

# A human rights-based framework for qualitative dementia research

## Abstract

*Background and objectives:* People living with dementia have historically been excluded from qualitative research and their voices ignored due to the perception that a person with dementia is not able to express their opinions, preferences and feelings. Research institutions and organizations have contributed by adopting a paternalistic posture of overprotection. Furthermore, traditional research methods have proven to be exclusionary towards this group. The objective of this paper is to address the issue of inclusion of people with dementia in research and provide an evidence-based framework for dementia researchers based on the five principles of human rights: Participation, Accountability, Non-discrimination and equality, Empowerment and Legality (PANEL).

*Design:* This paper adapts the PANEL principles to the research context, and uses evidence from the literature to create a framework for qualitative research in people with dementia. This new framework aims to guide dementia researchers in designing studies around the needs of people with dementia, to improve involvement and participation, facilitate research development and maximize research outcomes.

*Results:* A checklist is presented with questions related to the five PANEL principles. These questions cover ethical, methodological and legal issues that researchers may need to consider while developing qualitative research for people with dementia.

*Conclusions:* The proposed checklist offers a series of questions and considerations to facilitate the development of qualitative research in patients with dementia. It is inspired by current human rights work of recognized dementia researchers and organisations who have been directly involved in policy development. Future studies need to explore its utility in improving participation, facilitating ethics approvals and ensuring that outcomes are relevant to people with dementia.

## Keywords

Dementia research, human rights, participation, consent, capacity, research ethics

## 1. Introduction

People living with dementia are at an increased risk of having their voices suppressed and ignored (1, 2, 3) because of an inaccurate perception of dementia as a condition resulting in inability to hold and express opinions, preferences, and feelings (2). Such a perception is erroneous: people with dementia may still be able to communicate despite cognitive decline and may in fact wish to do so despite finding it difficult (4). Indeed, dementia affects people differently and no two people will have the same symptoms and experiences (2, 4, 5, 6). While dementia, including dementia care, has been extensively researched using conventional academic methods, interviewing people with dementia about their experiences for research purposes meets with restrictions and safeguards, making participation difficult, if not impossible

(2, 3, 5, 7). Nurses are of key importance in qualitative dementia research, both as research leaders and in implementing research findings into routine clinical practice to improve patient care, patient and carer experience, and outcomes. Nurses bring the real-world experience necessary to inform research study design and the development of evidence-based interventions. A good knowledge and understanding of the ethical issues arising in research in dementia, and particularly in qualitative studies, is therefore essential for nurses working in this area.

This paper addresses the issue of inclusion of people with dementia in qualitative research as a means of executing their right to express themselves and influence policies relevant to their lives and wellbeing (3, 5). The focus is primarily on qualitative research in which the evaluation of the experiences of people living with dementia through interview brings additional ethical complexities but the paper is also relevant to the inclusion of people with dementia in research more generally.

## **2. Background**

### ***What is dementia and what does it mean to live with dementia?***

Dementia is a syndrome comprising a decline in cognition resulting in loss of ability to complete activities of daily living which is caused by a number of disorders affecting the brain (8). The most common of these is Alzheimer's disease (50-75%) followed by vascular dementia (20%), dementia with Lewy bodies (5%) and frontotemporal lobar dementia (5%) (9). Symptoms include a decline in mental abilities such as memory, thinking, problem-solving, concentration, and perception and often, behavioural change (9). Dementia can be divided into an early, middle or late stage, depending on the person's cognitive impairment and loss of functional abilities (9).

Worldwide, around 50 million people have dementia with nearly 10 million new cases every year (10) and one new case every three seconds (11). In the UK, there are around 850,000 people with dementia, and with 225,000 new cases every year, these numbers are set to rise to over one million by 2025 and two million by 2051 (11). Although dementia is associated with older age as one in six people over the age of 80 have dementia, there are over 40 thousand people under 65 living with dementia in the UK (12).

Living with dementia entails a variety of challenges. Poor awareness in society results in the need to challenge "the stigma attached to dementia and confronting the portrayal of people with it as not having any self-agency or being able to think for themselves, because (...) personhood continues to survive when the brain cells are dying" (13). This lack of awareness reinforces negative stereotypes and contributes to exclusion from society (2, 14). At the same time, the person with dementia perceives these exclusions which may ultimately result in self-exclusion from activities including dementia research.

### ***Research into experiences of people living with dementia***

While the value of interviewing patients in healthcare research has been long established, particularly in the area of care quality improvement and the delivery of safe and effective care (15), this is not the case to the same extent in dementia research. Up until the 1990s, the perspectives of people living with dementia were generally ignored partly because their views were seen as difficult to access and unreliable. Although dementia research increasingly appreciates experiences of people who live with the condition (1, 3, 14, 16, 17), gaps remain in the evidence-base required to guide clinical practice and further research (18).

