STANDARDISED OUTCOMES IN NEPHROLOGY-

Glomerular Disease

(SONG-GD) WASHINGTON DC WORKSHOP: PROGRAM AND REPORT

CONFIDENTIAL | VERSION 01 | 5 NOV

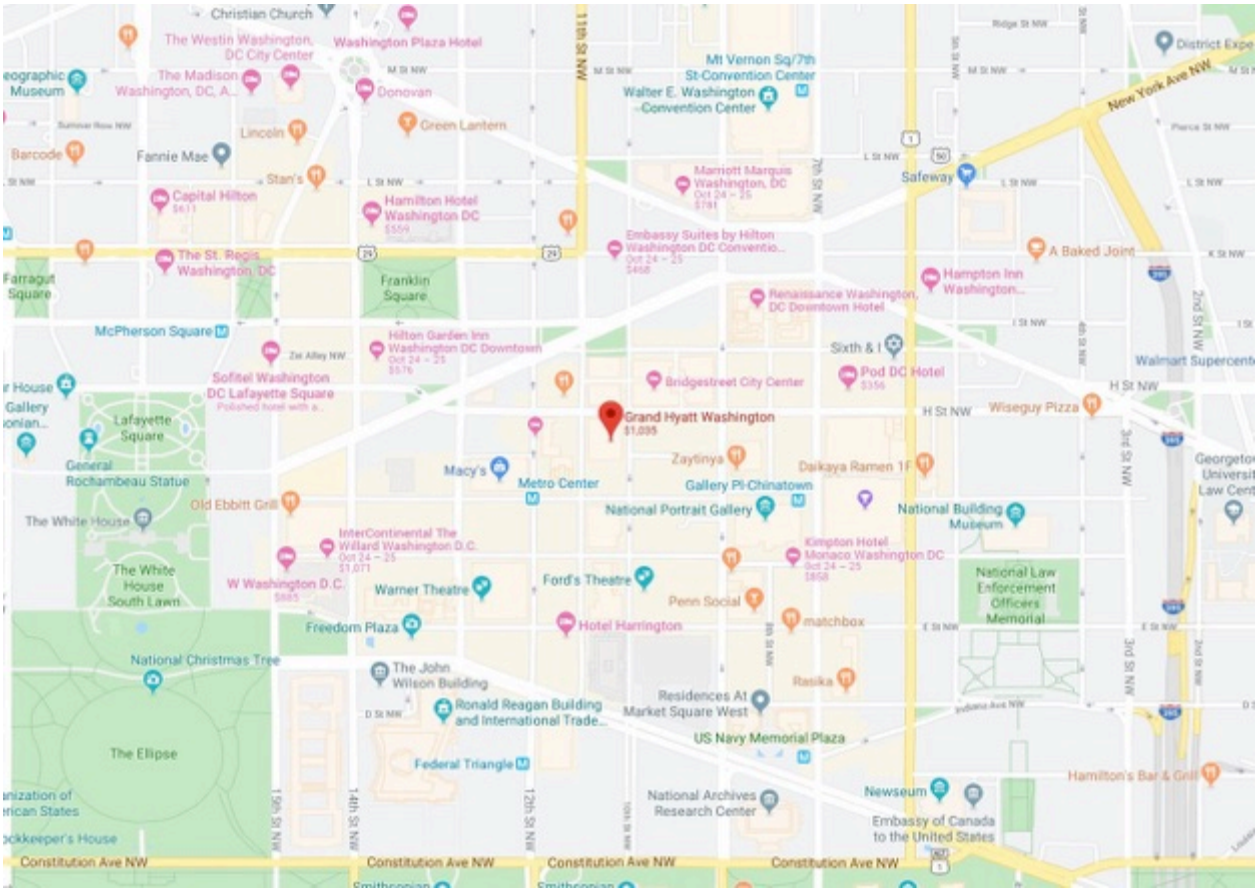
Contents

1 | Workshop details

Time: 12:30 pm – 2:00 pm (*please try to arrive by **12:15 pm** for a 12:30 pm start)*

Date: Saturday 9th November 2019

Location: Constitution Ballroom CDE Grand Hyatt 1000 H St NW, Washington DC 20001



Contacts

- Simon Carter +61467041123 simon.carter@health.nsw.gov.au
- Allison Tong allison.tong@sydney.edu.au

2 | Overview

The international SONG-GD Initiative aims to establish core outcomes for research in glomerular disease (GD) based on the shared priorities of patients, caregivers, clinicians, researchers, policy makers, and industry. This will help to ensure that research measures and reports outcomes that are meaningful and relevant to patients with glomerular disease, their families, and clinicians involved in their care.

Objectives

The objectives of the SONG-GD workshops are to:

- Provide an overview of the SONG-GD process and results
- Review and discuss the potential core outcomes set for research in GD
- Develop and discuss implementation strategies and action plans

Participants

This workshop brings together key stakeholders who have knowledge, experience or interest in GD outcomes for trials and other types of research. Participants will include patients who have knowledge or experience with GD and their family members, patient representatives, clinicians (nephrologists, nurses, allied health professionals), policy makers, regulators, funders, researchers and industry.

Materials

Each participant will be emailed a program that includes a report of the preliminary results of SONG-GD. A copy will be provided for each breakout group at the workshops.

3 | Program

Time	Session
12:00 – 12:45	Registration and lunch
12:45 – 12:50	Welcome and introduction to the SONG-GD Initiative *Jonathan Craig, Liz Lightstone*
12:50 – 1:05	Overview of the SONG-GD process and results *Simon Carter*
1:05 – 1:40	Break out discussion groups *Main facilitators: Liz Lightstone, Dan Cattran* • Review and discuss SONG-GD results
1:40 – 1:55	Plenary discussion with feedback from break out groups *Liz Lightstone, Dan Cattran*
1:55 – 2:00	Closing remarks *Liz Lightstone, Dan Cattran*

4 | Summary report

This report provides a brief summary of the SONG-GD process and preliminary results.

BACKGROUND

Glomerular disease (GD) includes many different diseases that affect the glomeruli (the filters in the kidney where the blood is cleaned). Kidney function in people with GD may be lost in a short period of time, or over many decades. People with GD may have a higher risk of mortality, cardiovascular events, and lower quality of life compared with the general population.

