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Conducting Research with the Elderly: Ethical Concerns For a Vulnerable Population

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Abstract

As one of the faster growing segments of the population, over 70 million American citizens will be considered elderly by 2030 (Centers for Disease Control and Prevention (CDC), 2007). The growth of this group is unprecedented in American history, owing in part to advances in health care research having a positive impact on longevity. Inevitably older adults will likely be more involved in research than ever before. Ethical protection becomes a principal concern when a group, such as the elderly, is identified as vulnerable. This article reviews concepts of autonomy, beneficence, and justice in relation to geriatric research and discusses ethical risks with case studies.

Keywords: Informed consent, research, ethics, geriatric, vulnerable population, ethical principles, case study

Introduction

As one of the fastest growing segments of the population, over 70 million American citizens will be considered elderly by 2030.[1] The growth of this group is unprecedented in American history, owing in part to advances in health care research having a positive impact on longevity. Inevitably older adults will likely be more involved in research than ever before. Ethical protection becomes a principal concern when a group, such as the elderly, is identified as vulnerable. The purpose if this paper is to identify and discuss ethical risks unique to this vulnerable population and propose possible solutions with case studies.

Conducting Research with the Elderly: Ethical Concerns For a Vulnerable Population

The increasing number of elderly Americans will propel research in multiple disciplines in an effort to describe, understand, and treat problems of aging. Medical research for physical aging, diseases and conditions, and pharmacologic and other interventions alone will consume vast research resources. In addition, psychological research will be conducted on memory, cognition, and personality; and social research will investigate effectiveness of social programs and services.[2] Marketing research will also be conducted to influence the buying decisions of a growing market sector.

Ethical principles guiding a person's participation in research have evolved substantially over the last 50 years, with special considerations for groups identified as vulnerable. The formation of a National Bioethics Advisory Commission[3] in 1995 followed a history of examination of moral and ethical behavior in research as a result of the Nuremburg Trials of World War II (WWII). The German city of Nuremburg was the location where physicians and staff of the Nazi military where brought to trial for "murders, brutalities, cruelties, atrocities, and other inhumane acts"[4] which were conducted under the guise of medical research. The involvement of physicians, calling what amounted to torture as 'research', galvanized the medical community into establishing an ethical code of conduct. The Nuremburg Code (1946-1949)[5] established ten principles to guide medical experiments, focusing on voluntary consent, avoidance of harm, and reduction of risk. This was followed in 1964 by the Helsinki Declaration drafted by the World Medical Association[6] which adopted and expounded on these principles.

However, continued infamous violations such as the Tuskegee Syphilis Study that unethically denied black men effective treatment for syphilis[7] and Milgram's obedience to authority experiment[8] lead, in part, to the creation of the Belmont Report .[9] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created by act of Congress in 1974. The Belmont Report represented the commission's work which delineated the boundaries of biomedical and behavioral research, assessing risk/benefit, guidelines for the selection of subjects, and the constitution of informed consent in diverse situations.[9]

The Belmont Report laid the cornerstones of bioethical practice with the principles of respect for persons, beneficence, and justice. Since that time, policy makers around the globe have adopted the principles laid out in the report.[10]

Respect for Persons (Autonomy)

The principle of respect for persons provides the right of the individual to choose. In biomedical research, this principle extends essentially to deciding whether to participate, free from coercion, in a research study (voluntariness).[11] Informed consent procedures provide respect for persons and are the outcome of the principle of autonomy. However, informed consent can only be made if there is

provision of adequate information and comprehension of the risks and benefits related to participation in research.[12] The Belmont Report[9] proposed the prime principle as respect for persons which recognizes the individual as autonomous unless the individual does not have the ability for self-determination, in which case, the individual is entitled to protection. Respect for persons also encompasses the right of the individual to have informed, voluntary participation, protection of his/her person and information when participating in research studies.

