The Principles of Biomedical Scientific Writing: Materials and Methods

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Abstract

The materials and methods (M&M) section is the heart of a scientific paper and is subject to initial screening of the editor to decide whether the manuscript should be sent for external review. If the M&M section of a scientific paper be considered as a recipe, its ingredients would be who, what, when, where, how, and why. M&M should effectively respond to the study question/hypothesis using the following basic elements including materials, study design, study population/subjects or animals, methods of measurements/assessments, and statistical analysis. A well-organized M&M permits other scientists to evaluate the study findings and repeat the experiments. Although there are several disciplinary differences in the M&M, similar dos and don’ts may be considered to organize a well-written M&M. Briefly, authors need to provide clear-cut, adequate, and detailed information in the M&M section. In this review, the structure, the principles, and the most common recommendations for writing the M&M section are provided, both in general and study-specific; these could help authors effectively prepare the M&M section of a scientific biomedical manuscript.

Keywords: Materials and Methods, Medical Writing, Medical Scientific Journals

1. Context

The principal mission of scientific writing is to convey the researcher’s message clearly and concisely to the scientific community (1). Although publishing a scientific paper is not the ultimate goal of a research, it contributes much to the progress of science and evidence-based decision-making (2). During the last decades, efforts have continued to improve the structure and content of research papers, which have resulted in the unified structure and style of scientific writing (3), that is the IMRAD (Introduction, Materials and Methods, Results, and Discussion) structure.

Although the materials and methods (M&M) section is the heart of a paper, it is very often poorly written (4). Despite this section seeming to be easier than other parts, the author encounters many challenges (5). Approximately 30% of rejections by journals are related to the M&M section (5). A well-written M&M helps the peer review process (6), enhancing the chances of acceptance of the manuscript (5); it also increases the chance of inclusion of study findings in secondary analysis of existing data, in systematic reviews and/or meta-analyses (7).

The M&M section of a scientific paper is a crossroads connecting the introduction to the results section to create a clear story line (8); it should clearly present the approach to answer the main study question(s) (9), i.e. questions like who, what, where, when, why, and how (10). We could also refer to this section as the Experimental section, Method description and Validation, or Patients/subjects and Methods (5, 11).

Following our previous report about the writing of the introduction section (12), in this review, we describe the main principles, general structure and common recommendations that can help authors to prepare the M&M section of a scientific biomedical manuscript more effectively. In addition, specific recommendations will be provided regarding the M&M section of clinical, experimental, epidemiological, and genetic studies.

2. Functions of the Materials and Methods Section

The M&M section of a paper has two main functions (13): To allow readers to repeat the work and to convince
them that the work has been done in an appropriate way. For hypothesis-testing papers, the most important function of the M&M section is to provide information on “what procedures were used to answer the main question(s) stated in the introduction” (14). The ultimate mission of this section is providing clear and precise descriptions to enable the readers to ascertain exactly how the authors implemented the experimental design (15). The M&M section should include sufficient details and references to allow other scientists to repeat experiments accurately (14). The M&M section provides sufficient details on when, where, why, and how the study procedures were performed, what materials were used, and who was included in the study.

Other functions of the M&M section are to facilitate interpretation of study results and convince readers regarding their validity of the results (8, 15) and to help them to understand how the results and conclusion were derived from the experiments (4); in addition, this section must explain how the study avoided or corrected for potential bias in selecting participants/subjects, measuring variables, and estimating associations between variables (7). In observational human studies, the M&M section also provides justification on how the findings from the sample studied can be generalized to the target population (7).

3. Components of the Materials and Methods

The basic elements of the M&M section of an original quantitative manuscript include Materials, Study design, Study population/subjects or animals, Methods of measurements/assessments, and Statistical analysis (Table 1). Ethical considerations of research (both for humans and animals) should also be reported in this section, and based on the journal policy, these are reported under the subheading Study population or under a separate heading. This section can be separated under corresponding subheadings to help readers to understand the various stages or components more easily (11). A common suggestion is that each paragraph or subheading in the M&M section should correspond with the related paragraph/subheading in the results section (5).

3.1. Materials

3.1.1. Chemicals

In this section, the authors should describe the chemicals (e.g., drugs, culture media, buffers, and gases) used in the research (14). Specifying the source (manufacturers) is not required for basic laboratory chemicals, but it needs to be clarified for other chemicals (16). In addition to details on the manufacturer, their location needs to be mentioned when first cited (16). These details should be used with appropriate punctuation; for example, we used N-(1-naphthyl) ethylene diamine dihydrochloride (NEDD; Sigma-Aldrich Chemical Co., St. Louis, MO).

