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Establishing a Core Outcome Measure for Life Participation: A Standardized Outcomes in Nephrology-kidney Transplantation Consensus Workshop Report

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Background. Kidney transplantation confers substantial survival and quality of life benefits for many patients with end-stage kidney disease compared with dialysis, but complications and side effects of immunosuppression can impair participation in daily life activities. Life participation is a critically important patient-reported outcome for kidney transplant recipients but is infrequently and inconsistently measured in trials. We convened a consensus workshop on establishing an outcome measure for life participation for use in all trials in kidney transplantation. **Methods.** Twenty-five (43%) kidney transplant recipients/caregivers and 33 (57%) health professionals from 8 countries participated in 6 facilitated breakout group discussions. Transcripts were analyzed thematically. **Results.** Four themes were identified. *Returning to normality* conveyed the patients' goals to fulfill their roles (ie, in their family, work, and community) and reestablish a normal lifestyle after transplant. *Recognizing the diverse meaning and activities of "life"* explicitly acknowledged life participation as a subjective concept that could refer to different activities (eg, employment, recreation, family duties) for each individual patient. *Capturing vulnerability and fluctuations posttransplant* (eg, due to complications and side-effects) distinguished between experiences in the first year posttransplant and the long-term impact of transplantation. *Having a scientifically rigorous, feasible, and meaningful measure* was expected to enable consistent and frequent assessment of life participation in trials in kidney transplantation. **Conclusions.** A feasible and validated core outcome measure for life participation is needed so that this critically important patient-reported outcome can be consistently and meaningfully assessed in trials in kidney transplantation to inform decision making and care of recipients.

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Kidney transplantation is the preferred therapy for many patients with end-stage kidney disease,¹ conferring substantial survival and quality of life benefits compared with dialysis.² However, the risk of serious comorbidities, including diabetes, cardiovascular disease, infection, and cancer, as well as debilitating symptoms due to immunosuppression such as cognitive impairment and gastrointestinal problems, and the resultant emotional distress can limit participation in daily activities.³⁻⁵ These challenges impair the overall quality of life of kidney transplant recipients.^{4,6,7} Being able to participate in various meaningful activities is a critical outcome for kidney transplant recipients, because they expect to be able to return to a healthy life after the transplant.⁸

Life participation has been established by the Standardized Outcomes in Nephrology-Kidney Transplantation (SONG-Tx) initiative as a critically important core outcome—along with graft health, mortality, cardiovascular disease, infection, and cancer—to be reported in all trials in kidney transplant recipients.⁹ The core outcomes were identified based on a systematic review of outcomes reported in kidney transplantation and consensus among more than 1000 kidney transplant recipients, caregivers, and health professionals worldwide.⁹⁻¹¹ In the early phases of the SONG-Tx process, patients prioritized “ability to work” as the most important patient-reported outcome to report in trials,¹⁰ but this had to be broadened for the outcome to be directly relevant to kidney transplant recipients across all stages of life. Thus, “life participation” was included in the core outcome set, defined as the ability to participate in activities that provide a sense of fulfillment, enjoyment, control, and hope. This encompassed a range of activities including, but not limited to, paid and volunteer work, family duties, social functions, recreational and leisure activities, and hobbies.⁹ Despite the critical importance of this outcome to patients and health professionals, life participation has been inconsistently defined and infrequently reported in the context of trials.

Studies that have evaluated life participation in kidney transplant recipients have used varying terms, such as “social participation” and “work ability.”¹²⁻¹⁴ Life participation is also embedded within broader constructs, such as “health status” and “quality of life.”^{2,15} Such heterogeneity is reflected in the measures used to assess this outcome. In a systematic review of 252 studies, 34 different measures, such as 36-Item Short Form Health Survey (SF-36)

and EuroQol-5D (EQ-5D), were used to assess “life participation.”¹⁶ It remains unclear if these measures capture “life participation” as conceptualized by kidney transplant recipients. Moreover, the comparative effect of interventions across trials is difficult to evaluate, given that these measures vary considerably in content (eg, dimensions of life participation), length, and psychometric properties.

