9SCI 331 Module 4 Assignment 3 (A case Study)
The Case History

Unethical Clinical Trials Still Being Conducted in Developing Countries

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QUESTIONS

Answer all questions in complete sentences. Type in your answers in MS words. Save the work in PDF format.

1. Who gets rotavirus infection? Describe the cause, symptoms, and treatment of the infection. (10pts)

   Rotavirus is a very contagious virus caused by a genus of double-stranded RNA viruses in the family of Reoviridae. The virus usually affects children under the age of five but has also been reported in adults as well. It is the number one cause of death and gastroenteritis in children worldwide. Symptoms of the infection develop suddenly one to three days after exposure to the virus and can range from mild to severe. Symptoms such as loose stools to severe watery diarrhea, vomiting and fever accompanies this virus. In the most severe cases, infants have developed extreme dehydration and shock, which can result in death. The illness usually lasts for three to seven days, but it can persist for as long as two to three weeks. The treatment for rotavirus is aggressive fluid replacement.

2. What is a placebo? What is the function of the placebo in a controlled experiment? (5pts)

   A placebo is a substance having no pharmacological effect but is administered as a control in experimental of clinical testing of a biologically active preparation. A placebo can be made to resemble an active medication or therapy so that it functions as a control. Therefore, in a controlled experiment it prevents the recipient or others from knowing whether a treatment is active or inactive, as expectations about efficacy can influence results.

3. Why was it unethical to administer salt water rather than one of the available effective vaccines to a group of patients? Explain. (10pts)

   Administering salt water rather than one of the available effective vaccines to a group of patients is unethical because it goes against the principle of informed consent. Saltwater injection was used as a placebo which reflects the troubling disregard for international

ethical principles for human subjects' research, particularly research involving disadvantaged subjects in the developing world. These researchers withheld valuable information from recipients which would have helped them to make an educated decision about participating in the clinical trial. The leading ethical position on this placebo-controlled clinical trial is that two effective vaccines for the rotavirus were already initiated at the time of this study. Therefore, the failure to provide infants with one of these two vaccines instead of a placebo violated international ethical standards for conducting human research. Whenever proven effective treatment exists for a given condition, it is unethical to test a new treatment for that condition against placebo.

4. What was W H O's recommendation regarding rotavirus vaccines? (5pts)

   The W H O'S recommendation regarding rotavirus vaccines is that it should be included in every national immunization program and must be considered a priority. Especially, in countries associated with a high rotavirus fatality rate. These include South and south - eastern Asia and sub-Saharan African.

5. Describe the India Vaccine Trial with rotavirus vaccine including the results. (10pts

   The India vaccine trial was conducted between March 11,2011 and November 5, 2012 in rural and Urban areas of the country. The clinical trial was funded by many Government and private sources. Approximately 6,800 infants were enrolled in this clinical trial. The experimental vaccine was given by injection in three doses at 6-7 weeks which is about two months, 10 weeks or older and 14 weeks or older. In the experimental group, two-third received the actual vaccine. While, one-third received saltwater placebo injections. During this time, the babies received their usual childhood vaccines. Such as diphtheria, whooping cough, tetanus, Hemophilus influenzae type B, hepatitis B and polio. The trial results showed that, as with the two available oral rotavirus vaccines, the new vaccine was effective in preventing severe rotavirus-induced gastroenteritis and hospitalizations due to such infections.

6. Examine the **Helsinki** — Ethical Principles. State one exception that can be made to this principle. (10pts)

   The Helsinki ethical principle outlines the ethical principles for medical research involving human subjects. It was initially adopted by the 18th Assembly of the World Medical Association in Helsinki, Finland in June 1964. It is widely regarded as the cornerstone document on human research ethics. The benefits, risks, burdens, and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances: Placebo being used , or no treatment is acceptable in studies where current intervention exists, or where for cogent scientifically sound methodological reasons the use of placebo is proven to be a necessary aspect to make the determination of the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any harmful ,

serious or irreversible outcomes. Therefore, extreme cautiousness must be taken to avoid the abuse of this option.