Beneficence. In addition to allowing the individual the right to choose whether to participate in research, the principle of beneficence ensures well-being while participating in a study[9] and maximizes any benefit that potentially accrues as a result of participation.[11] The principle of nonmaleficence states specifically that no harm should be knowingly inflicted.[11] Risks and benefits related to study participation are weighed under this principle

Justice. The principle of justice speaks to the ethic of fairness. Those who submit to the risks of research should have equal share in the potential benefit.[11] While the benefit may not directly affect the individual, any potential benefit may be for a similar population at a future date. Essentially, the principle of justice states that all people should be treated equally.[12]

Elderly as a Vulnerable Population

Aging does not intrinsically make one vulnerable. In fact, the NBAC[3] does not list the elderly as a vulnerable population even though children, the institutionalized, and women are recognized as more open to harm and vulnerable to coercion. However, the NBAC[3] states that vulnerability is context-specific and can be related to cognitive and communicative vulnerability. The Agency for Healthcare Research and Quality (AHRQ, a division of the U.S. Department of Health and Human Services),[13] states specifically that a vulnerable population may be at risk due to age, health, functional status, chronic or terminal illness, inability to effectively communicate, or financial circumstances, all of which may apply to the elderly.[13] Inequalities in emotional and physical power between the subject and the researcher, a situation that also relates to some elderly, can potentially compromise principles of ethics. Easy fatigability, shortness of breath, and severe pain are examples of factors which contribute to differences in physical power between researchers and potential elderly subjects.[14] High social vulnerability among the frail[15] can contribute to differences in emotional power.

Relevant Issues Related to Research with the Elderly

The CDC defines elderly as greater than 65 years of age.[1] But increases in lifespan have contributed to an emerging demographic of young old (65-74 years), old (75-84 years), and oldest old (over 85 years) as well the frail elderly (anyone over 65 years with physical and/or cognitive infirmity).[16] Increasing age

often corresponds with cognitive changes, and physical decrements in hearing and vision affects even the healthy elderly. In addition, independence often wanes requiring family support, agency support or assisted living, or institutionalization. In the following sections, ethical issues related to inclusion of sub-populations of the elderly in research will be discussed.

Issues Related to the Independent Healthy Elderly

Though age alone does not confer vulnerability, there are undeniable aspects of aging that open individuals to risks related to research. Physical changes in hearing and eyesight may mean that listening to the description of study risks and benefits, or reading pamphlets and consent forms may not be effective forms of communication.[17] Asking about such a disability may not always be answered honestly due to embarrassment, or even lack of awareness that these deficits exist.[2] Intellectual capacity also diminishes with age as situations representing increased complexity become inversely related to the ability to comprehend. Researchers may present complexity in the number of facts given, speed of presentation, length and complexity of sentences, or force of presentation which may result in decreased understanding.[11,18]

Socially, older individuals may be bored or lonely and willing to participate in a study in order to vary the routine in their lives, or spend time with another person.[18,19] While not intentionally coercive, researchers may inadvertently offer more than the risks and benefits outlined in the study by providing the benefit of social contact. Weighing risks and benefits may also be difficult with the elderly. What is not inconvenient, for example, a blood sample draw, for the average adult may be highly inconvenient and upsetting for an elderly person who must alter his or her routine.[17] The elderly, as a group born before 1942, tend to be more trusting of authority, especially the physician, more hesitant to refuse a request by someone viewed in authority, less likely to sign a document that appears as a contract, and less likely to break the contract once signed.[12,17-18,20]

Psychosocial resources available for dealing with stress may be limited or lacking for the elderly. At a time when the ability to cope becomes less, life changes such as illness, employment (retiring, loss of job), diminishment of income, and loss of spouse or loved ones can also increase vulnerability.[21] In fact, lack of social support may be one of the greatest indicators of vulnerability in this age group.[21] Loss of support contributes to feelings of powerlessness which may cause the elderly to participate in a study not because of the will to participate, but because s/he feels powerless to resist.[18,21]

The following case study illustrates issues related to recruitment of the independent healthy elderly. Areas of concern and threats to ethical research will be discussed based on this scenario

Case study. Sociologists at a nearby university are doing a study to determine if the local community could benefit from the addition of an assisted living center. Ms. Mildred, 66 years old, was contacted and asked to participate in the study. Ms. Mildred is currently employed full-time as a book keeper for a small office, and has stayed on past retirement age since her husband's unexpected death two years ago. She enjoys her job, but looks forward to the time she can spend with her daughter and her family in a nearby state.

After initial telephone contact at home, the lead researcher asked for Ms. Mildred's work phone number for contact during the day, and asked to meet Ms. Mildred during her lunch break at a nearby cafe to explain the study. Ms. Mildred agrees, but states it is important that she returns to work on time. Ms. Mildred listens to the presentation provided by Dr. Snow, the researcher, looks at the detailed pamphlet offered, signs the consent, and completes the survey before returning to the office at the end of the lunch break. Ms. Mildred's participation in the study ends at this point with no further researcher contact.

Case analysis. Determining if the participant in the case study was treated ethically requires application of a systematic set of criteria. The following questions guide determination of respect for persons in a research study.[2] Was the participant:

1. able to receive the information?
2. able to comprehend the information?
3. free from coercion?
4. able to cognitively evaluate the risks and benefits and make a decision?
5. involved in the research voluntarily?

All study participants should be able to see and hear study presentations. For the elderly, the use of larger, clear type fonts (without embellishments) or, enlargement of written materials,[22] and meeting in quiet locations to eliminate extraneous noise enhances delivery of study information. The elderly may not be aware of mild sensory losses, and minor deficits can be controlled for in this manner. The gainful employment of this participant may suggest that hearing and vision are adequate, but this may be in a quiet, well lit setting with reading glasses. If the subject wears reading glasses the researcher should ensure their wearing during the study presentation. Therefore, in the case scenario above, it is possible that Ms. Mildred did not receive adequate study information for the following reasons: meeting at a café during lunchtime (ambient noise), the pamphlet offered (font type and complexity), and possible need for reading glasses. Complexity was built into the meeting by conducting it during a lunch break necessitating speed of presentation. While the researcher's forcefulness cannot be gauged, it is not unreasonable to assume that lack of time added urgency and some forcefulness to the presentation. While we do not know if the researcher presented the study with fewer details and straightforward language,

unless this was purposefully done, there may not have been comprehension of the material.

Determining comprehension is essential, especially with a vulnerable population. Since complexity is inversely related to comprehension in the elderly, study presentations benefit from fewer facts with simple language and few compound sentences. The speaker's speed and force of speech during the presentation should be moderate. However, determination of comprehension may be difficult. The simplest test is to have the participant repeat, in her own words, the information given, for accuracy.

Coercion for the elderly is very subtle. Many older Americans have a strong respect for authority, and strong values, such as not giving up and keeping their word. To prevent an authoritative look, a young, researcher could make the presentation, dressed casually without references to an organization such as nametags or uniform, or use of titles. In addition, the consent should not have a contract format, but could be presented, for example, on pastel paper with a casual font (as opposed to New Times Roman, which appears more formal). Observing for clues that the participant is reluctant is another way to avoid coercion.[23]

Contact with the participant in the place of employment and meeting her in a café could violate her right to privacy. Rather than asking for the participant's work number, the researcher should have identified a mutually agreeable location.

In this case study, there may have been coercion by calling the participant at work concerning a study about assisted living. Possibly the participant did not want to be viewed as person who would soon by leaving employment due to infirmity and was uncomfortable having the researcher contact her at her place of work. She may have felt vulnerable to economic stress as she was employed past a point at which most Americans retire. It is conceivable that in an effort to avoid stressful contacts with the researcher, she agreed to the study to end further contact.

No remuneration was offered for study participation, but researchers should be aware that financial incentives may be unfairly compelling for those of moderate, low, or fixed incomes.[14] However, more valuable than financial incentives may be the fellowship of another human being and diversion from routine. Ms. Mildred, widowed and alone, may have been subject to coercion through the need for companionship rather than the merits of the study.

For the elderly, a support system is perhaps the most important factor in creating a vulnerable situation. Mildred no longer had her husband, and infrequently saw her daughter, but appeared to have a good relationship. However, the participant, by immediately signing the consent, did not have an opportunity to contact her support system to assist her cognitively to make the decision. While

she may have been capable of deciding to participate in the study, a two-phase process that allowed time for comprehension, reflection, and consultation with the support system would have assured respect for her as a person. Participants need time to make informed and autonomous decisions.[23]

The participant's social and education status were not clearly identified, but gainful employment in a technical job would suggest that the participant is not especially vulnerable related to these factors. Lack of education corresponds to vulnerability perhaps because those with higher education have access to more resources.[21]

Voluntariness occurs when the participant is free to participate or withdraw without undue influence.[2] Having given assent, the elderly are not often comfortable withdrawing. During the study, the participant should be given repeated opportunities to affirm assent or withdraw.[23] Therefore, the elderly should have multiple points where consent is evaluated during the course of the study. Frequent reassurance that it is acceptable to change one's mind about study participation is reasonable for this population.

