Medical journal questions ethics of some AIDS studies

Participants abroad denied effective drug

By DANIEL Q. HANEY
Associated Press

BOSTON — The New England Journal of Medicine has gone on the attack against a series of Third World AIDS studies, saying it's unethical to offer medication to some people while giving others placebos.

An editorial in today's issue argues that withholding proven AZT treatment from pregnant women with AIDS, even in places where the drug will never be widely available, clearly violates World Health Organization guidelines.

Every day around the world, at least 1,000 babies contract HIV from their mothers. Sixteen research projects, mostly in Africa, are trying to find affordable alternatives to weeks of AZT treatment, now the standard approach in prosperous countries to prevent infected mothers from passing on the AIDS virus.

The AZT regimen costs $1,000 per pregnant woman and is out of the question in countries where total per-capita spending on health care is less than $10 a year. As a result, most AIDS-infected women get no preventive treatment at all. The goal is to find some level of treatment that will work with as little as two or three pills and cost a few dollars.

To see if simple approaches are better than nothing, researchers have set up comparison studies in which some women get low doses of drugs and others get placebos.

The researchers contend this is the only practical way to solve this health crisis quickly, but their use of placebos raises one of the touchiest issues in international medical research — whether experiments that would never be considered in the United States or Europe should be conducted on the poor abroad.

Dr. Jack Killen, head of the National Institutes of Health's Division of AIDS, acknowledges that ethical principles in research sometimes conflict. And in this case, he said, it is most important to find information that will eventually help the people being studied.

"What we need to know is whether a medical intervention is better than nothing," Killen said. "Any other experimental design would not answer that question and would be an even more unethical thing to do."

The editorial was written by Dr. Marcia Angell, the journal's executive editor. It accompanied a detailed critique of this kind of research written by two members of the Public Citizen Health Research Group, a Washington-based advocacy group.

Angell noted that international rules require comparison groups to receive the best treatment available, not simply the standard in use where the study is being conducted.

In her view — and those of Drs. Peter Lurie and Sidney M. Wolfe of the health-research group — this means everyone treated in these studies should get AZT.

"The standard of care in the developing world is nothing, because these countries are poor and the drug is overpriced," Lurie said. "To use those social conditions to justify this research is exploitive and unethical."

"The decision to go ahead with a placebo-controlled trial, although not an easy one, was a consensus among research institutions and people from developing countries," said Dr. Joseph Saba, who directs a U.N. AIDS study in Africa. Without an untreated comparison group, he said, it would be impossible to know whether low doses of a drug are truly better than nothing at all.