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Consent and Inclusion of People Living with Dementia (PLWD) in Research: Establishing a Canadian Agenda for Inclusive Rights-Based Practices

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Abstract

Background People living with dementia (PLWD) may want to participate in research, but the guidelines and processes enacted across various contexts may prohibit this from happening.
Objective Understanding the experiences of people with lived experiences of dementia requires meaningful inclusion in research, as is consistent with rights-based perspectives. Currently, the inclusion of PLWD in Canadian research is complex, and guidelines and conceptual frameworks have not been fully developed.
Methods This research note outlines a three-year proof-of-concept grant on the inclusion and consent of PLWD in research.
Findings It presents a brief report on some of the contradictions and challenges that exist in legislation, research guidelines, and research practices and raises a series of questions as part of an agenda on rights and inclusion of PLWD in research.
Discussion It suggests conceptual, legal, and policy issues that need to be addressed and invites Canadian researchers to re-envision research practices and to advocate for law and policy reform that enables dementia research to align and respect the rights and personhood of PLWD.

Résumé

Context Les personnes qui vivent avec la démence pourraient vouloir participer à la recherche, mais les lignes directrices et processus en vigueur dans divers contextes pourraient les empêcher de le faire.
Objectif Pour comprendre le vécu des personnes atteintes de démence, il est nécessaire de les faire participer de manière significative à la recherche, comme le préconisent les approches fondées sur les droits. À l'heure actuelle, le processus d'inclusion des personnes vivant avec la démence dans les études canadiennes est complexe et les cadres conceptuels sont encore en cours d'élaboration.
Méthodes Cette note résume un projet d'étude de validation de concept sur l'inclusion des personnes vivant avec la démence dans la recherche et leur consentement. Cette étude est subventionnée et s'étendra sur trois ans.
Résultats La note donne un bref aperçu des contradictions et des défis que présentent les lois, les lignes directrices et les pratiques de recherche actuelles, et formule une série de questions que soulèvent les droits et l'inclusion des personnes vivant avec la démence dans la recherche.
Discussion Elle recense les enjeux conceptuels, juridiques et politiques qui doivent être abordés et invite les chercheurs canadiens à repenser les pratiques de recherche et à plaider en faveur d'une réforme des lois et des politiques qui permette à la recherche sur la démence de s'aligner sur les droits et l'identité individuelle des personnes vivant avec la démence, et de les respecter.

Introduction

Growing emphasis is placed on including people with dementia in research. This is consistent with a rights-based perspective. People living with dementia (hereafter PLWD) want to share their experiences and participate in decisions that affect their lives (Marlett & Emes, 2010; Schilling &

Gerhardus, 2017), and recent Canadian frameworks outline the importance of including older people and PLWD in the research process (Alzheimer Society of Canada, forthcoming; CIHR, 2022). However, contradictions and challenges exist for achieving this across Canadian research contexts. Research projects carried out in settings where older people live, such as at home, in the community, and in group living situations, such as long-term care, provide possible sites for meaningful involvement, voice, and inclusion. Yet, the current Canadian research terrain is fraught with a lack of clear national or provincial/territorial guidelines, confusion about the rights of PLWD, misunderstandings about vulnerability and capacity, and institutional practices whereby decisions made by gatekeepers – including institutional bodies, research ethics boards, and even researchers themselves – can limit the access and meaningful participation of PLWD in research. This is not to suggest that research with PLWD is not happening in Canada. Rather, the structures and processes through which research operates have led to inconsistent research practices, confusion, and barriers to inclusion which hinder the enactment of rights-based approaches to research with PLWD (Davis, 2017; Ries et al., 2019).

