

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<u>http://bmjopen.bmj.com</u>).

If you have any questions on BMJ Open's open peer review process please email <u>info.bmjopen@bmj.com</u>

**BMJ** Open

# **BMJ Open**

## Shared Decision-Making in Advanced Kidney Disease: a scoping review protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2019-034142
Article Type:	Protocol
Date Submitted by the Author:	06-Sep-2019
Complete List of Authors:	Engels, Noel; Santeon , de Graav, Gretchen; Maasstad Ziekenhuis, Internal medicine van der Nat , Paul; Sint Antonius Ziekenhuis Woerden van den Dorpel, Marinus; Maasstad Ziekenhuis, Internal medicine Bos, Willem Jan; Leiden University Medical Center, Internal Medicine Stiggelbout, Anne; University Medical Center Leiden, Medical Decisionmaking
Keywords:	shared decision making, advanced kidney disease, treatment modality, outcome measures, scoping review, protocol





I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our <u>licence</u>.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which <u>Creative Commons</u> licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

terez oni

Enseignement Superieur (ABES) Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies

## **Research protocol**

English title: Shared Decision-Making in Advanced Kidney Disease: a scoping review protocol

for peer teriew only

## Authors:

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Drs. N. Engels Dr. G.N. de Graav Dr. M.A. van den Dorpel Dr. P.B. van der Nat Prof. dr. W.J.W. Bos Prof. dr. A.M. Stiggelbout

Protocol title: Shared decision-making in Advanced Kidney Disease: a scoping review

## protocol

Protocol ID	NE/27082019/2.0
Short title	SDM in AKD: a scoping review protocol
Version	2.0
Date	27-08-2019
Word count abstract (does not include study duration)	275 words
Word count (does not include: title page, abstract,	2730 words
strengths and limitations, table of contents,	
references, footnotes or Appendices)	
Corresponding and first author	Drs. N. Engels
First reviewer	PhD candidate
	Santeon
	E-mail: n.engels@santeon.nl
	Phone: +31 6 31 74 73 25
	Herculesplein 38
	Kantoorgebouw Galghenwert (8 <sup>th</sup> floor)
	3584 AA Utrecht
	The Netherlands
Second reviewer and second author	Dr. G.N. de Graav
	Resident and researcher
	Dept. of Internal medicine
	Maasstad Hospital
	E-mail: graavg@maasstadziekenhuis.nl
	Phone: +31 10 291 2556
	Maasstadweg 21
	3079 DZ, Rotterdam
	The Netherlands
Third author	Dr. P.B. van der Nat
	Senior advisor board of directors
	St. Antonius Hospital
	E-mail: p.van.der.nat@antoniusziekenhuis.nl
	Phone: +31 88 320 3000
	Koekoekslaan 1
	3435 CM, Nieuwegein
	The Netherlands
	I

#### **BMJ** Open

Fourth author	Dr. M.A. van den Dorpel
	Nephrologist, Dept. of Internal medicine
	Maasstad Hospital
	E-mail: dorpelm@maasstadziekenhuis.nl
	Phone: +31 10 291 3367
	Maasstadweg 21
	3079 DZ, Rotterdam
	The Netherlands
Fifth author	Prof. dr. W.J.W. Bos
	Nephrologist, Dept. of Internal medicine
	Leiden University Medical Center and St Antonius
<b>O</b> .	Hospital
	E-mail: <u>w.j.w.bos@lumc.nl</u>
	Phone: +31 71 526 3082
	Albinusdreef 2
	2333 ZA, Leiden
	The Netherlands
Sixth author	Prof. dr. A.M. Stiggelbout
	Expert medical decision making
	Leiden University Medical Center
	E-mail: a.m.stiggelbout@lumc.nl
	Phone: +31 71 526 4574
	Albinusdreef 2
	2333 ZA, Leiden
	The Netherlands
Sponsor	ZonMW
	E-mail: <u>info@zonmw.nl</u>
	Phone: +31 70 349 5111
	Laan van Nieuw Oost-Indië 334
	2593 CE, Den Haag

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

## Abstract

**Introduction:** Patients with advanced kidney disease (AKD) are faced with many uncertainties and healthcare choices as their disease progresses towards end-stage renal disease (ESRD). When it comes to treatment modality decisions, international guidelines suggest shared decision-making (SDM) to help patients make decisions that align with their values and preferences. Papers that present a thorough overview of existing SDM-interventions for treatment modality decisions in AKD, their reported use, and effects are lacking. This limits 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 SDM-interventions by means of a scoping review of the literature. This article presents our study protocol.

**Methods and analysis:** the proposed scoping review will be performed in accordance with the Joanna Briggs Institute's methodology for scoping reviews. It will cover qualitative and quantitative scientific literature, as well as the grey literature on SDM-interventions for treatment modality decisions in AKD. Papers written in English and published between 1990 and 2019 will be considered for inclusion. Two reviewers will participate in the process of study selection and data extraction on the basis of predefined steps and pre-developed forms. Disagreements between the reviewers will be resolved by discussion until a consensus is reached, or by consultation with the study group. Results will be reported with descriptive statistics and diagrammatic or tabular displayed information, accompanied by narrative summaries.

**Ethics and dissemination:** ethical approval for the conduct of this study is not required. For the proposed scoping review we will analyse previously collected data. Results will be published in a peer-reviewed journal, and disseminated through conferences and/or seminars.

## Strengths and limitations of this study

- The scoping review conducted according to this protocol will be the first paper to systematically present an overview of existing SDM-interventions for treatment modality decisions in AKD. It will also be the first paper to evaluate the evidence on their reported use and studied effects, and to present an overview of interventions that are being developed or investigated.
- This will provide healthcare professionals and researchers with a comprehensive and much-• needed source of information on the subject, and can reveal knowledge gaps facilitating further research and development.
- As research on SDM is generally heterogeneous in study methods employed and reporting of . outcomes, a scoping review will be better suited to map, summarize and present this information than traditional systematic reviews or meta-analyses.
- As this study will only include papers written in English, potentially relevant findings from papers written in other languages will be missed.

#### Keywords

- Shared Decision-Making
- Advanced Kidney Disease
- treatment modality
- outcome measures
- scoping review
- protocol

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies

	Table of	contents	
--	----------	----------	--

1. Introduction	7
2. Study definitions	8
3. Study aim and objectives	9
4. Review questions	9
5. Context and concept	10
6. Methods and analysis	10
6.1. sources	11
6.2. Search strategy	11
6.3. Databases and additional sources	12
6.4. Study selection	13
6.5. Data extraction	13
7. Presentation of the results	13
8 Ethics and Dissemination	14
9. Conclusion	14
10. References	14
11. Footnotes	19
Appendices	
Appendix 1: Study design of proposed scoping review	20
Appendix 2: Draft version of paper screening form	21
Appendix 3: Draft versions of data extraction forms	22

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

## 1. Introduction

International guidelines in nephrology suggest shared decision-making (SDM) for treatment modality decisions in advanced kidney disease (AKD)<sup>1,2</sup>. AKD is defined as an estimated glomerular filtration rate (eGFR) of less than 30mL/min/1,73m<sup>2</sup>, and marks a stage in the lives of patients during which they are faced with many uncertainties and numerous healthcare choices as their disease progresses to end stage renal disease (ESRD). SDM 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<sup>3</sup>. 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, organization of care, and as novel tools to support the decision-making process<sup>4-8</sup>.

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<sup>9</sup>. Moreover, a systematic review on the implementation of Patient Decision Aids (PtDAs) stated that the underlying issues that militate against the use of PtDAs, and more generally, limit the adoption of SDM are underspecified and underinvestigated<sup>10</sup>. 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<sup>11,4</sup>. 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<sup>3</sup>. 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<sup>12</sup>. Finally, another scoping review identified multiple organizational- and system-level characteristics that play a role in the implementation of SDM in routine care, and concluded that healthcare organizations should consider these characteristics if they wish to support the adoption of SDM<sup>13</sup>.

Only three of these reviews report on the evidence for the effectiveness of SDM or PtDAs in the context of kidney disease<sup>3,4,13</sup>, and of the ten papers that are mentioned in these papers, only four were

#### **BMJ** Open

published<sup>14-17</sup>. Therefore, the relevance of the statements made in these papers may be questioned for AKD, or any other form of kidney disease. Moreover, when it comes to treatment modality decisionmaking in AKD, no papers present a thorough overview of existing SDM-interventions with evidence on any of their effects or novel developments in this field. Systematic reviews, including meta-analyses, have been written on: the perspectives of living with kidney failure<sup>18</sup>, factors influencing the decisionmaking process regarding treatment modalities for patients with AKD<sup>19-23</sup>, the readability of written materials for patients with CKD<sup>24</sup>, the effects of education and cognition of patients on SDM<sup>25-27</sup>, the validity of prognostic algorithms for this decision-making process<sup>28</sup>, advanced care planning<sup>29,30</sup>, and treatment outcomes in the elderly<sup>31-34</sup>. Additionally, a preliminary search for scoping reviews in the PubMed, MEDLINE, Embase, Web of science, Cochrane library, Emcare, 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<sup>35,36</sup>. Additionally, a protocol for a scoping review on the information available for SDM with older AKD patients considering their treatment options has been published<sup>37</sup>. Finally, numerous narrative reviews and overview articles on these topics in the context of kidney failure have been published as well<sup>38-59</sup>. 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 generalizability 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 all existing SDM-interventions, to evaluate the evidence on their reported use and studied effects, and to provide an overview of new interventions that are being developed or investigated. This article presents our study protocol.

#### 2. Study definitions

The following operational definitions will be used in this protocol:

- Advanced kidney disease: Chronic Kidney Disease Kidney Disease Improving Global Outcomes (CKD-KDIGO) G4-G5A<sub>1-3</sub> kidney failure<sup>2</sup>.
- 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.

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

- *Treatment modality:* kidney transplantation (living or post-mortal), hemodialysis (in-centre or home), peritoneal dialysis (Ambulatory Peritoneal Dialysis, i.e. APD or Continuous Automatic Peritoneal Dialysis, i.e. CAPD), or conservative care management.
  - *PtDAs:* tools designed to help people participate in decision-making about healthcare options, as defined by the International Patient Decision Aid Standards (IDPAS) collaboration<sup>60</sup>.
  - *SDM:* the process in which patients, caregivers, and healthcare professionals relate to, and influence each other as they collaborate in making healthcare decisions<sup>3</sup>.
  - *SDM-intervention:* any intervention in standard care promoting SDM between patients and healthcare professionals

#### 3. Study aim and objectives

The proposed scoping review will systematically collect and synthesize information on the topic of SDM-interventions for treatment modality decisions in AKD, in order to:

- Provide a comprehensive and up to date overview for healthcare professionals;
- Explore and define knowledge gaps on the subject, and;
- 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 effects;
- To provide an overview of interventions that are being developed or investigated.

#### 4. Review questions

The questions and subsequent sub-questions 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 effects of these SDM-interventions?

- Which of these interventions have been investigated for their effects on the decision-making process?
- What are the reported effects of these interventions on the decision-making process, on the decision 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 effects of these interventions?
- What effects or outcomes will be reported?
- When can we expect the results of these papers?

## 5. Context and concept

The proposed scoping review will investigate the literature on SDM-interventions for treatment modality decisions in the context of AKD, in both inpatient and outpatient care settings. SDM-Interventions for all existing treatment modalities will be included, i.e. kidney transplantation (living-donor or post-mortal), peritoneal dialysis (APD and CAPD), hemodialysis (in centre or home) and conservative care therapy. We will cover SDM-interventions targeting patients, healthcare professionals, or interventions targeting both. We will consider all digital, non-digital, or combined SDM-interventions, ranging from the training of healthcare professionals in conversational skills based on SDM-theories, to the use of PtDAs and/or prognostic algorithms during consultations. All developed tools will be investigated, whether they are validated or not. When possible, all reported effects, both qualitative and quantitative, of these SDM-interventions will be investigated and presented. Finally, we will provide an overview of SDM-interventions that are being developed or investigated, and when possible report on expected dates for the release of their findings.

On the basis previous readings, it is expected that articles on SDM-interventions for treatment modality decisions in patients with AKD will cover digital, non-digital and combined interventions, and will or will or not use PtDAs, that will or will not incorporate prognostic algorithms. Furthermore, it is expected that most articles will not compare the effects of these interventions to standard care, and that when they do compare these interventions to standard care, these effects will be reported with a broad range of methodological techniques. Finally, it is anticipated that when articles report on the effects of these interventions, they will do so by reporting on a broad range of varying outcomes, including PROMs and healthcare outcome measures.

## 6. Methods and analysis

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

The proposed scoping review will be performed in accordance with the Briggs Institute's methodology for scoping reviews<sup>61</sup>. Two reviewers will participate in the process of study selection and data extraction on the basis of pre-defined steps and pre-developed forms as described below. Disagreements between the reviewers will be resolved by discussion until consensus is reached, or by consultation with the third reviewer. Please refer to *Appendix 1* for a flow chart depicting the study design of the proposed scoping review.

