



SONG
STANDARDISED OUTCOMES IN NEPHROLOGY

STANDARDISED OUTCOMES IN NEPHROLOGY – Kidney Transplantation (SONG-Tx)

**CONSENSUS WORKSHOPS ON ESTABLISHING CORE
OUTCOME DOMAINS IN KIDNEY TRANSPLANTATION
FRIDAY 11th NOVEMBER 2016**
COMET Meeting, Amsterdam, The Netherlands

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SONG Initiative

The SONG Initiative aims to establish **core outcomes** across the spectrum of kidney disease for trials and other forms of research.

The outcomes will be based on the **shared priorities** of patients, caregivers, clinicians, researchers, policy-makers, and industry.

This will help to ensure that research is measuring and reporting outcomes that are **meaningful and relevant** to patients with kidney disease, their family, and their clinicians.



Kidney Transplantation (SONG-Tx)

Systematic review



International
Delphi
survey



Consensus
workshop

1. SONG-Tx Systematic review

Outcome	N (%)
Graft function	326 (82%)
Acute graft rejection	250 (63%)
Death	213 (54%)
Graft survival	203 (51%)
Infection	197 (50%)
Blood pressure	147 (37%)
Cholesterol	110 (28%)
Diabetes/glucose	103 (26%)
Adverse effects (non-specified)	103 (26%)
White blood cells	94 (24%)

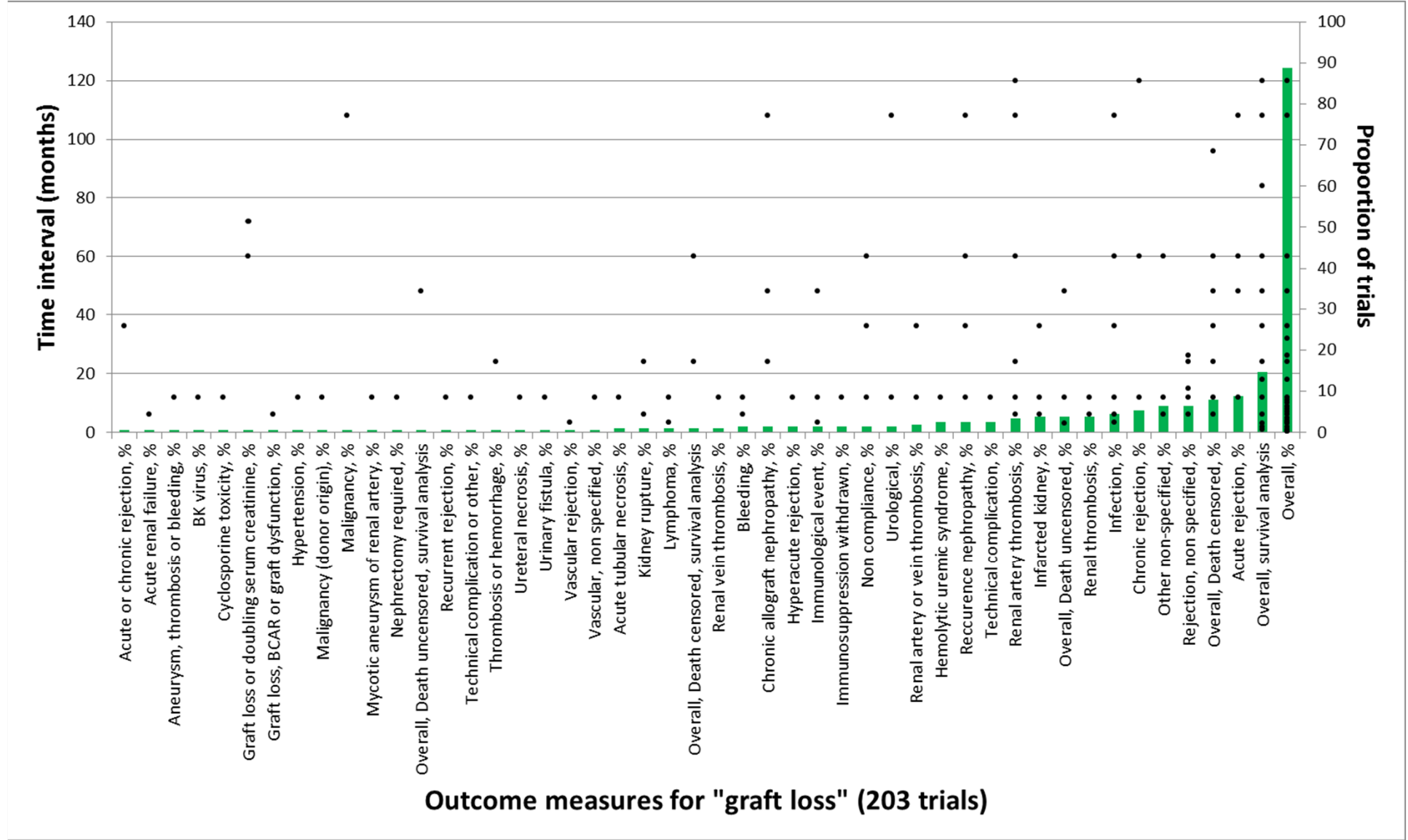
397 trials
 N = 63 514
 participants
 12 046 Outcomes
 measures reported

