Editorial

Methodological quality vs. ethics in research

The classic examples of ethical infractions in research, such as the studies conducted in Tuskegee on syphilis and in Vipeholm on dental caries, may lead some investigators to believe that in order for a research to be ethical, it is enough to guarantee that no harm will be inflicted on research participants. Within this perspective, they believe that methodological quality is a separate, isolated concept, and that it should not be evaluated by research ethics committees.

In fact, the ability of a study to provide an answer to the proposed question (its main objective) is a core value, and one that should be evaluated from an ethical point of view. The collection, analysis and dissemination of data on human beings are not justified if the study cannot *a priori* contribute to scientific knowledge. This assumption is particularly important in analytical studies, i.e., investigations that aim to detect associations, identify risk factors, establish prognosis, or estimate the effect of a given intervention. Differently from case reports or descriptive studies, the goal of analytical studies is to analyze data collected from a sample (using p values and/or confidence intervals) in order to make inferences about the population.

For instance: an investigator wishes to propose an intervention that is expected to reduce by half the risk of infection at a health care facility (from 20% to 10%). This investigator decides, on his own, to define his sample size at 100 participants, and successfully obtains the data expected: occurrence of infection in 10/50 (20%) of the patients in the control group and in 5/50 (10%) in the intervention group. However, this difference yields a p value of 0.16, which demonstrates that the intervention was not effective. If the same proportions were obtained from 300 subjects (30/150 vs. 15/150), the p value would be 0.015, then attesting to the effectiveness of the intervention. In the first case, the participants would have been included in a study that lacked the ability (power) to allow clinically relevant (not only statistically significant) differences to be detected. In other words, the first sample size prevented the research question from being adequately answered.

This example explains why research ethics committees have been requiring a description of the sample size calculation in analytical studies. The results from sample size calculation prevents that an insufficient (or excessive) number of participants will be used – evidently an ethical issue. According to Brazilian Resolution no. 196/96, research involving human beings, in any field of knowledge, should abide by the following requirements: a) be adequate to the

scientific principles that justify the study, with solid possibilities of answering uncertainties; and b) be based on scientific facts, previous experimentation, or adequate assumptions within the specific research area. For the same reason, the adequacy of data collection instruments (questionnaires and clinical records), the proposed research schedule, and staff training are also assessed by research ethics committees.

It is unthinkable that investigators will design and submit a research project without believing that their study will contribute to scientific knowledge. Adequate planning, with special attention to the principles underlying scientific investigation, is the first step in this process. More than obtaining approval by the ethics committee, this will allow the research question to be adequately answered. Furthermore, the results will show whether or not the variable under investigation represents a risk factor and whether or not the intervention should be applied in a real setting. Everybody benefits from this: the research team increases their chances of publishing the study, and the population benefits from the new knowledge acquired.

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