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Music Therapy: Research on Human Subjects with Mental Disorders

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Description

This case discusses how conflicts of interest between interested parties in the clinical setting be resolved when there is a question concerning informed consent, competence and confidentiality.

Body

Duncan, a graduate research assistant, is working on a large behavior genetic study of schizophrenia, which involves assessments of sensory processing. The protocol requires that the participants listen to auditory stimuli presented over headphones while their brain waves are recorded using noninvasive electroencephalographic (EEG) techniques. This procedure is simple and straightforward, and it has not been reported to exacerbate participants' symptomatically. The level of risk is minimal, including only the possibility of mild skin redness at the sites at which electrodes were applied, and embarrassment or discomfort from some of the interview questions (which the participant can refuse to answer). There are no direct benefits of the research to individual participants, but there is evidence to suggest that continued research will shed light on the genetics and pathophysiology of schizophrenia and ultimately assist in the identification of individuals at risk for this debilitating disorder.

Duncan arrives at the psychiatric unit on Wednesday afternoon to meet the research participant, Miriana. Miriana has a chronic mental illness, and her current hospitalization is only one of the many times she has been hospitalized for mental illness during her adult life. She was admitted last week, and has been receiving antipsychotic medications ever since.

Duncan obtained Miriana's informed consent at the outset to participate in the nontherapeutic research project. The project involves her participation in an eight-hour battery of tests that must be conducted in short sessions over the course of a couple of days. The sessions are limited in duration because the research project attempts to accommodate the patients' treatment schedule (e.g., scheduled occupational and physical therapy groups) so as to minimize interference with the patients' treatment.

The first six hours of the test involved taking measurements of Miriana's brain waves -- the raw data for the project. Now Duncan needs to complete the work by conducting a two-hour diagnostic interview, which is designed to obtain an accurate diagnosis of her disorder. Miriana's data would be included in the analyses with the experimental group only if Duncan were to diagnose her as having schizophrenia. If he diagnoses her as having some other disorder, her data will be placed with that of the psychiatric control group. The hospital's psychiatric staff has assigned a preliminary diagnosis to Miriana based on the limited information that she was able to provide upon her admission to the emergency room, but the research protocol requires that Duncan conduct a semi-structured diagnostic interview in order to determine Miriana's diagnosis in a rigorous, standardized fashion.

Conducting a thorough diagnostic procedure is standard for the research field so that a reliable and accurate diagnosis is achieved - the researchers do not rely on the hospital's diagnosis. Based on the information on her hospital chart, Miriana's disorder could be any of several conditions, including (but not limited to) bipolar disorder, major depression with psychotic features, or schizophrenia. It is entirely possible that the research diagnosis Duncan obtains will differ from the hospital's diagnosis. This discrepancy can occur for a variety of reasons. Unfortunately, in the age of managed care and revolving door psychiatric units (in which there is one psychiatrist for 20 or so patients, with 100 percent patient turnover possible from one week to the next), the diagnoses made by the hospital staff are often based on very limited information about a person's current symptoms, or on the basis of past diagnoses (which may themselves be suspect.) Also, the admitting psychiatrist may

not have access to the old hospital chart, and so must rely on the patient's (often quite poor) self-report in order to assign a preliminary diagnosis. In fact, the research diagnosis does not always agree with that of the attending physicians.

The research consent form routinely states that the patient's participation in the research will not affect the patient's relationship with the hospital and that the information obtained in the research is kept confidential and will be disclosed only with the patient's written permission. Thus, researchers could not share a new diagnosis of the patient with the patient's attending physician, unless the patient gave written consent to do so.

Given the possibility of conflicting diagnosis, the hospital's diagnosis and treatment could, in principle, affect the experimental results. It is possible for a patient to be receiving treatment for bipolar disorder, for example, while serving as a research participant under the classification of schizophrenia. In some instances, medication could affect brain waves and distort the experimental results. In this case, although all the research participants are on medication, none, including Miriana, are taking medications known to affect brain waves.

When the floor nurse sees Duncan approach, she shakes her head slightly. "Oh, you're here to work with Miriana? She hasn't been having a good day today. She's been really isolative, and when she does talk, she's not always real clear. But you can give it a try. I think she's watching TV."

Duncan approaches Miriana cheerfully. "Hi, Miriana. How are you doing today?"

Miriana barely looks up. She replies softly, without much expression, "All right."

"We had scheduled a time to go back to the second floor to finish up what we were working on," Duncan says. "Is this still a good time?"

"Yes," Miriana responds flatly.

Duncan accompanies Miriana to the laboratory and reminds her that they just have to complete the part in which he asks her about her life experiences. As Duncan turns on the tape recorder to begin the interview, Miriana leans over the tape recorder, apparently listening keenly. But the only sound is that of the tape turning.

"Miriana? Let's begin."

"I'm waiting," Miriana replies. "When will it begin?"

"Well, first I'd like to start out by asking you a few basic background questions." Duncan's voice trails off. Miriana is still leaning over the tape recorder, her ear only a few inches away, and she does not appear to be listening to him.

For the first time, Miriana looks up at him, expectantly. "Where is the music therapy? When's it gonna start?"

Duncan is startled. The research project is not a treatment study, let alone a treatment study involving music therapy (which is not an empirically supported treatment for psychiatric illnesses).OEC Staff: This remark about music therapy has been challenged by some visitors to the OEC. Since this case was not authored by the OEC staff--see the page on Graduate Research Ethics: Cases and Commentaries for its authors--, we are not in a position to make a judgment on this point. Duncan reflects briefly over the past few days. On Monday morning, he began the protocol in the usual way. He approached Miriana on the unit, explained the study to her, and invited her to participate. Miriana agreed, and, after receiving her doctor's permission, Duncan brought her down to the lab.

Before he began the testing, Duncan gave Miriana the informed consent form, which includes a section about audio-taping the interview, and she appeared to read the form. Before she signed it, he asked her whether she had any questions, and she said she did not. He then explained each component of the consent form, including the statement that her participation was not related to her treatment at the hospital, and that she was free to withdraw from participation at any time. After his explanation of each component, he asked her whether she understood what he was telling her, and each time, she said that she did. She then signed the form.

This informed consent procedure is relatively intensive, in response to current controversies surrounding obtaining informed consent from patients with schizophrenia. Schizophrenia is a disorder that can affect the patient's attention, concentration, orientation, and judgment, and therefore potentially his/her ability to give truly informed consent. Although not all participants in Duncan's study are ultimately diagnosed with schizophrenia, it is impossible to know at the outset of any individual's participation whether she or he has schizophrenia. Thus, the consent procedure is uniformly implemented with all psychiatric inpatients. The research protocol and consent procedure have been independently approved by the

institutional review boards of the granting agency, the university with which Duncan and his advisers are affiliated, and the hospital.

Duncan reflects on his conversations with Miriana since he obtained informed consent. Through the course of the testing since Monday, Duncan occasionally had to repeat instructions before Miriana understood and carried them out, but she was generally able to follow his directions, and she communicated coherently. Duncan reviewed Miriana's medical records on Tuesday in preparation for the diagnostic interview. He noticed no mention that she had ever been involved in any other research study, nor did he recall any indication that she was receiving, or had ever received, music therapy. He also noticed that she does not have a Legally Authorized Representative.

Duncan realizes that Miriana may not understand that she is not receiving treatment from him or even that she is participating in a research study. Thinking back over the way he approached her today, he realizes that he had not specified that he was from the research study, and that she may have misunderstood his affiliation. In fact, it is not clear to him whether she recognizes him at all. Duncan considers, however, that if he does not conduct this interview with Miriana, all of the data he has collected from her will be unusable, and he has been under pressure from his research adviser to collect more data each week. He further considers that much of the controversy in the field about informed consent has concerned patients with schizophrenia, but it is not clear at this point whether Miriana has schizophrenia. He wonders whether there might be a way that he can set things straight with Miriana and continue the interview.

Duncan has been pondering too long. Miriana asks once again, "Where's my music therapy?"

Discussion Questions

1. What are some possible courses of action that Duncan could take at this point?

a. Which do you think is the most appropriate, and why?

b. Identify one course of action that Duncan could take that would be decidedly inappropriate.

2. Miriana apparently believes that she is to receive treatment and does not seem to realize that she is in a research study. What issues does that raise?

3. Duncan considers whether the controversy over informed consent is relevant to his situation with Miriana, because she may not have schizophrenia. Is Miriana's ultimate diagnosis relevant to the issues at hand?

4. What responsibilities does Duncan have to Miriana? What responsibilities does Duncan have to the research project and his research adviser?

5. Duncan wonders whether there is a way that he can "set things straight with Miriana" and continue with the interview.

a. Is there any feasible way that he can do that?

b. If yes, how might Duncan respond to Miriana's questions?

c. If not, why not? How might he respond to her questions?

6. What procedures, if any, could be implemented with future participants to prevent this type of situation?

7. Duncan noticed in his chart review that Miriana does not have a Legally Authorized Representative.

a. Should he have taken this into consideration in his decision to recruit her for the study? If so, how? If not, why not?

b. If Miriana did have a Legally Authorized Representative, how might this situation have proceeded differently?

8. Suppose that some of the data Miriana has provided on Monday and Tuesday can be analyzed even if her diagnosis is never determined. Does the situation that arose on Wednesday raise any questions regarding Miriana's participation on Monday and Tuesday, or concerns about how those data should be used?

9. The case raises the point that diagnoses made by hospital staff and research staff may conflict, but patients are ensured that information obtained by the research team will be kept confidential.

a. Should the possibility of conflicting diagnoses be made explicit in the consent form and procedure?

b. What are the implications of conflicting diagnoses for the patient's psychiatric treatment? What responsibilities, if any, does the research team have in this regard?

c. Why, or why not, is the promise of confidentiality an important consideration in this context? For the patient's care and relationship with the hospital staff? For the results of the research? How could these potentially competing considerations be reconciled?

d. If a patient suffers from schizophrenia or another psychiatric condition, should he or she decide whether the information obtained by the research team is kept confidential from hospital staff?

Notes

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