For drugs, the authors need to mention some essential details including generic name, manufacturer, purity, and concentration; for solutions, the solvent, pH, temperature, total volume infused, and rate of infusion, should be specified if required (14). If the drug is placed in an organ bath or reservoir, its concentration should be calculated in fluid (14). For culture media and buffers, the components and their concentrations, temperature, volume, and pH, need to be specified if appropriate (14).

To avoid advertising, use of generic or chemical names is usually preferred to trade names (17). In contrast, it is also believed that if the name of the material is registered as trademark, the authors should include the superscript TM or ®, as provided by the supplier (16). In case of a complicated name of a chemical, its abbreviated name is suggested (16).

3.1.2. Experimental Materials/Animals/Humans

3.1.2.1. Experimental Materials

Experimental materials including molecules, cell lines, and tissues should be described in this section. For plants and micro-organisms, genera, species, and strain designations should be accurately identified (17). If organisms were collected for the experiment, the dates and locations of collection should also be included.

For cell lines, the sources, species, sex, strains, race, and age of donor should be clarified; whether the cell lines were primary or established and which specific tests were used for their preparation should also be mentioned (17).
Some guidelines for using cell lines are available online (Table 2).

3.1.2.2. Experimental Animals

In case of animal studies, source of animals, species, strains, weight, sex, and the number of animals used should be mentioned; conditions of evaluation of experimental animals as well as details of their care and treatment should be specified (14). Details regarding method and agents used for anesthesia in surgical procedures should be clearly provided (5, 18). For treatment/intervention, the authors need to clearly mention chemical names, doses, routes of administration, and duration of treatment (5). Details should be specified regarding housing of animals, including type of facility, type and size of the cage, breeding program, light/dark cycle, temperature, quality of water, type of food, access to food and water, and environmental enrichment (19). It is recommended that authors use the name of the animal (e.g., rat or mouse) and specify the type of animal model (e.g., db/db mouse) (14).

3.1.2.3. Participants/Subjects/Patients

For human observational studies, the eligibility criteria, the sources and methods of selection of participants, and methods of follow-up (in cohort studies) should be described (20). For case-control studies, the sources and methods of sampling of the control group and the rationale for the choice of cases and controls must be described (20). The number of exposed and unexposed participants (for cohort studies) and the number of controls per case and the criteria for matching (in case-control studies) should be stated (20, 21). For molecular epidemiologic studies, further details including any habits, clinical conditions, physiological factors, working or living conditions that might affect the characteristics or concentrations of the biomarker should also be specified for study populations (22).

For clinical trials, this section is expected to include the target population, sample size and sampling method, sample representativeness, recruitment and randomization procedures, the basic demographic profile of the study population (e.g., age, gender, and the racial composition), and inclusion and exclusion criteria. Such information are needed to evaluate both the internal and external validity of the study (15, 23). Selection criteria and rationale for enrolling patients into the study must be clearly stated (15). If the study includes a control group, more details on sampling, source of recruitment, and matching (e.g., age, ethnicity, and clinical condition) should be provided (24).

3.1.3. Ethics Statements

Ethical issues are important components of biomedical studies (25). The ethics section in a scientific biomedical paper should consist of a statement regarding obtaining approval from the ethics committee with its registration number; otherwise, they need to state that the study was conducted according to the protocols previously outlined such as the Declaration of Helsinki, a set of ethics principles developed by the World Medical Association (Table 2) to provide guidance to scientists and physicians in medical research involving human subjects (26).

In case of clinical trials, the registration number of study protocol obtained from the clinical trials’ registries (Table 2) should be mentioned. According to the Declaration of Helsinki-2008, “every clinical trial must be registered in an easily accessible database for the public before enrollment of the first participant” (27). This approach is believed to contribute substantially to the improvement of clinical trial transparency and reduce publication bias and selective reporting (28, 29). Practical guidelines for the registration of a clinical trial can be found elsewhere (30, 31).

For human studies, a statement regarding informed consent/assent forms should also be mentioned in the ethics approval section. Briefly, informed consent is a process by which an adult human subject confirms his/her willingness to participate in a research after being properly informed of the research protocol (25, 32). General principles like potential harm/benefit of the research, study protocols and registration, use of placebo, post-trial provisions (post-trial access to treatment for patients participating in a clinical trial) (33, 34), and research publication should be considered in written informed consent forms (25, 35). Table 2 provides useful links regarding clinical trial regulations. Assent, as a fundamental part of pediatric research ethics, is given by children in addition to parental consent (36).