#### 6.1. Sources

The proposed scoping review aims to identify qualitative and quantitative scientific literature, as well as grey literature that addresses the review questions within the defined study population. Papers written in English, published between 1990 and 2019 will be considered for inclusion. The following study designs and papers will eligible for inclusion:

- Systematic reviews, meta-analyses, scoping reviews, overview articles, narrative reviews;
- Experimental and quasi-experimental study designs, i.e. randomised or non-randomised controlled trials, controlled and uncontrolled pre-post studies, and (multiple) interrupted timeseries;
- Quantitative descriptive and analytical observational studies, i.e. retrospective and prospective cohort studies, case-control and cross-sectional studies, case series and case reports;
- Qualitative studies, using e.g. 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;

#### Exclusion criteria:

- Articles that do not address SDM-interventions for treatment modality decisions in AKD;
- Articles that only address patients with an eGFR > 30mL/min/1,72m<sup>2</sup>;
- Articles on paediatric patients;
- Articles in languages other than English.

#### 6.2. Search strategy

A three-step search strategy, as explained in the Joanna Briggs Institute Reviewer's Manual, will be followed for the proposed scoping review<sup>61</sup>. First, a limited search for peer reviewed, published papers on the PubMed database was performed. After this primary search, a research librarian was consulted

## **BMJ** Open

SDM in AKD: a scoping review protocol. Protocol ID NE/27082019/2.0

and after an analysis of the words contained in the titles, abstracts and index terms the following list of keywords was developed:

- share, shared, sharing;
- relation, relations;
- decision, decisions, participation, empowerment
- medical, clinical;
- treatment, making;
- patient, physician, doctor;
- advanced, chronic, end stage;
- kidney, renal;
- disease, diseases, failure;
- AKD, CKD, ESRD.

With the help of a research librarian, these keywords will be subsequently used for a secondary search across all relevant databases. After this secondary search, the references of the identified papers that will be included in the proposed scoping review will be searched for additional studies as well. 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 by phone or by e-mail 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.

## 6.3. Databases and additional sources

We will search the PubMed, MEDLINE, Embase, Web of Science, COCHRANE library, Emcare, PROSPERO, PsycINFO and Academic Search Premier database 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 the following 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 Kidney Disease Improving Global Outcomes (KDIGO) association, the Renal Physicians association (RPA), The American Society of Nephrology (ASN), the Canadian Society of Nephrology, the National Institute for Health and Care Excelence (NICE), the European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) and the Kidney Health Australia – Caring for Australians with Renal Impairment association.

## 6.4. Study selection

Both reviewers will participate in the second and third steps of the search strategy. After the removal of duplicates, the results of the second search strategy will be imported in RefWorks 2.0. Papers will be selected for inclusions based on full text examination. Every paper considered for inclusion will be registered and evaluated with a pre-developed paper screening form. Please refer to *Appendix 2* for a draft version of this form.

#### 6.5. Data extraction

The data of interest will be extracted with three pre-developed data extraction forms by the two reviewers, and entered into spreadsheets in Microsoft Excel, version 16. These forms have been adapted from the template available in the Joanna Briggs Institute Reviewer's Manual<sup>61</sup>. Please refer to *Appendix 3* for the draft versions of these forms. 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 is encountered.

#### 7. Presentation of the results

All extracted data will be presented in tabular or diagrammatic form. First, a table with the details of all included articles 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 on 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 effects;
- The validation of SDM-interventions;
- knowledge gaps on the subject, and;

- 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 (interquartile range) where appropriate. Categorical data will be expressed as frequencies (%), unless otherwise stated. IBM SPSS statistics version 23 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. Finally, overlapping themes in the reported effects will be discussed. It is expected that the identification of SDM-interventions and their reported effects will further refine the conceptual categories for data presentation.

## 8. 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.

## 9. Conclusion

International guidelines suggest SDM to support patients with AKD make treatment modality decisions as their disease progresses towards ESRD. However, papers that present a thorough overview of all existing SDM-interventions, evidence on any of their effects, or new interventions that are being developed or investigated for this decision are lacking. This leaves healthcare professionals and researchers guessing, which hampers further implementation, research and development.

Therefore, the proposed scoping review that will be written according to this protocol will map all existing SDM-interventions for AKD treatment modality decisions, summarize and report on the effectiveness of these interventions, and report on new developments or ongoing studies in this field. Our objective is 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.

## 10. References

1. Renal Physicians Association: Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis, 2nd Ed., Rockville, MD, Renal Physicians Association, 2010

2. KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. volume
3 | issue 1 | JANUARY 2013 http://www.kidney-international.org

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

 3. Légaré F, Adekpedjou R, Stacey D, Turcotte S, Kryworuchko J, Graham ID, Lyddiatt A, Politi MC, Thomson R, Elwyn G, Donner-Banzhoff N. Interventions for increasing the use of shared decision making by healthcare professionals. Cochrane Database of Systematic Reviews 2018, Issue 7.

Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt
 A, Thomson R, Trevena L. Decision aids for people facing health treatment or screening decisions. Cochrane
 Database of Systematic Reviews. 2017, Issue 4.

5. Verberne WR, Das-Gupta Z, Allegretti AS, Bart HAJ, van Biesen W, García-García G, Gibbons E, Parra E, Hemmelder MH, Jager KJ, Ketteler M, Roberts C, Al Rohani M, Salt MJ, Stopper A, Terkivatan T, Tuttle KR, Yang CW, Wheeler DC, Bos WJW. Development of an International Standard Set of Value-Based Outcome Measures for Patients With Chronic Kidney Disease: A Report of the International Consortium for Health Outcomes Measurement (ICHOM) CKD Working Group. Am J Kidney Dis. 2019 Mar;73(3):372-384.

6. Viecelli A, Tong A, O'Lone E, Ju A, Hanson CS, Sautenet B, Craig JC, Manns B, Howell M, Chemla E, Hooi LS, Johnson DW, Lee T, Lok CE, Polkinghorne K, Quinn RR, Vaccharajani T, Vanholder R, Zuo L, Hawley CM on behalf of the SONG-HD Vascular Access Workshop Investigators. Report of the standardized outcomes in nephrology – hemodialysis (SONG-HD) consensus workshop on establishing a core outcome measure for hemodialysis vascular access. American Journal of Kidney Disease 2018; 71(5):690-700

7. Ju A, Josephson MA, Butt Z, Jowsey-Gregoire S, Tan J, Taylor Q, Fowler K, Dobbels F, Caskey F, Jha V, Locke J, Knoll G, Ahn C, Hanson CS, Sautenet B, Manera K, Craig JC, Howell M, Rutherford C, Tong A; SONG-Tx Life Participation Workshop Investigators\*. Establishing a core outcome measure for life participation: a Standardized Outcomes in Nephrology – Kidney Transplantation (SONG-Tx) consensus workshop Report. Transplantation 2018; doi: 10.1097/TP.00000000002476. [Epub ahead of print]

8. Manera KE, Tong A, Craig JC, Brown EA, Brunier G, Dong J, Dunning T, Mehrotra R, Naicker S, Pecoits-Filho R, Perl J, Wang AY, Wilkie M, Howell M, Sautenet B, Evangelidis N, Shen JI, Johnson DW. Standardised Outcomes in Nephrology – Peritoneal Dialysis (SONG-PD): study protocol for establishing a core outcome set in peritoneal dialysis. Peritoneal Dialysis International 2017;37:639-47.

9. Légaré F, Ratté S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. Patient Educ Couns. 2008 Dec;73(3):526-35.

10. Elwyn G, Scholl I, Tietbohl C, Mann M, Edwards, Katherine, Légaré F, van der Weijden T, Lewis, Wexler R, Frosch D. The implementation of patient decision support interventions into routine clinical practice: a systematic review. BMC Med Inform Decis Mak. 2013;13 Suppl 2:S14.

11. Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, LyddiattA, Thomson R, Trevena L, Wu JHC. Decision aids for people facing health treatment or screening decisions.Cochrane Database of Systematic Reviews 2014, Issue 1.

12. Siyam T, Shahid A, Perram M, Zuna I, Haque F, Herrera CA, Vohra S, Olson K. A scoping review of interventions to promote the adoption of shared decision making (SDM) among healthcare professionals in clinical practice. Patient Educ Couns. 2019 Jun;102(6):1057-1066.

#### **BMJ** Open

13. Scholl I, LaRussa A, Hahlweg P, Kobrin S, Elwyn G. Organizational- and system-level characteristics that influence implementation of shared decision-making and strategies to address them – a scoping review.

14. Manns B J, Taub K, Vanderstraeten C, Jones H, Mills C, Visser M, et al. The impact of education on chronic kidney disease patients" plans to initiate dialysis with self-care dialysis: a randomized trial. Kidney International 2005;68 (4):1777–83

15. Registered Nurses' Association of Ontario. Decision support for adults living with chronic kidney disease. http:// rnao.ca/bpg/guidelines/decision-support-adults-living-chronickidney-disease. Toronto, Ontario: The Author, 2009.

16. Fortnum D, Smolonogov T, Walker R, Kairaitis L, Pugh D. 'My kidneys, my choice, decision aid': supporting shared decision making. J Ren Care. 2015 Jun;41(2):81-7. doi: 10.1111/jorc.12100. Epub 2014 Dec 10.

17. Mollicone D, Pulliam J, Lacson E Jr. The culture of education in a large dialysis organization: informing patientcentered decision making on treatment options for renal replacement therapy. Semin Dial. 2013 Mar-Apr;26(2):143-7. doi: 10.1111/sdi.12053. Epub 2013 Feb 14.

18. Bailey PK, Hamilton AJ, Clissold RL, Inward CD, Caskey FJ, Ben-Shlomo Y, Owen-Smith A. Young adults' perspectives on living with kidney failure: a systematic review and thematic synthesis of qualitative studies. BMJ Open 2018;8:e019926.

19. Murray MA, Brunier G, Chung JO, Craig LA, Mills C, Thomas A, Stacey D. A systematic review of factors influencing decision-making in adults living with chronic kidney disease. Patient Education and Counseling 76 (2009) 149–158.

20. Morton RL, Tong A, Howard K, Snelling P, Webster AC. The views of patients and carers in treatment decision making for chronic kidney disease: systematic review and thematic synthesis of qualitative studies. BMJ. 2010 Jan 19;340:c112.

21. Harwood L, Clark AM. Understanding pre-dialysis modality decision-making: A meta-synthesis of qualitative studies. International Journal of Nursing Studies 50 (2013). 109–120.

22. Tong A, Hanson CS, Chapman JR, Halleck F, Budde K, Papachristou C, Craig JC. The preferences and perspectives of nephrologists on patients' access to kidney transplantation: a systematic review. Transplantation. 2014 Oct 15;98(7):682-91

23. Hussain JA, Flemming K, Murtagh FE, Johnson, MJ. Patient and health care professional decision-making to commence and withrdraw from dialysis: a systematic review of qualitative research

24. Morony S, Flynn M, McCaffery KJ, Jansen J, Webster AC. Readability of Written Materials for CKD Patients: A Systematic Review. Am J Kidney Dis. 2015;65(6):842-850

25. Devoe DJ, Wong B, James MT, Ravani P, Oliver MJ, Barnieh L, Roberts DJ, Pauly R, Manns BJ, Kappel J, Quinn RR. Patient Education and Peritoneal Dialysis Modality Selection: A Systematic Review and Meta-analysis. Am J Kidney Dis. 2016 Sep;68(3):422-33.

26. Berger I, Wu S, Masson P, Kelly PJ, Duthie FA, Whiteley W, Parker D, Gillespie D, Webster AC. Cognition in chronic kidney disease: a systematic review and meta-analysis. BMC Med. 2016 Dec 14;14(1):206.

 27. Taylor DM, Fraser SDS, Bradley JA, Bradley C, Draper H, Metcalfe W, Oniscu GC, Tomson CRV, Ravanan R, Roderick PJ; ATTOM investigators. A Systematic Review of the Prevalence and Associations of Limited Health Literacy in CKD. Clin J Am Soc Nephrol. 2017 Jul 7;12(7):1070-1084.

28. Ramspek CL, Voskamp PW, van Ittersum FJ, Krediet RT, Dekker FW, van Diepen M. Prediction models for the mortality risk in chronic dialysis patients: a systematic review and independent external validation study.
Clin Epidemiol. 2017 Sep 5;9:451-464.

29. Lim CED, Ng RWC, Cheng NCL, Cigolini M, Kwok C, Brennan F. Advance care planning for haemodialysis patients. Cochrane Database of Systematic Reviews 2016, Issue 7.

30. O'Halloran P, Noble H, Norwood K, Maxwell P, Shields J, Fogarty D, Murtagh F, Morton R, Brazil K. Advance care planning with patients who have end-stage kidney disease: a systematic realist review. J Pain Symptom Manage. 2018 Nov;56(5):795-807.

31. Foote C, Kotwal S, Gallagher M, Cass A, Brown M, Jardine M. Survival outcomes of supportive care versus dialysis therapies for elderly patients with end-stage kidney disease: A systematic review and meta-analysis. Nephrology (Carlton). 2016 Mar;21(3):241-53.

32. Wongrakpanich S, Susantitaphong P, Isaranuwatchai S, Chenbhanich J, Eiam-Ong S, Jaber BL. Dialysis Therapy and Conservative Management of Advanced Chronic Kidney Disease in the Elderly: A Systematic Review. Nephron. 2017;137(3):178-189.

33. Verberne WR, Geers AB, Jellema WT, Vincent HH, van Delden JJ, Bos WJ. Comparative Survival among Older Adults with Advanced Kidney Disease Managed Conservatively Versus with Dialysis. Clin J Am Soc Nephrol. 2016 Apr 7;11(4):633-40.

34. Verberne WR, Dijkers J, Kelder JC, Geers ABM, Jellema WT, Vincent HH, van Delden JJM, Bos WJW. Valuebased evaluation of dialysis versus conservative care in older patients with advanced chronic kidney disease: a cohort study. BMC Nephrol. 2018 Aug 16;19(1):205.