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1. SONG-Tx Systematic review



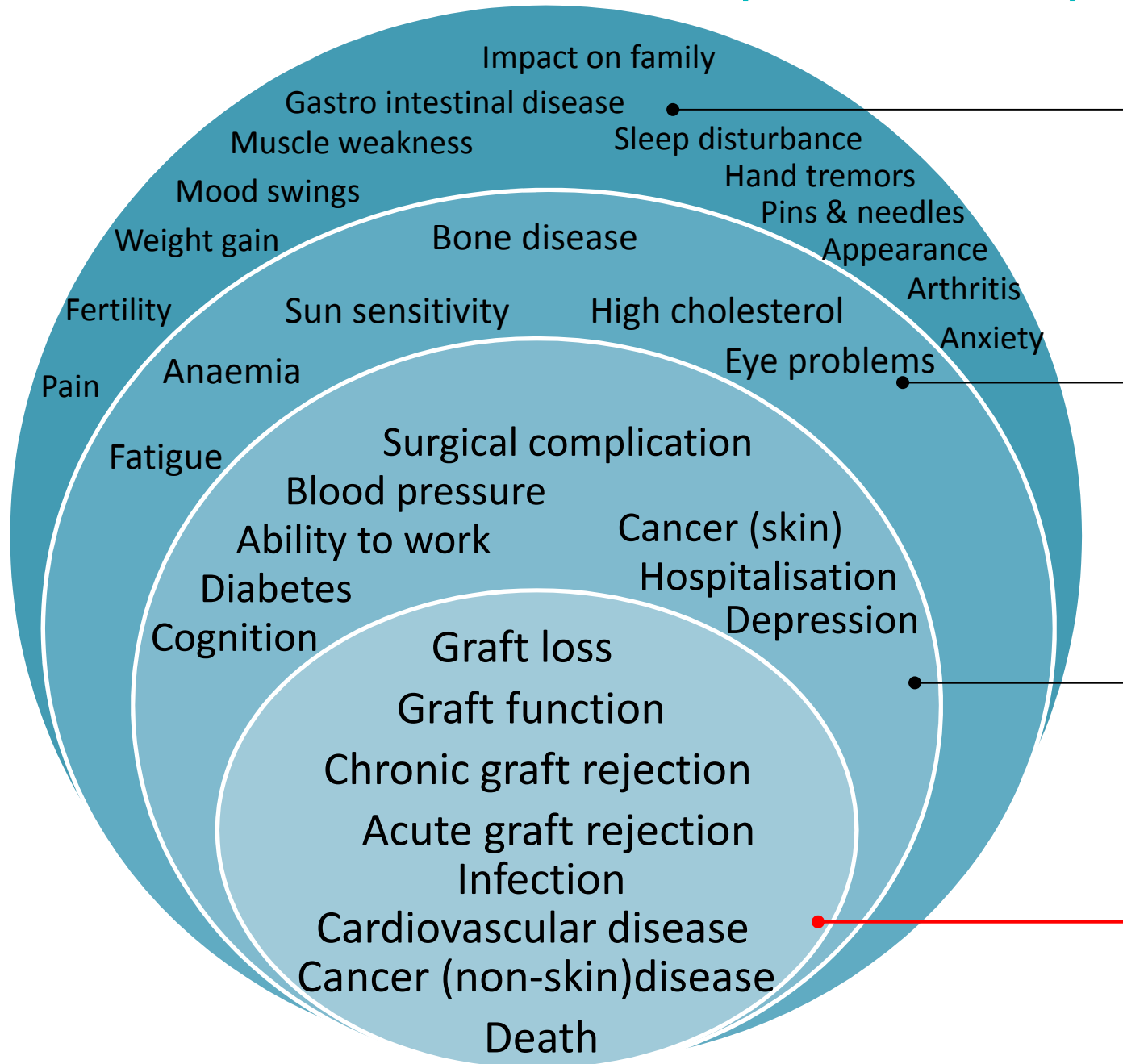
2. International Delphi survey

Stakeholder group	Round 1	Round 2	Round 3
Patients/caregivers	461	387 (84%)	360 (78%)
Health professionals	557	457 (82%)	419 (75%)
All	1018	844 (83%)	779 (77%)



countries

2. International Delphi survey



Rated important (but not critical) by both groups in Round 1

Not included in Round 2

Consider for trials

Rated important (but not critical) by both groups in Round 2

Not included in Round 3

Include in some trials

Rated "important" or "critically important" by both groups in Round 3

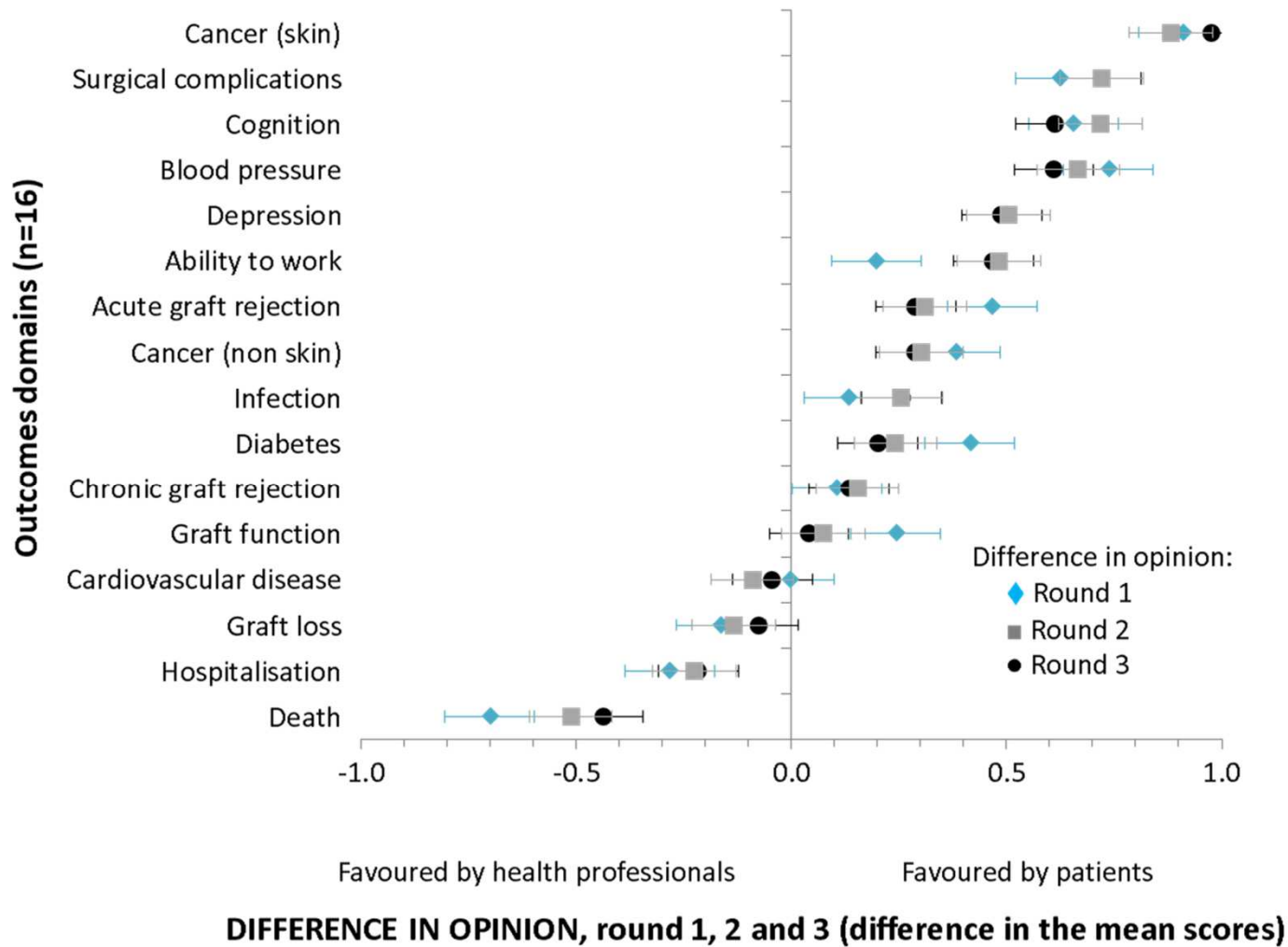
Include in some trials

Potential core outcomes

Given the highest scores by both groups in Round 3

Include in all trials

2. International Delphi survey



3. SONG-Tx consensus workshops

Objectives

1. Provide an overview of the SONG-Tx process and results (*buy in*)
2. Review the potential core outcome domains (*sense checking*)
3. Discuss implications for establishing the core outcome measures (*decision-making*)

SONG-Tx: 2 workshops

American Transplant Congress, Boston, 13th June 2016

- 17 patients/caregivers
- 51 health professionals



The Transplantation Society
August 2016

- 10 patients/caregivers
- 45 health professionals



Runsheets

Time	Detailed tasks and questions	Responsible
11:00	Set up	Benedicte, Fanny, Maddy, Camilla, Nick, Phil, Kieran, Allison
12:00 – 12:20 20 mins	Registration and lunch <ul style="list-style-type: none"> Consent: media release, acknowledgement by name Reimbursement (for patients only) Allocate people to tables (approx. 12 participants per group, see group allocation) 	Benedicte, Camilla, Maddy, Fanny
12:20 – 12:30 10 mins	Welcome and overview <ul style="list-style-type: none"> Welcome Introduce SONG Initiative (background, who is involved, supporters and contributors) Workshop objectives Program 	Jeremy Chapman
12:30 – 12:38 8 mins	SONG-Tx process and results <ul style="list-style-type: none"> Systematic review Delphi survey SONG-Tx core outcome set <ul style="list-style-type: none"> Re-define "core outcome domain" Clarify that these are outcome domains Outcomes will be distilled to approximately 3 outcomes These will be circulated in the workshop report (for final endorsement) Next step is to develop/identify outcome measures 	Allison Tong
12:38 – 12:40 2 mins	Break out discussion <ul style="list-style-type: none"> Objective and task: to review and discuss SONG-Tx results 	Jonathan Craig
