Brian Schrag's Commentary on "Music Therapy: Research on Human Subjects with Mental Disorders"

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A nontherapeutic experiment with minimum risk

In this case, it appears that the research is valuable and can be done only with the involvement of patients who are schizophrenic as research subjects. The research procedure involves having subjects "listen to auditory stimuli presented over headphones while their brain waves are recorded using noninvasive electroencephalographic (EEG) techniques." The participants are drawn from a pool that includes persons with a variety of mental disorders. Experimental subjects (patients with schizophrenia) and the control group (patients with dementia, bipolar disorder, and depression with psychotic features) will all undergo the same research procedures. The research is described as a nontherapeutic experiment with minimum risk.For a comprehensive discussion of the issues raised in this case, see National Bioethics Advisory Commission (NBAC), "Research Involving Persons With Mental Disorders," Volume I, Report and Recommendations of the National Bioethics Advisory Committee, http://bioethics.gov/capacity, December, 1998.

Minimum Risk

Does this experiment indeed entail minimum risk? The criterion of minimum risk is itself contested. According to the Federal Policy for the Protection of Human Subjects, also known as the "Common Rule," a study involves minimal risk if "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves that those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests."45 CFR 46.102(i)(1998). However, as the National Bioethics Advisory Committee notes, "The need for sensitivity in the application of risk categories is especially great when persons with mental disorders are among the potential subjects of a study. For some persons with mental disorders, their limited ability to understand the rationale for a specific intervention could cause them more distress than it would someone who fully understood the intervention."NBAC "Research Involving Persons With Mental Disorders," Chapter Five, "Moving Ahead in Research Involving Persons With Mental Disorders: Summary and Recommendations," p. 8. NBAC continues, "What may be a small inconvenience to ordinary persons may be highly disturbing to those with decisional impairments. Thus, for example, a diversion in routine can, for some dementia patients 'constitute real threats to needed order and stability, contribute to already high levels of frustration and confusion or result in a variety of health complications.'"Ibid., Chapter Four, "The Assessment of Risk and Potential Benefit," p. 6.

Is it so clear that the activity of listening to auditory stimuli over headphones for six hours while being wired up to EEG equipment "so researchers could read their thoughts" would not provoke some psychotic reaction in some subjects who are also patients? The case states the "procedure has not been reported to exacerbate participants' symptomatology." It is not clear whether this statement refers only to patients with schizophrenia or to patients with the entire range of disorders that might be represented in subjects.

The diagnostic interview itself may not be so harmless. The National Commission noted that subjects who are institutionalized with mental disorders may "react more severely than normal persons 'to routine medical or psychological exams.'"National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Research Involving Those Institutionalized as Mentally Infirm. Washington, D. C.: Department of Health, Education and Welfare, (1978), pp 8-9. One cannot be

sure, but it is worth asking if it really is clear that being subjected to these procedures carries a minimal risk of provoking an adverse reaction in some of these subjects. That may depend on whether one accepts the Common Rule definition of risk as adequate for those with mental disorders.

Benefit

Although this experiment is nontherapeutic, it may offer a benefit to the subjects. The case suggests that the diagnostic procedure administered by the researcher is likely to produce a more accurate diagnosis than the hospital's preliminary diagnosis, given the hospital staff's limited time resources for diagnosis. If so, then the one benefit subjects could gain from participation is a more accurate diagnosis of their condition, particularly if there is a possibility of conflict with the treatment team's diagnosis.

Informed consent process

A central issue in this case is obtaining informed consent to participate in a non-therapeutic experiment, from patients in a psychiatric ward. The issue of informed consent in this case is of special interest for several reasons. 1) The possible disorders of this population include dementia, schizophrenia, bipolar disorder, and depression with psychotic features. All of these disorders are recognized as placing a subject's decisional capacities at risk.NBAC, "Research Involving Persons With Mental Disorders," Chapter One "An Overview or the Issues," pp. 7-10. 2) The target population for the study is patients with schizophrenia, who are at even higher risk for impairment of decision-making capacity that others in this population. They also have the compounding effect of fluctuating capacity for decision making. 2) Many patients in this environment may be recently institutionalized, which is an experience also recognized as sometimes impairing decision-making capacity. 3) Duncan will have access to these patients as subjects for a fairly short time since some may be processed and sent on to institutional settings. This limited access may create some pressure to abbreviate the consent process. The short time frame also reduces the option of waiting until temporary forms of impairment pass. 4) Duncan appears to be under pressure to collect as much data as possible, which again may create pressure to abbreviate the consent process. 5) All his potential subjects are under the influence of anti-psychotic drugs at some point. It is unclear

whether they all receive medication before Duncan undertakes the informed consent procedure with them, although that is the case with Miriana. Presumably the impact of the anti-psychotic drug would be to increase their decision-making capacity, but that is not clear. 6) This study is nontherapeutic. Research in which the subjects receive ś no benefit or are at higher risk or when the researcher has a conflict of interest are all situations that, morally speaking, may require even more stringent consent procedures, such as the use of an independent professional to assess subjects' capacity to make decisions, an auditor to administer the consent procedure, plans for reconsent procedures for subjects with fluctuating capacity and involvement of a friend or family member of the subject in the disclosure and consent process.Ibid., Chapter Two, "Informed Consent and Limitations on Decisionmaking Capacity," p. 7.