35. Elliot MJ, Gil S, Hemmelgarn BR, Manns BJ, Tonelli M, Jun M, Donald M. A scoping review of adult chronic kidney disease clinical pathways for primary care. Nephrol Dial Transplant. 2017 May; 32(5): 838-846.

36. Qazi HA, Chen H, Zhu M. Factors influencing dialysis withdrawal: a scoping review. BMC Nephrol. 2018 Apr 24;19(1):96.

37. Raj R, KD Ahuja KD, Frandsen M, Jose M. Older patient considering treatment for advanced renal disease: a protocol for a scoping review of the information available for shared decision-making. BMJ Open. 2016 Dec 8;6(12):e013755.

38. Stryckers M, Nagler EV, van Biesen W. The need for accurate risk prediction models for road mapping, shared decision making and care planning for the elderly with advanced chronic kidney disease. ПРИЛОЗИ. Одд. за мед. науки, XXXVII 2–3, 2016.

39. Couchoud C, Hemmelgarn B, Kotanko P, Germain MJ, Moranne O, Davison SN. Supportive Care: Time to Change Our Prognostic Tools and Their Use in CKD. Clin J Am Soc Nephrol 11: 1892–1901, October, 2016.

40. Kadatz MJ, Lee ES, Levin A. Predicting Progression in CKD: Perspectives and Precautions. Am J Kidney Dis. 2016;67(5):779-786.

#### **BMJ** Open

41. Murtagh FEM, Burns A, Moranne O, Morton RL, Naicker S. Supportive Care: Comprehensive Conservative Care in End-Stage Kidney Disease. Clin J Am Soc Nephrol 11: 1909–1914, 2016.

42. Murray MA, Bissonnette J, Kryworuchko J, Gifford W, Calverley S. Whose Choice Is It? Shared Decision Making in Nephrology Care. Seminars in Dialysis—Vol 26, No 2 (March–April) 2013 pp. 169–174.

43. Llewellyn S. Concept Clarification: Uncertainty in Individuals with Chronic Kidney Disease. Nephrol Nurs J. 2017 Nov-Dec;44(6):513-539.

44. Cassidy BP, Getchell LE, Harwood L, Hemmett J, Moist LM. Barriers to Education and Shared Decision Making in the Chronic Kidney Disease Population: A Narrative Review. Can J Kidney Health Dis. 2018 Nov 2;5:2054358118803322.

45. Wilson S, Dhar A, Tregaskis P, Lambert G, Barton D, Walker R. Known unknowns: Examining the burden of neurocognitive impairment in the end-stage renal failure population. Nephrology (Carlton). 2018 Jun;23(6):501-506.

46. Santos J, Fonseca I. Incorporating Scoring Risk Models for Care Planning of the Elderly with Chronic Kidney Disease. Curr Gerontol Geriatr Res. 2017;2017:8067094.

47. Rosansky SJ, Schell J, Shega J, Scherer J, Jacobs L, Couchoud C, Crews D, McNabney M. Treatment decisions for older adults with advanced chronic kidney disease. BMC Nephrol. 2017 Jun 19;18(1):200.

48. Morton RL, Kurella Tamura M, Coast J, Davison SN. Supportive Care: Economic Considerations in Advanced Kidney Disease. Clin J Am Soc Nephrol. 2016 Oct 7;11(10):1915-1920.

49. Schmidt RJ. Advance Care Planning for Patients Approaching End-Stage Kidney Disease. Semin Nephrol. 2017 Mar;37(2):173-180.

50. Green JA, Boulware LE. Patient Education and Support During CKD Transitions: When the Possible Becomes Probable. Adv Chronic Kidney Dis. 2016 Jul;23(4):231-9.

51. Collister D, Russell R, Verdon J, Beaulieu M, Levin A. Perspectives on optimizing care of patients in multidisciplinary chronic kidney disease clinics. Can J Kidney Health Dis. 2016 May 12;3:32.

52. Berger JR, Jaikaransingh V, Hedayati SS. End-Stage Kidney Disease in the Elderly: Approach to Dialysis Initiation, Choosing Modality, and Predicting Outcomes. Adv Chronic Kidney Dis. 2016 Jan;23(1):36-43.

53. MacPhail A, Ibrahim JE, Fetherstonhaugh D, Levidiotis V. The Overuse, Underuse, and Misuse of Dialysis in ESKD Patients with Dementia. Semin Dial. 2015 Sep-Oct;28(5):490-6.

54. Ghahramani N. Potential impact of peer mentoring on treatment choice in patients with chronic kidney disease: a review. Arch Iran Med. 2015 Apr;18(4):239-43.

55. Muthalagappan S, Johansson L, Kong WM, Brown EA. Dialysis or conservative care for frail older patients: ethics of shared decision-making. Nephrol Dial Transplant. 2013 Nov;28(11):2717-22.

56. Brown EA, Johansson L. Dialysis options for end-stage renal disease in older people. Nephron Clin Pract. 2011;119 Suppl 1:c10-3.

57. Campbell KH, Dale W, Stankus N, Sachs GA. Older adults and chronic kidney disease decision making by primary care physicians: a scholarly review and research agenda. J Gen Intern Med. 2008 Mar;23(3):329-36.

58. White Y, Fitzpatrick G. Dialysis: prolonging life or prolonging dying? Ethical, legal and professional considerations for end of life decision making. EDTNA ERCA J. 2006 Apr-Jun;32(2):99-103.

59. Pfettscher SA. Making decisions about end-stage renal disease treatment: a review of theories and issues. Adv Ren Replace Ther. 1997 Jan;4(1):81-8.

60. http://ipdas.ohri.ca/what.html

61. Peters MDJ, Godfrey C, McInerney P, Baldini Soares C, Khalil H, Parker D. Chapter 11: Scoping Reviews. In: Aromataris E, Munn Z (Editors). *Joanna Briggs Institute Reviewer's Manual*. The Joanna Briggs Institute, 2017. Available from https://reviewersmanual.joannabriggs.org/

#### 11. Footnotes

#### Authors' contributions:

NE is the primary and corresponding author and was responsible for the first and all subsequent drafts of this scoping review protocol. GG, MD, PN, WB and AS 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.

#### Patient and public involvement:

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

#### Acknowledgements:

The authors thank the research librarian Drs. J.W. Schoones of the Leiden University Medical Center for his help in defining and generating the keywords necessary to perform the subsequent search query.

#### Data statement:

The data used to write this protocol is based on published literature, that is obtainable in the relevant online databases. NE, GG, MD, PN, WB and AS are the six authors of this scoping review protocol. As such, they will also be authors of the proposed scoping review. All authors have access to a RefWorks database in which the articles used for this protocol and the proposed scoping review are stored. The extracted data will be stored on servers of Santeon. Therefore, all authors will have continued access to the collected data for this scoping review protocol and the proposed scoping review.

#### **Funding statement:**

This work was supported by ZonMW as part of the "Experiment Ultkomst indicatoren Santeon". **Conflicts of interests:** 

None declared

## Appendices

## Appendix 1: study design of proposed scoping review

## Generated keywords after preliminary search:

share, shared, sharing, relation, relations, decision, decisions, participation, empowerment, medical, clinical, treatment, making, patient, physician, doctor, advanced, chronic, end stage, kidney renal, disease, diseases, failure, AKD, CKD, ESRD



## Appendix 2: Draft version of paper screening from

BMJ Open SDM in AKD: a scoping review protocol. Protocol ID NE/27082019/2.0 Appendix 2: Draft version of paper screening from								njopen-2019-034142 I by copyright, incluc			P
Table 1. Pa	per screening fro	om						on 2 ling :			
Paper Number	Title	primary author	Type or paper	Publication year	Concept of the paper	Context of the paper	Population	년 영 Eitseignemei forfuses related t	Methods	Passes exclusion criteria? Yes / No	Included? Yes / No
1*	A website intervention to increase knowledge about living kidney donation and transplantation among Hispanic/latino dialysis patients	Gordon, E.J.	Research	2016	Improving decisional capacity with an online PtDA	Improving knowledge on kidney transplantation for informed decisions	Patients aged between 18 and 75 years of age that self-identified as Hispanic/Latino, were on chronic hemodialysis, clinically eligible to receive a transplant, had never received an organ transplant or formal education about transplantation from a transplant center, gave acceptable responses to certain health literacy questions, and	Downloaded from http://bmjopen.bmj.com/ on June 9, 20 t Superieur (ABES) . text and data mining, Al training, and similar technologi	Pre-test and post-test intervention	Yes	Yes

\* this is an example

Agence Bibliographique de l

 njopen-2019-034142 on 2 1 by copyright, including

del

## Table 2. Data extraction form for question 1

Type of intervention?	Targeted treatment	Context of the	How is the	Duration of the	Reported effects?
	modality?	intervention	intervention	angervention?	
			introduced?	ry 20 relat	
Web-based education for	Transplantation	A culturally targeted,	After a 3 minute tutorial on	the erventation entailed	Yes
hispanic/latino dialysis		bilingual, educational	using the website by	o p wiew g 3 of 6 websites	
patients to enhance		website on living donor	research staff, participants	seguinans, for a total of 30	
informed decision making.	6	kidney transplantation	could view the website	and es.	
The interventation entailed			during their dialysis session	dat	
viewing 3 of 6 websites				a A B	
sections, for a total of 30		4		n h ES)	
minutes.				ng, · t <mark>t</mark> p:	
				n/ on June 9, 2025 milar technologies	
	Type of intervention?         Web-based education for         hispanic/latino dialysis         patients to enhance         informed decision making.         The interventation entailed         viewing 3 of 6 websites         sections, for a total of 30         minutes.	Type of intervention?       Targeted treatment modality?         Web-based education for hispanic/latino dialysis patients to enhance informed decision making.       Transplantation         The interventation entailed viewing 3 of 6 websites sections, for a total of 30 minutes.       Image: Comparison of the section of the sectio	Type of intervention?       Targeted treatment modality?       Context of the intervention         Web-based education for hispanic/latino dialysis patients to enhance informed decision making. The interventation entailed viewing 3 of 6 websites sections, for a total of 30 minutes.       Transplantation       A culturally targeted, bilingual, educational website on living donor kidney transplantation	Type of intervention?         Targeted treatment modality?         Context of the intervention         How is the intervention           Web-based education for hispanic/latino dialysis patients to enhance informed decision making. The interventation entailed viewing 3 of 6 websites sections, for a total of 30 minutes.         Transplantation         A culturally targeted, bilingual, educational website on living donor kidney transplantation         After a 3 minute tutorial on using the website by research staff, participants could view the website during their dialysis session	Type of intervention?         Targeted treatment modality?         Context of the intervention         How is the intervention         Fundation of the meta-presention?           Web-based education for hispanic/latino dialysis patients to enhance informed decision making. The interventation entailed viewing 3 of 6 websites sections, for a total of 30 minutes.         Transplantation         A culturally targeted, bilingual, educational website on living donor kidney transplantation         After a 3 minute tutorial on using the website by research staff, participants could view the website during their dialysis session         A fter a 3 minute tutorial on using the website by research staff, participants could view the website during their dialysis session         A tota total of 30 minutes.

Table 3. Data extraction	form for question 2
--------------------------	---------------------

				E	BMJ Open		njopen- 1 by cop		
DM in AKD:	a scoping review	protocol. Protocol ID NE/2	27082019/2.0				-2019-03 >yright, i		
able 3. Dat	a extraction j	form for question 2					4142 nclu		
Paper	Nature of	Reported effects	Reported effects	Reported	Compared	Scope of the	Impleneentation	Validation of	Imlementation as
Number	reported	on treatment	on decision-	effects on	to standard	effects?	as part $\widehat{\Phi}_{f}$	the	standard care?
	effects ?	modality	making process?	healthcare	care?		standard sate?	instrument?	
		decisions?		outcomes?			eign rela		
1*	Knowledge	No	No	No	Yes	A mean 17.1%	No d	Not available	No
						same day	to to		
			$()_{L}$			knowledge score	ext		
						increase between	erie and		
						pre-test and post-	dat dat		
						test ( <i>P</i> < .001).	a n		
						At 3 weeks	inir		
						knowledge scores	ng, ttp:/		
					$\mathbf{A}$	remained 11.7%	Al t		
						above pre-test (P <	rain		
						.001) values.	ing,		
this is an exar	nple						mj.com/ on June 9, 2025 at Agen and similar technologies.		
			For peer review only	y - http://bmjc	pen.bmj.com/s	site/about/guidelii	ice Bibliographique de l		2

## Table 4. Data extraction form for question 3

				BMJ	Open		njope I by c		
SDM in AKD:	a scoping review protocol. I	Protocol ID NE/2708	2019/2.0				n-20 opyri		
							19-03 ght, i		
Table 4. Do	ata extraction form for	question 3					4142 nclu		
Paper	Description of	Validation of	Duration of	Comparison to	Methods of	Outcomes of		Sample	Expected
number	SDM- intervention	the	the	standard care?	comparison?	interest?	for papulation	size	publication
	being developed	intervention?	intervention?				ibrua Ens		of results?
2*	An electronic health	No	Not available	Yes	Open-label, two-arm	Health related quali	tents aged ≥	N = 997	31-12-2022
	information tool and				randomised	of life, clinical patier	<b>19</b> years of age,		
	kidney transitions				controlled pilot trial	data, event data,	<b>o</b> with an eGFR <		
	specialist to		Dh			healthcare resource	330ml/min.173m <sup>2</sup>		
	supplement standard		6			use	an e of with an		
	treatment modality								
	treatment modality.			No.			<b>E D O O O O O O O O O O</b>		
* this is an exa	Imple						nin Sitt		
							mjopen.bmj.com/ on June 9, 2025 at training, and similar technologies.		
		Foi	r peer review on	ly - http://bmjoper	n.bmj.com/site/abou	ut/guidelines.xhtm	Agence Bibliographique de		24