The ethical principle of respect for persons may have been violated because continued assent for the study was not obtained during its administration. A step-wise consent process allowing several junctures to reconsider and withdraw from a study may be more appropriate for the elderly.[24,25] Ms. Mildred could have been given an opportunity to re-evaluate her participation during the survey.

As for the ethical principle of beneficence, it seems clear that Ms. Mildred could be a possible beneficiary of an assisted living facility in her community, and if not her, a like population that she represents. As for justice, the case study does not present enough information. But a question arises as to whether she was chosen fairly to represent the population. For the elderly, females outnumber males,[25] and ethnic and racial diversity will increase, with only 72% describing themselves as Caucasian, by 2030.[1] Not evident in this case, is the risk of exclusion related to the extra care needed during recruitment and research with the elderly. [26]

Conclusion. Ms. Mildred, despite the benignity of the situation, was vulnerable in several ways and should have been adequately protected. The research may have been unethical.

Issues Related to the Dependent Chronically Ill (Frail) Elderly

Ethical issues related to recruitment of the healthy independent elderly apply to dependent chronically ill elderly, but there are additional concerns generated by the presence of illness and loss of independence. Chronic illnesses increase vulnerability[21,25] because a reduction in nonmaterial resources, such as psychological and social health,[27] diminishes capacity to resist outside influence. In addition, dependence on others and perceived potential loss of support is

highly influential in motivating the elderly to comply. Loss of physical mobility, and reduced psychological and social resources causes physical and emotional power shifts away from the elderly.[25] Elderly who are placed in care facilities and nursing homes not may only fear loss of service, but of receiving a change in quality of care as a consequence of selecting non-participation.

Case study. Ms. May, a 76 year old African American woman living alone, has been housebound the last 2 years due to severe osteoarthritis. A social service delivers a hot meal to her home daily, and her children come on the weekends to cook and clean. Her primary physician, who owns stock in the drug company, has suggested she enroll in a study for a new medication to treat arthritis. She has agreed to talk with the researcher in her home. The presentation is given at a time convenient for Ms. May by a young man, a research assistant. He is dressed in business casual and spends time explaining the study simply and clearly. He answers her questions and leaves a brochure with basic facts, in a large, easy-to-read print, which states that she will have weekly contact and two blood sample draws, in her home, to check organ function. The study will last 6 months. He leaves a copy of the consent form, which, while several pages long, is in a large font on pastel blue paper. He agrees to return in a week. When he returns the consent is signed, and Ms. May appears eager to participate in the study.

Case analysis. In this case, the researcher has taken care to allow the participant time to reflect, contact her support system, and present the study clearly without pressure. However, as previously seen, elderly participants are vulnerable to subtle coercion.

The principle of beneficence requires full disclosure of risks and benefits for study participation but risks may be assessed differently between young and old, such as the inconvenience of blood draws. In this case, Ms. May have not felt free to decline the study, despite the inconvenience of blood draws and weekly visits, because it was her physician who suggested it. Not only did the physician represent authority, but also a potential loss of service if she felt she displeased him by declining. She may have also felt that her lunch time meals may be threatened if she declined, further compromising her ability to choose freely.

The physician recommending Ms. May's participation in the study created a conflict of interest, even though he was not the researcher. A conflict of interest occurs when personal, financial, or political concerns co-exist with potential to cause one interest to supersede another.[12] The conflict of interest resides in the situation, not in the action.[12] The physician involvement may not only be coercive of consent, but may influence the participant's report on the drug's efficacy, biasing study results. In addition, the prospect of an effective arthritis treatment to relieve pain and suffering may have affected Ms. May's assessment of study benefits by assigning unfair value to participation.[28]

There is no evidence that Ms. May ever contacted her support system to discuss the risks and benefits of the study. Perhaps in her eagerness for a change of routine and fellowship, she simply signed the consent and overlooked the risks. In addition, her comprehension of the study presentation was never assessed. Rikkert[24] suggested the use of a 10-item test that covers basic study information given after the presentation to assess comprehension. Such a test could be used if asking the participant to explain the study did not bring sufficient results. A better solution would be the presence of a family member or third party that could help the participant evaluate the presentation.[17,24]

Lastly, there were no procedures for ongoing consent to allow Ms. May an opportunity to withdraw from the study. Rikkert[24] proposed a try-out period of one week, which is reasonable for a long term study, to ensure assent. While initially Ms. May may have decided that companionship was a good reason to participate, she may later have found the change in routine a large inconvenience. Therefore, Ms. May's voluntariness for the study cannot be assumed. The concepts of beneficence and justice appear to be met as Ms. May was representative of the population who could benefit from this study, and could possibly have benefited herself.

Conclusion. The researcher in this situation recognized some of Ms. May's vulnerability, but failed to take into account others. While lack of evidence for Ms. May's comprehension and motivation for being in the study were troubling, the lack of voluntariness may have been the greatest ethical concern in this scenario.

Issues Related to the Demented and Cognitively Impaired Elderly.

Dementia in the elderly occurs in approximately 6-10% of the population over 65.[29] Inability to self-determine describes this population as vulnerable. However, with this population, there are special considerations related to advanced age. For example, persons with dementia (including Alzheimer's disease (AD) are more likely to indicate assent during study presentations that are not congruent with their wishes. Persons with dementia often agree with the researcher during consent procedures but are not necessarily indicating their willingness to participate.[30] During consent procedures anxiety is often provoked due to the cognitive demands and signature requirements on a contract-like document.[18]

For persons with dementia a surrogate with no vested interest in the study serves proxy for consent procedures.[2,17,31] The surrogate should make a decision based upon the risks and benefits, and also, the wishes of the participant were they able to make the decision for themselves.[2,31] The surrogate should ask themselves if they would participate in this study.

Case study. A research study is investigating the use of artificial sunshine to prevent 'sundown syndrome' in the elderly in a nursing home. Mr. Oscar, a 92 year old man with AD, is a potential subject for this study. His elderly wife visits

several times a week, and says that he has good days and bad, but generally is calm and content. The researcher explains the study will involve changing the light in Mr. Oscar's room and leaving it on several hours a day. Mr. Oscar's wife agrees and signs the consent.

Case Analysis. Mr. Oscar's wife served as the surrogate for this scenario, but due to her elderly age, she may have had some vulnerability as we saw in the previous scenarios. Since she is giving proxy consent, any vulnerabilities she may have need to be taken into consideration. Family members may also serve as proxy consent surrogates.[32] If the 55 year old granddaughter served as surrogate, the granddaughter would need to weigh risks and benefits on behalf of her grandfather and come to a decision congruent with any known past wishes. She should consider if she, herself, would have any reservations about participating in such a study. Her grandfather's institutionalized status would also need to be analyzed, for example, concerns that if study enrollment is refused, the grandfather's care in the institution could be affected. Respect for persons is conducted through the proxy. If a family member is not able to serve as a surrogate then the issue of confidentiality is raised.

Whether the administration of light would be harmful (maleficence) for Mr. Oscar is not known, and brings the ethics of this study related to beneficence into question. On grounds of justice, the study may not be ethical as Mr. Oscar does not have 'sundown syndrome' (not representative of the study population) and could not obtain personal benefit. The researchers should have allowed more time for the family to examine the merits of the study.

Conclusion. Ethical inclusion of demented persons in research studies is challenging. Surrogates may arbitrarily exclude participants from a study, not adequately weigh risks and benefits, or fail to monitor the process to provide on-going consent.

Conclusion

A vulnerable person is characterized by being open and potentially exposed to harm.[33] Circumstances may bring about a change in vulnerable status such as in health, financial, or social position.[25,33] The elderly, though not inherently vulnerable, often become vulnerable due to aging. Physical changes, decreased mobility, chronic illness, loss of support systems, and changes in cognitive ability can interfere with the freedom to choose.

Policies guiding ethical treatment of humans in research in the United States have evolved from historical events and led to development of the seminal Belmont Report. World research policies have been influenced by the principles of respect for persons (autonomy), beneficence (nonmaleficence), and justice. The NBAC acknowledged in 2001 that there are no written guidelines which apply to every situation.[3] The IRB Guidebook published by the Office for Human

Research Protections (formerly the Office of Protection from Research Risks (OPRR) has not been updated since 1993.[34] Regulations will always fall behind practice. The ethical researcher must independently examine and reflect before undertaking studies with people, especially the vulnerable elderly.

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