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**Shared decision-making in advanced kidney disease: a scoping review protocol**

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**ABSTRACT**

**Introduction** Patients with advanced kidney disease (AKD) have to make difficult treatment modality decisions as their disease progresses towards end-stage kidney disease. International guidelines in nephrology suggest shared decision-making (SDM) to help patients make timely treatment modality decisions that align with their values and preferences. However, systematic reviews or scoping reviews on these SDM interventions and on their reported use or outcomes are lacking. This limits the adoption of SDM in clinical practice and hampers further research and development on the subject. Our aim is to provide a comprehensive and up-to-date overview of these SDM interventions by means of a scoping review of the literature. Scoping reviews can provide a broad overview of a topic, identify gaps in the research knowledge base and report on the types of evidence that address and inform practices. This paper presents our study protocol.

**Methods and analysis** The proposed scoping review will be performed in accordance with the Joanna Briggs Institute’s (JBI) methodology for scoping reviews. It will cover both qualitative and quantitative scientific literature, as well as the grey literature on SDM interventions for treatment modality decisions in AKD. Only literature written in English will be considered for inclusion. Two independent reviewers will participate in an iterative process of screening the literature, paper selection and data extraction. Disagreements between the reviewers will be resolved by discussion until consensus is reached or after consultation with the research team when needed. Results will be reported with descriptive statistics and diagrammatic or tabular displayed information, accompanied by narrative summaries as explained in the JBI guidelines.

**Ethics and dissemination** Ethical approval for the conduct of this study is not required. We will analyse previously collected data for the proposed scoping review. Our results will be published in a peer-reviewed journal and disseminated through conferences and/or seminars.

**INTRODUCTION**

Advanced kidney disease is defined as an estimated glomerular filtration rate (eGFR) of less than 30 mL/min/1.73 m², and marks a stage in the lives of patients during which they have to make treatment modality decisions as their disease progresses to end-stage kidney disease (ESKD). As this process may take months or years, both patients and healthcare professionals face a considerable challenge in the anticipation of when kidney replacement therapy (KRT) will become necessary. Furthermore, questions regarding the eligibility of patients for all treatment options, the impact of these treatments on their lives, the concessions they are (not) willing to make and uncertainty regarding the outcomes they can expect, make this a difficult decision. Therefore, international guidelines in nephrology suggest shared decision-making (SDM) to help patients make timely treatment modality decisions that align with their preferences and values. Shared decision-making has been defined as a process during which patients, caregivers and healthcare professionals relate to and influence each other as they collaborate in making
healthcare decisions. Patient decision aids (PtDAs) have been developed to support this decision-making process, and in recent years, healthcare outcomes, including patient-reported outcome measures (PROMs), have been defined for benchmarking, organisation of care and as patient-reported outcome measures (PROMs), have been developed to support this decision-making process.1–3

As the concept of SDM has been gaining traction in the medical community, the body of literature reporting on the involvement of patients in this decision-making process has been expanding accordingly. In response to this growing body of literature, efforts have been made to compile and summarize the available evidence on the subject. A systematic review on the barriers and facilitators for the implementation of SDM in clinical practice stated that gaps in the knowledge for the effective implementation of SDM in clinical practice remain and should be prioritized in future studies.10 Moreover, a systematic review on the implementation of PtDAs stated that the underlying issues that militate against their use, and more generally limit the adoption of SDM, are under-specified and underinvestigated.11 In addition, a series of Cochrane reviews concluded that there is high-quality evidence that PtDAs improve the knowledge of patients on their options and reduce decisional conflict, that the evidence for PtDAs in activating patients for decision-making and improving risk perceptions is moderate and that the evidence for PtDAs in improving congruence between decisions and personal values is growing.1–12

Furthermore, when it comes to the effect of interventions to increase the use of SDM practices by healthcare professionals, another Cochrane review stated that it was uncertain whether any intervention is effective, because the certainty of the evidence is low or very low.3 Accordingly, a scoping review identified a number of interventions to promote the adoption of SDM in clinical practice, but due to heterogeneity in the assessments of their implementation and effectiveness, recommendations on the best strategies to promote the adoption of SDM could not be given.13 Finally, another scoping review identified multiple organisational-level and system-level characteristics that play a role in the implementation of SDM in routine care, and concluded that healthcare organisations should consider these characteristics if they wish to support the adoption of SDM.14 Of these reviews, only three report on the evidence for the effectiveness of SDM or PtDAs in the context of kidney disease,3,4,14 and of the ten papers that are mentioned in these papers, only four were published.15–18 Therefore, the relevance of the statements made in these papers may be questioned for AKD or any other form of kidney disease.