**BMJ** Open

# **BMJ Open**

## Shared Decision-Making in Advanced Kidney Disease: a scoping review protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2019-034142.R1
Article Type:	Protocol
Date Submitted by the Author:	15-Jan-2020
Complete List of Authors:	Engels, Noel; Santeon , de Graav, Gretchen; Maasstad Ziekenhuis, Internal medicine van der Nat , Paul; Sint Antonius Ziekenhuis Woerden van den Dorpel, Marinus; Maasstad Ziekenhuis, Internal medicine Bos, Willem Jan; Leiden University Medical Center, Internal Medicine Stiggelbout, Anne; University Medical Center Leiden, Medical Decisionmaking
<b>Primary Subject Heading</b> :	Renal medicine
Secondary Subject Heading:	Patient-centred medicine, Qualitative research, Evidence based practice
Keywords:	shared decision making, advanced kidney disease, treatment modality, outcome measures, scoping review, protocol





I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our <u>licence</u>.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which <u>Creative Commons</u> licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

terez oni

Enseignement Superieur (ABES) Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies

## **Research protocol**

English title: Shared Decision-Making in Advanced Kidney Disease: a scoping review protocol

t

## Authors:

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Drs. N. Engels Dr. G.N. de Graav Dr. P.B. van der Nat Dr. M.A. van den Dorpel Prof. dr. W.J.W. Bos Prof. dr. A.M. Stiggelbout

Protocol title: Shared decision-making in Advanced Kidney Disease: a scoping review

## protocol

Protocol ID	NE/15012020/4.0
Short title	SDM in AKD: a scoping review protocol
Version	4.0
Date	14-01-2020
Word count abstract	297 words
Word count paper (does not include: title page,	2838 words
abstract, strengths and limitations, keywords,	
references, footnotes or Appendices)	
Corresponding and first author	Drs. N. Engels
First reviewer	PhD candidate
	Santeon
	E-mail: <u>n.engels@santeon.nl</u>
	Phone: +31 6 31 74 73 25
	Herculesplein 38
	Kantoorgebouw Galghenwert (8 <sup>th</sup> floor)
	3584 AA Utrecht
	The Netherlands
Second reviewer and second author	Dr. G.N. de Graav
	Resident and researcher
	Dept. of Internal medicine
	Maasstad Hospital
	E-mail: graavg@maasstadziekenhuis.nl
	Phone: +31 10 291 2556
	Maasstadweg 21
	3079 DZ, Rotterdam
	The Netherlands
Third author	Dr. P.B. van der Nat
	Senior advisor board of directors
	St. Antonius Hospital
	E-mail: p.van.der.nat@antoniusziekenhuis.nl
	Phone: +31 88 320 3000
	Koekoekslaan 1
	3435 CM, Nieuwegein
	The Netherlands

#### **BMJ** Open

Fourth author	Dr. M.A. van den Dorpel
	Nephrologist, Dept. of Internal medicine
	Maasstad Hospital
	E-mail: dorpelm@maasstadziekenhuis.nl
	Phone: +31 10 291 3367
	Maasstadweg 21
	3079 DZ, Rotterdam
	The Netherlands
Fifth author	Prof. dr. W.J.W. Bos
	Nephrologist, Dept. of Internal medicine
	Leiden University Medical Center and St Antonius
	Hospital
	E-mail: <u>w.j.w.bos@lumc.nl</u>
	Phone: +31 71 526 3082
	Albinusdreef 2
	2333 ZA, Leiden
	The Netherlands
Sixth author	Prof. dr. A.M. Stiggelbout
	Expert medical decision making
	Leiden University Medical Center
	E-mail: a.m.stiggelbout@lumc.nl
	Phone: +31 71 526 4574
	Albinusdreef 2
	2333 ZA, Leiden
	The Netherlands
Sponsor	ZonMW
	E-mail: <u>info@zonmw.nl</u>
	Phone: +31 70 349 5111
	Laan van Nieuw Oost-Indië 334
	2593 CE, Den Haag

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

## Abstract

Introduction: Patients with advanced kidney disease (AKD) have to make difficult treatment modality decisions as their disease progresses towards end-stage renal disease (ESRD). 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 study group 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.

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies

## Strengths and limitations of this study

- The proposed scoping review will be the first paper to systematically search and map all existing SDM-interventions for AKD treatment modality decisions, evaluate the evidence on their reported outcomes, and report on new developments or ongoing studies in this field.
- It will provide a comprehensive overview by collecting information from both quantitative and qualitative research, as well as the grey literature and key experts on SDM.
- Research in SDM is heterogeneous in its methodology and the reporting of outcomes, therefore a • scoping review will be better suited to map, summarize and present this information than traditional systematic reviews or meta-analyses.
- Included studies will not undergo a formal quality assessment as scoping reviews attempt to provide an overview of all the existing evidence, regardless of its quality.
- Potentially relevant findings from papers written in other languages will be missed, as this study will only include papers written in English.

#### **Keywords**

- Shared Decision-Making
- Advanced Kidney Disease
- Treatment Modality
- Outcome Measures
- Scoping Review
- Protocol

#### Introduction

Advanced kidney disease is defined as an estimated glomerular filtration rate (eGFR) of less than 30mL/min/1,73m<sup>2</sup>, 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 renal disease (ESRD). As this process may take months or years, both patients and healthcare professionals face a considerable challenge in the anticipation of when renal replacement therapy (RRT) 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<sup>1,2</sup>. 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<sup>3</sup>. 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, organization of care, and as novel tools to support the decision-making process<sup>4-9</sup>.

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<sup>10</sup>. 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 underspecified and underinvestigated<sup>11</sup>. 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<sup>12,4</sup>. 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<sup>3</sup>. 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<sup>13</sup>. Finally, another scoping review identified multiple organizational- and system-level

 characteristics that play a role in the implementation of SDM in routine care, and concluded that healthcare organizations should consider these characteristics if they wish to support the adoption of SDM<sup>14</sup>.

Only three of these reviews report on the evidence for the effectiveness of SDM or PtDAs in the context of kidney disease<sup>3,4,14</sup>, and of the ten papers that are mentioned in these papers, only four were published<sup>15-18</sup>. Therefore, the relevance of the statements made in these papers may be questioned for AKD, or any other form of kidney disease. Moreover, 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<sup>19</sup>, factors influencing the decision-making process regarding treatment modalities for patients with AKD<sup>20-25</sup>, the readability of written materials for patients with chronic kidney disease (CKD)<sup>26,27</sup>, the effects of education and cognition of patients on SDM<sup>28-30</sup>, the validity of prognostic algorithms for this decisionmaking process<sup>31</sup>, advanced care planning<sup>32,33</sup>, and treatment outcomes in the elderly<sup>34-38</sup>. Furthermore, a preliminary search in the PubMed, MEDLINE, Embase, Web of science, Cochrane library, Emcare, 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<sup>39,40</sup>. Additionally, a protocol for a scoping review on the information available for SDM with older AKD patients considering their treatment options has been published<sup>41</sup>. Finally, numerous narrative reviews and overview papers on these topics in the context of kidney failure have been published as well<sup>42-63</sup>. 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 generalizability 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 all existing 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:
# **BMJ** Open

- Advanced kidney disease: Chronic Kidney Disease Kidney Disease Improving Global Outcomes (CKD-KDIGO) G4-G5A<sub>1-3</sub> kidney failure<sup>2</sup>.
- *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), hemodialysis (incentre or home), peritoneal dialysis (Ambulatory Peritoneal Dialysis, i.e. APD or Continuous Automatic Peritoneal Dialysis, i.e. CAPD), 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 (IDPAS) collaboration<sup>64</sup>.
- *SDM:* the process in which patients, caregivers, and healthcare professionals relate to, and influence each other as they collaborate in making healthcare decisions<sup>3</sup>.
- SDM-intervention: any intervention in standard care supporting SDM between patients and healthcare professionals (e.g. PtDAs, educational programs for patients or healthcare professionals, prognostic algorithms and peer support programs).

# Study aim and objectives

The proposed scoping review will systematically collect and synthesize information on the topic of SDM-interventions for treatment modality decisions in AKD, in order 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 sub-questions 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?

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

• 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<sup>65</sup>. Please refer to *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 *supplementary Appendix 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 study group 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. In order 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

#### **BMJ** Open

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 quasi-experimental study designs, i.e. randomised or non-randomised controlled trials, controlled and uncontrolled pre-post studies, and (multiple) interrupted time-series;
- Quantitative descriptive and analytical observational studies, i.e. retrospective and prospective cohort studies, case-control and cross-sectional studies, case series and case reports;
- Qualitative studies, using e.g. 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, 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 scolar.

The search for guidelines will include searches on the platforms of the Kidney Disease Improving Global Outcomes (KDIGO) association, the Renal Physicians Association (RPA), the American Society of Nephrology (ASN), the Canadian society of Nephrology (CSN), the National Institute for Health and Care Excellence (NICE), the European Renal association – European Dialysis and Transplant Association (ERA-EDTA), and the Kidney Health Australia – Caring for Australians with Renal Impairment association.

Papers will be excluded from this review if they:

### **BMJ** Open

- Do not address SDM-interventions for treatment modality decisions in AKD;
- Only address patients with an eGFR > 30mL/min/1,72m<sup>2</sup>;
- 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<sup>65</sup>. 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, e.g. 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 e-mail 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 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, version 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 is 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 (interquartile range) where appropriate. Categorical data will be expressed as frequencies (%), unless otherwise stated. IBM SPSS statistics version 23 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 (e.g. open coding or the framework approach) in Atlast.ti. 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 ESRD. However, papers that present a thorough overview of all existing SDM-interventions, evidence on any of their outcomes, or new interventions that are being developed or investigated for this decision are lacking. This leaves healthcare professionals and researchers guessing, which hampers further implementation, research and development. Therefore, the proposed scoping review will map all existing SDM-interventions for AKD treatment modality decisions, summarize 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 upto-date overview for healthcare professionals and researchers, explore and define knowledge gaps and facilitate future research and development.

# References

1. Renal Physicians Association: Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis, 2nd Ed., Rockville, MD, Renal Physicians Association, 2010

2. KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. volume
3 | issue 1 | JANUARY 2013 http://www.kidney-international.org

3. Légaré F, Adekpedjou R, Stacey D, Turcotte S, Kryworuchko J, Graham ID, Lyddiatt A, Politi MC, Thomson R, Elwyn G, Donner-Banzhoff N. Interventions for increasing the use of shared decision making by healthcare professionals. Cochrane Database of Systematic Reviews 2018, Issue 7.

4. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt
A, Thomson R, Trevena L. Decision aids for people facing health treatment or screening decisions. Cochrane Database of Systematic Reviews. 2017, Issue 4.

5. Verberne WR, Das-Gupta Z, Allegretti AS, Bart HAJ, van Biesen W, García-García G, Gibbons E, Parra E, Hemmelder MH, Jager KJ, Ketteler M, Roberts C, Al Rohani M, Salt MJ, Stopper A, Terkivatan T, Tuttle KR, Yang CW, Wheeler DC, Bos WJW. Development of an International Standard Set of Value-Based Outcome Measures for Patients With Chronic Kidney Disease: A Report of the International Consortium for Health Outcomes Measurement (ICHOM) CKD Working Group. Am J Kidney Dis. 2019 Mar;73(3):372-384.

6. Viecelli A, Tong A, O'Lone E, Ju A, Hanson CS, Sautenet B, Craig JC, Manns B, Howell M, Chemla E, Hooi LS, Johnson DW, Lee T, Lok CE, Polkinghorne K, Quinn RR, Vaccharajani T, Vanholder R, Zuo L, Hawley CM on behalf of the SONG-HD Vascular Access Workshop Investigators. Report of the standardized outcomes in nephrology – hemodialysis (SONG-HD) consensus workshop on establishing a core outcome measure for hemodialysis vascular access. American Journal of Kidney Disease 2018; 71(5):690-700

7. Ju A, Josephson MA, Butt Z, Jowsey-Gregoire S, Tan J, Taylor Q, Fowler K, Dobbels F, Caskey F, Jha V, Locke J, Knoll G, Ahn C, Hanson CS, Sautenet B, Manera K, Craig JC, Howell M, Rutherford C, Tong A; SONG-Tx Life Participation Workshop Investigators\*. Establishing a core outcome measure for life participation: a Standardized Outcomes in Nephrology – Kidney Transplantation (SONG-Tx) consensus workshop Report. Transplantation 2018; doi: 10.1097/TP.00000000002476. [Epub ahead of print]

8. Manera KE, Tong A, Craig JC, Brown EA, Brunier G, Dong J, Dunning T, Mehrotra R, Naicker S, Pecoits-Filho R, Perl J, Wang AY, Wilkie M, Howell M, Sautenet B, Evangelidis N, Shen JI, Johnson DW. Standardised Outcomes in Nephrology – Peritoneal Dialysis (SONG-PD): study protocol for establishing a core outcome set in peritoneal dialysis. Peritoneal Dialysis International 2017;37:639-47.

