Cultural Issues and Challenges of Informed Consent in Older Adults

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Abstract
Owing to the dramatic increase in an elderly population characterized by cultural diversity and changes in the aging process, performing informed consent in the elderly population can involve complex issues are a challenge for researchers. This article aims to discuss concepts and relevant information concerning informed consent in studies with cognitively intact older adults. A longitudinal study entitled the simplified Tai-Chi exercise program (STEP) was utilized to explain the dilemma and implications of informed consent for research with a cognitively intact elderly population. It is important for researchers to be culturally sensitive to their subjects and establish a trusting relationship during the process of informed consent. (Tzu Chi Nursing Journal, 2007; 6:5, 65-72.)

Key Words: cultural issues; informed consent; older adults

Introduction
Informed consent, a legal doctrine, is described as a voluntary and explicit agreement made by an individual who is sufficiently competent or autonomous, on the basis of adequate information in a comprehensible form and with adequate deliberation to make an intelligent choice about a proposed action (Aveyard, 2002). Informed consent can be generally implied and expressed. Expressed consent is either verbal or written. Consent may be implied from the individual’s conduct only after all relevant information is received by a competent individual (Aveyard, 2002; Pape, 1997). There is a lack of research indicating how researchers should employ implied consent in their studies. The purpose of the article is to describe the...
concept of informed consent and related information in studies with cognitively intact older adults and to use a study called the Simplified Tai-Chi Exercise Program (STEP) to address implications and the dilemma of informed consent for future research.

**Theoretical perspectives and elements of informed consent**

Legal and ethical principles are the foundation of informed consent. Two theories, deontological theory and consequentialism, dominate ethical principles guiding informed consent (Moore, Savage, Lucy, & Savage, 2002). Deontologists assert that each person’s binding duty is to society, and one has obligations that have to be fulfilled regardless of their outcome. Consequentialism emphasizes that the rightness or wrongness of an act depends on the consequences of that act, and all people are considered equal (Pape, 1997).

By the same token, the legal theory of informed consent represents various aspects of tort law that protect individuals from harm to person, property, and reputation. Tort law allows compensation for injury, deters corrupt conduct, and punishes those who are involved in wrongful behavior (Booth, 2002). The types of tort law theory related to informed consent include assault, battery, and negligence. Violating the right to informed consent places researchers in two main legal troubles: assault and battery, and negligence (Pape, 1997).

Even though the elements of informed consent are well discussed in the ethical literature (Ensign, 2003; Moore et al., 2002), the specific application of the elements of informed consent to research studies with cognitively intact older adults is less strong. A wide range of ethical studies have identified that informed consent involves two essential elements, information elements and consent elements (Moore et al., 2002). Information elements involve two components, disclosure and comprehension of information. Potential subjects are entitled to sufficiently truthful and pertinent information about the requirements, procedures, risks, benefits, and alternatives of the study to help them make their choice before becoming a human subject in research. To ensure potential subjects’ comprehension, the information should be disclosed at a level of potential subjects’ education, maturation, language, age, and cognitive ability (Moore et al., 2002). The commonly used media to convey the information to elderly subjects include easy-to-read materials on informed consent that may be supplemented with verbal reiteration and explanation, audiocassettes, and video recordings (Wilson, Racine, Tekieli, & Williams, 2003).

Competence, the ability to understand and decide about a choice of actions, and voluntariness, freedom of choice without coercion, are the requirements of consent (Pape, 1997). Both law and research require standards of competence that are associated with mental skills and linked with the qualities of an autonomous person (Pape, 1997). Consent to participate in a study is
ethically valid only if provided voluntarily and without duress or manipulation (Aveyard, 2002; Booth, 2002).

**Factors affecting informed consent**

A number of researchers have pointed out many factors that correlate with or influence the quality of informed consent in clinical practice, but there are fewer studies on issues involving cognitively intact elderly people. Among these studies describing socio-demographic factors, few report that age seems to be associated with the outcome of informed consent (Wilson et al., 2003). With aging, various physical changes (such as hearing and vision), illness, or impairment can affect the process and result of informed consent. For example, neurological changes can influence the speed at which information is processed, and if too much information is presented too quickly, there may be a delay in comprehension and a delay in responding (Heath, 1997). Moreover, cognitive impairment affects an older adult’s ability to convey the messages that he/she wishes (Heath, 1997). Older adults may have difficulty speaking and require more time to communicate, or they may refuse to answer questions because of their emotional status. Although any of these factors could be involved, having older adults paraphrase what they are told about procedures is perhaps the best way to determine whether they understand the disclosed information (Pape, 1997). Wilson et al. (2003) have stated that the conditions in which older adults are at greater risk of not complying include poor comprehension, multiple prescribed medications, and impaired cognition.

**Cultural sensitivity in informed consent**

Most countries have seen significant changes in their populations in the past decades as a consequence of migration across national borders, and this has resulted in multi-ethnicity in many societies. This has led to considerable challenges for those involved in research (Papadopoulos & Lees, 2002), and has also highlighted the need for cultural sensitivity in the process of informed consent. While the significance of culturally-sensitive research is well-documented, the definition of cultural sensitivity differs in various ways. Trans-cultural health studies have utilized “sensitivity” interchangeably with cultural knowledge, awareness, or competence. Some authors view cultural awareness, a state of being conscious of oneself as a cultural entity, as an antecedent to cultural sensitivity (Kim-Godwin, Clarke, & Barton, 2001). Based on the studies reviewed, cultural sensitivity can be summarized as a dynamic process of recognizing and respecting the values, beliefs, and language of the target group (Chio, 2002; Daddy & Clegg, 2001; Gerrish, 2000).

Papadopoulos and Lees (2002) summarize culture as integrated patterns of human behavior that are comprised of language, thoughts, actions, customs, beliefs, and values of ethnic or social
groups. Therefore, diverse cultural groups perceive the world through the lens of their cultural background. They usually interpret provided materials by their values and rules of behavior consistent with their culture, and consider whether the information fits with their own life (Papadopoulos & Lees, 2002). In addition, people’s cultural heritage cannot be separated from the way in which they communicate with each other. Clegg (2003) has found that south Asian cultures emphasize a degree of modesty which may be severely comprised by some western health care practices, such as the use of mixed sex washing and toilet facilities. Elderly people should not be patronized or infantilized in the process of communication, and their privacy and dignity should be maintained while respecting their autonomy (Heath, 1997). In the process of informed consent, they should be valued as individuals and worthy of being alive. Also, it should be recognized that older people would make decisions based on their own circumstances, values, needs, and beliefs. It is imperative to ensure that language used in informed consent must be acceptable to elderly people and respectful of their cultural beliefs and practices.

In summary, cultural sensitivity in informed consent among older people is a process of overcoming cultural differences and language barriers. Even if the majority of Asians have a similar ethnic and racial status, there are significant cultural variations in the value placed upon informed consent. People who live in Asia have differences in social and family patterns, religious traditions, rituals, languages, and healthcare needs. These aforementioned elements may influence the process of informed consent. For example, in a patriarchal and hierarchical society, family members, especially fathers, usually get involved in the process of informed consent. Hence, informed consent should begin with cultural awareness, that is, cross-cultural informers need to challenge their own assumptions and develop an understanding of the many layers of culture and subculture of the target elderly population. Furthermore, informed consent with verbal and non-verbal forms needs to be developed by respecting the nature of culture and individual differences.

Applications of informed consent

Informed consent, which may occur in many ways, has been broadly applied to therapeutic and research aspects. At present, provider-based informed consent in clinical practice receives more attention than when the consent process involves a study (Kaler & Ravella, 2002). In qualitative research as well as quantitative research, it is common for research subjects to participate in the consent process which involves the aforementioned information. This suggests that all information should be known and described before initiation of a study. When additional questionnaires or outcomes are added to a study, it is incumbent upon the researcher to provide additional information for the ongoing
informed consent (Duffin, 2001).

**An example of obtaining informed consent**

In a longitudinal study (NSC93-2314-B-242-002) approved by the Institution Review Board of Fooyin University, the researchers applied a simplified Tai-Chi exercise program (STEP) to improve the well-being of elderly people (Chen et al., 2005). A convenience sample of 51 subjects aged over 65 years old was recruited from two long-term care facilities in southern Taiwan. Eligibility criteria required that the subjects be cognitively intact, as indicated by a score of at least eight on the Short Portable Mental Status Questionnaire, have no previous experience with the practice of Tai Chi, be able to walk and stand alone, and consent to practice Tai-Chi exercises three times a week. All subjects whose average age was 77.61 years, were competent to make a decision on their own behalf. All were male veterans who lived on a monthly government pension ranging from NT 15,000 to NT 20,000. Their educational backgrounds were as follows: illiterate (9.8%), elementary school (56.1%), junior high school (22%), high school (9.8%), and college (2.4%). Based on the principles of informed consent described previously, in addition to employing written consent forms with a signature, the researchers provided participants alternatives, such as stamping, thumb-printing, nodding, and handshaking, for their consent to the study. The researchers reiterated the materials and explained the relevant information in detail to all potential subjects, and gave them enough time to make a decision.

