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Proxy decision-making about participation in palliative care research: A scoping review

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Abstract

Background: Palliative care research must be inclusive of those with impairments in decision-making to provide a representative evidence base for care and treatment. When capacity to consent to research is impaired, proxies may be asked to support decision-making. However, little is known about how proxies navigate this role or what supports their involvement.

Aim: To identify, describe, and synthesise empirical evidence on the use of proxies to support the involvement of adults with impaired mental capacity in palliative care research.

Design: A scoping review conducted and reported following the Joanna Briggs Institute guidance. Data were charted and are reported descriptively, organised by themes.

Data sources: Ovid Medline, Ovid EMBASE, EBSCO CINAHL, EBSCO Academic Search Ultimate, Scopus, Westlaw, HeinOnline, APA PsycINFO, and Social Sciences Citation Index for studies published between 2007 and 2025.

Results: Proxy decision-making was found to be context-dependent, shaped by consent models and varying across jurisdictions. Proxies' confidence and willingness to act were influenced by their understanding of consent requirements, perceived research value and power dynamics. Significant international variation exists in the legal and ethical frameworks that guide proxy involvement.

Conclusion: Proxy decision-making in research is complex, involving legal, ethical, emotional, relational, and contextual factors. Demands on proxies are particularly pertinent in a palliative care context, where substituted decision making must be balanced alongside personal values and emotional burden. To promote inclusion, accessible, jurisdiction-specific guidance, training for proxies and researchers, and ongoing support mechanisms are essential. In a palliative care context, advance research planning might support proxy decision-making.

Keywords

palliative care, proxy, third-party consent, informed consent, cognitive dysfunction, legislation, jurisprudence

What is already known about the topic

- Where appropriate, proxies can be used to support research participation for adults with impaired mental capacity, particularly in end of life care research.
- The process of proxy decision-making is influenced by interpersonal, emotional, and contextual factors, yet comprehensive support for proxies remains limited.

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What this paper adds

- Proxies' willingness to support research participation is shaped by their understanding of consent processes, perceptions of research value, and relational dynamics with clinical teams.
- Evidence suggests that proxies value clarity, early engagement, and practical communication support when asked to make research decisions on behalf of others.

Implications for practice, theory or policy

- There is an urgent need for updated, jurisdiction-specific guidance and training for both researchers and proxies, especially in palliative care contexts.
- Future policy and practice should explore models of early and structured advance research planning to support proxy involvement and uphold participant preferences.

Introduction

The involvement of advocates or "proxy decision-makers" is a familiar concept within palliative care. Many incurable illnesses, and the dying process itself, are characterised by a progressive impairment of cognition, communication or consciousness, and people receiving palliative care are encouraged to plan for who should "speak for them" if mental capacity is impaired. The need for decision making on behalf of another person at the end of life is common; in a large US study of 3746 deaths 42.5% of people required medical decision making near the end of life, 70.3% of whom lacked capacity to do so.[1]

Generating the evidence needed to answer important questions about the care of dying patients, such as how to reduce delirium, upper airway secretions, pain and other symptoms at the end of life, requires the inclusion of participants who are unable to provide informed consent.[2] Intervention studies in palliative care are rare compared to other medical specialities and often exclude adults unable to consent to participation.[3] Under-representation of people with impaired capacity in research means that palliative care practice may not be fully evidence based, resulting in a "circular paradox"—where the lack of inclusion of this population limits the evidence needed to improve their care.[4]

Whilst supported decision-making is fundamental to ethical inclusion in palliative care research, proxy involvement may offer a vital route to participation in research when conventional consent processes are not possible. This is particularly relevant for older, socially isolated adults and people receiving palliative care who have pre-existing cognitive impairments, such as those with dementia or profound learning disabilities, for whom standard models of consent are often inaccessible.[3,5] Recent evidence suggests that study participation, even in the last days of life, can provide a sense of purpose for participants and their informal carers.[6]

In most jurisdictions there a consensus that it is ethico-legally permissible, in certain circumstances, for one person to have decisional authority about another's involvement in research. Despite this, there is little consistency internationally on the legislative procedures and ethical governance that underpin proxy involvement.[7,8] Heterogeneity in the terminology, legislation, and ethical frameworks concerning the use of proxies in research can hinder international research collaboration, lead to confusion for the parties involved and may ultimately prevent a person's wishes about research involvement being honoured at the end of life.[7–9] The situation is particularly challenging in the US, where there is state-level variation, and little national consensus despite many people accessing care, treatment and research across state boundaries.[8] In the UK, there is variation across the devolved nations and depending on the type of research study.[10]

For consistency, the term "proxies" is used throughout this review to encompass all forms of third-party involvement in supporting or making decisions about research participation involving a person with impaired capacity. This ranges from circumstances in which consent is not possible in any circumstances (e.g. unconsciousness) through to situations in which informed consent might be possible with appropriate information and support. Indeed, understanding how decision making can be supported by a trusted other, without the need for substituted decision making is a key consideration for the preservation of autonomy and human rights of people with disabilities.[11] We acknowledge that the term "proxy" spans different legal and ethical roles, and may encompass unpaid carers, health, social care, legal professionals and those working in an advocacy role.

Requirements of a proxy within research depends on the model of consent being sought for research (Table 1), which in turn is dictated by study design. Furthermore, there may be variation in the ethical framing of the decision a proxy is asked to support.[9] For example, a proxy may be asked whether they feel a person would wish to take part if able, if able to consent for themselves ("substituted judgement"). Alternatively, a proxy may be asked to consider whether participation would benefit the individual ("best interests").

Table 1. Definitions of models of consent.

Model of consent	Definition
Informed consent	People give voluntary agreement to participate in research or receive treatment, based on adequate knowledge and understanding of relevant information.[12]
Assent	Process by which children or other individuals not able to provide full informed consent are involved in the decision-making process and agree to participate in research to the extent possible for their mental capacity.[13]
Deferred consent	Research interventions take place in the absence of prospective informed consent (e.g. in an emergency situation), with informed consent is sought at the earliest feasible opportunity.[12]
Surrogate consent	Consent is obtained from a legally authorised representative, in accordance with applicable law.[12]
Advance research consent	Individuals consent to participate in a research study in advance of developing impaired capacity to provide informed consent due to illness or other circumstances.[13]

Researchers have begun mapping the "*daunting range of methodological, structural and systemic barriers*" to participation of people with impaired capacity across a range of disciplines relevant to end of life research.[14] Clarifying who should act as a proxy, and how best to support them, is essential for improving the ethical inclusion of adults with impaired capacity. Several strategies have been identified to try and address challenges in recruiting adults with impaired capacity into end-of-life research, including advance designation of a proxy before capacity is lost.[3,5] However, there is uncertainty about how best to engage proxies, with an expert think tank unable to reach consensus on specific recommendations around their use.[3,5] Further research is therefore needed to determine optimal approaches to proxy engagement to enhance the inclusion of adults with impaired capacity in research.

