



Topic Brief: Patient Activation in Chronic Kidney Disease

Date: 1/14/2021

Nomination Number: 0944

Purpose: This document summarizes the information addressing a nomination submitted on December 2, 2020 through the Effective Health Care Website. This information was used to inform the Evidence-based Practice Center (EPC) Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue: Chronic kidney disease (CKD) and end-stage renal disease (ESRD) are prevalent and require significant management on the part of the patient. Low patient engagement, however, poses a barrier to patients effectively implementing necessary lifestyle changes to manage health outcomes. Interventions to increase patient activation in their self-management of chronic disease conditions could slow or halt the progression of disease severity and provide more flexible treatment options including home dialysis.

Program Decision:

While we found a small evidence base to support a systematic review, the EPC Program will not develop a new systematic review because of competing programmatic priorities.

Key Findings

- We found seven studies that would support a limited systematic review on patient activation interventions for CKD.
- We found five ongoing/upcoming studies that address the nomination.
- Although a systematic review would be limited in size, the impact of information regarding patient management of CKD could be great given the prevalence of the disease. Further, ongoing and/or upcoming studies may allow for a larger body of evidence at the time of the review.

Background

Chronic kidney disease (CKD) is a condition in which the kidneys are damaged and cannot filter blood to the necessary extent, causing excess fluid and waste from the blood to accumulate in the body. Chronic kidney disease can progress to kidney failure, also known as end-stage renal disease (ESRD). Kidney diseases represent the ninth leading cause of death in the United States, and an estimated 37 million American adults (15%) have CKD. In 2017, Medicare costs for CKD and ESRD treatment amounted to \$84 billion and \$36 billion, respectively.¹

Recommendations for managing CKD include diet, exercise, and medications for glycemic control.² If CKD progresses, kidney replacement therapy or dialysis may be required.³ Chronic disease management strategies require significant patient involvement especially as providers increasingly recommend remote management and in-home dialysis.⁴

Patient activation is defined as a patient's knowledge, skill, and confidence to manage their health.⁵ A positive relationship exists between levels of patient activation and health outcomes.⁶ Interventions to improve patient activation have been associated with increased physiological, psychosocial, and behavioral health status in chronic disease patients.⁸ Patient activation interventions may include improving physician-patient communication and providing coaching (education and support) tailored to the individual patient's activation level.^{9,10}

The nominator for this topic is specifically interested in understanding how patient activation interventions slow the progression of CKD, facilitate the transition to dialysis, facilitate decision-making surrounding kidney transplant, and influence health, quality of life, and cost outcomes. Once the efficacy of these patient activation interventions for CKD have been established, the nominator plans to use an evidence-based report to influence the development of practice guidelines.

Nomination Summary

We initially developed the scope of the potential systematic review in collaboration with the nominators. The topic met the initial criteria for consideration by the review board. The review board determined that the literature yield was too small, and proposed expanding the scope. Following the review board's determination, the nominators were not available to further engage in the topic development process to confirm the proposed expansion of the scope or their continued plans to use a potential evidence product to promote practice change.

Scope

1. What are the effectiveness and harms of patient activation interventions on the progression of chronic kidney disease (CKD)?
 - a. How does the effectiveness of patient activation interventions vary by patient characteristics (e.g., socioeconomic factors, gender, race, age, geographical location)?
 - b. How does the effectiveness of patient activation interventions vary by intervention characteristics (e.g., mode of delivery, setting, service provider)?

Table 1. Questions and PICOs

Questions	1. Patient activation in CKD
Population	Adults with chronic kidney disease and/or their families/caregivers Consider patient characteristics (e.g., socioeconomic factors, gender, race, age)
Interventions	Any patient activation intervention to 1) slow the progression of the disease at early stages (e.g., lifestyle/diet changes); 2) facilitate the transition to dialysis (and decisions surrounding type/setting of dialysis) if the condition progresses; 3) facilitate decision-making surrounding kidney transplant, facilitate getting on the transplant list, and facilitate the patient in staying healthy enough to receive the transplant Consider patient activation intervention characteristics (e.g., mode of delivery, setting, service provider)
Comparators	Any (e.g., other activation strategies), none
Outcomes	<ul style="list-style-type: none"> • Measures of progression of chronic kidney disease (e.g., measures indicating hyperkalemia, metabolic acidosis, hypertension, anemia, mineral and bone disorders, uremia, creatinine clearance, proteinuria) • Placement of permanent vascular access

	<ul style="list-style-type: none"> • QOL for patient and/or family/caregivers • PAM • Health care costs (to the national healthcare system, and to patient personal finances) • Health behaviors (e.g., diet, exercise, medication adherence) • Harms (e.g., side effects from medications)
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Abbreviations: CKD=chronic kidney disease; PAM=patient activation measure; PICOS=population, intervention, comparator, outcome; QOL=quality of life.

Assessment Methods

See Appendix A.

Summary of Literature Findings

From a limited search of literature published in the past five years, we found a small group of completed studies that address the nomination, as well as a small group of protocols for ongoing and/or upcoming studies, indicating continuing investment in the topic area. This evidence leads us to believe that a new systematic review addressing the nomination would be small, but feasible.

We found four randomized controlled trials (RCTs); three addressing the main key question (KQ1), and one that could contribute to KQ1a on addressing patient characteristics as a factor in the effectiveness of patient activation interventions. The three RCTs that addressed KQ1 used different interventions to facilitate patient activation, including a decision-support intervention to facilitate patient treatment choice,¹¹ a health coaching intervention,¹² and a home-based program that included initial lifestyle coaching and support from community health resources.¹³ Investigators conducting the fourth RCT used a culturally-tailored, home-based kidney care intervention and evaluated the impact of diabetes status on patient activation measures (KQ1a).¹⁴ We also found three relevant non-RCTs, one that evaluated a mobile app to help patients manage their condition,¹⁵ one that evaluated a structured group-education program,¹⁶ and one qualitative study that evaluated a portal for patients to access part of their health records.¹⁷ While we did not find any studies with a primary aim of evaluating the effectiveness of different intervention characteristics (KQ1b), there may be useful information embedded within the identified studies to contribute to this question.

Additionally, we found five ongoing and/or upcoming studies in ClinicalTrials.gov. Patient activation interventions in these studies were varied, and consisted of a home-based care intervention ([Study 1; estimated completion date of December 2020](#)), questionnaires and/or worksheets to facilitate patient education and communication with healthcare providers ([Study 2; estimated completion date of December 2022](#), [Study 3; estimated date of completion December 2020](#), [Study 4; estimated date of completion June 2021](#)), and a physical activity program ([Study 5; estimated date of completion of February 2022](#)).

Table 2. Literature identified for each KQ

Question	Systematic reviews (1/2016-1/2021)	Primary studies (1/2018-1/2021)
Question 1: Patient activation in CKD	Total: 0	Total: 7 <ul style="list-style-type: none"> • RCT: 4 • Non-RCT: 3 Clinicaltrials.gov: 5

Abbreviations: CKD=chronic kidney disease; KQ=key question; RCT=randomized controlled trial.

See Appendix B for detailed assessments of all EPC selection criteria.

Summary of Selection Criteria Assessment

Chronic kidney disease (CKD) affects many people in the United States and generates high levels of annual health costs. A systematic review that evaluates patient activation interventions to improve outcomes for people with CKD would likely be small, but may be impactful due to the large number of people affected by the disease and the nominator's plans to influence the development of practice guidelines. Furthermore, the presence of ongoing and/or upcoming studies relevant to this topic indicate continued investment in patient activation strategies for CKD, which may result in a larger literature base over time.

Please see Appendix B for detailed assessments of individual EPC Program selection criteria.