When it comes to treatment modality decision-making in AKD, no papers present a thorough overview of existing SDM interventions with evidence on any of their outcomes or novel developments in this field. Systematic reviews, including meta-analyses, have been written on: the perspectives of living with kidney failure;19 factors influencing the decision-making process regarding treatment modalities for patients with AKD;20–25 the readability of written materials for patients with chronic kidney disease (CKD);26–27; the effects of education and cognition of patients on SDM;28–30; the validity of prognostic algorithms for this decision-making process;31–33; advanced care planning and treatment outcomes in the elderly.34–38 Furthermore, a preliminary search in the PubMed, Medline, Embase, Web of Science, Cochrane Library, Emcare, International Prospective Register of Systematic Reviews (PROSPERO), PsycINFO and Academic Search Premier databases did not identify any scoping reviews on this subject. Scoping reviews have been written on the clinical pathways for patients with CKD in the primary care setting and on factors influencing dialysis withdrawal.39 40 Additionally, a protocol for a scoping review on the information available for SDM with older patients with AKD considering their treatment options has been published.41 Finally, numerous narrative reviews and overview papers on these topics in the context of kidney failure have been published as well.42–63 All of these papers are either limited to a single aspect of the decision-making process or their methodological framework limits their validity due to uncertainties in the generalisability and reproducibility of the reported findings. This hampers adoption of the SDM concept by healthcare professionals and hinders further research and development on the subject.

Therefore, our aim is to write a comprehensive and up-to-date scoping review on SDM-interventions for treatment modality decisions in AKD. Our objectives are to map these SDM interventions to evaluate the evidence on their reported use and studied outcomes and to provide an overview of new interventions that are being developed or investigated. This will provide healthcare professionals and researchers with a much needed source of information on the subject and can reveal knowledge gaps facilitating further research and development. This article presents our study protocol.

**STUDY DEFINITIONS**

The following operational definitions will be used in this protocol:

- **Advanced kidney disease**: CKD—Kidney Disease Improving Global Outcomes (KDIGO) G4–G5A1–3 kidney failure.2
- **Patients with AKD**: all patients with AKD ≥18 years of age that have to make treatment modality decisions.
- **Healthcare professionals**: nephrologists, nurse practitioners, social workers and dietitians that are involved in the decision-making process regarding treatment modality choices.
- **Treatment modality**: kidney transplantation (living donor or deceased donor), haemodialysis (in-centre or home), peritoneal dialysis (ambulatory peritoneal dialysis or continuous automatic peritoneal dialysis) or conservative care management.
- **PtDAs**: tools designed to help people participate in decision-making about healthcare options, as defined...
by, but not limited to, the International Patient Decision Aid Standards collaboration. SDM: the process in which patients, caregivers and healthcare professionals relate to and influence each other as they collaborate in making healthcare decisions.

SDM intervention: any intervention in standard care supporting SDM between patients and healthcare professionals (eg, PtDAs, educational programme for patients or healthcare professionals, prognostic algorithms and peer support programme).

STUDY AIM AND OBJECTIVES
The proposed scoping review will systematically collect and synthesise information on the topic of SDM interventions for treatment modality decisions in AKD to:

- Provide a comprehensive and up-to-date overview for healthcare professionals.
- Explore and define knowledge gaps on the subject.
- Facilitate future research and development.

The objectives of the proposed scoping review are:

- To map all existing SDM interventions for treatment modality decisions in AKD.
- To evaluate the evidence of their reported use and studied outcomes.
- To provide an overview of interventions that are being developed or investigated.

REVIEW QUESTIONS
The questions and subsequent subquestions for the proposed scoping review are as follows:

1. What SDM interventions for treatment modality decisions in AKD have been developed?
   - Which and how many treatment options are targeted by these interventions?
   - What do these interventions consist of?

2. What is the evidence for the reported use and outcomes of these SDM interventions?
   - Which of these interventions have been investigated for their outcomes?
   - What are the reported effects of these interventions on the decision-making process, on the decisions made and on healthcare outcomes?
   - How many of these interventions have been implemented in clinical practice as part of standard care?