This scoping review was undertaken to identify, describe, and synthesise empirical evidence on the roles of proxies in supporting the participation of people with impaired capacity to consent to research. It also aimed to highlight existing knowledge gaps, with the overarching goal of developing consensus guidance on the ethical and effective use of proxies in palliative care research. Palliative care is one of several specialities where consent challenges and proxy involvement are particularly relevant. Similar issues arise in intensive care, emergency medicine, dementia, and mental health—fields in which impaired capacity is common and standard consent processes may be unworkable.

This review therefore examines proxy involvement across all areas of health and social care research, with a particular focus on interventions and findings applicable to palliative care. It forms part of a wider NHS England research engagement project on structural barriers to research participation for adults with impaired capacity towards the end of life. Our research question was co-developed through workshops and discussions with people who have lived experience of palliative care, impaired capacity, and proxy decision-making. A scoping review methodology was chosen due to the recognised paucity of evidence in this field.[15] Exploring these complex issues from an international perspective enabled both the challenges and facilitators to be captured from a broad range of jurisdictions and contexts.

A preliminary search of MEDLINE, the Cochrane Database of Systematic Reviews, PROSPERO and Joanna Briggs Institute (JBI) Evidence Synthesis was conducted, and no current or underway systematic reviews or scoping reviews on the topic were identified.

Review question

How can proxies be supported to involve adults with impaired capacity in research towards the end of life?

The following sub questions were addressed:

1. Who should act as a proxy for a person with impaired capacity to consent to participation palliative care research?
2. What constitutes "best practice" for the use of proxies in supporting the involvement of adults with impaired capacity in research
3. What roles do volunteers/independent advocates play in supporting ethically-sound research for those with impaired capacity towards the end of life?
4. What support or preparation do all potential proxies require to support involvement of adults with impaired capacity in ethically-sound research?

Methods

Design

A scoping review was selected as the most appropriate method to identify the scope of the evidence in this area, which we expected to have significant gaps, breadth and heterogeneity.[16] Given the absence of standardised reporting guidance on proxies in research, we sought to identify the types of evidence available, identifying key concepts/characteristics where possible. We were also interested in practice internationally, to understand how

legal and ethical frameworks differ. The scoping review was undertaken in accordance with the Joanna Briggs Institute (JBI) framework.[17]

Scoping reviews can be used to inform research agendas and identify implications for policy or practice. The review has been reported in line with the PRISMA extension for scoping reviews (PRISMA-Scr).[18,19] The protocol was prospectively registered in Open Science Framework (https://osf.io/etp7g/).

Search strategy

A three-step search strategy was utilised in this review, in consultation with a senior medical librarian (MH). It consistent of three main concepts identified from the research aim: consent, proxies and research. First an initial limited search of MEDLINE (PubMed) and CINAHL (EBSCO) was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a full search strategy (see Supplemental Appendix 1). The search strategy, including all identified keywords and index terms, were adapted for each included database and/or information source.

This scoping review considered all studies published in English since 2007 (when the MCA 2005 came into effect) to January 2025. Ovid Medline, Ovid EMBASE, EBSCO CINAHL, EBSCO Academic Search Ultimate, Scopus, Westlaw, HeinOnline, APA PsycINFO, and Social Sciences Citation Index were searched using identified search terms. The search strategy was structured using the Population, Concept, Context framework. For population, we used terms relating to third party decision maker, such as proxies, consultees, or surrogates. For concept, we used terms relating to consent and decision making in research, such as competency and patient participation. For context, we initially limited our search to palliative care settings, however this yielded few results, so we therefore expanded our search to all relevant health and care settings where research is conducted (e.g. community, primary care, hospices) with a view to having specific regard to findings relevant to palliative care during data analysis. These concepts were combined using Boolean operators (AND/OR), and adapted for each database (MEDLINE, CINAHL, Scopus, etc.). A full search string is provided in Supplemental Appendix 1. We used backward citation searching to identify any potentially relevant studies not captured in database searches.

Types of sources

This review considered published, peer reviewed studies and grey literature/policy articles of any intervention that describes the use of proxies in the participation of adults with impaired capacity in research to enable detection of all relevant research.[17]

Inclusion/exclusion criteria

The Population, Concept, Context framework was used to determine our key inclusion criteria, as a broader alternative to the conventional PICO (Population, Intervention, Comparator and Outcome[17]) which is less suited to a scoping review[17]; our criteria is described in Table 2.

Study selection

Following the search, all identified citations were collated and uploaded into EndNote® and duplicates removed. This set was uploaded to the Rayyan systematic review platform®. Titles and abstracts were screened for assessment against the inclusion criteria for the review. The first 10% of publications were reviewed by two reviewers (CB, MC) to ensure the eligibility criteria are being applied correctly and then these reviewers (CB, MC) completed their share of the remaining screen independently. The full text of selected citations was assessed in detail against the inclusion criteria. Reasons for exclusion of sources of evidence at full text that do not meet the inclusion criteria were recorded and reported. Any disagreements that arose between the reviewers at each stage of the selection process were resolved through discussion.

Data extraction

Data were extracted from papers by two independent reviewers (CB, MC) using a data extraction tool developed by the reviewers (Supplemental Appendix 2). The first 10 papers were cross checked by both reviewers to ensure consistency of data extraction. Data extracted including general study information, (author, year, geography, study methods), study population and details pertinent to context and concept. Data were identified and mapping to a pre-defined list which was developed from key components of the research question(s), the authors' prior work in this area, and discussions with those with lived experience. These were: models of proxy involvement; education and training needs; challenges and barriers of involvement; known legal, ethical and/or regulatory frameworks. In addition to descriptive data, any outcomes/evaluative findings were also recorded. The two reviewers met regularly to discuss issues encountered or required amendments of the data extraction tool.

Data analysis and presentation

Descriptive data from each paper are presented in tables. Following data extraction, studies were categorised into

Table 2. Inclusion and exclusion criteria.

