Were the rights of human subjects violated at the Arms Mill in Manchester, New Hampshire in 1957 during the human anthrax vaccine trials?

Abstract

Ethical limitations of the clinical trial of anthrax vaccine as exemplified at the Arms Mill in Manchester, New Hampshire in 1957 are described and discussed. Researchers and physicians have codes to “do no harm.” Once the epidemic began and one worker had died, far better coordination should have occurred between the Arms Mill, local hospitals, local physicians, and the government specialists in anthrax infections. It would be interesting to have today’s institutional review boards evaluate the design of the 1955-1959 trials. It is doubted that the design would be considered ethically acceptable today, as well as lacking sufficient protocols for protecting workers should they become infected. Thus, not only were the design and statistical issues in the trials problematic, but the procedures and protocols of the study can be challenged from an ethical standpoint. As it reviews the efficacy and safety of the anthrax vaccine, the Food and Drug Administration should consider the root of the tree, the uncertain ethical validity of this key study of the anthrax vaccine.

Keywords: Anthrax vaccine, limitations of research, scientific ethics, Manchester epidemic, inhalation anthrax