



STANDARDISED OUTCOMES IN NEPHROLOGY- Kidney Transplantation

(SONG-TX) HONG KONG CONSENSUS WORKSHOP PROGRAM AND SUMMARY REPORT

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Workshop details

Time: 12:00 pm – 1:30 pm
Date: Saturday 20th August 2016
Location: **Meeting room S228 (Level 2)** Hong Kong Convention and Exhibition Centre, Hong Kong



Contacts

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Overview

The international SONG-Tx Initiative aims to establish core outcomes for research (clinical trials) in kidney transplantation 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 kidney transplant recipients, their family, and clinicians involved in their care.

Objectives

The objectives of the SONG-Tx workshops are to:

- Provide an overview of the SONG-Tx process and results
- Review and discuss the potential core outcomes set for trials and other forms of research in kidney transplantation
- Develop and discuss implementation strategies and action plans

Stakeholder workshops

1. 12:30 pm – 2:30 pm 13th June 2016 Boston www.songinitiative.org/song-tx (for summary/attendees)
2. 12:00 pm – 1:30 pm 20th August 2016 Hong Kong

Participants

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

Materials

Each participant will be emailed and given a hardcopy of this Program and Report. The full SONG-Tx Delphi Panel report containing the results will be emailed to all attendees and a copy will be provided for each breakout group. Please review the materials prior to the workshop.

Program

Time	Session
12:00 – 12:20	Registration and lunch
12:20 – 12:30	Welcome and introduction to the SONG-Tx Initiative <i>Jeremy Chapman</i>
12:30 – 12:40	Overview of the SONG-Tx process and results <i>Allison Tong</i>
12:40 – 1:10	Break out discussion groups <i>Main facilitator: Jonathan Craig</i> <ul style="list-style-type: none">• Review and discuss SONG-Tx results• Develop implementation strategies and action plans
1:10 – 1:20	Plenary discussion with feedback from break out groups and close <i>Jonathan Craig</i>

Participants and contributors

The list of SONG-Tx Hong Kong workshop participants and contributors is current as of **24th August 2016**. The participants include patients, caregivers/family members, healthcare providers, researchers, and policy makers. Please see www.songinitiative.org/song-tx/ for the full list of collaborators (including Boston Workshop attendees, and collaborators).

Name	Organisation	Country
SONG Executive Committee		
* Jonathan Craig	The University of Sydney	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 Winkelmayr	Baylor College of Medicine	United States
* Allison Tong	The University of Sydney	Australia
Nicole Evangelidis	The University of Sydney	Australia
SONG-Tx Steering Group		
* Jeremy Chapman	Westmead Hospital	Australia
Anthony Warrens	Queen Mary University of London	United Kingdom
David Rosenbloom	ESRD Network 18	United States
* Germaine Wong	The University of Sydney	Australia
* John Gill	University of British Columbia	Canada
* Klemens Budde	Charité – Universitätsmedizin	Germany
* Lionel Rostaing	Toulouse University Hospital	France
Lorna Marson	The University of Edinburgh	United Kingdom
Michelle Josephson	The University of Chicago	United States
Peter Reese	University of Pennsylvania	United States
Tim Pruett	University of Minnesota	United States
SONG-Tx Hong Kong attendees (health professionals)		
* Beatriz Dominguez-Gil	Organización Nacional de Trasplantes	Spain
* Benedicte Sautenet	The University of Sydney	Australia
* Benita Padilla	National Kidney and Transplant Institute	Philippines
* Camilla Hanson	The University of Sydney	Australia
* Curie Ahn	Seoul National University Hospital	South Korea
* Dirk Kuypers	University Hospitals Leuven	Belgium
Dorry Segev	The Johns Hopkins Hospital	United States
Elmi Muller	Groote Schuur Hospital	South Africa
* Fabian Halleck	Charité – Universitätsmedizin	Germany
* Frank Dor	Imperial College London	United Kingdom
Frans Claas	Leiden University Medical Centre	The Netherlands
* Greg Knoll	University of Ottawa	Canada
* Hai An Ha Phan	Viet Duc University Hospital	Vietnam
* Hatem Amer	Mayo Clinic	United States
* Helen Pilmore	Auckland Hospital	New Zealand
Huong Tran	Cho Ray Hospital	Vietnam
* Jayme Locke	University of Alabama	United States
* Jongwon Ha	Seoul National University	South Korea
* Kai Ming Chow	The Chinese University of Hong Kong	Hong Kong

