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A Preliminary Study of Interactive Questioning Methods to Assess and Improve Understanding of Informed Consent Among Patients with Schizophrenia

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Abstract

Growing recognition of the inadequacy of traditional methods of providing informed consent, especially for individuals vulnerable to impaired decisional capacity, has spurred recent interest in how to assess and improve components of consent-related decision-making. In this preliminary study, we aimed to compare different methods of interactive questioning during presentation of research consent information among patients with schizophrenia. Patients were randomized to receive either standard administration (SA) of a consent form or one of two interactive questioning methods: Corrective Feedback (CF), in which the correct answer was provided following the participant's response, or Errorless Learning (EL), in which correct answers were provided just prior to the question. The MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) was used to measure understanding, appreciation, reasoning, and expression of a choice following presentation of the consent form. There was no significant effect of condition (SA vs. EL vs. CF) on any of the components of decisional capacity. Understanding scores measured during the consent process were higher than those measured afterward, but the two scores were highly correlated. Thus, the results of this randomized study suggest that interactive questioning neither helped nor harmed understanding, appreciation, or reasoning among patients with schizophrenia. Other considerations, however, may favor use of such methods in the consenting process.

Key Words: Informed consent, decisional capacity, competence, schizophrenia

1. Introduction

There has been growing awareness that the process of obtaining informed consent for research or treatment should involve more than just the presentation of a paper form to be signed (Appelbaum and Grisso, 2001; Jeste et al., 2003). This is particularly true in situations in which decisional capacity may be impaired, such as among patients with schizophrenia or other forms of severe mental illness associated with cognitive deficits (Roberts, 2000). One question that can be raised in this regard is, "How should one best assess and document decisional capacity?" Some Institutional Review Boards have begun to require that investigators demonstrate that individuals at risk for impaired decisional capacity have, at least, adequate understanding of the elements of a consent form before enrolling them in research. The method of this assessment, however, varies widely, and ranges from no assessment to simple post-consent questionnaires to use of standardized instruments such as the MacArthur Competency Assessment Tool for Clinical Research (MacCAT-CR) (Appelbaum and Grisso, 2001). A second question that has received increased attention is, "How can the informed consent process be improved to maximize the ability of at-risk groups to understand, appreciate, and reason about a potential study or treatment?" A number of reports have shown that relatively simple modifications of the process (e.g., repeating information, providing bullet points and summaries) can significantly improve understanding among patients with schizophrenia, often up to the level of healthy individuals (Grisso and Appelbaum, 1995; Wirshing et al., 1998; Carpenter et al., 2000; Dunn and Jeste, 2001; Dunn et al., 2001; Dunn et al., 2002).

In this preliminary study, we aimed to address both of these questions by examining the effects of different methods of interactive questioning on eventual post-

consent understanding, appreciation, and reasoning. There are at least two potential benefits of asking questions during the presentation of the consent form. First, it assures that individuals understand each element of the consent form as they go along. This would be particularly useful in situations in which understanding of later elements is predicated on adequate comprehension of earlier components. Second, it would provide cues to the potential participant as to which elements of the consent form are most important to remember. This could be of benefit for individuals with difficulties in attention and concentration.

There are also several potential concerns that might be raised about an interspersed questioning approach, however. First, if understanding is assessed only during the consent process and not also after all the information is presented, the degree of understanding at the time of the decision may be overestimated. For example, individuals with memory problems might be able to answer an understanding question immediately after the information is presented, but may forget that element of the protocol by the time they have to make a decision. In contrast, a different concern might be that by probing understanding in the middle of the consent form, an opportunity exists for wrong answers by the potential participant to get confused with correct answers, and thereby interfere with subsequent understanding at the time of decision making. This is similar to the argument that is given to support the use of errorless learning (EL) in cognitive rehabilitation among individuals with brain damage and mental illness. Learning of new skills is facilitated if there is little or no opportunity to make errors, presumably because erroneous responses, once made, are difficult to unlearn (O'Carroll et al., 1999; Kern et al., 2003; Tailby and Haslam, 2003).

To test these alternatives, we randomly assigned individuals with schizophrenia to one of two methods of interspersed questioning or to a standard administration (SA) of a consent form for an actual functional magnetic resonance imaging study, and compared post-consent understanding, appreciation, reasoning, and expression of choice as assessed by the MacCAT -CR. We also examined how understanding as assessed by interspersed questioning *during* the presentation of the consent form (concurrent understanding) related to *post*-consent understanding as evaluated with the MacCAT-CR. The two interspersed questioning conditions differed in the opportunity to make errors. In the Corrective Feedback (CF) condition, participants were asked questions as they went along and the correct answer was provided following their response. In the EL condition, questions were interspersed at the same points, but correct answers were provided just prior to the question, so that the participant only needed to repeat the answer in his/her own words. We hypothesized that 1) each method of interspersed questioning would lead to better subsequent understanding compared to SA, 2) within each interspersed questioning method, concurrent understanding scores would be higher than post-consent scores, but would be strongly correlated, and 3) participants in the EL condition would have better post-consent understanding than individuals in the CF condition.

