Describing the Methodology: Getting down to the Brass Tracks

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Abstract
The Methods section of a research paper intends to inform the readers about how the research study was carried out. It allows them to judge if the methodology followed and material used were appropriate for testing the hypothesis, whether the study findings would be applicable to the patients that they treat and if the conclusions drawn and recommendations made are valid, fair and reasonable.

Introduction
The Methods section (variously known as Methodology, Material and Methods, Patients and Methods, Study design or Subjects and Methods) is an important part of a research paper. Although, it is generally believed that an average practitioner is more interested in knowing the results of the study and its implications, it is the Methods section that provides vital information on the basis of which the credibility of the findings and conclusions of the study rests. No wonder then that editors and reviewers read the Methods section diligently for determining the value of the study and deciding if the submitted manuscript deserves to be published. Thus, authors can ignore writing a well-thought out Methods section only at their peril.

Purpose
The methods section describes the manner in which the study was conducted. It answers the questions who, what, when, where and how of the study. Reading the methods section, the readers can decide for themselves if the participants included in the study, the study design selected, the techniques used to measure variables and the statistical tests applied were appropriate for the research question being probed. It also allows them to determine if the study results would be applicable to the patients that they see in their practice. In addition, the study description is of value to a researcher who wishes to conduct a similar study in his settings.

What Should be Written in the Methods Section?
The “instructions to authors” put up at the Journal website generally provides a good idea about what needs to be stated in the Methods section. It is advisable to write the section divided into various relevant sub-headings, such as setting, study design, participants, study procedure, follow-up and statistical plan. Although the content will depend upon the study being described, certain essential features are described below:

Setting: Here, the authors should inform the readers about where the study was conducted. Many authors provide only the name of the institution or clinic where the study was carried out. Although important, the reader would want to know much more. A description of the level of care that the doctor or the institution offers is important for the reader to understand the kind of patients who were included. For example, if a study was done in patients with recurrent or chronic headache; it is important for the readers to know if the participants were enrolled from a general practice clinic, neurology outpatient department, ‘Speciality Headache clinic’ or neuro-surgery department. The prevalence of various causes of headache, the severity of manifestations and other patient characteristics are likely to be quite different based on the study settings. The duration of recruitment, exposure, follow-up and data collection can also be included under this heading.

Study Design: The authors should specify the study design employed using standard terminology that includes terms such as: prospective or retrospective, observational or experimental, comparative or non-comparative, descriptive or analytical, randomized or non-randomized, etc. If a complex study design was used, most readers would require a brief description in addition to the study design label. The readers can then conclude if this was the most appropriate, feasible,
efficient and ethically permissible design for answering the research question. In case of a randomized trial, description of the method used for sequence generation, type of randomization used, details of restriction (e.g. blocking and block size) and steps taken to implement random allocation should be included. These details help readers (including reviewers prior to acceptance) to determine if the process of randomization was properly implemented. It is not uncommon for editors to receive papers that state that the participants were randomized to receive one of the two regimens and find that alternate participant is assigned to the two groups. If blinding was resorted to, it is necessary to state clearly who were blinded. The authors should desist from merely describing the blinding as single-blind or double blind. They should clarify if participants, investigator, care providers, assessor, technician and/or statistician were blinded. Where applicable, the similarities between interventions should also be described.

Participants: A complete description of participants includes listing the eligibility (inclusion and exclusion) criteria, and describing the recruitment process. In case of case control studies, the eligibility criteria of both cases and controls should be provided. The description should also include the sources and methods of case ascertainment and control selection along with rationale for the choice of cases and controls. For cohort studies, where cases and controls are matched, it is imperative to enlist the matching criteria. Complete and appropriate description of participants enables the reviewers and editors to decide if the participants enrolled were apt for the research question asked and it allows readers and practitioners to judge if the study findings would be applicable to the patients they manage.

For studies involving animals, it is important to state the species or strain, their gender, age, weight and physiological or pathological state and describe their rearing method, nutritional state and diet provided during the maintenance and treatment periods.1,2

Procedures including Interventions: In experimental studies, the intervention should be clearly described in a manner that will allow other investigators to conduct studies using the same intervention. So, if a drug was the intervention applied, the authors should provide its name (trade name and generic name) and completely describe the dose, frequency, duration and route of administration. Other procedures carried out in the study also need to be explained adequately. In case the procedure is a standard one that is known to most practitioners, just stating the name of the method could be enough (e.g. determination of blood pressure using a sphygmomanometer). If a procedure is described in literature but is not widely known, or is non-standard or if it has been described recently, the authors should name the method and cite a reference where the method has been completely described. However, if the authors have used a new procedure or technique, they would be required to describe it in detail. Attention should be paid to providing information about chemicals, reagents or biological materials used for the various study procedures and tests. The description of these materials (such as name, concentration, pH, solvent, storage conditions, temperature, etc.) needs to be provided if they are not routinely available or commonly used in the laboratory.2,5

Variables: Here, the authors should list the pre-defined primary and secondary outcome measures and explain how and when they were assessed. For observational studies all outcomes, exposures, predictors, potential confounders and effect modifiers should be defined. Whenever applicable, diagnostic criteria and terminologies used for the purpose of the study should be clearly delineated. It is necessary to state the manner in which the variables were determined: independent readings, consensus readings or average of a fixed number of readings. Equipment and instruments used for determination of variables should also be described. When specialized equipment is used for the study, the authors should include its name, name of the manufacturer, location, specifications and calibration and validation procedures2,6 in their description.

