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Are there Adverse Consequences of Quizzing during Informed Consent for HIV Research?

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Abstract

Introduction—While quizzing during informed consent for research to ensure understanding has become commonplace, it is unclear whether the quizzing itself is problematic for potential participants. In this study, we address this issue in a multinational HIV prevention research trial enrolling injection drug users in China and Thailand.

Methods—Enrollment procedures included an informed consent comprehension quiz. An informed consent survey (ICS) followed.

Results—525 participants completed the ICS (Heng County, China=255, Xinjiang, China=229, Chiang Mai, Thailand=41). Mean age was 33 and mean educational level was 8 yrs. While quizzing was felt to be a good way to determine if a person understands the nature of clinical trial participation (97%) and participants did not generally find the quiz to be problematic, minorities of respondents felt pressured (6%); anxious (5%); bored (5%); minded (5%); and did not find the questions easy (13%).). In multivariate analysis, lower educational level was associated with not minding the quizzing (6–10 yrs versus 0–5 yrs: OR=0.27, p=0.03; more than 11 yrs versus 0–5 yrs: OR=0.18, p=0.03). There were also site differences (Heng County versus Xinjiang) in feeling anxious (OR=0.07; p=<0.01), not minding (OR=0.26; p=0.03), being bored (OR=0.25; p =0.01), and not finding the questions easy (OR=0.10; p=<0.01).

Conclusions—Quizzing during the informed consent process can be problematic for a minority of participants. These problems may be associated with the setting in which research takes place and educational level. Further research is needed to develop, test and implement alternative methods of ensuring comprehension of informed consent.

Trial Registration—clinicaltrials.gov number NCT00270257.

Keywords

informed consent; research ethics; ethics; attitudes

Introduction

Informed consent is a fundamental ethical requirement of clinical research, which is intended to protect the rights and interests of research participants [1–4]. Studies on informed consent, however, have consistently shown that study participants often do not fully understand the requirements of the research study in which they are enrolled [5–13]. When research poses substantial risk to participants or there may be some question about the capacity of potential participants to provide informed consent, methods to assess potential participants' comprehension prior to study enrollment, such as quizzes, have been incorporated into the informed consent process. Such methods are now commonplace for certain types of clinical research, such as large, multi-site HIV prevention trials [14–18] and clinical research involving substance users [19]. Yet, participant acceptability and cultural appropriateness of these assessment methods have not been well studied, especially in vulnerable populations who may have had limited formal education, engage in illegal or stigmatized activities (e.g., drug use, sex work) or otherwise be unaccustomed to being quizzed.

Our study intended to address this gap in the literature by assessing participants' opinions about an informed consent comprehension quiz administered as part of a large, multi-site HIV prevention clinical trial and to assess their feelings when completing the quiz.

Methods

Our evaluation was embedded within a phase III randomized controlled trial to evaluate the efficacy of different modalities of drug treatment for the prevention of HIV infection and death among opiate dependent injectors. Additional information about the study is available at: http://www.hptn.org/research_studies/hptn058.asp. Study sites included Xinjiang Uighur Autonomous Region Centers for Disease Control and Prevention in Xinjiang, China; Guangxi Zhuang Autonomous Region Centers for Disease Control and Prevention in Guangxi, China; and the Research Institute for Health Sciences in Chiang Mai University in Chiang Mai, Thailand.

The study was reviewed and approved by the following ethics committees: Chiang Mai University Research Institute for Health Sciences (RIHES), Thailand; Ministry of Public Health Ethical Review Committee for Research in Human Subjects (MOPH), Nonthaburi, Thailand; Guangxi Center for Disease Prevention and Control Institutional Review Board (IRB), China; Xinxiang Uighur Autonomous Region Bureau of Health Disease Control and Treatment IRB, China; The Chinese National Center for AIDS/STD Control and Prevention IRB; and Johns Hopkins Medicine IRB #2, United States. Participants provide their informed consent for the informed consent survey as part of the enrollment consent process for the trial, although they were given the option to decline participation in the survey when it was offered and still participate in the trial. As part of the trial's informed consent and enrollment process, participants must first pass an informed consent comprehension quiz by answering at least 9 of 12 questions (75%) correctly within three attempts, prior to signing the consent form. Only participants who passed the informed consent comprehension quiz and gave informed consent to participate in the trial were asked to complete the informed consent survey (ICS). Often the ICS was administered immediately following the administration of the comprehension quiz and signing of the consent form, but participants were permitted to complete the ICS at any time during their enrollment study visit. One study staff member administered the informed consent comprehension quiz and a different study staff member administered the ICS to reduce bias associated with socially desirable responses. The ICS was always administered orally.

Questions on the ICS were informed by educational literature on test taking [20–21] and included 6 questions that asked participants to agree or disagree using a 5-point Likert scale (i.e., strongly disagree, disagree, neither disagree or agree, agree, strongly agree) on feelings they experienced when answering the informed consent comprehension quiz, such as being anxious or annoyed. Two additional questions assess participants' opinions on whether quizzing is an appropriate method to measure comprehension among potential study participants. Several rounds of field-testing were conducted with study staff and members of the community advisory boards in two sites (Chiang Mai and Heng County) to ensure that the all items and response categories were culturally and linguistically appropriate across the sites. The ICS was translated into the local languages and back-translated to confirm questions on the translated versions and the English version all reflect the same meaning. The final items included in the ICS are listed in Table 1 and the ICS instrument is provided in the Appendix. The Chiang Mai site obtained the necessary regulatory approvals to implement this evaluation at a much later date, and enrolled far fewer participants than the sites in China, and hence there were fewer participants available for analysis.

Data were analyzed using standard descriptive and inferential statistics for ordered and unordered variables. Factor analyses were then conducted.

For each attitude question, the five point Likert scale was collapsed to positive and negative attitudes (Table 1). Logistic regression was used to compute the odds ratios of a negative attitude for each question for site, gender, age, and education. Significant covariates (p-value less than 0.05) were retained in a multivariate logistic regression model.

Factor analysis was used to define combinations of the attitude questions that had commonality across the participants. Specifically, factor analysis with varimax rotation was applied to the eight attitude questions, after mapping the Likert scale using numeric scores of −2, −1, 0, 1 and 2, with positive attitudes mapped to positive scores. A scree plot test was examined to guide the selection of factors capturing most of the variance in attitude. The resulting selected factors combine the original attitude questions using factor loadings, so questions with high (absolute) factor loadings are interpreted as defining a given factor's characteristics.

Results

587 participants were asked if they were willing to complete the ICS and 525 completed it (255 from Heng County, 229 from Xinjiang, and 41 from Chiang Mai). The response rates for the ICS were 100% in both Chiang Mai (41/41) in Chiang Mai and Heng County (255/255), and 81% (229/282) in Xinjiang. Overall, the mean age was 33; 7% were female; mean educational level was 8 yrs (Table 2). No significant differences in demographic characteristics (age, gender and educational level) were found between those who did and did not complete the ICS in Xinjiang.

While quizzing was felt to be a good way to find out if a person understands the clinical trial (97%) and was not problematic for the majority of participants, minorities of respondents felt pressured (6%); anxious (5%); bored (5%); minded being quizzed (5%); and didn't find the questions easy (13%) (Table 3).

In multivariate analysis, there were site differences (Heng County versus Xinjiang) in feeling anxious (OR=0.07; p=<0.01), not minding the quizzing (OR=0.26; p=0.03), being bored (OR=0.25; p =0.01), and not finding the questions easy (OR=0.10; p=<0.01). Lower educational level was associated with not minding the quizzing (6–10 yrs versus 0–5 yrs: OR=0.27, p=0.03; > 11 yrs versus 0–5 yrs: OR=0.18, p=0.03) (Table 4).

The loadings of the first two factors (Table 5) define a first factor by attitudes related to emotions about quizzing (high loadings on the first four questions), and the second factor related to the content of the quiz (high loadings on the last two questions).

Discussion

While quizzing during the informed consent process is aimed at helping to ensure that potential research participants have adequate understanding of the proposed research, and participants in general believe that quizzing is a good way to assess understanding, it can be problematic for some participants.

In a multivariate analysis, those with more education were more likely to mind being quizzed. Perhaps, those with more education view quizzing in such a situation to be excessive or insulting. Alternatively, they might associate quizzing with stressful experiences in school.

In addition, in this study the extent to which quizzing is problematic relates at least in part to the setting in which the research takes place. In multivariate analyses, there were significant differences among the two sites in China (which each have substantially more respondents than the site in Thailand). Participants in Heng County compared to those in Xinjiang were more likely to report that they minded answering the quiz and not finding the questions easy; yet they were less likely to be bored or anxious due to quizzing. It is conceivable that these findings are related to a variety of factors such as culture, ethnicity, and the urban (Xinjiang) versus rural (Heng County) location of the sites.

Of course, these findings should be interpreted with several limitations in mind. First, respondents' reports about quizzing during the informed consent process may be subject to a social response bias, in which respondents are inclined to report that the quizzing was not problematic. Such bias would be understandable since the participants have just given informed consent to participate in the parent trial and may want to please the research team by not 'complaining.' In order to minimize the likelihood of such a bias, in this study separate study staff members administered the informed consent survey from those who did the quizzing itself. Related, those participants who completed the informed consent survey all passed the quiz, which may have influenced their evaluation of it. Also, the small number of participants in Chiang Mai limits our power to detect anything other than very substantial site differences in attitudes in Thailand compared to the China sites. While the response rate was high in Chiang Mai and Heng county, as many as 20% refused to participate in the ICS in Xinjiang, raising the potential for non-response bias in this site, although no differences were observed in the demographic characteristics among responders and non-responders. Despite these possibilities, this analysis indicates variability in attitudes towards quizzing, suggesting that the instrument was able to overcome these limitations. In addition, although we have data from a large number of participants and the response rate was high, it is important to remember that our data derive from a single parent study taking place in 3 sites in 2 countries that includes quizzing about the particularities of that trial. Therefore, it would not be surprising if findings from a similar evaluation would differ if it were to be conducted in other geographic regions and cultures or for another trial. While it is conceivable that quizzing during the informed consent process may be more or less problematic in other instances, such variability alone would be an interesting finding. Moreover, it would be arguably important to identify trials and sites where quizzing would be especially problematic so that alternative means of assessing comprehension might be used.

Accordingly, further research is needed to assess satisfaction with quizzing during the informed consent process in other studies and in different geographic regions. Fortunately, as we have demonstrated in this study, evaluating attitudes towards quizzing during the informed consent process can be relatively easily implemented in actual clinical trials using standard clinical trial procedures. Others wishing to evaluate the process could elect to use the informed consent survey we developed, perhaps eliminating those items which did not add information based on the factor analysis described above. Regardless, careful attention should be paid to ensure that the items translate and back-translate properly.

These pending issues notwithstanding, concerted effort should be directed at ensuring comprehension during the informed consent process. While at first glance quizzing seems to provide a relatively easy means of appearing to fulfill this objective, there remains a surprisingly difficult set of questions which remain regarding quizzing; these include what constitutes adequate understanding, what aspects of the study are important to understand, and what effects will this quizzing have on potential participants, including not only their attitudes, but also on their willingness to participate, trust, and adherence to study requirements. These issues warrant rigorous attention, both conceptually and empirically. In the meantime, formative research should be conducted in settings in which quizzing is being

proposed to evaluate comprehension during the informed consent process so that alternative means for ensuring comprehension might be developed and implemented in settings where quizzing may be problematic.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Informed Consent Evaluation Survey Items (English Version)

Question	Five-point Likert Scale	Three-point Likert Scale	Binary Scale
You were anxious	Strongly Disagree Disagree	Disagree	Positive
	Neither Disagree or Agree	Neutral	
	Agree Strongly Agree	Agree	Negative
You did not mind	Strongly Disagree Disagree	Disagree	Negative
	Neither Disagree or Agree	Neutral	
	Agree Strongly Agree	Agree	Positive
You were bored	Strongly Disagree Disagree	Disagree	Positive
	Neither Disagree or Agree	Neutral	
	Agree Strongly Agree	Agree	Negative
You were irritated	Strongly Disagree Disagree	Disagree	Positive
	Neither Disagree or Agree	Neutral	
	Agree Strongly Agree	Agree	Negative
You found the questions easy	Strongly Disagree Disagree	Disagree	Negative
	Neither Disagree or Agree	Neutral	
	Agree Strongly Agree	Agree	Positive
You felt pressured	Strongly Disagree Disagree	Disagree	Positive
	Neither Disagree or Agree	Neutral	
	Agree Strongly Agree	Agree	Negative
Taking the comprehension quiz made you feel like the researchers really wanted you to understand the clinical trial	Strongly Disagree Disagree	Disagree	Negative
	Neither Disagree or Agree	Neutral	

Question	Five-point Likert Scale	Three-point Likert Scale	Binary Scale
	Agree	Agree	Positive
	Strongly Agree		
Testing is a good way to find out if a person really understands the clinical trial	Strongly Disagree	Disagree	Negative
	Disagree		
	Neither Disagree or Agree	Neutral	
	Agree	Agree	Positive
	Strongly Agree		

Table 2

Demographic Characteristics of Respondents

	Heng County, China	Xinjiang, China	Chiang Mai, Thailand
Age			
18 – 25	74/255 (29%)	31/229 (14%)	5/41 (12%)
26 – 35	122/255 (48%)	86/229 (38%)	14/41 (34%)
36 – 45	55/255 (22%)	100/229 (44%)	14/41 (34%)
More than 45	4/255 (2%)	12/229 (5%)	8/41 (20%)
Gender			
Male	244/255 (96%)	205/229 (90%)	40/41 (98%)
Female	11/255 (4%)	24/229 (10%)	1/41 (2%)
Years of Education			
0 – 5	30/255 (12%)	20/229 (9%)	37/41 (90%)
6 – 10	216/255 (85%)	112/229 (49%)	4/41 (10%)
11 – 12	9/255 (4%)	71/229 (31%)	0/41 (0%)
13 – 16	0/255 (0%)	25/229 (11%)	0/41 (0%)
17 – 20	0/255 (0%)	1/229 (<1%)	0/41 (0%)
21+	0/255 (0%)	0/229 (0%)	0/41 (0%)

Table 3

Attitudes about the informed consent questionnaire

Informed Consent Evaluation Survey	**Answers (Bivariate)**		
Questions for Participants	**Agree**	**Neutral**	**Disagree**
Were anxious	28/525 (5%)	41/525 (8%)	456/525 (87%)
Did not mind	446/525 (85%)	55/525 (10%)	24/525 (5%)
Were bored	28/525 (5%)	14/525 (3%)	483/525 (92%)
Were irritated	5/525 (1%)	7/525 (1%)	513/525 (98%)
Found questions easy	358/525 (68%)	98/525 (19%)	69/525 (13%)
Felt pressured	29/524 (6%)	72/524 (14%)	423/524 (81%)
Felt that quizzing indicated that the researchers really wanted them to understand the clinical trial	520/525 (99%)	4/525 (1%)	1/525 (<1%)
Felt testing is a good way to find out if a person really understands the clinical trial	511/525 (97%)	13/525 (2%)	1/525 (<1%)

