ADVANCE PLANNING FOR HEALTHCARE AND RESEARCH PARTICIPATION: LAW, ETHICS AND PRACTICE

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Declarations

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List of thesis publications

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ABSTRACT

This thesis focuses on advance planning for health-related matters, including medical care and participation in research. It brings interdisciplinary attention to the legal and ethical frameworks that govern how people can plan for future incapacity and investigates how the rights to plan ahead are acted upon and supported in practice. Dementia is a particular focus of this thesis as it is a leading cause of cognitive impairment among older people, and advance planning for incapacity is considered part of good dementia care. Advance care planning (ACP) can improve healthcare experiences and end-of-life outcomes, while advance research planning can help to support the appropriate inclusion of people with cognitive impairment in research studies.

Papers 1–3 focus on advance planning for medical care, with attention to the under-examined role of lawyers in assisting older clients with ACP. Paper 1 provides a literature review and considers how collaboration between health and legal professionals can strengthen ACP. Paper 2 presents a framework for action to build connections between these typically "siloed" professions. Paper 3 presents findings from a survey of legal practitioners on their practices and experiences in advising clients on ACP. Lawyers perceive this activity as part of their professional role, but report gaps in their knowledge of health system policies and procedures relevant to ACP. These findings support the need for collaborative ACP strategies that involve the legal and health sectors.

Papers 4–7 focus on advance research planning and the inclusion of older people with cognitive impairment in research studies. The under-representation of people with dementia in research limits the evidence base to inform advances in treatment and care for this population. The principles and processes that undergird ACP can be applied to planning for involvement in

research activities during future periods of incapacity, allowing greater representation of people with dementia in research. Paper 4 examines the Australian ethical and legal context for inclusion of people with dementia in research. Papers 5–7 report on the results of surveys exploring the attitudes of older adults and researchers toward research involving people with dementia. Paper 5 reveals positive attitudes among older adults to involvement in a wide range of research activities in the event of future incapacity, and to making an advance research directive to document their preferences for future research participation. Papers 6 and 7 report on a national survey of Australian dementia researchers, revealing persistent ethical, legal and practical barriers to involving people who lack decisional capacity in research, but positive views on the benefits of advance research planning as a strategy to support inclusion.

The thesis includes studies completed in Australia and Canada, two countries with ageing populations and similar health and legal systems. The work advances knowledge to inform strategies to build collaboration between the health and legal sectors, strengthen professional practices, enable older adults to act on their rights to plan for future incapacity and overcome barriers to research participation for people living with reduced decisional capacity.

SYNOPSIS

This thesis by publication focuses on advance planning for health-related matters, including medical care and participation in research. It brings original, interdisciplinary attention to the health and legal issues that arise in the context of planning for decisional incapacity.

Applying the candidate's scholarly and professional background in law, the research considers legislative and ethical frameworks that govern how people can plan for future incapacity. To bridge the gap between the macro-level rules and what happens in practice, the candidate applies empirical methods of behavioural science to investigate the attitudes and practices of legal and health research practitioners and older community members. The findings produce new knowledge on how the rights to plan ahead are understood and acted upon, and can be supported.

The PhD research involved three empirical studies, and seven papers were prepared for publication. At the time of thesis submission, four papers have been published in peer-reviewed journals, one has been accepted for publication and two are under current editorial review. The thesis consists of an introduction, the seven papers and a concluding chapter.

The **Introduction** articulates the context for the PhD research. It first discusses the salience of advance planning for incapacity in the contemporary context of ageing populations where more people are living with dementia and other conditions that impair cognitive functioning. The Introduction defines advance planning, summarises the benefits of engaging in ACP and discusses the need for whole-community approaches to improve awareness and uptake of the rights to plan for incapacity. Despite lawyers' important role in educating and advising clients on advance planning rights, virtually no research engages with the legal profession to understand

lawyers' attitudes, beliefs and practices in relation to ACP. The involvement of lawyers in assisting clients with advance planning is highlighted as an under-explored topic that this thesis investigates.

The principles and processes that undergird ACP can be applied to the concept of advance planning for research participation. There are numerous gaps in the evidence to inform interventions that are available for people with progressive neurocognitive illness. The Introduction discusses the importance of including people with impaired cognition in research in order to ameliorate gaps in the evidence to inform care and supports for people with dementia and other neurocognitive disorders. The concept of advance research planning is presented as a means to enable people, when they have decision-making capacity, to express their wishes about involvement in research during future incapacity and to select a proxy decision-maker for research matters. The Introduction concludes by identifying the need for empirical research to inform potential approaches to advance research planning.

Papers 1–3 focus on advance planning for medical care, with attention to the gap between the right to engage in ACP and its uptake in practice and the under-examined role of the legal profession in advising clients on advance planning. **Paper 1**, based on a comprehensive literature review, analyses the important medico-legal intersections that arise in the context of ACP, both at the macro-level of public policy and the micro-level of individual planning and decision-making. Importantly, law establishes the framework in which ACP occurs, and yet lack of knowledge of relevant legal rules is a factor that inhibits health practitioners from broaching ACP with their patients. This paper, published in the *Journal of Law and Medicine,* highlights the ways in which greater collaboration between legal and health professionals can address barriers to ACP at client, practitioner and system levels.

Paper 2 builds on the analysis in Paper 1 to develop a framework for action to support health-legal collaboration. The framework is a continuum that represents an increasing degree of connection between health and legal professionals. For example, practitioners can use common best practices to support clients in ACP, participate in interprofessional training and jointly deliver ACP clinics. At the highest degree of collaboration, lawyers can be integrated into healthcare teams, such as dementia or palliative care services. This paper is published in *Healthcare Policy.*

Paper 3 reports on a survey that investigates lawyers' practices, their perspectives on barriers and enablers to ACP, and their preferences for resources that would help them better serve their clients. The survey was undertaken in the province of Alberta, Canada, as part of a broader research project investigating implementation aspects of a provincial strategy to promote the uptake of ACP. The survey respondents (n=104) were experienced lawyers, the majority of whom (69%) reported they assist clients with ACP on a daily or weekly basis. They viewed ACP activities as a significant part of a lawyer's role, including initiating ACP conversations, providing ACP information, drafting specific legal documents, advising on how to minimise future disputes, and encouraging clients to discuss their wishes with key others, especially their appointed decision-makers. Respondents had positive attitudes toward ACP and confidence in the value for their clients of documenting their wishes for future healthcare. As part of advance planning, just over 40% of respondents said they always or often prompt their clients to express their wishes about participation in medical research. About half of lawyers revealed some degree of concern regarding their lack of knowledge about the medical aspects of ACP and health sector policies and practices. Most respondents (over 80%) thought practical resources would be useful; possible resources include an ACP best practice guide, information about health service initiatives, and worksheets for clients to identify and express their values, wishes and preferences. Findings from this descriptive study are an important first step toward developing

interventions to improve lawyers' practices and build collaboration between lawyers and healthcare professionals. This paper is published in the *Alberta Law Review*.

Compared to ACP, there has been scant attention to advance planning for research, and **Papers 4–7** contribute new knowledge to this field. An important starting point in considering research participation and advance research planning is to understand the legal and ethical rules in a jurisdiction and the degree to which they support or hinder research involving people who may not be able to give their own consent. **Paper 4** provides a critical analysis of Australian ethical and legal rules, concluding that national ethics guidelines support research inclusion for people with cognitive impairment, but there is wide variation in relevant state and territorial laws. The paper makes recommendations for reform to improve clarity and consistency in the law and reduce barriers that may exclude people with dementia from participating in ethically approved research.

There is a paucity of Australian data on the perspectives of older adults and researchers on involving people with dementia-related cognitive impairment in research. Understanding the views of these key stakeholders is essential to inform strategies to support research participation for this population. **Paper 5**, published in the *Journal of Bioethical Inquiry*, investigates these topics in a survey of people aged 60 years and older attending outpatient clinics at a major hospital in New South Wales, Australia (n=174). The findings reveal positive attitudes to involvement in research activities during future incapacity. Over 90% of respondents reported that if they had dementia they would agree to participate in a wide range of research activities, including cognitive testing, physical measurements, imaging procedures and blood draws. Over three-quarters of respondents (79%) expressed interest in making an advance research directive to document their preferences about future research participation.

Papers 6 and 7, both under editorial review, report on a national survey of dementia researchers in Australia (n=70), revealing persistent ethical, legal and practical barriers to involving people who lack decisional capacity in research, but positive views on the benefits of advance research planning as a strategy to support inclusion. Paper 6 reports on researchers' views on the participation of people with dementia in research. Most respondents (97%) agreed with the importance of including people at all stages of dementia in research. However, about three-quarters of respondents perceived ethical and legal rules and processes to be unduly restrictive or time-consuming. Researchers reported varying practices for assessing participants' capacity to consent to research, and the majority of respondents (80%) had experience seeking consent from a proxy decision-maker for a person with dementia, such as legally appointed guardians or family carers. The survey findings suggest a need for improved strategies to assess and enhance the decision-making capacity of people with dementia to enable appropriate opportunities for research involvement. Education for ethics committees, proxy decision-makers and other gatekeepers is also needed to reduce barriers to participation in research.

Paper 7 reports on researchers' views and experiences with advance research directives (ARD). Over 80% of respondents agreed that such directives would be advantageous in promoting individual self-determination, informing researchers and other decision-makers of the wishes of a person with dementia, and enabling appropriate inclusion in research. A majority of respondents would offer individuals an opportunity to make ARDs to document their views about being involved in various types of research activities; for example, 70–75% of respondents would offer ARDs for research involving cognitive tests, observing behaviour, doing surveys or interviews, taking physical measures or accessing personal information, such as medical records. While researchers had positive views about advance research planning, almost no respondents

had used an ARD. In addition to clearer ethical and legal rules for such directives, there is a need for evidence-informed resources and training to support advance research planning.

Finally, the **Conclusion** describes the new knowledge gained from the thesis studies, discusses the lessons learned in the conduct of the research and identifies areas for future work. The areas of new knowledge centre on: strategies to build collaboration between the health and legal sectors to support advance planning activities; the role of lawyers in assisting clients with advance planning; the attitudes of older adults and researchers toward involving people with dementia in research and in using advance research directives; the ethical and legal barriers researchers encounter in seeking to involve people with dementia in research, especially issues related to decision-making capacity and consent; and the impact of legal and ethical frameworks as system-level barriers and enablers to advance planning for health-related matters. The Conclusion discusses areas for future research to support health and legal practitioners to: (1) use common practices to assist clients with advance planning; (2) take part in interprofessional training; (3) collaborate in advance planning clinics; and (4) form partnerships in healthcare settings.

A note on scope: This thesis includes research undertaken in Australia and Canada. There were several reasons for including studies in these two jurisdictions. The candidate has experience working in both countries and collaborates with Canadian and Australian researchers in areas of advance care planning and dementia. The countries have similarities in their laws, research ethics rules, healthcare institutions, professional practices and the challenges of meeting the needs of ageing populations. In addition, another Canadian research team (with which the candidate does not have connections) has published several studies that are relevant to advance

planning for care and research and has conducted one of the few experimental interventions to integrate research directives into a broader process of advance health-related planning.

INTRODUCTION

Ageing populations and the right to plan for incapacity

In Australia and across the globe, populations are ageing and more people are living longer with chronic illnesses.[1,2] Fifty percent of people in Australia over 65 years report having a disability, and dementia-related conditions are now the main cause of disability in this age group.[3] Dementia is an umbrella term for a number of major neurocognitive disorders characterised by progressive impairment in brain functioning; Alzheimer's disease is the most common, followed by vascular dementia and dementia with Lewy bodies.[4,5] Dementia is the second leading underlying cause of death in Australia, with the number of deaths from dementia increasing by 68% over the past ten years.[6] By 2050, the global prevalence of dementia is expected to exceed 130 million cases, with about one million cases in Australia.[7] *The Lancet* has recently described dementia as "the greatest global challenge for health and social care in the 21st century".[2(p2673)]

Many older adults with neurocognitive disorders will experience fluctuating or reduced capacity to make decisions in relation to health, financial, lifestyle and other matters.[8,9] Decisional capacity may be affected by impairments in memory and executive functioning, including difficulties in retaining, understanding and applying information in order to make decisions. A recent systematic review of decision-making in dementia observed that "[t]he ability to make decisions is an important exercise of a person's independence, control and autonomy. Decision-making allows the application of personal, social, professional and legal control over one's life".[10(p1)] For older people experiencing cognitive decline, the loss of autonomy and shift of decision-making power to others can negatively impact their quality of life and relationships, especially with spouses, adult children or others who take on decision-making responsibilities.[11,12,13] Engaging in advance planning processes can help to allay these difficulties

by enabling people to exercise choice and control over what happens to them in the future and by guiding those who become decision-makers for people with serious illness.[14]

Advance planning processes

An international expert panel recently defined advance care planning as follows:

> Advance care planning is a process that supports adults at any age or stage of health in understanding and sharing their personal values, life goals, and preferences regarding future medical care. The goal of advance care planning is to help ensure that people receive medical care that is consistent with their values, goals and preferences during serious and chronic illness.[15 (p826)]

In many jurisdictions, lawmakers have enacted statutory regimes with two main features that enable advance planning for incapacity.[16,17,18] First, people may appoint trusted individuals to act as their substitute or proxy decision-makers for healthcare and other personal matters during periods of incapacity. Legally, this is accomplished by making an enduring appointment; statutory terms vary but these may be known as enduring guardian or enduring power of attorney appointments. Second, people may make advance directives to communicate their values, wishes and preferences concerning health-related matters should they lose the capacity to make their own choices in the future.

In a review of advance care planning legislation and literature from the 1970s to the present, Sabatino observes that advance directives "have become public policy's choice for championing patient autonomy in the face of incapacity".[19(p219)] However, ACP involves more than making legal documents[20] and must also include discussing one's wishes with key others, especially an appointed decision-maker, ensuring a directive will be accessible in case it is needed, and re-visiting and updating one's wishes if they change with advancing age and ill health.[15]

Benefits of advance care planning

Receiving information and appropriate professional supports to understand and act on advance planning rights is now considered part of good psychosocial care for people diagnosed with dementia.[4,21] ACP has important benefits in promoting respect for autonomy and supporting person-centred care. People with advance directives experience fewer unwanted and burdensome medical interventions and are more likely to receive care that accords with their documented wishes.[22] In contrast, without effective care plans in place, people in the final stages of dementia are more likely to have emergency hospital admissions and inadequate palliative care.[23] Effective ACP reduces stress and conflicts in families[24] and gives greater certainty to loved ones and professionals about a person's wishes when they are unable to speak for themselves**.** While there is a need for more methodologically rigorous research,[25,26] ACP is suggested to have a positive impact on end-of-life outcomes[27] and is cited as a factor in experiencing a good death.[28,29] ACP interventions can be cost-effective with sufficient uptake and adherence to directives,[30] especially if respect for patient wishes avoids unwanted interventions in costly intensive care units.[31,32]

Improving advance planning through community and cross-sector collaborations

Ideally, people should engage in advance planning before crisis situations arise, in consultation with their families, friends and relevant professional advisors, and while they have the capacity to make and communicate their decisions. Yet, while many older people express interest in ACP, only a minority undertake such planning: "Although ACP has existed as an idea for decades, acceptance and operationalization of ACP within routine practice has been slow, despite evidence of its benefits."[33(p662)] For example, in a national telephone survey of Australians aged 18 and over, representative of age and state populations, just 14% of people reported having an advance care directive.[34] An audit of health records for approximately 2200 Australians aged 65

and older found that 30% had at least one type of advance care documentation, such as an enduring appointment or advance directive, with residents of aged care facilities more likely to have such documentation compared to older adults living in the community.[35] A Canadian study of nearly 300 community-dwelling older adults found that almost 80% said ACP was important, but only a quarter of respondents had a written directive and about 40% had appointed substitute decision-makers.[36] With few people acting on their legal rights to plan ahead, many older people who experience incapacity are at risk of being the subjects of decisions that do not accord with their values and wishes.[37,38]

In recent years, there is growing consensus that improving the uptake and effectiveness of advance planning requires whole-community approaches and cross-sector collaborations. In a landmark 2014 report, the Institute of Medicine championed a "whole-community" approach where health, legal, government and other service sectors promote advance planning initiatives.[39] A 2015 systematic review of barriers to ACP stressed the need to "transform systemic processes across a range of institutional settings".[40(p1027)] Adding to this point, a recent international study of ACP across 12 healthcare organisations highlighted that care providers' uncertainties about medico-legal aspects is a barrier and called for ACP initiatives that involve the public and organisations outside the health sector.[41] Most recently, a 2018 review of systematic reviews on ACP concluded that "[a] key and constant message … is to use a 'whole-system strategic approach'. This means to see ACP as an interconnected set of elements relying on each other" and to attend to the ways in which "health and legal systems influenc[e] ACP",[25(p455)] both at the macro-level of law and policy and the micro-level of individual planning and decision-making behaviours.

At the macro-level, literature on ACP often does not address the legal context for decision-making or advance planning. In a systematic review of decision-making for dementia care Larsson and Österholm noted as a "striking observation" that discussion of legal frameworks was mostly absent from the literature and recommended that "knowing and informing the reader about the (potential) legal and organizational context of the decisions in question is vital for future knowledge production in the area".[14(pp1856,1860)] The importance of understanding legal frameworks is highlighted by new Australian initiatives to create online sources with plain-language explanations of the law, such as Advance Care Planning Australia's review of legal requirements in each state and territory[42] and a legal toolkit as part of the End-of-Life Directions for Aged Care website.[43]

At the micro-level, Carr and Luth recently observed that "[c]ommunity-based initiatives are a promising route for bringing [advance] planning options to a broad base of older adults".[29(p6)] They noted in particular that both healthcare providers and lawyers "may be instrumental in shaping older adults' ACP", and it is therefore important "to identify factors associated with meaningful and productive conversations" between these practitioners and their patients/clients.[29(p7)] Indeed, best-practice care for people diagnosed with dementia and other life-limiting diagnoses includes referrals to legal assistance to engage in advance planning for health, financial and other personal matters.[21(p12)] Collaboration across health and legal sectors is therefore an important systemic transformation to improve advance planning processes, especially among older clients at risk for cognitive decline.

The under-explored role of legal practitioners in advance planning

The role of the legal profession in supporting ACP and the need for cross-sector collaboration is now being recognised. However, little published research explores lawyers' attitudes and

practices in this area. This is a surprising gap since legal practitioners routinely advise their clients on advance planning and draft relevant instruments to articulate clients' wishes in accordance with the law. Studies in several countries report that people who have written advance directives are more likely to have received assistance in preparing the document from a lawyer than from a doctor. A survey of residents in one Canadian province found that almost half of the respondents who had a written directive had sought help from a lawyer to prepare the document, while only 5% had consulted with a doctor.[36] Another study found that patients of a family practice clinic were more likely to have discussed advance planning with lawyers than their doctors.[44] A nation-wide Canadian study of sick, elderly patients and their family members found that participants discussed their end-of-life care wishes as often or more often with lawyers than with family doctors or medical specialists.[37]

In the United States, a survey of hospitalised adults in California found that of those with advance directives at the time of admission, half (49%) had received help from lawyers to prepare advance planning documents and only 6% had received help from doctors.[45] Thirty-five percent of those with directives viewed lawyers as helpful sources of expertise in assisting with writing the documents, while only 1% said physicians were. An earlier study in Connecticut found that, among people admitted to hospital with advance directives, 76% had prepared the documents with lawyers and only 7% had prepared them with doctors.[46] German researchers surveyed 53 people who had advance directives to find out if they had obtained help from professionals in preparing the documents.[47] Just under a quarter of people had sought such help and, among those, legal professionals were the most common source of advice.

Since lawyers are a key source of help for people who want to engage in advance planning, research is needed to determine lawyers' attitudes, beliefs and practices in this important area.

Gaining an understanding of what lawyers currently do in practice, especially their perspectives on barriers and enablers and their preferences for resources that would help them better serve their clients, is an important first step in devising interventions to improve lawyers' practices and enhance interprofessional collaboration between legal and health sectors in the area of ACP.

From advance care planning to advance research planning

ACP asks people to express their wishes for care during future periods of incapacity and aims to have positive impacts on future treatment decisions and outcomes. Yet, paradoxically, there are numerous gaps in the evidence to inform interventions available for people with progressive neurocognitive illness. Carefully made plans may well end up being used in circumstances of evidentiary ambiguity. Reviews of clinical practical guidelines and quality care standards for dementia highlight the limited evidence base,[48,49] including in palliative and end-of-life care for people with dementia.[50] Many guidelines rely on expert opinion due to the lack of high-quality empirical research.

In Australia, Clinical Practice Guidelines for Dementia were published in 2016.[21] Of the 109 recommendations in the guidelines, only 29 are considered "evidence-based", that is, based on a systematic review and synthesis of available scientific evidence. Of these, 22 recommendations are based on evidence judged to be of very low to low quality and seven are based on moderate quality evidence. None of the 109 recommendations is based on high-quality evidence. A Dutch review of nine years of study protocols concluded that participants in biomedical dementia studies are not representative of the broader population of people with dementia.[51] People with more advanced cognitive impairment and co-morbidities and who live in residential care facilities are less likely to be included in studies. In short, it has recently been stated that "people with dementia remain a neglected group".[52(p2)]

The need for inclusion in research

Initiatives to improve the uptake and quality of ACP should be paralleled by inclusive research practices that strengthen the evidence base for care and supports that are provided to people living with progressive cognitive decline. Indeed, lack of confidence in the quality of future care is an identified barrier to engaging in ACP.[52] Improving the quality of care for people with dementia and other neurocognitive disorders depends on well-designed research that includes large and representative samples of people living with the conditions. This includes ensuring adequate representation of people at varying stages of cognitive impairment, including those in more advanced stages. There are notable "differences in the issues of concern, experiences and needs of people with dementia at the mild, moderate and severe stages"; therefore, the "inclusion [in research] of persons with dementia at all stages is essential" to understand and respond to these varying needs.[53(p815)]

Addressing ethical and legal complexities

People with dementia have commonly been excluded from research, due in part to assumptions that they lack the capacity to make their own decisions.[54,55] In general, the ethical and legal complexities of involving people with cognitive impairment in studies have posed significant barriers for including this group in research.[56,57] A survey of dementia researchers in the United States and Australia concluded that investigators and ethics committees are "nervous about including this population in their studies".[58(p705)]

The detrimental impacts of these exclusions are now being recognised, with scholarly literature, advocacy statements and ethics guidelines increasingly calling for the involvement of people with dementia in research.[59,60] The contemporary view is that people with cognitive impairment should have opportunities to participate in meritorious research, in line with the ethical principle

of justice. The 2016 update of the *International Ethical Guidelines for Health-Related Research Involving Humans* recognises the distinctive needs of people with conditions that impair cognition and urges their inclusion in research: "Adults who are not capable of giving informed consent must be included in health-related research unless a good scientific reason justifies their exclusion."[61(p61)] In Australia, the National Statement on Ethical Conduct in Human Research states that people with a cognitive impairment "are entitled to participate in research."[62(p73)]

Supporting appropriate research inclusion through advance planning

Practical strategies are needed to realise the aspiration of inclusion in research for people living with cognitive impairment. Respect for these prospective participants means not only "abiding by the values of research merit and integrity, justice and beneficence" but also "having due regard" for their beliefs, values and preferences.[62(p11)] Advance research planning, similar to advance care planning, is a way to support people, when they have the capacity to do so, to reflect on and express the participants' values and preferences for being involved in research studies during future periods of incapacity.[63,64]

The concept of advance research planning was endorsed 20 years ago by the United States National Bioethics Advisory Commission.[65] However, "benign neglect" stalled the development of strategies to support it.[66(p1646)] Early sceptics of advance research planning thought few people would care enough to do it. Clinician and dementia researcher Greg Sachs argued that "the fear of missing out on being a subject in a promising dementia study, or of being inappropriately volunteered by one's relatives, is simply not a prevalent or powerful concern".[67(p22)]

Today, these concerns cannot be dismissed. The ageing population increases the need for research into conditions, including dementia and other neurocognitive disorders, that are

prevalent among older adults. Yet research is not keeping pace with the personal and social impacts of dementia.[68] People living with a diagnosis have faced exclusions from studies, particularly when their capacity to give their own consent is questioned (rightly or wrongly) and substitute decision-making raises ethical, legal and practical complexities.[56,69] The harms of unjustifiable exclusions are now acknowledged[59], and people with dementia are concerned – and even angry – about barriers to being involved in research.[70] Dementia advocacy organisations, researchers and governments are increasingly interested in ethically appropriate strategies to support research participation for people with dementia.[69,71] Advance research planning, supported by clear ethical and legal rules, is one such strategy.[72,73]

Through a process of advance research planning, people can identify one or more trusted individuals they would like to be involved in decisions about their participation; in effect, to be a substitute decision-maker for research choices. They can also document their wishes in advance research directives that would guide substitute decision-makers, researchers and ethics committees at times when people are unable to make in-the-moment decisions.

While advance directives are typically understood as a component of advance planning for medical care, legal and ethical rules may also recognise directives as a means to express wishes in relation to participation in research. For example, in Australia, Victoria's *Medical Treatment Planning and Decisions Act 2016*, which came into effect in March 2018, establishes a comprehensive statutory framework for advance planning and includes provisions for people to appoint decision-makers and make advance directives both for medical care and participation in research. These wishes may take the form of instructional directives that document consent or refusal for specific procedures or activities. The statute also recognises values directives, by which people can express their general views and preferences concerning medical interventions

and research participation. The New South Wales Law Reform Commission recently recommended new legislation to replace the *Guardianship Act 1987* that would establish a similar statutory framework for care directives and research directives.[74] Australia's *National Statement on Ethical Conduct in Human Research* supports advance research planning by recommending that researchers and participants discuss and document views on future research participation, particularly when cognitive decline over the course of the study is anticipated.[62(p74)] The *International Ethical Guidelines for Health-Related Research Involving Humans* also support the use of advance research directives, stating: "If participants have made advance directives for participation in research while fully capable of giving informed consent, the directives should be respected."[61(p61)] While advance directives have legal and ethical recognition in some jurisdictions, there are scant data on their prevalence and use. A survey in Québec, Canada – where ARDs are permissible – reported that about 7% of community-dwelling older people had formal directives that documented their wishes about research participation.[75] No Australian studies have investigated the uptake of advance research directives.

Advance research planning is an area ripe for investigation and can be informed by studies and experiences with advance care planning.[25,26,76,77] The principles that underlie ACP – respect for autonomy, self-determination and preparation for future incapacity – apply similarly to advance planning for research participation. Making a research directive and designating a research decision-maker can be particularly beneficial when a person is recruited into a project that will involve research activities over a longer period, such as enrolment into a dementia research registry or a longitudinal study on ageing. Documenting wishes in a research directive and discussing values and preferences with a designated decision-maker could help to facilitate the appropriate inclusion of people with cognitive impairment in research. The limited empirical studies on advance research planning indicate that the majority of older people who make

research directives express a willingness to be involved in studies in the future, and only a small minority reject any future involvement. For example, an American study found that 87% of people who made ARDs expressed willingness to take part in future research.[78] A recent Canadian randomised controlled trial resulted in 80% of older adults in the experimental group making ARDs after taking part in educational sessions and advance planning facilitation.[79] Of these participants, 61% documented their willingness to take part in clinical research during future periods of incapacity and 15% indicated they would not want to be involved in research. Developing and implementing processes to support advance research planning could therefore help to progress research and strengthen the evidence for effective interventions to improve the quality of care for people in later stages of neurocognitive illness.

To date, there is a paucity of research in Australia on the perspectives of older adults and researchers on including people with cognitive impairment in research and on advance research planning. The views of researchers and older people who could take part in research (including people who already have a dementia diagnosis) are important to inform strategies for supporting appropriate inclusion in research of people with cognitive impairment. For example, it is important to understand community members' willingness to participate in research in case of future incapacity, the acceptability of advance research planning, their willingness to document their wishes in advance directives, and their preferred substitute decision-makers for research decisions. It is also important to investigate researchers' experiences in undertaking research with this population, perspectives on advance research planning, including the use of advance research directives, and barriers that need to be addressed to facilitate inclusion of people with cognitive impairment in research.

A comprehensive approach to advance planning

Improving the uptake and quality of advance planning for medical care and research participation requires strategies to change behaviours and overcome barriers at person, practitioner and system levels.[80] In the chapters that follow, this PhD thesis advances knowledge relevant to all these levels. With attention to the system level, the research analyses the legal and ethical frameworks that govern advance planning and set out specific rights, restrictions and processes. At the individual and practitioner levels, empirical studies investigate under-examined perspectives, including lawyers' role in ACP and the views of older people and researchers on involving people with dementia in research and the use of research directives. These descriptive data are important for understanding current attitudes and practices, which are necessary for informing future intervention studies to test strategies that support desired behaviour changes and outcomes in relation to advance planning for medical care and research participation.

Several years ago, an editorial in *Palliative Medicine* averred that advance planning "deserves more of our interdisciplinary attention, conversations, health research and practice, joining up professions, social movements, cultural and psychological research, health and social care policy".[81(p998)] This call to action provided forceful motivation for this PhD research and the ambition to undertake interdisciplinary research to advance knowledge that informs changes to law, ethics and practice. Ultimately, this PhD thesis advocates for a comprehensive approach to advance planning for medical care and research that promotes the rights of older adults and is supported by collaboration across health and legal sectors.

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[16] For information on legal frameworks in all Australian jurisdictions, see for example, Dementia Australia. Planning Tools. Available from*:* https://www.dementia.org.au/planning-ahead/planning-tools; and Advance Care Planning Australia. Advance care planning in your state or territory. Available from: https://www.advancecareplanning.org.au/resources/advance-care-planning-for-your-state-territory.

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[18] For discussion of Canadian laws, see for example: Gilmour J, Death. Dying and decision-making about end of life care. In: Downie J, Caulfield T, Flood C, editors. Canadian health law and policy. 4th ed. Canada: LexisNexis; 2011. p. 437.

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PAPER 1: LAWYERS AND ADVANCE CARE AND END OF LIFE PLANNING: ENHANCING COLLABORATION BETWEEN LEGAL AND HEALTH PROFESSIONS

Overview

In Australia and internationally, advance care planning (ACP) is emphasised as an important means by which individuals can express their wishes for healthcare during future periods of incapacity. ACP has mainly been promoted in healthcare settings, and the role of lawyers is underexplored, despite the fact that some people are more likely to discuss their healthcare wishes with lawyers than with doctors. This paper involved a comprehensive review of literature on legal professionals and ACP, as well as an analysis of how collaboration between health and legal professionals can occur to assist clients with advance care and end-of-life planning.

The paper, published in the *Journal of Law and Medicine*, articulates the importance of law and lawyers in ACP and discusses the medical-legal partnership model as a means to increase interprofessional collaboration. This model, developed in the United States and now being adapted in Australia and Canada, is an innovative approach to service provision that integrates lawyers into healthcare teams.[1] The paper also analyses how collaboration between legal and health professions can help to overcome client, practitioner and system-centred barriers and recognise ACP as a preventive legal and healthcare practice that supports clients' interests and promotes their autonomy. This paper discusses ACP in the Australian healthcare context.

[1] National Center for Medical-Legal Partnership, *International Medical-Legal Partnerships – Canada and Australia*, <http://medical-legalpartnership.org/partnerships/international>. Health Justice Australia < https://www.healthjustice.org.au/>.

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Lawyers and advance care and end-of-life planning: Enhancing collaboration between legal and health professions

Nola M Ries*

In Australia and internationally, advance care planning (ACP) is emphasised as an important means by which individuals can express their wishes for health care during future periods of incapacity. ACP has mainly been promoted in health care settings and very little is said about the role of lawyers, despite the fact that some people are more likely to discuss their health care wishes with a lawyer than with a doctor. This article addresses this significant gap and advocates for collaboration between legal and health professionals to assist clients with advance care and end-of-life planning. It articulates the importance of law and lawyers in ACP and discusses the medical-legal partnership model as a means to increase inter-professional collaboration. It analyses how collaboration can tackle client, practitioner and system-centred barriers and recognise ACP as a preventive legal and health care practice that supports clients' interests and promotes their autonomy.

INTRODUCTION

Advance care planning refers to a process by which a person considers, discusses and documents their wishes for their health care during future periods of incapacity when the person is unable to make decisions.[1] The person who engages in this process may prepare a written plan, known as an advance or personal directive or a "living will", to document their health care preferences. The person may also authorise someone to act as their guardian or substitute decision-maker to make health care choices, ideally in accordance with the person's prior wishes expressed in a written plan or verbally. Advance care planning is not a static, one-time event. To be most effective in reflecting a person's current wishes and values, the care plan and choice of decision-maker should be reviewed periodically and updated in light of significant health and life events. Such planning is done with the expectation that the person's wishes ought to be respected.

Advance care planning is an area where law and health care intersect, both at the macro level of public policy and at the micro level of individual decision-making. Lawmakers in many jurisdictions have endorsed advance care planning as a means to protect and promote individual autonomy and have reformed laws to provide specific statutory frameworks for advance directives and the appointment of substitute decision-makers.[2] Recognising the right of a person to make these choices in advance can give greater certainty to health care providers and loved ones about a person's wishes and help avoid legally and ethically fraught conflicts over the provision and cessation of treatment. In a

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[1] For a definition of advance care planning, see, eg International Society of Advance Care Planning and End of Life Care, *ACP Definition* (2011) <http://acpelsociety.com/acp_definition.php>.

[2] Australian legal frameworks are discussed in the next part. Every jurisdiction in the United States has legislation covering advance health care directives and substitute decision-makers: Institute of Medicine, *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life* (National Academies Press, Washington, 2014) 3-6. For discussion of Canadian laws, see, eg J Gilmour, "Death, Dying and Decision-Making about End of Life Care" in J Downie, T Caulfield and C Flood (eds), *Canadian Health Law and Policy* (LexisNexis, Canada, 4th ed, 2011) 437.

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review of advance care planning legislation and literature from the 1970s to present, Sabatino observes that advance directives "have become public policy's choice for championing patient autonomy in the face of incapacity".[3]

At the individual level, a person who wishes to plan for their future health care will often want to deal with other legal matters, including estate planning, writing a will, and designating a person with power of attorney to manage their finances and property. Advance *health care* planning is therefore a subset of *advance planning* or, colloquially, organising one's affairs. Legal practitioners routinely advise their clients on advance planning and draft relevant instruments to articulate clients' wishes in accordance with the law. The National Framework for Advance Care Directives, produced by the Australian Health Ministers' Advisory Council, notes that people may complete an advance care directive with the aid of a lawyer and identifies the need for practical guidance for lawyers in this area.[4] Very little research exists, however, about lawyers' roles in assisting people with advance care planning and how they can perform this role more effectively to ensure their client's wishes are known and respected during periods of incapacity. This is a surprising gap considering the broader policy drive to implement and evaluate initiatives to promote advance care planning.[5]

This article focuses on the role of lawyers in advance care planning and advocates for greater collaboration between legal and health professionals to help their clients plan for future periods of incapacity. Health services and policy research constantly stresses the need to break down professional silos in health care systems to improve patient care and outcomes.[6] This article contends that the siloed professions of law and medicine should similarly co-operate to recognise and promote advance care planning as a form of *preventive* legal and health care practice that supports clients' interests in expressing their values, wishes and preferences and preserves their autonomy and dignity when they can no longer speak for themselves.

The article begins with a literature review summarising the benefits of advance care planning and describing the barriers that contribute to its currently low uptake. It discusses both advance directives and the role of substitute decision-makers. Next, the article articulates the importance of law and lawyers in advance care planning. It reports the results of a comprehensive search to identify published literature on the role of lawyers in advance care planning.[7] It also discusses the significant knowledge gaps of health practitioners about the law, which is a factor that inhibits them from

[3] C Sabatino, "The Evolution of Health Care Advance Planning Law and Policy" (2010) 88(2) *Milbank Quarterly* 211, 219.

[4] Clinical, Technical and Ethical Principal Committee of the Australian Health Ministers' Advisory Council, *A National Framework for Advance Care Directives* (September 2011) <http://www.coaghealthcouncil.gov.au/Publications/Reports/ArtMID/514/ArticleID/63/National-Framework- for-Advance-Care-Directives>.

[5] See, Senate Community Affairs References Committee, Parliament of Australia, *Palliative Care in Australia* (Canberra, 2012) see esp "Advance Care Planning", 193-216 <http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Completed_inquiries/2010-2013/palliativecare/report/index>; H Swerissen and S Duckett, *Dying Well* (Grattan Institute, 2014) <http://grattan.edu.au/wp-content/uploads/2014/09/815-dying-well.pdf>; Victorian Law Reform Commission, *Guardianship*, Final Report No 24 (Melbourne, 2012) see esp "Documenting Wishes about the Future", 205-235 <http://www.lawreform.vic.gov.au/projects/guardianship-final-report>; Advance Care Planning Australia <http://advancecareplanning.org.au>; Alzheimer's Australia, *Start2Talk* <http://start2talk.org.au/>; Legal and Social Issues Committee, Legislative Council, Parliament of Victoria, *Inquiry into End of Life Issues*, Final Report (Melbourne, 2016) see esp Ch 5 "Improving Advance Care Planning", 141-168 <http://www.parliament.vic.gov.au/images/stories/committees/SCLSI/EOL_Report/LSIC_58-05_Text_WEB.pdf>.

[6] See, eg Commonwealth Department of Health, *Review of Australian Government Health Workforce Programs* (2013) <https://www.health.gov.au/internet/main/publishing.nsf/ Content/work-health-workforce-program-review>; S Leggatt, *Changing Health Professionals' Scope of Practice: How Do We Continue to Make Progress?* (Deeble Institute, 2014) <http://ahha.asn.au/system/files/docs/publications/deeble_issues_brief_nlcg-4_changing_health_professionals_scope_of_ practice.pdf>.

[7] A literature review of legal and medical journals was performed. The following databases were utilised in the search: Medline, Embase, PsycINFO, Cinahl, AGIS Plus Text, and Hein Online. Varying combinations of search terms were used, such as: [(advance care planning / or advance directives / or living wills) or (end of life issue*) and (lawyers) or (legal or law* adj5 seminar* or information* or education* or consult*)]; [(community legal education) or (legal information outreach)] and [(effect adj5 behavio*) or (impact and behavior*) or (end of life)], [(role of law*) or (legal information)] and [(advance care planning or advance care directive) or (end of life)]; [(consult*) and (advance care planning or advance care directive) or (end of life) and (law*)]; [(lawyers) and (advance care planning)]; [(lawyer*) and (role) and (advance care planning) or (end of life)]; [(lawyer*) and (consult*) and (advance care planning) or (end of life)].

addressing advance care planning with their patients. The article then advocates a greater role for lawyers in advance care planning. It discusses the medical-legal partnership model as a means to increase inter-professional collaboration and analyses the ways in which such collaboration can deal with client-, practitioner- and system-centred barriers to advance care planning. To conclude, the article identifies key areas for future research and stresses the importance of comprehensive evaluation studies to appraise the impacts of novel initiatives to promote collaboration between legal and health professionals.

ADVANCE CARE PLANNING

Advance directives

A majority of older adults will lack the capacity to make their own choices when decisions need to be made about medical interventions in end-of-life situations.[8] An advance directive can communicate the person's values and preferences to the treating health practitioners and guide the choices that a substitute decision-maker may be called upon to make. Advance directives may take two forms and a person may complete both. One type of directive is a more general expression of the person's values and goals where, for example, cultural and spiritual practices important to the person can be documented.[9] The other type of directive deals with specific health care interventions the person would or would not want in future circumstances.[10]

Advance care planning has been shown to benefit the patient, their loved ones, and care providers. Having a written plan "positively impacts the quality of end-of-life care",[11] improves compliance with the person's preferences, improves satisfaction for both patients and their significant others, and reduces family stress.[12] Advance directives assist care providers by giving them insight into an incompetent person's wishes and values. As a result, people who prefer comfort care instead of intensive life-prolonging interventions generally receive less invasive medical treatment at the end of life. People who live at home or in community care facilities and who do not want to be transferred to hospital for life-saving treatments are more likely to have their wishes respected and avoid an unwanted hospital death.[13] Indeed, up to 70% of Australians say they would prefer to die at home.[14]

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[8] M Silveira, S Kim and K Langa, "Advance Directives and Outcomes of Surrogate Decision-Making Before Death" (2010) 362(13) *New England Journal of Medicine* 1211.

[9] See, eg Alzheimer's Australia, *Worksheet 1.4: General Statement About Values, Wishes and Preferences* <http://www.start2talk.org.au/worksheet-1-4>. This Worksheet asks questions such as: "Do you have religious, spiritual or lifestyle beliefs that are important to you and that you want others to acknowledge and respect? How might these influence the care you want to receive?"; "What activities would you like to do/keep doing even when you cannot request that any more?"; "If you were living at home, at what point would you accept the need to go into residential care? This may include physical health, safety, support available and impact on your family of trying to care for you etc?"; "In terms of your views about your quality of life in the future, at what point would you want the goals of medical care to switch from intensive treatments aimed at prolonging life to focusing on palliative or comfort care? Some people describe this in terms such as the irreversible loss of ability to recognise people, feed themselves, walk, talk etc?"

[10] See, eg Alzheimer's Australia, *Worksheet 1.5: Advance Care Directions About Specific Treatments* <http://www.start2talk.org.au/worksheet-1-5>. This Worksheet asks about specific care preferences (eg CPR, mechanical ventilation, kidney dialysis, tube feeding) for a future period where the person has a poor quality of life and an irreversible medical condition that will not improve. The Worksheet provides: "This statement sets out clearly what treatments I would, and would not, consent to under the conditions outlined below. I am making this statement willingly because there may be some time in the future when I am unable to express these things myself, because of illness or injury. If this situation occurs, I want my substitute decision-makers and any treating doctors to respect my wishes and follow the directions I have given. I accept that some of the treatments listed below may be considered medically futile in end-stage disease and may not be offered as a treatment option."

[11] A Brinkman-Stoppelenburg, J Rietjens and A van der Heide, "The Effects of Advance Care Planning on End-of-Life Care: A Systematic Review" (2014) 28(8) *Palliative Medicine* 1000, 1021.

[12] C Houben et al, "Efficacy of Advance Care Planning: A Systematic Review and Meta-Analysis" (2014) 15(7) *Journal of the American Medical Directors Association* 477.

[13] DA Kossman, "Prevalence, Views, and Impact of Advance Directives Among Older Adults" (2010) 7 *Journal of Gerontological Nursing* 44.

Many people, especially older adults, express interest in planning ahead for their health care and other life choices, but only a minority do so: "Although [advance care planning] has existed as an idea for decades, acceptance and operationalization of [advance care planning] within routine practice has been slow, despite evidence of its benefits."[15] In Australia, it is reported that a mere 14% of the population has an advance directive, 30% have appointed someone to manage their finances and 59% have a will.[16] A Canadian study of nearly 300 community-dwelling older adults reported that almost 80% said advance care planning was important, but only a quarter of respondents had a written directive and around 40% had appointed a substitute decision-maker.[17] A recent United Kingdom survey found that only 7% of the 2,000 respondents reported having a written health care directive. In the United States, a national *Patient Self-Determination Act* enacted in 1990 has supported extensive efforts to encourage advance care planning and writing advance directives. It is estimated that around 25% of the general population has an advance directive, though uptake is higher in Americans over age 60.[18]

Various studies have identified factors that are associated with completion of an advance directive.[19] People who have been diagnosed with serious illness, are living with significant functional impairments, have an ill spouse, or are widowed are more likely to have an advance directive. Being married, of older age and having higher education and income are also factors associated with advance directive completion.[20] People who have spoken about advance care planning with a doctor or a lawyer are also more likely to have an advance directive.

Lack of awareness and understanding of advance care planning is a common reason why people do not have an advance directive.[21] A belief that one is currently in good health and reluctance to think about future illness and dying are other reasons why people do not engage in advance care planning.[22] Many individuals, including those with diagnoses that will involve mental decline, do not realise the importance of planning ahead, or they avoid the process until it is too late and they are no longer able to express their wishes. Some people do not prepare an advance directive because they are uncertain about the document's legal status and whether its instructions will be followed.

A recent systematic review identified factors that support or hinder advance care planning in health care settings[23] and focus group research has explored barriers specific to the Australian hospital

[14] H Swerissen and S Duckett, "What Can We Do to Help Australians Die the Way They Want To?" (2015) 202(1) *Medical Journal of Australia* 10. Currently around 14% of Australians die at home.

[15] IA Scott et al, "Difficult but Necessary Conversations – The Case for Advance Care Planning" (2013) 199 *Medical Journal of Australia* 662, 662.

[16] B White et al, "Prevalence and Predictors of Advance Directives in Australia" (2014) 44(10) *Internal Medicine Journal* 975.

[17] D Goodridge, "Planning for Serious Illness Amongst Community-Dwelling Older Adults" (2013) 2013 *Nursing Research and Practice* 7.

[18] Institute of Medicine, n 2, 3-8. JK Rao et al, "Completion of Advance Directives Among US Consumers" (2014) 46(1) *American Journal of Preventive Medicine* 65.

[19] A Lovell and P Yates, "Advance Care Planning in Palliative Care: A Systematic Literature Review of the Contextual Factors Influencing its Uptake 2008-2012" (2014) 28(8) *Palliative Medicine* 1026; JJ Rhee, NA Zwar and LA Kemp, "Uptake and Implementation of Advance Care Planning in Australia: Findings of Key Informant Interviews" (2012) 36 *Australian Health Review* 98; White et al, n 16.

[20] S Moorman, D Carr and K Boerner, "The Role of Relationship Biography in Advance Care Planning" (2014) 26(6) *Journal of Aging and Health* 969; M Moorman and M Inoue, "Persistent Problems in End-of-Life Planning Among Young- and Middle-Aged American Couples" (2013) 68(1) *Journals of Gerontology Series B: Psychological Sciences and Social Sciences* 97.

[21] Lovell and Yates, n 19; Scott, n 15.

[22] Moorman and Inoue, n 20.

[23] S Lund, A Richardson and C May, "Barriers to Advance Care Planning at the End of Life: An Explanatory Systematic Review of Implementation Studies" (2015) 10(2) *PLoS One* 1, DOI:10.1371/journal.pone.0116629.

context.[24] Health care practitioners say they do not initiate care planning discussions with patients because they do not feel confident in their knowledge and skills, they are concerned about upsetting patients, they have competing work demands, they do not have time to deal with patients' emotional needs, they think advance care planning is not their responsibility, and they are resistant to shared decision-making.[25] Measures that help to integrate and routinise advance care planning in health care settings increase their uptake and use.

While individuals with advance directives are more likely to receive care consistent with their documented wishes, there are well-known problems with lack of compliance with directives. A person may prepare a directive but family members or health practitioners may not know about it or have access to it when needed, with the result that the person's wishes remain unknown.[26] A directive may be made available, but its instructions may be vague or not relevant to the patient's situation. Moreover, care providers may not follow the wishes expressed in a directive if they are concerned about the validity of the document and whether the instructions reflect the person's current preferences.[27] This situation may be exacerbated when substitute decision-makers and family members question the directive and want care that contradicts its instructions.

Substitute decision-makers

As part of advance care planning, people may designate a substitute decision-maker to make legally permitted health care choices on their behalf during future periods of incapacity. If a decision-maker has not been appointed, the law sets out a hierarchy of individuals who become default decision-makers within statutorily prescribed parameters.[28] In theory, substitute decision-makers are to make choices consistent with what the patient would choose for himself or herself, taking into account the patient's known instructions, preferences and values. In reality, a decision-maker's knowledge of

[24] J Boddy et al, "It's Just Too Hard! Australian Health Care Practitioner Perspectives on Barriers to Advance Care Planning" (2013) 19 *Australian Journal of Primary Health* 38.

[25] See also J Clayton et al, "Clinical Practice Guidelines for Communicating Prognosis and End-of-Life Issues with Adults in the Advanced Stages of a Life-Limiting Illness, and their Caregivers" (2007) 186(12) *Medical Journal of Australia* 77.

[26] Various initiatives are underway to deal with the problem of advance directives not being available. In Australia, a person may add an advance directive to their personally controlled electronic health record: National E-Health Transition Authority, *Advance Care Directive Custodian* (2014) <https://www.nehta.gov.au/implementation-resources/clinical-documents/ advance-care-directive-custodian>. In the United States, some State Government departments have implemented Advance Directive Registries. See, eg California Secretary of State, *Advance Health Care Directive Registry* (2014) <http://www.sos.ca.gov/registries/advance-health-care-directive-registry>; North Carolina Department of the Secretary of State, *Advance Health Care Directive Registry* <https://www.secretary.state.nc.us/ahcdr/>.

[27] In *Hunter & New England Area Health Service v A* (2009) 74 NSWLR 88; [2009] NSWSC 761, the Area Health Service sought a judicial declaration as to the validity of a health care planning "worksheet" completed by the patient, A, one year prior to his hospitalisation. The Court held the document was a valid advance care directive applicable to A's current medical situation. In *QLB (Guardianship)* [2012] TASGAB 31, the Tasmanian Guardianship and Administrative Board dealt with a guardianship appointment application for a person, Q, with advanced Huntington's disease who was serving a life term of imprisonment and needed to be moved to a health care facility for appropriate care. It was submitted that Q had completed an advance care plan that communicated his wishes and obviated the need for an appointed guardian. The Board described the document as follows: "The first part of the document expresses QLB's purported views on 'Lifestyle directions' in relatively simple language including some preferences between particular Aged Care facilities, funeral and burial arrangements, religious affiliations, entertainment preferences, preferences for colours, temperatures, food and drink. The second part of the document contains 'Medical Directives' including nine directions expressed in formal language purportedly expressing QLB's views on a preference for palliation over life sustaining treatment, a refusal of a percutaneous endoscopic gastronomy tube and various other requests. The second part of the document appears to be formulaic, being expressed in more sophisticated language than the 'lifestyle directions' and gives the impression of having been copied from documents popularly circulated amongst members of the medical community as model 'advance care directives'" (at [20]). The Board did not have jurisdiction to determine the validity of the document as a common law advance directive but commented that it could assist the appointed guardian in understanding Q's wishes.

[28] See, eg statutory provisions regarding the "person responsible" for an individual with decisional incapacity in *Guardianship Act 1987* (NSW) s 33A; *Guardianship and Administration Act 1986* (Vic) s 37; *Consent to Medical Treatment and Palliative Care Act 1995* (SA) s 14(1). For discussion, see S Allan and M Blake, *The Patient and the Practitioner: Health Law and Ethics in Australia* (LexisNexis Butterworths Australia, 2014) 171-176, esp Table 4.1 Statutory Substitute Decision-Makers by State/Territory.

the patient's preferences may be "only slightly better than chance".[29] Various factors explain this troubling fact. First, people often do not discuss their values and wishes with those who may have to make choices for them in the future. Secondly, decision-makers are influenced by their own values, feelings of guilt, and possible conflicts with others involved in the patient's life.[30] These decision-makers have a role defined by law, but the reality of their decision-making is far from what the law ideally expects.

A recent study of an Australian intensive care unit reported on incidences of conflict regarding the substitute decision-maker role, discrepancies between who the patient identified as a preferred decision-maker and the person recorded as a decision-maker in the medical file, and lack of communication about the patient's wishes.[31] Many substitute decision-makers feel emotionally burdened with their responsibilities and the negative effects can be significant and lasting.[32] Family members of persons with conditions like dementia express regret if they have not discussed their loved one's wishes for specific health care interventions and living arrangements.[33] The serious nature and impact of decision-makers' duties underscores the need for effective communication in advance care planning, including preparing and sharing written directives to guide difficult choices.

THE ROLE OF LAW AND LAWYERS IN ADVANCE CARE PLANNING

Why are the law and lawyers relevant in a discussion of advance care planning and why is greater legal-health collaboration important in this area? This part explains three key responses to this question and sets a foundation for the argument below for inter-professional collaboration. First, the law establishes a framework for advance care planning, and those involved in the process – including individuals, their families and care providers – must do so within the relevant legal rules. Secondly, studies reveal that many health practitioners do not have an accurate understanding of the law and this inhibits them from raising advance care planning with their patients, to the disadvantage of all concerned. Thirdly, people seek assistance from lawyers in preparing advance directives, often as part of seeking legal help on other aspects of advance planning. Indeed, people may be more likely to talk to their lawyer than their doctor about care planning.

Law sets a framework for advance care planning

In general, the law is recognised as an important influence on health: "By establishing the social framework in which populations live, face disease and injury and die, law forms an important social determinant of population health."[34] In regard to advance care planning, the law establishes the means by which a person can make an advance directive and appoint a substitute decision-maker. In Australia, there is inter-jurisdictional variation in the applicable legal definitions, rules, policies and processes. New South Wales and Tasmania do not have statutory rules for making advance directives; instead, the common law provides a basis for advance directives.[35] The other four States and two Territories have specific, but varying statutory rules regarding the making of advance directives,

[29] LG Collins, SM Parks and L Winter, "The State of Advance Care Planning: One Decade After SUPPORT" (2006) 23(5) *American Journal of Hospice and Palliative Medicine* 378, 379; DI Shalowitz, E Garrett-Mayer and D Wendler, "The Accuracy of Surrogate Decision-Makers: A Systematic Review" (2006) 166(5) *Archives of Internal Medicine* 493.

[30] Shalowitz, Garrett-Mayer and Wendler, n 29. See also Y Schenker et al, "I Don't Want to Be the One Saying 'We Should Just Let Him Die': Intrapersonal Tensions Experienced by Surrogate Decision-Makers in the ICU" (2012) 27(12) *Journal of General Internal Medicine* 1657.

[31] JL Mendoza and C Burns, "Letter to the Editor 'Who Will Talk for Me?' Next of Kin is Not Necessarily the Preferred Substitute Decision-maker: Findings from an Australian Intensive Care Unit" (2015) 29(4) *Palliative Medicine* 391.

[32] D Wendler and A Rid, "Systematic Review: The Effect on Surrogates of Making Treatment Decisions for Others" (2011) 154(5) *Annals of Internal Medicine* 336; JW Buckey and O Molina, "Honouring Patient Care Preferences: Surrogates Speak" (2012) 65(4) *Omega: The Journal of Death and Dying* 257.

[33] K Hirschman, J Kapo and J Karlawish, "Identifying the Factors that Facilitate or Hinder Advance Planning by Persons with Dementia" (2008) 22(3) *Alzheimer Disease and Associated Disorders* 293.

[34] W Parmet, *Populations, Public Health and the Law* (Georgetown University Press, Washington, 2009) 31.

[35] See, eg *Hunter & New England Area Health Service v A* (2009) 74 NSWLR 88; [2009] NSWSC 761.

including requirements as to witnessing the document and, in some cases, mandating the use of a prescribed form.[36] South Australia and the Northern Territory both implemented new advance directive laws in 2014. In South Australia, the *Advance Care Directives Act 2013* (SA) prescribes a directive form that replaces three advance planning instruments previously in use.[37] In the Northern Territory, the *Advance Personal Planning Act 2014* (NT) enables people to make a plan that gives consent for future health care, appoints substitute decision-makers for health care and financial decisions, and describes their values and beliefs that should inform decisions concerning their care or other matters.[38]

The statutes have important differences as to the types of decisions that can be made in an advance directive. For example, some statutes cover both consent to and refusal of future health care interventions, while others only permit an advance directive to refuse certain treatments in the future. The statutes also describe circumstances in which a medical practitioner may disregard a directive, for example, where the doctor reasonably believes the instruction is inapplicable to the patient's current circumstances.[39] Where legislation exists, the common law is generally assumed also to apply, meaning that advance directives that do not meet statutory requirements may nonetheless be accepted as legally valid.[40]

There is similar cross-jurisdictional variation in legislation governing other aspects of advance planning, including the appointment of financial and health care decision-makers, the hierarchy that establishes default decision-makers, and statutory provisions for dispute resolution processes and the role of tribunals as decision-making and review bodies.[41] The law also defines the requirements for capacity to make different types of decisions and advance planning instruments, including the capacity to consent to health care, make an advance directive, appoint a substitute decision-maker, make a power of attorney, and prepare a will.[42]

Health practitioners' knowledge of the law

Advance care planning is promoted in health care settings but legal and health issues overlap for an individual who wishes to, or is encouraged to, engage in advance planning. In particular, patients who receive a diagnosis of serious or terminal illness often want to organise their affairs, and in addition to planning for their future health care, are often prompted to think about their plans concerning their finances, property, living situation and care arrangements for dependents. In this context, "questions frequently arise that many physicians feel ill-equipped to answer, including whether patients need a

[36] *Medical Treatment Act 1988* (Vic); *Guardian and Administration Act 1990* (WA); *Powers of Attorney Act 1998* (Qld); *Medical Treatment (Health Directions) Act 2006* (ACT).

[37] These three instruments, previously in place under the *Consent to Medical Treatment and Palliative Care Act 1995* (SA), were Enduring Powers of Guardianship, Medical Powers of Attorney and Anticipatory Directions. Such documents retain legal effect, notwithstanding the new *Advance Care Directives Act 2013* (SA). On the new form, a person may appoint a substitute decision-maker and state their wishes in regard to future health care. For further information, see <https://www.advancecaredirectives.sa.gov.au/>.

[38] The Advance Personal Plan document is available online at <http://www.nt.gov.au/justice/pubtrust/app/documents/Advance-personal-plan-web-FINAL.pdf>. For more information, see <http://www.nt.gov.au/justice/pubtrust/app/index.shtml>.

[39] See, eg *Advance Care Directives Act 2013* (SA) s 36(2); *Powers of Attorney Act 1998* (Qld) s 103.

[40] See discussion by Victorian Law Reform Commission, n 5.

[41] For discussion, see, eg B White, L Willmott and SN Then, "Adults Who Lack Capacity: Substitute Decision-Making" in B White, F McDonald and L Willmott (eds), *Health Law in Australia* (Thomson Reuters, 2nd ed, 2014).

[42] See, eg N O'Neill and C Peisah, *Capacity and the Law* (Sydney University Press, Sydney, 2012) <http://www.austlii.edu.au/au/journals/SydUPLawBk/2011/3.html>; Allens and Queensland Advocacy Incorporated, *Queensland Handbook for Practitioners on Legal Capacity* (2014) <http://www.qls.com.au/Knowledge_centre/Ethics/Resources/Client_instructions_and_capacity/Queensland_Handbook_for_Practitioners_on_Legal_Capacity>; Law Society of New South Wales, *When a Client's Capacity is in Doubt: A Practical Guide for Solicitors* (2009) <http://www.lawsociety.com.au/cs/groups/public/documents/internetcontent/023880.pdf>.

last will and testament, are eligible for disability benefits, or should appeal insurance denials".[43] In regard to advance care planning, health practitioners have the expertise to advise patients on their prognosis and treatment options, but they often lack knowledge about the legal rules relevant to advance directives, substitute decision-makers and, in general, end-of-life decision-making.[44]

Surveys of health practitioners in Australia reveal gaps and inaccuracies in their knowledge about the legal framework for advance planning. Medical specialists most likely to treat patients at the end of life have important gaps in their knowledge of the law concerning, for instance, the validity of advance directives and the authority of substitute decision-makers.[45] A survey of 260 general practitioners and specialists in New South Wales found that over half did not have a clear understanding that a person with enduring power of attorney, who is empowered only to manage financial matters, does not have the legal authority to make health care decisions.[46] A survey of practitioners working in residential aged care facilities in Australia found that a majority did not have confidence in their knowledge about relevant law, including the role of substitute decision-makers and how disagreements about end-of-life care are resolved.[47] Palliative care specialists have a better knowledge of end-of-life law than other medical specialists, but still have important gaps in their understanding.[48]

For the benefits of advance care planning to be realised, health care practitioners require accurate information about relevant legal rules and processes to better support their patients to plan for their care and to ensure their wishes are respected. Various commentators emphasise the need for strategies to increase health practitioners' knowledge about the legal rules that apply when a patient loses capacity and how to deal with conflict among family members.[49] Health practitioners who lack this knowledge are more likely to commit errors in the provision of end-of-life care, including not complying with a valid advance directive and obtaining consent from a person who does not have legal authority to make decisions for the patient.[50] Health practitioners want to avoid conflicts, complaints and litigation and effective advance care planning can help reduce these risks.[51]

People discuss advance care planning with lawyers

People who wish to write an advance directive sometimes seek advice from a lawyer; in fact, they may be more likely to talk to a lawyer than with their doctor. In some cases, a lawyer raising the issue of advance care planning prompts a client to discuss their wishes with family members and prepare legal documents to organise their affairs to be prepared for a future period of incapacity.

In Saskatchewan, Canada, a 2012 survey of 827 adults found that 137 (16.6%) reported having a written advance care plan.[52] Of these respondents, nearly half (47.4%) had obtained assistance from a lawyer to prepare the document, while only 5% had consulted with a doctor. One-fifth had prepared

[43] K Rodabaugh et al, "A Medical-Legal Partnership as a Component of a Palliative Care Model" (2010) 13(1) *Journal of Palliative Medicine* 15, 15.

[44] B White et al, "Doctors' Knowledge of the Law on Withholding and Withdrawing Life-Sustaining Medical Treatment" (2014) 201 *Medical Journal of Australia* 1.

[45] The study involved a survey of over 850 New South Wales, Victoria and Queensland specialists in emergency medicine, geriatric medicine, intensive care, medical oncology, palliative medicine, renal medicine and respiratory medicine.

[46] C Cartwright et al, "Medical Practitioners' Knowledge and Self-Reported Practices of Substitute Decision-Making and Implementation of Advance Care Plans" (2014) 44 *Internal Medicine Journal* 234.

[47] W Silvester et al, "Quality of Advance Care Planning Policy and Practice in Residential Aged Care Facilities in Australia" (2013) 3 *BMJ Supportive & Palliative Care* 349.

[48] C Cartwright et al, "Palliative Care and Other Physicians' Knowledge, Attitudes and Practice Relating to the Law on Withholding/Withdrawing Life-Sustaining Treatment: Survey Results" (2016) 30(2) *Palliative Medicine* 171.

[49] Cartwright et al, n 48; White et al, n 44.

[50] P Chidwick et al, "Checklist to Meet Ethical and Legal Obligations to Critically Ill Patients at the End of Life" (2011) 14(4) *Healthcare Quarterly* 60.

[51] JJ Rhee, NA Zwar and LA Kemp, "Advance Care Planning and Interpersonal Relationships: A Two-Way Street" (2013) 30(2) *Family Practice* 219.

[52] D Goodridge et al, "Planning for Serious Illness by the General Public: A Population-Based Survey" (2013) *ISRN Family*

their plan on their own without consulting a legal or health professional. Of those over age 55, 25% reported having a written advance care plan, 50% had obtained assistance from a lawyer and 4% had consulted with a health care professional. The authors speculate that "it may be that older adults are more willing to consider planning for serious illness under the umbrella of estate planning than health".[53] Another Canadian study involving 500 elderly patients and their family members found that participants discussed their end-of-life care wishes as often or more often with a lawyer than with a family doctor or medical specialist.[54]

In a 2010 German study, researchers surveyed 53 people who had an advance health care directive to find out if they had obtained help from a professional in preparing the document.[55] Just under a quarter of people had sought such help and, among those, legal professionals were the most common source of advice. Eight of the 12 people had obtained assistance from a legal professional, three had consulted a health care practitioner and one saw a self-employed advisor.

An American investigation into the views of healthy older adults on advance care planning reported that lawyers and financial planners are more likely than doctors to assist clients with advance care planning:

> One possible explanation for the contrast was that lawyers and financial planners played a prominent role in guiding elders through end-of-life decisions. Many of the participants shared that a lawyer or financial planner had assisted them in making final arrangements, such as drafting a will, designating a healthcare proxy or power of attorney, or planning for a funeral and burial. As one woman said, "My lawyer was the first person who brought advance care planning up to me. He told me I should fill out the healthcare proxy form".[56]

Likewise, a study of advance planning for persons with dementia found that many people "identified non-health care professionals such as lawyers, accountants, and financial planners as individuals who help them plan for the future".[57] The authors point out that interventions to promote advance care planning have typically focused on health care professionals, but with mixed results. They recommend interventions to help other types of professionals to engage their clients in advance planning discussions and argue that "non-health care professionals can play an important part in helping families begin their discussions and put together documentation to assist these families when their relative can no longer express preferences".[58]

These studies reveal that lawyers have an important role to play in helping clients prepare advance directives and other future planning documents. Indeed, the principles of therapeutic jurisprudence and preventive lawyering offer strong support for lawyers' roles in advance care planning and greater medical-legal collaboration in this area.[59] Therapeutic jurisprudence recognises law's psychosocial impacts on people and, integrated with preventive lawyering, seeks to minimise legal disputes and use legal tools to promote the wellbeing of clients and others affected by legal rules and processes. In regard to meeting the needs of an ageing population, it has been argued that "to fulfil

Medicine 1 <http://dx.doi.org/10.5402/2013/483673>.

[53] Goodridge et al, n 52, 5.

[54] D Heyland et al, "Failure to Engage Hospitalized Elderly Patients and their Families in Advance Care Planning" (2013) 173(9) *JAMA Internal Medicine* 778, see esp Table 3, 784.

[55] M Becker et al, "Did you Seek Assistance for Writing Your Advance Directive? A Qualitative Study" (2010) 122 *Wiener Klinische Wochenschrift* 620.

[56] H Malcomson and S Bisbee, "Perspectives of Healthy Elders on Advance Care Planning" (2009) 21(1) *Journal of the American Academy of Nurse Practitioners* 18, 21. The authors continue (at 21): "Because there are professionals (eg, lawyers and financial planners) who make it their business to guide clients through the complex transactions associated with death, it is understandable that elders seem so prepared for the logistics of death. There is no such group of professionals who have embraced the work of guiding elders through anticipatory end-of-life care planning."

[57] Hirschman, Kapo and Karlawish, n 33, 298. The authors report that half of their study participants said that discussions with a lawyer or an accountant prompted them to engage in advance planning.

[58] Hirschman, Kapo and Karlawish, n 33, 297.

[59] T Hafemeister, "End-of-Life Decision-Making, Therapeutic Jurisprudence, and Preventive Law: Hierarchical v Consensus-Based Decision-Making Model" (1999) 41 *Arizona Law Review* 329.

their professional responsibilities, lawyers rendering advice [particularly] to older clients should give explicit consideration to maintaining or enhancing the client's psychological well-being",[60] for instance, by helping the client to plan ahead to express their wishes for a future period of incapacity.

LEGAL-HEALTH COLLABORATION

This part of the article advocates for increased collaboration between legal and health professionals to support clients in planning ahead for their health and related needs. Advance care planning should be understood as part of preventive lawyering and preventive health care practice, whereby improved inter-professional collaboration can help ensure the client's interests are best protected and conflicts and confusion are minimised. Provision of accurate legal advice about the rules and processes relevant to advance planning can prevent misconceptions about the law, and clear medical advice about prognosis and treatment options enables well-informed health care choices. With effective care planning, the individual can prevent the future administration of health care interventions they do not want. Communication and discussion about one's values and preferences can prevent disagreements between health care practitioners and the patient's significant others. The stresses of acting as a substitute decision-maker can also be alleviated as the decision-maker and health professionals are guided by the patient's own expression and documentation of their wishes.

At a minimum, legal practitioners can adopt a routine practice of raising advance health care planning with clients who see them for related legal issues, such as making a will or selling assets as part of a transition into aged care.[61] Barbara Noah observes that "the irony persists that clients often make elaborate plans about how their worldly goods will be distributed after their death, while remaining reluctant to articulate preferences about their own journey".[62] Some older adults are said to be more prepared for death, such as having paid for their funeral and burial, but their "preparedness for death stands in stark contrast to the general lack of communication and planning regarding the period of dying".[63] It has been argued that advance care planning should be a part of health care providers' "core business";[64] likewise, discussion of health care planning should be routine when lawyers assist clients with other aspects of advance planning.

More ambitiously, the medical-legal partnership model may be adopted to enable lawyers to deliver their services in health care settings in closer collaboration with health professionals. As Goodridge and colleagues advocate:

> New forms of interprofessional collaborations should be considered to increase the interface between physicians and lawyers. Advance care planning clinics in which lawyers work alongside health care providers could provide a value-added service to clients interested in preparing formal documents.[65]

The medical-legal partnership model developed largely in the United States and is currently being adapted in the Australian context in initiatives known as advocacy-health alliances or health-justice partnerships.[66] Such collaborations are a model for service delivery in which legal help is connected with the provision of health care with the aim of reducing the health-harming stressors of unmet legal

[60] D Stolle, "Professional Responsibility in Elder Law: A Synthesis of Preventive Law and Therapeutic Jurisprudence" (1996) 14 *Behavioural Sciences and the Law* 459, 460.

[61] It is suggested that individuals review their planning documents when any of the events known as the "5 Ds" occurs – each new decade of life, the death of a loved one, divorce, a significant medical diagnosis, and a significant functional decline: A Sutton, *Advance Directives Evolve to Ensure Better End-of-Life Planning* (Centre for Advancing Health, 2010) <http://www.cfah.org/hbns/2010/advance-directives-evolve-to-ensure-better-end-of-life-planning>.

[62] B Noah, "A Role for Law in Preparing for Death" (September 2014) *Trusts & Estates* 55.

[63] Malcomson and Bisbee, n 56, 21.

[64] White et al, n 16, 979, citing Scott et al, n 15.

[65] Goodridge et al, n 52, 4.

[66] For background information on the medical-legal partnership movement in the United States, see National Centre for Medical Legal Partnership, <http://medical-legalpartnership.org/>. In Australia, see Justice Connect *Health Justice Partnerships* <http://www.justiceconnect.org.au/what-we-do/what-we-are-working/health-justice-partnerships>. The term "medical-legal partnership" denotes the professionals involved while the terms "advocacy-health alliance" or "health-justice partnership" are

needs.[67] The degree of connection may vary, with the highest degree of integration involving lawyers providing services on-site at health care organisations. Other models involve co-ordinated referrals to an off-site legal service organisation that partners with the health care institution. Effective partnerships typically involve: inter-professional training for health and legal practitioners to support a common understanding of relevant law and each profession's roles in addressing clients' overlapping health and legal needs; implementation of "legal check-up" screening tools to enable health care providers to identify and prioritise clients who have unmet legal needs; timely consultation with a lawyer; and appropriate communication between health and legal practitioners.

Some examples exist of lawyers collaborating with health care providers to support clients with advance planning. Hallarman et al have proposed a model for incorporating the medical-legal partnership model into palliative care, arguing that inter-professional collaboration can help "in identifying and addressing major sources of financial-legal-social anxieties surrounding legacy planning, guardianships/planning for minor children and disabled adult children, future planning documents, access to care, and next steps in care".[68] Rodabaugh and colleagues have reported on an American program to provide free legal help to low-income patients with a life-limiting cancer diagnosis.[69] Over a three-year period, nearly 300 referrals occurred and the dominant legal issues included advance care planning, benefits advocacy, guardianship matters, estate planning and housing issues. In Australia, a pilot medical-legal partnership at a major Melbourne Hospital offers a "legal triage" service where lawyers are available two days each week to provide free legal advice, including on matters related to advance planning, such as making wills and preparing guardianship documents.[70] Justice Connect, a pro bono legal organisation, offers seniors law clinics in several health care facilities in metropolitan Melbourne and provides an on-site lawyer at one community health centre to provide integrated services for older adult clients.[71]

Medical-legal partnerships are founded on the recognition that unmet legal needs and problems can have adverse impacts on a person's health and wellbeing. They have three overarching aims.[72] First, such partnerships enable multidisciplinary collaboration to address a client's health care and legal needs in a more co-ordinated manner. Secondly, partnerships aim to transform health and legal practices and institutions. Thirdly, partnerships are an advocacy tool for law and policy reform. The tripartite aims of medical-legal partnerships can help address the three major categories of barriers to advance care planning: client-centred, practitioner-centred and system-centred.[73]

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arguably more client-centred in referring to the types of services that are delivered and the outcomes that are sought. The term "health" also implies a role for a wider range of health practitioners, not just medical practitioners. For a comprehensive report on medical-legal partnerships, see L Gyorki, *Breaking Down the Silos: Overcoming the Practical and Ethical Barriers of Integrating Legal Assistance into a Healthcare Setting* (Winston Churchill Memorial Trust of Australia, 2013) <https://www.churchilltrust.com.au/media/fellows/Breaking_down_the_silos_L_Gyorki_2013.pdf>.

[67] See generally M Sandel et al, "Medical-Legal Partnerships: Transforming Primary Care by Addressing the Legal Needs of Vulnerable Populations" (2010) 19 *Health Affairs* 1697.

[68] L Hallarman et al, "Blueprint for Success: Translating Innovations from the Field of Palliative Medicine to the Medical-Legal Partnership" (2014) 35(1) *Journal of Legal Medicine* 179, 180.

[69] Rodabaugh et al, n 43.

[70] Maurice Blackburn Lawyers, *HeLP Patient Legal Clinic* (2015) <http://www.mauriceblackburn.com.au/about/in-the-community/help-patient-legal-clinic/>; Monash University, *Legal Aid Helps Patients at The Alfred* (2014) <http://monash.edu/news/show/legal-aid-for-patients-at-the-alfred>.

[71] Justice Connect, *Health Justice Partnership* <http://www.justiceconnect.org.au/our-programs/seniors-law/get-help/health-justice-partnership>; Justice Connect, *Seniors Law Clinics* <http://www.justiceconnect.org.au/our-programs/seniors-law/get-help/seniors-law-clinics>.

[72] E Lawton et al, "Medical-Legal Partnership: A New Standard of Care for Vulnerable Populations" in E Tobin Tyler et al (eds), *Poverty, Health and Law: Readings and Cases for Medical-Legal Partnership* (Carolina Academic Press, Durham, 2011) 71.

[73] Boddy et al, n 24.

Client-centred

Members of the public who are interested in advance care planning as part of planning for their future are sometimes not sure whom to ask for help: "Do I have to go and pay a solicitor to do all this with me or can I just see my GP?"[74] Health practitioners report that some patients mistakenly believe their will covers issues related to medical decision-making.[75] Lawyers can help educate clients by providing accurate legal information and clearly explaining different legal documents and actions, including making a will, appointing financial and health care decision-makers, and preparing an advance directive.

Clients sometimes fear that appointing financial or health care decision-makers means they are giving away control to others;[76] however, lawyers can clarify that advance planning is a means for people to maintain control over their future by recording and communicating their wishes and designating trusted people as decision-makers. Lawyers can also counsel clients on the importance of reviewing and updating their documents periodically to reflect any changes in their wishes and providing copies to significant others who need to know about and act on the client's current instructions. These may include medical practitioners, persons appointed to make property and health decisions, and financial institutions.

People who have a written health care directive are also likely to have a will and a financial power of attorney.[77] To improve the uptake of advance care planning, the challenge is to promote more people to become "planners" of this sort. Behaviour change theory shows that people transition through stages of knowledge acquisition, contemplation, the development of a sense of self-efficacy, and, finally, readiness to act.[78] Lawyers can play an important role in facilitating behaviour change by raising health care planning with their clients, providing them with legally accurate resources, and encouraging clients to discuss their wishes with significant others and health care professionals. This can help normalise advance preparation and reduce barriers related to a lack of knowledge about planning for one's future.

Health practitioners acknowledge that "[a]dvance care planning is widely recommended by professional, regulatory, and [government] institutions but it is still not in common use" and suggest that "[a] powerful stimulus to change would be patients taking the lead and requesting advance care plans".[79] If lawyers help to raise awareness among their clients and prompt them to talk to their health care providers about advance care planning, this stimulus is more likely to happen.

Practitioner-centred

Overcoming practitioner-centred barriers requires work to deal with the professional silos between lawyers and health care providers. In a report on the legal needs of older adults, the New South Wales Law and Justice Foundation identified that many older people lack knowledge of the legal aspects of advance planning and suggested:

> it may be more effective to place responsibility for the dispensation of advice on EPOAs [enduring power of attorney] (and potentially other areas of substitute decision-making) on the medical profession, rather than the legal profession. Possible reasons for this are that older people are more likely to consult with medical practitioners on a regular basis than with lawyers, and that the issue of capacity will most likely be raised by a medical practitioner before a lawyer is consulted.[80]

[74] Boddy et al, n 24, 40. A health practitioner focus group participant reported that a patient asked her this question.

[75] Boddy et al, n 24.

[76] Boddy et al, n 24, 41, noting that some patients fear giving up control and they do not realise they can change advance directives and substitute decision-maker appointments.

[77] White et al, n 16.

[78] RL Sudore et al, "Development and Validation of a Questionnaire to Detect Behavior Change in Multiple Advance Care Planning Behaviors" (2013) 8(9) *PLoS One* 1, DOI: 10.1371/journal.pone.0072465.

[79] T Eynon, MK Lakhani and R Baker, "Never the Right Time: Advance Care Planning with Frail and Older People" (2013) 63(615) *British Journal of General Practice* 511, 512.

[80] S Ellison et al, *The Legal Needs of Older People in NSW* (Law and Justice Foundation of New South Wales, 2004) 309

Collaboration between legal and health professionals is a better solution to provide more effective and holistic advance care planning help for their clients. Planning ahead requires an individual to make choices with the benefit (ideally) of both legal and medical input and, while some people see a doctor regularly, they may nonetheless be as or more likely to discuss advance care planning with a lawyer. The studies summarised earlier reveal that some health practitioners already feel they are too time pressured to support their clients in advance care planning and they lack knowledge of the law. It is unrealistic to place responsibilities on doctors to explain to patients the legal aspects of advance care and end-of-life planning.[81] Moreover, a recent study reveals:

> Problems were reported when ACDs [advance care directives] were prepared by people with little knowledge of the legal issues associated with the preparation and use of ACDs. This was a particular concern when advance care planning was left to junior medical staff who lacked the necessary skills and legal knowledge.[82]

Inter-professional training opportunities are one important strategy to address these knowledge gaps. Lawyers can provide legal information resources to help health practitioners understand the law relevant to advance directives, appointment of a health care guardian, decision-making if a guardian is not appointed, and dispute resolution processes in the event of conflict over care for a person who does not have decision-making capacity. As discussed earlier, health practitioners feel ill equipped to deal with the issues that arise, especially in circumstances where a patient has fluctuating capacity and family members are in conflict and possibly acting against the interests of the patient. In these circumstances, health practitioners may feel:

> powerless to do as much as they would like to help remedy their patients' problems. But reframing those patient problems can help. Quite often, the problems are legal ones where an expert is already trained to address them.[83]

More formalised connections between health and legal professionals can ensure that clients receive timely assistance to deal with legal situations that may be health stressors and undermine the quality of their care.

Similarly, lawyers can learn from health care professionals who have expertise in advance care planning and end-of-life care. Lawyers generally do not have adequate knowledge to explain the medical language and scenarios often used in advance directive templates[84] and they sometimes contribute to problems with ineffective advance care plans by giving clients complicated directive documents obtained from outdated or unreliable sources. There are numerous directive templates available online and lawyers and clients may fail to tailor them to the person's particular circumstances. One study reported that if a legal professional drafted an advance directive or downloaded a template from a website, "[n]one of these forms was amended according to individual needs of the [client] by the legal professional or the [client]", who simply signed the document and

<http://www.lawfoundation.net.au/ljf/site/articleIDs/6FFEB98D3C8D21 F1CA25707E0024D3EB/$file/older_law_report.pdf>.

[81] Ellison et al, n 80, 309 acknowledged this concern: "many medical practitioners have a limited understanding of issues surrounding capacity and of the purpose of EPOAs." Australian clinical practice guidelines on end-of-life care communication also acknowledge the complexity of law in this area. See Clayton et al, n 25, 95: "In-depth discussion of advance directives and enduring medical powers of attorney are beyond the scope of these guidelines. The status of advance directives and the status and responsibilities of representatives of incompetent patients is complex and varies from jurisdiction to jurisdiction. Legal advice may need to be sought."

[82] C Johnson et al, "Palliative Care Health Professionals' Experiences of Caring for Patients with Advance Care Directives" (2015) 39 *Australian Health Review* 154, 156.

[83] J Teitelbaum, *The Medical-Legal Partnership Approach to the Social Determinants of Health* (Community Health Forum, 2014) <http://medical-legalpartnership.org/medical-legal-partnership-featured-community-health-center-magazine/>.

[84] For example, directives may refer to different levels of care (intensive, active, limited, palliative), various types of medical interventions that may be available, and scenarios of varying prognoses. For a comprehensive example, see S Graham et al, *My Health, My Future, My Choice: An Advance Care Directive for New South Wales* (Advance Care Directive Association Inc, 2013, 4th ed) <http://www.advancecaredirectives.org.au/pdf/ADCA-WEB-2014-My-Health-My-Future.pdf>.

made no subsequent changes.[85] This troubling practice indicates that lawyers, like health practitioners, must have training and access to appropriate resources to help them support clients in the preparation of personalised advance planning documents.

Another shortcoming of a legal approach is that it may too narrowly convey advance care planning as the one-time drafting of legal documents. Goodridge observes:

> Members of the public rely heavily on lawyers to prepare planning documents ... [and] ... Lawyers' professional training focuses on the legal aspects of end of life planning. Whether drafting estate wills or advance care plans, lawyers are trained to understand the default legislative provisions in their jurisdiction, the flexibility individuals have to alter the default regime, and the legal procedure necessary to bring about this alteration. This method of giving voice to the clients' wishes may cause many lawyers to view end of life decisions through a legal rather than a holistic lens, potentially limiting the clinical utility of advance care plans.[86]

Health and legal practitioners who assist a client with advance care planning must understand and emphasise to clients that it is not a single event; rather, it is an iterative process of communication between the client, their significant others and care providers.[87] Sabatino describes this paradigm shift:

> For most of [their] history ... advance directive laws predominantly emphasized standardized legal forms characterized by mandatory formalities and restrictions, with procedural requirements and limitations intended to serve as protections against abuse and error. This approach could be characterized as a "legal transactional approach". Over the past two decades, this approach has been slowly and incrementally moving toward an approach that more strongly acknowledges an ongoing and flexible process of communication. This newer model could be described as a "communications approach".[88]

Capacity assessment is another area where improved medical-legal collaboration would support better and more consistent processes to determine an individual's capacity to make health care choices, prepare an advance directive, designate a health care decision-maker, and execute other legal documents. Capacity assessments ideally involve co-operation between lawyers and health professionals, and there has been recent criticism of the prevailing practice of "unsatisfactory, ad hoc implementation of various methods tailored to suit individual practitioners, be they legal or medical".[89] The New South Wales Office of the Legal Services Commissioner reports that more complaints are being made against lawyers for failing to deal appropriately with capacity issues and the Office is undertaking work to determine if professional standards need to be strengthened in this area.[90] A survey of Australian solicitors[91] revealed a wide range of means for assessing capacity and some inadequacies in lawyers' practices. Almost 50% of the respondents expressed interest in further training. Boddy and colleagues report that health practitioners also express confusion about capacity issues, for example, being uncertain when, legally, a person is considered not to have capacity to make

[85] Becker et al, n 55, 623.

[86] Goodridge et al, n 52, 4.

[87] L Castillo et al, "Lost in Translation: The Unintended Consequences of Advance Directive Law on Clinical Care" (2011) 154(2) *Annals of Internal Medicine* 121. The authors (at 122) criticise "a strict, legal-transactional approach to advance care planning that is akin to signing a will".

[88] Sabatino, n 3, 218. In its recent report, *Dying in America*, the US Institute of Medicine also stresses that advance care planning is not "a one-time activity, but instead emphasize discussion of goals, values, and care preferences among individuals, family, health care agents, and care providers over the life span. Ideally, these discussions would start early in adulthood, addressing global values and the identification of potential surrogate decision-makers, and focusing on more specific treatment preferences for older persons and those facing serious illness. With changes in health status, they would take on increasing specificity. 'Putting it in writing' remains important but does not substitute for the discussion": Institute of Medicine, n 2, 118.

[89] K Purser and T Rosenfeld, "Evaluation of Legal Capacity by Doctors and Lawyers: The Need for Collaborative Assessment" (2014) 201(8) *Medical Journal of Australia* 483, 483.

[90] NSW Office of the Legal Services Commissioner, *Annual Report 2012-2013*, 30; NSW Office of the Legal Services Commissioner, *Annual Report 2013-2014*, 18.

[91] E Helmes, VE Lewis and A Allan, "Australian Lawyers' Views on Competency Issues in Older Adults" (2004) 22 *Behavioural Sciences and the Law* 823.

decisions or engage in advance care planning.[92] For instance, some practitioners wonder if the capacity needed to appoint a substitute decision-maker is lower than that required to make an advance directive. These findings indicate a need for inter-professional education and collaboration involving legal and health practitioners.

Changes in professional cultures may be needed to overcome practitioner-centred barriers and encourage both lawyers and doctors to adopt new practices that offer more co-ordinated supports for their clients. White and colleagues observe:

> Attitudes must also shift; doctors who are under ever-increasing time pressures must be satisfied that knowing the law is valuable ... A good start is to ensure that doctors recognise that lack of legal knowledge places their patients' interests and rights at risk – and them at legal risk.[93]

Knowing and complying with the law is crucial to reduce health care providers' liability risks and avoid medical errors in end-of-life care.[94]

Another practitioner-centred issue to address is that of paternalism. The emphasis on advance planning in health care aims to promote patient autonomy and reduce the paternalistic role of a health practitioner making decisions for the patient. The anti-paternalism trend is also evident in efforts to implement shared decision-making models in health care.[95] Likewise, the lawyer-client relationship is grounded in the theory that the practitioner gives expert advice about the law and options, then the client chooses a course of action based on their own values and interests. In practice, however, lawyers, like health care providers, must guard against implicit assumptions that they know best and avoid undermining the client's wishes. Bellard cautions:

> One of the dangers of lawyer paternalism is that it prevents attorneys from competently assessing their clients' values ... [it] hamper[s] client participation by devaluing client expression. As a result of their experience and education, attorneys have a tendency to "dominate" the attorney-client relationship ... Lawyers who draft advance medical directives can also fall into this trap when they act upon their own belief about what is in the client's best interests without adequately assessing their client's values and wishes.[96]

Lawyers must carefully elicit what the client wants and prepare advance planning documents that express those wishes. Where templates are used (either statutorily mandated or generic), the client's specific directions must be documented to tailor the instrument to the client's circumstances:

> these "fill in the blank forms" may not be enough for most clients. Clients who make the effort to speak with their attorney deserve the undivided attention of an attorney who will help them realize and enunciate their own values.[97]

It is worth noting that within collaborative service models, legal and health practitioners must ensure they fulfil their individual ethical obligations to their clients.[98] For example, a lawyer who provides services in a health care setting must be clear about who their client is and ensure he or she represents the client's interests, not those of the partnering health care organisation. Where a formal medical-legal partnership is established and health practitioners screen and refer clients to the on- or off-site legal service, an agreement typically states that the lawyer will not deal with patients' allegations of negligence or misconduct on the part of health care providers and institutions.

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[92] Boddy et al, n 24, 43.

[93] White et al, n 44, 232.

[94] T Allison and R Sudore, "Disregard of Patients' Preferences Is a Medical Error: Comment on 'Failure to Engage Hospitalized Elderly Patients and Their Families in Advance Care Planning'" (2013) 173(9) *JAMA Internal Medicine* 787.

[95] F Legare et al, "Interventions for Improving the Adoption of Shared Decision-Making by Healthcare Professionals" (2014) 15(9) *Cochrane Database of Systematic Reviews* 1.

[96] L Bellard, "Restraining the Paternalism of Attorneys and Families in End-of-Life Decision-Making While Recognizing that Patients Want More than Just Autonomy" (2001) 14 *Georgetown Journal of Legal Ethics* 803, 808.

[97] Bellard, n 96, 821.

[98] A full discussion of ethical issues is outside the scope of this article, but see generally P Galowitz et al, "Ethical Issues in Medical-Legal Partnership" in E Tobin Tyler et al (eds), *Poverty, Health and Law: Readings and Cases for Medical-Legal Partnership* (Carolina Academic Press, Durham, 2011) p 157.

System-centred

To promote the uptake and effectiveness of advance care planning, there is a need to "transform systemic processes across a range of institutional settings".[99] Lund and colleagues make an important observation that "barriers and facilitators are not opposites of each other. This means that doing more of the things that facilitate the delivery of ACPs may not reduce the effects of those things that undermine them."[100] A major barrier is that no professional group sees advance care planning as its core responsibility. The systemic response that is needed is what the United States Institute of Medicine calls a "whole-community model" where legal and health professions, governmental and non-governmental organisations, community groups and others promote advance care planning and see it as everyone's responsibility.[101] Greater collaboration among lawyers and health practitioners is a step toward this transformation in the context of two dominant domains of professional practice and institutions relevant to advance care planning.

Another major system-oriented change would be health insurance reimbursement for legal services in health settings:

> The ideal set-up would be having a lawyer as a part of that multidisciplinary team, either funded by the government, in the case of public services, or potentially funded as any other allied health practitioner or nurse practitioner would be funded in a community setting. Maybe the dream is to have Medicare line items for lawyers![102]

In current circumstances, however, legal-health collaborations must rely on other funding sources. Existing partnerships typically involve provision of pro bono services by private firms or legal aid organisations. Public and philanthropic funding may support some programs; for instance, in 2014 the Legal Services Board of Victoria awarded $2.6 million to support nine legal-health partnership initiatives over one- to three-year periods.[103]

Legal clinics operated by law schools[104] also provide an opportunity to meet the dual objectives of providing practical learning opportunities for students and addressing unmet legal needs in the community. Commentators have called for enhanced health care education to ensure the next generation of clinicians is better prepared to have advance care planning conversations with patients.[105] Similarly, providing law students with opportunities to participate in clinics can help build their substantive knowledge of the law relevant to advance planning, and also to gain supervised, practical experience in interviewing and providing information to clients, dealing with possible capacity issues, and drafting relevant documents. A commitment to legal-health collaboration can also be implemented in inter-professional clinics where students in disciplines such as law, medicine, nursing and social work gain experience working together.[106]

Where new models of legal-health collaboration rely on scarce funding sources, clients must be prioritised to ensure support is provided first to those at greatest need. As medical-legal partnerships

[99] Lovell and Yates, n 19.

[100] Lund, Richardson and May, n 23.

[101] Institute of Medicine, n 2, 6-20.

[102] A McGilvray, "Prescribing the Law" (2014) 200(8) *Medical Journal of Australia* 1, 2, quoting Dr Lander, a former advocacy-health alliance co-ordinator at Justice Connect, a peak body for pro bono legal services.

[103] For an overview of the funded projects, see Victorian Legal Services Board and Commissioner, *Major Grants* <http://lsbc.vic.gov.au/?page_id=177>; Victorian Legal Services Board and Commissioner, *Grants Program E-Bulletin* (October 2014) <www.lsb.vic.gov.au/documents/Newsletter_11_Grants_Program_2014.PDF>.

[104] Various examples exist in the United States, such as the Yale Health Law & Policy Society, *Medical-Legal Partnerships* <http://www.law.yale.edu/academics/yhelps_partnerships.htm>; The University of Kansas, *Medical-Legal Partnership Clinic* <http://law.ku.edu/mlpclinic>; Georgia State University, *HeLP Legal Services Clinic* <http://law.gsu.edu/clinics/help-legal-services-clinic/>. For scholarly discussion of such clinics, see, eg J Wettach, "The Law School Clinic as a Partner in Medical-Legal Partnership" (2008) 75 *Tennessee Law Review* 305.

[105] See, eg Institute of Medicine, n 2; BH Levi et al, "An Interactive Exercise in Advance Care Planning for Medical Students" (2013) 16 *Journal of Palliative Medicine* 1523.

[106] For discussion, see, eg R Pettignano, L Bliss and S Caley, "The Health Law Partnership: A Medical-Legal Partnership Strategically Designed to Provide a Coordinated Approach to Public Health Legal Services, Education, Advocacy, Evaluation,

typically involve pro bono services, precedence is given to clients with low income and reduced means to hire a lawyer privately. Clients with financial resources can be referred to external legal practitioners for assistance. Priority should also be given to people in later stages of illness who wish to make or update legal instruments to plan for potentially more imminent periods of incapacity and decline. Patients with dysfunctional families and socially isolated patients who have few people close to them may also benefit more from having an advance directive; a doctor in one study worried that without an advance directive, the care of such patients would "be 'left a bit to the fates'".[107] These priority groups are consistent with the goals of preventive lawyering and therapeutic justice: "[u]nresolved financial and legal issues can be a source of intense suffering and adversely impact a patient's ability to copy with the extreme challenge of advanced illness."[108] Social workers or patient navigators can help to identify patients at highest need and refer them for legal help. Advance planning clinics could also be offered in residential aged care facilities.[109]

Finally, as part of increased collaboration, legal and health practitioners can advocate for law reforms to improve the uptake and effectiveness of advance care planning. Input from both professional groups is crucial. Health practitioners can identify practical, "front line" problems that could be solved, at least in part, by legal reform. Lawyers can identify areas for greater clarity, consistency and simplicity in the law.[110]

In Australia, both legal and health commentators have called for "standardisation of the laws governing ACP across different jurisdictions and health systems".[111] White and colleagues reason that the prevalence of advance directives is higher in South Australia and Queensland because those States have well recognised statutorily mandated advance directive forms.[112] In contrast, New South Wales and Tasmania, States that rely on the common law to give force to advance directives and do not have legally standardised templates, have lower rates of uptake.

Legislative variation and burdensome legal rules have also been criticised as unintended barriers to advance care planning and problems with procedural and substantive aspects of legislation have been identified. In the United States, for example, a nationwide review of advance directive statutes criticised onerous and formalistic requirements for witnessing advance directives that may deter some people from creating the documents or invalidate their legal effect.[113] This review also identified problematic gaps or restrictions in legislation, such as not recognising same-sex or domestic partners as a default substitute decision-maker and limiting who may act as a decision-maker and the types of decisions they may make. Moreover, the reviewers criticised the statutory language in general, commenting that it exceeded a high school literacy level.

Research, and Scholarship" (2014) 35(1) *Journal of Legal Medicine* 57; S Gross, J Seymour and R Frasso, "Medical Legal Partnership Education: A Survey of Existing Programs and Recommendations for National Curriculum" (Paper presented at the American Public Health Association Annual Meeting, New Orleans, 18 November 2014).

[107] Rhee, Zwar and Kemp, n 51, 223.

[108] L Hallarman and D Snow, "The Medical Legal Partnership: Addressing Medical-Legal Suffering for Patients with Advanced Illness" (2012) 15(1) *Journal of Palliative Medicine* 123.

[109] See, eg Swerissen and Duckett, n 14. The authors recommend that advance care planning should be offered, inter alia, to all residents of aged care facilities.

[110] See, eg A Venkat and J Becker, "The Effect of Statutory Limitations on the Authority of Substitute Decision-Makers on the Care of Patients in the Intensive Care Unit: Case Examples and Review of State Laws Affecting Withdrawing or Withholding Life-Sustaining Treatment" (2014) 29(2) *Journal of Intensive Care Medicine* 71, 71. The authors "provide case examples of how statutory limitations on substitute decision-making authority for next of kin can impede the care of patients … [and] review possible ethical and legal solutions".

[111] Rhee, Zwar and Kemp, n 19, 102. See also the Senate Community Affairs References Committee, n 5; Swerissen and Duckett, n 14.

[112] White et al, n 16. The authors' survey found that rates of advance directive completion were 21% in South Australia and 19% in Queensland. In New South Wales and Tasmania, the rates are 13% and 15%, respectively.

[113] Castillo et al, n 87.

Some people prepare advance directives on their own using templates accessed from a government, health or advocacy organisation[114] and these templates often require literacy well above the Year 5 or Year 6 grade level that is typically recommended for public documents: "Most advance directives (which often contain complex legal constructions and descriptions of medical technologies and procedures) require at least a twelfth-grade reading level."[115] The American researchers recommended better plain-language legislative drafting, statutory allowance for oral advance directives, and removing witnessing requirements. Some of these recommendations could apply equally in the Australian context and collaboration between legal and health professionals can identify specific areas for reform.

CONCLUSION

This article ends by identifying areas for future research and offering some concluding thoughts. The studies summarised above reveal that people discuss advance care planning with legal professionals, however, there is virtually no research investigating the nature of lawyer-client interactions in this area. A literature review on the topic revealed few published studies in medical and legal journals.[116] Not much has changed since Mansell and colleagues observed in 1999 that "[t]he medical literature has little information about the role of attorneys in advance directive discussions and completion".[117] Important questions should be investigated in future research. For example, does the lawyer or the client initiate advance care planning discussions? What circumstances prompt a client to consult a lawyer about planning ahead for their health care, finances and other matters? Many health care providers feel poorly equipped to discuss advance care planning with patients; do lawyers have similar qualms about a lack of training to deal with clients' emotional and other needs? Do lawyers encourage their clients to speak to their health care providers and family members about their wishes for future health care? What resources do lawyers use to guide advance planning discussions with clients? Do lawyers feel there are gaps in resources available to them? What role might law societies and legal professional associations play in providing guidance to lawyers? Clinical practice guidelines exist for health care providers; should such guidelines be developed for lawyers?

In addition to learning more about lawyers' practices in helping their clients with advance planning, it is critical to evaluate the impact of novel legal-health collaborations that aim to support clients in advance care planning. High quality evaluation data is particularly important to attract new system level investments. Some evaluation tools have been proposed for medical-legal partnerships[118] and "[e]merging evidence demonstrates that patient-clients benefit substantially from the addition of legal expertise to the patient care team".[119] Work is under way to develop appropriate tools for local contexts. For instance, representatives of health, justice and community sectors in New South Wales hosted a recent workshop on evaluation tools and resources for such partnerships.[120]

Measures must go beyond simply tracking the number of client referrals from health practitioners to lawyers and files opened and resolved, but also include collecting data on the experiences and outcomes for clients, substitute decision-makers, family members, health practitioners, and health care

[114] L Mueller, K Reid and P Mueller, "Readability of State-Sponsored Advance Directive Forms in the United States: A Cross Sectional Study" (2010) 11(1) *BMC Medical Ethics* 6.

[115] Castillo et al, n 87. The authors note that a US National Work Group on Literacy and Health recommends documents be at a fifth grade level.

[116] See n 7.

[117] D Mansell et al, "Roles of Physicians, Attorneys, and Illness Experience in Advance Directives" (1999) 92(2) *Southern Medical Journal* 197.

[118] J Teufel et al, "Process and Impact Evaluation of a Legal Assistance and Health Care Community Partnership" (2009) 10(3) *Health Promotion Practice* 378.

[119] Hallarman et al, n 68, citing, eg T Beeson et al, *Making the Case for Medical-Legal Partnerships: A Review of the Evidence* (National Centre for Medical-Legal Partnership, 2013) 2. The importance of evaluation is recognised locally, with a recent workshop on the evaluation of health-justice partnerships: Health Justice Partnerships Community of Practice, *Evaluation of Health Justice Partnerships: Seminar and Workshop* (25 February 2015) <https://healthjusticecop.wordpress.com/events/>.

[120] Health Justice Partnerships Community of Practice, n 119.

institutions. For example, does greater collaboration between legal and health professionals increase the prevalence of advance care planning, including the appointment of substitute decision-makers and the preparation of advance directives? Does collaboration improve the quality of advance directive documents by providing a clear and accurate personal expression of the individual's wishes in accordance with relevant legal rules? Do people, especially those with serious diagnoses of progressive or terminal illnesses, report reduced stress and better emotional preparation for their future if they have had co-ordinated legal and medical help in their advance planning? Do substitute decision-makers and family members report reduced stress and improved understanding of the wishes of the person who is ill? Do health practitioners report greater confidence in the legal validity of directives and in delivering care in accordance with the patient's documented wishes? Where collaboration involves training for health practitioners about the legal rules for advance care planning, does practitioners' knowledge of the law improve?

Data on financial costs and benefits are also needed, as evidence of broader socio-economic gains may lead to more sustainable funding:

> While the primary objective of advance care planning is delivery of care that is consistent with patient wishes, it is also possible that more widespread use of advance care planning might yield efficiencies for the healthcare system. When patient preferences are unknown near the end of life, decisions about care can be uncertain and faltering. With thoughtful advance care planning, patient preferences become less ambiguous and the potential exists for care that is deliberate, seamless, and respectful. If care delivery approaches this ideal, payers stand to benefit from more widespread use of advance care planning and might consider incentivizing providers to boost participation in advance care planning activities.[121]

Long-term data collection is needed to measure if health care cost savings are realised by reducing intensive medical interventions and hospitalisation in accordance with individual wishes. Positive evaluation results of collaboration between health and legal practitioners can support arguments for allocating funds within the health system to pay for legal services, much as the services of social workers and psychologists are eligible for coverage.

"Advance care planning deserves more of our interdisciplinary attention, conversations, health research and practice, joining up professions, social movements, cultural and psychological research, health and social care policy."[122] Indeed, the goal of this article is to contribute to this interdisciplinary attention and argue for more "joined up" collaboration between legal and health professions. Much existing work has focused on interventions to improve advance care planning processes in health care settings and between health practitioners and patients, often advocating a "collaborative model between patient, family, and physician".[123] Lawyers, too, can play an important role in this collaboration.

If they do not already do so as part of their professional practice, lawyers ought to discuss all aspects of advance planning with their clients, including planning in advance for health care by preparing written directives and appointing a substitute decision-maker. By discussing advance care planning with clients, lawyers can stimulate psycho-social readiness to engage in "planning ahead" behaviours. Lawyers also have expertise in the procedural aspects by which "plans can be made, legitimized, recorded and shared".[124] Recognising advance care planning as a process of communication, lawyers must encourage clients to discuss their wishes and plans with significant others and their health care providers.

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[121] Malcomson and Bisbee, n 56, 22.

[122] S Russell, "Advance Care Planning: Whose Agenda Is It Anyway" (2014) 28(8) *Palliative Medicine* 997.

[123] Collins, Parks and Winter, n 29, 380.

[124] Lund, Richardson and May, n 23, 12.

Moving outside the silo of their own practice, lawyers can develop more formalised collaborations with health practitioners and share their knowledge and expertise in health care settings. Advance care planning often raises "emotionally, clinically and legally complex problems"[125] and co-ordinated support from legal and health practitioners will help achieve the preventive benefits of advance planning for clients, substitute decision-makers and families. Inter-professional training and collaboration will also enhance practitioners' knowledge and skills to provide this support and foster shifts in organisational cultures and institutions toward a "whole-community" approach to advance care planning.

[125] Lund, Richardson and May, n 23.

PAPER 2: DOCTORS, LAWYERS AND ADVANCE CARE PLANNING: TIME FOR INNOVATION TO WORK TOGETHER TO MEET CLIENT NEEDS

Overview

Paper 2, published in *Healthcare Policy*, advocates for greater collaboration between health and legal professionals to better support clients in advance care planning (ACP). It presents a framework for action to build connections between these typically siloed professions. The framework is a continuum that represents a gradually increasing degree of connection between health and legal professionals. For example, practitioners can use common best practices to support clients in ACP, participate in interprofessional training and jointly deliver ACP clinics. At the highest degree of collaboration, lawyers can be integrated into healthcare teams, such as dementia or palliative care services. To provide a comparative perspective with the Australian context discussed in Paper 1, this paper situates ACP in the Canadian context.

Citation: Ries N, Douglas M, Simon, J., Fassbender, K. (2016). Doctors, lawyers and advance care planning: Time for innovation to work together to meet client needs. Healthcare Policy | Politiques de Santé. 2016;12(2), 13-18. doi:10.12927/hcpol.2016.24944.

DISCUSSION AND DEBATE

Doctors, Lawyers and Advance Care Planning: Time for Innovation to Work Together to Meet Client Needs

Médecins, avocats et planification préalable de soins : innover et travailler ensemble pour satisfaire les besoins du client

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Abstract

Health organizations in Canada have invested considerable resources in strategies to improve knowledge and uptake of advance care planning (ACP). Yet barriers persist and many Canadians do not engage in the full range of ACP behaviours, including writing an advance directive and appointing a legally authorized decision-maker. Not engaging effectively in ACP disadvantages patients, their loved ones and their healthcare providers. This article advocates for greater collaboration between health and legal professionals to better support clients in ACP and presents a framework for action to build connections between these typically siloed professions.

Résumé

Les organismes de santé au Canada ont investi des ressources considérables dans des stratégies afin d'améliorer les connaissances sur la planification préalable de soins (PPS). Malgré tout, des obstacles demeurent et plusieurs Canadiens n'ont pas encore totalement adopté les comportements reliés à la PPS, tels qu'écrire une directive médicale anticipée et nommer une personne légalement autorisée à prendre des décisions. Le manque d'efficacité de la PPS désavantage les patients, leurs proches et les prestataires de soins de santé. Cet article recommande une meilleure collaboration entre les professionnels de la santé et les avocats afin d'offrir un meilleur service de PPS aux clients, et présente un cadre d'intervention pour bâtir des liens entre ces deux professions habituellement cloisonnées..

The Canadian population is ageing, more people are living longer with chronic conditions and, importantly, many people say they want more control over their care, especially at the end of life. The recent report of the Advisory Panel on Healthcare Innovation (2015) urges more work to break down siloed professions and create person-centred teams. Doing so is necessary to find new ways to deal with the persistent inadequacies in healthcare systems, including in the delivery of chronic disease care, aged care and end-of-life care.

The call for change comes in well-researched reports, like that of the Advisory Panel, and also in personal stories, like Dr. Duncan Sinclair's essay (2015) on dignified care for the frail elderly and reflections on the deaths of two high-profile Canadian doctors, Dr. Donald Low and Dr. Larry Librach (Taylor and Martin 2015). Dr. Sinclair articulates his wishes – "respect for my continued dignity and personhood; staying in my home; no pain or suffering; and not being a burden to others" – that are described with remarkable consistency as what people want to prepare for a good death (Smith 2000). Dr. Sinclair also writes of his own sense of duty to "write those expectations down and put them on record" so others can meet their obligation "to follow my advance directive."

Health organizations in Canada have invested considerable resources in strategies to improve knowledge of advance care planning (ACP) among health professionals and patients and to encourage people to think about and communicate their wishes for future healthcare (see, for example, the work of the National Advance Care Planning Task Group: <www.advancecareplanning.ca/about-advance-care-planning/advance-care-planning-national-task-group>). Despite these efforts, barriers persist: members of the public misunderstand ACP; professionals report they lack the time and confidence to broach ACP conversations with clients; and systems are inadequate to ensure plans are available when needed to guide healthcare decisions (Hagen et al. 2015; Lund et al. 2015). Many Canadians still do not engage in the full range of ACP behaviours, including writing an advance directive and appointing a substitute decision-maker to ensure their values, wishes and preferences are known (Teixeira et al. 2013).

Not engaging effectively in ACP disadvantages patients, their loved ones and their healthcare providers. Patients with an advance directive experience fewer medical interventions at the end of life, are less likely to be moved from their home or community care facility to a hospital and are less likely to die in a hospital (Lum et al. 2015). Substitute decision-makers often report a significant negative emotional burden (Wendler and Rid 2011), but this burden can be eased if the decision-maker is guided by the values and preferences expressed in an advance directive. A study of Canadian hospitals found alarmingly low rates of communication between healthcare providers and terminally ill patients about whether they had advance directives and about their wishes for care during their hospital admission (Heyland et al. 2013). It was reported that "close to 70% of the physician orders concerning intensity of treatment (such as cardiopulmonary resuscitation and intubation) were discordant with current patient wishes. In any other area of medicine, this would be viewed as an egregious 'failure of communication' error" (Allison and Sudore 2013: 787).

A recent systematic review concluded that improvement in the uptake and effectiveness of ACP depends on the ability to "transform systemic processes across a range of institutional settings" (Lovell and Yates 2014: 1027). We agree and propose that one important systemic transformation is greater collaboration between heath and legal professionals to better support their clients in ACP. As Dr. Sinclair and others observe, we need the "silos of our healthcare 'system' to work together in a boundary-free way" (Sinclair 2015) but we also need to recognize that older adults and people with chronic or terminal illnesses typically have intersecting medical and legal issues, and failing to address those issues in a coordinated way undermines their quality of life and care.

Three Reasons Why Health–Legal Collaboration Is Important

First, working within their professional silos, neither doctors nor lawyers are optimally effective in helping their clients with ACP. Uncertainties about the legal validity of advance directives and the authority of substitute decision-makers are barriers to doctors having ACP conversations with patients. Fears about liability for limiting care at the end of life

are a further medico-legal obstacle. Lawyers also face challenges in helping their clients with ACP. A main criticism is that lawyers are too "transactional," helping clients prepare ACP documents, but not promoting the ongoing communication that is vital to ensuring the client's wishes are known and respected (Castillo et al. 2011). Physicians express frustration with directives that use vague phrases like "no heroic measures" and focus on the rarely encountered vegetative state, but do not provide guidance to inform the range of in-the-moment decisions needed in care at the end of life (Sudore and Fried 2010). Doctors encounter situations where decision-makers for an incompetent patient say they do not know what the patient would want (Shalowitz et al. 2006). Teams provide intensive medical interventions to sustain a patient's life only to be informed days or weeks later that a directive has been found that says the person would refuse these life-prolonging interventions.

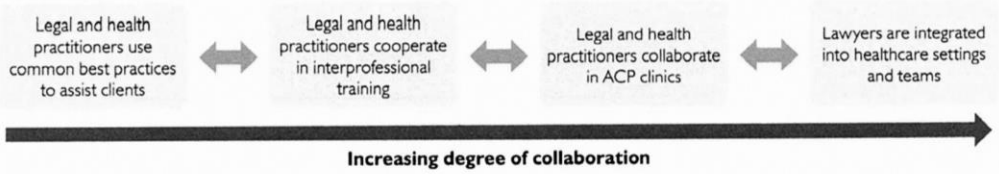
Second, some patients are more likely to talk to a lawyer than a physician about ACP. A Saskatchewan survey found that nearly half of people who had a written care plan had sought help from a lawyer to prepare the document, while only 5% had consulted with a doctor (Goodridge et al. 2013). Similarly, patients at an Ontario family practice clinic were more likely to have discussed ACP with a lawyer than their family doctor (O'Sullivan et al. 2015). A national study of sick, elderly patients and their family members found that participants discussed their end-of-life-care wishes as often or more often with a lawyer than with a family doctor or medical specialist (Heyland et al. 2013). These findings are not surprising when one considers that people seek help from lawyers to plan for their future in various ways such as writing a will and appointing someone to manage their finances. Planning for future healthcare is a logical topic for such discussions.

Third, each Canadian province and territory has its own legislation governing ACP (see Resource Library here: <http://advancecareplanning.ca/resource-library/#resource-library|category:your-province-or-territory>). Doing ACP right requires an accurate understanding of the rules and policies in effect in the jurisdiction where the patient lives and receives care.

Health–Legal Collaboration to Support Advance Care Planning: A Framework for Action

How can we break down the silos between doctors and lawyers to better support clients with ACP? We suggest a framework for interprofessional collaboration along a continuum that represents a gradually increasing degree of connection between health and legal professionals. Professionals can develop specific activities within this framework based on local needs and can move back and forth along the continuum. This framework advances the recommendation of other Canadian ACP researchers that "new forms of interprofessional collaboration should be considered to increase the interface between physicians and lawyers" (Goodridge et al. 2013: 4). We advocate that new approaches should be evaluated and findings disseminated through health and legal sector organizations to build a strong evidence base for collaborative practices.

FIGURE 1. Framework for health–legal collaboration



Legal and health practitioners use common best practices to assist clients

Interventions to build professionals' skills and confidence in discussing ACP are typically implemented and evaluated in health settings; however, best practice approaches can be adapted for use by legal professionals, including resources such as conversation scripts, workbooks and training programs available on national and provincial websites (for example: <www.advancecareplanning.ca/resource/acp-workbook/> and <https://myhealth.alberta.ca/Alberta/Pages/advance-care-planning-resources.aspx>). Organizations that produce ACP resources should disseminate them to the legal profession. Clients should receive common messages and information about ACP. For example, both health and legal professionals should promote ACP not as a one-time event but rather a process of communication and clients should be encouraged to share a care directive with key people who need to know their wishes.

Legal and health practitioners cooperate in interprofessional training

Continuing professional development events should bring legal and health professionals together for joint ACP training so they can learn from one another. Health professionals can increase their awareness of the law and lawyers can gain a better understanding of the practical realities of healthcare delivery. In Alberta, our research team recently delivered a continuing education event, *Advance Care Planning: How Lawyers Can Help Their Clients*. A palliative medicine specialist and a wills and estates lawyer shared their experiences of the challenges of doing effective ACP and suggested solutions and resources to an audience of Alberta legal professionals.

Legal and health practitioners collaborate in ACP clinics

Clinics would bring together lawyers and health professionals to lead ACP sessions for clients in community settings, aged care facilities and hospitals. This strategy can improve access to lawyers for people who are physically unable to attend law offices. Interprofessional clinics would facilitate the delivery of consistent messages and follow-up referral pathways can also be developed between legal and health organizations. Clinics can help identify clients who may need additional support, especially those with more complex situations, so they can access professional help before medical and legal crises develop.

Lawyers are integrated into healthcare settings and teams

The medical–legal partnership model (which is most developed in the US: http://medical-legalpartnership.org/) may be used to establish formal arrangements for lawyers to provide

services to clients in healthcare settings. Examples exist of lawyers working with cancer and palliative care programs to help clients with legal matters, including estate and guardianship planning and benefit claims (Hallarman et al. 2014). Hallarman et al. observe that "[e]merging evidence demonstrates that patient-clients benefit substantially from the addition of legal expertise to the patient care team" (2014: 184) and, indeed, high quality evaluation data are crucial to sustain innovative models of collaborative service delivery beyond pilot projects. The Advisory Panel on Healthcare Innovation heard "laments about the pervasiveness of pilot projects in Canada" and noted the "failing ... in the capacity of our healthcare systems to spread or scale up the best ideas from those projects" (2015: 27). Others have reflected on factors that support the spread of successful innovations to achieve integrated systems (Suter et al. 2009), especially collective work to engage and train key groups and shift cultures of practice (Zelmer 2015).

Each increasing degree of connection in the health–legal collaboration framework presented here involves costs, benefits and a need to determine the cost-effectiveness of specific collaborative activities. Importantly, when using interprofessional approaches, members of each profession must meet their ethical duties to clients. These are not insurmountable barriers; however, as demonstrated by the success of medical–legal partnerships involving *pro bono* legal services (such as Pro Bono Law Ontario's Medical-Legal Partnerships for Children: <www.pblo.org/volunteer/medical-legal-partnerships-children/>).

ACP requires more "interdisciplinary attention, conversations, health research and practice [and] joining up professions..." (Russell 2014). Just as researchers have asked health professionals about barriers and enablers to ACP, we need to find out similar information from lawyers. Our research team will soon report on a survey of lawyers in Alberta to find out more about their experiences with ACP, their perspectives on barriers and facilitators and the resources that would help them. To our knowledge, no such survey has been done elsewhere and the results will help stakeholders in health, legal and government sectors to understand better the role that lawyers play. The results will also provide an evidence base for strategies to advance the first two components of the collaboration framework, namely, how legal and health practitioners can use common best practices to assist clients and ways in which legal and health practitioners can cooperate in interprofessional training.

Healthcare providers and lawyers need not be estranged by different professional cultures and language. To realize the benefits of ACP, they ought to find a common ground in preparing people for serious illness and death, helping people communicate what is important to them and allowing them to guide their care even beyond a time when they can speak for themselves.

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PAPER 3: LAWYERS' PRACTICES, ATTITUDES AND BELIEFS REGARDING ADVANCE CARE PLANNING: A SURVEY OF LEGAL PRACTITIONERS IN ALBERTA, CANADA

Overview

Papers 1 and 2 provide a scholarly foundation and framework for health-legal collaboration to underpin Paper 3, which reports on a survey of lawyers in Alberta, Canada regarding advance care planning (ACP). The literature review undertaken for Paper 1 discussed research on barriers and enablers to advance planning for healthcare providers and patients. These studies show that complex factors at personal, organisational and system levels influence advance planning behaviours.[1] Interventions to promote advance planning occur mainly in healthcare settings using strategies such as educational programs for care providers and clients, worksheets and forms, and deployment of trained facilitators.[2] In recent years, there is growing consensus that improving the uptake and effectiveness of advance planning requires whole community approaches and cross-sector collaborations, especially involving the health and legal sectors.[3]

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[2] Martin RS, Hayes B, Gregorevic K, Lim WK. The effects of advance care planning interventions on nursing home residents: A systematic review. J Am Med Dir Assoc. 2016;17(4):284-93.

[3] See eg Jimenez G, Tan WS, Virk AK, Low CK, Car J, Ho AHY. Overview of Systematic Reviews of Advance Care Planning: Summary of Evidence and Global Lessons. J Pain Symptom Manage. 2018;56(3):436-459.

Paper 3 focuses on the important role that legal professionals have in advising and assisting clients with advance planning. It reports the results of a survey of experienced lawyers in the province of Alberta, Canada. To the candidate's knowledge, this is the first survey that reports on lawyers' practices in relation to advance planning for health-related matters. This survey was motivated by previous studies, summarised in Papers 1 and 2, which reveal that people who have written advance directives are more likely to have received assistance from lawyers than from doctors in preparing the documents. The survey results reveal lawyers' practices in relation to ACP, their perceptions of their professional role, and factors that support or hinder lawyers in working with clients on ACP, and their preferences for resources to assist them in helping their clients. The research findings support the need for collaborative ACP strategies that involve the legal and health sectors.

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HOW DO LAWYERS ASSIST THEIR CLIENTS WITH ADVANCE CARE PLANNING? FINDINGS FROM A CROSS-SECTIONAL SURVEY OF LAWYERS IN ALBERTA

NOLA M. RIES,* MAUREEN DOUGLAS,** JESSICA SIMON,*** AND KONRAD FASSBENDER****

Advance care planning (ACP) is the process of thinking about, discussing and documenting one's preferences for future health care. ACP has important benefits: people who have a written directive are more likely to receive care that accords with their preferences, have fewer hospitalizations, and die in their preferred location. This article focuses on the important role that legal professionals have in advising and assisting clients with ACP. Studies report that people who have a written advance care plan are more likely to have received assistance in preparing the document from a lawyer than from a doctor. Yet virtually no research engages with the legal profession to understand lawyers' attitudes, beliefs, and practices in this important area. This article starts to fill this gap by reporting the findings of a survey of lawyers in the province of Alberta. The results reveal lawyers' practices in relation to ACP, their perceptions of their professional role and factors that support or hinder lawyers in working with clients on ACP, and their preferences for resources to assist them in helping their clients. To the authors' knowledge, this is the first survey of lawyers on their practices in relation to ACP.

TABLE OF CONTENTS

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I. INTRODUCTION

Advance care planning (ACP) is a process of thinking about, discussing and documenting one's preferences for future health care. Specific legal rules and processes vary across countries, but in general, ACP is supported by laws that recognize the right of adults with decision-making capacity to express their wishes for future health and personal matters, with the expectation they will be followed. These rights are underpinned by common values and aims. The right to plan for what happens to oneself during future periods of incapacity promotes self-determination, respects individual autonomy, and enables person-centered care. A person may document specific wishes and personal values in a written advance care directive and designate decision-makers who will have legal authority to make choices on their behalf during periods of incapacity. People who have a written directive are more likely to receive care that accords with their preferences, have fewer hospitalizations, and die in their preferred location.[1] Substitute decision-makers report reduced decisional conflict when their choices are guided by prior ACP conversations.[2] Effective ACP may also have economic benefits by reducing health care costs.[3]

Much research has focused on the barriers and enablers to ACP for health care providers and patients. Complex factors at personal, organizational, and system levels influence ACP behaviours.[4] Interventions to promote ACP occur mainly in health care settings using diverse strategies that include educational programs for care providers and clients, ACP worksheets and forms, and deployment of trained ACP facilitators.[5] Researchers have called for better-

1 Arianne Brinkman-Stoppelenburg, Judith AC Rietjens & Agnes van der Heide, "The Effects of Advance Care Planning on End-of-Life Care: A Systematic Review" (2014) 28:8 Palliative Medicine 1000 at 1000; Carmen HM Houben et al, "Efficacy of Advance Care Planning: A Systematic Review and Meta-Analysis" (2014) 15:7 J American Medical Directors Assoc 477 at 484; Hilary D Lum, Rebecca L Sudore & David B Bekelman, "Advance Care Planning in the Elderly" (2015) 99:2 Medical Clinics North America 391 at 393.

2 Jared Chiarchiaro et al, "Prior Advance Care Planning is Associated With Less Decisional Conflict Among Surrogates for Critically Ill Patients" (2015) 12:10 Annals American Thoracic Society 1528 at 1533.

3 Rory O'Sullivan et al, "Advance Directives: Survey of Primary Care Patients" (2015) 61:4 Can Family Physician 353.

4 Aline De Vleminck et al, "Barriers and Facilitators for General Practitioners to Engage in Advance Care Planning: A Systematic Review" (2013) 31:4 Scandinavian J Primary Health Care 215; NA Hagen et al, "Advance Care Planning: Identifying System-Specific Barriers and Facilitators" (2015) 22:4 Current Oncology 237; Susi Lund, Alison Richardson & Carl May, "Barriers to Advance Care Planning at the End of Life: An Explanatory Systematic Review of Implementation Studies" (2015) 10:2 PLoS One 1.

5 Ruth S Martin et al, "The Effects of Advance Care Planning Interventions on Nursing Home Residents: A Systematic Review" (2016) 17:4 J American Medical Directors Assoc 284 at 288–90.

designed studies and the development of rigorous evaluation frameworks to build the evidence base on what works to improve the uptake and use of ACP.[6]

Discussion and documentation of clients' wishes is vital in health care settings, but it is equally important to improve engagement with ACP in other contexts. In its landmark report, *Dying in America*, the Institute of Medicine championed a "whole-community" approach to the promotion of ACP.[7] Ideally, people should engage with ACP before crisis situations arise, in consultation with family, friends, and relevant professional advisors, while they have the capacity to make and communicate their decisions.

This article focuses on the important role that legal professionals have in advising and assisting clients with ACP. Our work is motivated by previous studies reporting that people who have a written advance care plan are more likely to have received assistance in preparing the document from a lawyer than from a doctor. In Canada, a survey of residents of the province of Saskatchewan found that almost half of the respondents who had a written care plan had sought help from a lawyer to prepare the document, while only 5 percent had consulted with a doctor.[8] In Ontario, patients of a family practice clinic were more likely to have discussed ACP with a lawyer than their family doctor.[9] A national study of sick, elderly patients and their family members found that participants discussed their end-of-life care wishes as often or more often with a lawyer than with a family doctor or medical specialist.[10]

In the United States, a survey of adults admitted to four hospitals in California found that of those with advance directives at the time of admission, 49 percent had received help from a lawyer to prepare ACP documents and only 6 percent had received help from a doctor.[11] Thirty-five percent of those with directives viewed lawyers as helpful sources of expertise in assisting with writing the documents and only 1 percent said physicians were. An earlier study in Connecticut found that, among people admitted to a hospital with an advance directive, 76 percent had prepared the document with a lawyer and only 7 percent had been prepared with a doctor.[12] In Germany, Matthias Becker and co-authors surveyed 53 people who had an advance directive to find out if they had obtained help from a professional in preparing the document. Just under a quarter of people had sought such help and, among those, legal professionals were the most common source of advice.[13]

Lawyers are a key source of help for people who want to do ACP, yet virtually no research engages with the legal profession to understand lawyers' attitudes, beliefs, and

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6 *Ibid* at 284. See also Patricia D Biondo et al, "How Healthcare Systems Evaluate Their Advance Care Planning Initiatives: Results From a Systematic Review" (2016) 30:8 Palliative Medicine 720 at 721.

7 Institute of Medicine, *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life* (Washington, DC: National Academies Press, 2014) at 3–6.

8 D Goodridge et al, "Planning for Serious Illness by the General Public: A Population-Based Survey" [2013] ISRN Family Medicine 483673, online: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4041261/>.

9 See O'Sullivan et al, *supra* note 3.

10 Daren K Heyland et al, "Failure to Engage Hospitalized Elderly Patients and Their Families in Advance Care Planning" (2013) 173:9 JAMA Internal Medicine 778.

11 Marc Tunzi, "Advance Care Directives: Realities and Challenges in Central California" (2011) 22:3 J Clinical Ethics 239.

12 Natalya Thorevska et al, "Patients' Understanding of Advance Directives and Cardiopulmonary Resuscitation" (2005) 20:1 J Critical Care 26.

13 Matthias Becker et al, "Did You Seek Assistance for Writing Your Advance Directive? A Qualitative Study" (2010) 122:21 & 22 Wiener Klinische Wochenschrift 620.

practices in this important area. This article aims to start filling that gap. Gaining an understanding of what lawyers currently do in practice, especially their perspectives on the barriers and enablers to ACP and the resources that would help them better serve their clients, is a vital first step in devising interventions to improve lawyers' practices and enhance interprofessional collaboration between lawyers and health care professionals.

This article reports on a survey of lawyers in the province of Alberta. The objective of this study was to find out about lawyers' practices in relation to ACP, their perceptions of their professional role and the factors that support or hinder lawyers in working with clients on ACP, as well as their preferred resources for assisting their clients.

II. METHODS

A cross-sectional survey of lawyers practicing in Alberta was undertaken in 2016. The online, anonymous survey was promoted over a four-month period (late February to late June) to practicing lawyers via email, in addition to websites, e-newsletters and social media from the Canadian Bar Association, the Law Society of Alberta and the Legal Education Society of Alberta. Due to anti-spam legislation, the legal professional organizations that disseminated the survey were unable to email the survey invitation directly to lawyers who self-identify as practicing in our target areas of wills and estates, elder law, and health law. A screening question at the start of the survey asked respondents whether, in their current professional role, they assist clients with planning for future mental incapacity by writing a personal directive, enduring power of attorney, appointing an agent, or other matters related to ACP. Lawyers who responded "no" were discontinued from completing the survey.

A. SURVEY CONTEXT

With a population of nearly 4.2 million people, Alberta is Canada's fourth most populous province and around 12 percent of residents are aged 65 and over.[14] The government health department, Alberta Health Services, promotes ACP through its *Conversations Matter* initiative.[15] The Alberta *Personal Directives Act*[16] gives adults with decision-making capacity the right to document their wishes for future health care and to appoint a person (an agent) with legal authority to make health care decisions during the appointer's future periods of incapacity. The government provides a personal directive form as a guide,[17] however, a person making a directive can use another document for this purpose provided it is signed and witnessed as required by the statute. A person may file their directive with a voluntary government registry.[18] The Alberta *Powers of Attorney Act*[19] enables a person to appoint a

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14 Statistics Canada, "Chart 4: Proportion of the Population Aged 0 to 14 Years and 65 Years and Older, July 1, 2015, Canada, Provinces and Territories," online: <www.statcan.gc.ca/daily-quotidien/150929/cg-b004-eng.htm>.

15 Alberta Health Services, "Conversations Matter — Advance Care Planning Goals of Care Designation: A Guide for Making Health Care Decisions," online: <goals.conversationsmatter.ca>.

16 RSA 2000, c P-6.

17 Alberta Human Services, "Write a Personal Directive," online: <www.humanservices.alberta.ca/guardianship-trusteeship/write-a-personal-directive.html>.

18 Alberta Human Services, "Register a Personal Directive," online: <www.humanservices.alberta.ca/guardianship-trusteeship/register-a-personal-directive.html>.

19 RSA 2000, c P-20.

person, known as an enduring power of attorney, to make decisions about financial matters or property if the appointer loses capacity.

B. SURVEY DEVELOPMENT

The survey instrument was developed through a multi-disciplinary consultative process involving members of the legal profession in Alberta. We used Susan Michie and co-authors' Theoretical Domains Framework to inform the survey development,[20] taking account of the 14 domains that influence behaviour change and the uptake of new practices.[21] As the survey focused on individual practitioner behaviours, we explored seven domains: knowledge, skills, professional/social role and identity, beliefs about capabilities, emotion, beliefs about consequences, and social influences. Dialogue between members of our research team and the legal profession began in 2014 with a series of meetings involving a total of around 100 lawyers who are members of the Canadian Bar Association (CBA),[22] a professional association for lawyers. The lawyers participated in interest groups for three practice areas relevant to ACP: wills, estates and trusts, elder law, and health law. The meetings were an opportunity to introduce our multidisciplinary research team to members of the legal profession, especially to those in CBA leadership positions. Topics discussed included the types of issues clients raise with lawyers in relation to ACP, legislation governing advance personal planning, and lawyers' perceptions of barriers and facilitators to engaging their clients with ACP.

In 2015, the research team convened two focus groups of 12 to 15 lawyers and other stakeholders, including chairs of the CBA interest groups, lawyers in private practice with significant ACP experience, lawyers working in the legal aid and government health sector, and representatives from the Legal Education Society, the Office of the Public Guardian and Trustee (the provincial government office that promotes advance personal planning and deals with guardianship matters for people with cognitive disabilities),[23] palliative care physicians, ethicists, social workers, and patient advisors. We discussed the draft survey and pre-tested it with eight lawyers, two government health policy experts, and a patient advisor.

The survey consisted of 15 questions that were primarily close-ended items with Likert category responses.[24] For many questions, respondents could select "other" as a response with an option to provide an open-ended answer in a text box. The first section of the survey asked lawyers about their experiences and current practices in assisting their clients with ACP, including the topics they cover in ACP conversations and the resources they use. Several questions explored their beliefs about their professional role in relation to ACP, as well as their views on the perceived benefits of ACP and the barriers to assisting their clients. The middle section of the survey asked lawyers about their preferences for the types of ACP

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20 S Michie et al, "Making Psychological Theory Useful for Implementing Evidence Based Practice: A Consensus Approach" (2005) 14:1 Quality & Safety in Health Care 26 at 29–30.

21 See also Hagen et al, *supra* note 4.

22 The Canadian Bar Association, online: <https://www.cba.org/>.

23 Ontario Ministry of the Attorney General, "The Office of the Public Guardian and Trustee (OPGT)," online: <https://www.attorneygeneral.jus.gov.on.ca/english/family/pgt/>.

24 Likert scales in surveys ask respondents to indicate their level of agreement with statements, for example, on a scale from strongly agree to strongly disagree. For discussion see e.g. Gail M Sullivan & Anthony R Artino Jr, "Analyzing and Interpreting Data From Likert-Type Scales" (2013) 5:4 J Graduate Medical Education 541.

resources they would find useful, as well as their preferred format for accessing resources. The final section of the survey collected demographic information.

C. STATISTICAL ANALYSIS

We performed descriptive analyses to describe the frequency of responses in each Likert category and to rank responses by frequency of facilitators and barriers to engaging clients in ACP. The full results are available in Appendix A. For ease of interpretation, we present collapsed results in three categories: Never or Seldom; Sometimes; Often or Always.

III. RESULTS

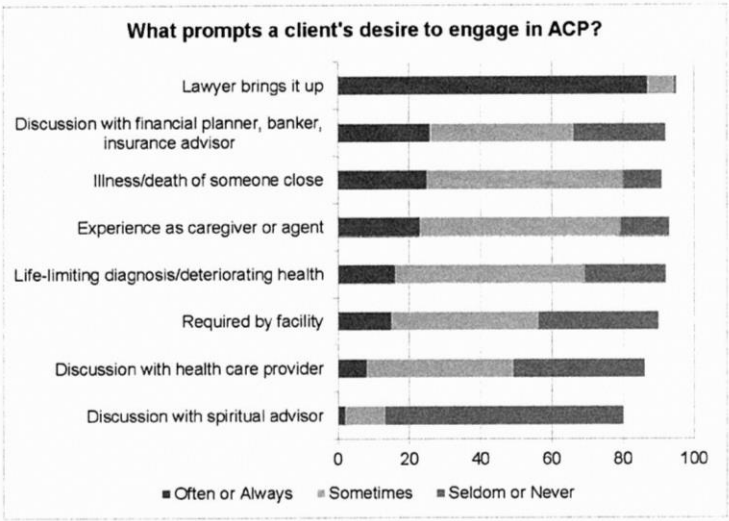
The total number of survey respondents was 133, with 104 surveys completed in full. We estimate a 7.7 percent response rate based on the 1,840 lawyers in the province who are listed in Law Society records as practicing in wills and estates, the practice group targeted by the newsletters and social media activity that promoted the survey. The Law Society of Alberta advised us that it typically expects a response rate of 3 to 4 percent when it conducts surveys of lawyers; as a result, we did not aim for our study to produce results that would represent the practices of lawyers across the province or produce statistically significant associations between respondents' characteristics and their reported beliefs and experiences. Instead, the responses of the lawyers who completed the survey provide valuable and novel insights into the views of an experienced and knowledgeable population of practitioners. Over three-quarters of respondents (77 percent) reported ten or more years of experience in legal practice, 17 percent had between two and ten years of experience and 6 percent had been in practice for less than two years. Two thirds of respondents (66 percent) are sole practitioners or work in small firms of two to nine lawyers, and 20 percent work in mid-size or large firms (between 10-49 lawyers and 50 or more lawyers, respectively). A majority of respondents (69 percent) reported they assist clients with ACP on a daily or weekly basis. The remainder (31 percent) said they advise clients on a monthly basis. The fact that most respondents have significant experience and regularly engage in ACP provides greater confidence in using the survey results as an informative starting point for further work with the legal profession, including the development of resources to respond to knowledge and practice gaps revealed by this study.

A. FACTORS THAT MOTIVATE CLIENT ENGAGEMENT WITH ACP

Respondents were asked what factors motivate a client to engage in ACP (see Figure 1). Ninety percent of lawyers said they often or always bring up the topic as part of a broader discussion of advance personal planning, such as writing a will and appointing a decision-maker to manage financial matters during any future periods of incapacity. Declining personal health and experiencing the illness or death of someone close them are strong motivators for clients to engage in ACP. Nearly three-quarters of the respondents (73 percent) said that clients were motivated to engage in ACP after receiving a medical diagnosis with life-limiting implications or due to deteriorating health. Even more lawyers reported that clients wanted to do ACP because they had experience as a caregiver or substitute decision-maker for another person (80 percent) or someone close to them had been ill or died (88 percent). Interestingly, lawyers reported it was more common for a client to engage in ACP following a discussion with a financial sector advisor (70 percent reported

this was is sometimes or often the motivator) than with a doctor or other health care provider (54 percent said this is sometimes or often a motivator). Several respondents volunteered that other factors prompting their clients included discussions with family or friends about ACP or media reports about end-of-life issues.

FIGURE 1:
FACTORS THAT PROMPT A CLIENT TO ENGAGE IN ACP



B. TOPICS LAWYERS DISCUSS WITH CLIENTS

Lawyers were asked about the topics they discuss with clients during consultations about ACP (see Figure 2). Eighty to 90 percent of respondents say they always or often discuss: the appointment of a suitable person to act as a substitute decision-maker should the client experience future periods of impaired capacity; the client's views on other people who should be involved in consultations with health care providers if the client loses capacity to make their own decisions; and the client's values and wishes concerning future care. Three-quarters of respondents said they often or always discuss with the client whether they would want specific medical interventions (e.g. CPR, tube feeding) and around 60 percent said they always or often ask the client about their preferences for living arrangements or accommodation in the future, as well as their views on organ donation and who should have access to their health records. Just over 40 percent of respondents said they always or often ask their clients about their wish to participate in medical research. We did not define "medical research" in the survey, however, we suspect that lawyers understood this question to refer to discussions about the client's interest in donating their body for post-mortem research, not the client's wishes about inclusion in research during future periods of incapacity.[25]

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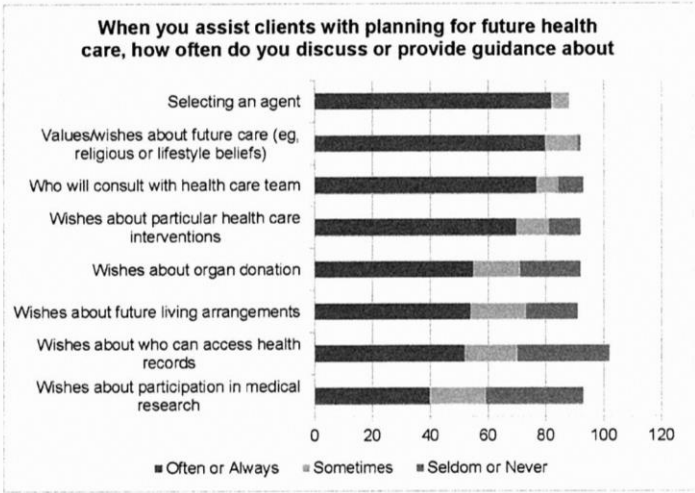
[25] Several researchers in Canada are investigating strategies to increase the uptake of advance directives both for health care and research participation. See Gina Bravo et al, "Promoting Advance Planning for Health Care and Research Among Older Adults: A Randomized Controlled Trial" (2012) 13:1 BMC Medical Ethics, online: <https://www.biomedcentral.com/1472-6939/13/1>.

FIGURE 2:
TOPICS LAWYERS AND CLIENTS DISCUSS AS PART OF ACP



As communication of one's wishes with key people is an important component of ACP, lawyers were asked who they encourage their clients to speak to about their wishes for future health care. Nearly all respondents (99 percent) said they always or often encourage clients to speak to the person they appoint as their designated health decision-maker and nearly 80 percent said they always or often encourage conversations with family members, care givers, or friends other than the named decision-maker. Surprisingly, the results were less uniform with regard to encouraging clients to talk to their doctor or health care provider about their wishes. Just over 20 percent of respondents said they never or seldom encourage this, around 35 percent said they sometimes do, and less than half (44 percent) said they often or always do so.

In general, spiritual advisors are not reported as key people. Nearly 70 percent of the lawyers we surveyed never or seldom encourage their clients to talk to spiritual advisors about their wishes for health care, and three-quarters of respondents said that conversations with spiritual advisors are never or seldom a factor that prompts their clients to engage in ACP.

IV. BARRIERS TO ASSISTING CLIENTS WITH ACP

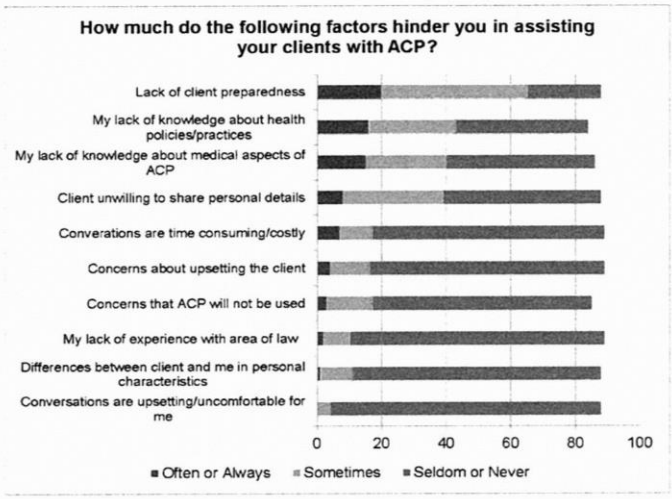
Lawyers were asked about barriers they feel impede them in assisting their clients with ACP (see Figure 3). The options presented to them covered both practitioner and client-centered barriers. The most significant client-centered barrier was the clients' lack of preparedness to engage in ACP; nearly three-quarters (73 percent) of respondents said this is sometimes or often a problem. A client's unwillingness to share personal details with a lawyer was identified as a hindrance to ACP for slightly under half (44 percent) of lawyers, and 55 percent said such reticence is seldom or never a problem.

For a majority of lawyers, the potentially emotional nature of discussing future medical treatment and end-of-life care preferences with clients was not a barrier to ACP discussions. Almost 95 percent of lawyers said they never or seldom find ACP discussions upsetting or uncomfortable and 82 percent said concerns with upsetting the client were never or seldom an issue. Similarly, for most respondents (86 percent), age, cultural, or religious differences between the lawyer and client are seldom or never a barrier. Only around 20 percent of lawyers cited the additional time needed for ACP conversations — and thus higher costs for clients — as a barrier.

Just under half of lawyers revealed some degree of concern with their own lack of knowledge about the medical aspects of ACP and health sector policies and practices. A strong majority of respondents expressed confidence in their knowledge of the law relevant to ACP, a finding consistent with the level of experience of the respondent population.

In general, respondents had positive attitudes toward ACP and confidence in the value for their clients of documenting their wishes for future health care. Around three-quarters of respondents stated they believe ACP significantly benefits their clients and that advance care plans will be used in practice.

FIGURE 3:
BARRIERS TO ENGAGING CLIENTS WITH ACP

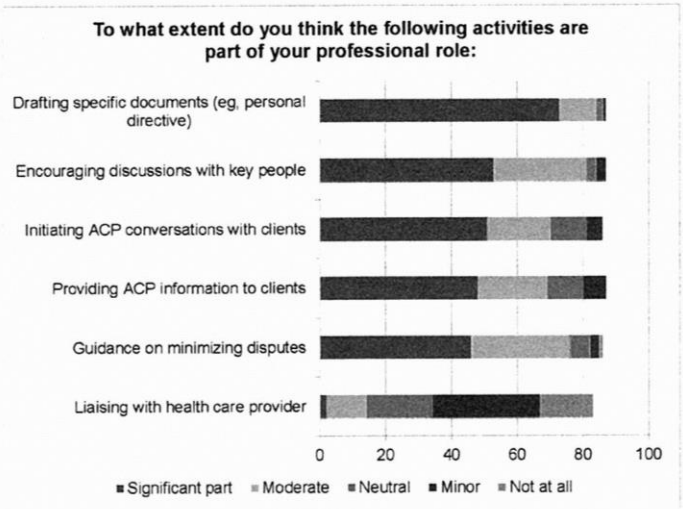


V. PROFESSIONAL ROLE PERCEPTIONS

Given that ACP is often promoted in health care settings, we sought to determine lawyers' views on the extent to which various ACP-related activities were perceived as part of a lawyer's professional role (see Figure 4). Respondents had consistent views about the activities they viewed as a significant part of a lawyer's role, including initiating ACP conversations, providing ACP information, drafting specific legal documents, advising on how to minimize future disputes, and encouraging clients to discuss their wishes with key

others. In contrast, most respondents said that liaising with a client's health care provider (with the client's consent) was not at all, or only minimally part of their role.

FIGURE 4:
LAWYERS' ROLE PERCEPTIONS ABOUT ACP ACTIVITIES



A. LAWYERS' KNOWLEDGE OF SPECIFIC HEALTH CARE SYSTEM DOCUMENTS AND PROCESSES

The survey asked about lawyers' knowledge of two key provincial health system initiatives aimed at improving communication about and compliance with people's health care wishes, especially for end-of-life care. These are the Goals of Care Designation (GCD) and Green Sleeve.[26] A GCD is a medical order that communicates the general intent of care (resuscitative, medical, or comfort care) and provides direction on specific interventions and locations of care. A doctor or nurse practitioner prepares the order in consultation with the patient (or a legally authorized decision maker if the patient lacks decision-making capacity). The Green Sleeve is a green plastic folder used to store ACP documents, including a conversation tracking record, advance directive, and GCD order. Patients can obtain a Green Sleeve from their health care provider and are directed to keep their care planning documents in the folder and to bring it to all appointments. Health care providers are trained to ask patients for their Green Sleeve and to check whether documents in the folder accurately reflect their current wishes. Patients are also educated to keep the Green Sleeve on or near their refrigerator at home as emergency medical responders are trained to look for it in that location.

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[26] For more information, see Government of Alberta, "Advance Care Planning: Conversations Matter," online: <https://myhealth.alberta.ca/Alberta/Pages/advance-care-planning-conversation-matters.aspx>.

Since lawyers are important advisors for clients on ACP, ideally they should be aware of government and health sector initiatives and be able to educate their clients using messages that are consistent with what they hear in health care settings. Approximately half of respondents (51 percent) said they knew what a GCD is, and 46 percent were familiar with a Green Sleeve. Just over one third of lawyers reported that their clients have discussed or shared their Green Sleeve and associated documents during a legal appointment.

B. RESOURCES LAWYERS CURRENTLY USE AND WHAT THEY WOULD FIND HELPFUL

A majority of the respondents (97 percent) use an advance directive template. Legislation in Alberta does not mandate the use of a specific statutory form and lawyers reported varying sources for the template they use. Lawyers commonly said that they used a law firm precedent or a template they had personally developed. Only one lawyer reporting getting health care provider feedback on the template they developed. Several respondents volunteered that they review and modify templates periodically (for example, every two years) to take account of new legal or policy developments. In contrast, one lawyer stated that the firm rarely modifies its template, with specific religious requests of a client being one basis for modifying the standard form. Lawyers who mentioned an external source for a directive template commonly mentioned the Legal Education Society of Alberta, an organization that provides continuing professional education and development for lawyers in the province.[27]

Respondents were asked about the usefulness of eight different ACP resources. The vast majority of respondents rated all but one of the resources as "useful" or "very useful": information about how GCD orders and Personal Directives function together in practice (89 percent of respondents said "useful" or "very useful"); a best practice guide for ACP (83 percent); information about health care service policies and resources (83 percent); worksheets for clients to identify and express their values, wishes and preferences (81 percent); legal resources (78 percent); and an explanation of relevant health care issues, language or specific disease and treatment (78 percent). Just over half of respondents (52 percent) said that a third party with specialized training in ACP would be useful or very useful.

Nearly three-quarters (74 percent) of respondents said they would prefer an online format for these ACP resources. When asked about their preferred format for continuing professional development, the majority (64 percent) said they prefer in-person seminars. Printed and webinar formats were preferred by 47 percent and 34 percent of respondents, respectively.

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[27] Legal Education Society of Alberta, online: <https://www.lesaonline.org>.

VI. DISCUSSION

A. COMPARING HEALTH AND LEGAL PROFESSIONALS

Various studies have investigated health care providers' perceptions of barriers that hinder them in engaging patients in ACP. In a 2015 systematic review, Susi Lund and co-authors reported that key barriers were competing work demands, the potentially emotional and time-consuming nature of ACP conversations, and beliefs that care plans will not be followed even if they are made.[28] It has been urged that health care providers must overcome the taboos of talking about future incapacity and the end-of-life in order to engage their clients in ACP; practitioners who avoid these conversations miss "a golden opportunity to let the person open up to what is important in their lives and what is worrying them."[29] ACP must be normalized into medical care; just as doctors counsel on disease screening and healthy lifestyles, they ought to raise ACP if they are to achieve person-centered care that includes the values and preferences of patients in medical decision making.

Our survey results show that lawyers who regularly see clients about matters related to advance planning, such as making a will, believe that discussing ACP is a significant part of their professional role and that they routinely raise the topic with their clients. Concerns about the emotional aspects of ACP conversations were not identified as barriers. This may reflect differences in the physical and psychological environment of a law office compared to a medical setting. When a care provider raises ACP in hospital, the immediacy and gravity of incapacity and end-of-life choices may have a more potent emotional impact for the practitioner and the patient. However, as Ebony Lewis and co-authors suggest, "the timing of broaching the subject of ACP does not have to be at the vulnerable moment of irreversible crisis. It is more productive to discuss [advance care directives] before the terminal stages, during routine examinations before drastic decisions are required."[30]

Another possible difference between legal and health care professionals is that lawyers may see ACP as an empowering act for clients and an important way for clients to protect their interests, both in terms of what happens to their property and what happens to their body. In contrast, health care professionals may worry that ACP distresses clients and takes away their hope, despite evidence that a majority of elderly and frail people want to discuss end-of-life care.[31] The relationship between a lawyer and client is a highly confidential one and, as in the doctor and patient relationship, the promise and expectation of confidentiality are important to encouraging open communication. Client reluctance to share personal details with lawyers was not reported as a frequent barrier to ACP discussions. Lawyers are also trained to elicit and take instructions from their clients and the nature of this professional obligation means lawyers must raise potentially sensitive topics to determine what the client wants, then express these instructions in legal documents. In health care settings, there is

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28 Lund, Richardson & May, *supra* note 4 at 11.

29 Joel J Rhee, Nicholas A Zwar & Lynn A Kemp, "Uptake and Implementation of Advance Care Planning in Australia: Findings of Key Informant Interviews" (2012) 36:1 Australian Health Rev 98 at 100.

30 Ebony Lewis et al, "Evidence Still Insufficient That Advance Care Documentation Leads to Engagement of Healthcare Professionals in End-of-Life Discussions: A Systematic Review" (2016) 30:9 Palliative Medicine 807 at 816.

31 Tim Sharp et al, "Do the Elderly Have a Voice? Advance Care Planning Discussions With Frail and Older Individuals: A Systematic Literature Review and Narrative Synthesis" (2013) 63:615 British J General Practice 657 at 659.

evidence of persistent deference to medical authority where patients and family members rely on a doctor's advice of the best course of action.[32]

There has been criticism that lawyers are too transactional in their approach to advance planning and focus merely on the preparation of documents.[33] Our results show that lawyers do encourage conversations between their clients and key people who need to know the person's wishes, including their appointed decision maker, family members, and friends. Our respondents had confidence in the value of ACP for their clients and some of the lawyers we consulted in focus groups to develop the survey were alarmed by anecdotal accounts that advance directives were not always followed in practice. Lawyers were also concerned to learn that statements in advance directives are not always relevant to subsequent medical situations. This may reflect lawyers' distance from the practical reality of healthcare delivery and the complexity of decision-making when a client becomes seriously ill and end-of-life care choices need to be made.

B. PROFESSIONAL SILOES

Our survey results exposed the siloed nature of legal and health care practice. Surprisingly, it is not standard practice for lawyers to encourage their clients to discuss their health care wishes with their doctor. Lawyers also do not see liaising with health care providers as part of their professional role. While the time and cost of advising clients about planning for future incapacity was not a barrier to ACP discussions, these factors may be an impediment to greater collaboration between legal and health professionals. A lawyer who spends time making contact with a client's health care provider will typically charge a client more for that service, and public funding for health services in Canada does not include reimbursement for this type of medical-legal collaboration. The siloes between legal and medical expertise may contribute to some of the known deficiencies with ACP. For example, directives may be held by lawyers and the client, but not produced to health care providers when needed.

We have argued elsewhere for a framework for action on health-legal collaboration to support ACP.[34] We call for legal and health practitioners to use common best practices to assist their clients, cooperate in interprofessional training and, where feasible, offer joint ACP clinics to clients and even move to integrating legal professionals into health care teams. An important first step is to meet lawyers' needs for resources that can help them more effectively assist their clients with planning for future health care.

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32 Michelle Olding et al, "Patient and Family Involvement in Adult Critical and Intensive Care Settings: A Scoping Review" (2016) 19:6 Health Expectations 1183 at 1194.

33 Lesley S Castillo et al, "Lost in Translation: The Unintended Consequences of Advance Directive Law on Clinical Care" (2011) 154:2 Annals Internal Medicine 121 at 122.

34 Nola M Ries et al, "Doctors, Lawyers and Advance Care Planning: Time for Innovation to Work Together to Meet Client Needs" (2016) 12:2 Healthcare Policy 12 at 13.

C. THE NEED FOR RESOURCES

Our respondents reported a strong interest in resources to assist them with ACP consultations. Clients' lack of preparedness is a commonly cited barrier by lawyers and health care providers alike and resources like worksheets can help clients think about and articulate their wishes. This could improve the comprehensiveness of the instructions that clients give to their lawyers and could enhance the quality of documents that lawyers draft for their clients. Resources to increase lawyers' knowledge of health system policies and procedures, as well as basic educational materials on medical terminology and treatments, would also help bridge the divide between the legal and health care domains. Strategies developed to promote ACP and the sharing of documents (Alberta's Green Sleeve initiative, for example)[35] should be communicated to lawyers as they are important advisors for clients on organizing their affairs and planning for future incapacity and death. Organizations that develop and disseminate ACP resources should liaise with legal professional associations about lawyers' needs, and those associations can themselves provide further continuing professional education on ACP.

VII. STRENGTHS, LIMITATIONS, AND IMPLICATIONS FOR RESEARCH AND PRACTICE

To our knowledge, this is the first survey of lawyers regarding their practice in relation to ACP. Our respondents represent experienced professionals who regularly assist clients with ACP. The response rate was low, but higher than what the Law Society suggested we could expect. Our survey was promoted during a period when lawyers also received numerous communications from the Law Society about volunteering to support residents and lawyers evacuated from a city that was severely affected by a wildfire that swept the area and destroyed over 2,000 homes and buildings.[36] The urgency of this appeal may have overshadowed our survey.

The findings reflect the practices and attitudes of lawyers in one Canadian province, but having worked extensively with the legal profession and other stakeholders in the survey development, we hope to use it to collect data in at least three other Canadian provinces.

Previous studies note that barriers and enablers to ACP exist in three domains: client/patient; professional/provider; and system-level. Our survey focused on the lawyer and client domains, and future research could explore system-level factors that influence legal practice, as well as barriers and enablers to collaboration among health care and legal professions to provide more integrated supports for ACP.

There is also a need for more in-depth research about lawyers' practices. For example, a majority of our survey respondents said they use a template for ACD. The source, content, and user experiences with such templates — both lawyers and clients — are areas for further

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35 See Government of Alberta, *supra* note 26.

36 For the legal profession responding to calls for support for wildfire victims, see David Dias, "Alberta Law Firms Offer Generous Support to Wildfire Victims," *Canadian Lawyer* (12 May 2016), online: <www.canadianlawyermag.com/legalfeeds/alberta-law-firms-offer-generous-support-to-wildfire-victims-6898/>.

investigation. Studies elsewhere have shown that the quality of such templates may be a concern. In Germany, Matthias Becker and co-authors found that lawyers who downloaded templates from the Internet rarely modified them to deal with their clients' particular circumstances.[37] It has been observed that directives in legalistic and complicated language are unlikely to influence treatment decisions.[38]

It is important to investigate whether the documents that lawyers prepare accurately reflect their clients' wishes and whether clients understand the documents. Friedemann Nauck and co-authors interviewed 53 people who had recently completed advance directives and compared what the people said they wanted with what was recorded in the directive.[39] They found that advance directive templates often used vague phrases (for example, "to die with dignity") and were rarely tailored to reflect the circumstances of the individual making the directive.[40] A qualitative study of doctors' experiences of using advance directive templates found that doctors viewed the form as a tool to start a conversation, with some "explicitly claim[ing] that it is not the form, but the conversation itself that matters to them."[41] It appears that lawyers, trained to draft legal documents, place emphasis on the completion of documents and then, to some degree, encourage their clients to have conversations with their loved ones.

Just under half of our respondents reported that they feel they lack adequate information about the medical aspects of ACP. In turn, their clients may be ill-informed as well, especially if they do not discuss their directive with a doctor. Nauck and co-authors found that many people who had made an advance directive "had a poor knowledge of particular clinical situations and the relevance of potential measures."[42] Natalya Thorevska and co-authors reported similar results:

> This study suggests that patients with living wills did not understand the life-sustaining therapies mentioned in their advance directives. Their preferences for CPR and mechanical ventilation changed when they were provided with American Thoracic Society-approved information. This study confirms that patients with living wills did not fully understand them and had end-of-life wishes that were not reflected fully in their documents. Patients drafted their living wills with the assistance of lawyers and family members, but physicians were generally left out of the process. This is 1 potential explanation for poor understanding of the medical issues (i.e. understanding of terminal illness, end-of-life scenarios, and life-sustaining therapies) in which advance directives are applicable.[43]

Lawyers in our survey reported that diagnosis with a life-limiting illness or declining health were common reasons for clients wanting to engage in ACP and it is worth investigating whether their specific illness is addressed in their directive. Nauck and co-

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37 See Becker et al, *supra* note 13 at 623.

38 Neil A Halpern et al, "Advance Directives in an Oncologic Intensive Care Unit: A Contemporary Analysis of Their Frequency, Type, and Impact" (2011) 14:4 J Palliative Medicine 483 at 487.

39 Friedemann Nauck et al, "To What Extent Are the Wishes of a Signatory Reflected in Their Advance Directive: A Qualitative Analysis" (2014) 15:52 BMC Medical Ethics, online: <www.biomedcentral.com/1472-6939/15/52>.

40 *Ibid* at 7.

41 Ina Carola Otte et al,"The Utility of Standardized Advance Directives: The General Practitioners' Perspective" (2016) 19:2 Medicine, Health Care & Philosophy 199 at 203.

42 Nauck et al, *supra* note 39 at 8.

43 See Thorevska et al, *supra* note 12 at 30 [footnotes omitted].

authors found that people with chronic or terminal illness did not mention "their existing disease in their AD" nor did they go "beyond considering commonly feared scenarios such as artificial nutrition/hydration or being in pain or a coma. Probable end-of-life scenarios relating to their disease were not discussed."[44]

Finally, studies should follow up with people who make advance directives and appoint decision-makers to determine the impact of their efforts to plan for what happens to them in the future. As Patricia Biondo and co-authors point out: "Clearly the goal of ACP is not simply to encourage conversations but to ensure that care received is in line with patients' wishes and preferences."[45]

VIII. CONCLUSION

The wealth of literature on ACP in health contexts is an important body of knowledge that reveals current practices and investigates strategies that can overcome barriers to improve the uptake of ACP and decision-making that accords with patients' wishes. We believe that a similar evidence base needs to be developed for other professionals involved in promoting and assisting clients with ACP. This study of lawyers is an important step in this direction.

44 See Nauck et al, *supra* note 39 at 8.
45 See Biondo et al, *supra* note 6 at 727.

APPENDIX A: DETAILED SURVEY RESULTS[46]

FACTORS THAT MOTIVATE CLIENT ENGAGEMENT WITH ACP

Question: Typically, from your experience, what prompts a client's desire to engage in advance care planning?						
	Never	**Seldom**	**Sometimes**	**Often**	**Always**	**Do not know or not sure**
The lawyer brings it up as part of a discussion about wills, power of attorney, etc. with the client (n=96)	0, 0.0%	1, 1.0%	7, 7.3%	44, 45.8%	43, 44.8%	1, 1.0%
The client has received a medical diagnosis with life limiting implications and/or is experiencing deteriorating health (n=93)	5, 5.4%	18, 19.4%	53, 57.0%	15, 16.1%	1, 1.1%	1, 1.1%
The client has had a discussion with physician or other health care provider (n=91)	5, 5.5%	32, 35.2%	41, 45.1%	8, 8.8%	0, 0.0%	5, 5.5%
The client is required to do ACP by residential facility (e.g. nursing home, supportive living) (n=93)	10, 10.8%	24, 25.8%	41, 44.1%	14, 15.1%	1, 1.1%	3, 3.2%
The client has had a discussion with financial planner, banker, insurance advisor (n=94)	3, 3.2%	23, 24.5%	40, 42.6%	26, 27.7%	0, 0.0%	2, 2.1%
The client has had a discussion with a spiritual advisor (n=89)	36, 40.4%	31, 34.8%	11, 12.4%	2, 2.2%	0, 0.0%	9, 10.1%
The client has had experience as caregiver or agent to another	3, 3.2%	11, 11.7%	56, 59.6%	22, 23.4%	1, 1.1%	1, 1.1%
There has been an illness or death of someone close to client (n=93)	1, 1.1%	10, 10.8%	55, 59.1%	27, 29.0%	0, 0.0%	0, 0.0%

[46] Data is reported as n, %, where n is the raw number of responses, and % is the percentage of lawyers that made that particular response.

TOPICS LAWYERS DISCUSS WITH CLIENTS

Question: When you assist clients with planning for future health care, how often do you discuss or provide guidance about?						
	Never	**Seldom**	**Sometimes**	**Often**	**Always**	**Do not know or not sure**
Selecting an agent (n=88) [Note: an agent is a person appointed to make health and personal decisions]	0, 0.0%	0, 0.0%	6, 6.8%	17, 19.3%	65, 73.9%	0, 0.0%
Their values and wishes concerning future care (e.g., religious or lifestyle beliefs important to the client that they want others to acknowledge and respect) (n=93)	0, 0.0%	1, 1.1%	11, 11.8%	29, 31.2%	51, 54.8%	1, 1.1%
Their wishes about whether they would accept or refuse particular health care interventions (e.g., cardiopulmonary resuscitation, mechanical ventilation, tube feeding, kidney dialysis) (n=93)	2, 2.2%	9, 9.7%	11, 11.8%	21, 22.6%	49, 52.7%	1, 1.1%
Their wishes about future accommodation/living arrangements (n=93)	3, 3.2%	15, 16.1%	19, 20.4%	24, 25.8%	32, 34.4%	0, 0.0%
Their wishes for who should be involved in consultations with the client's health care team (n=93)	2, 2.2%	7, 7.5%	7, 7.5%	23, 24.7%	54, 58.1%	0, 0.0%
Their wishes for who should have access to their health-related records (n=92)	5, 5.4%	17, 18.5%	18, 19.6%	20, 21.7%	32, 34.8%	0, 0.0%
Their wishes about participation in medical research (n=93)	15, 16.1%	19, 20.4%	19, 20.4%	14, 15.1%	26, 28.0%	0, 0.0%
Their wishes about organ donation (n=92)	7, 7.6%	14, 15.2%	16, 17.4%	16, 17.4%	39, 42.4%	0, 0.0%

BARRIERS TO ASSISTING CLIENTS WITH ACP

Question: How much do the following factors hinder you in assisting your clients with ACP? (n=89)						
	Never	**Seldom**	**Sometimes**	**Often**	**Always**	**Do not know or not sure**
Concerns about upsetting the client	45, 50.6%	28, 31.5%	12, 13.5%	4, 4.5%	0, 0.0%	0, 0.0%
Conversations are upsetting or uncomfortable for me	63, 70.8%	21, 23.6%	4, 4.5%	0, 0.0%	0, 0.0%	1, 1.1%
Client is unwilling to share personal details with me	15, 16.9%	34, 38.2%	31, 34.8%	8, 9.0%	0, 0.0%	1, 1.1%
Differences between the client and me in age, cultural, religious or other personal characteristics	43, 48.3%	34, 38.2%	10, 11.2%	1, 1.1%	0, 0.0%	1, 1.1%
Lack of client preparedness for advance care planning	13, 14.6%	10, 11.2%	45, 50.6%	20, 22.5%	0, 0.0%	1, 1.1%
My lack of knowledge about medical aspects of advance care planning (e.g., lack of knowledge about medical interventions and their implications for a client)	25, 28.1%	21, 23.6%	25, 28.1%	9, 10.1%	6, 6.7%	3, 3.4%
My lack of knowledge about health sector policies/practices (n=88)	25, 28.4%	16, 18.2%	27, 30.7%	13, 14.8%	3, 3.4%	4, 4.5%
It is time-consuming (and therefore costly) to have advance care planning conversations with clients	43, 48.3%	29, 32.6%	10, 11.2%	6, 6.7%	1, 1.1%	0, 0.0%
Concerns that an advance care plan will not be used in practice	49, 55.1%	19, 21.3%	14, 15.7%	2, 2.2%	1, 1.1%	4, 4.5%
My lack of experience with law in this area	62, 69.7%	17, 19.1%	8, 9.0%	2, 2.2%	0, 0.0%	0, 0.0%

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PAPER 4: INCLUDING PEOPLE WITH DEMENTIA IN RESEARCH: AN ANALYSIS OF AUSTRALIAN ETHICAL AND LEGAL RULES AND RECOMMENDATIONS FOR REFORM

Overview

The literature on advance care planning (ACP) covered in the previous papers revealed concerns about the gaps in evidence to inform care for people living with cognitive impairment. While ACP is a process by which people can express their values and preferences in relation to healthcare during periods of decisional incapacity, high-quality evidence is often not available to inform provision of care for people with progressive neurocognitive illness. It is therefore crucial to involve people with impaired cognition in research in order to ameliorate gaps in the evidence base.

When considering strategies for research inclusion, an important starting point is to understand legal and ethical rules and the degree to which they support or hinder research involving people who may not be able to give their own consent. This paper analyses the ethical and legal rules in Australia relevant to the inclusion of people with dementia in research. It presents key ethical principles in the National Statement on Ethical Conduct in Human Research, provides a comprehensive review of applicable legal rules in state and territorial statutes, and highlights significant differences and ambiguities. It concludes with recommendations for reform to improve clarity and consistency in the law and reduce barriers that may exclude persons with

dementia from participating in ethically approved research. It discusses how advance planning for research, including making research directives, may be undertaken in accordance with the National Statement and relevant state and territorial laws. This study underpins Papers 5–7, which report on survey studies that explore the views of older people on participating in research and the views and experiences of dementia researchers in Australia.

This is the first national-in-scope analysis of Australian ethical and legal rules that govern research participation for people with cognitive impairment. The candidate used this research to inform submissions to the NSW Law Reform Commission's 2017–2018 inquiry into the *Guardianship Act 1987*, particularly its rules governing clinical research participation by people unable to give their own consent. This work adds to the few scholarly analyses of law and ethics in relation to this issue in other countries.

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ORIGINAL RESEARCH

Including People with Dementia in Research: An Analysis of Australian Ethical and Legal Rules and Recommendations for Reform

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Abstract Research is crucial to advancing knowledge about dementia, yet the burden of the disease currently outpaces research activity. Research often excludes people with dementia and other cognitive impairments because researchers and ethics committees are concerned about issues related to capacity, consent, and substitute decision-making. In Australia, participation in research by people with cognitive impairment is governed by a national ethics statement and a patchwork of state and territorial laws that have widely varying rules. We contend that this legislative variation precludes a consistent approach to research governance and participation and hinders research that seeks to include people with impaired capacity. In this paper, we present key ethical principles, provide a comprehensive review of applicable legal rules in Australian states and territories, and highlight significant differences and ambiguities. Our analysis includes recommendations for reform to improve clarity and consistency in the law and reduce barriers that may exclude persons with dementia from participating in ethically approved research. Our recommendations seek to advance the national decision-making principles recommended by the Australian Law Reform Commission, which emphasize the rights of all adults to make their own decisions and for those with impaired capacity to have access to appropriate supports to help them make decisions that affect their lives.

Keywords Research ethics · Law · Dementia · Consent · Substitute decision-making · Advance directives

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Introduction: The Imperative of Including People with Dementia in Research

Dementia, a clinical syndrome caused by various neurological diseases, is one of the most pressing health issues in industrialized countries with ageing populations. Dementia can affect the ability to understand, retain, apply, and act on information. It can impair communication, cause behavioural changes, and limit abilities to carry out activities of daily life (Burns and Iliffee 2009). Globally, an estimated 46.8 million people live with dementia, and this number is expected to double every twenty years, reaching 131.5 million people in 2050 (Alzheimer's Disease International 2015). In Australia, over 400,000 people are living with dementia and around 240 new diagnoses are made each day (Alzheimer's Australia 2017). It is the second leading underlying cause of death (Australian Bureau of

Statistics 2016). By 2050, an estimated one million Australians will be living with dementia.

Research is crucial to advancing knowledge about dementia, including its causes, possible therapeutic interventions, and ways to improve the quality of life of people living with dementia. People with dementia should receive respectful, beneficent, and just care that optimizes their outcomes. Appropriate care depends upon the availability of well-designed research, conducted and analysed with rigour (LeBlanc et al. 2010).

Yet, the burden of the disease outpaces research activity, and there are many inadequacies in the knowledge base that informs clinical care (Lam et al. 2015). For instance, of 109 recommendations in recently published Australian practice guidelines for dementia care, only twenty-nine are categorized as evidence-based recommendations, meaning they are formulated from a systematic analysis of published research findings (Guideline Adaption Committee 2016). Of these, twenty-two recommendations are based on evidence assessed as being of low or very low quality and only seven are based on moderate-quality evidence. None of the recommendations are based on high-quality evidence. A clinician's confidence in the effectiveness of these recommended actions must necessarily be guarded.

The 2015 World Alzheimer's Report urges an increase in research investment for dementia proportionate to the social cost of the disease (Alzheimer's Disease International 2015). In Australia, dementia is a National Health Priority Area, and research funding has been targeted to dementia (Australian Institute of Health and Welfare n.d.). We are concerned, however, that differing legal frameworks across the country may restrict the types of research undertaken and inappropriately exclude people with dementia from participating in research. As a consequence, research may fail to tackle some of the more pressing issues, especially for people in later stages of dementia and those living in socially isolated circumstances.

Research often excludes people with cognitive impairment (Taylor et al. 2012) because "many researchers and ethics committees are nervous about including this population in their studies" (Pachana et al. 2015, 705). Relying on the participation of those who are judged to be unequivocally competent is problematic for all research but particularly for dementia research, as these individuals comprise a potentially small and atypical subset of people with dementia. Excluding those who have reduced decisional capacity raises doubt about the external validity of research findings (Kim 2011).

Scientific study to advance knowledge about dementia and improve the quality of evidence to inform care depends on people with the condition participating in research (Dresser 2001). Literature reports "differences in the issues of concern, experiences and needs of people with dementia at the mild, moderate and severe stages" and stresses that "inclusion [in research] of persons with dementia at all stages is essential" to understand and respond to their varying needs (Murphy et al. 2015, 800). Yet, researchers who propose to include people with dementia in research have reported obstacles arising from the complexities of obtaining ethical and legal approval, including issues of capacity, and the challenges of seeking consent from substitute decision-makers who are uncertain about what the person with dementia would want (Cubit 2010; Monroe 2013). Special complexities arise in multi-jurisdiction studies that require compliance with differing legislative rules and processes.[1]

In Australia, participation in research of people with cognitive impairment is governed by the National Statement on Ethical Conduct in Human Research[2] (the "National Statement") (NHMRC 2007) and a patchwork of state and territorial laws that establish rules for how decisions concerning health and personal matters should happen for a person who lacks capacity. There is significant variation across the country. The law in several jurisdictions is largely silent on research participation by people with impaired capacity, meaning researchers must follow the National Statement and any specific policies on research developed by health departments or facilities. Other jurisdictions set out detailed statutory rules governing approvals and substitute decision-making for research involving people who lack capacity to give their own consent. In some cases, statutes impose greater restrictions than what is laid out in the National Statement. A further complexity is that statutes vary in how they define research, meaning some types of research (such as clinical trials) are covered by legislation and other types (such as

[1] Despite a process for National Mutual Acceptance of the scientific and ethical review of multisite human research in Australia (NSW Government 2017a), jurisdiction specific laws impose varying consent and substitute decision-making rules that must be followed.

[2] The National Statement is produced by the National Health and Medical Research Council in accordance with its statutory obligations under s10 of the *National Health and Medical Research Council Act* 1992 (Cth) to issue guidelines for research involving humans.

observational studies) are excluded from statutory rules. Statutes also allow people, when they have capacity, to designate individuals who will act as decision-makers for health and personal matters should the appointer lose capacity in the future. Yet some statutes preclude a designated decision-maker from making choices about certain types of research. People have a legal right—recognized at common law and in statutes in some states and territories—to record their wishes on health and personal matters in advance directives with the expectation that their wishes will be respected during periods of incapacity. Advance directives for research are rarely encountered in practice, however.

In our view, this wide legislative variation has no rational foundation, precludes a consistent approach to research governance and participation, and hinders research that seeks to include people with impaired capacity, especially multi-jurisdictional studies. This article analyses the ethical and legal rules in Australia relevant to the inclusion of people with dementia in research. We present key ethical principles in the National Statement, provide a comprehensive review of applicable legal rules in state and territorial statutes, and highlight significant differences and ambiguities. Our analysis includes recommendations for reform to improve clarity and consistency in the law and reduce barriers that may exclude persons with dementia from participating in ethically approved research. Our recommendations seek to advance the national decision-making principles advocated by the Australian Law Reform Commission (2014), which emphasize the rights of all adults to make their own decisions and for those with impaired capacity to have access to appropriate supports to help them make decisions that affect their lives.[3] Our focus is on dementia, but our recommendations are relevant for research that involves people with other conditions or injuries that impair cognitive abilities.

We start from the premise that the National Statement provides an equitable set of core values and principles for individuals and organizations that carry out human research. We agree with its aims to protect vulnerable persons, empower people with reduced autonomy, and advance knowledge through meritorious research. Compliance with the National Statement is mandatory for "research that is funded by, or takes place under the auspices of" any of the national bodies that developed it, which are the National Health and Medical Research Council, the Australian Research Council, and Universities Australia (NHMRC 2007, 6). The statement also sets standards for "human research undertaken by governments, industry, private individuals, organisations, or networks of organisations" (NHMRC 2007, 6).

Consistent with the principles in the National Statement, we assert that people with cognitive impairment are entitled to participate in research and, where they are able, they should be supported to express their preferences regarding research participation, including future participation, and have those wishes respected. The law should not, as a default, preclude a decision-maker appointed by a person from making choices about research participation for that person should he or she lose capacity. Clear and timely processes are needed to allow substitute decision-making about research participation for people with impaired capacity who do not have family members or friends available to make such choices. Law reform should eliminate duplication and inconsistencies; in particular, laws should not require a duplicative review by a body such as a guardianship tribunal where a research ethics committee has already reviewed and approved a research study. Indeed, the National Statement requires that *all* research that proposes participation by people with cognitive impairment be reviewed and approved by a human research ethics committee, unless the research involves only negligible risk (i.e., no foreseeable risks of discomfort or harm) or the use of previously collected non-identifiable data, such as an anonymized chart review (NHMRC 2007, 69, [5.1.6]).

As will be discussed in the following section, statutes in some states and territories set out rules that apply for certain types of research. Whether and how a research project falls into a category covered by legislation has important consequences for researchers, potential

[3] The four national decision-making principles contained in the report (2014, 11) are:

(1) The equal right to make decisions: All adults have an equal right to make decisions that affect their lives and to have those decisions respected.
(2) Support: Persons who require support in decision-making must be provided with access to the support necessary for them to make, communicate, and participate in decisions that affect their lives.
(3) Will, preferences, and rights: The will, preferences, and rights of persons who may require decision-making support must direct decisions that affect their lives.
(4) Safeguards: Laws and legal frameworks must contain appropriate and effective safeguards in relation to interventions for persons who may require decision-making support, including to prevent abuse and undue influence.

participants, and substitute decision-makers. For example, in New South Wales and Queensland, research covered by state laws triggers a requirement to obtain the approval of a guardianship tribunal to include people with impaired capacity. Other jurisdictions do not require a process of tribunal approval for ethically approved research but may define research in a statute that establishes rules for substitute decision-makers, for instance, by identifying who can act as a decision-maker and the factors they must consider in making choices for a person with impaired capacity. Legally and ethically, however, the starting point is that consent for research participation must be sought from the adult if she or he has decision-making capacity in relation to the proposed research activities.

Respecting the Right of a Person with Dementia to Make Their own Decisions Where Able

There is clear legal and ethical recognition of the right of adults with capacity to make decisions about their own body and personal interests.[4] If a person with a diagnosis of dementia, or other condition that affects cognition, has capacity to make decisions about a proposed research study, consent must be sought from that individual, not a substitute decision-maker. Making assumptions that people with dementia are unable to make decisions about participating in research reinforces negative stereotypes of dementia (NHMRC 2007) and denies them the opportunity to make meaningful contributions to research and share in its benefits (Slaughter et al. 2007).

According to the National Statement, consent requires the capacity to form an "adequate understanding of both the proposed research and the implications of participation in it" (NHMRC 2007, 16, [2.2.2]). The statement notes that the law may prescribe further rules for determining when capacity is present. The law assumes adults have capacity to make their own decisions unless there is evidence to the contrary (Re MB [1997] 2 FCR 533). In most states and territories, a person would be considered to have capacity to consent to a research study if she or he understands the general nature and effect of procedures or activities involved in the study and is able to communicate a decision (*Guardianship Act 1987* (NSW) s 33(2); *Guardianship and Administration Act 2000* (Qld) Sch 3; *Guardianship and Administration Act 1986* (Vic) s 36(2); *Consent to Medical Treatment and Palliative Care Act 1995* (SA) s 4(2); *Advance Personal Planning Act 2013* (NT) s 6(1)).

Some legislation reinforces the point that fluctuating capacity does not mean a person should be labelled as incompetent to make choices. Victoria's *Guardianship and Administration Act* explicitly recognizes that capacity to consent may fluctuate and, in relation to research, requires an assessment of whether the person is likely to be able to consent to the research procedure within a reasonable time (*Guardianship and Administration Act 1986* (Vic) s 42R). If this is the case, the research procedure cannot be carried out on the basis of consent from a substitute decision-maker. Similarly, South Australian legislation states that a person should not be considered incapable simply because their cognitive function fluctuates and they have difficulty understanding technical details or retaining information for more than a short period (*Advanced Care Directive Act 2013* (SA) s 7(2); *Consent to Medical Treatment and Palliative Care Act 1995* (SA) s 4(3)). Legislation in the Northern Territory lists factors that, on their own, do not indicate that capacity is impaired, including having a diagnosis of disability or illness, engaging in "unconventional behaviour," having a lifestyle or making decisions with which others disagree (e.g., choice of living arrangement), or engaging in particular cultural practices (*Advance Personal Planning Act 2013* (NT) s 6(5)). Some statutes articulate a principle of minimal interference with the rights of people with impaired capacity. In New South Wales, the *Guardianship Act* instructs that individuals with conditions that affect capacity should be "restricted as little as possible" in their "freedom of decision and freedom of action" (*Guardianship Act 1987* (NSW) s 4). Queensland's statute recognizes "the right of an adult with impaired capacity to the greatest possible degree of autonomy in decision-making" as well as the need for "adequate and appropriate support for decision-making" (*Guardianship and Administration Act 2000* (Qld) s 6).

To give effect to these ethical and legal principles, the decision to participate in research should, first and foremost, be that of the individual. People living with dementia or other conditions that affect cognition should

[4] In *Schloendorff v Society of New York Hospital* (1914) 211 NY 125, Cardozo J famously wrote that "[e]very human being of adult years and sound mind had has a right to determine what shall be done with his own body" (at 129). This principle has been adopted in Australian law: see for example, *Rogers v Whitaker* [1992] HCA 58 and *Hunter and New England Area Health Service* (2009) 74 NSWLR 88.

not be routinely excluded from the opportunity to participate in research based on assumptions about decisional capacity. At the conclusion of this article, we offer some recommendations for assessing a person's capacity to consent to a research study and supporting people with dementia in making their own choices. If, however, a person is determined to lack capacity to make a decision about participating in a study, the National Statement and relevant state and territorial laws establish rules that determine whether and how that person may participate in research.

The Rules Governing Research Participation for People Who Lack Capacity

If an individual does not have capacity to consent to take part in a study, the National Statement requires researchers to seek consent for research participation from a legally appointed guardian or from any other person or organization authorized by law to provide consent for the individual (NHMRC 2007, 59, [4.5.5]). A researcher must then look to relevant law to determine the rules and processes that must be followed. There is significant variation across the states and territories, first, in defining categories of research covered by the law, and second, in the rules for substitute decision-making for a person who lacks capacity to give their own consent. Laws dealing with advance directives are also relevant as they enable people to record their wishes for health and personal matters in advance of loss of decisional capacity, and to appoint trusted individuals to act as decision-makers on specified matters. Each of these issues is discussed for the jurisdictions that have relevant law.

New South Wales

The *Guardianship Act* requires researchers to obtain approval from a guardianship tribunal if they wish to involve people who lack capacity in a clinical trial or give them "special treatment," a term that encompasses innovative clinical practices that have not yet gained common acceptance (*Guardianship Act 1987* (NSW) s 33).[5] The Guardianship Division of the NSW Civil and Administrative Tribunal has offered some inconsistent interpretations of what constitutes a clinical trial (Turner 2015) but recently stated that the statute would not apply to "trials of a currently accepted treatment for the condition in question" (Application for approval for adults unable to consent to their own treatment to participate in a clinical trial (ADRENAL Trial) [2015] NSWCATGD 23 [125]). From a research perspective, the difference between "special treatment" and a "clinical trial" would not always be apparent, yet the statutory categorization dictates the legally required consent process. Only the tribunal can consent for a person who lacks capacity to receive "special treatment," but a legally authorized substitute decision-maker (who may be a spouse or other family member) can give consent for participation in a clinical trial. The following discussion focuses on the statutory rules that must be followed in order to enrol people who lack capacity in a trial.

A principal investigator or a representative of a pharmaceutical company conducting the trial must apply for approval from the tribunal (NCAT 2016). The tribunal requires evidence that an ethics committee has approved the proposed research in accordance with any relevant NHMRC guidelines. This requires investigators to go through the ethics process first and then apply to the tribunal, providing copies of the clinical trial protocol, the ethics committee application, the ethics committee approval, the information sheet that explains the study and any risks of participation, and the consent form. The tribunal, comprised of a legal, a professional, and a community member, conducts a hearing and the applicant must attend in person, and other knowledgeable people, such as a clinical trial coordinator, should be available in person or by phone to answer questions (NCAT 2016). To approve the application, the tribunal must be satisfied that several criteria are met: the intervention being studied in the trial must be "intended to cure or alleviate" a condition the participant has; there must be no "known substantial risk" of harm to participants, or any material risks must not be greater than those involved in current treatments for the condition; "safety and ethical considerations" must militate in favour of making the intervention available to persons with the target condition, even though they are unable to give consent; and weighing up the risks and potential benefits, it is in the best interests of people with the condition to participate in the trial (*Guardianship Act 1987* (NSW) s 45AA(2)(a)-(e)).

[5] At the time of writing, the NSW *Guardianship Act 1987* is under review and the NSW Law Reform Commission has been charged, *inter alia*, with examining the statutory rules concerning clinical trials (NSW Government 2017b).

If the tribunal approves a clinical trial, it then determines if consent for specific individuals who lack capacity will be sought from someone recognized as a decision-maker for the prospective participant (known as a "person responsible") or by application to the tribunal (*Guardianship Act 1987* (NSW) s 40). The "person responsible" is, in hierarchical order: the person's guardian, if a guardianship appointment is in place that confers power to consent to medical treatment; the person's spouse, as long as they are in a close and continuing relationship; the person's carer (unpaid); or a close friend or relative who has regular contact with the person and an interest in their welfare. In making its determination, the tribunal reviews the consent document and information statement proposed for use in the research and determines their adequacy in enabling a person responsible to make a decision (*Guardianship Act 1987* (NSW) s 45AB(2)). The person responsible has a statutory duty to take into account the views, if any are known, of the person who lacks capacity to make their own choice about research participation.

If tribunal consent is sought to enrol a specific person who lacks capacity in a trial, notice of the application must be given to the proposed participant, the person proposing the treatment as part of a trial, and each person responsible who can be located (*Guardianship Act 1987* (NSW) s 43). In considering the application, the tribunal must take account of any known views of these parties. If the person with impaired capacity previously prepared an advance directive that recorded preferences for research participation, these wishes would be considered if the directive is produced to the tribunal.

Queensland

Similar to the law in New South Wales, the Queensland *Guardianship and Administration Act* requires researchers to seek Guardianship Tribunal approval in order to include people without decisional capacity in two categories of research: (1) "special medical research or experimental health care," categorized together in the Act as "special health care," and (2) "clinical research" (*Guardianship and Administration Act 2000* (Qld), Schedule 2, s 12(1), 13). The Act clarifies that clinical research does not include "a comparative assessment of health care already proven to be beneficial" (*Guardianship and Administration Act 2000* (Qld), Schedule 2, s 13(1A)). The Act also does not apply to psychological research, a term not defined in the Act (*Guardianship and Administration Act 2000* (Qld), Schedule 2, s 12(2)).

The tribunal is charged with making consent decisions in relation to special healthcare for people who lack capacity. For clinical trials, once the tribunal has approved the research, investigators must seek consent from an individual with legal authority to make decisions for the prospective participants who lack capacity. As in New South Wales, the distinction between the categories of "special care" and "clinical research" is sometimes blurry and, where possible, the tribunal may be inclined to categorize activities as clinical research to avoid the delays that would ensue if it were "special care" that required tribunal consent for each participant (*Re Application of Dr. Matthew Hope* [2012] QCAT 191).

Once it is determined that a study involving people with impaired capacity constitutes a clinical trial, the tribunal may approve the study if it is satisfied that: it has been approved by an ethics committee; any drugs or techniques being trialled are intended to diagnose, maintain, or treat a condition affecting the research participants; the research will not involve any known substantial risks, or any known material risks are no greater than those a participant would face in existing healthcare interventions for the condition; it is appropriate on safety and ethical grounds to trial experimental drugs or techniques on participants who cannot give their own consent; and "having regard to the potential benefits and risks of participation, on balance it is not averse to the interests of the participants to participate" (*Guardianship and Administration Act 2000* (Qld), Schedule 2, s 13(3)). If the tribunal approves the clinical research, consent to enrol a specific person with impaired capacity must then be sought from a legally authorized decision-maker for the person (*Guardianship and Administration Act 2000* (Qld), Schedule 2, s 13(5)). This may be a health decision-maker appointed by the person (an attorney for health decisions appointed under the *Powers of Attorney Act 1998*), a guardian for health decisions appointed under the *Guardianship and Administration Act 2000*, or a decision-maker set out in the statutory hierarchy that includes a spouse, unpaid carer, close friend, or relative (*Powers of Attorney Act 1998* (Qld), s 63).

The guardianship and powers of attorney statutes set out principles that guide those who make decisions on behalf of a person who lacks capacity (*Guardianship*

and Administration Act 2000 (Qld), s 11 and Sch 1; *Powers of Attorney Act 1998* (Qld), s 76 and Sch 1). Decision-makers must consider the importance of empowering an adult to exercise their basic human rights, an individual's right to respect for their human worth and dignity, the individual's value as a member of society, and how best to maximize the person's participation in decisions affecting their life. Substitute decision-makers should make choices that are the least restrictive of the adult's rights and that promote the adult's health, well-being, and best interests. The substitute decision-maker should seek the adult's views and wishes and take them into account, along with any information given by the adult's healthcare provider.

The *Powers of Attorney Act* enables an adult to make a statutory healthcare directive and prescribes a lengthy advance directive form (see Queensland Government 2004). After twelve pages covering instructions for future healthcare, page thirteen provides a section for a personal statement on additional matters, which could include wishes concerning research participation. The healthcare instructions must be signed and witnessed by a doctor, and the entire form must be witnessed by a qualified person, such as a justice of the peace, lawyer, or notary public. The legislation *does not* allow a decision-maker appointed in a directive to make decisions about special experimental treatments (*Powers of Attorney Act 1998* (Qld), s 35). The guardianship legislation states that the tribunal may not give consent for a person with impaired capacity if the person has an advance directive that indicates an unwillingness to participate in the type of research or experimental care proposed (*Guardianship and Administration Act 2000* (Qld) s 72(3)).

Victoria

In Victoria, the *Guardianship and Administration Act 1986* deals with research participation for adults who lack capacity to consent. The Act defines a "medical research procedure" to mean "a procedure carried out for the purposes of medical research, including, as part of a clinical trial, the administration of medication or the use of equipment or a device" (*Guardianship and Administration Act 1986* (Vic) s 3(1)). The Act specifically excludes certain activities from the definition of a medical research procedure: non-intrusive examinations, such as measuring height and weight or visually examining a person's eyes or mouth; observing a person's activities; administering a survey; and collecting or using identifiable information about a person, including details about their physical, mental, or psychological health.

Prior to 2006, the Victorian Civil and Administrative Tribunal had to approve research participation for people who lacked decisional capacity (Victorian Law Reform Commission 2012). Statutory amendments in 2006 eliminated the need for tribunal approval, a change described as an important way "to provide a balance between advancing medical knowledge and protecting vulnerable people from exploitation or unnecessary intrusion" (Victorian Law Reform Commission 2012, 309). The Act now focuses on consent processes for including a person with capacity impairment in research that has been approved by an ethics committee. If a person with impaired capacity is likely to regain the capacity to consent to the research within a reasonable time, the research activity must be delayed until that time to ensure the individual has an opportunity to make their own choice about consenting or refusing to take part (*Guardianship and Administration Act* 1986 (Vic) s 42R). If this is not likely, a "person responsible" has legal authority to give consent for a person with impaired capacity to participate in medical research procedures (*Guardianship and Administration Act* 1986 (Vic) s 42S). The "person responsible" is, in order of priority, a person legally appointed as a healthcare decision-maker, the person's spouse, the primary carer, or a nearest relative (*Guardianship and Administration Act 1986* (Vic) s 42S). The person responsible must be reasonably available and willing and able to make a decision about research participation (*Guardianship and Administration Act 1986* (Vic) s 37). The person responsible must believe that the research procedure would not be against the person's best interests, and the consent must accord with any requirements specified in the ethics approval (*Guardianship and Administration Act 1986* (Vic) s 42S(3)-(4)).

If a person responsible cannot be identified or contacted despite adequate steps to do so, the statute authorizes a registered practitioner to carry out or supervise a research procedure without the consent of a person responsible if the practitioner reasonably believes: the research procedure is not contrary to the person's best interests; the procedure would not be against the person's wishes; the ethics committee has approved the research knowing that a person responsible may not be available to give consent; the research

aims to assess the effectiveness of the therapy being studied; the risk of the research is no greater than the risk "inherent in the patient's condition and alternative treatment" (*Guardianship and Administration Act 1986* (Vic) s 42T(2)(f)(ii)); and the research is "based on valid scientific hypotheses that support a reasonable possibility of benefit for the patient as compared with standard treatment" (*Guardianship and Administration Act 1986* (Vic) s 42(2)(g)). The practitioner must sign a certificate attesting to their beliefs, maintain a copy on the patient's clinical file, and promptly send a copy to the Public Advocate and the ethics committee (see Office of the Public Advocate 2013). For a study involving repeated procedures, monthly certificates must be submitted (see Office of the Public Advocate n.d.). If the participant regains capacity or a person responsible is identified, the practitioner must inform them about the research and, if relevant, provide an opportunity to withdraw from continued participation. For an ongoing study, continuing steps must be taken to locate a person responsible to seek consent (*Guardianship and Administration Act 1986* (Vic) s 42T(8)). The *Medical Treatment Planning and Decisions Act 2016* (Vic), set to come into effect in March 2018, confirms the processes summarized above for including a person with impaired capacity in research and also establishes a statutory framework for advance directives both for healthcare treatment and participation in medical research.

South Australia

In South Australia, statutory changes that took effect in 2014 substantially reformed the law to consolidate the rules for healthcare consent, including consent to research, into one statute, the *Consent to Medical Treatment and Palliative Care Act 1995* (SA). A statutory "person responsible" may consent for a person who lacks capacity to participate in research that investigates healthcare or medical treatment, broadly defined in South Australian legislation to encompass studies into preventive, diagnostic, and treatment services and procedures, including physical, surgical, psychological, and drug therapies (*Consent to Medical Treatment and Palliative Care Act 1995* (SA). S 4 and 14).

The statutory decision-making hierarchy of a "person responsible" is as follows: an appointed guardian, if one is in place and the appointment would reasonably cover health-related matters relevant to the proposed research; a relative; a friend; or a person with responsibility for the person's care and well-being. Relatives or friends must have a close and continuing relationship with the person, and, in all cases, the person responsible must be willing to make a decision. The decision of the person responsible must "as far as is reasonably practicable, reflect the decision that the patient would have made in the circumstances had his or her decision-making capacity not been impaired" (*Consent to Medical Treatment and Palliative Care Act 1995* (SA) s 14C). If no person responsible is available or willing to act, the tribunal may, on application by a relative, medical practitioner proposing treatment, or another person with a valid interest, become the legally authorized decision-maker.

The 2014 *Advance Care Directives Act* creates a statutory form for individuals to express wishes and instructions for future healthcare, living arrangements, and other personal matters. The aim of this Act is to give people, at a time when they have capacity, the right to express wishes and values and give directions about future personal affairs, including interventions they wish to avoid (*Advance Care Directive Act 2013* (SA) s 9). The Act defines neither "personal affairs" nor "interventions," but a decision about participation in research fits within the concept of a "personal affair" and, depending on the research, could involve "interventions." In a directive, the maker may designate a person to have decision-making authority should the maker lose capacity in the future. A directive must be in the form prescribed by the statute (Government of South Australia n.d.) and any designated decision-maker must agree in writing to that role. The form does not specifically prompt a person to record preferences concerning research participation, but invites a person to record matters of importance to them, outcomes they prefer to avoid, and dying wishes. The Act disallows a person from including a provision in a directive that would, "if given effect, cause a health practitioner or other person to contravene a professional standard or code of conduct (however described) applying to the health practitioner or person" (*Advance Care Directive Act 2013* (SA) s 12(1)(a)(iii)). For example, a person could not in a directive authorize medical researchers to use experimental dementia drugs without the need for ethical approval.

Australian Capital Territory

In the Australian Capital Territory, the *Powers of Attorney Act 2006* (ACT) was recently amended by the

Powers of Attorney Amendment Act 2016 (ACT) "to remove barriers to people with impaired decision-making capacity participating in medical research" (Legislative Assembly for the Australian Capital Territory 2015). The amendments came into force in September 2016 and have changed the law that previously prevented a person from giving their enduring power of attorney authority to make decisions about medical research or experimental care (*Powers of Attorney Act 2006* (ACT), ss 35, 37). The amendments enable a person to designate a decision-maker to make choices about research participation (a medical research power of attorney) and give directions about their preferences for research participation. It also sets out principles substitute decision-makers must follow when making a choice about research participation on behalf of a person who lacks capacity. These rules apply to several categories of decision-makers, including enduring attorneys appointed under the *Powers of Attorney Act*, and a guardian or health attorney appointed under the *Guardianship and Management of Property Act 1991*.

The Act as amended applies to participation in "low risk research" and "medical research" (defined collectively in the Act as a "medical research matter") (*Powers of Attorney Act 2006* (ACT), s12A). Low-risk research is defined to mean "research carried out for medical or health purposes that pose no foreseeable risk of harm to the person, other than any harm usually associated with the person's condition and does not change the treatment appropriate for the person's condition" (*Powers of Attorney Act 2006* (ACT), s 41A). Low-risk research does not include any activity that is part of a clinical trial (*Powers of Attorney Act 2006* (ACT), s 41A). The Act gives examples of low-risk research, such as studies using personal health information collected during routine healthcare, non-intrusive examinations for research purposes, observing the person's activities, and collecting information through a survey ((*Powers of Attorney Act 2006* (ACT), s 41A). A statutory substitute decision-maker may consent to the person with impaired capacity participating in low-risk research provided the research has been ethically approved (*Powers of Attorney Act 2006* (ACT), s 41C and 41D).

"Medical research" is defined to mean research "in relation to the diagnosis, maintenance, or treatment of a medical condition that a person has or has had or to which the person has a significant risk of being exposed" (*Powers of Attorney Act 2006* (ACT) s 41a). Medical research includes experimental healthcare, defined as "research into health care that has not yet gained the support of a substantial number of practitioners in that field of health care and may but need not be medical in nature and delivered as part of a test or a trial" (*Powers of Attorney Act 2006* (ACT), s 41a). Examples include a trial of increased physical therapy for patients on a ventilation apparatus or a trial of a new absorbent material after bathing to treat a dermatological condition (*Powers of Attorney Act 2006* (ACT), s 41a). Medical research also covers the administration of medication or the use of equipment or a device as part of a clinical trial (*Powers of Attorney Act 2006* (ACT), s 41a).

A medical research power of attorney must be satisfied that the person is not likely to regain decision-making capacity in time to make their own choice about participating in a study (*Powers of Attorney Act 2006* (ACT), s 41D(2)(b)). An independent doctor must assess the likelihood of the person regaining decision-making capacity (*Powers of Attorney Act 2006* (ACT), s 41D(2)(b)). Before providing consent, the attorney must be satisfied that: the research relates to the diagnosis or treatment of a condition the person has or has had or to which the person has a significant risk of being exposed; the research may benefit the person or others with the condition and the potential benefit outweighs risks of participation; and participating in the research will not unduly interfere with the person's privacy (*Powers of Attorney Act 2006* (ACT), s 41D(2)).

Substitute decision-makers must exercise their authority in accordance with specified decision-making principles (*Powers of Attorney Act 2006* (ACT), s 41B). For instance, they must give effect to the person's wishes as far as they can be determined and, if specific wishes are unknown, the person's interests must be promoted (*Powers of Attorney Act 2006* (ACT), s 41B). Decision-makers must comply with any directions the person has expressed in accordance with the *Medical Treatment (Health Directions) Act 2006* (*Powers of Attorney Act 2006* (ACT), s 41B(2). Amendments to this latter Act enable a person to give directions about their preferences in regard to medical research matters.

The Act now establishes a limited role for the ACT Civil and Administrative Tribunal (ACAT) to assist a decision-maker to make a research participation choice for a person who lacks capacity and to review consent or refusal decisions on application from an "interested person." Such a person includes the individual who designated the medical research power of attorney and

enables a person with fluctuating capacity to seek review of decisions made on their behalf during periods of incapacity (*Powers of Attorney Act 2006* (ACT), s 74). The ACT Government rejected the New South Wales and Queensland models and chose not to give ACAT a statutory role of making decisions about research participation for individuals. It did so for three reasons: to avoid workload burdens for ACAT; to encourage research decision-making by a decision-maker designated by the person with impaired capacity rather than an "unknown person or panel"; and to reduce barriers to research involving people with cognitive impairments (Legislative Assembly for the Australian Capital Territory 2015, 2–3).

Northern Territory

The *Guardianship of Adults Act 2016* (NT) was revised and assented to in June 2016. Under this Act, the Civil and Administrative Tribunal may appoint a guardian to make decisions for an adult who lacks capacity; however, a guardian with authority to make healthcare choices cannot make consent decisions concerning "restricted health care" (*Guardianship of Adults Act 2016* (NT) s 23). Restricted healthcare is defined to include healthcare provided for medical research purposes but excludes from this definition research that involves non-intrusive examinations, observing a person's activities, and collecting information from or about a person (*Guardianship of Act 2016* (NT) s 8). For research activities that fall into the category of restricted healthcare, consent would need to be sought from a local court.

The *Advance Personal Planning Act*, implemented in 2014, allows a person who has capacity to make a written plan to express "advance consent decisions," "advance care statements," and to appoint a decision-maker to act in the event of future periods of incapacity (*Advance Personal Planning Act 2013* (NT) s 8(1)). Advance-consent decisions are statements in which people either consent to or refuse future healthcare actions, including lifesaving or other measures (*Advance Personal Planning Act 2013* (NT) s 8(1)(a)). Advance-care statements "set out the adult's views, wishes and beliefs as the basis on which he or she wants anyone to act if they make decision for him or her" (*Advance Personal Planning Act 2013* (NT) s 8(1)(b)). A person's views on participation in research could be included in an advance personal plan, particularly as an advance-care statement, and provide guidance to researchers and decision-makers as to the person's preferences during future periods of incapacity.

In an advance personal plan, the maker may designate one or more people as decision-makers to make decisions about healthcare, finances, and property. The decision-maker cannot, however, make consent decisions about medical research participation, unless the consent is for a psychological study or approved clinical research (though both these terms are not defined in the legislation) (*Advance Personal Planning Act 2013* (NT) s 4(3)). For other types of medical research, consent from a local court would need to be sought under the *Adult Guardianship Act 2016*.

A decision-maker for a person who lacks capacity must comply with the decision-making principles set out in the Act (*Advance Personal Planning Act 2013* (NT) s 22). For example, the decision-maker must follow any relevant advance care statements, take account of any currently expressed views and, so far as possible, make a decision the person would make if she or he had capacity to do so. If the decision-maker is unable to form a reasonable belief about what the adult would have done in the circumstances, they must exercise their authority in the way they believe is in the adult's best interests. A decision-maker may make a decision that reasonably benefits another person if the benefit is of a kind that the adult could be expected to provide and would not significantly adversely affect the adult's best interests. The Act gives as an example a decision-maker consenting to an adult who lacks capacity undergoing a bone marrow donation procedure to treat the adult's child who has leukemia, even though the procedure would involve some degree of risk to the adult. Similarly, a decision-maker could agree to research participation that, in some sense benefits a researcher or other people with dementia, provided these criteria are met.

Northern Territory law does not include any hierarchy of "persons responsible" who may make decisions for a person who lacks capacity. This further restricts the opportunity to include people with dementia in research. Many people living with dementia do not have an advance personal plan that appoints a decision-maker who could make research decisions, and it is burdensome to seek a guardianship order or court approvals for each individual with dementia who could be invited to participate in a research study. Moreover, a guardianship order implies stripping away some degree of autonomy from a person, and a tribunal seems unlikely to impose

guardianship merely so that a person can participate in research.

Other States and Territories

The other states and territories do not have specific statutory regimes that deal with research participation by people who lack capacity, but researchers may nonetheless need to be aware of other laws that touch on research issues or policies developed to fill legislative voids.

In Western Australia, the *Guardianship and Administration Act 1990* (WA) does not include rules about substitute consent for research participation by an individual who lacks capacity. The Western Australia Department of Health has adopted research governance policy and procedures that say researchers may only include people who do not have capacity to consent to a study in circumstances where they consider that it would not be against the best interest of the person to participate (Department of Health 2012). The policy states that, in practice, this means the only research studies that can involve people who lack capacity are those that are observational in nature and where there is no best standard of care already in place (Department of Health 2012). An intervention being studied for research purposes must be considered an important part of the treatment of the participant (Department of Health 2012).

Under WA Health's Research Governance Policy and Procedures, the "senior responsible person," who is the participant's nearest relative or guardian, is required to sign a consent form that provides information about the research project (Department of Health 2012). The researcher seeking consent should ask the responsible person whether the participant has ever expressed views regarding research participation to ascertain whether or not the participant would be likely to consent or object to participation (Department of Health 2012).

Analysis and Recommendations

Tribunal Review and Definitions of Research

The National Statement requires ethical review and approval of any research above negligible risk that proposes to involve people with cognitive impairment. Legislators in New South Wales and Queensland should consider the value, if any, in mandating a guardianship tribunal approval that creates a duplicative process that can introduce significant delays to the process.[6] If the aim is to protect people who may be vulnerable due to impaired capacity, existing ethics review processes can achieve that goal by requiring researchers to minimize risks in the design of research and by requiring ethics committee review of protocols and ongoing monitoring for compliance with the National Statement.

Moreover, requiring tribunal approval of research that proposes to include people with dementia or other conditions where capacity may fluctuate is different from research where it is reasonable to assume that nearly every participant for a proposed study will lack capacity (e.g., a study of people with serious head injuries arriving at an emergency department). In New South Wales and Queensland, researchers who propose to include people with cognitive impairment must get tribunal approval in advance of recruitment. However, some potential participants may well have capacity to give their own consent. The need to obtain tribunal approval of a proposed research study accentuates a presumption of incapacity in relation to people with dementia that is at odds with respect for equal decision-making rights for people with decision-making disabilities.

A guardianship tribunal should be a dispute resolution and review venue, instead of an approver of research that has already been approved by a human-research ethics committee. In Victoria, for example, the Civil and Administrative Tribunal does not approve research but has statutory authority to make orders or give opinions related to an individual's participation in medical research procedures and to issue guidelines on such procedures (See *Guardianship and Administration Act 1986* (Vic) ss 42V, 42W and 42X). It may hear applications to resolve questions or disputes as to whether research participation is in the best interests of the patient. However, a health practitioner involved in the research cannot seek tribunal review if the person responsible refuses to consent to the individual having a research procedure (See *Guardianship and Administration Act 1986* (Vic) ss 42V). Reforms in the Australian Capital Territory adopt a similar model.

[6] A submission to the NSW Government about the *Guardianship Act* 1987 (NSW) reform noted that it took eighteen months to obtain a tribunal decision on a research study that sought to include people with impaired capacity (South Eastern Sydney Local Health District Human Research Ethics Committee 2016).

Legislative definitions of research covered by statutory rules should be clarified, and the purpose and aims of regulating certain types of research and excluding others should be made explicit. The boundary between categories of research is not always clear, and some laws say they do not apply to certain kinds of research, such as "psychological research," but do not define the meanings of such terms. Statutory definitions of research are not explicitly risk-based, yet they mostly cover research involving medical treatments or procedures, which implies some degree of physical intervention and thus a potential for harm that exceeds mere inconvenience. If the intent is to regulate the inclusion of people with impaired capacity in higher-risk research, the indicia of such research should be stated and done so in a way that does not introduce inconsistency with the National Statement.

Substitute Decision-Making

The National Statement requires the consent of a legally authorized decision-maker for a person with cognitive impairment to participate in research. It is up to state and territorial laws to set out clear rules for who is authorized to make decisions. In general, existing laws deal with the appointment of a guardian to manage the affairs of a person who lacks capacity and to make decisions on health, financial, and other personal matters. Some statutes prescribe a decision-making hierarchy of "persons responsible" and other statutes allow a person to designate decision-makers to act during future periods of incapacity. Decision-making about research participation is handled variably in state and territorial legislation and inconsistencies and gaps create obstacles for researchers who seek to include people with dementia in research. For instance, some statutes that establish such decision-makers say that the substitute decision-making function does not extend to choices about research covered by the legislation. Statutes that empower a person to designate their own decision-maker for future periods of incapacity may similarly preclude the decision-maker from making research decisions.

Legislation should allow a person to give a trusted decision-maker authority to make decisions about research participation. The justification for excluding research decisions from the substitute decision-making power is unclear, especially when decision-makers may be called on to make profound decisions about healthcare. The appointment of a person to make health-related decisions, including choices about research participation, can support the expression of the appointer's wishes (Porteri and Petrini 2015). The appointer can select a trusted person and discuss their wishes and values with that person. It is generally thought that a person entrusted to make healthcare decisions would also be likely to safeguard a person's interests in the research context (Dresser 2001). Some studies have found that older adults generally support allowing substitute consent for participation in dementia research (De Vries 2013). Amendments to the ACT *Powers of Attorney Act* provide a helpful model for a medical research power of attorney.

Legislators may be concerned about substitute decision-makers making choices that could put the person at risk of harm without a reasonable prospect of benefit. However, research ethics committees must review and approve any study that is more than negligible risk and be satisfied that the potential benefits of the research outweigh any risks to participants with a cognitive impairment. Thus, this general risk–benefit assessment will have occurred before substitute decision-makers are called upon to consider the interests of the specific person for whom they are making choices.

If research consent is sought from a substitute decision-maker, statutory rules generally limit purely altruistic participation. Instead, participation in research must have some connection to treatment relevant to a condition the person has or has had or be the best way of providing treatment to the person (Parker 2013). The motivation is presumably to ensure that people who do not have capacity to make their own choices are not recruited into research that offers no prospect of personal benefit. However, statutory rules that have this effect limit the National Statement's broad principle that a person with cognitive impairment is entitled to participate in research for altruistic reasons. One approach to this problem would be moving away from the need to enrol people with dementia in research only "in their best interests" but allow such enrolment when it is not *against* their best interests; Victoria's *Guardianship and Administration Act* already incorporates this principle (s 42(S)). The importance of this seemingly subtle shift is apparent when considering that the principle of therapeutic equipoise would argue that much research cannot be considered in a person's best interests, and many types of research such as questionnaire-based research are clearly unlikely to benefit (or harm) participants.

When no Decision-Maker is Available

Legislation should set out a clear process for dealing with research consent if a person does not have a decision-maker, sometimes because no one eligible for this role is able to be located or there may be no one willing or able to make a decision. This would help overcome additional obstacles to including people with dementia in research. Researchers may find it too onerous in such cases to apply to a guardianship tribunal to make a determination about including the person with dementia in a research study, and guardianship bodies may not see enrolling patients in research as an appropriate reason to seek guardianship.

As a consequence, the people who participate in research may be only those who have supportive family members, carers, or friends. People who live alone, are distant from family members, or have dysfunctional families may be excluded from research. As one Australian researcher said in a recent survey:

> It is very difficult to conduct research with older people who do not have a carer or family member who can give consent in addition to the older person. As a result, older people who do not have a carer tend to not be included in the sample. (Pachana et al. 2015, 704)

The Victorian legislation deals with this problem by allowing a registered practitioner to carry out or supervise the carrying out of a medical research procedure on a person who does not have capacity to give consent and does not have a person responsible (*Guardianship and Administration Act 1986* (Vic) s 42S). While this provision allows researchers to overcome the need to resort to a tribunal, it has been criticized for creating a conflict of interest by inappropriately delegating decision-making authority to researchers (Victorian Law Reform Commission 2012). This problem could be rectified by authorizing a practitioner to consent for a person with dementia to participate in research only if the practitioner has no connection to or interest in the research being conducted.

Eliciting and Respecting the Wishes of the Person with Dementia

People with dementia who are able to give consent to participate in research and who choose to do so should be afforded the opportunity to express their wishes for future participation. The National Statement recommends that, when seeking consent from the person with a cognitive impairment, researchers should discuss with the person their wishes regarding continued research participation in the event of temporary or permanent loss of capacity in the future:

> The process of seeking the person's consent should include discussion of any possibility that his or her capacity to consent or to participate in the research may vary or be lost altogether. The participant's wishes about what should happen in that circumstance should be followed unless changed circumstances mean that acting in accordance with those wishes would be contrary to the participant's best interests. (NHMRC 2007, 59, [4.5.7])

In effect, this recommendation contemplates the making of advance research directives (ARD). The common law recognizes a person's right to document in a directive personal wishes and instructions about what is done to their body (*Hunter and New England Area Health Service* (2009) 74 NSWLR 88). As discussed earlier, some states and territories have legislation covering advance directives that would enable a person to make a directive that expresses wishes about research participation.

When a person with dementia consents to participate in a particular study, they should be given an opportunity to document wishes about their continuing participation should they experience reduced capacity in the future, as suggested in the National Statement (Pierce 2010). This measure would be most effective for research that is expected to continue as participants' cognitive capacity declines, such as a longitudinal study of ageing and cohort studies of people with dementia. When making an ARD, a person would need to consider how study participation could affect them if they lose capacity and the degree of risk they would accept. There is debate as to whether advance consent may be given for research above minimal risk (Buller 2015; Jongsma and van de Vathorst 2015; Andorno et al. 2016). This is an important matter to consider, particularly for researchers who adopt the practice recommended in the National Statement of offering ARDs to participants whose condition will likely cause periods of cognitive impairment. Future research activities and their attendant risks and benefits must be carefully explained to participants. At all times,

researchers must ensure they minimize risks in their research design and ensure that the potential benefits of participation outweigh any risks.

Improved information statements and consent materials could be used to overcome the difficulties created by the future-oriented nature of ARDs. Videos, observations of research taking place with people with dementia, and discussions with current dementia research participants would help newly recruited participants make choices about continuing to be a part of a research study during future periods of incapacity. Adopting these measures would increase the "moral legitimacy" of ARD and ensure they are not merely a formalistic consent document (Dresser 2001). Some studies report that older adults favour greater education and support for people to make research directives early in a dementia diagnosis (De Vries 2013).

Advance research directives are more problematic when they purport to consent to research that has not commenced when the person still has capacity. It may be possible to specify some research projects well enough that legitimate consent can be obtained for them. In other cases, general statements about wishing (or not) to participate in future research would be useful as evidence of the person's preferences that an authorized decision-maker takes into account in making a decision about a specific research study. Statutorily prescribed advance directive forms could be amended to prompt people to document any values or wishes they have in relation to participation in medical research.

Advance planning documents, including ARDs, are sometimes criticized on the grounds that the impact of dementia on memory and personality fundamentally changes a person and they should not be bound to the choices made by their "former self" (Pierce 2010, 626). However, the National Statement and some legislation requires that dissent from a person with dementia must be respected, including verbal utterances or body language indicating the person opposes or does not wish to take part in a research procedure or activity (Slaughter et al. 2007). Where dissent is respected, a person with dementia may opt out of research even if they have previously consented to be involved.

Conclusion

Law reforms should reduce unjustified legal barriers that do not serve a defensible protective purpose and have the effect of excluding people with cognitive impairments from opportunities to participate in ethically approved research. Recent statutory changes in Victoria, South Australia, and the two territories indicate that some legislators are concerned with modernizing laws that impact the lives of people with impaired capacity. Further reforms should promote the equal human rights of people with conditions that affect cognition and should enable them to make choices about their own lives and to be supported in doing so, including in relation to research participation.

There is also a need to build greater awareness of research inclusion issues specifically in relation to dementia, including rights to make advance research directives and to appoint decision-makers for research purposes. Education and resources should be tailored for people with dementia and those who help support them, for healthcare practitioners, and for researchers.

Those involved in recruiting people with dementia into research should adopt a supported decision-making approach to maximize the individual's capacity to make their own choice about research participation. Information to enable decision-making should be presented in a manner suited to individuals' needs. Researchers should be aware of factors that affect capacity and seek consent at a time and under conditions when capacity is maximized. Practical measures include discussing research participation when energy levels and cognition are likely to be higher; use of decision aids and enhanced consent forms where information is communicated using techniques such as audio narration, videos, and graphics; and leaving time for longer and repeat discussions. We also encourage researchers to evaluate consent strategies to produce evidence on the measures that help maximize decisional capacity for people with dementia or other cognitive impairments, including the effects of different strategies on participant understanding of studies, satisfaction with consent processes, and consent rates (Nishimura et al. 2013; Mittal et al. 2007). Researcher experiences with consent strategies and cost implications should also be studied.

To facilitate the appropriate inclusion of people with dementia in research, more work needs to be done to develop valid and convenient tools to assess participants' comprehension of information presented in research consent discussions. American researchers have developed a brief capacity assessment tool that has been validated to assess participants' understanding and reasoning in regard to an invitation to participate in

research (Jeste 2007). They explain that "an ideal capacity screening tool would need to include assessment and documentation of additional essential elements such as comprehension of protocol procedures, appreciation of the potential significance of study risks, and the voluntary nature of participation" (Jeste 2007, 966). This tool has been piloted with promising findings in a sample of people with mild to moderate cognitive impairment (Seaman et al. 2015; Duron et al. 2013). Further research is also needed to develop consensus on advance research directives and possible templates and to study stakeholder attitudes towards research directives, including the views of people with dementia, researchers, and members of research ethics committees.

The law reforms and strategies we recommend here can help to promote the appropriate inclusion in research of people with dementia and ultimately improve the evidence base for prevention, treatment, and cure of conditions that comprise a major and growing burden of disease in Australia.

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PAPER 5: PLANNING AHEAD FOR DEMENTIA RESEARCH PARTICIPATION: INSIGHTS FROM A SURVEY OF OLDER AUSTRALIANS AND IMPLICATIONS FOR ETHICS, LAW AND PRACTICE

Overview

The analysis in Paper 4 concluded that national ethics guidelines support research inclusion for people with cognitive impairment. However, there is wide variation in relevant state and territorial laws. Macro-level legislative reforms can improve clarity and consistency in the law, and should be informed by the perspectives of key stakeholders. There is a paucity of research exploring the views of older Australians on research participation in the context of a dementia diagnosis and reduced decisional capacity.

This paper is the first Australian study to explore older people's attitudes toward research participation and advance research directives in the context of dementia. The findings advance knowledge on older people's willingness to take part in research in situations where their decisional capacity is impaired by dementia, their preferences for substitute decision-makers in such circumstances, and their interest in making advance research directives. Community members' views on the acceptability of research participation for people with cognitive impairment and advance research planning processes can help to inform changes to laws that govern the involvement of people who lack decisional capacity in research.

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PLANNING AHEAD FOR DEMENTIA RESEARCH PARTICIPATION: INSIGHTS FROM A SURVEY OF OLDER AUSTRALIANS AND IMPLICATIONS FOR ETHICS, LAW AND PRACTICE

Abstract

People with dementia have commonly been excluded from research. The adverse impacts of this exclusion are now being recognised and research literature, position statements and ethics guidelines increasingly call for inclusion of people with dementia in research. However, few published studies investigate the views of potential participants on taking part in research should they experience dementia-related cognitive impairment.

This cross-sectional survey examined the views of people aged 60 and older (n=174) attending hospital outpatient clinics about clinical research participation if they had dementia and impaired decision-making ability. Over 90 per cent of respondents were agreeable to participating in a wide range of research activities, such as cognitive testing, physical measurements, imaging procedures and blood draws. For drug studies, however, agreement dropped to 60 per cent. Altruism was a strong motivator for research participation. In regard to who should be involved in decisions about their participation in research during periods of incapacity, respondents mostly preferred the person they appoint as their substitute decision-maker for healthcare matters (88%) or a doctor or health professional on the research team (78%). Over three-quarters (79%) expressed interest in making an advance research directive.

The study findings are discussed in relation to law reforms in Australia that aim to strengthen respect and inclusion for people with impaired decision-making capacity, especially by providing frameworks for advance planning for research participation.

Key words Dementia; Cognitive impairment; Research; Capacity to consent; Ethics; Law; Advance research directive

Introduction

Until recently, people with a dementia diagnosis have been routinely excluded from participating in research studies (Taylor et al. 2012; Rivett 2017). They have been assumed to lack the capacity to make their own decisions and the ethical and legal complexities of involving them in studies have posed significant barriers for researchers (Holland and Kydd 2015; Dunn and Palmer 2017; West et al. 2017). Consequently, research inquiries have tended to focus on people other than the person with the dementia diagnosis, including healthcare providers, carers and family members (Higgins 2013). Even where people with dementia are involved in research, a recent review of nine years of study protocols concluded that research participants are not representative of the broader population of people with dementia (Jongsma et al. 2016). People with more advanced cognitive impairment, co-morbidities and who live in residential care facilities are less likely to be included in studies. As a consequence, there are numerous gaps in the evidence to inform dementia care and supports (Aspe Juaristi and Harrison Dening 2016; Prusaczyk et al. 2017). Reviews of clinical practical guidelines and quality care standards for dementia highlight the limited evidence base (Ngo and Holroyd-Leduc 2015), including in areas such as palliative and end of life care for people with dementia (Candy 2015) and management of dementia and co-morbidities (Damiani 2014).

The adverse impacts of these exclusions are now being recognised. The contemporary view is that people with cognitive impairment should have opportunities to participate in meritorious research, in line with the ethical principle of justice. The 2016 update of the *International Ethical Guidelines for Health-Related Research Involving Humans* recognises the distinctive needs of people with conditions that impair cognition and urges their inclusion in research: ‘Adults who are not capable of giving informed consent must be included in health-related research unless a good scientific reason justifies their exclusion.’ (Council for International

Organizations of Medical Sciences 2016, 61) These guidelines depart from their prior blanket labelling of all people with cognitive impairment as vulnerable (van Delden and van der Graaf 2017) and call for more nuanced considerations of the rights, interests and abilities of people living with cognitive impairment. For example, with communication tailored to their needs, people with mild to moderate cognitive impairment are able to participate in decision-making processes, including decisions about taking part in research (Black, Wechsler, and Fogarty 2013; Rookhuijzen et al. 2014). The specific need to include people with dementia in research is urged in a 2017 Alzheimer's Europe position statement (Gove et al. 2017) and by the United States National Advisory Council on Alzheimer's Research, Care and Services (Lepore et al. 2017).

A range of factors may present barriers to involving people with dementia in research. Researchers may encounter difficulties in the ethical review of research proposals involving people with dementia (Pachana et al. 2015). 'Protectionism' and gate-keeping by healthcare providers may prevent access to people with dementia (Holland and Kydd 2015). Legal and practical concerns about the role of substitute decision-makers and study partners also limit opportunities to involve people who have reduced capacity in research (McKeown et al. 2010; Bartlett, Milne, and Croucher 2018). Optimal strategies to support inclusion are needed and must be acceptable to prospective research participants, including those with or at risk for dementia (Murphy et al. 2015; Novek and Wilkinson 2017).

Only a few published studies investigate the views of potential participants on taking part in research in circumstances where their ability to make their own choices may be impaired by symptoms of dementia (Karlawish et al. 2009; Black, Wechsler, and Fogarty 2013; Calamia, Bernstein, and Keller 2016; Robillard and Feng 2017). The process of advance planning for research has also received little attention (Bravo et al. 2016). Like advance planning for

healthcare, research planning involves considering one's values and wishes in relation to research, documenting preferences in an advance research directive, and selecting a substitute decision-maker, provided a suitable person is available for this role.

The present study expands this knowledge base by investigating the views of older Australians on research decision-making, including making advance research directives, and participation in research during future periods of dementia-related cognitive impairment. Investigating the views of this group is important since they are likely to have personal experience with people with dementia, and are at increased risk of developing dementia themselves. No prior published research has reported on older Australians' views in relation to research participation in the context we explore. Yet, in Australia, as in many countries around the world, dementia is a matter of serious health, social and economic concern. Dementia currently affects one out of ten Australians over the age of sixty-five, three out of ten over age eighty-five, and it is a leading cause of death (Australian Bureau of Statistics 2017a). By 2050, an estimated one million Australians will be living with dementia and global prevalence is expected to surpass 130 million (Prince et al. 2016). Clinical trial activity is not keeping up with the health and social impacts of dementia (Lam et al. 2015) and Australian researchers, like their international peers, encounter barriers to including people with dementia in their studies (Cubit 2010; Pachana et al. 2015).

Aims

This study examined the views of people aged at least 60 years attending hospital outpatient clinics about their willingness to be involved in research if they had dementia-related cognitive impairment. Participants were asked about the types of research activities they would be willing to be involved in, their motivations for taking part in research, and their preferred substitute decision-makers for choices about research participation. They were also asked about their

interest in making an advance research directive to express their preferences in regard to future research participation during periods of impaired capacity.

Method

Setting

Data were collected in outpatient clinics at a major tertiary referral hospital in regional New South Wales, Australia. Ethics approval was obtained from the Hunter New England Health Human Research Ethics Committee and the University of Newcastle Human Research Ethics Committee.

Participant eligibility criteria

Eligible participants were aged 60 years and older, either a patient attending the clinic for a medical appointment or a support person accompanying the patient, English speaking, able to provide informed consent, and mentally and physically well enough to complete a touchscreen survey. The age group of people 60 and older was chosen as this population was expected to have greater personal experience with dementia, such as having a diagnosis or knowing or supporting a person living with dementia. Completion of the survey mirrored a process of advance planning by asking respondents to reflect on their wishes for a future when they have impaired decision-making capacity.

Recruitment and data collection

An information statement was made available at the clinic reception area. A trained research assistant approached people in the waiting area to confirm their eligibility and provide information about the study. Consent was implied by commencement of the survey. The survey

was completed on an iPad and took approximately 10 minutes. The research assistant recorded the gender and age group of non-consenting individuals. Data were collected between March and September 2017.

Measures

Survey development

A study-specific survey was developed by the authors and is reproduced in Appendix 1. The content areas were informed by a review of published studies that explored the views of potential participants on being involved in research during periods of impaired incapacity, as well as Australian ethics guidelines and legal requirements for research involving people who may lack decisional capacity. The survey instrument was pilot tested with 26 eligible participants to assess understanding and acceptability of items. No changes were made based on pilot testing. Respondents were asked to answer all the questions. Further details on measures are provided below.

Involvement in research during future periods of dementia-related cognitive impairment

The study information sheet provided the following plain language description of dementia: 'Dementia (sometimes called "Alzheimers") affects thinking, behaviour and the ability to do everyday tasks.' Participants were asked about their views on being involved in research in the future if they had dementia. Respondents' level of agreement with each item was elicited on a five-point Likert scale (strongly agree, agree, unsure, disagree, strongly disagree).

Willingness to participate in research activities. Respondents were asked to imagine they had dementia-related cognitive impairment, described as 'quite a few troubles with memory, thinking and doing everyday activities.' Considering this future state, they were asked about their

willingness to be involved in a range of clinical research activities. They were told to assume certain conditions that would safeguard their interests as a research participant; for example, the study would be approved by an ethics committee and their privacy would be protected. Eleven research activities were listed, covering varying degrees of risk and invasiveness, such as observing behaviour, taking blood samples and receiving experimental drugs (see Table 2). The selection of these activities was informed by the main categories of research listed on Australian ethics application forms. Short examples of each research activity were provided. For instance, 'I would be willing to be included in a research study that involves observing my behaviour (example: watching how I act if I listen to music).'

Factors motivating research participation. Respondents were asked about the factors that would motivate them to participate in research. They were asked to indicate their level of agreement with three statements: 'I would be willing to be included in a study that: (1) Benefits me directly (example: taking part in research could improve my quality of life); (2) Does not benefit me directly but could help other people; (3) Does not have benefits for me or other people with dementia, but could help researchers understand other diseases or health problems.'

Views on who should be involved in research participation decisions. Respondents were asked who should be involved in decisions about their inclusion in research in a situation where they have dementia and cannot make their own choices. Participants were asked to indicate their level of agreement with the following options: (1) 'The person who is responsible for making my healthcare decisions should be involved in decisions (example: spouse or adult child)'; (2) 'An independent legal body should be involved in decisions (example: a judge)'; (3) 'A doctor or other health professional who is part of the research team'; and (4) 'A doctor or other health professional who is not part of the research team.' These options were presented as they reflect

the types of decision-makers in Australian laws who may play a role in determining whether a person who cannot give their own consent can be included in research.

Interest in making an advance research directive

The following definition of an advance research directive (ARD) was provided: 'An Advance Directive for Research is a document where you can write down whether you agree or disagree with being involved in research studies in the future. You make the Directive at a time when you are able to think through your opinions and make choices. If you later lose the ability to make decisions due to a medical condition, your Directive will tell people your wishes, such as your doctor, your caregiver, or a researcher.' Participants were asked to indicate their interest in making an ARD if presented with an opportunity to do so. Response options were: very interested; somewhat interested; unsure; not very interested; not at all interested. Those who were unsure or not interested were asked to indicate a reason for their response. Options were: 'I am not interested in taking part in research in the future'; 'I do not think it is important to write down my wishes for taking part in future research'; 'I would prefer for someone else to make decisions about my participation in research if I am no longer able to make my own decisions'; 'I do not think it matters what happens after I lose the ability to make decisions'; and 'I am not sure.'

Sociodemographic characteristics

Participants reported their gender, age, highest level of education, whether they know someone with dementia (alive or deceased) and, if yes, their relationship to that person. They were also asked whether they had been diagnosed with dementia by a health care professional with response options of: yes, no, unsure, or prefer not to say.

Data analysis

Descriptive statistics including frequencies and percentages were calculated for each aim, using non-missing data. Responses were pooled for Agree/Strongly Agree responses, and Disagree/Strongly Disagree responses. A supplemental file provides frequency distributions for all response options. Chi squared tests were used to compare the characteristics of those who did and did not consent to complete the survey.

Results

A total of 440 people were approached and 96 were ineligible. Reasons for ineligibility included being under age 60 (n=59), non-English speaking (n=3), and not feeling well enough to complete the survey (n=15). Of the 344 people who were eligible, 199 consented to participate (consent rate of 58%). There were no significant differences (p=0.05) in age (p=0.25) or gender (p=0.35) between people who did and did not consent to participate in the survey. Twenty-five people who consented to participate were removed from the dataset as they did not provide complete data for at least one aim, leaving 174 participants available for analysis.

Demographic characteristics of respondents

Respondent demographics are reported in Table 1. More women than men completed the survey (56% and 46%, respectively) and the majority of respondents (72%) were aged between 60 and 74 years and the remainder were aged 75 or older. According to census data, these gender and age proporations are generally representative of the Australian population aged over 60 (Australian Bureau of Statistics 2017b).[1] Three-quarters of respondents (76%) reported knowing someone with dementia, mostly a friend, parent or other relative. Only one participant reported a dementia diagnosis.

Table 1: Demographic characteristics* (n=174)

Characteristic	n (%)
Gender	
Female	97 (56%)
Male	77 (46%)
Age	
60-74 years	126 (72%)
Over 75 years	48 (28%)
Highest level of education	
High school or below	94 (57%)
Trade or vocational training	46 (28%)
Tertiary / university	24 (15%)
Diagnosed with dementia	
Yes	1 (0.6%)
No	155 (99%)
Know someone with dementia (alive or deceased)	
Yes	116 (76%)
Relationship to this person	
Partner or spouse	9 (8%)
Friend	42 (37%)
Parent	24 (21%)
Other (mostly reported as other relatives)	39 (34%)
No	37 (24%)

** Demographic questions were divided between the start and end of the survey. Frequencies may not sum to 174 due to missing data. Percentages are calculated based on number of responses available for each question.*

Willingness to take part in research activities

Table 2 reports participants' willingness to take part in research activities if they had dementia and impaired decisional capacity. Overall, there was a high level of willingness with agreement exceeding 90 per cent for 12 of the 13 research activities, including doing cognitive tests,

undergoing imaging procedures, having physical measures taken, wearing a device to track data and providing blood samples. The one exception was participating in a study that involved taking experimental medicine, where 60 per cent of respondents indicated a willingness to participate.

Table 2: Willingness to be included in research activities (n=174)

As a person with dementia, I would be willing to be included in a research study that involves:	**Agree n (%)**	**Unsure n (%)**	**Disagree n (%)**
a) **Asking me questions in a survey or interview** (example: asking about my experiences or opinions)	159 (91%)	10 (6%)	5 (3%)
b) **Observing my behaviour** (example: watching how I act if I listen to music as part of a therapy program)	166 (95%)	4 (2%)	4 (2%)
c) **Testing my memory or thinking** (example: asking me to draw a picture or remember specific words)	167 (96%)	5 (3%)	2 (1%)
d) **Giving me psychological therapy** (example: counselling for anxiety or depression)	158 (91%)	9 (5%)	7 (4%)
e) **Giving me physical therapy** (example: moving my arms or legs, massaging my muscles)	161 (93%)	9 (5%)	3 (2%)
f) **Giving me experimental medicine** (example: an experimental drug that might reverse damage in my brain)	100 (60%)	47 (28%)	19 (11%)
g) **Taking x-rays or scans of my body** (example: to help researchers see how dementia is affecting my brain)	161 (97%)	2 (1%)	3 (2%)
h) **Taking a measurement about my body** (example: my weight, blood pressure)	158 (96%)	4 (2%)	2 (1%)
i) **Putting something on my body, like a bracelet, that keeps track of information** (example: how much time I spend in bed)	151 (92%)	10 (6%)	3 (2%)

As a person with dementia, I would be willing to be included in a research study that involves:	Agree n (%)	Unsure n (%)	Disagree n (%)
j) **Taking a sample of my blood or other body fluid for genetic research**	167 (97%)	2 (1%)	4 (2%)
k) **Taking a sample of my blood or other body fluid for non-genetic studies**	162 (94%)	4 (2%)	7 (4%)
l) **Looking at my personal records, such as medical records or test results stored in a hospital**	156 (92%)	10 (6%)	3 (2%)
m) **Using my blood or other body fluid or tissues taken in the past and stored in a hospital or other facility**	155 (92%)	9 (5%)	5 (3%)

Note: Respondents were asked to imagine a scenario where they had dementia and quite a few troubles with memory, thinking and doing everyday activities. Frequencies may not sum to 174 due to missing data. Percentages are calculated based on number of responses available for each question.

Factors motivating research participation

A substantial majority of respondents – 90 per cent and above – agreed or strongly agreed that if they had dementia they would take part in research that: offered the prospect of direct benefit (95%); would not benefit them directly but could benefit others with dementia (94%); or would help scientists understand other diseases (90%).

Who should be involved in decisions about research participation

Table 3 reports respondents' opinions about who should be involved in decisions about their inclusion in research should they develop dementia and lack the capacity to make their own choices. Nearly 90 per cent of respondents (88%, n=144) preferred that the person responsible for making decisions about their healthcare treatment should also be involved in decisions about their participation in research. Nearly 80 per cent of respondents (78%, n=127) were agreeable to a doctor or other health professional on the research team being involved in such decisions. In contrast, agreement dropped substantially for decision-makers at 'arms-length' from the person

or research team. Approximately 30 per cent of respondents agreed or strongly agreed with a doctor or health professional external to the research team (33%, n=52) or an independent legal body (29%, n= 46) being involved in these decisions.

Table 3: Preferred decision-makers for research participation (n=174)

If I had dementia and could not make my own choices, who should be involved in decisions about whether I take part in a research study?	**Agree n (%)**	**Unsure n (%)**	**Disagree n (%)**
Person responsible for making my healthcare decisions	144 (88%)	13 (8%)	6 (4%)
Doctor or other health professional who is <u>part</u> of the research team	127 (78%)	25 (15%)	10 (6%)
Doctor or other health professional who is <u>not part</u> of the research team	52 (33%)	56 (35%)	52 (33%)
Independent legal body (example: a judge)	46 (29%)	60 (37%)	55 (34%)

Note: Frequencies may not sum to 174 due to missing data. Percentages are calculated based on number of responses available for each question.

Interest in making an advance research directive

Over three-quarters (79%, n=134) of respondents were very or somewhat interested in making an ARD. Around 16 per cent (n=27) were unsure and just 5 per cent (n=8) were not very or not at all interested. Of these latter respondents who gave a reason for their answer (n=33), the most frequent responses were that they were not sure why they would not want to make an ARD (52%) or they would prefer that someone else make decisions about their research participation during any future periods of incapacity (24%). The remainder were mostly not interested in taking part in future research (12%) or said it did not matter to them what happens after they lose the ability to make decisions (6%).

Discussion

The ethical and legal governance of dementia research must strike a balance between the protection of potentially vulnerable participants (Meek Lange, Rogers, and Dodds 2013) and the conduct of meritorious research to fill gaps in knowledge and contribute to improved outcomes for people with dementia (West et al. 2017). In Australia, the National Statement on Ethical Conduct in Human Research (Australian Government 2015) and a patchwork of state and territorial laws regulate the inclusion of people with cognitive impairment in research (Ries, Thompson, and Lowe 2017). The National Ethics Statement is subject to rolling review and revision, and several state and territorial governments are modernising laws that deal with health decision-making in both treatment and research contexts. In discussing the survey results, several recent legal reforms in Australia are highlighted that aim to strengthen respect and inclusion for people with impaired capacity, especially by providing clearer frameworks for advance planning for research participation.

Strong interest in research participation

We found a high level of willingness among older people in being involved in research during future periods of reduced decisional capacity. An overwhelming majority of respondents would be agreeable to participating in a wide range of research activities if they had dementia, ranging from observations of their behaviour and collection of physical measures, to activities that would involve some greater degree of intervention with their body, such as blood draws, imaging and physical manipulation. This finding is consistent with a US study of over 500 older adults, which found that three-quarters of participants would agree to research with more than minimal risks if they were unable to consent due to Alzheimer's disease (Karlawish et al. 2009). Our findings suggest that older adults' views support ethical and legal frameworks that enable more inclusive approaches to involving people with dementia in research.

Notably, respondents indicated a high level of willingness to participate in research that some commentators describe as raising special privacy concerns (van der Vorm et al. 2009; Kang et al. 2010). For example, 92 per cent of respondents agreed with taking part in research involving a wearable device that would track physiological or behavioural data. Approximately 95 per cent agreed they would be willing to have blood samples taken for research, including for genetic studies, which the survey described as having the potential to reveal whether relatives are at higher risk of developing dementia. (The survey gave the following explanation of genetic research: 'Genetic research looks at diseases that can run in families. You inherit genes from your parents and you pass your genes to your children. Genes control things like your eye colour and your risk of getting some diseases.') This strong level of agreement suggests that our respondents do not hold exceptionalist views about genetic information (Sulmasy 2015). In line with our findings, Bravo et al found that 89 per cent of their Canadian study participants would be agreeable to a blood sample being taken for research if they had severe dementia (Bravo et al. 2016) and Karlawish et al found that 83 per cent of their study participants would be willing to give advance consent for a blood draw for research purposes (Karlawish et al. 2009).

Agreement dropped for research that would involve taking experimental drugs, with 40 per cent of respondents stating they would be unsure or unwilling to take part in this type of research if they had dementia and reduced decisional capacity. Previous studies report differing findings. One US survey found that 92 per cent of a sample of community members aged 50 and over expressed willingness for future inclusion in a dementia drug trial should they lack capacity to make decisions (Kim et al. 2013). In contrast, an American interview-based study found that drug trials had the lowest level of interest among older adults (Calamia, Bernstein, and Keller 2016). In Canada, around 65 per cent of older people in a trial on advance research planning

expressed willingness to be included in a pharmaceutical study if they had severe dementia (Bravo et al. 2016). In light of our results and the inconsistencies in these previous studies, further research is needed to inform recruitment and communication strategies for dementia-related drug trials, particularly to ensure risks, benefits and protections are explained appropriately (Fargo 2016).

Altruistic motivation

A majority of our survey respondents were altruistically motivated and would participate in research without an expectation of direct benefit. Similarly, Karlawish et al. found a high level of support among older adults for altruistic research that involves people with dementia who are unable to give their own consent (Karlawish et al. 2009). Studies on actual (rather than hypothetical) dementia research decisions also report altruism as a strong motivator (Black, Wechsler, and Fogarty 2013; Rookhuijzen et al. 2014). Karlawish et al. suggest 'that overarching values such as trust and altruism shape attitudes about the ethics of research in which noncompetent subjects are enrolled, not specific views about the disease under study.' (Karlawish et al. 2009, 187)

Australia's National Ethics Statement acknowledges altruistic motivations, stating that people with a cognitive impairment 'are entitled to participate in research, and to do so for altruistic reasons' and 'research involving these people need not be limited to their particular impairment, disability or illness' (Australian Government 2015, 58). Some state laws are more restrictive; for example, providing that a person with impaired capacity may only take part in a clinical trial if it aims to cure or ameliorate a medical condition the person has (Ries, Thompson, and Lowe 2017). Such requirements should be reviewed as they could exclude a person with dementia

from taking part in prevention-oriented studies, such as trials of interventions to prevent falls, unnecessary hospital admissions or negative outcomes in care transitions (Prusaczyk et al. 2017).

Research approval processes and substitute decision-making

Barriers to research can arise from rules about substitute decision-making and who can authorise studies involving people with impaired capacity. Rules in these areas vary across Australia and, in some circumstances, researchers conducting clinical trials of medical treatments must obtain approval of an ethics committee and consent from a statutory guardianship tribunal if they wish to involve people who may not have capacity to give their own consent. This requirement has contributed to delays in studies (Ries, Thompson, and Lowe 2017) and may deter researchers from including people with cognitive impairment in research. In some parts of the country, however, lawmakers 'are moving away from affording power to an unknown person or panel of people to make [such] decisions,' recognising that requirements for external approval may 'undermin[e] the aim of facilitating involvement in ethically-approved and potentially beneficial medical research' (Turner, Bolzonello, and Vanrenen 2017, 25). Most recently, in a 2018 review of guardianship legislation, the New South Wales Law Reform Commission recommended that tribunal approval should no longer be required for ethically approved medical research activities (New South Wales Law Reform Commission, 2018).

Indeed, only a minority of our respondents agreed with legal bodies (28%) having a role in decisions about their participation in a research study should they lack capacity to make their own choice. Most respondents preferred that a person responsible for making decisions about their healthcare treatment make decisions about their involvement in research. Under Australian laws, such substitute decision-makers may be a trusted individual the person appoints to make future decisions or a spouse, family member or friend who has a close and ongoing relationship

with the person. Our respondents' views align with studies of actual research decision-making which indicate that people living with fluctuating or reduced capacity prefer a process of collaborative discussion with their selected decision-maker (Black, Wechsler, and Fogarty 2013). A trusted family member or friend who knows the person with dementia may be better able to involve them in the decision using supportive strategies (Keeling 2016). As discussed further below, early in a dementia diagnosis, people should be supported to identify their preferred decision-makers for a range of health, financial and other personal matters, and this can include discussion of research decision-making (Michael, O'Callaghan, and Sayers 2017).

At the same time, it must also be recognised that some people may not have family or friends to take on supportive or substitute decision-making roles. This circumstance, whether due to social isolation, family conflicts or other reasons, should not prevent people from opportunities to take part in research should they be interested in doing so. Our results suggest that one acceptable alternative would be to involve a physician in the decision-making process for prospective participants who do not have a trusted family member or friend. Over three-quarters (78%) of our respondents were agreeable to a doctor or other health professional on the research team being involved in decisions about their participation. Several studies indicate that many prospective participants would prefer to have research recruitment and consent discussions with their doctor, yet many ethics review boards view such involvement as inappropriate (Aspe Juaristi and Harrison Dening 2016; Kraft et al. 2016; Robillard and Feng 2017).

Ethical rules for clinician-researchers, such as the World Medical Association's Declaration of Helsinki, require doctors to be 'particularly cautious' in their involvement in research consent processes involving their patients (World Medical Association 2013, para. 27). The potential for conflicts of interest requires safeguards and legislation in Victoria provides one model whereby a

medical practitioner may, provided certain conditions are met, involve a person with impaired capacity in a research project without consent if no substitute decision-maker is available (*Medical Treatment Planning and Decisions Act 2016* (Vic) s 80). Among other conditions, the practitioner must have a reasonable belief that the research is not contrary to the person's values, preferences or well-being (taking account, for example, of wishes in an ARD), an ethics committee approved the research knowing that consent may not be possible, the risk involved in the research is no greater than the risk involved in the patient's condition, and there is a prospect of benefit to the person. The practitioner must document these matters in a certificate that is filed with the Office of the Public Advocate and the ethics committee (see www.publicadvocate.vic.gov.au/medical-research-procedures). This approach provides safeguards to reduce the likelihood of conflicts of interest, and may increase opportunities to participate in research for those without a relative or friend to serve as a substitute decision-maker. Interestingly, in a recent legislative review, the New South Wales Law Reform Commission did not endorse a similar role for medical practitioners and instead recommended that consent should be sought from a legal tribunal for prospective participants who cannot give their own consent to research and who do not have a substitute decision-maker (New South Wales Law Reform Commission 2017).

Advance planning for research participation

Our results indicate strong support among older community members for taking part in research during future periods of impaired decision-making ability. Practical strategies are needed to translate older people's support and interest into real opportunities for research participation, including when reduced capacity occurs. The survey data support more attention to advance planning for research, especially for people with a diagnosis of dementia. In their study of older adults' views on research participation, Karlawish et al. found that 93 per cent of their

interviewees, who were 65 years and older, understood concepts related to scientific research, being a research participant, planning for the future, and the role of substitute decision-makers (Karlawish et al. 2009). These results indicate that most older adults could engage in a process of advance research planning, provided opportunities to do so are offered to them.

Recent Canadian research reports on strategies to promote the uptake of advance research planning (Bravo et al. 2011; Bravo et al. 2016). Approximately 120 adults aged 70 and older and their selected substitute decision-maker participated in social worker-led sessions on planning both for future medical care and research participation. This intervention resulted in 80 per cent of older adult participants completing an advance planning booklet to document their preferences for future medical care and research participation (Bravo et al. 2016). This outcome indicates that advance planning for research may be incorporated into a comprehensive process of advance planning for health-related matters. As a more targeted approach, advance research planning would be particularly valuable when a person with dementia is recruited into a specific study that will involve interventions and data collection over time or into a research registry (Krysinska et al. 2017). When engaging in consent discussions to join a registry or study, researchers can discuss and document with the participant their preferences for future research involvement during periods of reduced capacity. They can also identify the participant's preferred substitute decision-maker for research participation.

The capacity to engage in advance research planning activities is an important consideration for individuals already living with cognitive impairment as they need to be able to 'understand the complex future oriented issues at stake' (Karlawish et al. 2009, 187). A growing body of work centres on strategies to assess capacity to consent to research (Gilbert et al. 2017; Palmer, Harmell, Pinto, et al. 2017), as well as simplified and process-based approaches to consent that

take account of reduced or fluctuating capacity (Higgins 2013; Nishimura et al. 2013; Guarino et al. 2016; Palmer, Harmell, Dunn, et al. 2017). People who do not have capacity to decide about participating in a particular study, such as a complex clinical trial, may nonetheless have capacity to complete some elements of advance research planning, such as selecting who they want to make such choices for them (Prusaczyk et al. 2017).

Advance research directives

Our survey findings suggest that many people may be willing to make an ARD if given an opportunity to do so. A developing body of literature discusses ARDs (Pierce 2010; Buller 2014; Jongsma and van de Vathorst 2015a, 2015b; Davis 2017) and they are explicitly acknowledged in some ethics statements and legislation. The 2016 *International Ethical Guidelines for Health-Related Research Involving Humans* state: 'If participants have made advance directives for participation in research while fully capable of giving informed consent, the directives should be respected.' (Council for International Organizations of Medical Sciences 2016, 61) As another example, Canada's national ethics statement instructs: 'Where individuals have signed a research directive indicating their preferences about future participation in research in the event that they lose decision-making capacity or upon death, researchers and authorized third parties should be guided by these directives during the consent process.' (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada 2010, art 3.11) Australia's National Statement encourages researchers to discuss and document views on future research participation with participants who anticipate periods of cognitive impairment (Australian Government 2015, para. 4.5.7); in effect, this is the making of an ARD, however, the term is not used explicitly.

Some Australian laws recognise ARDs. In Victoria, the *Medical Treatment Planning and Decisions Act 2016* establishes a statutory framework for advance directives and authorises

people to document their wishes both for healthcare treatment and participation in medical research in anticipation of future periods of incapacity. These wishes may take the form of an instructional directive that documents consent or refusal for specific procedures or activities. The statute also recognises values directives, which allow for a more general expression of a person's views and preferences concerning clinical care and research participation. A directive made in accordance with the statute is intended to be legally binding (s 12(1)). For the categories of research covered by the legislation - for example, a trial of drugs, equipment or devices – a researcher 'must make reasonable efforts' to find out whether a prospective participant has made a directive that deals with research (s 73(1)). This duty applies to researchers who are registered health professionals and failure to do so is deemed to constitute unprofessional conduct (s 73(2)).

The legislation states that advance consent to a research procedure as documented in an instructional directive is sufficient to include a person in an ethically approved study and it is not necessary to seek agreement from a substitute decision-maker (s 75). If there is concern that a directive no longer reflects the person's preferences and values, an application may be made to a statutory tribunal for a determination about the validity of the directive (s 22-24). The New South Wales Law Reform Commission recently recommended a similar statutory framework for ARDs (New South Wales Law Reform Commission 2018).

Appointing decision-makers for research participation

In addition to preparing a research directive, a person engaged in advance research planning may also wish to select a trusted individual to be involved in decisions about their research participation during periods of incapacity. In the Australian Capital Territory, power of attorney laws have been updated to allow a person to appoint a medical research power of attorney who has legal authority to make research participation choices if the appointer loses capacity (*Powers*

of Attorney Amendment Act 2016 (ACT)). In other jurisdictions, a substitute decision-maker for medical treatment may also have the authority to make choices about at least some types of research participation for the person who lacks capacity. Victoria's *Medical Treatment Planning and Decisions Act 2016* prescribes the duties of a person appointed to make decisions about research participation. This decision-maker must make choices they believe the appointer would have made, taking account of wishes communicated in a values directive or otherwise expressed (s 77). Where there is uncertainty about the person's preferences, the decision-maker must make a choice 'that promotes the personal and social wellbeing' of the person (s 77(3)). The new law is also the first in Australia to formally recognise supported decision-making. It permits a person to appoint a supporter to assist them in making and communicating their decisions during periods of reduced capacity, including decisions about taking part in research (s 32). This support person role could be particularly helpful to maximise the decision-making abilities of people living with dementia.

To ensure that substitute and supportive decision-makers can perform their roles effectively, it is vital to encourage and enable communication with the person who appointed them. Without the benefit of such discussions, decision-makers often underestimate the willingness of older adults to participate in research (Kim et al. 2013) and their personal views may differ from what prospective participants would want (Bravo et al. 2016). Researchers could support discussion between a study participant and their appointed decision-maker on future-oriented issues, such as preferences concerning uses of stored data or biological samples (Thorogood, Deschênes St-Pierre, and Knoppers 2017).

Recommendations for future research

Further quantitative and qualitative research on the views of both prospective and current research participants will provide valuable insights to inform legal and ethical frameworks and the practices of researchers, ethics committees and other stakeholders. A recent Canadian study, for instance, sought patient perspectives on the ethical aspects of dementia research (Robillard and Feng 2017). The authors contend that their findings reveal some disjuncts between respondents' preferences and prevailing research ethics norms and practices. They aspire for their work to 'lay the foundation for further empirical investigation into issues at the intersection of patient engagement and research ethics' (Robillard and Feng 2017, 2) Our study adds to this foundation and highlights several areas for future research.

Where ethical and legal frameworks support advance research planning, practical resources, such as ARD templates, should be developed and tested. Bravo and colleagues used a simple ARD template in their experimental intervention to promote advance research planning (Bravo et al. 2016). People who were willing to be involved in research during future periods of incapacity could select research that might benefit them personally (selected by 40%), research that would not benefit them but could benefit others (26%), or both types of research (33%). The form included space for participants to note any preferences for the types of research projects in which they would or would not want to be included. Participants could also choose to state that they would not want to be involved in any future research regardless of benefits or risks to themselves or others (selected by 14%). A more comprehensive ARD template could be developed based on the categories of research activities used in our study, which would enable people to express their preferences across a greater selection of choices.

It will be important to explore the feasibility and acceptability of advance research planning strategies and ARDs among people with dementia, their supporters and substitute decision-makers, researchers, and ethics committees. Even if ARDs are not used on their own to authorise participation in a study – for instance, if the ARD expresses values rather than specific instructions – they may offer promise in improving concordance of decisions with the preferences of the person who lacks capacity and mitigate the ambiguity of 'best interests' determinations in relation to research participation (Johansson and Brostrom 2016). The stability over time of preferences for research participation also warrants attention (Lingler et al. 2010), similar to research that investigates the stability of wishes documented in advance care directives (Auriemma et al. 2014). Factors that prompt changes in views should also be explored, such as the impact of receiving a dementia diagnosis or of gaining experience as a research participant. Our findings about older people's views on who should be involved in research decision-making raise questions for future investigation, particularly in relation to their views on the ethical responsibilities of clinician-researchers and their trust in and expectations of clinicians internal and external to research teams.

Future work on advance planning strategies and participation in specific research projects should also explore ways to enable people already living with cognitive impairment to be involved in the decisions that affect them. This will require effective tools to assess decision-making capacity, as well as communication, recruitment and consent techniques tailored to the needs of prospective participants. Supported and shared decision-making strategies that are being developed and evaluated in health and social care contexts (Miller, Whitlatch, and Lyons 2016) can be adapted for use in relation to research planning and participation.

Our study did not aim to explore cultural perspectives in relation to research participation and this is an important area for future investigation, especially to determine how advance research planning with culturally and linguistically diverse groups could help to address knowledge gaps in relation to ageing and dementia (Federation of Ethnic Communities' Councils of Australia 2015). While our survey focused on involvement in research as a participant, effective strategies are also needed to support the meaningful involvement of people with dementia as co-researchers or research advisors; this is a vital area of burgeoning attention (Di Lorito 2017; Gove, 2017; Rivett, 2017; Stevenson and Taylor 2017).

More broadly, the incorporation of research planning into a comprehensive process of health-related planning will require training and resources for health and legal professionals who educate clients and assist them with preparing relevant documents (Ries et al. 2016) A recent survey of Canadian lawyers on how they assist their clients with advance care planning found that just over 40 per cent of respondents regularly asked clients about their wishes in regard to medical research (Ries et al. 2018). While this discussion may typically focus on post-mortem body or tissue donation for research, the survey findings highlight that lawyers are an important professional group to include in efforts to improve clients' awareness of broader research opportunities.

Indeed, ambitious goals to increase the number of people with dementia participating in research will require efforts beyond the healthcare sector. For example, the U.K. Government's dementia strategy seeks to more than double the proportion of people with a diagnosis who participate in research studies (U.K. Government 2015). It calls for '[e]very newly diagnosed person with dementia and their carer receiving information on what research opportunities are available and how they can access these' via a national dementia research website (U.K. Government 2015,

29). People with a dementia diagnosis are often encouraged to seek legal advice on advance planning matters and future work could investigate strategies for lawyers to discuss planning for research participation with interested clients. Just as health and social care providers are urged to 'signpost interested individuals [with dementia] to research' (U.K. Government 2015, 38), lawyers have a role in assisting clients with making legally effective advance directives and appointing substitute decision-makers in relation to healthcare treatment and research matters.

Limitations

Several limitations of this study are acknowledged. The findings reflect a convenience sample of people aged 60 and older attending outpatient clinics in one tertiary referral hospital in a mid-sized Australian city. Only one respondent reported having a dementia diagnosis and future work should seek the views of people living with dementia, as well as their decision-makers for research participation. However, 76 per cent of our respondents reported knowing someone with dementia and would likely have some degree of personal knowledge and experience of symptoms and support needs that informed their survey responses. The consent rate of 58 per cent indicates there is a possibility that nonparticipation bias could have influenced the findings. It is possible that people who agreed to participate may be more biased in support of research and people who declined may have different views. Our participation rate was slightly higher than the 53 per cent consent rate reported by US researchers who used a similar recruitment method, plus a $20 gift card, to survey hospital clinic attendees' views on participation in medical research (Kraft et al. 2016).

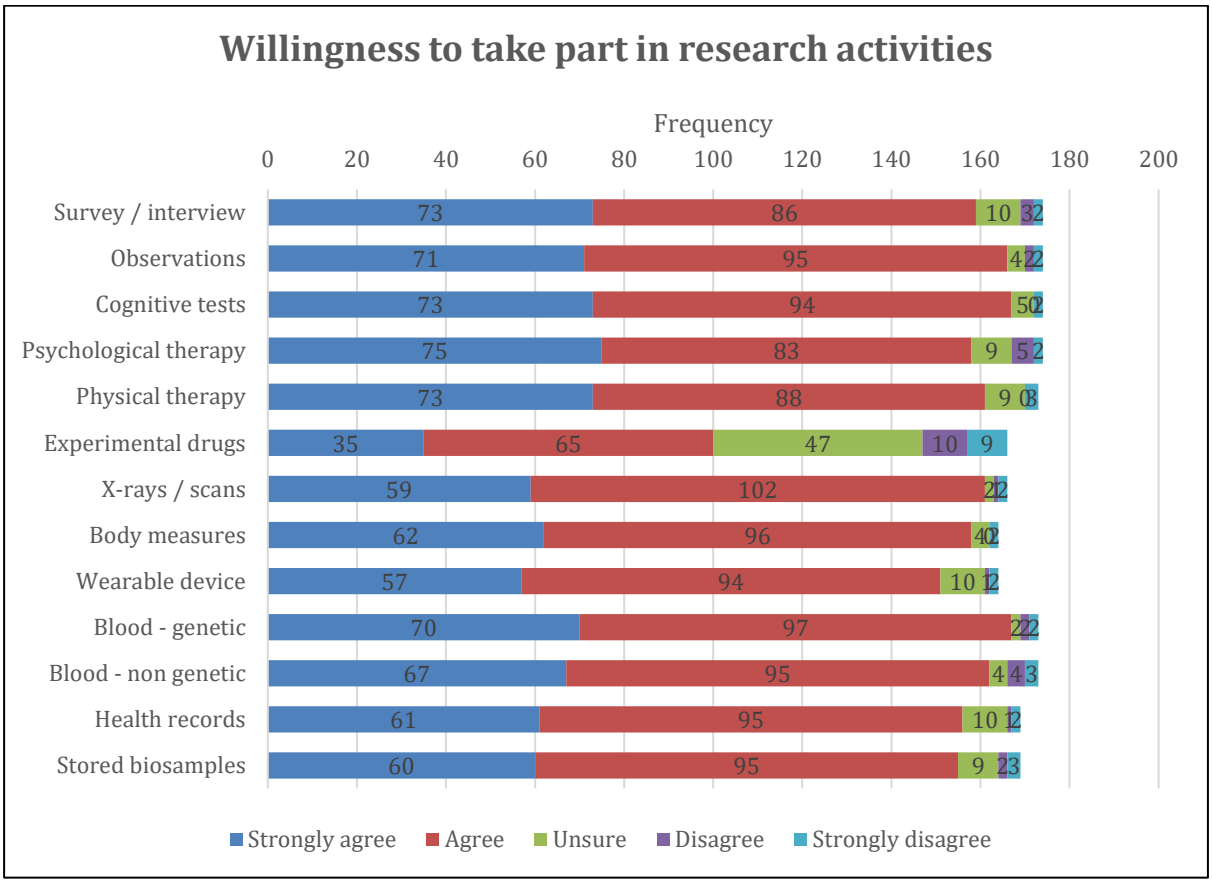
Conclusion

This study offers insights into the views of a representative sample of older Australians on research participation, many of whom have family or friends with dementia and who, as they

age, will themselves face the prospect of a dementia diagnosis. The results reveal a high level of acceptability for participation in a wide range of clinical research activities during future periods of incapacity, with altruism as a strong motivator for willingness to take part in research. These findings underscore the value in designing, implementing and evaluating strategies to support advance research planning. Such planning could help to facilitate the appropriate inclusion of people with dementia in research by supporting individuals, at a time when they have capacity, to document their values and preferences and select a substitute decision-maker. We have also highlighted the importance of ethical and legal rules in promoting respect and self-determination for people living with cognitive impairment.

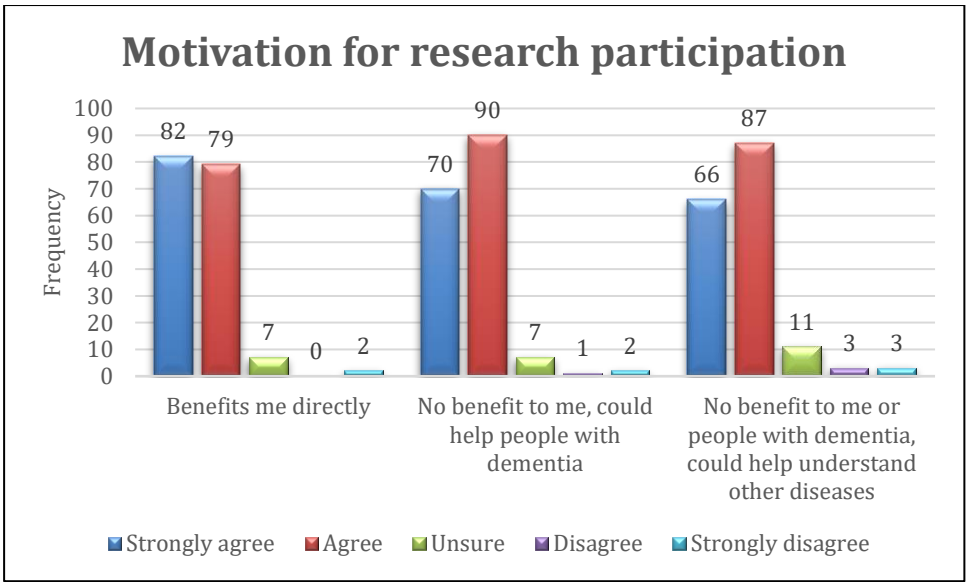
Supplemental Data

Figure 1: Willingness to be included in research activities (n=174)



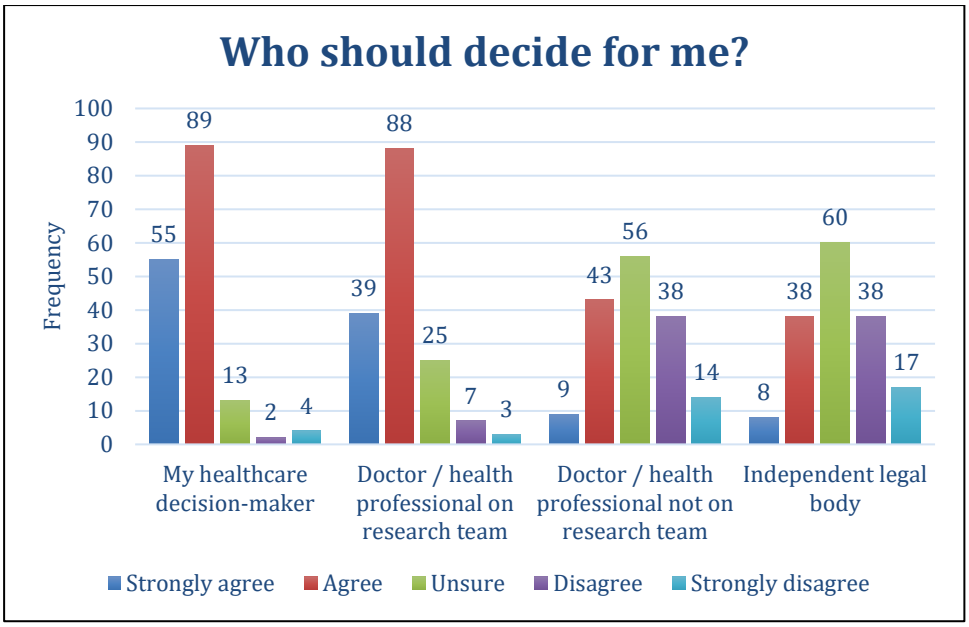
Note: Respondents were asked to imagine a scenario where they had dementia and quite a few troubles with memory, thinking and doing everyday activites. Frequencies may not sum to 174 due to missing data.

Figure 2: Factors motivating research participation (n=174)



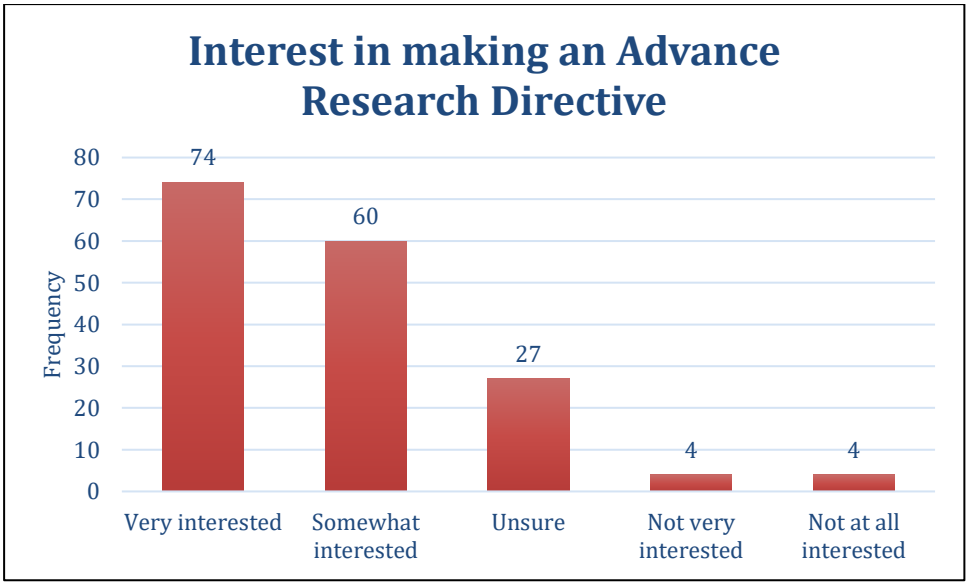
Note: Frequencies may not sum to 174 due to missing data.

Figure 3: Preferred decision-makers for research participation (n=174)



Note: Frequencies may not sum to 174 due to missing data.

Figure 4: Interest in making an Advance Research Directive (n=174)



Note: Frequencies may not sum to 174 due to missing data.

Declaration of contribution of authors

All authors contributed to the conception and design of the study. NR and EM led data collection and analysis. NR led the drafting of the manuscript; EM and RSF reviewed and provided critical input. All authors have read and approved the final manuscript.

Statement of conflict of interest

The authors have no conflicts of interest to declare.

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Notes

[1] The 2016 Australian census data reports that, of people aged 65 and older, 54 per cent are women and 46 per cent are men. People aged 60-74 are 14.5 per cent of population and those 75 and over are 6.9 per cent of the population. The census reports that 58 per cent of people aged 60-64 had a non-school qualification, referring to educational attainments other than those of primary and secondary school qualifications. Our survey sample is older than that reflected in the census data, likely explaining the lower post-secondary attainment reported by our respondents.

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PAPER 6: ETHICAL AND LEGAL ASPECTS OF RESEARCH INVOLVING OLDER PEOPLE WITH COGNITIVE IMPAIRMENT: A SURVEY OF DEMENTIA RESEARCHERS IN AUSTRALIA

Overview

Australia's National Statement on Ethical Conduct in Human Research states that people with a cognitive impairment are entitled to participate in research and to do so for altruistic reasons.[1] However, in the context of dementia studies, researchers encounter ethical and legal complexities, especially pertaining to the decision-making capacity of prospective participants and the involvement of substitute decision-makers. To ensure people with dementia are afforded appropriate opportunities for research participation, there is a need to identify and address inconsistencies in practice and barriers limiting their participation in research. To complement the study on older people's views on the acceptability of including people with dementia in research (Paper 5), this paper reports the findings of the first national survey of dementia researchers in Australia in relation to inclusion of people with dementia in research. It reports on researchers' experiences in involving people with dementia in studies, including practices for assessing capacity and seeking proxy consent where necessary, and the consequences of ethics review processes. The paper discusses strategies to assess and enhance the decision-making capacity of people with dementia in relation to research participation.

[1] Australian Government. National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). Available from: https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018, para. 4.5.3.

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ETHICAL AND LEGAL ASPECTS OF RESEARCH INVOLVING OLDER PEOPLE WITH COGNITIVE IMPAIRMENT: A SURVEY OF DEMENTIA RESEARCHERS IN AUSTRALIA

Abstract

People with dementia are under-represented in clinical research, in part due to the ethical and legal complexities of involving people in studies who may lack capacity to consent. Excluding this population from research limits the evidence to inform care. The attitudes and practices of researchers are key to the inclusion of people with dementia in research. However, there are few empirical studies on researchers' perspectives in this area.

A cross-sectional study involved researchers in Australia who had experience in the ethical aspects of conducting dementia-related studies with human participants (n=70). Data were collected via an online survey from November 2017 to January 2018.

Most respondents (97%) agreed with the importance of including people at all stages of dementia in research, yet around three-quarters of respondents perceived ethical and legal rules and processes as unduly restrictive or time-consuming. Researchers reported variable practices in assessing prospective participants' capacity to consent to their studies. Various tools are used for this purpose, ranging from tools designed for research (eg, MacArthur Competence Assessment Tool for Clinical Research) to more general cognitive function screens (eg, Mini Mental State Exam).

Few respondents (14%) routinely exclude people from studies who are unable to give their own consent, but instead seek permission from proxy decision-makers, such as legally appointed guardians or family carers. Respondents reported positive and negative outcomes of ethics review processes. Positive outcomes included strengthening the protections for participants with cognitive impairment while negative outcomes included delays and inconsistent decisions from different ethics committees.

The findings suggest a need for improved strategies in the research context to assess and enhance the decision-making capacity of people with dementia to support appropriate opportunities for inclusion. Education for ethics committees, proxy decision-makers and other gatekeepers is also needed to reduce barriers to participation in research.

Keywords: dementia; research; ethics; survey; Australia

Introduction

The population is ageing in many countries around the world, challenging health and aged care sectors to provide services for a growing number of older people with chronic illnesses, including dementia and other neurocognitive disorders (Prince et al., 2015). The strength of the evidence to inform care and supports for ageing populations is limited in part by the general underrepresentation of older people in clinical research (Watts, 2012; Whitham and Stott, 2017). The problem of exclusion from research is even more pernicious for older people living with dementia. People without the capacity to give their own consent to research have often been excluded from studies for ethical, legal and practical reasons, including worries about their vulnerability as research participants, the complexities of substitute decision-making in the research context, the risk of participant attrition, concerns about compliance with study protocols, and the need for study partners to help them take part in research activities (Rivett, 2017; Prusaczyk et al., 2017; West et al., 2017).

Support for inclusion of people with dementia in research

The harms and injustices of this exclusion from research are increasingly acknowledged, however, and inclusive research practices are now urged by dementia advocacy organisations, researchers across a range of disciplines, and governments faced with providing health services for ageing populations (Bartlett, Milne & Croucher, 2018; Gove et al., 2018; Phillipson and Hammond, 2018). In 2017, Alzheimer Europe announced in a position statement that it is "keen to promote the involvement of people with dementia in research" (Gove et al., 2018: 723). A 2018 report of a National Summit of the United States National Advisory Council on Alzheimer's Research, Care and Services urges "research methods that will result in evidence-based programs and service" to benefit all persons living with dementia (Gitlin & Maslow, 2018: 12). The UK Government (2015) aspires to more than double research participation among

people diagnosed with dementia and Alzheimer's Disease International (2018) calls for a doubling of global research output on dementia by 2025.

International ethical and legal frameworks emphasise the rights of people with disabilities to be supported to participate in society, including in research. The *International Ethical Guidelines for Health-Related Research Involving Humans* recognise the distinctive needs of people with conditions that impair cognition and urges their inclusion in research: "Adults who are not capable of giving informed consent must be included in health-related research unless a good scientific reason justifies their exclusion." (Council for International Organizations of Medical Sciences, 2016: 61 [CIOMS]) The World Medical Association's Declaration of Helsinki (2018: para 13) calls for historically underrepresented groups to have opportunities to take part in research.

The United Nations Convention on the Rights of Persons with Disabilities (CRPD) (2006) emphasises the importance of autonomy for persons with disabilities, including the freedom to make their own choices and to enjoy full participation and inclusion in society (Article 3). At the same time, people with disabilities have the right not to be exploited and mistreated in the non-consensual conduct of medical and scientific experimentation (Article 15). Research ethics committees and those who support and care for older people with cognitive impairment have important roles in protecting the interests of those unable to give their own consent, however, they must also guard against decisions based on stereotypes and assumptions. Both the CRPD (Article 12) and the Declaration of Helsinki (World Medical Association, 2018: para 25) require that a person who is capable of making their own decisions be enabled to do so and their decisions respected. Where a person with a disability lacks decisional capacity, substitute decision-makers should make choices that reflect the values and preferences of that person.

Researchers' views on involving people with dementia in research

The attitudes and practices of researchers are key to supporting the appropriate inclusion of people with dementia in research, especially participants with reduced decision-making capacity, however, there is limited research on this topic. Prusaczyk et al. (2017: 8) recently pointed out that there is "a shortage of articles that explicitly state the challenges researchers have faced on this issue … [and] it is critical that common challenges and solutions are identified and reported in detail so that other studies can learn from and replicate successes." Prior survey studies in the United States investigated consent practices among researchers in an Alzheimer's disease clinical trials network (Karlawish et al., 2002), as well as dementia researchers' views on how ethics rules affect study feasibility and protections for participants (Stocking et al., 2003). More recently, Black et al. (2014) conducted an ethnographic study of 17 dementia researchers' perceptions of study partners as well as a key informant study of assent and dissent practices in dementia research (Black et al., 2010). In Canada, Bravo et al. (2013) surveyed researchers in ageing about their practices in including participants with impaired decisional capacity and their knowledge of relevant law. Qualitative studies involving 13 dementia researchers in the Netherlands and 16 German and Israeli professionals in gerontology fields explored their attitudes toward advance directives for research (Jongsma and van de Vathorst, 2015; Werner and Schicktanz, 2018). To our knowledge, the only other study involving researchers from Australia was a joint Australia-US project that surveyed 157 researchers across both countries about their experiences of seeking ethics review of studies involving older adults (Pachana et al., 2015). Respondents included academic researchers, undergraduate and postgraduate research students, and clinician-researchers. To add to this scant literature, we undertook a cross-sectional national survey of researchers in Australia with experience in conducting dementia-related studies with human participants.

Aims

The study investigated researchers':

1) perceptions of the importance of involving people at varying stages of dementia in research, and barriers to such research;
2) practices in determining the capacity of a person with dementia to consent to research and in seeking consent from substitute decision-makers where necessary; and
3) experiences with ethics committees when seeking approval for studies involving people with dementia who have fluctuating or reduced capacity.

Method

Participant eligibility criteria

Researchers were eligible if they conducted research in Australia and had direct experience in the ethical aspects of conducting dementia-related studies with human participants, for example, handling ethics review processes, recruiting participants, assessing capacity to consent, and seeking consent from substitute decision-makers. An initial survey question confirmed eligibility and respondents who reported they did not have relevant experience exited the survey.

Recruitment and data collection

Eligible researchers were identified from publicly available announcements of dementia grant recipients from major Australian funding bodies, the National Health and Medical Research Council, the Dementia Collaborative Research Centres and the Dementia Australia Research Foundation. Researchers' institutional website profiles and publication lists were reviewed to confirm whether they met the eligibility criteria. Research collaborators of funding recipients who met the study inclusion criteria were also invited to participate. The lead author (N.R.) contacted eligible researchers using their publicly available email with an invitation to complete

the online survey. Two reminder emails were sent after three and eight weeks of non-response from the date of initial contact. Commencement of the survey was taken as implied consent. Survey responses were received from November 2017 to the end of January 2018.

Measures

The survey consisted of questions with Likert rating scales as well as multiple choice response options. For some questions, optional open-ended text boxes were used to collect qualitative data. The survey instrument was developed based on a thorough review of literature on the ethical aspects of including people with dementia in health-related research, as well as ethics guidelines and legal requirements for research involving people who may lack decisional capacity. The initial survey instrument was reviewed by approximately 10 researchers experienced in conducting dementia studies with human participants to ensure all major content areas and potential response categories were included, and to check clarity and flow.

Perceived importance of and barriers to involving people with dementia in research.

Respondents were asked how important it is to include people with varying stages of dementia in research (very, somewhat, not at all important). They were then asked to rate their level of concern in relation to six ethical, legal and practical barriers to involving people with dementia in research who have fluctuating or reduced capacity (very, somewhat, not at all concerned; see Table 2). They could add other concerns in a text box.

Practices in determining capacity to consent to research and seeking consent from substitute decision-makers.

Respondents were asked how often they exclude people with dementia who are unable to give their own consent to participate in a study (always, very often, sometimes, rarely, never). They were asked if they had ever sought consent from another person or entity to include a person

with dementia in a study (yes, no, don't recall). If yes, they were asked how often they sought consent from each of the following: a legal body, such as a guardianship tribunal or court; an individual with formal authority to make decisions for the person, such as an enduring guardian for health decisions; or an individual with informal authority, such as a family carer (always, very often, sometimes, rarely, never). They could specify in a text box any other decision-makers from whom they had sought consent.

These respondents were also asked how often in their research the following were involved in determining whether a person with dementia has capacity to consent to a study: a health professional external to the research team, such as the prospective participant's doctor; a member of the research team; or a legal body, such as a guardianship tribunal (always, very often, sometimes, rarely, never). They could specify in a text box anyone else involved in determining capacity to consent. Respondents were asked if a specific tool or questionnaire was used to assess capacity to consent to research for participants in their studies (yes, no, don't know) and, if yes, to specify the tool(s).

Experiences with research ethics committees

Respondents were asked whether they had experience of seeking approval from an ethics committee to involve people with dementia in research where participants had fluctuating or reduced capacity (yes, no). If yes, they were asked about both the positive and negative consequences of the ethics review process (eg, improved protections for research participants; guidance in planning for future research; excessive delay in commencing research, with self-report of the length of delay; inconsistent responses from different ethics committees to the same study protocol). They were also asked about matters that required considerable discussion with the committee to obtain study approval (eg, recruitment and consent processes). 'Considerable

discussion' was defined as meaning more than two rounds of feedback were provided by the committee about the issue and/or more than one hour of conversation was required to resolve the issue. The survey questions about positive and negative consequences and matters requiring considerable discussion were adapted from a survey instrument reported by Edwards et al. (2011). For these questions, respondents were asked to select all applicable options and could specify additional issues in a text box.

Demographic items

Respondents were asked to indicate: years of experience conducting research involving human participants, as well as years of research experience specifically conducting research with people with dementia; the population focus of their research (people with dementia living in the community, in institutional settings such as a care facility, or a mix of both); whether they have involved people with dementia as co-researchers to assist with study design, data collection, data analysis, or other research activities; discipline of research; whether they have served on a human research ethics committee and, if yes, their years of experience; the state or territory in which they carry out the majority of their research; and their gender.

Data analysis

Survey responses are reported using descriptive statistics, including frequencies and percentages for each variable of interest. Fifteen participants did not complete the full survey, but were included in the analysis for each aim where they had complete data. Quotations from comments made in text boxes are included to illustrate respondents' additional concerns and experiences beyond the quantitative data.

Results

Response rate and sample characteristics

The survey was sent to 135 eligible researchers and 70 usable surveys were returned for a response rate of 52%. The survey respondents represent an experienced sample of researchers in a range of disciplines from all states and territories in Australia, with a majority working in the most populous states of New South Wales (50%) and Victoria (21%). Table 1 reports key demographic characteristics.

Table 1: Demographic characteristics

Characteristic	Response	% (n)
Years of research experience (n=58)	1-7 years	26% (15)
	8-15 years	34% (20)
	> 15 years	40% (23)
Years of experience conducting research with people with dementia (n=58)	1-7 years	45% (26)
	8-15 years	19% (11)
	> 15 years	36% (21)
Population focus of research (n=63)	People with dementia in community settings	29% (18)
	People with dementia in institutional settings	16% (10)
	Mix of both	56% (35)
Experience involving people with dementia as co-researchers (n=70)	Yes	41% (29)
	No	59% (41)
Discipline of research (n=58)	Other*	22% (13)
	Psychology	21% (12)
	Medicine	17% (10)
	Nursing	17% (10)
	Neuroscience	14% (8)
	Allied health	9% (5)
	**Other areas specified were health services research, palliative care, pharmacy, social sciences and arts.*	

Characteristic	Response	% (n)
Experience serving on a human research ethics committee (n=57)	Yes	37% (36)
	No	63% (21)
Gender (n=58)	Female	71% (41)
	Male	22% (13)
	Other/prefer not to say	7% (4)

Demographic questions were divided between the start and end of the survey; complete demographic data is not available for respondents who did not finish the survey. Percentages are calculated based on number of responses available for each question.

Perceived importance of and barriers to involving people with dementia in research

Nearly all respondents (97%, n=68) stated it is very (74%, n=52) or somewhat important (23%, n=16) to include people at varying stages of dementia in studies. Yet, as reported in Table 2, many respondents expressed concern about barriers to research inclusion for people with dementia who have fluctuating or reduced decision-making capacity.

Table 2: Perceived barriers to inclusion of people with dementia in research (n=70)

Barriers of concern to dementia researchers	% (n) very /somewhat concerned
Difficult or time consuming to recruit such participants	84% (59)
Difficult to retain such participants in a study over time	80% (56)
Ethics rules unduly restrict participation by people with fluctuating or reduced capacity	80% (56)
Legal rules unduly restrict participation by people with fluctuating or reduced capacity	74% (52)
Difficult or time consuming to get ethics approval	74% (52)
Difficult or time consuming to obtain consent for research participation	73% (51)

Practices in determining capacity to consent to research and seeking consent from substitute decision-makers

When asked how often they exclude people with dementia who are unable to give their own consent, just 14% (n=10) of researchers reported they always or very often use this exclusion criterion, 36% (n=25) said sometimes, while 49% (n=34) responded rarely or never. Consequently, most respondents (80%, n=56) reported they had experience in seeking consent from another person or entity to include a person with dementia in a study. These respondents were asked about who is involved in assessing capacity to consent, and the people who most frequently act as substitute decision makers for people with reduced decisional capacity (Table 3).

Determining capacity to consent to research

In relation to their research studies, the respondents reported variation in how and by whom a prospective participant's decision-making capacity is assessed (Table 3). A majority of respondents (59%, n=33) said a research team member is very often or always involved in determining whether a person with dementia has capacity to consent to a study and 38% (n=21) stated that an external health professional is very often or always involved. A minority (16%, n=9) said a legal body is sometimes involved in capacity determinations. Family members, informal carers and aged care facility staff were noted as other people who are sometimes involved in determining capacity to consent.

Just over one third of respondents (36%, n=20) reported that a specific tool was used to assess the capacity to consent of participants in their studies. These varied from tools specific to research participation, such as the Evaluation to Sign Consent (Resnick et al., 2007) and the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) (Appelbaum & Grisso, 2001) to more general cognitive function screens, such as the Mini Mental State Exam

(MMSE). Other tools noted were the Rowland Universal Dementia Assessment Scale (RUDAS), the Montreal Cognitive Assessment (MoCA), Psychogeriatric Assessment Scales (PAS), Geriatric Dementia Rating Scale (GDRS), Functional Assessment Staging of Alzheimer's Disease (FAST) and the General Practitioner Assessment of Cognition (GPCOG).

Seeking consent from substitute decision-makers

Of researchers who indicated they had experience in seeking consent from another person, a majority (60%, n=34) reported they very often or always seek consent from an individual with formal legal authority to make decisions on behalf of the person with dementia, such as a legally appointed enduring guardian. About half of the respondents (51%, n=29) reported they very often or always seek consent from an individual with informal responsibility, such as a family member or carer. Few respondents had applied to a tribunal or court for approval to include a person with impaired capacity in a study. About 20% (n=11) reported they had approached others for permission to include a person with dementia in a study, including the person's general medical practitioner or specialist, or a senior staff member of an aged care facility. Some respondents referred to this as seeking 'assent' for the older person's participation.

Table 3: Who is involved in determining capacity and giving substitute consent (n=56)

In your research, how often are the following involved in determining if a person with dementia has capacity to consent to a research study? % (n)					
	Always	Very often	Sometimes	Rarely	Never
Member of the research team	20% (11)	39% (22)	20% (11)	9% (5)	11% (6)
Doctor/health professional external to research team	7% (4)	30% (17)	30% (17)	13% (7)	20% (11)
External legal body (eg, guardianship tribunal)	0	0	16% (9)	18% (10)	63% (35)
In your research, how often have you sought consent from the following decision-makers for a person with dementia? % (n)					

Individual with formal legal authority for the person (eg, family member formally appointed as decision-maker)	25% (14)	36% (20)	28% (15)	4% (2)	9% (5)
Individual with informal responsibility for the person (eg, family or other carer)	14% (8)	38% (21)	32% (18)	4% (2)	13% (7)
A legal body (eg, guardianship tribunal)	0	4% (2)	18% (10)	14% (8)	54% (30)

Experiences with research ethics committees

Nearly 70% of the survey respondents (n=48) said they had experience of seeking approval from an ethics committee to involve people with dementia in research where the participants had fluctuating or reduced capacity.

Positive and negative consequences of the review process

These respondents reported both positive and negative outcomes of the ethics review process. Positive outcomes included strengthening the protections for participants with cognitive impairment and helping researchers plan for future research involving this population. Half of respondents (n=24) reported they had received inconsistent outcomes from different committees, for example, in multi-site studies. Almost 30 per cent (n=14) felt that ethics review processes had caused excessive delays, reported as ranging from six to 18 months. In a few cases, respondents commented that approval delays resulted in the abandonment of proposed studies, including by doctoral research candidates.

Table 4: Consequences of the ethics review process (n=48)

Which of the following have occurred as the result of the ethics review process of your research studies involving people with fluctuating or reduced capacity? % (n)	
Inconsistent responses from ethics committees (eg, same or similar study had different outcomes)	50% (24)
Improved protections for research participants	38% (18)
Excessive delay of a project	29% (14)
Helped me plan for future research	23% (11)

Which of the following have occurred as the result of the ethics review process of your research studies involving people with fluctuating or reduced capacity? % (n)	
Would not approve the study or required substantive changes to study design	15% (7)
Had a negative impact on collaborations or relations with research partners	10% (5)

Note: Respondents could select more than one item. Items with 5 or more responses are reported.

Issues requiring considerable discussion

Half of respondents (n=24) reported considerable discussion about the process for seeking consent for participants with cognitive impairment to take part in their studies. A quarter to a third of respondents reported considerable discussion about processes for: approaching or inviting potential participants (33%, n=16); seeking consent from a substitute decision maker (29%, n=14); and assessing the decision-making capacity of the person with cognitive impairment (25%, n=12).

Comments about ethics committees and other gatekeepers

Respondents cited the importance of improving the understanding of dementia among ethics committee members: "Most Ethics committees consider any person with dementia, at any stage of the disease as 'vulnerable' and unable to make a decision about participation." "Lack of understanding of ethics committees and researchers about the use of inclusive research approaches contributes to barriers. As do expectations that people with dementia should have to fit into standard research designs." Another respondent criticised pro forma recruitment documents expected by ethics committees: "The templates used as research information sheets and consent forms are completely inadequate to support someone with dementia [to] make an informed decision."

Beyond the formal gatekeeping role of ethics committees, the survey respondents identified that family members, clinicians and care facility staff are informal gatekeepers who can help or

hinder research inclusion. Similar to comments about ethics committees, one survey respondent remarked that these gatekeepers "bring certain beliefs or assumptions about the person's capacity, which can derail attempts to approach them" to discuss research opportunities and assess decisional capacity. Another researcher observed that "clinicians and carers may also act as gatekeepers if they have different views on the benefits of participation for the person with dementia." They may assume the person with dementia would not be interested in or capable of being part of a study: "I think we miss a vital voice within the research if there are institutional processes which makes it hard to include people living with dementia. There also seem to be layers of informal 'gatekeepers' who think people wouldn't want to participate in particular kinds of research." Another researcher stressed the need to address "[s]tigmatisation which assumes people living with dementia are not able to participate."

Involving people with dementia as co-researchers

Our survey focused on researchers' views and experiences in relation to involving people with dementia as participants in studies. However, we included a demographic question asking whether respondents had experience involving people with dementia as co-researchers, such as to assist with study design, data collection, data analysis or other research activities. A sizeable minority (41%) reported they had this experience and several qualitative comments alluded to the benefit of this involvement: "earlier consumer input [helps] us articulate the importance of the research and structure the design to be consumer focused." In turn, it was suggested that the need for back and forth discussion with ethics committees on recruitment and consent processes can be reduced if the protocol is developed with input from consumers.

Discussion

Inclusion is important but barriers persist

While almost all of our survey respondents agreed with the importance of including people with dementia in research, a majority – around three-quarters and above – reported concerns with ethical, legal and practical barriers. A previous US-Australia survey concluded that many researchers are nervous about including people with cognitive impairment in research (Pachana et al., 2015) and other researchers offer autoethnographic accounts of barriers they have encountered (Cubit, 2010; Monroe et al., 2013). The dominant concerns for our respondents were about recruitment and retention, which highlights the need for strategies that advance the responsible research goals of ensuring that people with dementia are aware of research opportunities and that study processes are tailored to overcome participation barriers for people with dementia and their study partners (Bartlett et al., 2018).

Many respondents perceived ethical and legal rules and ethics review processes as unduly restrictive or time-consuming. Australia has a National Statement on the Ethical Conduct of Human Research that provides a nationally consistent ethics framework, however, each state and territory has its own laws governing health-related decision-making for people who lack capacity. A recent analysis argued that "this wide legislative variation has no rational foundation, precludes a consistent approach to research governance and participation, and hinders research that seeks to include people with impaired capacity, especially multi-jurisdictional studies." (Ries, Thompson & Lowe, 2017: 361) We comment further below on improving consent processes and the benefits of clear legal rules to guide decision-making when a prospective participant cannot give their own consent.

Determining capacity to consent to research

Capacity is decision and time-specific (Werner & Schicktanz, 2017) and dementia must not be equated with an assumption of global incapacity (Palmer et al., 2017). To respect autonomy, consent for research participation must be sought from the prospective participant if they are capable of making their own choice on the matter. Our results indicate there is no clear and consistent approach for assessing decision-making capacity for research studies. While researchers are often involved in these determinations, respondents reported a variety of approaches to assessing capacity, including use of the MMSE and other tools not specific to the research context. Variation in approaches to assessing consent was also reported among Canadian researchers conducting ageing-related studies (Bravo et al., 2013). Just under 30% of researchers in that survey (28.6%) reported using a specific capacity assessment tool, with the MMSE most commonly cited.

These findings suggest a need for improving awareness among researchers of appropriate strategies to assess decisional capacity specific to the research context. Capacity assessment processes should explore the prospective participant's understanding of concepts related to research, as well as the requirements, benefits and risks of taking part in a particular study. A MMSE score may be useful in identifying prospective participants with potentially reduced capacity, but should not on its own rule people in or out of opportunities to take part in studies. One quarter to one half of people who are rated as moderately cognitively impaired (MMSE score of 12-19) may nonetheless be able to make a choice about taking part in a study (Whelan et al., 2009; Guarino et al., 2016). Moreover, around 15% of those judged to have milder impairment (MMSE 20-26) may lack decisional capacity in regard to clinical trial participation (Guarino et al., 2016). Palmer et al. (2017) recently reported that nearly a third of people with

mild to moderate Alzheimer's disease had capacity to consent to research in the context of medium risk (drug trial) and higher risk (immunotherapy trial) protocols.

Various tools have been developed to assess capacity to consent in the research context, including six tools that have been evaluated in older adults with cognitive impairment (Gilbert et al., 2017). The MacCAT-CR is supported by the most empirical research (Appelbaum & Grisso, 2001), however it takes around 20 minutes to administer and requires special training. The 10-item UCSD Brief Assessment of Consent Capacity (UBACC) (Jeste et al., 2007; Seaman et al., 2015) shows promise for use in dementia research. Guarino et al. (2016) recently described the value of an informed consent questionnaire designed to assess prospective participants' understanding of a specific study as well as their rights as research participants. In general, Palmer et al. (2017: 31) recommend that "at minimum, a structured assessment of the ability to describe, in the participant's own words, the purpose, procedures, and potential risks of the research, should be conducted for each trial." Researchers may need to educate gatekeepers, such as aged care facility managers or medical practitioners, on the importance of study-specific consent discussions to ensure that potentially eligible and interested participants are not excluded based on assumptions of incapacity (Goodman et al., 2011).

Lengthy information sheets and consent forms were criticised by some of our respondents as poor ways to communicate with people with dementia. This critique applies with even more force for people with neurocognitive disorders who also have limited formal education. Palmer et al. (2017) found that a diagnosis of Alzheimer's disease, combined with lower educational attainment and poor health and research literacy, was associated with a lack of capacity to consent to a study. Communication strategies suited to the needs of people with dementia (Eggenberger, Heimerl & Bennett, 2013) can enhance their understanding and decision-making about taking part in research and help to overcome these barriers. Once involved in a study,

process consent can be used for ongoing checks of the participant's willingness to take part (Dewing, 2008; Juaristi & Dening, 2016).

The role of substitute decision-makers

An important finding of our survey is that many dementia researchers do not automatically exclude a person who is unable to give their own consent, but instead seek consent from substitute decision-makers, such as a formally appointed guardian or a family carer. Research ethics rules typically require the consent of a legally authorised representative when the prospective participant is unable to give their own consent. However, legislation may not clearly specify who has this legal authority or it may not permit a person's healthcare decision-maker to consent to experimental research interventions (Ries, Thompson & Lowe, 2017). Our study showed that researchers often seek substitute consent from family members, yet the legal authority for this consent may be unclear. Our survey did not test respondents' knowledge of the law, a limitation we note below, however a Canadian study found that just over one quarter (28%) of researchers had a correct understanding of the law and many assumed that family members had legal authority to give consent to research participation (Bravo et al., 2013).

Laws should provide clear rules on who can consent to research participation for a person who lacks capacity to make their own choices (Thorogood et al., 2018), for example, by recognising a Power of Attorney for Research (Heesters et al., 2017; Davis, 2017). Researchers also need simple and accessible resources to help them understand and follow legal requirements. These measures should be complemented by strategies to support substitute decision-makers in understanding and carrying out their role in the research context. For example, where a substitute decision-maker is approached, researchers should ensure that study consent materials clearly explain their decision-making role, in line with any relevant legal rules in the study jurisdiction,

such as a statutory obligation to make a decision that reflects the known values and preferences of the person with impaired capacity.

Research ethics committees and other gatekeepers

Our results add to the findings of a previous US-Australia survey in which researchers expressed concern about ethics committees holding "overly protective and potentially patronizing or ageist" assumptions about older people and those with conditions affecting cognition (Pachana et al., 2015: 704). Researchers in that study felt an onus to educate committees about older adults and inclusive research approaches and described a "big learning curve" to surmount (Pachana et al., 2015: 703). Our findings revealed that the proposed processes for seeking consent from a person with cognitive impairment commonly require considerable discussions between researchers and ethics committees. This finding may reflect committee members' inaccurate assumptions about dementia that could be addressed through education. However, the absence of consistent, widely accepted processes for assessing capacity to consent to research likely also contributes to the need for discussion, delays and changes to study protocols. At the same time, dialogue with ethics committees can improve protections for participants with cognitive impairment, as reported by nearly 40% of our respondents.

Half of our respondents reported receiving inconsistent outcomes from different ethics committees. In Australia, a majority of states and territories participate in a National Mutual Acceptance scheme for the ethical and scientific review of some multi-site studies, however investigators must ensure their research protocols comply with laws in their jurisdiction, which may impose differing rules on matters such as consent, substitute decision-making and data collection (National Health and Medical Research Council, 2018a). Ambitious proposals to streamline ethics review processes are being advocated elsewhere, such as regulatory changes in North America to provide a single review committee for multi-site clinical trials on

neurodegenerative diseases (Knopman et al., 2017; Gauthier, Robillard and de Champlain, 2018).

Respondents also commented on 'gatekeepers' aside from ethics committees, including family members, clinicians and care facility staff, with whom researchers must collaborate to involve people with dementia in studies. These findings add to accounts from dementia researchers in other countries about the power of gatekeepers (Brooks, Savitch & Gridley, 2017; Holland & Kydd, 2015) and the importance of effective engagement with study partners (Largent, Karlawish & Grill, 2018; Black et al., 2018) and clinicians (Manthorpe et al., 2013) who support and care for people with dementia. Researchers must address their concerns about the burdens of research activities and provide practical supports for inclusive approaches (Bartlett et al., 2018). Doing so can have multiple benefits. For example, if a member of the research team is responsible for conducting a study-specific assessment of a person's capacity to consent, this will reduce the burden on clinicians to determine capacity.

Future research

Where a person with dementia has the requisite decisional capacity, they may wish to engage in advance research planning to reflect on, discuss and document their preferences for being involved in study activities during future periods of incapacity (Pierce, 2010; Porteri, 2018). This strategy would provide evidence of the person's values and wishes to guide substitute decision-makers, researchers and ethics committees. This form of planning has support in some research ethics guidelines. Australia's National Ethics Statement encourages researchers, at the time of recruitment, to discuss and document future preferences with participants, especially if cognitive decline over the course of the study is anticipated (National Health and Medical Research Council, 2018b: para 4.5.7). The *International Ethical Guidelines for Health-Related Research Involving Humans* states that valid advance research directives should be respected (CIOMS,

2016: 61). A Canadian randomised controlled trial of an advance research planning intervention resulted in 80% of older adult participants documenting their preferences for future research participation (Bravo et al., 2016). Further studies are needed to investigate the feasibility, acceptability and effectiveness of advance research planning for the various stakeholders involved.

Strategies for enhancing and supporting decision-making about research participation by people with dementia is a key area for future investigation. Supported decision-making as envisioned by the UN CRPD and some domestic laws (Keeling, 2016; Then et al., 2018) puts new responsibilities on family members, study partners and researchers to adopt inclusive practices that enable people living with cognitive impairment to make their own choices, including about taking part in research. To date, there is little practical guidance in this context. A European research project currently underway aims to provide recommendations for supported decision-making and capacity assessment in clinical dementia research (Haberstroh, Oswald & Pantel, 2017; Vollmann, Gather & Scholten, 2017). Tools to help prospective participants understand and make choices about a study are also needed. Memory aids with simple and plain language information about an early phase clinical trial enhanced the ability of people with mild to early moderate Alzheimer's disease to make their own decisions (Rubright et al., 2010). In contrast, a recent study with a similar population found that multi-media tools, including video clips and animations, did not enhance decision-making capacity (Palmer et al., 2018). The investigators suggested that multimedia tools may be inadequate to overcome the rapid forgetting experienced by some people with dementia and recommend further work on memory aids as well as supported decision-making processes in the research recruitment context.

Other recent work has focused on innovative strategies to support qualitative research involving people with dementia (Novek & Wilkinson, 2017), including the use of arts-based and visual

methods such as photography and videorecording (Phillipson & Hammond, 2018) and participatory action research to promote culture changes in community and institutional care settings (Mann & Hung, 2018). A pan-European consultation recently sought the views of people with dementia on meaningful outcomes for psychosocial interventions (Øksnebjerg et al., 2018). These initiatives offer valuable contributions to inclusive research practices, but acknowledge that they have focused on people with mild to moderate symptoms and barriers persist in involving people with more advanced dementia in research. Resonant with our findings, this literature underscores the challenges in using innovative methods, including "complexities…around recruitment, ethics and consent processes…complicated and rigid ethics processes and from a funding perspective, a lack of acknowledgment of the time required to build and participate in meaningful research interactions involving people with dementia" (Phillipson & Hammond, 2018: 11). Moreover, further work is needed on optimal strategies for involving carers as study partners, especially to strike an "appropriate balance between carers supporting people with dementia to have a voice, and carers speaking for the person with dementia and inhibiting the person's own contribution" (Øksnebjerg et al., 2018: 8).

Several recent reviews discuss the merits and challenges of co-research in aging-related research (Schilling & Gerhardus, 2017), including with older people living with dementia (Di Lorito et al., 2017; Stevenson & Taylor, 2019) and emphasise the need for further work in this area. Strategies to assist researchers in appropriately including people with impaired cognition as participants can also inform their involvement as co-researchers (Rivett, 2017). More published accounts are needed that offer the forthright views of all the parties in co-research relationships (Littlechild, Tanner & Hall, 2015) on key issues such as ensuring inclusive and meaningful collaborations (Bindels et al., 2014), methodological rigour (Buffel, 2018), especially in more complex study designs (Heaven et al., 2016), and planning for the role of co-researchers experiencing progressive cognitive decline (Iliffe, McGrath & Mitchell, 2013). Funding for

dementia research should take into account the support needed to effectively involve people with dementia as co-researchers.

Limitations

The survey did not test researchers' knowledge of the law in their jurisdiction, for example, to determine if researchers seek consent from the legally appropriate decision-maker. Previous American and Canadian studies show that consent practices may not follow legal requirements, suggesting the need for legal educational resources tailored for researchers (Karlawish et al., 2002; Bravo et al., 2013). The majority of our sample was female (64% of researchers contacted and 71% of respondents), similar to Pachana et al.'s (2015) survey of Australian and American ageing researchers where 73% of respondents were women. We have highlighted some points of agreement and difference between our findings and other empirical studies of researchers in Canada, the US and the Netherlands; cultural and legal differences in other countries may reveal different attitudes and experiences among researchers. For example, Werner and Schicktanz (2018) recently considered how differing legal frameworks influence the views of researchers in Germany and Israel on advance directives for dementia research. Our survey instrument used fixed choice questions and provided space for respondents to add comments in text boxes. While many of them did so, this technique does not allow for in-depth exploration of attitudes and experiences. A follow-up qualitative interview study with a subset of the survey respondents is planned for this purpose.

Conclusion

There is burgeoning international attention to the need for inclusive research practices that provide appropriate opportunities for people at risk of or living with dementia to be involved in studies. Researchers are key stakeholders in this transformative project. Our survey of dementia researchers in Australia provides insights on current practices and experiences related to the

ethical, legal and practical complexities of involving participants who may lack capacity to consent. These findings can inform strategies and future research in relation to practices for assessing and enhancing consent and the role of research decision-makers and gatekeepers. Further empirical investigations in these areas are needed and should complement broader strategies to increase community awareness of dementia research and to enable meaningful patient and public involvement in research.

Ethics Statement: The study received ethics approval from the authors' university human research ethics committee. Survey respondents were advised that survey findings would be reported anonymously.

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United Nations (2006). *Convention on the Rights of Persons with Disabilities*. Available online at https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities.html [Accessed 1 November 2018].

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Werner P, Shicktanz S (2018). Practical and Ethical Aspects of Advance Research Directives for Research on Healthy Aging: German and Israeli Professionals' Perspectives. *Frontiers in Medicine*, 5.

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Whitham MD, Stott DJ (2017). Conducting and reporting trials for older people. *Age and Ageing* 46, 889-894.

World Medical Association (2018). *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects*. Available online at https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ [Accessed 1 November 2018].

PAPER 7: ADVANCE RESEARCH DIRECTIVES: INSIGHTS FROM A NATIONAL SURVEY OF DEMENTIA RESEARCHERS IN AUSTRALIA

Overview

When recruiting people with cognitive impairment into research, Australia's National Statement on Ethical Conduct in Human Research recommends that researchers discuss and document participants' preferences for continuing participation during future periods of reduced capacity. Researchers' knowledge of and compliance with this guidance is unknown. Anecdotal reports indicate that advance research directives are rarely made and used.

This paper reports on a component of the national survey of dementia researchers that focused on researchers' awareness, attitudes and experiences concerning advance research directives. These data are timely as several domestic law reform initiatives aim to provide clearer frameworks, including statutory rules specific to research directives, for involving people in research who lack capacity to give their own consent.

In line with older adults' views, the findings from Paper 7 indicate that researchers are also in support of the concept of advance planning for research participation. Linking back to Papers 1–3 on advance planning for medical care, this paper concludes by recommending that lessons learned from the volume of research and experience with advance care planning can be used to inform strategies to support advance research planning.

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ADVANCE RESEARCH DIRECTIVES: INSIGHTS FROM A NATIONAL SURVEY OF DEMENTIA RESEARCHERS IN AUSTRALIA

Abstract

Advance research directives (ARDs) are a means by which people can document their wishes about research participation in the event of future incapacity. A survey of dementia researchers in Australia (n=63) was undertaken to examine their views on ARDs. Australia's National Statement on Ethical Conduct in Human Research supports advance research planning, especially for participants who may experience cognitive impairment. Many researchers (>80%) thought ARDs would promote autonomy in decision-making and enable opportunities for people with cognitive impairment to be included in research. Respondents indicated concern about directives not being available when needed (71%) and that ethics committees would not accept ARDs (60%). Few respondents had used ARDs, but a majority (from 57-80%) would be willing to offer ARDs for a range of research activities, such as observing behaviour, taking measures, accessing records, and taking blood samples or scans. Nearly all respondents (92%) agreed that current dissent should override prior wishes stated in an ARD. The survey findings are discussed with suggestions for ethics guidelines, laws and practices to support advance research planning.

Keywords: dementia; research; advance research directive; survey; Australia

Introduction

Importance of involving people with dementia in research

The ageing population and rising prevalence of dementia in many countries around the world [1] have prompted calls for greater investment in research to inform practices and policies to meet the needs of older people living with neurocognitive disability.[2] There is also increasing advocacy for the inclusion of people at all stages of dementia in research.[3] It is recognised that the needs of people with dementia change as symptoms progress and the exclusion of people with moderate to advanced dementia from research leaves significant gaps in the evidence base for effective care and supports.[4]

Yet, people living with cognitive impairment have often been excluded from clinical studies due to concerns about their capacity to consent to and take part in research activities.[5] Involving people with dementia on the basis of substitute consent by another decision-maker also raises ethical and legal concerns. Substitute-decision making is notoriously difficult and inaccurate[6]; proxies' views often differ from what prospective participants would want[7] and they tend to

[1] Prince, M., Bryce, R., Albanese, E., Wimo, A., Ribeiro, W., & Ferri C. P. (2013). The global prevalence of dementia: A systematic review and metaanalysis. *Alzheimer's & Dementia: The Journal of the Alzheimer's Association*. 9, 63-75.e62.
[2] Alzheimer's Disease International. (2018). *From Plan to Impact: Progress Towards Targets of the Global Action Plan on Dementia*. London: Alzheimer's Disease International; Prince, M. J., Wu, F., Guo, Y., Gutierrez Robledo, L. M., O'Donnell, M., Sullivan, R., & Yusuf, S. (2015). The burden of disease in older people and implications for health policy and practice. *The Lancet*. 385, 549-562.
[3] Alzheimer Europe. (2011). *The Ethics of Dementia Research.* Retrieved from https://www.alzheimer-europe.org/Ethics/Ethical-issues-in-practice/2011-Ethics-of-dementia-research; West, E., Stuckelberger, A., Pautex, S., Staaks, J., & Gysel, M. (2017). Operationalising ethical challenges in dementia research—a systematic review of current evidence. *Age and Ageing*. 46, 678-687; Prusaczyk, B., Cherney, S. M., Carpenter, C. R., & DuBois, J. M. (2017). Informed Consent to Research with Cognitively Impaired Adults: Transdisciplinary Challenges and Opportunities. *Clinical Gerontologist*. 40, 63-73.
[4] West et al., *op. cit.* note 3; Murphy, K., Jordan, F., Hunter, A., Cooney, A., & Casey, D. (2015). Articulating the strategies for maximizing the inclusion of people with dementia in qualitative research studies. *Dementia*. 14(6), 800–824
[5] Rivett, E. (2017). Research involving people with dementia: a literature review. *Working with Older People*. 21, 107-114; West et al., *op. cit.* note 3.
[6] Wendler, D. (2017). The Theory and Practice of Surrogate Decision-Making. *Hastings Center Report*. 47, 29-31.
[7] Bravo, G., Trottier, L., Dubois, M., Arcand, M., Blanchette, D., Boire-Lavigne, A. … Painter, K. (2016). Does promoting research advance planning in a general elderly population enhance completion of a research directive and

underestimate the willingness of older adults to participate in research.[8] Moreover, the legal basis for substitute decision-making about research participation may be absent or unclear in some jurisdictions[9] and researchers may incorrectly assume family members have authority to make such decisions.[10] Advance research planning, including the making of an advance research directive (ARD), has been proposed as a means to overcome these difficulties.

Advance research planning and advance research directives

Advance research planning, similar to the process involved in advance care planning,[11] involves reflecting on and articulating one's preferences for being involved in research during future periods of incapacity and identifying a substitute decision-maker to make decisions when necessary. Depending on relevant law,[12] the person engaged in advance research planning may document their preferences in an ARD and a proxy may be formally appointed through an enduring instrument, such as a Medical Research Power of Attorney or an Enduring Guardian appointment.[13] Such processes respect the autonomy and self-determination of a person who

proxies' predictive ability? a randomized controlled trial. *AJOB Empirical Bioethics*. 7, 183-192; Stocking, C. B., Hougham, G. W., Danner, D. D., Patterson, M. B., Whitehouse, P. J. & Sachs, G. A. (2006). Speaking of research advance directives: Planning for future research participation. *Neurology*. 66(9), 1361.

[8] Kim, S. Y., Kim, H., Ryan, K., Appelbaum, P. S., Knopman, D. S., Damschroder, L., & De Vries, R. (2013). How important is 'accuracy' of surrogate decision-making for research participation?. *PLoS One*. 8(1), e54790.

[9] Ries, N. M., Thompson, K. A., & Lowe, M. (2017). Including People with Dementia in Research: An Analysis of Australian Ethical and Legal Rules and Recommendations for Reform. *Journal of Bioethical Inquiry*. 14, 359-374; Davis, D. S. (2017). Ethical issues in Alzheimer's disease research involving human subjects. *Journal of Medical Ethics*. 43, 852-856; Thorogood, A., Dalpé, G., McLauchlan, D., & Knoppers, B.M. (2018). Canadian Consent and Capacity Regulation: Undermining Dementia Research and Human Rights? *McGill Journal of Law & Health*. 12(1), 67-122.

[10] Bravo, G., Wildeman, S., Dubois, M. F., Kim, S. Y., Cohen, C., Graham, J., & Painter, K. (2013). Substitute consent practices in the face of uncertainty: a survey of Canadian researchers in aging. *International Psychogeriatrics*. 25, 1821-1830.

[11] Sudore, R. L., Lum, H. D., You, J. J., Hanson, L. C., Meier, D. E., Pantilat, S. Z. … Heyland, D. K. (2017). Defining Advance Care Planning for Adults: A Consensus Definition From a Multidisciplinary Delphi Panel. *Journal of Pain and Symptom Management*. 53, 821-832.e821.

[12] For discussion of various legal frameworks, see eg, Andorno, R., Gennet, E., Jongsma, K., & Elger, B. (2016). Integrating Advance Research Directives into the European Legal Framework. *European Journal of Health Law*. 23, 158-173; Peisah, C., Vollmer-Conna, U., & Kim, S. Y. H. (2012). Capacity to consent to research: The evolution and current concepts. *Asia-Pacific Psychiatry*. 4, 219-227.

[13] Ries et al., *op. cit.* note 9; Heesters, A. M., Buchman, D. Z., Anstey, K. W., Bell, J. A. H., Russell, B. J., & Wright, L. (2017). Power of Attorney for Research: The Need for a Clear Legal Mechanism. *Public Health Ethics*. 10, 100-104.; Porteri, C. (2018). Advance directives as a tool to respect patients' values and preferences: discussion on the case of Alzheimer's disease. *BMC Medical Ethics*. 19(1), 9.

wishes to plan for future incapacity, can help ensure that substitute decision-making reflects the values and wishes of the person with cognitive impairment, and can support inclusion in research where a person has expressed their prior interest in participation.[14]

The concept of advance research planning, including making an ARD, was supported 20 years ago by the US National Bioethics Advisory Commission.[15] Other developments have occurred in the past decade. A 2009 consensus statement of the World Psychiatric Association section on old age psychiatry recommended that older people engaged in advance care planning "should be encouraged to include a statement addressing their wishes concerning participation in research."[16] A 2011 Alzheimer Europe position statement endorsed ARDs as a means to document preferences for or against future research participation and makes it clear that researchers, medical practitioners and substitute decision-makers should respect the wishes set out in an ARD unless, for example, the person expresses dissent in relation to an activity they previously indicated as acceptable in an ARD.[17] The 2016 *International Ethical Guidelines for Health-Related Research Involving Humans* states: 'If participants have made advance directives for participation in research while fully capable of giving informed consent, the directives should be respected.[18] An international expert panel recently proposed recommendations for consent to

[14] See eg, Pierce, R. (2010). A changing landscape for advance directives in dementia research. *Social Science and Medicine.* 70, 623–630.
[15] National Bioethics Advisory Commission (NBAC). (1998). *Research involving persons with mental disorders that may affect decisionmaking capacity*. Rockville: National Bioethics Advisory Commission. This report cites commentary on advance research decisions from the mid-1980s, see pages 71-72. See also Keyserlingk, E. W., Glass, K., Kogan, S., & Gauthier, S. (1995). Proposed guidelines for the participation of persons with dementia as research subjects. *Perspectives in Biology & Medicine*. 38(2), 319-361, especially pages 346-347 for an overview of the advantages and disadvantages of ARDs.
[16] Katona, C., Chiu, E., Adelman, S., Baloyannis, S., Camus, V., Firmino, H. … Warner, J. (2009). World psychiatric association section of old age psychiatry consensus statement on ethics and capacity in older people with mental disorders. *International Journal of Geriatric Psychiatry*. 24, 1319-1324, 1323.
[17] Alzheimer Europe, *op. cit.* note 3.
[18] Council for International Organizations of Medical Sciences. (2016). *International ethical guidelines for health-related research involving humans*. Geneva: Council for International Organization of Medical Sciences.

research and data sharing involving people with dementia and endorsed advance research planning processes.[19]

Empirical investigations

To date, ARDs have received scant attention in empirical studies to elicit stakeholder perspectives and to provide evidence on how to implement advance research planning. In Wales, researchers conducting a randomised medical care trial among nursing home residents sought the views of residents, their relatives, staff and general practitioners on an advance consent process.[20] The researchers proposed to seek residents' consent to participate in the trial up to one year before their randomisation into the treatment or placebo arm, at which point their decisional capacity could be impaired.[21] Participants had divided views on whether the advance consent would be legally sufficient to permit ongoing participation or whether permission should be sought from an authorised decision-maker for a resident with impaired capacity. In the Netherlands, an interview study of 13 clinical dementia researchers elicited their views on arguments for and against ARDs and perceived practical utility.[22] Most recently, scholars in Germany and Israel conducted focus groups and interviews on the ethical and practical aspects of ARDs with 16 stakeholders in those countries, including dementia researchers, experts in medical law and ethics, and policymakers.[23] These latter studies emphasised the need to "better

[19] Thorogood, A., Maki-Petaja-Leinonen, A., Brodaty, H., Dalpe, G., Gastmans, C., Gauthier, S. … Ageing and Dementia Task Team. (2018). Consent recommendations for research and international data sharing involving persons with dementia. *Alzheimer's & Dementia*. 14(10), 1334-1343. The panel was comprised of ten experts from Europe, Canada and Australia in areas of clinical research, ethics, law and patient advocacy. Consumer representatives provided input on draft recommendations.

[20] Wood, F., Prout, H., Bayer, A., Duncan, D., Nuttall, J., Hood, K. … PAAD Study Team. (2013). Consent, including advanced consent, of older adults to research in care homes: a qualitative study of stakeholders' views in South Wales. *Trials*. 14, 247.

[21] Randomisation would occur when the resident was prescribed an antibiotic, which could be anytime within a one-year window of consenting to be part of the trial.

[22] Jongsma, K., & van de Vathorst, S. (2015). Advance directives in dementia research: The opinions and arguments of clinical researchers − an empirical study. *Research Ethics*. 11, 4-14. The interviewees were from fields of neurology, gerontology, aged care medicine, psychiatry and psychology.

[23] Ibid; Werner, P., & Schicktanz, S. (2018). Practical and Ethical Aspects of Advance Research Directives for Research on Healthy Aging: German and Israeli Professionals' Perspectives. *Frontiers in Medicine*. 5.

understand how researchers look upon the use of ARDs"[24] and to "advance knowledge and solve dilemmas associated with ARD implementation."[25]

In regard to implementation, two older American studies and a more recent Canadian project examined the feasibility and uptake of ARDs. Over a six-month period in 2000, all patients admitted to a US National Institutes of Health research hospital were given an opportunity to make an ARD and 11% (261 of 2,371 patients) did so.[26] In 2007, results were published from the first randomised controlled trial (RCT) of an ARD intervention targeted to people with dementia and their proxy decision-makers.[27] Patients and their proxies were presented with five hypothetical clinical trials involving varying risk levels and were asked to reflect separately on their views about the patient's participation.[28] The 69 dyads then had a joint interview to discuss their views and prepare a Planning Ahead Together (PAT) document designed to instruct the proxy about future decisions. This study found that patients and their proxies were willing to discuss and document preferences for future research participation, however the experience of completing the PAT document was found not to make a difference in later enrolment decisions about an actual clinical trial and the reported ease of making those decisions.[29] In 2016, Canadian researchers reported on their RCT to promote the uptake of advance directives for treatment and research decisions.[30] Their intervention consisting of educational sessions and

[24] Jongsma and van de Vathorst, *op. cit.* note 22, p. 6.
[25] Werner and Schicktanz, *op. cit.* note 23, p. 9.
[26] Muthappan, P., Forster, H., & Wendler, D. (2005). Research Advance Directives: Protection or Obstacle? *American Journal of Psychiatry*. 162, 2389-2391.
[27] Stocking, C. B., Hougham, G. W., Danner, D. D., Patterson, M. B., Whitehouse, P. J., & Sachs, G. A. (2007). Empirical assessment of a research advance directive for persons with dementia and their proxies. *Journal of the American Geriatrics Society*. 55, 1609-1612. The proxies were typically family caregivers and were not necessarily legally appointed as a decision-maker for health-related matters.
[28] Stocking et al., *op. cit.* note 7, p. 1361.
[29] Stocking et al., *op. cit.* note 27.
[30] Bravo, G., Arcand, M., Blanchette, D., Boire-Lavigne, A., Dubois, M., Guay, M. … Bellemare, S. (2012). Promoting advance planning for health care and research among older adults: a randomized controlled trial. *BMC Med Ethics*. 13, 1; Bravo, G., Trottier, L., Dubois, M., Arcand, M., Blanchette, D., Boire-Lavigne, A. … Painter, K. (2016). Does promoting research advance planning in a general elderly population enhance completion of a research directive and proxies' predictive ability? A randomized controlled trial. *AJOB Empirical Bioethics*. 7(3),183-192.

personalised facilitation resulted in 80% of older adults in the experimental group making an ARD, a majority of whom documented preferences in favour of future research participation.[31]

The aims and context for our Australian study

We undertook a national survey of dementia researchers in Australia that investigated their views and experiences concerning the involvement of people with dementia in studies, including practices for assessing capacity to consent to research, seeking proxy consent and consequences of ethics review processes. A component of the survey, reported here, focused on ARDs, with the aims of determining researchers' (1) awareness of Australian ethics guidance on advance research decision-making; and (2) attitudes about ARDs, including (i) perceived benefits, disadvantages and acceptability to ethics committees; (ii) willingness to offer an ARD for various research activities; and (iii) factors that should override an ARD. The survey also aimed to determine the proportion and experiences of researchers, if any, who had proposed or used an ARD to involve participants in research during periods of decisional incapacity.

Seeking the views of Australian researchers is timely as several domestic law reform initiatives aim to provide clearer frameworks for involving people in research who lack capacity to give their own consent. Legally, advance directives (ADs) are recognised in all Australian states and territories, either by statute, common law or both.[32] ADs are typically understood as referring to advance decisions about healthcare treatment, but a law in the state of Victoria that took effect in March 2018 explicitly recognises ARDs.[33] According to this statute, an ARD may document consent or refusal instructions for specific research procedures or activities. A person may also use an ARD to record their values in relation to research participation. Advance consent to a research procedure as documented in an instructional directive is sufficient to include a person in

[31] Bravo et al., (2016), *op. cit.* note 30.
[32] Ries et al., *op. cit.* note 9.
[33] *Medical Treatment Planning and Decisions Act 2016* (Vic).

an ethically approved study and it is not necessary to seek agreement from a substitute decision-maker.[34] For the categories of research covered by the legislation – for example, a trial of drugs, equipment or devices[35] – a researcher "must make reasonable efforts" to find out whether a prospective participant has made a research directive.[36] If there is concern that a directive no longer reflects the person's preferences and values, an application may be made to a statutory tribunal for a determination about the validity of the directive.[37] The Law Reform Commission in the most populous state of New South Wales recently recommended a new law that would establish a similar statutory framework for ARDs.[38]

The Australian Capital Territory recently updated its statutes governing powers of attorney and medical decision-making to "remove barriers to people with impaired decision-making capacity participating in medical research."[39] A person who wishes to plan for future research may now appoint a Medical Research Power of Attorney and document wishes and preferences to guide the attorney in their decision-making role.[40]

Australia's National Statement on Ethical Conduct in Human Research encourages researchers to discuss and document views on future research participation with participants who anticipate periods of cognitive impairment:

[34] *Medical Treatment Planning and Decisions Act 2016* (Vic) s. 75; see also s. 12(1).
[35] See *Medical Treatment Planning and Decisions Act 2016* (Vic) s. 3 for definition of "medical research procedure".
[36] *Medical Treatment Planning and Decisions Act 2016* (Vic) s. 73(1). This duty applies to researchers who are registered health professionals and failure to do so is deemed to constitute unprofessional conduct: s. 73(2).
[37] *Medical Treatment Planning and Decisions Act 2016* (Vic) ss. 22-24.
[38] New South Wales Law Reform Commission. (2017). *Review of the Guardianship Act 1987 - Draft Proposals*. Retrieved from https://www.lawreform.justice.nsw.gov.au/Documents/Current-projects/Guardianship/Report/Report%20145.pdf. See pp 181-192 for discussion of advance directives for research.
[39] Legislative Assembly for the Australian Capital Territory. (2015). *Powers of Attorney Amendment Bill 2015 explanatory statement*. Retrieved from https://www.legislation.act.gov.au/View/es/db_53083/20151119-62368/PDF/db_53083.PDF.
[40] Ibid.

> The process of seeking the person's consent should include discussion of any possibility that his or her capacity to consent or to participate in the research may vary or be lost altogether. The participants' wishes about what should happen in that circumstance should be followed unless changed circumstances mean that acting in accordance with those wishes would be contrary to the participant's best interests.[41]

A participant's documented wishes about future participation should be witnessed by a person independent of the research team, ideally someone close to the participant.[42] The National Statement also recognises that individuals may give broad consent to future uses of data and tissue in research and provides that the "necessarily limited information and understanding about research for which extended or unspecified consent is given can still be sufficient and adequate for the purpose of consent."[43]

Method

Eligibility: Researchers in Australia were eligible to complete the survey if they had experience with the ethical aspects of conducting dementia-related studies with human participants, such as requesting ethics approvals, recruiting participants and seeking consent for participation. An initial survey question confirmed eligibility.

Recruitment and data collection

Researchers were identified from publicly available lists of Australian dementia grants awarded by the National Health and Medical Research Council, the Dementia Collaborative Research

[41] National Health and Medical Research Council. (2018). *National Statement on Ethical Conduct in Hman Research (2007)*. Canberra: Australian Government, p. 59, para. 4.5.7.
[42] Ibid: para. 4.5.8.
[43] Ibid: 18, para. 2.2.14.

Centres and the Dementia Australia Research Foundation. A preliminary screen for eligibility was conducted using researchers' institutional profiles. Research collaborators of funding recipients who met the study inclusion criteria were also invited to participate. The lead author (N.R.) sent emails to 140 researchers with an invitation to complete the online survey. Two reminder emails were sent after three and eight weeks of non-response. Data were collected between November 2017 and January 2018.

Measures

The survey questions were informed by current literature on ARDs and relevant Australian ethical and legal principles. The survey was pilot tested with approximately 10 dementia researchers who provided feedback on its content, organisation and flow. The following definition was provided at the start of the survey: "An advance research directive (ARD) is a written statement of a person's wishes regarding research participation during future periods of incapacity. A person makes an ARD when they have decision-making capacity."

Researchers' awareness of Australian ethics guidance

Respondents were asked whether the National Statement on Ethical Conduct in Human Research gives guidance on advance research decisions/directives (yes/no/unsure). The Statement does not explicitly refer to ARDs, but as noted earlier, it recommends discussion and documentation of participants' preferences for future participation if cognitive decline is anticipated.

Researchers' attitudes about ARDs

Perceived benefits, disadvantages and acceptability to ethics committees: Respondents were asked about their level of agreement with specific benefits and disadvantages of using ARDs in dementia research on a four-point Likert scale (strongly agree to strongly disagree). A text box allowed them to note any additional benefits or disadvantages. They were asked for their view on

the likelihood that the ethics committee they deal with most often would accept an ARD as a valid expression of a person's willingness to participate in research (likely to accept; unlikely to accept; not sure).

Willingness to offer an ARD: Researchers were asked to imagine they were recruiting a person with dementia who has capacity to make research participation decisions but who may experience reduced capacity in the future. Respondents were asked to indicate their willingness to offer the person an opportunity to make an ARD for various research activities. Thirteen research activities were listed, covering varying degrees of risk and invasiveness, such as observing behaviour, accessing medical records, taking blood samples and giving experimental drugs (see Table 4). Willingness was indicated on a Likert scale (would definitely offer, would probably offer, would probably not offer, would definitely not offer, not sure/no opinion).
Factors that should override an ARD: Assuming a person with capacity made an ARD agreeing to participate in research activities during future periods of incapacity, researchers were asked what should override the ARD. They indicated their level of agreement (strongly agree to strongly disagree) with the following options: the person who made the ARD and now lacks capacity expresses objection to a research activity, such as through body language or verbalisation; a family member or carer for the person who made the ARD expresses an objection; a health practitioner for the person expresses an objection; or an ethics committee expresses an objection. They could specify in a text box anything else they thought should override the wishes stated in an ARD.

Researchers' experiences with ARDs

Respondents were asked whether they had used or proposed the use of an ARD to document individuals' preferences for future research participation. While the survey included follow-up

questions for those who indicated they had used an ARD, these data are not reported due to the low number of respondents who answered affirmatively to the question about previous use of ARDs.

Demographic items

Respondents were asked to indicate: years of experience conducting research involving human participants, as well as years of research experience specifically with people with dementia; the population focus of their research (people with dementia living in the community, in institutional settings such as a care facility, or a mix of both); whether they have involved people with dementia as co-researchers to assist with study design, data collection, data analysis, or other research activities; discipline of research (eg, medicine, nursing); whether they have served on a human research ethics committee (HREC) and, if yes, their years of experience; the state or territory in which they carry out the majority of their research; and their gender.

Data analysis

Survey responses are reported using descriptive statistics, including frequencies and percentages calculated using available data for each aim. Data are pooled for some response options as indicated in each table. Quotations from respondents' comments are included to illustrate further perspectives and experiences beyond the quantitative data.

Results

Response rate and respondent characteristics

The survey was sent to 135 eligible researchers and 70 usable surveys were returned for an overall response rate of 52%. Slightly fewer respondents (n=63) completed the section on ARDs (47% response rate) and these data are reported here. The survey respondents represent an

experienced sample of researchers from a range of disciplines. Over half had at least eight years of experience in dementia-related research and a sizeable minority (37%) had served on a HREC. The survey included respondents from all states and territories in Australia. Table 1 reports key demographic characteristics.

Table 1: Demographic characteristics (n=63)

Characteristic	Response	% (n)
Years of research experience	1-7 years	26% (15)
	8-15 years	34% (20)
	> 15 years	40% (23)
Years of experience conducting research with people with dementia	1-7 years	45% (26)
	8-15 years	19% (11)
	> 15 years	36% (21)
Population focus of research	People with dementia in community settings	27% (15)
	People with dementia in institutional settings	14% (8)
	Mix of both	59% (33)
Experience involving people with dementia as co-researchers	Yes	46% (29)
	No	54% (34)
Discipline of research	Other*	22% (13)
	Psychology	21% (12)
	Medicine	17% (10)
	Nursing	17% (10)
	Neuroscience	14% (8)
	Allied health	9% (5)
	**Other areas specified were health services research, pharmacy, palliative care, social sciences and arts.*	
Experience serving on a human research ethics committee	Yes	37% (36)
	No	63% (21)
Gender	Female	71% (41)
	Male	22% (13)
	Other/prefer not to say	7% (4)

Demographic questions were divided between the start and end of the survey; complete demographic data is not available for respondents who did not finish the survey. Frequencies may not add to 63 due to missing data. Percentages are calculated based on number of responses to the specific question.

Awareness of National Statement guidance

A majority of respondents (66%, n=42) were unsure whether the National Statement contains guidance on advance research decisions/directives; 11% (n=7) said yes and the remainder (n=14) said the Statement does not provide such guidance.

Attitudes about ARDs

Perceived benefits, disadvantages and acceptability of ARDs to ethics committees

A majority of respondents – 78 to 87% – agreed or strongly agreed with the possible benefits of ARDs as listed in Table 2. These benefits relate to autonomy in decision-making, informing others of a person's wishes and enabling appropriate inclusion in research.

Table 2: Benefits of advance research directives in dementia research (n=63)

Respondents' agreement with benefits of ARDs	% (n) agree / strongly agree
Enable people to make their own choices about future research participation	87% (55)
Help other decision-makers know the wishes of the person with impaired capacity	87% (55)
Help researchers know the wishes of a person with impaired capacity	84% (53)
Help to include people with impaired capacity in research	81% (51)
Provide HRECs with evidence of the wishes of a person with impaired capacity	78% (49)

Just over one-quarter of respondents (27%, n=17) added text box comments that elaborated on the benefits of ARDs. For the person planning for cognitive decline, making a directive would give them "the benefit of knowing they can contribute to research after they no longer have capacity to consent." Expanding on the importance of people making their own choices, ARDs could promote "dignity and respect for the person with dementia" and avoid "formal and informal 'gatekeepers' speaking for the person without considering their preferences." Further, a valid ARD could help to ensure a "proxy does not disrespect or overrule" the person's documented wishes either in favour of or against participating in research.

Beyond the benefits for the person who makes a directive, ARDs could "perhaps provide some formality and protection for [those] involved in facilitating recruitment or obtaining informed consent (e.g. researchers, health professionals, family members)." For researchers, ARDs would allow them "to undertake their research with the confidence that the prior consent of the individual has been offered." At a societal level, the promotion of ARDs could help to raise

awareness of research – "Greater awareness of the role of research in improving the lives of people with dementia" – and "develop a culture of inclusivity." It was also suggested that ARDs could streamline ethics review processes: "The processes of obtaining ethics approval and recruitment should be clearer and less time consuming for the researcher, thus reducing costs of research."

Respondents had more divided views on the disadvantages of ARDs, as shown in Table 3. Substantial proportions had concerns about ARDs not being available when needed or that ethics committees would not accept ARDs. Few respondents perceived ARDs as less reliable than consent from a substitute decision-maker.

Table 3: Disadvantages of advance research directives in dementia research (n=62)

Respondents' agreement with disadvantages of ARDs	%(n) agree /strongly agree
Time lag between person making ARD and losing capacity may mean directive is not available when needed (eg, has been misplaced)	71% (44)
HRECs might not accept ARD as valid evidence of consent	60% (37)
ARD would not adequately protect the interests of person with impaired capacity	42% (26)
ARD are not as reliable as seeking consent from a substitute decision maker for the person with impaired capacity	11% (7)

Just over 40% of respondents (42%, n=26) added written text box comments elaborating on potential difficulties with ARDs. Half of those (n=13) noted the importance of periodically reviewing and updating directives to record any changes in preferences, as well as the need for assent processes at the time of study activities to determine, where possible, the person's current wishes about participation. (The survey explored this issue in a later question on what should override an ARD.) Several respondents expressed concern that the practice of using ARDs could create a new form of exclusion from research if ethics committees come to expect them as evidence of a person's wishes: "introducing this practice [ARDs] could lead to less involvement

of people with dementia in research, because once it becomes accepted practice HRECs might require ARDs from all people with dementia as a blanket policy approach."

However, when asked whether the ethics committee they deal with most often would accept an ARD as a valid expression of a person's willingness to participate in research, over half (56%, n=33) of respondents were unsure. Around a quarter (24%, n=14) believed their committee would be likely to accept an ARD while 20% (n=12) thought the opposite.

Willingness to offer an ARD

As reported in Table 4, a majority of respondents – 57 to 80% – would offer participants an opportunity to make an ARD in relation to a wide range of research activities. Slightly under half (48%) would offer an ARD covering future pharmaceutical studies.

Table 4: For what activities would researchers offer an ARD to participants? (n=60)

Research activity	Would definitely or probably offer
Putting a device on the body (example: bracelet) that keeps track of information about the person such as their activity level	80% (48)
Testing cognitive abilities (example: assessing memory)	75% (45)
Observation of behaviour	73% (44)
Surveys or interviews	72% (43)
Taking physical measures (example: weight, blood pressure)	72% (43)
Accessing personal records, such as medical records or test results	70% (42)
Accessing previously collected body tissues, blood or other body fluids	63% (38)
Taking a sample of blood or other biospecimen for genetic research (example: to identify genetic risk factors for dementia)	63% (38)
Taking x-rays or scans	62% (37)
Taking a sample of blood or other biospecimen for non-genetic studies (example: for a study investigating a link between infection and dementia risk)	62% (37)
Giving physical therapy (example: massage or other non-invasive therapies)	62% (37)
Giving psychological therapy (example: counselling for anxiety or depression)	57% (34)
Giving experimental medicines	48% (29)

Factors that should override an ARD

When asked about factors that should override an ARD, nearly all respondents (92%, n=54) agreed or strongly agreed that a participant's current objection or dissent should override prior consent stated in an ARD. Written text box comments elaborated on this point: "An individual may still change their mind and withdraw their consent after an ARD giving consent. It is important that researchers are able to assess 'assent', i.e. no visible signs of disagreement or distress in participants."

Around half of respondents (49%, n=29) thought the objection of a family member or carer should override an ARD. Slightly fewer respondents agreed that the objections of a health practitioner for the person (42%, n=25) or an ethics committee (37%, n=22) should override an ARD. Just over 20% of respondents (22%, n=13) volunteered other circumstances in which an ARD should not be followed, including: changes in ethics norms, such that research agreed to in an ARD is subsequently considered ethically or scientifically unjustified; the risks of participating in a study outweigh the potential benefits; or the validity of the ARD is questioned, such as "clear and compelling evidence that the person signed under duress or when they were already impaired to the extent they would not have been aware of the decision and its consequences."

Table 5: Overriding an ARD (n=59)

If a person made an ARD agreeing to participate in research during periods of incapacity, which of the following do you think should override the wishes stated in the ARD?	**Agree**	**Neutral**	**Disagree**
The participant who made the ARD and now lacks capacity expresses an objection to a research activity (eg, through body language or verbalisation)	92% (54)	2% (1)	7% (4)
A family member or carer for the person who made the ARD expresses an objection	49% (29)	24% (14)	27% (16)
A health practitioner for the person who made the ARD expresses an objection	42% (25)	22% (13)	36% (21)
A human research ethics committee expresses an objection	37% (22)	36% (21)	27% (16)

.Note: Data are pooled for 'strongly agree' and 'agree' responses and for 'strongly disagree' and 'disagree'

Experiences with ARDs

Nearly all respondents (95%, n=55) reported they had not used or proposed the use of an ARD as a way to document a person's preferences for research participation during future periods of incapacity. One respondent who reported use of an ARD noted s/he is part of an international research team and investigators in another country are seeking advance consent at the time of study enrolment for post-mortem brain autopsy. Another respondent reported using an ARD for a project that involved follow-up tests on people with mild cognitive impairment. These examples do not reflect the use of ARDs as contemplated in ethics statement and laws, which refer to directives as evidence of the wishes of a person who is alive but lacks decisional capacity.

Discussion

This study reveals that dementia researchers in Australia perceive that ARDs would be advantageous, and while ARDs seem rarely used in practice, the respondents expressed a willingness to offer them for a variety of research activities. The key findings are discussed here with suggestions for ethics guidelines, laws and practices to support the implementation of advance research planning processes, including making ARDs.

Awareness about ethics guidance

Australia's National Ethics Statement encourages researchers and participants to discuss and document preferences about involvement in studies during periods of incapacity. However, a majority of our respondents were unsure about the existence of ethical guidance on advance research decisions/directives. Updating the National Statement to refer explicitly to ARDs would provide clearer direction to researchers, ethics committees, participants and substitute decision-makers. A recent German-Israeli study found that professionals' knowledge and familiarity with

ARDs was higher in Germany than Israel due to public debate over law reforms that included provisions for ARDs.[44] In contrast, the ARD term was unfamiliar to many Israeli professionals, since such directives are not mentioned in local laws and policies. Explicit rules for ARDs would be beneficial to provide a solid ethical and legal foundation, augmented by awareness campaigns and resources to support their use, including education for researchers and ethics committees.

Attitudes about ARDs

Perceived benefits, disadvantages and acceptability to ethics committees

Our survey findings reveal positive views about ARDs among Australian dementia researchers. The respondents perceived that ARDs would promote individuals' decision-making autonomy, provide helpful evidence of a prospective participant's preferences to guide researchers, ethics committees and substitute decision-makers, and support inclusion in research for people with dementia. Similar benefits were highlighted in recent studies of dementia researchers and other stakeholders in the Netherlands, Germany and Israel.[45] A previous study of substitute decision-makers for people with dementia found that proxies who strive to "honor patients' historical values" look for evidence of those values "whether expressed in past conversations or behaviors, or embodied in patients' character traits."[46] For example, in making a choice about her father taking part in a study, one daughter reflected on what he would want: "[W]ould he believe in promoting science and moving forward with knowledge …? Yes. Would he tolerate small amounts of discomfort for a greater benefit? Yes."[47] ARDs could strengthen this decision-

[44] Werner and Schicktanz, *op. cit.* note 23, p. 6.
[45] See Jongsma and van de Vathorst, *op. cit.* note 22; Werner and Schicktanz, *op. cit.* note 23.
[46] Overton, E., Appelbaum, P. S., Fisher, S. R., Dohan, D., Roberts, L. W., & Dunn, L. B. (2013). Alternative Decision-Makers' Perspectives on Assent and Dissent for Dementia Research. *The American Journal of Geriatric Psychiatry.* 21, 346-354, 351.
[47] Ibid.

making process by providing written evidence of the person's wishes and reducing speculation about their preferences and recourse to a generic 'best interests' standard.

The most prevalent downside of ARDs cited by our respondents was the practical concern that the time lag between making and needing the directive might mean it cannot be located. This problem could be overcome in the context of dementia research registries and longitudinal studies that recruit participants at pre- or early symptomatic phases.[48] In these circumstances, researchers could engage participants in advance research planning and maintain copies of ARDs to inform future decisions when necessary. To the extent that research planning is incorporated into a process of advance care planning – as done in a Canadian study[49] – the importance of sharing documents with key others and storing copies in an accessible and known location would need to be emphasized,[50] including adding ARDs to electronic health records.

Many researchers were concerned about ethics committees not accepting an ARD as valid evidence of willingness to take part in research. Clear ethical and legal rules for making and using ARDs are important to minimise uncertainty about their status; new legislation in the Australian state of Victoria, summarised earlier, provides one model. Other attitudinal barriers to ARDs also need to be countered; for example, a previous survey of American and Australian researchers in ageing fields reported that ethics committees may have "overly protective and

[48] Nuno, M. M., Gillen, D. L., Dosanjh, K. K., Brook, J., Elashoff, D., Ringman, J. M., & Grill, J. D. (2017). Attitudes toward clinical trials across the Alzheimers disease spectrum. *Alzheimer's Research & Therapy*. 9, 81.
[49] Bravo, et al., (2016), *op. cit.* note 30.
[50] A recent expert consensus panel on the outcomes of successful advance care planning stressed the importance of directive documents being accessible when needed: Sudore, R. L., Heyland, D. K., Lum, H. D., Rietjens, J. A. C., Korfage, I. J., Ritchie, C. S. … You, J. J. (2018). Outcomes That Define Successful Advance Care Planning: A Delphi Panel Consensus. *Journal of Pain and Symptom Management*. 55, 245-255.e248.

potentially patronizing or ageist" views about involving older people with dementia in research.[51]

Contrariwise, several respondents worried that ethics committees might come to expect or require ARDs as evidence of agreement to research for participants with cognitive impairment, a drawback that Muthappan et al identified in a prior study of the uptake of ARDs among people admitted to a clinical research hospital.[52] This would be an unintended and undesired outcome of promoting ARDs and training for ethics committees would need to discourage such blanket approaches. Moreover, ARDs should only be referred to in cases where the prospective participant does not have current capacity to consent.

Willingness to offer an ARD

Our results indicate that many researchers would be willing to offer ARDs to prospective participants. Some guidance documents recommend that ARDs should prompt people to articulate their preferences according to different types of research activities and the levels of risk or burden that may be involved.[53] Our study provides insights into the research activities that researchers believe would be suitable to cover in an ARD. In a separate survey study, we asked people aged 60 years and older attending hospital outpatient clinics (n=174) whether they would

[51] Pachana, N. A., Liddle, J., Peel, N. M., Beattie, E., Juang, C., & Knight, B. G. (2015). Can we do better? Researchers' experiences with ethical review boards on projects with later life as a focus. *Journal of Alzheimer's Disease*. 43, 701-707, 704. Inconsistency in ethics committee decision-making is also a concern; for discussion see eg, Trace, S., & Kolstoe, S. E. (2017). Measuring inconsistency in research ethics committee review. *BMC Medical Ethics*. 18, 65.

[52] Muthappan, et al., *op. cit.* note 26. All patients admitted to an NIH research hospital were given an opportunity to make an advance research directive. During the six month study period, 11% of the patients (261 of 2,371) completed an ARD. Of these, just 13% said they would not want to be involved in any research during future periods of incapacity. The authors noted that many people might be willing to be involved in research but not formalise their preferences in a written directive. Thus "proposals to require a formal research advance directive could exclude many impaired adults whose competent preferences supported research participation": p. 2390

[53] Alzheimers Europe, *op. cit.* note 3; Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. (2014). *Tri-Council Policy Statement 2*. Retrieved from http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf. See discussion of Research Directives: pp. 44-46.

want to be included in these same research activities if they had dementia-related cognitive impairment.[54]

The views of researchers were largely consistent with those of older adults, with some exceptions. A majority of researchers stated they would offer an ARD for a wide variety of research activities and older adults indicated they would be willing to participate in a range of research activities if they had dementia. Interestingly, while some literature on ethical issues in dementia raises privacy concerns about wearable devices,[55] our respondents' willingness to offer an ARD was highest for research that would involve wearing a device that tracks behavioural or physiological data. A large majority of our outpatient survey respondents (92%) said they would be willing to be included in this research activity during future periods of dementia-related incapacity.

The researchers' willingness to offer an ARD dropped to just over 60% for the activity of taking blood or other biological samples for genetic or non-genetic research. In contrast, previous studies of the views of older people, including those with a dementia diagnosis, on future research participation during periods of decisional incapacity show that 80 to 90% would be agreeable to blood draws for research.[56] Our outpatient survey found a similarly high level of agreement of over 90% for blood draws for both genetic and non-genetic studies. The extensive

[54] Ries, N. M., Mansfield, E. & Sanson-Fisher, R. Planning Ahead for Dementia Research Participation: Insights from a Survey of Older Australians and Implications for Ethics, Law and Practice. *Journal of Bioethical Inquiry* (manuscript accepted for publication).
[55] Meiland, F., Innes, A., Mountain, G., Robinson, L., van de Roest, H., Garcia-Casal, J. A. … Franco-Martin, M. (2017). Technologies to Support Community-Dwelling Persons With Dementia: A Position Paper on Issues Regarding Development, Usability, Effectiveness and Cost-Effectiveness, Deployment, and Ethics. *JMIR Rehabil Assist Technol*. 4(1), e1.
[56] Bravo, et al., (2016), *op. cit.* note 30; Karlawish, J., Rubright, J., Casarett, D., Cary, M., Ten Have, T., & Sankar, P. (2009). Older Adults' Attitudes Toward Enrollment of Noncompetent Subjects Participating in Alzheimer's Research. *American Journal of Psychiatry.* 166(2), 182-188.

debates over the ethics of biobanking and genomics research[57] may influence researchers to hold more conservative views on ARDs for future blood draws than those held by members of the public.

Our survey results add to existing studies that indicate greater hesitance about involving people with impaired capacity in experimental drug studies. Just under half of our researcher respondents (48%) would offer an ARD to a person to express their preferences about future pharmacological research. In our outpatient survey, willingness to be involved in drug studies during future periods of incapacity attracted the lowest level of agreement: 60% compared to over 90% for all the other listed research activities. In a Canadian trial of an advance research planning intervention, around 65% of older people expressed willingness to be included in a pharmaceutical study if they had severe dementia.[58] Older Americans involved in a longitudinal study on cognitive ageing also reported a lower level of interest in taking part in dementia drug trials compared to other research activities.[59] These findings suggest a need to ensure that recruitment strategies provide accurate information about risks and the safety protections for participants in drug studies.[60]

[57] See e.g. Grady, C., Eckstein, L., Berkman, B., Brock, D., Cook-Deegan, R., Fullerton, S. M. … Wendler, D. (2015). Broad Consent for Research With Biological Samples: Workshop Conclusions. *American Journal of Bioethics.* 15(9), 34-42; Caulfield, T., & Murdoch, B. (2017) Genes, cells, and biobanks: Yes, there's still a consent problem. *PLoS Biology.* 15(7), e2002654.
[58] Bravo, et al., (2016), *op. cit.* note 30.
[59] Calamia, M., Bernstein, J. P. K., & Keller, J. N. (2016) I'd Do Anything for Research, But I Won't Do That: Interest in Pharmacological Interventions in Older Adults Enrolled in a Longitudinal Aging Study. *PLoS ONE*. 11(7), e0159664.
[60] Fargo, K.N., Carrillo, M.C., Weiner, M.W., Potter, W.Z., & Khachaturian, Z. (2016). The crisis in recruitment for clinical trials in Alzheimer's and dementia: An action plan for solutions. *Alzheimers & Dementia*. 12(11), 1113-1115.

Overriding an ARD

The survey findings reveal researchers' awareness of the need to balance respect for the precedent autonomy of people who express preferences in ARDs with adequate protections if they are later involved in research when their cognitive abilities are impaired.[61] Most notably, the results demonstrate the importance that researchers place on eliciting and respecting the present-day preferences of a person with cognitive impairment, with over 90% stating that current dissent should override agreement previously documented in an ARD. Studies in other countries reveal a similar emphasis on seeking assent and respecting dissent. All but one dementia researcher in a Dutch study said that current dissent should override an ARD.[62] Bravo et al's study in Canada found that nearly 80% of surveyed researchers seek the assent of an older person with cognitive impairment before undertaking a study activity.[63] A US study that examined key informants' views on assent and dissent in dementia research emphasised "the primacy of respecting an individual's objection to participating in research."[64]

A majority of our respondents indicated an ARD would be more reliable than seeking consent from a substitute decision-maker, consistent with empirical studies that show discordant views between individuals and their proxies about research participation.[65] Yet, half of the respondents thought an objection of a family member or carer should override wishes stated in an ARD. Similarly, Dutch researchers would want consent to research as documented in an ARD confirmed by a decision-maker for the person who lacks capacity.[66] A Welsh study of an advance decision-making process in a nursing home found mixed views on this issue, with

[61] Jongsma and van de Vathorst, *op. cit.* note 22.
[62] Jongsma and van de Vathorst, *op. cit.* note 22. This qualitative study involved 13 interviewees.
[63] Bravo, et al., (2016), *op. cit.* note 30.
[64] Black, B. S., Rabins, P. V., Sugarman, J., & Karlawish, J. H. (2010). Seeking Assent and Respecting Dissent in Dementia Research. *The American Journal of Geriatric Psychiatry*. 18(1), 77-85.
[65] Bravo, et al., (2016), *op. cit.* note 30.
[66] Jongsma and van de Vathorst, *op. cit.* note 22. This qualitative study involved 13 interviewees.

facility staff preferring to seek permission from an authorised decision-maker and local GPs believing this to be unnecessary if the resident had given advance consent.[67] Residents and family members had mixed views on whether relatives should be consulted and what should happen if they disagreed with the resident's prior consent to research participation. A point of consensus in the German-Israeli study of professional stakeholders was that "the role of the proxy remains very important as a safeguard … the proxy needs to balance the patient's [current] welfare and … wishes" stated in an ARD.[68]

The characterisation of autonomy offered by Werner and Schicktanz helps to reconcile the apparent tension between respect for the person who made an ARD and the role of proxies. They describe autonomy "as being relational, processual, and as self-expression through the support and interpretation of others."[69] In other words, the proxy, in their relationship with the person with reduced cognitive capacity, could use supported and shared decision-making processes to enable the person to articulate their current wishes for as long as possible.[70] Using this approach, neither the ARD nor the proxy alone speak for the participant; rather, her or his contemporary preferences are elicited to guide, but not necessarily dictate, decision-making.

A rule that current dissent must be followed may not, however, take adequate account of the nuances that substitute decision-makers encounter. Overton et al's study of assent and dissent in dementia research found that some decision-makers would override indications of dissent in

[67] Wood, et al, *op. cit.* note 20.
[68] Werner and Schicktanz, *op. cit.* note 23, p. 5.
[69] Werner and Schicktanz, *op. cit.* note 23, p. 3.
[70] Findings from a current European research project on supported decision-making in clinical dementia research will be valuable to inform practical strategies in this context: Haberstroh, J., Oswald, F., & Pantel, J. (2017). ENSURE Project: Supported Decision-Making and Capacity Assessment in Clinical Dementia Research. *Innovation in Aging*. 1, 729. An Australian team has recently produced guidance on supported decision-making for people living with dementia, however it does not focus specifically on decision-making to participate in research: see Cognitive Decline Partnership Centre. (2018). *Supported Decision-Making*. Retrieved from http://sydney.edu.au/medicine/cdpc/resources/supported-decision-making.php.

situations of "minor inconveniences or discomforts" where they believed that taking part in the research was consistent with the person's long-held values. For example, if the person with dementia expressed boredom or mild discomfort with a research activity, some decision-makers would encourage them to persist and take part. Black et al suggested that signs of dissent must be respected if they are sustained after efforts to address a participant's concerns.[71]

Practical experience with ARDs – a gap to address in future work

Almost no one in our respondent group of experienced dementia researchers had used an ARD. In addition to clearer ethical and legal rules for such directives, there is a need for evidence-informed resources and training to support advance research planning. Further studies are needed that involve key stakeholders, including people with conditions that affect cognition, research participants, substitute decision-makers, researchers and ethics committees. As a follow-up to this survey study, we plan to conduct qualitative interviews with a subset of respondents to explore their views on the content to include in an ARD template and processes for advance research planning, including feasibility, acceptability and implementation aspects.

Well-designed intervention studies are needed to investigate the processes and outcomes of advance research planning strategies. Previous American and Canadian trials used a dyadic approach involving older people and their family carers or proxies, with differing approaches to ARD documentation. The American study asked participants to express their preferences in relation to five hypothetical clinical trials involving varying levels of risk: blood draw for an Alzheimer disease test; blood draw for genetic marker; experimental oral medication; lumbar puncture for Alzheimer disease marker; and intracranial stem cell implant.[72] The Canadian study used a basic ARD template that offered several choices about future research participation: no

[71] Black, et al., *op. cit.* note 63.
[72] Stocking, et al., *op. cit.* note 7.

participation regardless of benefits or risks; consent to research that might offer personal benefits; consent to research with no personal benefits but that might benefit others; or both of the latter options.[73] The template included space for people to note any special interests in or objections to particular areas of research. An ARD template based on the categories used in our survey could be developed to allow choices for a range of research activities, including observations of behaviour, bloods draws for genetic and non-genetic studies, imaging procedures, and physical and psychological therapy interventions. Preferences for future uses of biosamples and records could also be documented, as recommended by a recent expert panel on consent to dementia research and data sharing.[74]

The impact that ARDs would have on increasing or decreasing research participation remains to be seen, however several study findings suggest they could support inclusion and ameliorate the underrepresentation of people with cognitive impairment in research. In the Canadian RCT study a majority of older people documented preferences in favour of future research participation.[75] An earlier study by Muthappan et al also found that 87% of people who made an ARD expressed willingness to take part in future research.[76] Our outpatient survey revealed strongly positive attitudes among people aged 60 and older in being involved in research during future periods of incapacity and a large majority (79%) expressed interest in making an ARD if they had the opportunity to do so.

[73] Bravo, et al., (2016), *op. cit.* note 30.
[74] Hake, A. M., Dacks, P. A., Arnerić, S. P., & CAMD ICF Working Group. (2017). Concise informed consent to increase data and biospecimen access may accelerate innovative Alzheimer's disease treatments. *Alzheimer's & Dementia: Translational Research & Clinical Interventions*. 3, 536-541; Thorogood, A., Deschenes, S. C., & Knoppers, B. M. (2017). Substitute consent to data sharing: a way forward for international dementia research? *Journal of Law and the Biosciences*. 4, 133-158.
[75] Bravo, et al., (2016), *op. cit.* note 30.
[76] Muthappan, et al., *op. cit.* note 26.

Limitations

The results are limited by the sample size, however the respondents represent an experienced group of dementia researchers with nearly 40% having served on a human research ethics committee. The survey instrument used fixed choice questions and provided optional text boxes for respondents to add comments. Many of them did so, however this method does not allow for detailed exploration of their attitudes and experiences. As noted above, a planned follow-up interview study will provide additional qualitative data on ARD content and advance research planning processes.

Conclusion

This study showed that Australian dementia researchers perceived a number of advantages to using ARDs and, although few respondents had used ARDs in practice, a majority of respondents indicated they would be willing to offer ARDs for a range of research activities. These results suggest dementia researchers would be receptive to implementing advance research planning processes, which would be enabled by improved clarity and awareness of ethical and legal rules.

In the context of dementia research, ARDs could enable people at early stages of a diagnosis to document their preferences for being involved in research activities as their symptoms progress. The lessons learned from the extensive research and experience with advance care planning can be used to inform strategies to support research planning.[77] In particular, any kind of advance

[77] See e.g, Jimenez, G. (2018). Overview of Systematic Reviews of Advance Care Planning: Summary of Evidence and Global Lessons. *Journal of Pain and Symptom Management.* 56(3), 436; Bryant, J., Turon, H., Waller, A., Freund, M., Mansfield, E., & Sanson-Fisher, R. (2018). Effectiveness of interventions to increase participation in advance care planning for people with a diagnosis of dementia: A systematic review. *Palliative Medicine*, doi: 10.1177/0269216318801750; Piers, R., Albers, G., Gilissen, J., De Lepeleire, J., Steyaert, J., Van Mechelen, W. … Van den Block, L. (2018). Advance care planning in dementia: recommendations for healthcare professionals. *BMC Palliative Care*. 17(1), 88; Gilessen, J., Pivodic, L., Smets, T., Gastmans, C., Vander Stichele, R., Deliens, L., &

planning should be understood not as a one-time completion of a directive but as an ongoing process of reflection and communication with key others, including substitute decision-makers.[78] A written directive provides valuable evidence of a person's values, wishes and preferences and should be periodically reviewed and updated as necessary for as long as the person is able to do so, including with supportive communication and decision-making strategies.

Van den Block, L. (2017). Preconditions for successful advance care planning in nursing homes: A systematic review. *International Journal of Nursing Studies*. 66, 47-59.

[78] Sudore, et al., *op. cit.* note 50.

CONCLUSION

Thesis overview

The population is ageing in many countries around the world and more people are living longer with chronic co-morbidities, including dementia and other neurocognitive disorders.[1] These demographic facts have prompted attention to the quality of care and quality of dying for older people with serious illness, with a concomitant focus on advance care planning (ACP) as a way for people to communicate their wishes and exert some control over future medical care during periods of incapacity. Laws in various countries support ACP,[2] and when done well, such planning can benefit patients, their substitute decision-makers and loved ones, clinicians and healthcare systems.[3] It can help to reduce the provision of unwanted and expensive medical interventions, improve the uptake of palliative care, and reduce stress and conflicts among family members and care providers.[3] Yet many older adults do not act on their legal rights to make advance directives or appoint substitute decision-makers.[4] Whole-community approaches that involve "innovative public policies, community initiatives and educational programs"[4(p4)] are now needed to improve the uptake of advance planning.

Effective healthcare and supports for older people depend on high-quality research that involves relevant patient populations, including those with dementia. Older people are generally underrepresented in clinical research,[5,6] and people with dementia have often been excluded from studies; this has limited the evidence to inform care, especially at moderate to advanced illness stages and the end-of-life period.[7] Strategies are needed to support inclusion in research of older people living with cognitive impairment, particularly to ensure that their values and preferences guide decisions about research participation during periods of decisional incapacity. Improving

participation in research can strengthen the evidence for care options for older people living and dying with dementia.

A comprehensive approach to advance planning for health-related matters

This PhD thesis has focused on advance planning for health-related matters, encompassing healthcare treatment and participation in research. The thesis has advocated a comprehensive approach to advance health planning, which has two implications. First, it means that planning for future research participation can be integrated into ACP processes. Second, it means that if advance research planning is done separately from ACP – for example, at the point of enrolment into a longitudinal study on ageing – the research evidence on implementing ACP can inform processes to support research planning.

While this thesis advocates this comprehensive approach, the differences between treatment and research are acknowledged. Healthcare treatment is provided to benefit the patient, and consent or refusal choices for interventions are not optional when clinicians require input on care, such as for a person who lacks decisional capacity in the final stages of dementia or other terminal illness. In contrast, participation in research is optional and often offers no or limited prospect of benefit for the participant. In addition, advance care directives have typically been viewed as instruments to protect against unwanted interventions. Patients with written directives are less likely to receive invasive interventions,[8] suggesting their dominant purpose may be as evidence of refusal of consent (and advance care directives cannot be used to compel treatments that are "futile" or not clinically indicated[9]). Advance research directives, however, are typically characterised as a means for people to indicate the types of research they would be willing to be involved in during future periods of incapacity.

Despite these differences, advance planning for treatment and research promotes the same core interests and goals. Expressing and communicating one's values and wishes respects individual autonomy and enables a person who anticipates loss of capacity to exercise a degree of control over what happens to them in the future. Advance planning also guards against the will of others overriding that of the individual and provides greater certainty about the values and preferences of that person to inform the actions of others, including substitute decision-makers, healthcare providers, researchers and ethics committees. Ultimately, effective planning should help to avoid or minimise ethical dilemmas and legal disputes in the future.

Identifying and responding to research gaps – from care planning to research planning

An international expert panel recently defined ACP as a process that supports people to consider and communicate "their personal values, life goals, and preferences regarding future medical care. The goal of [ACP] is to help ensure that people receive medical care that is consistent with their values, goals and preferences during serious and chronic illness".[2(p826)] Such planning may involve selecting and preparing a substitute decision-maker to make choices if called on to do so and documenting values and preferences in an advance directive.

Similar to the process for ACP, advance planning for research participation involves reflecting on and articulating one's preferences for being involved in research during future periods of incapacity and choosing a substitute decision-maker to make choices about study participation, if needed. Compared to ACP, there has been scant attention to advance research planning in the 20 years since the concept was endorsed by the United States National Bioethics Advisory Commission.[10] Renewed interest in the topic is now emerging as dementia advocacy organisations, researchers and other stakeholders seek to engage people with dementia in research and ameliorate the impacts of their past exclusion.[7,11,12,13]

Changing behaviour and the need for strategies at individual, practitioner and system levels

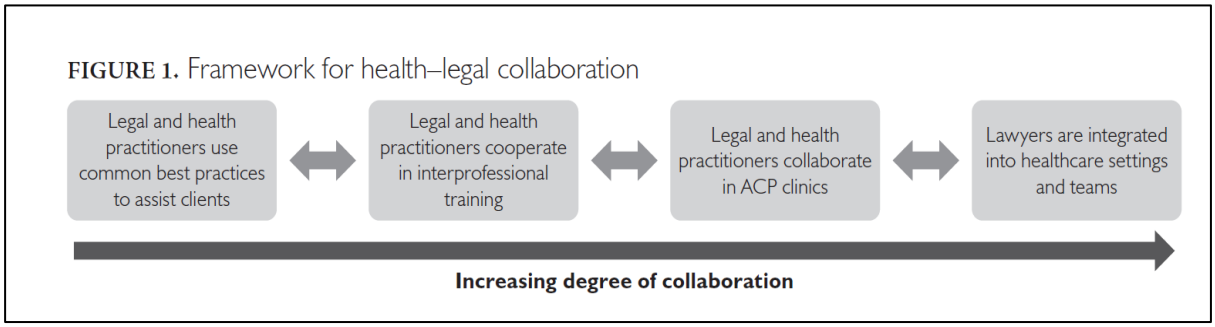
For the reasons noted above, it is desirable to improve the uptake and quality of advance planning for treatment and research among older people, especially those living with dementia. Achieving these goals requires strategies to overcome the barriers to advance planning that exist at person, practitioner and system levels. This PhD research has advanced knowledge relevant to all these levels. At the system level, the research has analysed the legal and ethical frameworks that govern advance planning and set out specific rights, restrictions and processes. At the individual and practitioner levels, the empirical studies have produced original findings that reveal under-examined perspectives, including lawyers' role in ACP and the views of older people and researchers on dementia research participation. This descriptive research is important to understand current attitudes and practices, which is necessary to inform future intervention research to test strategies that support desired behaviour changes.[14] Comparative perspectives have been incorporated by empirical work conducted in Australia and Canada and also by considering the PhD research findings in the context of internationally available literature on the topic of advance planning for care and research.

This concluding chapter has three aims: (1) to present the key thesis research findings that advance knowledge in the field; (2) to comment on lessons learned in the conduct of the empirical studies for this PhD thesis and the strengths, limitations and challenges of this work; and (3) to identify areas for future research, especially to advance collaborations across health and legal sectors that support older people in planning for healthcare and participation in research.

Key findings

1) Several strategies can build collaboration between health and legal sectors to support advance planning activities.

Advance planning for health-related matters is an area where law and healthcare intersect. A conclusion across the PhD papers is that strategies to connect the health and legal sectors are needed to improve practices and overcome the barriers to planning at individual, practitioner and system levels (discussed in Paper 1). The strategies to support health-legal collaboration exist along a spectrum from low to high levels of connection. An important contribution of Paper 2 was the development of a framework for health-legal collaboration (Figure 1).



At one end of the spectrum, legal and health practitioners work in their usual professional contexts (or siloes) but use common best practices to assist their clients with advance planning on health-related matters. The other end of the spectrum represents the highest level of collaboration whereby lawyers are integrated in healthcare settings and teams. The medical-legal partnership model, which was discussed in Papers 1 and 2, is an example of this kind of integration.

2) Lawyers are an under-investigated professional group who have an important role in assisting clients with advance planning.

As reported in Paper 1, research conducted in several countries shows that people who have written healthcare directives are much more likely to have received help from lawyers than doctors in preparing the documents. For instance, a survey in one Canadian province found that half of people over age 55 who reported having written directives (25% of the survey sample) had obtained assistance from lawyers while a mere 4% had consulted doctors.[15] An American study of ACP among people with dementia found that this group identified lawyers as important advisors.[16] Lawyers have a professional role in ensuring that clients have comprehensive and accurate advice about their legal rights to plan ahead for future incapacity. Discussions about these rights can stimulate clients' readiness to engage in advance planning behaviours, a point supported by White et al's finding that people who have advance care directives are more likely to have made other advance planning documents, such as wills and financial power of attorney.[17] Despite the important role of lawyers in advising on and normalising advance planning, Paper 1 reported that no empirical studies have sought data from legal practitioners about their attitudes and practices in relation to assisting clients with ACP. The survey of lawyers conducted in Alberta, Canada (Paper 3) addressed this gap. While the response rate was low (discussed further below), the survey respondents represented an experienced group of practitioners who regularly engage with clients on ACP. Over three-quarters of respondents (77%) reported ten or more years of experience in legal practice, and 69% reported they assisted clients with ACP on a daily or weekly basis.

A barrier to engaging people in ACP is that no professional group – at least in the health system – sees ACP as a core responsibility, and conversations can "easily get squeezed out"[18] of busy clinical practice. For some lawyers, however, advising clients on ACP is a central part of their

work. Ninety percent of our survey respondents said they often or always raise ACP as part of a broader discussion about planning for incapacity and death, such as writing a will and appointing a decision-maker to manage financial matters during future periods of incapacity. Respondents also had consistent views about the activities they believe are a significant part of a lawyer's role, including initiating advance planning conversations, providing advance planning information, drafting legal documents and advising on how to minimise future disputes. Echoing findings from studies of health professionals,[19] lawyers reported that clients' lack of preparedness to engage in ACP was a commonly encountered barrier.

The findings reported in Paper 3 refute some common criticisms of lawyers' involvement in ACP, for example (as summarised in Paper 1) that they focus on the one-time preparation of legal documents and do not encourage clients to discuss their wishes with key others. Nearly all respondents to the lawyer survey (99%) said they always or often encourage clients to speak to the persons they appoint as their substitute decision-makers, and nearly 80% said they always or often encourage conversations with family members, carers or friends other than the named decision-makers. However, the findings exposed the professional siloes that exist between law and healthcare. An issue of concern is that many lawyers (75%) said they discuss medical issues with their clients (e.g. wishes regarding cardio-pulmonary resuscitation, tube feeding and other medical interventions) while, at the same time, nearly half expressed concern about their own lack of knowledge about the medical aspects of ACP and health sector policies and practices. Most lawyers (83%) did not perceive contact with their clients' healthcare providers as part of their professional role, and less than half (44%) said they often or always encourage their clients to talk to their doctors about their wishes for future care. About half of this experienced respondent group said they did not know about two key initiatives promoted by the Canadian

provincial government health department to promote consistent practices in how advance care directives are stored and shared.

In regard to advance research planning, about three-quarters of lawyers sometimes or regularly ask their clients during ACP discussions about their wishes regarding participation in medical research. These questions are probably more likely to relate to post-mortem body or tissue donation for research, rather than to participation in research while alive but incapacitated. However, as discussed in Paper 5, the fact that lawyers raise research-related questions with their clients highlights the fact they are a professional group to involve in increasing the uptake of advance planning for research, especially where laws recognise advance research directives.

These major findings underscore a need for strategies to foster connections and collaboration across health and legal sectors, both to support client readiness to engage in advance planning behaviours and to improve practitioners' competencies to assist clients in reflecting on and communicating their wishes and preferences. Since publishing Papers 1–3, I have been contacted by the American Bar Association's Commission on Law and Aging in relation to a new initiative being launched in the United States (US) to improve collaboration across legal and health sectors to promote ACP (personal communication with Charles Sabatino). A national summit was held in Washington DC in February 2018 to bring together "legal and clinical experts in advance care planning to identify best practices that will promote greater collaboration and synergy between the two professions to better assist clients and patients and their families in meaningful and effective advance care planning" (summit document on file with candidate). This project aims to produce best practice guidelines with practical resources "to educate and empower legal and medical professionals to be part of a shared, collaborative strategy to ensure that the goals and wishes of the individuals they serve are incorporated into their care, regularly reviewed, and

honored throughout their life course" (summit document on file with candidate). The chair of the Commission on Law and Aging sought permission to distribute Paper 3 to the attendees at this national summit. This American initiative will be important to follow as it progresses.

3) Older adults and researchers have positive attitudes toward involving people with dementia in research and in using advance research directives as a means to communicate preferences for future research participation.

The survey of outpatients aged 60 and older (Paper 5) is the first of its kind in Australia and provides new insights into the views of older people on participation of people with dementia in research. Similarly, the findings of the national survey of dementia researchers in Australia (Papers 6 and 7) reveal new knowledge about the views and experiences of this group on the ethical aspects of involving people with cognitive impairment in research. While a previous survey by Pachana et al[20] included researchers in ageing fields from both Australia and the US (n=157), that study focused exclusively on experiences with human research ethics committees. Our survey covered a wide range of topics, including practices in assessing capacity to consent, seeking consent from substitute decision-makers and views on advance research directives (ARDs).

Our surveys revealed positive attitudes among older people and researchers toward the inclusion of people with dementia in research. An overwhelming majority of the outpatient survey respondents reported they would agree to being involved in a wide range of research activities if they had dementia and could not give their own consent. As discussed in Paper 5, these results suggest that older Australians' views are similar to those reported in Canadian and American studies.

As reported in Paper 6, researchers believe it is important to include people at all stages of dementia in research, and a majority do not routinely exclude participants who lack the capacity to give their own consent. In addition, Paper 5 sheds light on whom older people want to be involved in decisions about their research participation; a majority reported they would agree to a family member being involved in the decision. In contrast, a majority of respondents disagreed with or were unsure about a legal body being involved in this decision. This finding demonstrates public support for laws that do not require approval of an administrative tribunal to involve people who lack capacity in research, as discussed in Paper 3. These data were summarised in submissions to the NSW Law Reform Commission's review of the *Guardianship Act 1987*.[21] The May 2018 final report of this review cited these submissions and recommended that the Guardianship Division of the NSW Civil and Administrative Tribunal no longer perform approval and consent functions for involving a person who lacks decisional capacity in ethically approved research.[22(p181)]

Older people and dementia researchers also have positive views toward ARDs. The findings of the outpatient survey (Paper 5) suggest that many older Australians may be willing to make ARDs if offered opportunities to do so. This is consistent with research conducted by Bravo et al in Canada.[23] The respondents to the dementia researcher survey (Paper 7) reported positive attitudes toward ARDs and would offer ARDs to enable people to document their preferences in relation to a range of research activities. Another important finding is that researchers have little experience using ARDs. There is clearly a need to increase awareness among researchers of the process recommended in the National Ethics Statement for researchers to discuss and document wishes for future research participation when a person is recruited to a study, especially if they are at risk of cognitive decline (as discussed in Paper 4).

The researcher survey findings (Paper 7) help to dispel worries that ARDs may be used to carry out research with cognitively impaired individuals in ways that are against their current interests.[24] Over 90 per cent of respondents stated that current dissent expressed by an individual with dementia should override agreement to a research activity that they previously documented in an ARD.

These findings strengthen the case for strategies to support advance planning for research. This is especially important for jurisdictions that have clear laws recognising advance directives for research.

4) Researchers encounter ethical and legal barriers to involving people with dementia in research, and issues related to decision-making capacity and consent are key barriers.

A troubling finding from the study of researchers (Paper 6) was that the majority of the respondents – about three-quarters and above – reported that they encountered ethical, legal and practical barriers to including people with dementia in research. For example, many respondents perceived ethics rules and approval processes to be unduly restrictive (80%) and time-consuming (74%), and difficulties also arose in recruitment (84%) and retention (80%) of participants living with dementia.

Consent-related issues were common concerns for researchers, including assessing the capacity of a person with dementia to give their own consent and processes for seeking consent from substitute decision-makers where necessary. These matters often required considerable discussion and navigation with ethics committees and other gatekeepers. The survey respondents reported a variety of approaches to assessing a prospective participant's capacity to consent to research. It is more common for a member of the research team to assess capacity, rather than an

external assessor such as the person's doctor. However, a range of questions or cognitive screening tools were reported, suggesting a need for greater consistency in practices in this area. The literature review in Paper 1 highlighted inconsistent practices among lawyers in how they assess clients' decisional capacity, suggesting that capacity assessment raises complexities across health and legal fields and there is a cross-sector need for training on capacity assessment and implementation of best (or at least better) practices in this area.

The researcher survey revealed two key findings in relation to ethics committees (Paper 6). First, half of respondents reported that the processes for seeking consent required considerable discussion with ethics committees (more than two rounds of feedback and/or more than one hour of conversation), again suggesting a need for clearer guidance on consent, including strategies to support people with reduced capacity in making their own decisions where possible, as well as guidance on seeking consent from substitute decision-makers. Second, half of respondents reported receiving inconsistent outcomes from different ethics committees, and qualitative comments suggested a need for training for ethics committee members on dementia and inclusive research practices. These findings add to the literature on the challenges that researchers in ageing-related fields can experience in ethics review processes[20] but also highlight the positive and important role that ethics committees have in ensuring appropriate safeguards – 38% of the survey respondents stated that ethics review had strengthened the protections for participants with cognitive impairment.

5) Legal and ethical frameworks act as system-level barriers and enablers to advance planning on health-related matters.

Law and ethics provide the system-level framework within which advance planning occurs. Therefore, the PhD research has incorporated analysis of existing laws, proposals for law reform,

and national and international ethical guidelines. A key conclusion of the research is that advance planning for healthcare treatment and research participation depends on clear legal and ethical rules to enable people to make advance directives and to appoint preferred decision-makers covering both healthcare and research contexts.

As discussed in Papers 1–3, laws in Australia and Canada provide frameworks to support ACP. While there is variation on specific rules and room for harmonisation efforts, at a general level the law allows people to plan ahead for future incapacity, document healthcare preferences in advance care directives, and appoint trusted persons to act as their substitute decision-makers. In contrast, Paper 4's analysis of Australian ethical and legal frameworks for research involving people with cognitive impairment revealed a patchwork of state and territorial laws, with significant variations in whether and how people who cannot give their own consent may be included in research. Paper 4 highlighted the need for Australia to develop more appropriate and consistent rules regarding research participation by people with impaired capacity. Without such reform, the rights of older adults in planning for their future will continue to be impeded. This analysis laid the foundation for the empirical research reported in Papers 5–7.

In the survey of dementia researchers discussed in Paper 6, many respondents reported that they perceived ethical and legal rules and ethics review processes as unduly restrictive or time-consuming. An important conclusion from the research is that legislative variation precludes a consistent approach to research governance and participation, which, in turn, can hinder research needed to inform care and support for people with neurocognitive disorders.

The findings reported in Paper 5 indicated areas where the views of older Australians align with and diverge from ethical and legal frameworks. For example, altruism was reported as a strong motivator for many respondents' interest in being involved in research, and a large majority

(about 90%) would take part in studies that did not offer a prospect of direct benefit but might benefit others. This view aligns with the National Ethics Statement, which states that people with a cognitive impairment are entitled to participate in research for altruistic reasons.[25] However, as discussed in Papers 4 and 5, some laws do not permit a person who lacks capacity to be part of a study if it is about a condition unrelated to that person's own health status. The inconsistency between legal and ethical frameworks is an area for reform and should be guided by the views of community members, including older people and those already living with a dementia diagnosis.

Lessons about the conduct of research

This section reflects on lessons learned from the empirical work undertaken in the PhD studies and how the experiences gained will influence future work. Reflections are also offered on the evidence-based movement in the context of health and legal disciplines, noting the extent to which law lags behind in the use of evidence to inform practice. In the healthcare context, practising in an evidence-based way refers to "the conscientious, explicit, and judicious use of current best evidence in making decisions."[26] Law, however, is often:

> made, administered and evaluated in what often amounts to a scientific vacuum. … Clients are advised, litigants represented and judged, statutes enacted and implemented in important areas of community life on the basis of 'knowledge' which, if it were medical, would place us as contemporaries of Pasteur, if it related to aeronautics, as contemporaries of the Wright Brothers.[27]

Descriptive research – strengths and limitations

It is important to acknowledge the strengths and limitations of the descriptive research undertaken for this PhD thesis. Descriptive studies provide information on the characteristics of a population of interest and allow description of the frequency with which particular views are held or experiences have been encountered. For example, the survey data revealed new information about the attitudes and experiences of several groups on topics relevant to advance

planning for health-related matters. The survey instruments were developed following thorough reviews of literature, including prior qualitative and quantitative studies, and the pilot testing feedback indicated that no major response options were missing. However, the quantitative approach used constrained responses to the fixed-choice questions in the surveys and did not allow for in-depth exploration of attitudes and experiences. The surveys provided some open-ended text boxes for respondents to specify responses other than those listed or to elaborate on their answers. This content was incorporated into Papers 3, 6 and 7 to highlight additional experiences and comments. The respondents to the survey of dementia researchers were asked for their permission to be contacted for a follow-up qualitative interview study. Approximately one-third of respondents agreed to be contacted, and a follow-up study will further explore their views and preferences with respect to ARDs, including sample templates for such directives.

Non-participation bias is noted as a limitation for all three surveys, and respondents who completed the surveys may have more positive views about the topics explored (e.g. advance care planning, participation in research) than would non-responders. Another limitation of the survey of outpatients is that participants were asked to imagine they had dementia-related cognitive impairment, and their views may not necessarily reflect the views of people living with a dementia diagnosis (only one respondent revealed a diagnosis). However, three-quarters of the respondents (76%) said they knew someone with dementia, and therefore they would likely have some understanding of symptoms and support needs, based on their personal experience.

As will be discussed in the final section of this chapter, my goal is to conduct intervention research in the future to develop and trial strategies to promote effective collaboration between the health and legal sectors to improve the uptake of advance planning. The descriptive data from the PhD research provide an important foundation for this subsequent research.

Research in Australia and Canada – strengths and limitations

The PhD study includes research conducted in Canada and Australia, for several reasons. The two countries have similarities in their laws, research ethics rules, healthcare institutions, professional practices, and the challenges of meeting the needs of ageing populations. I have experience working in both countries and collaborate with Canadian and Australian researchers in areas of ACP and dementia. These collaborations have focused on ACP in healthcare settings. After considering the important medico-legal aspects of planning for incapacity, we identified a lack of scholarly attention to the legal profession, as well as a need to extend analysis of planning to include future research participation. Another Canadian research team (with which I do not have connections) has published several studies that are relevant to advance planning for care and research. They analysed Canadian legal and ethical rules governing research participation by people who lack capacity and found significant variations, ambiguities and uncertainties in relevant legislation.[28,29] These findings echo the results of my analysis of Australian ethics guidelines and laws (Paper 3). The Canadian team has conducted one of the few experimental interventions to integrate research directives into a comprehensive process of advance health-related planning. This intervention resulted in 80% of older adult participants documenting their preferences for taking part in future research, with the majority expressing agreement rather than an advance refusal.[23] My analysis of Australian law and ethics and the empirical studies eliciting the views of dementia researchers and older people (Papers 4–7) provided data that can add to the findings of this body of work from Canada, as well as a few other empirical studies on these topics conducted in other countries.[13,30,31]

The limits of drawing comparisons between multiple countries are acknowledged. Even between countries as similar as Australia and Canada, local requirements, practices and attitudes may vary; for example, the advance health planning intervention and directive template developed by

the Canadian researchers had to comply with Québec-specific rules on permissible research involving people unable to give their own consent. This example illustrates the point that research findings and recommendations, as well as specific intervention approaches, need to be adapted to local contexts.

To expand the data available for comparative analysis, I took steps to conduct the lawyer survey in other jurisdictions. My Canadian collaborators and I applied for funding to conduct the survey in three other provinces but were not successful with our application. In addition, I also planned to carry out the survey in New South Wales (NSW) to allow for a comparative analysis of lawyers' attitudes and experiences in Canadian and Australian settings. I obtained ethics approval to conduct the survey and had in-principle agreement from the NSW Law Society to promote the survey in a weekly newsletter to lawyers across the state. However, at about the same time, I received funding for a project on elder abuse that would require engagement with lawyers. As elder abuse is a priority topic for the Law Society, I opted not to proceed with the ACP survey as I did not want to make multiple requests for involvement with research, especially when the Canadian experience demonstrated the recruitment challenges that can arise.

Low response rate for the survey of lawyers

As previously noted, the literature review for Paper 1 yielded no empirical studies investigating how lawyers assist their clients with ACP. This was a major gap to address in this PhD research. However, my collaborators and I were uncertain about the response rate our survey of lawyers in Canada would attract. The Law Society of Alberta advised us that it typically receives a response rate of only 3–4% when it conducts surveys of lawyers. Anti-spam laws prevented direct emails to lawyers who self-identify in Law Society records as practising in the areas of elder law, wills and estates, and health law. As a result, we had to rely on general promotion of the survey

through announcements via websites and online newsletters of relevant legal professional organisations. Ultimately, a survey response rate was estimated at nearly 8%, which was low, but higher than what the Law Society suggested might be achieved. It is noteworthy that the lawyers who completed the survey were an experienced group of practitioners: 77% had been in practice for 10 or more years, and 69% reported they assist clients with ACP on a daily or weekly basis. However, the findings from this sample may not be not representative of the broader population of less experienced lawyers and those who provide only occasional assistance with ACP.

To develop the survey instrument, my collaborators and I engaged extensively with experienced members of the legal profession, including the chairs of professional association groups in elder law, wills and estates, and health law. In hindsight, given the low response rate to the survey, this engagement could have been formalised into a qualitative focus group study to understand how experienced practitioners in these specialist areas assist their clients with ACP.

Research and evidence-based practice – differences in health and legal disciplines

In general, legal and health practitioners receive very different training in research and the need for evidence to inform practice, and this may affect recruitment and participation in research studies. The evidence-based movement has had a transformative impact on education and practice in medicine and health fields; through their university training and in continuing education, professionals are inculcated on the importance of practice supported by research evidence.[32] Evidence-based law and legal practice is, to date, an underdeveloped concept,[33] especially outside the criminal justice field (where criminologists have had more influence in empirical research). Evaluation research is increasingly being undertaken in the legal aid and community legal sectors to provide evidence in support of government funding requests.[34] In regard to law and policy reform, however, recent research found that "policy decisions were

often based on ‘available’ recent evidence of current similar policies performed in other jurisdictions, regardless of the scientific merit or quality of the evidence”.[35] In its recent review of the *Guardianship Act 1987*, for example, the NSW Law Reform Commission recommended a new law that formally recognises supported decision-making but also acknowledged the “limited evidence on the efficacy of the various forms of supported decision-making”.[22(p20)]

Despite some of these shifts in the legal sector, research training in law school focuses dominantly on doctrinal research; that is, teaching the knowledge and skills required to identify and understand legal doctrine (rules), as expressed in legislation and by legal decision-makers such as courts and tribunals. Undergraduate law students who pursue elective subjects in socio-legal research methods may gain a rudimentary understanding of how social science research methods can be applied to investigate how law functions in society. This topic is covered in a single chapter in a 2018 law textbook on research methods, which provides an overview of descriptive quantitative and qualitative research, but not experimental research.[36]

Many legal practitioners will have little or no training and experience in empirical research methods and the hierarchy of evidence. Invitations to participate in research to investigate their attitudes and practices and what works to achieve desired outcomes will be relatively rare for many lawyers, especially those in private practice settings. Recruitment may be a challenge if practitioners do not readily appreciate the importance of research to the advancement of legal practices and institutions. Burdening busy practitioners with research invitations can also deter participation, a consideration noted above in the decision not to pursue a survey of NSW lawyers on advance care planning. Promotion of evidence-based practice by law schools, regulatory authorities and professional associations may, over time, encourage empirical research that involves lawyers and supports participation rates. Legal practitioners are also gatekeepers to

their clients, and engagement with lawyers can advance research that aims to understand clients' views and experiences regarding law and legal service provision. Lessons on recruitment and retention strategies for time-poor medical practitioners can inform studies that seek to recruit lawyers.[37]

Needs of culturally and linguistically diverse groups

While this PhD research did not focus on the specific needs of people from culturally and linguistically diverse (CALD) groups, I acknowledge the importance of advance planning strategies that are accessible and culturally appropriate.[38] The survey of lawyers (Paper 3) found that most respondents (86%) did not perceive that age, cultural or religious differences between them and clients hindered ACP discussions. However, previous studies reveal that the uptake of advance planning is lower among non-Caucasian people, and socio-economic disadvantage and social isolation are also barriers.[4] In general, these populations are less likely to be aware of their legal rights and to access legal services.[39]

As CALD groups are also under-represented in research,[40] with language barriers identified as a key concern,[41] Paper 5 recommended further work on strategies to facilitate advance research planning with CALD groups and to investigate whether doing so would help to address knowledge gaps in relation to ageing and dementia.[42] Resources and strategies recommended in this PhD research, such as toolkits with advance care and research directives, should be accessible in languages other than English. Training for practitioners in health and legal sectors should incorporate knowledge and skills to build cultural competency. Australian research ethics rules address participation from CALD groups,[25] and some laws relevant to advance planning emphasise that "a person has the right to be shown respect for [their] culture, beliefs, values".[43]

The proposed *Assisted Decision-Making Act* for NSW clarifies that relatives according to indigenous kinship systems would be eligible substitute decision-makers.[22]

Areas for future research

This section draws on the framework for health-legal collaboration proposed in Paper 2 to identify areas for future research. This framework (reproduced earlier in this chapter) is organised around four areas to strengthen practice whereby health and legal practitioners: (1) use common best practices to assist clients; (2) take part in interprofessional training; (3) collaborate in advance planning clinics; and (4) form partnerships in healthcare settings. Paper 2 proposed this framework in the context of ACP, and I extend it here to consider strategies to support advance planning for future research participation.

1) Best practices to assist clients

Tools to support advance planning, including directive templates

Many resources are available to support ACP, such as toolkits with advance directive templates and questionnaires to assist people in identifying their values and wishes for care at the end of life.[44,45,46] These resources are often developed and tested in the health sector and, as recommended in Papers 2 and 3, legal practitioners are another professional group to be targeted in knowledge translation and implementation strategies. Lawyers who specialise in elder law, wills and estates, and health law should be a priority group as they are likely to advise clients on financial, medical and other aspects of advance planning. As discussed in Paper 3, it is important for ACP resources to help clients with life-limiting conditions to prepare directives tailored to the medical and personal circumstances expected in their disease trajectory. For example, templates for advance directives specific to dementia are available[47] and may guide

conversations on an individual's preferred care – as well as research participation – during future periods of symptomatic progression.

As noted at the outset of this chapter, the research base to inform ACP strategies is much more developed than that for advance research planning. American researchers who conducted the first randomised controlled trial (RCT) of an advance research planning process advocated – now over a decade ago – that "the more extensive research conducted on advance directives for clinical (nonresearch) decision-making should be explored … and the lessons from those studies taken and applied directly to the research arena".[48(p1611)] Bravo et al's recent advance planning RCT in Canada,[23] the literature emerging in Europe on ARDs,[13,49] and the Australian research for this PhD thesis contribute to the overdue development of this field. An important recommendation of this PhD work is the need for further study on ARDs, including the design and testing of specific templates and their acceptability to and use by prospective participants, researchers, ethics committees and substitute decision-makers for people with dementia. Since people with a new diagnosis are often encouraged to seek legal advice on advance planning to organise their affairs,[50] future work should investigate strategies for lawyers to discuss planning for research participation with interested clients. This would include lawyers assisting their clients with making advance directives for healthcare and research (where ARDs are recognised) and appointing substitute decision-makers in relation to healthcare treatment and research matters. Paper 7 acknowledged that the legal and ethical status of ARDs is ambiguous in some jurisdictions,[49,51] and research in countries where ARDs are permitted will provide an evidence base to inform reviews of legal and ethical frameworks elsewhere.

Studies should be designed to investigate the degree to which directives are used to inform decision-making during periods of impaired capacity. These data could be collected via

interviews with appointed substitute decision-makers, clinicians (for care directives) and researchers (for research directives). Medical record audits could also be undertaken to examine concordance between preferred and actual care. Cost-effectiveness analysis should be incorporated into intervention studies to compare the costs and effects of strategies to improve the uptake of advance planning for health matters.

Capacity assessment practices

Capacity assessment practices are another key area for further work in health, legal and research settings. Paper 1 noted the increasing number of complaints against lawyers for failing to take adequate steps to ensure that a client had the capacity to make decisions in relation to advance planning documents, such as an enduring appointment or a will. Paper 6 reported that researchers use variable practices to assess capacity to consent to a research study. In a recent critique of capacity assessment, medical ethics scholar Jeffrey Spike argues there has been a "steady pull … to transform capacity into a technical concept" requiring specialist evaluation.[52(p95)] He emphasises that a diagnosis of dementia or other neurocognitive disorder does not mean a person lacks capacity to make particular decisions about healthcare or other matters – a point that was stressed in Papers 4 and 6. Spike calls for a simplified approach to capacity assessment that does not rely on a particular cognitive screening tool, such as the Mini-Mental State Exam or the Montreal Cognitive Assessment. Instead, a core set of open-ended questions should probe the person's ability to understand their options and associated consequences and to make choices, with questions tailored to the specific decisions to be made. This suggestion echoes the recent literature discussed in Paper 6 that recommends that capacity to consent to a research study should focus on the prospective participant's ability to understand the purpose, procedures and risks of the study, as well as their rights as research participants.[53,54,55] The use of simplified consent materials and multi-media tools, especially memory aids to overcome the rapid

forgetting that many people with dementia experience, is another area for continuing investigation.[56]

Supported decision-making practices

Papers 4–7 highlighted recent or proposed changes to domestic and international law and ethics frameworks that aim to provide clearer rules for involving people with cognitive impairment in research and that emphasise the rights of people with disabilities to be supported to make choices about matters affecting their lives. In particular, the United Nations Convention on the Rights of Persons with Disabilities calls for people with disabilities to have access to supports to enable decision-making and sees substitute decision-making as a last resort. Legislative reforms are being made in Australia to align with these CRPD principles; these include changes to Victoria's *Powers of Attorney Act 2014*[57] to establish a supportive attorney role, as well as the NSW Law Reform Commission's recommendation to replace the *Guardianship Act 1987* with an *Assisted Decision-Making Act.*[22]

Research is needed to determine how to optimally support older people with dementia or other neurocognitive disorders to make decisions about healthcare treatment and participation in research, as well as to engage in advance planning. An Australian legal expert on disability rights observes that "there has been only minimal research to date on the practical implementation of supported decision-making" and "[t]he issues at stake for people with cognitive and psychosocial disabilities and the public interest are too significant and potentially grave to be decided … [without] careful empirical research and pilot programs to guide legislative and social policy reform".[58(p199)]

As a starting point, research should investigate whom older people would prefer to appoint as their supporters and whether they would want different supporters for different decision-making domains (e.g. medical treatment, research participation, financial management). As Paper 5 reported, older people preferred that their substitute decision-makers for medical treatment should also be involved in decisions about research participation where necessary. Future work should also investigate the training and resources needed for effective "supporter-supportee" relationships, especially for people with dementia and their care partners. To date, most work on supported decision-making has focused on younger people with intellectual disability or mental health conditions.[59] The few initiatives focused on older people with cognitive impairment include recent Australian guidelines on supported decision-making for people with dementia in residential aged care facilities[60] and, overseas, a European research project that aims to provide recommendations for supported decision-making and capacity assessment in clinical dementia research.[61] Outcomes from this project will be of considerable interest to inform further work in Australia.

2) Interprofessional training

Continuing professional development

With ageing populations and more people living longer with chronic conditions, professionals in the health and legal sectors require training on the needs and rights of older people to help preserve decision-making autonomy and support advance planning, especially for clients living with dementia. Interprofessional training – when "two or more professions learn about, from and with each other to enable effective collaboration and improve health outcomes"[62] – should be a priority, given the intersecting medico-legal issues involved in advance health planning. For example, continuing professional development activities can provide training on topics such as capacity assessment, supported decision-making and legal rules, with the aim of improving

health, research and legal literacy across professions. This would benefit lawyers who may be unfamiliar with healthcare matters (as discussed in Papers 1–3) and clinicians who may be unfamiliar with the law.[63,64]

In health and social care, interprofessionalism in education and practice is a topic of significant research activity.[65,66] This body of work can inform future research to investigate interprofessional activities that connect health and legal professionals, which should be designed to provide high-quality evidence. A 2017 Cochrane Review recommends RCTs, controlled before and after studies and interrupted time series studies with qualitative components to strengthen knowledge on the key components needed for effective interprofessional training.[65]

To date, the quality of the evidence on interprofessional training to improve dementia care is low.[67] Available studies have mostly focused on outcomes related to practitioners' knowledge and skill acquisition, with less attention to measuring changes in behaviour and organisational practices.[67] The impact of interprofessional training on patient and carer outcomes is under-explored; a recent editorial argued: "The only way to tackle better team working is to ensure organisational practitioners and managers focus on the service user."[68(p33)] The focus on the client is essential in interprofessional interventions aimed at enhancing practitioners' capability to facilitate advance planning activities. After all, the goal is to support people in reflecting on and communicating their preferences for future healthcare and participation in research. Future studies should be designed to overcome the limitations of the current body of research and provide higher-quality evidence on practitioner, client and carer outcomes.

A future study could compare single-profession training (e.g. geriatrician only) with interprofessional training (e.g. geriatrician and elder law solicitors) to determine any differences in outcomes, such as knowledge about medico-legal issues, willingness to collaborate with

respect to client capacity assessments, implementation of common tools to support advance planning, and the uptake and quality of advance directives among clients.

University training

Strengthening cross-disciplinary knowledge and interaction can occur during university training as well. Australian researchers in medicine, law and ethics have recently advocated for integrating more substantive legal and ethical training into the medical school curriculum. Parker et al argue that law and ethics "have been historically sidelined … in the hierarchy of evidence" and call for the explicit integration of law into this hierarchy.[69(p102)] They contend that "where the law is clear, law may be called on to overrule professional medical ethical views, since it [law] is the distillation of current community wisdom on matters about which the medical profession can claim no superior insight".[69(p108)] For instance, where a person has made an advance directive that is relevant to their current clinical circumstances, it must be heeded, especially where the law states that a clear instructional directive is to be legally binding, as in Victoria's *Medical Treatment and Planning Decisions Act 2016*.[70]

While Parker and colleagues characterise law as "the distillation of current community wisdom", law-making is also the result of political compromise. When governments establish new laws, such as laws for advance healthcare and research directives or laws for medical research powers of attorney, they should be accompanied by research and evaluation to investigate the impacts of these legislative changes (if any). Are the objectives of the laws achieved in practice, and what are the barriers and enablers to their achievement? What practical interventions are needed to implement legal and policy goals, and to whom should they be targeted to overcome identified barriers? Changes in laws and policies create opportunities for natural experiments to answer

these types of questions, and scholars have recently offered guidance for strengthening the methodological rigour of such research.[35]

Parker et al call for law and ethics to be integrated into medical education. A corollary argument can be made to integrate some basic health-related content into the law curriculum, especially in the area of capacity assessment. A lawyer's central professional duty is to act only on "lawful, proper and competent instructions"[71] which, as discussed above, requires the lawyer to ensure that their client has capacity to give instructions. This obligation is particularly salient for lawyers practising in elder law and wills and estates areas, where it must be determined that a client is able to give instructions about advance planning matters. In addition, an evidence-based law movement – adapted from the evidence-based movement in medicine – would require greater exposure for law students to empirical research skills and critical evaluation of research.

3) Advance planning clinics

Legal and health professionals can collaborate in clinics to provide advice and assistance on advance planning. Research from ACP interventions in the health sector can be adapted to inform strategies that involve lawyers as part of interprofessional clinics.[18] Practitioners involved in such clinics can be supported with skills training, and clients can receive toolkits to prepare them for advance planning; this dyadic approach is effective in improving communication about advance planning.[72] Researchers in the US found that group visits on ACP for older people (2 x 2 hour sessions led by a doctor and a social worker) substantially increased the uptake of ACP.[73] At 12 months follow-up, 89% of participants had documented substitute decision-maker preferences and 67% had completed advance care directive forms.

Clinics can be delivered using an outreach model to provide education and services at community locations convenient for older adults. In previous work, I led a pilot project that

involved law students in the delivery of education seminars on advance planning, which covered wills, enduring appointments for financial and healthcare decisions, and advance care directives.[74] These seminars were delivered at various locations, including a general practice clinic, a residential aged care facility, a community centre, and a support group for people with life-limiting illness and their carers. The results of this pilot project found that receiving legal education in a healthcare or community setting improved attendees' knowledge of their rights to plan ahead and, importantly, motivated some attendees to discuss their values and wishes with family members and to seek legal help to make relevant legal documents.[74]

Trials of advance planning interventions in residential aged care facilities should be a priority. Residential facilities are important sites for involving older people in research, including those who are at risk of or already diagnosed with dementia or other conditions that affect cognitive abilities.[75] Supporting residents to engage in advance research planning could be a component of establishing "research-ready" care facilities.[76] In regard to ACP, there is a need to improve the uptake, consistency and quality of care planning in aged care settings. A NSW study of 24 facilities found that only 5% of residents had advance care directives,[77] and a Victorian audit of 19 facilities found that only half had written policies on advance care planning and none of these policies covered all best-practice components.[78] A more recent analysis of 26 residential aged care facilities across six states and territories reported that nearly half of residents (47.7%) had some form of advance care documentation; however, only 3.8% had statutory advance care directives, 14.2% had documents appointing substitute decision-makers, and 36.3% had non-statutory directives, such as written statements of wishes or preferences that were not in a statutorily prescribed format.[79] The authors of this study acknowledge a possible selection bias since facilities participated in the audit by way of an expression of interest; those that did so may

place greater institutional emphasis on ACP, and rates of uptake may be lower in facilities that chose not to participate.

4) Partnerships in healthcare settings

The health-justice partnership movement is developing quickly in Australia, especially with the 2016 launch of Health Justice Australia as a national centre to promote such partnerships. Health-justice partnerships work at three levels: (1) to meet the needs of underserved clients; (2) to enhance professional capabilities in addressing socio-economic determinants of health; and (3) to advocate for legal and policy changes to reduce inequalities and disadvantage.

To date, several partnerships in Sydney, Melbourne and other centres target older clients.[80] During the medical appointment, the clinician may conduct a brief screen with older patients to identify unmet legal needs. The patient can then be referred for a private consultation with the on-site lawyer. The lawyer often provides training for clinical team members and participates in team meetings to discuss patient case management. Health-justice partnerships, especially those connected with cancer, palliative and geriatric care services, provide sites for clients to receive information and assistance in advance planning.

As noted in Paper 1, more research is needed on the benefits and costs of such partnerships. Research from the US on partnerships that include lawyers in cancer and palliative care teams concluded that "[e]merging evidence demonstrates that patient-clients benefit substantially from the addition of legal expertise to the patient care team".[81(p184)] A 2017 systematic review on interventions to address patients' socio-economic needs in healthcare settings reported that "there is mounting observational evidence to support the integration of legal services into clinical care delivery",[82(p725)] with data demonstrating positive impacts on patients' disease management and well-being, as well as some cost-effectiveness data. The review recommended experimental studies to strengthen the evidence in relation to health-justice partnerships.

Health Justice Australia is currently leading a systematic review project to identify the types of outcomes that partnerships aim to achieve and the indicators and metrics that are used to measure those outcomes. It will also identify what is known and the gaps in our knowledge about the impact of health-justice partnerships. I am participating as a member of an external advisory group for this review project.

Community action approaches

Extending beyond the health-legal collaboration framework proposed in Paper 2, I propose one further area for research. Improving uptake of advance planning arguably requires a broader "whole-of-community" approach to support desired behaviour changes at person, practitioner and system levels.[83] This would involve engaging with professionals across health, legal and community service sectors, mobilising support from influential community groups, and the use of media campaigns to increase public awareness of individuals' rights in relation to advance planning and where they can access information and advice. Initiatives such as National Advance Care Planning Week[84] or Dementia Awareness Month[85] provide opportunities to launch such initiatives. Community action initiatives can also raise awareness of opportunities to participate in research; the United Kingdom's Join Dementia Research platform is an example of a national initiative[86] and, in Australia, StepUp for Dementia Research aims to become a hub connecting researchers with interested participants across the country.[87]

I am part of a research team seeking to advance the science of community action approaches to improve the uptake and quality of advance personal planning.[88] Our model integrates multiple evidence-based strategies across a variety of access points, including health, legal, community and social service settings. Community members, professionals, and government and non-

government organisations collaborate to design and systematically implement strategies to support effective advance planning. The research conducted in my PhD studies will make a valuable contribution to this community action research project.

Conclusion

A conclusion from the sum of these PhD studies is that the time is ripe for a comprehensive approach to advance planning for health-related matters that covers planning for medical treatment and participation in research. Practitioners in the health and legal sectors have important roles in supporting clients in advance planning processes. These processes include reflecting on and communicating values and preferences, identifying preferred supporters and substitute decision-makers, communicating plans, and re-visiting them as personal circumstances change with advancing illness. These processes must be based on accurate and relevant information about the law and legal rights, as well as the medical and research situations being addressed in the planning process. Various strategies can support health-legal collaboration, ranging from the use of common practices to team-based practice approaches. The findings from this PhD research advance knowledge in under-examined areas and provide an important foundation for further studies.

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APPENDICES

Appendix 1: Co-authorship declarations

Co-authorship declaration for Paper 2

UON Graduate Research

Co-authorship declaration

TITLE AND CITATION	Nola M Ries, Maureen Douglas, Jessica Simon & Konrad Fassbender. Doctors, Lawyers and Advance Care Planning: Time for Innovation to Work Together to Meet Client Needs. *Healthcare Policy* 2016;12(2): 12-18.

AUTHOR POSITION	AUTHOR	SPECIFICS OF CONTRIBUTION TO RESEARCH REPORTED AND WRITING OF THE FINAL PAPER	% CONTRIBUTION TO PAPER	SIGNATURE
1	Nola Ries	Led the conception of ideas presented in the paper, led the research and prepared the manuscript.	50	
2	Maureen Douglas	Contributed to a critical revision of the manuscript and approved the final version.	20	
3	Jessica Simon	Contributed to a critical revision of the manuscript and approved the final version.	15	
4	Konrad Fassbender	Contributed to a critical revision of the manuscript and approved the final version.	15	

AUTHOR POSITION	AUTHOR	SPECIFICS OF CONTRIBUTION TO RESEARCH REPORTED AND WRITING OF THE FINAL PAPER	% CONTRIBUTION TO PAPER	SIGNATURE
1	Nola Ries	Led the conception of ideas presented in the paper, led the research and prepared the manuscript.	50	
2	Maureen Douglas	Contributed to a critical revision of the manuscript and approved the final version.	20	
3	Jessica Simon	Contributed to a critical revision of the manuscript and approved the final version.	15	
4	Konrad Fassbender	Contributed to a critical revision of the manuscript and approved the final version.	15	

Assistant Dean Research Confirmation: By signing below I confirm that Nola Ries contributed to the conception of ideas, research and writing of the publication referenced at the top of this form.

Professor Liz Sullivan Date: 11/03/19

Deputy Head of Faculty, Health and Medicine

Co-authorship declaration for Paper 3

UON Graduate Research

Co-authorship declaration

TITLE AND CITATION	Nola M Ries, Maureen Douglas, Jessica Simon & Konrad Fassbender. How Do Lawyers Assist Their Clients with Advance Care Planning? Findings from a Cross-Sectional Survey of Lawyers in Alberta, Canada. *Alberta Law Review* 2018;55(3):683-701.

AUTHOR POSITION	AUTHOR	SPECIFICS OF CONTRIBUTION TO RESEARCH REPORTED AND WRITING OF THE FINAL PAPER	% CONTRIBUTION TO PAPER	SIGNATURE
1	Nola Ries	Contributed to study design, data collection, data analysis and prepared the manuscript.	40	
2	Maureen Douglas	Contributed to study design, data collection, and data analysis. Contributed to critical revision of the manuscript and approved the final version.	30	
3	Jessica Simon	Contributed to study design and a critical revision of the manuscript. Approved the final version.	15	
4	Konrad Fassbender	Contributed to study design and a critical revision of the manuscript. Approved the final version.	15	

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3	Jessica Simon	Contributed to study design and a critical revision of the manuscript. Approved the final version.	15	
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Assistant Dean Research Confirmation: By signing below I confirm that Nola Ries contributed to the study design, data collection, data analysis and writing of the publication referenced at the top of this form.

Professor Liz Sullivan Date: 11/03/19

Deputy Head of Faculty, Health and Medicine

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THE UNIVERSITY OF NEWCASTLE AUSTRALIA

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1	Nola Ries	Led the conception of ideas presented in the paper, conducted research and prepared the manuscript.	45	
2	Katie Thompson	Contributed to ideas presented in the paper conducted research and assisted with manuscript drafting. Approved the final version.	40	
3	Michael Lowe	Contributed to ideas presented in the paper and to a critical revision of the manuscript. Approved the final version.	15	

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3	Rob Sanson-Fisher	Contributed to study design and survey development. Contributed to critical revision of the manuscript and approved the final version.	20	

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Professor Liz Sullivan Date: 11/03/19

Deputy Head of Faculty, Health and Medicine

Appendix 2: Survey of Lawyers in Alberta, Canada (Paper 3)

1. In your current professional role, do you assist clients with planning for future decision-making incapacity by writing/revising a personal directive, appointing an alternate decision-maker or other matters related to advance care planning?

Note: Advance Care Planning (ACP) is a process of communication by which a person can express their values, wishes and preferences for healthcare during future periods when the person lacks capacity to make their own decisions. ACP may involve appointing an enduring guardian and/or writing an advance care directive.

- ❒ Yes
- ❒ No *[If no: Thank you for your response. Unfortunately you are not eligible to complete the rest of the survey.]*

2. If yes, approximately how often do you assist clients with advance care planning (ACP)? *[Select one]*

- ❒ daily (eg, majority of practice is wills and estates)
- ❒ weekly (eg, general or split practice)
- ❒ monthly (eg, generalist)

3. Typically, from your experience, what prompts a client's desire to engage in advance care planning (ACP)?

Likert scale responses for each item: seldom, sometimes, often, always, don't know/not sure

- The lawyer brings it up as part of a discussion about wills, power of attorney, etc, with the client
- The client has received a medical diagnosis with life limiting implications and/or is experiencing deteriorating health
- The client has had a discussion with a doctor or other healthcare provider
- A residential facility requires the client to do ACP (eg, aged care facility)
- The client has had a discussion with financial planner, banker, insurance advisor
- The client has had a discussion with a spiritual advisor
- The client has had experience as decisions-maker/carer for another
- There has been an illness or death of someone close to the client
- Other (specify)

  _____

4. When you assist clients with planning for future health care, how often do you discuss or provide guidance about:

Likert scale responses for each item: seldom, sometimes, often, always, don't know/not sure

- Selecting an agent [enduring guardian]
- Their values and wishes concerning future care (eg, religious or lifestyle beliefs important to the client that they want others to acknowledge and respect)

- Their wishes about whether they would accept or refuse particular healthcare interventions (eg, cardiopulmonary resuscitation, mechanical ventilation, tube feeding, kidney dialysis)
- Their wishes about future accommodation/living arrangements
- Their wishes for who should be involved in consultations with the client's healthcare team
- Their wishes for who should have access to their health-related records
- Their wishes about participation in medical research
- Their wishes about organ donation
- Other (specify)

  _____

5. When you assist clients with advance care planning (ACP), how often do you encourage your clients to speak to the following people about their wishes for future healthcare:

Likert scale responses for each item: seldom, sometimes, often, always, don't know/not sure

- Their agent [enduring guardian]
- Other family members, carers, friends (other than the named agent [enduring guardian])
- Their family doctor or other healthcare provider
- A spiritual advisor
- Other (specify) _____

6. Currently, when you assist clients with advance care planning (ACP), what resources do you find helpful? *[Select all that apply]*

❒ Informational documents (eg, pamphlets, fact sheets)

❒ Decision-making aids (eg, worksheets for clients to complete, checklists)

❒ Websites

❒ Other (specify)

7. Is there a specific template or precedent you use for drafting an advance directive?

❒ yes
- Note source of advance directive template, for example, public website (please specify), developed in-house, etc.:

  _____

❒ no

8. How much do the following factors hinder you in assisting your clients with advance care planning?

Likert scale responses for each item: seldom, sometimes, often, always, don't know/not sure

- Concern about upsetting the client
- Conversations are upsetting or uncomfortable for me
- Client is unwilling to share personal details with me
- Differences between the client and me in age, cultural, religious or other personal characteristics
- Lack of client preparedness for advance care planning
- My lack of knowledge about medical aspects of advance care planning (eg, lack of knowledge about medical interventions and their implications for a client)
- My lack of knowledge about health sector policies/practices
- It is time-consuming (and therefore costly) to have advance care planning conversations with clients
- Concerns that an advance care plan will not be used in practice
- My lack of experience with the law in this area
- Other (specify)

  _____

9. To what extent do you believe that ACP benefits clients?

Likert scale response: not at all beneficial; slightly beneficial; moderately beneficial; very beneficial; don't know/not sure

10. To what extent do you think the following activities are part of your professional role:

Likert scale responses: not at all part of my role; seldom part of my role; sometimes part of my role; often part of my role; always part of my role

- Initiating ACP conversations with clients
- Providing clients with information about ACP
- Drafting specific documents (eg, enduring guardian appointment, advance directive)
- Provide guidance to client on preparing documents and/or organising affairs to minimise disputes between key people (eg, enduring guardian, family members, healthcare providers)
- Encouraging clients to discuss their wishes and values with key people
- Liaising with the client's healthcare providers (with client/guardian consent)
- Other role for lawyers in ACP (specify below)

11. How useful would you find the following resources in assisting your clients to plan in advance for their healthcare?

Likert scale responses for each item: not at all useful; somewhat useful; very useful; not sure

- A best practice guide for ACP (eg, summary of the benefits of ACP, steps for engaging clients in ACP)
- Question & answer sheet or script for lawyers to use when having ACP conversations with clients

- Worksheets for clients to identify and express their values, wishes and preferences
- Information about Health Department or other health sector policies and resources
- Explanation of relevant healthcare issues, healthcare language, specific diseases and medical interventions
- Legal resources (eg, legislation, forms/templates, research on legal issues related to ACP)
- A third party with specialised training in ACP to whom I can refer clients
- Other (specify):
  _____

12. What is your preferred format for the resources described above?

❒ online

❒ print

❒ other (specify):
_____

13. What is your preferred format for continuing professional development?

❒ Online/web-based (including webinars)

❒ In person sessions

❒ Print materials

❒ No preference

❒ Other (specify):
_____

14. Reflecting on the survey, is there anything else you would like to add (about lawyers and ACP, about the survey generally)? _____

Demographics

15. How many years have you practiced law?

❒ 0-2 years

❒ 3-5 years

❒ 6-10 years

❒ 11-15 years

❒ more than 15 years

16. Please list your main practice area(s) (eg, wills and estates, family law):

_____

17. What is the size of the firm or organisation where you work?

- ❒ sole practice
- ❒ small firm (2-9 lawyers)
- ❒ mid-size firm (10-49 lawyers)
- ❒ large firm (50 or more lawyers)

18. What is your main location of practice?

- ❒ city
- ❒ suburban
- ❒ country

19. What is your gender?

- ❒ Male
- ❒ Female
- ❒ Prefer not to say

20. What is your age?

- ❒ 24 or younger
- ❒ 25-34
- ❒ 35-44
- ❒ 45-54
- ❒ 55-64
- ❒ 65+
- ❒ prefer not to say

Appendix 3: Survey of Outpatients Aged 60 Years or Older on Dementia Research Participation and Advance Research Directives (Paper 5)

The following questions are hypothetical and do not ask about your current health.

Imagine the following situation: **You have dementia and you have quite a few troubles with memory, thinking and doing everyday activities.** **You could take part in a research study. This study is testing ways to improve dementia care or to prevent dementia.** **An independent committee has reviewed the study to make sure it is safe and ethical. Your privacy will be protected. The researchers doing the study work at a university or public hospital. It does not cost you any money to take part in the study.** **How much do you agree or disagree with the following statements (remember the questions are hypothetical):**					
1. As a person with dementia, I would be willing to be included in a research study that involves:	Strongly agree	Agree	Unsure	Disagree	Strongly disagree
a) Asking me questions in a survey or interview *(example: asking about my experiences or opinions)*	1	2	3	4	5
b) Observing my behaviour *(example: watching how I act if I listen to music)*	1	2	3	4	5
c) Testing my memory or thinking *(example: asking me to draw a picture or remember specific words)*	1	2	3	4	5
d) Giving me psychological therapy *(example: counselling for anxiety or depression)*	1	2	3	4	5
e) Giving me physical therapy *(example: moving my arms or legs, massaging my muscles)*	1	2	3	4	5
f) Giving me experimental medicine *(example: an experimental drug that might reverse damage in my brain)*	1	2	3	4	5
g) Taking x-rays or scans of my body *(example: to help researchers see how dementia is affecting my brain)*	1	2	3	4	5
h) Taking a measurement about my body *(example: my weight, blood pressure)*	1	2	3	4	5
i) Putting something on my body, like a bracelet, that keeps track of information *(example: how much time I spend in bed)*	1	2	3	4	5

j) Taking a sample of my blood or other body fluid for **genetic research** *(example: to find out if I and my relatives have a gene that increases the risk of getting dementia)* Note: **Genetic research** looks at diseases that can run in families. You inherit genes from your parents and you pass your genes on to your children.	1	2	3	4	5
k) Taking a sample of my blood or other body fluid for **non-genetic research** *(example: to find out if my blood shows I had an infection in the past that increases my risk of dementia*)	1	2	3	4	5
l) Looking at my personal records, such as medical records or test results stored at my doctor's office or hospital *(example: to study how a past illnesses might be related to my dementia)*	1	2	3	4	5
m) Accessing stored samples of my blood, body fluids or other tissues *(example: If I had blood taken in the past for another reason, researchers might ask the hospital for access to that blood for study)*	1	2	3	4	5
2. If I developed dementia I think I would be willing to be included in a research study that:	Strongly agree	Agree	Unsure	Disagree	Strongly disagree
Benefits me directly (example: taking part in research could improve my quality of life).	1	2	3	4	5
Does not benefit me directly but **could help other people with dementia**.	1	2	3	4	5
Does not have benefits for me or other people with dementia, but could help researchers understand other diseases or health problems.	1	2	3	4	5

An **Advance Research Directive** is a document where you can write down whether you **agree or disagree** with being involved in research studies in the future. You make the Directive at a time when you are able to think through your options and make choices. If you later lose the ability to make decisions due to a medical condition, your Directive will tell people your wishes, such as your doctor, your caregiver, or a researcher.

3. If it were possible for you to complete an Advance Research Directive, how interested would you be in doing this?	1) Very interested → Go to 5 2) Somewhat interested → Go to 5 3) Unsure → Go to 4 4) Not very interested → Go to 4 5) Not at all interested → Go to 4
4. Why are you <u>not</u> interested in making an Advance Research Directive?	6) I am not interested in taking part in research in the future 7) I do not think it is important to write down my wishes for taking part in future research 8) I would prefer for someone else to make decisions about my participation in research if I am no longer able to make my own decisions 9) I do not think it matters what happens after I lose the ability to make decisions 10) I am not sure 11) Other (specify)

5. If you ever developed dementia and cannot make your own choices, others may be involved in decisions about whether or not you should be included in a research study.

Please indicate the extent to which you agree with the following statements:	Strongly agree	Agree	Unsure	Disagree	Strongly disagree
The person who is responsible for making my healthcare decisions should be involved in decisions (example: your spouse or adult child)	1	2	3	4	5
An independent legal body should be involved in decisions (example: a judge)	1	2	3	4	5
A doctor or other health professional who is part of the research team should be involved in decisions	1	2	3	4	5
A doctor or other health professional who is <u>not</u> part of the research team should be involved in decisions	1	2	3	4	5

Questions about You

Are you?	❒ Male ❒ Female ❒ Prefer not to say
What is your age?	❒ 60-74 years ❒ Over 75 years
Are you visiting the hospital today as a patient or a person accompanying a patient?	❒ Patient ❒ Person accompanying a patient
What is your relationship status?	❒ Married or in a relationship ❒ Single, divorced or widowed
What is the highest level of education you finished?	❒ High school or below ❒ TAFE/trade/diploma ❒ Tertiary/university

Have you previously completed an advance **healthcare directive**? This is a document where you write down your wishes for the medical treatments you would or would not want in the future if you are too ill to make your own decisions.	❒ Yes ❒ No ❒ Unsure
What clinic are you attending today?	❒ Cardiology ❒ Respiratory ❒ Neurology ❒ Gastroenterology ❒ Endocrinology ❒ Orthopaedics ❒ Ear/nose/throat surgery ❒ Vascular surgery ❒ Urology ❒ Other (please specify)
Have you been diagnosed with dementia by a health care professional?	❒ Yes ❒ No ❒ Unsure ❒ Prefer not to say
Do you know someone with dementia? (A person who is alive or a person who has passed away.)	❒ Yes ❒ No
If yes, what is your relationship to this person?	The person is my: ❒ Partner or spouse ❒ Friend ❒ Parent ❒ Other (please specify)

Appendix 4: Survey of Dementia Researchers on the Ethical Aspects of Including People with Cognitive Impairment in Research (Papers 6 and 7)

Appendix 4: Survey of Researchers on the Ethical Aspects of Including People with Dementia in Research (Papers 6 and 7)

Do you have experience dealing with the ethical aspects of dementia-related research studies that involve human participants? For example, seeking ethics approval, recruiting participants, or conducting research activities with participants. Please note that the survey applies only to research conducted in Australia.	❒ Yes ❒ No [survey does not continue]		
Please select the response that best describes the main focus of your research:	❒ People with dementia living in the community ❒ People with dementia in institutional settings (eg, care facility) ❒ My research involves a mix of both populations		
Have you involved people with dementia in your research as co-researchers (eg, they assisted with study design, data collection, data analysis or other research activities)	❒ Yes ❒ No		
In general, how important do you think it is to include people with varying stages of dementia in research studies?	❒ Very important ❒ Somewhat important ❒ Not at all important		
In general, how concerned are you that the following factors are barriers to including in research people with dementia who have fluctuating or reduced capacity?	Very concerned	Somewhat concerned	Not at all concerned
Difficult or time consuming to get ethics approval	1	2	3
Difficult or time consuming to recruit such participants	1	2	3
Difficult or time consuming to obtain consent for research participation	1	2	3
Difficult to retain such participants in a study over time	1	2	3
Ethics rules unduly restrict participation by people with fluctuating or reduced capacity	1	2	3
Legal rules unduly restrict participation by people with	1	2	3

fluctuating or reduced capacity					
Do you have any other concerns about barriers to including people with dementia in research?	❒ Yes (please specify) ❒ No				
Experiences with involving people with dementia in research					
In your research, how often do you exclude people with dementia who are unable to give their own consent to participate in the study?	❒ Always ❒ Very often ❒ Sometimes ❒ Rarely ❒ Never				
In your research, have you ever sought consent from another person or entity to include a person with dementia in a study?	❒ Yes ❒ No ❒ Don't recall				
Please indicate how often you have sought consent from the following decision makers. Select all that apply.					
	Always	Very often	Sometimes	Rarely	Never
A legal body (eg, guardianship tribunal, court)	1	2	3	4	5
An individual with formal legal authority (eg, family member formally appointed as a decision-maker for the person with dementia)	1	2	3	4	5
An individual with informal responsibility (eg, family member or other carer)	1	2	3	4	5
Are there any other decision makers from whom you have sought consent?	❒ Yes (please specify) ❒ No				
In your research, how often have the following been involved in determining if a person with dementia has capacity to consent to the research?					
	Always	Very often	Sometimes	Rarely	Never
A health professional external to the research team (eg, prospective participant's doctor)	1	2	3	4	5

A member of the research team	1	2	3	4	5
An external legal body (eg, guardianship tribunal)	1	2	3	4	5
Has anyone else been involved in determining if a person with dementia has capacity to consent?	❒ Yes (please specify) ❒ No				
For participants in your studies, was a specific tool/ questionnaire used to assess capacity to consent to research?	❒ Yes (please specify, eg, name of assessment tool) ❒ No ❒ Don't know				
Views on advance research directives An advance research directive (ARD) is a written statement of a person's wishes regarding research participation during future periods of incapacity. A person makes an ARD when they have decision-making capacity.					
Does the National Statement on Ethical Conduct in Human Research give guidance on advance research decisions/directives ?	❒ Yes ❒ No ❒ Unsure				
To what extent do you agree with the following statements about the **benefits** of using advance research directives in dementia research?					
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
ARD would enable people to make their own choices about future research participation	1	2	3	4	5
ARD would help to include people with impaired capacity in research	1	2	3	4	5
ARD would help researchers know the wishes of a	1	2	3	4	5

person with impaired capacity					
ARD would provide Human Research Ethics Committees (HRECs) with evidence of the wishes of a person with impaired capacity	1	2	3	4	5
ARD would help other decision-makers know the wishes of the person with impaired capacity	1	2	3	4	5
Do you think there are any other benefits of using ARD in dementia research?	❒ Yes (please specify) ❒ No				
To what extent do you agree with the following statements about the **disadvantages** of using advance research directives in dementia research?	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
HRECs might not accept ARD as valid evidence of consent	1	2	3	4	5
ARD would not adequately protect interests of person with impaired capacity	1	2	3	4	5
ARD are not as reliable as seeking consent from a substitute decision maker for the person with impaired capacity	1	2	3	4	5
Time lag between person making ARD and losing capacity may mean directive is not available when needed (eg, has been misplaced)	1	2	3	4	5
Do you think there are any other	❒ Yes (please specify)				

disadvantages of using ARD in dementia research?	❒ No				
Imagine you are recruiting a person with dementia into a study and they have capacity to make decisions about research participation. Would you offer the person the opportunity to make an ARD to document their wishes about participating in the following research activities during future periods of reduced capacity?					
Research activity	Would definitely offer	Would probably offer	Would probably not offer	Would definitely not offer	Not sure/no opinion
Surveys or interviews	1	2	3	4	5
Observation of behaviour	1	2	3	4	5
Testing cognitive abilities (example: assessing memory)	1	2	3	4	5
Giving psychological therapy (example: counselling for anxiety or depression)	1	2	3	4	5
Giving physical therapy (example: massage or other non-invasive therapies)	1	2	3	4	5
Giving experimental medicines	1	2	3	4	5
Taking x-rays or scans	1	2	3	4	5
Taking physical measures (example: weight, blood pressure)	1	2	3	4	5
Putting a device on the body (example: bracelet) that keeps track of information about the person such as their activity level	1	2	3	4	5

Taking a sample of blood or other biospecimen for **genetic research** (example: to identify genetic risk factors for dementia)	1	2	3	4	5
Taking a sample of blood or other biospecimen for **non-genetic studies** (example: for a study investigating a link between infection and dementia risk)	1	2	3	4	5
Accessing personal records, such as medical records or test results	1	2	3	4	5
Accessing previously collected body tissues, blood or other body fluids	1	2	3	4	5

Imagine a person with capacity makes an ARD agreeing to participate in certain types of research activities during future periods of incapacity. Which of the following do you think should override the wishes stated in the ARD?

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
The person who made the ARD and now lacks capacity expresses an objection to a research activity (eg, through body language or verbalisation)	1	2	3	4	5
A family member or carer for the person who made the ARD expresses an objection	1	2	3	4	5
A health practitioner for the person who made the ARD expresses an objection	1	2	3	4	5
A human research ethics committee expresses an objection	1	2	3	4	5
Is there anything else that you think should override the wishes stated in the ARD?	❒ Yes (please specify) ❒ No				

To what extent do you think the HREC you deal with most often would accept an ARD as a valid expression of a person's willingness to participate in research?	❒ Likely to accept ❒ Unlikely to accept ❒ Not sure
Where you have recruited people **with capacity** into a study, have you used or proposed the use of an ARD as a way to document the participants' preferences for research participation in the future should they lose decision-making capacity?	❒ Yes ❒ No (if no, survey skips to questions on Experiences with Human Research Ethics Committees)
Approximately how many times have you used or proposed the use of an ARD?	Number of times: _____
How have HRECs responded to the proposed use of an ARD? (Select all that apply)	❒ Would not approve use of ARD ❒ Required major changes to ARD ❒ Required minor changes to ARD ❒ No concerns about ARD ❒ Different HRECs had differing responses to same ARD (example: one HREC accepted ARD and another HREC did not) ❒ Other (specify)
Do you have any comments about HREC responses to your proposed use of an ARD (eg, what changes did an HREC require; why was an ARD not approved?)	❒ Yes (please specify) ❒ No
Have you offered participants an opportunity to complete an advance research directive?	❒ Yes *If yes then*: Number of participants: _____ *Then to % question immediately below.* ❒ No (branches to "Have you conducted research activities where you relied on an ARD…"
What percentage of participants were willing to make an ARD?	❒ Over 75% willing to make ARD ❒ 50-75% willing to make ARD ❒ 25-49% willing to make ARD ❒ Less than 25% willing to make ARD
Have you conducted research activities where you relied on an ARD as evidence of the participant's willingness to participate in the study?	❒ Yes ➢ If yes, briefly explain (eg, types of research activities) ❒ No
Experiences with Human Research Ethics Committees This section asks about your experiences of seeking approval from a Human Research Ethics Committee to involve people with dementia in research where the participants would have fluctuating or reduced capacity.	
Do you have this experience?	❒ Yes *[proceed to next question]* ❒ No *[skips to demographic questions]*

Which of the following have occurred as the result of the HREC review process of your research studies involving people with fluctuating or reduced capacity. Select all that apply.	❒ Would not approve the study ❒ Excessive delay of a project ➢ State estimated length of delay: ❒ Dissuaded me or my colleagues from seeking to include people with fluctuating or reduced capacity in future studies ❒ Required that I make substantive changes to my study design ❒ Had a negative impact on collaborations or relations with research partners ❒ Inconsistent responses by HRECs (eg, same or similar study had different HREC outcomes) ❒ Improved protections for research participants ❒ Helped me plan for future research ❒ None of the above
Have any other consequences occurred as a result of the HREC review process of your research studies involving people with fluctuating or reduced capacity?	❒ Yes (please specify) ❒ No
Have any of the following issues required considerable discussion with your HREC in obtaining approval for a study that includes participants with fluctuating or reduced capacity? 'Considerable discussion' means more than two rounds of feedback were provided by the committee about the issue and/or more than 1 hour of conversation was required to resolve the issue. Select all that apply.	❒ Process for approaching/inviting potential participants ❒ Process for assessing participant capacity ❒ Process for obtaining participant consent ❒ Process for seeking consent from another party (eg, substitute decision maker for the person with fluctuating or reduced capacity) ❒ None of the above ❒ Other (please specify)
Demographic questions	
What is your main area of research? Please select one answer.	❒ Medicine [branching question - Respondents will indicate area of medicine: General practice, Geriatrics, Psychiatry, Other (specify)] ❒ Nursing ❒ Psychology

	❒ Allied health [branching question - Respondents will indicate area of allied health: Physiotherapy, Occupational therapy, Speech pathology, Other (specify)] ❒ Pharmacy ❒ Nutrition ❒ Neuroscience ❒ Other (please specify)
What is your most frequent work activity?	❒ Research ❒ Clinical ❒ Administration ❒ Teaching ❒ Counseling ❒ Other (please specify)
Approximately how many years of research experience do you have?	❒ 1 – 7 years ❒ 8 – 15 years ❒ More than 15 years
Approximately how many years of research experience do you have working with people with dementia?	❒ 1 – 7 years ❒ 8 – 15 years More than 15 years
Have you ever served as a member on a Human Research Ethics Committee?	❒ Yes ➢ If yes, number of years of experience: _____ ➢ What type of HREC: _____ ❒ No
In which state or territory do you conduct the majority of your research?	❒ Australian Capital Territory ❒ New South Wales ❒ Northern Territory ❒ Queensland ❒ South Australia ❒ Tasmania ❒ Victoria ❒ Western Australia
Gender	❒ Male ❒ Female ❒ Other / prefer not to say

Invitation for follow-up interview

The investigators are interested in interviewing some survey respondents to learn more about their experiences and to find out their suggestions for how to appropriately include people with dementia in research studies.

Are you willing to be contacted to be invited for an interview?

❒ **Yes.** Agreeing to be contacted does not indicate consent to take part in the interview. Rather, you are consenting to the researchers contacting you to tell you more about the interview. You can then decide if you wish to participate. *[Then branching to add details.]*

❒ **No.** Thank you for your time. You will now exit the survey.

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Thank you for your interest in being contacted for an interview. Please note that your survey responses will be linked to your name and contact information.

Name:
Email address:
Telephone:
Organisational affiliation:

The survey is now complete. Thank you for your time.