Original Article

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Consent for audio-video recording of informed consent process in rural South India

Abstract

Introduction and Objectives: In recent times, audio-video (A-V) recording of consent process for all the study subjects entering a clinical trial has been made mandatory. A-V recording of informed consent process is a big challenge due to confidentiality and the sociocultural environment in India. It is important to find out the acceptability for A-V recording of the consent process and reasons for refusal, if any to address this new challenge. **Materials and Methods:** A descriptive survey was done among 150 residents of a rural community of South India. Acceptability for A-V recording of consent process was assessed among those who had given the informed written consent for participation in the study. An attempt to find the factors determining the refusal was also made. **Results:** More than one-third (34%) of the study subjects refused to give consent for A-V recording of consent process. Not interested in recording or don't like to be recorded (39%) were the most common reasons to refuse for A-V recording of consent process. The refusal was higher among female and younger age-group adult subjects. Socioeconomic status was not found to be significantly associated with refusal to consent for A-V recording. **Conclusion:** Refusal for A-V recording of consent process is high in the South Indian rural population. Before any major clinical trial, particularly a field trial, an assessment of consent for A-V recording would be helpful in recruitment of study subjects.

Key words: Audio-video recording, clinical trials, informed consent

INTRODUCTION

In India, the clinical trials involving human subjects are regulated under the provisions of Drugs and Cosmetics Rules 1945 and as per the Schedule Y, in all trials, a freely given, informed, written consent is to be obtained from each study subject.[1] The investigator must provide information about the study, verbally as well as using a patient information sheet, in a language that is nontechnical and understandable by the study subjects. The subject's consent must be obtained in writing, using an "Informed Consent Form." If the Subject or his/her legally acceptable representative is unable to read/write then an impartial witness should be present during the entire informed consent process who must append his/her signatures to the consent form.[2]

Access this article online

Quick Response Code:

Website: www.picronline.org

DOI: 10.4103/2229-3485.159941

In recent years, there have been many controversies centered particularly on the quality of informed consent.[3,4] Therefore, Central Drug Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Government of India, proposed to make draft rule that "an audio-video (A-V) recording of the informed consent process of individual subjects, including the procedure of

providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record" while conducting clinical trials in India.[5] This was further supported by supreme court order dated October 21, 2013, regarding A-V recording of the consent process before conducting clinical trials.[6]

Prior consent of the subject should be taken for A-V recording of informed consent process, and the same should be documented by the investigator. Such consent may be taken orally. Only those subjects who give the consent for the A-V recording shall be included in the clinical trial.[7] Also, A-V recording of informed consent process is a big challenge due to confidentiality and the sociocultural environment in India. Many subjects are refusing to be videotaped due to several reasons like discomfort with and suspicion of being videotaped as well as hesitancy into entering into a videotaped discussion.[8]

As the order on A-V, recording is very recent, and the number of new-clinical trials in India is negligible, it will take a few months before we get a better and deeper understanding of the practical challenges in A-V recording of informed consent. This study will explore the subject's acceptability to A-V recording and reasons for refusal if any; and based on the refusal rate, appropriate measures to recruit the adequate number of study subjects could be taken.

MATERIALS AND METHODS

This observational study was conducted in Keezhputhupattu village in Tamilnadu state of South India. The study area is served by the Department of Community Medicine of Pondicherry Institute of Medical Sciences. The majority of its population is Hindu and speaks the Tamil language.

The interview schedule was designed to assess the consent of study subjects regarding A-V recording of consent process. The schedule was developed in English, translated into the local language, and validated by back translation. In order to administer the interview schedule, 150 households were selected systematically, and from the available eligible subjects in a household, one participant was chosen randomly to interview.

Written informed consent was taken from all the study subjects before starting the interview. The interview was structured around a given hypothetical scenario in which A-V recording of the consenting process was planned. The subject's willingness to participate in the study, if A-V recording of consent process is to be done, was assessed and further the main reason of not consenting for A-V recording was elicited. Only the subjects with written informed consent were included in the study.

The interviews were conducted by trained community nursing staff working in the area those were fluent in the language. The responses to the open ended questions were coded after data collection was complete. The data was entered in Microsoft Excel 2010 and was analyzed by using SPSS Statistics for Windows, Version 17.0 (SPSS Inc.). Descriptive statistics were calculated for study variables of interest and Chi-square test was applied to find the association of refusal for A-V recording of consent process.

RESULTS

Among 150 subjects interviewed, majority (70%) were female, and 38% belongs to age-group of 18-29 years. Approximately one-third (30%) were illiterate or had no formal education. Most of them were engaged in household work and farming. Majority of them (54%) have personal income of < 1000 Indian rupee/month and were living as nuclear families [Table 1].

All the study subjects who gave verbal consent also gave written informed consent. However, among those, who gave informed written consent, almost one-third (34%) refused to give consent for A-V recording of consent process.

Further those, who refused for give consent for A-V recording of consent process, most (39.2%) responded that they are not interested in A-V recording. Another one-fourth (27.4%) responded that they would feel shy, 13.7% were not groomed well, 5.8% were not comfortable and another 13.7% did not want the recording of anything [Table 2].

The refusal of consent for A-V recording of consent process was apparently higher among females as compared to male, but the difference was not statistically significant. Younger subjects were more likely to consent for A-V recording of consent process ($P < 0.05$). Homemaker and those involved in fishing were more likely to refuse to participate. Education, occupation, personal income was not found to be associated with consent for A-V recording of consent process ($P > 0.05$).

DISCUSSION

Quality of informed written consent is an important ethical issue particularly in developing countries where

Table 1: Participant's characteristics and consenting for A-V recording of consent process

Characteristic	Frequency		*P*
	Subjects (*n*=150)	Consented (*n*=99) (%)	
Gender			
Female	105	68 (64.8)	0.625
Male	45	31 (68.9)	
Age-group			
18-29	57	36 (63.2)	0.038
30-39	39	22 (56.4)	
40-49	28	25 (89.3)	
50-59	14	10 (71.4)	
≥60	12	6 (50.0)	
Education			
Illiterate	45	31 (68.9)	0.398
Primary	46	32 (69.6)	
Middle-intermediate	46	26 (56.5)	
Graduate and above	13	10 (76.9)	
Occupation			
Unemployed	21	13 (61.9)	0.354
Homemaker	57	34 (59.6)	
Farmer	29	22 (75.9)	
Fishermen	7	3 (42.9)	
Daily wager	14	10 (71.4)	
Others	22	17 (77.3)	
Personal income (INR)			
<1000	81	58 (71.6)	0.108
1000-4999	43	27 (62.8)	
5000-9999	20	9 (45.0)	
≥10,000	6	5 (83.3)	
Type of family			
Nuclear	113	78 (69.0)	0.171
Joint	37	21 (56.8)	

INR= Indian rupee, A-V= Audio-video

Table 2: Consent for A-V recording of consent process and reasons for refusal to give consent

Characteristic	Frequency (%)
Consent for A-V recording	
Yes	99 (66.0)
No	51 (34.0)
Reason for not consenting (*n*=51)	
Didn't groomed well	7 (13.7)
Don't want	7 (13.7)
Feel shy	14 (27.4)
Not comfortable	3 (5.8)
Not interested/don't like	20 (39.2)

A-V= Audio-video

a large proportion of the population is illiterate and poor. Following the order from the Supreme Court, CDSCO issued a directive on November 19, 2013 that in all clinical trials, in addition to obtaining written informed consent, A-V recording of the informed consent process of each trial subject is required.[8] There are many anticipated advantages of A-V recording like reliability, transparency, and improvement in quality of conduct of informed consent process, however, at the same time the investigators will face many challenges in getting consent for A-V recording.[9]

Most professional bodies including the Indian Society for Clinical Research support the A-V recording of informed consent. , However, like many other stakeholders the concern is with the hasty decision; without proper appreciation of logistic issues, process to be followed in instances where due to religious and sociocultural reasons patients may not want to be video-graphed and applicability of the order with immediate effect. Present study found that more than one-third (34%) of the subjects, who gave informed written consent and participated in the study, refused to give consent for A-V recording of the consenting process. Similarly, other studies reported that only 30% of Indian patients are likely to consent for a clinical trial and of these 30% may not agree for A-V recording of consent process.[10,11] In private settings also, 11-14% patients objected to video recording of their consultation.[12] In some other settings almost 50% of the subjects, particularly female patients, have refused to get their consent recorded as per the A-V recording norms. The refusal to video recording varies widely among various study subjects and settings.[13]

In the present study, subjects were refusing to be videotaped due to several reasons. Most of them (39%) responded that they do not want themselves to be video recorded and were not interested in this at all. Discomfort with and suspicion of being videotaped, feeling shy and hesitancy were some of the responses for refusal by the study subjects. Many of them, who refused to give consent for A-V recording said that they are not groomed well but if they were given the option of getting well-dressed before video recording, none of them consented. Hence A-V recording is really a cause of concern for both investigators and regulatory bodies as despite interest of participating in the clinical trial, subjects were not ready to consent for A-V recording, and the refusal rate was high. The refusal rate and reasons may vary from one to another setting and also with the nature of the trial. Thus, without finding the refusal rate for A-V recording of consent process, it is very difficult to estimate the number of subjects to be recruited to achieve the require a sample size. Although A-V recording will improve the quality of informed consent but also will be a barrier to the participation of subjects.[14]

In the present study, subjects were not really exposed to A-V recording; this survey does have limitations of self-reporting and may not be reflective of true practice patterns. Therefore, a higher refusal is expected on doing A-V recording of consent process. However, this pilot survey does provide some insight regarding acceptance of A-V recording as a method of evidence for improved quality of informed consent taking. As the order on A-V recording is very recent, and the number of new clinical trials in India is negligible, it is recommended to

do some studies as per the CDSCO guidelines for A-V recording, to assess the feasibility and to get a better and deeper understanding of the practical challenges in A-V recording of informed consent.

CONCLUSION

The consent for A-V recording of consent process is lower as compared to the written informed consent only. Whenever planning for a clinical trial and particularly during sample size estimation and recruitment, investigators must keep in mind the issues related to the refusal for A-V recording of consent process. As the refusal rate would vary from one study population to another, a pilot study is recommended to assess the acceptability of A-V recording in a particular study setting.

ACKNOWLEDGMENT

Authors would like to thanks all the study subjects, without whom this work could not be possible. Furthermore, authors would like to thank nursing students of medical sociology, who collected the data for this study.

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How to cite this article: Chauhan RC, Purty AJ, Singh N. Consent for audio-video recording of informed consent process in rural South India. Perspect Clin Res 2015;6:159-62.

Source of Support: Nil. **Conflict of Interest:** None declared.