Owing to an untrusting relationship among people in this industrial society. Over 90% of the potential subjects initially hesitated to take part in the study because they felt uncomfortable and insecure about leaving their signatures, stamps, or thumb prints on a document. To obtain consent from our potential subjects, the researchers adopted several strategies in the process of informed consent. The priority action was to ask for administrative help from a social worker who was in charge of these elderly people’s affairs. The social worker implemented the following two additional interventions related to consent: 1) arranging a comfortable, quiet interview room for researchers and potential subjects; and 2) developing a list of interested and likely eligible participants for the research team. Then, the researchers, who wore identification tags, provided a valid document approved by the Institution Review Board and explained the content of the study to those potential subjects. After we conveyed all relevant information about the study to potential subjects and ensured they understood the details, the majority of potential subjects signed consent forms and shook hands with our researchers to indicate their agreement. Only a few potential subjects with cataracts and difficulty in writing followed the Chinese traditional method of stamping and thumb printing to deliver their consents.

The main challenges of informed consent
in our study included the following: 1) how to gain potential subjects’ trust and communicate with them, 2) how to provide information to potential subjects with both impaired vision and hearing, and 3) how to be sensitive to the potential subjects’ needs and subculture, such as life disciplines, customs and taboos. To deal with these dilemmas, it may be useful to ask for administrative help from significant people in the process of informed consent. The key elements in developing a trusting relationship with potential subjects can be honesty, sincerity, and truth-telling. Although all subjects in our study were Chinese with the same culture, we still valued them as unique individuals and were aware of their concerns. Not only did we respect their viewpoints on patriotism and patriarchism but also we communicated with them in a way familiar to them.

All subjects in our study were veterans who followed a military code of discipline. “Being a soldier” was one of their subcultures. Acting as a soldier meant they had their own codes, symbols, attitudes, perceptions, and values that were meaningful attributes of their communication pattern. For instance, subjects usually gave us a soldier’s style salute rather than saying “hello” when we met. Further, interviewers were taught to avoid political topics because most subjects were loyal to their own political parties. In addition, we called our subjects “uncle” instead of calling them by name because they were raised in a patriarchal society in which older men should be respected by young people, and calling elderly people by name is not allowed. Moreover, we used not only verbal explanations and written materials but also non-verbal explanations to disclose all relevant information to potential subjects who suffered from visual and hearing problems.

**Conclusions**

Informed consent is an agreement between a potential subject and researcher to verify that the potential subject understands all the information disclosed and volunteers to participate in a study. It should be viewed as a continuous process rather than an outcome to be achieved or a rigid process, due to the changeable nature of an elderly person’s competence over time and in various tasks (Booth, 2002). The principles guiding informed consent need to be established on ethical and legal grounds. Informed consent should consist of information elements and consent elements. The factors of informed consent change based on different variables. Cultural sensitivity in informed consent is sensitive to the beliefs and values of potential subjects from all cultures. Informed consent can be widely applied to research with the use of diverse methods. This review of the literature has noted that there is still ambiguity about informed consent in elderly populations in the literature and among researchers concerning issues involved in the consent process and there is confusion and lack of consistency in practice. The following three issues still need attention: how to
better use the alternatives of informed consent (e.g. stamping, thumb-printing, nodding, and handshaking), how to apply cultural sensitivity to the informed consent process among elderly individuals, and how to utilize the elements of informed consent when an elderly person’s autonomy is limited. It is essential that informers should first assess the diverse layers of culture and subculture of the target elderly population and then develop a form of informed consent based on the nature of their culture and individual differences. Afterwards, informers should utilize a language or an alternative that is acceptable to older adults and respectful of their cultural beliefs to disclose information to them. More importantly, older adults should not be infantilized but should be valued as autonomous individuals in the process of informed consent, and their life disciplines, customs, taboos, and communication patterns need to be maintained.

References


老人知情同意的文化議題和挑戰

中文摘要

由於擁有多元文化和老化過程的老年人口極劇增加，執行老年人族群的知情同意將經歷複雜的議題，且此議題將成為從事老人研究者的一個挑戰。本篇文章最主要在探討知情同意的概念和相關的資訊於進行認知正常老人研究時的運用。一個被命名為「簡易太極運動課程」(simplified Tai-Chi exercise program)的縱貫式研究被用來說明知情同意運用於認知正常老人研究時所遇的困境和知情同意的含意。對研究者而言，能感受被研究對象的文化以及在知情同意的過程中與他們建立信任的關係是重要的。(志為護理, 2007; 6:5, 65-72.)

關鍵字：文化議題、知情同意、老年人。