

Title: Disulfiram

Author: Peter Finn, in *Research Ethics: Cases and Materials*, edited by Robin Levin Penslar, Indiana University Press, 1995

Description: A researcher designs an experiment to test the effectiveness of disulfiram alone versus in combination with three other treatments (alcohol education, relapse prevention, or Alcoholics Anonymous). Subjects are volunteers who have sought treatment for alcoholism elsewhere but cannot afford to enter a clinic program.

Headings: Study Design and Risk-Benefit Analysis; Experimental designs (randomization, clinical trials); Risks and benefits; Mental health disorders, participants with (including addictive disorders and developmental disabilities)

Case Type: Decision making

Disulfiram

Disulfiram is a widely used drug that was introduced as a treatment for alcoholism in 1948. Disulfiram produces an adverse drug-alcohol interaction, which discourages alcoholics who take it from consuming alcohol. It takes up to two weeks to metabolize. If alcohol is consumed during the two-week period when the disulfiram is in an active form in the individual's system, he or she will experience discomfort that can be extreme. The disulfiram-alcohol interaction first produces facial flushing and redness that spreads to the chest and limbs. This effect is followed by nausea, palpitations, and hypotension. Other side effects may include disorientation, psychosis, depression, and a loss of libido. The risk that the latter side effects will occur is small, but significant enough to require that disulfiram be administered only by prescription and pursuant to a physician's supervision.

The strength of the disulfiram treatment program rests in complete patient knowledge of the disulfiram-alcohol interaction. Patients will abstain from alcohol consumption in order to avoid the disulfiram-alcohol interaction. Disulfiram thus acts as a temporary self-imposed restraint on drinking. The disulfiram-induced period of abstinence allows the patient to receive other treatments, both psychological therapies and biochemical treatment such as antidepressant medications. Although when used in combination with other treatments a disulfiram program may be the most successful way to treat alcoholism, there is a debate in the scientific literature over the ultimate usefulness of disulfiram. While there are no statistics on effectiveness of this drug, experience has shown that it is ineffective unless combined with psychotherapy, and that its real effectiveness may rest solely on the patient's motivation. In addition, some clinics discourage the use of disulfiram because they fear patients might choose to remain on the drug, thus replacing alcohol dependency with disulfiram dependency.

Dr. Sober is interested in developing an effective disulfiram treatment program for alcoholism. He designs an experiment to test the effectiveness of disulfiram in combination with various other social, psychological, and nonchemical treatments. He has four experimental groups. One receives the

disulfiram treatment alone, and the others receive disulfiram in combination with one of three other types of treatment: alcohol education, relapse prevention, or Alcoholics Anonymous.

Subjects are volunteers who have sought treatment for alcoholism elsewhere, but who cannot afford to enter a clinic program. They have been referred to Dr. Sober by a number of different clinics and individual physicians. After being divided into the experimental groups, subjects are given a detailed explanation of the side effects and usage of disulfiram. After the termination of the experiment, subjects have the option of receiving the most effective treatment (which might include disulfiram).

What ethical responsibilities, if any, does Dr. Sober have to the subjects? What ethical problems, if any, does the experiment present?

Questions for Further Reflection

What issues of informed consent does this experiment raise?

The design of the experiment presents several questions:

Does it matter how subjects are recruited into the study?

Does it matter how subjects are assigned to the four alternative treatment groups?

Is it acceptable for some of the people seeking treatment to be given possibly less effective treatments?

What if the most effective treatment becomes evident before the end of the experiment?

Must Dr. Sober then inform the other participants in the study of this development and allow them to participate in the more effective treatment strategy?

If you were a member of an IRB that was reviewing this protocol, would you vote to approve the research?

What information, if any, would you want Dr. Sober to provide the IRB before making a decision?

What changes, if any, would you request that Dr. Sober make?