Willingness to participate in a clinical trial and understanding of informed consent information among medical students

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Abstract

Studies have shown that the decision to participate or not participate in a clinical trial does not necessarily imply that the volunteers have completely understood the clinical trial process. A study carried out among medical and non-medical student volunteers revealed that even though the former group had a better recollection of the key facts, their understanding was still below expectation. In our study, medical students were invited to voluntarily take part in a hypothetical exercise in which they were presented with an informed consent form to indicate their willingness to participate in an anti-malarial drug trial. They were encouraged to clarify their doubts and asked to answer a questionnaire to determine their willingness/unwillingness. They were asked to state their reasons and recall key information given in the informed consent form. Responses were submitted by 155 students and 51% of the respondents consented to participate in the trial. As many as 13.5% did not know the name of the drug under study, 14.8% could not recall the main adverse effects to be expected, and 12.3% did not know that they could opt out of the study, this being significantly more in those who had consented to participate ($p<0.05$). As is evident from our study, even presenting a detailed consent form containing an explanation might leave a considerably large number of potential volunteers with an incomplete understanding of the study. Therefore, it is necessary to make an active effort to ensure that the counselling of the volunteers is based on their ability to comprehend the information provided.

Introduction

Informed consent is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation (1). The consent document is not only central to the volunteer's understanding of the study in which he/she is going to participate, but also an important component of evidence of the volunteer having been recruited into the study after being fully apprised of the risks and benefits of participation. An ideal informed consent session should be interactive, rather than a matter of the participant just reading and signing the document. While the comprehensibility of the informed consent document has rightly been the focus of many studies as well as regulatory guidelines, meagre attention has been paid to the personnel providing the information on the study process. Studies have shown that the decision to participate or not participate in a clinical trial does not necessarily imply that the volunteers have completely understood the clinical trial process (2, 3). Also, a high level of satisfaction among the patients with respect to the trial does not correlate with their level of knowledge. Subjects tend to overestimate their knowledge about a clinical trial (4). A study carried out among medical and non-medical student volunteers revealed that even though the former group had a better recollection of the key facts, their understanding of the study was still below expectation (5). Recall is just one part of overall reading comprehension, which depends not only on the text, but also the active integration of the information into the subject's previous knowledge or situational experience (5).

The aim of this study was to determine the understanding of the information contained in an informed consent document among second-year medical students who were about to complete the pharmacology course. Medical students were considered the subjects for this study as they were fully qualified in terms of general and subject-specific knowledge, as well as the ability to easily remember the clinical facts presented to them. This would make them ideal subjects as far as understanding information in informed consent forms is concerned.

Method

Fifth-semester students who were about to complete their pharmacology course from a medical college in southern India were invited to voluntarily take part in a hypothetical exercise in which they were presented with an informed consent form to indicate their willingness to participate in an anti-malarial drug trial. The informed consent form was developed on the basis of the World Health Organization informed consent templates and the instructions contained therein were adhered to wherever applicable (6). Approval from the institutional ethics committee was obtained prior to the initiation of the study. The information in the consent document was presented to the students in a group with the help of a PowerPoint presentation. The information was read out verbally during the presentation. Key information, such as the objectives of the study, the intervention, and the risks and benefits, were repeated to ensure proper comprehension of the information. The students were encouraged to ask questions for further clarification regarding the trial process. They were then asked to answer a questionnaire to determine their willingness/unwillingness to participate in the trial. They were asked to state their reasons and recall key information provided in the informed consent form. The demographic data collected included the students' age and gender, as well as the annual income of the parents.

Table 1.
Willingness to participate in a drug trial among medical students in terms of gender and economic status

Respondent group		Willing to participate in the drug trial (%)	Unwilling to participate in the drug trial (%)
Males		49.2	50.8
Females		52.2	47.8
Parents' annual income (in INR)	**< 5 lakh**	41.8	53.9
	5–10 lakh	38.0	26.3
	> 10 lakh	12.7	15.8
	Undisclosed	7.6	3.9

The specific questions asked with regard to the information in the informed consent form are mentioned in Table 2. The influence of gender and the parents' income on the willingness to participate in the clinical trial was also determined.

Statistical analysis

The difference between the groups was determined by using the chi-square test. A p-value of <0.05 was considered statistically significant.

Results

Of the 208 students invited to participate in the exercise, 155 participated and submitted their responses. Nine students did not answer any of the questions, except those on the demographic data and their willingness to participate. Hence, their response was not considered when evaluating the understanding and recall of key information. Of the total respondents, 58.1% were female. Fifty-one per cent of the respondents expressed a willingness to participate in the drug trial. The economic status of the students did not significantly affect their willingness to participate in the trial. The effect of gender and the economic status of the parents on the willingness to participate is shown in Table 1.

The students' comprehension and recall of the information pertaining to the study is presented in Table 2. No significant gender difference was seen in the responses. However, the number of respondents who consented to participate in the study formed a significantly large proportion of those who did not know that they could withdraw any time without providing any reason (p<0.05).

The most common reasons provided by the medical students for participation/non-participation in the drug trial are given in Table 3.

Discussion

Of the 155 students who took part in the exercise, 51% were willing to participate in the drug trial. Altruistic motives were the most commonly cited reason for the willingness to participate, while uncertainty regarding the risks involved was the main reason for not participating. These reasons are comparable to those reported by volunteers participating in clinical studies. As this was a hypothetical exercise involving medical students, the willingness to participate in a clinical study due to a possible personal health benefit was justifiably not the common reason (7, 8). Probably for the same reason, financial benefit did not appear to be a significant factor. As many as 12%–16% of the students did not answer one or more of the questions correctly. More importantly, 14.8% could not recall any of the main adverse effects, while 12.4% did not know they were free to opt out. The lack of understanding of the freedom to opt out of a study has been observed in other similar studies (9). Incomplete comprehension of each point of the information in Table 2 might lead to incomplete participation (an incomplete understanding of the duration of the study and the number of visits), a loss of faith in the healthcare providers, and a feeling of injustice (in the case of

Table 2.
Medical students' comprehension and recall of information provided in the informed consent document

Questions asked	Correct response in percentage*	Incorrect response in percentage*
▸ What are the names of the drugs being used in this clinical trial?	86.5	13.5
▸ What is the trial drug given for?	89.7	10.3
▸ How long will this study last?	72.3	27.7
▸ What body fluids will we be collecting?	95.5	4.5
▸ What side-effects can the drug have?	85.2	14.8
▸ Can you opt out of the study before completion?	87.7	12.3
▸ Why is this study being conducted?	83.9	16.1

*n=146. Of the 155 students who participated, nine did not answer any of the questions.

Table 3.
Reasons provided by the medical students for participation/non-participation in the drug trial

Reasons for participating in the drug trial
1. Will help in the availability of a better drug and thus, the society
2. To bring out a better drug for malaria
Reasons for unwillingness to participate in the drug trial
1. Do not want to take the risk
2. Adverse events

adverse effects). It may also result in participation due to fear. The gender or economic background of the students did not make any significant difference.

A study carried out to test the recall, following surgery, of the information provided in informed consent forms among Indian patients showed that approximately two-thirds of both males and females were able to recollect the details, there being hardly any difference between the genders (10). Older and poorer patients found it more difficult to recall the facts explained to them before surgery. Comprehension of the information seemed to improve with increasing education. Depending on the social and cultural setting, female patients may not readily give their consent to participation in a trial as they may not be in a position to take independent decisions (9).

Health literacy has a significant bearing on the level of comprehension of information provided to volunteers. National assessment of adult literacy data indicates that only 12% of the adult population in the USA has proficiency in health literacy skills (11). While the consent forms are designed to be understood by a lay person, most health professionals are not aware of their patients' low levels of health literacy or the fact that most patients are too embarrassed to let their healthcare providers know that they have not really understood their instructions (12). Several methods have been studied to improve patient volunteers' understanding of the information presented in consent forms. While the use of multimedia, enhanced consent forms, questionnaires and feedback can play a role in improving comprehension, it is probably the role of the investigator or the trained personnel providing the information that needs more attention (13). A meaningful discussion with a trained person, who can gauge the degree of the volunteer's comprehension of the information and address the deficient areas appropriately, is important.

Our study has certain drawbacks. The response of the medical students was obtained as a part of a hypothetical exercise. Being aware of the hypothetical nature of the exercise, the students might not have been as attentive and involved as they would have been in a real scenario. This might have affected their response.

Conclusions

While proper care might be taken to obtain the informed consent of the participants in a trial, they might not be fully aware of all the important information presented to them. This hypothetical exercise, conducted among well-educated medical students with a knowledge of pharmacology, highlights this issue. Presenting a consent form with an explanation of the details might still leave a considerably large number of potential volunteers with an incomplete understanding of the study they would participate in. Therefore, an active effort is necessary to enhance the level of the volunteers' comprehension, which can be achieved by counselling them on the basis of their ability to understand the information provided.

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