



CANN-NET
Canadian Kidney
Knowledge Translation
and Generation Network



interdisciplinary chronic disease collaboration

St. Michael's
Inspired Care.
Inspiring Science.



In collaboration with the James Lind Alliance (UK)

Priority Setting Partnership for People with Kidney Failure on Dialysis

PROTOCOL September 2012

Steering group members:

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Braden Manns
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Purpose

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

Steering Group

The Dialysis PSP will be led and managed by the following:

Patient representative/s:

- Kidney Foundation of Canada
 - Wim Wolfs, *National Director of Research*

- Patients and care providers
 - Annette Cyr, Halifax
 - Michael Gladish, Whitehorse
 - Claire Large, Calgary
 - Howard Silverman, Montreal
 - Brenda Toth, Saskatoon

Clinical representative/s:

- Dr. Brenda Hemmelgarn, *Nephrologist and Associate Professor, Departments of Medicine and Community Health Sciences, University of Calgary*
- Dr. Braden Manns, *Nephrologist and Associate Professor, Departments of Medicine & Community Health Sciences, University of Calgary*

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*
- The James Lind Alliance (JLA)
 - Sally Crowe, *Director Crowe Associates Ltd and Chair James Lind Alliance Monitoring and Implementation Group*
- Erin Lillie, MSc, *Research Coordinator, Li Ka Shing Knowledge Institute of St. Michael's Hospital*

Background to the PSP for People with Kidney Failure on Dialysis

Because they live with their disease, patients with severe kidney failure and their care providers should have a voice in determining research priorities. The clinicians who care for patients should also contribute to research priority-setting. In this protocol, the term “care provider” 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 on dialysis, as well as patients with severe kidney disease who are considering renal replacement therapy options.

Unless they are eligible to receive a kidney transplant, people with kidney failure require hemodialysis or peritoneal dialysis as a life-sustaining therapy, and these patients and their care providers become “experts” in their disease. Despite important advances in treatment, the quality of life of most dialysis patients is often adversely affected, and considerable responsibilities are placed upon them and their care providers. For instance, care providers may be required to assist patients with kidney failure in administering their dialysis therapy in the home setting, care for their numerous physical and psychological co-morbidities, and support them with their medical procedures and appointments. Thus, dialysis as a condition is one in which consulting patients, care providers 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 care providers 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 Failure 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, care providers and clinicians, and then to prioritise the questions which patients and clinicians agree are the most important.

The objectives of this PSP are:

- To work with patients, care providers and clinicians to identify uncertainties about management of the disease (in terms of diagnosis, prognosis, treatment, and anything else).
- 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 dialysis patients, including patients on both peritoneal and haemodialysis (both in-centre and home dialysis modalities), and people with severe kidney disease not yet on dialysis (judged to be within one year of the need for dialysis by their clinician).
- Carers of people who are dialysis patients
- Medical doctors, nurses, pharmacists, social workers and other professionals with clinical experience interacting with patients on dialysis

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, care providers 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

The administrative process for convening this meeting will be managed by Erin Lillie and Andreas Laupacis at St. Michael's Hospital, Toronto.

Following the meeting, organisations which have decided to participate in the PSP will be asked to complete a declaration of interests, including disclosing relationships with the pharmaceutical, device and dialysis product industries.

3. Identifying treatment uncertainties

Potential research priorities will be identified by means of a survey (available in electronic and paper-based format) of patients, their care providers and clinicians. A period of 3 months will be given to complete this exercise.

Patients and care providers will be contacted in two ways. First, we will post a questionnaire on the web site of CANN-NET, with links on the websites of the Kidney Foundation of Canada and the Canadian Society of Nephrology. 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 dialysis; and by dialysis units and clinics across Canada who will make their patients aware of the questionnaire. We expect the online survey to be "open" for 2-3 months.

Second, because many patients on dialysis are not web-savvy, and because sicker dialysis patients are less likely to respond to the approach mentioned above, a finite number of Canadian dialysis centres (between 6-10) will provide hard copies of the questionnaire to their patients, and invite them to complete the questionnaire (with the option to complete the questionnaire online if they prefer). These dialysis 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, and a mixture of in-centre hemodialysis, home hemodialysis, and peritoneal dialysis.

The background information (to be included in the survey) 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 non-identifiable data will be requested in the survey: age group, gender, ethnic group, geographic location, whether the participant is a patient, care provider, health professional, or member of an organisation representing people with kidney failure on dialysis. Patients and care providers will be asked if they (or the patient they are caring for) are about to start dialysis; are on peritoneal or hemodialysis dialysis; are receiving dialysis at home or in a satellite/clinic setting. 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 will complete the surveys anonymously. At the present time, we have not decided whether or not to enter the uncertainties into UK DUETS (www.library.nhs.uk/duets); if we were to pursue this option, permission of participants would need to be obtained in order for the uncertainties to be published.

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 dialysis and/or kidney failure. 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 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 and clinicians.

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/care providers and clinicians. This meeting will be facilitated by Sally Crowe from Oxford, UK who has extensive experience facilitating JLA priority-setting meetings.

Findings and research

It is anticipated that the findings of the dialysis 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 2012 - August 31, 2012	Month: September 1 – November 30, 2012	Month: December 1 – February 28, 2013	Month: March- April 2013
Goal: Identify partners, develop taxonomy and survey	Goal: Survey distribution	Goal: Development of interim list of research priorities	Goal: Final priority setting meeting

Signed by the Steering Group

The undersigned agree to follow the Dialysis Priority Setting Protocol.

[Insert name and organisation]

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Date:

[Insert name and organisation]

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Date:

[Insert name and organisation]

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Date:

[Insert name], The James Lind Alliance

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Date: