CASE STUDIES

Case Study 5

Background

Evaluating the use of traditional medicines

A plant common to South Asia, 'thankuni' (Hydrocotyle asiatica), when dried, ground up, and added to water is reported to be effective in the treatment of bloody diarrhea. One paper suggesting that 'thankuni' has an effect on decreasing bloody diarrhea, has appeared in an unrefereed journal from an institute of traditional medicine in India. 'Thankuni' is the only ingredient of a popular traditional medicine, 'Ajorno', which is produced by a local company. This medicine is widely available, very popular, and quite inexpensive. No clinical studies have been conducted on this product and the specific chemical composition has not been determined .
An investigator at an international research institution in Bangladesh is intrigued by this product and wishes to evaluate its clinical effectiveness. The present treatment for dysentery (by far the most common cause of bloody diarrhea in the country) is fluid and ampicillin, an antibiotic that is clinically effective and bactericidal. Ampicillin, however, is often unavailable outside the major cities (80% of the population is rural) and when available is too expensive for many people. The investigator reasons that if the traditional medicine proves effective, therapy will be more accessible to everyone because of availability and cost.

He submits a protocol to the institute's Scientific Review Committee (SRC} for a double-blinded study that compares the clinical effectiveness and bactericidal properties of 'Ajorno' against ampicillin. Adult patients admitted or seen on an outpatient basis with a history of dysentery will be randomly assigned to one of the treatment groups after a rectal swab has been taken for a bacteriological diagnosis. 'Ajorno', which is in a powdered form, will be put into a gelatin capsule so that it is indistinguishable from the antibiotic.

The SRC meets and decides that it cannot approve the protocol for the following reasons: (1) the specific chemical composition of 'Ajorno' (i.e. 'thankuni'} is not known; (2) the prior reports of effectiveness have been for "bloody diarrhea" which might include any number of diagnoses including dysentery and amoebiasis; and (3) there are no studies reported in peer- reviewed journals that have indicated that the traditional medicine is effective or have suggested a mechanism for its reported effectiveness. The investigator, who was asked to attend the SRC meeting to answer some specific questions about the protocol, notes that it would be next to impossible to define all of the ingredients of this traditional medicine and if attempted, would be a costly undertaking. He argues that the reported effectiveness of the drug is most likely due to the interaction of the different ingredients, not one or two ingredients alone. As the concerns of the SRC are related to him, he suggests that those on the review panel who voted against approval are biased against traditional medicines, are denigrating the indigenous science of the country, and are trying to impose their own "Western biases" on scientific research.
1
In a discussion that ensued following the departure of the investigator some members of the SRC recognize that they are not sure whether it is
appropriate to stop the study since they do not fully understand the scientific and ethical issues involved.

Questions

You are the chair of the Institute's Research Ethics Review Committee (RERC). You receive a call from the chair of the Scientific Review Committee requesting that the RERC review the study and provide an opinion to the SRC about the study's ethical acceptability.

Provide a decision about the ethical acceptability of the proposed trial and a justification for your position.

Bibliography

1. Freedman B. Scientific value and validity as ethical requirements of research: a proposed explication. IRB: A Review of Human Subjects Research 1987; Nov/Dec: 7-10

2. Freedman B. Equipoise and the ethics of clinical research. New England Journal of Medicine 1987; 317(3): 141-145.

3. Research Guidelines for Evaluating the Safety and Efficacyof Herbal Medicines. WHO Regional Office of the Western Pacific, Manila 1993.

FROM HARVARD SCHOOL OF PUBLIC HEAL TH PROVIDED BY DR RICHARD CASH