PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol for a national prevalence study of advance care planning documentation and self-reported uptake in Australia
AUTHORS	Ruseckaite, Rasa; Detering, Karen; Evans, Sue; Perera, Veronika; Walker, Lynne; Sinclair, Craig; Clayton, Josephine; Nolte, Linda

VERSION 1 – REVIEW

REVIEWER	Sarah Mitchell Warwick Medical School University of Warwick Gibbet Hill Road Coventry CV4 7AL
REVIEW RETURNED	13-Jun-2017

GENERAL COMMENTS	The protocol would benefit from more clarity around it being a pilot / feasibility study. This is mentioned on page 5 and in Methods on page 9, but could be made more clear earlier on in the protocol. The methods are well considered. There will be a lot of data from the survey; Surveys have some limitations in terms of collecting sensitive data and understanding the experience of Advance Care Planning which could be discussed in more detail. The data will be highly relevant to clinical practice and policy in this area internationally, and it is the intention of the authors that the study findings have influence in this way, so it would be good to see plans for impact other than academic papers and conference presentations. It would be interesting to hear whether there are plans to have impact through other means of dissemination. The administrative details of ethical approval are provided. The protocol could be improved with the provision of a summary of the ethical concerns and how the research team plan to address these. The proposed dates of the study are not detailed, nor is the date of the ethical approval.

REVIEWER	Ericka E Tung, MD, MPH Mayo Clinic College of Medicine, United States
REVIEW RETURNED	22-Jun-2017

GENERAL COMMENTS	I appreciate the opportunity to review this well designed study protocol. First-- the introduction describing current gaps in the medical literature (on ACP) is well written and well developed-- it makes a strong case for this study. 1. The standardized approach for data collection is appropriate, but further clarification about this process could strengthen the paper. Namely: What is the educational background or professional training of the data collectors (RN's, Social Workers etc? How much experience do they have navigating the medical record?) Will there be secondary adjudicators to ensure that the data collectors have appropriately performed the chart review? I think that this safeguard is necessary and will strengthen your methods. 2. You mention a number of secondary study aims/outcomes (i.e. quality and validity). Do you have secondary hypotheses respective to these aims? Additionally, please describe how you will measure quality and validity of the ACP (i.e. is there a standard measure of ACP quality that you could utilize?) 3. Please clarify the age cut-off, some places say >65 others say >/= 65. 4. Why is there a reduced age cut off for ATSI peoples? 5. Line 189, you mention group 2 of randomization. Please clarify what you mean, is this the group that is not studied? 6. How will capacity to participate be assessed ? A significant proportion of inpatients will suffer from acute or chronic cognitive impairment. If the individual does not have decision making capacity, will their proxy be interviewed instead? 7. The data collection tool is well done-- but does not include a field for "does the ACP include an expression of the individual's values?" Expression of values is an important element of ACP quality. 8. Please provide more explanation of Table 4 with regard to determination of population size. Readers may not follow your process here.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

1. The protocol would benefit from more clarity around it being a pilot / feasibility study. This is mentioned on page 5 and in Methods on page 9, but could be made clearer earlier on in the protocol.

Thank you for your feedback. We have now amended the last paragraph of the Background section by including the following explanation: “This will be a pilot study aiming to examine the feasibility of an approach that is intended to ultimately be used in a largely scale prevalence study in future”.

2. The methods are well considered. There will be a lot of data from the survey; Surveys have some limitations in terms of collecting sensitive data and understanding the experience of Advance Care Planning which could be discussed in more detail.

Thank you very much for this feedback. We agree that surveys have limitations in collecting a sensitive data and understanding experiences of advance care planning. However, it is also known that many people are familiar with survey design, and they also feel more comfortable responding to a survey than participating in an interview. Finally, administration of the survey does not require many resources, and analysis and tabulation of closed-ended responses is an easy and straightforward process.

To address this feedback, we have added the following explanation to the text: “The questions for the survey were based on examples from other ACP prevalence surveys found during the literature review. Despite limitations surveys have in collecting sensitive data on person’s experiences, they are widely used in medical research and are suitable for gathering data about abstract ideas or concepts that are otherwise difficult to quantify, such as opinions, attitudes and beliefs (27). Administration of the survey requires minimal resources, and the results arising from analysis of closed-ended responses can be easily compared with the findings from the records audit. We hypothesize that there will be differences between the record audit and the survey responses regarding the existence of ACDs.”

3. The data will be highly relevant to clinical practice and policy in this area internationally, and it is the intention of the authors that the study findings have influence in this way, so it would be good to see plans for impact other than academic papers and conference presentations. It would be interesting to hear whether there are plans to have impact through other means of dissemination.

To address this comment we have included the following explanation at the end of the Ethics and Dissemination section: “The results will be highly relevant to clinical practice and policy nationally and internationally; therefore the findings of this study will also be disseminated through relevant government departments, as well as through various national and international professional bodies, societies and peer review networks.”

4. The administrative details of ethical approval are provided. The protocol could be improved with the provision of a summary of the ethical concerns and how the research team plan to address these.

There is a small chance that participants might experience distress during some of the questions, as some of the questions will ask about the end-of-life issues and death. To address this ethical concern we have now included the following explanation to the Informed consent section: “As some of the questions will ask about the end-of-life issues and death, there is a small chance that participants might experience distress or concern during the survey. To address this respondents are offered telephone numbers of relevant support services in the Explanatory Statement.”

5. The proposed dates of the study are not detailed, nor is the date of the ethical approval.

To reflect this comment we have now amended the Ethics and Dissemination section as follows: “This research protocol for this study was approved on the 2nd May 2017 by Austin Health Human Research Ethics Committee (reference number: HREC/17/Austin/83). The anticipated date for completion of the study is the 31st December 2017.”

Reviewer: 2

1. The standardized approach for data collection is appropriate, but further clarification about this process could strengthen the paper. Namely: What is the educational background or professional training of the data collectors (RN's, Social Workers etc? How much experience do they have navigating the medical record?) Will there be secondary adjudicators to ensure that the data collectors have appropriately performed the chart review? I think that this safeguard is necessary and will strengthen your methods.

Organisations responding to the expression of interest will be required no nominate two or three experienced staff members who have experience in retrieving information from health records, can assist participants to complete the survey where necessary and are available to answer questions from participants about advance care planning, or refer them to their health care team. It is expected that data collectors will be hospital quality managers, nurses or social workers. This explanation has now been added in the Study design and population section in the text.

To test the processes and feasibility of the study design and to understand potential problems that might arise during the study we will conduct a trial at the lead site. Due to the limited resources and time we will not be able to offer secondary adjudicators to ensure that the data collectors have appropriately performed the chart review. However, prior the study data collectors will be provided a data collection manual and a list of frequently asked questions; they will also be encouraged to contact the research team should any questions arise. To address this issue, the following explanation has been added to the text: “To test the processes and feasibility of the study design, and data collection tools, and to identify potential problems that might arise we will conduct a trial of the audit with three staff and approximately fifteen participants at the lead site.”

2. You mention a number of secondary study aims/outcomes (i.e. quality and validity). Do you have secondary hypotheses respective to these aims? Additionally, please describe how you will measure quality and validity of the ACP (i.e. is there a standard measure of ACP quality that you could utilize?)

In regard to Aim 2, it is hypothesised that the ACP documentation will be signed by the document maker and witnessed by a person authorized to witness statutory declarations in formal ACDs or any other person in informal documents. This hypothesis has now been added to the Aims and hypotheses section: “In regards to aim 2 we hypothesise that the ACP documentation will be signed by the person making the document, and witnessed according to the legislative requirements in each of the jurisdictions for formal ACDs, but there will be issues with validity of the documents based on failure to meet the witnessing requirements”

There is no standard measure for quality and validity of ACP documentation in Australia. Statutory documents need to be signed by the person and witnessed by specific authorities such as a doctor, a legal practitioner, a Justice of the Peace and in some jurisdictions also by the appointed decision-maker. Unsigned documents are not legally valid, and therefore presence or absence of such signatures will be used to determine the validity of the ACP documentation. This explanation has now been added to the Statistical analysis section.

3. Please clarify the age cut-off, some places say >65 others say >/= 65.

People will be aged 65 years or more. This has now been fixed accordingly in the text.

4. Why is there a reduced age cut off for ATSI peoples?

The Indigenous population in Australia is younger than non-Indigenous with only 3% of the ATSI people aged 65 years and over. This explanation and reference 24 has now been included in the manuscript, line 199-200.

5. Line 189, you mention group 2 of randomization. Please clarify what you mean, is this the group that is not studied?

Group 2 will comprise of those not-randomised for the study, and therefore this groups will not be studied. An explanation has now been added to the text, line 214.

6. How will capacity to participate be assessed? A significant proportion of inpatients will suffer from acute or chronic cognitive impairment. If the individual does not have decision making capacity, will their proxy be interviewed instead?

The person's capacity to give consent will be judged on the day(s) of the study by a nurse or other clinician in hospitals/residential aged care facilities, or by a nurse/doctor/other clinician in general practice, based on established principles of informed consent. This has been explained in the Informed consent section and additional sentence has been added in the Recruitment section to state that individuals lacking decision-making capacity will be excluded from the survey.

7. The data collection tool is well done-- but does not include a field for "does the ACP include an expression of the individual's values?" Expression of values is an important element of ACP quality.

Thank you for your feedback. This is currently addressed in Questions 11 "Other preferences" of the audit, under the Person's Preferences section.

8. Please provide more explanation of Table 4 with regard to determination of population size. Readers may not follow your process here.

To reflect this comment, the heading of the left-most column has been changed to "Proportion of records with the ACP/ACDs (%)", and the following sentence has also been added to the Population size section: "Based on the previous knowledge of ~14% of the Australian population having an ACP/ACD (21), the 95% confidence limits for the sample of 50 people would range from 3 to 22%."

VERSION 2 – REVIEW

REVIEWER	Ericka E. Tung, MD, MPH Mayo Clinic College of Medicine Rochester, MN, United States
REVIEW RETURNED	15-Aug-2017

GENERAL COMMENTS	The authors responded to each of my concerns carefully and thoughtfully. I appreciated the extra explanation of methods and specific clarity provided.