Establishing a Core Outcome Set for Peritoneal Dialysis: Report of the SONG-PD (Standardized Outcomes in Nephrology–Peritoneal Dialysis) Consensus Workshop

Karine E. Manera, David W. Johnson, Jonathan C. Craig, Jenny I. Shen, Talia Gutman, Yeoungjee Cho, Angela Yee-Moon Wang, Edwina A. Brown, Gillian Brunier, Jie Dong, Tony Dunning, Rajnish Mehrotra, Saraladevi Naicker, Roberto Pecoits-Filho, Jeffrey Perl, Martin Wilkie, and Allison Tong, on behalf of the SONG-PD Workshop Investigators

Outcomes reported in randomized controlled trials in peritoneal dialysis (PD) are diverse, are measured inconsistently, and may not be important to patients, families, and clinicians. The Standardized Outcomes in Nephrology–Peritoneal Dialysis (SONG-PD) initiative aims to establish a core outcome set for trials in PD based on the shared priorities of all stakeholders. We convened an international SONG-PD stakeholder consensus workshop in May 2018 in Vancouver, Canada. Nineteen patients/caregivers and 51 health professionals attended. Participants discussed core outcome domains and implementation in trials in PD. Four themes relating to the formation of core outcome domains were identified: life participation as a main goal of PD, impact of fatigue, empowerment for preparation and planning, and separation of contributing factors from core factors. Considerations for implementation were identified: standardizing patient-reported outcomes, requiring a validated and feasible measure, simplicity of binary outcomes, responsiveness to interventions, and using positive terminology. All stakeholders supported inclusion of PD-related infection, cardiovascular disease, mortality, technique survival, and life participation as the core outcome domains for PD.

Introduction

Peritoneal dialysis (PD) is a cost-effective dialysis modality that enables patients to have a greater degree of autonomy and freedom compared with hemodialysis. However, major challenges to the uptake and longevity of PD remain, including technique failure, infection, catheter problems, and treatment burden. Despite the increasing number of trials aiming to improve outcomes for patients receiving PD, the evidence for interventions to improve patient-important outcomes remains limited by the predominant use of surrogate end points that have not been validated and highly heterogeneous outcomes, many of which may not be relevant to patients.

Mortality and technique failure are reported in only 38% and 29% of trials, respectively. Outcomes related to quality of life, including flexibility with time, the ability to travel or work, and fatigue, are of high priority for patients receiving PD and their families. However, quality of life is reported in <15% of trials in PD, and fatigue, in <5% of trials. The absence of patient-important outcomes in trials in nephrology and other medical specialties is well recognized. Initiatives such as the Core Outcome Measures in Effectiveness Trials (COMET), Outcome Measures in Rheumatology (OMERACT), and Standardized Outcomes in Nephrology (SONG) have been launched to bring together patients, caregivers, and health professionals to identify critically important outcomes, to ensure that trials consistently report relevant and meaningful outcomes to better inform shared decision making.

The SONG-PD initiative commenced in 2016 and aims to develop a core outcome set to be reported in all trials in PD. A core outcome set is defined as an agreed minimum set of standardized outcomes to be measured and reported in all trials in a defined clinical population. Having identified a consensus-based prioritized list of outcome domains through an international online Delphi survey, a consensus workshop was convened for patients, caregivers, and health professionals to review and discuss the potential core outcome domains. The aim of this workshop report is to describe stakeholders’ perspectives and considerations on the core outcome set for PD and to establish the core outcome set to be used in all trials in PD.

SONG-PD Consensus Workshop

Overview and Context

The SONG-PD consensus workshop was convened at the 17th Congress of the International Society for Peritoneal Dialysis (May 7, 2018) in Vancouver, Canada, to elicit stakeholder perspectives on the potential core outcome set for PD. The potential core outcomes were based on data from an international 3-round Delphi survey that was completed online by patients, caregivers, and health professionals with experience or expertise in PD. The Delphi survey included outcome domains reported in trials in PD, as well as from previous studies with patients receiving PD. The SONG-PD process for establishing core outcome domains is shown in Figure 1.
Participants and Contributors

We invited patients and caregivers with current or previous experience of PD and health professionals (allied health, industry representatives, physicians, policy makers, researchers, and surgeons) to attend the workshop. This was the first Congress of the International Society for Peritoneal Dialysis to actively invite patients and caregivers to attend, and those who registered for the conference were invited to the SONG-PD workshop. Patients/caregivers who attended the workshop received CaDS$30 reimbursement. Health professionals were purposively identified to include a range of practice locations, clinical experience, and roles in research, policy, and industry.

