



Challenges in Involving People with Dementia as Study Participants in Research on Care and Services

Background Paper

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Additional information can be found at the Summit website (<https://aspe.hhs.gov/national-research-summit-care-services-and-supports-persons-dementia-and-their-caregivers>) or the National Alzheimer's Project Act website (<https://aspe.hhs.gov/national-alzheimers-project-act>). The opinions and views expressed in this report are those of the authors. They do not necessarily reflect the views of HHS, the contractor or any other funding organization.

Introduction

This background paper addresses key issues related to involving people with dementia as participants in research on care and services, including recruiting, research ethics, the processes of informed consent and assent/dissent to participate in research, and evaluating the capacity of people with dementia to participate in studies. Until the 1990s, research largely ignored the perspectives of people with dementia (Hubbard et al., 2003). This omission from the research was supported by commonly held views of people with dementia as incompetent and incapable of providing reliable reports, and a biomedical focus on neuropathology with limited attention to personal histories, social interactions, and social contexts (Lloyd, Gatherer, & Kalsy, 2006; O'Connor et al., 2007; Smebye, Kirkevold, & Engedal, 2012; Wilkinson, 2002). However, these views fail to account for the abilities and diversity of people with dementia (Moore & Hollett, 2003).

Recruitment

Recruiting people with dementia differs in important ways from recruiting individuals without cognitive impairment. Racial and ethnic minorities tend to be underrepresented in all types of research on Alzheimer's disease and related dementias, which raises issues about the generalizability of interventions beyond the non-Hispanic white population (Lines, Sherif & Wiener, 2014).

- *Gatekeepers*--Commonly, people with dementia are not recruited by researchers directly, but are recruited with the aid of "gatekeepers"--individuals who have relationships with people with dementia and may control researchers' access to these individuals--including health care and long-term services and supports providers, such as physicians and directors of residential care settings or nursing homes, and informal (e.g., family) caregivers (Hellstrom et al., 2007). Bartlett and Martin (2002) note that gatekeepers may deny people with dementia the right to decide whether to participate in research, and recruiting people with dementia may depend on how gatekeepers perceive the research, gatekeepers' relationships with the people with dementia, and the gatekeepers' judgments about who should be involved in research.
- *Terminology*--Although there are no easy solutions to navigating gatekeepers (Hellstrom et al., 2007), the terminology used in recruitment efforts can be influential. The terminology used regarding the person with dementia's condition--such as *dementia*, *cognitive impairment*, or *memory problem*--can influence recruitment (McKeown et al., 2010). Currently researchers use different terminology for different reasons. For example, Hellstrom et al. (2007) elected to use the term *memory problem* and to only use the word *dementia* if it first was introduced by people with dementia or by their family members who were key gatekeepers in the study. However, Bartlett and Martin (2002) contend that using the term *memory problem* could be considered deceptive and question whether informed consent is possible if the person with dementia is not fully aware of his or her diagnosis, but concomitantly, recognize that harm and distress may be evoked in people with dementia by researchers unwittingly informing people that they have dementia. Reid et al. (2001) concluded that it is important to meet people with dementia on their own terms and not insist on them admitting that they have dementia. Research on how different terminology affects recruitment could help clarify the effectiveness of these various approaches.

- *Diverse Contexts of Recruitment*--The recruitment of people with dementia in research can occur in diverse contexts, including health and long-term services and supports settings, at individuals' private homes, and through online sources. Memory care clinics have been identified as potentially effective sites to recruit people with dementia (Bachman et al., 2009). Community outreach, social marketing, and partnerships with community leaders and organizations also can support recruitment (Nichols et al., 2004; Williams et al., 2011). For example, researchers successfully recruited a sample of strained sedentary family caregivers of people with Alzheimer's disease (N = 327), of whom 34 percent were minorities, by partnering with faith-based organizations and caregiver support groups to distribute study fliers (Etkin et al., 2012).
- *Research Registries*--Registries of older individuals who are willing to consider participating in research can support efficient recruitment, but may not be representative of the general population. Registries may specify the types of studies in which individuals are (and are not) interested in participating and may include direct or proxy contact information. Registry information can help researchers contact potential study participants quickly (Grill & Galvin, 2014). Registries that may be particularly useful for researchers seeking to recruit people with dementia for studies of dementia care and services include ResearchMatch, the Alzheimer's Prevention Registry, and the Alzheimer's Association's TrialMatch. Additionally, the National Institute on Aging, the Centers for Disease Control and Prevention, and the Administration for Community Living are collaborating with these registries on the Recruiting Older Adults into Research project to encourage older adults and their family caregivers, including underrepresented populations, to consider participating in research and are starting with a focus on Alzheimer's disease and related demented research (National Institute on Aging, 2015).
- *Recruitment Supported by Other Online/Electronic Sources*--Some researchers suggest that online groups might support recruitment of people with dementia, as online recruitment has shown effectiveness with other populations (e.g., minority men at risk for HIV [Grill & Galvin, 2014; Young et al., 2013]). Additionally, in some clinical settings electronic medical record systems can be used to identify potential research participants (Deshmukh, Meystre, & Mitchell, 2009; Embi et al., 2005; Grill & Galvin, 2014). However, analysis of Medicare claims data suggests that medical records and insurance claims may underreport and misidentify people with and without dementia (Feng, Coats, Kaganova & Wiener, 2013; Lin et al. 2010; Taylor et al. 2002, 2009). However, these sources may be useful in combination with other screening criteria.

