



Determining the research priorities for kidney disease: Engaging patients, caregivers, clinicians and policy-makers

**PROTOCOL
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Steering group members:

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Purpose

The purpose of this protocol is to set out the aims, objectives and commitments of the Kidney Disease Priority Setting Partnership (PSP) and the basic roles and responsibilities of the partners.

Steering Group

The Kidney Disease PSP will be led and managed by the following:

Patient representative/s:

- Kidney Foundation of Canada
 - Wim Wolfs, *National Director of Research*
- Patients: to be determined

Clinical representatives:

- Dr. Brenda Hemmelgarn, *Nephrologist and Professor, Departments of Medicine and Community Health Sciences, University of Calgary*
- Dr. Sofia Ahmed, *Nephrologist and Associate Professor, Department of Medicine University of Calgary*
- Dr. Neesh Pannu, *Nephrologist and Associate Professor, Department of Medicine University of Alberta*

The Partnership and the priority setting process will be supported and guided by:

- Dr. Andreas Laupacis, *Executive Director, Li Ka Shing Knowledge Institute of St. Michael's Hospital*
- Erin Lillie, MSc, *Research Coordinator, Li Ka Shing Knowledge Institute of St. Michael's Hospital*

Background to the PSP for People with Kidney Disease

Because they live with their disease, patients with chronic kidney disease (CKD) not yet on dialysis and their caregivers should have a voice in determining research priorities. The clinicians and policy-makers who are involved in the care for these patients should also contribute to research priority-setting. In this protocol, the term “caregiver” is used in reference to relatives and friends of individuals on dialysis who help them manage their illness. We use the term “clinician” to refer to physicians, nurses, social workers, pharmacists and other allied health care professionals who care for patients with kidney disease, and “policy-maker” refers to people with ability to influence or determine policies and practices related to health care delivery for kidney disease at an international, national, regional or local level.

Patients with kidney disease and their caregivers become “experts” in their disease. Despite important advances in treatment, the quality of life of most patients with kidney disease is often adversely affected, and considerable responsibilities are placed upon them and their caregivers. For instance, caregivers may be required to assist patients with kidney disease in medical treatments, care for their numerous physical and psychological co-morbidities, and support them with their medical procedures and appointments. Thus, kidney disease as a condition is one in which consulting patients, caregivers and clinicians about their research priorities is particularly important.

This protocol is based upon the approach successfully used in the UK by the James Lind Alliance (JLA) involving patients, their caregivers and clinicians in research priority setting (www.lindalliance.org).

Research priorities for this initiative will be identified through five key steps: identification and invitation of potential partners, initial stakeholder meeting by teleconference, collection of research uncertainties, refinement of uncertainties, and prioritisation (interim and final stages). The steps are outlined in greater detail below.

Aims and objectives of the PSP

The aim of the PSP for People with kidney disease not yet on dialysis is to identify the unanswered questions about management of the condition (i.e. in terms of diagnosis, prognosis, and treatment) from the perspective of patients, caregivers, clinicians and policy makers involved in their care, and then prioritise the questions which patients and clinicians agree are the most important.

The objectives of this PSP are:

- To work with patients, caregivers, clinicians and policy-makers to identify uncertainties about the management of their disease.
- To agree by consensus on a prioritised list of those uncertainties, for research
- To publicise the results of the PSP and the process
- To take the results to research commissioning bodies and researchers, so these priorities will be considered when setting research priorities or undertaking research projects

Partners

Organisations and individuals representing the following groups will be invited to take part in the PSP:

- Adult kidney disease patients not yet on dialysis
- Carers of people who have kidney disease
- Medical doctors, nurses, pharmacists, social workers and other professionals with clinical experience interacting with patients with kidney disease
- Policy-makers who have the ability to influence or determine policies or practices related to health care delivery for kidney disease at the international, national, regional or local levels

Organisations wishing to participate in the PSP will be required to demonstrate their commitment to the aims and values of the process. The underlying principles of the project are: transparency of process, balanced inclusion of patient, caregiver and clinician interests and perspectives, exclusion of non-clinician researchers for voting purposes (but they may be involved in other aspects of the process), exclusion of groups/organizations that have significant competing interests (e.g. pharmaceutical companies and device manufacturers), an audit trail of the original submitted uncertainties to the final prioritized list, and recognition that making priority decisions does not create new knowledge, but reviews existing evidence of uncertainty. Details about the commitment procedure can be found at: www.lindalliance.org.

METHODS

This section describes a schedule of proposed stages through which the PSP aims to fulfil its objectives. The process is iterative and dependent on the active participation and contribution of different groups. The methods adopted in any stage will be agreed through consultation between the partners, guided by the PSP's aims and objectives. More details and examples can be found at: www.JLAguidebook.org.

1. Identification and invitation of potential partners

Potential partner organisations will be identified through a process of peer knowledge and consultation through the Steering Group members' networks. Potential partners in addition to the Kidney Foundation of Canada (KFOC) and the Canadian Kidney Knowledge Translation and Generation Network (CANN-NET) will include the Canadian Society of Nephrology (CSN), Canadian Association of Nephrology Nurses and Technologists (CANNT), Renal Pharmacist Network (RPN), Interdisciplinary Chronic Disease Collaboration (ICDC), and the Canadian Renal Administrative Collaborative (CRAC). Potential partners will be contacted and informed of the establishment and aims of the dialysis PSP and invited to participate.

