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Informed consent among nursing students participating in biomedical research

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Abstract

For consent in biomedical research, it is essential that research participants understand the need for research, the study protocol, the risk and benefits of participation, the freedom to participate or decline and the right to leave the study at any time. A structured questionnaire was used to assess understanding and knowledge among nursing trainees participating in a cohort study investigating exposure and latent tuberculosis at a tertiary care hospital. Data were collected for 138 participants. While 97% were aware of their enrolment into a research protocol, only 78% could state that it was a study on tuberculosis. Approximately two-thirds were aware of plans for blood collection, but not all of them knew the timings or number of samples. The majority (59%) participants had consulted others before making the decision to participate, and only 73% felt that their participation was completely voluntary. Even among healthcare trainees, emphasis needs to be placed on testing both the knowledge and understanding of participants to ensure the principle and practice of truly informed consent.

Introduction

Informed consent is an integral part of ensuring respect for participants in research. It is essential that research participants understand the reasons why the research is being conducted, the study protocol, the risks and benefits of participation and that they are free to participate in or leave the study at any time (1). The process of administering informed consent usually requires an initial written communication, which then leads to a dialogue between the patient and the research worker and gives an opportunity for the potential research participant to ask questions and get a better understanding of the treatment or procedure. It is necessary not only that good communication takes place but also that the communication is documented. A well-designed, signed informed consent form provides documentation that the principle and process of ensuring that the decision to participate has been considered and voluntary. However, even if a research participant signs a consent form, it does not necessarily mean that the individual has understood all the key aspects of the study and therefore given full, informed consent (2). Therefore in many settings, particularly clinical trials, quizzes have been developed to assess whether or not the potential participant has understood key aspects of the research protocol (3).

In general, participants taken from a healthcare environment might be expected to have a better understanding of the need for research and for the processes followed to obtain data for answering important study questions. Although there are no direct data that healthcare workers or students understand the need for research, there are data that show that students

in healthcare-related fields are better informed about chronic health conditions, including HIV, than other students (4).

At the Christian Medical College (CMC), Vellore, a large tertiary care institution, we had previously carried out two studies on informed consent in community-based participants enrolled in observational and interventional research protocols and found that in both studies, the provision of free or concessional healthcare was perceived as being a major motivator for participation in research, whether or not such care was promised during the discussion of the study and the informed consent process (5, 6).

Since healthcare is provided free for students and staff at the institution, in order to assess our processes and the perception and recall of informed consent in a non-community based study, we designed a study carried out among nursing trainees enrolled in a study on tuberculosis (TB) incidence and prevalence (6). Among healthcare workers in developing countries, nurses spend a proportionately greater amount of time in direct contact with TB patients, and are at high risk for acquisition of TB infection and disease. The study on TB was designed to understand the epidemiology of nosocomial TB among nurses and recruited a cohort of young nursing trainees at CMC to determine exposure and disease during follow-up, and these data have been published (7, 8).

In order to assess understanding of the nature of informed consent and recall of the study procedures, a study was designed to assess i) knowledge of the rationale for research, ii) procedures included in the study protocol, iii) understanding of the voluntary nature of consent and iv) understanding of the risks and benefits of participation.

Methods

A cohort study designed by the Department of Pulmonary Medicine, to study the incidence and prevalence of latent TB infection in nursing trainees was carried out with institutional review board and administrative approval at the Christian Medical College, Vellore in 2008-2009. To initiate the study, the principal investigator (PI) addressed the entire student body to explain the concept, followed by separate sessions with each class. Once again the PI or sub-investigator explained the basis of the study and the methodology with the help of a multimedia slide presentation. Their participation was requested and their right to choose or decline participation and to withdraw from the trial without citing any reason for their decision was explained to them. The study described here was a follow-on study regarding comprehension of informed consent conducted as described below.