* Kirsten Howard	The University of Sydney	Australia
* Lalitha Raghuram	Mohan Foundation	India
* Madeleine Didsbury	The University of Sydney	Australia
* Maggie Ma	The University of Hong Kong, Queen Mary Hospital	Hong Kong
* Martin Howell	The University of Sydney	Australia
* Mirjam Tielen	Erasmus MC University Hospital	Netherlands
Nancy Ascher	University of California San Francisco	United States
* Nick Larkins	The University of Sydney	Australia
* Paul Harden	Oxford University	United Kingdom
* Penny Allen	The University of Sydney	Australia
* Peter Stock	University of California San Francisco	United States
* Peter William Nickerson	University of Manitoba	Canada
Phil O'Connell	Westmead Hospital	Australia
* Richard Allen	The University of Sydney	Australia
* Romina Danguilan	National Kidney and Transplant Institute	Philippines
* Ron Shapiro	Mount Sinai Hospital – Recanati Miller Transplantation Institute	United States
* Samuel Fung	Princess Margaret Hospital	Hong Kong
* Shigeru Satoh	Akita University	Japan
* Stephen McDonald	Royal Adelaide Hospital	Australia
Steve Chadban	The University of Sydney	Australia
* Tahir Aziz	Sindh Institute of Urology and Transplantation	Pakistan
* Teck Chuan Voo	National University of Singapore	Singapore
* Terence Kee	Singapore General Hospital	Singapore
Thu Du Thi Ngoc	Cho Ray Hospital	Vietnam
* Vasant Sumethkul	Ramathibodi Hospital	Thailand
* Vathsala Anantharaman	National University Hospital Singapore	Singapore
* Vivekanand Jha	George Institute for Global Health India	India
Williem Weimer	Erasmus MC University Hospital	The Netherlands
SONG-Tx Hong Kong attendees (patients/family members)		
* Mr Brian Chi Yuen Tse		
* Mr Chi Yan Yuen		
* Ms Choi Fong Hau		
* Ms Deneb Cheung		
* Mr Jif Wong		
* Ms Janet Hui		
* Ms Joen Hui		
* Ms Lin Ping		
* Ms Marina Ng		
* Mr Nga Lun Mok		

Summary report

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

BACKGROUND

While advances in treatment have dramatically improved short-term graft survival and acute rejection in kidney transplant recipients, long-term graft outcomes have not substantially improved. Transplant recipients also have an increased risk of cancer, cardiovascular disease, diabetes, and infection, which all contribute to appreciable morbidity and premature mortality.

Many trials in kidney transplantation are short-term, frequently use un-validated surrogate endpoints, outcomes of uncertain relevance to patients and clinicians, and do not consistently measure and report key outcomes like death, graft loss, graft function, and adverse effects of therapy. This diminishes the value of trials in supporting treatment decisions that require patients and clinicians to make multiple trade-offs between graft survival and the risk of side effects, adverse events, and mortality.

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.

Researchers can add other outcomes.

AIM

The Standardised Outcomes in Nephrology –Transplantation (SONG-Tx) initiative aims to develop a core outcome set for trials in kidney transplantation that is based on the shared priorities of all stakeholders.