### ***The ethical issues in recruitment of people with dementia for qualitative research***

The perceived risks related to recruiting people with dementia in qualitative research include the view that the participant's impaired cognition is a sensitive topic in itself such that participants may not wish to be reminded of their difficulties or to have these highlighted further by the research process (2, 4). In addition, the perceived risks to people with dementia arising from their vulnerability, has resulted in their frequent exclusion from research with the somewhat paternalistic justification that it is for their own protection, thus preventing them from contributing to and benefiting from research (2, 19).

While being interviewed carries some risks, it also has benefits for those sharing their experiences. The risks include unintended harm if reflecting on traumatic experiences, having one's anonymity breached and healthcare compromised, being misinformed about the research intent, and having one's narrative exploited without benefiting from the research. The benefits of being interviewed include "catharsis, self-acknowledgment, sense of purpose, self-awareness, empowerment, healing, and providing a voice for the disenfranchised" (20) p. 161.

Balancing the risks and benefits is important in every research population but is particularly important in research recruiting from a vulnerable population in which the benefits may be overlooked owing to a predominant focus on protection from the risks. Currently, there are strategies available to support safe and inclusive research for people with dementia (3, 4, 21) but awareness is limited and some aspects are not applicable to qualitative research.

This paper was prompted by our experiences in developing a qualitative research study evaluating the views and experience of people with dementia undergoing hospital in-patient care. The research team wanted to minimize the barriers to recruitment in order to ensure a representative sample and generalizable findings. However, we experienced a number of challenges around study design including in patient recruitment and inclusion/exclusion criteria, and in obtaining ethical approval, for which there was a lack of relevant guidance. We therefore used a human-rights based approach to develop a framework for the inclusion of people with dementia in qualitative research. The framework aimed to balance the risks and benefits of participation based on the five principles of human rights: Participation, Accountability, Non-discrimination and equality, Empowerment and Legality (PANEL (22)). We operationalized the framework in the form of a checklist to guide researchers in their study design in 1) understanding the right of people with dementia to participate in research, 2) balancing participation and protection of participants with dementia, and 3) consistently applying the principles when delivering or monitoring delivery of studies.

### **3. Developing the framework for inclusion of people with dementia in qualitative research**

Kate Swaffer, CEO and co-founder of Dementia Alliance International, living with dementia herself, has been a vocal advocate in the global fight for human rights for people living with dementia (23) including in relation to their specific needs (24, 25). Dementia Alliance International, together organisations such as Alzheimer's Disease International, represent, support and educate others living with the disease as well as the wider dementia community, with the aim to support their human rights, autonomy and improve quality of life. There are now multiple national and international organisations involved (e.g., Alzheimer Europe, Alzheimer

Society, Dementia UK, Alzheimer Scotland and the Alzheimer Association) demonstrating that supporting the human rights of people living with dementia is a common global objective.

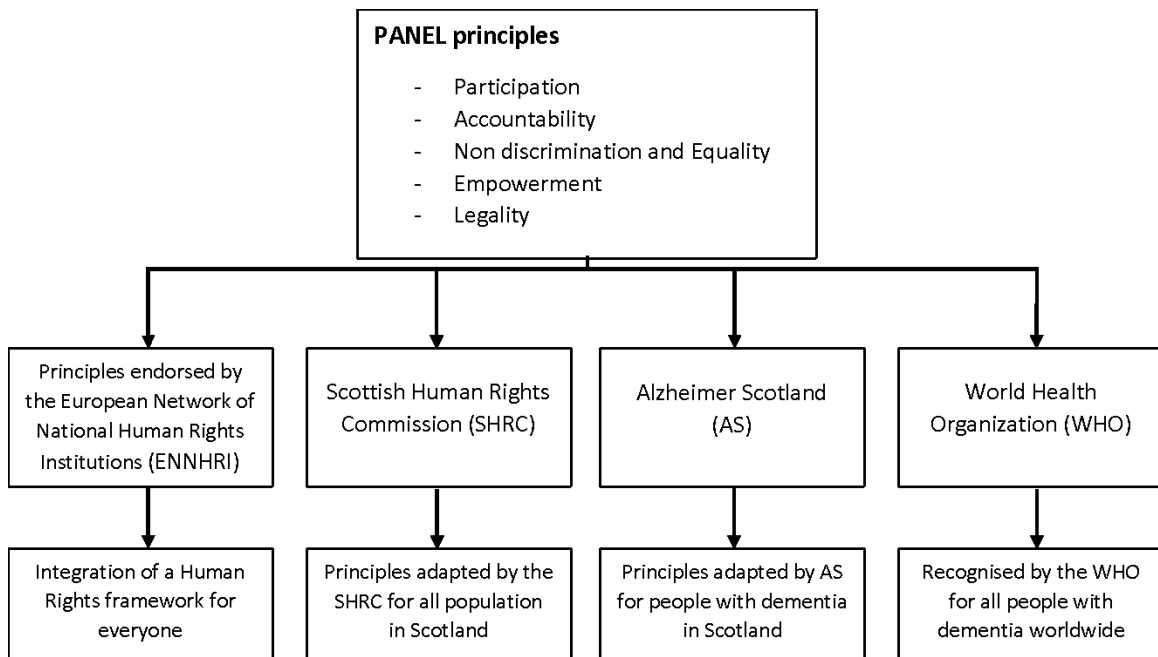
The human rights-based approach is the European Network of National Human Rights Institutions (ENNHRI) approved system of making sure that internationally recognized human rights are put at the centre of European policies and practices. In the research context, this means raising awareness around the inclusion of patients with dementia in research and promoting the use of inclusive methods.

