Online Ethics Center
FOR ENGINEERING AND SCIENCE

Complex Concerns

Year

1999

Description

This case discusses issues related to the testing of pharmacologic agents in children specifically problems associated with inadequate studies in children and concerns with designing trials involving the pediatric population.

Body

Part 1

Cureall, a pharmaceutical company, markets the antiviral compound, Eradovir, the first choice therapeutic for the treatment of adult AIDS patients. Eradovir has been shown to increase the life expectancy of certain AIDS patients. It is well known to Cureall scientists that many pediatricians use Eradovir for pediatric AIDS cases, although no clinical studies have evaluated the safety and efficacy of this agent, or any other antiviral agent, in children with AIDS.

Representatives of the American Academy of Pediatrics have been pleading with Cureall executives to begin pediatric clinical trials for Eradovir. The pediatricians explain that adult drug responses do not necessarily extrapolate to children due to their differing physiology. Pediatricians are currently forced to prescribe antivirals to children with AIDS without knowing whether they are safe and/or effective in the pediatric population.

Cureall has agreed to pursue the studies and is developing a study protocol. The overall study design involves initial investigation to determine the appropriate dose of Eradovir to use in a long-term therapeutic trial. The study will compare Eradovir with a placebo. The study has been limited to children 2-12 years of age, but is not confined to certain stages of disease progression. Patients' families or guardians will be compensated for participation by receiving free medical checkups for the subjects during the study, $100 for every month of participation and reimbursement for incurred costs. The company has made appropriate arrangements with four large, urban children's hospitals, chosen on the basis of their large pediatric AIDS caseloads.

A meeting of Cureall scientists for the preparation of the final clinical protocol has sparked debate on the following issues: 1) Is it justified to include an inactive placebo arm to this study? 2) Is the compensation for this study appropriate? 3) Should the payment go to the parent/guardian or child?

Part 2

Nine months have passed, and all four participating institutions have approved the protocol.

Mary T. is foster mother of Liz, a 3-year-old child who contracted HIV from her mother *in utero*. Liz's mother has since died from AIDS. Mary and Liz are at the pediatrician's office at Hospital A, one of the four clinical centers participating in the Eradovir children's clinical study. The pediatrician, Dr. Kid, has informed Mary T. of the clinical trial involving Eradovir. The doctor feels that Liz would be a perfect candidate for the study. In keeping with federal guidelines, Dr. Kid goes over the patient consent form with Mary. The consent form details, in lay person's terminology, what the study is investigating and the potential risks and benefits associated with it. Dr. Kid notices that Mary is most concerned with the part of the consent form stating that Eradovir might cause severe kidney, pancreas and gastrointestinal problems. The kidney problems could be fatal in rare cases. Dr. Kid is quick to reassure Mary that this is an extremely rare occurrence, one that he has never witnessed in any of his patients, nor is likely ever to see. Dr. Kid highlights the potential benefits for Liz - a longer life and improved quality of life. In addition, the close medical attention that is part of the protocol will ensure that Liz's progress is

closely monitored. Mary decides to sign the consent form and allows Liz to be a study subject in the Eradovir trial.

Discussion Questions

1. Do you think it was appropriate for Dr. Kid to reassure Mary about the potentially serious side effects? Could this be considered coercive behavior on Dr. Kid's part?
2. Mary is Liz's foster mother. Do you think her decision was"easier" to make since Liz was not her biological child? Should Dr. Kid have taken the foster relationship into consideration when approaching Mary about Liz's participation in the study?
3. If Liz were a 10-year-old child, should she be asked her opinion regarding trial participation?
4. If 3-year-old Liz were your biological child, would you let her participate in this trial? Why? Why not?

Notes

Brian Schrag, ed., Research Ethics: Cases and Commentaries, Volume 3, Bloomington, Indiana: Association for Practical and Professional Ethics, 1999.

Contributor(s)

Brian Schrag

Editor(s)

Brian Schrag

Rights

Resource Type

Case Study / Scenario

Parent Collection

Graduate Research Ethics: Cases and Commentaries - Volume 3, 1999

Topics

Human Subjects Research
Vulnerable Populations

Discipline(s)

Life and Environmental Sciences
Pharmacology
Research Ethics

Publisher

Association for Practical and Professional Ethics
Authoring Institution
Association for Practical and Professional Ethics (APPE)