It should be noted that any information that might allow someone to identify human subjects (e.g., names, initials, or hospital identification numbers) is not allowed to be included in the M&M section (16).

In animal studies, in addition to state approval of the institutional ethics committee (19), the authors need to determine whether they have applied the 3Rs, namely, replacement, refinement, and reduction of the number of animals used in experiments (6).

3.2. Methods

3.2.1. Study Design

The study design section of a scientific paper is the road map of the study method, which leads to a clear understanding of the data obtaining approach and helps the reader to interpret the results properly (37). The study design should be the first subsection of the methods in a hypothesis-testing paper (37). It provides an overview of the procedures used to answer the question(s) and is followed by the relevant details in separate subsections (14).
Table 2. Useful Links

| Contents                                                                 | Links                                                                 |
|-------------------------------------------------------------------------|----------------------------------------------------------------------|
| Reporting guidelines for main types of studies                         | http://www.equator-network.org                                      |
| Guidance for the description of animal studies                         | https://www.nap.edu/download/1324#                                   |
|                                                                        | https://www.nc3rs.org.uk/arrive-guidelines                           |
| WMA Declaration of Helsinki (ethical principles for medical research involving human subjects) | https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ |
| Flow diagrams for study population                                      | For RCTs: http://www.consort-statement.org/consort-statement/flow-diagram |
|                                                                        | For observational studies:                                           |
|                                                                        | https://www.ncbi.nlm.nih.gov/books/NBK259294/figure/?report=objectonly |
| Clinical trial regulations                                              | https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation |
| UKCCCR guideline for deriving or using cell lines                      | https://europepmc.org/backend/ptpmcrender.cgi?accid=PMC2363383&blobtype=pdf |
| Guidelines for the use of cell lines in biomedical research             | https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4453835/pdfbjc2014166a.pdf |
| The gene nomenclature for human and rat                                 | https://www.genenames.org/                                           |
|                                                                        | http://rgd.mcw.edu/nomen/nomen.shtml                                |
| NCBI reference sequence database                                        | https://www.ncbi.nlm.nih.gov/refseq/                                |
| Glossary of common terms in RCTs                                        | https://www.ncbi.nlm.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms |
|                                                                        | https://www.consort-statement.org/resources/glossary                  |
| RCT registries                                                         | https://clinicaltrials.gov/                                          |
|                                                                        | https://www.rct Ir                                                   |
| Details about units                                                    | http://physics.nist.gov/cuu/Units/                                  |

Abbreviations: RCT, randomized clinical trial; STROBE, strengthening the reporting of observational studies in epidemiology; UKCCCR, United Kingdom Coordinating Committee on Cancer Research; WMA, World Medical Association.

For hypothesis-testing papers, study question(s), intervention(s), variables measured, and the order of the measurements should be explained (14). Furthermore, it is expected that this section covers the information including dependent and independent variables, controls (e.g., baseline, control group, and placebo), study duration, and sample size (14).

The authors should present the specific design of the study, for example, randomized controlled trial, prospective/retrospective cohort study, case-control study, cross-sectional survey, and experimental study, or describe its key components (interventional vs. observational study, longitudinal vs. cross-sectional design) (8). An overview on observational and interventional study designs can be found elsewhere (38, 39).

For observational studies, study location and relevant dates (i.e., period of recruitment, period of exposure, follow-up, and data collection) should be described (20). An extension of the STROBE statement (Table 2) suggests more details for the study design section in molecular epidemiologic studies (22); these details describe the specific study designs (nested case-control and case/cohort) (40) and the setting of the biological sample collection (amount of sample, nature of sample collection procedures, participant conditions, time between sample collection and relevant clinical or physiological endpoints), biological sample storage and processing until biomarker analysis (centrifugation, timing, and additives), and biomarker biochemical characteristics (half-life of the biomarker and chemical and physical characteristics).

For human clinical studies, the authors are requested to specify the trial design (e.g., parallel and factorial), phase of clinical trial (phase I, II, III, or IV), and the allocation ratio (ratio of intended numbers of participants in each of the comparison groups) (41). More information regarding common terms and designs of clinical trials are provided as useful links in Table 2.

A further subheading entitled procedures or interventions may also be considered for clinical trials. In this section, authors need to provide detailed information for randomization procedures, including the method used to generate the random allocation sequence (computer-generated random numbers) and mechanisms used to implement the random allocation sequence (sequentially numbered containers), stratification, and random block sizes (if applicable) (41). According to the CONSORT statement (Table 2), it also should be described who generated the random allocation sequence, who enrolled participants, and who randomly assigned participants to interventions (41).

If applicable, the authors should state which type of
In this section, the authors need to clearly describe how study variables (i.e., exposures or independent variables, outcomes or dependent variables, covariates, or potential modifiers) were measured \((8, 15)\). If applicable, diagnostic criteria need to be clarified for the variables (i.e., exposure, outcome and/or confounder); moreover, sources of data and details of methods of assessments (measurements) should be described for each variable of interest.

In animal studies, details of how, when (time of day), where (home cage and laboratory), and why (rationale for dose and route of administration) for each procedure should be reported \((19)\).

According to minimum information for publication of quantitative real-time PCR experiments (MIQE), details about sample processing and storage, RNA and DNA extraction and quantification, primer and probe characteristics, reverse transcription details, sample normalization, PCR efficiency, and data analysis should be provided in real-time quantitative PCR (qPCR) experiments \((46)\).

For genetic association studies, authors need to describe laboratory methods, including source and storage of DNA, genotyping methods and platforms (including the allele calling algorithm used and its version), and error and call rates. The name of the laboratory or center where genotyping was performed and comparability of laboratory methods (if there is more than one group) needs to be clarified. According to the STREGA statement, authors should specify whether genotypes were assigned using all the data from the study simultaneously or separately in smaller batches \((43)\).

To describe instruments, the manufacturer and model as well as the calibration procedures should be described; in addition, it should be clearly described how measurements were taken \((10, 15)\). Details of measurement characteristics (i.e., reproducibility, validity, and responsiveness) that influence the interpretation of the main results should also be described \((8)\); validity and reliability, key indicators of the quality of measurement instruments (e.g., equipment and questionnaires) used for data collection or measurement should be appropriately reported \((18)\).

| Method                                      | How to Report                                                                 |
|---------------------------------------------|-------------------------------------------------------------------------------|
| Familiar for everyone in the field          | Not to be mentioned                                                          |
| Well-established methods, protocols, standards or previously published methods | Should be described in brief with appropriate citation                        |
| Relatively uncommon methods                 | Should be described in sufficient details with reference to original description and specific modifications made |
| Newly developed method                      | Should be described in more details including all reagents, conditions, and equipments |

3.2.2. Methods of Measurements/Assessments

Although describing details in the M&M section depends on the type of study and the target audience, authors need to maintain a balance. As a rule of thumb, the details of the procedures should be included if the study replication would fail without them. All that reader needs to understand is how the key findings in this paper were derived. However, this section should not be like a procedure manual or a cookbook \((4)\).

The term “condensed” or “extended” has been used to describe levels of details used in the methods section \((44)\). In the condensed methods, little elaboration or justification is provided, whereas in the extended methods, authors need to provide a rationale of why and how the procedures were performed \((44)\). In practice, depending on the novelty of the methods used in the study, different levels of details may need to be described \((Table 3)\). To summarize documented methods, authors may begin with “in brief”; use of “briefly” instead is a common mistake because “briefly” describes the following verb and does not indicate the author’s intention to be brief \((16)\).

The rationale for method choices and characteristics of the study design may also be provided in the methods section \((10, 11)\). From an editor’s point of view, advantages and disadvantages, values and limitations of the techniques and methods, especially new ones, are better to be described using a general background of the field \((45)\).
3.2.3. Statistical Analysis

The basic requirement of writing the statistical section is providing description and justification for the statistical approaches and selection of statistical tests (14). General considerations for preliminary, primary, and supplementary analyses derived from statistical reporting guidelines (47, 48) and the common pitfalls (49, 50) in writing the statistical section are provided in Box 1. The Vancouver guideline states “describe statistical methods with enough details to enable a knowledgeable reader with access to the original data to verify the reported results” (51).

