

End-Stage Renal Disease Patient Reported Outcomes Focus Groups

Summary Report

April & May, 2018

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1. Introduction

The University of Michigan, under contract with CMS is developing patient reported outcome (PRO) quality measures for use in the ESRD dialysis facility setting. The contract name is End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support. The contract number is HHSM-500-2013-13017I.

In 2015, CMS tasked UM-KECC to produce a white paper investigating Patient Reported Outcomes (PRO). The focus of the paper was to obtain information from the ESRD community on existing PRO measures, data sources, and potential PRO related items that are important to patients. UM-KECC hosted conference calls with patient organizations, provider organizations, and PRO subject matter experts between December 2015 and July 2016.

The final report delivered to CMS was posted publically on DialysisData.org in January 2017.

Subsequent to the PRO report, UM-KECC convened the Patient Reported Outcomes (PRO) Technical Expert Panel (TEP) on May 23-24, 2017. The TEP was tasked with reviewing existing health-related quality of life (HRQoL) and PRO measures. The TEP was asked to make recommendations on the potential development of PRO measures including health-related quality of life, recovery time, and measures derived from PROMIS item banks/domains, or potentially other measures identified by the TEP.

The TEP was composed of providers, patients, and measure development experts. Approximately half of the TEP members were patients. The TEP provided recommendations on future PRO Development including investigation of new PROs for patient life goals and patient safety. The complete TEP recommendations are provided in the PRO Summary Report at the following link:

https://dialysisdata.org/sites/default/files/content/ESRD_Measures/ESRD_Patient_Reported_Outcomes_TEP_Summary_Report.pdf.

In October 2017, CMS tasked UM-KECC to convene focus groups to review draft questions on patient safety and patient life goals.

UM-KECC conducted a literature review to collect information on any existing measures for use in healthcare settings and reviewed recommendations provided by the PRO TEP. Based on the PRO TEP recommendations, UM-KECC produced draft questions for Assessment of Patient Feeling of Safety (hereafter patient safety) and Assessment of Patient Life Goals (hereafter patient life goals).

This report summarizes the feedback received from both patient and provider specific focus groups on draft questions sets for patient safety and patient life goals.

1b. Recruitment

In preparation for the focus groups, UM-KECC sent out blast emails to a stakeholder list that includes providers, patients and patient advocacy groups, and other interested groups and individuals in the kidney community inviting them to nominate kidney patients, patient caregivers, and dialysis providers to serve on the focus groups. The call for focus group nominations ran from January 23, 2018 to February 28, 2018.

For the Patient and Caregiver Focus Groups, final recruitment targeted patients with ESRD including patients currently on dialysis, and caregivers of dialysis patients (specifically for pediatric or elderly/frail patients). For the Provider Focus Group, dialysis providers (nephrologists, nephrology nurses, social workers, and other clinicians) with experience treating ESRD dialysis patients were targeted for final recruitment. UM-KECC received 9 completed Provider Focus Group nominations and 21 completed Patient and Caregiver Focus Group nominations. Ten individuals were selected for the Patient and Caregiver Focus Group on Patient Life Goals. Nine individuals were selected for the Patient and Caregiver Focus Group on Patient Safety and 9 were selected for the Provider Focus Group. A majority of the selected nominees were able to participate in the focus group calls. Seven individuals participated in the Patient and Caregiver Focus Group on Patient Life Goals; the Patient and Caregiver Focus Group on Patient Safety had 7 members, and 9 members participated in the Provider Focus Group.

1c. Pre-Focus Group Planning

Focus group participants were provided with version 0.1 (v0.1) of the draft questions on life goals and patient safety ahead of the focus group calls. Each set of draft questions contained both global level questions as well as more specific drill-down questions. During the call introductions, focus group members were provided a background on the PRO work completed including a summary of the TEP recommendations. During the calls, UM-KECC presented the draft PRO questions and informed focus group members these draft questions are an early step in the measure development process. To help frame the discussion and feedback for the draft questions, it was noted that these should be treated as a pool of a question items (for life goals and patient safety, respectively) and not complete questionnaires. Participants were also asked to consider whether they preferred global questions, more specific drill-down questions with choice sets, or some combination of the two. It was also noted that future survey format may depend on whether the survey was administered using a using a paper form, an electronic form, or potentially computer adaptive testing (CAT) if appropriate.

UM-KECC informed focus group members that UM-KECC took feedback from the TEP and reviewed the literature in order to draft the draft measures questions. UM-KECC stated that the questions were not based on any existing life goals surveys.

The focus groups were held as webinar teleconference meetings in order to avoid travel burden on participants. The focus group sessions were not open to the public. Focus group participants were

informed the calls were recorded in order to produce a summary report. The individual statements and opinions of focus group members were anonymized in order to protect anonymity.

A total of four focus groups sessions were conducted between April 2018 and May 2018. The Patient and Caregiver Focus Group on Patient Safety was held on April 18, 2018. The Patient and Caregiver Focus Group on Patient Life Goals was held on April 19, 2018. The Provider Focus Groups on Life Goals and Patient Safety were held on May 2, 2018 and May 3, 2018.

2. Focus Group Feedback: Patient Safety

To help frame the discussion UM-KECC explained to focus group members that the one of the themes that emerged out of the TEP is that patients may have a broad patient feeling of safety. UM-KECC reported that there are no existing patient reported outcomes specific to patient safety in the ESRD population. UM-KECC explained that they produced draft questions that address both concepts of global patient safety and specific dialysis-related patient safety concerns.

2a. Draft Questions: Patient Safety v0.1

A copy of the draft questions for Assessment of Patient Feeling of Safety version 0.1 (v0.1) is provided below.

Draft questions: Assessment of Patient Feeling of Safety v0.1

1. Do you feel safe when you are receiving your dialysis treatment?

5=safe; 4=somewhat safe; 3=not sure; 2=somewhat unsafe; 1=unsafe

2. If you answered “unsafe” or “not sure” is it because: (select one only)

- a. Staff did not use the right skills or show experience in delivering your treatment
- b. You were worried about getting an infection
- c. Staff were not paying enough attention
- d. You did not feel well and staff did not respond quickly enough
- e. Doctors, nurses, or staff ignore or silence dialysis machine alarms
- f. Other _____

- 3. In the last 2 weeks have you experienced anything with your dialysis treatment that made you feel unsafe?**
 - a. No
 - b. Yes
 - c. Not sure
- 4. If yes, did the facility help to resolve your concern?**
 - a. No
 - b. Yes
 - c. Not sure
- 5. Do the nurses and technicians do a good job managing your vascular access during dialysis treatments at the facility?**

(5= all of the time; 4=most of the time; 3=some of the time; 2=rarely; 1=never)
- 6. Do the doctors and the people taking care of you follow handwashing and other infection control practices at the facility?** (5= all of the time; 4=most of the time; 3=some of the time; 2=rarely; 1=never)
- 7. Do you feel facility staff are paying attention to your care during dialysis?**

(5= all of the time; 4=most of the time; 3=some of the time; 2=rarely; 1=never)
- 8. At the facility, do doctors, nurses and staff speak to you in a way that shows respect?**

(5= all of the time; 4=most of the time; 3=some of the time; 2=rarely; 1=never)
- 9. In the last 2 weeks have you experienced any potential issues at the facility not directly related to your dialysis treatment?**
 - a. No
 - b. Yes
 - c. Not sure
- 10. If yes, did the facility help to resolve the issue?**
 - a. No
 - b. Yes
 - c. Not sure

2b. General Feedback on Patient Safety Questions by Patients

Focus group members reviewed the draft patient safety questions and provided general feedback in several areas.

Suggestions included to revise several questions to be more specific, clear, and to use more straightforward and non-technical language to make the questions easier for patients to respond. Focus group members also recommended using active statements for the draft questions about the standard of care that is expected (if there is a source that can be cited) and then ask patients if that standard of care is currently happening. For example, one question would begin with an active statement that “Facility staff are supposed to wash their hands to prevent infections.” The second part of the question would then ask patients “Do facility staff wash their hands?”

Focus group members recommended patients be asked the patient safety questions at a frequency ranging from each week to each month, which would result in more frequent safety events being reported.

Focus group members stressed the importance of how the questions would be administered to patients, to mitigate patient’s fear of retaliation; to protect respondent anonymity; and to minimize patient survey burden. On the topic of fear of retaliation, several focus group members stated they would feel uncomfortable completing the patient safety questions if their answers were provided directly to facility staff. Focus group members stressed the importance of anonymity in order to protect patients from fear of retaliation by facility staff. The focus group members also stressed that the questions and the responses are actionable to the facility so that responses would be used to improve the level of safety in the facility.

Several focus group members stated the patient safety questions may be of better use to patients if the questions are administered electronically, such as using a mobile app or a television in the facility, while patients are receiving dialysis. This might minimize survey burden on the patient. UM-KECC explained that the topic of survey administration will be addressed further along in the process once a quality measure has been developed.

Focus group members agreed with including both global and specific drill-down questions. Focus group members also highlighted that further clarification in some questions was needed in order to group safety questions by broad facility-related versus treatment-related issues.

Individual focus group members suggested using a one to five scale; including an optional comment box for some questions, and including home hemodialysis patients in the patient safety survey.

2c. Feedback on Specific Patient Safety Questions by Patients

Focus group members agreed that question one (Q1) was an important question. The feeling was that if patients feel unsafe, then a conversation needs to happen between the facility and the patients. Focus group members also mentioned the importance of including a question asking if facilities resolved the patient's safety issue.

Opinions varied regarding the appropriateness of including Q5 on vascular access management on a patient safety survey.

Members of the focus group also mentioned other items that play a role in facility safety, such as facility location, safety and comfort of the patient waiting room (e.g., keeping it comfortable, clean, clear of obstacles, and safe), and patient parking. Several individual recommendations made included adding the topic of respect to Q8, re-ordering the questions in chronological order (starting with a patient entering the facility parking lot and ending with a patient leaving the clinic), and asking patients if they are receiving enough dialysis treatment.

An individual focus group member raised a concern that facilities may not have a staff call button at patient chairs for patients to use while they are receiving treatment. The focus group member stated that often patients cannot get the attention of staff if they have an issue while receiving treatment.

Focus group participants were asked if patient safety summary results were publically reported on DFC, whether they thought the results patients would be useful to them as patients and caregivers. One focus group member stated they would use information about patient safety for background on a facility when deciding where to arrange treatment while travelling.

2d. General Feedback on Patient Safety Questions by Providers

UM-KECC explained to focus group members that the one of the themes that emerged out of the TEP is that patients may have a broad patient feeling of safety. UM-KECC reported there are no existing patient reported outcomes specific to patient safety in the ESRD population. UM-KECC explained they produced draft questions that address both concepts of global patient safety and specific dialysis-related patient safety concerns.

Focus group members stated that often patients have a fear of retaliation when it comes to patients reporting on patient safety. Focus group members also stressed the importance of readability and designing the questions at a fifth-grade reading level (which is standard practice to ensure interpretability across a range of respondents).

One focus group member recommended that questions should be ordered so that the most important ones are asked first. This might help address concerns about survey fatigue due to too many questions that may not be relevant to the patient.

Opinions varied on whether to include any open-ended questions or just to use an “other” option for some of the draft questions that provided discreet choice sets. Focus group members also provided differing opinions on whether a single global question was preferred over a formal survey.

One additional topic discussed among focus group participants was administering a simple one-question survey asking the patient if they had a good treatment experience, for example, a potential single question such as “I had a safety concern about dialysis treatment” or “I felt unsafe during my care here today”. A single question could be administered frequently. Several focus group members stated that a simple question or rating would be easy to administer and that more patients would likely respond. Several focus group members stated they were open to the possibility of using an electronic platform, such as patients selecting a button indicating their experience that day at the facility; or some other simple question rather than complete a longer formal questionnaire.

Focus group members also provided potential quality measure topics such as measuring the rate of facility response to the alert buttons.

2e. Feedback on Specific Patient Safety Questions by Providers

One focus group member stated that Q1 directly addresses the majority of recommendations from patients on the TEP. Patients on the TEP referenced the importance of asking if patients felt safe in their dialysis facility. Another focus group member offered an alternative to Q1: “Do patients feel safe from a medical procedure perspective?” The focus group member stated that safety may be related to the dialysis experience but not necessarily the procedure itself.

Focus group members provided several recommendations to update Q2 including asking patients how they felt, allowing patients to select more than one option, and to include an item about sensing that staff did not care.

Focus group members provided differing opinions on whether to list facility staff separately by role (doctors, nurses, etc.) or to list them as facility staff on Q2, Q5, Q6, Q7, and Q8.

Several focus group members agreed that Q3 was a useful question. One focus group member offered an alternative to Q3: “Have there been instances when you have felt unsafe over the past two weeks?” Then, patients could answer the following: Yes (once), Yes (more than once), or No.

The focus group provided input on how to best update Q4. The focus group recommended the question address the following in the patient’s own opinion: “Did patients share their concern?”, “Did the facility acknowledge the concern?”, and “Did the facility do something appropriate with the patient concern?” One focus group member stated they liked Q4 being a follow-up to Q3.

One focus group member recommended a question be added that asks patients if they feel comfortable.

One focus group member stated that they thought questions 5, 6, 7, and 8 were good questions.

One focus group members stated Q9 may be unclear and could be open to individual interpretation.

3. Focus Group Feedback: Patient Life Goals

UM-KECC stated the draft questions were based on general feedback from the TEP on the type of questions to ask but that these draft questions are not based on any existing life goals surveys.

As brief background to frame the discussion, the patient and provider focus groups were provided with several examples of patient life goals such as going back to school or to work. For example, a discussion of life goals may inform patient choice of a specific modality that fits with going to work, travelling, and so forth. These were examples that emerged during the 2017 TEP discussions.

3a. Draft Questions: Patient Life Goals v0.1

A copy of the draft questions for Assessment of Patient Life Goals version 0.1 (v0.1) is provided below.

Draft questions: Assessment of Patient Life Goals v0.1

- 1. How well did you feel supported by this dialysis facility care team starting and getting used to dialysis (first 90-120 days)?**
10=full support; 5= some support; 1=no support, N/A=I started dialysis in a different facility
- 2. Does the dialysis facility care team currently support your dialysis-related needs?**
 - a. Yes
 - b. No
 - c. Not sure
- 3. Right now, do you feel like you have the amount of input you want in decisions about your dialysis care?**
 - a. Yes
 - b. No
 - c. Not sure

4. Does your current care plan reflect your personal life goals?

- a. Yes
- b. No
- c. Not sure

5. Did anyone from your dialysis facility care team talk with you about your life goals?

- a. Yes
- b. No
- c. Not sure

6. If yes,

- a. Who talked with you about your life goals (select all that apply):

Nurse ___
Kidney doctor ___
Social worker ___
Patient care technician ___
Dietician ___
Other _____

- b. How often have you talked about it with members of your care team? _____

- c. After I had this conversation I understood that I might be (better) able to _____ (i.e., keep working, travel, and spend more time with family)

7. Overall, how well were you supported by your dialysis facility care team to pursue your life goals?

10=full support; 5=some support; 1=no support

8. Have any of your life goals been met?

- a. Yes
- b. No

3b. General Feedback on Patient Life Goals Questions by Patients

Focus group members stressed the life goals conversation ought to occur between patients, providers, and the care team on an ongoing basis, (quarterly, semi-annual and/or yearly basis) in order for responses to be actionable, or when there may be some change in patient's treatment status or major life event. Some focus group participants stated the life goals conversation is not happening uniformly across all facilities.

The focus group members recommended first defining important terms such as "life goals", "dialysis related needs", and "care team" for those question items and to provide examples of these terms so patients can understand what they are being asked. Focus group members further stressed the importance of readability, keeping the survey questions simple, and writing the question in present tense where possible in order to support the idea that the life goals conversation is ongoing. Focus group members stated the importance of the survey being anonymous (or having the option to be anonymous) in order to protect patients against the fear of retaliation from facility staff.

Focus group members recommended the patient life goals survey length be approximately ten meaningful questions. Several focus group members were in favor of including an optional free-text box or write-in option for the existing life goals questions in order to best capture patient life goals.

3c. Feedback on Specific Patient Life Goals Questions by Patients

Focus group members commented that Q2 should be more specific and recommended it be revised to say "dialysis related needs to achieving individual life goals."

Several focus group members felt the term "input" in Q3 was unclear on what it meant to convey or what patients were being asked to answer. In particular one focus group member stated that input sounds like a one way discussion, as opposed to discussion, which may convey an ongoing conversation. One focus group member proposed the following as a replacement for Q3: "Do you feel like you have enough input on the decisions of your dialysis care?"

One focus group member proposed adding a comment box to Q5 so that patients who answer "no" can include free-text to explain why the facility staff was not talking to them about their life goals.

Focus group members stated it was important for the wording of the question about a "life goals conversation" be in the present tense in order to make clear this should an ongoing conversation, not something that only happens once. UM-KECC offered an alternative to Q6: "Who has talked to you about your life goals and is the conversations ongoing?" Several focus group members stated this proposed alternative was better.

Several focus group members stated Q8 should be reworded to include "since starting dialysis treatment."

Some additional feedback applied to several of the questions. For example, some participants suggested using the term “recent care plan” for questions that ask about the care plan.

3d. General Feedback on Patient Life Goals Questions by Providers

The provider focus group stressed the importance of readability, using present tense where possible, and defining technical terms (such as “potential issues”, “dialysis facility care team”, “directly related”, and “life goals”).

The focus group members recommended providing examples of life goals at the beginning of the survey in order to help ensure patients understand more specifically what is meant by life goals. Participants felt doing so would help patients complete the survey. Several also commented that the life goals definition will need to take into account potential variation of meaning across different patient demographic groups (e.g., ethnicity, race).

Several focus group members agreed they like the combination of using global questions and specific questions in order to drill down to specific issues when appropriate.

One focus group member recommended all of the questions be asked in the same format. They recommended that the questions be affirmative, for example, “I feel supported by my dialysis facility care team when I started dialysis” and to use a 1-5 (Likert) scale for all the questions. They felt this structure would be better understood by a wider demographic of patients.

Individual focus group members also provided the following suggestions: ordering the questions in a way that makes sense to patients (such as asking global, then specific questions); wording questions so they are applicable to pediatric patients (e.g., life goals may include participating in activities specific to this patient sub-population).

One focus group member stated they like a mixture of global and specific questions. The focus group member further stated that if these questions were administered via an electronic platform (e.g., on a computer) then it would be easy to have a drop down list with examples of life goals.

One focus group member asked that the question design take into account home patients (hemodialysis, peritoneal dialysis) in mind for this survey because often they have different challenges than home patients.

Some participants stated that the main focus of the life goals survey should be on life goals and not include questions about the patient’s dialysis treatment.

3e. Feedback on Specific Patient Life Goals Questions by Providers

One focus group member stated that in Q1 the time period of 90 days may not be interpretable to some people answering the question. They suggested referencing time in months.

Focus group members stated that Q3 is important and provided several potential wording changes and suggestions to Q3. These included allowing the additional items in the drill down or ask a follow-up questions. Another suggestion was to ask “does you care team listen to your concerns about dialysis?” or “Do you feel like your care plan reflects your decisions and feeling about your care?”

Individual focus group members suggested leaving out the word dialysis from Q3. Focus group members briefly talked about Q5 and Q6, but there was no discussion of specific suggestions, aside from one or two minor wording changes. Participants also stated that Q5 and Q6 were good questions and should be included in the question set.

The focus group members proposed several potential revisions to Q7 such as “Do you feel comfortable to talk about your life goals with the staff at dialysis or the nurses or the physicians or the nurse practitioners?”, “Does your dialysis team help you reach your life goals?”, “Do you feel your dialysis team helped you reach your life goals?” or “Does the dialysis team respect and consider your life goals?”

4. Summary of Focus Group Recommendations and Possible Next Steps

Overall focus group participants provided feedback on the content and in some cases scope of the draft questions for patient safety and life goals. Specific revisions were also suggested for several of the draft questions for both patient safety and life goals question sets. Some focus group participants also made suggestions about how to order questions for a future survey(s); mode of administration; frequency of administration.

Based on the feedback received the following emerged as the main focus group recommendations:

- Revise language for several patient safety and life goals questions to make terms and question meaning more interpretable to a range of different reading levels; avoid using technical terms where possible; use present tense and active voice in question wording
- Include a combination of both global questions and specific drill-down questions. Drill-down questions in some cases can include additional item choices for patients to select and a free-text option(s)
- A goal for development of future surveys should be to keep them as brief as possible to minimize administrative burden and risk of survey fatigue

- Define life goals prior to the first question so that patients have an appropriate context for the following questions about life goals
- The Patient and Caregiver Focus Group members strongly emphasized that the questionnaires should be administered in a manner that preserves patient anonymity.
- The Provider Focus Group members recommended consideration of one simple patient safety question that is asked frequently

Next steps include applying several of the suggested revisions to individual question items for both the patient safety and life goals question sets. The revised question sets will be delivered to CMS subsequent to the final summary report.