Draft Stakeholder Feedback for the ESRD Patient Life Goals Survey (PaLS) Measure Technical Expert Panel Summary Report

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Produced by the University of Michigan Kidney Epidemiology and Cost Center

Introduction

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to collect stakeholder feedback for the ESRD Patient Life Goals Survey (PaLS) measure. As part of its measure development process, the University of Michigan Kidney Epidemiology and Cost Center convenes groups of stakeholders who guide measurement development efforts and provide thoughtful contributions about content and purpose of proposed measures. This report is a summary of the TEP discussion that took place on March 19, 2024.

Technical Expert Panel Objectives

UM-KECC has been tasked by CMS to collect stakeholder feedback for the ESRD PaLS measure to evaluate supporting evidence and face validity. This measure was designed to collect patient-level data about discussions with providers about life goals when making treatment decisions about dialysis modality; this measure is being considered for use as a quality measure to help foster collaborative treatment decisions among patients and providers. The goal of this specific TEP is to gather stakeholder feedback about the importance and usability of the PaLS. This information will be used to inform policy decisions about the use of this tool in future quality measure efforts in this population.

Technical Expert Panel Composition

This TEP was comprised of the following individuals. Dr. Jennifer Flythe and Mr. Paul Conway agreed to serve as co-chairs for the TEP, and assisted in facilitating the March 19th meeting.

Table 1. TEP Membership List

Name, Credentials, Professional Role*	Organizational Affiliation, City, State*	Conflict of Interest Disclosure*
Shameka Ausborn Patient Advocate	American Association of Kidney Patients, National Kidney Foundation, NxStage Jacksonville, FL	
Mary Baliker Patient Advocate	National Forum of ESRD Networks Middleton, WI	
Kerri Cavanaugh MD MHS Physician-Scientist Health Services Researcher	Vanderbilt University Medical Center, Veterans Affairs – TVHS Nashville, TN	

Name, Credentials, Professional Role*	Organizational Affiliation, City, State*	Conflict of Interest Disclosure*
Paul T. Conway Chair of Policy and Global Affairs	American Association of Kidney Patients Tampa, FL	
Jane DeMeis MS Patient Advocate	National Kidney Foundation, American Association of Kidney Patients Fairport, NY	
Jennifer Flythe, MD MPH Medical Director Associate Professor of Medicine with Tenure and Vice Chief, Division of Nephrology and Hypertension	UNC Hospitals Dialysis Services University of North Carolina (UNC)-Chapel Hill Chapel Hill, NC	I conduct research in Fresenius Medical Care dialysis clinics. The research is federally funded. I had a research grant from the Robert Wood Johnson Foundation that aimed to develop a life goal-based program for dialysis care plans. I am a member of the NKF KDOQI Quality Measurement Workgroup.
Michael Gilchrist Caregiver	LIVING on Dialysis Roy, UT	
Christina Gilchrist Patient Advocate	LIVING on Dialysis Roy, UT	
Kevin Hamilton Home Health Physical Therapist	Namaste Home Health and Hospice Louisville, CO	
Kristal Higgins Patient Advocate	Olive Branch, MS	
Angela J. Hurst, MSN, RN, FNP-C Advanced Practice Registered Nurse, Nephrology	Watson Clinic, LLP Lakeland, Florida	
Toni Martin Patient Advocate	American Association of Kidney Patients Mason, OH	
Klemens Meyer, MD Professor of Medicine Medical Director of Home Dialysis and In-Center Hemodialysis Programs, DCI-Somerville Physician	Tufts University Medical Center DCI – Somerville Boston, MA	
Dori Muench LCSW, MSW, CCTSW, NSW-C Interim Clinical Manager Transplant Social Worker	Atrium Health Wake Forest Baptist Medical Center, Winston Salem, NC	
Dale Rogers Patient Advocate Board of Directors, AAKP	American Association of Kidney Patients	
Brigitte Schiller MD, FACP, FASN SVP, Medical Officer Home Therapies	Fresenius Medical Care Waltham, MA	

