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CAPACITY TO CONSENT OF PEOPLE WITH DEMENTIA: A NARRATIVE REVIEW FROM AN ETHICAL PERSPECTIVE

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ABSTRACT

People with dementia have impairment to execute daily life activities by presenting as a deterioration of mental processes, such as memory, thinking, reasoning, and judgment. Many participants in dementia research may lack the capacity to provide informed consent. Additional safeguards are needed for dementia research participants' protection because of their vulnerability. Only after carefully weighing the risks and possible benefits for the participants in the research may it be decided to use vulnerable participants. The intention to prevent harm pushes against the removal of autonomy. This dilemma is the driving force behind this article's narrative review of the capacity to consent problems in dementia research. For this critical narrative review, we conducted a thorough search of Scopus, PubMed, and Wiley Open Library for literature addressing the ethical and legal issues on the capacity to consent of people with dementia. We outline the dilemmas and difficulties that surround them including the related ethical principles, the informed consent process, capacity to consent, and safeguards for the participant in research involving people with dementia.

Keywords: Capacity to Consent; Decision-making Capacity; Dementia; Research Ethics

INTRODUCTION

Dementia is a condition that substantially affects a person's capacity to execute activities of daily life by presenting as a deterioration of mental processes, such as memory, thinking, reasoning, and judgment.[1] Globally, dementia is the leading major cause of impairment and reliance. In 2030, there will be an estimated 78 million cases of dementia globally, and that number will rise to 139 million by 2050.[2] It is increasingly important to do research to identify strategies for treating behavioral and other dementia-related symptoms given there is no curative therapy for the disease. However, it can be challenging to conduct studies on participants with dementia-related cognitive decline. The difficult process of seeking and securing informed consent in a moral and ethical manner is the most challenging.

There are a large number of participants in dementia research who may lack the capacity to provide informed consent, and it is unknown how cognitive function and capacity interact.[3] A person's capacity to give informed consent reflects their comprehension of the nature of the research, awareness of the consequences of involvement, and capacity to make a sound decision.[4] As of now, no profession or specialization has full authority over or a court-approved standard for determining capacity. The understanding of the idea of capacity and its assessment by researchers and clinicians has been disputed in the earlier study.[5] Furthermore, there are only a few decisional capacity assessment tools available to assist researchers to determine whether a person with dementia has the capacity to consent to participate in research.[6]

It has been determined that cognitively impaired people require special protection in

order to achieve an equilibrium between the preservation of their autonomy and society's need to develop knowledge. Only after carefully considering the harms and potential benefits for the participants in the research may it be decided to use vulnerable volunteers. The intention to prevent harm pushes against the removal of autonomy. The debate centers on various opinions about how to achieve the right balance between people's rights to choose their own fate and the necessity to care for those who cannot look after themselves. This dilemma serves as the impetus for this article to present a narrative review of the field of capacity to consent issues in dementia research.

In this review, we discuss the ethical issue of the capacity to consent of people with dementia based on empirical findings, legal, and theoretical aspect. Topics to be discussed include an overview of ethical issues in dementia research, informed consent from the theoretical and legal aspects, the decision-making capacity of people with dementia from an ethical perspective, and safeguards for research participants.

For this critical narrative review, we conducted a thorough search of Scopus, PubMed, and Wiley Online Library for literature addressing the ethical and legal issues on the capacity to consent of people with dementia. The literature used in this article was derived from recent high-quality meta-analyses, systematic reviews, and selected literature. Moreover, we included manuscripts with interest in the theory and application of capacity to consent in research. Furthermore, we also included manuscripts related to the safeguards of research participants in this field. The search was only limited to English and Indonesian. The year of publication or study was not limited.

RESULT AND DISCUSSION

This section aims to explore the ethical issue and the implication of research involving people with dementia. We outline the strategies used in response to these complicated issues, as well as some of the dilemmas and difficulties that surround them including the ethical principles, informed consent, decision-making capacity, and safeguard for the participant in research involving people with dementia.

