

**Taking an active role in your own healthcare: A Delphi Survey for
key stakeholders to identify priority self-management outcomes for
Chronic Kidney Disease (SM-CKD Delphi Study)**

Protocol

BACKGROUND AND RATIONALE:

Chronic Kidney Disease (CKD) is a progressive condition affecting more than 1.8 million people in England (Kerr, 2012). CKD poses a global health challenge, and is associated with lower health-related quality of life and other non-communicable diseases including diabetes and cardiovascular issues (Nguyen et al., 2018). In the financial year 2009/10 an estimate of £1.45 billion of NHS England expenditure was spent towards CKD care (Kerr, 2012). Developing optimal strategies for non-dialysis CKD to help patients manage their condition was considered one of the top 10 research questions from the perspectives of patients, caregivers, policy-makers and clinicians in Canada (Hemmelgarn et al., 2017). The importance of self-management has been highlighted in a systematic review collating international data for preventing and delaying progression of End of Stage Renal Disease (ESRD) (Tong et al., 2015).

In the UK, the NHS have emphasised the importance of self-management support for patients with long-term conditions in the Long-term care plan (NHS, 2020) and an increase in support for commissioning self-management services for long-term conditions (Richards, 2012; Addicott et al., 2013). CKD is a growing problem and facilitating self-management in people with CKD is important as it can potentially lead to positive health outcomes (Bonner et al., 2014; Peng et al., 2019). Self-management in its broadest term can be summarised as individuals participating in the day-to-day management of their chronic condition and thus undertaking actions and health behaviours over the course of their illness (Lorig & Holman, 2003).

Different types of outcomes have been used to measure the effectiveness of a particular self-management intervention for CKD patients; this includes a mix of physiological measures and patient-reported outcomes (Bonner et al., 2014; Peng et al., 2019). There are multiple outcomes to assess for effectiveness, however, which outcomes are relevant and important is not studied. A recent review by Boger et al. (2015) identified a lack of research investigating outcomes that are valued for self-management support amongst different stakeholder groups. The review focused on diabetes, colorectal cancer and stroke. This review inferred priority outcomes from quantitative intervention studies and qualitative papers which only focused mostly on patient perspective, with no commissioners' viewpoints. Reidy et al. (2016) examined commissioner views of self-management support of long-term conditions and suggested the need to identify important outcome measures from stakeholder groups to assess self-management for long-term conditions. Identifying essential outcome measures would be useful for the development of policies and commissioning of self-management programmes.

In CKD, Patient self-management is now increasing (Bonner et al., 2014; Donald et al., 2018). Self-management support tools and interventions have been studied in research settings (Donald et al., 2018) and particular self-management programmes have been developed with the aim to implement in clinical practice (Lightfoot, Wilkinson & Smith, 2021). The review by Boger et al. (2015) investigated valued outcomes of self-management support for long term conditions, but did not report potential priority outcomes for CKD. One limitation of this study is that it did not explicitly measure important outcomes of long-term conditions from different stakeholder groups but inferred this from intervention studies. Self-management outcomes measured in studies for CKD include but are not limited to eGFR, knowledge, number of hospitalisation and Health related Quality of Life (Bonner et al., 2015). Donald et al. (2018) noted that physiological measures are most commonly assessed in CKD studies which are therefore lacking more holistic patient driven outcomes that may be more important to the patient population.

Due to the prevalence and burden of CKD and the importance of self-management, it is important to investigate stakeholder views of priority outcomes of self-management in CKD. Most self-management interventions focus on advance stages in CKD (Welch., 2015), with a few studies focussing on or aiming to focus on evidence to support for non-dialysis CKD (Bonner et al., 2014; Lightfoot et al., 2021) There is also a lack of commissioners and policymakers' views on self-management in general (Reidy et al., 2016). Therefore, this study will identify priority outcomes of self-management for early stages CKD from different stakeholder groups including commissioners and policymakers using a Delphi process. A Delphi technique can be used when opinions of the population or study group is important (Barrett & Heale, 2020; Thangaratinam & Redman., 2005). Consensus will be gained from the Delphi process and this can inform research on important domains when evaluating self-management programmes, commissioning and policymaking of CKD self-management programmes.

OBJECTIVE AND AIM:

The purpose of this Delphi survey is to engage people with CKD, their significant others, healthcare professionals (HCPs), commissioners/policymakers (involved in developing, designing and implementing kidney care services) and researchers interested in CKD and self-management to identify priority outcomes of self-management from different perspectives. The findings of this study

will be used to measure success during the evaluation of a new self-management resource, and to support implementation, commissioning and uptake.