Common causes of GD include IgA and membranous nephropathy, focal segmental glomerulosclerosis, minimal change disease, C3 glomerulonephritis as well as systemic causes such as lupus nephritis and ANCA-associated vasculitis. The impacts of different types of GD are diverse but there are common key features (e.g. protein in the urine, high blood pressure), symptoms (such as swelling), treatments and all can lead to poor kidney function or kidney failure.

What is an outcome? In clinical trials, treatments are developed and tested by researchers to make sure they work and are safe. Researchers look at the effects those treatments have on patients and do this by measuring an "outcome". An outcome is something that can be measured, and can arise or change because of a health condition or treatment.

Core outcome set: an agreed standardised set of outcomes that should be reported, **as a minimum**, in all clinical trials in specific areas of health or healthcare because they are critically important to patients, caregivers and health professionals.

There are many clinical trials that have been conducted in people with GD to try and understand what treatments may be effective, but they do not always report outcomes that are important and meaningful to patients, family members and their clinicians. This means that the research may not be useful for informing decisions about treatment. Also, the outcomes are measured and reported in different ways, which makes it hard to compare the effect of treatments across the studies.

AIM

SONG-GD aims to develop a core outcome set for trials in glomerular disease that is based on the shared priorities of all stakeholders.

PROCESS

Identifying core outcome domains

SONG-GD follows a process that has been used in similar initiatives including the Outcome Measures in Rheumatology (OMERACT) and Core Outcome Measures in Effectiveness Trials (COMET). OMERACT outcomes have been endorsed by the World Health Organisation (WHO) and the US Food and Drug Administration, and have improved the reporting and relevance of outcomes in rheumatology trials. The process is outlined in the following:

Systematic review to identify outcomes that have been reported → **Nominal group technique** to identify outcomes important to patients and caregivers → **Stakeholder interviews** to elicit perspectives of health professionals → **International Delphi survey** to generate a prioritised list of core outcome domains based on consensus → **Consensus workshop** to review and discuss core outcome domains

Identifying outcome measures

The core outcome domains will inform subsequent work in the development and regular review of outcome measures for evaluating outcomes that are meaningful and relevant to users of the research – who are primarily patients and their clinicians.

INTERIM RESULTS | SONG-GD Delphi Survey (English)

The SONG-GD Delphi process

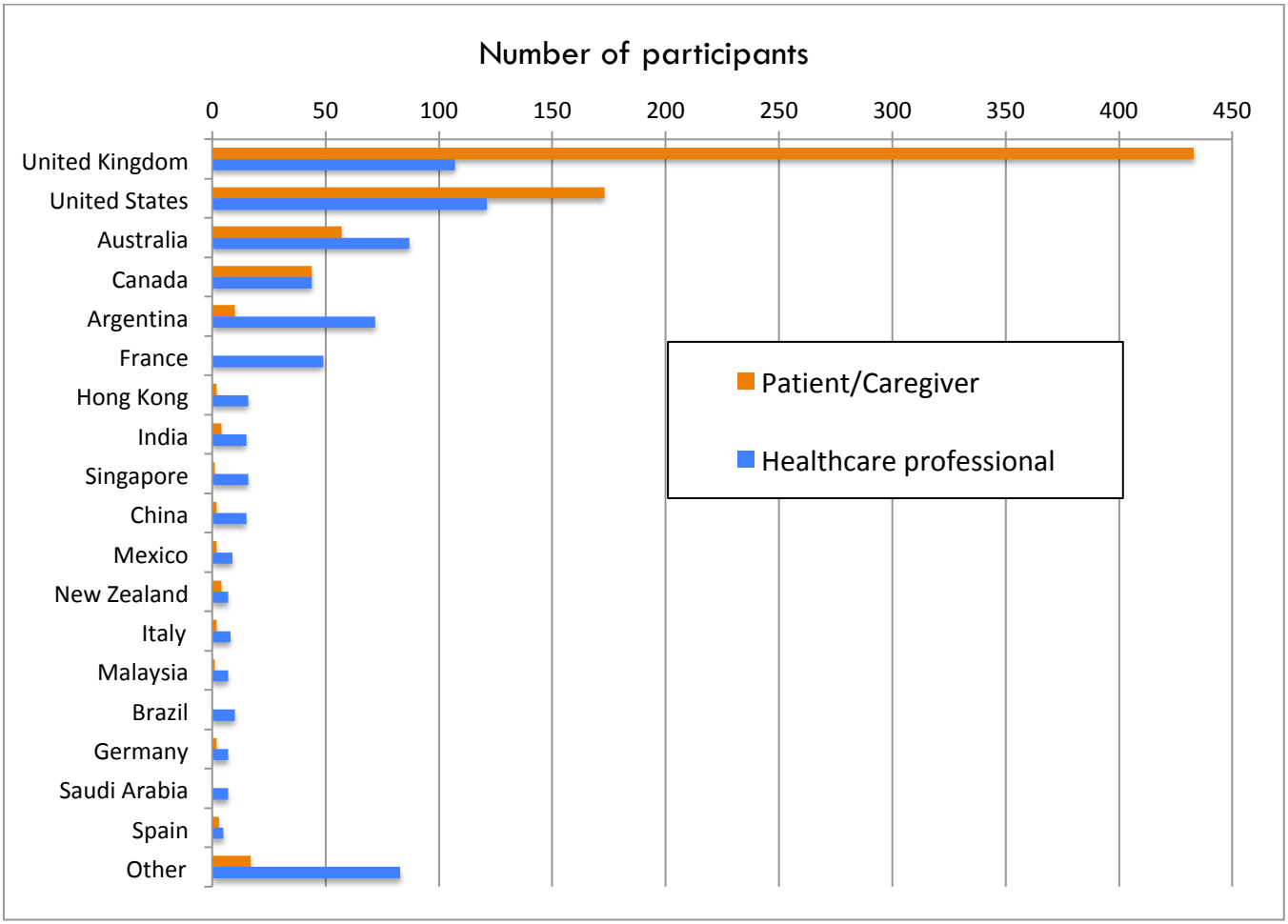
The preliminary results of the nominal groups and Delphi survey will be presented at the workshop. This section will provide an overview of the initial results from the SONG-GD Delphi Survey. The process and outcome definitions are provided in Appendices A and B.

