DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on End-Stage Renal Disease in the Medicare Population

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *End-stage Renal Disease in the Medicare Population,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: Submission Deadline by July 22, 2019.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *End-stage Renal Disease in the Medicare Population.* AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *End-stage Renal Disease in the Medicare Population,* including those that describe adverse events. The entire research protocol is available online at: *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/topicrefinement/esrd-protocol-2019.pdf.*

This is to notify the public that the EPC Program would find the following information on End-stage Renal Disease in the Medicare Population helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

Key Question 1

In studies of frequency and duration of hemodialysis in non-institutionalized individuals, what are the characteristics of the patients and dialysis modality (including home or dialysis center setting and flow rate)? What is the length of follow up on patients in the studies? How does this compare to the general population of patients on dialysis?

Key Question 2

In hemodialysis patients, does more frequent hemodialysis (more than 3 times a week) improve objective outcomes (including hypertension control, mortality, QOL) over the long term (more than 6 months) compared to usual hemodialysis frequency (3 times a week)? What is the impact of patient characteristics and modality of dialysis used in the studies on outcomes?

Key Question 3

In hemodialysis patients, does extended hemodialysis duration (daytime, 4 or more hours per session, or nocturnal, overnight) improve objective outcomes (including hypertension control, mortality, QOL) over the long term (more than 6 months) compared to usual length hemodialysis duration (less than 4 hours)? What is the impact of patient characteristics and modality used in the studies on outcomes?

TABLE 1—EXPLANATION OF DURATION AND FREQUENCY OF HEMODIALYSIS UNDER CONSIDERATION FOR KQS 1–3

		Duration (hours per session)	
		Less than 4 hours	4 hours and more
Frequency (treatment N) per week	3 sessions	9-<12* hours per week	>= 12 hours per week

TABLE 1—EXPLANATION OF DURATION AND FREQUENCY OF HEMODIALYSIS UNDER CONSIDERATION FOR KQS 1–3—Continued

		Duration (hours per session)	
		Less than 4 hours	4 hours and more
	4 or more sessions	9- to <16** hours per week	>=16 hours per week

* Usual care involves 3 sessions per week with 3–4 hours per session.
** The duration of each dialysis session is generally shorter when dialysis is done more frequently.

Key Question 4

What instruments have been used to measure QOL in studies of people with ESRD treated by dialysis?

Subquestion 4a: What are the psychometric properties of instruments used to measure QOL in studies of people with ESRD treated by dialysis?

Subquestion 4b: What is the minimal clinically important difference for instruments used to measure QOL in studies of people with ESRD treated by dialysis?

Subquestion 4c: How have instruments used to measure QOL in studies of people with ESRD treated by dialysis been validated?

Subquestion 4d: What is the impact of placebo effect in studies used to measure QOL in people with ESRD treated by dialysis and what study designs are needed to mitigate the impact?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Population(s)

- *All KQs:* US ESRD Medicare population (non-institutionalized)
- *KQ 1:* Adults and children with ESRD on hemodialysis (no age restriction)
- *KQs 2 and 3:* Adults and children with ESRD on hemodialysis
- *KQ 4:* Adults and children with ESRD treated with any dialysis or other non-transplant treatment

Interventions

- *KQ 1:* Different frequency or duration of hemodialysis
- *KQ 2:* More frequent hemodialysis (3 versus > 3 sessions/week)
- *KQ 3:* Increased duration of hemodialysis sessions (12 hours versus > 12 hours per week; or daytime versus night time)
- *KQ 4:* For this question, we will include studies of QOL in people with ESRD receiving any type of dialysis.
- We will abstract data on all home hemodialysis machines (2008K@ Home Hemodialysis Machines, NxStage® System One, NxStage® System S) as well as all devices used in-center (a large variety of machines used in center exist and all will be considered for data collection)

Comparators (see Table 1)

- *KQs 1 and 4:* Usual care (3 times per week and 3–4 hours per treatment)
- *KQ 2:* More frequent hemodialysis (>3 session/week); usual care
- *KQ 3:* Increased duration of hemodialysis sessions (> 12 hours per week, or nocturnal, overnight); usual care

Outcomes

- *KQ 1:* Not applicable (see Appendix A for a list of the patient characteristics that will be considered for this KQ)
- *KQs 2 and 3:*
  - *Final health outcomes (see Appendix B for a detailed list of outcomes):* Clinical outcomes including cardiovascular events, hospitalizations, QOL, pregnancy outcomes, and mortality
  - *Adverse events (see Appendix B for a detailed list of outcomes):* Intradialytic hypotension, access complications, loss of residual kidney function, infectious events, myocardial stunning hospitalizations, and patient and caregiver burden
  - *Intermediate outcomes (see Appendix B for a detailed list of outcomes):* Metabolic/inflammatory control, blood pressure control, dialysis recovery time
- *KQ 4:*
  - Instruments used to measure QOL in dialysis patients
  - Psychometric properties of these instruments
  - Minimal clinically important difference for these instruments
  - Validation of these instruments
  - Placebo effect in studies of QOL in dialysis patients and what study designs are needed to mitigate the impact

Timing

- *KQs 1–3:* Minimum of 6 months of follow-up after the intervention is initiated
- *KQ 4:* No minimum follow-up

Setting

- Home dialysis, and dialysis center (Non Institutionalized)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–16JO]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Pregnancy Risk Assessment Monitoring System (PRAMS) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 31, 2018 to obtain comments from the public and affected agencies. CDC received four comments related to the previous notice, two non-substantive, two in support of the data collection; no modifications were made to the PRAMS plan in response to comments. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information,