2. Methods

This study was approved by the UCSD Human Research Protection Program. Forty-four patients with DSM-IV-based (American Psychiatric Association, 1994) diagnoses of schizophrenia or schizoaffective disorder were consecutively recruited from Board-and-Care homes in San Diego County. Many of the potential participants had previously participated in research studies, and thus were generally familiar with the

consent process. Patients were divided into age- and gender-strata to improve eventual matching between groups, and randomly assigned to one of three consent conditions. Participants in each condition were asked to consider participation in an actual functional magnetic resonance imaging (fMRI) study. Thus, the study presented was not hypothetical. In the event that a potential participant indicated during the process that he/she would be unwilling to participate in the fMRI study (e.g., because they were claustrophobic), they were asked to continue with the consent process until all information and questions had been presented, and then could decline to participate. Thirteen (out of 44) declined. All participants were paid for their time, regardless of whether they consented to the fMRI study. In the SA condition (n=12), an examiner simply read aloud from the paper consent form. In the two experimental conditions, the examiner periodically stopped to ask questions (presented on a flip-chart) that probed understanding of the presented information. There were 22 questions that assessed various elements of the protocol such as purpose, procedures, risks, benefits, and the voluntary nature of the study. Responses were scored on a 0- to 2-point scale similar to that used in the MacCAT-CR scoring.

The method of questioning differed between the two experimental conditions. In the EL condition (n=12), participants were shown the correct answer immediately after a question. For example, after having the voluntariness of study participation explained, the participant saw: "Q: Is participation in this study voluntary? A: Yes, participation in this study is voluntary and you can withdraw at any time. Probe: In your own words, is participation in this study voluntary?" Participants in the CF condition (n=20) saw each question alone, and were asked to generate an answer. Following his/her response, the

correct answer was shown on the flip-chart. In this way, the only difference between the questioning of participants in the EL and CF conditions was in the timing of the presentation of the answer (either before or after the participant was asked to respond). Randomization was somewhat biased toward assignment to the CF condition (ratio of SA:EL:CF = 1:1:1.67) in order to increase the power to examine the relationship between concurrent understanding and post-consent understanding, which we presumed would be most evident in this condition. One research assistant, an individual with 9 years' experience administering the consent process to patients with schizophrenia, presented the consent information to individuals in all three groups. Responses of the potential participants to each question in the EL and CF groups were transcribed and scored later.

After the entire consent form had been presented, a study author (HM), who was masked to consent condition, administered a modified version of the MacCAT-CR to assess four components of capacity: Understanding, Appreciation, Reasoning, and Expression of Choice. The instrument was tailored to the consent form for the present study, and therefore, focused on elements such as the risks and benefits of fMRI. Understanding questions, unlike those in the usual MacCAT-CR, were asked all at once without any additional presentation of consent information. Whenever possible, the 15 Understanding questions were worded differently from those used during the consent presentation in order to avoid rote recapitulation of answers by the participants. HM had been trained to administer and score the MacCAT-CR by experienced examiners, and any uncertainty in scoring was discussed with another author (LTE) before reaching a consensus (prior to unmasking of condition).

The effect of condition (EL vs. CF vs. SA) on MacCAT-CR scores was examined using ANOVA; planned comparisons between pairs of conditions were performed employing Student's *t*-tests. Paired *t*-tests were used to compare concurrent understanding and post-consent MacCAT-CR Understanding, and Pearson's correlations were used to test the association between these two scores. The distribution of scores on the Expression of Choice and Appreciation subtests were highly skewed. Only one participant in the SA group, one in the EL group, and none in the CF group failed to receive full credit on Expression of Choice, so this variable was not statistically compared between groups. The nonparametric Kruskal Wallis test was used to examine the effect of condition on Appreciation scores. All other measures met parametric assumptions.