The participants

Invitations to register for the Delphi survey were sent via recruiting hospitals, professional and patient partner organisations (see http://songinitiative.org/index.php/who-we-are/partners-and-supporters/). The following table shows the number of participants by stakeholder groups for round 1 and 2 to date.

Stakeholder group	Round 1	Round 2
Patients/caregivers	675	284 (42%)
Health professionals	579	257 (44%)
TOTAL	**1254**	**541 (43%)**

Figure 1. Round 1 completion rates by country and participant group. Participants were from 58 countries.



*Others: 40 countries with a total number of participants <5 (Belgium, Greece, Ireland, Philippines, Portugal, Viet Nam, Denmark, Republic of Korea, Austria, Bolivia, Egypt, Guatemala, Indonesia, Netherlands, Peru, Poland, Russia, Slovakia, Switzerland, Thailand, Turkey, Bangladesh, Bulgaria, Cape Verde, Chile, Colombia, Costa Rica, Cyprus, Czech Republic, Ecuador, Finland, Hungary, Montenegro, Myanmar, Pakistan, Romania, Serbia, South Africa, Sweden, United Arab Emirates)

Results | Outcomes and scores

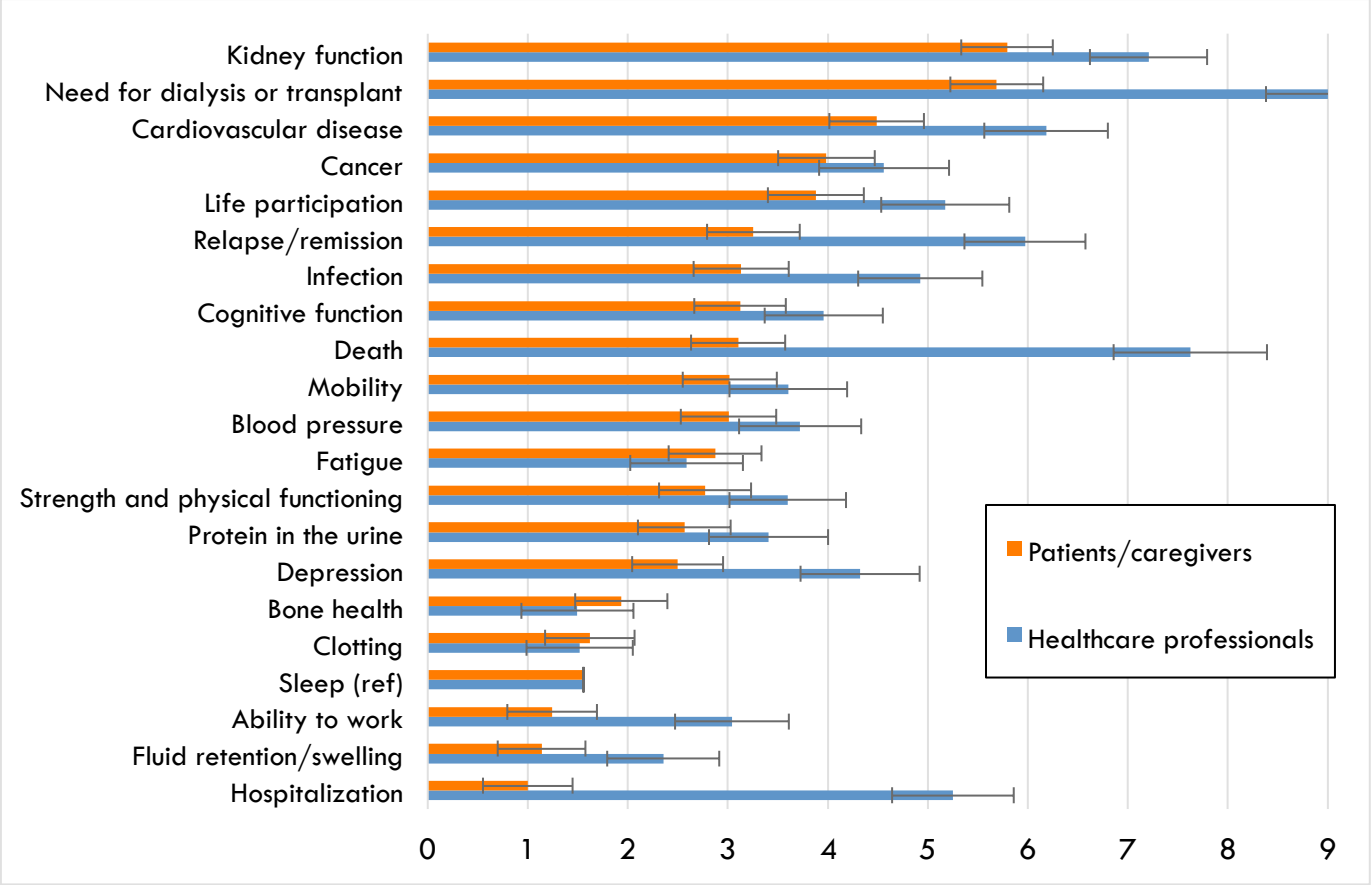
Round 1. 38 outcomes were included in Round 1. Outcomes were retained for Round 2 if for any group the mean was ≥7 and median ≥7 and at least 50% ranked the outcome as critical. Outcomes dropped from round 2 are still considered important but are not candidates for the core outcome set.

Round 2. The preliminary scores for outcomes in Round 2 are provided below. Outcomes in red are rated as having a mean of 8 or more by both patients and healthcare professionals and a median of 9.