9. Breckenridge K, Bekker HL Gibbons E et al., How to routinely collect data on patient-reported outcome and experience measures in renal registries in Europe: an expert consensus meeting. Nephrol Dial Transplant. 2015 Oct;30(10):1605-14.

10. Légaré F, Ratté S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. Patient Educ Couns. 2008 Dec;73(3):526-35.

 11. Elwyn G, Scholl I, Tietbohl C, Mann M, Edwards, Katherine, Légaré F, van der Weijden T, Lewis, Wexler R, Frosch D. The implementation of patient decision support interventions into routine clinical practice: a systematic review. BMC Med Inform Decis Mak. 2013;13 Suppl 2:S14.

12. Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, LyddiattA, Thomson R, Trevena L, Wu JHC. Decision aids for people facing health treatment or screening decisions.Cochrane Database of Systematic Reviews 2014, Issue 1.

13. Siyam T, Shahid A, Perram M, Zuna I, Haque F, Herrera CA, Vohra S, Olson K. A scoping review of interventions to promote the adoption of shared decision making (SDM) among healthcare professionals in clinical practice. Patient Educ Couns. 2019 Jun;102(6):1057-1066.

14. Scholl I, LaRussa A, Hahlweg P, Kobrin S, Elwyn G. Organizational- and system-level characteristics that influence implementation of shared decision-making and strategies to address them – a scoping review. Implement Sci. 2018 Mar 9;13(1):40

15. Manns B J, Taub K, Vanderstraeten C, Jones H, Mills C, Visser M, et al. The impact of education on chronic kidney disease patients" plans to initiate dialysis with self-care dialysis: a randomized trial. Kidney International 2005;68 (4):1777–83

16. Registered Nurses' Association of Ontario. Decision support for adults living with chronic kidney disease. http:// rnao.ca/bpg/guidelines/decision-support-adults-living-chronickidney-disease. Toronto, Ontario: The Author, 2009.

17. Fortnum D, Smolonogov T, Walker R, Kairaitis L, Pugh D. 'My kidneys, my choice, decision aid': supporting shared decision making. J Ren Care. 2015 Jun;41(2):81-7. doi: 10.1111/jorc.12100. Epub 2014 Dec 10.

18. Mollicone D, Pulliam J, Lacson E Jr. The culture of education in a large dialysis organization: informing patientcentered decision making on treatment options for renal replacement therapy. Semin Dial. 2013 Mar-Apr;26(2):143-7. doi: 10.1111/sdi.12053. Epub 2013 Feb 14.

19. Bailey PK, Hamilton AJ, Clissold RL, Inward CD, Caskey FJ, Ben-Shlomo Y, Owen-Smith A. Young adults' perspectives on living with kidney failure: a systematic review and thematic synthesis of qualitative studies. BMJ Open 2018;8:e019926.

20. Murray MA, Brunier G, Chung JO, Craig LA, Mills C, Thomas A, Stacey D. A systematic review of factors influencing decision-making in adults living with chronic kidney disease. Patient Education and Counseling 76 (2009) 149–158.

21. Morton RL, Tong A, Howard K, Snelling P, Webster AC. The views of patients and carers in treatment decision making for chronic kidney disease: systematic review and thematic synthesis of qualitative studies. BMJ. 2010 Jan 19;340:c112.

22. Harwood L, Clark AM. Understanding pre-dialysis modality decision-making: A meta-synthesis of qualitative studies. International Journal of Nursing Studies 50 (2013). 109–120.

23. Tong A, Hanson CS, Chapman JR, Halleck F, Budde K, Papachristou C, Craig JC. The preferences and perspectives of nephrologists on patients' access to kidney transplantation: a systematic review. Transplantation. 2014 Oct 15;98(7):682-91

#### **BMJ** Open

SDM in AKD: a scoping review protocol. Protocol ID NE/15012020/4.0

24. Hussain JA, Flemming K, Murtagh FE, Johnson, MJ. Patient and health care professional decision-making to commence and withrdraw from dialysis: a systematic review of qualitative research

25. Winterbottom A, Bekker HL, Conner M, Mooney A. Choosing dialysis modality: decision making in a chronic illness context. Health Expect. 2014 Oct;17(5):710-23.

26. Morony S, Flynn M, McCaffery KJ, Jansen J, Webster AC. Readability of Written Materials for CKD Patients: A Systematic Review. Am J Kidney Dis. 2015;65(6):842-850

27. Winterbottom A, Conner M, Mooney A & Bekker HL. Evaluating the quality of patient leaflets about renal replacement therapy across UK renal units. Nephrol Dial Transplant. 2007 Aug;22(8):2291-6.28. Devoe DJ, Wong B, James MT, Ravani P, Oliver MJ, Barnieh L, Roberts DJ, Pauly R, Manns BJ, Kappel J, Quinn RR. Patient Education and Peritoneal Dialysis Modality Selection: A Systematic Review and Meta-analysis. Am J Kidney Dis. 2016 Sep;68(3):422-33.

29. Berger I, Wu S, Masson P, Kelly PJ, Duthie FA, Whiteley W, Parker D, Gillespie D, Webster AC. Cognition in chronic kidney disease: a systematic review and meta-analysis. BMC Med. 2016 Dec 14;14(1):206.

30. Taylor DM, Fraser SDS, Bradley JA, Bradley C, Draper H, Metcalfe W, Oniscu GC, Tomson CRV, Ravanan R, Roderick PJ; ATTOM investigators. A Systematic Review of the Prevalence and Associations of Limited Health Literacy in CKD. Clin J Am Soc Nephrol. 2017 Jul 7;12(7):1070-1084.

31. Ramspek CL, Voskamp PW, van Ittersum FJ, Krediet RT, Dekker FW, van Diepen M. Prediction models for the mortality risk in chronic dialysis patients: a systematic review and independent external validation study.
Clin Epidemiol. 2017 Sep 5;9:451-464.

32. Lim CED, Ng RWC, Cheng NCL, Cigolini M, Kwok C, Brennan F. Advance care planning for haemodialysis patients. Cochrane Database of Systematic Reviews 2016, Issue 7.

33. O'Halloran P, Noble H, Norwood K, Maxwell P, Shields J, Fogarty D, Murtagh F, Morton R, Brazil K. Advance care planning with patients who have end-stage kidney disease: a systematic realist review. J Pain Symptom Manage. 2018 Nov;56(5):795-807.

34. Foote C, Kotwal S, Gallagher M, Cass A, Brown M, Jardine M. Survival outcomes of supportive care versus dialysis therapies for elderly patients with end-stage kidney disease: A systematic review and meta-analysis. Nephrology (Carlton). 2016 Mar;21(3):241-53.

35. Wongrakpanich S, Susantitaphong P, Isaranuwatchai S, Chenbhanich J, Eiam-Ong S, Jaber BL. Dialysis Therapy and Conservative Management of Advanced Chronic Kidney Disease in the Elderly: A Systematic Review. Nephron. 2017;137(3):178-189.

36. Verberne WR, Geers AB, Jellema WT, Vincent HH, van Delden JJ, Bos WJ. Comparative Survival among Older Adults with Advanced Kidney Disease Managed Conservatively Versus with Dialysis. Clin J Am Soc Nephrol. 2016 Apr 7;11(4):633-40.

37. Verberne WR, Dijkers J, Kelder JC, Geers ABM, Jellema WT, Vincent HH, van Delden JJM, Bos WJW. Valuebased evaluation of dialysis versus conservative care in older patients with advanced chronic kidney disease: a cohort study. BMC Nephrol. 2018 Aug 16;19(1):205.

38. A comparison of treatment options for management of end stage kidney disease in elderly patients: a systematic review. JBI Database of Systematic Reviews and Implementation Reports. 12(7):374–404, JULY 2014.

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

39. Elliot MJ, Gil S, Hemmelgarn BR, Manns BJ, Tonelli M, Jun M, Donald M. A scoping review of adult chronic kidney disease clinical pathways for primary care. Nephrol Dial Transplant. 2017 May; 32(5): 838-846.

40. Qazi HA, Chen H, Zhu M. Factors influencing dialysis withdrawal: a scoping review. BMC Nephrol. 2018 Apr 24;19(1):96.

41. Raj R, KD Ahuja KD, Frandsen M, Jose M. Older patient considering treatment for advanced renal disease: a protocol for a scoping review of the information available for shared decision-making. BMJ Open. 2016 Dec 8;6(12):e013755.

42. Stryckers M, Nagler EV, van Biesen W. The need for accurate risk prediction models for road mapping, shared decision making and care planning for the elderly with advanced chronic kidney disease. Pril (Makedon Akad Nauk Umet Odd Med Nauki). 2016 Nov 1;37(2-3):33-42..

43. Couchoud C, Hemmelgarn B, Kotanko P, Germain MJ, Moranne O, Davison SN. Supportive Care: Time to Change Our Prognostic Tools and Their Use in CKD. Clin J Am Soc Nephrol 11: 1892–1901, October, 2016.

44. Kadatz MJ, Lee ES, Levin A. Predicting Progression in CKD: Perspectives and Precautions. Am J Kidney Dis. 2016;67(5):779-786.

45. Murtagh FEM, Burns A, Moranne O, Morton RL, Naicker S. Supportive Care: Comprehensive Conservative Care in End-Stage Kidney Disease. Clin J Am Soc Nephrol 11: 1909–1914, 2016.

46. Murray MA, Bissonnette J, Kryworuchko J, Gifford W, Calverley S. Whose Choice Is It? Shared Decision Making in Nephrology Care. Seminars in Dialysis—Vol 26, No 2 (March–April) 2013 pp. 169–174.

47. Llewellyn S. Concept Clarification: Uncertainty in Individuals with Chronic Kidney Disease. Nephrol Nurs J. 2017 Nov-Dec;44(6):513-539.

48. Cassidy BP, Getchell LE, Harwood L, Hemmett J, Moist LM. Barriers to Education and Shared Decision Making in the Chronic Kidney Disease Population: A Narrative Review. Can J Kidney Health Dis. 2018 Nov 2;5:2054358118803322.

49. Wilson S, Dhar A, Tregaskis P, Lambert G, Barton D, Walker R. Known unknowns: Examining the burden of neurocognitive impairment in the end-stage renal failure population. Nephrology (Carlton). 2018 Jun;23(6):501-506.

50. Santos J, Fonseca I. Incorporating Scoring Risk Models for Care Planning of the Elderly with Chronic Kidney Disease. Curr Gerontol Geriatr Res. 2017;2017:8067094.

51. Rosansky SJ, Schell J, Shega J, Scherer J, Jacobs L, Couchoud C, Crews D, McNabney M. Treatment decisions for older adults with advanced chronic kidney disease. BMC Nephrol. 2017 Jun 19;18(1):200.

52. Morton RL, Kurella Tamura M, Coast J, Davison SN. Supportive Care: Economic Considerations in Advanced Kidney Disease. Clin J Am Soc Nephrol. 2016 Oct 7;11(10):1915-1920.

53. Schmidt RJ. Advance Care Planning for Patients Approaching End-Stage Kidney Disease. Semin Nephrol. 2017 Mar;37(2):173-180.

54. Green JA, Boulware LE. Patient Education and Support During CKD Transitions: When the Possible Becomes Probable. Adv Chronic Kidney Dis. 2016 Jul;23(4):231-9.

55. Collister D, Russell R, Verdon J, Beaulieu M, Levin A. Perspectives on optimizing care of patients in multidisciplinary chronic kidney disease clinics. Can J Kidney Health Dis. 2016 May 12;3:32.

# **BMJ** Open

 56. Berger JR, Jaikaransingh V, Hedayati SS. End-Stage Kidney Disease in the Elderly: Approach to Dialysis Initiation, Choosing Modality, and Predicting Outcomes. Adv Chronic Kidney Dis. 2016 Jan;23(1):36-43.

57. MacPhail A, Ibrahim JE, Fetherstonhaugh D, Levidiotis V. The Overuse, Underuse, and Misuse of Dialysis in ESKD Patients with Dementia. Semin Dial. 2015 Sep-Oct;28(5):490-6.

58. Ghahramani N. Potential impact of peer mentoring on treatment choice in patients with chronic kidney disease: a review. Arch Iran Med. 2015 Apr;18(4):239-43.

59. Muthalagappan S, Johansson L, Kong WM, Brown EA. Dialysis or conservative care for frail older patients: ethics of shared decision-making. Nephrol Dial Transplant. 2013 Nov;28(11):2717-22.

60. Brown EA, Johansson L. Dialysis options for end-stage renal disease in older people. Nephron Clin Pract. 2011;119 Suppl 1:c10-3.

61. Campbell KH, Dale W, Stankus N, Sachs GA. Older adults and chronic kidney disease decision making by primary care physicians: a scholarly review and research agenda. J Gen Intern Med. 2008 Mar;23(3):329-36.

62. White Y, Fitzpatrick G. Dialysis: prolonging life or prolonging dying? Ethical, legal and professional considerations for end of life decision making. EDTNA ERCA J. 2006 Apr-Jun;32(2):99-103.

63. Pfettscher SA. Making decisions about end-stage renal disease treatment: a review of theories and issues. Adv Ren Replace Ther. 1997 Jan;4(1):81-8.