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Appendix A: Methods

We assessed nomination for priority for a systematic review or other AHRQ Effective Health Care report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix B for detailed description of the criteria.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Absence of Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years 1/19/2018 – 1/19/2021 on the questions of the nomination from these sources:

- AHRQ: Evidence reports and technology assessments
 - AHRQ Evidence Reports <https://www.ahrq.gov/research/findings/evidence-based-reports/index.html>
 - EHC Program <https://effectivehealthcare.ahrq.gov/>
 - US Preventive Services Task Force <https://www.uspreventiveservicestaskforce.org/>
 - AHRQ Technology Assessment Program <https://www.ahrq.gov/research/findings/ta/index.html>
- US Department of Veterans Affairs Products publications
 - Evidence Synthesis Program <https://www.hsrd.research.va.gov/publications/esp/>
 - VA/Department of Defense Evidence-Based Clinical Practice Guideline Program <https://www.healthquality.va.gov/>
- Cochrane Systematic Reviews <https://www.cochranelibrary.com/>
- PROSPERO Database (international prospective register of systematic reviews and protocols) <http://www.crd.york.ac.uk/prospetro/>
- PubMed <https://www.ncbi.nlm.nih.gov/pubmed/>

Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of New Evidence Review

We conducted a limited literature search in PubMed and PsycInfo for the last five years, 1/19/2016 – 1/19/2021. We reviewed all studies identified titles and abstracts for inclusion. We classified identified studies by question and study design to estimate the size and scope of a potential evidence review.

Search strategy

"renal insufficiency, chronic"[MeSH Terms] OR "chronic kidney disease"[All Fields] OR "CKD"[All Fields] "patient activation"[All Fields] OR "patient participation"[MeSH Terms] (((((((groups[tiab])) OR (trial[tiab])) OR (randomly[tiab])) OR (drug therapy[sh])) OR (placebo[tiab])) OR (randomized[tiab])) OR (controlled clinical trial[pt])) OR (randomized controlled trial[pt]) 2018/01/19:3000/12/31[Date - Entry] AND "english"[Language]

[ClinicalTrials.gov Link](#)

Value

We assessed the nomination for value. We considered whether or not the clinical, consumer, or policymaking context had the potential to respond with evidence-based change; and if a partner organization would use this evidence review to influence practice.

Appendix B. Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the United States?	Yes
1b. Is the nomination a request for an evidence report?	Yes
1c. Is the focus on effectiveness or comparative effectiveness?	Yes
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	Yes. It is estimated that 37 million American adults (15%) have CKD and it is the 9 th leading cause of death in the United States.
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the United States population or for a vulnerable population	Yes. It is estimated that 37 million American adults (15%) have CKD and it is the 9 th leading cause of death in the United States
2c. Incorporates issues around both clinical benefits and potential clinical harms	Yes
2d. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes. In 2017, Medicare costs for CKD and ESRD treatment were \$84 billion and \$36 billion, respectively. ¹
3. Desirability of a New Evidence Review/Absence of Duplication	
3. A recent high-quality systematic review or other evidence review is not available on this topic	Yes. We did not find any systematic reviews addressing the nomination.
4. Impact of a New Evidence Review	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	Yes. Guidelines for CKD do not include recommendations for patient activation interventions. ^{2, 18}
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	Yes. Given the rigid schedule and symptom burden often experienced by patients receiving in-center hemodialysis for CKD and ESRD, home dialysis and kidney transplantation are often recommended to patients to provide more flexibility to treatment for kidney failure. However, these modalities are heavily underutilized in the United States which may be due, in part, to the need for high levels of engagement in patient care and support from care partners and/or family members.
5. Primary Research	
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	We found 7 completed studies and 5 ClinicalTrials.gov studies. The estimated size of a new systematic review is limited.
6. Value	

6a. The proposed topic exists within a clinical, consumer, or policy-making context that is amenable to evidence-based change	Yes. Patient activation is amenable to change.
6b. Identified partner who will use the systematic review to influence practice (such as a guideline or recommendation)	Unclear. The nominator represents Coral Initiative, a group made up of multiple quality improvement organizations. Despite several attempts, we were not able to clarify how the systematic review would be utilized and if it would inform the nominator's ongoing or future initiatives.

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; CKD=chronic kidney disease; ESRD=end-stage renal disease