**What are the PANEL principles?**

The ENNHRI endorsed five principles to guide the application of a human-rights-based approach, the PANEL principles (22), now used by many organisations as a practical tool in applying human rights policies (Figure 1). The PANEL principles were adopted by the Scottish parliament and by the Scottish Human Rights Commission as a universal framework to put human rights at the very centre of policies and practices (22). Alzheimer Scotland extended the PANEL principles specifically to people with dementia in Scotland’s National Dementia Strategy and the Charter of Rights for People with Dementia and their Carers (dementia-adapted PANEL principles (26)) to inform policy at government level. In 2015, the World Health Organisation (WHO) recognized the PANEL principles and also adopted a human-rights based approach for people with dementia in its dementia-adapted principles (17), thus highlighting their importance worldwide.

While there has been progress in promoting the rights of people with dementia in society in general using a human rights-based approach, there has been a relative lack of guidance specifically relating to research. Although the dementia-adapted PANEL principles mention research and the responsibility of organisations to support and include this group in research, these are underdeveloped and left to interpretation.

Figure 1. Development and adaptation of the PANEL principles for people with dementia



## 4. Human rights-based approach to the inclusion of people with dementia in research

The development of the dementia adapted PANEL principles has enabled us to propose a research framework for the inclusion of people with dementia in qualitative research underpinned by a human rights-based approach (22). The framework aims to balance the right to protection with the right to participation in research. Table 1 outlines the dementia adapted PANEL principles (left column) developed by the WHO in 2015, and the proposed PANEL principles (right column) to be applied in research involving people with dementia.

Table 1. The dementia adapted PANEL principles in the research context

The basic principles of human rights for people with dementia (WHO 2015)	The basic principles of human rights for people with dementia adapted to the research context
<b>Participation</b>	
<i>People living with dementia and their caregivers have the right to participate in all decisions which affect their lives and wellbeing</i>	<i>All individuals living with dementia have the right to be involved in research which affects their lives and wellbeing</i>
<b>Accountability</b>	
<i>People living with dementia should be able to exercise their human rights and fundamental freedoms in all aspects of their daily lives including full respect for their dignity, beliefs, individual circumstances and privacy. Effective monitoring of human rights standards and remedies for breaches must be in place</i>	<i>People living with dementia have the right to access safe and inclusive research. Researchers, research governance bodies, sponsors, funders and ethics committees should provide effective monitoring of human rights standards and remedies for breaches to ensure dignity, beliefs, individual circumstances and privacy are fully respected</i>
<b>Non-discrimination and equality</b>	
<i>People living with dementia and their caregivers have the right to be free from discrimination based on any grounds such as age, disability, gender, race, sexual orientation, religious beliefs, health status and also directly because of their dementia</i>	<i>People living with dementia should not experience discrimination in research solely because of their dementia diagnosis</i>
<b>Empowerment</b>	
<i>People living with dementia should be empowered to claim their rights rather than simply wait for policies, legislation or the provision of services. As rights-holders, they should be able to exercise their rights in all circumstances.</i>	<i>People living with dementia should be empowered to make decisions about their participation in research. Researchers and research bodies have the responsibility to facilitate the person's right to choose.</i>
<b>Legality</b>	

<p><i>All measures related to dementia adopted by States and other stakeholders should be linked to human rights standards contained in, and principles derived from, the Universal Declaration of Human Rights and other international human rights instruments.</i></p>	<p><i>All measures related to participation of people living with dementia in research should be adapted by the research community and the responsible bodies to ensure human rights standards. It should be recognized that these rights are legally enforceable.</i></p>
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The proposed dementia adapted PANEL principles for research involving people with dementia aim to introduce clarity and consistency throughout the research process and to inform decisions of all stakeholders (researchers, research committees, research organisation) at all stages of planning, approving, delivering, and monitoring research (27).

In order to operationalize the dementia-adapted PANEL principles for research involving people with dementia, we developed a practical tool in the form of a checklist (Appendix 1). Our approach was based on similar work done by the Mental Health Foundation (28), to develop a set of key questions based on the dementia-adapted PANEL principles to support implementation of the human rights of people with dementia on a macro level (a policy level). To inform the items of our checklist, we reviewed the dementia-adapted PANEL principles in the context of evidence supporting inclusive qualitative research in people with dementia.

Whilst we review each PANEL principle individually below, it must be recognized that they are interlinked and interdependent as is clearly illustrated when considering ‘informed consent,’ a key concept of research ethics and a complex issue in research involving people with dementia. Informed consent, the process of decision making about one’s participation, encompasses the right to contribute to and benefit from research (P), being given a choice (N) and having one’s choice enabled (E), respected (A), and legally protected (L).

#### **4.1. PARTICIPATION**

*“People living with dementia have the right to participate in research which may affect their life and wellbeing” (taken from the dementia-adapted PANEL principles).*

##### **The right to contribute to research informing healthcare practices and policies**

Dementia is currently a public health priority worldwide as reported by the WHO together with Alzheimer’s Disease International. In 2018, there were 27 countries with a national dementia plan with further 29 developing theirs (11). The WHO encourages the different governments to make dementia a research priority to improve health system efficiency and to develop methods for conducting global and inclusive research on dementia (17). In the UK, the Alzheimer Scotland and Alzheimer’s Society UK work with the national and local authorities to make sure that all decisions regarding policy, strategy, services and legislation on dementia are informed by people with dementia and their carers; this includes research, where these non-governmental institutions campaign for the rights of people with dementia to be involved in research.

Dementia Alliance International demands for dementia research to focus as much on care as on cure (24). Research into dementia care requires finding out about people’s experiences and, according to Swaffer, the best place to start is to listen to the consumer (in this case the person with dementia), not only about their choices, but also about human rights for people with dementia (29). Involving people with dementia as consumers of health and social care is necessary to understand their concerns, and obtain a truly holistic view of their needs and

experiences (3). Their views and opinions are highly important in dementia research and, without them, services cannot be developed effectively (14).

### **Informing the research question**

One of the initiatives of Dementia Alliance International is to involve people with dementia as equals in the development of policy: all policies that relate to dementia should be co-written with a consortium of Dementia Non-Governmental Organisations (NGOs) including people with dementia (24). In the research context, this means involving the public throughout the research process as recognized by the National Institute of Health Research (30) in informing the research question and recruitment method, commenting on the implications of findings for policy and practice, and dissemination of results. Barriers to participation should be mitigated at the planning and delivery stages.

However, the Scottish Dementia Working Group Research Sub-Group (2014) reported that whilst people with dementia were involved in research as participants, there was little evidence that they were consulted regarding research priorities (14). This is despite the fact that some studies have shown that involvement of people with dementia as collaborators in the research design and development stages is not only useful, but also necessary (7, 31).

### **Participation with support from a family member or a trusted person - risks and benefits**

Involving people with dementia in research may entail inclusion of family members or others they trust, either as participants or in supporting the person with dementia throughout the research process. As participants, family and friends are important in informing research in dementia care. When taking a supporting role, family or friends may help by acting as an advocate ensuring the wishes of the person with dementia are respected at all times, by facilitating effective communication, and providing background information (2).

However, the voices of people with dementia may be excluded if they are substituted by the experiences of other people. For example, an informant may be interviewed rather than the person with dementia as it is more straightforward (including in obtaining ethics approval). Alternatively, the accompanying person may be over-protective or controlling or may dominate the interview acting according to their own wishes thereby disrespecting the autonomy of the person with dementia and minimising their responses. Lack of inclusion/participation may worsen feelings of lack of control over the situation in the person with dementia (3, 14, 32, 33, 34).

It is good clinical practice to consult the person with dementia on whether they wish a family member or a trusted person to be involved with their care and by extension this should include any research process (Scottish Dementia Working Group (35)). Participants with dementia may request the presence of family (7, 21, 33), but they should remain the central focus of the research, with the family member taking the role of supporter rather than controller (4).

## **4.2. ACCOUNTABILITY**

*People living with dementia should be able to exercise their human rights and fundamental freedoms in all aspects of research including full respect for their dignity, beliefs, individual circumstances and privacy. Effective monitoring of human rights standards and remedies for breaches must be in place.*

Accountability relates to the researchers' responsibility for protection of participants' human rights throughout the research process; it entails respecting participants' dignity (maintaining their self-respect and a feeling of being valued by giving them the opportunity to consent and respecting their decisions) while attending to their beliefs, individual circumstances, and privacy (23, 36, 37). While researchers are accountable for adapting the research to each individual according to their particular abilities, the researcher's compliance should be enforced and guaranteed by placing the researcher within an appropriate research governance environment in charge of approving, monitoring and evaluating research that ensures that the participants' human rights are met and their choices acknowledged. However, in seeking to hold researchers to account, research governance bodies, sponsors, funders and ethics committees must be careful to avoid overloading researchers with further specific regulatory requirements that will result in indirect exclusion of people with dementia (2, 4, 21, 33, 38, 39).

### **The complexity of 'informed consent' in research with people with dementia**

Giving the opportunity to consent, seeking consent and respecting decisions about an individual's decision to participate in research comprises the process of 'informed consent.' The person taking consent for research is required to "provide sufficient information to a potential participant, in a language which is easily understood by him/her, so that he/she can make the voluntary decision regarding "to" or "not to" participate in the research study" (40). The three elements of valid consent are a) adequate information about what the research is about and what it involves, b) voluntariness with no obligation to participate and the right to withdraw at any time, and c) competence - a consenting person must be able to understand what participation entails and have the capacity to make a free and informed choice (41).

The current theoretical underpinnings of informed consent have largely been derived from bioethics and research ethics, providing transparency alongside what is often a bureaucratic process suited to governmental regulatory mechanisms (42, 43). This may lead to the process of informed consent being exclusionary rather than inclusive (2, 4), particularly for some individuals or communities. In the case of people with dementia, cognitive impairment may limit their ability to provide informed consent because of lack of competency but this should not be assumed on the basis of the dementia diagnosis alone. The Mental Capacity Act (MCA) 2005 aims to empower people to make decisions for themselves wherever possible and states that capacity should be assumed unless proven otherwise (44). In particular, individuals should be given all practicable help and support to make their own decisions.

### **Strengthening accountability regarding consent processes and by effective monitoring and addressing breaches**

Research governance bodies, sponsors, funders and ethics committees are responsible for holding researchers to account regarding the research consent process for people with dementia and that this follows the guidance in the Mental Capacity Act (2005). The consent process should include the appropriate support for participants to make their own decisions where possible (45), and should allow for the inclusion for those lacking capacity using proxy/consultee assent where appropriate (4, 43). This should also be considered in the design of longitudinal studies where capacity may be lost over time. However, regulatory bodies may have different interpretations of the risks and benefits of participation, and a balanced human rights-based approach to inclusion of people with dementia in research may be lacking. As a result, the view that 'it is safer to exclude people with dementia for their and the researcher's



safety' may dominate, meaning that researchers are not in fact held to account regarding inclusion.

Research processes need to be kept under review to ensure that they remain inclusive and do not become a disabling barrier for people who have dementia (39). According to the Scottish Human Rights Commission, monitoring bodies should systematically challenge and record breaches of human rights in research where possible for potential issues that may arise where participants are unable themselves to raise concerns (46).

#### **Strengthening accountability by obtaining dementia (research) expertise**

Researchers should also be held accountable for ensuring that the research is informed by and draws on the expertise of clinicians and researchers with expertise in dementia care. Conducting research with people who have dementia is complex and requires dementia-specific knowledge and skills (5, 39). In addition, expert researchers will be better able to uphold participants' rights regarding their dignity and individual beliefs since (7) they understand the impact dementia may have on participant's decision-making, thinking, and communication including in expressing fatigue or discomfort (2, 21, 47). The Scottish Dementia Working Group (35) encourages researchers without dementia experience to seek mentorship from experienced staff and to engage with dementia organisations (21).

### **4.3. NON-DISCRIMINATION AND EQUALITY**

*People living with dementia have the right to be free from discrimination in research based on any grounds such as age, disability, gender, race, sexual orientation, religious beliefs, health status, and also directly because of their dementia.*

#### **Discrimination in dementia research because of the diagnosis of dementia**

Equality as a principle means that although all people are different, everyone should be accepted as part of human diversity, with equal access to opportunities, full participation in society and no discrimination because of age, gender, ethnicity, or disability. People with dementia are often excluded from research because of a dementia diagnosis without rationale (48). When justification for exclusion is given, it is usually based on cognitive screening tools and perceived reliability of data.

Participation in research for persons with dementia is possible even in the latter stages of dementia, although may be challenging for both researchers and participants. Most research on dementia is therefore done in the early stages of dementia and does not represent the full spectrum of the condition (3). In addition, discrimination may occur on the basis of age: people with early onset dementia may be excluded as unrepresentative whereas the oldest old may be seen as too old to be able to participate (28).

Arbitrary exclusion of people with dementia is discriminatory and will result in non-generalizability of research findings. There is a need for a more inclusionary framework to facilitate research participation irrespective of age and stage of dementia. Researchers should be required to demonstrate the necessary safeguards to avoid discrimination and should provide a robust rationale for any specific exclusion criteria (16, 33).

#### **4.4. EMPOWERMENT**

*People living with dementia should be empowered to initiate research important to them and make decisions about their participation in research*

Empowerment as a concept explains the authority or power given to someone to do something, to become strong and confident, to control one's life and claim one's rights. For people with dementia, empowerment means their right to make their own decisions no matter the diagnosis. Applied to research, it means enabling participants with dementia to initiate research, to inform research questions, and to make informed decisions about their involvement in research and to give informed consent where possible (49, 50).

As stated previously, people with dementia have been excluded from research because of the assumption that they were deemed incapable to consent to participate and that their contribution was of little or no value (2). Such a conclusion is not surprising if the recruitment, consent process, and methods of data collection disempower people with dementia through not being adapted to their needs (2, 3, 4, 38, 51). Although the presence of cognitive decline in participants presents researchers with ethical and methodological challenges, researchers should seek to find creative solutions that facilitate their involvement (21).

##### **Empowering people with cognitive impairment in the consent process**

The Mental Capacity Act (2005) seeks to empower people to make their own decisions wherever possible. The act states that a person must be given all practicable help before it is decided that they are not able to make their own decision (44). Researchers should therefore provide study information including the participant information sheet in simple and easy to understand language and consider providing non-verbal information (4, 21, 51, 52, 53). Researchers should also consider staging the consent process and leaving more time for potential participants to make a decision, particularly since the behavioural and psychological responses of someone with dementia may fluctuate and this may impact decision-making capacity (1, 4, 47).

It should be noted that people with dementia may be disempowered by certain specific assessment strategies. For example, the use of cognitive tests such as the Mini Mental State Examination (MMSE) in isolation as a means to determine capacity to consent to research or to be able to participate in studies is not supported by the literature, and leads to exclusion (1, 2, 3, 4). Further, people with dementia have reported that being asked to complete an MMSE is insulting and makes them feel insecure (2). In the UK, the use of the MMSE in consent processes in isolation is decreasing as it conflicts with the guidance in the Mental Capacity Act (44). A person with dementia may also experience changes/fluctuations in their condition over the course of the research process (4, 14, 21, 54). The researcher should therefore make the research schedule flexible, and be alert for any indication of distress, including non-verbal signs and changes in the person's behaviour (4). Careful planning will help ensure that the participant is protected whilst being empowered to continue participation wherever possible (3, 4, 14).

The consenting process need to be adapted to the needs of people with dementia, otherwise the conventional ways of consenting may hinder engagement with the process and promote exclusion from research (2, 4, 47, 54, 55). Proposing a tailored method of consenting participants promotes empowerment as it encourages the person with dementia to make their own decisions (2). James McKillop, Chairman of the Scottish Dementia Working Group, highlights the empowering effects of participation, and states that researchers should always ask the person with dementia first as they should be granted the right to decide. However, the researcher must

make any safety considerations clear and should avoid causing a confrontation where there is a disagreement between the person with dementia and the proxy (2, 56).

### **Adapting the consent process in the context of dementia to promote empowerment**

Researchers should consider alternative methodologies and ways to adapt the research design for people with dementia according to their capabilities (2, 4, 33, 47, 54). Understanding consent as a continuous process rather than a one-off judgement may be more appropriate for people with cognitive impairment (4). Existing literature shows that the process of assessment often seems less important than the process of consenting, and in some instances, participants with dementia were excluded over communication concerns (55). The ongoing consent process (Dewing's Process Consent) rejects the traditional approach based on assessment of cognitive capacities without taking into account situational factors, and proposes a person-centred inclusionary approach, considering the interests of the person with dementia and all parties involved (1, 3, 4, 5, 21).

Process consent (4) requires the creation of a research relationship with the person with dementia, and the people they trust to gain insight into the person as an individual, the best methods of giving information and understanding how the person consents to day-to-day activities. Once all information has been collected, consent should be established not only initially, but on a regular basis, taking into account the well-being of the participant at each time. This method requires the researcher to be extremely flexible, open and transparent, but provides an opportunity to involve people who otherwise might be excluded from research enabling an individualized approach with time for the participant to express any issues or concerns (3, 4, 47). The development of the research relationship as part of Dewing's Process Consent is time consuming and might not suit studies with a limited timeframe (7). In addition, it is advisable that it should be complemented by other more traditional methods, such as using proxy consent, in order to satisfy research ethics requirements.