64. http://ipdas.ohri.ca/what.html

SDM in AKD: a scoping review protocol. Protocol ID NE/15012020/4.0

65. Peters MDJ, Godfrey C, McInerney P, Baldini Soares C, Khalil H, Parker D. Chapter 11: Scoping Reviews. In: Aromataris E, Munn Z (Editors). *Joanna Briggs Institute Reviewer's Manual*. The Joanna Briggs Institute, 2017. Available from https://reviewersmanual.joannabriggs.org/

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies

# Footnotes

#### Authors' contributions:

NE is the primary and corresponding author and was responsible for the first and all subsequent drafts of this scoping review protocol. GG, MD, PN, WB and AS 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.

# Acknowledgements:

The authors thank the research librarian Drs. J.W. Schoones of the Leiden University Medical Center for his help in defining and generating the keywords necessary to perform the subsequent search query.

# Data statement:

The data used to write this protocol is based on published literature, that is obtainable in the relevant online databases. NE, GG, MD, PN, WB and AS are the six authors of this scoping review protocol. As such, they will also be authors of the proposed scoping review. All authors have access to a RefWorks database in which the papers used for this protocol and the proposed scoping review are stored. The extracted data will be stored on servers of Santeon. Therefore, all authors will have continued access to the collected data for this scoping review protocol and the proposed scoping review.

#### **Funding statement:**

This work was supported by ZonMW as part of the "Experiment Uitkomst indicatoren Santeon". Conflicts of interests: None declared.



# Appendix 2: Draft version of paper charting table

BMJ Open by robust a scoping review protocol. Protocol ID NE/15012020/4.0 BMJ Open 2019-034142 c									P		
Table 1. Pa	per charting tab	le Primary	Type of	Publication	Concent of the	Context of the	Population	n 27 19 for	Methods	Passas	Included?
Number	mie	author	paper	year	paper	paper	Population	Enseigneme uses related	Wethous	exclusion criteria? Yes / No	Yes / No
1*	A website	Gordon.	Research	2016	Improving	Improving	Patients aged between	<u>655</u>	Pre-test and	Yes	Yes
	intervention to	E.J.		16	decisional capacity	knowledge on	18 and 75 years of age	wnl ext a	post-test		
	increase			1 6	with an online	kidney	that self-identified as	oad erie and	intervention		
	knowledge				PtDA	transplantation	Hispanic/Latino, were	ed f ur () data			
	about living					for informed	on chronic	ABE			
	kidney donation					decisions	hemodialysis, clinically	nin S)			
	and						eligible to receive a				
	transplantation						transplant, had never	bmj l tra			
	among						received an organ	ainii			
	Hispanic/latino						transplant or formal	ng,			
	dialysis patients						education about	and			
							transplantation from a	l sin			
							transplant center, gave	√ or			
							acceptable responses	ר Ju r teo			
							to certain health	Ine			
							literacy questions, and	9, 2 oloj			
							were able to use a	025 gies			
							computer.	. at			

\* this is an example

Agence Bibliographique de l

 Type of intervention?

Web-based education for

hispanic/latino dialysis

informed decision making.

The interventation entailed

viewing 3 of 6 websites

sections, for a total of 30

minutes.

patients to enhance

# Table 1. Data extraction table for question 1

	BMJ Open		njopen 1 by co	
2020/4.0			-2019-0 pyright,	
tion tables			34142 on including	
Targeted treatment	Context of the	How is the	Dur <b>g</b> tion of the	Reported
modality?	intervention	intervention	ធ្លូ ៣ ទុ ជាក្មខេត្តvention?	outcomes?
		introduced?	relate	
Transplantation	A culturally targeted,	After a 3 minute tutorial on	The interventation entailed	Yes
	bilingual, educational	using the website by	Aviewag 3 of 6 websites	
	website on living donor	research staff, participants	sections, for a total of 30	
	kidney transplantation	could view the website	and er des.	
		during their dialysis session	dat	
	4		n <mark>h</mark> ES)	
	F		ng, ,	
	erie	?h 0/	/bmjopen.bmj.com/ on June 9, 2 Al training, and similar technolo	

I training, and similar technologies

\* this is an example

Paper number

1\*

bmjopen.bmj.com/ on June 9, 2025 at Agence Bibliographique de l For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

2	
3	
4	
5	
6	
7	
/	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
10	
20	
20	
21	
22	
23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
22	
24	
54 25	
35	
36	
37	
38	
39	
40	
41	
42	
43	
44	
45	
46	

1

# Table 2. Data extraction table for question 2

SDM in AKD:	a scoping review pr	rotocol. Protocol ID NE	/15012020/4.0	E	3MJ Open		njopen-20' 1 by copyri			
Table 2. Dat	a extraction ta	ble for question 2					19-034142 ght, inclu			
Paper	Nature of	Reported	Reported	Reported	Compared	Scope of the	Implenentation	Validation of	Imlementation as	1
Number	reported	outcomes on	outcomes on	outcomes	to standard	outcomes?	as part of T	the	standard care?	
	outcomes?	treatment	decision-making	on	care?		standaថ្លៃ៨ ភ្លួជខ្លួនខ្	instrument?		
		modality	process?	healthcare			eigr rela			
		decisions?		outcomes?			2020 neme			
1*	Knowledge	No	No	No	Yes	A mean 17.1%	No te so	Not available	No	_
			0r			same day	vnlc xt a			
			6			knowledge score	rieu nd c			
				5		increase between	hr (A lata			
						pre-test and post-	mir			
						test ( $P < .001$ ).	s) . S) .			
						At 3 weeks	, Al			
						remained 11.7%	traii			
						above pre-test (P <	ning			
					ľ C	.001) values.	l, an			
* this is an exai	nple	1		I	1	0	.com/ on Ju d similar te			
							une 9, chnol			
							2028 ogie			
							5 at / s.			
							Ager			
							nce			
							Bibli			
							iogr			
							aph			
							ique		2	1
			For peer review only	/ - http://bmjc	pen.bmj.com/s	ite/about/guideli	nes.xhtml			

Table 3.	Data extraction table for question 3	
----------	--------------------------------------	--

				BMJ	Open	L DY C	1 by 2	njope		
SDM in AKD	: a scoping review protocol. I	Protocol ID NE/1501	2020/4.0				opyrin	n-201		
						, ,	<b>•</b>	9-034		
Table 3. Do	ata extraction table for	r question 3						142		
Paper	Description of	Validation of	Duration of	Comparison to	Methods of	Outcomes of	in i	Study	Sample	Expected
number	SDM- intervention	the	the	standard care?	comparison?	interest?		apulation	size	publication
	being developed	intervention?	intervention?				Ens	brua		of results?
2*	An electronic health	No	Not available	Yes	Open-label, two-arm	Health related quality		tients aged ≥	N = 997	31-12-2022
	information tool and				randomised	of life, clinical patient		years of age,		
	kidney transitions				controlled pilot trial	data, event data,		with an eGFR <		
	specialist to					healthcare resource	s up	ml/min.173m <sup>2</sup>		
	supplement standard		6			use	and Beric	ອັwith an ອ		
	care in choosing a					La ca		creased risk of		
	treatment modality.					<u>ة</u>	β B B	lipease Q		
¥ 11 · · ·							S S S			
							aining and similar tachnologias	iopen.bmj.com/ on June 9, 2025 at Agence Bib		
		Foi	r peer review on	y - http://bmjoper	າ.bmj.com/site/abou	ut/guidelines.xhtml		ographique de l		:

**BMJ** Open

# **BMJ Open**

# Shared Decision-Making in Advanced Kidney Disease: a scoping review protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2019-034142.R2
Article Type:	Protocol
Date Submitted by the Author:	31-Jan-2020
Complete List of Authors:	Engels, Noel; Santeon , de Graav, Gretchen; Maasstad Ziekenhuis, Internal medicine van der Nat , Paul; Sint Antonius Ziekenhuis Woerden van den Dorpel, Marinus; Maasstad Ziekenhuis, Internal medicine Bos, Willem Jan; Leiden University Medical Center, Internal Medicine Stiggelbout, Anne; University Medical Center Leiden, Medical Decisionmaking
<b>Primary Subject Heading</b> :	Renal medicine
Secondary Subject Heading:	Patient-centred medicine, Qualitative research, Evidence based practice
Keywords:	shared decision making, advanced kidney disease, treatment modality, outcome measures, scoping review, protocol





I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our <u>licence</u>.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which <u>Creative Commons</u> licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

terez oni

Enseignement Superieur (ABES) Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies

# **Research protocol**

English title: Shared Decision-Making in Advanced Kidney Disease: a scoping review protocol

t Kor peer teriew ont

# Authors:

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Drs. N. Engels Dr. G.N. de Graav Dr. P.B. van der Nat Dr. M.A. van den Dorpel Prof. dr. W.J.W. Bos Prof. dr. A.M. Stiggelbout

Protocol title: Shared decision-making in Advanced Kidney Disease: a scoping review

protocol

Protocol ID	NE/31012020/5.0
Short title	SDM in AKD: a scoping review protocol
Version	5.0
Date	31-01-2020
Word count abstract	297 words
Word count paper (does not include: title page,	2838 words
abstract, strengths and limitations, keywords,	
references, footnotes or Appendices)	
Corresponding and first author	Drs. N. Engels
First reviewer	PhD candidate
	Santeon
	E-mail: <u>n.engels@santeon.nl</u>
	Phone: +31 6 31 74 73 25
	Herculesplein 38
	Kantoorgebouw Galghenwert (8 <sup>th</sup> floor)
	3584 AA Utrecht
	The Netherlands
Second reviewer and second author	Dr. G.N. de Graav
	Resident and researcher
	Dept. of Internal medicine
	Maasstad Hospital
	E-mail: graavg@maasstadziekenhuis.nl
	Phone: +31 10 291 2556
	Maasstadweg 21
	3079 DZ, Rotterdam
	The Netherlands
Third author	Dr. P.B. van der Nat
	Senior advisor board of directors
	St. Antonius Hospital
	E-mail: p.van.der.nat@antoniusziekenhuis.nl
	Phone: +31 88 320 3000
	Koekoekslaan 1
	3435 CM, Nieuwegein
	The Netherlands

# **BMJ** Open

Fourth author	Dr. M.A. van den Dorpel			
	Nephrologist, Dept. of Internal medicine			
	Maasstad Hospital			
	E-mail: dorpelm@maasstadziekenhuis.nl			
	Phone: +31 10 291 3367			
	Maasstadweg 21			
	3079 DZ, Rotterdam			
	The Netherlands			
Fifth author	Prof. dr. W.J.W. Bos			
	Nephrologist, Dept. of Internal medicine			
	Leiden University Medical Center and St Antonius			
	Hospital			
	E-mail: <u>w.j.w.bos@lumc.nl</u>			
	Phone: +31 71 526 3082			
	Albinusdreef 2			
	2333 ZA, Leiden			
	The Netherlands			
Sixth author	Prof. dr. A.M. Stiggelbout			
	Expert medical decision making			
	Leiden University Medical Center			
	E-mail: a.m.stiggelbout@lumc.nl			
	Phone: +31 71 526 4574			
	Albinusdreef 2			
	2333 ZA, Leiden			
	The Netherlands			
Sponsor	ZonMW			
	E-mail: <u>info@zonmw.nl</u>			
	Phone: +31 70 349 5111			
	Laan van Nieuw Oost-Indië 334			
	2593 CE, Den Haag			

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

# Abstract

**Introduction:** Patients with advanced kidney disease (AKD) have to make difficult treatment modality decisions as their disease progresses towards end-stage kidney disease (ESKD). 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 study group 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.

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies

# Strengths and limitations of this study

- The proposed scoping review will be the first paper to systematically search and map all existing SDM-interventions for AKD treatment modality decisions, evaluate the evidence on their reported outcomes, and report on new developments or ongoing studies in this field.
- It will provide a comprehensive overview by collecting information from both quantitative and qualitative research, as well as the grey literature and key experts on SDM.
- Research in SDM is heterogeneous in its methodology and the reporting of outcomes, therefore a • scoping review will be better suited to map, summarize and present this information than traditional systematic reviews or meta-analyses.
- Included studies will not undergo a formal quality assessment as scoping reviews attempt to provide an overview of all the existing evidence, regardless of its quality.
- Potentially relevant findings from papers written in other languages will be missed, as this study will only include papers written in English.

# **Keywords**

- Shared Decision-Making
- Advanced Kidney Disease
- Treatment Modality
- Outcome Measures
- Scoping Review
- Protocol

# Introduction

Advanced kidney disease is defined as an estimated glomerular filtration rate (eGFR) of less than 30mL/min/1,73m<sup>2</sup>, 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<sup>1,2</sup>. 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<sup>3</sup>. 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, organization of care, and as novel tools to support the decision-making process<sup>4-9</sup>.

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<sup>10</sup>. 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 underspecified and underinvestigated<sup>11</sup>. 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<sup>12,4</sup>. 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<sup>3</sup>. 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<sup>13</sup>. Finally, another scoping review identified multiple organizational- and system-level

 characteristics that play a role in the implementation of SDM in routine care, and concluded that healthcare organizations should consider these characteristics if they wish to support the adoption of SDM<sup>14</sup>.

