Obtaining Informed Consent in an Illiterate Population

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ABSTRACT

BACKGROUND

Esophageal cancer is highly prevalent among the Turkman people in Northeastern Iran. In order to evaluate its etiology, there is an on-going prospective cohort study in this area involving approximately 50000 subjects over the age of 40 years. The majority of these subjects are illiterate, thus obtaining informed consent is very important and difficult.

METHODS

Initially, we explained the aim and study method to religious leaders and health-sanitary officials. One week prior to obtaining informed consent, potential participants were given adequate information about the research process by trained health personnel at their own home. Thus, participants had sufficient time to consider the research and consult with local health personnel, religious authorities, family, neighbors, friends and those who previously participated in the study. Potential participants could observe the research process directly and then be included in the study if they agreed.

RESULTS

A total of 50045 individuals agreed to participate in the study, of which 70% were illiterate. There were no refusals due to the medical ethical aspects of this study.

CONCLUSION

The method of awareness in this study can be a useful pattern for research on elderly and illiterate individuals who are participants in research studies in Iran and other countries.

KEYWORDS

Medical ethic; Illiterate; Old age; Informed consent

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INTRODUCTION

Informed consent is an essential component of a research project. Obtaining informed consent enables research and clinical procedures to be conducted both ethically and legally.

Consent is considered 'informed' when given by a person who understands the purpose and the nature of research, and what is required of themselves as participants, in addition to the potential benefits and

risks resulting from the study.[1,2] Elements of valid consent include the capacity of participants to provide consent, disclosure of necessary and important information, freedom to choose to participate without coercion (i.e., freedom not to participate), and consent of participants.[3]

Literacy and language are important factors for comprehension; previous studies have shown that both are educational barriers which may lead to poor comprehension or the lack of understanding consent information.[4-7]

According to data from UNESCO's Institute for Statistics in 2012, there are nearly 793 million illiterate adults in the world (age 15 and over) that represent 18% of the adult population.[8]

It would be pointless to obtain written consent from those who are illiterate as they are unable to read an informed consent form and understand the risks and benefits of a medical intervention. In these situations a translator familiar with the patient's dialect and medical terminology is essential.

Comprehension of informed consent is enhanced when researchers provide the study community or individuals with information prior to obtaining consent and when study communities are engaged in discussions about the research through meetings with local leaders or public forums.[9-11]

However, beliefs about individual autonomy vary considerably throughout the world because they are embedded within social practices that reflect family and community obligations.[12,13] Thus in many international settings, family members or community leaders are expected to be involved in decisions concerning scientific research.[14]

Northeastern Iran has among the highest incidence rates of esophageal cancer worldwide. Tehran Medical University's Digestive Disease Research Center has designed a cohort study to determine the etiology of this cancer in 50000 residents over the age of 40 years in the city and villages of Gonbad and Kalaleh. Turkman ethnicity form the basic population of this area and about 70% of the inhabitants are illiterate. This study aims to research the method of obtaining informed consent in this population.[15]

METHODS AND MATERIAL

Initially the research method was explained for the local religious leaders and health-sanitary officials. One week prior to obtaining informed consent from selected potential participants, trained health personnel went to the homes of future participants and discussed the study. Potential participants were given one week to consider the research and consult with Behvarzan (auxiliary health personnel), religious authorities, family, neighbors, friends and those who were already study participants. Potential participants would then come to the study research center to directly observe the research process and if they agreed, be included in the study.

RESULTS

From 2003 until 2008, there were 68024 (35516 females) individuals of which 51425 were rural residents who were invited to participate in this study. Of these, 50237 came to the Golestan Cohort Center where only 114 females and 78 males refused to participate after observing the study process, either due to fear of blood draws or because they were known addicts. The main cause for consent refusal in the male population was their occupation with daily work. A total of 50045 agreed to participate in the study of which 70% were illiterate. There were no refusals due to the medical ethical aspects of the study. Tables 1 and 2 show characteristics of participants and non-participants in the cohort study.[15]

DISCUSSION

Developing effective informed consent documents requires thoughtful consideration of the language of participants as well as the social and cultural context where a study will be implemented.[16] In resource poor settings where illiteracy rates are high, challenges associated with comprehension of informed consent documents may be exacerbated. Translation of consent forms from one language to another adds an additional layer of complexity to the preparation of the consent forms.[14]

Trust is an essential aspect of communication

Table 1: Characteristics of study participants.

Variables		Invited	Participated	Acceptance rate (%)
Total		68024	50045	70
Gender	Female	35516	28804	81
	Male	32508	21241	65
Place of residence	Urban	16599	10037	61
	Rural	51425	40008	78

Table 2: Characteristics of subjects who refused to participate.

Variables		Refused participation	Urban (%)	Rural (%)
Total		18308	37.8	62.2
Gender	Female	6947	35.9	64.1
	Male	11361	34.7	65.3

during the consent process and influences decisions regarding participation.[17-19] Levels of trust vary considerably depending upon an individual's or communities past experience with research and factors associated with social status and power. Socioeconomic background, residence, gender, age, and education both express and reinforce differences in the relative power of individuals during the consent discussion. Individuals are more likely to experience trust when the person seeking their consent shows respect for their cultural beliefs, language, perceptions of risks, and social and political history.[20,21]

Documentation of informed consent is an important issue for all researchers, particularly those who work with culturally diverse populations in areas with high illiteracy rates. Informed consent documents should describe the study in clear and simple language.

Verbal consent is appropriate when risks associated with research are low and the potential harm for participants is unlikely.[14] Hyder and Wali have surveyed more than 200 researchers involved in collaborative international studies and found that almost 40% did not use written consents. Physician researchers were more likely to use written consent than nonphysicians and that written consent was more likely to be used in areas of high literacy. Moreover, in many cultural settings, agreements based upon trust do not require a signature.[22]

For example, in comparing the negotiation of informed consent in Pakistan and Swaziland, Upvall and Hashwani have reported that some participants were uncomfortable signing the form if they were illiterate or did not understand its contents.[23]

In some international settings, individuals may need to consult with another individual such as a spouse or head of the household before consenting to participate in a study. When necessary, researchers should allow individuals to discuss the project with others who are important to them. In some cases, investigators may need to consult with local community leaders or elders prior to implementing a study.[14]

Study justification and obtaining consent from illiterate persons by giving adequate information both to potential participants and local, familial and religious advisors in addition to observing the process of research is ethical. This enables potential participants to accept participation.

This unique study shows that attention to the conditions of medical ethical aspects in rural areas of Golestan Province that have varying cultures and dialects is essential. The method of awareness in this study can be a basic model both in Iran and worldwide, particularly in Islamic countries, and is a method which could be used in other areas with low literacy rates.

CONFLICT OF INTEREST

The authors declare no conflict of interest related to this work.

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