Domain	Inclusion criteria	Exclusion criteria
Population	• Volunteers, personal and professional consultees, legal representatives, researchers involved in research • Countries, legal entities, and other organisations involved in the governance of research	Any studies where the primary focus involves children (under the age of 18). Animal studies
Concept	• Studies that address recruitment to studies involving individuals with impaired capacity, with a particular focus on the strategies used to inform, educate, or support proxies in making research-related decisions. • Existing ethical guidance from regulatory or governance bodies concerning the role of proxies in such contexts.	Studies concerning proxy decision making in non-research issues such as health or finance
Context	• Any setting in which health and social care research relevant to the research question is being conducted e.g. acute hospital, community, hospice, care facilities	
Timeframe	• 2007– present	Before 2007
Language	• English Language Studies	Non-English Studies (if not translated)
Evidence type	• All descriptions of interventions that described or evaluated the use of proxies in research involving adults with impaired capacity. • Experimental and quasi-experimental study designs; randomised controlled trials, non-randomised controlled trials, before and after studies and interrupted time-series studies, and studies within a trial (SWAT); analytical observational studies, prospective and retrospective cohort studies; case-control studies and analytical cross-sectional studies; descriptive observational study designs, case series, surveys, individual case reports and descriptive cross-sectional. • Qualitative studies focussing on experiences, perceptions, and social processes; methods include phenomenology, grounded theory, ethnography, qualitative description, action research, and feminist research. • Protocols for studies that include proxies in research were also considered.	Case reports, case series, literature reviews, opinion pieces or letters.

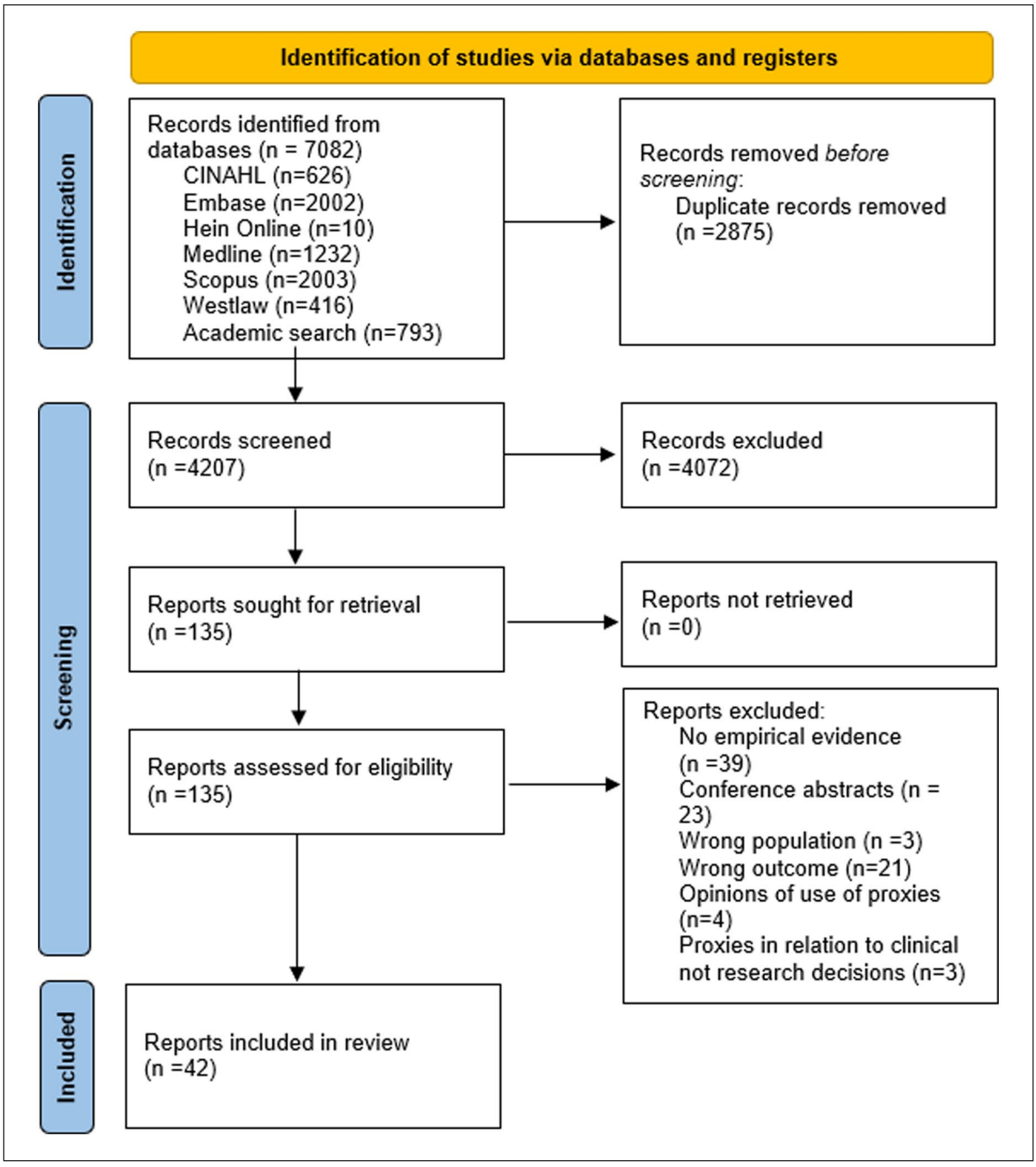

Figure 1. Selection of reports for literature review.[20]

one or more of our pre-defined themes based on their findings. Over the course of the review, the themes were discussed, and revised with all authors (which includes those with lived experience).

Results

A total of 7082 records were initially identified for inclusion in this review. After the removal of 2875 duplicates, 4072 articles were excluded following title and abstract screening. This left 135 reports for full-text review, from which 42 reports were ultimately included in the final synthesis. The selection process is summarised in Figure 1.

Characteristics of included studies

42 studies were conducted across 10 countries; the USA[21–37] ($n = 17$), the UK[38–46] ($n = 9$), Canada[47–50] ($n = 4$), the Netherlands[51–53] ($n = 3$), Australia[54–56] ($n = 3$), India[57,58] ($n = 2$), Switzerland[59] ($n = 1$) France[60] ($n = 1$) Germany[61]

(*n* = 1) and Latin America[62] (*n* = 1). Settings included intensive care (*n* = 10), care homes (*n* = 2), emergency care (*n* = 2) mental health settings (*n* = 2), acute hospitals (*n* = 5), research institutions (*n* = 1), hospice (*n* = 1) and clinics (*n* = 1). The remaining 17 studies were conducted with members of the public and were not aligned to a specific health social care setting. This spread highlights the diversity of both geographical contexts and research settings, with a notable concentration of studies in the USA[21–37] and acute or intensive care environments.[22,30–33,35–37,47–50,52,53,57,59,60] A substantial number of studies also involved public perspectives in predetermined populations,[23–25,28,34,38–43,56,61] offering insight into societal attitudes towards proxy decision-making.

Table 3 describes the extent of the geographic distribution and settings of data collection of the included reports in this review.