	Mean			Median			Percentage scored 7-9 (critically important)		
	Patients	Carers	HCP	Patients	Carers	HCP	Patients	Carers	HCP
Kidney function	8.8	9.0	8.9	9	9	9	99	100	99
Need for dialysis or transplant	8.7	8.8	8.8	9	9	9	97	95	98
Life participation	8.4	8.4	8.2	9	9	9	95	95	93
Remission/Relapse	8.4	8.4	8.6	9	9	9	93	90	96
Blood pressure	8.4	8.4	8.3	9	9	9	95	95	93
Protein in the urine	8.4	8.5	8.4	9	9	9	92	95	91
Fatigue	8.3	8.1	7.8	9	8	8	95	95	88
Cardiovascular disease	8.3	8.7	8.4	9	9	9	92	100	97
Infection	8.3	8.6	8.4	9	9	9	94	100	96
Mobility	8.2	8.1	7.8	9	9	8	92	90	88
Cognitive function	8.2	8.4	7.9	9	9	8	92	90	87
Cancer	8.2	8.8	8.0	9	9	8	91	100	87
Physical functioning/strength	8.1	8.1	7.8	8	9	8	92	90	91
Death	8.1	8.7	8.7	9	9	9	86	95	98
Ability to work	8.0	7.8	8.0	8	8	8	89	85	91
Sleep	8.0	7.6	7.4	9	8	7	87	76	79
Bone health	7.9	8.0	7.4	8	8	8	89	95	80
Depression	7.8	7.9	7.7	8	8	8	85	85	87
Fluid retention/swelling	7.8	8.1	7.5	8	9	8	85	90	86
Clotting	7.6	8.2	7.4	8	9	8	79	95	76
Hospitalization	7.5	7.8	8.1	8	8	8	78	90	93

Best Worst Scale Survey | Preliminary results

A best-worst scale survey (BWS) was included at the end of Round 2 (English version). This forced ranking exercise compares the relative importance of each outcome to all other outcomes in the survey.



The top ten outcomes for patients and healthcare professionals (based on BWS scores) are shown below.

Outcomes	Patients	Healthcare professionals
Kidney function	1	3
Need for dialysis/transplant	2	1
Cardiovascular disease	3	4
Cancer	4	9
Life participation	5	7
Relapse/remission	6	5
Infection	7	8
Cognitive function	8	11
Death	9	2
Mobility	10	13
Proteinuria	14	15
Hospitalization	21	6

Results | Comments from the Delphi Survey

Outcome	Comment
Kidney function	Kidney function can be correlated with feeling healthy and quality of life - *Patient* Best single outcome measure - *HCP* A critical measure for general health and life expectancy – *Patient* This goes up and down so not always a good indicator – *HCP* Maintaining life and overall health may be more important than maintaining renal function 'at any price' – *Patient* My symptoms sometimes don't match my eGFR. Focusing on just this number isn't the whole picture of me! – *Patient*
Need for dialysis or transplant	Will often be irrelevant in short-term trials, but still should be reported – *HCP* Hard and life-changing outcome - *Patient* As important as kidney function but less feasible [for trials] – *Nephrologist* Hopefully we can look at a doubling of serum creatinine as a near term endpoint – *HCP* Outcome that patients equate with death – *HCP* Dialysis is a horrible alternative, it is medieval – *Patient* I seem to be heading this way so its importance to me is growing – *Patient* Not applicable - *Patient*
Remission/ Relapse	The importance depends on how remission is defined and which disease – *HCP* May be critical for some trials - *HCP* Recurrence of disease is devastating psychologically for patients – *HCP* This creates uncertainty – *Patient* Depends on each disorder – *Patient* No kidney function so relapse impossible – *Patient* Especially worrying and important post transplant - *Patient* Never really had a remission mine has always been progressive – *Patient*
Proteinuria	It is a marker of disease but even when the glomerular disorder is corrected there could be proteinuria related to chronic kidney disease and not to the glomerular disease – *HCP* A surrogate marker that we use for monitoring and making treatment decisions for patients on a daily basis – *HCP* Important marker of disease activity and risk of progression- *HCP* Is an earlier marker [than eGFR] for progression or lack of treatment response – *HCP* It's a prognostic marker and guide for treatment response – *HCP* Only useful disease marker and indicator of treatment benefit – *HCP* Not relevant being on dialysis or with low kidney function – *Patient* Can be used as a benchmark to gauge treatment response or deterioration – *Patient* Seems to be important to my doctors but doesn't affect me – *Patient* This is how my disease was found so early/picked up a relapse 3 months before my next check-up - *Patient*
Life participation	Without life participation, what kind of life is it? – *Patient* Not sure what the purpose of life is if someone is not able to participate in every day life and activities - *Patient* Extremely important for independence and mental health – *Patient* Interested that health professionals do not see this as important as patients do. - *Patient* Impact on quality of life during treatment was not something I was told and nor was it easy to find online – *Patient* Carrying out daily routines and hobbies is vital otherwise what is the point? – *Patient* This is a soft measure… budgets are finite… this is not a medically important measure even though it is of great social importance – *HCP*
Death	It's so important to understand the risk to life, to give time to think about what this means - *Patient* People need to be aware how their disease will affect their longevity. Often we don't tell them… but it does not lend understanding to how important treatment is and that without treatment death may happen sooner - *HCP* Not always relevant for each study (e.g. short duration) but should still be reported with the

	caveat that this should be interpreted with caution in shorter studies – *HCP* One thing worse than living with CKD, is no longer living with CKD – *Patient* Linked to quality of life. If we are going to die can I at least live first – *Patient* Very poor information on the likelihood of this occurring – *Patient* While kidney disease does increase this I prefer to focus on what I can control - *Patient*
eGFR= estimated glomerular filtration rate, HCP=healthcare provider	