Study Size / Sample size and Sampling Methods: It is necessary to inform readers about how the sample size was calculated and the formula used (citing the reference) and the assumptions made for the sample size calculations. They should also explain the sampling method (random, consecutive, convenience, systematic, representative, etc.) employed.7,8

Statistical methods: It is essential that authors describe the manner in which the data was handled and presented. They should include the name of the statistical tests and software used and state the p value used to determine statistically significant difference.1 Tests and methods used to check for ‘normal distribution’, for control of confounding, for subgroup analysis or for sensitivity analysis, etc., if used, need to be mentioned.4 They should also inform how missing data was handled and if the analysis was done on an “intention-to-treat” or “per-protocol” basis.

Ethics: It is important to assure the reviewers and readers that the study was carried out adhering to the highest ethical standards. The two cornerstones of ethical research, namely independent ethical review and respecting the autonomy of the participants should be mentioned. Hence,
the authors should state about the approval by an independent ethics committee and enrollment of research participants after obtaining written informed consent. Certain studies can be done without ethical approval. However, the authors should state if the waiver from ethical review was granted by the ethics committee. Similarly, the ethics committee in certain circumstances may allow the investigator to enroll participants without obtaining written informed consent. Again, the fact that such a waiver was granted by the ethics committee should be mentioned in the Methods section. Children aged seven years or older are enrolled after obtaining their assent for participation. This should also be reported. In certain studies, especially dealing with sensitive issues, specific steps such as making the community leaders aware about the project, informing and educating the whole community about the details of the research study and obtaining approval of the community for its implementation are taken. It may be prudent to include these aspects in the section. The authors may also make a statement stating their adherence to the national or international guidelines related to research study they conducted. Unless specifically stated otherwise in “Instructions to authors”, the information about registration of the study in a database/registry (along with the relevant registration number) should be mentioned here. For animal studies, the authors should mention regarding the approval from the relevant ethics committee or regulatory body and declare if the study was carried out as per local, national or international standards.

Miscellaneous: Other relevant aspects of the study such as interim analysis, stopping rules, changes done in outcome measures, assessment criteria, or methodology after the initiation of the study, withdrawal criteria, data safety monitoring boards etc. may also be included.

Azevedo et al have succinctly summarized what needs to be included in the Methods section: First, it should describe the “materials” (for example, human beings, animals, tissues, cells, etc.) and the interventions (drugs, equipment, devices, etc.) employed in the study. Second, it should also explain methods pertaining to the selection, observation and manipulation of subjects (or objects), measurement of variables and analysis of data. Reading this one cannot but think that the nomenclature of “Material and Methods,” is probably more apt for the Methods section.

How to Write the Methods Section?

Caramelli, in his Editorial writes that many scientists find writing research paper quite onerous, as it requires abilities and skills that are quite different from those needed for conducting a study. For example, writing a paper requires the ability to understand the mental states of others, anticipate the readers’ interpretation, and then communicate in a manner that it would respond to readers’ interpretation upfront. These skills are definitely necessary for writing Introduction and Discussion sections. However, the Methods section, being the most technical and objective part of the manuscript, is probably the easiest one to write for most scientists. In addition, a written research protocol that has been followed throughout the study is already available and can be used as a base for writing the Methods section. For these very reasons, many experts suggest that writing of the manuscript could commence with the Methods section.

Before beginning to write the Methods section, the authors should familiarize themselves with the “instructions to authors” provided by the journal. These give an idea about the journal expectations and while writing the manuscript they override all other advices about the manner and format of the article. The authors should also refer to CONSORT, STROBE and similar guidelines that provide advice regarding the essential elements that should be included in research manuscripts depending upon the study design. Although the Study Protocol is to be used as the base for writing the Methods section, there are specific differences between these two documents. A protocol is written in the imperative voice describing a series of steps to be carried out. These steps are listed in a sequential or temporal order. In contrast, the Methods section is written in logical order in the past tense. While the protocol is usually a voluminous document, methodology is written as one of the sections of a manuscript and hence has to adhere to the word count limits set by the journal. The protocol needs to be detailed as it is supposed to guide and instruct investigation team about what each one is supposed to do and how. In contrast, the Methods section is written to so that the readers are able to understand, evaluate and replicate the research study.

The Methods section is written in a direct and precise manner. Compound sentence structures and including unimportant details should be avoided. Although, it is generally recommended that manuscripts be written in active voice; passive voice is also used for writing the Methods section. A mixture of active and passive voice breaks the monotony and makes the section easier to read. The authors also need to strike the right balance between providing enough information and brevity. They need to provide sufficient details to allow replication and validity verification, at the same time not falling into the trap of giving non-essential technical details.
of the section are written, this first draft should be then be edited for arrangement of contents in a logical order, improvement of clarity, condensation of the text and improving presentation. Authors may then decide if a part of the information is better presented in tabular format or with the help of figures. This is generally resorted to, if the move saves a large amount of text, improves clarity or is likely to enhance readers’ understanding. For example, definition of several terminologies can be presented in a tabular format and complex protocol steps (e.g. in the treatment protocol for cancer chemotherapy consisting of several cycles) can be depicted better in the form of a figure or a flow chart. The authors also need to steer clear of the common errors and pitfalls (Table 1).

Once the whole manuscript is finalized, it should be reviewed to check for consistency among different sections of the paper. This needs to be done at every revision, whether carried out prior to submission of the manuscript or those carried out in response to reviewers’ comments.

To summarize, the Methods section is one of the comparatively easier sections to write. It should be written in an objective and precise manner. It informs readers about the way the study was carried out. The importance of the section can be judged by the fact that this is the one section that provides credibility to the whole research paper. If it is written poorly; there is a risk that reviewers would undervalue the study’s worth and recommend that the paper be rejected. Similarly, it might rob the study findings of their real importance and readers may then consider even thoughtfully drawn conclusions as lacking in validity.

References