### **Use of accessible information during the research process including obtaining consent**

People with dementia may have difficulty in understanding and communicating information depending on the type of dementia, the stage, the person's cognitive status and fluctuation in symptoms (21). Therefore, different strategies may be necessary to accommodate each individual's needs including in communication (21, 33). The WHO human rights report states that information for people who have dementia should be provided in an accessible way that empowers them to participate in all decisions that impact them (57). (4, 14). Tailoring the information to each individual participant gives them more control over the situation (7, 51, 53, 58, 59, 60) and helps avoid frustration and limited participation (33).

The Scottish Dementia Working Group Research Sub-Group, The Dementia Engagement and Empowerment Project, Alzheimer's Disease International, Alzheimer's Society (UK) and some other organisations provide resources to support research with people who have dementia including information sheets and consent forms in an easy-read format, or guidelines for using clear and accessible language (61, 62). There are also studies that identify available tools, methods and techniques to support communication for people with dementia based on personalized pictures or objects (18). However, although this information is available, it is

dispersed and not compiled in a single source. Using inclusive language, and avoiding stigmatizing terms has been shown to enable people with dementia to understand and complete research documents with minimal assistance (3, 5, 21, 52) and thereby to actively participate (4, 14, 16, 21, 60). Actions such as using visual prompts while explaining a procedure, cue cards, or just simplified writing has been shown to increase decision-making capacity (5, 14).

#### **4.5. LEGALITY**

*All measures related to participation of people living with dementia in research adapted by a research community should be linked to human rights standards. It should be recognized that rights are legally enforceable.*

Legality in the context of dementia means that despite the diagnosis of dementia, people have the right to have the full range of their human rights respected, protected and fulfilled (26) by public and private bodies, organisations and individuals. (26). In the research context, research governance organisations, sponsors and ethics committees as well as individual researchers are required to work within the legal framework that supports people to make their own decisions and facilitates informed consent (63).

##### **What is the relevant legislation aligned with international laws?**

In December 2013, after the G8 Dementia Summit was held in London, the WHO developed the Global Action plan on the public health response to dementia (64) which stated that legislation, policies, intervention and programmes must be sensitive to the needs, expectations and human rights of people with dementia. Partners accountable for the effective implementation of legislation include academic institutions and research agencies, while administrative offices must include codes of practice and mechanisms of protection to audit the implementation of legislation and ensure that human rights are respected (65). In research contexts, relevant legislation covers legal capacity, decision-making processes, and power of attorney.

In England and Wales, the Mental Capacity Act 2005 (MCA) provides a comprehensive legal framework to protect and empower adults who may lack the mental capacity to make their own decisions about their care and treatment. The MCA (2005) defines capacity as “the ability to understand information and make decisions about your life. Sometimes it can also mean the ability to communicate decisions about your life” (66). A person lacks capacity if he or she is unable to make or communicate a decision about a particular matter because of an impairment of, or a disturbance in, the mind or the brain (44). The MCA (2005) established five core principles:

- People must be assumed to have capacity unless it is established that they lack capacity
- Before treating people as unable to make decisions, all practicable steps must have been tried to help them to do so
- Making an unwise or ‘risky’ decision does not mean people lack capacity
- Decisions on behalf of others who lack capacity must be in their best interests
- Before any act or decision is made on behalf of another said to be lacking in capacity, the least restrictive option for the person’s rights and freedom of action should be considered.

These principles are rooted in common law, ethical guidelines and best practice and are designed to be fully compliant with the relevant sections of the Human Rights Act. The MCA (2005) places a legal requirement on researchers to obtain assent from a consultee for any

research involving people without capacity, including research involving the administration of questionnaires, interviews or observations. Such research involving a person who lacks capacity would be unlawful unless approved by an appropriate body.

### **Legal requirements in people with dementia lacking capacity to consent to research**

The use of proxy consent is a method that relies on an authorized representative to give consent on behalf of the person with dementia. It could be a relative, a legal representative or a clinician/healthcare professional. Seeking proxy consent is currently seen by ethics committees as a means to protect the person with dementia (4). However, it does not support active participation and disempowers people with dementia from having control of their own life decisions (14). The reason behind using proxy consent is the general belief that the proxy knows the person with dementia and will base the decision on their values and preferences (5, 35, 47).

Although the MCA (2005) requires that consent from a proxy is required before a person with dementia who lacks capacity can be legally included in research, there are potential conflicts in using proxy consent including the possibility of differing views and beliefs between participant and proxy. Although the mechanism of proxy assent exists to protect participants, in some cases, the proxy's opinions may override those of the participant (2). There is also the issue of potential added burden to the proxy as decision maker and practical guidance in the use of proxies is lacking. In addition, use of proxy assent, does not mean that the person with dementia should lose their autonomy. People with dementia have the right to exert their autonomy, to assure that their wishes and preferences are considered (47, 67) and assent from the participant with dementia should always be sought even when they cannot legally give consent (4, 5, 14, 16, 53). The participant's assent, as for process consent, should be continuously assessed during the study (3) based on body language and behavioural indications (4, 14) such as signs of fatigue or irritation which might indicate that an individual might not wish to continue (47). In participants lacking capacity, researchers should consider the MCA (2005) principles of the need to consider the individual's "best interests" and the "least restrictive option" throughout the research process.

## **5. Discussion**

The right of people with dementia to be included in qualitative research has been widely discussed with examples of good and poor practice (2, 4, 48, 52, 68). Involvement of people with dementia in policy development and research is slowly gaining global importance thanks to the hard work and dedication of dementia organisations and researchers around the world.

This paper discussed the benefits of implementing the PANEL principles in the research context. The key points covered were:

1. The practical implications of using a human rights-based framework in the planning, execution and evaluation of a qualitative research study;
2. The definition of each PANEL principle and its relevance to qualitative research practice;
3. Development of a practical checklist for dementia qualitative research studies based on the PANEL principles.

The PANEL principles are widely used in political and governmental contexts, as they can be easily interpreted and are a useful tool to support practical interventions ensuring that human rights are protected. We built on the extensive existing work in the area in applying the PANEL principles to dementia research, with a particular focus on qualitative research. However, linking

each PANEL principle to the qualitative research context was challenging as the principles are intertwined and often overlap. For example, all the individual PANEL principles are relevant to the process of informed consent: consent has ethical and legal implications, should be non-discriminatory, requires participation, results in empowerment through individual decision-making and requires the researcher and research bodies to be accountable for the process including facilitating/adapting it as required.

Despite the challenges, we were nevertheless able to create a practical checklist which could facilitate future research based on a human rights-based approach through applying the PANEL principles to the dementia research context. The checklist provides a list of actions and considerations for researchers who wish to do qualitative research involving people with dementia, with the aim of facilitating the development and selection of appropriate research methods. The checklist draws on the existing literature addressing the challenges around dementia research and the methods to facilitate such research including ways to engage and communicate with participants with dementia, and the development of accessible research materials.

Although we focussed the development of the framework and the application of the PANEL principles specifically to qualitative studies in which interviewing people with dementia presents particular challenges and guidance is lacking, our approach is applicable to other types of research involving people with dementia and the checklist could therefore facilitate a broad range of studies.

The challenge remains for researchers to develop suitable and flexible approaches to the inclusion of people with dementia in research in the face of time and funding restrictions, and the need to satisfy ethical and institutional demands. There is no doubt that some level of protection and ethical standards are necessary when conducting research involving people with dementia, however, the expertise and clinical skills of those researchers applying for regulatory approvals should also be considered.

## **6. Conclusion**

Research involving people with dementia is increasing worldwide with many countries declaring dementia research to be a priority. In parallel, the need to consider the human rights of people with dementia has been highlighted to national and international policy makers. Nurses are key in leading and delivering (qualitative) dementia research as their experience gives them a unique perspective on the challenges and specific needs of individuals with dementia and their families necessary for the development of tailored interventions and support strategies. This study aimed to inform nurse researchers of the specific human rights needs of people with dementia participating in qualitative research, and to provide researchers with a practical tool that will not only save time and effort including for sponsors and funding bodies, but also promote and facilitate the involvement of people with dementia in research.

The proposed checklist was inspired by the work of recognized dementia researchers and organisations who have been directly involved in policy development in relation to human rights. The checklist is based on the PANEL principles and incorporates a series of statements and prompts for researchers to facilitate the study design, as existing information is dispersed and difficult to access. However, we acknowledge the limitation that the checklist has yet to be tested in practice and may require modifications as a result.

We believe that our human rights-based framework for dementia qualitative researchers will help deliver more high-quality qualitative evidence necessary to inform healthcare and better support people with dementia and their carers at all stages of the disease. As Hellstrom (2) stated, “the issue is not should we include the person with dementia but how can we best do it”.

## Conflict of interest

None.

## Funding

ADG and STP were supported by the Oxford NIHR Biomedical Research Centre

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