2. Initial stakeholder meeting via teleconference

An initial stakeholder meeting will be held via teleconference with the Steering Committee and representatives of the partners mentioned above. This meeting will have several key objectives:

- to welcome and introduce potential members of the PSP
- to present the proposed plan for the PSP
- to initiate discussion, answer questions and address concerns
- to identify additional potential partner organisations which will commit to the PSP and identify individuals who will be those organisations' representatives and the PSP's principal contacts
- to establish principles upon which an open, inclusive and transparent mechanism can be created for contributing to, reporting and recording the work and progress of the PSP

3. Identifying treatment uncertainties

Potential research priorities will be identified by means of a survey (available in electronic (Fluid Survey) and paper-based format) of patients, caregivers, clinicians and policy-makers. A period of 2 months will be given to complete this exercise.

Patients, caregivers, clinicians and policy-makers will be contacted in two ways. First, we will post a questionnaire (Fluid Survey) on the web site of CANN-NET, the Kidney Foundation of Canada and the Canadian Society of Nephrology using Fluid Survey. The existence of the survey will be advertised through the Kidney Foundation of Canada (KFOC) web site and newsletter, as well as other organizations that focus on patients with kidney disease; and by chronic kidney disease clinics who will make their patients aware of the questionnaire through newsletters and posters. We expect the web site to be "open" for 2-3 months.

Second, because many patients with kidney disease are not web-savvy, and because sicker patients are less likely to respond to the approach mentioned above, a finite number of Canadian kidney disease centres (between 6 and 10) will provide hard copies of the questionnaire to their patients, and invite them to complete the questionnaire (patients can complete the questionnaire on the web if they prefer). These kidney disease centres will be chosen so that, taken together, they are reasonably representative of Canada's geography, and care for patients who are rural and urban.

The background information (to be included in the survey form) as well as the wording of the survey items will be designed to be clear and easy to understand by all participants. In addition, the following identifiable data will be requested in the survey: age, gender, ethnic group, profession, whether the participant is a patient, carer or relative of a patient, a health professional, or a member of an organisation representing people with end stage renal failure. These data will be collected in an effort to determine whether the population of interest has been successfully captured, and to study whether research priorities are influenced by these factors.

Participants may complete the surveys anonymously.

Existing sources of information about treatment uncertainties and research questions for patients and clinicians will be searched. These can include research recommendations

in systematic reviews and clinical guidelines; protocols for systematic reviews being prepared, and registers of ongoing research. In the past JLA projects, between 100 and 1000 potential research priorities have been identified at this stage.

4. Refining questions and uncertainties

The consultation process will produce “raw” unanswered questions about management of kidney disease. These raw questions will be assembled and categorised and refined by the Steering Group into questions which are clear, addressable by research and understandable to all. Similar or duplicate questions will be combined where appropriate.

The existing literature; particularly clinical practice guidelines and systematic reviews, will be researched by Dianne Lorenzetti at the University of Calgary to see to what extent these refined questions have, or have not, been answered by previous research.

Sometimes, uncertainties are expressed that can in fact be resolved with reference to existing research evidence (for example studies have been done, but a systematic review of all of the studies has not yet been done). These uncertainties will be categorized separately from the 'true uncertainties', where new research is needed.

A taxonomy specific for dialysis patients which can be used to characterize the uncertainties will be developed by the steering group to categorise potential research uncertainties, and to guide respondents when they are responding to the initial survey.

5. Prioritisation – interim and final stages

The aim of the final stage of the priority setting process is to prioritise through consensus the identified uncertainties relating to the management of patients on dialysis, or about to start dialysis. This will be carried out by members of the Steering Group and the wider partnership that represents patients, caregivers, clinicians and policy-makers.

The interim prioritization stage, to proceed from a long list of uncertainties to a shorter list (e.g. up to 20), may be carried out over email, whereby organisations consult their membership and ask for the top 15-20 most important uncertainties, ranked or unranked.

The final stage will be conducted in a face-to-face meeting of about 20 participants, who will be asked to identify the 10 most important research priorities from the short list. Prior to the meeting, participants will receive the short-list of research priorities identified, as well as detailed information about the process by which they were generated. The meeting will use a Nominal Group Technique, with a combination of small and full group discussion. Attendees will be chosen by the Steering Group, and will consist of approximately equal numbers of patients/caregivers and clinicians. This meeting will be facilitated by 4 individuals with experience facilitating JLA priority-setting meetings.

Findings and research

It is anticipated that the findings of the kidney disease PSP will be reported to funding and research agenda setting organisations such as CANN-NET (which includes heads of renal programs across Canada, knowledge translation specialists, and a pan-Canadian kidney disease clinical trials network), the Kidney Foundation of Canada, the Canadian Society of Nephrology, the Canadian Institutes of Health Research, the Health Charities Coalition of Canada, directed mailings to other research granting agencies (such as the Heart and Stroke Foundation of Canada and the Canadian Diabetes Association), and international charities focused on kidney disease. The findings will also be distributed through scientific meetings, web sites and social media. The prioritized list, along with a description of the process, will be submitted as a peer-reviewed publication.

Timelines:

Month: June 2014 - August 31, 2014	Month: November 1 2012 – Jan 15 2015	Month: February 1, 2015 – May 2015	Month: June 2015
Goal: Identify partners, develop taxonomy and survey	Goal: Survey distribution	Goal: Development of interim list of research priorities	Goal: Final priority setting meeting