3. What new SDM interventions are being developed or investigated?
   - Are there any new SDM interventions for treatment modality decisions in AKD being created or studied?
   - Will the creators report on the outcomes of these interventions?
   - What outcomes will be reported?
   - When can we expect the publication of these outcomes?

METHODS AND ANALYSIS
The proposed scoping review will be performed in accordance with the Joanna Briggs Institute’s methodology for scoping reviews. Please refer to online supplementary appendix 1 for a flow chart depicting the study design.

Two independent reviewers will participate in an iterative process of screening the literature, paper selection and data extraction on the basis of paper charting and data extraction tables. Please refer to online supplementary appendices 2 and 3 for draft versions of these tables. Disagreements between the reviewers will be resolved by discussion until a consensus is reached or after consultation with the research team when needed.

Context and concept
We will investigate the literature on SDM interventions for treatment modality decisions in the context of AKD, in both inpatient and outpatient care settings. To keep the focus of this review on interventions regarding treatment modality decisions, or interventions regarding a switch from treatment modalities, we will refrain from reviewing interventions that focus on advance care planning or the withdrawal from treatment. All developed tools will be investigated, whether they have been validated or not. When possible, we will report on outcomes of these SDM interventions as well. We expect that most papers will not report on outcomes, and that when they do, they will not compare these outcomes to standard care. Finally, we will provide an overview of SDM interventions under development or investigation and report on expected dates for the publication of their outcomes.

Eligible study designs and papers
The proposed scoping review will cover both qualitative and quantitative scientific literature, as well as the grey literature on SDM interventions for treatment modality decisions in AKD. Only literature written in English will be considered for inclusion. The following study designs and papers will be eligible for inclusion:

- Systematic reviews, meta-analyses, scoping reviews, overview papers, narrative reviews.
- Experimental and quasiexperimental study designs, that is, randomised or non-randomised controlled trials, controlled and uncontrolled pre–post studies and (multiple) interrupted time series.
- Quantitative descriptive and analytical observational studies, that is, retrospective and prospective cohort studies, case-control and cross-sectional studies, case series and case reports.
- Qualitative studies, using for example, grounded theory, phenomenology and study designs such as ethnography, action research and qualitative descriptions.
- Letters to the editors, professional opinion papers.
- (International) guidelines, papers on the meetings of expert panels and available published research protocols of studies not yet completed.

Databases and additional sources
We will search the PubMed, Medline, Embase, Web of Science, Cochrane library, Emcare, PROSPERO,
Open access

PsycINFO and Academic Search Premier databases for relevant, peer-reviewed, published papers and research protocols on the subject.

The search for grey literature and additional research protocols will include searches on electronic sources such as Open Grey, psycEXTRA, BIOSIS, researchgate.net, europepmc.org, clinicaltrials.gov, trialregister.net and Google Scholar.

The search for guidelines will include searches on the platforms of the KDIGO association, the Renal Physicians Association, the American Society of Nephrology, the Canadian Society of Nephrology, the National Institute for Health and Care Excellence, the European Renal association—European Dialysis and Transplant Association and the Kidney Health Australia—Caring for Australians with Renal Impairment Association.

Papers will be excluded from this review if they:

► Do not address SDM interventions for treatment modality decisions in AKD.
► Only address patients with an eGFR>30 mL/min/1.72 m².
► Report on SDM for paediatric patients.
► Are written in any language other than English.

Search strategy

A three-step search strategy, as explained in the Joanna Briggs Institute Reviewer’s Manual, will be followed. The first step, a limited search for peer-reviewed, published papers on the PubMed database, has already been performed. After this first step, a research librarian was consulted and an analysis of the words contained in the titles, abstracts and index terms generated the following list of keywords:

► Share, shared, sharing.
► Relation, relations.
► Decision, decisions, participation, empowerment.
► Medical, clinical.
► Treatment, making.
► Patient, nurse, physician, doctor.
► Advanced, chronic, end stage.
► Kidney, renal.
► Disease, diseases, failure.
► AKD, CKD, ESRD.