Name, Credentials, Professional Role*	Organizational Affiliation, City, State*	Conflict of Interest Disclosure*
Sherrie Shivley Patient Advocate	Hamden, CT	
Jenn Trunk Patient Advocate	Chaska, MN	
Curtis Warfield Patient Advocate	National Kidney Foundation Indianapolis, IN	
UM-KECC Staff		
Claudia Dahlerus, PhD		
Jonathan Segal, MD		
Joseph Messana, MD		
Noelle Carlozzi, PhD		
Jen Miner, MBA		
Jennifer Sardone, PMP		
CMS Representatives		
Stephanie Clark, MD MPH MSHP		
Golden Horton, MS		
Wil Agbenyikey, Sc.D, MPH		

TEP Meeting Summary

Charter Approval

Dr. Dahlerus reviewed the purpose of the TEP as described in the TEP Charter, which is to obtain feedback on the importance and usability of the Patient Life Goals Survey (PaLS) process measure. She emphasized that changes to PaLS measure are outside scope of this TEP, and that there have been no decisions yet by CMS on how the measure would be implemented and/or how the PaLS would be administered. There were no questions or objections from TEP members about the Charter. The Charter can be found in Appendix C.

Background

To set the stage for the discussion, Dr. Dahlerus gave an overview of the Patient Life Goals Survey (PaLS) development process and purpose. In 2017, CMS tasked the UM-KECC with developing a new patient reported outcome quality measure for potential future implementation in CMS' public reporting on dialysis provider quality. The PaLS was developed subsequent to recommendations from a technical expert panel of ESRD patients and dialysis providers. The panel identified the need for a life goals patient reported outcome (PRO) measure because they felt that these discussions are not always happening. Discussion of patient life goals with one's dialysis care team can lead to better understanding by facilities and providers of those life goals, and support shared decisions that are informed by patient life goals.

The PaLS is brief, with 8 questions and an estimated 2 minutes required to complete (a copy of the survey can be found in Appendix A). Dr. Dahlerus emphasized that there are no right or wrong life goals, and they are not being judged by anyone. The PaLS measure simply provides information as reported by the patient, specifically whether life goals discussions are happening and not the realization of life goals. Goal achievement is outside the scope of dialysis care team control and facility not being judged on whether goals achieved. The following logic model illustrates the cyclical relationship of life goals discussions and treatment planning to achieve patient-centered care.

Figure 1. Logic Model of the Patient Life Goals PRO

Dr. Dahlerus reviewed how the items on the survey would be scored. First, Question 1 includes a list of possible life goals one can select. It is intended to provide the facility with a starting place to engage patients in life goals discussions. Next, a T-score would be calculated based on patient responses to the 6 Likert response questions (2a-2c and 3a-3c). Finally, Question 4 would report on “who” is talking with patients about life goals. (see slides in Appendix B for more detail).

Dr. Dahlerus explained that the current PaLS measure is a *process* measure that applies to all prevalent adult chronic dialysis patients (≥18 y/o) treated by the facility (both In-Center and Home Dialysis) for greater than 90 days during the reporting period, who read and understand English (additional work is being done to create a Spanish-language version of the survey). The numerator is the number of eligible patients from the denominator that completed at least one scorable item of the PaLS (i.e., at least one of the six Likert-type items).

One TEP member asked for clarification about when the survey would be administered (at the beginning of care, for example). Dr. Dahlerus clarified that CMS has not decided when, where, or how often the survey would be administered.

Summary of Survey Development and Testing

Dr. Noelle Carlozzi spent some time reviewing the specific steps that were taken to develop and test the life goals survey. Development took place in three stages.

Stage 1: A qualitative study to identify the most important concepts for treatment planning for people with ESKD. UM-KECC convened a TEP (2017), Focus Groups (2018), and cognitive debriefing (2019) to identify major themes that could be used as the basis for a patient reported outcome. For example, as a result of the TEP held in 2017, there were three themes that emerged that informed the development of PaLS:

- Life goals discussions were not happening (quality gap exists)
- Life goals should inform treatment planning
- Starting the life goals conversation

This qualitative testing also included discussions with patients about the items UM-KECC developed, whether they were understandable and accessible. During this time there was also a translatability review conducted to confirm that the words used in the survey would be translatable into other languages in the future, such as Spanish.