PROCESS

Identifying core outcome domains

SONG-Tx 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



International Delphi survey to generate a prioritised list of core outcome domains based on consensus



Consensus workshops to review and discuss core outcome domains

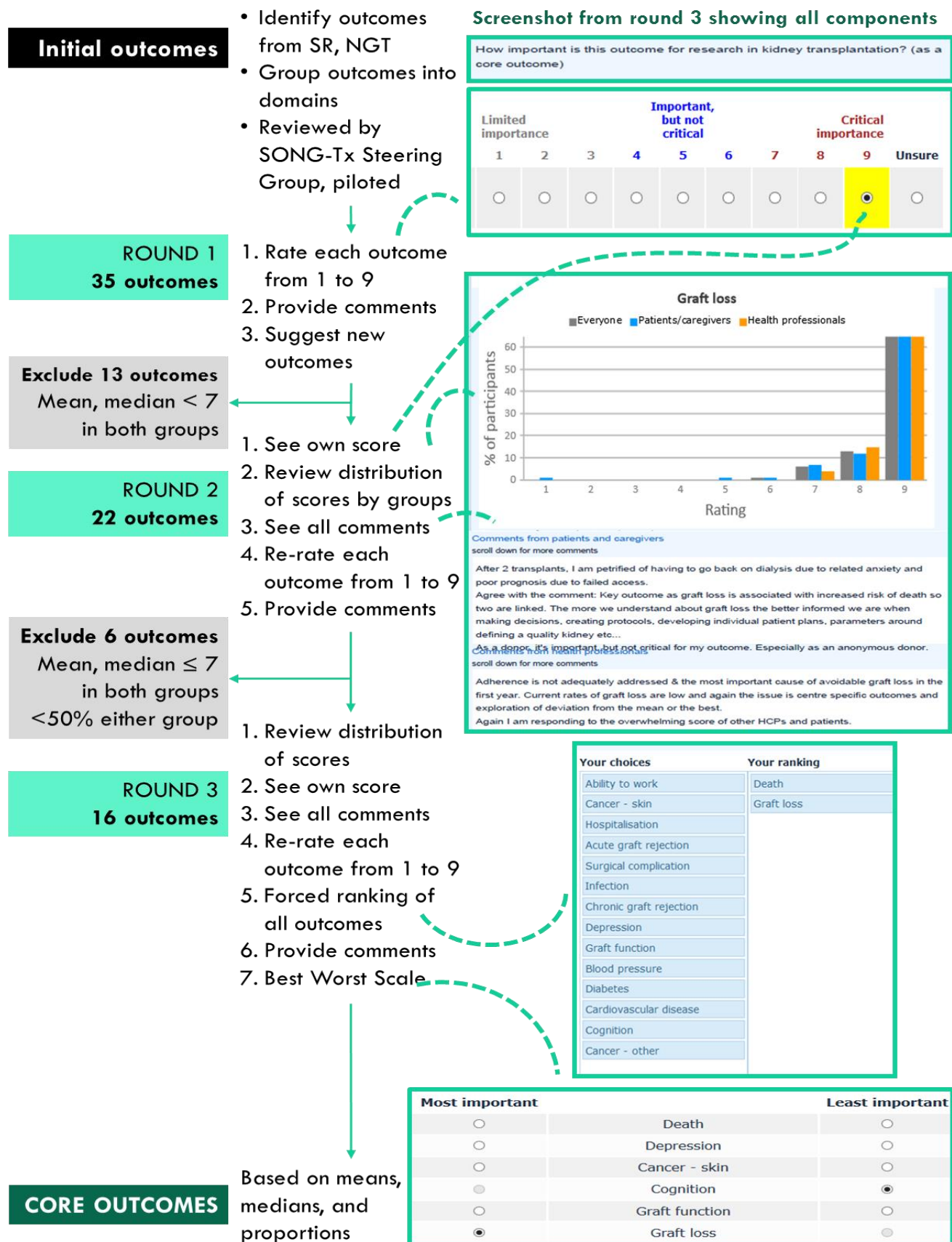
Identifying outcome measures

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.

PRELIMINARY RESULTS | SONG-Tx Delphi Survey

The SONG-Tx Delphi process

The results of the systematic review and Delphi survey will be presented at the workshop. This section will provide an overview of the initial results from the SONG-Tx Delphi Survey. Below is the flowchart of the Delphi survey.