This research note draws attention to contradictions that exist at the intersection of human rights and research ideals about inclusion, institutional practices, and guidelines for research consent and how these contradictions shape the enactment of research practice with older people. Situated as part of a larger proof-of-concept grant, this research note aims to set a research agenda, point to gaps and challenges in need of exploration, and invite Canadian researchers to re-envision research in ways that respect the rights and personhood of PLWD and achieve appropriate involvement of PLWD in the research that affects their lives. We begin by sketching some immediate contradictions that brought our team to propose the proof-of-concept project. We then highlight how these contradictions and/or lack of guidelines create challenges for the inclusion of PLWD in research, particularly as they operate through formal mechanisms (i.e. legislative frameworks, university research ethics boards, institutional research settings, etc.) and the research practices of researchers and their teams. It outlines questions that need to be addressed and presents a three-year proof-of-concept project aimed at beginning to address them.[1] Building on this, this research note summarizes a research agenda for research, policy, and practice in Canada.

Why focus on informed consent in Canadian dementia research?

Our collective experience in the fields of aging, law, and dementia research with older people brought us to propose the proof-of-concept project. A number of challenges are present in the Canadian research context on dementia. First, all Canadians should have the right to participate in research. Most typically, access to do so occurs through processes of informed consent governed by Tri-Council agreements such as the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2) (CIHR, 2022) and established via processes set out by university ethics boards and the institutional contexts within which the research is conducted – typically health or community settings. While international frameworks such as the Universal Declaration of Human Rights (UDHR) (United Nations, 1948) and the Convention on the Rights of Persons with Disabilities (CRPD) (United Nations, 2006), provide a set of boundaries to enshrine rights and foster the access and inclusion of people living with dementia and/or disabilities, these sets of ideas are typically not considered in the formal institutional processes that shape research (also see Canadian Association for Community Living, 2014; Government of Canada, 2017). Further, despite calls for inclusion and the recognition of rights and citizenship that operate in the academic literature on dementia and disability (Bartlett & O'Connor, 2007; O'Connor et al., 2022; Shakespeare et al., 2019; Thomas & Milligan, 2018), there is both a lack of clear Canadian guidelines about how to facilitate rights and inclusion in research and wide variations in understanding the extent to which PLWD can participate in research across the country.

Second, there is widespread misunderstanding about consent and mental incapacity in relation to PLWD and a gap with regard to consent in the context of research – particularly for research that is conducted outside of hospitals and institutions. Formal guidelines for consent in the context of research do not exist Canada-wide, resulting in misinformed and incorrect applications of ideas and/or processes intended for care or personal decision-making or that are jurisdiction-specific. This becomes problematic in a system whereby informed consent implicitly (and explicitly) operates to structure access to research participation, and thereby imposes limits on the achievement of inclusion and human rights. Without clear guidelines about consent that have been broadly made known to researchers and/or adapted for the research context (e.g. Canadian Association for Community Living, 2014; Government of Canada, 2017), researchers are left to individually negotiate access and inclusion of PLWD with few formal tools or guidelines. Together, the lack of clear Canadian guidelines for inclusion, misunderstandings about informed consent, and the absence of connections to human rights or disability framework mean that the Canadian landscape of dementia research operates via practices characterized by misleading ideas, discrimination, and bias that block participation, inclusion, and the achievement of rights.

Against this backdrop, a key problem is presumed incapacity. That is, the idea that PLWD do not have the capacity to make informed decisions about their participation and must be automatically excluded from research processes. Presumed incapacity is known to operate in decisions made by research ethics boards, funding agencies, and individual researchers. However, the presence of dementia is not synonymous with incapacity or vulnerability (Clough, 2017), and although PLWD may be vulnerable due to factors that are both related and unrelated to their dementia, the presumption of incapacity, and its operational enactment across a range of settings, violates legal presumptions of capacity. Indeed, it is the core fundamental principle in law that a person is presumed mentally capable to make a decision, unless specifically proven otherwise, and the limitation on decision-making must be done in the least intrusive, most effective way possible, with regular review for change in ability to decide, including for improvement and a 'resumption' of capacity. To get around presumed incapacity, institutional gatekeepers (including research ethics boards) often suggest involving a substitute (or proxy) decision-maker such as a carer or a family member in lieu of the PLWD. Yet, these 'next of kin' or substitute decisionmakers (including through a power of attorney, legislative authority, or guardianship) do not have the

[1]This project received funding through the proof-of-concept competition of the Alzheimer's Society Canada and ethical approval from the University of Toronto.

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legal authority to make research decisions.[2] The practice of involving a proxy rather than the PLWD violates presumptions of capacity and can be challenged where inclusive access, rights, and best practices of supported decision-making are concerned (Sinclair et al., 2019). While dementia is a condition that *may* bring about vulnerability or incapacity, these states may change over time and the course of the research and require thoughtful deliberation, planning, and support rather than outright exclusion (see Largent et al., 2020; Ries et al., 2019).

The research consent of PLWD: A proof-of-concept grant

Project rationale and objectives: Our three-year proof-of-concept study aims to identify and understand the inclusion of PLWD in research at the intersections of existing structural parameters and guidelines, institutional processes, and research experiences. Our project is the first study to thoroughly examine the law on consent for research participation in every jurisdiction in Canada for both medical and social research, and the first to combine this with an in-depth exploration of everyday research practices. It aims to clarify existing legal parameters and formal guidelines across Canada; identify inconsistencies within and between provinces; explore the inclusion of PLWD in Canadian dementia research via the experiences of researchers in health and social sciences; and locate gaps and processes that impact inclusion and rights. Given the centrality that processes of informed consent play in opening or closing access to research participation, consent is a key principle through which to understand inclusion. The project, however, is not only about consent: it is more broadly about access, inclusion, and the fulfilment of rights. The foundation for our research is based on human rights and the radical starting point that PLWD can thoughtfully and effectively participate in dementia research across Canada. Our team is concerned with exploring processes and practices of consent to participate in research as a way of recognizing rights, understanding the experiences of PLWD, and achieving the meaningful inclusion of PLWD in decisions about their lives. As such, we query processes of systemic bias and exclusion from research, regularly suggested strategies such as substitute decision-making, and other ethically problematic methodological shortcuts and gather information about how researchers negotiate and balance concerns about vulnerability with access, inclusion, rights, and personhood.

Questions for the proof-of-concept project are:

1) What laws, policies, and institutional frameworks govern consent for the participation of PLWD in medical/social research (in each jurisdiction)? What boundaries and parameters exist? What are the gaps?
2) How do social and medical/health researchers understand and enact rights and processes of informed consent with regard to research with PLWD? What are their experiences of carrying out dementia research in Canada?
3) What processes have researchers used to achieve the access, inclusion, personhood, and rights of PLWD in their respective research? What limits, challenges, or barriers have they encountered? Do similarities and differences exist across types of research or context?
4) What existing frameworks could be used to foster the achievement of rights, access, and inclusion? What best practices exist? How can research practices, institutional processes, and legal frameworks be modified to meaningfully include PLWD in the research about their lives?

Methods: Our three-year proof-of-concept grant draws together experts from social gerontology, law, and dementia research, including one person with lived experience of dementia as a co-investigator. The project deploys a multi-method approach comprised of legal research, literature and document review, and qualitative interviews to address the research questions. We will also produce guidelines to equip Canadian researchers with the supports they need to enact inclusive and rights-based approaches. The legal research is comprised of a review of substantive literature on consent, the laws and policies of consent in each province and territory in Canada, and a review of legal and conceptual frameworks pertaining to inclusion, rights, and vulnerability, including but not limited to international frameworks on human rights such as the Universal Declaration of Human Rights (UDHR) (United Nations, 1948) and the Convention on the Rights of Persons with Disabilities (CRPD) (United Nations, 2006). This will be followed by a minimum of 15 semi-structured qualitative conversational interviews with researchers from social and medical research on dementia in Canada. As data are collected the team will compare and contrast results; identify themes, contradictions, and gaps; and, based on this, develop resources including plain-language summaries and guides to assist researchers and institutions to respect rights and achieve access and inclusion at the same time as protecting people who are vulnerable to harm.