In total, 70 participants (19 patients/caregivers and 51 health professionals) attended the workshop. Patients/caregivers were from 13 countries, including Canada (n = 16), the United States (n = 2), and Hong Kong (n = 1). Health professionals were from 13 countries, including Canada (n = 12), the United States (n = 8), Australia (n = 8), United Kingdom (n = 5), Singapore (n = 4), Hong Kong (n = 3), Brazil (n = 3), Belgium (n = 2), Japan (n = 2), Bangladesh (n = 1), Lebanon (n = 1), Poland (n = 1), and South Korea (n = 1).

Workshop Program and Materials

Participants received the workshop program 1 week in advance. During the workshop, an overview of the SONG-PD process, results of the Delphi survey, and a list of potential core outcomes were presented. Participants were allocated to 7 breakout groups with 8 to 12 members, and each group included patients/caregivers, physicians, policy makers, and industry representatives to allow for a diverse exchange of ideas, knowledge, and experience. Each facilitator was provided with a question guide (Item S1) before the workshop.

Facilitators asked participants to reflect and comment on the potential core outcomes identified in the SONG-PD Delphi survey. Three to 5 outcome domains are recommended in a core outcome set for feasibility and should include at least 1 patient-reported outcome (ie, an outcome that is directly reported by the patient and reflects how they feel or function). Seven outcome domains were identified as critically important from the Delphi survey: PD-related infection, membrane function, PD failure, cardiovascular disease, catheter complications, death, and life participation. Although fatigue did not meet the threshold ratings for critical importance, it was the second highest rated patient-reported outcome. Therefore, we included questions about combining clinical outcomes (PD infection, membrane function, and catheter complications) and selection of a patient-reported outcome (life participation or fatigue). During the final plenary discussion, the Chair (D.W.J.) asked the nominated speaker from each breakout group to provide a summary of their discussion.

All breakout and plenary discussions were audiotaped and transcribed. Transcripts were entered into HyperResearch (ResearchWare Inc, version 3.0) to facilitate coding and analysis of the data. K.E.M. inductively identified and coded concepts into themes reflecting the range of perspectives on the core outcome domains for PD.
Box 1. Selected Quotations From the Workshop Discussions to Illustrate Each Theme

**Identification of Core Outcomes**

**Life participation as a main goal of PD**

*Reflecting the need for flexibility and freedom*

“People that choose PD want to participate [in life], do all these other things. It’s the reason why they selected PD, that’s what brings value in their selection of PD, and studying what the intervention does to that may be more meaningful than studying fatigue.” [G3, health professional]

“…I find being able to work and have a life is super important with PD and being on PD, and having the choice doing PD.” [G3, patient]

“Life participation, being able to work, being able to maintain that schedule and flexibility and travel is super important. To me I’ll put that higher.” [G3, patient]

**An indicator of treatment success**

“It always bugs me just a little bit when, with each visit to my PD department, the nurses, the social workers, they come around and they want to know are you eating? How are you doing with it, are you still comfortable doing your PD? What they don’t ever ask at all is are you doing anything outside of it? Are you maintaining your activity? Are you putting in your interest time? Have you still got your hobby you’re doing? Any number of things like that I think would be a more important tell of where the patient was.” [G7, patient]

“If you told me that someone’s fatigue on PD went up and down depending on the time of the day, the day of the week, the month of the year, the season. I would be less inclined to say this is a standard outcome where depending on when you catch the patient you’re going to get a different metric of fatigue, whereas if life participation activities was like the hemoglobin A1c of an overall outcome like I would think from day to day would fluctuate less, so a more robust measure over time.” [G1, health professional]