A standardized measure that assesses life participation in a way that is relevant and meaningful to kidney transplant recipients that can be used across all trials will facilitate comparisons of the effect of interventions on this outcome, and ultimately may strengthen the evidence informing shared decision making in relation to the critically important outcome of life participation. This workshop report aims to describe the perspectives of patients, caregivers, and health professionals on establishing a core outcome measure for life participation to be used in all trials involving kidney transplant recipients. Although the scope of this workshop is to establish a core outcome measure for life participation to be used in trials, it may also be relevant in other settings, including transplant registries.

CONTEXT AND SCOPE

The SONG-Tx Life Participation consensus workshop was convened in Chicago on May 1, 2017, during the American Transplant Congress, to enable wider participation among the transplant community.

ATTENDEES AND CONTRIBUTORS

Of the 58 attendees, 16 (28%) were kidney transplant recipients, 9 (15%) were caregivers, and 33 (57%) were health professionals including nephrologists, surgeons, psychiatrists, psychologists, nurses, researchers, policy makers, and industry representatives. Attendees were from 8 countries including Australia, Austria, Canada, France, Norway, United Kingdom, United States, and Vietnam. We invited health professionals with clinical experience in kidney transplantation, interest in research relating to life participation of kidney transplant recipients, and/or an advisory or leadership role in relevant professional societies (including the American Society of Transplantation, The Transplantation Society, Canadian Society of Transplantation, Transplantation Society of Australia and New Zealand), regulatory and agencies (including the Food and Drug Administration and United National Organ Sharing), funding organizations (National

analysis, and provided intellectual input on the article and contributed to article writing. F.C. participated in the research design, data analysis, and provided intellectual input on the article and contributed to article writing. V.J. participated in the research design, data analysis, and provided intellectual input on the article and contributed to article writing. J.L. participated in the research design, data analysis, and provided intellectual input on the article and contributed to article writing. G.K. participated in the research design, data collection, data analysis, and provided intellectual input on the article and contributed to article writing. C.A. participated in the research design, data analysis, and provided intellectual input on the article and contributed to article writing. C.S.H. participated in the research design, data collection, data analysis, and provided intellectual input on the article and contributed to article writing. B.S. participated in the research design, data analysis, and provided intellectual input on the article and contributed to article writing. K.M. participated in the research design, data collection, data analysis, and provided intellectual input on the article and contributed to article writing. J.C.C. participated in the research design, data analysis, and provided intellectual input on the article and contributed to article writing. M.H.

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*A complete list of the SONG-Tx Life Participation Workshop Investigators is provided in SDC, Materials and Methods 1, <http://links.lww.com/TP/B641>.

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Institutes of Health), and registries (including the Scientific Registry of Transplant Recipients, UK Renal Registry and Australian and New Zealand Dialysis and Transplantation Registry). Local patients and caregivers were invited by United States SONG-Tx Life Participation workshop investigators, and received reimbursement for parking and ground transportation. All contributors who were unable to attend the workshop received a copy of the workshop program and draft report to provide feedback. Comments and feedback from nonattending contributors were integrated into the final report (**Supplemental Materials and Methods 1, SDC**, <http://links.lww.com/TP/B641>).

WORKSHOP PROGRAM AND BREAK OUT DISCUSSIONS

The workshop program and background materials were sent to all attendees and collaborators 2 weeks before the workshop. All participants were preassigned to 1 of 6 break out discussion groups comprising a mix of patients/caregivers and health professionals to ensure diversity of discussion and exchange of expertise. Each group had 9 to 11 participants, with at least 2 patients and caregivers. The breakout discussions commenced after participants were informed of the aims and background for the day through a short presentation on the SONG-Tx initiative and examples of current measures for life participation. Each group had a facilitator who moderated the discussion using a question guide developed by the SONG-Tx Life Participation Expert Working Group and Investigators (**Supplemental Materials and Methods 2, SDC**, <http://links.lww.com/TP/B641>).