The terminology used to describe proxies varied across studies, and countries. Six reports used the term "proxy": two from USA[21,34], two from Australia,[55,56] and the others from India[57] and Switzerland.[59] Three reports from Canada[47–49] and another from USA[37] used the term "Surrogate Decision Maker," whilst other reports from USA used the term "surrogate."[26,33,36] Personal consultee or legal representative was the model of proxy involvement in three UK reports[38,43,46] with another describing a nominated consultee.[45]

The methods of data collection across the included reports were diverse, ranging from hypothetical scenarios examining participants' attitudes and perspectives,[21,23–25,28,29,34,57,58,63,64] to participants' experiences of research involvement research.[30,32,33,35,38,40,43,48,50,56,59] Table 3 provides a detailed overview of the characteristics of these included reports.

The model of consent described in the studies also demonstrated wide variation. In most of the included reports, informed consent was the primary model of consent discussed, appearing in 24 reports.[22,29–32,35–40,42–44,46–48,50,51,54,56,59–61] Data relating to guidance or information used to help inform and/or prepare proxies on the optimal way to support involvement of adults with impaired capacity in research was extracted alongside views and experiences of proxies. This data is reported in our Supplemental materials (Supplemental Appendix 3).

Our analysis identified five themes, with international relevance to researchers undertaking work with populations at risk of impaired capacity towards the life, where proxies may be required to support involvement:

- Communicating Value: understanding role, importance and relevance of research
- Respectful Responsiveness: Getting the timing right
- Trust and Connexion: Ensuring the right people are involved
- Balancing Power and Reciprocity in decision making
- Navigating uncertain legal, ethical and policy contexts

Communicating value: Understanding the role, importance & relevance of research

Twenty-seven reports identified knowledge and understanding as key influences on proxy decisions to support research participation. Being informed about the research project, in terms of benefits, risks and burdens to the participant, and the proxy, was a central theme in this rev iew.[24,27,29–33,35–40,44,46,48,50–57,59–61] Understanding cannot be assumed; sub-optimal communication, complex study materials and poor timing of discussions can result in proxies lacking knowledge or confidence to make an informed decision about the study.[35,50,53,57,60] In a 2022 study of proxy recall after written or verbal consent for an intervention trial, only 36% recalled the purpose of the trial, with regression analysis demonstrating no association between recall, time spent question asking or consent modality.[59]

Proxies emphasised the need for accessible, clear information with "everyday" references to help their own understanding, and to support decision making of the person with impaired capacity.[54] This includes emphasising that participation in research is voluntary, that consent/participation can be withdrawn at any point, and that refusal will not affect ongoing care.[31,33,34,36,49] Additionally, proxies often reported needing clarity about their role in the research process, such as what is expected of them and what role they have in decision-making.[35,38–40,43,45] For example, distinguishing between whether they are being asked to provide information about a person's prior wishes or preferences about research, whether they are being asked to support the decision making by the person in question or whether they are being asked to determine whether research participation might benefit the individual, on their behalf.

Respectful responsiveness: Getting the timing right

In non-acute settings, early engagement in the research process may increase participation.[21,25,27,34,40,41,45] In both acute and non-acute contexts, the stage of a person's illness influences decisions about research participation; with participation more likely if someone is judged to be in a stable condition.[47,51,52,55] The exceptions to this are emergency and intensive care, where a study may be perceived as more acceptable if it confers a potential survival benefit in a critical situation. Spending time to explain the research, pre, during and post study was important to

Table 3. Characteristics of included studies.

Author (year)	Country	Research question	Method of data collection	Setting	Target population and sample size	Model of consent examined	Overall conclusion from the paper as it relates to proxies
Barrett et al. (2012)[47]	Canada	What are SDMs attitudes and preferences regarding their involvement in the consent to research process in the ICU	Structured interview	ICU	Adult, English speaking SDMs; *n* = 136	Informed consent	SDMs who agree to have a relative participate in a study are motivated by the potential benefit to the patient and altruism. SDMs who decline participation, are fearful of study-related harm or dis-comfort for the patient, and are too anxious to consider a research study at that time.
Black et al. (2013)[26]	USA	How do dementia patients or their caregivers make decisions about participation in research and would they want future decisions to be made?	Semi-structured interviews	General public	Surrogates and proxies for PWD; *n* = 85 (46 surrogates)	Assent	Surrogates tended to play a greater role in decision-making when subjects were more cognitively impaired. The recommended approach for enrolling cognitively impaired participants in dementia research using proxy informed consent with subject assent if the individual lacks consent capacity
Bogaerts et al. (2023)[51]	Netherlands	Which factors play a role in decision making on behalf of patients with dementia to participate in an RCT on the deprescribing of antihypertensive treatment?	Semi-structured interviews	Nursing home	Legal guardian (LG)/volunteer LG; *n* = 37 (18 refraining LGs)	Informed consent	When making a decision, LGs weigh factors related to study and patient, leading to benefit- risk evaluation, Decision is influenced by attitudes of LGs, other proxies and HCPs.
Brune et al. (2021)[61]	Germany	What are the motivations for the decision of both legal guardians and legally supervised persons for participation in research projects?	Questionnaire	General public	Legal guardian (also called "supervisor"); *n* = 102 (82 legal guardians)	Informed consent	Generally, a positive attitude towards research among the participants. Perceived risks to patients and possible burden were reasons not to participate.
Burns et al. (2017)[48]	Canada	What are the experiences of SDMs in being approached for consent for critically ill patients to participate in research?	Semi structured interviews	ICU	Substitute decision makers; *n* = 26	Informed consent	Surrogates' assessments of the risks and benefits of participation and their trust in healthcare professionals were critical factors in research decision-making.
Burns et al. (2015)[49]	Canada	What is the experience of SDMs in being approached for research participation?	Questionnaire	ICU	SDMs of critically ill adult, physicians, research coordinators; *n* = 80	No specific model reported	SDMs prioritised the personal attributes of the person approaching them over professional designation and preferred physician time to be dedicated to patient care.
Campwala et al. (2020)[36]	USA	What were the experiences of patients and surrogates who were enrolled in the PAMPer EFIC study?	Interviews	Air Medical	Patients and surrogates about EFIC for emergency research and trial participation; *n* = 93 (23 participant & surrogate 34 only surrogate)	Informed consent	Participants and surrogates are generally accepting of exception from informed consent.
Clarridge et al. (2015)[30]	USA	What is the relationship between a surrogate's difficulty in providing substituted judgement and their receptivity to permitting study enrolment?	Questionnaire	ICU	Surrogate decision makers for critically ill adults; *n* = 445	Informed consent	Racial background and attitudes about research strongly influenced surrogate interest in study enrolment. Factors which influence decision making in research may not correspond to those involved in making therapeutic decisions.
Corneli et al. (2018)[34]	USA	Is an early enrolment strategy using advance consent for research on health care–associated pneumonia acceptable to stakeholders?	Semi-structured telephone interviews with stakeholder groups	General public	1. Researchers, 2 patients 3 cares, 4 representatives of institutional review boards and 5. Study co-ordinators; *n* = 52	Advance research consent	An early enrolment strategy for research is reported to be acceptable. This will help caregivers to provide proxy consent.
De Vries et al. (2010)[23]	USA	Is a deliberative democracy approach for generating informed public opinion on the ethically challenging issue of surrogate based research effective?	Survey	General public	Caregivers or primary decision-makers for persons with dementia; *n* = 212	Surrogate consent (legal guardian versus concerned family member versus a combination of the two)	The need for sacrifice, the difficulty of deciding for others, and the search for answers influence public opinion of surrogate-based research.
De Vries et al. (2011)[24]	USA	Is a framework for assessing the quality of democratic deliberation a useful tool for bioethics?	Deliberation	General public	General public (aged 50 years or older); *n* = 503	Surrogate consent	Outcomes not specific to proxies
De Vries et al. (2013)[25]	USA	What major themes emerged from a discussion and debate around the ethics of surrogate consent for dementia research?	Deliberation	General public	General public (aged 50 years or older); *n* = 212	Research advance directives/surrogate consent	The public appears cautiously supportive of surrogate consent, trusting the scientific process and oversight to act responsibly. This trust is dynamic and may shift depending on how well society manages the inclusion of vulnerable, incapacitated individuals in research.

(continued)

Table 3. (continued)

Author (year)	Country	Research question	Method of data collection	Setting	Target population and sample size	Model of consent examined	Overall conclusion from the paper as it relates to proxies
Dixon-Woods and Angell (2009)[38]	UK	How have research ethics committees interpreted the legal requirements governing adults who lack capacity to consent to research?	Analysis of research applications	General public	Personal/nominated consultee, personal/professional legal representative; *n* = 50	Informed consent	Confusion exists around the consultee process.
Dunn et al. (2011)[29]	USA	What factors influence proxies' decisions to enrol their relatives with Alzheimer's disease in research?	Semi-structured interview	Geriatric psychiatry outpatient clinic	Spouses, adult children or grandchildren, friends, or other carers for people with AD; *n* = 82	Informed consent	Proxies weighed numerous factors, incorporating both substituted judgement and best interests standards, in their decision-making process.
George et al. (2018)[57]	India	What factors influence f inpatients with non-organic psychiatric disorders, and of their key relatives, to participation in RCTs?	Prospective, mixed-methods study	Adult inpatient units of the department of psychiatry	Adults admitted for at least 1 week on a voluntary or involuntary basis, with a clinical diagnosis of a mental disorder; *n* = 24 (12 patient- key relative dyad)	No specific model reported	Routine assessments of the capacity of psychiatric research participants, and of relatives providing proxy consent, appear to be warranted.
Ho et al. (2018)[54]	Australia	What are the challenges in gaining informed consent for a research study investigating falls in people with intellectual disability?	Supported consent methodology	General public	Persons with intellectual disability, their caregivers, legal guardians; *n* = 37	Informed consent	Caregiver to provide their opinion, the researcher to provide a clinical judgement and the participant themselves, within the limits of their cognitive abilities, to provide informed consent to participate in the study.
Huttner et al. (2022)[59]	Switzerland	What are the differences with patient and proxy recall after providing written or oral informed consent to participate in an interventional trial?	Questionnaire	Acute hospitalisation	All patients with capacity and all proxies of patients without capacity participating at a single site; *n* = 231	Informed consent	The ability of proxies, physically healthy but emotionally stressed, to provide truly informed consent requires further exploration.
Kasner et al. (2009)[22]	USA	What are the factors associated with participation in clinical trials of novel therapeutic agents for acute stroke?	Prospective survey (structured interview)	Stroke treatment units	Patients admitted with stroke/ cerebral haemorrhage); *n* = 200 (106 proxies)	Informed consent	Demographic factors, clinical factors, and prior knowledge about research have little impact on the decision to participate in acute stroke clinical trials. Preexisting negative attitudes and external influences about research strongly inhibit participation. Patients are more inclined to participate than their proxy decision-maker.
Kauffman et al. (2013)[27]	USA	How to engage hard-to-reach patients in research design, implementation and dissemination?	Focus groups (one interview)	General public	Hard to reach (group that does not typically participate in research due to cultural or socioeconomic barriers, or owing to physical or cognitive impairment) individuals or their caregivers; *n* = 160 (65 carers/ parents/physician/nurse)	No specific model reported	To make patient-centred outcomes research more meaningful to patients and carers, it should focus on building and maintaining trust through early community engagement and ongoing involvement of participants and their communities.
Krutsinger et al. (2024)[37]	USA	What are the barriers and facilitators of critical care trial enrolment? What are surrogate decision-makers' perspectives on proposed interventions to facilitate trial enrolment?	Qualitative study	ICU	SDMs of patients in the ICU; *n* = 20	Informed consent	Health system trust, study risks and benefits, altruism, knowledge generation, interference with clinical care, and placebos are key concerns and barriers for surrogate decision-makers to enrol patients in critical care trials.
Labruyère et al. (2022)[60]	France	What are families' perceptions regarding their involvement in decisions about research participation on behalf of a loved-one?	Semi-directive interviews	ICU	Relatives of adults admitted to ICU and consented to clinical trial; *n* = 15	Informed consent	Family members often feel legitimate in providing consent due to their trust in ICU physicians and France's clinical research regulations. Clear communication and high-quality information from care staff is important in decision making. Their limited understanding of research can lead to feelings of vulnerability.
Mehta et al. (2012)[50]	Canada	Why do substitute decision makers provide or decline consent for ICU research studies?	Questionnaires	ICU	SDMs who agreed and declined participation in study; *n* = 96	Informed consent	SDMs' major motivations to agree to research study are potential patient benefit, altruism, and the desire to advance medical progress. SDMs who decline are not opposed to research in principle but are too apprehensive about their loved ones to consider research.

(continued)

Table 3. (continued)

Author (year)	Country	Research question	Method of data collection	Setting	Target population and sample size	Model of consent examined	Overall conclusion from the paper as it relates to proxies
Misra et al. (2014)[58]	India	What are the attitudes, expectations and reasons of epilepsy patients and their attendants for participating in research on status epilepticus?	Semi-structured interviews	Neurology	Epilepsy patients and attendants; *n* = 76 (32 patients 44 attendants)	Proxy consent waived consent pre-consent	Unwillingness to participate is research was due to apprehension and lack of will. Proxy consent was preferred to other models such as waived consent and pre-consent.
Noori et al. (2024)[52]	Netherlands	What factors could influence healthcare professionals' decision-making during recruitment of patients for interventional studies?	Semi-structured interviews	Emergency care	Physicians and nurses working in emergency trauma care; *n* = 10	Deferred consent	A general lack of knowledge seemed to be the most important reason for a negative attitude towards deferred consent procedures in clinical studies among HCPs involved in patient enrolment.
Overton et al. (2013)[28]	USA	How do proxies conceptualise assent and dissent to research?	Surveys and in-depth interviews	General public	Proxy decision makers (adult children, stepchildren, grandchildren, spouses and siblings); *n* = 25	Assent/dissent	Outputs of the study point towards potential directions for improved guidelines and policy making regarding the surrogate consent process.
Ries and Mansfield (2021)[55]	Australia	How do dementia researchers feel that advance research directives should be implemented and used to facilitate planning and involvement for future research?	Survey and semi-structured interview, based on protocol ARD	Research active sites and institutions	Researchers in Australia with direct involvement in the ethical aspects of dementia-related research; *n* = 11	Advance research consent	An advance research directive template should prompt the person to name one or more trusted individuals to be involved in future decisions about research. Discussing wishes in advance can improve confidence in future decision making and reduce uncertainty for proxy decision makers.
Scicluna et al. (2019)[35]	USA	What are the positive and negative experiences that drive patients and surrogates to be involved in research?	Interviews	MI/stroke units	Patients (or surrogates enrolled in an acute MI or acute stroke trial); *n* = 27	Informed consent	Participants identified productive ways to demonstrate respect for patients during enrolment conversations. These include key researcher behaviours, concentrating consent discussions on what participants find most important, and structured post enrolment follow-up.
Shelton et al. (2015)[31]	USA	How does a new, computer-based education module affect surrogates' understanding of the process of informed consent?	Pilot study (educational tool) with post-intervention testing	ICU waiting room	Potential surrogate consenters in the future; *n* = 134 (65 experiment 69 control)	Informed consent	Preparing patients' family members who may consider serving as surrogate consenters is critical to facilitating genomics research in critical care.
Shepherd et al. (2022)[39]	UK	What constitutes a high-quality proxy informed consent decision?	Cognitive interviews	General public	Family members of someone with a condition that affects (or may affect) their ability to provide consent; *n* = 11	Informed consent	Development and validation of the CONCORD scale, a measure of the quality of proxy decisions. A higher quality decision is defined as "one in which the proxy is prepared and supported to make a decision and feels satisfied they have made a decision based on the preference of the person they are representing and where they accept the uncertainty they experience"
Shepherd et al. (2019)[40]	UK	What are the experiences of family members of individuals who lack capacity and who have been approached to participate in a research study?	Semi-structured interviews	General public	Family members who had experience as a proxy for making decisions about participation in research; *n* = 17	Informed consent	Proxy decision-making for research is a complex process with inter-woven layers of decision-making. Decisions can be problematic for some proxies who may benefit from decision support to make an informed decision about research participation on behalf of a family member.
Shepherd et al. (2024)[41]	UK	What are the issues around the implementation of advance research planning in the UK?	Semi-structured interviews	General public	Researchers, practitioners, and members of the public; *n* = 27	Advance research planning (ARP)	Six key themes emerged: including (2) A missing part of the puzzle – how ARP can inform proxy decision-making.
Shepherd et al. (2021)[42]	UK	What concepts and considerations do proxies use to make decisions in research?	Qualitative study	General public	Family members who had acted as a research proxy for a person who lacks capacity; *n* = 17	Informed consent	Emergent concepts/considerations: integration of interests and preferences, focus on authenticity rather than decision accuracy, fundamental role of trust.
Shepherd et al. (2019)[43]	UK	"What written information is provided to proxies who have been approached to be involved in decision-making about research participation for an adult who lacks the capacity to provide his/her own consent? "	Content analysis (pragmatic content analysis approach, incorporating both quantitative and qualitative analyses)	General public	Current or recently completed studies from the NIHR co-ordinated UK Clinical Trials Gateway public database; *n* = 30 studies	Informed consent	Proxies should be provided with adequate and accurate information which complies with the legal frameworks.

(continued)

Table 3. (continued)

Author (year)	Country	Research question	Method of data collection	Setting	Target population and sample size	Model of consent examined	Overall conclusion from the paper as it relates to proxies
Shepherd et al. (2021)[44]	UK	Can a core outcome set for the evaluation of interventions o improve proxy decisions about trial participation on behalf of adults who lack capacity to consent?	Scoping review, Delphi consensus	General public	Stakeholder groups: People with experience of living with a condition, Family members, Researchers, Ethicists and methodologists with an interest in trials and/or informed consent; *n* = 28	Informed consent	Enhancing the quality of proxy trial participation decisions will ensure that they better reflect the preferences of people who are unable to provide their own consent and reduce the emotional and decisional burden experienced by their proxies.
Sole et al. (2017)[32]	USA	What are the enrolment challenges in critical care nursing research?	Cohort analysis	ICU	Participants in an ICU intervention; *n* = 319 (Proxies provided consent in 99% of cases.)	Informed consent	Inadequate study staff, unit involvement and a short enrolment window in a setting where most patients are unable to provide consent creates a challenging barrier when waiver of consent is not permissible.
Stanley and Nwosu (2021)[45]	UK	Can the use of advance consent methodology and a healthcare professional consultee facilitate research participation in dying patients?	Case report	Hospice	Consultee (this can be any family member, friend or healthcare professional; *n* = 1	"Consent"	Methodological and ethical challenges in end-of-life research need to be considered when designing studies to ensure patients and their families feel safe to participate.
Stocking et al. (2007)[21]	USA	Does a research advance directive, the Planning Ahead Together document have a positive effect on outcomes?	Interviews	Alzheimer's centres/ memory centre	Patients with dementia and their family caregivers or proxies; *n* = 149 dyads	Informed, proxy and advance consent	Mixed opinions as to the usefulness of the document. Proxies' opinions were slightly more favourable.
Terry et al. (2017)[33]	USA	To what extent do patients and their surrogates endorse deferred consent for minimal risk ICU based research?	Structured interview (survey)	ICU	Newly admitted ICU patients (and their caregivers); *n* = 28	Deferred consent	Participation in the study was more likely when consent was sought from patient rather than surrogate.
Towers et al. (2016)[46]	UK	What is the acceptability and feasibility of using the Adult Social Care Outcomes Toolkit (ASCOT) to inform practice in care homes?	General observations, conversions, structured interviews	UK care homes (includes dementia)	Staff and residents (or their consultee); *n* = 58 (31 consultees)	Informed consent	Outcomes not specific to proxies.
Undurraga et al. (2023)[62]	Global forum Latin America	What safeguards should be in place to protect adults who lack decisional capacity participating in research?	Case study	Outpatient mental health treatment	People with mental health disorders; *n* = 2	Assent/dissent: advance directive	Research studies need to have safeguards in place to enable inclusion of participants with impaired capacity to consent; this includes the use of appropriate proxy decision makers.
van den Bos et al. (2021)[53]	Netherlands	What are patient and proxies' attitudes towards deferred consent in randomised trials of acute treatment for stroke?	In-depth, semi-structured interviews	Stroke treatment units	Patients or their proxies who provided consent; *n* = 23 (7 proxies)	Deferred consent	Participants usually considered deferred consent acceptable and felt capable of providing consent. The best timing for deferred consent remains unclear.
Yoon (2023)[56]	Australia	How can proxy intervention interview as potentially a successful way to explore the artistic experiences of those artists who cannot speak or articulate their thoughts and expression directly through verbal or written conversation?	Proxy intervention interview method	General public	People with cognitive disability who are developing professional careers as artists; At least 4	Informed consent	"Proxy intervention interview" is shown to be an inclusive research approach for incorporating the voices of individuals who cannot articulate their thoughts or describe their experiences.