“I’d be more interested in the paper that tells me about life participation because I think that more holistically covers what I’m more interested in about my life.” [G1, patient]

**Impact of fatigue**

“As a caregiver, I would like to say that fatigue for my client is probably the number one issue. It relates more work for the caregiver and the lack of exercise, the lack of get-up-and-go, the lack is a constant worry that things are diminishing. As a caregiver I would think that this is an important thing to be discussing. As a client, he’s probably… this is nice, I’ll just turn on the TV.” [G6, caregiver]

“The more tired, the more discouraged, or the more sick and weak one feels, the less you’re going to do.” [G7, patient]

“I went to school and I still did everything but I was still tired. I participated in what I wanted to do, but I probably picked and chose what I could do.” [G2, patient]

“I’ll say there’s also the component of emotional fatigue. Sometimes for people who have been doing PD for such a long time, they’re just exhausted emotionally about the day in, day out of having these tasks that they have to do.” [G6, health professional]

**Empowerment for preparation and planning**

“I know nowhere near enough detail about the process that you people do, but as far as I’m concerned, that membrane is the only thing that’s diffusing the stuff out of me. If it isn’t doing it, I’m back in hemo[dialysis] which I don’t want. Literally, that is my definition of failure.” [G7, patient]

“I really believe [membrane function] is an important one, because I was not aware of it until it happened to me. When I went on PD, I thought I’ll be on PD until I get a transplant. Then four years ago, they said no. No more, it’s not working. I was shocked because I didn’t know that was something that could happen. I think that’s very important. Extremely important.” [G5, patient]

“With the membrane function, I think as patients it’d be nice to know about what it is exactly and the tests, any tests, the results of the tests and stuff to know so that we have more information. Because I know sometimes as patients we want to know all the information [about our membrane function], because then later on if something happens then we can understand, okay, when they’re explaining it to us. Okay, that makes sense and this is why. Getting more information for patients, I think is a huge thing. Having to know membrane function would be nice.” [G3, patient]

**Separation of contributing factors from core**

“Membrane failure is a cause of technique failure and that’s the main issue with it. Catheter complications can be far less than technique failure, it can be pain or the catheter not working very well, which is very common.” [G2, health professional]

“If you report all catheter complications there’s tons of them happening all the time. And it really depends on the severity of them, and if it’s a core one it would be very difficult to track… If you restrict them to ones that are PD terminating or PD interrupting, then it’s a much shorter list. It’s kind of similar to membrane function, so I don’t think catheter complications in themselves should be a core measurement.” [G4, health professional]

“The failure of the technique is more important than the membrane as a core outcome for these trials.” [G5, health professional]

“It’s special because peritonitis in particular is an important thing to capture independent of its cause of failure.” [G5, health professional]“
### Standardizing patient-reported outcomes

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<tr>
<th>Considerations for Implementation</th>
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<tr>
<td>“Some people like to do more, some people like to do less, and so again I think the challenge will be to establish boundaries.” [G1, health professional]</td>
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<tr>
<td>“For each individual person, it will be slightly different. There are some people that just want to be able to go to the shops every day…Whereas some people want to go back to work.” [G4, health professional]</td>
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<tr>
<td>“On the cultural side it will be very different. I guess socioeconomic status, developed and developing countries to have very standardized [measures of] life participation would be quite hard.” [G1, health professional]</td>
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### Requiring a validated and feasible measure

| “When we do these trials and measure quality of life, we often have these instruments that are seventy questions, then we have you do them every three months, and there’s five different questionnaires. Would you have the appetite to answer those questions?” [G5, health professional] |
| “We need to abbreviate the instruments we use to measure your quality of life or your life participation to make them more manageable.” [G5, health professional] |
| “At the end of the day that’s the purpose, to try and identify what’s important and then find tools to measure how to effectively measure that outcome.” [G3, health professional] |