Stage 2: Fielding testing to calibrate the newly developed items. After the qualitative activities were completed, calibration testing was carried out with a sample of 517 patients (recruited in 2020-2021) with ESKD on chronic dialysis in the US. Through this process, the 6 Likert-type items in the survey (the "item bank") were tested several different ways to ensure they were each performing as expected (together and individually). Details about the sample and results can be found in the slides in Appendix B). One TEP member asked for a quantification of how the survey results change as patient quality of life changes. Dr. Dahlerus stated that while they didn't have the results at their fingertips, she felt that they were clinically meaningful. Dr. Dahlerus stated that she would follow up after the meeting with the specific testing results. *Stage 3: Qualitative validity study.* Using an independent sample (420 people in 2022-2023) we tested whether the survey was measuring what it was intended to measure. With this testing, the survey was re-administered at 3 months, and again at 6 months. Several reliability and validity tests were performed, and in summary, the results were in support of the reliability and validity of the survey. Details about the testing and results can be found in the slides in Appendix B).

Mr. Conway asked UM-KECC to clarify the type of the current PaLS measure in order to set the stage for the discussion. Dr. Dahlerus explained that the current measure is a process measure, at the patient level, that measures the percentage of patients at a facility that completed at least one scoreable item of the survey[1]. The process measure is an initial step to encourage discussion about life goals and have an indicator of how many patients are completing the survey. Additional data and facility level testing are needed to move beyond the process measure, and that is planned for the future.

Dr. Flythe added that process measures are important to show that this survey data can be collected regularly and reliably. While the measure may or may not become a quality measure, it is valuable to raise awareness of life goals for people taking care of patients, in addition to providing information about whether the information can be collected across facilities.

Discussion

Dr. Flythe started the discussion by asking the group to weigh in on the first of a series of questions designed to elicit feedback on the PaLS survey and process measure.

Discussion question 1: Describe the Importance of the life goals survey to support treatment discussions. How important is it to patients? How important is it to providers? Are there any other aspects of treatment and clinical outcomes relevant to the life goals survey?

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[1] The Patient Life Goals survey and scoring was developed using Item Response Theory (IRT), which is an analytical approach that enables a score to be computed assuming at least one item is answered. Thus, a single item is sufficient for score generation of the proposed process measure.

One of the provider TEP members started the discussion by noting that when they are working with new dialysis patients, their number one concern is how their life is going to change; sometimes providers unintentionally brush over the discussion and the seriousness of the question. A patient TEP member agreed, noting that a social worker asked her what her life goals where when she was a teenager and at the time, she didn't think she was going to live. A subsequent discussion of life goals when she received a transplant was instrumental in her going on to college. Several other patient TEP members chimed in agreeing with the importance of having the conversation about life goals when patients are new to dialysis. They felt it was important to helping patients feel like dialysis is not a death sentence. One TEP member also noted the importance of including caregivers in the discussion.

Dr. Flythe asked if any of the other providers on the call wanted to provide their perspective. One provider TEP member explained that the conversation has them thinking about operational flexibility in home modalities vs. in-center dialysis, which is more structured and rigid in terms of schedule. They think this instrument can impact discussions that patients have with their care team, and facility staff may be able to better prepare and be responsive to patient goals when planning treatment. Another provider agreed that the survey is potentially very valuable to enriching individual relationships, and to making patients feel heard. They noted that the major barrier that may arise would be concerns about survey burden on the facility, but they also recognized that this survey could be administered by other members of the care team (not just the nephrologist). A TEP member noted that the measure is in line with the larger theme within CMS of patient centered outcomes, and there is a feeling of engagement and empowerment that comes with asking these questions.