12:40 – 1:10 30 mins	Break out discussion <ul style="list-style-type: none"> Opening and introduction: 5 minutes For the next 40 minutes, we would like to hear your feedback on the results of SONG-Tx, and to discuss strategies and action plans for establishing and implementing core outcomes. We'll quickly go around the group and in 30 seconds, please say your name and in one sentence, your interest in kidney transplant recipient outcomes – who would like to go first? (then go around) Identify a spokesperson MAIN FOCUS Feedback on results: 20 minutes <ul style="list-style-type: none"> What are your initial thoughts and reflections on the core outcomes identified in SONG-Tx? Are there any outcomes that you would like to discuss or clarify on? What do you think needs to be considered in establishing the core outcome set for research (trial) in kidney transplantation? <ul style="list-style-type: none"> The top 8 outcomes are clearly separated from the combined? (pragmatic implications for trials vs. variations of same outcome and may inadvertently push other "important" outcomes over) Death, cancer, infection, CVD are also in the top 8. Should we include a quality of life outcome domain? Or is this implicit in gratified-related outcomes? Are there tools or measures that have been developed or need to be developed for these outcomes? Implementation: 5 minutes <ul style="list-style-type: none"> How can these core outcomes be shared, disseminated or published for use in kidney transplantation trials and other forms of research? (healthcare providers, patients/patient groups, researchers, policy makers and funders, industry) How do we encourage trialists and stakeholders in kidney transplantation trials to potentially switch from what they usually do to using these core outcomes? What would successful implementation of core outcomes look like? How could it be measured? Do you have other comments? (risks, opportunities, useful networks, experts) 	Jonathan Craig Camilla Hanson Kieran Howard Germaine Wong Allison Tong
1:10 – 1:20 10 mins	Plenary discussion <ul style="list-style-type: none"> Group feedback (each group to provide 2 minute summary) Plenary discussion Summary 	Jonathan Craig
1:20 – 1:30 10 mins	Closing remarks <ul style="list-style-type: none"> Summary of the day Completion of agreement form: feedback and named collaborator workshop reports and publications; ratification of core outcomes 	Jeremy Chapman