### Simplicity of binary outcomes

| “The way I look at it PD failure is like a mortality outcome, you die, PD is not working you have to switch to HD. Membrane functioning is different.” [G1, health professional] |
| “Technique failure may be an easier thing to identify in a binary fashion. You are on PD or you’re not on PD, whereas evaluating membrane function may have different metrics depending on the researcher that’s doing it, and that may make standardizing this as a reportable outcome difficult.” [G1, health professional] |
| “Membrane function is sort of an esoteric [outcome]. It’s whether it works or not, that’s tangible.” [G7, health professional] |

### Responsiveness to interventions

| “You could end up with trials that have got nothing to do with the membrane at all having to do membrane function tests simply to answer this part of the question and that actually adds burden to the trial, it really could be a negative thing.” [G1, health professional] |
| “If you’re laying a blueprint that’s going to put this burden on every single study that’s going to be conducted for the rest of time, you really have to think of the cost implications.” [G4, health professional] |
| “If we are talking about the outcomes for clinical trials, there may be trials looking at aspects we hardly imagine would affect membrane function. We would always be interested to know whether there is any effect on PD failure. Say for example, we talk about treatment of anemia in PD patients—why on earth do we report membrane function?” [G5, health professional] |

### Using positive terminology

| “Failure does sound like something scary.” [G4, patient] |
| “The worst is when I’ve heard staff say ‘oh the patient failed PD.’ Of course you didn’t fail PD.” [G3, health professional] |
| “Our table was trying to not use the pejorative in PD failure, but talking about technique survival, modality transitions, and it was unanimous.” [G3, health professional] |
| “From a patient point of view it sounds very negative, PD failure, it fails. But actually it may be the right thing, if somebody’s come off PD.” [G4, health professional] |

Abbreviations: G, group; HD, hemodialysis; PD, peritoneal dialysis.

### Identification of Core Outcome Domains

**Life Participation as a Main Goal of PD**

Reflecting Need for Flexibility and Freedom. The reasons why patients chose PD as their preferred treatment modality included the desire to have the flexibility and autonomy to enable patients “to work and have a life.” Some patients emphasized the importance of life participation in PD by comparing it to their experiences on hemodialysis: “with PD I find I can work and I can do more things. You have your fatigue days and weeks maybe, but it’s way better than sitting at home and not working, and not having to worry about not being able to work.” For these reasons, many participants prioritized life participation over fatigue as the core patient-reported outcome. **An Indicator of Treatment Success.** Participants regarded life participation to be as important as key clinical outcomes, such as cardiovascular disease, infection, or mortality, explaining that simply by being alive you could be “a success from the medical point of view,” but this did not take into account many important aspects of the patient’s life, including their interests, activities, or hobbies. Some health professionals thought that life participation “from day
Box 2. Key Workshop Recommendations for Establishing and Implementing Core Outcome Domains for PD

Core outcome domains for PD should:
- capture the patient priorities of life participation.
- reflect patient goals of maximizing technique survival (ie, avoiding transfer to hemodialysis).
- be relevant for patients from all backgrounds and cultures.
- be attributed to a single outcome (ie, not combining multiple related outcome domains). Factors contributing to low technique survival or life participation may be disaggregated and addressed separately in trials if researchers wish to do so.

Implementation of core outcomes requires:
- outcome measures validated in the PD population.
- ease of administration with minimal additional resources.
- positively framed or neutral terms.

Abbreviation: PD, peritoneal dialysis.

Impact of Fatigue
Participants recognized that fatigue was a “major factor” that affected patients and could make a patient feel “totally wiped out.” While fatigue was recognized by some participants as its own distinct issue, many participants were concerned about the effects of fatigue on a patient’s ability to participate in life. Caregivers expressed that it “prohibits [the patient] to do things,” creates “more work for the caregiver,” and results in diminished quality of life for the patient because they “couldn’t do the usual small things that [they] would like.” Patients discussed how they could “continue to do what they choose to do, but it might not be to the best of their ability because of their fatigue,” suggesting that it is important to recognize not just one’s ability to do something, but “how bad you feel when you try to do something.” Some participants also considered fatigue to incorporate a mental component, including emotional fatigue and depression, which they thought was a “tremendously important aspect that needs to be dealt with.”