LG: legal guardian; ICU: intensive care unit; SDM: surrogate/substitute decision maker; PWD: patients with dementia; NIHR: national institute for health and care research; HCP: healthcare professional.

proxies, as was the ability to delay decision making if more time was needed.[44]

Where considered, there was a strong interest in how early conversations about advance research planning[41,55] and advance consent[45] might support research participation for people who go onto to development impairments in mental capacity. The need for tools to help people involve family members in these discussions has been identified, not least because such individuals may go onto to provide the practical support and care needed to participate in research.[41] Targeted educational initiatives around advance research planning (e.g. during will writing or as part of advance care planning activities) might increase public awareness.[25] Evidence suggests that advance research planning or advance consent can facilitate research inclusion, particularly in dementia care[55] and hospice settings.[45]

Trust and connexion: Ensuring the right people are involved

A proxy's decision to support research participation is shaped by relational factors, including their interpersonal and prior experiences with the person they represent, family dynamics, and their connexion, new or existing, with the research team.[25,28,41–43,48] Proxies reported greater willingness to participate when they had access to someone they could ask questions and receive updates from.[24,27,29,39,44] Building rapport is particularly important for people with cognitive impairments and their carers, to enable the carers to contribute to a supportive environment for discussion, based around that person's communication requirements.[56] Inclusive community engagement may help widen opportunities to engage with research, particularly around advance research planning.[41]

Proxies valued researcher attributes such as kindness, confident tone, an unhurried communication style, and openness to questions.[48] A 2015 Canadian study found that proxies prioritised these personal qualities over the researcher's professional designation.[49] Proxy suitability depends on multiple factors, including the research context, availability of a trusted individual, legal frameworks, and the consent model used. An Ethiopian case study highlighted the complexity of proxy roles in mental health trials, where carers' treatment priorities and involvement in coercive practices (e.g. restraint) created ethical tensions.[62]

Legal frameworks include the use of independent advocates to support individuals without family or friends in medical and social care decisions,[65,66] but we found no evidence of equivalent advocacy roles in other jurisdictions for supporting research involvement. Across studies, proxies were almost exclusively family or unpaid carers,[21,24,29–32,40,42,43,45,60] highlighting a critical gap in ethical infrastructure for people with impaired capacity who have no informal support network.

We were unable to answer our research question from the literature to determine who should act as a proxy. Given the complexity of proxy decision-making and its reliance on trust, motivation, and ethical sensitivity, how and why a proxy is involved may matter more than who the proxy is.

Balancing power and reciprocity in decision making

Acting as a proxy can be emotionally challenging, especially when being asked to take responsibility for making decisions on behalf of someone with impaired capacity.[24,40,49,50,60] In addition to emotional strain, practical burdens related to the study itself also affect proxy decisions.[26,46,51,54,55,61] Ries and Mansfield noted that even when an advance research directive is in place, proxies still bear logistical burdens like arranging transport to research sites.[55]

Five reports identified concerns about potential coercion from clinicians during the research consent process.[26,37,49,60,62] Power imbalances can influence proxy views, a known issue under many forms of mental capacity legislation, where healthcare professionals often serve as decision makers for health and care decisions.[66] These power dynamics may be subtle; for example, one study found that proxies were more likely to agree to participation in research, if asked immediately after a clinical update from a medical professional.[47] Favourable attitudes towards research were associated with high level of trust in clinicians.[30] Proxies may also be guided by their own values rather than the patient's wishes.[28]

Terminology is important; whilst the use of "participants" was common, for others, this was perceived as reducing them passive subjects, disconnected from the study processes and demeaning of their valuable contributions to research. Respectful engagement was seen as critical to maintain trust and ethical involvement.[27]

Navigating uncertain legal, ethical and policy contexts

This review of international literature highlights heterogeneity in the legal and ethical frameworks governing research across countries. Studies from the Netherlands and France suggest that high trust in national legislation is associated with greater participant willingness to consent to research.[51,52,60] The development of policies to support proxy decision-making may further facilitate ethical participation[23,28,40,62]

Conversely, it was identified that inconsistencies or inaccuracies in the way that statutory and regulatory bodies (such as research ethics committees) viewed, reviewed or interpreted proxies in research had the potential to exclude people who may be eligible to be consulted.[38,40,60]

Irrespective of the prevailing ethico-legal framework in the country where they reside, proxies often weigh their own hopes, needs, and expectations[28,44,48] alongside the perceived wishes and best interests of the pati ent.[25,28,32,34,39–45,48,50,55] Nine studies reported that both potential individual and societal benefits factored into decision-making, with societal benefit often carrying more weight[25,26,29,33,37,40,42,50,51]

No definitive guidance exists on how proxies should decide about research participation for people who are unable to provide informed consent, nor how to determine the person's wishes. Many aspects of "best practice" may vary by study design and jurisdiction. Key challenges include the setting in which consent is sought,[32,33,35,47,52,53] the communicator's approach,[32,35,48,49,53] and the often time-sensitive nature of these decisions.[22,32,35,37,47,49,50,52,53,57]

What support or preparation do all potential proxies require? A consensus statement on involving proxies in end-of-life research[5] highlighted structural and procedural improvements, like early involvement, clear role definition, and national support, but it does not fully elaborate on how proxies can be trained or supported to optimise the involvement of the person they represent. This is a notable gap, especially considering that international human rights treaties[11] call for reasonable adjustments and communication supports to enable the person's own preferences and participation to the greatest extent possible, which logically extends to supporting proxies to enable this.

Discussion

This review offers an international perspective on proxy involvement in research with adults impaired capacity, revealing considerable variation in consent models, data collection methods, and legal-ethical frameworks across jurisdictions. While previous studies have explored proxies' views and ethical issues,[9,40] this is the first to systematically synthesise the structures and mechanisms required to support proxies in this role.

