

How to Write the Methods Section of a Research Paper

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The methods section of a research paper provides the information by which a study's validity is judged. Therefore, it requires a clear and precise description of how an experiment was done, and the rationale for why specific experimental procedures were chosen. The methods section should describe what was done to answer the research question, describe how it was done, justify the experimental design, and explain how the results were analyzed. Scientific writing is direct and orderly. Therefore, the methods section structure should: describe the materials used in the study, explain how the materials were prepared for the study, describe the research protocol, explain how measurements were made and what calculations were performed, and state which statistical tests were done to analyze the data. Once all elements of the methods section are written, subsequent drafts should focus on how to present those elements as clearly and logically as possible. The description of preparations, measurements, and the protocol should be organized chronologically. For clarity, when a large amount of detail must be presented, information should be presented in sub-sections according to topic. Material in each section should be organized by topic from most to least important. Key words: publications; research; research methodology; clinical trials; laboratory research; writing; manuscripts, medical. [Respir Care 2004;49(10):1229–1232. © 2004 Daedalus Enterprises]

Introduction

The methods section is the most important aspect of a research paper because it provides the information by which

the validity of a study is ultimately judged. Therefore, the author must provide a clear and precise description of how an experiment was done, and the rationale for the specific experimental procedures chosen. It must be written with enough information so that: (1) the experiment could be repeated by others to evaluate whether the results are reproducible, and (2) the audience can judge whether the results and conclusions are valid. In this article I describe

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one approach to writing the methods section. Because this section is so intimately related to the principles of scientific research, I begin with a review of basic research concepts, and then follow with a discussion of important points to incorporate when writing the methods section.

Basic Research Concepts

The scientific method attempts to discover cause-and-effect relationships between objects (ie, physical matter or processes). In the physical sciences objects are regarded as variables, and a variable is anything that can assume different values. Elucidating a cause-and-effect relationship between objects requires that variables are classified as independent, dependent, or confounding. An *independent variable* is one that, when manipulated, causes a change in another variable. The variable that changes in response to that manipulation is referred to as a *dependent variable*. For example, arterial oxygen tension is a dependent variable that responds to manipulations in independent variables such as barometric pressure and oxygen concentration. A *confounding* or extraneous variable is anything other than the independent variable of interest that may affect the dependent variable. Therefore, a change in a dependent variable may be due wholly or in part to a change in a confounding variable. For example, a change in minute ventilation can alter arterial oxygen tension by its effect upon alveolar carbon dioxide partial pressure.

Evaluation of a potential cause-effect relationship between 2 objects is accomplished through the development of the study design. A study design is simply a strategy to control and manipulate variables that provide an answer to the research question regarding potential cause-and-effect relationships.

Validity refers to the credibility of experimental results and the degree to which the results can be applied to the general population of interest. *Internal validity* refers to the credibility of a study and is determined by the degree to which conclusions drawn from an experiment correctly describe what actually transpired during the study.¹ *External validity* refers to whether (and to what degree) the results of a study can be generalized to a larger population.¹ Unfortunately, all biological systems are profoundly complex, so simple, unambiguous, direct relationships between objects can be difficult to ascertain. The internal validity of a study is judged by the degree to which its outcomes can be attributed to manipulation of independent variables and not to the effects of confounding variables. Therefore, the study protocol must be designed to control (eg, to keep constant) as many extraneous factors as possible so that any potential cause-and-effect relationship between 2 objects can be judged accurately. It is important

to emphasize that confounding variables can never be fully controlled. Furthermore, the influence of these variables may not be fully appreciated by those conducting the research. External validity is primarily determined by how subjects are selected to participate in a study and by the use of randomization procedures that limit potential bias in how subjects are assigned to treatment groups.

Content and Writing Style of the Methods Section

Historically, the methods section was referred to as the "materials and methods" to emphasize the 2 distinct areas that must be addressed. "Materials" referred to what was examined (eg, humans, animals, tissue preparations) and also to the various treatments (eg, drugs, gases) and instruments (eg, ventilators) used in the study. "Methods" referred to how subjects or objects were manipulated to answer the experimental question, how measurements and calculations were made, and how the data were analyzed.

The complexity of scientific inquiry necessitates that the writing of the methods be clear and orderly to avoid confusion and ambiguity. First, it is usually helpful to structure the methods section by:

1. Describing the materials used in the study
2. Explaining how the materials were prepared
3. Describing the research protocol
4. Explaining how measurements were made and what calculations were performed
5. Stating which statistical tests were done to analyze the data²

Second, the writing should be direct and precise and in the past tense. Compound sentence structures should be avoided, as well as descriptions of unimportant details. Once all elements of the methods section are written down during the initial draft, subsequent drafts should focus on how to present those elements as clearly and logically as possible. In general, the description of preparations, measurements, and the protocol should be organized chronologically. For clarity, when a large amount of detail must be presented, information should be presented in subsections according to topic. Within each section and subsection, material should always be organized by topic from most to least important.

Subjects

Judging the external validity of a study involving human subjects (ie, to whom the study results may be applied) requires that descriptive data be provided regarding the basic demographic profile of the sample population, including age, gender, and possibly the racial composition of the sample. When animals are the subjects of a study, it is important to list species, weight, strain, sex, and age.

Who is chosen for inclusion in a study (as well as how treatments are assigned) in large measure determines what limits are placed on the generalizations that can be made regarding the study results. Thus, when writing the methods section, it is important to describe who the subjects were *in the context* of the research question. The selection criteria and rationale for enrolling patients into the study must be stated explicitly. For example, if the study proclaims to examine whether noninvasive ventilation reduces the need for intubation of patients with cardiogenic pulmonary edema, then one would not anticipate that surgical patients with respiratory failure would be recruited.

In addition, it is important when describing patients to provide some evaluation of their health status that is relevant to the study. For example, when examining therapies that may impact mortality in acutely ill patients, the study subjects' health status can be assessed with a scoring system such as the Simplified Acute Physiology Score.³ If studying patients in a rehabilitation setting, then a general quality-of-life questionnaire such as the Sickness Impact Profile can be used.⁴

Ethical Considerations

When working with human or animal subjects, there must be a declaration that the medical center's institutional review board governing research on living matter has determined that the study protocol adheres to ethical principles. Without such approval, no research project can be conducted nor can it be published in a reputable, peer-review science journal.

Preparations

In studies involving animal models or mechanical models, a detailed description must be provided regarding the preparations made prior to beginning the experimental protocol. In studies involving animals a detailed description should be provided on the use of sedation and anesthesia, the route of administration, and how its efficacy was evaluated.² In addition, all aspects of animal or tissue preparation required prior to initiation of the research protocol must be described in detail. With any animal preparation or mechanical model there must be enough detail provided so that the reader can duplicate it or evaluate its relevance. When a study involves the use or evaluation of drugs, the generic drug name should be used and the manufacturer, concentration, dose, and infusion rate should be specified. Likewise, when medical gases are used, the concentration and flow rates should be specified.

It is worth noting that the introduction of any novel method for measuring a variable, or preparing/designing a model will require intense discussion. Depending on how unique (or unorthodox) the new method is, its validation

probably should be established in a separate publication, published prior to submission of the main study.

Protocol Design

The research protocol is the sequence of manipulations and measurement procedures that make up the experiment. Its description should follow the exact sequence of how the procedures were executed.² Typically, this first involves a description of baseline conditions and any associated baseline measurements, followed by the sequence of manipulations of the independent variable and the subsequent measurement of changes in the dependent variable. It is also important to describe all relevant aspects of clinical management not controlled by the protocol in the peri-experimental period.

When writing the methods section, it is important to bear in mind that the rationale or assumptions on which some procedures are based may not always be obvious to the audience. This is particularly true when writing for a general medical audience, as opposed to members of a subspecialty. Therefore, the writer must always keep in mind who his/her audience is. The rationale and assumptions on which experimental procedures are based should be briefly stated in the methods section and, if necessary, described in more detail in the discussion section. Whenever it is not obvious, the purpose of a procedure should be stated in relationship either to the research question or to the entire protocol. Writing the methods section in this style is called a purpose-procedure format.²

Measurements and Calculations

The next step in the methods section is to describe what variables were measured and how those measurements were made. The description of measurement instruments should include the manufacturer and model, calibration procedures, and how measurements were made. It also may be necessary to justify why and how certain variables were measured. This becomes particularly important when the object of the experiment can be approached only indirectly. Tangentially, whenever a value for a variable is used to signify a state or condition, this should be stated explicitly. For example, one could state: "Adequate intravascular volume status was indicated by a central venous pressure of ≥ 8 mm Hg." A listing of all calculations used in the study typically follows the description of measurements.

Data Analysis

The last step in the methods section is to describe how the data will be presented in the results section (eg, mean vs median), which statistical tests will be used for the infer-

ential data, and what p value is deemed to indicate a statistically significant difference.

Summary

The methods section is the most important part of a research paper because it provides the information the reader needs to judge the study's validity. Providing a clear and precise description of how an experiment was done, and the rationale for specific experimental procedures are crucial aspects of scientific writing.

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A man making notes of readings from equipment in a laboratory (old negative).
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