Writing Methods: How to Write What You Did?

SHILPA KHANNA ARORA AND *DHEERAJ SHAH

*From Departments of Pediatrics; PGIMER and Dr Ram Manohar Lohia Hospital, and *University College of Medical Sciences and GTB Hospital; New Delhi, India.*

Correspondence to: Prof. Dheeraj Shah, Department of Pediatrics, University College of Medical Sciences and GTB Hospital, Dilshad Garden, Delhi 110 095, India. shahdheeraj@hotmail.com

The section on Methods is the most vital part of a study as well as of a manuscript. It is the most critically evaluated section of a paper not only by the reviewers but often by the readers as well. It should always be written in a simple and clearly understandable language, and should be objective. Apart from being the most vital part, it is also generally the lengthiest section of any research paper, unless a methodology paper for that research is published separately [1]. While writing this section, the authors must ensure that it is crisp, concise and complete in every aspect to address all the queries pertaining to the study like 'who', 'where', 'when', 'what' and 'how' [2].

GENERAL CONCEPTS, FRAMEWORK AND WRITING STYLE

This section, while being written for a research paper, must present exactly the same information as in 'Material and Methods' section of the study protocol or thesis. Thus, it must be meticulously built up, giving the maximum time and thought, while preparing the research protocol. A precise and objectively written methods section in a protocol will save time and efforts, as often it can be simply replicated in the final manuscript. The main difference between the two would be of the tense *i.e*. future tense in the protocol and past tense in the paper [3]. Often, authors need to truncate the 'Methods' in the final paper so as to match with the Results that are presented for that particular paper, and also to avoid unnecessary details keeping in mind the recommended word count limits of the journal. Describe methodology in such a manner that it has all the information (including references) reader needs to replicate the study/ experiment without access to the detailed study protocol [4].

The authors must ensure fluency while writing the methods. A common mistake that makes the write-up appear disjointed is use of both passive as well as active voice within the same section. For example,

"The participants were recruited from the outpatient department of the xyz hospital. We collected blood samples from all the patients. The samples were stored at -80 °C. We analyzed the serum antibody levels of the stored samples after all the patients were recruited."

One must stick to either the point of view of the experiment (passive voice) or the point of view of the experimenter (active voice) throughout a paragraph to ensure coherence [5]. Though style manuals prefer the active voice for medical and scientific writing, the passive voice has its place in the Methods section. Hence, you can alternatively modify the above statement in either of the following ways:

"We recruited participants from the outpatient department of the xyz hospital. We collected blood samples from all the patients, and stored the samples at –80 °C. We analyzed the serum antibody levels of the stored samples after recruiting all the patients" Or

"The participants were recruited from the outpatient department of the xyz hospital. Blood samples from all the patients were collected, and stored at –80 °C. The serum antibody levels of the stored samples were analyzed after all the patients were recruited."

You can present the methodology in a structured or an unstructured format, depending on the journal's requirements. Structured representation makes it more clear and objective for easier comparability between different studies. Unstructured format, though lacks objectivity, may be a better option for some types of studies like descriptive and qualitative studies [6]. Print journals often prefer unstructured format to save space. Irrespective of the framework, the components of this section essentially remain the same, and have been provided in ***Box* 1** as a checklist.

Study Setting, Duration and Design

Study setting description involves mentioning the place where the study was conducted which may be more than

Box 1 CHECKLIST FOR METHODS SECTION

- Study setting and place
- Duration
- Study design
- Ethical considerations
- Consent and assent
- Funding information
- Patient confidentiality
- Trial registration details (if any)
- Follow standard reporting guidelines
- Participant selection and sampling
  - Definition of participants (cases and controls)
  - Sampling technique used
  - Inclusion criteria
  - Exclusion criteria
- Method of randomization (for controlled studies), including group allocation details
- Blinding details (if applicable)
- Exact procedure/Intervention (with references)
- Primary and secondary outcome variables
- Sample size calculation
- Statistical analysis

one in case of multi-centric studies. Specify the place from where the patients/samples/clinical records were recruited/obtained like out-patient department/inpatient department/emergency/medical record department, for a hospital-based study. The place of study may be a school, village or district in case of a community-based study. One should also mention all the departments involved in carrying out the study apart from the primary department. The exact duration over which the study was carried out must also be specified, including period of enrolment of participants and their follow-up.

Study design must be specified in the beginning of the Methods section. Medical research is broadly classified as primary and secondary. Secondary research involves summarizing the results available from primary research in the form of systematic reviews and meta-analyses. Primary research that involves synthesizing the evidence can broadly be classified into basic medical research, clinical research and epidemiological research; though there is no rigid demarcation in these study areas [7]. The commonly used epidemiological study designs are depicted in ***Fig.* 1**. Descriptive studies help to generate a hypothesis by simple description of certain population parameters and finding some associations. Analytical studies help test such hypothesis to establish causation. Analytical studies can be observational or experimental. The purpose of an observational study is to follow the natural course of events in one or more groups formed on the basis of presence/absence of exposure, risk factor or disease. Whereas in an experimental study, the investigator intentionally manipulates one or more independent variables after controlling the effect of potential confounders and analyzes the results of that intervention [8]. Apart from these, there are certain areas of special research like qualitative research, decision analysis, operations research, health systems research, quality assurance, cost-effectiveness/ economic analysis, which are beyond the scope of this article.