Participants were asked to discuss the importance of life participation as an outcome for trials and provide specific input on establishing and implementing a core measure for this outcome. To prompt discussion, we provided 3 questions as proposed measures (EQ-5D Usual Activities - life participant subscale,¹⁷ and a question each on severity and frequency of limitation in life participation), as well as examples of frequently used measures including the SF-36 (daily activities subscale) and the Kidney Disease Quality of Life-Short Form (interference of kidney disease in life scale). Participants were asked to discuss the 3 examples in terms of interpretability, relevance of content, diction, and were asked to suggest other measures where appropriate. The groups reconvened to provide a brief summary in the final plenary session, which was moderated by the workshop Chair (M.J.). At the conclusion of the workshop, the Chair (M.J.) summarized the key points presented across all groups.

The plenary and break out discussions were audio-taped and transcribed verbatim. All transcripts were imported into HyperRESEARCH software for qualitative data management. We used thematic analysis to summarize the discussion.¹⁸ The first author (A.J.) read and conducted line-by-line coding of the transcripts to inductively identify preliminary concepts related to establishing a core outcome measure for life participation. The transcripts were coded to existing concepts, and new concepts were added when necessary. Similar concepts were grouped into themes. The coding structure was reviewed independently by a second investigator (A.T) and discussed to ensure that the themes captured the full range and depth of the

discussion. All attendees and contributors were invited to provide feedback on a draft report containing a description of the themes after the workshop within 2 weeks of receipt. Comments and feedback were integrated into the final report.

SYNTHESIS OF WORKSHOP DISCUSSION

We identified 4 themes that reflected important aspects of life participation that should be included in an outcome measure for life participation. Two themes pertained to the content (ie, conceptualization of life participation) to be captured in the measure: returning to normality and recognizing the diverse meaning and activities of “life.” The 2 other themes related to measurement characteristics: capturing vulnerability and fluctuations in issues post-transplant and having a scientifically rigorous, feasible, and meaningful measure. Both patients and health professionals contributed to the themes unless otherwise indicated. The following section describes these themes, and quotations to support each theme are presented in Table 1. Recommendations that emerged from the consensus workshop are listed in Table 2.

Returning to Normality

Adjusting to a New Normal

Some patients accepted that their lives after transplantation were not going to be the same as it was before being diagnosed with end-stage kidney disease for various reasons including the need to adjust to medication with associated side-effects, fear and anxiety of graft loss, and restrictions in diet. Rather than feeling limited, there was a strong focus on returning to normality but within their capabilities as a transplant recipient. One patient mentioned that they were “not inhibited, [he] just need[s] to adjust.”

Fulfilling One’s Role

Some participants noted that the “activities” of life participation could relate to what enabled them to function and accomplish important milestones in their lives as well as have the ability to resume their “roles.” For example, kidney recipients who were parents or the “breadwinners” for their family emphasized that it was important for them to be able to “fulfill [their] daily roles in the family.” Furthermore, one patient mentioned that as a parent, life participation meant being healthy enough to see their “kids at a young age grow up to a certain age, send them off to college” and other “big achievements.”

Recognizing the Diverse Meaning and Activities of “Life”

Differentiating Enjoyment and Participating in Activities

Participants explained that being able to enjoy an activity was different than, but just as important as, being able to participate in the activity. Some participants felt that survival would be meaningless if they could not enjoy or derive satisfaction from the tasks they were able to participate in. Life participation contributed to overall quality of life and patients agreed that they were “more interested in quality of life than longevity.”

TABLE 1.**Quotations to support each theme**

Themes and illustrative quotations

Returning to normality

Adjusting to a new normal

I'm not inhibited, I just have to adjust—P3

That's part of the challenge, trying to think about how they build their new normal—P3

You start making adjustments to your lifestyle—P4

I think this measure we are talking about here, what is, at different time points after transplant, how much have you achieved by life participation... in the view of going back to normal life, active life... measuring against not an unrealistic expectation, but a realistic expectation—P4

I think about [the kidney] all the time, I have stuff on my phone to remind me, time to take meds and stuff like that but I don't let it restrict anything I want to do—P3

Fulfilling one's role

It's just different but everybody has responsibilities, [things] to take care of—P3

The important part to me is to have purpose, its, seeing your kids at a young age grow up to a certain age, send them off to college that's a big achievement—P3

how well you carry out your usually social activities and roles—H4

Recognizing the diverse meaning and activities of "life"

Differentiating enjoyment and participation in activities

[patients] might be able to get themselves together to go to a family gathering, but they might have been in the bed all week, things that count as opposed to the things that don't count, that would be the only thing—P1

I'm going housework, I have a moderately hard time doing it but I do it, I push myself to do it, but then again I have a lot of other issues, not being able to do stuff... I can't participate... like going to the mall—P2

See you feel different about going to work, than you do about cutting grass, so I go to work because if they don't, they don't like me and they don't pay me anymore, I can let the grass grow—P4

Combination of obligatory and nonobligatory activities

If you said you can only go to work but you can't travel, it seems kind of, those are, you have to put together, they are both a kind of requirement of life—P5

I think what's mandatory differs from person to person, life stage to life stage, so I think it would be hard to, unless you are going to make a survey that's you know really granular I think it would be hard to determine—P6

In terms of whether one should make mandatory, versus nonmandatory, I'm in favor of not, because for, for my son, he'll participate in sports, that is his life, so now, I'm really, I used to be an athlete, I don't really care about exercise anymore, it really depends on which stage in your life and so I think whatever we develop has to be able to incorporate all those things—C6

[The measure has to be] flexible enough to really show what's meaningful in a person's life at that moment—C6

I would lump them together because that's what life, you have mandatory mixed in with the nonmandatory—P4

Subject to individual interpretation

Everybody has a different purpose and a different way of evaluating what they have achieved—P3

Everybody has a different idea of what they want, and that should be what we are measuring against, not an unrealistic expectation, but a realistic expectation, because for some people, it could be sitting on the couch all the time, and [different] for somebody else who may be a professional athlete... life participation is that you can participate in what, what percentage of things you want to do, can you achieve, at which time point—H4

Capturing vulnerability and fluctuations in issues posttransplant

Distinguishing first year posttransplant as a critical period of adjustment

I wouldn't ask patients/recipients to do this during the first year, wait at least a year post transplant—H3

After a year, you sort of know, what you, how it's affecting your life—P3

We're a year into it and now it's just like, now we can go to our actual routine, we don't have to come here every 2 weeks or something—C3

duration or interval may need to change as a function of how far you are out after transplant so in the initial period, this might be significantly quick enough, that you may need to capture 1 week of experience, whereas later down the line, when you're in a routine, that, more global experience over a month would probably capture what, your sort of experiencing—H6

Assessing the long-term impact of transplantation

So we're basically saying for this is that we think this [recall period of a week] is too limited, these questions, for patient life experience and we think maybe just expand it a little bit—H1

A week seems too short there's too many things that can happen—P1

Because you could just be sick that week or you might have had a doctor appointment that week and that disrupted you going to a meeting maybe at work or you had to go to the doctor, I wouldn't necessarily call that a problem, it's just something you have to deal with, and maybe you only go once a month of once every 6 months, or it could be that week—P3

My first reaction was well if you ask me this at the beginning of May I may have a different answer in August, I mean I look, last week, how narrow is that—P4

I would say a month is a time that's a fair reflection—P6

Continued next page

TABLE 1. (Continued)

Having a scientifically rigorous, feasible and meaningful measure

I think there is a consensus here that whatever it is it needs to be simple—C2

Something that's validated—H2

Whatever we do, it would have to be validated—H5

I think whatever we develop has to be able to incorporate all those things, and flexible enough to really show what's meaningful in a person's life at that moment—H6

Simplicity is really critical . . . make it easier, the simpler the better the question is understood and you get appropriate response with the question—H4

C, caregiver, the number corresponds to the breakout group ID; H, health professional; P, patient.

Combination of Obligatory and Nonobligatory Activities

“Life” was conceptualized as an integration of activities required for survival and those that were for enjoyment and leisure. Although participants noted the distinction between the 2, they believed that disaggregating them was unnecessary and difficult because in reality, the combination of all mandatory and nonmandatory activities defined “life.” Furthermore, what one patient classifies as mandatory may be nonmandatory for others. One patient acknowledged that traveling could be classified or perceived as nonmandatory but they considered travel “a must, to be able to say that [they] got back to normal life participation.” Furthermore, it was considered too granular and impractical to ask specifically about an individual or a group of activities such as working, studying, playing sport or traveling for the purpose of assessing life participation as a core outcome.

