remuneration

### 5. Improve quality of life for CKD patients

- Identify major sources of quality-of-life burden - most critical factors leading to poor quality of life and worsening of symptoms (e.g. mental health, cognitive, pain, itching, cramping, fatigue)
- Basic and translational investigations into the diverse etiology of CKD symptoms - who they affect, when, how, and why they occur
- Develop and/ or assess management strategies which most effectively treat these patient-relevant symptoms
- Develop systematic data collection processes which can obtain relevant patient outcome measures on an ongoing basis

### 6. Assess and enhance models of care

- Identify current models of care in place across Canada, variations in care, and which outcomes can be associated with health system factors (i.e. as opposed to biological and other factors)
- Identify current models of care in place across Canada for patients with early and more advanced forms of pre-dialysis chronic kidney disease
- Compare models of care to identify what works best for who, when and under what circumstances
- Identify major causes of practice variation, and assess strategies to increase uptake of best practice and most effective models of care
- Develop pragmatic methods to assess the impact of health system change
- Develop primary care-led approaches, including usable appropriate guidelines to enhance early identification, risk stratification and management of patients with early CKD
- Identify, assess and implement approaches to translating evidence into practice in line with known best practice, measuring and changing - optimize what we know
- Improve patient safety and outcomes with interventions that increase appropriate drug prescribing and adherence, for example, working with community pharmacists

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<sup>9</sup> Canadian Network for Observational Drug Effect Studies : <http://www.cnodes.ca/>

# Next steps in start-up

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There may be upcoming large-scale research funding initiatives which could support our vision for better pre-dialysis CKD outcomes – but there may not. If we wait for those opportunities to be launched, we will not be ready if they are - and we will miss our chance if they aren't. In consequence, we must build enthusiasm for a national approach, create our own opportunities to bring this strategy into reality in the short-term, and demonstrate impacts which will be widely compelling to a range of funders.

We thus suggest an incremental and layered approach rather than the big-bang creation of a single new national entity. Over the next year, we will slowly and surely refine research priorities, build links and start to connect goals, approaches, infrastructure and projects. The emphasis will be on keeping it simple and within the realm of currently-attainable resources – but with each new project and activity, to increase the consistency and connectedness of people, data, methodology, outcomes, and key partners. In so doing, the community will increasingly contribute to, and have access to a much larger scope and scale of ideas, data, patients, findings, samples, comparative models and shared outcomes. Where, for example, can we agree on simple parameters for future data collection or protocols, that will enable each contributor to access much larger pools of patients, data, samples, findings? Where can we readily leverage existing infrastructure, such as CANN-NET and the emerging SPOR SUPPORT Units?

We need to focus on finding opportunities to create quick wins, and to demonstrate proof of principle of this connected, strategic approach to kidney health to our future potential funders – and even more so, to our own community and partners. Our intent is not to mandate collaboration, but to make it the attractive to all by creating opportunities to link, and enable our community to experience, and to demonstrate, the value of doing so.

## 1. Establish a national working group

- Planning must be expanded beyond the initial CSN and KFOC support, to reflect the broad community which must lead this strategy (range of researchers/ practitioners, renal agencies...)
- Initial volunteers were solicited at the November planning workshop; members will continue to be incorporated to fill geographic, and expertise gaps
- Over the next 12 months, the working group will:
  - Engage and prepare the community to create compelling national proposals
  - Develop a draft Canadian CKD research strategy
  - Propose a structure and approach to implement the strategy
  - Engage key partners, leaders and collaborators
  - Identify and address key start-up needs and opportunities
  - Ensure that key background work identified below is completed on schedule

## 2. Engage/ prepare community to create compelling national proposals

- Identify shared needs, clearly articulate urgency and value offered to potential participants
- Identify the major types of participants, teams and partners who must be engaged
- Articulate core principles – e.g. patient engagement, multidisciplinary, data sharing, importance of research investment within as well as translating across all four pillars
- Prepare MOU drafts/templates connecting key participants to a shared vision and approach
- Create a series of focused working groups to develop specific areas of the national strategy, particularly the research priorities

### 3. Engage key partners, leaders and collaborators

- Engage and integrate with key communities; **priority to CIHR INMD diabetes meeting Jan 2014**
- Engage and integrate primary care as key leaders and partners; CIHR Integrated Care initiative
- Engage and integrate patients as key leaders and partners; CIHR Integrated Care initiative
- Connect and ultimately integrate with SUPPORT Units, look for shared opportunities to connect and show early wins
- Incorporate a patient-engagement strategy that identifies and refines research priorities that are most relevant to patients, caregivers and the health care professionals who care for them
- Create mechanisms to engage patients; could range from leveraging KFOC patient dataset (in development) to each of us identifying within our own practice patients who might be / willing to participate
- Engage national policy leaders; including work with PHAC to integrate CKD into chronic disease agenda; link with Conference of Deputy Ministers of Health
- Identify relevant national and provincial bodies which could help connect or coordinate

### 4. Develop a draft Canadian pre-dialysis CKD research strategy

- Draft a comprehensive research strategy to describe links between research platforms, infrastructure and priority areas
- Create framework to prioritize research projects, resources needed
- Develop name, branding reflective of broad participant priorities and needs
- Draft business plan, looking at traditional and non-traditional funding sources addressing both projects and broader programs, as well as other kinds of relevant activity. A short term (1 year) plan to support short term activities and a longer term business / funding plan will be required

### 5. Propose structure and approach to implement the strategy

- Identify parameters to achieve fair, equitable and effective participation; transparency and accountability in decision making
- Develop and assess options for long-term governance structure

### 6. Identify and address key start-up needs and opportunities

- Identify and address major gaps and needs to connect nationally, and to create compelling national proposals
- Identify opportunities and resources to support development activities
- Look for and exploit opportunities for proof-of-principle, early wins
- Identify opportunities to fill gaps and begin connecting participants, data, resources; such as:
  - Assess feasibility of extending data collection to nondialysis CKD through CORR
  - Develop an asset map, including existing infrastructure, data, resources, personnel, expertise and collaborations with relevant partners/ stakeholders (create template)
  - Distill existing clinical practice guidelines to be useful in primary care settings (or prepare the ground for doing so)
  - Identify and assess utility and coherence of available sources of relevant data (research and administrative databases, EMRs, registries, biobanks, etc)
  - Undertake environmental scan of validated measures of patient-reported outcomes, assess usability
  - Assess current clinical trials activity and infrastructure in Canada



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Canadian Society of Nephrology/  
Société canadienne de néphrologie  
CSN/SCN

# Annex 1: Workshop participants list

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## Developing a Canadian research strategy in pre-dialysis Chronic Kidney Disease

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# Annex 2: Workshop presentations

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*From the November 5, 2013 Atlanta workshop:*

*Developing a Canadian research strategy in pre-dialysis chronic kidney disease*

1. **National CKD Strategy Development Workshop:  
The Road Towards this Workshop**  
Norman Rosenblum
2. **CKD: Research Priorities of Stakeholders**  
Neesh Pannu, Sarah Gil, Braden Manns
3. **Research Priorities of People with Chronic Kidney Disease: A pilot**  
Brenda Hemmelgarn, Sofia Ahmed, Neesh Pannu
4. **Funded and ongoing studies in nondialysis CKD**  
Braden Manns, Cello Tonelli, Neesh Pannu, Michael Walsh

## Footnotes

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<sup>4</sup> Chui BK, Manns B, Pannu N, Dong J, Wiebe N, Jindal K, Klarenbach SW. Health care costs of peritoneal dialysis technique failure and dialysis modality switching. *Am J Kidney Dis.* 2013 Jan;61(1):104-11.

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