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Table 4

Association between attitudes and site, age and education

		Univariate			Multivariate		
Questions	**Effect**	**OR**	**95% CI**	**p-Value**	**OR**	**95% CL**	**p-Value**
Participants were anxious							
Site	Xinjiang	1.00			1.00		
	Chiang Mai	1.79	(0.67, 4.77)	0.24	0.91	(0.23, 3.64)	0.90
	Heng County	0.08	(0.02, 0.36)	<0.01	0.07	(0.02, 0.32)	<0.01
Age	18–35	1.00			1.00		
	36–45	1.28	(0.54, 3.02)	0.58	0.81	(0.34, 1.96)	0.65
	>45	5.98	(1.95, 18.34)	<0.01	2.70	(0.81, 9.04)	0.11
Education (years)	0–5	1.00			1.00		
	6–10	0.35	(0.15, 0.86)	0.02	0.70	(0.20. 2,42)	0.57
	>11	0.52	(0.18, 1.52)	0.23	0.42	(0.10, 1.72)	0.23
Participants did not mind							
Site	Xinjiang	1.00			1.00		
	Chiang Mai	5.57	(2.14, 14.5)	<0.01	1.74	(0.49, 6.15)	0.39
	Heng County	0.32	(0.10, 1.01)	0.05	0.26	(0.08, 0.87)	0.03
Education (years)	0–5	1.00			1.00		
	6–10	0.14	(0.06, 0.35)	<0.01	0.27	(0.08, 0.87)	0.03
	>11	0.17	(0.05, 0.60)	0.01	0.18	(0.04, 0.83)	0.03
Participants were bored							
	Xinjiang	1.00			1.00		
	Chiang Mai	2.14	(0.79, 5.79)	0.14	2.14	(0.79, 5.79)	0.14
	Heng County	0.25	(0.09, 0.69)	0.01	0.25	(0.09, 0.69)	0.01
Participants were irritated	No Significant Effect						
Participants found questions easy							
	Xinjiang	1.00			1.00		
	Chiang Mai	1.25	(0.59, 2.66)	0.57	0.98	(0.34, 2.80)	0.97
	Heng County	0.08	(0.03, 0.20)	<0.01	0.10	(0.04, 0.24)	<0.01

		Univariate			Multivariate		
Questions	**Effect**	**OR**	**95% CI**	**p-Value**	**OR**	**95% CL**	**p-Value**
Education (years)	0–5	1.00			1.00		
	6–10	0.35	(0.18, 0.68)	<0.01	0.58	(0.23, 1.43)	0.23
	>11	1.34	(0.67, 2.67)	0.41	0.92	(0.35, 2.39)	0.86
Participants felt pressured							
Age	18–25	1.00			1.00		
	26–35	1.51	(0.40, 5.68)	0.54	1.52	(0.40, 5.73)	0.54
	36–45	2.99	(0.83, 10.75)	0.09	2.80	(0.77, 10.2)	0.12
	>45	7.13	(1.48, 34.33)	0.01	5.59	(1.12, 27.9)	0.04
Education (years)	0–5	1.00			1.00		
	6–10	0.38	(0.16, 0.90)	0.03	0.49	(0.20, 1.21)	0.12
	>11	0.51	(0.18, 1.50)	0.22	0.57	(0.19, 1.71)	0.31

Table 5

Factor Analysis

	Score		After Rotation	
Question	**Mean**	**STD**	**Factor 1 Loading**	**Factor 2 Loading**
Were anxious	0.90	0.64	0.75	−0.07
Were bored	0.99	0.62	0.81	0.02
Were irritated	1.17	0.51	0.76	0.02
Felt pressured	0.81	0.63	0.57	0.24
Did not mind	0.83	0.63	0.12	0.32
Found questions easy	0.59	0.75	0.18	0.35
Felt researchers really wanted them to understand	1.09	0.33	−0.02	0.86
Felt testing is a good way to find out if a person really understands	1.06	0.34	−0.08	0.89
Variance Explained by Each Factor (%)			27.14	22.86