Only three of these reviews report on the evidence for the effectiveness of SDM or PtDAs in the context of kidney disease<sup>3,4,14</sup>, and of the ten papers that are mentioned in these papers, only four were published<sup>15-18</sup>. Therefore, the relevance of the statements made in these papers may be questioned for AKD, or any other form of kidney disease. Moreover, 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<sup>19</sup>, factors influencing the decision-making process regarding treatment modalities for patients with AKD<sup>20-25</sup>, the readability of written materials for patients with chronic kidney disease (CKD)<sup>26,27</sup>, the effects of education and cognition of patients on SDM<sup>28-30</sup>, the validity of prognostic algorithms for this decisionmaking process<sup>31</sup>, advanced care planning<sup>32,33</sup>, and treatment outcomes in the elderly<sup>34-38</sup>. Furthermore, a preliminary search in the PubMed, MEDLINE, Embase, Web of science, Cochrane library, Emcare, 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<sup>39,40</sup>. Additionally, a protocol for a scoping review on the information available for SDM with older AKD patients considering their treatment options has been published<sup>41</sup>. Finally, numerous narrative reviews and overview papers on these topics in the context of kidney failure have been published as well<sup>42-63</sup>. 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 generalizability 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 all existing 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:

#### **BMJ** Open

- Advanced kidney disease: Chronic Kidney Disease Kidney Disease Improving Global Outcomes (CKD-KDIGO) G4-G5A<sub>1-3</sub> kidney failure<sup>2</sup>.
- *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), hemodialysis (incentre or home), peritoneal dialysis (Ambulatory Peritoneal Dialysis, i.e. APD or Continuous Automatic Peritoneal Dialysis, i.e. CAPD), 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 (IDPAS) collaboration<sup>64</sup>.
- *SDM:* the process in which patients, caregivers, and healthcare professionals relate to, and influence each other as they collaborate in making healthcare decisions<sup>3</sup>.
- *SDM-intervention:* any intervention in standard care supporting SDM between patients and healthcare professionals (e.g. PtDAs, educational programs for patients or healthcare professionals, prognostic algorithms and peer support programs).

# Study aim and objectives

The proposed scoping review will systematically collect and synthesize information on the topic of SDM-interventions for treatment modality decisions in AKD, in order 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 sub-questions 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?

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

• 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<sup>65</sup>. Please refer to *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 *supplementary Appendix 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 study group 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. In order 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

#### **BMJ** Open

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 quasi-experimental study designs, i.e. randomised or non-randomised controlled trials, controlled and uncontrolled pre-post studies, and (multiple) interrupted time-series;
- Quantitative descriptive and analytical observational studies, i.e. retrospective and prospective cohort studies, case-control and cross-sectional studies, case series and case reports;
- Qualitative studies, using e.g. 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, 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 scolar.

The search for guidelines will include searches on the platforms of the Kidney Disease Improving Global Outcomes (KDIGO) association, the Renal Physicians Association (RPA), the American Society of Nephrology (ASN), the Canadian society of Nephrology (CSN), the National Institute for Health and Care Excellence (NICE), the European Renal association – European Dialysis and Transplant Association (ERA-EDTA), and the Kidney Health Australia – Caring for Australians with Renal Impairment association.

Papers will be excluded from this review if they:

### **BMJ** Open

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies

- Do not address SDM-interventions for treatment modality decisions in AKD;
- Only address patients with an eGFR > 30mL/min/1,72m<sup>2</sup>;
- 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<sup>65</sup>. 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, e.g. 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 e-mail 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 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, version 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 is 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;

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

# • 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 (interquartile range) where appropriate. Categorical data will be expressed as frequencies (%), unless otherwise stated. IBM SPSS statistics version 23 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 (e.g. open coding or the framework approach) in Atlast.ti. 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 all existing SDM-interventions, evidence on any of their outcomes, or new interventions that are being developed or investigated for this decision are lacking. This leaves healthcare professionals and researchers guessing, which hampers further implementation, research and development. Therefore, the proposed scoping review will map all existing SDM-interventions for AKD treatment modality decisions, summarize 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 upto-date overview for healthcare professionals and researchers, explore and define knowledge gaps and facilitate future research and development.

# References

1. Renal Physicians Association: Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis, 2nd Ed., Rockville, MD, Renal Physicians Association, 2010

2. KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. volume
3 | issue 1 | JANUARY 2013 http://www.kidney-international.org

3. Légaré F, Adekpedjou R, Stacey D, Turcotte S, Kryworuchko J, Graham ID, Lyddiatt A, Politi MC, Thomson R, Elwyn G, Donner-Banzhoff N. Interventions for increasing the use of shared decision making by healthcare professionals. Cochrane Database of Systematic Reviews 2018, Issue 7.

4. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt
A, Thomson R, Trevena L. Decision aids for people facing health treatment or screening decisions. Cochrane Database of Systematic Reviews. 2017, Issue 4.

5. Verberne WR, Das-Gupta Z, Allegretti AS, Bart HAJ, van Biesen W, García-García G, Gibbons E, Parra E, Hemmelder MH, Jager KJ, Ketteler M, Roberts C, Al Rohani M, Salt MJ, Stopper A, Terkivatan T, Tuttle KR, Yang CW, Wheeler DC, Bos WJW. Development of an International Standard Set of Value-Based Outcome Measures for Patients With Chronic Kidney Disease: A Report of the International Consortium for Health Outcomes Measurement (ICHOM) CKD Working Group. Am J Kidney Dis. 2019 Mar;73(3):372-384.

6. Viecelli A, Tong A, O'Lone E, Ju A, Hanson CS, Sautenet B, Craig JC, Manns B, Howell M, Chemla E, Hooi LS, Johnson DW, Lee T, Lok CE, Polkinghorne K, Quinn RR, Vaccharajani T, Vanholder R, Zuo L, Hawley CM on behalf of the SONG-HD Vascular Access Workshop Investigators. Report of the standardized outcomes in nephrology – hemodialysis (SONG-HD) consensus workshop on establishing a core outcome measure for hemodialysis vascular access. American Journal of Kidney Disease 2018; 71(5):690-700

7. Ju A, Josephson MA, Butt Z, Jowsey-Gregoire S, Tan J, Taylor Q, Fowler K, Dobbels F, Caskey F, Jha V, Locke J, Knoll G, Ahn C, Hanson CS, Sautenet B, Manera K, Craig JC, Howell M, Rutherford C, Tong A; SONG-Tx Life Participation Workshop Investigators\*. Establishing a core outcome measure for life participation: a Standardized Outcomes in Nephrology – Kidney Transplantation (SONG-Tx) consensus workshop Report. Transplantation 2018; doi: 10.1097/TP.00000000002476. [Epub ahead of print]

8. Manera KE, Tong A, Craig JC, Brown EA, Brunier G, Dong J, Dunning T, Mehrotra R, Naicker S, Pecoits-Filho R, Perl J, Wang AY, Wilkie M, Howell M, Sautenet B, Evangelidis N, Shen JI, Johnson DW. Standardised Outcomes in Nephrology – Peritoneal Dialysis (SONG-PD): study protocol for establishing a core outcome set in peritoneal dialysis. Peritoneal Dialysis International 2017;37:639-47.

9. Breckenridge K, Bekker HL Gibbons E et al., How to routinely collect data on patient-reported outcome and experience measures in renal registries in Europe: an expert consensus meeting. Nephrol Dial Transplant. 2015 Oct;30(10):1605-14.

10. Légaré F, Ratté S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. Patient Educ Couns. 2008 Dec;73(3):526-35.

 11. Elwyn G, Scholl I, Tietbohl C, Mann M, Edwards, Katherine, Légaré F, van der Weijden T, Lewis, Wexler R, Frosch D. The implementation of patient decision support interventions into routine clinical practice: a systematic review. BMC Med Inform Decis Mak. 2013;13 Suppl 2:S14.

12. Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, LyddiattA, Thomson R, Trevena L, Wu JHC. Decision aids for people facing health treatment or screening decisions.Cochrane Database of Systematic Reviews 2014, Issue 1.

13. Siyam T, Shahid A, Perram M, Zuna I, Haque F, Herrera CA, Vohra S, Olson K. A scoping review of interventions to promote the adoption of shared decision making (SDM) among healthcare professionals in clinical practice. Patient Educ Couns. 2019 Jun;102(6):1057-1066.

14. Scholl I, LaRussa A, Hahlweg P, Kobrin S, Elwyn G. Organizational- and system-level characteristics that influence implementation of shared decision-making and strategies to address them – a scoping review. Implement Sci. 2018 Mar 9;13(1):40

15. Manns B J, Taub K, Vanderstraeten C, Jones H, Mills C, Visser M, et al. The impact of education on chronic kidney disease patients" plans to initiate dialysis with self-care dialysis: a randomized trial. Kidney International 2005;68 (4):1777–83

16. Registered Nurses' Association of Ontario. Decision support for adults living with chronic kidney disease. http:// rnao.ca/bpg/guidelines/decision-support-adults-living-chronickidney-disease. Toronto, Ontario: The Author, 2009.

17. Fortnum D, Smolonogov T, Walker R, Kairaitis L, Pugh D. 'My kidneys, my choice, decision aid': supporting shared decision making. J Ren Care. 2015 Jun;41(2):81-7. doi: 10.1111/jorc.12100. Epub 2014 Dec 10.

18. Mollicone D, Pulliam J, Lacson E Jr. The culture of education in a large dialysis organization: informing patientcentered decision making on treatment options for renal replacement therapy. Semin Dial. 2013 Mar-Apr;26(2):143-7. doi: 10.1111/sdi.12053. Epub 2013 Feb 14.

19. Bailey PK, Hamilton AJ, Clissold RL, Inward CD, Caskey FJ, Ben-Shlomo Y, Owen-Smith A. Young adults' perspectives on living with kidney failure: a systematic review and thematic synthesis of qualitative studies. BMJ Open 2018;8:e019926.

20. Murray MA, Brunier G, Chung JO, Craig LA, Mills C, Thomas A, Stacey D. A systematic review of factors influencing decision-making in adults living with chronic kidney disease. Patient Education and Counseling 76 (2009) 149–158.

21. Morton RL, Tong A, Howard K, Snelling P, Webster AC. The views of patients and carers in treatment decision making for chronic kidney disease: systematic review and thematic synthesis of qualitative studies. BMJ. 2010 Jan 19;340:c112.

22. Harwood L, Clark AM. Understanding pre-dialysis modality decision-making: A meta-synthesis of qualitative studies. International Journal of Nursing Studies 50 (2013). 109–120.

23. Tong A, Hanson CS, Chapman JR, Halleck F, Budde K, Papachristou C, Craig JC. The preferences and perspectives of nephrologists on patients' access to kidney transplantation: a systematic review. Transplantation. 2014 Oct 15;98(7):682-91

#### **BMJ** Open

SDM in AKD: a scoping review protocol. Protocol ID NE/31012020/5.0

24. Hussain JA, Flemming K, Murtagh FE, Johnson, MJ. Patient and health care professional decision-making to commence and withrdraw from dialysis: a systematic review of qualitative research

25. Winterbottom A, Bekker HL, Conner M, Mooney A. Choosing dialysis modality: decision making in a chronic illness context. Health Expect. 2014 Oct;17(5):710-23.

26. Morony S, Flynn M, McCaffery KJ, Jansen J, Webster AC. Readability of Written Materials for CKD Patients: A Systematic Review. Am J Kidney Dis. 2015;65(6):842-850

27. Winterbottom A, Conner M, Mooney A & Bekker HL. Evaluating the quality of patient leaflets about renal replacement therapy across UK renal units. Nephrol Dial Transplant. 2007 Aug;22(8):2291-6.28. Devoe DJ, Wong B, James MT, Ravani P, Oliver MJ, Barnieh L, Roberts DJ, Pauly R, Manns BJ, Kappel J, Quinn RR. Patient Education and Peritoneal Dialysis Modality Selection: A Systematic Review and Meta-analysis. Am J Kidney Dis. 2016 Sep;68(3):422-33.

29. Berger I, Wu S, Masson P, Kelly PJ, Duthie FA, Whiteley W, Parker D, Gillespie D, Webster AC. Cognition in chronic kidney disease: a systematic review and meta-analysis. BMC Med. 2016 Dec 14;14(1):206.

30. Taylor DM, Fraser SDS, Bradley JA, Bradley C, Draper H, Metcalfe W, Oniscu GC, Tomson CRV, Ravanan R, Roderick PJ; ATTOM investigators. A Systematic Review of the Prevalence and Associations of Limited Health Literacy in CKD. Clin J Am Soc Nephrol. 2017 Jul 7;12(7):1070-1084.

31. Ramspek CL, Voskamp PW, van Ittersum FJ, Krediet RT, Dekker FW, van Diepen M. Prediction models for the mortality risk in chronic dialysis patients: a systematic review and independent external validation study.
Clin Epidemiol. 2017 Sep 5;9:451-464.

32. Lim CED, Ng RWC, Cheng NCL, Cigolini M, Kwok C, Brennan F. Advance care planning for haemodialysis patients. Cochrane Database of Systematic Reviews 2016, Issue 7.

33. O'Halloran P, Noble H, Norwood K, Maxwell P, Shields J, Fogarty D, Murtagh F, Morton R, Brazil K. Advance care planning with patients who have end-stage kidney disease: a systematic realist review. J Pain Symptom Manage. 2018 Nov;56(5):795-807.

34. Foote C, Kotwal S, Gallagher M, Cass A, Brown M, Jardine M. Survival outcomes of supportive care versus dialysis therapies for elderly patients with end-stage kidney disease: A systematic review and meta-analysis. Nephrology (Carlton). 2016 Mar;21(3):241-53.

35. Wongrakpanich S, Susantitaphong P, Isaranuwatchai S, Chenbhanich J, Eiam-Ong S, Jaber BL. Dialysis Therapy and Conservative Management of Advanced Chronic Kidney Disease in the Elderly: A Systematic Review. Nephron. 2017;137(3):178-189.