Expected results: Our team expects to find a lack of clarity and guidance with regard to rights, access, and inclusion among PLWD and a related set of institutional practices that create barriers to participation for PLWD. In speaking with researchers, we seek to understand how current research practices may create and/or reinforce stigma, exclusion, and the non-realization of rights for PLWD and identify avenues for change. Moreover, we expect that there are both substantive and legal gaps in knowledge and practice which further complicate this terrain and cause contradictions for researchers who are attempting to include PLWD in research. Our intent is to clarify the legal parameters in dementia research; challenge taken-for-granted assumptions that operate through formal and informal research processes; highlight changes that need to be made, particularly at the levels of law and policy reform; and assist dementia researchers in a variety of fields to carry out their research and feel confident engaging PLWD in research. In doing so, we anticipate starting conversations and developing practices that respect the rights of PLWD to consent or refuse to participate in research and which are mindful of vulnerability and protection, as well as achieve the goal of meaningful inclusion via informed and supported decision-making. This will likely involve both materials to guide researchers on achieving access and the inclusion of a group that is too often presumed to have no capacity and excluded from research, and the amendment of legal structures and institutional guidelines such as research ethics boards to support access and involvement, challenge stigma and discrimination, and ensure the meaningful engagement of PLWD in research that ultimately affects their lives. The following section sketches initial research findings identified via complementary research methods including team meetings, literature review, and document

[2]Note that the law on substitute decisionmakers (SDM) varies across the provinces and territories of Canada. Sometimes the province or territory does not allow an SDM to be appointed for research, and sometimes the only eligible substitute decisionmaker is a power of attorney with authority over only financial decisions.

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review in year 1 of the exploratory proof-of-concept project. Together, these form the basis for further investigation through document analysis of legal frameworks, case law, and interviews in years 2 and 3.

Inclusion through informed consent: Challenges in research practice(s)

This section focuses on initial results pertaining to questions 1 and 4, on the existing parameters, gaps, and frameworks. It begins by documenting the importance of consent and drawing attention to the contradictions between the stated ideals of inclusion and the actual practices in medical and social research that can produce exclusion and non-realization of the rights of PLWD. Our results highlight that understanding and enacting inclusion of PLWD through processes of capacity and consent represents a challenging practical, legal, and theoretical landscape in Canadian research. Our project narrows in on the parameters of informed consent as a topic of investigation because it is via these processes that PLWD come to access and participate in research or are blocked or excluded from doing so. Achieving informed consent from PLWD is central to recognizing their rights, as well as hearing and including the voices of people with lived experience. At present, the inclusion of PLWD in Canadian research is complicated because formal structures and institutional guidelines have not been fully developed. Although legal parameters exist for consent to procedures and/or medical treatment, for example, few Canadian legal studies focus on the law of consent for research participation, and there are no existing formal guidelines for including PLWD (and their supporters) in research, and particularly research outside of hospital or care settings. When we dive into the academic literature, we see that Canadian academic research focused on the consent of PLWD to participate in research acknowledges that informed consent is an ongoing process, although there exists much variability in these perspectives and limited discussion of the associated legal and ethical issues (Bravo et al., 2010; Kirby et al., 2012; Qureshi & Johri, 2008; Thorogood et al., 2018). The lack of clarity about consent, however, both in legal definition and formal guidelines, raises challenges for PLWD to consent to participate in medical and social research in Canada, making it difficult to achieve access, meaningful participation, and the fulfilment of human rights.

Our initial results from team meetings, the academic literature, and a review of the legal context within which consent operates point to a number of practical, ethical, and philosophical issues. Although PLWD may have the desire to participate in research, and researchers and Canadian funding bodies may strive for access and inclusion across all population groups, questions and challenges about how to do so abound (Davis, 2017; Downie & McDonald, 2004; Ries et al., 2019). Decisionmakers, gatekeepers, and researchers, for example, may be uncertain and/or unaware of when PLWD can independently make the decision to participate (capacity) and who can provide substitute consent and in which circumstances; misunderstand capacity or the rights and responsibilities of substitute decisionmakers; and/or be confused by provincial variations in law (Bravo et al., 2005). Take, for example, the contradictory sets of knowledge and practice whereby ethics committees may require proxy consent to achieve inclusion, but where research indicates that the beliefs and values of PLWD are not always accurately represented by the chosen proxy (Chandra et al., 2021). In this case, the lack of formal guidelines and/or misunderstandings of consent in practice can inadvertently sustain the exclusion of PLWD from research about their lives and prevent researchers from abiding by ethical, legal, and rights-based frameworks, or following best practices grounded in supportive decision-making. Without a solid understanding of how to achieve consent and who can legally provide consent, researchers cannot carry out research that includes and takes account of the experiences of PLWD. Biases in frameworks and institutional practices that operate based on presumed incapacity, a lack of jurisdictional knowledge about consent (and substitute consent) among PLWD, and/or practices which default to substitute decisionmakers may limit inclusion and jeopardize the human rights of PLWD.

Setting our collective initial findings against one of the only guidelines for research as it is implemented by Canadian researchers – the TCPS2 – reveals a series of larger questions about who can be included in research and how to achieve access, inclusion, and rights. The *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* (TCPS2) states that it is unethical to exclude individuals or group(s) from participating in a study on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, sex, gender, or age, unless there is a valid reason for the exclusion (Article 4.1) (CIHR, 2022). Yet, the guidelines are silent with regard to a diagnosis or inclusion of PLWD, and hence subject to interpretation. There are no specific rules or guidelines indicating that PLWD must be excluded from research or research requirements for proving incapacity among PLWD. Furthermore, despite emerging agendas on inclusion, are there no guidelines to facilitate access and inclusion. Not surprisingly, contradictions regularly arise between ideals and practices of inclusion of PLWD. In the absence of specific guidelines about including PLWD in medical and social research, university research ethics committees and institutional review boards are charged with assessing the risks and benefits related to the participation of PLWD in research and view themselves as tasked with protecting individuals from risk and potential harms (Chandra et al., 2021; Dickert et al., 2017). On the ground, research processes of recruitment and achieving consent in research with PLWD range from the outright exclusion of PLWD from research to limited involvement via proxy or substitute consent, to involvement as participants and, in some cases, co-researchers.

A number of readers may suggest that existing documents such as the TCPS2 outline the components and processes for achieving consent. However, the question of who provides consent is often unaddressed, unstated, and subject to interpretation, raising challenges for inclusion and the fulfilment of rights. The existing TCPS2[3] guidelines on consent outline that all research participants must be fully informed about the study, its risks and benefits, and that research participants must give free consent to participate (CIHR, 2022). Rather than stating, for example, that all persons

[3]The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS or the Policy) is a joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). This Policy expresses the agencies' continuing commitment to the people of Canada to promote the ethical conduct of research involving humans. It has been informed, in part, by leading international ethics norms, all of which may help, in some measure, to guide Canadian researchers – in Canada and abroad – in the conduct of research involving humans (TCSP, 2022).

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have the right to participate in research, the TCPS2 and its enactment seem to implicitly operate under the assumption that people have to prove their capacity (which is inconsistent with common law). Here, uncertainty about PLWD and presumed incapacity present practical challenges to both the realization of rights and inclusion in research. Anecdotal accounts of ethics boards holding up research involving PLWD as participants and/or co-researchers have been known to occur, as have practices that have assumed diminished or a lack of decision-making capacity and/or required an authorized third party (A3P) to give substitute consent or substitute confirmation (see also Cubit, 2010; Ries et al., 2019; Shepherd et al., 2018).[4] A major problem is that practices underpinned by presumed incapacity and/or substitute decision-making as a default, although sometimes endorsed by health and social care institutions or research ethics boards, brush up against legal definitions of capacity and incapacity, as well as rights-based and personhood approaches. Consider, for example, the practice of having others speak for PLWD regardless of whether the substitute decisionmaker has the legal authority (or not) and regardless of whether the PLWD is capable of speaking on their own behalf. The academic literature outlines that both the practices of outright exclusion from research and bypassing the PLWD to obtain consent from a proxy (such as a family member) need to be re-examined with regard to the law and rights of PLWD, particularly as these may reinforce stigma and create barriers to inclusion (Ballenger, 2017; Batsch & Mittelman, 2012; Behuniak, 2011; Nguyen & Li, 2020; O'Connor et al., 2018; Swaffer, 2014; Werner & Doron, 2017).

Moving from the academic context for enacting inclusion via consent to the legal context reveals that no current guidelines exist to facilitate the inclusion of PLWD via the process of consent for research in all jurisdictions across Canada. Putting aside the issue of complete exclusion for the moment, even practices of relying on substitute consent often violate the law and are fraught with ethical problems. Unless a guardian has been appointed under the Patient's Property Act, capacity is always presumed (Patients Property Act, 1996). Even if there is a substitute decision-maker, this person cannot override the decision of the person who has capacity in that moment, which can vary according to environmental and other factors. To get a sense of the complexity, consider British Columbia's (BC) unique legal framework. Some people in BC may have one or more substitute decisionmakers, such as a representative appointed under a representation agreement (Representation Agreement Act, 1996), an attorney appointed under an enduring power of attorney (Power of Attorney Act, RSBC, 1996), or a personal or property guardian appointed by the court (Adult Guardianship Act, 1996; Representation Agreement Act, 1996). The requirements for and authority of each of these substitute decisionmakers are different, and rarely would any of these documents explicitly address medical or social research. However, consent to medical procedures, if part of a research study, is covered under the Health Care (Consent) and Care Facility (Admission) Act (1996), and there is a thorough list of who can be a temporary substitute decisionmaker and their responsibilities (c 181). However, even in these circumstances of duties that fall under the temporary decisionmaker, there is an expectation that the adult's wishes, beliefs, and values be considered.[5] While the academic literature on dementia outlines the importance of right-based perspectives and process-based consent (Dewing, 2008), the existing legal provisions do not discuss the research context,[6] vary across jurisdictions, and provide no guidelines to facilitate shifting types of participation or the levels of support that PLWD may require. This raises questions with regard to inclusion and rights via existing research practices and, in particular, the reliance on substitute decisionmakers.

In Canada, the lack of formal guidelines pertaining to the participation of PLWD can jeopardize the achievement of rights, meaningful inclusion, and may inadvertently stigmatize PLWD. The concern is that the absence of formal guidelines for inclusion via process of consent as one example has resulted in research practices and methodologies that are grounded in confusion, bias about the (in)capacity of PLWD to provide consent, and a lack of respect for the rights of PLWD. This can result in the exclusion of PLWD from research about their lives and may even violate law, depending on the jurisdiction. Illustrations of this challenge in practice include the tendency to focus on ambiguous notions of potential risk, harms, and protection over the non-realization of rights; the lack of attention to the injuries linked to stigma or outright exclusion; and the common practice of wrongly assuming that family members can be proxy decisionmakers for research participation. The literature in the field of dementia studies underscores informed consent and the protection of PLWD as a crucial component of the research process (Jongsma & van de Vathorst, 2015; Thorogood, 2019), and the practices of research ethics boards are designed according to the spirit of protection from harm (e.g., TCPS2) (CIHR, 2022). However, the challenge is how researchers, and the institutions that govern research practices, go about and achieve the balance of protection with access, inclusion, and rights. The idea of consent as an ongoing process is a proposed best practice in dementia studies (Dewing, 2008), and this is in line with rights-based and person-centred approaches long advocated by the dementia research community (Bartlett & O'Connor, 2007, 2010; Boyle, 2008; Butchard & Kinderman, 2019; Downs, 2013). Accompanying this is the suggestion that practices need to be created to foster and allow for supported decision-making (Cubit, 2010; Ries et al., 2019; Shepherd et al., 2018). When viewed in the context of everyday research practices, a notable gap exists in enacting rights, inclusion, and best practices based on ongoing consent and supported decision-making in Canadian research. Without awareness and detailed guidelines, PLWD risk continued exclusion from having a say in the decisions that affect treatment, programs, and response.

The results from our first year of the proof-of-concept project suggest a critical need to examine the law and practices about consent for research participation in every jurisdiction in Canada

[4]An A3P is defined as 'any person with the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to decide … to participate … in a particular research project … any person with the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to decide whether to participate or to continue to participate in a particular research project'.

[5]For example, under duties of the temporary decisionmaker the Act states: '(3) When deciding whether it is in the adult's best interests to give, refuse or revoke substitute consent, the person chosen under section 16 must consider: (a) the adult's current wishes, and known beliefs and values, (b) whether the adult's condition or well-being is likely to be improved by the proposed health care, (c) whether the adult's condition or well-being is likely to improve without the proposed health care, (d) whether the benefit the adult is expected to obtain from the proposed health care is greater than the risk of harm, and (e)whether a less restrictive or less intrusive form of health care would be as beneficial as the proposed health care.'

[6]Note that the Human Tissue Gift Act (15) contains additional consent requirements for medical research involving human tissue.

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and to understand the relationship between inclusion, consent, and capacity as implemented through formal and informal research practices and, in particular, pertaining to tensions between notions of vulnerability, protection, and rights. Canadian researchers, ethics boards, and institutions need clear formal guidelines to ethically and practically engage PLWD (and those who support them) in a manner that respects their human rights, recognition as persons in their own right, and decisional autonomy. Researchers also need guidelines that are flexible enough to encompass a wide range of disciplinary and context-specific differences between jurisdictions, as well as medical and social research conducted in community or institutional settings. A current challenge is that while TCPS2 (CIHR, 2022) corresponds with tri-council funding and is thus national (i.e. Canadian level), legal requirements for consent are generally provincial/territorial and vary between jurisdictions. Further complicating this, consent (and substitute consent) to research for medical treatment can be governed under different legislation, and some jurisdictions have no applicable legislation. This means that some research with participants who are deemed to lack decision-making capacity cannot be addressed through a substitute decision-making framework because there is no provincial/territorial law allowing for substitute consent in research. The strategy of bypassing the participation of PLWD to get consent (e.g. family) thus not only excludes PLWD from participation, fails to respect the rights of PLWD, and overlooks best practices in dementia research, and tri-council guidelines around diversity, access, and inclusion (CIHR and SSHRC Equity, Diversity, and Inclusion initiatives), but may also have no legal foundation depending on jurisdiction.

Establishing an agenda for the inclusion of PLWD: Research, policy, and practice

The study of inclusion of PLWD in research via processes of consent holds the potential for stimulating a positive change in research, policy, and practice. Our proof-of-concept project is a first step to understanding and clarifying the research landscape across Canada, including how PLWD gain access and inclusion in ways that recognize their rights. The project will provide detailed knowledge about how researchers carry out their work, point to what is needed, and make recommendations for Canadian dementia research. The challenges outlined above draw attention to three overarching questions to inspire a new agenda of inclusive research in the Canadian context: (1) How can researchers include PLWD in research to recognize lived experience, achieve meaningful participation, and ensure rights are respected? What guidelines and processes need to be developed to foster inclusion and authentic consent of PLWD in research that affects their lives? (2) Is it legal, right, ethical, or fair to exclude PLWD from participating in research that ultimately affects their lives? How might best practices of rights, ongoing consent, and supported decision-making be built into research guidelines to promote inclusion even when capacity to consent may be impaired, fluctuating, or diminishing? and (3) If a substitute decisionmaker is to be used to ensure participation among those deemed not to have capacity, who is permitted to participate and/or legally provide substitute consent? In which conditions/contexts? Both issues of presumed incapacity and substitute decision-making require thoughtful challenge from the research community.

Together, this set of questions renders visible the complex web researchers and advocates must negotiate to carry out research from rights- and personhood-based perspectives. One avenue we expect to develop is the idea that existing frameworks such as international framework on human rights, including the Universal Declaration of Human Rights (UDHR) (United Nations, 1948) and the Convention on the Rights of Persons with Disabilities (CRPD) (United Nations, 2006), and their Canadian interpretations provide intellectual spaces to grapple with the tension between protection from harm and meaningful inclusion in research. These frameworks help to address structural barriers and offer additional parameters to extend the discussion beyond value statements of ensuring access and/or fostering participation into action by pairing these with guidelines and strategies for inclusion. These conceptual frameworks, and the relationships between them can be considered part of a larger international effort to include PLWD. Working from this premise, for example, has the potential to extend the Canadian landscape on inclusive, responsible, and empowering research (Alzheimer Society of Canada, forthcoming; CIHR, 2022, 2023; SSHRC, 2019) to include PLWD and be responsive to the voices and needs of groups deemed vulnerable in society (see Grenier et al., 2017).

Second, insights from the project will clarify the legal parameters for consent and capacity for participation in medical and social research in Canada and leverage these to create guidelines for research practice as part of a larger agenda on inclusion. Without legally sound conceptual and practical guidelines, many researchers will continue to overlook the knowledge and experience of PLWD and be placed in a difficult position ethically, legally, and morally if they are committed to just, fair, and engaged research (with and for) the betterment of PLWD. Research practices cannot in good faith speak about access and inclusion without rethinking how PLWD can access and meaningfully participate in research. There is a pressing need to reconsider the involvement of PLWD in research in the contemporary discursive landscape of access and inclusion; to understand the relationship between inclusion, consent, and capacity, particularly with regard to vulnerability and rights; to examine the law on consent for participation in every jurisdiction in Canada to ensure consistency; to clarify if, when, and how to ethically engage PLWD and their family members in a manner that respects the rights and decisional autonomy of PLWD; and to advocate for law and policy reform. Failure to address these vital issues will, without doubt, sustain approaches based on inherent bias about the (in)capacity of PLWD to provide consent, exclude and stigmatize PLWD from research, and result in the non-realization of rights. Our hope is that our project will start a much-needed conversation about the relationship between statements about inclusion and rights, and the processes – such as ethics approval, informed consent, and the protection from harm – by which these are achieved (or not).

Third, knowledge from the collective insight of social and medical researchers across the country will provide detailed insights into gaps, contradictions, and best practices. It will allow us to move towards the creation of educational and training resources aimed to improve research practices with PLWD. For example, it may reveal how, although designed with best intentions, some institutional practices organized around risk and protection may be misplaced and/or represent acts of discrimination in disguise. Such an awareness would lead to the need to translate findings into guidelines that facilitate the meaningful involvement of PLWD across a range of research contexts and practices. Questions about access and inclusion are most often articulated with regard to gender, ethnicity, (dis)ability, and race, and there is a need

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to extend this attention to how these intersect with advanced age, mental health, disability, and cognitive status (Calasanti & Giles, 2018). At the moment, it would seem that ageism and ableism are arguably so embedded in everyday practices of research and policy that exclusion operates unnoticed, particularly where ideas of presumed incapacity, dementia, and disability/impairment are concerned. Our interviews across disciplines and research contexts will help to identify major challenges and innovative practices and consider models built on meaningful inclusion, authentic partnerships, and/or co-design and whereby PLWD participate in ways that they deem meaningful. This may include but not be limited to determining subject matter and/or guiding the research process (see Dementia Enquirers, 2019; Dupuis et al., 2011; Mann & Hung, 2018). An agenda built on access, inclusion, and rights of PLWD is not only the 'right' thing to do, but also promotes stronger, more relevant, and useful research findings.

Conclusion

This research note provided a brief report on the challenges of achieving the inclusion and meaningful participation of PLWD through existing institutional and legal parameters on consent with regard to medical and social research in Canada. It presented a three-year proof-of-concept project focused on understanding, exploring, and clarifying the relationship between consent and meaningful inclusion of PLWD in Canadian research. Highlighting initial findings, it drew attention to the contradictions between the stated desire for inclusion, existing guidelines such as the TCSP2 and research ethics boards, the various legislative frameworks that exist across the country, and the academic literature in the field of dementia. Most notably, it raised problems associated with the issues of presumed incapacity and the use of substitute decision-makers that operate to obscure the meaningful participation of PLWD in Canadian research. In doing so, it flagged the need for an agenda to challenge existing biases about incapacity, identify processes of automatic exclusion or limited participation, and address misinformation about consent (and substitute consent) across Canada. It also underscored the need to clarify legal parameters (and/or lack thereof) for PLWD to participate in Canadian dementia research and to develop conceptually sound and jurisdictionally relevant guidelines on legal consent for medical and social research with PLWD. It concluded with a call for a Canadian agenda rooted in the rights of PLWD to access and be included and meaningfully involved in research processes.

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