



Online Ethics Center
FOR ENGINEERING AND SCIENCE

A Cognitive Enhancing Drug Requiring Blood Draws

Author(s)

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Year

2000

Description

A scenario about research in which blood is drawn from patients with dementia who cannot understand the reason why.

Body

According to the cholinergic hypothesis, lowered levels of the neurotransmitter acetylcholine are implicated in AD. Researchers want to interrupt the action of the molecule that breaks down acetylcholine (acetylcholinesterase). A new drug intended to achieve this goal is being studied with AD patients in the early and moderate stages of the disease. No other drugs are available. This drug is associated with living toxicity in as many as half of the patients/subjects, all of whom must be monitored with a bi-weekly blood draw.

For those patients/subjects who lack insight into the purpose of the blood draw, reaction to the sight of the needle can be emotionally acute and cause considerable agitation. A family caregiver accompanies the patient/subject to the clinic in order to provide comfort, assistance, and if necessary, persuasion in such cases of initial dissent.

Family surrogates can provide informed consent in this study; patients/subjects need not be competent to consent because the study has limited risks that are being monitored and provides potential therapeutic benefits for the participants. (See [key issues](#) in dementia research.) Family surrogates are very hopeful about this first AD anti-dementia drug, although there is of yet no evidence that it is effective.

- Why might the subject's informed consent be valuable in this kind of study?
- How should the burdens and benefits of this study for the subject/patient be described in the consent form?
- How seriously should the patient/subject's dissent be taken? To what extent should the manipulation of dissenting be allowed?
- Would you characterize against the framework of risk and therapeutic benefit?

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 Some information in these historical modules may be out-of-date; for instance, there may be a new edition of the professional society's code that is referred to in an item.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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Resource Type

Case Study / Scenario

Parent Collection

Scenarios for Ethics Modules in the Responsible Conduct of Research

Topics

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Informed Consent
Institutional Review Boards
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Discipline(s)

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