Ethical and legal aspects of research involving older people with cognitive impairment: A survey of dementia researchers in Australia

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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 (INITIALS BLINDED) 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.

< Insert Table 1 about here >

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.

< Insert Table 2 about here >

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.

< Insert Table 3 about here >

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.

< Insert Table 4 about here >

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. An analysis of relevant laws 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) 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 underway 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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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.*	
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.

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)

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)

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)
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.