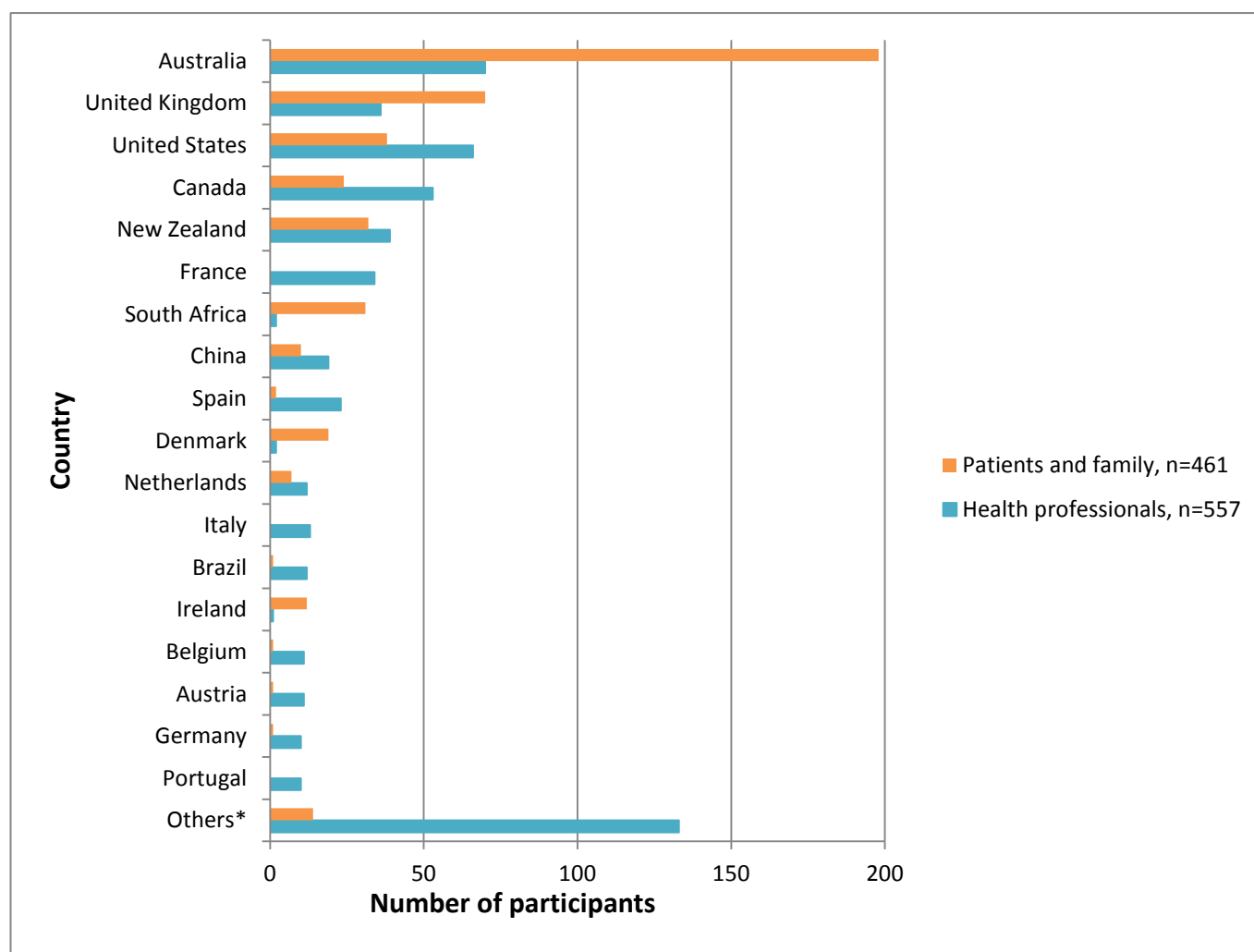


The participants

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

Stakeholder group	Round 1	Round 2 (% response)	Round 3 (% response)
Patients/caregivers	461	387	360
Health professionals*	557	457	419
TOTAL	1018	844 (83%)	779 (77%)

There was a similar proportion of males and females, and a wide range of ages (18 years to over 81 years). The participants in Round 1 were from 79 countries.



*Others: countries with a total number of participants <10 (61 countries: India, Greece, Romania, Finland, Egypt, Saudi Arabia, Mexico, Switzerland, Czech Republic, Poland, Argentina, Colombia, Sweden, Slovenia, Turkey, Japan, Montenegro, Serbia, Thailand, Vietnam, Luxembourg, Cameroon, Chile, Croatia, Kosovo, Lithuania, Nigeria, Norway, Oman, Singapore, Slovakia, Ukraine, United Arab Emirates, Cyprus, Georgia, Libya, Uruguay, Algeria, Bangladesh, Bolivia, Bulgaria, Cape Verde, Chad, Ecuador, Guatemala, Honduras, Hungary, Iran, Jordan, Kenya, Korea South, Macedonia, Malaysia, Burma, Pakistan, Panama, Philippines, Sri Lanka, Taiwan, Trinidad & Tobago, Venezuela)

Results | Outcomes and scores

Round 1

The mean and median scores for outcomes in Round 1 are provided below. Outcomes that had a mean and median of less than 7 in both groups (patients/caregivers and health professional) were removed from Round 2.

Please note, outcomes that were removed are still considered important but will not necessarily be included in the core outcome set. The outcomes highlighted in grey were removed from Round 2.

Outcome	Mean scores		Median scores		Proportion 7-9 score	
	Patients/ caregivers	Health professionals	Patients/ caregivers	Health professionals	Patients/ caregivers	Health professionals
Graft loss	8.3	8.4	9	9	88.3	91.4
Graft function	8.1	7.9	9	8	85.7	83.3
Chronic graft rejection	7.9	7.8	9	8	82.6	84.2
Acute graft rejection	7.9	7.4	9	8	81.1	73.2
Death	7.6	8.3	8	9	71.1	84.6
Infection	7.6	7.4	8	8	75.3	77.6
Cancer (non skin)	7.5	7.1	8	7	74.8	69.3
Cardiovascular diseases	7.4	7.4	8	7	73.3	77.0
Cancer (skin)	7.3	6.4	8	6	70.1	48.8
Diabetes	7.2	6.8	7	7	68.5	57.3
Blood pressure	7.2	6.5	7	7	69.6	50.1
Surgical complication	7.1	6.5	7	7	66.2	51.9
Cognition	6.9	6.3	7	6	64.0	47.2
Ability to work	6.8	6.6	7	7	59.4	54.9
Depression	6.8	6.3	7	6	58.1	48.1
Bone disease	6.7	5.8	7	6	56.0	33.9
Fatigue	6.7	5.6	7	6	56.4	29.6
Anaemia	6.7	5.6	7	6	56.6	28.4
Eye problems	6.6	5.4	7	5	54.7	24.8
High cholesterol	6.5	5.6	7	6	52.1	29.1
Sun sensitivity	6.4	5.0	7	5	49.7	19.2
Hospitalisation	6.3	6.6	7	7	50.8	56.0
Gastrointestinal disorders	6.4	5.7	6	6	48.2	30.9
Muscle weakness	6.4	5.3	6	5	48.8	22.6
Impact on family	6.3	6.1	6	6	47.9	40.4
Weight gain	6.3	5.8	6	6	44.9	31.2
Mood swings	6.3	5.5	6	6	47.3	26.4
Sleep disturbance	6.2	5.4	6	6	46.2	23.5
Pain	6.1	5.6	6	6	43.4	30.5
Anxiety	6.1	5.3	6	5	43.6	24.1
Arthritis	6.0	5.2	6	5	39.7	17.1
Appearance	5.8	5.4	6	6	41.2	23.3
Hand tremors	5.7	5.1	6	5	34.9	17.8
Pins and needles	5.5	4.8	6	5	30.6	14.2
Fertility	5.4	5.8	6	6	34.7	33.0

Round 2

The means and median scores for outcomes in Round 2 are provided below. Outcomes that had a mean and median of 7 or below in both groups (patients/caregivers and health professional) were removed from Round 3. Any outcome that had more than 50% of participants in both groups rating the outcomes as 7-9 (critical importance) were retained. The outcomes highlighted in **grey** were removed from Round 3.