One patient TEP member asked if there is a mechanism for facility staff to follow up on the life goals that are identified during the survey process – for example, providing resources to help achieve specific goals. Additionally, there should be follow-up discussions with patients, for example if things have changed. A provider TEP member stated that although this is only a process measure at this time, it is a much needed process measure in order to encourage these discussions.

Dr. Flythe then oriented the conversation to discussing what facilities/providers will do with the information in the survey, even though the current process measure does not include any requirements beyond completion of the survey – and that no decisions have been made on how it would be administered. Mr. Conway clarified that as proposed, the PaLS is not about goal *realization*, it is about encouraging important conversations that can impact a patient's treatment plan. A patient TEP member agreed, noting that having an opportunity to express their goals to dialysis facility staff is an important opportunity for patients to take ownership of their dialysis experience.

Discussion question 2: Are there concerns about burden of taking or administering the PaLS survey?

Mr. Conway directed the discussion to the concept of survey fatigue. He asked patients to consider what they are getting surveyed about, and in that context what is the burden of taking this particular survey? Would it have an impact on patient experience? As the UM-KECC staff described in the beginning of the call, the survey is estimated to take 2 minutes to complete.

One patient TEP member felt that the survey is straight forward and to the point, while still gathering important information. They noted that they started dialysis recently hand have taken several surveys that were very long, and there was no follow up afterwards. A number of other patient TEP members agreed with this sentiment, and one pointed out that this survey is different from the others because it is focused on the patient (compared to other surveys, which contributes to the fatigue patients may feel). Another patient TEP member noted that surveys can be difficult to take when connected to a dialysis machine, so providing assistance if the survey is a paper survey would be important.

One provider TEP member explained that the question of who at the facility administers the survey has been on their mind, particularly when considering provider burden. This TEP member assumed it would be someone in the immediate care team of the patient, but wanted to know if this information would be shared with other members of the care team? Dr. Dahlerus took this opportunity to clarify that the intention of the survey is that only the first question (asking about specific life goals) would be shared with the care team. The rest of the information would be anonymized and aggregated for scoring purposes. One provider TEP member noted that some life goals might be of a sensitive nature and patients may be hesitant to share them. Another TEP member agreed, explaining that for some people, talking about life goals may be upsetting if they feel that have no goals or feel very desperate.

One provider TEP member explained that they realized that as implemented in the facility, it may be that patients fill out a survey and the provider just get these results from the government (rather than having a conversation, which is less ideal). Dr. Flythe explained that the intent of the survey is the conversation – one of the questions asks whether someone on your care team had discussed life goals with you. The survey is intended to incent those conversations. One patient TEP member relayed their experience with a nurse asking about life goals but it was very clear that she (the nurse) wasn't interested in the conversation, so having such a measure that asks the patient for their feedback on whether a meaningful conversation took place would be helpful.

A few TEP members raised possible concerns about privacy and sensitivity of sharing information from the survey. Dr. Dahlerus attempted to address the concerns about sharing life goals and what is ultimately done with the information patients provide on the PaLS. She said the UM-KECC are aware of these concerns. UM-KECC conducted focus groups to review the initial draft of the survey, and the theme of facility retribution was a pronounced theme in the discussion. While the first question, listing life goals, will be made available to the facility and associated with the patient, the remainder of the questions are *not* shared with the facility at the individual level. They would receive an aggregated score based on all of the surveys taken. UM-KECC and Dr. Dahlerus reiterated this point again later in the discussion when the issue came up again. Dr. Messana also noted that there may be an opportunity to clarify the instructions for the first question to make it clear that the first question is not being scored.

Several patient TEP members expressed that they would want to know what the intended outcome of the survey would be – would the facility be providing resources to achieve specific life goals? When thinking about that question, another patient TEP member reiterated that they are concerned about privacy in terms of who has access to that list of life goals, wondering if it would be anyone at the clinic or other medical providers. Dr. Dahlerus explained that the survey results would be handed like all other Protected Health Information (PHI). One provider TEP member reiterated the point that this is a process measure that is intended as a means to address a clearly identified gap in care and encourage a patient-centered cultural shift. A patient TEP member hoped that patients would want to shout their life goals from the rooftops – which may be more likely to happen if the conversation is meaningful.

