ETHICAL ISSUES IN ALZHEIMER’S DISEASE

Placebo Control

COMMON QUESTIONS

■ When is it unethical to use placebos in medical research?

■ Given that there are drugs currently approved for treating Alzheimer’s disease, is it ethical to allow individuals with Alzheimer’s to receive a placebo when participating in a research study?

BACKGROUND INFORMATION

A placebo is an inactive substance that is used in medical research. In many clinical trials, participants receive either the drug under investigation or a placebo. Neither the people administering the treatment nor the participants know who is getting the actual drug. This method provides researchers with a well-defined control group against which they can compare the effect of the drug. Many scientists prefer placebo-controlled studies because the results are often easier to interpret and the studies require fewer participants and less time. However, if a clearly beneficial treatment, or “standard of care,” exists for a particular disease, it cannot ethically be withheld from research participants. In these circumstances, people in the control group receive the drug considered the standard of care, and researchers compare the safety and effectiveness of the new drug against that of the standard treatment.

ASSOCIATION POSITIONS

In order to address this issue as it relates to clinical trials in Alzheimer research, the Association’s Ethics Advisory Panel met on April 27, 1998, with the Internal Ethics Committee of the Alzheimer’s Disease Cooperative Study, a consortium of Alzheimer research centers. The participants in this discussion focused on whether the drugs currently approved by the U.S. Food and Drug Administration (FDA) for Alzheimer’s were sufficiently effective to be considered “standard of care.” The discussions were summarized in the Association document Are Placebo-Controlled Trials Ethical When Testing Alzheimer Drugs?

Presently, all of the FDA-approved Alzheimer drugs are cholinesterase inhibitors, which are designed to boost the level of a chemical messenger that plays a role in cognitive abilities. The statement of the Ethics Advisory Panel concluded that cholinesterase inhibitors could not be defined as a standard of care for the following reasons:

1. the efficacy of the drugs is mild and varies greatly from one patient to the next;
2. the drugs only treat the cognitive symptoms of Alzheimer’s; and
3. cholinesterase inhibitors do not reverse or change the course of the disease.

Therefore, the Ethics Advisory Panel concluded that placebo-controlled studies remain ethically acceptable in Alzheimer research. The panel noted, however, that as more effective treatments are developed—particularly those that may alter the course of the disease—the Association will need to reassess its support of placebo-controlled trials of potential Alzheimer treatments.

To receive additional Association materials on this topic, log onto the Association’s Web site (http://www.alz.org) or call (800) 272-3900.
Care and Patients’ Rights
Respect for Autonomy

**COMMON QUESTIONS**

- What factors should be considered when determining the competence of an individual with Alzheimer's?

- What are the ethical considerations of taking away a person's right to autonomous decision making?

**BACKGROUND INFORMATION**

Concern for the autonomy of a person with dementia requires an assessment of an individual's competence, or capacity to understand the relevant options and consequences of a particular task or decision in light of one's own values. Judgments of competence in a specific area are routinely made informally by attending physicians, other health care professionals, and family members. Such assessments can be straightforward and based on common sense, particularly when the person is obviously incoherent in conversation, retains little or no information, responds to the same repeated question with opposing statements, and lacks insight into the consequences of a decision or its alternatives. If information is neither grasped nor manipulated, an assessment is not difficult. However, an assessment of competence may not be definitive because a person may be obviously incompetent one day but competent the next. Even the person with somewhat advanced dementia may have periods of lucidity that allow for significant decision making.

In almost all cases, judgments of competence to make medical decisions can be accomplished without the need for legal proceedings. The standard definition of competence for medical treatment decisions includes the essential element of the patient's ability to understand the nature, purpose, risks, benefits, and alternatives of the proposed treatment. More specifically, a patient needs to be able to demonstrate the following abilities:

1. appreciate that he or she has a choice;
2. understand the medical situation and prognosis, the nature of the recommended care, the risks and benefits of each alternative, and the likely consequences; and
3. maintain sufficient decisional stability over time, in contrast to the profound vacillation that indicates an absence of capacity.

**ASSOCIATION POSITIONS**

In general, allowing the person with Alzheimer's disease to feel that his or her autonomy is being respected, to the extent possible, is ethically important and the appropriate alternative to unnecessary coercion. A consistent theme across discussions of the Ethics Advisory Panel is that people with dementia should be allowed to exercise their remaining capacities for choice, consistent with their cultural expectations. Denying this free exercise challenges their independence and dignity.

It is obligatory to protect a person with dementia from seriously harmful consequences, but it is equally obligatory to respect his or her competent decisions. Neither law nor ethics allows interference with a competent person's choices purely on the grounds that the caregiver or another individual knows what is best for the patient. The following principles should be considered to protect an individual's need for autonomy: