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Review Article

Finding Solutions to the Challenges of Informed Consent for Research with Nursing Home Patients with Decisional Capacity

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ABSTRACT

Obtaining informed consent for research with nursing home patients is not only difficult in more ways than one but also raises ethical challenges. Nursing home research has increasingly improved the quality of life of older adults living in nursing homes. Informed consent constitutes the foundational principle of all research, yet there is a lack of explicit guidelines for obtaining consent. Through a synthesis of comprehensive research findings on planning, study recruitment, and ecological factors, this study proposes a best practice approach to obtain genuine informed consent from nursing home patients with decisional capacity. The aforementioned variables are indispensable to sound medical and research ethics, patient dignity, and the corresponding conclusions drawn from such research. A three-pronged approach that includes consideration of the nursing home setting, the research design, and recruitment helps to ensure genuine informed consent from older adults who consent to participate in the research. Informed consent, when properly secured and implemented through special considerations, respects the inherent dignity of every patient. This article proposes such a protocol that operationalizes obtaining informed consent from those elderly individuals with decisional capacity. It contributes to the nursing literature and best practices in the nursing home on informed consent.

Keywords: Informed consent; Nursing; Decisional capacity; Diagnostic interventions; Clinical trials; Research ethics

INTRODUCTION

The method of getting informed consent for nursing home research is two-tiered, starting with institutional level consent from the long-term care community and moving on to individual level participation. This study discusses the practical ramifications of the duty of nurse investigators to secure informed consent among participants in long-term care research. It does so by drawing on a review of the literature, the authors' research experiences, and their service on institutional review boards. The recommendations include using a community consent model for long-term care research, encouraging an evidence-based strategy for safeguarding people with decisional impairment, and drawing more attention from researchers to ethical concerns concerning long-term care workers.

THE SETTING

In the United States, over 1.3 million people reside in nursing homes [1]. The definition of a nursing home or skilled nursing facility varies from country to country. In the United States, the federal government defines a nursing home as an organization that provides long-term custodial care that goes beyond the room and board [2]. Due to advances in medicine, surgical procedures, and social initiatives, such as Social Security and Medicare, it is estimated that two-thirds of today's 65-year-olds will spend time in Long Term Care (LTC) or Long Term Residential Facilities (LTRF) in their remaining years, and approximately 20% of them will require skilled nursing. Given the present state of LTC facilities, this population can expect little in the way of high-quality care [3]. There is, thus, an urgent need to research on the

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problems affecting people who require LTC, and the structures and patterns of delivery of such care.

Older adults living in nursing homes comprise a unique population that deserves to be included in research not only for their possible benefit but also for the entire society's benefit. Research results from other settings appear not generalizable to this population because their needs are very different [4]. Results obtained directly from nursing homes confer more benefit to the residents, because as a group, their frailty, comorbidities, and institutionalization contribute to their uniqueness.

In nursing homes, a deficit of knowledge remains about the effects of medical, surgical, and diagnostic interventions, including simple epidemiological issues that could benefit the residents [5]. Research on LTRF has increasingly improved geriatric medicine and quality of care [6]. Such research has resulted in valuable knowledge on various subjects, such as the lack of benefit in the prescription of intensive statin drugs for preventing stroke in nursing home populations, the examination of the effectiveness of probiotics against antibiotic-associated diarrhea, and the use of cranberry supplements for bacteriuria and pyuria, which are very common problems for the population of focus [7-9].

The other relevant practices studied include the effectiveness of pneumococcal vaccine, the questionable therapy of intense physical rehabilitation within days of death and the value of music and memory therapy for patients with Alzheimer's disease [10-12]. The investigation of organizational processes, shared decision-making, and perception of quality of life occur with the direct participation of nursing home populations. Other pressing subjects that warrant further research include the sexual abuse of older adults and the ethics of using cameras in facilities to monitor resident activities [13-17].

The ethical obligations owed to this group require solutions to the challenges beleaguering informed consent for research. A three-pronged approach to this challenge proposed in this paper helps researchers recruit participants and ensure genuine informed consent from those living in nursing homes. Subsequently, a preliminary protocol that operationalizes obtaining informed consent from older adults with decisional capacity is presented.

However, the ethical challenges of conducting research in nursing home populations and concerns regarding the validity of the participants' informed consent persist. Informed consent, the bedrock of contemporary bioethics in clinical practice and research, ensures respect for individuals [18]. All biomedical and health research involving human participants ethically and legally requires informed consent, which refers to a voluntary choice made by individuals as research subjects who have been informed about and understand the study in which they are participating [19]. These conditions may be difficult to meet with nursing home residents.

The ethical recruitment of subjects remains one of the most daunting aspects of research. In nursing homes, infirmities due to age and morbidities, and how these factors affect an individual's ability to give informed consent needs to be considered in determining the older adults' participation in research. As many as 61% of nursing home residents in the United States have moderate or severe cognitive impairment, leading to informed consent challenges [20]. Alzheimer's disease, dementia, or other cognitive impairment disorders limit but does not exclude autonomous decision-making. Older adults with dementia qualify to participate in studies that focus on their everyday lives and whose data are gathered through observation and interviews [21]. Their own or substitute decision-making by legally authorized representatives makes it possible to obtain the older adults' valued participation.

Comprehension about the content of consent requires determination even within a smaller sample of older adults with decisional capacity. Questions arise on the voluntariness of the participation when nursing home residents submit to authority or feel coerced to participate as captive audience [22]. Nevertheless, they readily participate in the research either to increase their human contact or for the benefit of diversion [23]. Those who are at the end of life treat their participation as a valuable contribution to the future lives of others, a sentiment that offers substantial therapeutic benefits to the participants themselves [24]. Some may participate to get the attention they seek, please their caregivers, or show their loyalty to the healthcare institutions [25].

THE EMPIRICAL EVIDENCE

Situational variables associated with the research design affect informed consent. The same conditions of informed consent voluntariness, disclosure, and comprehension that apply to other populations pertain to the older adult population as well. Recruitment of the participants precedes informed consent. Clinical trials in nursing homes, more so than surveys, observational studies, or clinical trials in a different healthcare setting entail complex and time-consuming processes [26]. The nursing home, considered a "highly unstable environment" due to the high attrition and turnover of staff and residents, along with regulatory changes, affects participation [27]. Staff turnover as high as 50% among licensed administrators, 40% among nurses, and 65% among nurses' aides impacts research participation [28,29]. Participants often prefer to receive treatment over the placebo, which contributes to the degree of enrollment in a study [30]. On average, low-risk observational studies experience significantly higher recruitment rates than pharmacological studies with residents with frail conditions.

The lack of explicit guidelines for obtaining informed consent in nursing homes remains. A recent systematic literature review conducted by Hall et al. revealed the absence of protocols for informed consent, which supports the conclusion that a solution to these challenges requires further exploration [31].

Obtaining informed consent requires time-consuming efforts [32]. Older adults require extra time to process information and need more time to read materials, and arrive at their own decisions. Large typeface and adequate white space assist in their reading [33]. Typically, the consent process should include the reading, discussion, and signing of the consent form before participation in a study. Comprehension must be measured through a survey at the end of the form. Fatigue also limits the decision to continue participating in a study [34].

In two nursing home studies conducted in Finland, researchers found that they needed time to chat with the residents about a benign topic, such as the weather, to determine whether the participants had the ability to understand the study or if they wanted visitors [35]. The participants' unrealistic expectations were accompanied by their involvement. They may expect their circumstances to change or their voices to be heard, which may point to comprehension issues during the consent process. Since no definitive markers of changes in patients' cognition exist, researchers need to pay attention to their participants' level of understanding throughout the study.

As a solution to determining participant comprehension, ethnographic research has revealed several procedural tips. When researchers in an ethnographic or field study collect data, they necessarily form personal relationships with the informants they study. Ethnographic studies on informed consent in nursing home research reveal ethical issues related to the reciprocal relationship between researchers and participants. For instance, researchers must be sensitive to their informants' expressions and gestures as indicators of their comprehension or discomfort. They can also observe and detect the participants' submissiveness to authority as an indicator of the genuineness of their consent [36].

In England, in a study using qualitative interviews with nursing home residents (N=18), one of the most significant challenges found apart from involving staff and family members in the facilitation of informed consent was finding a private place to conduct the interviews. Older people often experience a range of symptoms, such as pain, fatigue, and hearing or visual problems, which severely affect the time needed to obtain informed consent and conduct research.

In the same study, to inform potential participants, the researcher left materials for the older adults to read along with an "expression of interest" form for them to fill out. Later, five residents reported that they knew nothing about their form. Ten could not remember filling out the form or reading the information. As a part of determining comprehension, the researcher explained the study to the prospective participants to ensure that they understood it reasonably well. Six individuals who completed the form did not understand their involvement in the study, which led to their exclusion from the research. In these cases, the researcher engaged in a short conversation with these individuals and thanked them for their time. None of the individuals expressed concerns about being eliminated. The researchers saw the importance of time to monitor the participants' comprehension in non-threatening ways and tact when excluding people who cannot provide informed consent Hall et al. concur with this observation. Zermansky et al. recommend including a 24-hour period between the face-to-face discussion and the signing of the informed consent form [37,38].

In another study conducted in England, the researchers achieved a consent rate of only 42% from the original sample because those initially judged to be capable of giving informed consent were ultimately found to be not competent [39]. The researchers found that questions arose about the external validity of their outcomes because even those deemed mentally competent did not comprehend the study in the end. The researchers also raised questions about the benefits of interventions that lack measurements within their target group.

In Finland, a randomized control intervention trial (N=1410 men and women, ages 57–78 years) used a questionnaire on the effects of diet and exercise [40]. After the study, a majority of the patients expressed satisfaction with the informed consent process. However, a minority expressed dissatisfaction with the information they received or did not completely understand it. Similar to the findings of Zermansky et al., these researchers questioned whether all participants truly gave informed consent.

SPECIAL CONSIDERATIONS: WHAT SHOULD BE DONE?

The American Medical Directors Association (AMDA) maintains the importance of improving the care of residents in LTRF. The AMDA specifies that the research must be well defined, and its question worth investigating. The residents should receive all the protections required by federal and state law, irrespective of the study's funding. The special vulnerability of residents in LTRF necessitates the expansion of protection standards and special considerations.

The benefits derived from evidence-based research on clinical care, safety, and the treatment of chronic illnesses and mental health disorders benefit current and future patients, family members, nursing staff, and physicians by improving their understanding of the residents' conditions. Participants may also derive no benefit from a study. The recruitment methods in a study involve considering the unique life circumstances and limitations of its target population, and the comfort and care of its participants. The assumption that there is only a single methodology for obtaining informed consent for all patients may be the reason why informed consent sometimes fails [41].

The disclosure of "reasonable" and "foreseeable" risks constitutes one of the most problematic parts of informed consent as such terms lack universal definitions [42]. "Low risk" remains hard to define and may be contextual for the study population. The vulnerabilities that accompany aging may convert traditional low risks into higher risks for nursing home residents and complicate the ethical requirement to minimize risks to subjects, as described in the United States government regulation 45 CFR 46.

A consideration of empirical studies reveals that the informed consent process in nursing homes necessitates re imagination and explication. As Lam et al. noted in their literature review, there are still no guidelines or protocols for securing informed consent from older adults with decisional capacity in nursing homes. This gap in research highlights the need for a protocol detailing factors for obtaining informed consent. Special considerations can be adopted in nursing homes research to provide solutions to the challenges of obtaining informed consent. Older adults lack experience in research participation or remain accustomed to not being heard. The synthesis of several suggestions derived from empirical nursing home research contributes to a preliminary protocol for finding

solutions to the challenges of obtaining informed consent from older adults with decisional capacity that live in nursing homes (Table 1).

