## PEER REVIEW HISTORY

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## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | Protocol for a national advance care directive prevalence study: a prospective multicentre cross-sectional audit among older Australians accessing health and residential aged care services |
| **AUTHORS** | Detering, Karen; Buck, Kimberly; Sellars, Marcus; Kelly, Helana; Sinclair, Craig; White, Ben; Nolte, Linda |

## VERSION 1 – REVIEW

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| **REVIEWER** | Birgitte schoenmakers<br>University of Leuven<br>Belgium |
| **REVIEW RETURNED** | 12-Jun-2019 |

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| **GENERAL COMMENTS** | please see attachment. I do appreciate the research objective but was at the same time not able to unravel the particular purpose of it. I would also have kept the design much more simple but perhaps this consideration is given by the fact that is was not really clear what the authors aimed to investigate.<br><br>The reviewer provided a marked copy with additional comments. Please contact the publisher for full details. |

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| **REVIEWER** | Dr Mikaela Jorgensen<br>Macquarie University, Australia |
| **REVIEW RETURNED** | 22-Jul-2019 |

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| **GENERAL COMMENTS** | Thank you to the authors for the opportunity to review this manuscript. This is a protocol for a study that primarily aims to determine the prevalence of advance care directives in hospitals, residential aged care facilities and general pratices in Australia. This is an important study; the push to increase uptake of ACP in Australia has been long and slow, and routine measurement of progress is needed. I have several questions for the authors that I believe require clarification to improve this manuscript.<br><br>Major comments:<br>1) Ethical approval, part 1. The investigators have received ethical approval for their study, but note that "This study is being undertaken as a quality improvement activity within services and will therefore not require informed consent from people whose records are audited."(page 16) However, if the investigators wish to report their findings, consent *is* required from participants - unless a HREC grants a waiver of consent under specific conditions (see National Statement on Ethical Conduct in Human Research, 2.3.10). Could the investigators clarify whether a waiver of consent has been sought and granted? |

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| | 2) Ethical approval, part 2. The investigators note in Table 2 that they will be collecting information on Indigenous status. Indigenous people in Australia have uniquely recognised rights to self-determination, including control of how their data is used (www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-research-aboriginal-and-torres-strait-islander-peoples). Reporting of data relating to Aboriginal and Torres Strait Islander peoples typically requires consultation with a AH&MRC Human Research Ethics Committee. Was this undertaken by the investigators?<br><br>3) Ethical approval, part 3. Yes, apologies but I do sit on an ethics committee! In box 1, hospitals are required to obtain ethics approval within six-eight weeks of notification of successful application. Is this timeline feasible? Will you be excluding hospitals who don't meet that benchmark?<br><br>4) Representativeness. The investigators are trying to determine "national advance care directive prevalence" (title). How will the investigators determine whether their sample is representative? This is not my area of expertise, but I'm aware estimating national prevalence would generally require weighting responses in order to obtain accurate population estimates. Could the investigators comment on this?<br><br>5) Definition of secondary outcomes (page 13). More detail is required on how the secondary outcomes will be measured. For example, how will assessors examine the 'content and quality of ACDs'? Perhaps this information is in Table 2, but each outcome should be clearly defined for the reader in the text. Including a copy of the audit tool might be handy. Do medical treatment orders also need to be found within 15 minutes of accessing the record?<br><br>Minor comments:<br>6) Abstract/methods/discussion. It is not immediately clear that the data collectors will be staff from participating sites, rather than the research team. I would suggest noting this in the study design on page 7. What are the implications of this data collection method?<br><br>7) Page 7, last para. How many rounds of data collection will be done? i.e. will rounds continue until sample size target reached?<br><br>8) Page 9. Why are audit participants required to have been admitted for at least 48 hours prior to audit? I'm not saying this is not valid, it just requires an explanation.<br><br>9) Page 8. The investigators note that "sites participating in earlier rounds will be eligible to participate in subsequent rounds". How will this be dealt with during analysis (e.g. clustering with repeated measures)?<br><br>10) Page 10. It is not immediately clear why randomisation is being done. Could the investigators please refine this section to help the reader.<br><br>11) Page 11, line 42. Will the data collectors access patients' My Health Record to look for ACDs? |

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| | 12) Page 12. The investigators note that data collectors will "estimate the person's level of functional disability" if an ECOG rating is not available. How will this be dealt with in analysis?<br><br>13) Page 14/Table 3. It is more appropriate to calculate the overall agreement on the 40 records - this can be done with multiple categories.<br><br>14) Page 15, sample size. Does your study have enough power for your multilevel model? A precision of +/- 8% is quite wide (page 14)?<br><br>15) Typos - "currently and underexplored" (page 12); table 2 should be table 3 (page 14). |

**VERSION 1 – AUTHOR RESPONSE**

Reviewer: 1

1. I do appreciate the research objective but was at the same time not able to unravel the particular purpose of it. I would also have kept the design much more simple but perhaps this consideration is given by the fact that is was not really clear what the authors aimed to investigate.

In the revised manuscript, we have refined the abstract, strengths and limitations summary points, introduction and methods to clarify the aims, rationale and methodology of the study. We have also reordered some sections of the manuscript to assist with readability and understanding.

2. "In Australia, ACP documentation includes advance care directives (ACD), a term encompassing documents recognised by state-based legislation (statutory ACD: preferences for care or statutory ACD: appointment of SDM) or common law (non-statutory ACDs) that are completed and signed by a competent adult." What is the difference in terms of execution?

We understand this comment about execution to be about the completion of these documents and how they come into force. To address this, we have revised the manuscript, as follows:

"While the specific execution requirements for these three types of ACDs vary, all must be completed by a person with decision-making capacity and they only come into effect once that capacity is lost."

3. "(2) an audit of health records of people admitted to or attending participating services?" How did you retrieve data about the non-registered ACDs? And also this way you reached a selected population, what about the population that is not visiting a health care provider or organisation? you risk to only reach the worried well, in particular when one of you aims was to determine what the distribution of non statutory versus the statutory ACD looked like

As is now more clearly articulated in the introduction, the aim of this study was to assess ACD prevalence at the point of care in health and residential aged care services, where this documentation will be most effective in guiding medical treatment decisions. Thus, we were only interested in ACDs and other documented outcomes of ACP that were available to health professionals in people's health records. Whilst we acknowledge that assessing ACD prevalence among the wider community is an important avenue for future research, this was beyond the scope of the current study. We have included this as a limitation, as follows:

"As the study focuses on ACD prevalence at the point of care in health and residential aged care services, findings are not generalisable to the wider Australian community."

4. “The 2017 pilot study (28, 30) provided key learnings that have informed a new study protocol. The protocol required adaptions to site recruitment processes and information collection, training and support for data collectors, data items, and data collection tools. These modifications and associated rationale are outlined in relevant sections below. In the pilot study, eligible people whose record was audited were invited to complete a survey. (30) Feedback received identified significant burdens and complexities associated with conducting the survey. Given the primary focus of this study is on ACD prevalence at the point of care, the survey has been removed. By doing so, we anticipate this will enable the participation of a wider range of smaller and regional/rural sites who would not have had the resource capacity to conduct both the health record audit and participant survey.” I think this is important information but too vague to leave it here stand alone

In the revised manuscript, we have included a new section at the beginning of the Methods and Analysis section (‘Overview of modifications to the original pilot study protocol’) to draw attention to the fact that this manuscript details modifications to the original pilot feasibility study protocol, including adjustments to the study design. The information about the removal of the self-report survey has been moved to the Study Design section and rephrased to more clearly explain why the survey was excluded from the current protocol, as follows:

“The pilot study included a self-report survey of people whose records were included in the audit. (27) Feedback received indicated the survey substantially increased the time and resourcing required to complete data collection, leading to significant additional burdens on study sites. In response, the survey has been removed from the current protocol. We anticipate this will enable the participation of a wider range of smaller and regional/rural sites that would not have had the resource capacity to conduct both a health record audit and participant survey. “

5. Line 48 – A minimum or 30 and a maximum of 50 eligible people - why this restriction? If you expect a low number of ACDs, who sure will you be then of the representatively of the sample

As suggested, we have revised this section to explain why minimum and maximum audit numbers were applied:
“Sites will be required to audit the records of a minimum of 30 and a maximum of 50 eligible people. These lower and upper limits are to ensure that sites audit similar numbers of records, thus allowing for meaningful comparison between sites. In the pilot study, sites were required to audit 50 records. However, feedback during recruitment in the pilot study suggested that this precluded the participation of smaller sites that were unlikely to have at least 50 patients/residents meeting eligibility criteria, particularly in rural or regional areas. Thus, the minimum of 30 record audits was applied in the current study to increase opportunities for smaller services to participate, facilitating greater representativeness among participating sites.
We have also stated that the data will be weighted for representativeness, as follows:
“For all analyses, data will be weighted for relevant population characteristics (e.g., age, gender, jurisdiction) as necessary, using the latest data from the Australian Bureau of Statistics.”
The following has been included in the dissemination section of the paper:
“However, we will exercise caution in reporting jurisdictional or setting prevalence results when such results are primarily driven by only one or two sites.”

6. Page 12, line 30- “other ACP documentation” see also comment above, this is to be expected is the Australian system. It would be more interesting if you also recruited and questionned in 'public'.

Please see response to comment 3.

7. Page 13 – Outcomes. I believe that only now I start to understand the purpose: you want to check how accessible an ACD is in case of emergency?

As stated above in response to comment 1, we have revised the abstract, introduction, aims and methods to clarify the aims and purpose of the study.

8. Where is the result section?

As stated in the BMJ open guidelines for protocol papers" While some baseline data can be presented, there should be no results or conclusions present in the study protocol."

Reviewer: 2

1. Ethical approval, part 1. The investigators have received ethical approval for their study, but note that "This study is being undertaken as a quality improvement activity within services and will therefore not require informed consent from people whose records are audited."(page 16) However, if the investigators wish to report their findings, consent *is* required from participants - unless a HREC grants a waiver of consent under specific conditions (see National Statement on Ethical Conduct in Human Research, 2.3.10). Could the investigators clarify whether a waiver of consent has been sought and granted?

The paragraph has been removed and replaced with the following:

"A waiver of consent application was made as part of the original ethics application. However, the committee deemed the waiver of consent unnecessary on the basis that only de-identified information was being collected in the study."

2. Ethical approval, part 2. The investigators note in Table 2 that they will be collecting information on Indigenous status. Indigenous people in Australia have uniquely recognised rights to self-determination, including control of how their data is used (https://clicktime.symantec.com/3BfZNzdbiNtPdjaXezjkwoL7Vc?u=www.nhmrc.gov.au%2Fresearch-policy%2Fethics%2Fethical-guidelines-research-aboriginal-and-torres-strait-islander-peoples). Reporting of data relating to Aboriginal and Torres Strait Islander peoples typically requires consultation with a AH&MRC Human Research Ethics Committee. Was this undertaken by the investigators?

This study did not aim to specifically recruit Aboriginal and Torres Strait Islander peoples, but recognised some may be included. The lead HREC did not advise additional ethics review by a specialist committee.

However, we thank the reviewer for pointing out this admission and we have therefore removed this variable in our protocol. We will seek necessary approval for future rounds of data collection so as to include information on Indigenous status.

3. Ethical approval, part 3. Yes, apologies but I do sit on an ethics committee! In box 1, hospitals are required to obtain ethics approval within six-eight weeks of notification of successful application. Is this timeline feasible? Will you be excluding hospitals who don't meet that benchmark?.

Box 1 had been amended, as follows:
"Hospitals will also be required to obtain additional ethics approval and/or a site-specific assessment at their site, ideally within six-eight weeks of notification of successful application. Advance Care Planning Australia will provide support in obtaining necessary approvals as required."

4. Representativeness. The investigators are trying to determine "national advance care directive prevalence" (title). How will the investigators determine whether their sample is representative? This is not my area of expertise, but I'm aware estimating national prevalence would generally require weighting responses in order to obtain accurate population estimates. Could the investigators comment on this?.

As suggested, we have included a statement to indicate that data will be weighted by relevant population characteristics, as follows:

“For all analyses, data will be weighted for relevant population characteristics (e.g., age, gender, jurisdiction) as necessary, using the latest data from the Australian Bureau of Statistics. Other data sources for weighting such as hospital and aged care demographics will be accessed as required.”

5. Definition of secondary outcomes (page 13). More detail is required on how the secondary outcomes will be measured. For example, how will assessors examine the 'content and quality of ACDs'? Perhaps this information is in Table 2, but each outcome should be clearly defined for the reader in the text. Including a copy of the audit tool might be handy. Do medical treatment orders also need to be found within 15 minutes of accessing the record?

As suggested, we have provided further detail on how the secondary outcomes will be measured in the revised manuscript, as follows:

“Currently in Australia, there is no standard measure for quality and validity of ACDs. Therefore, documents will be assessed based on requirements specified in jurisdictional legislation, (13, 33) and quality criteria outlined in the Australian National Framework for ACDs (34), including whether the document contains the name, date of birth and address of the person, the date of completion, whether the document is signed by the person and/or witnesses, and whether any instructions have been provided for the SDM (for statutory ACD: SDM only). To assess concordance between the person’s preferences for care and treatment instructions documented in medical orders, the consistency between treatment and/or other preferences specified in the person’s ACD will be compared with treatment limitations outlined in their medical treatment order.”

Medical orders do need to be identified within the same 15-minute timeframe. This has been clarified, as follows:

“Data collectors will obtain selected paper and/or electronic records (including My Health Record, if applicable) and attempt to locate relevant documentation within 15 minutes of opening the record. This timeframe was selected in recognition that for ACP documentation and/or medical orders to be useful, they need to be located quickly.”

6. Abstract/methods/discussion. It is not immediately clear that the data collectors will be staff from participating sites, rather than the research team. I would suggest noting this in the study design on page 7. What are the implications of this data collection method?

We have clarified that data collectors are staff of participating sites in the manuscript, as follows:

“Health records of people aged 65 years or older admitted to, or attending services on study day(s) will be audited by trained staff of participating sites.”

“The National Advance Care Directive Prevalence Study is a national prospective multi-centre cross-sectional study consisting of two parts: (1) site-level data, collected during the expression of interest

process and (2) an audit of health records of eligible people accessing participating services, conducted by trained staff from participating sites."

"It is expected that data collection will be completed by staff from participating sites. It is not practical to utilise external data collectors for a national study of this size. Key learnings from the 2017 pilot study have been utilised to improve the accuracy of collection. Staff will undertake compulsory training in study methodology, and data collection. Importantly, by supporting staff within organisations to complete data collection, it is anticipated that staff will increase their knowledge and ability to undertake future audits, generating opportunities for implementing ACP initiatives within their services."

7. Page 7, last para. How many rounds of data collection will be done? i.e. will rounds continue until sample size target reached?

As suggested, we have clarified this point in the revised manuscript as follows:

"A first round of data collection for the National ACD Prevalence Study was completed in 2018-19. One further round of data collection is anticipated in 2020. Further rounds of data collection are likely but will depend on funding availability, which is yet to be confirmed."

8. Page 9. Why are audit participants required to have been admitted for at least 48 hours prior to audit? I'm not saying this is not valid, it just requires an explanation.

As suggested, we have clarified this point in the revised manuscript, as follows:
"The requirement for admission for at least 48 hours prior to audit is to ensure adequate time for relevant documentation to have been provided or retrieved from the person, the SDM or another service."

9. Page 8. The investigators note that "sites participating in earlier rounds will be eligible to participate in subsequent rounds". How will this be dealt with during analysis (e.g. clustering with repeated measures?)

This section has been clarified with respect to the broader study aims, expectation that the majority of participating sites will be unique, and the statistical approach that will be used to accommodate sites who participate in multiple rounds:

"Sites will be eligible to participate in more than one round of data collection. However, as the study is cross-sectional rather than longitudinal, it is expected that the proportion of sites who participate in more than one data collection round will be low."

"If sites participate in more than one data collection round, and there is an analysis that compares prevalence rates over time, then the model will include time, in order to account for repeated measures. If study sample size is insufficient to allow for such a model, data from these returning sites will be limited to the first round of data collection in which they participated."

10. Page 10. It is not immediately clear why randomisation is being done. Could the investigators please refine this section to help the reader.

As suggested, this section has been refined to clarify the purpose and procedure of the randomisation, as follows:

"Record selection

In hospitals and residential aged care facilities, health records will be randomly selected from a list of eligible people using a simple randomisation procedure, designed to protect against selection bias. On the first day of the study at the site, the site Study Lead will contact their organisation's Health Information Management team (or similar) to obtain a list of current people who meet eligibility criteria. Each eligible person will be assigned a number chronologically, creating an 'Eligible Records List'. These chronological numbers will be used for randomisation. No identifiable information will be provided.
The Study Lead will then inform ACPA of the total number of eligible records, and the number (30-50 records) they intend to audit. Randomisation will be conducted by an ACPA researcher using a random number generator ('Research Randomizer', www.randomizer.org). Records will be assigned to group 1 (include) or group 2 (do not include) within an 'Allocation List', which will be returned to the Study Lead. The Study Lead will match the 'Allocation List' to their 'Eligible Records List' to determine which files to audit. Group 1 will also contain a supplementary list of 10 records which are to be used (consecutively) as needed if any of the initial list are unavailable (e.g. patient discharged).
Feedback from Study Leads involved in the pilot study indicated that the randomisation procedure was difficult to understand and implement in practice. To address these issues, Study Leads will receive specific training in the randomisation process, and be invited to complete a trial randomisation procedure prior to the nominated study date. Detailed instructions are also provided in study manuals and online education.
For practicality purposes, consecutive eligible records will be audited in general practices until the required number has been achieved."

11. Page 11, line 42. Will the data collectors access patients' My Health Record to look for ACDs?

My Health Record is considered part of the electronic record, and therefore would be included - if accessible. To clarify, the line has been amended in the revised manuscript, as follows:

"Data collectors will obtain selected paper and/or electronic records (including My Health Record, if applicable) and attempt to locate ACP documentation within 15 minutes of opening the record."

12. Page 12. The investigators note that data collectors will "estimate the person's level of functional disability" if an ECOG rating is not available. How will this be dealt with in analysis?

As suggested, we have included a statement to indicate how this will be dealt with in analysis:

"These items may be combined during analysis into an overall 'estimated' level of functional disability."

13. Page 14/Table 3. It is more appropriate to calculate the overall agreement on the 40 records - this can be done with multiple categories.

We confirm the percentage of agreement was calculated using the total 40 records and have removed the number of documents from the bracket to minimise any confusion.

14. Page 15, sample size. Does your study have enough power for your multilevel model? A precision of +/- 8% is quite wide (page 14)?

The power calculation has been performed for the primary outcome measure only, that being the presence of at least one ACD that can be located within 15 minutes of opening the record. Whilst we have not performed a power calculation for the multilevel model, recruitment in the first round has exceeded expectations, and it is likely there will be adequate power.

We also noted some errors in the precision estimates in this section have been corrected:

“Sample size calculations are necessary in prevalence studies to ensure that estimates are obtained with adequate precision. (35-37) The minimum number of records required for this audit was calculated as 505. This calculation assumes an expected average ACD prevalence of 0.3 (based on pilot study), (28) confidence level of 95% and desired precision of +/- 4%.
“Whilst a simple estimate of prevalence shows a minimum of 505 records are required, to allow for three health sectors to be represented across all eight jurisdictions, 24 sites are required. A minimum sample of 30 records from each of the 24 sites was chosen to minimise the data collection burden, while providing an adequate sample size for site-level results to be reported with a precision of +/- 3.5%. Therefore, the minimum total sample size required will be 720 health records. “

15. Typos - "currently and underexplored" (page 12); table 2 should be table 3 (page 14).

These errors have been addressed in the resubmission.

**VERSION 2 – REVIEW**

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| **REVIEWER** | Birgitte Schoenmakers<br>University of Leuven<br>Dept of Public Health and primary care |
| **REVIEW RETURNED** | 11-Sep-2019 |

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| **GENERAL COMMENTS** | Dear Authors,<br>the quality of the research significantly improved after this revision.<br>Kind regards<br>birgitte |

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| **REVIEWER** | Mikaela Jorgensen<br>Macquarie University, Australia |
| **REVIEW RETURNED** | 22-Sep-2019 |

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| **GENERAL COMMENTS** | Thank you to the authors for the opportunity to re-review this manuscript. I have a couple of remaining clarifications.<br><br>1. Response to reviewer 2, #1.<br>The investigators note that a waiver of consent was deemed not necessary by the ethics committee on the basis that only de-identified information was being collected. While the information *used* in this study is de-identified, the information at the point of collection is not (staff will be looking at medical records). Again, consent is required for data relating to individual participants, unless a waiver of consent is granted under specific conditions (see National Statement on Ethical Conduct in Human Research, 2.3.10). Could the investigators please provide evidence of their communication on this issue with the ethics committee?<br><br>2. Response to reviewer 2, #13.<br>There are still six kappas calculated for this table for what appears to be a total of 40 records. Could the investigators please clarify?<br><br>3. page 7, line 39.<br>The colons make this sentence difficult to read - "there will be more non-statutory ACDs and statutory ACD: appointment of SDM |

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| | than statutory ACD: preferences for care." The investigators may wish to check this phrasing throughout the manuscript.<br><br>4. page 7, line 46.<br>Could the investigators clarify the purpose of self-report survey in the pilot? |

**VERSION 2 – AUTHOR RESPONSE**

Reviewer: 1

Dear Authors, the quality of the research significantly improved after this revision.

Thank you.

Reviewer: 2

1. The investigators note that a waiver of consent was deemed not necessary by the ethics committee on the basis that only de-identified information was being collected. While the information *used* in this study is de-identified, the information at the point of collection is not (staff will be looking at medical records). Again, consent is required for data relating to individual participants, unless a waiver of consent is granted under specific conditions (see National Statement on Ethical Conduct in Human Research, 2.3.10). Could the investigators please provide evidence of their communication on this issue with the ethics committee?

Thank you for raising this again. We have gone back and reviewed all the ethics communication. We initially applied for and received approval for (on 28th June 2018) a waiver of consent. We have included the documentation regarding the application for your information. For reasons that are unclear, the ethics committee later advised a waiver was not required (despite this having already been granted).

The manuscript has therefore been amended as follows:

“A waiver of consent application was made and granted as part of the original ethics application.”

We apologise for the confusion and hope this now addresses your concerns.

2. There are still six kappas calculated for this table for what appears to be a total of 40 records. Could the investigators please clarify?

We were interested in each of the three types of advance care directives as well as overall agreement for the primary outcome measure. We also wanted to look at reliability testing for the two secondary outcomes measures, thus there are six kappas. We have modified the manuscript to clarify this as follows:

“Both a percentage agreement and a kappa statistic were calculated for primary (total as well as for each of the three types of advance care directives) and secondary outcome variables (documentation completed by health professionals and by someone else). For each of the primary outcome measures, percentage of agreement between the first and second data collector was 100% respectively and kappa statistic level of agreement was very high (Table 3).”

3. The colons make this sentence difficult to read - "there will be more non-statutory ACDs and statutory ACD: appointment of SDM than statutory ACD: preferences for care." The investigators may wish to check this phrasing throughout the manuscript.

We have reviewed this sentence and have added “” to assist. As suggested we reviewed other sections but did not feel other changes were necessary due to use of formatting / brackets.

4. Could the investigators clarify the purpose of self-report survey in the pilot?

The purpose of the self-report survey was to collect information from the person’s perspective, regarding their views about, and their experience of advance care planning. To date one manuscript has been published; others will follow. (Buck K, Detering KM, Pollard A, Sellars M, Ruseckaite R, Kelly H, et al. Concordance Between Self-Reported Completion of Advance Care Planning Documentation and Availability of Documentation in Australian Health and Residential Aged Care Services. J Pain Symptom Manage 2019;58(2):264-74.)

The manuscript has been amended as follows:

“The pilot study included a self-report survey of people whose records were included in the audit. (27) The purpose of this survey was to collect information from the person’s perspective, regarding their views about, and experience with advance care planning”.