Welcome and overview

- Introduce SONG initiative
- Workshop objectives

SONG-Tx process and results

- Systematic review results
- Delphi survey results
- SONG-Tx core outcome set

Break-out discussion (group of 10–12 participants)

- Introduction
- Feedback on results
- Implementation

Plenary discussion

- Group feedback
- Summary

Closing remarks

Break-out & plenary discussions were audiotaped and transcribed for inductive and descriptive analysis

Summary of o

Reflections on propo

- Reflects a complex immunosuppression
- Combine graft outcome chronic graft rejection
 - Inadvertently pu
 - Interrelated, dif
 - All points to gra
- Clarification of death responsibility) vs in own life)

“Both patients and providers felt that clinical complications of immunosuppression such as infection, cancer and cardiovascular disease were critical to include as core outcomes” *Group feedback*

“That’s why, those outcomes, are what you say, graft loss, graft function, rejection, rejection a year, its not very very different, they are exactly related, you don’t want to go back on dialysis, that’s the thing” *Patient*

“We’re all eventually going to die at some point, whereas a healthy graft will prevent that day from coming for a very long time, so I don’t really know that death should even be in there because we’re all going to die eventually” *Patient*

“I don’t worry about death, I worry about living, doing stuff, right now I can’t travel, I can’t do things, because of dialysis or whatever” *Patient*

“If you had a drug that produced an inferior survival, patient survival, but superior graft survival then you’ve got a problem” *Health professional*

Summary of discussion and implications

Reflections on proposed core outcome domains

- Need to include a quality of life outcome domain
 - Life participation

- Relevance

- Emotional
- Subjective

“Different people might have different quality of life goals, I mean if you’re retired, ability to work isn’t going to be meaningful to you at all, and ability to be able to go to church like you said, or the ability to sort of do moderately, work life function, might be quite important.”
Health professional

“The core has to be very tight I think, and then you could say you could compartmentalise the rest and say well if you’re doing a study of this sort, these are important core items to include, if you’re doing a study of that sort, then these are important core” *Health professional*



What's next?

Establish a core outcome measure for each outcome domain

- Expert working group
- Systematic review
- Survey (GRADE rating and Best–Worst Scaling)
- Workshop/s



Thank
you





Acknowledgements

Cochrane Kidney and Transplant
Dialysis Outcomes and Practice Patterns
Study (DOPPS)
International Society of Nephrology (ISN)
Kidney Disease | Improving Global Outcomes
(KDIGO)
PKD International
The Transplantation Society (TTS)
World Transplant Games Federation
Australian and New Zealand Society of
Nephrology (ANZSN)
Australian Kidney Trials Network (AKTN)
Christchurch Kidney Society
Kidney Health Australia (KHA)
Kidney Health Australia – Caring for
Australasians with Renal Impairment
Guidelines (KHA-CARI)
Kidney Health New Zealand (KHNZ)
PKD Foundation of Australia
Renal Society of Australasia (RSA)
Transplant Australia
The Kidney Foundation of Canada (KFOC)
Canadian Society of Nephrology (CSN)

British Kidney Patient Association
British Renal Society (BRS)
European Kidney Patients Federation
(EKPF)
European Kidney Transplant Association
(EKITA)
European Society of Transplantation
(ESOT)
European Renal Best Practice (ERBP)
UK National Kidney Federation (NKF)
PKD Charity
Soci t  Francophone de Transplantation
The Renal Association
American Association of Kidney Patients
National Kidney Foundation Southern
California

National Health and Medical Research