Table 1: A research protocol for securing informed consent from nursing home patients with decisional capacity.

Planning
Provide justification for the research question.
Articulate the scientific aim of the study and evaluate any alternative means of answering it.
Determine the appropriateness of the research design to the NH population.
Secure local IRB approval for the study from the Board of Advisors and the Medical Director.
Assure the informed consent document complies with all the requirements of local and regulatory norms.
Guarantee training for the Board by the researchers or the NH proprietors to understand the research process and the challenges of informed consent.
Enumerate the special considerations for the subjects and how to enact them
Recruitment
Determine the method for recruitment of subjects.
Determine parameters of competency for participation.
Explain the purpose of the study to the potential participants.
Provide sufficient time for answering their questions.
Assess language and literacy skills of the participants.
Outline and explain the informed consent process.
Determine comprehension of the study and process.
Ascertain that the language of the informed consent document offers easy to read, non-technical language set in an easy-to-read font and point size.
Explain the steps the participant needs to take to drop out of the study or express discomfort.
Offer prospective participants 24 hours between their face-to-face discussion and their signing of the informed consent form.
Have staff and nurses adequately trained to assist in securing informed consent.
Assign someone to monitor participants' discomfort, distress, and anxiety levels and changes in cognition.
Ecological factors
Build enough time into the study to accommodate slow mobility, fatigue, response time, residents' care, meals, naps, bedtime, bathing, toileting, activities, and other events on their schedule.
Allot extra time for participants with poor hearing, speech impediments, or language problems.
Offer a private, quiet, and comfortable study environment.

Nursing home research increasingly improves the quality of life and the delivery of geriatric medicine for older adults in nursing homes. These patients deserve to participate in research exploring their unique conditions and circumstances. As the existing studies show, a dearth of evidence on the challenges of obtaining informed consent from nursing homes residents with decisional capacity requires correction. Informed consent constitutes the foundational principle of all research, yet there is a lack of explicit guidelines for obtaining it. Situational variables such as age, infirmity, and institutional culture affect genuine informed consent for those with decisional capacity. A lack of participant comprehension compromises obtaining informed consent from participants.

Through a synthesis of comprehensive research findings on planning, study recruitment, and ecological factors, a best practice approach demonstrates that genuine informed consent from nursing home patients with decisional capacity mitigates and accommodates many of the existing challenges in nursing home research. These processes are indispensable to sound medical and research ethics, patient dignity, and the corresponding conclusions drawn from the said research. Additional challenges that future studies should look to address include the inclusiveness of ethnic minorities and study comprehension.

DISCUSSION

The fact that appear to be a consistent norm among doctors for evaluating decision-making competence only serves to exacerbate these problems. The problem of informed, consenting decision-making consequently has a significant impact on the social and medical dynamics of institutions, caregivers, and patients. Clinicians must have a thorough awareness of the challenges associated with handling informed consent correctly while not obstructing appropriate medical care.

CONCLUSION

Understanding diagnostic and treatment information, realizing the personal relevance of this knowledge, weighing the risks and advantages in light of one's personal values, and expressing a personal choice make up a broadly accepted model for medical decision-making capacity. For different kinds of judgments, multiple models are available. Any accurate evaluation of a person's ability for making decisions must first conduct a thorough clinical interview in which the doctor tries to grasp the subject's background, values, and worries or concerns. When

information was not explained to a patient by the practitioner in a way that could be understood, it might often raise doubts about the patient's decision-making processes. Knowing the patient as a human being and ensuring that they are aware of the suggested therapies the clinician can be in a better position to promote autonomy and convey respect for the patient's dignity.

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