7. Why was the rotavirus clinical trial considered to display ethical double standard? (10pts)

   An ethical double standard is defined as principles that apply more strictly to one group than to another. The rotavirus clinical trial displayed ethical double standard because the use of placebo would have never been permitted in a developed country. Whereas, because India is a developing county the same ethical principles were not considered. At the time that this trial was done, there were two vaccines for the rotavirus infection. Therefore, a placebo should have never been considered, and goes against the Helsinki principle. The same regard for informed consent and human safety were not taken to account. Whereas, in a developed country these protocols would have had to be followed, or there would be consequences.

8. Why do researchers from developed countries, like US enroll human subjects from developing countries in the clinical trials? Give three reasons. (10pts)

   There are a number of reasons researchers from developed countries enroll human subjects from developing countries in clinical trial. One of those reasons being disease prevalence in other countries may make them relevant subjects to conduct an experiment on. Also, it is less fund investment when research is done in a developing county. Whereas, doing a research in a developing country may be funded by the government, private and health care facilities and that money goes directly towards the study. Also, the gain access to more diverse facilities and participants in research is another reason for conducting research in a developing country. Furthermore, the same ethical standard usually becomes a double standard in developing countries which may make it easier for scientist to withhold information if they feel participants would decline. Making developing countries an easy place to find research participants.

   The practice of outsourcing clinical trials to developing countries poses a spectrum of fundamental questions for research with human subjects.

9. Briefly describe the ethical protocols of clinical trials in USA. (10pts)

   Social and clinical value
   Every research study is designed to answer a specific question. Answering certain questions will have significant value for society or for present or future patients with a particular illness. An answer to the research question should be important or valuable enough to justify asking people to accept some risk or inconvenience for others.

Scientific validity
A study should be designed in a way that will get an understandable answer to the valuable research question. This includes considering whether the question researchers are asking is answerable, whether the research methods are valid and feasible, and whether the study is designed with a clear scientific objective and using accepted principles, methods, and reliable practices

Fair subject selection
Who does the study need to include, to answer the question it is asking? The primary basis for recruiting and enrolling groups and individuals should be the scientific goals of the study — not vulnerability, privilege, or other factors unrelated to the purposes of the study. Consistent with the scientific purpose, people should be chosen in a way that minimizes risks and enhances benefits to individuals and society.

Favorable risk-benefit ratio
Uncertainty about the degree of risks and benefits associated with a drug, device, or procedure being tested is inherent in clinical research — otherwise there would be little point to doing the research. And by definition, there is more uncertainty about risks and benefits in early-phase research than in later research.

Independent review
To minimize potential conflicts of interest and make sure a study is ethically acceptable before it even starts, an independent review panel with no vested interest in the particular study should review the proposal and ask important questions, including: Are those conducting the trial sufficiently free of bias?

Informed consent
For research to be ethical, most agree that individuals should make their own decision about whether they want to participate or continue participating in research. This is done through a process of informed consent in which individuals (1) are accurately informed of the purpose, methods, risks, benefits, and alternatives to the research, (2) understand this information and how it relates to their own clinical situation or interests, and (3) make a voluntary decision about whether to participate.

Respect for potential and enrolled subjects
Individuals should be treated with respect from the time they are approached for possible participation—even if they refuse enrollment in a study—throughout their participation and after their participation ends

10. What constitutes free and informed consent? (10pts)

Free, Prior and Informed Consent (FPIC) is a specific right that pertains to indigenous peoples and is recognized in the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). It allows them to give or withhold consent to a project that may affect them or their territories. Free and informed consent is telling subjects risk benefits

and every information about a research so that can decide based on true and knowledgeable factors.

11. How can this this double standard be prevented? Give two ethical rules or standards. (10pts)

    This double standard can be prevented by exercising the two ethical principles of respect for potential subject and informed consent. Researcher should treat participants with respect. Having respect for participants mean informing of all of the risk associated with the research. It means not withholding information from subjects to influence their decision. Exercising informed consent can prevent this double standard because if people knew what some of the research entails, they would not partake, which, is their human right.