Outcome	Mean scores		Median scores		Proportion 7-9 score	
	Patients/ caregivers	Health professionals	Patients/ caregivers	Health professionals	Patients/ caregivers	Health professionals
Graft loss	8.6	8.8	9	9	97.7	99.6
Chronic graft rejection	8.5	8.3	9	9	94.8	96.5
Graft function	8.5	8.4	9	9	95.1	95.6
Acute graft rejection	8.2	7.9	9	8	90.2	83.8
Death	8.1	8.7	9	9	87.8	96.9
Infection	8.0	7.8	8	8	89.9	90.8
Cancer (non skin)	7.7	7.4	8	7	84.5	82.4
Cardiovascular diseases	7.6	7.7	8	8	83.6	90.8
Cancer (skin)	7.4	6.6	8	7	75.4	54.5
Ability to work	7.3	6.8	8	7	73.1	60.8
Surgical complication	7.3	6.6	7	7	72.5	58.6
Diabetes	7.2	7.0	7	7	74.0	65.4
Cognition	7.2	6.5	7	7	73.4	51.9
Blood pressure	7.2	6.5	7	7	70.2	50.5
Depression	6.9	6.4	7	7	61.3	53.2
Hospitalisation	6.5	6.7	7	7	53.0	61.5
Fatigue	6.8	5.7	7	6	56.2	24.9
Anaemia	6.7	5.6	7	6	59.7	24.3
Bone diseases	6.7	5.8	7	6	54.1	25.7
Eye problems	6.6	5.3	7	5	52.3	17.3
Sun sensitivity	6.3	5.1	6	5	43.7	16.0
High cholesterol	6.2	5.4	6	6	42.6	19.5

Round 3

The preliminary means and median scores for outcomes in Round 3 are provided below.

Outcome	Mean scores		Median scores		Proportion 7-9 score	
	Patients/ caregivers	Health professionals	Patients/ caregivers	Health professionals	Patients/ caregivers	Health professionals
Graft loss	8.8	8.9	9	9	98.6	99.5
Chronic graft rejection	8.6	8.8	9	9	96.7	98.6
Graft function	8.6	8.6	9	9	97.2	97.6
Acute graft rejection	8.3	8.5	9	9	92.2	98.1
Death	8.3	8.1	9	8	91.3	87.4
Infection	8.1	7.9	8	8	93.9	94.0
Cancer (non skin)	7.8	7.8	8	8	85.7	94.5
Cardiovascular diseases	7.8	7.5	8	8	86.4	89.3
Cancer (skin)	7.5	7.1	8	7	78.6	72.3
Ability to work	7.5	7.0	8	7	75.8	66.1
Surgical complication	7.3	6.8	7	7	77.8	67.3
Diabetes	7.3	6.6	7	7	76.4	58.0
Cognition	7.3	6.6	7	7	76.2	59.9
Blood pressure	7.1	6.6	7	7	71.0	57.0
Depression	7.0	6.5	7	7	66.4	58.5
Hospitalisation	6.6	6.5	7	6	58.1	49.6