Subject to Individual Interpretation

When reading the proposed questions for life participation (**Supplemental Materials and Methods 2, SDC, <http://links.lww.com/TP/B641>**), participants interpreted

the concept of “life participation” and the word “activities” in their own context. Participation in activities that were important for one participant was not necessarily a high priority for another. For example, participants may have the same ability to participate in activities such as work, but some felt this was more important if they had to provide for their family, but less critical for those who were retired, living alone, and/or on a pension. The values attached to different activities varied at an individual level, and a patient remarked: “in view of going back to normal life, active life... everyone has a different idea of what they want, and that is what we should be measuring against.”

In addition, using only one specific measurement dimension of life participation, such as “how *often* are you limited in your ability to participate in life activities?” (frequency) was seen as impractical and less meaningful than one that captured a broader dimension such as “I have no/slight/moderate/severe problems doing/unable to do my usual activities” (EQ-5D).¹⁷ The latter was preferred as it would require patients to incorporate both severity and frequency of participation in answering the question.

TABLE 2.

Summary of workshop recommendations for establishing a core outcome measure for life participation

Implications for establishing a core outcome measure for life participation

- The core outcome measure for life participation needs to be applicable for all kidney transplant recipients, and should not specify or categorize activities. This will enable patients to interpret life participation in their own contexts based on their own individual priorities, goals, and values.
- Making a distinction between mandatory and nonmandatory activities is unnecessary and impractical because the way in which patients would classify specific activities as “necessary” would vary widely. Patients want to interpret “life” in their own realm, in reference to what is important in their current circumstances.
- A recall time frame that is longer than a week (suggestions range from 3 wk to 6 mo) is recommended. A week is too short as it is restrictive and may not capture the overall experience of the patient, which may fluctuate on a weekly basis (particularly during the first year posttransplant).
- The time points of administering the outcome measure would depend on the duration of time since kidney transplantation. More frequent assessments of life participation may be required in the first-year post transplant due to the higher risk of complications, adjusting to medication and the associated emotional distress during this vulnerable period.

Capturing Vulnerability and Fluctuations in Issues Posttransplant

Distinguishing First Year Posttransplant as a Critical Period of Adjustment

Both patients and health professionals stated that life participation would be more limited in the first year posttransplantation than compared with subsequent years. They explained that this was because of the higher doses of immunosuppression used for induction therapy, adjustment to medications, having to attend regular appointments, undergo tests, and increased vulnerability to possible complications such as infections. For example, a patient observed that when they caught a cold, they were “sicker...it takes a while to get back [recover] because of me immune system.” After the first year, patients were seen to be more stable and they “sort of know how [the transplant] is affecting [their] life.” Thus, participants recommended that the duration or the interval of administering the core outcome measure for life participation in a clinical trial should be varied to reflect the length of time posttransplant. They suggested that patients within their first year posttransplant may need more frequent assessments of life participation than in subsequent years after having adjusted to their transplant.

Assessing the Long-term Impact of Transplantation

Overall, participants felt that a recall period of 1 week to assess life participation in kidney transplantation is “meaningless and too restrictive” as patients can have a “bad week” that may bias the results. Suggestions of optimal recall periods ranged from 3 weeks to 6 months.

Having a Scientifically Rigorous, Feasible, and Meaningful Measure

Participants believed that an outcome measure would be regarded as acceptable, valid and useful if it captured the patients’ concept and interpretation of life participation after kidney transplantation. The measure had to be “simple” and produce “measurable and reproducible” data to ensure uptake of this measure by the trialists.

DISCUSSION

Life participation is a critically important outcome for both kidney transplant recipients and health professionals who define this concept as “the ability to participate in activities that give patients a sense of fulfillment, enjoyment, control and hope in their lives.” Although the outcome refers to a broad range of activities, patients preferred to interpret this based on their own values, goals, and priorities. Differences between mandatory and non-mandatory activities were noted, but participants agreed that the disaggregation of the 2 was unnecessary and difficult as it may differ according to the individual patient’s own interests and circumstances. Therefore, classifying different activities was considered too granular and impractical. Similarly, assessing life participation on a single measurement dimension, such as severity or frequency was also regarded as too specific and a combination of both was desired. A longer period of recall (more than 1 week) was recommended to capture fluctuations in their level of life participation, particularly in the first year after transplant.

A simple and meaningful measure to assess life participation in trials involving kidney transplant recipients will enable more reliable and valid assessments about the efficacy of interventions in trials. The discussions arising from this workshop demonstrate that patients conceptualize life participation based on their own context, priorities and values, which suggests that measures assessing life participation need to be framed so as to be sufficiently broad to allow individual interpretation. In this way, the outcome measure will consistently capture life participation as experienced and meaningful to each patient. Attempting to narrow down and classify different aspects of “life” with terms, such as “social,” “role,” “physical,” and specific type of activities will not capture life participation as experienced by all kidney transplant recipients in various stages of life.

Internationally, there is growing interest in using patient-reported outcome measures in research to assess how a patient feels and functions. Emerging evidence suggests that providing the tool to report symptoms and their conditions through monitoring patient-reported outcomes may be associated with better outcomes survival.¹⁹ The US Food and Drug Administration have mandated the inclusion of patient reported outcomes to support labeling claims for drugs and devices.^{20,21} Patient-reported

outcome measures should be selected based upon what is important to patients with the condition being investigated. Through a consensus process, kidney transplant recipients have identified life participation to be a critically important outcome.^{9,10}

The discussions and recommendations arising from this workshop (provided in Table 2) will directly inform the identification of a suitable, existing measure or the development of a new core outcome measure that is relevant to the kidney transplant recipients. The themes derived from the discussion will contribute to the content validity of the outcome measure. To potentially identify a suitable, existing measure, we will consider a wide variety of existing measures for the outcome measure, including frequently used measures, such as the EQ-5D¹⁷ and the Patient-Reported Outcomes Measurement Information System item bank for “ability to participate in social roles and activities.”²² If we identify a potentially suitable existing measure based upon the recommendations from our workshop, we will pilot this through cognitive interviews with kidney transplant recipients to ascertain comprehension, retrieval, judgment and response.²³ Before advocating for implementation in clinical trials, the proposed outcome measure will also undergo rigorous validation using frameworks established by initiatives such as Consensus-based Standards for the selection of health Measurement Instruments-Core Outcome Measures in Effectiveness Trials²⁴ and Outcome Measures in Rheumatology.²⁵ Psychometric properties such as reliability, responsiveness and content validity can be population-specific and may not necessarily be transferrable across different populations.^{26,27} Therefore, validation studies are necessary to ensure the measure is appropriate for the population in which it is being used. However, if existing measures are not sufficient, we will either modify an existing measure or develop a new core outcome measure for life participation. Once we have preliminary evidence from the validation study, we plan to disseminate the core outcome measure through research, journals, guidelines, trial networks and registries, professional societies, funders, policy/regulators, and patients/consumers.²⁸

Establishing a valid and relevant outcome measure for life participation is expected to improve the consistency and reliability in how life participation is assessed and reported in trials in kidney transplantation. This will better inform decision making and may contribute to the development and evaluation of effective interventions to ultimately improve life participation in kidney transplant recipients.

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*Health professionals (*includes 2 patients from the SONG-Tx Graft Health Expert Working Group)*—Zeeshan Butt, Camilla Hanson, Paul Harden, Carmel Hawley, Hallvard Holdaas, Ajay Israni, Michelle Jesse, Michelle Josephson, Sheila Jowsey-Gregoire, Angela Ju, Brenna Kane, John Kanellis, Bryce Kiberd, Joseph Kim, Greg Knoll, Chris Larsen, Alan Leichtman, Krista Lentine, Andrew Malone, Karine Manera, Roslyn Mannon, Rainer Oberbauer, Rachel Patzer, John Devin Peipert, Hai An Phan, Emilio Poggio, Rihannon Reed, Benedicte Sautenet, John Scandling, Jane Tan, Ignatius Tang, Allison Tong, Chris Watson,

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