The aim of the study is to seek consensus between different stakeholder groups on important outcomes of self-management for people with early-stage non-dialysis CKD (i.e stages 3-4). Any potential disparities between stakeholder groups will also be evaluated.

STUDY DESIGN:

A Delphi study process will be conducted. This is an iterative process of survey rounds until consensus is achieved. In this case we anticipate carrying out three rounds, with a possible fourth if required. Each survey round will be conducted approximately 2-6 months apart.

- Round One will ask participants to provide free text responses describing their top three priority outcomes for self-management in CKD.
- The responses from Round One will be grouped thematically to produce a list of potential priority outcomes.
- Round Two will present this list to participants and ask them to indicate a priority ranking to each one on a Likert scale, according to their personal viewpoint.
- Round Two responses with low priority scores will be excluded and the list re-presented to participants in Round 3 to refine the priority consensus.

Participants:

The participants in this study will be adults over the age of 18 who are based in the UK and identify with one of the stakeholder groups:

1. People living with a diagnosis of CKD. This survey focusses on people with non-dialysis CKD, typically stages 3-4. However, we will not exclude participation by those at a more advanced stage or receiving renal replacement therapy (dialysis or transplant) as these people also have lived experience of earlier stages to draw on
2. Carers and Supporters of people living with CKD (expected to be a significant other i.e., spouse or partner, close family member or friend that are involved in the regular care and support to a person living with CKD)
3. Healthcare professionals (HCPs) who look after people with CKD in the UK
4. Anyone involved in designing, developing, managing and commissioning of CKD healthcare in the UK
5. Researchers interested in self-management or CKD

Recruitment:

We aim to recruit representative from each stakeholder group through:

- direct email invitation to our professional contacts, followed up with social media advert if email does not elicit sufficient responses;
- social media advert inviting patients and their carers/supporters, disseminated via our own social media platforms and those of relevant UK kidney organisations and groups
- interested patients will be asked to share the survey with their carers/supporters if they wish to do so

In all rounds, the survey text and questions will be exactly the same for participants from all stakeholder groups. However, for Round 1 there will be two separate links to the survey for patients/carers and for professional groups. This is because use of the different primary recruitment channels may require us to close the survey to patients/carers (social media recruitment) at a different time to professionals (direct email recruitment).

We aim to recruit 10-20 representatives of each stakeholder group. Exact numbers will depend on responses to the email invitations and social media posts and it is possible that recruitment figures in some groups could be higher if a lot of responses are received in a short time period.

Materials:

Surveys will be administered online for each round.

In each round, the survey starts with an overview of the background to the topic, an explanation of the Delphi process, and the purpose of this survey. A link to the full Participant Information Sheet is provided, and it is clearly stated that completing and submitting the survey form implies consent to participation and for the research team to use the information provided for the purposes of this study only. Participation is anonymous, although participants are requested to provide an email address which will be used for the sole purpose of sending the next survey round, and a summary of the results at the end of the study.

The first section of the actual survey asks for some basic demographic details for the purposes of identifying each participant's stakeholder group, and describing the cohort:

- Stakeholder group
- Gender
- Age group
- Ethnicity

The first round of the survey then asks two open-ended questions, requesting free text responses on the participant's views of the three most likely and the three most important benefits (outcomes) of self-management for people with CKD 3-4.

Subsequent survey rounds will present lists of the most common themes identified in Round One and ask each participant to rank them for likelihood/importance on a Likert scale. The exact nature of these rounds will depend on the responses to Round One and will be designed and submitted for ethical review as an amendment after the previous round has been analysed.

When sufficient participants have completed the form, the survey will be closed. The link will continue to function but the survey will be replaced with a message thanking the prospective participant for their interest, informing them that the survey has closed, and providing our contact details in case they have any questions or comments or want further information.

STUDY PROCEDURE:

INFORMED CONSENT:

Consent will be implied for all participants by completion and submission of the survey form. A statement will be placed next to the submit button saying that that if they submit, they are consenting to participate in the survey round which means their data will be used for analysis. If they have provided an email address in the survey (an optional field), then they are consenting to be contacted in the future survey rounds.

Demographic information

The survey is anonymous and participants are not asked to reveal any identifiable information except their email address (optional) which will be used solely for the purpose of sending invitations to each subsequent round of the Delphi survey process.

At the start of each round, there is a short series of "multiple choice"-style demographic questions to establish:

- Stakeholder group
- Gender
- Age group
- Ethnicity

These questions are included at the start of the survey in all the rounds.

Round 1:

In open-ended questions, participants will be asked to provide free text describing the 3 most likely and 3 most important outcomes (benefits) of self-management in CKD based on their own viewpoint. The outcomes described by participants in round 1 will be independently reviewed and categorised inductively based on outcomes and key concepts by the research team. These responses will inform the second survey.

Round 1 Survey closure

Recruitment to Round 1 will include social media distribution of the invitations and therefore they may continue to be shared by third parties after sufficient responses have been received. At this stage, we will close the survey by replacing the Round 1 survey questions with a statement thanking the potential participant for their interest and explaining that sufficient responses have already been submitted. We will provide the research team contact details for further information should the intended respondent be interested.

Round 2:

For round 2, the themes identified as most likely and most important in Round 1 will be presented as lists. Participants will be asked to rate each one for likelihood/importance on a Likert scale. A free text box will also be provided for participants to explain their rankings or suggest any other item, outcome or concept they believe should be included in the next round.

The round 2 survey invitation (including the link to the online survey) will be sent to participants who provided their email address in the first round.

Data will be analysed by stakeholder group and overall cohort to identify a consensus score for each item, and those scoring the least will be discarded. The exact details of the analysis will depend on the nature of the results obtained in Rounds 1 and 2 and will be refined at that time.

Round 3:

After discarding themes which scored low for likelihood/importance in Round 2, the remaining themes will be re-presented in Round 3, again asking participants who provided an email address in round 1 to either rate items on a Likert scale or rank items in order of priority as appropriate. Details

of the most appropriate analysis will depend on the nature of the data and will be finalized at the time.

Evidence suggests that 3 rounds is generally sufficient for consensus to be achieved, but a fourth round may be carried out if required.

STATISTICAL & DATA ANALYSIS:

Participant characteristics will be summarised using either mean, standard deviation or median and interquartile range for continuous variable and percentages for categorical variable. If necessary, a normal distribution will be carried out. For the Delphi study and for each round an appropriate statistical test will be conducted. Heiko (2012) review based on prior Delphi study and quality assurance of Delphi study may be used for guidance to determine Delphi consensus

Qualitative:

In the first-round participant comments will be inductively analysed to determine relevant categories and comments. In the further rounds of the survey participants have the option to comment if they wish on their ranking. All comments will be imported into Nvivo for qualitative analysis. If relevant and appropriate comments are made then they will be coded and grouped into common themes within and across panels. The themes will be reviewed with the researchers of this study NP, CL, AS, CJ

Defining Consensus:

Item rating data will be collected via Likert scales for Rounds 2 and 3. The exact choice of Likert scale and the most appropriate approach to analysis will depend on the nature of the information obtained in Round 1 and cannot be defined at this stage.

We expect to analyse the proportion of highly rated items as a percentage, the mean (Standard deviation, SD) and Median (Interquartile Range, IQ) in form of group statistic on each item for each stakeholder (panellist) and overall score for all stakeholders.

A test to measure differences in ranking across the different panels may be carried out using a Kruska-Wallis test. If appropriate t-test, F-statistic, chi-squared test of independence or Mann Whitney U may be carried out to analyse disagreement, lack of consensus or dissent.

If necessary, to assess stability a Wilcoxon signed-rank test will be performed on paired results between round 2 and 3. If the responses were not statistically significant ($p\text{-value} \geq 0.05$), the responses are considered stable and there is no need to carry out another round.

Significance will be defined as P value < 0.05 , and confidence intervals (CI95) (set at 95%) and effect sizes may be used to establish data estimates and strength. The latest available versions of SPSS provided by the university will be used.

DATA HANDLING AND RECORD KEEPING:

This is an online survey study for which data will be entered into Excel and SPSS. This data will only be accessible to the researchers of the study on a password protected University of Leicester computer. The online survey generates random anonymous ID numbers to the participants. So, they are not identifiable in any way. However, participants have the option to provide their email address in the first round to be contacted for subsequent rounds and to receive the results at the end of the study. Identifiable information such as email address will be stored in a trial site file or electronic excel file. This will only be accessible to the researchers of the study. The data will be kept on a password protected computer or in a locked office that is only accessible to the research group.

DATA PROTECTION AND DATA SUBJECT CONFIDENTIALITY

All research staff will comply with the requirements of GDPR legislation with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Regulations core principles. Participants will be guaranteed confidentiality and as this is an online survey participants will remain anonymous. However, participants will be asked to provide their email address (this is placed as an option in the survey) to be contacted for subsequent survey rounds. This will be stored on a password protected computer and will only be accessible to the researchers of the study. After the study has been conducted and the results disseminated the email addresses will be deleted from the files. Any data recorded will be on a password protected University of Leicester Computer on a secure drive only accessible to the researchers of the study. This study will use the platforms called 'Jisk online Surveys' is suitable for collecting personal data under GDPR; further details can be found here: <https://www.onlinesurveys.ac.uk/gdpr/>. All computer records relating to the study will be password-protected on University of Leicester computers on a secure drive accessible only to the research team.

Dissemination of results

Results will be disseminated via reports published in scientific/medical journals, presentations at national and international conferences, social media platforms, directly to the study participants who opt to provide their email address, and any organisations which assisted in disseminating the invitations.

Conflict of Interest:

None

REFERENCES:

- Addicott, R., Buck, D., Goodwin, N., Harrison, T., Ross, S., Sonola, L., ... & Curry, N. (2013). Transforming our health care system. *The King's Fund, London*. Retrieved November 29, 2021 from <https://hiyos.org/wp-content/uploads/2015/07/kings-fund-10-priorities.pdf>
- Barrett, D., & Heale, R. (2020). What are Delphi studies?. *Evidence-based nursing*, 23(3), 68-69.
- Boger, E., Ellis, J., Latter, S., Foster, C., Kennedy, A., Jones, F., ... & Demain, S. (2015). Self-management and self-management support outcomes: a systematic review and mixed research synthesis of stakeholder views. *PloS one*, 10(7), e0130990.
- Bonner, A., Havas, K., Douglas, C., Thepha, T., Bennett, P., & Clark, R. (2014). Self-management programmes in stages 1–4 chronic kidney disease: a literature review. *Journal of Renal Care*, 40(3), 194-204.
- Donald, M., Kahlon, B. K., Beanlands, H., Straus, S., Ronksley, P., Herrington, G., ... & Hemmelgarn, B. R. (2018). Self-management interventions for adults with chronic kidney disease: a scoping review. *BMJ open*, 8(3), e019814.
- Heiko, A. V. D. G. (2012). Consensus measurement in Delphi studies: review and implications for future quality assurance. *Technological forecasting and social change*, 79(8), 1525-1536.
- Hemmelgarn, B. R., Pannu, N., Ahmed, S. B., Elliott, M. J., Tam-Tham, H., Lillie, E., ... & Laupacis, A. (2017). Determining the research priorities for patients with chronic kidney disease not on dialysis. *Nephrology Dialysis Transplantation*, 32(5), 847-854.
- Kerr, M. (2012). Chronic kidney disease in England: the human and financial cost. *NHS Kidney Care*.
- Lorig, K. R., & Holman, H. R. (2003). Self-management education: history, definition, outcomes, and mechanisms. *Annals of behavioral medicine*, 26(1), 1-7.
- National Health Service. (March 10, 2020). Supported self-management: Summary guide. Retrieved November 10, 2021 from <https://www.england.nhs.uk/wp-content/uploads/2020/03/supported-self-management-summary-guide.pdf>
- Nguyen, N. T., Cockwell, P., Maxwell, A. P., Griffin, M., O'Brien, T., & O'Neill, C. (2018). Chronic kidney disease, health-related quality of life and their associated economic burden among a nationally representative sample of community dwelling adults in England. *PLoS One*, 13(11), e0207960.
- Peng, S., He, J., Huang, J., Lun, L., Zeng, J., Zeng, S., Zhang, L., Liu, X., & Wu, Y. (2019). Self-management interventions for chronic kidney disease: a systematic review and meta-analysis. *BMC nephrology*, 20(1), 142. <https://doi.org/10.1186/s12882-019-1309-y>
- Reidy, C., Kennedy, A., Pope, C., Ballinger, C., Vassilev, I., & Rogers, A. (2016). Commissioning of self-management support for people with long-term conditions: an exploration of commissioning aspirations and processes. *BMJ open*, 6(7), e010853.
- Richards, T. (2012). Experts urge commissioners to invest in self management courses for patients with chronic disease. *BMJ*, 345, e7875
- Thangaratnam, S., & Redman, C. W. (2005). The delphi technique. *The obstetrician & gynaecologist*, 7(2), 120-125.
- Tong, A., Chando, S., Crowe, S., Manns, B., Winkelmayer, W. C., Hemmelgarn, B., & Craig, J. C. (2015). Research priority setting in kidney disease: a systematic review. *American Journal of Kidney Diseases*, 65(5), 674-683.

Turoff, M., & Linstone, H. A. (2002). The Delphi method-techniques and applications.

Welch, J. L., Johnson, M., Zimmerman, L., Russell, C. L., Perkins, S. M., & Decker, B. S. (2015). Self-management interventions in stages 1 to 4 chronic kidney disease: an integrative review. *Western journal of nursing research*, 37(5), 652-678.