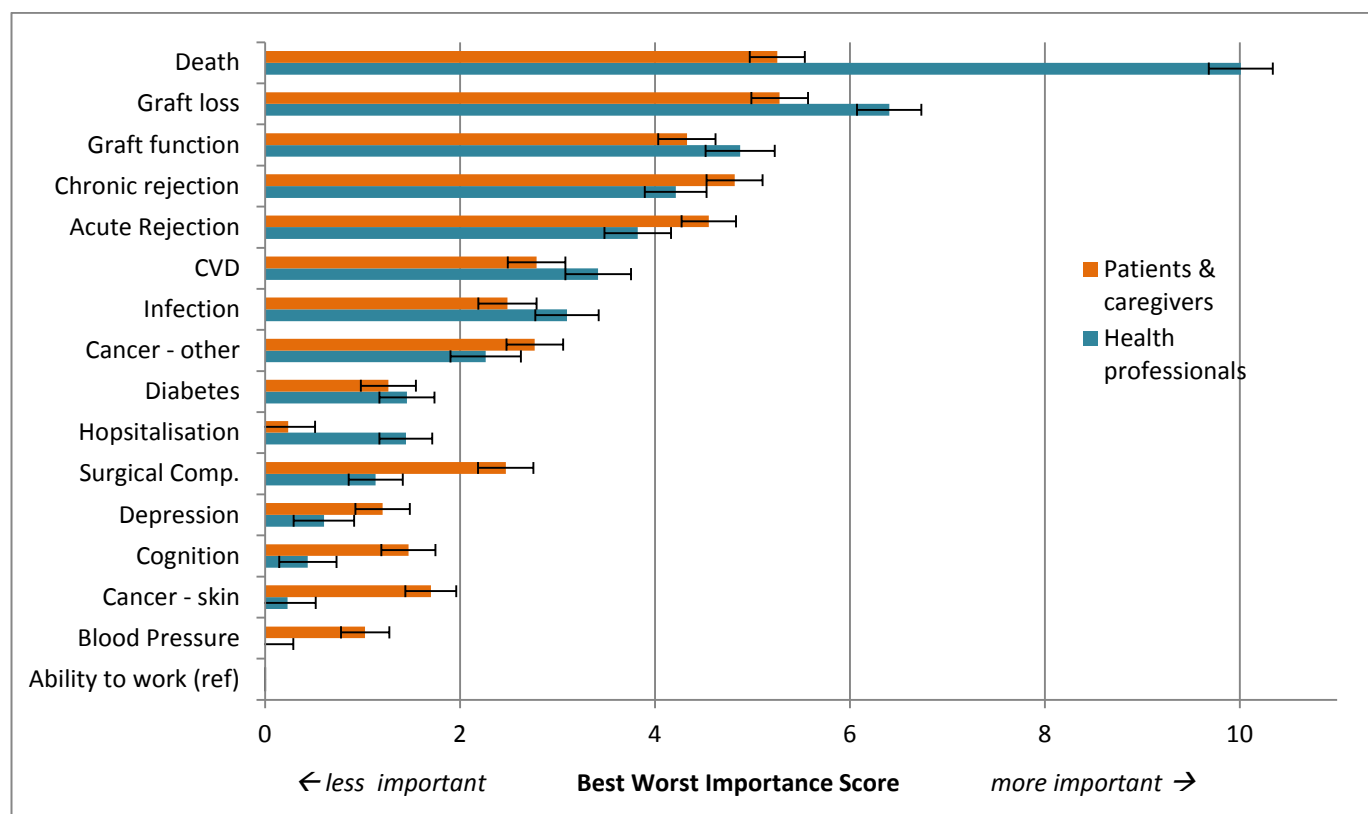
The eight outcomes in the red box were of highest importance to patients/caregivers and health professionals. These eight outcomes had a:

- Mean and median of more than seven in both groups AND
- More than 75% in both groups rated the outcome 7-9 (of critical importance)

Please refer to the SONG-TX Delphi Panel Report for more details including quotations and definitions provided for each outcome.

Best Worst Scale Survey

An optional best worst scale (BWS) survey was included at the end of Round 3, to identify the relative importance of all outcomes (i.e. compared to all other outcomes). For example, if one outcome has an importance score of 6 and a second 3, then the first outcome is twice as important as the second. The optional BWS was completed by 396 participants (204 patients/caregivers, 192 professionals).



Mean Best Worst importance scores and 95% confidence intervals for each outcome and each group calculated relative to the ability to work with a reference score of 0. The higher the score the more important the outcome.

Core outcome domains

The core outcome domains will be determined based on the Delphi results (means, medians and proportions in Round 3), results from the ranking exercise and Best Worst Scale, and will be informed by the discussions during the SONG-Tx consensus workshops.