This review highlights substantial international variation in proxy involvement, reflecting diverse legal, ethical, and cultural frameworks that govern research. Perceptions of research importance also vary culturally. For instance, a French study described participation as a "citizens' duty,"[60] while a Korean–U.S. survey of institutional review boards found Korean respondents prioritised communal benefit, whereas U.S. respondents emphasised individual rights.[64] In palliative care, where person-centred, individualised decision-making is central, these ethical and cultural differences must be navigated with sensitivity.[3,5,67]

Differences also emerged between acute and non-acute settings. In non-acute settings, proxies expressed a need for clear contacts and ongoing updates.[27,29,39,42] Barriers included indecision, risk aversion, and emotional burden.[45,46,58] Researchers can address these through thoughtful study design, including building rapport through physical presence, providing clear information about the research team, and offering consistent contact points.[44] In hospice settings, which may lack dedicated research teams, exploring partnerships with volunteers or advocates, common in palliative care, may offer a valuable future strategy.

Proxies frequently reported being guided by the previously expressed wishes and values of the people they represent.[25,28,34,39–45,55] This underscores the importance of early engagement in research discussions, ideally initiated while the individual retains capacity.[21,25,27,34,41,43,45,55] Community awareness initiatives were also identified as valuable in preparing both potential participants and proxies for future involvement.[27] A phased approach to introducing advance research planning, starting with "priority" populations in whom it is most likely to be relevant (e.g. conditions characterised by progressive cognitive impairment) has been recommended, whilst taking care to avoid any sense of a moral obligation to participate.[55] In palliative care, where relatives or carers are often already involved in broader conversations about future care preferences, advance research discussions with potential proxies may offer a practical and ethically sound extension of existing practices. However, there is a need for more guidance and tools to support all those involved in advance research planning activities.

The burden placed on proxies emerged as a significant concern across multiple studies.[26,46,51,54,55,61] Researchers must acknowledge and address this burden by developing protocols that support proxies as well as participants. In palliative care, this support should extend beyond the participant's lifetime and into bereavement. Consideration should be given to how and when research findings are communicated to bereaved relatives, with sensitivity to timing, content, and emotional impact.

Education and understanding about the research and its potential effects consistently emerged as a key theme across the literature, serving both as a barrier and an enabler to participation.[24,27,29–33,35–40,44,46,48,50–57,59–61] A systematic review reinforces that adequate knowledge and comprehension significantly influence willingness to participate, while insufficient understanding can undermine the validity of informed consent.[68] Furthermore, education plays a critical role in addressing the "gatekeeping" phenomenon frequently observed in palliative care settings, where clinical staff may hesitate to approach potential participants or proxies for research involvement.[3,5]

Although providing clear and accurate information to proxies is essential to support participation, this is not always achieved in practice. International variation in statutory and ethical procedures may hinder the development of consensus guidance which might support proxy

involvement, with some jurisdictions having out of date guidance leading to further uncertainty.[69] Understanding how study materials might meet the requirements of research ethics boards, whilst remaining comprehensible and accessible for people with cognitive impairments, and their proxies is a key consideration.

Best practice for involving proxies in supporting research participation for adults with impaired capacity requires an approach that is adaptive, multidimensional, and responsive to context.[70] The Context and Implementation of Complex Intervention Framework offers a valuable lens for understanding the range of contextual determinants that influence proxy decision-making. This framework comprises of three interacting dimensions; context, implementation and setting, with context further divided into seven domains: geographical, epidemiological, socio-cultural, socio-economic, ethical, legal, and political.[71] Each domain operates at micro, meso, and macro levels, from national policy to interpersonal relationships.

Applying the Context and Implementation of Complex Intervention Framework to proxy decision-making in palliative care research helps generate hypotheses about the determinants of inclusion, revealing how broader, macro-level policies and governance structures shape individual decisions at the point of care. We propose that these hypotheses be further explored in future empirical research to inform evidence-based recommendations for practice.

To promote the ethical inclusion of this underserved group, future work should focus on the development of co-produced, context-specific complex interventions that reflect the diverse legal and cultural contexts in which proxy decision-making occurs.[72]

Limitations

As a scoping review, this study aimed to map the breadth and nature of existing literature rather than critically appraise study quality. Despite a comprehensive search, some relevant evidence may have been missed due to publication bias, database limitations, or language restrictions. No formal risk of bias assessment was conducted, limiting conclusions about study quality. Variations in consent models, data collection methods, and healthcare contexts contribute to heterogeneity, so findings may not be fully transferable to palliative care settings. Furthermore, due to the inherent variation observed across jurisdictions, our ability to produce definitive generalisable conclusions is limited.

The Context and Implementation of Complex Interventions framework[71] is a conceptual tool for organising understanding of context, implementation, and intervention complexity, rather than an analytical method. Caution is needed to avoid "retrofitting" findings to the framework instead of creating themes inductively.

Conclusion

This review underscores the urgent need for clearer guidance, targeted education, and ethical support for proxies making research decisions on behalf of adults with impaired capacity. Proxy decision-making is complex, involving legal, ethical, emotional, relational, and contextual factors. Variations in consent models place differing demands on proxies as they interpret and apply the person's wishes and interests, often while managing personal values and emotional burden. To promote equitable research inclusion, accessible, jurisdiction-specific guidance, training for proxies and researchers, and ongoing support mechanisms are essential.

These challenges are especially pronounced in palliative care, where individuals may experience rapid or progressive loss of capacity due to conditions such as advanced cancer, dementia, or neurological disease. In such contexts, proxy involvement may be the only viable route to research participation, underscoring the need for sensitive and timely support.

However, efforts to address these challenges may be hampered by a lack of legal reform or updating of the ethical and professional codes which govern this area of research. For example, in England and Wales where the authors of the review are located, the delayed update of the Mental Capacity Act 2005 Code of Practice highlights the pressing need for practical, comprehensive guidance to support ethical, inclusive research and clarify proxy roles in evolving legal frameworks. We only have one opportunity to ensure people receive the best care at the end of their life. If palliative care research is to be "fit for purpose" to provide the best evidence for care at the end-of-life care, there is a pressing need for practical, comprehensive guidance to support ethical, inclusive research and clarify proxy roles in evolving legal frameworks.

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CB conceptualised the study idea, goals and aims with input from VS, GP, KB and RH. CB, VS, GP, KB, MH and RH developed the methodology and search strategy. CB and MC screened abstracts and extract the data. CB and MC wrote the initial draft. All authors were involved with reviewing, editing and approving the final version of the paper. All authors approved the final version. CB is the guarantor.

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Supplemental material

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