Empowerment for Preparation and Planning
When considering the proposed core clinical outcomes, patients thought that it was extremely important to be mentally and physically equipped to deal with potential PD failure because there was a “fear and expectation that things have to go well.” Some patients thought that they knew “nowhere near enough detail about the process” and were “shocked” when they experienced unexpected complications such as membrane failure and had to transition to hemodialysis. Patients wanted more information about their membrane function to be best able to keep themselves “on the healthy side of the line” because it was generally agreed that “what matters to [patients] is how long they can stay on PD.”

Separation of Contributing Factors From Core
Participants acknowledged that both membrane function and catheter complications were contributing factors to PD...
Considerations for Implementation

Standardizing Patient-Reported Outcomes
Participants discussed the subjectivity of life participation and agreed that it “depends how much people want to do” and would be “understood differently for different people.” This was particularly pertinent when considering the applicability of this outcome across countries because it was recognized that the “culture difference[s]” would result in varying levels and preferences for life participation. Participants also thought that there may be “many aspects of life participation that you may want to assess” because some patients may consider life participation as being able to “go to the shops,” while for others, it may mean being able to “go back to work.”

Requiring a Validated and Feasible Measure
Participants agreed that there was “no validated way of measuring life participation” and so conferred about existing instruments that measured similar concepts, such as quality of life. Health professionals commented that these existing instruments were “really difficult” and ask “too many questions”; therefore, the measure for life participation needs to be “more manageable” than existing related measures. Some participants recognized that fatigue was a core outcome in hemodialysis (SONG-HD) and thought that it might be appealing to have the same outcome for both dialysis modalities to facilitate uptake of the patient-reported outcome and enable comparison across modalities. However, participants agreed that it was necessary to identify what outcomes are most important for PD.

Simplicity of Binary Outcomes
Health professionals considered the effort required to measure the clinical core outcomes in all trials and thought that an outcome measured in a binary way, such as mortality or PD failure, would be “an easier thing to identify” and standardize as a reportable outcome: “death is very easy to measure, because it’s just yes or no, did it happen. That wouldn’t be a big deal to layer death into every single trial that’s ever done.” Some health professionals also agreed that it is “much easier to measure PD failure” than membrane function because it is more “tangible” and “like a mortality outcome”−−“you are on PD or you’re not on PD.” However, others recognized the nuances and complexities of defining and measuring PD failure because there are different “levels of interruption or delay” that should not necessarily be considered PD failure, hence the need for a standardized definition.

Responsiveness to Interventions
When considering the applicability of the potential core outcomes to PD trials, health professionals thought that outcomes, such as membrane function and catheter complications, were “not really relevant” and “just not practicable” as core outcomes to be reported in all trials. They believed that the resources required to measure and report outcomes that are not relevant to all interventions would place a “burden on every single study.” However, health professionals believed that some critically important outcomes, including PD-related infection, cardiovascular disease, mortality, and PD failure, should always be reported regardless of the intervention; “we would always be interested to know whether there is any effect on PD failure.”

Using Positive Terminology
Participants thought that the inclusion of the word “failure” in the outcome “PD failure” was considered “pejorative” and a “negative term.” Some patients thought that failure “sound[s] like something scary” and health professionals also noted that there is “a very negative connotation that shifts everybody’s attitudes a certain way” when a patient discontinuing PD for any reason is termed a failure. Positively framed alternatives were suggested, including “technique survival” and “modality transitions.” Participants also believed that researchers “need to be really clear” what they mean by PD failure because there are many reasons why a patient may discontinue PD and that “it may be the right thing if somebody’s come off PD,” therefore it should not be perceived as a failure; “When I hear PD failure I’m assuming that it is a not feasible anymore period. It has nothing to do with me quitting.”

Postworkshop Consultation
All participants received a draft workshop report and were asked to provide feedback within a 2-week time frame. The SONG-PD core outcome set (Fig 2) was also sent to all participants for review and comment and was uploaded on the SONG website for feedback and comment (https://songinitiative.org/projects/song-pd/). Feedback was integrated into the final report, and the findings from the
workshop were used to establish the SONG-PD core outcome domains.

