People With Dementia: Capacity to Consent to Research Participation

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Embarking on research with older adults whether in the community, in assisted living, or in the long-term care setting can be challenging from the very beginning. Depending on the purpose and specific aims of a study, the sample may include older adults who have some level of dementia. If so, the question of the older adult with dementia’s capacity to give informed consent may be in question. This challenge to the ability to provide informed consent could preclude researchers from even pursing research with this population. However, the negative public health impact of dementia is so severe that this population needs further study. The challenge for us as nurse researchers is to recognize and protect the rights and interests of individuals with dementia who are asked to provide informed consent to participate in research (Slaughter, Cole, Jennings, & Reimer, 2007).

Informed consent is defined as the provision of voluntary authorization given by an individual who has the capacity to understand the research protocol and decide whether to participate in the research (Black et al., 2008). Key elements of informed consent process include the verbal and written description of the expectations of participation in the research protocol including the purpose, risks, and benefits. Also included in the expectations of informed consent is that individual’s participation is voluntary and that a participant can withdraw at any time without penalty (Black et al., 2008; Karlawish, 2008).

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Capacity to make decisions, also known as decisional capacity, is a concept described which includes four decision-making abilities: understanding, appreciation, reasoning, and choice (Grisso & Applebaum, 1998; Karlawish, 2008). Understanding is the ability to absorb the meaning of the information presented. Appreciation is the ability to distinguish how the information applies to the individual, particularly the risks and benefits of the information presented. Reasoning is the ability of evaluate options and surmise the results of the choices to be made. Choice is the ability to express a decision (Beattie, 2009; Grisso & Applebaum, 1998; Karlawish, 2008). Capacity to make decisions is a clinical judgment made by a clinician after an interaction with the individual. Capacity is different from competency. Competency is adjudicated by a judge based on the recommendations and evaluations by two physicians. A judge makes the legal declaration of whether an individual is competent (Karlawish, 2008).

An individual’s capacity is a point along a continuum and can vary depending on their daily performance and the complexity of the decision that the individual must make. For example, an individual may be able to understand and appreciate the purpose, risks, and benefits to participating in a low-risk research study and be able to make a reasoned choice to participate. This same individual may not have the capacity to manage their own investments or to grasp the necessary elements of participating in a high-risk research study. This perspective of determining capacity in an individual is considered a relational determination that is specific to the individual and the context of the situation and choice to be made (Slaughter et al., 2007). Researchers evaluating older adults with Alzheimer’s disease, a specific type of dementia, have found that in mild to moderate stages of Alzheimer’s disease, there is a decreased ability to understand and appreciate but that there is relative preservation of the individual’s abilities to reason and choose (Karlawish, 2008). Unfortunately, in another study, many older adults with a dementia diagnosis, who were followed over a year for their capacity to provide their own informed consent, were found to have lost their capacity to consent within the following year (Moye, Karel, Gurrera, & Azar, 2006).

When an individual has been determined not to have capacity to provide consent, proxy consent can be sought. A proxy is a decision maker usually a spouse, child caregiver, or other trusted individual who the person with dementia may already rely on for decisions regarding daily activities and/or medical care (Alzheimer’s Association, 2004). This person may already have been formally designated as the participant’s decision maker for health care or even research participation within an advanced directive document. However, more often than not, this is an informal designation based on a family or trusted
relationship. When proxy consent is obtained, the proxy should be instructed to decide on the participant’s involvement in the research study based on the participant’s expressed wishes or what the participant would have wanted in light of his or her prognosis, values, and beliefs (Alzheimer’s Association, 2004). This concept of substituted judgment, choosing what the participant would have chosen if they were able, is often difficult for proxy decision makers to preserve when making decisions for their loved ones. Instead proxies often decide what is in the best interest of the participant (Karlawish et al., 2008).

When proxy consent is obtained, it is important to determine if the participant is capable of providing affirmative agreement or assent to participate (Alzheimer’s Association, 2004). Assent may be expressed clearly and verbally or inferred when an individual cooperates with the research process (Slaughter et al., 2007). Depending on the severity of the dementia, assent should be judged on behavior (Alzheimer’s Association, 2004). An institutional review board (IRB) may require assent be obtained at the beginning of every observation period (Beattie, 2009). The progressive nature of dementia adds an additional challenge of monitoring for signs of dissent if the research is longitudinal. Dissent is the opposite of assent and has been equated with the refusal to participate even when there has been proxy consent obtained. Dissent is often determined by whether the individual cooperates with the research (Slaughter et al., 2007). Dissent should be monitored for in participants with dementia who may have the inability to express verbally that they no longer wish to participate.

Dissent for any study-related procedure should be respected (Alzheimer’s Association, 2004). Some researchers recommend that an older adult with dementia should provide consistent dissent due to variations in dementia-related behaviors. Guidelines have been recommended for determining dissent which include, first developing rapport with the participant with dementia, asking permission to ask a few questions, responding to a no answer by trying to create a comfortable environment over a few minutes and trying again, and if the participant refuses again then returning on a different day (Slaughter et al., 2007). If the participant continues to refuse, this is considered dissent and the participant should be withdrawn from the study (Alzheimer’s Association, 2004; Slaughter et al., 2007).

There are a few decisional capacity assessment tools available to aid the researcher in determining an individual with dementia’s capacity to consent to participate in research. These include the Capacity to Consent to Treatment Interview (CCTI; Marson, Ingram, Cody, & Harrell, 1995), the Hopemont Capacity Assessment Interview (HCAI; Edelstein, 1999), the MacCarthur
Competence Assessment Tool–Treatment (MacCAT-CR; Grisso & Applebaum, 1998), and Evaluation to Sign Consent (ESC; Resnick et al., 2007). Research has also demonstrated that individuals with problems with naming, delayed memory, and flexibility may have limited decisional capacity (Moye et al., 2006). The use of these research tools is still relatively new in, and not mandated by, many IRBs (Beattie, 2009).

The most commonly used research tool to evaluate for capacity is the MacCAT-CR developed by Applebaum and Grisso (2001). This tool’s format is a semistructured interview that guides the clinician through the four domains of capacity to make a decision: understanding, appreciation, reasoning, and expressing choice (Gurrera, Moye, Karel, Azar, & Armesto, 2006). The Consent to Treatment Interview developed by Marson and colleagues (1995) uses two vignettes presented orally and in written form to address the components of capacity (Gurrera et al., 2006). The Hopemont Capacity Assessment Interview (Edelstein, 1999) format first provides a description of the concepts of choice, risk, and benefit to the participant and then uses two divergent clinical vignettes to the participant (Gurrera et al., 2006). A newer capacity assessment instrument developed by a nurse research team (Resnick et al., 2007) is the Evaluation to Sign Consent Instrument. This instrument was developed to determine an older adult’s capacity to provide consent for a randomized controlled trial. The scale consists of five items and one open-ended question that makes and assessment of a participant’s ability to name: at least, two risks from participating in the study and two expectations of the study from their participation. The potential participant is asked to state what they would do if they no longer wanted to participate in the study, and then the participant is asked to describe the randomization process. When developed, the ESC was compared with the MacCAT-CR and was found to be highly correlated (Resnick et al., 2007).

Improving clinical care for individuals with dementia depends on being able to pursue research with this population, research which the individuals with dementia and their families are eager to participate in hopes of benefiting others in the future (Alzheimer’s Association, 2004). Whether an instrument to assess decisional capacity for research participation is used or not, it is essential when completing research in participants with dementia that their rights and dignity be preserved and protected. IRBs will require an informed consent procedure that is clear and consistently applied to protect the rights of research participants with dementia. Work closely with your own IRB to meet the requirements for protecting this vulnerable population.
References