With the help of our research librarian, these keywords will subsequently be used for the second step in our search strategy, a secondary search across all included databases and sources. As grey literature resources often lack advanced search features, identifying relevant grey literature can be a time-consuming process and is often not reported transparently. To keep our search strategy manageable and reproducible, we will use search terms consistently between different resources and limit the screening process to a set number of pages, for example, the first 50 results. Additionally, we will report the resource name and URL, the dates searched and the used search terms. After this secondary search, the third step will be performed. We will examine the references of the identified papers that have been selected for full-text review and the papers that will be included in the proposed scoping review. The reviewers intend to contact the authors of papers for further information if this is deemed relevant. Additionally, the reviewers intend to contact experts on SDM, identified through the literature, by phone or by email to inquire on new SDM interventions that are being developed or on ongoing studies in this field. Each search query and additional steps relating to the search of the proposed scoping review will be published as appendices in the scoping review.

Study selection

After the removal of duplicates, the results of the secondary search will be imported in RefWorks V.2.0. Both reviewers will independently screen all titles and abstracts and select papers they deem eligible for inclusion. After this process, both reviewers will compare their results and decide which papers to include. Finally, both reviewers will screen and select references from all included papers and repeat the same process for this selection.

Data extraction

The data of interest will be extracted with the data extraction tables by the two reviewers and entered into spreadsheets in Microsoft Excel V.16. If the data in a single paper is relevant to multiple research questions, these data will then be extracted using multiple tables. Results will be categorised according to the review questions and charted in an iterative process, allowing the reviewers to continuously update these charts when additional unforeseen data are encountered.

PRESENTATION OF THE RESULTS

All extracted data will be presented in tabular or diagrammatic form. First, a table with the details of all included papers will be given. After this, the results will be presented in the following main conceptual categories that are based on the research questions that form the basis of this scoping review:

► Number and characteristics of SDM interventions.
► Basic demographics of patients and outcome variables used in the included papers.
► Reported effects of the SDM interventions on treatment modality decisions that have been made, and if applicable, reported differences with comparators.
► Reported effects of the SDM interventions on the decision-making process, and if applicable, reported differences with comparators.
► Reported effects of the SDM interventions on healthcare outcome measures, and if applicable, reported differences with comparators.
► Overlapping themes in the reported outcomes.
► The validation of SDM interventions.
► Knowledge gaps on the subject.
► Implementation in daily practice.
► New and/or ongoing developments and/or studies on SDM interventions.
Descriptive statistics will be used to provide an overview of the basic demographics and outcome variables of the included papers. Continuous data will be expressed as a mean±SD or as the median (IQR) where appropriate. Categorical data will be expressed as frequencies (%), unless otherwise stated. IBM SPSS Statistics V.25 will be used for all statistical analyses. Narrative summaries will accompany the tabulated and/or diagrammatic results and describe how the results relate to the research questions regarding SDM interventions for treatment modality decisions in AKD.

Qualitative data will be displayed in tabular or diagrammatic form. A combination of inductive and deductive approaches will be used to analyse the data (eg, open coding or the framework approach) in Atlasti. Emergent themes will be discussed in the research team. It is expected that the identification of SDM interventions and their reported effects will further refine the conceptual categories for data presentation.

**Patient and public involvement**

There was no patient or public involvement in the design of this scoping review protocol.

**ETHICS AND DISSEMINATION**

Ethical approval for the conduct of this study is not required because this scoping review will analyse previously collected data. Results will be published in a peer-reviewed journal and disseminated through conferences and/or seminars.

**CONCLUSION**

International guidelines suggest SDM to support patients with AKD make treatment modality decisions as their disease progresses towards ESKD. However, papers that present a thorough overview of SDM interventions for these decisions, evidence on any of their outcomes or new interventions that are being developed or investigated are lacking. This leaves healthcare professionals and researchers guessing, which hampers further implementation, research and development. Therefore, the proposed scoping review will map these SDM interventions for treatment modality decisions in AKD, summarise and report on the effectiveness of these interventions and report on new developments or ongoing studies in this field. Our objectives are to provide a comprehensive and up-to-date overview for healthcare professionals and researchers, explore and define knowledge gaps and facilitate future research and development.

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**Contributors** NE is the primary and corresponding author and was responsible for the first and all subsequent drafts of this scoping review protocol. GEg, MvdD, PvdN, WJB and AMS all participated in discussions on the study design. Additionally, they contributed to the design of this study protocol and revised drafts critically for improvements. All six authors approved the final version to be published. All authors have agreed to be held accountable for all aspects of this study protocol.

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