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Statistics and Ethics in Medical Research

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ABSTRACT: *Ethical conduct is an essential component in research, especially in medical research. Statistical methods for design and analysis are powerful research tools if used properly. Abuse of these principles and methods are just as unethical as other laboratory or clinical misconduct. Inadequate research design can produce worthless results and thus wastes effort and valuable resources. For clinical research, patient resources are wasted. Inappropriate analysis of data can also produce misleading results and conclusions. For clinical research, inferior therapy might be given to patients as a consequence. These ethical concerns can have implications for and affect the individuals responsible for the statistical design and analysis. Examples are provided which illustrate some possible abuses and inappropriate pressures.*

A second study illustrates patient bias.[27] Vitamin C had been claimed to be the cure for the common cold. Investigators at NIH decided to conduct an experiment to test this hypothesis. NIH employees with a cold were randomized in a double-blind experiment to receive either placebo or vitamin C. Duration of cold symptoms was the outcome measure. Since the patients in the study were NIH employees, they had access to analytical methods to determine the content of the tablets. At the end of the experiment, the patients were asked if they had unblinded themselves.

Relying on their scientific integrity, their answers were recorded along with their duration of cold symptoms. When the data were analyzed, no differences in duration of cold were observed between treatment groups. However, if the data were stratified by blinding status, those patients who had unblinded themselves and were on placebo had a longer duration of cold symptoms than those who had unblinded themselves and were on vitamin C. For those who had remained blinded, there was no difference in duration of symptoms. Apparently belief about treatment effect among the scientists who were the trial subjects led to substantial bias in the outcome.

27. Karlowski, T.R.. Chalmers. T.C, Frenkel, L.D., Kapikian, A.Z., Lewis. T.L.. Lynch, J.M. (1975) Ascorbic acid for the common cold: a prophylactic and therapeutic trial. *Journal of the American Medical Assocociation* 231(10): 1038-1042.