Development of a core outcome set for pharmacist interventions in chronic kidney disease (COSP-KD): a protocol for e-Delphi consensus study

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Abstract

Background: Research has demonstrated the benefits of interventions delivered by pharmacists in people with chronic kidney disease (CKD). However, significant variation exists for reported outcomes and the inconsistency in measures used limits effective interpretation of the evidence. This can be addressed by developing a core outcome set (COS), which are the minimum outcomes that should be measured and reported across all trials for a particular therapeutic area.

Aims: To develop a COS for clinical trials evaluating the effectiveness of interventions involving pharmacists in people with CKD.

Methods: An online survey, e-Delphi survey, and a consensus workshop will be conducted.

Findings: The findings of this study will be published in a peer-reviewed journal, where the results will be presented in lay language with appropriate infographics online and via social media.

Conclusion: The development of a pharmacist-specific COS in CKD will address a gap for achieving consensus in outcomes and improve the consistency of outcomes reported.

Keywords: Chronic kidney disease, pharmacist, interventions, outcomes, Delphi study, core outcome set

Key points

1. Chronic kidney disease (CKD) is a progressive disease associated with increased morbidity and premature mortality.

2. Several systematic reviews have been conducted looking at pharmacist interventions, but there is significant heterogeneity of reported outcomes and outcome measures used. This hinders the interpretation of findings and reduces any potential impact on clinical practice.

3. A core outcome set (COS) describes the minimum outcomes that are of importance to various stakeholders, such as researchers and patients, in which they should consistently be measured and reported across trials.

4. Currently, no COS exists for CKD in relation to pharmacy research. Developing a pharmacist-specific COS in CKD will aid future research by addressing a gap in attaining consensus and improving the consistency of outcomes reported in trials.

Reflective questions

1. What is a core outcome set?

2. Why are core outcome sets important?

3. What are the key processes of Delphi methodology to consider?

Introduction

People living with chronic kidney disease (CKD) are characterised by significant morbidity and premature mortality, poor quality of life (QoL), and complications such as anaemia and mineral and bone disorders (Webster et al. 2017). With multiple long-term conditions, the presence of two or more chronic conditions, which is common in CKD (Hawthorne et al. 2023), patients face an increase in healthcare utilisation, increased symptom burden, and are required to take multiple medications (Navickas et al. 2016). Given the large focus on pharmacological management in the care of an individual with CKD, pharmacists are well-placed with their clinical and therapeutic knowledge to improve outcomes in CKD patients. In the management of kidney disease, pharmacists play a multifaceted role and are responsible for various activities, including but not limited to, answering medication inquiries from consultants and multi-disciplinary teams, and supporting the implementation of local and national guidelines. More advanced pharmacists may deal with primary care pharmacist enquiries and running patient medicine optimisation clinics (British Renal Society 2020).

In clinical research, an outcome is an observation or a variable that can be measured to determine the effect of treatment or exposure (Williamson et al. 2017). An outcome measure is the specific measure or tool utilised for assessing an outcome (SONG - Standardised Outcomes in Nephrology). Whilst several systematic reviews have demonstrated the benefits of interventions delivered by pharmacists (Stemer and Lemmens-Gruber 2011; Salgado et al. 2012; Al Raiisi et al. 2019), this evidence is often difficult to interpret as there is significant variability in terms of the outcomes reported and an inconsistency with the measures used. For example, a systematic review by Al Raiisi *et al.* (Al Raiisi et al. 2019) of interventions provided by pharmacists for CKD patients identified a range of outcomes including clinical outcomes (e.g., change in blood pressure (BP)), humanistic

outcomes (e.g., patient satisfaction), and economic outcomes (e.g., cost-savings). Furthermore, some outcomes, such as medication adherence, were measured by a variety of different means.

The large heterogeneity of outcomes and outcome measures reported in randomised controlled trials (RCTs) investigating the impact of interventions involving pharmacists have on CKD patients make it difficult to draw comparisons of the effects. Consequently, this affects the quality of research and limits research synthesis, particularly for meta-analyses (Kirkham et al. 2013; Gargon et al. 2014). Issues around inconsistent outcome reporting could be addressed with the development and application of agreed standardised sets of outcomes, which have the potential to reduce waste in research and are often required by funders (Hughes et al. 2019). Indeed, the significant range of outcomes in the CKD pharmacy literature has led to the suggestion that further research is required to establish a core outcome set (COS) in CKD in relation to pharmacy practice (Al Raiisi et al. 2019).

A COS is a collection of outcomes that are standardised and agreed upon and as a minimum should be measured and reported in all trials for a particular clinical topic (Williamson et al. 2017). They are of importance as input is provided from a variety of stakeholders such as patients, researchers, family members, carers, and healthcare professionals, and as such relevant outcomes are more likely to be identified (Kirkham et al. 2016; Webbe et al. 2018). Moreover, they help to reduce heterogeneity and reporting bias (Kirkham et al. 2016; Webbe et al. 2018), where only significant results are reported (Williamson et al. 2005).

In 2014, the Standardised Outcomes in Nephrology (SONG) initiative was launched (Tong, Manns, et al. 2017) to improve consistency in the reporting of outcomes for trials in nephrology. The SONG initiative has developed COS for trials relevant for disease stage (e.g., haemodialysis (Tong, Manns,

et al. 2017), peritoneal dialysis (Manera et al. 2020), transplantation (Tong, Gill, et al. 2017) and for diagnosis (e.g., polycystic kidney disease (Cho et al. 2020)). Nonetheless, the focus of SONG is not to develop interventions-specific COS (e.g., as needed for pharmacist interventions).

Several COS have been developed for research involving pharmacists, which include interventions addressing medication review in multimorbid older patients with polypharmacy (Beuscart et al. 2018) and optimising prescribing in care homes (Millar et al. 2017). Although none of these studies specifically focused on CKD, some of the outcomes reported in these studies (e.g., QoL, potentially inappropriate medications) (Millar et al. 2017; Beuscart et al. 2018) are likely relevant to any COS developed for CKD research that include pharmacist input. Currently, no COS has been established in CKD with regards to pharmacy practice and research. Our objective is to develop a COS for clinical trials evaluating the efficacy or effectiveness of pharmacist interventions (i.e., interventions provided to patients that are either pharmacist-led or involve their input) in people with CKD.

Methods

Study design

Prior to commencement, the study ('Development of a core outcome set for pharmacist-led interventions in chronic kidney disease: a survey and e-Delphi consensus study' (COSP-KD)) was prospectively registered in the Core Outcome Measures in Effectiveness Trials (COMET) database (COMET Initiative 2023) and at ClinicalTrials.gov (NCT05987280). This protocol was developed in accordance with the COMET handbook (1.0) (Williamson et al. 2017) and written in accordance with the 'Core Outcome Set-STAndarised Protocol Items' (COS-STAP) statement (Kirkham et al. 2019). The findings of the project will be reported in line with the 'Core Outcome Set-STAndards for Reporting'

(COS-STAR) statement (Kirkham et al. 2016). Ethical approval has been obtained from the University of Leicester (UoL) (reference: 40350).

This study will consist of three phases (Figure 1): Phase 1) generating and refining a long-list of outcomes via a systematic review (Ardavani et al. 2023) and survey of key stakeholders; Phase 2) an e-Delphi survey, and Phase 3) a consensus workshop to elicit consensus on the final list of outcomes to be included in the COS.

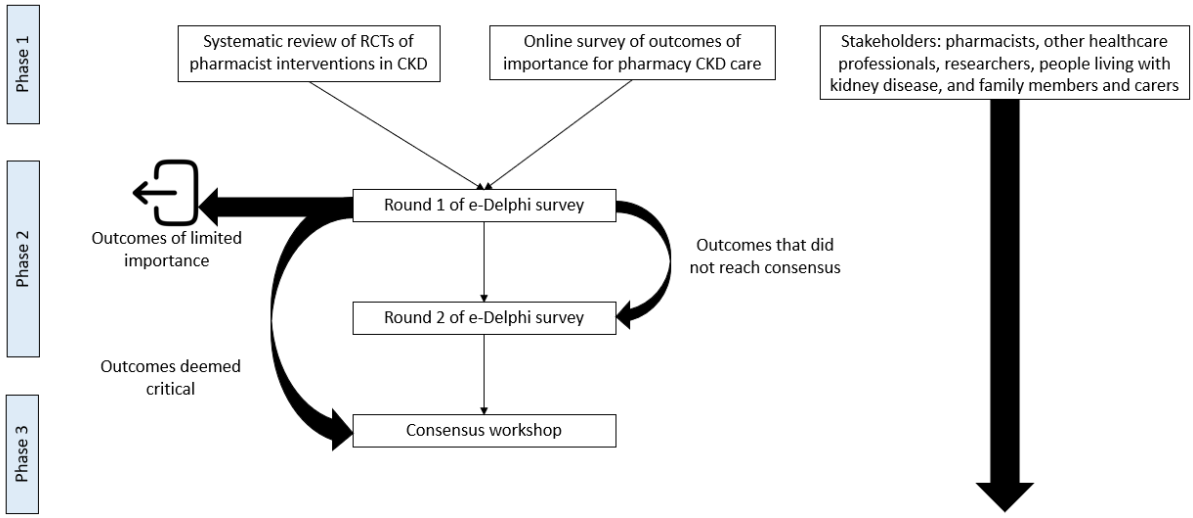

Figure 1 - Overview of study design

Phase 1: Generating and refining a long-list of outcomes

The aim of Phase 1 is to generate a long-list of outcomes that will be used to populate an online e-Delphi process (Phase 2). The long-list of outcomes will be generated through: 1) a systematic review and 2) an online survey of key stakeholders.

1. Systematic review of pharmacist interventions in CKD

We are currently conducting an ongoing systematic review that aims to identify interventions in RCTs conducted in CKD that involve a pharmacist, including kidney replacement therapy (KRT) and non-KRT patients, and the effect on clinical, economic, and humanistic outcomes, compared to usual care or appropriate comparison group (e.g., non-pharmacist intervention). The methods of this systematic review have previously been described elsewhere (Ardavani et al. 2023). We will use the list of outcomes collected as part of this review to contribute to a long-list of outcomes for Phase 2.

2. Online survey of key stakeholders

In addition to the outcomes extracted from the systematic review, outcomes of importance to each stakeholder group will be identified through an online survey.

Stakeholders

The stakeholders that will be invited to participate in this survey include: 1) pharmacists involved in the care of kidney patients and non-renal pharmacists; 2) researchers involved in CKD and pharmacy research; 3) nurses and physicians involved in CKD management; 4) people living with kidney disease; and 5) carers and family members. It is likely that participants will not fit into distinct homogeneous groups; for example, researchers may also be registered pharmacists. Participants will answer questions adapted to their group. All participants will be over the age of 18 will be invited to take part in the survey.

Sample size

As participants will be invited into the e-Delphi process (Phase 2, described below), it is important to ensure there are enough participants following potential dropouts as the study progresses through

each phase. Whilst there is no consensus on the minimum required sample size for Delphi studies (Hsu and Sandford 2007), we aim to recruit at least 100 participants, 20 from each stakeholder group, for this initial survey. This should ensure an appropriate number and representation of participants throughout Phase 2.

Recruitment process

Participants will be recruited in several ways. Researchers of papers of the systematic review and researchers known in the field will be contacted to take part. Other participants will be recruited via searching for publicly available contact details or using our team's professional networks, existing patient and public involvement (PPI) groups, or social media. X and Facebook are nominated as the social media primary platforms for recruitment due to their ability to reach into the specific communities of interest we require. We have extensive networks available to disseminate the study including social media pages of the National Institute for Health and Care Research (NIHR) Applied Research Collaboration East Midlands (ARC-EM), the UK Renal Pharmacy Group, and the Leicester Kidney Lifestyle Team. We will also promote the study at appropriate events, such as medical conferences or meetings. Organisations such as Kidney Research UK, National Kidney Foundation, Kidney Care UK, and the Kidney Patient Involvement Network will be contacted to disseminate the study to their members. We will also allow for a "snowball sampling" approach and we will encourage participants to send invitations to other potentially relevant participants. The peer network structures of social media platforms will facilitate this process. People living with kidney disease will be asked to share the survey with other people they think are appropriate (e.g., family and friends).

Data collection

The survey will be conducted in English using Jisc. Online Surveys. Interested participants will be provided with a link to the survey. Upon opening the survey link, participants will be asked to read an online participant information sheet (PIS). The PIS will contain information on the rationale of the study and other details concerning participation. Participants will be provided with contact details of the study to ask any questions. Upon reading the PIS, participants can then complete the rest of the survey. Completing the survey and submitting a response will infer implied consent to the study. The survey will take approximately 5-10 minutes to complete.

For the main body of the questionnaire, we will use open questions developed to elicit potential additional outcomes related to pharmacist-led interventions conducted in CKD. These questions will be framed around what participants believe as important and adapted for each group to improve understanding. Participants will be asked to respond using free-text responses. These questions can be found in Table 1.

Table 1 - Phase 1 survey for each group

Group	Question
All	Which group best describes you? The questions in this part of the survey depend on which group you pick. You can pick more than one group if you want.
Pharmacists Researchers Other HCPs	What are the key roles of a pharmacist in managing CKD?
Pharmacists Researchers	What is important to measure when assessing the role of a pharmacist in successful CKD management?

Other HCPs	
Pharmacists Researchers Other HCPs	In pharmacy research, what are the most important things that need to be measured?
Patients Family member/carer	What do you think a pharmacist does in relation to looking after someone with kidney disease?
Patients Family member/carer	How do we know if a pharmacist has helped someone with kidney disease? What can we measure to show what they do has worked?
Researchers	If relevant, what outcomes did you measure in prior research that have utilised a pharmacist?
Researchers	Which outcomes do you think should require standardisation in terms of the outcome measures used?
All	Is there anything else you would like to say?

The views of a patient and public involvement (PPI) group will be sought to confirm the appropriateness of questions and instructions. This survey will be open for eight weeks. Participants will be asked to provide an email if they are interested in taking part in Phase 2 (e-Delphi survey).

Analysis and refinement of outcome list in preparation for Phase 2

Once all outcomes are identified from the systematic review and the survey, they will be analysed and refined, where any duplicates will be removed (Millar et al. 2017). The outcomes will be grouped together for Phase 2, in which three of five members of the core research team, who are not participants of the e-Delphi survey, will review them independently and decide which outcome should be included or excluded from Phase 2 (Millar et al. 2017). Only outcomes that will reach a

unanimous decision to be excluded will not be included in the e-Delphi survey (Millar et al. 2017). A lay definition of each outcome will be provided.

Phase 2: e-Delphi survey

The second phase of the COS development will utilise a Delphi exercise to achieve consensus across the participant groups on outcomes to be included in the final COS. The Delphi process is a structured process used for forming a consensus, where stakeholder groups provide their opinions in an iterative approach for answering questions over several rounds (Tyler et al. 2020). Following each round, the responses provided by the participants will be summarised and redistributed for discussion in the subsequent round (Tyler et al. 2020). The Delphi process enables participants to reflect on the answers they provide, where they can re-evaluate their opinion when considering the anonymised opinions of others (Barrett and Heale 2020). The flexibility it offers in collating the views of key stakeholders and enabling them to reconsider their opinions, taking into consideration the anonymous views of others, encourages integrity and reflection amongst participants, the latter of which is missing in qualitative studies such as focus groups or interviews (Barrett and Heale 2020).

We will conduct two rounds using a commercially available software programme (Welphi, Lisbon, Portugal). The outcome list and instructions for the questionnaires will be reviewed for face validity, understanding, and acceptability by a PPI group.

Stakeholders

Participants who expressed an interest (and who provided an email) from the survey in Phase 1 will be approached to take part. If required, recruitment methods described for Phase 1 may also be

used to recruit new participants. Whilst there is no consensus on the minimum required sample size for Delphi studies (Hsu and Sandford 2007), we aim to recruit at least 75 participants into Phase 2. Completing each round will infer implied consent.

Round 1

The final long-list from Phase 1 will be used to develop the first Delphi round. Interested participants will be provided a link to round 1 of the survey via the email they provided. The purpose of round 1 is to determine which of the outcomes are most and least important from the different stakeholders' perspectives. Several studies have also used a similar approach in round 1 for establishing a COS (Remus et al. 2021; Ram et al. 2022). Participants will be provided with the list of outcomes to rank in terms of importance. Each item will be supplemented with a brief explanation of the outcome, as illustrated in this example below:

BP: "A measure of the force that the heart uses to pump blood around the body" (NHS 2022).

Whilst there is no definitive research indicating the optimal number of points to have on a Likert scale, scales between 5 and 9 points have the best reliability (Preston and Colman 2000). We will use a 9-point Likert scale: a score of 1-3 indicates "limited importance", 4-6 indicates "important, but not critical, and 7-9 indicates an outcome is of "critical importance". This scale has previously been used in COS generation (Van't Hooft et al. 2016; Evangelidis et al. 2017; Meher et al. 2019). Participants will also be able to select 'unable to score' if they feel unable to offer an opinion on a particular outcome; this will be assigned a score of 0.

There will be a free-text comment box so participants can provide further comments on their choice of Likert scale response that could be fed back anonymously in later rounds. Participants will also be able to suggest additional outcomes, which will be reviewed by the core research team. This round will remain open for three weeks. To enhance response rate, participants will be sent reminder emails after one and a half weeks of the initial email requesting participation. Participants who fully complete round 1 will have their data analysed.

Consensus criteria has been defined a priori as:

- Outcomes scored as 'critically important' (7-9) by 75% or more of the overall group will be determined as reaching consensus for inclusion and will be included in the provisional COS in Phase 3.
- Outcomes scored as being of 'limited importance' (1-3) by 75% or more will be defined as having reached consensus for exclusion and will be excluded in future rounds.
- Outcomes not fulfilling both criteria above will be defined as not having reached consensus and will be entered into round 2.

Although several Delphi studies have used a minimum consensus of 70% (Vogel et al. 2019; Veugelers et al. 2020), a minimum of 75% was chosen to increase sensitivity (Santaguida et al. 2018; Tyler et al. 2020).

Round 2

Outcomes from round 1 for which no consensus is achieved following analysis of results will be retained for round 2. In round 2, the median scores for each outcome and anonymous comments from the previous round will be presented to each group. Participants will be asked to reflect on the

information presented and score each outcome again. We will also include any additional outcomes suggested by participants from round 1. Round 2 responses will be analysed by applying the same consensus criteria as in round 1. This round will remain open for four weeks. To enhance response rate, participants will be sent reminder notices after one week of the initial email requesting participation. Following round 2, outcomes for which no consensus is achieved will not be included in the final provisional COS. Outcomes will be grouped into categories by the core research team. Based on response rates, we may choose to close or extend round durations as necessary.

Phase 3: Final consensus workshop

The results of the Delphi process will be presented at a consensus meeting. The main goal of the consensus meeting will be to decide which items will be included in the final COS. To ensure a representative sample, two to three participants from each stakeholder group will be invited to attend. Depending on availability, we will host the consensus meeting either in-person or virtually. The results from the e-Delphi survey will be presented to the group, where each outcome of the preliminary COS will be considered. The stakeholder groups will discuss which outcomes should be included and excluded, along with their reason(s) for excluding outcomes. The outcomes that reached a consensus for inclusion will be ranked in terms of order of importance and any outcome measures that could be used to evaluate the outcome will be discussed.

Conclusion

The development of a pharmacist-specific COS in CKD will address an important gap for achieving consensus and improve the consistency of outcomes reported. It will also ensure outcomes that are of relevance to the various stakeholders will be consistently reported in trials, which will help reduce

waste in research and make it more meaningful (Hughes et al. 2019). Delphi studies have several strengths, including providing participants the flexibility to re-assess their opinions based on the anonymous feedback of others, as well as the ability to self-reflect on their responses (Barrett and Heale 2020). Moreover, e-Delphi studies are more suitable for those in which it is impractical to conduct the study in person, for example, where panel members are geographically distributed across the world (Fink-Hafner et al. 2019). However, it is important to state Delphi studies have limitations as they can be time-consuming, difficult to generalise to the wider population owing to sample size, and the lack of agreement on how participants should be selected (Fink-Hafner et al. 2019). Furthermore, with e-Delphi studies, technical issues can occur when attempting to access survey software (Fink-Hafner et al. 2019). To mitigate this risk, triangulation can be used to validate the Delphi results (Fink-Hafner et al. 2019).

Our study is strengthened by aiming to recruit a large range of key stakeholders, including researchers, pharmacists, and people living with kidney disease. In particular, many outcomes used in clinical trials have had limited input from patient partners (Heneghan et al. 2017). Therefore, patient participation in Delphi surveys is key in the development of COS, to ensure outcomes are important to the people that matter most (Barrington et al. 2021) and involving people with lived experience of the condition is stated in the 'Core Outcome Set-STAndards for Development' (COS-STAD) guidance (Kirkham et al. 2017).We will ensure processes around the Delphi methodology are carefully explained to participants to ensure maximal engagement and PPI will be used to help inform lay wording as appropriate.

The results will be written up for publication in a peer-reviewed journal, in which participants will be offered a copy of the findings. Moreover, social media will be used to present the findings using an

online infographic. To drive the adoption of the COS, findings will be presented at appropriate medical and public forums and made available on our institution webpage. We will also engage with local and national health bodies such as the Health Innovation Networks to disseminate results further.

Funding

This study is funded by the National Institute for Health and Care Research (NIHR) Applied Research Collaboration East Midlands (ARC-EM), and University of Leicester (UoL). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Conflicts of interest

The authors declare no conflicts of interest.

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