



The Patient Wants to Withdraw

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Description

A scenario meant to stimulate discussion about the ethical issues that arise when a patient wishes to withdraw from a clinical study and the researcher disputes the patient's competency.

Body

You are the psychiatric resident on-call tonight and your responsibilities include all admissions to the adult locked units as well as covering the current inpatient population. The head nurse pages you to assist in resolving a very complicated issue involving a patient who is quite agitated.

Upon arriving to the ward, you are informed by the nurse that the patient, Mr. Johnson, had been admitted to the ward that afternoon after experiencing an exacerbation of his psychotic symptoms that included paranoia and auditory hallucinations. He was currently enrolled in a research study involving a new oral antipsychotic drug. His psychiatrist is conducting the study. Mr. Johnson was now in week two of the study following a wash-out period of his previous psychotropic. He had agreed to participate in the study because, despite experiencing reasonable control of his psychotic symptoms, the side effects were intolerable and the sexual

side effects embarrassing. He decompensated during this second week and his psychiatrist decided to admit him and continue the study.

As the day progressed, Mr. Johnson became increasingly agitated, was visibly responding to internal stimuli, and was unable to respond to staff's request to return to his room. Mr. Johnson refused to follow staff's instructions until they could convince his doctor to stop giving him that "pill from Hell." His psychiatrist was informed of the patient's request but the psychiatrist insisted that the patient's current condition precluded him from making a rational decision. No other neuroleptics were to be used as this would nullify the study. Therefore, the staff on the ward have been unable to pacify the patient and the situation escalated further. The nurse requests that you "Do something!" You determine that Mr. Johnson, though agitated, is willing to discuss his concerns.

During his conversation with you, his volume of speech is loud and, at times, frightening, but he does not threaten violence. His thoughts were organized and, despite his admitting to hearing voices during the conversation, the content was clear. He would prefer the side effects of his "old faithful drug" than endure these present symptoms. You are aware that competent research subjects are free to opt out of research studies at any time.

- What is your responsibility in this matter?
- What factors help determine issues of competency when there are active psychotic symptoms?
- At what point does the question become about the harm to the patient?
- At what point is the patient competency an issue?
- What, if anything, can the resident do if s/he disagrees with the recommendation of the patient's psychiatrist? The attending physician?

Notes

Caroline Whitbeck introduced methods and modules for discussing numerous issues in responsible conduct of research at a Sigma Xi Forum in 2000. Partial funding for the development of this material came from an NIH grant.

You can find the entire sequence on the OEC at [Scenarios for Ethics Modules in the Responsible Conduct of Research](#). Some information in these historical modules may be out-of-date; for instance, there may be a new edition of the professional society's

code that is referred to in an item. If you have suggestions for updates, please contact the OEC.

Contributor(s)

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