36. Verberne WR, Geers AB, Jellema WT, Vincent HH, van Delden JJ, Bos WJ. Comparative Survival among Older Adults with Advanced Kidney Disease Managed Conservatively Versus with Dialysis. Clin J Am Soc Nephrol. 2016 Apr 7;11(4):633-40.

37. Verberne WR, Dijkers J, Kelder JC, Geers ABM, Jellema WT, Vincent HH, van Delden JJM, Bos WJW. Valuebased evaluation of dialysis versus conservative care in older patients with advanced chronic kidney disease: a cohort study. BMC Nephrol. 2018 Aug 16;19(1):205.

38. A comparison of treatment options for management of end stage kidney disease in elderly patients: a systematic review. JBI Database of Systematic Reviews and Implementation Reports. 12(7):374–404, JULY 2014.

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

39. Elliot MJ, Gil S, Hemmelgarn BR, Manns BJ, Tonelli M, Jun M, Donald M. A scoping review of adult chronic kidney disease clinical pathways for primary care. Nephrol Dial Transplant. 2017 May; 32(5): 838-846.

40. Qazi HA, Chen H, Zhu M. Factors influencing dialysis withdrawal: a scoping review. BMC Nephrol. 2018 Apr 24;19(1):96.

41. Raj R, KD Ahuja KD, Frandsen M, Jose M. Older patient considering treatment for advanced renal disease: a protocol for a scoping review of the information available for shared decision-making. BMJ Open. 2016 Dec 8;6(12):e013755.

42. Stryckers M, Nagler EV, van Biesen W. The need for accurate risk prediction models for road mapping, shared decision making and care planning for the elderly with advanced chronic kidney disease. Pril (Makedon Akad Nauk Umet Odd Med Nauki). 2016 Nov 1;37(2-3):33-42..

43. Couchoud C, Hemmelgarn B, Kotanko P, Germain MJ, Moranne O, Davison SN. Supportive Care: Time to Change Our Prognostic Tools and Their Use in CKD. Clin J Am Soc Nephrol 11: 1892–1901, October, 2016.

44. Kadatz MJ, Lee ES, Levin A. Predicting Progression in CKD: Perspectives and Precautions. Am J Kidney Dis. 2016;67(5):779-786.

45. Murtagh FEM, Burns A, Moranne O, Morton RL, Naicker S. Supportive Care: Comprehensive Conservative Care in End-Stage Kidney Disease. Clin J Am Soc Nephrol 11: 1909–1914, 2016.

46. Murray MA, Bissonnette J, Kryworuchko J, Gifford W, Calverley S. Whose Choice Is It? Shared Decision Making in Nephrology Care. Seminars in Dialysis—Vol 26, No 2 (March–April) 2013 pp. 169–174.

47. Llewellyn S. Concept Clarification: Uncertainty in Individuals with Chronic Kidney Disease. Nephrol Nurs J. 2017 Nov-Dec;44(6):513-539.

48. Cassidy BP, Getchell LE, Harwood L, Hemmett J, Moist LM. Barriers to Education and Shared Decision Making in the Chronic Kidney Disease Population: A Narrative Review. Can J Kidney Health Dis. 2018 Nov 2;5:2054358118803322.

49. Wilson S, Dhar A, Tregaskis P, Lambert G, Barton D, Walker R. Known unknowns: Examining the burden of neurocognitive impairment in the end-stage renal failure population. Nephrology (Carlton). 2018 Jun;23(6):501-506.

50. Santos J, Fonseca I. Incorporating Scoring Risk Models for Care Planning of the Elderly with Chronic Kidney Disease. Curr Gerontol Geriatr Res. 2017;2017:8067094.

51. Rosansky SJ, Schell J, Shega J, Scherer J, Jacobs L, Couchoud C, Crews D, McNabney M. Treatment decisions for older adults with advanced chronic kidney disease. BMC Nephrol. 2017 Jun 19;18(1):200.

52. Morton RL, Kurella Tamura M, Coast J, Davison SN. Supportive Care: Economic Considerations in Advanced Kidney Disease. Clin J Am Soc Nephrol. 2016 Oct 7;11(10):1915-1920.

53. Schmidt RJ. Advance Care Planning for Patients Approaching End-Stage Kidney Disease. Semin Nephrol. 2017 Mar;37(2):173-180.

54. Green JA, Boulware LE. Patient Education and Support During CKD Transitions: When the Possible Becomes Probable. Adv Chronic Kidney Dis. 2016 Jul;23(4):231-9.

55. Collister D, Russell R, Verdon J, Beaulieu M, Levin A. Perspectives on optimizing care of patients in multidisciplinary chronic kidney disease clinics. Can J Kidney Health Dis. 2016 May 12;3:32.
## **BMJ** Open

 56. Berger JR, Jaikaransingh V, Hedayati SS. End-Stage Kidney Disease in the Elderly: Approach to Dialysis Initiation, Choosing Modality, and Predicting Outcomes. Adv Chronic Kidney Dis. 2016 Jan;23(1):36-43.

57. MacPhail A, Ibrahim JE, Fetherstonhaugh D, Levidiotis V. The Overuse, Underuse, and Misuse of Dialysis in ESKD Patients with Dementia. Semin Dial. 2015 Sep-Oct;28(5):490-6.

58. Ghahramani N. Potential impact of peer mentoring on treatment choice in patients with chronic kidney disease: a review. Arch Iran Med. 2015 Apr;18(4):239-43.

59. Muthalagappan S, Johansson L, Kong WM, Brown EA. Dialysis or conservative care for frail older patients: ethics of shared decision-making. Nephrol Dial Transplant. 2013 Nov;28(11):2717-22.

60. Brown EA, Johansson L. Dialysis options for end-stage renal disease in older people. Nephron Clin Pract. 2011;119 Suppl 1:c10-3.

61. Campbell KH, Dale W, Stankus N, Sachs GA. Older adults and chronic kidney disease decision making by primary care physicians: a scholarly review and research agenda. J Gen Intern Med. 2008 Mar;23(3):329-36.

62. White Y, Fitzpatrick G. Dialysis: prolonging life or prolonging dying? Ethical, legal and professional considerations for end of life decision making. EDTNA ERCA J. 2006 Apr-Jun;32(2):99-103.

63. Pfettscher SA. Making decisions about end-stage renal disease treatment: a review of theories and issues. Adv Ren Replace Ther. 1997 Jan;4(1):81-8.

64. http://ipdas.ohri.ca/what.html

SDM in AKD: a scoping review protocol. Protocol ID NE/31012020/5.0

65. Peters MDJ, Godfrey C, McInerney P, Baldini Soares C, Khalil H, Parker D. Chapter 11: Scoping Reviews. In: Aromataris E, Munn Z (Editors). *Joanna Briggs Institute Reviewer's Manual*. The Joanna Briggs Institute, 2017. Available from https://reviewersmanual.joannabriggs.org/

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies

### Footnotes

#### Authors' contributions:

NE is the primary and corresponding author and was responsible for the first and all subsequent drafts of this scoping review protocol. GG, MD, PN, WB and AS 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.

#### Acknowledgements:

The authors thank the research librarian Drs. J.W. Schoones of the Leiden University Medical Center for his help in defining and generating the keywords necessary to perform the subsequent search query.

## Data statement:

The data used to write this protocol is based on published literature, that is obtainable in the relevant online databases. NE, GG, MD, PN, WB and AS are the six authors of this scoping review protocol. As such, they will also be authors of the proposed scoping review. All authors have access to a RefWorks database in which the papers used for this protocol and the proposed scoping review are stored. The extracted data will be stored on servers of Santeon. Therefore, all authors will have continued access to the collected data for this scoping review protocol and the proposed scoping review.

#### **Funding statement:**

This work was supported by ZonMW as part of the "Experiment Uitkomst indicatoren Santeon". Conflicts of interests: None declared.



# Appendix 2: Draft version of paper charting table

SDM in AKD: Appendix	BMJ Open by copyright, including for the context of the paper by copyright, including for the context of the paper by copyright, including for the context of the paper context of the paper Population Methods Passes including for the context of the paper   umber author paper year paper paper paper paper paper paper Yes / No										
Table 1. Pa	per charting tab	le Primary	Type of	Publication	Concent of the	Context of the	Population	n 27 formale	Methods	Passas	Included?
Number	nue	author	paper	year	paper	paper	Population	Engeigneme Sebruary 2020 Engeigneme	Methous	exclusion criteria? Yes / No	Yes / No
1*	A website	Gordon.	Research	2016	Improving	Improving	Patients aged between		Pre-test and	Yes	Yes
	intervention to	E.J.			decisional capacity	knowledge on	18 and 75 years of age	wnl wr a	post-test		
	increase			1	with an online	kidney	that self-identified as	oad erie and	intervention		
	knowledge				PtDA	transplantation	Hispanic/Latino, were	ed f ur () data			
	about living					for informed	on chronic				
	kidney donation					decisions	hemodialysis, clinically	nin S)			
	and						eligible to receive a	9, A			
	transplantation						transplant, had never	bmj l tra			
	among						received an organ				
	Hispanic/latino						transplant or formal	ng,			
	dialysis patients						education about	and mj.			
							transplantation from a	l sin			
							transplant center, gave	√ or			
							acceptable responses	n Ju r teo			
							to certain health	Ine			
							literacy questions, and	9, 2 oloj			
							were able to use a	025 gies			
							computer.	. at			

\* this is an example

Agence Bibliographique de l

4

5 6

7 8

9 10

11

12

13

14

15 16

17

18

19

20

43

44 45 46 Context of the

A culturally targeted,

bilingual, educational

website on living donor

kidney transplantation

intervention

Type of intervention?

Web-based education for

informed decision making.

The interventation entailed

viewing 3 of 6 websites

sections, for a total of 30

minutes.

hispanic/latino dialysis

patients to enhance

Targeted treatment

modality?

Transplantation

# Table 1. Data extraction table for question 1

	14142 on 2
How is the	Durgtion of the
intervention	ត្ត ញុទ្ធ័ ពួកចូទ្ធvention?
introduced?	ary 20 eigne
After a 3 minute tutorial on	the interventation entailed
using the website by	Aview Bg 3 of 6 websites
research staff, participants	sections, for a total of 30
could view the website	an en
during their dialysis session	dat
	an froi
	ng, t

erien on

d by copyright, njopen-2019-03

bmjopen.bmj.com/ on June 9, 2025 at Agence Bibliographique

del

I training, and similar technologies

Reported

outcomes?

Yes

thic	ic	an	ovamnlo

Paper number

1\*

2	
3	
4	
5	
6	
7	
/	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
10	
20	
20	
21	
22	
23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
22	
24	
34 25	
35	
36	
37	
38	
39	
40	
41	
42	
43	
44	
45	
46	

1

## Table 2. Data extraction table for question 2

				E	BMJ Open			njopen 1 by col		
SDM in AKD:	a scoping review pr	rotocol. Protocol ID NE/1	15012020/4.0					-2019-03 pyright, i		
Table 2. Dat	ta extraction ta	ble for question 2						4142 nclue		
Paper	Nature of	Reported	Reported	Reported	Compared	Scope of the	Impler	ngentation	Validation of	Imlementation as
Number	reported	outcomes on	outcomes on	outcomes	to standard	outcomes?	as par		the	standard care?
	outcomes?	treatment	decision-making	on	care?		stando		instrument?	
		modality	process?	healthcare				ary 2 rela		
		decisions?		outcomes?				2020. Iteme		
1*	Knowledge	No	No	No	Yes	A mean 17.1%	No	Dov te	Not available	No
			Ur			same day		vnlo upe xt ai		
						knowledge score		ade rieu nd d		
						ncrease between		d fro r (AE ata I		
						test ( <i>P</i> < .001).		om h BES		
						At 3 weeks		ng,		
					N.	knowledge scores		//bm Al tr		
						remained 11.7%		jope aini		
						above pre-test (P <		ng, a		
* this is an ava	mala					.001) values.		and :		
tnis is an exa	тріе							om/ on , similar t		
								June echn		
								9, 2( olog		
								025 a Jies.		
								at Aç		
								yenc		
								ëB		
								blio		
								grap		
								ohiq		
								ue		4

del

Table 3.	Data extraction table for question 3	
----------	--------------------------------------	--

				BMJ	Open	cy cy	hv	njope		
SDM in AKD	: a scoping review protocol. I	Protocol ID NE/1501	2020/4.0			u py ng	onvrin	n-201		
						,	iht in	9-034		
Table 3. Do	ata extraction table for	r question 3						.142		
Paper	Description of	Validation of	Duration of	Comparison to	Methods of	Outcomes of	ina	Saudy	Sample	Expected
number	SDM- intervention	the	the	standard care?	comparison?	interest?		ppulation	size	publication
	being developed	intervention?	intervention?				Ens	brua		of results?
2*	An electronic health	No	Not available	Yes	Open-label, two-arm	Health related quality	reign Reign	₩ Natients aged <u>&gt;</u>	N = 997	31-12-2022
	information tool and				randomised	of life, clinical patient		years of age,		
	kidney transitions				controlled pilot trial	data, event data,	f ent	with an eGFR <		
	specialist to					healthcare resource	s S L	Sml/min.173m <sup>2</sup>		
	supplement standard		6			use	and	or with an		
	care in choosing a					2	d L	it reased risk of		
	treatment modality.						A BI	dipease O		
* 11.*- *										
							aining and similar technologies	jopen.bmj.com/ on June 9, 2025 at Agence Bib		
		For	r peer review on	y - http://bmjoper	n.bmj.com/site/abou	ut/guidelines.xhtml		ographique de l		: