BASMATTIE UDITSUKHU

New York City College of Technology.

Healthcare Ethics PHIL 2203 WD72(66121)

#5. Describe and explain at least two of the articles/cases presented in Chapter 4 concerning human and animal testing. Be sure to specify the major ethical issues involved in each article. What position on these cases do you think are right? Use one or more ethical theories we read about in Chapter 1 to argue for the position you agree with and against the others. Be sure to fully describe the ethical theory before you use it.

The two articles, Research in developing countries: taking benefits seriously by Glanz, Annas, Grodin and Mariner and Ethical issues in Clinical Trials in Developing Countries by Baruch Brody highlights different perspectives on the ethical issues involved in using subjects in developing countries to conduct research.

For the article written by Glanz et al, a researcher named Ronald Munger attempted to obtain ten drops of blood samples from a group of extremely impoverished people in the Philippine Island of Cebu.This was minimal risk. The objective was to study whether there was a genetic cause for this group's unusually high incidence of cleft palate. One obstacle encountered was to obtain the co-operation of the local officer. His intentions were questionable as to his bonafide interest in protecting the population versus looking for a bribe. Although the article did not clearly state that he took a bribe and in turn allow the research to be conducted on his citizens, In my opinion he should have dealth differently and involve a committee in making his decisions if there was no local IRB present. In such case he would have rid himself of any such speculations and remained very transparent in the eyes of everyone. According to Kantian deontology, it is morally wrong for any person to use any other person merely as a means and if the use of the subjects is unavoidable then one must refrain from coercion and ensure voluntary consent. In this theory there is an ethics of respect for others as well. Additionally was the Principle of Autonomy was violated? No definite conclusion can be made.

Some of the potential benefits were that the mothers would learn their blood types, which they apparently desired. If anemic, they would be given iron pills. Lunch would be served and raffles arranged. Researchers indicated that if the hypothesis were correct, the research would benefit the population. If the research shows that increased folate and Vit B6 reduces the risk of

cleft palate, families could reduce the risk of facial deformities. In this research, there were clearly significant benefits and minimal risks and from a utilitarian perspective, which I strongly agree with, according to the principle of act-utilitarianism, a person ought to act so as to produce the greatest balance of good over evil, everyone considered. The findings of this research will greatly assist this population in a significant manner. In my opinion Kant does not have any argument here concerning the use of this population knowing the potential benefits to this population.

There are numerous other issues that are presented in developing countries and these may include: The goal of the research must be relevant to the population: In this case the population, there was a high incidence of cleft palate and thus this population stands to benefit from the research. Another concern is that of informed consent. The potential subjects thought that participation in the research was related to free surgical care in the facility. This was not true. Another consideration is the level of education of the population, and as quoted in the text: Can one adequately explain genetic hypothesis to an uneducated population? The citizens were protected from the risk of economic discrimination by the profound poverty in which they live.

One may ask, is it acceptable to use citizens of developing countries as research subjects? Before considering this argument, lets consider peculiar traits of this population. They are at risk for deliberate exploitation by researchers from developed countries and are considered a vulnerable population because of their lack of political power, lack of education, unfamiliarity with medical interventions, extreme poverty and dire need for healthcare, this makes them appropriate subjects especially vulnerable to exploitation. The combination of the need and vulnerability lead to the development of guidelines for the appropriate use of research of research subjects from underdeveloped communities. One of the guidelines is that in order for the

research to be ethically conducted, it must offer the potential of actual benefit to the inhabitants of that developing country, with reference to this population; there is a potential benefit, that is the reduction of the incidence of cleft palate. At the completion of the study, any products developed must be made reasonably available to the inhabitants of the underdeveloped community in which the research was carried out. If these subjects could not afford this treatment then they were exploited.

Are these CIOMS guidelines strong enough to prevent exploitation? This was presumably demonstrated in the second study of this article by Glanz, The African Maternal-Fetal HIV transmission studies. The goal of this study was to see if the lower dose of the drug AZT than those used in the US could reduce the rate of maternal child transmission of HIV. From this story there were some already established facts, doses of AZT that cost $800 reduced maternal fetal transmission of HIV by as much as 2/3 in the US. Obviously this was not affordable in Africa; hence the decision was made to attempt to see if this lower dose/lower cost would prevent maternal-fetal HIV. But would the African subjects be able to afford the drug at the lower cost? One would conclude that since the African subjects could not afford the lower cost, they were exploited and the CIOM guidelines were violated. Let's consider the article written by Brody. Brody argues that the research was done on subjects in an underdeveloped country, these subjects were in need of less expensive regimens, at least when these trials were completed, those who were present in developing countries and could have afforded it would be able to purchase the lower dose, knowing that it would be effective. Again in my opinion there would be a greater good for a larger number of people. A strong utilitarian perspective.

Although the article by Glanz purports the idea of exploitation, Brody had a reasonable argument, which in my opinion is feasible and practical and may at least be considered as a

workable solution to begin with. According to the Brody article, studies are only appropriate if there is a reasonable likelihood that the population in which they are carried out stand to benefit from the results, thus availability of the "fruits" would be limited to the participants. In my opinion this is more reasonable and practical since there are costs associated with conducting the research itself, especially in a foreign country. Besides providing the fruits of the research to the entire nation would result in astronomical costs and even discourage future research in these developing countries that could be more beneficial to them than the developed countries

From the Glantz article one gets the idea that the subjects were exploited and the information would be used to provide the lower dose of the AZT to pregnant women in developed countries. As Brody points out, the women in developed countries were already receiving the higher dose/cost the findings of this study was not desperately needed for the women in developed countries when compared with the developing countries. The Glantz article which would tend to reflect exploitation would support an argument for Kant. According to him, Humans are not objects to be used for others and the rights of the individual takes precedence over any such abstract good as the advancement of science. The principle of Justice may also apply which demands the equitable distribution of the benefits. However in my opinion the utilitarian arguments are much stronger.

It is also my argument that there does not exist a question as to whether a placebo would have been given to a subject in the developed country. The developed countries have mechanisms in place to ensure their population of pregnant women be given any treatment needed during pregnancy whether they could or could not have afforded it. The rationale is to protect the unborn child and to prevent undue economic burden for something that could have been prevented. The financial burden is lesser in prevention than in "curing" or treating. These

mechanisms that are in place were put in place after others had suffered and someone acted. The experiment would at least give the subjects a possible workable solution rather than none at all. At least possible affordability was within reach.

Another argument that was brought up by Broody was whether injustice was done to the control group in each of these trials and that sections of The Declaration of Helsinki were violated, “In any medical study, every patient, including those of control groups, if any should be assured of the best proven diagnostic and therapeutic method”. As clearly argued and concluded, that “nothing was being denied to them that they would have otherwise received”. The point was that the justice or injustice of what was done to the control groups depends on what members of that group would received if the trial had not been conducted. I agree with this line of argument but also, in my opinion in order for an experiment to have both internal validity and external validity and to be credible and infer generalization, control mechanisms such as this was needed to rule out other errors.

If one also considers the tremendous sacrifice and risks to which others were exposed for the invention of medical interventions and newer treatments, some of who did not necessarily benefited from it, nevertheless they took the risk and so called “injustice” as in this case and others have benefited tremendously, it is only fair that others be willing to take risks as well. In fact the initial research to determine whether AZT therapeutic effect on the transmission was an even bigger risk that turned out very successful. This trial was just to determine whether a lower dose, which will, transcend into a lower cost, would be effective. Again a strong utilitarian argument is present here.

The article from Brody also addressed the Issue of Coercion. As outlined the trials were coerced into participating because of their desperation. The women did not have an alternative to

protect their children from HIV. One of the requirements for an ethical research is voluntary participation, free of any coercion, however it was argued that the potential subjects were offered the opportunity improved their situation and the offer was too good to refuse. In my opinion I believed that the subjects were not coerced but attempted to protect their own interest and well being. Participation was voluntary; the subjects assessed their own needs and made attempt to benefit from the situation

As new disease pattern emerges and researchers continues to make strides in the development of new medical treatment, there will continually be a need to use humans as subjects in research. At the same time there will continue to more ethical dilemmas to be resolved. No one has a duty to participate in research. Others in the past have seen the need and volunteered to be participants for the benefits of the others and in my opinion, it is morally required because its future benefits and prevention of harm to many will far outweighs its harmful consequences. There are guidelines to protect the vulnerable population nevertheless at other times compromises may need to be made that are reasonable.