| Box 1. Useful Tips and Common Pitfalls in Writing the Statistical Method Section (47-50) |
|---------------------------------------------|
| **Useful tips**                                    |
| Identify statistical procedures used to modify raw data or calculate new variables (transformation of data to close to normality, calculation of ratios, calculation of derived variables, categorization of variables) |
| Specify primary analyses                                      |
| Identify included variables in the analysis (dependent variables, independent variables, and potential confounders) |
| Make clear which method was used for analysis (e.g., sample t-test was used to compare the means) |
| Verify that data conforms to the assumptions of the test (e.g., use of non-parametric tests for skewed data, and use of linear regression for linear associations) |
| Describe adjustments were made for multiple comparisons |
| Indicate which approach was used for treating outliers |
| Identify whether test was one- or two-tailed |
| Define within- or between-subject factors |
| Define the statistical significance level (e.g., 0.05) |
| Describe supplementary analyses |
| Describe methods used for ancillary analyses (e.g., sensitivity analysis, imputation of missing data, or testing the assumptions for methods) |
| Describe post-hoc analysis, unplanned subgroup analysis, or exploratory analysis |
| Describe the methods used to determine statistical power (in case of reporting null or negative results) |
| **Common pitfalls**                                    |
| Inadequate description of methods and analysis |
| Inadequate specification for statistical methods |
| Lack of clarification for categorizing continuous variables |
| Failure to use correct names of statistical methods |
| Lack of appropriate citation or clear explanation for unusual statistical methods |
| Failure to address missing data |

Statistical tests should be discussed in order to be applicable for data analysis (52). Typically, this section is initiated by preliminary analysis and descriptive statistics, describing the study population, and then it is followed by specific tests describing the association of variables or assessing the effect of experiments (52).

The exact value of sample size, e.g., the number of human subjects, animals, or cells for each analysis and how the data were presented (mean, median, standard deviation, standard error, or confidence intervals) should be specified. Furthermore, the statistical methods used to determine strategies for randomization/stratification and sample size estimation need to be clarified (14). Appropriate identification (i.e., name, version, company, city, state, and country) for the statistical package or program used for analysis must be mentioned.

4. General Considerations for Materials and Methods Section

4.1. Length

Typical length of the M&M section is 2 - 3 pages (each page is considered one page in a word processor, with conventional margins, 1.5 line spacing, and font size of 11), consisting of 6 - 9 paragraphs (each paragraph usually contains 100 - 200 words, not exceeding 750 words) (19); however, depending on the discipline and field of study, the length of this section may vary from the condensed to the extended form (44). Method sections of chemistry, mycology, and molecular biology may be categorized as condensed-form, whereas public health and medical research are considered as intermediate, and psychology, sociology, and education are organized in the extended-form (44). To keep the M&M more concise, some details of materials and methods may be allowed as appendix or supplementary documents that are published online (45).

To organize paragraphs, topic sentences can be used to signal the topic of a paragraph, especially when a subsection has more than one paragraph (14). Use of linking or transition phrases/ clauses (purpose phrases, time-related linking phrases, or causal linking phrases) to signal the topic of a paragraph is highly recommended (Table 4) (11, 14, 44).

The M&M section may include up to 5 - 15 references (19). Never reference a document that you have not read (53).

4.2. Tables and Figures in Methods: Yes or No?

Use of appropriate tables and figures helps authors to summarize large amounts of complex information of the study procedures; a common recommendation to reduce the word count (11). Flowchart of the study design may be a common form of figure referenced within the M&M section. Some guidelines are available to organize study flowcharts for different study designs, for instance, the CONSORT flow diagram for clinical trials (54) and the STROBE flowchart of study participants for observational designs like cohort studies (21), as shown in Table 2. This...
section does not include results (14, 55), although intermediate results such those used for calculations that are used for obtaining results for the study question such as standard curves are recommended to be included in this section (14).

4.3. Ordering Procedures in the Materials and Methods Section

Several parts of the M&M section should be written in a logical or chronological order; presenting the methods in a logical order helps the text to make complete sense; however, the actions should be mentioned in chronological order within a paragraph or sentence. Some believe that the use of numbers or bullets to describe a sequential procedure, provided that be acceptable by the journal, make the M&M section easier to read (11). As a general suggestion, no more than two actions should be presented in a sentence. To increase readability, the subject and verb in a sentence should preferably be close together (11).

4.4. Tenses and Voices

A general recommendation is that the M&M section should be written in the past tense, either in active or passive voice (5). Depending on the author’s field, the journal style, or the action described in the M&M section, the present simple tense may also be used, for example, this tense is required when a standard method is described or when the authors present their procedure, model, software, or device (11).

Although passive voice (e.g., was/were investigated, was/were evaluated, or was/were performed) is the more common form of verbs in this section, using the active voice to show the ownership of the investigators (e.g., we performed, we evaluated, or we implemented) have recently taken priority (5). However, there is a belief that the active voice is not appropriate for the M&M section because the focus would be shifted from the research to the researchers (11, 56).

4.5. Self-Assessing the Quality of the Materials and Methods Section

Self-assessment of the quality of the M&M section may be the last, but it is certainly not the least important step in the writing of the M&M section. Authors need to ask themselves “would a researcher be able to reproduce the study with the information provided in the method section?” (8). Using this approach, the authors would be reassured that all the critical information has been included, and unnecessary and redundant data have been excluded from this section; this process is useful to keep the paper’s storyline (8). In Box 2, a checklist comprised of the most important questions for general quality assessment of the method section is provided.

To ensure all the necessary information is included in the methods section, referring to reporting guidelines that are available for the most common study types (e.g., CONSORT for clinical trials, STROBE for observational studies, STARD for diagnostic research, PRISMA for systematic reviews and meta-analyses, and ARRIVE for animal studies) is highly recommended (Table 2).

Table 4. Useful Phrases to Organize Paragraphs of Method Section (8, 44)

| Aim | Phrases/Clauses |
|-----|----------------|
| To state purpose of method (purpose phrases at the beginning of sentence) | To detect, to avoid, in order to identify/understand, to enable, to allow, to determine, to control, to establish whether, to compare, in an attempt to make |
| To link related time procedures | Before, after, during, prior to, on arrival |
| To state a reason (causal related phrases) | Based on, on the basis, because of, in spite of, in light of |
| To justify use of a special method | We believe, we think |
| To state similarity with previous methods | Is reported, is detailed, as described, as explained, as proposed, is based on, was inspired by, is practically the same |
| To describe the apparatus and materials | Use, adopt, employ, consists of, is made up of, is composed of, is based on, design, develop, set up, incorporate, exploit |

Box 2. Most Important Questions for Self-Assessment of Method Section (11, 44)

| Questions |
|---------------------------|
| Does the method describe the procedures such that reader can easily follow and replicate it? |
| Is the length of the method section (number of paragraphs and sentences) appropriate? |
| Are the subheadings and paragraphs appropriately organized? |
| Has every step been covered in a clear and complete manner? |
| Has choosing of the methods been clearly justified? |
| Is the method as concise as possible, with clear and short sentences? |
| Has the previous methods been properly cited? |
| Has everything been provided in a logical and/or chronological order? |
| Have linking phrases (purpose statements, time-related phrases, justifying phrases) been properly used? |
| Does the method section meet the grammatical constructions correctly? |
| Have the correct tenses (past simple vs. present simple) been used throughout the text? |
| Have abbreviations been used minimally and in a proper and reasonable way? (Use standard abbreviations instead of writing complete words; define each abbreviation the first time that it is used) |
| Has the method section been organized according to the journal’s style? |

5. Conclusions

The M&M section is the most important part of a research paper because it provides detailed information to
other scientists/researchers to reproduce the study and judge the validity of the study’s findings. In the M&M section, “materials” refers to what was examined (e.g., humans, animals, cell lines, or tissues) and various chemicals and treatments (e.g., drugs, culture media, and gases), and the instruments used in the study. “methods” presents how subjects or objects were employed to answer the study question, that is, how measurements and calculations were made and how data analysis was carried out. Useful tips and common pitfalls in the M&M section are briefly reviewed in Box 3.

Box 3. Brief Review of Useful Tips and Common Pitfalls in the Materials and Methods Section

**Useful tips**

- Describe the study design, setting and participants, data collection, data analysis, and ethics approval
- Keep a logical or chronological order in writing
- Provide n values for number of the patients, animals, or number of cells, organs, and biopsies for in vitro study
- Provide inclusion and exclusion criteria of the subjects
- Describe details for recruitment of the study subjects, randomization and/or blinding
- In case of intervention, provide dose, administration route, timing of administration, duration of intervention
- Provide exact information about the control group (e.g. placebo, saline, vehicle)
- Describe primary, secondary, and other outcomes
- Describe details of the measurements
- Describe validity and reliability of measurement tools

**Common pitfalls**

- Too little or too much information
- Lack of providing method for all results
- Use of “dangling modifier” because of overreliance on passive voice
- Lack of approval by an institutional review board
- Lack of approval by the ethics research committee
- Inappropriate, suboptimal, insufficiently described instrument
- Insufficient description of study population
- Incomplete description of the sampling method
- Lack of adequacy in addressing confounding variables
- Describing methods like an advertisement

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