Discussion question 3: is it helpful to know how well facilities do in talking about life goals?

Dr. Flythe directed the conversation to the third discussion question, about whether it is helpful to know how well facilities do in talking about life goals. One patient TEP member wondered about the difference in administering the survey to home dialysis patients vs. in-center. As a home dialysis patient, they said they have a great care team; when on in-center at the dialysis facility, their experience is that everyone was deferential to the nephrologist. Dr. Flythe explained that since the survey is agnostic to who has the conversation with the patient (nurse, nephrologist, social worker) the "who" can be tailored to the individual patient and their dialysis experience. The TEP member followed up with a concern about who is accountable for administering the survey. Dr. Dahlerus explained that the decision on who administers the survey has not been finalized by CMS, but it's possible that it would be administered by a third party (not the facility itself).

To follow up to those comments, one provider TEP member talked about the intended outcome of the measure being a focus on the patient, and not the process when treating ESRD. This provider TEP member also questioned whether or not a life goals quality metric, which was deemed important, is something that should be implemented by CMS; rather, should the kidney community make that cultural change by recognizing treatment planning and care for patients needs to be humanized which includes asking patients what is important to them. Dr. Flythe agreed that the process measure is in some sense a surrogate for those ideals because it is very personalized and provides a structure for evaluating at least one aspect of individualized care. Another provider TEP member was cautious in stating that the survey would be an effective surrogate, given the wide range of approaches to a life goals conversation and the tendency for patients to not trust their units. A patient TEP member echoed those concerns, noting that experiences may vary widely depending on the facility staff. A provider TEP member emphasized the importance of how this survey is administered in relation to how successful it is in leading to patient centered care.

Dr. Flythe responded to these concerns by stating that the survey that is intended to find out that a life goals conversation is happening, but also to collect life goals. The hope is that the facility is capturing that information in their own way for patients, as they care for them. The clinic can choose to capture the information about life goals however they choose; it could be a conversation with a social worker, a conversation as a part of the annual care plan, it could be part of the day to day rounding by nephrologists. The intent is not to specify how that happens, it's to encourage a facility to figure out how to facilitate or to encourage those conversations

One patient TEP member pointed out the importance of patient education in the experience of a dialysis patient, especially in terms of how they may achieve life goals. Another patient TEP member has been thinking about small facilities and how patients may not be anonymous if there is only a small pool. Dr. Dahlerus reiterated that it was possible that the survey would be administered by a third party, not the dialysis facility, and that only the first question about life goals would be associated with individual patients.

Summary and Consensus

The TEP co-chairs summarized what they heard from participants during the discussion and those areas where they heard consensus.

Co-Chair Dr. Flythe said that from the discussion there was agreement by the TEP that facilities should be having discussions about life goals with their patients, and that care should be individualized to patients by aligning treatment with patient life goals. Next, Co-Chair Mr. Conway said there was general consensus among the TEP that the PaLS instrument and the questions it asks are a positive thing; there was also consensus that life goals conversations are always happening with and among dialysis patients given the serious nature of their health situation (as reported by patients on this TEP, as well patients on the 2017 TEP). Mr. Conway went on to say there was consensus that this type of survey should not become another "check-box exercise" because the discussion about life goals is so important. He went on to say that there was general agreement CMS still needs to decide on the logistics of implementing the survey and how the survey would be operationalized in practice. The co-chairs said they did not hear dissent to their summary of the discussion.

Based on the discussion and closing summary, the main takeaway from the discussion is that both the PaLS content is important and asking and having conversations about life goals is important. There are also questions about how the future measure would be operationalized, including how the survey would be administered; how often; and what information facilities will receive to help support on-going life goals conversations with their patients. In line with that is the takeaway point about respecting patient concerns about sensitive information and general trust issues related to facilities knowing how patients responded to the survey.

Appendix

Appendix A: Patient Life Goals Survey

Appendix B: TEP Meeting Slides

Appendix C: TEP Charter