1. Ethical Principles

It is generally known that any research involving human subjects must adhere to fundamental ethical principles. For example, the Belmont Report (United States National Commission for Protection of Human Subjects of Biomedical and Behavioral Research 1978) was one of the first national statements on research ethics to be implemented. In addition, The Declaration of Helsinki was created by the World Medical Association (WMA) as a statement of ethical principles for medical research involving human subjects. Several ethical principles are especially underlying research involving people with dementia are:

- Beneficence – The maximization of benefits and the minimization of any harmful effects of the study are obliged under the beneficence principle.[7]
- Non-maleficence – In the context of medical research, non-maleficence (often known as "do no harm") indicates that one ought to not damage a person regardless of any potential benefits to others.[7]
- Resepect for autonomy – According to Beauchamp and Childress (1994), respect for autonomy is based on the concept that every person is deserving of respect and has the capacity to determine his or her own future.[8]

The principle to do good, often known as the principle of beneficence, is in danger when researchers conduct studies on dementia patients. In some situations, including those where a research study includes more than minimal risk to the subject and at the same time there is no guarantee of benefit for the participant, subjecting incompetent participants to research may even constitute a violation of the duty to do no harm to the patient. It is difficult to argue that a patient's involvement in a study is in their best interests, particularly in dementia research.

The research subject is not the primary or only beneficiary of the study's objectives. The expansion of information, which in most cases entails gaining a deeper understanding of the physiological origins of this disease and improving diagnostic techniques, is the main objective of the research. But we should remember that although producing new knowledge is the main goal of medical research, the rights and interests of specific research participants must always come first.[9] Furthermore, it is stated in the Declaration of Helsinki that only when medical research cannot be conducted on non-vulnerable groups and is in response to the health needs or goals of the vulnerable group is it justified. This group should also stand to gain from any knowledge, procedures, or treatments that come out of the research.

Moreover, attention is made to the ways in which the attribution of unawareness is used to justify withholding autonomy, highlighting the conflicts that exist between the imperatives of doing no harm and of maintaining autonomy in addressing legal and ethical difficulties. Traditional medical ethics emphasizes patients' autonomy as their primary important fundamental right, and this perspective has its roots in moral philosophy.[10] The autonomy of the patient is seen as being respected and protected through informed consent. That informed consent must be given by an individual who has the capacity to make decisions.[11] On the other hand, determining the capacity to give consent to people with cognitive impairment such as dementia is still a major concern. However, on many occasions, family members or professional caretakers come to the conclusion that the person's autonomy is subordinate to beneficence or non-maleficence.[12] The welfare of research participants should always come first, before the study's objectives.

The current practice of Research Ethics Committees emphasizes the importance of nonmaleficence over autonomy in research review.[13] Respect for individual autonomy is a crucial ethical principle, but it is not absolute in the sense that it cannot be compared to other significant values. The underlying principle must be how to meaningfully encourage inclusiveness.

2. Informed Consent and Capacity to Consent

One of the essential components for safeguarding the welfare of patients or study participants is informed consent. Medical ethicists have a tendency to believe that informed consent procedures are the best approach to respect people's autonomy and that autonomous decisions are fundamentally deserving of respect. Informed consent is defined by Black et.al as the provision of voluntary consent obtained by a person capable of comprehending the research protocol and determining whether to participate in the research.[14] Informed consent to participate in research must be given by a person who has the legal capacity to give valid consent or refusal, be voluntary, informed, cover the procedure or study to be conducted, and be given voluntarily.[15] When a person has the cognitive capacity to comprehend the information provided and to comprehend the consequences of a choice to participate or not, their consent may really be regarded as "informed".[16]

There is currently a lack of scientific data on the assessment of consent capacity in dementia research, and the majority of research groups have little to no experience creating informed consent protocols that are specially tailored to this field of study. Moreover, as of now, no profession or specialization has full authority over or a court-approved standard to assess capacity.[16] Determining a person's capacity to give consent is a major challenge in research with participants who have a cognitive impairment, such as dementia. Cognitive and functional impairments are merely a portion of the wide range of disabilities that people with

Alzheimer's disease and associated dementias suffer. Additionally, they suffer deficits in what is known as decision-making capacity. The concept of decision-making capacity includes the abilities of:[17]

- Understanding – the capacity to comprehend the importance of the information provided
- Appreciation – the ability to determine how information pertains to a given person, especially with regard to risks and benefits of the information supplied
- Reasoning – the ability to weigh possibilities and anticipate how decisions will turn out
- Choice – the ability to convey a choice.

Based on the particular clinical or research topic that triggered the assessment of capacity to consent, a variety of tools are available. The MacCAT-CR, created by Applebaum and Grisso, is the most widely used research tool to assess capacity. A semi-structured interview and a review of the patient's medical records make up the assessment, which is scored on four different capacity categories.[18] Some other instruments are described in table 1. Most assessments include scoring systems based on the examined ability (understanding, reasoning, appreciation, evidencing a choice, etc).