Participants

The total number of participants enrolled in the TB study in 2008 was 436, of which 350 students were present on the rolls when this study on informed consent approved by the Institutional Review Board in November 2008, was initiated after obtaining all relevant administrative permission in August 2009. The study included student nurses from all six programmes offered at the College of Nursing, CMC, Vellore including: nursing diploma, BSc, post diploma BSc courses, fellowship courses, MSc, and doctoral (PhD) programmes. Students with a past history of TB were excluded from the study at recruitment. Most students in the nursing programmes at CMC come from lower middle class or middle class backgrounds, and from all over India, though mainly from the southern part of the country. Approximately 300 students attended an introductory meeting, where the investigator explained the purpose of the study, answered queries and distributed information sheets requesting participation. The process for data collection, the consent process, and confidentiality issues were explained. Of those attending the meeting, 180 students took the questionnaire and 138 completed forms were received.

Data collection and analysis

A questionnaire-based tool was designed for data collection. The tool had questions that were intended to elicit information about i) knowledge of the disease being studied (tuberculosis); ii) knowledge of the rationale for the study; iii) awareness of study procedures; iv) perception of risks and benefits of participation; v) the process of obtaining and giving informed consent for the study; and vi) understanding of the voluntary nature of informed consent. The data from the completed questionnaires were entered into an Excel database and the summary statistics generated were presented using the functions in the same software. The binomial probability test was used to compare whether an observed proportion significantly varied from an expected probability with the expected probability set at 50%.

Results

As reported in the publication of the original study to assess TB exposure, participants were mainly female and over 80% were 18-22 years of age (7). The participants of this study on informed consent were constituted by all available participants in August 2009. A total of 138 student nurses participated in this study on informed consent.

The data were analysed initially to assess awareness regarding participation and the protocol (Table). Although two-thirds of participants were aware that blood collection formed part of the study protocol, less than 10% knew the need for additional testing if the initial tests were negative.

Although CMC offers free healthcare to all students and trainees, 47 (34.0 %) students believed that participation would offer access to better treatment from CMC if they were diagnosed, while 91 (66.0%) felt that there would be no change in the quality of their care. One hundred and three (74.6%) participants were of the opinion that the study would benefit others in the future, although 33 (23.9%) stated that they did not expect any direct personal benefit from participation and two participants did not respond. 86 (62.3%), perceived no risk from participation, although 50 (36.2%) responded that they were not sure.

Knowledge of study enrolment and procedures

	Aware		
	Number	Percent (95% CI)	P value*
Awareness of enrolment in a research study	135	97.8 (93.8 - 99.5)	<0.0001
Knowledge of study rationale	101	73.2 (65 - 80.4)	<0.0001
Knowledge of disease studied (tuberculosis)	108	78.3 (70.4 - 84.8)	<0.0001
Knowledge of study procedures (blood collection)	88	63.8 (55.2 - 71.8)	0.0015
Awareness of risks of participation	86	62.3 (53.7 - 70.4)	0.0048
Awareness of benefits of participation	104	75.4 (67.3 - 82.3)	<0.0001
Awareness of freedom to withdraw	77	55.8 (47.1 - 64.2)	0.2015

** Obtained from two-tailed binomial probability test with an expected awareness of 50%*

The questionnaire also evaluated the decision-making process regarding participation, and potential treatment availability if needed. Of the total 138 participants, 82 (59.4%), had consulted others before making the decision regarding participation, mainly parents and friends. Overall, 101 (73.2%) said that they had joined of their own free will and no compulsion was placed on them to be part of the TB study. Regarding decision-making for treatment in case evidence of disease was found, 52 (37.7%) said that they would abide by the doctor's advice, while 44 (31.9%) said they would make the decision. For 39 (28.3 %) the parents would be the decision makers. Three participants did not respond.

Discussion

This study shows that even in a healthcare environment, the understanding of participation in research and the processes and nature of informed consent among participants can be insufficient. In educational institutions, students can be considered a vulnerable group where participation in research should take place under the strict supervision of institutional authorities and possibly, an IRB appointed committee to ensure that participation is voluntary and free from coercion. Whether data from nursing students at this institution are applicable to nursing students in other institutions, or students enrolled in other courses within the same institution, is not clear and would require larger scale and more detailed studies.

For informed consent to be valid, participants should understand the risks, potential benefits, procedures, and alternatives. The International Conference on Harmonisation (ICH) Good Clinical Practices guidelines list 20 items as essential to informed consent, including the risks, potential benefits, expenses and duration of the study in question (9). The first item on the ICH list states that potential participants should understand that the study involves research. The Council for International Organisations of Medical Sciences (CIOMS) guidelines list 26 essential elements to informed consent, the first of which mandates that individuals understand they are being invited to 'participate in research.'(10) However, Wendler and Grady point out that it is unclear what potential participants need to understand in order that they are sufficiently aware of key features regarding the study, such that their informed consent is valid and the fact of participation in research is understood (11). Their analysis of individuals' interests suggests that potential participants need to understand three key facts in addition to the study processes and these are "1) **research contribution**: those who enrol in the study will be contributing to a project designed to gather generalisable knowledge to benefit others in the future; 2) **research relationship**: the investigators will rely on participants' efforts to gather the generalisable knowledge to benefit others; and 3) **research impact:** the extent to which participating in the study will alter what participants do and what happens to them." However, it is extremely difficult for researchers to know how much information needs to be provided and what determines a failure of understanding on the part of the participant.

Information is needed for people to make decisions on whether or not to participate in biomedical research. In many scandals related to research, participants have lacked important pieces of information. However, the current trend seems to be based on the apparent belief that the more the information, the more respect is given to a participant's autonomy, which may not be the case (12). Long consent forms do not necessarily result in a better understanding of studies (13). It is a researcher's responsibility to ensure "truly informed consent" but most mandated procedures do not take into account that different people assimilate information differently, with some benefitting more from oral than written information, some needing technical details while others prefer general principles, some preferring to make autonomous decisions, while others require the support of family or friends (12).

Researchers who have specifically examined the participation of students in health-related fields, particularly nursing, have developed a framework for ethical research practice emphasising the need for participants to understand the contribution of the study to generalisable knowledge, the reliance on participant-derived data for benefit and the potential impact on participants themselves (14). Others have pointed out the need for avoiding potential conflict of interest and provision of confidentiality as key issues for this group of participants (15).

While the need for ensuring voluntary participation is paramount, another issue to consider is the rights of the individual over the group as a whole. Taking the original study (to look at the incidence and prevalence of TB infection in

nursing trainees) as an example, tuberculosis is a contagious disease, and this study sought to determine as early as possible when exposure occurs in a high risk group of individuals, i.e. nursing students. If TB infection is detected early, the initiation of prophylactic treatment as planned could potentially reduce the chance of progress to disease in the individual. This, in turn, is likely to prevent further transmission to the community of students in the hostel, the patients and their colleagues in the hospital. The study could be classified as one of low risk, and potentially of benefit to the participant and the community. It has been suggested that in such situations, 'opt-out' consent may be appropriate (16). In the absence of discussion and guidelines on such issues, a decision regarding an appropriate approach may be difficult.

This study had limitations in assessing aspects of informed consent since it was carried out more than a year after enrolment, when it has been shown that accurate recall is difficult even in well educated volunteers (17). In addition, the questionnaire did not attempt to explore reasons for a lack of recall in some participants. Social and demographic factors could also have influenced understanding and recall, but this was not assessed. Nonetheless, the data show that even among healthcare trainees participating in a research protocol in a large educational institution in India, knowledge and understanding of the nature of consent and study protocols was inadequate. In addition to developing guidelines for structuring such research, emphasis also needs to be placed on testing both knowledge and understanding to ensure the principle and practice of truly informed consent.

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