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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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-031691
Article Type:	Protocol
Date Submitted by the Author:	15-May-2019
Complete List of Authors:	Detering, Karen; Austin Health, Advance Care Planning Australia; University of Melbourne, Faculty of Medicine, Dentistry and Health Science Buck, Kimberly; Austin Health, Advance Care Planning Australia Sellars, Marcus; Austin Health, Advance Care Planning Australia Kelly, Helana; Austin Health, Advance Care Planning Australia Sinclair, Craig; University of New South Wales, Centre of Excellence in Population Aging Research White, Ben ; Queensland University of Technology, Institute of Health and Biomedical Innovation Nolte, Linda; Austin Health, Advance care planning Program
Keywords:	advance care planning, advance care directive, prevalence, health service, quality, Audit < CARDIOLOGY

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Title: 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

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Word count

Abstract: (max 299)

Main text: (max 4000) currently 3971

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Abstract

Introduction: Advance care planning (ACP) is an ongoing communication and planning process with the aim of clarifying the person's values and care preferences, so these can guide decision-making if the person becomes unable to make their own decisions. Ideally, ACP results in completion of advance care directives (ACD), documents completed by competent people outlining their values, treatment preferences and/or appointment of a substitute decision-maker. Australian governments fund initiatives and have developed policy aimed at increasing ACP uptake. However, there is currently no standardised Australian data on ACD prevalence, thereby making ACP evaluation efforts difficult. This study aims to determine the prevalence of ACDs in Australian hospitals, aged care facilities and general practices.

Methods and analysis: This is a national multicentre cross-sectional prevalence study in residential aged care facilities, hospitals and general practices. Following a pilot feasibility study in 2017, a new protocol incorporating key learnings was developed. Sites will be recruited via an expression of interest process. People aged 65 years or older admitted to, or attending services on study day(s) will have their health record audited by specifically trained data collectors. Site level data will also be collected. The primary outcome measure will be presence of at least one ACD in the record. Secondary outcomes will include prevalence of other types of documented outcomes of ACP (by health practitioner(s) or family/substitute decision-maker), assessment of quality and content of ACDs and concordance between the person's documented preferences and medical orders completed by doctors. Characteristics of individuals and sites where ACDs are present will be explored.

Ethics and dissemination: This protocol has been approved by the Austin Health Human Research Ethics Committee, Melbourne, Australia (reference HREC/18/Austin/109). Results will be submitted

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to international peer-reviewed journals and presented at international conferences. Participating sites and jurisdictions will receive individualised reports of study findings.

Strengths and limitations of this study

- This multicentre cross-sectional prevalence study in residential aged care facilities, hospitals and general practices will recruit organisations across all eight Australian states and territories.
- Data collectors from participating sites will conduct the audit of health records to identify advance care directives.
- This study has built upon the key findings and learnings from a 2017 pilot feasibility study to improve training of data collectors, standardisation of data collection, ACD document classification.
- The results of this study will contribute to the methodology of undertaking research into the prevalence of ACP documentation and will inform ACP implementation strategies and evaluation processes
- The recruitment strategy for sites, using an expression of interest process, is likely to result in a selection bias towards organisations with an interest in advance care planning.

INTRODUCTION

Background

Advance care planning (ACP) is a coordinated communication and planning process that aims to clarify and share the person's values and preferences for medical treatment and personal care so as to guide health care decision-making should the person subsequently lose the capacity to make or communicate such decisions in the future. (1, 2) The ultimate goal of ACP is to ensure care received is consistent with the person's known preferences. (2) ACP has been shown to improve outcomes for patients, their families, healthcare staff and the health care system. (3-6)

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Ideally ACP discussions should result in documentation recording a person's values and preferences and/or appointment of a substitute decision-maker (SDM). (2, 7) Documentation is an important component of ACP. It has been shown to improve outcomes for people and provides information and support for SDMs, caregivers and clinicians who may be required to make treatment decisions on behalf of a person whose decision-making capacity is impaired. (2, 8-10) However, for the potential benefits of ACP documentation to be realised, documentation needs to be accessible at the point-of-care should the person be unable to participate in decision-making. (11, 12)

The names, scope and legal requirements of ACP documentation vary considerably within Australia and internationally. (10, 13-19) 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. (20) ACP documentation may also be completed on behalf of the person by a health professional or someone else (SDM / family). Additionally, medical order documents, such as "Goals of Care", "Resuscitation Plans", and "Physician Orders for Life-Sustaining Treatment", which describe action to be taken in an emergency, may also include reference to a person's preferences for care. (21-23)

Interest in ACP continues to grow. An increasing number of scientific publications, including systematic reviews, have been published in recent years (2, 3) and ACP is increasingly being supported in policy and legislative frameworks internationally. (6, 17, 18) Australian Governments have committed to addressing the palliative care and ACP needs of Australians through the National Palliative Care Strategy 2018 (24) and through jurisdictional programs and policy (25, 26). The need for comprehensive data regarding the prevalence , content and quality of ACDs in Australia is recognised as a priority (24, 27). Without such information, governments have limited ability to

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monitor the effectiveness and impact of ACP policy and programs of work, and organisations lack evidence to inform service-level programs and initiatives.

In 2017, an Australian pilot study conducted by Advance Care Planning Australia (ACPA) assessed the prevalence of ACP documentation among older adults accessing 51 Australian health and residential aged care services via an audit of health records. (28) The study found that 30% of 2285 audited records contained at least one ACD. Prevalence was significantly higher in residential aged care facilities (48%) compared to hospitals (16%) and general practices, (3%) and varied considerably across participating sites. (28) The study also found that 20% of people had 'other ACP documentation'. This likely included documents that were not ACDs (e.g. personal letters) or documentation completed on behalf of the person (e.g. by a health professional, a family member or the SDM). Although studies from Australia and elsewhere (3, 6, 12, 29) have found that ACP documentation is sometimes completed by people other than the person concerned, this is currently an underexplored area of ACP implementation. Furthermore, the legal effect and utility of this type of other ACP documentation in informing healthcare decisions is uncertain. (10, 14)

During 2018-20, ACPA has been funded by the Australian Government to deliver the *Prevalence of Advance Care Planning Documentation in Australian Health and Residential Aged Care Services* study. This study will build upon the findings and methodology of the 2017 study (28, 30) to collect a national dataset on the uptake of ACDs across jurisdictions, sectors, and services. The findings of this study have implications for policy makers, stakeholder organisations, service providers and the community, within Australia and internationally. The findings will also contribute to the methodology of undertaking research into the prevalence of ACP documentation.

Aims and Hypotheses

The aims of this study are to:

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1. Determine the prevalence of ACDs and other documented outcomes of ACP in paper and/or electronic health records of people aged ≥65 years admitted to hospitals or residential aged care facilities, or attending general practices.
2. Assess the content and quality of identified ACDs.
3. Explore consistency between medical orders and the person's documented preferences for care.
4. Explore the characteristics of individuals and study sites where ACDs are present in the health record.

Based on previous Australian studies (28, 31, 32), we hypothesise that the overall prevalence of ACDs will be low, and there will be more non-statutory ACDs and statutory ACD SDM appointments than statutory ACDs preferences for care. We expect to find various other ACP documents completed by health professionals, SDMs and/or family. We anticipate prevalence will be highest in residential aged care and lowest in general practice and expect a wide range of ACD prevalence rates within each sector. We hypothesise that there will be variation in the content and quality of ACDs, and that many ACDs will not meet signing and witnessing requirements specified in jurisdictional legislation, (14, 33) or quality criteria outlined in the Australian National Framework for ACDs. (33) We hypothesise that where there is an ACD, medical orders will be consistent with the person's preferences. We expect a range of individual and site factors to be associated with the presence of an ACD, including demographic and clinical characteristics and site self-reported organisational support for ACP.

METHODS AND ANALYSIS

Study design

This national prospective multi-centre cross-sectional study consists of two parts: (1) study site data, collected during the expression of interest process and (2) an audit of health records of people admitted to or attending participating services. Multiple rounds of data collection are anticipated.

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Sites participating in earlier rounds will be eligible to participate in subsequent rounds; however, as this is a cross-sectional rather than longitudinal study, participating sites are likely to differ across data collection periods.

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.

Part 1. Study Sites

Study sites will include Australian general practices, public and private hospitals and residential aged care facilities, recruited from all eight Australian jurisdictions (states and territories). A minimum of 24 sites will be included in each round of data collection. Study sites are required to nominate a Study Lead at their site.

Recruitment

Sites will be recruited through an expression of interest process, coordinated by ACPA and promoted via state and territory departments of health and stakeholder networks utilising newsletters and websites. Depending on responses to the expression of interest process for each round of data collection, additional sites may be approached by the project team to promote representativeness

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across sectors (residential aged care facilities, hospital and general practice) and jurisdictions. All prospective sites will be required to complete an online expression of interest application (see site-level data collection below). Based on feedback from the pilot, detailed application guidelines including a set of general and sector-specific eligibility criteria (Box 1) were developed.

Box 1 about here

Site-level data collection

Section one of the expression of interest application assesses site eligibility. Sites must meet all criteria before they can proceed. Section two and three of the application collects site-level data. (Table 1) Data items are informed by the pilot study, a literature review of system factors potentially important for ACP/ACD implementation and uptake, and guidance from the prevalence study advisory group.

Table 1 about here

Part 2: Health record audit

Audit participants will comprise people aged 65 years or older who are admitted to participating hospitals or residential aged care facilities for at least 48 hours prior to audit; or attending general practices on the nominated day(s) of the study. Sites will be required to audit the records of a minimum of 30 and a maximum of 50 eligible people. In contrast to the pilot where sites were expected to audit 50 records, a minimum of 30 record audits was set aiming to increase opportunities for smaller services thereby promoting diversity amongst sites. Sites are required to nominate how many records they intend to audit prior to randomisation and/or their study day(s).

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Health records of people in hospital and residential aged care facilities will be randomly selected from a list of eligible people. In general practices consecutive eligible records will be audited until the required number has been achieved.

Randomisation

In hospitals and residential aged care facilities, the site Study Lead will contact their organisation's Health Information Management team (or similar) on the (first) morning of their study day(s) 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 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.

Data collection: training, procedures, and support

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Participating sites will identify up to three data collector(s) (may include Study Lead), to undertake the audit. Study Leads and data collectors are expected to complete compulsory online training (approximately 60 minutes) and will have access to a data collection manual (Box 2). ACP legislation in Australia is determined by each jurisdiction, (14) and therefore jurisdiction-specific manuals will be provided. Researchers based at ACPA will be available via telephone for consultation throughout the study.

Box 2 about here

ACPA may provide data collector(s) to undertake audit in general practices, and in hospitals and aged care facilities in remote or regional areas that would otherwise be unable to participate due to limited resources. These auditors will not be members of the research team, will complete all required training and will meet privacy and confidentiality requirements of the organisation where they collect data.

Data collection will occur during defined periods in 2018-2020. Sites are required to nominate 1-3 consecutive days for data collection. Data collectors will obtain selected paper and/or electronic records and attempt to locate ACP documentation within 15 minutes of opening the record. This timeframe was selected in recognition that for ACP documentation to be useful, it needs to be located quickly. Data variables extracted will include demographic and clinical information, and details regarding the type and content of documentation (Table 2)

Table 2 about here

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All data will be entered directly into a password protected online database specifically built for this project, and hosted by REDCap (www.project-redcap.org). The database will be available via web-based user interface using a personal computer, laptop or tablet. Each data collector will receive a unique login name and password. Each site will have an identification number which will be known only to the site and the researchers conducting the analyses. Online data storage will ensure customised data security control for each organisation and is suitable for distributed collection environments. The database will have in-built validation and range checks to reduce data errors.

The pilot study identified important issues with some data variables. In particular, data collectors reported difficulty classifying ACP documentation. Furthermore, based on free text responses it is likely that some documents were incorrectly classified. Thus in this study, further information is provided regarding the nature of different documents they may encounter and characteristics of each to facilitate consistent classification. Whilst the pilot study showed ACD prevalence of 30%, a further 20% of people had 'other ACP documentation'. (30) The nature of these documents is unclear. ACDs are documents completed by competent people and come into effect if the person subsequently loses capacity to make their own decisions. However, ACP (and documentation of the outcomes) may also be of benefit for people without an ACD, who no longer have capacity. This is currently and underexplored area of ACP practice. Consequently, in this study, the process of facilitating correct classification of documentation has changed. We have developed a process and flow chart based on who completed documentation, (flow chart 1) and have provided detailed instructions and examples in education and study manuals.

Feedback from the pilot indicated that data collectors had difficulty classifying some medical conditions from the person's record. To address this, data collectors will be instructed to record only current/active medical conditions, and a range of examples will be provided for each of the medical condition categories. The pilot also had a substantial amount of missing data (30%) for the Eastern Cooperative Oncology Group (ECOG) status variable. The revised audit tool includes an additional question asking data collectors to estimate the person's level of functional disability based on

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available information in the person's record if the actual ECOG rating is not available. In the pilot, there was also evidence of data entry errors in the database. For this study, the database logic has been reviewed, more detailed instructions will be provided within the database and study manuals, and additional in-built validation checks will be added. We will also conduct comprehensive user testing of the database and improve education provided to data collectors regarding database usage.

Data de-identification

A study ID number will be assigned to each person on the audit list, and will be used for data entry. Participating sites will be able to match study IDs with specific people. Identifiable information will not be recorded or disclosed to the research team.

Outcomes

The primary outcome will be the presence of at least one ACD (statutory ACD: preferences for care, statutory ACD: SDM, and/or non-statutory ACD) that are located within 15 minutes of accessing the record. Secondary outcomes will include prevalence of other documented outcomes of ACP (documents completed by a health practitioner or someone else, such as family or the SDM), assessment of content and quality of ACDs, and concordance between the person's preferences for care as documented in their ACD and medical treatment orders.

Reliability testing

To estimate any potential bias in rating the primary and secondary outcome variables, two data collectors independently rated the same 40 health records and a reliability analysis was undertaken. Both a percentage agreement and a kappa statistic were calculated for primary and secondary outcome variables. For the primary outcome, percentage of agreement between the first and

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second data collector was 100% respectively and kappa statistic level of agreement was very high. (Table 2) For secondary outcome variables percentage of agreement ranged between 97.1% and 100% and kappa level of statistic was good or very good.

Sample size estimation and justification

Sample size calculations are necessary in prevalence studies to ensure that estimates are obtained with adequate precision. (34-36) The minimum number of records required for this audit was calculated as 504. This calculation assumes an expected average ACD prevalence of 0.3 (based on pilot study), (28) confidence level of 95% and desired precision of +/- 2%.

Whilst a simple estimate of prevalence, shows a minimum of 504 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 +/- 8%. Therefore, the minimum total sample size required will be 720 health records.

Statistical Analysis

Descriptive statistics will be calculated for the total sample and by major grouping site or participant variables. Overall prevalence of ACDs will be calculated for the total sample and separately for healthcare sectors and jurisdictions. Prevalence rates of the types of ACDs, and "other documentation" will also be reported. Comparisons will be made using *t-tests* for the continuous type variables and chi-square contingency table analysis for the categorical type variables.

Similar to the previous study, descriptive statistics will be used to describe the content and quality of ACDs, other ACP documentation, and the specific preferences for care specified in ACDs in comparison to the content of medical orders. (28, 30) Currently in Australia, there is no standard measure for quality and validity of ACDs. Therefore, documents will be assessed based on

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requirements specified in jurisdictional legislation, (13, 33) and quality criteria outlined in the Australian National Framework for ACDs. (33)

Due to the nesting of individual records within sites, generalised linear mixed model regression will be performed to determine the predictive value of demographic, clinical and site-level variables on the presence of ACD in the person's record. The level of significance will be set at 0.05.

Project governance

This study is led by ACPA, and will be overseen by a project advisory group, who will meet approximately four times per year via teleconference. The advisory group is chaired by ACPA, and includes academics and clinicians with interdisciplinary expertise relevant to this study including in medicine, nursing, allied health, law and policy. The advisory group also includes representation from hospital, general practice and aged care sectors. The advisory group will co-opt a statistician to provide methodological and statistical advice.

The advisory group will review and endorse the project methodology, and provide advice regarding site recruitment across sectors, risk management, intellectual property and ethical concerns. They will provide advice, drawing on their interdisciplinary expertise, on the collection and interpretation of data and on contextual and jurisdictional aspects of the study.

Confidentiality and Privacy

To avoid any potential breach of confidentiality, only staff of the participating organisations directly involved in collection of data will have access to health records. ACPA auditors will be required to adhere to privacy principles of the services they attend. Data will be handled, stored and disposed of according to the Australian National Health and Medical Research Council Code of Responsible

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Conduct of Research and the National Statement on Ethical Conduct in Research involving Humans.(37, 38) All results will be de-identified and presented in an aggregate format.

Patient and public involvement

The specific intent of this project is to inform service-level initiatives and future ACP programs and policy. People whose records will be audited will not be involved in the audit, the study design or recruitment. As only de-identified information will be collected, it is not possible to provide results to participants. However, study sites will receive de-identified individualised reports including information about their service and how they compare to similar services. The study results will also be provided and discussed with the "National ACP Engagement Advisory Group", which includes representation from consumers and consumer organisations including "National Seniors, Dementia Australia, Palliative Care Australia, and the Victorian Cancer Council.

Ethics and dissemination

The research protocol for this study was approved on 14 June 2018 by Austin Health Human Research Ethics Committee (reference number: HREC/18/Austin/109).

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. Only de-identified data will be entered into the Prevalence Study database. Data will not be re-identifiable by the research team.

Study results will be provided to the participating sites and the Australian Government. No reports will identify any specific site but jurisdictional comparisons will be possible. 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

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various national and international professional bodies, societies and peer review networks. Findings will be presented at relevant conferences and published in peer-reviewed journals, on the ACPA website and in lay and social media where appropriate. Investigators will review manuscript drafts, abstracts, press releases and any other publications arising from the study. Authorship will be determined in accordance with the International Committee of Medical Journal Editors guidelines.

Discussion

Effectiveness of national ACD prevalence research requires standardisation of methodology including the accurate classification of ACP documentation, thereby facilitating meaningful measurement and comparison. The current study has built upon the findings and key learnings from the pilot feasibility study, (28, 30) particularly with respect to training of data collectors, standardisation of methodology and facilitation of consistency regarding document classification.

Strengths

The protocol retains the key study design features of the pilot that were shown to be feasible and successful and improves upon the identified limitations. It will generate one of the largest and most comprehensive datasets on ACD prevalence in Australia and internationally. This dataset will provide information on the types and characteristics of ACP documentation being used within and across three health sectors that can be used to better understand current practice and inform future ACP strategies and initiatives. This study aims to recruit a diverse range of services increasing the generalisability of the measured outcomes.

Data collectors from participating sites are trained in audit methodology and ACD classification using a standardised approach. This should facilitate meaningful comparison of prevalence rates between services. Furthermore, given that data collectors are staff from participating sites, education provided as part of this study has the potential to increase knowledge and awareness at the sites, and therefore contribute to capacity building within these sites.

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Limitations

Recruitment via an expression of interest process means there is a likely selection bias towards sites with an existing interest in ACP. Whilst the aim of this study is to recruit sites across all three health sectors and all eight Australian jurisdictions is it is likely that not all sectors will be similarly represented nor will states and territories, thus limiting generalisability of findings by sector and jurisdiction. This study utilises an audit methodology, and therefore, it is not possible to determine quality and extent of ACP conversations known to be an important determinant of a successful ACP programme. Furthermore, given the audit methodology, it will not be possible to determine whether documentation translates into care that is consistent with the person's preferences, the ultimate goal of ACP.

Trial status

Site recruitment for the first round of data collection occurred from June 1st to August 31st 2018. Data collection occurred from October 1st 2018 to 18th January 2019. Data analysis for this round will commence in May 2019. Planning for subsequent rounds of data collection has not commenced.

Authors' contributions: KD and LN were involved in the conception, design, protocol development, and drafting the manuscript; KB was involved in the design, protocol development, and drafting the manuscript; MS, HK, BW and CS were involved in the design, protocol development review of the manuscript. All authors read and approved the final manuscript.

Acknowledgements: We acknowledge the valuable contribution of the national prevalence study advisory group. We acknowledge the important contribution and feedback provided by Study Leads and Data Collectors from the 2017 pilot study.

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Funding statement: This work was supported by the Australian Government Department of Health.

Competing interests statement. The authors declare that they have no competing interests.

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Box 1. Site eligibility criteria

General criteria: General practices, hospitals and residential aged care facilities are eligible to apply if they:

1. Are an accredited organisation according to sector requirements
2. Have the approval and endorsement of their executive team
3. Can nominate one staff member as the Study Lead (responsible for coordination of the study at the site and will be the key contact person for the research team)
4. Have internet, email and telephone access
5. Have access to devices for online data collection (e.g., computer, laptop or iPad)
6. Have policies in place about privacy and confidentiality
7. Agree that the information provided in their application will be used to generate a Research Collaboration Agreement if successful and are willing to sign this preferably within four weeks of being notified of successful application
8. Meet all sector-specific eligibility criteria.

Sector-specific eligibility criteria.

Hospitals and residential aged care facilities are eligible to apply if they:

1. Expect that their site will have at least 50 patients/ residents on the day(s) of the study that are aged 65 years or older and have been admitted for at least 48 hours*
2. Have a records management system with the ability to extract a list of all admissions of people aged 65 years or older who have been admitted for more than 48 hours on the day(s) of the study
3. Can nominate up to two additional staff members to collect the data for the study.
4. Are willing to support the Study Lead and data collectors(s) to undertake mandatory online training in data collection procedures
5. Have the capacity to review a minimum of 30 health records.

Hospitals will also be required to obtain additional ethics approval and/or a site-specific assessment at their site, within six-eight weeks of notification of successful application.

* A minimum of 30 health records will be randomly selected from eligible records on the day(s) of the study.

General practices are eligible to apply if they:

1. Expect that at least 30 patients aged 65 years or older will attend their practice on the day(s) of the study
2. Have a records management system with the ability to extract a list of all people aged 65 years or older attending the practice on the day(s) of the study
3. Can nominate up to two additional staff members to collect the data for the study OR agree to data collector(s) being provided by Advance Care Planning Australia.

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Box 2. National Advance Care Directive Prevalence Study: Data collection training and manual

Online training

Key content	Mode of delivery

• Advance care planning and advance care directives
• Overview of the National Advance Care Directive Prevalence Study
• Advance care planning documentation: definitions, classification for study
• Review of data items and how to collect data
	• PowerPoint presentation
	• Role plays demonstrating:
	  ○ A data collector undertaking the audit and entering data
	  ○ A Study Lead performing the randomisation procedure
	• Interactive discussion regarding:
	  ○ Types of advance care planning documentation
	  ○ Demonstration of how to use flow chart for classification
	  ○ Tips for success

Data Collection Manual

Section 1: Background information and context for the National Advance Care Directive Prevalence Study.

Section 2: Overview of the National Advance Care Directive Prevalence Study.

Section 3: Description of how to collect study data including the documentation sought during the audit.

Section 4: Instructions on how to use the online data collection database.

Section 5: Additional information relevant to Study Leads.

Section 6: Troubleshooting instructions for problems.

Section 7: List of frequently asked questions.

Section 8: Test questions (with answers) to be used to assess knowledge and understanding of the terminology and concepts needed to conduct the audit.

Attachments

Contains documents to assist with study and data collection. These include:

- A flowchart of relevant documentation to the audit
- A decision tree to help with classification of advance care planning documentation
- A list of statutory advance care directives used in Australia
- Checklists for Study Leads to prepare for study day
- A list of contact numbers

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Table 1: Site-level data variables

Category	Variable(s)
Demographic information	Jurisdiction, location, funding (government, not-for-profit, private), record management system used.
Size of service	Number of beds, number of health staff
Advance care planning (ACP) program / activity	Current ACP program/activity within the service, when this commenced, ACP training available for staff and how ACP is funded and/or implemented Presence/absence of ACP policy, consumer resources, and Advance care directive templates/forms. (*Sites will be asked to upload their ACP policy documents and / or blank ACD templates/forms utilised in their service.)*

Table 2: Participant data variables

Category	Variable(s)
Demographic information	Age, gender, postcode, country of birth, Indigenous status, relationship status, religion, English or other language spoken
Clinical information	Date of admission/visit, current/active medical conditions (categorised by organ systems), palliative care status, Eastern Cooperative Oncology Group (ECOG) status (or estimated functional status if ECOG not available)
Type of documentation (see Flow chart) *Classified based on who completed documentation*	Completed by: • The person (statutory and non-statutory advance care directives; other e.g. letter) • A health professional (medical orders/clinical care plans; advance care planning documentation) • Someone else (advance care planning documentation by family, substitute decision-maker etc.) • Miscellaneous advance care planning material (e.g. brochure)
Details of documentation	Time taken to find document, location of document in the health record, date of document, whether the document contains the person's name, address and date of birth, information regarding who signed documentation (including witnesses where appropriate), treatment preferences and/or other preferences specified in the document, characteristics of medical orders

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Table 3. Reliability analysis (n=40)

Variable	% Agreement	Kappa (95%CI)	Kappa agreement	*p*
ACP documentation by the person	**100 (5 documents)**	**1.0**	**Very good**	**<.001**
Statutory ACD: preferences for care	100 (0 documents)	1.0	Very good	<.001
Statutory ACD: SDM	100 (4 documents)	1.0	Very good	<.001
Non-statutory ACP documentation	100 (2 documents)	1.0	Very good	<.001
Documentation by a health professional	**97.1 (33 of 34 documents)**	**0.804 (0.541-1.0)**	**Good**	**<.001**
Documentation by someone else	**100 (1 document)**	**1.0**	**Very good**	**<.001**

Note. ACP = advance care planning; ACD = advance care directive; CI = confidence interval; SDM = substitute decision-maker.

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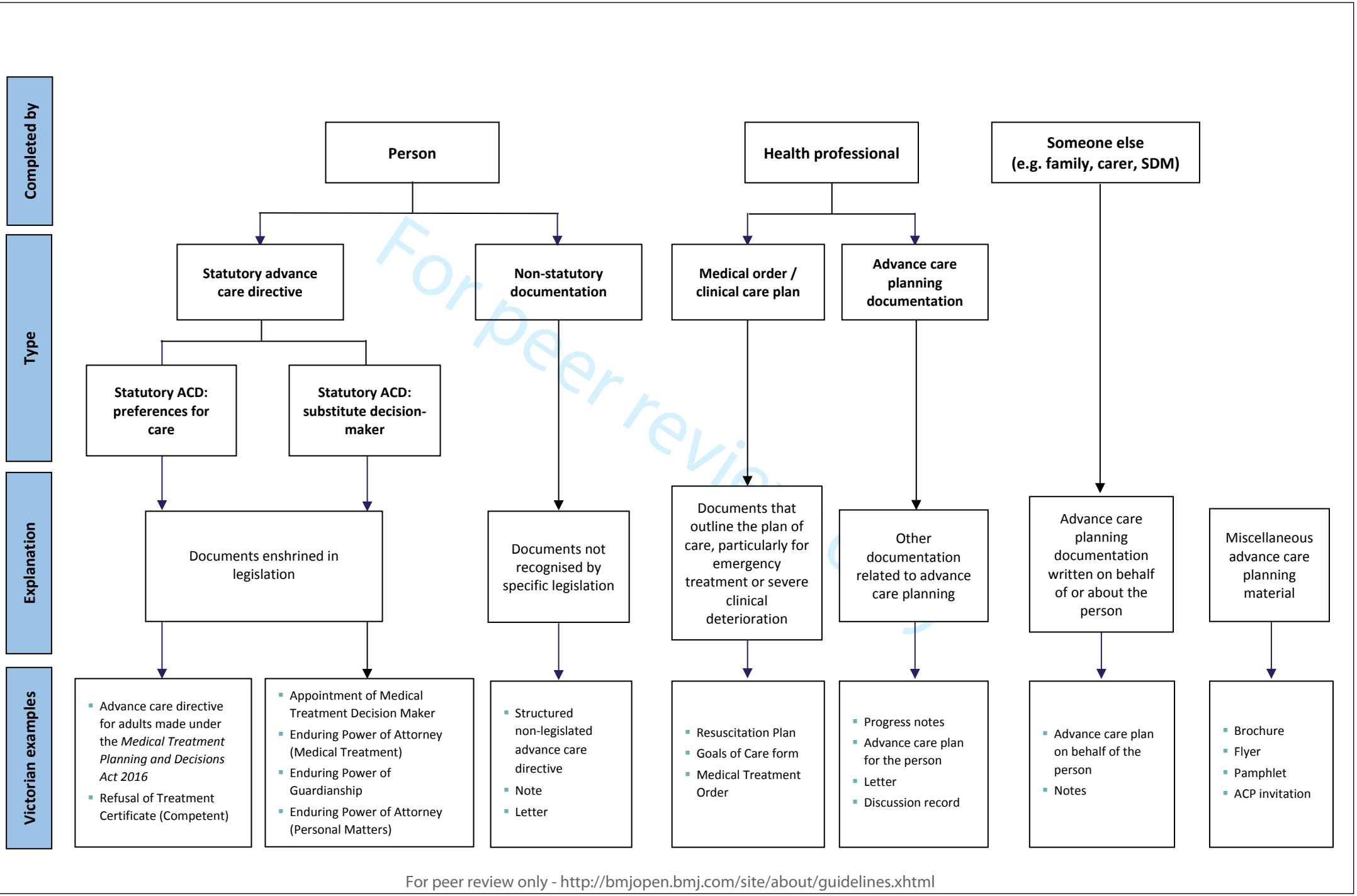

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Documentation flowchart - Victoria

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BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-031691.R1
Article Type:	Protocol
Date Submitted by the Author:	05-Sep-2019
Complete List of Authors:	Detering, Karen; Austin Health, Advance Care Planning Australia; University of Melbourne, Faculty of Medicine, Dentistry and Health Science Buck, Kimberly; Austin Health, Advance Care Planning Australia Sellars, Marcus; Austin Health, Advance Care Planning Australia Kelly, Helana; Austin Health, Advance Care Planning Australia Sinclair, Craig; University of New South Wales, Centre of Excellence in Population Aging Research White, Ben ; Queensland University of Technology, Institute of Health and Biomedical Innovation Nolte, Linda; Austin Health, Advance care planning Program
Primary Subject Heading:	Health services research
Secondary Subject Heading:	General practice / Family practice, Geriatric medicine, Patient-centred medicine
Keywords:	advance care planning, advance care directive, prevalence, health service, quality

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Manuscripts

Title: 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

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Word count

Abstract: (max 299)

Main text: (max 4000) currently 3971

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Abstract

Introduction: Advance care planning, (ACP) an ongoing communication and planning process, aims to clarify a person's values and preferences, so these guide decision-making if the person becomes unable to make their own decisions. Ideally, ACP results in completion of advance care directives (ACD), documents completed by competent people outlining their values, treatment preferences and/or appointment of a substitute decision-maker. ACDs are most effective at the point-of-care, where they can be used to inform treatment decisions. Australian governments fund initiatives and have developed policy to increase ACD completion rates. However, little is known about the prevalence of ACDs at the point-of-care in Australian health services, making ACP evaluation efforts difficult. This study aims to determine the prevalence of ACDs in records of older people in Australian hospitals, aged care facilities and general practices.

Methods and analysis: This is a national multicentre cross-sectional prevalence study in selected aged care facilities, hospitals and general practices. Following a 2017 feasibility study, a new protocol incorporating key learnings was developed. Sites will be recruited via expression of interest process. Health records of people aged ≥ 65 years, admitted to, or attending services on study day(s) will be audited by trained staff from sites. Site-level data will be collected during the expression of interest. The primary outcome is the presence of at least one ACD in the health record. Secondary outcomes include prevalence of other documented outcomes of ACP (by health practitioner(s)/family/substitute decision-maker), assessment of ACD quality and content and concordance between the person's documented preferences and any medical treatment orders. Individuals and sites Characteristics where ACDs are present will be explored.

Ethics and dissemination: Protocol approval by Austin Health Human Research Ethics Committee, Melbourne, Australia (reference:HREC/18/Austin/109). Results will be dissemuinated via peer-

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reviewed journals and conferences. Participating sites and jurisdictions will receive individualised reports of findings.

Strengths and limitations of this study

- This national multicentre cross-sectional prevalence study aims to determine the prevalence and characteristics of advance care directives in Australian residential aged care facilities, hospitals and general practices.
- Trained data collectors from participating sites will conduct the audit of health records to identify advance care directives.
- This protocol builds upon the key findings and learnings from a 2017 pilot feasibility study and includes improvements in the training of data collectors, standardisation of data collection, and classification of documents.
- The results of this study will contribute to the methodology of undertaking research into the prevalence of advance care planning documentation and will inform advance care planning implementation strategies and evaluation processes.
- The recruitment strategy for sites, using an expression of interest process, is likely to result in a selection bias towards organisations with an interest in advance care planning.

INTRODUCTION

Background

Advance care planning (ACP) is a coordinated communication and planning process that aims to clarify and share a person's values and preferences for medical treatment so as to guide health care decision-making should the person subsequently lose the capacity to make or communicate such decisions in the future. (1, 2) The ultimate goal of ACP is to ensure care received is consistent with the person's known preferences. (2) ACP has been shown to improve outcomes for patients, their families, healthcare staff and the health care system. (3-6)

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Ideally ACP discussions should result in documentation recording a person's values and preferences and/or appointment of a substitute decision-maker (SDM). (2, 7) Documentation is an important component of ACP. It has been shown to improve outcomes for people and provides information and support for SDMs, caregivers and clinicians who may be required to make treatment decisions on behalf of a person whose decision-making capacity is impaired. (2, 8-10)

The names, scope and legal requirements of ACP documentation vary considerably within Australia and internationally. (10-16) 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. (17)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. ACP documentation may also be completed on behalf of the person by a health professional or someone else (SDM / family). Additionally, medical treatment orders that describe action to be taken in an emergency, such as "Goals of Care", "Resuscitation Plans", and "Physician Orders for Life-Sustaining Treatment", may also include reference to a person's preferences for care. (18-20). These are completed and signed by a doctor.

For the potential benefits of ACDs and other documented outcomes of ACP to be realised, it is critical that documentation is accessible at the point-of-care should the person be unable to participate in decision-making. (21, 22) If health care providers do not have access to the person's documented preferences when treatment decisions are required, the person may receive care that is inconsistent with their preferences (23). In Australian health services, a range of systems are used to store and retrieve ACDs, including service-specific electronic health record systems, scanned

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medical records, hardcopy files, or a combination. (23) Most health services also now have access to 'My Health Record', a new centralised national e-health record that offers online storage of ACDs. While some services may have mechanisms to elicit existing ACDs upon admission, many will rely on the person to provide their documentation to relevant providers. (23)

Although support for ACP and ACDs continues to grow in Australian policy and legislative frameworks, (8, 17, 24, 25) there is a lack of national data on the prevalence, content and quality of ACDs at the point of care in Australian health services. Without this information, governments have limited ability to monitor the effectiveness and impact of ACP policy and programs, and organisations lack evidence to inform service-level programs and initiatives to increase ACD uptake.

In 2017, an Australian-first pilot feasibility study was conducted by Advance Care Planning Australia (ACPA) to assess the prevalence of ACDs among older adults accessing Australian health and residential aged care services. (26) Of 2285 health records audited across 51 sites, 30% contained at least one ACD. The ACD prevalence was significantly higher in residential aged care facilities (48%) compared to hospitals (16%) and general practices, (3%) and varied considerably across participating sites. (26) A further 20% of people had 'other ACP documentation'. This likely included documents that were not formal ACDs (e.g. personal letters) or documentation completed on behalf of the person (e.g. by a health professional, a family member or the SDM). However, the exact nature or authorship of this "other ACP documentation" was unclear. (26)

During 2018-20, ACPA has been funded by the Australian Government to deliver the *National ACD Prevalence Study*. This study will build upon the findings and methodology of the pilot feasibility study (26, 27) to collect a national dataset on the prevalence and characteristics of ACDs and other documented outcomes of ACP among older people accessing general practices, hospitals and

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residential aged care facilities across Australia. The study will provide data to assist organisations and governments understand how well ACP is being implemented in Australia and identify areas for improvement. It will also contribute to the methodology of undertaking research into the prevalence of ACP documentation.

Aims and Hypotheses

The aims of the *National ACD Prevalence Study* are to:

1. Determine the prevalence of ACDs and other documented outcomes of ACP among people aged ≥65 years accessing Australian general practices, hospitals and residential aged care facilities.
2. Assess the content and quality of identified ACDs.
3. Explore consistency between medical orders and the person's documented preferences for care.
4. Explore the characteristics of individuals and study sites where ACDs are present in the health record.

Based on previous Australian studies (26, 28, 29), we hypothesise that the overall prevalence of ACDs will be low, and there will be more non-statutory ACDs and statutory ACD: appointment of SDM than statutory ACD: preferences for care. We expect to find various other ACP documents completed by health professionals, SDMs and/or family. We anticipate prevalence will be highest in residential aged care facilities and lowest in general practice and expect a wide range of ACD prevalence rates within each sector. We hypothesise that there will be variation in the content and quality of ACDs, and that many ACDs will not meet signing and witnessing requirements specified in jurisdictional legislation (8, 11) or quality criteria outlined in the Australian National Framework for ACDs. (8) We hypothesise that where there is an ACD, medical orders will be consistent with the person's preferences. We expect a range of individual and site factors to be associated with the

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presence of an ACD, including demographic and clinical characteristics and site-reported organisational support for ACP.

METHODS AND ANALYSIS

Overview of modifications to the original pilot study protocol

The 2017 pilot feasibility study (26, 27) provided key learnings that have informed the current protocol for the *National ACD Prevalence Study*. Based on these learnings, a number of modifications were made to the study design, 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.

Study design

The *National ACD Prevalence Study* is a 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 those services, conducted by trained staff from participating sites.

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.

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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."* . 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.

Part 1. Study Sites

Study sites will include Australian general practices, public and private hospitals and residential aged care facilities, recruited from all eight Australian states and territories (jurisdictions). A minimum of 24 sites will be included in each round of data collection.

Recruitment

Sites will be recruited through an expression of interest process, coordinated by ACPA and promoted via state and territory departments of health and stakeholder networks utilising newsletters and websites. Depending on responses to the expression of interest process for each round of data collection, additional sites may be approached by the project team to promote representativeness across sectors (residential aged care facilities, hospital and general practice) and jurisdictions. All prospective sites will be required to complete an online expression of interest application (see site-level data collection below). Based on feedback from the pilot study, detailed application guidelines including a set of general and sector-specific eligibility criteria (Box 1) were developed.

Box 1 about here

Site-level data collection

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Section one of the expression of interest application assesses site eligibility. Sites must meet all criteria before they can proceed. Section two and three of the application collects site-level data. (Table 1) Data items are informed by the pilot study, a literature review of system factors potentially important for ACP/ACD implementation and uptake, and guidance from the project advisory group. Study sites are also required to nominate a Study Lead and one to three data collectors in the expression of interest application.

Table 1 about here

Part 2: Health record audit

Audit participants will comprise people aged 65 years or older who are admitted to participating hospitals or residential aged care facilities for at least 48 hours prior to audit, or attending general practices on the nominated day(s) of the study. 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.

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.

Sites are required to nominate how many records they intend to audit (minimum of 30 and maximum of 50 records) prior to their study day(s).

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Record selection

In hospitals and residential aged care facilities, health records will be randomly selected from a list of all eligible people using a simple randomisation procedure, designed to protect against selection bias. On the first day of the study, 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.

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For practicality purposes, consecutive eligible records will be audited in general practices until the required number has been achieved.

Data collection: training, procedures, and support

Participating sites will identify up to three data collector(s) (may include Study Lead), to undertake the audit. Study Leads and data collectors are expected to complete compulsory online training (approximately 60 minutes) and will have access to a data collection manual (Box 2). ACP legislation in Australia is determined by each jurisdiction, (11) and therefore jurisdiction-specific manuals will be provided. Researchers based at ACPA will be available via telephone for consultation throughout the study.

Box 2 about here

Data collection will occur during defined periods. Sites are required to nominate one to three consecutive days for data collection. 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. Data variables extracted will include demographic and clinical information, and details regarding the type, content and characteristics of ACP documentation and/or medical orders (Table 2).

Table 2 about here

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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.

ACPA may provide data collector(s) to undertake audit in general practices, and in hospitals and aged care facilities in remote or regional areas that would otherwise be unable to participate due to limited resources. These auditors will not be members of the research team, will complete all required training and will meet privacy and confidentiality requirements of the organisation where they collect data.

All data will be entered directly into a password protected online database specifically built for this project, and hosted by REDCap (www.project-redcap.org). The database will be available via web-based user interface using a personal computer, laptop or tablet. Each data collector will receive a unique login name and password. Each site will have an identification number, which will be known only to the site and the researchers conducting the analyses. The database will have in-built validation and range checks to reduce data errors.

The pilot study identified important issues with some data variables. In particular, data collectors reported difficulty classifying ACP documentation. Furthermore, based on free text responses it is likely that some documents were incorrectly classified. Thus in the present study, further information is provided regarding the nature of different documents they may encounter and characteristics of each to facilitate consistent classification. Whilst the pilot study showed ACD prevalence of 30%, a further 20% of people had 'other ACP documentation'. (27) The nature of these documents is unclear. ACDs are documents completed by competent people and come into effect if

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the person subsequently loses capacity to make their own decisions. However, ACP documentation is sometimes completed by people other than the person concerned, (3, 6, 21, 26, 30) which may also be of benefit for people without an ACD, who no longer have capacity. This is currently an underexplored area of ACP practice. Consequently, in this study, the process of facilitating correct classification of documentation has changed. We have developed a process and flow chart based on who completed documentation (Figure 1) and have provided detailed instructions and examples in education and study manuals.

Feedback from the pilot indicated that data collectors had difficulty classifying some medical conditions . To address this, data collectors will be instructed to record only current/active medical conditions, and a range of examples will be provided for each of the categories. The pilot also had a substantial amount of missing data (30%) for the Eastern Cooperative Oncology Group (ECOG) status variable. The revised audit tool includes an additional question asking data collectors to estimate the person's level of functional disability based on available information in the person's record if the actual ECOG rating is not available. These items may be combined during analysis into an overall 'estimated' level of functional disability. In the pilot, there was also evidence of data entry errors in the database. For this study, the database logic has been reviewed, more detailed instructions will be provided within the database and study manuals, and additional in-built validation checks will be added. We will also conduct comprehensive user testing of the database and improve education provided to data collectors regarding database usage.

Data de-identification

A study ID number will be assigned to each person on the audit list, and will be used for data entry. Participating sites will be able to match study IDs with specific people. Identifiable information will not be recorded or disclosed to the research team.

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Outcomes

The primary outcome will be the presence of at least one ACD (statutory ACD: preferences for care, statutory ACD: SDM, and/or non-statutory ACD) that are located within 15 minutes of accessing the record. Secondary outcomes will include prevalence of other documented outcomes of ACP (documents completed by a health practitioner or someone else, such as family or the SDM), assessment of content and quality of ACDs, and concordance between the person's preferences for care as documented in their ACD and medical treatment orders. 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, (10, 11)and quality criteria outlined in the Australian National Framework for ACDs , (8) 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.

Reliability testing

To estimate any potential bias in rating the primary and secondary outcome variables, two data collectors independently rated the same 40 health records and a reliability analysis was undertaken. Both a percentage agreement and a kappa statistic were calculated for primary and secondary outcome variables. For the primary outcome, percentage of agreement between the first and second data collector was 100% respectively and kappa statistic level of agreement was very high

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(Table 3). For secondary outcome variables, percentage of agreement ranged between 97.1% and 100% and kappa statistic level of agreement was good or very good.

Sample size estimation and justification

Sample size calculations are necessary in prevalence studies to ensure that estimates are obtained with adequate precision. (31-33) 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), (26) 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.

Statistical Analysis

Descriptive statistics will be calculated for the total sample and by major grouping site or participant variables. Overall prevalence of ACDs will be calculated for the total sample and separately for healthcare sectors and jurisdictions. Prevalence rates of the types of ACDs, and "other documentation" will also be reported. Comparisons will be made using *t-tests* for the continuous type variables and chi-square contingency table analysis for the categorical type variables.

Similar to the pilot study, descriptive statistics will be used to describe the characteristics and content of ACDs and other documented outcomes of ACP (e.g. by a health professional or

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family/SDM), and the specific preferences for care specified in ACDs in comparison to the content of medical orders. (26, 27)

Due to the nesting of individual records within sites, generalised linear mixed model regression will be performed to determine the predictive value of demographic, clinical and site-level variables on the presence of ACD in the person's record. 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. The level of significance will be set at 0.05.

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.

Project governance

This study is led by ACPA, and will be overseen by a project advisory group, who will meet approximately four times per year via teleconference. The advisory group is chaired by ACPA, and includes academics and clinicians with interdisciplinary expertise relevant to this study including in medicine, nursing, allied health, law and policy. The advisory group also includes representation from hospital, general practice and aged care sectors. The advisory group will co-opt a statistician to provide methodological and statistical advice.

The advisory group will review and endorse the project methodology, and provide advice regarding site recruitment across sectors, risk management, intellectual property and ethical concerns. They

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will provide advice, drawing on their interdisciplinary expertise, on the collection and interpretation of data and on contextual and jurisdictional aspects of the study.

Confidentiality and Privacy

To avoid any potential breach of confidentiality, only staff of the participating organisations directly involved in collection of data will have access to health records. ACPA auditors will be required to adhere to privacy principles of the services they attend. Data will be handled, stored and disposed of according to the Australian National Health and Medical Research Council Code of Responsible Conduct of Research and the National Statement on Ethical Conduct in Research involving Humans.(34, 35) All results will be de-identified and presented in an aggregate format.

Patient and public involvement

The specific intent of this project is to inform service-level initiatives and future ACP programs and policy. People whose records will be audited will not be involved in the audit, the study design or recruitment. As only de-identified information will be collected, it is not possible to provide results to participants. However, study sites will receive de-identified individualised reports including information about their service and how they compare to similar services. The study results will also be provided and discussed with the "National ACP Engagement Advisory Group", which includes representation from consumers and consumer organisations including National Seniors, Dementia Australia, Palliative Care Australia, and the Victorian Cancer Council.

Ethics and dissemination

The research protocol for this study was approved on 14 June 2018 by Austin Health Human Research Ethics Committee (reference number: HREC/18/Austin/109). A waiver of consent

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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.

Study results will be provided to the participating sites and the Australian Government. No reports will identify any specific participant or site but jurisdictional comparisons will be possible. However, we will exercise caution in reporting jurisdictional or setting prevalence results when such results are primarily driven by only one or two sites.

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. Findings will be presented at relevant conferences and published in peer-reviewed journals, on the ACPA website and in lay and social media where appropriate. Investigators will review manuscript drafts, abstracts, press releases and any other publications arising from the study. Authorship will be determined in accordance with the International Committee of Medical Journal Editors guidelines.

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Discussion

Effectiveness of national ACD prevalence research requires standardisation of methodology including the accurate classification of ACP documentation, thereby facilitating meaningful measurement and comparison. The current study has built upon the findings and key learnings from the pilot feasibility study, (26, 27) particularly with respect to training of data collectors, standardisation of methodology and facilitation of consistency regarding document classification.

Strengths

The protocol retains the key study design features of the pilot that were shown to be feasible and successful and improves upon the identified limitations. The study aims to recruit a diverse range of services increasing the generalisability of the measured outcomes. Data collectors from participating sites are trained in audit methodology and ACD classification using a standardised approach. This should facilitate meaningful comparison of prevalence rates between services. Furthermore, given that data collectors are staff from participating sites, education provided as part of this study has the potential to increase knowledge and awareness at the sites, and therefore contribute to capacity building within these sites.

The *National ACD Prevalence Study* will generate one of the largest and most comprehensive datasets on ACD prevalence in Australia and internationally. This dataset will provide information on the types and characteristics of ACP documentation being used within and across three health sectors that can be used to better understand current practice and inform future ACP strategies and initiatives. The findings will also contribute to the methodology of undertaking research into the prevalence of ACP documentation.

Limitations

Recruitment via an expression of interest process means there is a likely selection bias towards sites with an existing interest in ACP. Whilst the aim of this study is to recruit sites across all three health sectors and all eight Australian jurisdictions is it is likely that not all sectors will be similarly represented nor will states and territories, thus limiting generalisability of findings by sector and jurisdiction. 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. This study utilises an audit methodology, and therefore, it is not possible to determine quality and extent of ACP conversations known to be an important determinant of a successful ACP programme.

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Furthermore, given the audit methodology, it will not be possible to determine whether documentation translates into care that is consistent with the person's preferences, the ultimate goal of ACP.

Trial status

Site recruitment for the first round of data collection occurred from June 1st to August 31st 2018. Data collection occurred from October 1st 2018 to 18th January 2019. Data analysis for this round will commence in May 2019. Planning for subsequent rounds of data collection has not commenced.

Authors' contributions: KD and LN were involved in the conception, design, protocol development, and drafting the manuscript; KB was involved in the design, protocol development, and drafting the manuscript; MS, HK, BW and CS were involved in the design, protocol development, and review of the manuscript. All authors read and approved the final manuscript.

Acknowledgements: We acknowledge the valuable contribution of the national prevalence study advisory group. We acknowledge the important contribution and feedback provided by Study Leads and Data Collectors from the 2017 pilot study.

Funding statement: This work was supported by the Australian Government Department of Health.

Competing interests statement. The authors declare that they have no competing interests.

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Box 1. Site eligibility criteria

General criteria: General practices, hospitals and residential aged care facilities are eligible to apply if they:

1. Are an accredited organisation according to sector requirements
2. Have the approval and endorsement of their executive team
3. Can nominate one staff member as the Study Lead (responsible for coordination of the study at the site and will be the key contact person for the research team)
4. Have internet, email and telephone access
5. Have access to devices for online data collection (e.g., computer, laptop or iPad)
6. Have policies in place about privacy and confidentiality
7. Agree that the information provided in their application will be used to generate a Research Collaboration Agreement if successful and are willing to sign this preferably within four weeks of being notified of successful application
8. Meet all sector-specific eligibility criteria.

Sector-specific eligibility criteria.

Hospitals and residential aged care facilities are eligible to apply if they:

1. Expect that their site will have at least 50 patients/ residents on the day(s) of the study that are aged 65 years or older and have been admitted for at least 48 hours*
2. Have a records management system with the ability to extract a list of all admissions of people aged 65 years or older who have been admitted for more than 48 hours on the day(s) of the study
3. Can nominate up to two additional staff members to collect the data for the study.
4. Are willing to support the Study Lead and data collectors(s) to undertake mandatory online training in data collection procedures
5. Have the capacity to review a minimum of 30 health records.

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.

* A minimum of 30 health records will be randomly selected from eligible records on the day(s) of the study.

General practices are eligible to apply if they:

1. Expect that at least 30 patients aged 65 years or older will attend their practice on the day(s) of the study
2. Have a records management system with the ability to extract a list of all people aged 65 years or older attending the practice on the day(s) of the study
3. Can nominate up to two additional staff members to collect the data for the study OR agree to data collector(s) being provided by Advance Care Planning Australia.

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Box 2. National Advance Care Directive Prevalence Study: Data collection training and manual

Online training

Key content	Mode of delivery

• Advance care planning and advance care directives
• Overview of the National Advance Care Directive Prevalence Study
• Advance care planning documentation: definitions, classification for study
• Review of data items and how to collect data
	• PowerPoint presentation
	• Role plays demonstrating:
	  ○ A data collector undertaking the audit and entering data
	  ○ A Study Lead performing the randomisation procedure
	• Interactive discussion regarding:
	  ○ Types of advance care planning documentation
	  ○ Demonstration of how to use flow chart for classification
	  ○ Tips for success

Data Collection Manual

Section 1: Background information and context for the National Advance Care Directive Prevalence Study.

Section 2: Overview of the National Advance Care Directive Prevalence Study.

Section 3: Description of how to collect study data including the documentation sought during the audit.

Section 4: Instructions on how to use the online data collection database.

Section 5: Additional information relevant to Study Leads.

Section 6: Troubleshooting instructions for problems.

Section 7: List of frequently asked questions.

Section 8: Test questions (with answers) to be used to assess knowledge and understanding of the terminology and concepts needed to conduct the audit.

Attachments

Contains documents to assist with study and data collection. These include:

- A flowchart of relevant documentation to the audit
- A decision tree to help with classification of advance care planning documentation
- A list of statutory advance care directives used in Australia
- Checklists for Study Leads to prepare for study day
- A list of contact numbers

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Table 1: Site-level data variables

Category	Variable(s)
Demographic information	Jurisdiction, location, funding (government, not-for-profit, private), record management system used.
Size of service	Number of beds, number of health staff
Advance care planning (ACP) program / activity	Current ACP program/activity within the service, when this commenced, ACP training available for staff and how ACP is funded and/or implemented Presence/absence of ACP policy, consumer resources, and Advance care directive templates/forms. (*Sites will be asked to upload their ACP policy documents and / or blank ACD templates/forms utilised in their service.)*

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Table 2: Participant data variables

Category	Variable(s)
Demographic information	Age, gender, postcode, country of birth, relationship status, religion, English or other language spoken
Clinical information	Date of admission/visit, current/active medical conditions (categorised by organ systems), palliative care status, Eastern Cooperative Oncology Group (ECOG) status (or estimated functional status if ECOG not available)
Type of documentation (see Figure 1) *Classified based on who completed documentation*	Completed by: • The person (statutory and non-statutory advance care directives; other e.g. letter) • A health professional (medical orders/clinical care plans; advance care planning documentation) • Someone else (advance care planning documentation by family, substitute decision-maker etc.) • Miscellaneous advance care planning material (e.g. brochure)
Details of documentation	Time taken to find document, location of document in the health record, date of document, whether the document contains the person's name, address and date of birth, information regarding who signed documentation (including witnesses where appropriate), treatment preferences and/or other preferences specified in the document, characteristics of medical orders

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Table 3. Reliability analysis (n=40)

Variable	% Agreement	Kappa (95%CI)	Kappa agreement	*p*
ACP documentation by the person	**100 (5 documents)**	**1.0**	**Very good**	**<.001**
Statutory ACD: preferences for care	100 (0 documents)	1.0	Very good	<.001
Statutory ACD: SDM	100 (4 documents)	1.0	Very good	<.001
Non-statutory ACP documentation	100 (2 documents)	1.0	Very good	<.001
Documentation by a health professional	**97.1 (33 of 34 documents)**	**0.804 (0.541-1.0)**	**Good**	**<.001**
Documentation by someone else	**100 (1 document)**	**1.0**	**Very good**	**<.001**

Note. ACP = advance care planning; ACD = advance care directive; CI = confidence interval; SDM = substitute decision-maker.

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Caption

Figure 1

Example of a jurisdiction-specific flowchart provided to data collectors to help them classify documentation identified in the audit.

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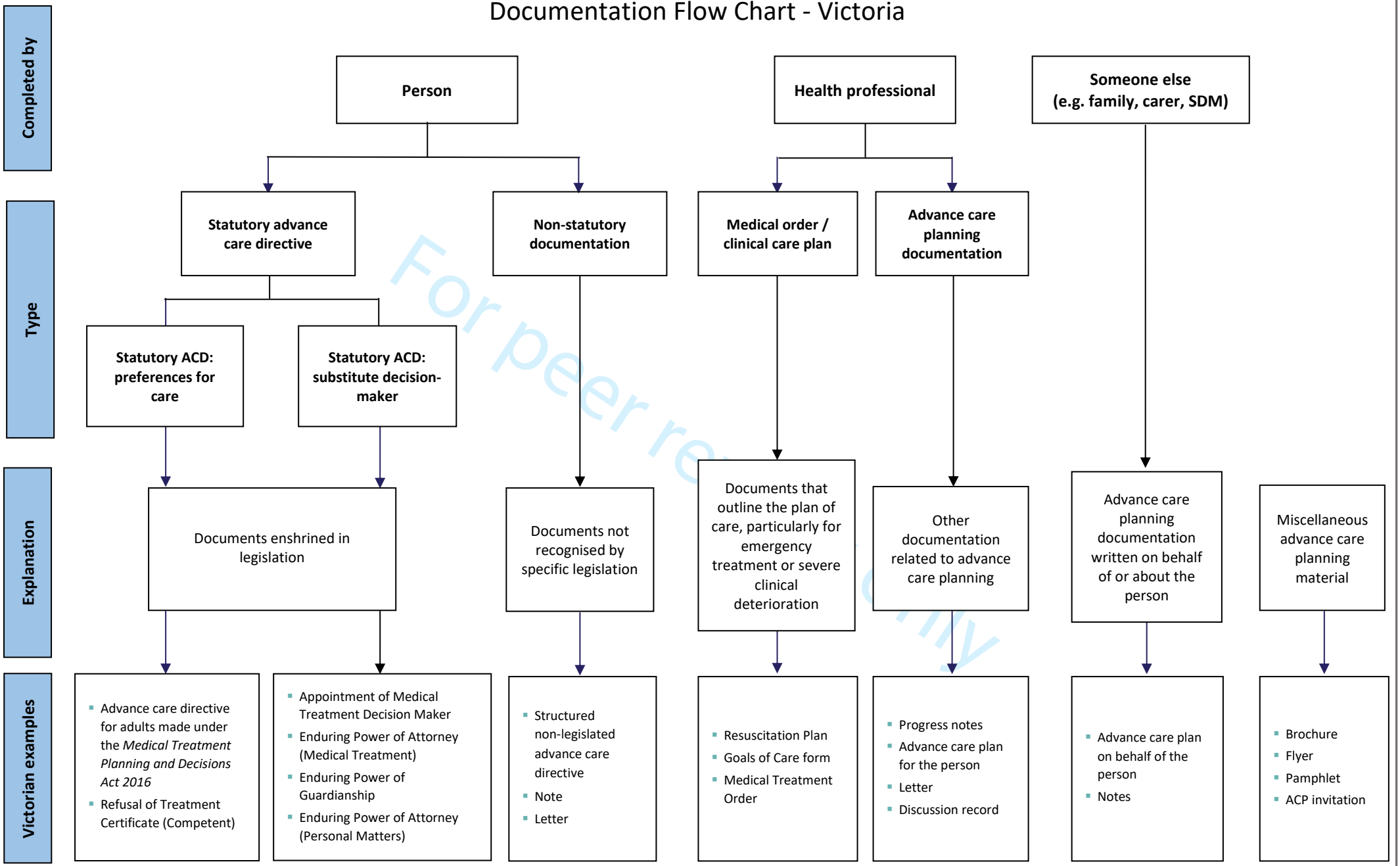
Documentation Flow Chart - Victoria



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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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-031691.R2
Article Type:	Protocol
Date Submitted by the Author:	28-Sep-2019
Complete List of Authors:	Detering, Karen; Austin Health, Advance Care Planning Australia; University of Melbourne, Faculty of Medicine, Dentistry and Health Science Buck, Kimberly; Austin Health, Advance Care Planning Australia Sellars, Marcus; Austin Health, Advance Care Planning Australia Kelly, Helana; Austin Health, Advance Care Planning Australia Sinclair, Craig; University of New South Wales, Centre of Excellence in Population Aging Research White, Ben ; Queensland University of Technology, Institute of Health and Biomedical Innovation Nolte, Linda; Austin Health, Advance care planning Program
Primary Subject Heading:	Health services research
Secondary Subject Heading:	General practice / Family practice, Geriatric medicine, Patient-centred medicine
Keywords:	advance care planning, advance care directive, prevalence, health service, quality

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Title: 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

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Word count

Abstract: (max 299)

Main text: (max 4000) currently 3971

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Abstract

Introduction: Advance care planning, (ACP) an ongoing communication and planning process, aims to clarify a person's values and preferences, so these guide decision-making if the person becomes unable to make their own decisions. Ideally, ACP results in completion of advance care directives (ACD), documents completed by competent people outlining their values, treatment preferences and/or appointment of a substitute decision-maker. ACDs are most effective at the point-of-care, where they can be used to inform treatment decisions. Australian governments fund initiatives and have developed policy to increase ACD completion rates. However, little is known about the prevalence of ACDs at the point-of-care in Australian health services, making ACP evaluation efforts difficult. This study aims to determine the prevalence of ACDs in records of older people in Australian hospitals, aged care facilities and general practices.

Methods and analysis: This is a national multicentre cross-sectional prevalence study in selected aged care facilities, hospitals and general practices. Following a 2017 feasibility study, a new protocol incorporating key learnings was developed. Sites will be recruited via expression of interest process. Health records of people aged ≥ 65 years, admitted to, or attending services on study day(s) will be audited by trained staff from sites. Site-level data will be collected during the expression of interest. The primary outcome is the presence of at least one ACD in the health record. Secondary outcomes include prevalence of other documented outcomes of ACP (by health practitioner(s)/family/substitute decision-maker), assessment of ACD quality and content and concordance between the person's documented preferences and any medical treatment orders. Individuals and sites Characteristics where ACDs are present will be explored.

Ethics and dissemination: Protocol approval by Austin Health Human Research Ethics Committee, Melbourne, Australia (reference:HREC/18/Austin/109). Results will be disseminated via peer-

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reviewed journals and conferences. Participating sites and jurisdictions will receive individualised reports of findings.

Strengths and limitations of this study

- This national multicentre cross-sectional prevalence study aims to determine the prevalence and characteristics of advance care directives in Australian residential aged care facilities, hospitals and general practices.
- Trained data collectors from participating sites will conduct the audit of health records to identify advance care directives.
- This protocol builds upon the key findings and learnings from a 2017 pilot feasibility study and includes improvements in the training of data collectors, standardisation of data collection, and classification of documents.
- The results of this study will contribute to the methodology of undertaking research into the prevalence of advance care planning documentation and will inform advance care planning implementation strategies and evaluation processes.
- The recruitment strategy for sites, using an expression of interest process, is likely to result in a selection bias towards organisations with an interest in advance care planning.

INTRODUCTION

Background

Advance care planning (ACP) is a coordinated communication and planning process that aims to clarify and share a person's values and preferences for medical treatment so as to guide health care decision-making should the person subsequently lose the capacity to make or communicate such decisions in the future. (1, 2) The ultimate goal of ACP is to ensure care received is consistent with the person's known preferences. (2) ACP has been shown to improve outcomes for patients, their families, healthcare staff and the health care system. (3-6)

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Ideally ACP discussions should result in documentation recording a person's values and preferences and/or appointment of a substitute decision-maker (SDM). (2, 7) Documentation is an important component of ACP. It has been shown to improve outcomes for people and provides information and support for SDMs, caregivers and clinicians who may be required to make treatment decisions on behalf of a person whose decision-making capacity is impaired. (2, 8-10)

The names, scope and legal requirements of ACP documentation vary considerably within Australia and internationally. (10-16) 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. (17)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. ACP documentation may also be completed on behalf of the person by a health professional or someone else (SDM / family). Additionally, medical treatment orders that describe action to be taken in an emergency, such as "Goals of Care", "Resuscitation Plans", and "Physician Orders for Life-Sustaining Treatment", may also include reference to a person's preferences for care. (18-20). These are completed and signed by a doctor.

For the potential benefits of ACDs and other documented outcomes of ACP to be realised, it is critical that documentation is accessible at the point-of-care should the person be unable to participate in decision-making. (21, 22) If health care providers do not have access to the person's documented preferences when treatment decisions are required, the person may receive care that is inconsistent with their preferences (23). In Australian health services, a range of systems are used to store and retrieve ACDs, including service-specific electronic health record systems, scanned

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medical records, hardcopy files, or a combination. (23) Most health services also now have access to 'My Health Record', a new centralised national e-health record that offers online storage of ACDs. While some services may have mechanisms to elicit existing ACDs upon admission, many will rely on the person to provide their documentation to relevant providers. (23)

Although support for ACP and ACDs continues to grow in Australian policy and legislative frameworks, (8, 17, 24, 25) there is a lack of national data on the prevalence, content and quality of ACDs at the point of care in Australian health services. Without this information, governments have limited ability to monitor the effectiveness and impact of ACP policy and programs, and organisations lack evidence to inform service-level programs and initiatives to increase ACD uptake.

In 2017, an Australian-first pilot feasibility study was conducted by Advance Care Planning Australia (ACPA) to assess the prevalence of ACDs among older adults accessing Australian health and residential aged care services. (26) Of 2285 health records audited across 51 sites, 30% contained at least one ACD. The ACD prevalence was significantly higher in residential aged care facilities (48%) compared to hospitals (16%) and general practices, (3%) and varied considerably across participating sites. (26) A further 20% of people had 'other ACP documentation'. This likely included documents that were not formal ACDs (e.g. personal letters) or documentation completed on behalf of the person (e.g. by a health professional, a family member or the SDM). However, the exact nature or authorship of this "other ACP documentation" was unclear. (26)

During 2018-20, ACPA has been funded by the Australian Government to deliver the *National ACD Prevalence Study*. This study will build upon the findings and methodology of the pilot feasibility study (26, 27) to collect a national dataset on the prevalence and characteristics of ACDs and other documented outcomes of ACP among older people accessing general practices, hospitals and

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residential aged care facilities across Australia. The study will provide data to assist organisations and governments understand how well ACP is being implemented in Australia and identify areas for improvement. It will also contribute to the methodology of undertaking research into the prevalence of ACP documentation.

Aims and Hypotheses

The aims of the *National ACD Prevalence Study* are to:

1. Determine the prevalence of ACDs and other documented outcomes of ACP among people aged ≥65 years accessing Australian general practices, hospitals and residential aged care facilities.
2. Assess the content and quality of identified ACDs.
3. Explore consistency between medical orders and the person's documented preferences for care.
4. Explore the characteristics of individuals and study sites where ACDs are present in the health record.

Based on previous Australian studies (26, 28, 29), we hypothesise that the overall prevalence of ACDs will be low, and there will be more non-statutory ACDs and "statutory ACD: appointment of SDM", than "statutory ACD: preferences for care". We expect to find various other ACP documents completed by health professionals, SDMs and/or family. We anticipate prevalence will be highest in residential aged care facilities and lowest in general practice and expect a wide range of ACD prevalence rates within each sector. We hypothesise that there will be variation in the content and quality of ACDs, and that many ACDs will not meet signing and witnessing requirements specified in jurisdictional legislation (8, 11) or quality criteria outlined in the Australian National Framework for ACDs. (8) We hypothesise that where there is an ACD, medical orders will be consistent with the person's preferences. We expect a range of individual and site factors to be associated with the

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presence of an ACD, including demographic and clinical characteristics and site-reported organisational support for ACP.

METHODS AND ANALYSIS

Overview of modifications to the original pilot study protocol

The 2017 pilot feasibility study (26, 27) provided key learnings that have informed the current protocol for the *National ACD Prevalence Study*. Based on these learnings, a number of modifications were made to the study design, 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.

Study design

The *National ACD Prevalence Study* is a 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 those services, conducted by trained staff from participating sites.

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. 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.

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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."* . 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.

Part 1. Study Sites

Study sites will include Australian general practices, public and private hospitals and residential aged care facilities, recruited from all eight Australian states and territories (jurisdictions). A minimum of 24 sites will be included in each round of data collection.

Recruitment

Sites will be recruited through an expression of interest process, coordinated by ACPA and promoted via state and territory departments of health and stakeholder networks utilising newsletters and websites. Depending on responses to the expression of interest process for each round of data collection, additional sites may be approached by the project team to promote representativeness across sectors (residential aged care facilities, hospital and general practice) and jurisdictions. All prospective sites will be required to complete an online expression of interest application (see site-level data collection below). Based on feedback from the pilot study, detailed application guidelines including a set of general and sector-specific eligibility criteria (Box 1) were developed.

Box 1 about here

Site-level data collection

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Section one of the expression of interest application assesses site eligibility. Sites must meet all criteria before they can proceed. Section two and three of the application collects site-level data. (Table 1) Data items are informed by the pilot study, a literature review of system factors potentially important for ACP/ACD implementation and uptake, and guidance from the project advisory group. Study sites are also required to nominate a Study Lead and one to three data collectors in the expression of interest application.

Table 1 about here

Part 2: Health record audit

Audit participants will comprise people aged 65 years or older who are admitted to participating hospitals or residential aged care facilities for at least 48 hours prior to audit, or attending general practices on the nominated day(s) of the study. 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.

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.

Sites are required to nominate how many records they intend to audit (minimum of 30 and maximum of 50 records) prior to their study day(s).

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Record selection

In hospitals and residential aged care facilities, health records will be randomly selected from a list of all eligible people using a simple randomisation procedure, designed to protect against selection bias. On the first day of the study, 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.

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For practicality purposes, consecutive eligible records will be audited in general practices until the required number has been achieved.

Data collection: training, procedures, and support

Participating sites will identify up to three data collector(s) (may include Study Lead), to undertake the audit. Study Leads and data collectors are expected to complete compulsory online training (approximately 60 minutes) and will have access to a data collection manual (Box 2). ACP legislation in Australia is determined by each jurisdiction, (11) and therefore jurisdiction-specific manuals will be provided. Researchers based at ACPA will be available via telephone for consultation throughout the study.

Box 2 about here

Data collection will occur during defined periods. Sites are required to nominate one to three consecutive days for data collection. 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. Data variables extracted will include demographic and clinical information, and details regarding the type, content and characteristics of ACP documentation and/or medical orders (Table 2).

Table 2 about here

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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.

ACPA may provide data collector(s) to undertake audit in general practices, and in hospitals and aged care facilities in remote or regional areas that would otherwise be unable to participate due to limited resources. These auditors will not be members of the research team, will complete all required training and will meet privacy and confidentiality requirements of the organisation where they collect data.

All data will be entered directly into a password protected online database specifically built for this project, and hosted by REDCap (www.project-redcap.org). The database will be available via web-based user interface using a personal computer, laptop or tablet. Each data collector will receive a unique login name and password. Each site will have an identification number, which will be known only to the site and the researchers conducting the analyses. The database will have in-built validation and range checks to reduce data errors.

The pilot study identified important issues with some data variables. In particular, data collectors reported difficulty classifying ACP documentation. Furthermore, based on free text responses it is likely that some documents were incorrectly classified. Thus in the present study, further information is provided regarding the nature of different documents they may encounter and characteristics of each to facilitate consistent classification. Whilst the pilot study showed ACD prevalence of 30%, a further 20% of people had 'other ACP documentation'. (27) The nature of these documents is unclear. ACDs are documents completed by competent people and come into effect if

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the person subsequently loses capacity to make their own decisions. However, ACP documentation is sometimes completed by people other than the person concerned, (3, 6, 21, 26, 30) which may also be of benefit for people without an ACD, who no longer have capacity. This is currently an underexplored area of ACP practice. Consequently, in this study, the process of facilitating correct classification of documentation has changed. We have developed a process and flow chart based on who completed documentation (Figure 1) and have provided detailed instructions and examples in education and study manuals.

Feedback from the pilot indicated that data collectors had difficulty classifying some medical conditions . To address this, data collectors will be instructed to record only current/active medical conditions, and a range of examples will be provided for each of the categories. The pilot also had a substantial amount of missing data (30%) for the Eastern Cooperative Oncology Group (ECOG) status variable. The revised audit tool includes an additional question asking data collectors to estimate the person's level of functional disability based on available information in the person's record if the actual ECOG rating is not available. These items may be combined during analysis into an overall 'estimated' level of functional disability. In the pilot, there was also evidence of data entry errors in the database. For this study, the database logic has been reviewed, more detailed instructions will be provided within the database and study manuals, and additional in-built validation checks will be added. We will also conduct comprehensive user testing of the database and improve education provided to data collectors regarding database usage.

Data de-identification

A study ID number will be assigned to each person on the audit list, and will be used for data entry. Participating sites will be able to match study IDs with specific people. Identifiable information will not be recorded or disclosed to the research team.

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Outcomes

The primary outcome will be the presence of at least one ACD (statutory ACD: preferences for care, statutory ACD: SDM, and/or non-statutory ACD) that are located within 15 minutes of accessing the record. Secondary outcomes will include prevalence of other documented outcomes of ACP (documents completed by a health practitioner or someone else, such as family or the SDM), assessment of content and quality of ACDs, and concordance between the person's preferences for care as documented in their ACD and medical treatment orders. 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, (10, 11)and quality criteria outlined in the Australian National Framework for ACDs , (8) 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.

Reliability testing

To estimate any potential bias in rating the primary and secondary outcome variables, two data collectors independently rated the same 40 health records and a reliability analysis was undertaken. 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 someone else). For each of the primary outcome measures, percentage of agreement between the first and second data collector was 100%

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respectively and kappa statistic level of agreement was very high (Table 3). For secondary outcome variables, percentage of agreement ranged between 97.1% and 100% and kappa statistic level of agreement was good or very good.

Sample size estimation and justification

Sample size calculations are necessary in prevalence studies to ensure that estimates are obtained with adequate precision. (31-33) 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), (26) 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.

Statistical Analysis

Descriptive statistics will be calculated for the total sample and by major grouping site or participant variables. Overall prevalence of ACDs will be calculated for the total sample and separately for healthcare sectors and jurisdictions. Prevalence rates of the types of ACDs, and "other documentation" will also be reported. Comparisons will be made using *t-tests* for the continuous type variables and chi-square contingency table analysis for the categorical type variables.

Similar to the pilot study, descriptive statistics will be used to describe the characteristics and content of ACDs and other documented outcomes of ACP (e.g. by a health professional or

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family/SDM), and the specific preferences for care specified in ACDs in comparison to the content of medical orders. (26, 27)

Due to the nesting of individual records within sites, generalised linear mixed model regression will be performed to determine the predictive value of demographic, clinical and site-level variables on the presence of ACD in the person's record. 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. The level of significance will be set at 0.05.

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.

Project governance

This study is led by ACPA, and will be overseen by a project advisory group, who will meet approximately four times per year via teleconference. The advisory group is chaired by ACPA, and includes academics and clinicians with interdisciplinary expertise relevant to this study including in medicine, nursing, allied health, law and policy. The advisory group also includes representation from hospital, general practice and aged care sectors. The advisory group will co-opt a statistician to provide methodological and statistical advice.

The advisory group will review and endorse the project methodology, and provide advice regarding site recruitment across sectors, risk management, intellectual property and ethical concerns. They

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will provide advice, drawing on their interdisciplinary expertise, on the collection and interpretation of data and on contextual and jurisdictional aspects of the study.

Confidentiality and Privacy

To avoid any potential breach of confidentiality, only staff of the participating organisations directly involved in collection of data will have access to health records. ACPA auditors will be required to adhere to privacy principles of the services they attend. Data will be handled, stored and disposed of according to the Australian National Health and Medical Research Council Code of Responsible Conduct of Research and the National Statement on Ethical Conduct in Research involving Humans.(34, 35) All results will be de-identified and presented in an aggregate format.

Patient and public involvement

The specific intent of this project is to inform service-level initiatives and future ACP programs and policy. People whose records will be audited will not be involved in the audit, the study design or recruitment. As only de-identified information will be collected, it is not possible to provide results to participants. However, study sites will receive de-identified individualised reports including information about their service and how they compare to similar services. The study results will also be provided and discussed with the "National ACP Engagement Advisory Group", which includes representation from consumers and consumer organisations including National Seniors, Dementia Australia, Palliative Care Australia, and the Victorian Cancer Council.

Ethics and dissemination

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The research protocol for this study was approved on 14 June 2018 by Austin Health Human Research Ethics Committee (reference number: HREC/18/Austin/109). A waiver of consent application was made and granted as part of the original ethics application.

Study results will be provided to the participating sites and the Australian Government. No reports will identify any specific participant or site but jurisdictional comparisons will be possible. However, we will exercise caution in reporting jurisdictional or setting prevalence results when such results are primarily driven by only one or two sites.

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. Findings will be presented at relevant conferences and published in peer-reviewed journals, on the ACPA website and in lay and social media where appropriate. Investigators will review manuscript drafts, abstracts, press releases and any other publications arising from the study. Authorship will be determined in accordance with the International Committee of Medical Journal Editors guidelines.

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Discussion

Effectiveness of national ACD prevalence research requires standardisation of methodology including the accurate classification of ACP documentation, thereby facilitating meaningful measurement and comparison. The current study has built upon the findings and key learnings from the pilot feasibility study, (26, 27) particularly with respect to training of data collectors, standardisation of methodology and facilitation of consistency regarding document classification.

Strengths

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The protocol retains the key study design features of the pilot that were shown to be feasible and successful and improves upon the identified limitations. The study aims to recruit a diverse range of services increasing the generalisability of the measured outcomes. Data collectors from participating sites are trained in audit methodology and ACD classification using a standardised approach. This should facilitate meaningful comparison of prevalence rates between services. Furthermore, given that data collectors are staff from participating sites, education provided as part of this study has the potential to increase knowledge and awareness at the sites, and therefore contribute to capacity building within these sites.

The *National ACD Prevalence Study* will generate one of the largest and most comprehensive datasets on ACD prevalence in Australia and internationally. This dataset will provide information on the types and characteristics of ACP documentation being used within and across three health sectors that can be used to better understand current practice and inform future ACP strategies and initiatives. The findings will also contribute to the methodology of undertaking research into the prevalence of ACP documentation.

Limitations

Recruitment via an expression of interest process means there is a likely selection bias towards sites with an existing interest in ACP. Whilst the aim of this study is to recruit sites across all three health sectors and all eight Australian jurisdictions is it is likely that not all sectors will be similarly represented nor will states and territories, thus limiting generalisability of findings by sector and jurisdiction. 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. This study utilises an audit methodology, and therefore, it is not possible to determine quality and extent of ACP conversations known to be an important determinant of a successful ACP programme.

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Furthermore, given the audit methodology, it will not be possible to determine whether documentation translates into care that is consistent with the person's preferences, the ultimate goal of ACP.

Trial status

Site recruitment for the first round of data collection occurred from June 1st to August 31st 2018. Data collection occurred from October 1st 2018 to 18th January 2019. Data analysis for this round will commence in May 2019. Planning for subsequent rounds of data collection has not commenced.

Authors' contributions: KD and LN were involved in the conception, design, protocol development, and drafting the manuscript; KB was involved in the design, protocol development, and drafting the manuscript; MS, HK, BW and CS were involved in the design, protocol development, and review of the manuscript. All authors read and approved the final manuscript.

Acknowledgements: We acknowledge the valuable contribution of the national prevalence study advisory group. We acknowledge the important contribution and feedback provided by Study Leads and Data Collectors from the 2017 pilot study.

Funding statement: This work was supported by the Australian Government Department of Health.

Competing interests statement. The authors declare that they have no competing interests.

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Box 1. Site eligibility criteria

General criteria: General practices, hospitals and residential aged care facilities are eligible to apply if they:

1. Are an accredited organisation according to sector requirements
2. Have the approval and endorsement of their executive team
3. Can nominate one staff member as the Study Lead (responsible for coordination of the study at the site and will be the key contact person for the research team)
4. Have internet, email and telephone access
5. Have access to devices for online data collection (e.g., computer, laptop or iPad)
6. Have policies in place about privacy and confidentiality
7. Agree that the information provided in their application will be used to generate a Research Collaboration Agreement if successful and are willing to sign this preferably within four weeks of being notified of successful application
8. Meet all sector-specific eligibility criteria.

Sector-specific eligibility criteria.

Hospitals and residential aged care facilities are eligible to apply if they:

1. Expect that their site will have at least 50 patients/ residents on the day(s) of the study that are aged 65 years or older and have been admitted for at least 48 hours*
2. Have a records management system with the ability to extract a list of all admissions of people aged 65 years or older who have been admitted for more than 48 hours on the day(s) of the study
3. Can nominate up to two additional staff members to collect the data for the study.
4. Are willing to support the Study Lead and data collectors(s) to undertake mandatory online training in data collection procedures
5. Have the capacity to review a minimum of 30 health records.

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.

* A minimum of 30 health records will be randomly selected from eligible records on the day(s) of the study.

General practices are eligible to apply if they:

1. Expect that at least 30 patients aged 65 years or older will attend their practice on the day(s) of the study
2. Have a records management system with the ability to extract a list of all people aged 65 years or older attending the practice on the day(s) of the study
3. Can nominate up to two additional staff members to collect the data for the study OR agree to data collector(s) being provided by Advance Care Planning Australia.

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Box 2. National Advance Care Directive Prevalence Study: Data collection training and manual

Online training

Key content	Mode of delivery

• Advance care planning and advance care directives
• Overview of the National Advance Care Directive Prevalence Study
• Advance care planning documentation: definitions, classification for study
• Review of data items and how to collect data
	• PowerPoint presentation
	• Role plays demonstrating:
	  ○ A data collector undertaking the audit and entering data
	  ○ A Study Lead performing the randomisation procedure
	• Interactive discussion regarding:
	  ○ Types of advance care planning documentation
	  ○ Demonstration of how to use flow chart for classification
	  ○ Tips for success

Data Collection Manual

Section 1: Background information and context for the National Advance Care Directive Prevalence Study.

Section 2: Overview of the National Advance Care Directive Prevalence Study.

Section 3: Description of how to collect study data including the documentation sought during the audit.

Section 4: Instructions on how to use the online data collection database.

Section 5: Additional information relevant to Study Leads.

Section 6: Troubleshooting instructions for problems.

Section 7: List of frequently asked questions.

Section 8: Test questions (with answers) to be used to assess knowledge and understanding of the terminology and concepts needed to conduct the audit.

Attachments

Contains documents to assist with study and data collection. These include:

- A flowchart of relevant documentation to the audit
- A decision tree to help with classification of advance care planning documentation
- A list of statutory advance care directives used in Australia
- Checklists for Study Leads to prepare for study day
- A list of contact numbers

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Table 1: Site-level data variables

Category	Variable(s)
Demographic information	Jurisdiction, location, funding (government, not-for-profit, private), record management system used.
Size of service	Number of beds, number of health staff
Advance care planning (ACP) program / activity	Current ACP program/activity within the service, when this commenced, ACP training available for staff and how ACP is funded and/or implemented Presence/absence of ACP policy, consumer resources, and Advance care directive templates/forms. (*Sites will be asked to upload their ACP policy documents and / or blank ACD templates/forms utilised in their service.)*

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Table 2: Participant data variables

Category	Variable(s)
Demographic information	Age, gender, postcode, country of birth, relationship status, religion, English or other language spoken
Clinical information	Date of admission/visit, current/active medical conditions (categorised by organ systems), palliative care status, Eastern Cooperative Oncology Group (ECOG) status (or estimated functional status if ECOG not available)
Type of documentation (see Figure 1) *Classified based on who completed documentation*	Completed by: • The person (statutory and non-statutory advance care directives; other e.g. letter) • A health professional (medical orders/clinical care plans; advance care planning documentation) • Someone else (advance care planning documentation by family, substitute decision-maker etc.) • Miscellaneous advance care planning material (e.g. brochure)
Details of documentation	Time taken to find document, location of document in the health record, date of document, whether the document contains the person's name, address and date of birth, information regarding who signed documentation (including witnesses where appropriate), treatment preferences and/or other preferences specified in the document, characteristics of medical orders

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Table 3. Reliability analysis (n=40)

Variable	% Agreement	Kappa (95%CI)	Kappa agreement	*P*
ACP documentation by the person	**100 (5 documents)**	**1.0**	**Very good**	**<.001**
Statutory ACD: preferences for care	100 (0 documents)	1.0	Very good	<.001
Statutory ACD: SDM	100 (4 documents)	1.0	Very good	<.001
Non-statutory ACP documentation	100 (2 documents)	1.0	Very good	<.001
Documentation by a health professional	**97.1 (33 of 34 documents)**	**0.804 (0.541-1.0)**	**Good**	**<.001**
Documentation by someone else	**100 (1 document)**	**1.0**	**Very good**	**<.001**

Note. ACP = advance care planning; ACD = advance care directive; CI = confidence interval; SDM = substitute decision-maker.

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Caption

Figure 1

Example of a jurisdiction-specific flowchart provided to data collectors to help them classify documentation identified in the audit.

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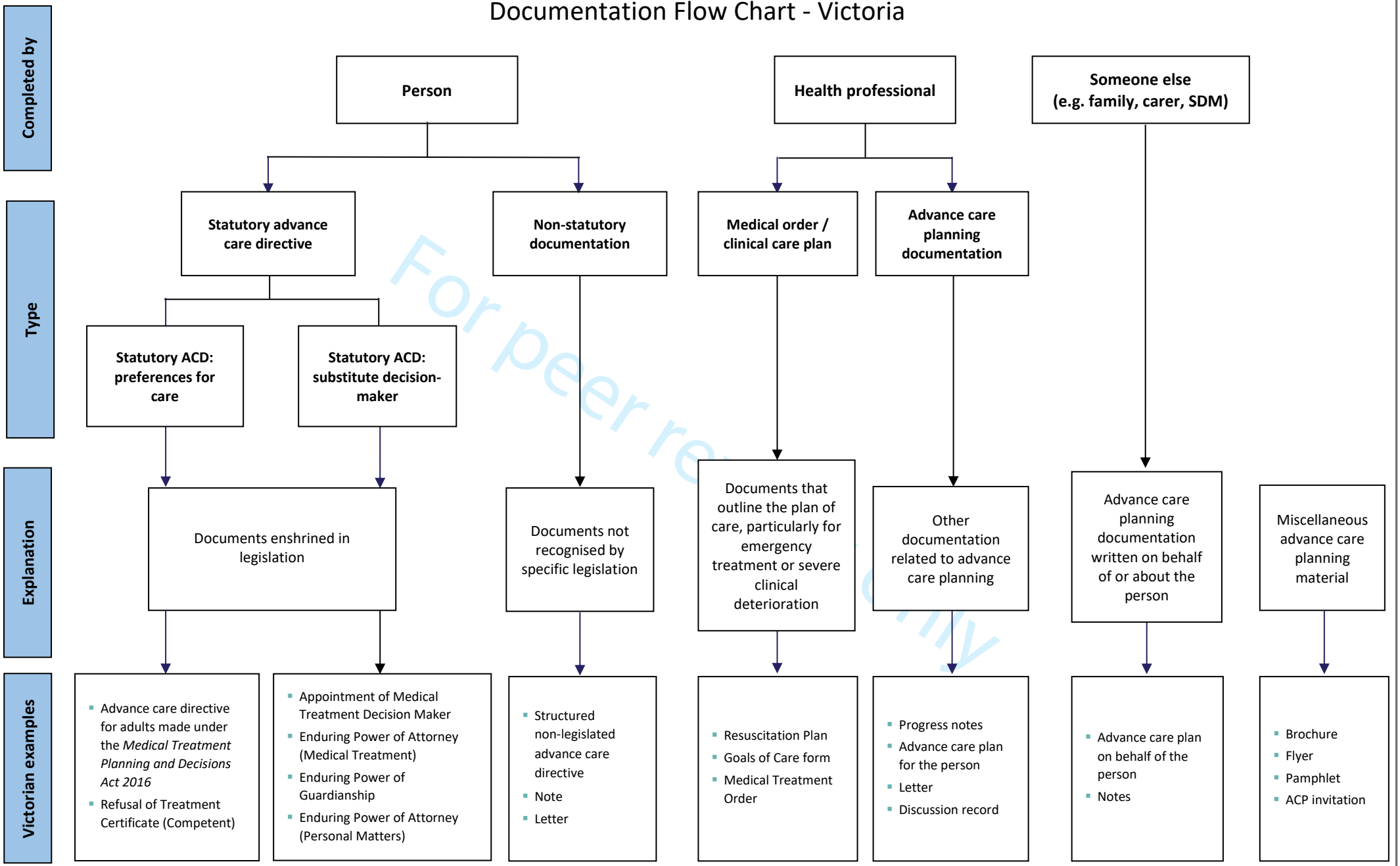
Documentation Flow Chart - Victoria



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