Given his subject population, Duncan has strong reason to take special care and use a more sophisticated assessment procedure in the consent process than one might use with other populations. This population is at higher risk for impaired decision-making capacities when he approaches them. It is not clear that Duncan has made an effort to assess the degree to which his potential subjects demonstrate of each of four relevant decision-making capacities (capacity to express choice, understand relevant information, appreciate the situation and its consequences, and reason) and the degree to which they can apply those capacities during his consent process. As the researcher -- and one under pressure to produce data -- as well as the one who assesses potential subjects' capacities, Duncan has a conflict of interest. Since the issue of whether this population is at risk might be debatable, perhaps he should follow the NBAC's recommendation that he use an independent professional to assess potential subjects' decision-making capacities.Ibid., Chapter Five, p.10.

When he first seeks her informed consent, Duncan does not know, based on his own assessment, Miriana's diagnosis or that of the other subjects from whom he obtains informed voluntary consent. Both the "experimental" group and the "controls" go through the entire procedure including the data collection as well as the two-hour diagnostic examination. It is possible, perhaps even likely, that a number of patients with schizophrenia as well as others would exhibit variable decisional capacity during the period of the procedure. Given the population with which he is dealing, it would appear prudent to have in place a procedure for dealing with those in either group whose decisional capacities, although at an acceptable level in the beginning, diminish during the research. Duncan apparently has not planned for that

contingency since he is uncertain what to do when he encounters that situation. That procedure, whatever it is, should be addressed in the consent session and consent obtained if that event occurs.

Duncan should build into the consent procedure his plan for dealing with patients if they exhibit a decline or fluctuation in decision-making capacities. This plan may include an indication in the informed consent process of what is to be done if the subject experiences fluctuating capacity during the procedure. Possible responses might include the subjects' designating someone to serve as a surrogate decision maker or an indication that should such a situation develop, the researcher would suspend the research activity with the subject until he or she is competent to reconsent.Ibid., Chapter Five, p. 19. Finally, it might involve indicating that if decision-making capacities declined or fluctuated, the subject would be suspended from the program.

Because of potential subjects' risk of decisional incapacity and fluctuating decision-making capacity, it may be wise in this experiment to routinely seek to have the potential subject's family, friend or legal advocate sit in on the consent and informational procedures and, with the patient's agreement, serve as a representative or an advocate for the patient/subject during the research.Ibid., Chapter Two, p.12; Chapter Three, "Advance Planning, Surrogate Decisionmaking, and Assent or Objection." p.7; Chapter Five, p. 16.

One can imagine a patient/subject or more likely a patient advocate being concerned that the research process might trigger a psychotic event in the patient /subject. It would be natural for them to want to consult with their physician before consenting to participate in the study. Suppose the subject or his or her representative requests that the patient's treatment team be present at the consent process and assist in making the decision on subject participation in the experiment. Should the researcher be open to that request? Should that practice be incorporated into the consent procedure? One difficulty for the researcher is that such a procedure may blur the line between research and treatment activity in the mind of the patient/subject or that of the advocate.

Some might argue that since this research appears to be low risk, such precautions in the consent process are not warranted. However, it is a mistake to assume that only the threat of risk in research justifies or requires attention to proper informed voluntary consent. Subjects can be wronged, even if not harmed, by failure to treat

them with the respect due autonomous beings. Involving them in a nontherapeutic study without gaining their informed, voluntary consent falls in that category.

Content of informed consent

Not only is there an issue of *how* the informed consent procedure is conducted and obtained, there is also a question of *what* the potential subjects are told about the study. Everyone who consents is subjected to a two-hour diagnostic interview to allow the researcher to arrive at an accurate diagnosis of the subject's illness. Is that made clear to the subjects? It would be hard to imagine a thorough explanation of the research activity during the experiment that failed to explain that two of the eight hours are devoted to diagnosis. Would it also be made clear that the diagnostic assessment is done because the hospital preliminary diagnosis is judged insufficiently accurate for the purposes of research? There is a reference in the case to Miriana's hospital charts. Duncan apparently has access to Miriana's records and is aware of her preliminary diagnosis. If that is so, are the patients aware that Duncan has access to their records?

Once the potential subjects are aware that part of the research activity is a diagnosis of their illness, it would certainly be natural for them or their representatives to ask that that diagnosis be shared with them. It is not clear from the case if they are told that the results of this diagnosis will be shared with them. If the diagnosis is to be shared with subjects, then one would think it might also be shared with the attending physician. If so, will the subjects be told that the diagnosis will be shared with the attending physician? (More below about whether the diagnosis *should* be shared with subjects or their physician.)