**Discussion**

Patients who participated in the workshop valued the flexibility of PD therapy and wanted to preserve and prolong technique survival and avoid transfer to hemodialysis, which were critical for consideration in identifying the core outcome domains. Fatigue was recognized as a potentially debilitating symptom that could impair life participation. Clinical outcomes (ie, membrane function and catheter complications) that did not necessarily lead to irreversible PD technique failure were not considered eligible for use as core outcomes to be reported in all trials. Key considerations for implementing the core outcome domains included the need to establish a validated measure for life participation that is simple to administer and applicable to all patients, including those in low- and middle-income countries. Although there was overlap among life participation and fatigue, as well as membrane function and PD technique failure, participants believed that separating these into single-attribute outcomes was better for clarity. Health professionals acknowledged the burden of outcome measurement in trials and therefore agreed that the core outcomes need to reflect what is most important for all stakeholders to know.

The discussions from this workshop have been used to establish the core outcome domains to be reported in PD trials and other forms of research (Fig 2). Participants agreed that the core outcome domains for PD should include PD-related infection, cardiovascular disease, mortality, technique survival, and life participation. PD-related infection, cardiovascular disease, and mortality were identified in both the Delphi survey and workshop discussions as core outcomes to be reported in all PD trials regardless of intervention type. Technique survival, which was reworded from PD failure to be positively framed, was regarded by all stakeholders as a highly consequential and relevant outcome, and as such it was included as a core outcome domain. Membrane function and catheter complications were not sufficiently relevant for all trials and were moved to the middle tier. Life participation was included as the core patient-reported outcome domain, which reflects the priorities of patients who participated in the workshop and prior Delphi survey and reinforces the reason for choosing PD as a dialysis modality. Some health professionals challenged its inclusion due to measurement difficulties, but participants believed that separating these into single-attribute outcomes was better for clarity.

Fatigue was recognized as one aspect that affects the overall life participation for patients receiving PD, but other factors, including the need to perform exchanges multiple times a day and having to be constantly vigilant to avoid infection, have also been reported to impact on life participation. In comparison, for patients receiving hemodialysis, fatigue has been reported as a predominant concern and one of the main symptoms that affects quality of life.

Although workshop participants remarked that no validated measures for life participation were available for the PD population, they may not have considered potentially suitable existing measures (or subscales for life participation). We will conduct subsequent studies including a systematic review of measures for life participation in PD and a consensus workshop on life participation. We will identify whether an existing measure is sufficient or there is the need to modify an existing measure or develop a new outcome measure for life participation. In accordance with the Consensus-based Standards for the Selection of Health Measurement Instruments–COMET (COSMIN-COMET) framework, we will conduct further work to validate the potential measure to ensure that it is appropriate for use in the PD population.

We acknowledge that the number of participants at this workshop was relatively small. However, the outcomes discussed at this workshop were informed by a large international Delphi survey completed by more than 800 participants, including patients, caregivers, health professionals, regulators, and industry. We have also conducted a separate workshop on the implementation of core outcome sets in nephrology (including SONG-PD), which involved regulators and industry and will be used to inform strategies for implementing this core outcome set in trials.

Subsequent core outcome measures for each of the outcome domains will need to be developed based on the workshop recommendations outlined in Box 2. This includes the need for standardized outcome measures that...
are easily administered and validated in the PD population and do not impose an excessive burden to trials. This will facilitate the acceptance and uptake of the core outcomes so that trials and research in PD report outcomes that are important to patients, their families, and clinicians.