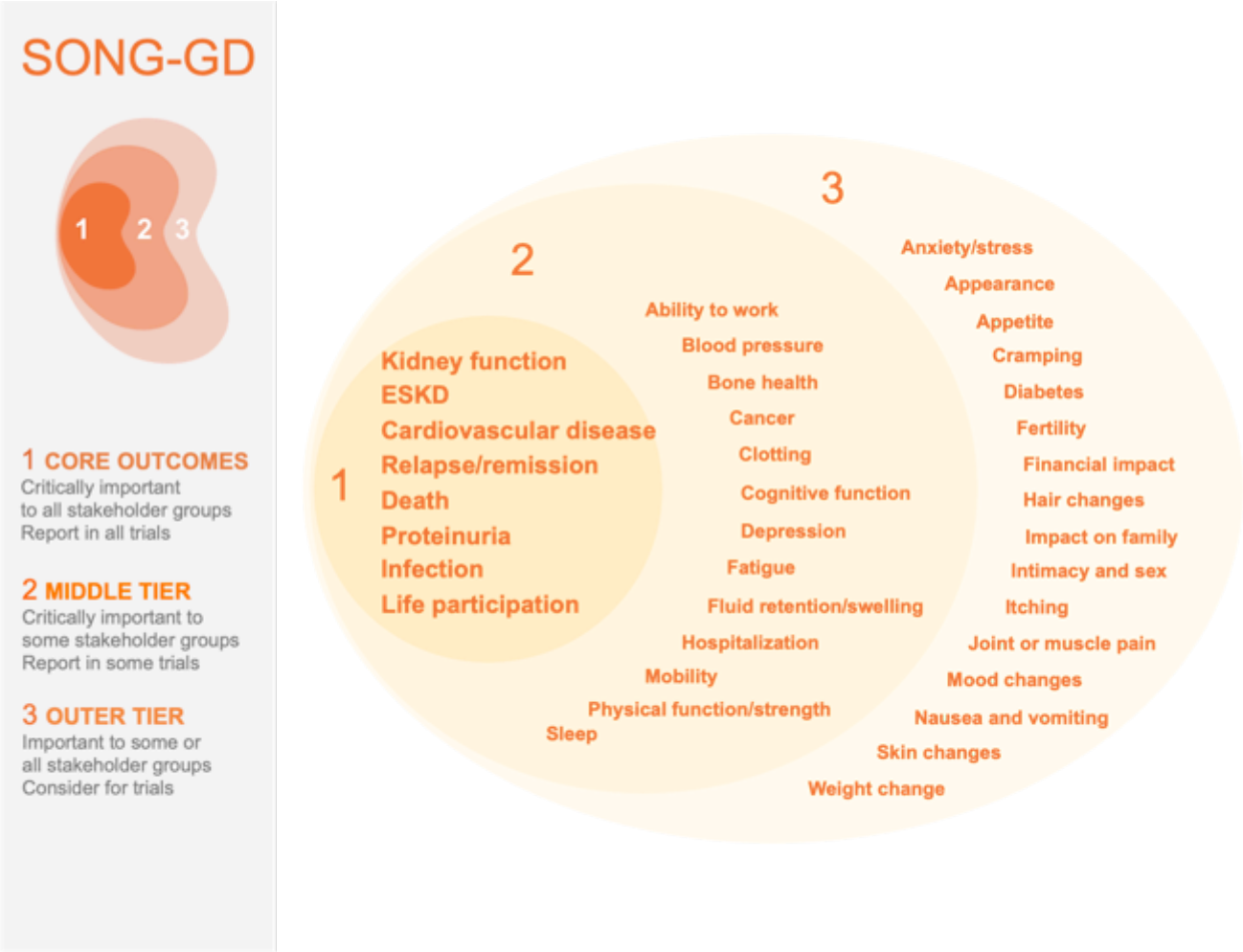
5 | Melbourne Workshop: April 2019

We held a SONG-GD workshop in April 2019 to present and discuss the preliminary results from the focus groups and round 1 of the Delphi survey. Summary points from the discussion were provided below:

- The top-rated outcomes from the Delphi were relevant and important in glomerular disease
- Kidney function and need for dialysis/transplant (end stage kidney disease) are on the same spectrum
- Kidney function, proteinuria and relapse/remission have considerable overlap but relapse/remission may be more disease-dependent
- Patient-reported outcomes were important but there are challenges with measuring them. The most important patient-reported outcome was life participation, which overlapped considerably with fatigue.

6 | SONG-GD Workshop questions

The possible outcomes to include in the core outcome set are shown below:



To ensure feasibility, SONG core outcome sets include 3 to 5 outcome domains. The following questions will be discussed to inform the selection of outcome domains for the core outcome set.

1. Does kidney function capture need for dialysis or transplant (end stage kidney disease) - can we combine them?
2. Relapse/remission measures disease activity. Measures of kidney function and proteinuria capture disease activity and therefore currently define relapse/remission - but they also capture long-term kidney health.
    a) Should relapse/remission be changed to disease activity?
    b) Does proteinuria sit entirely within both kidney function and relapse/remission? (can it be considered simply a measure of these)
3. Should death (mortality, survival) be a core outcome and why?
4. Life participation is the top patient-reported outcome. Should it be a core outcome?
5. Cardiovascular disease and infection are important, highly ranked outcomes. Are they both important to all disease types? Should they both be included in the core outcome set?
6. How can these critically important core outcomes be implemented in all trials? What are the barriers and how can we overcome them?

7 | Participants and contributors

The list of SONG-GD Melbourne workshop participants and contributors is current as of 5th **November 2019.** The participants include patients, caregivers/family members, healthcare providers, researchers, and policy makers (* indicates collaborators who will be attending the workshop).