Table 1. Capacity Assessment Instrument in Dementia Research

Instrument	Properties	Abilities of capacity tested
MacArthur Competence Assessment Tool, Clinical Research Version (MacCAT-CRV)[19]	Semi-structured interview with each ability scored individually	Understanding, appreciation, reasoning, and expressing choice
The Hopemont Capacity Assessment Interview[20]	An explanation of the concept of choice, risk, and reward followed by two clinical vignettes	Understanding, appreciation, and expressing choice
Aid to Capacity Evaluation (ACE)[21]	a semi-structured interview that assesses decision-making capacity based on a patient's real health problem	Understanding, appreciation, and expressing choice
Assessment of Capacity for Everyday Decision-making (ACED)[22]	Semi-structured interview with three regular decision-making scenarios.	Understanding and expressing choice
Assessment method by Schmand et al.[23]	a vignette method to evaluate the capacity to consent of patients with dementia	Understanding, appreciation, and expressing choice

To ascertain the level of capacity to consent required for research, it is important to carefully assess the invasiveness, risk, and burden of an intervention against the benefits of the study. The needed levels of consent should be greater as the risk and burden increase. The requirements of capacity to consent may be lowered the more likely it is that patients would benefit from research. This idea is called the principle of proportionality for capacity to consent assessment.[24]

In mild to moderate stages of Alzheimer's disease, a particular form of dementia, there is

a lower capacity for understanding and appreciating things, but the person's capacity for reasoning and making decisions is still mostly intact, according to research on older adults with the disorder.[25] However, as dementia worsens, the individual becomes less capable of understanding and appreciating the implications of participating in research.[26] When a person's capacity to give consent has been ruled to be insufficient, proxy consent may be requested.[27]

A quality consent strategy (such as double consent) should be viewed as vital to dementia research as the research design, the choice of the intervention, and the outcome measurements. It is crucial that participants with dementia have their rights and dignity upheld while doing research on them, regardless of whether a tool to assess decisional capacity for study involvement is utilized.

3. Safeguards for Participants

Many safeguards are employed in human research, including informed consent, managing conflicts of interest, maintaining confidentiality, and institutional review board monitoring. Care must be taken to guarantee that the human rights of individuals with dementia are upheld while they are being considered as research participants. Ethical researchers must maintain the participants' dignity and respect while also acknowledging that any possibility of harming them is avoided. Only after carefully weighing the risks and possible benefits for the participants in the research may it be decided to use vulnerable volunteers. Researchers should pay close attention to verbal and nonverbal cues that might be construed as evidence of discomfort brought on by involvement in the study activity, especially with these vulnerable participants. When this happens, the individual has to be removed from the research procedure right away.[28]

In order to do research, researchers must understand and abide by the ethical principles of beneficence, justice, and respect for people, as well as get legal clearance from research ethics committee when necessary.[29] Participants with cognitive impairment are permitted in the study, but researchers and research ethics committee must be highly aware of their potential vulnerability, including exploitation risk and a decreased capacity to understand information. When developing materials, forms, guidelines, and protocols for gaining informed consent, effective ways to enhance the understanding of informed consent information should be taken into account.

To protect the rights of research participants with dementia, the IRB (Institutional Review Board) will demand that an informed consent method be used in a way that is both clear and consistent. The appropriate ethical committee's clearance of research should ensure, among other things, standardized quality control of consent procedures. Unfortunately, the way that research is now conducted lacks this homogeneity. However, the evaluation of informed consent procedures by ethical review boards varies greatly between and within nations.[30] Researchers should collaborate with patients, caregivers, and ethical research committees in order to address the enormous challenge of doing dementia research that is both relevant and ethically correct.

CONCLUSION

Various points of discussion emerge relating to the ethics issues in dementia research. Those issues include the recruitment of people with dementia for research. To the greatest extent possible, this procedure should

use a supported decision-making approach, allowing the participant to make their own decision about participating in the research. Additionally, there is a need to raise awareness of concerns related to dementia-specific research inclusion, such as the right to appoint decision-makers for research and the ability to make prior research directives.

More effort must be done to provide reliable and practical measures to evaluate participants' understanding of the material offered in study consent dialogues in order to promote the proper involvement of persons with dementia in research. An existing, established technique for determining consent capacity might be used. To enable researchers to include persons with dementia while safeguarding this expanding pool of prospective participants, guidelines for study need to be improved by research ethics boards. Education and materials ought to be created for dementia patients, those who assist them, medical professionals, and researchers in mind.

Empirical ethics is a vast and important topic that can only strengthen the collaboration between patients, communities, and researchers as dementia research broaden and moves in new directions, many of which will provide new and unforeseen ethical challenges.

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