3. Results

Given the stratified randomization utilized, the three experimental groups were similar in age and in gender ratio (Table). The level of education also was similar. As postulated, participants in the EL group made fewer understanding errors during presentation of the consent form (concurrent understanding) than those in the CF group ($t(30)=2.9$, p(2-tailed) = 0.007), although performance was completely errorless only for 4 out of 12 participants in this condition. Post-consent Understanding, as assessed by the MacCAT-CR, was slightly, but non-significantly, better in each of the interspersed questioning groups than with SA. There was no significant difference in post-consent understanding between EL and CF conditions. There was no significant effect of condition on Reasoning or Appreciation scores. In the EL and CF groups, concurrent Understanding scores were significantly higher than post-consent Understanding scores

(CF: $t(19) = 2.2$, $p = 0.04$; EL: $t(11) = 4.1$, $p = 0.002$). This also was true when a matched subset of eight questions with identical content in the concurrent and post-consent (MacCAT) assessments were compared (CF: Concurrent mean (SD) = 11.8 (3.2), Post-test mean (SD) = 9.6 (4.3), $t(19) = 2.2$, $p = 0.04$; EL: Concurrent mean (SD) = 14.2 (1.7), Post-test mean (SD) = 9.4 (4.5), $t(11) = 4.1$, $p = 0.002$). Concurrent Understanding (all items) was significantly correlated with post-consent Understanding (all items) in both the experimental groups (CF: $r(18) = 0.59$, $p = 0.003$; EL: $r(10) = 0.49$, $p = 0.05$), however.

4. Discussion

This randomized experiment, which aimed to test whether interactive questioning methods might improve understanding, appreciation, and reasoning regarding a consent form, failed to show a significant benefit of such methods. Contrary to our hypothesis, asking questions during the consent process did not lead to significantly superior post-consent understanding compared to standard methods, but also did not disrupt it. Potential participants demonstrated better understanding during the consent process (as assessed by interspersed questions) than at the end of the process in both interactive questioning conditions.   In both these groups, concurrent and post-consent Understanding scores were highly correlated, suggesting that those who understand well initially are also those who best retain the information presented. Contrary to our prediction, EL methods did not lead to better subsequent understanding of consent information compared to CF. This could be because of the immediacy of the correction in the CF condition or because EL techniques are more beneficial in skill learning than in comprehension of consent-related information.

The results of this preliminary study suggest that there are unlikely to be large differences in the effect of interspersed questioning vs. post-consent questioning on understanding, appreciation, or reasoning. Thus, decisions about whether to use interspersed questioning perhaps should be driven primarily by other considerations. To the extent that it is desirable to assure that earlier elements are understood prior to presentation of later ones, an interspersed questioning method might be preferable. In addition, interactive methods may increase rapport with the research team or could generate greater satisfaction with the consent process (factors not assessed in the current study). Since Concurrent Understanding scores were highly correlated with post-consent Understanding scores, interspersed assessment appears to be an adequate proxy measure of the ability to understand consent-related information at the end of the consent process (at least in this population). Ideally, however, post-consent understanding should also be assessed in order to know how much information is retained by the potential participant at the time the consent decision is made.

The main weakness of this study is its relatively small sample size, which might have diminished our ability to detect differences between the experimental groups. In addition, the results of this study may not be applicable to other populations at risk for impaired decisional capacity, such as dementia patients who suffer from rapid forgetting. However, the results of this randomized study suggest that interactive questioning has no detrimental effect on later understanding, reasoning, or appreciation, and thus could be considered for possible use in the consenting process. More generally, it is hoped that further research will be aimed at evaluating methods of assessing and improving decisional capacity among vulnerable populations. While progress has been made

regarding evaluation of and compensation for poor understanding, additional research is

needed into ways of measuring deficits in appreciation and reasoning, and especially

methods for enhancing these abilities. Ultimately, vulnerable populations deserve the

best possible conditions under which to consider possible research or treatment options,

and the field of medicine can only benefit from improving the informed consent process.

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Table. Demographic characteristics and consent-related performance of the three experimental groups of patients with schizophrenia.

	Standard Administration (N=12)	Corrective Feedback Condition (N=20)	Errorless Learning Condition (N=12)
Mean (SD) Age (in years)	43.3 (8.8)	48.8 (12.4)	45.2 (11.5)
Mean (SD) Education (in years)	11.3 (2.1)	11.7 (1.3)	12.0 (1.8)
Gender Ratio (Women:Men)	1:1	1:1	1:1
Mean (SD) Understanding Score During Consent Presentation (% correct)	N/A	77.5 (18.2)	93.6 (7.9)[a]
Mean (SD) Post-Consent MacCAT-CR Scores (% correct)			
Understanding	56.7 (17.2)	68.2 (22.7)	66.7 (25.5)
Appreciation	84.7 (21.9)	76.7 (21.2)	86.1 (21.1)
Reasoning	72.9 (28.1)	83.1 (20.8)	72.9 (32.8)
Expression of a Choice	95.8 (14.4)	100 (0)	95.8 (14.4)

[a]Errorless Learning > Corrective Feedback : $t(30)=2.9$, p(2-tailed) = 0.007

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