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Materials and Methods^{*}

MaryAnn Foote

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Materials and Methods*

A Recipe for Success

MaryAnn Foote, PhD

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Key words: Consolidated Standards of Reporting Trials guidelines; manuscripts; medical writing

Abbreviation: CONSORT = Consolidated Standards of Reporting Trials

Recipes for some dishes, such as stew, can be followed with a bit of culinary leeway, while those for other dishes, such as soufflés, must be followed with a bit more care if the cook hopes to produce something esculent and attractive. Woe is the baker who omits a critical ingredient from the cake recipe transcribed for an admirer! These culinary caveats are relevant because the Materials and Methods section of a hypothesis-testing article often is compared to a recipe. Like the intricate soufflé, the Materials and Methods “recipe” must be described precisely as followed. This precise description assures readers that the correct supplies and processes were used to answer the research question posed in the Introduction of the article and ensures that other researchers have the information necessary to replicate the study. The bulk of the Materials and Methods section is, therefore, a detailed description of all materials and methods used during the conduct of the study. Because hypothesis-testing studies usually are prospectively planned, an overview of the experiments (*ie*, the study design) must be included.

It should be noted that *CHEST* has adopted the Consolidated Standards of Reporting Trials (CONSORT) guidelines (see accompanying editorial). Information on the CONSORT guidelines is available at www.consortstatement.org. Manuscripts that report data

from randomized clinical trials must include a flow diagram, showing the numbers of study subjects assessed, excluded, randomly assigned to treatment, discontinued, and so forth throughout the entire trial, and information required by the CONSORT checklist. Authors new to the CONSORT format will find that the checklist is invaluable to ensure that all critical elements of a scientific paper are included in their manuscript. As with other articles in the series,^{1,2} the examples provided here are fictional and are for illustrative purposes only.

MAIN POINTS TO CONSIDER

Format

In general, the Materials and Methods section is called Patients and Methods in the clinical paper. It is one section that is best served by several subheadings: (1) Patients; (2) Study Design; (3) Study Drugs/Interventions; (4) Study End Points (Efficacy End Points, Safety End Points); and (5) Statistical Analysis. These subheadings are somewhat arbitrary but do serve to guide the reviewer. Once the paper has been accepted for publication, the journal copy editor may decide to omit some subheadings. Data corresponding to each of these headings, except for Statistical Analysis, will need to be presented, in the same order, in the Results section.

Content

Very often, the Materials and Methods section will be the longest section of an article. Enough detail must be given for an educated researcher to duplicate the study; however, some information generally can be omitted as common knowledge (*eg*, most studies have exclusion criteria for enrollment of pregnant or lactating women or subjects who are receiving other investigational drugs). If a particular method or procedure has been described previously in detail in another publication or is very commonly known, the most recent edition of the uniform

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Correspondence to: MaryAnn Foote, PhD, M A Foote Associates, 4284 Par Five Court, Westlake Village, CA 91362; e-mail: fmawriter@aol.com

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requirements³ suggests that only a reference to the method should be used; however, modifications of previously published or well-known methods should be explained in detail. The specific information to be considered includes the following:

Patients: I prefer to write in a chronologic order of events, so I usually start with the institutional review board/independent ethics committee approval and informed consent statement: "The protocol was approved by the institutional review board of all participating institutions, and all patients gave written informed consent before any study-related procedures were done." While the actual patient population will be described in the Results section, protocol-specific demographics of age, sex, and disease state should be provided. Specific cardiac, renal, hepatic, or hematologic variables should be provided: "Patients were required to have a hemoglobin concentration > 9.0 g/dL or a hematocrit $> 27\%$, and liver transaminase and bilirubin concentrations were to be no more than twice the upper limit of normal." The start and stop dates of the study can be added here or in the Results section, but the time frame of the study should be provided.

Study Design: This subsection provides an overview of the study to assure the reader that study variables were measured at prespecified times, but it does not tell how they were measured. This information is generally provided in the End Point and Statistical Analysis sections. The Study Design subsection presents information on the study progress, including washout and titration periods: "During the initial 12-week dose-titration phase of the open-label extension study, patients received escalating doses of drug X every 3 weeks at 30 to 100 mg to achieve plasma concentrations ≤ 250 pg/mL. During the subsequent 2-year maintenance phase, higher doses of drug X (up to 180 mg) were administered to patients who did not achieve the target." Information concerning laboratory monitoring should be provided: "Laboratory data were collected weekly during the titration phase, every 8 weeks during the first year of the maintenance phase, and every 12 weeks during the second year of the maintenance phase."

Study Drugs/Interventions: It is important to provide the name of the study drugs, dosage (*ie*, amount and frequency), and manufacturer. Most journals allow the use of the trade name once here, after the generic name, without a registration symbol, which is fitting for a scientific paper. It should be unnecessary to state that all drugs, including those of the competitor, be given equal presentation and fair balance, without marketing messages.

Study End Points: This section should describe the study end points to be reported in the article. While description of efficacy end points for treatments is important, description of safety end points is equally important. Because the article must describe all the methods used to obtain all results, I devised a technique to number the primary end points reported for both safety and efficacy.⁴ Each end point also should be reported, in the same order, in the abstract of the article. Enough statistical information should be provided to show that each end point was analyzed appropriately: "The primary efficacy end point was the proportion of patients who did not have progressive disease measured after 12 months of therapy. Secondary end points were survival time and the need for palliative therapy. The primary safety end points were reports of adverse events and changes in laboratory parameters."

Statistical Analysis: The description of the statistical analysis in an article does not need to be as comprehensive as that in a regulatory report of the same study. The article must, however, show that every end point was appropriately measured: "All patients who received at least one dose of drug X were evaluated for efficacy and safety. The primary end point was tested with the ABC test with a two-sided significance level (α) of 0.05. The secondary end points of survival and need for palliative were to be tested using the ABC test only if the primary end point was significant. For the secondary endpoints, if the larger of the two p values from the secondary end points was < 0.05 , then both of these secondary end points were concluded to be significant. Baseline laboratory values and patient characteristics are expressed as means \pm SEM, and categorical variables are expressed as a percentage of all patients in the data set. The incidence of all adverse events was summarized by organ system and preferred terms."

Style

The Materials and Methods section is written in the past tense when describing procedures: "Subjects were assigned randomly to treatment . . ." and "Drug was administered as a subcutaneous injection . . ." The exception is the explanation of data presentation within the statistical analysis subsection of data presentation: "Data are presented as mean \pm SD." While regulatory documents are written using "study subjects," manuscripts traditionally refer to "patients." Information is often included in parentheses, particularly the name of the manufacturer, city and state, or model number, after first mention of a material. If several methods use the same material or instrumentation, it is not necessary to repeat the city and state or model number after the first use.

POTENTIAL PROBLEMS

One of the most common problems with the Materials and Methods section is the inclusion of results, including tables and figures. The Materials and Method section provides only information about the study population, study drugs, design, and analysis. No results are presented. Figures and tables generally are not included in this section. A relatively easy way to decide what should be go where is to remember that what is known at the start of the study is included the Materials and Methods section and what is learned during the conduct of the study is included in the Results section.

Another potential problem is writing in too much of a cookbook style (*eg*, too sparse, short, choppy sentences). Because a manuscript has a limited word count, methods must be clear but not elaborate. It is presumed that an educated scientist would know basic laboratory methods to repeat the study.

TAKE-HOME LESSON

When writing the Materials and Methods section, remember the following:

- Provide enough detail and references to enable a scientist to evaluate or repeat your work. Make sure that methods are provided for each of the end points reported.
- List the experimental materials and experimental population studied.
- Describe the purpose of all methods.
- Give the statistical methods used; describe how the data were summarized; and state which variables were compared and at which time points.
- Divide the Methods section into subsections (*eg*, Patients, Safety End Points, Efficacy End

Points, Analysis of Sata). The copy editor may remove them later, but subsections help guide the reviewers.

- Make the Materials and Methods section as long as needed to describe what you did, but omit unnecessary words and details (*ie*, make it concise).
- Use the past tense to describe methods (*eg*, “We measured . . .”), but use the present tense to describe how data are presented (*eg*, “Data are summarized as mean \pm SD”).
- Refer to the CONSORT checklist to ensure that all required items have been addressed and that the manuscript page where the information can be found is accurate.

By following a recipe format and checking for inclusion of all required data listed on the CONSORT checklist, writing the Materials and Methods section (to use another food analogy) should be a “piece of cake.” Presenting your methods and procedures fully and accurately will help reviewers to make a rapid decision on publication of your clinical manuscript.

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