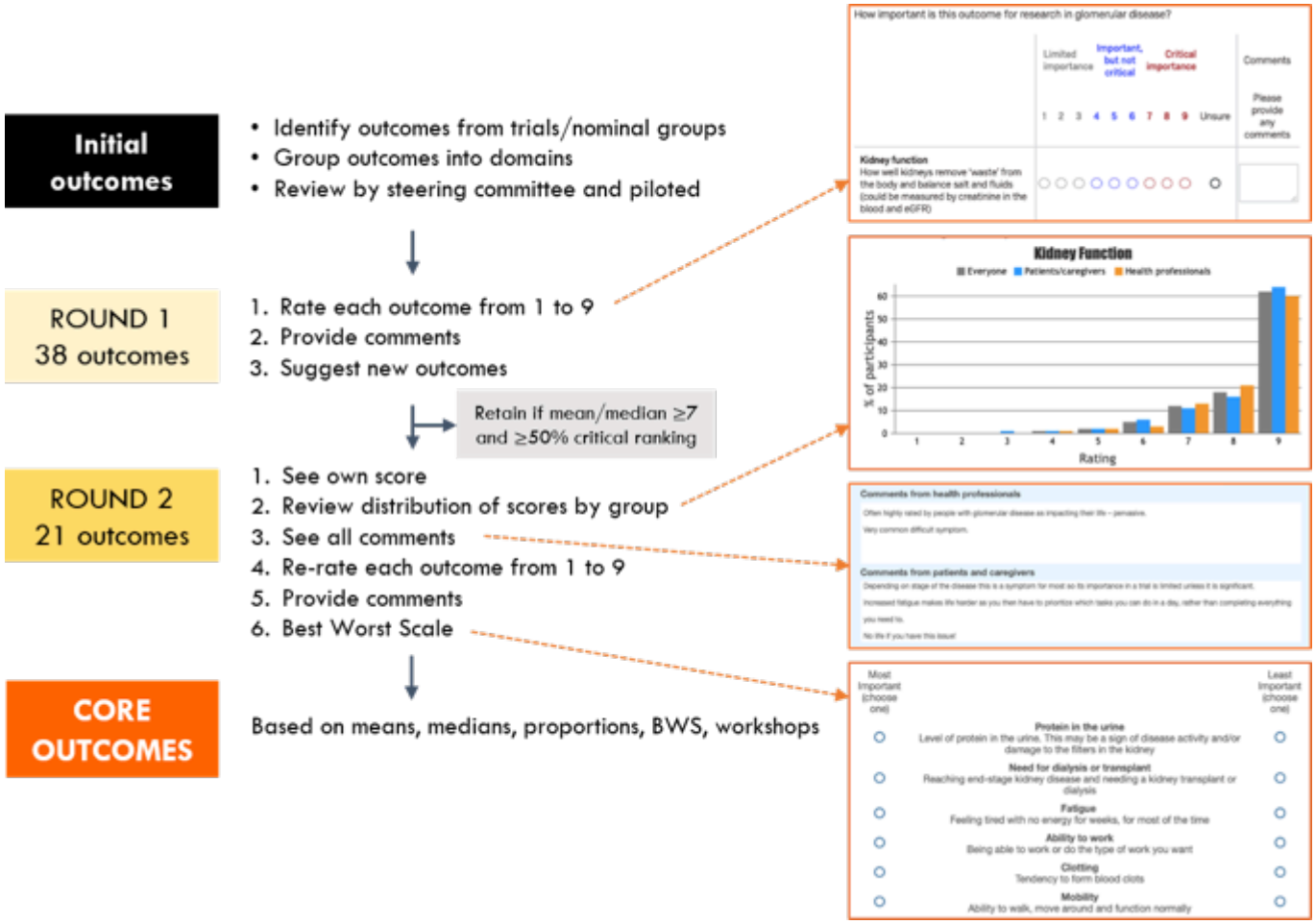
	Name	Organisation	Country
SONG Executive Committee			
*	Jonathan Craig	Flinders University	Australia
	Braden Manns	University of Calgary	Canada
	Brenda Hemmelgarn	University of Calgary	Canada
*	David Wheeler	University College London	United Kingdom
*	John Gill	University of British Columbia	Canada
	Peter Tugwell	University of Ottawa	Canada
	Sally Crowe	Crowe Associates Ltd	United Kingdom
	Tess Harris	PKD International	United Kingdom
	Wim van Biesen	University of Ghent	Belgium
	Wolfgang Winkelmayer	Baylor College of Medicine	United States
	Roberto Pecoits-Filho	Pontifical Catholic University of Parana	Brazil
*	Angela Yee-Moon Wang	The University of Hong Kong	Hong Kong
*	Allison Tong	The University of Sydney	Australia
SONG-GD Steering group			
*	Ana Malvar	Hospital Fernandez	Argentina
	Arvind Bagga	All India Institute of Medical Sciences	India
*	Brad Rovin	Ohio State University	United States
*	Dan Cattran	University of Toronto	Canada
	Dawn Caster	University of Louisville	United States
*	Fernando Fervenza	Mayo Clinic	United States
	Hong Zhang	Peking University First Hospital	China
	Hernan Trimarchi	Hospital Britanico de Buenos Aires	Argentina
	Jai Radhakrishnan	Colombia University Medical Centre	United States
*	John Boletis	University of Athens	Greece
*	Jon Barratt	University of Leicester	United Kingdom
*	Jonathan Hogan	University of Pennsylvania	United States
*	Jürgen Floege	Aachen University	Germany
*	Liz Lightstone	Imperial College London	United Kingdom
*	Michelle Hladunewich	University of Toronto	Canada
*	Nicole Scholes-Robertson	University of Sydney	Australia
*	Richard Kitching	Monash University	Australia
	Richard Lafayette	Stanford University	United States
	Rosanna Coppo	Regina Margherita Hospital	Italy
*	Sean Barbour	University of British Colombia	Canada
SONG Coordinating Committee			
*	Amanda Baumgart	The University of Sydney	Australia
	Amelie Bernier-Jean	The University of Sydney	Australia
	Amy Kelly	The Children's Hospital at Westmead	Australia
*	Andrea Viecelli	University of Queensland	Australia
	Ankit Sharma	The University of Sydney	Australia
	Angela Ju	The University of Sydney	Australia
	Ankit Sharma	The University of Sydney	Australia
	Armando Teixeira-Pinto	The University of Sydney	Australia
	Ayano Kelly	Australia National University	Australia
	Benedicte Sautenet	AHU en Thérapeutique	France