Ethics of Involving People with Dementia as Research Participants

Potential ethical issues with research involving people with dementia include respecting their abilities to make decisions, securing consent to participate from proxy decision-makers (e.g., family members) without directly seeking assent (i.e., agreement) to participate from the person with dementia (Slaughter et al., 2007), or simply excluding people with dementia from research because of cognitive impairment (Hellstrom et al., 2007).

Basic ethical principles that guide researchers include respect for persons, beneficence, and justice. The principle of respect for persons emphasizes the conviction that individuals should

be treated as autonomous agents, and people with diminished autonomy are entitled to protection; the principle of beneficence holds that it is an obligation to maximize possible benefits and minimize possible harms of research; and the principle of justice requires that equals be treated equally (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Researchers can uphold the ethical principles of respect, beneficence, and justice through the informed consent/assent process and by assessing the risks and benefits of participation in research (Aselage, Conner, & Carnevale, 2009).

Informed Consent

The process of informed consent requires individuals who have the capacity to understand the research protocol to decide whether they voluntarily agree to participate in a study (Black et al., 2008). Institutional Review Boards (IRBs) have strict requirements for the informed consent process that include both verbal and written descriptions of what participation in the study would entail, including the purpose of the research and any potential risks and benefits. Studies involving people with dementia are subject to heightened scrutiny by IRBs as a vulnerable population. Informed consent also allows study participants to withdraw from the research without penalty at any time (Black et al., 2008; Karlawish, 2008). The ability of some people with dementia to provide informed consent, such as those in early to moderate stages of Alzheimer's disease, has been established (Karlawish, 2008). However, dementia is progressive, and longitudinal research on the capacity of people with dementia to provide informed consent shows declines in capacity over time (Moye, Karel, Gurrera, & Azar, 2006).

Whether an individual is capable of decision making depends on whether he or she can communicate relatively consistently, understand basic information about choices, evaluate the implications of different choices, and rationally comprehend the risks and benefits associated with different options (Karel et al., 2010; Woods & Pratt, 2005). Because these capacities fluctuate over time and different decisions require different levels of capacity, a diagnosis of dementia--or even a specific score on a cognitive test--may not be the only criterion for determining decision-making capacity (Woods & Pratt, 2005).

Several decisional capacity assessment tools exist that can aid researchers in determining capacity to consent to research participation among people with dementia (Cacchione, 2011). These instruments include the Evaluation to Sign Consent (Resnick et al., 2007), the Hopemont Capacity Assessment Interview (Edelstein, 1999), the Capacity to Consent to Treatment Interview (Marson, Ingram, Cody, & Harrell, 1995), and the MacCarthur Competence Assessment Tool-Treatment (Grisso & Applebaum, 1998). Limited decisional capacity among individuals with dementia also may be indicated by difficulties with naming and delayed memory (Moye et al., 2006). There is no "gold standard" for determining capacity (Mitty, 2012).

Proxy Consent

When it is determined that an individual does not have the capacity to provide consent, researchers may seek proxy consent. Proxy decision makers commonly are spouses or other caregivers who may already assist the person with dementia in decision making around various issues, such as daily activities and medical care (Alzheimer's Association, 2004). Although some decision makers are formally designated through advance directives or legal guardianship, this designation is most often informal and based on familial or other close relationships. When engaging proxy decision makers in the informed consent process, researchers are encouraged to instruct them to make decisions based on the person with dementia's expressed wishes or in alignment with the person with dementia's values and beliefs (Cacchione, 2011). However, research shows that proxy decision-makers commonly make

research enrollment decisions based on what they think will maximize the well-being of the person with dementia, not a substituted judgment of what the person with dementia would decide (Karlavish et al., 2008). The assent process, discussed next, can help verify that the person with dementia agrees to participate.

Rather than include people with dementia in research, some studies include their proxies, such as caregivers or family members. However, data provided by proxies commonly differ from data provided by people with dementia (Clarke & Keady, 2002; Sands, Ferreira, Stewart, Brod, & Yaffe, 2004). For example, people with dementia have been found to have higher hopes for their quality of life than their caregivers do for them (Thorgrimsen et al., 2003).

Assent and Dissent

When conducting research with people with dementia, researchers are required to obtain both informed consent and assent (Slaughter et al., 2007). Over the past two decades, assent has been variously defined as “the agreement to participate in research based upon less than full understanding” (Keyserlingk et al., 1995, p. 340); “the initial and ongoing willingness of the participants themselves to participate” (Brodaty et al., 1999); “a subject’s affirmative agreement to participate in research” (Cahill & Wichman, 2000); and “*an affirmative agreement to participate as expressed verbally (i.e., orally) or a non-verbal indication of willingness to cooperate with study procedures*, both at the time of enrollment and over the course of the study” [italics in original] (Black et al., 2010, pp. 4-5). The capacity to assent is different from the capacity to give informed consent in that informed consent requires that individuals have the capacity to understand the research protocol to decide whether they voluntarily agree to participate in a study (Black et al., 2008). In contrast, to give assent an individual must only have the ability to indicate a meaningful choice and have at least a minimal level of understanding (Black et al., 2010). Black and colleagues explain that this means the choice to participate in the study authentically reflects the individual’s willingness to participate. Furthermore, Black and colleagues (2010, p. 4) explain: “Seeking assent acknowledges that many individuals who lack consent capacity have residual abilities to understand, appreciate, reason, and express a choice at some level and demonstrates that their remaining abilities and opinions have value and should be respected.” In contrast to assent, dissent is defined as “a verbal or non-verbal indication of unwillingness to participate in study procedures” (Black et al., 2010, pp. 4-5).

Researchers are encouraged to consider the severity of dementia when seeking assent, and observation of the individual’s behavior can help with determining assent or dissent when verbal communication is not feasible (Black et al., 2010). Although an individual may be able to express assent or dissent clearly and verbally, assent and dissent also may be inferred by whether the individual cooperates with the research process (Dresser, 2001; Slaughter et al., 2007). Although cooperation can be difficult to clearly define in the context of people with dementia participating in research, Keyserlingk and colleagues (1995) indicate that objections of people with dementia, or lack of cooperation with research, may be expressed through indications of frustration, discomfort, unhappiness, or passivity.

In longitudinal research that includes study participants with dementia who may be unable to verbally express that they no longer wish to participate in the research at a later point in the study, ongoing monitoring for signs of dissent is necessary because of the progressive nature of dementia (Cacchione, 2011). Some IRBs may require that researchers obtain assent at the beginning of every observation period (Beattie, 2009).

Research Gaps

Although numerous strategies for involving people with dementia as study participants in research on care and services have been documented, controlled comparisons of these various strategies are lacking, and information on the cost-effectiveness of these strategies is limited. Additionally, strategies that are effective at improving the participation of minority groups in research require additional examination, and studies are needed that compare barriers to participation (e.g., attitudinal factors that might deter research participation, such as distrust of the health care establishment, or logistical burdens, such as limited access to transportation or communication technologies) among specific minority populations (Grill et al., 2014). Further, several decisional capacity assessment tools can help researchers in determining capacity to consent to research participation among individuals with dementia, but multiple approaches to assess capacity over the course of the study might often need be used. To determine a “gold standard” for assessing capacity to consent, additional research is needed.

Conclusion

Although people with dementia were once commonly excluded from research (Hubbard et al., 2003), researchers increasingly are encouraged to involve them as study participants in research on care and services. Including people with dementia as research participants is particularly important because proxy participants, such as family members or caregivers, often have different views and provide different data than people with dementia. Ethical principles that guide researchers--including respect for persons, beneficence, and justice--both support and help guide the involvement of people with dementia in research.

The informed consent/assent process can help researchers uphold these ethical principles; however, not all people with dementia can provide informed consent. The ongoing nature of the consent process throughout the study and the progressive nature of dementia need to be especially considered when people with dementia participate in research; in some studies participation assent needs to be obtained at the beginning of every observation period.

Researchers seeking to include people with dementia as study participants may need to attend to the role of gatekeepers (e.g., informal caregivers, professional service providers) in recruitment. Additionally, clinic-based recruitment, community-based approaches to recruitment, and the use of research registries have promise for supporting efforts to recruit people with dementia, but they may not be representative of all people with dementia.

Finally, additional research is needed on the effectiveness of various strategies for involving and recruiting people with dementia in research, on decisional capacity assessment tools for use with people with dementia, and on the reliability and validity of data in studies that include people with dementia.

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