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Study Design and Statistics

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Statistical concepts, such as the margin of error in a public opinion poll or the probability of rain or snow, appear in everyday conversation. But, just as one may understand how the heart functions and how blood circulates but not be able to perform a cardiac catheterization, an understanding of statistical concepts does not enable one to perform the work of a statistician. Although the concepts may be familiar, the tools of statistics may be misapplied and the results misinterpreted without a statistician's help. In medical research, the quality of the statistical analysis and clarity of presentation of statistical results are critical to a study's validity. Decisions about statistical analysis are best made at the time that the study is designed and generally should not be deferred until after the data have been collected. Even the most sophisticated statistical analysis cannot salvage a fundamentally flawed study. Regardless of the statistician's role, authors (who may include statisticians) are responsible for the appropriate design, analysis, and presentation of the study's results...

The Manuscript: Presenting Study Design, Rationale, and Statistical Analysis

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Each portion of the manuscript should contribute to the reader's understanding of why and how the study was done and should help persuade the reader that (1) the hypothesis or study question is clearly stated, carefully considered, and important, (2) the methods are designed to answer the question and the analysis is appropriate, (3) the results are credible, and (4) the implications are placed in context and the limitations do not preclude interpretation of the results.Words used herein that are defined in the glossary (see , Glossary of Statistical Terms) are .UPDATE: We will discontinue using quotation marks to identify

Observational Studies

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In an observational study, the researcher identifies a condition or outcome of interest and then measures factors that may be related to that outcome. Although observational studies cannot lead to strong causal inferences, they may nonetheless suggest certain causal hypotheses. To infer causation in observational studies, investigators attempt to establish a sequence of events if event A generally precedes event B in time, then it is possible that A may be responsible for causing B. Such studies may be either (the investigator tries to reconstruct what happened in the past) or prospective (the investigator identifies a group of individuals and

Randomized Controlled Trials

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The randomized controlled trial (RCT) generally leads to the strongest inferences about the effect of medical treatments. Randomized controlled trials assess efficacy of the treatment intervention in controlled, standardized, and highly monitored settings, and usually among highly selected samples of patients. Thus, their results might not reflect the effects of the treatment in real-world settings, or in other groups of individuals who were not enrolled in the trial. Information from RCTs may thus be supplemented by results of observational studies (see , Observational Studies) as well as other types of studies.The methods of RCTs must be described in detail to

Cost-effectiveness Analysis, Cost-Benefit Analysis

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Although a treatment or screening technique may be shown to be effective in an RCT, recommending it in general practice would not necessarily be rational. Such interventions may be prohibitively expensive, or they may benefit only a small number of people at the expense of a large number of people, or they may lead to significant “downstream” costs that would eventually negate any immediate savings or benefit. Thus, it is possible that interventions that appear less effective may actually lead to the greatest societal benefits over the long term.Cost-effectiveness and cost-benefit analyses comprise a set of mathematical techniques to model

Survey Studies

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In a survey study, a representative sample of individuals are asked to describe their opinions, attitudes, or behaviors. For surveys of behavior (eg, diet, exercise, smoking), authors should provide evidence that the survey instrument correlates with the actual, observed behaviors of a similar sample of individuals. That is, the survey instrument should have been shown to have . If the survey instrument is different in any way from that given to the previous validation sample (eg, wording, order, or omission of questions), then it may no longer be a valid measure of those behaviors.For surveys, as for other studies, it

Meta-analysis

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Meta-analysis is a systematic pooling of the results of 2 or more studies to address a question of interest or hypothesis. According to Moher and Olkin, [Meta-analyses] provide a systematic and explicit method for synthesizing evidence, a quantitative overall estimate (and confidence intervals) derived from the individual studies, and early evidence as to the effectiveness of treatments, thus reducing the need for continued study. They also can address questions in specific subgroups that individual studies may not have examined.A meta-analysis quantitatively summarizes the evidence regarding a treatment, procedure, or association. It is a more statistically powerful test of the null

Studies of Diagnostic Tests

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Correct treatment depends on accurate diagnosis. Diagnostic tests may include simple procedures such as physical signs or physical examination, as well as blood tests and radiologic imaging. Few diagnostic tests, however, can be relied on to yield accurate diagnoses 100% of the time. Thus, it is important to study the performance of diagnostic tests. Bossuyt et al stated: Exaggerated and biased results from poorly designed and reported diagnostic studies can trigger their premature dissemination and lead physicians into making incorrect treatment decisions. A rigorous evaluation process of diagnostic tests before introduction into clinical practice could not only reduce the number

Significant Digits and Rounding Numbers

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When numbers are expressed in scientific and biomedical articles, they should reflect the degree of accuracy of the original measurement. Numbers obtained from mathematical calculations should be rounded to reflect the original degree of precision.The use of a numeral in a numbers column (eg, the ones column) implies that the method of measurement is accurate to that level of precision. For example, when a reporter attempts to estimate the size of a crowd, the estimate might be to the nearest tens of number of people, but would not be expressed as an exact number, such as 86, unless each individual

Statistical Symbols and Abbreviations

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The following may be used without expansion except where noted by an asterisk. For a term expanded at first mention, the abbreviation may be placed in parentheses after the expanded term and the abbreviation used thereafter (see also , Abbreviations, Clinical, Technical, and Other Common Terms). Most terms other than mathematical symbols can also be found in , Glossary of Statistical Terms.