	Camilla Hanson	The University of Sydney	Australia
*	Charlotte Logeman	The University of Sydney	Australia
	Claudia Rutherford	The University of Sydney	Australia
	Daniel Sumpton	The University of Sydney	Australia
*	Emma O'Lone	The University of Sydney	Australia
*	Eric Au	The University of Sydney	Australia
	Gail Higgins	Cochrane Kidney and Transplant	Australia
	Jenny Shen	University of California	United States
	Karine Manera	The University of Sydney	Australia
	Karolis Azukaitis	Vilnius University	Lithuania
	Louese Dunn	Sheffield Teaching Hospitals	United Kingdom
	Martin Howell	The University of Sydney	Australia
*	Melissa Nataatmadja	University of Queensland	Australia
	Nicole Evangelidis	The University of Sydney	Australia
	Richard McGee	The University of Sydney	Australia
*	Samaya Anumudu	Baylor College of Medicine	United States
	Sarah Bernays	The University of Sydney	Australia
*	Simon Carter	The University of Sydney	Australia
	Talia Gutman	The University of Sydney	Australia
	Yeoungjee Cho	University of Queensland	Australia
Health professionals, researchers, industry and regulators			
*	Adeera Levin	University of British Colombia	Canada
*	Adrian Liew	Tan Tock Seng Hospital	Singapore
*	Alice Smith	University of Leicester	United Kingdom
	Aliza Thompson	US Food and Drug Administration	United States
*	Amy Earley	Kidney Disease: Improving Global Outcomes (KDIGO)	United States
*	Barbara Gillespie	University of North Carolina; Covance CRO	United States
*	Ben Fisher	US Food and Drug Administration	United States
	Bhadran Bose	University of Sydney	Australia
	Bonnie Schneider	IgA Nephropathy Foundation of America	United States
	Carmel Hawley	University of Queensland	Australia
	Daniel Tak Mao Chan	University of Hong Kong	Hong Kong
*	David Jayne	University of Cambridge	United Kingdom
	David Johnson	University of Queensland	Australia
*	Debbie Gipson	University of Michigan	United States
*	Denis Fouque	Centre Hospitalier Universitaire de Lyon	France
	Diana Clynes	American Association of Kidney Patients	United States
	Dick de Zeeuw	University of Groningen	Netherlands
*	Duvuru Geetha	John Hopkins University School of Medicine	United States
	Elisabeth Hodson	Centre for Kidney Research	Australia
*	Erin Kahle	American Association of Kidney Patients	United States
*	Frank Bridoux	Centre Hospitalier Universitaire de Poitiers	France
*	Frank Cortazar	Massachusetts General Hospital	United States
	Harold Feldman	University of Pennsylvania	United States
*	Heather Beanlands	Ryerson University	Canada
*	Heather Reich	University of Toronto	Canada
*	Laurence Beck	Boston University Medical Centre	United States
*	Jack Wetzels	Radboud University Medical Centre Nijmegen	Netherlands
	Jan-Stephan Sanders	University Medical Centre Groningen	Netherlands
*	Jens Kristensen	Calliditas Pharmaceuticals	Sweden
	Jessica Ryan	Monash University	Australia
	Joanne Bargman	University of Toronto	Canada
*	Josh Tarnoff	NephCure International	United States
*	Juan Mejia-Vilet	Instituto Nacional de Ciencias Medicas Y Nutricion Salvador Zubiran	Mexico

*	Kathy Machuzak	Retrophin	United States
*	Kelly Burdge	North Shore Medical Centre	United States
	Kelly Helm	NephCure International	United States
*	Kirk Campbell	Icahn School of Medicine at Mount Sinai	United States
*	Krassimir Mitchev	Calliditas Therapeutics	United States
*	Laurence Beck	Boston University School of Medicine	United States
*	Lauren Lee	NephCure International	United States
*	Laura Mariani	University of Michigan	United States
	Leslie Hanrahan	Lupus Foundation of America	United States
	Lisa Guay-Woodford	George Washington University	United States
	Manuel Praga	Hospital 12 de Octubre	Spain
	Marcello Tonelli	University of Calgary	Canada
*	Marc Uknis	Achillion	United States
*	Martin Wilkie	Sheffield Teaching Hospitals NHS	United Kingdom
	Masaomi Nangaku	University of Tokyo	Japan
	Matthew Roberts	Monash University	Australia
*	Matthias Kretzler	University of Michigan	United States
	Michael Cheung	KDIGO	Belgium
	Michael Choi	Georgetown University Medical Center	United States
*	Michelle Tarver	US Food and Drug Administration	United States
	Moin Saleem	University of Bristol	United Kingdom
	Nigel Toussaint	University of Melbourne	Australia
*	Patrick Nachman	University of Minnesota	United States
	Philip Li	Chinese University of Hong Kong	Hong Kong
	Pierre Ronco	Sorbonne University	France
*	Rajnish Mehrotra	University of Washington	United States
*	Richard Glassock	David Geffen School of Medicine at UCLA	United States
*	Robert Huizinga	Aurinia Pharmaceuticals	Canada
	Sergio Mezzano	Universidad Austral	Chile
*	Sharon Adler	David Geffen School of Medicine at UCLA	United States
	Shilpa Jesudason	University of Adelaide	Australia
	Stephen Alexander	The University of Sydney	Australia
*	Stephen Seliger	University of Maryland	United States
	Suetonia Palmer	University of Otago	New Zealand
*	Sydney Tang	University of Hong Kong	Hong Kong
	Sunil Badve	George Institute for Global Health	Australia
	Tom Barbour	University of Melbourne	Australia
*	Vivek Jha	George Institute for Global Health	India
*	Vladimir Tesar	Charles University	Czech Republic
	William Barrington		United States
Patients, caregivers and family members			
*	Ashley Embrey-Critzer	-	United States
*	Bernie Lorenz	-	United States
*	Brett Love	-	United States
*	Carlton Walton	-	United States
*	Chang Liu	-	United States
*	Christina Orefice	-	United States
*	David Kleehammer	-	United States
*	Dwuan June	-	United States
*	Elisabet Bjanes	-	United States
*	Gary Orefice	-	United States
*	Imani Mintz	-	United States
*	James Ryan	-	United States
*	Jane Ryan	-	United States

*	Jerica Gerena	-	United States
*	Jessica Embrey-Critzer	-	United States
*	Jocelyn Lorenz	-	United States
*	John Goodwin	-	United States
*	Johnnie Walker	-	United States
*	Judith Perini	-	United States
*	Kevin Molloy	-	United States
*	Laura Walker	-	United States
*	Lonnell Lewis	-	United States
*	Lynette Saar	-	United States
	Martin Katz	-	United States
*	Michael Mittelman	-	United States
*	Nieltje Gedney	-	United States
*	Pam Duquette	-	United States
*	Patricia Molloy	-	United States
*	Rajiv Choudhary	-	United States
*	Rosie Love	-	United States
*	Ryan Estorninos	-	United States
*	Sharon Walker	-	United States
*	Susan Shaffer	-	United States
	Susanne Katz	-	United States
*	Talia Katz	-	United States
*	Wenrui Hao	-	United States
*	William Saar	-	United States

Appendix A. Process of SONG-GD Delphi Survey



Appendix B. SONG-GD Delphi Survey: definitions for outcomes

Outcome	Definition
Ability to work	Being able to work or do the type of work you want
Anxiety	Feeling anxious or stressed
Appearance	Changes in the way you look, body image
Appetite	Loss or change in appetite, enjoyment of food
Blood pressure	The number to indicate the pressure in the arteries, high (hypertension) or low (hypotension) blood pressure
Bone health	Bone strength or density, risk of fractures
Cancer	Any type of cancer. A disease caused by abnormal cell growth with the potential to invade or spread to other parts of the body
Cardiovascular disease	Disease of the heart and blood vessels (including stroke, heart attack or heart failure)
Cognitive function	Ability to remember things (short and long-term), think clearly, problem solve
Cramping	Painful or uncomfortable contraction or spasms in muscles
Death	Number of people who die, risk of death, how long the patient will live
Depression	Feeling down, low mood, strong and persistent feelings of sadness, hopelessness, despair for most of the time, over a long time
Diabetes	Abnormally high levels of sugar in the blood because the body cannot produce enough insulin or insulin is not working properly
Fatigue	Feeling tired or having no energy for weeks, most of the time
Fertility	Ability to have children
Financial impact	Impact on the person's ability to earn a living, resources, stability and monetary security. Includes insurance and debt
Fluid retention/swelling	An increase in body fluid causing swelling
Hair changes	Abnormal loss or change in the amount or quality of hair (includes too much hair growth and hair loss)
Hospitalisation	Staying in hospital for a health problem or complication
Impact on family/friends	Impact of the patient's family, caregivers
Infection	Infectious from any of viruses, bacteria, fungi/yeast or parasites
Intimate relationships and sexual function	Ability to have intimate relationships, desire for and enjoyment of sex
Itch	Dry or itchy skin, irritating sensation that makes a person want to scratch
Joint or muscle pain	Aches or pains in the joints, back and/or muscles
Kidney function	How well kidneys remove 'waste' from the body and balance salt and fluids (could be measured by creatinine in the blood and eGFR)
Life participation	Ability to participate or do daily activities including socialising, study, hobbies
Mobility	Ability to walk, move around and function normally
Mood	Unusual changes in emotion, crying easily, feelings of anger or agitation towards others
Nausea, vomiting	Often feeling like throwing up, retching, sick in the stomach, acid reflux
Need for dialysis or transplant	Reaching end stage kidney disease and needing a kidney transplant or dialysis
Protein in the urine	Level of protein in the urine. This may be a sign of disease activity and/or damage to the filters in the kidney
Relapses	Disease comes back again; 'flares' or recurs – either slowly or suddenly.
Remission	Disease gets better (i.e. partial remission) or goes away (complete remission); either temporarily or for the longer term
Skin changes	Change in skin such as stretch marks, thin skin and acne
Sleep	Trouble getting to sleep, staying asleep or poor quality sleep
Strength and physical functioning	Being able to do physical tasks, feeling strong in the body
Weight change	Loss or gain in body weight (not because of fluid)

Supplemental File 2. Facilitator credentials and question guide for break out discussions.

Facilitator gender, credentials, occupation and experience:

- Samaya Anumudu: female, MD, FASN, Nephrologist, SONG co-ordinating committee member, qualitative researcher with facilitator experience (focus groups and workshops)
- Simon Carter: male, MBBS(Hons), FRACP, Nephrologist, SONG co-ordinating committee member, qualitative researcher with facilitator experience (focus groups, workshops)
- Jonathan Craig: male, PhD, MBChB, DCH, MMed (Clin Epi), FRACP, FAHMS, Professor, Epidemiologist, Nephrologist, SONG executive committee member, qualitative and facilitator experience (workshops)
- Talia Gutman: female, PhD, MPH, SONG co-ordinating committee member, qualitative researcher, facilitator experience (focus groups, interviews, workshops)
- Liz Lightstone: female, MA (Cantab), MBBS (Hons), PhD, FRCP, Professor of Renal Medicine, Nephrologist, SONG-GD co-chair, facilitator experience (workshops)
- Emma O'Lone: female, MD, PhD, FRACP, SONG co-ordinating committee member, qualitative researcher, facilitator experience (focus groups, workshops)
- Nicole Scholes-Robertson: female, BAppSci, Physiotherapist, qualitative researcher, patient partner, facilitator experience (focus groups, interviews, workshops)
- Allison Tong: female, MPH, PhD, Professor, SONG executive committee member, qualitative researcher, facilitator experience (focus groups, interviews, workshops)
- Andrea Viecelli: female, MD, PhD, FRACP, Associate Professor, SONG co-ordinating committee member, qualitative researcher, facilitator experience (focus groups, workshops)

Workshop 1 | World Congress of Nephrology 2019

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1. What are your thoughts about the results so far, focusing on the highest ranked outcomes?
2. Glomerular disease includes a whole range of different diseases – do you think the outcomes at the very top are relevant and important to treatment decision making across all types?
3. What do you think needs to be considered in establishing the core outcome set?
4. Can we combine outcomes that overlap or are measured in very similar ways? E.g. remission/relapse, ESKD/kidney function
5. Should patient-reported outcome(s) (i.e. impacts of treatment/disease that reflect how patients feel and function) be included in the core outcome set?
   a) Which ones and why?
   b) Are any aspects unique to people with GD? E.g. Life participation, fatigue
6. Implementation and uptake

a) How can these critically important core outcomes (once these and the measures are finalized) be implemented in all trials?

7. What are some of the barriers and how can we overcome these?

Workshop 2 | American Society of Nephrology Kidney Week 2019

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1. Does kidney function also capture end stage kidney disease? Can we combine kidney function and need for dialysis or transplant?
2. Relapse/remission measures disease activity. Kidney function (eGFR/creatinine) and proteinuria measure disease activity but also overall kidney health. Should relapse/remission be called disease activity? Is proteinuria more a measure rather than an outcome? Which are the core outcomes?
3. Should death (mortality, survival) be a core outcome and why?
4. Death and life participation were critically important outcomes – were you surprised?
5. Infection and cardiovascular disease are also important outcomes. Are they important to all disease types and therefore be included in the core outcome set?
6. Implementation and uptake
   a) How can these critically important core outcomes (once these and the measures are finalised) be implemented in all trials?
   b) What are some of the barriers and how can we overcome these?

NB. For workshop 1, preliminary results of Round 1 of the SONG-GD Delphi survey were presented. For workshop 2, preliminary results of Round 2 were presented and discussion was directed towards potential core outcomes based on the results of the Delphi survey.