**Supplementary Material**

**Supplementary File (PDF)**

**Item S1:** Breakout discussion questions.

**Article Information**

**SONG-PD Consensus Workshop Investigators:**
Health Professionals: Adeera Levin, PhD, Adrian Liew, MD, Alfonso Cueto Manzano, MD; Ali Abu Alfa, MD; Alicia Neu, MD; Allison Tong, MD; Aamanda Baumgart; Amelie Bernier-Jean; Amy Kelly; Ana Figueiredo; Andrea Matus; Andrea Veeckel; Angela Ju; Angela Yee-Moon Wang; Anjali Saxena; Ankit Sharma; Anne-Claire Nadeau-Fredette; Armando Teixeira-Pinto; Asher Mendelson; Ayano Kelly; Bak Leong Goh; Benedicte Sautenet; Braden Manns; Brenda Hemmeglern; Bruce Robinson; Camilla Hanson; Catherine Cheung; Chandana Guha; Charlotte Logeman; Cheuk-Chun Szeto; Claudia Rutherford; Daniel Schwartz; Daniel Sumpton; David Johnson (Chair); David Wheeler; Edwina Brown; Emma O’Lone; Eric Au; Eric Goffin; Fred Finkelstein; Georgi Abraham; Gillian Brunier; Greg Gemmio; Helen Hurst; Hideki Kawanishi; Htay Htay; Hui Kim Yap; Iacov Teitelbaum; Jeffrey Port; Jenny Chen; Jenny Shen; Jie Dong; Joanna Neumann; Joanne Bargman; Johann Morelle; Jonathan Craig; Kajru Gadi Kilonzo; Karen Yeates; Karine Manera; Karolis Azukaitis; Kim Linh Van; Louise Dunn; Mahesh Krishnan; Mark Lambie; Martin Howell; Martin Schreiber; Martin Wilkie; Matthew Oliver; Mauricio Rafael Sanabria; Melissa Nataatmadja; Monika Lichodziejewska-Niemierko; Nancy Verdin; Neelam Mann; Neil Boudville; Nicole Evangelidis; Nicole Scholes-Robertson; Peter Blake; Peter Nourse; Peter Tugwell; Philip Kam-Tao Li; Rajnish Mehrrota; Richard McGee; Robert Quinn; Roberto Pecotic-Filho; Sally Crowe; Samaya Anumud; Sarah Bernays; Sarara Naicker; Scott Wilson; Sharon Nessim; Sharon Teo; Simon A. Carter; Simon Davies; Soheli Ahmed Sweety; Talia Gutman; Ted Toffelmire; Vanita Jassal; Vivekanand Jha; Viviane Calice da Silva; Wim Van Biesen; Wolfgang Winkelmayer; Yasuhiko Ito; Yeounghee Cho; Yong-Lim Kim; Zeeshan Butt; University of British Columbia, CA; Tan Tock Seng Hospital, SG; Salvador Zubirán National Institute of Health Sciences and Nutrition, MX; American University of Beirut, LB; Johns Hopkins University School of Medicine, US; The University of Sydney, AU; Pontifical Catholic University of Rio Grande do Sul, BR; The Children’s Hospital at Westmead, AU; University of Queensland, AU; Queen Mary Hospital, The University of Hong Kong, HK; Stanford University, US; Hôpital Maisonneuve-Rosemont, CA; Western University, CA; Australian National University, AU; Serdang Hospital, MY; University of Tours, FR; University of Calgary, CA; Arbor Research Collaborative for Health, US; Fraser Health Authority, CA; Chinese University of Hong Kong, HK; University College London, UK; Imperial College London, UK; Université catholique de Louvain, BE; Bridgeport Hospital, US; Pondicherry Institute of Medical Sciences, IN; Sunnybrook Research Institute, CA; National Institute of Diabetes and Digestive and Kidney Diseases, US; Manchester University Foundation Trust, UK; Tsukiji General Hospital, JP; Singapore General Hospital, SG; National University of Singapore, SG; University of Colorado Hospital, US; University of Toronto, CA; Prince of Wales Hospital, AU; University of California, US; Peking University, CN; Satellite Healthcare, US; Cliniques universitaires Saint-Luc, BE; Finders University, AU; Kilimanjaro Christian Medical Centre, TZ; Queen’s University and Kingston Health Sciences Centre, CA; Vânis University, LT; University of Sheffield, UK; DaVita, US; Keele University, UK; NHS Sheffield Teaching Hospital, UK; Universidad De Los Andes, CO; Medical University of Gdansk, PL; Alberta Health Services, CA; University of Western Australia, AU; Red Cross War Memorial Children’s Hospital, ZA; University of Ottawa, CA; University of Washington, US; Pontifícia Universidade Católica do Paraná, BR; Crowe Associates Ltd, UK; Baylor College of Medicine, US; Wits University, ZA; Monash University, AU; McGill University, CA; University Hospital of North Midlands, UK; Dhaka Medical College Hospital, BD; Fresenius Medical Care, CA; The George Institute for Global Health, IN; Universidade Católica de Pelotas, BR; University of Ghen, BE; Nagoya University, JP; Kyungpook National University School of Medicine, KR; Northwestern University, US. Patients/Caregivers: Agnes Lau, HK; Allen Chi, CA; Ana Tepper, CA; Annette Spence, CA; Bruno Rossi, CA; Carol Wilcox, CA; Chris Coello, CA; Dave White, US; Denise Eilers, US; Derek Forfang, US; Elise Meyers, CA; Gary Froats, CA; Gurjit Pawar, CA; Julie Yuen, CA; Joan Froats, CA; Lana Wong, CA; Larry Wilcox, CA; Leroy Spence, CA; Marielle Schelp, CA; Marjorie Lindo, CA; Nicole Jefferson, US; Nieltee Gedney, US; Patrick Gee, US; Rachel Rossi, CA; Sandford Schelp, CA; Sharon Kidwell, CA; Sheila Le Motte, CA; Stanley Wong, CA; Tress Harris, UK; Tony & Sue-Ann Dunning, AU.