Presumably there will also be thorough discussion of the purposes of the six-hour experimental activity. If Miriana can be confused by the presence of a tape recorder, what mistaken conceptions might other psychotic subjects acquire regarding the activity of listening to headphones for six hours?

The information process should also make clear to the potential subjects and their advocates that there is no implicit quid pro quo in which subjects ought to participate in the experiment carried out on the ward in exchange for treatment given in the ward.Ibid., Chapter Three, p. 9.

Should the researcher acknowledge in the informed consent process that subjects will be given a diagnostic assessment as part of the procedure? It is hard to believe that subjects or their advocates would not want to know this information or could give informed consent without it. The subjects or their advocates would want to know about the administration of the assessment not only because of its possible effect on the subject; they may also want to know the actual diagnosis, if indeed it is a more accurate diagnosis than that of the hospital. An accurate diagnosis may well appear to be a benefit for the patient, particularly if it conflicts with the hospital's diagnosis.

Confidentiality

The subject's perspective

It is difficult to see how subjects or their advocates can be adequately informed without being told that part of the process is a diagnosis of their illness. The subjects in this case are also patients. Once they know that a diagnostic assessment will be conducted, it will be difficult for subjects/advocates to separate their concerns as subjects from their concerns as patients. It may be hard to avoid discussing with the subjects/advocates why another diagnosis is needed in addition to the hospital's diagnosis. It will be difficult to avoid the question of sharing diagnostic findings with subjects/patients or advocates. Many patients who have a mental illness or their advocates may want all the diagnostic information they can gather. If the diagnosis is shared, it could have adverse implications for the dynamics of between the patient and the treatment team, particularly if the hospital's and researcher's diagnoses are inconsistent. It could be especially difficult if physicians are unaware that a diagnosis has been shared or that it differs from their own.

Suppose that, as in this case, the informed consent agreement includes the provision that the diagnosis remains confidential and is not shared with the hospital without the subject's written permission. This provision places patients with possibly impaired judgment in the position of deciding to withhold potentially important information from the persons charged with their treatment or care. A decisional capacity sufficient to agree to a nontherapeutic experiment is not necessarily the same as a capacity sufficient to make decisions that could affect treatment.

The researcher's perspective

The case indicates that in the consent process, Duncan assures potential subjects the diagnosis will be kept confidential and not shared "with the attending physician unless the patient gives written consent to do so." A reassurance about confidentiality could be essential to ensuring the accuracy of the researcher's data. As the other commentator notes, subjects may tell the researcher things they do not want the treatment team to know. Some patients, particularly patients with schizophrenia, may have an adversarial relationship with their treatment teams. If subjects know that the information given the researcher will be shared with physicians with or without their consent, they may have an incentive to downplay their symptoms or use of drugs since that information could affect decisions made about them in the treatment program.

If patients have the right to decide whether to release the diagnosis, that allows the possibility that they can manipulate the treatment team by releasing only "good" diagnoses. It may also give subjects an incentive to manipulate the researcher's diagnosis by selective sharing of facts with the researcher. Obviously, all that could affect the accuracy of the researcher's diagnosis as well interpretation of the experimental data.

Impact on voluntary consent

If, in general, the researcher's diagnosis proved to be more accurate than the hospital's, the hospital may have an incentive to encourage patients to enroll in the program, which raises obvious issues of whether the researcher can obtain voluntary consent.

The treatment team's perspective

The treatment team could hardly consider it desirable for patients to be informed of a diagnostic assessment of their illness by someone other than patients' caregivers, particularly if that diagnosis conflicts with that of the treatment team. From their perspective, it would surely be even worse for the patient or the patient's representative to receive such a diagnosis without the treatment team's knowledge. Unknown to them, the patient and/or the patient's representative is now aware that there are conflicting diagnoses. This situation could create all kinds of difficulties in patient-physician relations and treatment. The treatment team may not place

confidence in the researcher's diagnosis, in which case they may not be willing to accept it or alter treatment on the basis of that diagnosis; they may find it frustrating to have to defend their diagnosis against that of the researcher; and they may perceive sharing that diagnosis with their patient as undermining patient confidence. If they do accept the diagnosis, then the patient may benefit from an improved diagnosis. In this case, the treatment (using antipsychotic drugs) may be the same whatever the diagnosis. It might be difficult for the patient or advocate to understand that the diagnosis is really irrelevant as far as treatment is concerned.

There may be no good resolution of this issue. The option of failing to inform the subject that part of the procedure is a diagnostic assessment does not satisfy the requirements of informed consent. The option of sharing the results with the hospital without informing the patient would also violate voluntary consent and subjects' confidentiality. A third option would to be to inform subjects of the assessment but indicate that they will not be told the researcher's diagnosis. If that keeps subjects from joining the study, so be it. That would mean that they would not receive the benefit of a free diagnosis. A fourth option would be to inform the subjects/patients of the diagnosis and let the subject choose whether it is to be released to the treatment team. That alternative would be somewhat analogous to a patient seeking a second opinion.