

Author's Commentary on "Ethical Issues in Research with Children"

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Ethical Issues in Research with Children

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Question 1

The researchers have carefully considered the risks and benefits of the study. If a death from anaphylactic shock were likely to occur, there would be little moral justification for the research. This research poses a very low initial risk to the children: 1 in 1 million.

There are several aspects of the research that the investigators can address. First is the issue of respect, which would include informing the parents and children of the potential risk and requesting informed consent. In addition, the researchers will try to maximize the benefit to the participants by dropping the nonsymptomatic control group because these children have much less to gain from participating than children who have respiratory symptoms. Only symptomatic children, who would have more to gain from the skin testing, will be recruited.

If one child enrolled in the study developed anaphylactic shock, the consequences could be devastating - the death of the child; the loss to family and friends; anger and fear in the community directed at the researchers, the school administration and the public health department. A child's death would also affect the research policies of the school administration and the public health department. It is likely that more conservative policies would be adopted, which would limit the ability to identify disease in at-risk subpopulations and implement measures to reduce disease.

The researchers should take several steps to prevent a death from anaphylactic shock. First, they should have trained staff who know what to do immediately if a child begins to go into shock. Second, they can conduct the research in a medical clinic with quick access to medical expertise if the emergency epinephrine does not work. With these measures in place, the researchers will have maximized the benefits to the participants and minimized the risks.

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Question 2

In the Tuskegee research, investigators deceived members of the African-American community and enrolled them in a study to follow the natural history of untreated syphilis. These men were allowed to remain untreated for syphilis for forty years, from the 1930s to the 1970s, even though treatment became available in the 1940s with the dissemination of penicillin. With the legacy of the Tuskegee experiment, the African-American community has had much less trust in governmental institutions and outside investigators conducting research in their community.

Issues of respect, beneficence and justice do not change; they are universal principles in our society. However, we as researchers can learn from the past. Clearly the Tuskegee study violated the three tenets published in the *Belmont Report*. People who participate in research are entitled to respect, beneficence and justice.

Little respect was shown for the African-American men who participated in the Tuskegee experiment. They were treated like children or experimental lab animals; they did not give informed consent; crucial information about the experiment was withheld from them. Nor was there much concern for the welfare of participants in the 40-year duration of the experiment.

The participants did not obtain any benefits from taking part in the study. Although the men received a few free meals and palliative treatment for some of their symptoms, these were of negligible benefit compared to the harm they experienced as the disease progressed to advanced stages. Nor were they told they had syphilis. The men did not benefit from being under medical surveillance. In fact, they were placed at higher risk from procedures such as lumbar punctures to test for neural

syphilis. Justice was not served by research conducted at the expense of a subpopulation of African-American men to obtain information designed to benefit the entire U.S. population. Moreover, there were no clear benefits to the population of all syphilitics.

Researchers in today's environment can ensure that they take the *Belmont Report's* tenets into account when planning and conducting research. In the asthma study, parents and children who are invited to participate in the study receive a clear explanation of the risks and benefits that would be incurred with participation. The informed consent forms are written in easily understood language with little jargon. Moreover, only children who seem to be at risk of asthma or wheezing are invited to participate because they are the children most likely to benefit from the study. They will learn what potential allergens they are allergic to, as well as receiving information on how to reduce their exposure or deal with asthma. They will also be enrolled in the medical clinic and have better access to care for their wheezing symptoms. In addition, all participants will receive the plastic bed covers and cockroach traps.

In considering the tenet of justice, the question stated in the *Belmont Report* is, "Who ought to receive the benefits of research and bear its burdens?" In the case of the asthma research, the intervention is low cost, specifically targeted for families with little money or time to spend. Thus, the subjects are being systematically selected for reasons directly related to the problem being studied rather than their easy availability or their manipulability. (National Commission, 1979) Moreover, these subjects are recruited from a pool of children who were found to have wheezing symptoms, so they would benefit greatly from a reduction in allergen levels.

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References

- Jones, James H. *Bad Blood: Tuskegee Syphilis Experiment*, 2nd edition. New York: Free Press, 1993.
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