**Authors’ Full Names and Academic Degrees:**

Karine E. Manera, MPH, David W. Johnson, PhD, Jonathan C. Craig, PhD, Jenny I. Shen, MD, Talia Gutman, MPH, Yeounghee Cho, PhD, Angela Yee-Moon Wang, PhD, Edwina A. Brown, MD, Gillian Brunier, MScN, Mary Chain, MD, Australia, CA; Martin Howell, MBBS, FRCP; Karine Manera, MD, PhD, Roberto Pecotic-Filho, PhD, Jeffrey Perl, MD, Martin Wilkie, MD, and Allison Tong, PhD.

**Authors’ Affiliations:**

Sydney School of Public Health, University of Sydney (KEM, TG, AT); Centre for Kidney Research, The Children’s Hospital at Westmead, Sydney, NSW (KEM, TG, AT); Department of Nephrology, Princess Alexandra Hospital (DWJ, YC); Australasian Kidney Trials Network, School of Medicine, University of Queensland (DWD, YC); Translational Research Institute (DWD, YC); Centre for Kidney Disease Research, University of Queensland at Princess Alexandra Hospital, Brisbane (DWD); College of Medicine and Public Health, Flinders University, Australia (JCC); Division of Nephrology and Hypertension, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, Torrance, CA (JIS); Department of Medicine, Queen Mary Hospital, University of Hong Kong, Hong Kong (AY-MW); Imperial College Renal and Transplant Centre, Hammersmith Hospital, London, United Kingdom (EAB); Sunnybrook Research Institute, Toronto, Ontario, Canada (GB); Renal Division, Department of Medicine, Peking University First Hospital, Beijing, China (JD); South Bank TAFE, Brisbane, Australia (TD); Kidney Research Institute and Harbormedical Center, Division of Nephrology/Department of Medicine, University of Washington, Seattle, WA (RM); Department of Internal Medicine, School of Clinical Medicine, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa (SN); School of Medicine, Pontificia Universidade Católica do Paraná, Curitiba, Paraná, Brazil (RP-F); Arbor Research Collaborative for Health, Ann Arbor, MI (RP-F); Division of Nephrology, Department of Medicine, St. Michael’s Hospital, University of Toronto, Toronto, Ontario, Canada (JP); and Department of Nephrology, Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, United Kingdom (MW).

**Address for Correspondence:**
Karine E. Manera, PhD, Centre for Kidney Research, The Children’s Hospital at Westmead, Westmead, NSW 2145, Sydney, Australia. E-mail: karine.manera@sydney.edu.au
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