The exact layout of Methods section depends on the type of study design. Nowadays, majority of the journals recommend the authors to adhere to the respective reporting guidelines for different types of studies to promote transparent, accurate and good quality reporting (***Table* I**) [4,9-17]. These guidelines help the authors elaborate the study in detail that makes the evaluation and analysis of medical literature easy for not only the editors and reviewers, but also for the readers and researchers [4].

Ethical Considerations, Confidentiality, Clinical Trial Registry and Funding Information

All the clinical studies involving human subjects need ethical clearance from the local/institutional ethical committee/review board before initiation of recruitment of subjects. The same is applicable for animal studies as well. A declaration about the ethical clearance is mandatory in virtually every medical journal specifying the authority from where it has been obtained. The study must comply with the principles of the Declaration of Helsinki [4] – a set of ethical principles regarding experimentation involving human subjects developed for the medical community by the World Medical Association (WMA) [18]. It was first adopted in 1964 and has undergone several revisions with the latest one in 2013. The ICMR guidelines on research on human subjects (available from *http://icmr.nic.in/ethical_guidelines.pdf*) can also be utilized for this purpose [19].

The authors need to maintain patient confidentiality; hence should refrain from using patients' names, initials, or hospital numbers, especially in illustrative material. One must specify the details regarding obtaining informed consent from the participants/guardians for inclusion in the study and publication of clinical details or/and clinical photographs. Assent must be taken from all the subjects more than 7 years of age and the same must be mentioned in the manuscript.

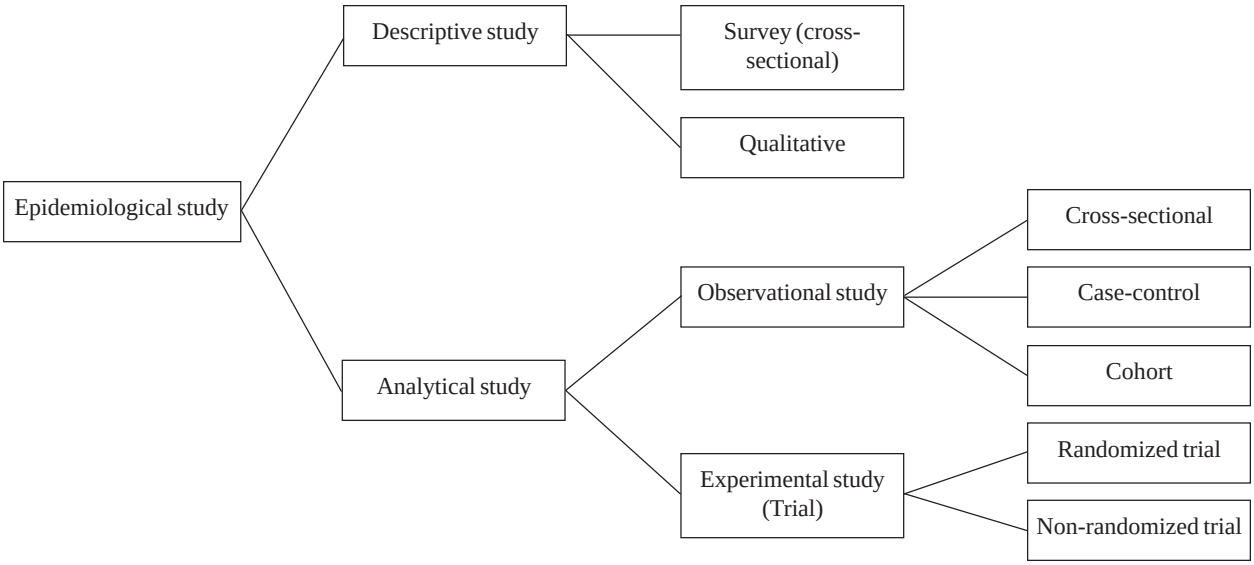

Fig. 1: *Some common epidemiological study designs.*

Most of the medical journals recommend that all clinical trials involving human subjects to be registered in a public trial registry before the onset of patient enrolment, and hence also publish the trial registration number in the manuscript at the end of abstract [4]. Clinical trial registration helps in preventing duplication of research activities, and attempts to prevent selective reporting of research outcomes. One may access these registries to acquire knowledge regarding current researches going on in a particular field. Due to these reasons, International Committee of Medical Journal Editors (ICMJE) encourages registration of the studies with non-trial research designs as well, even though it is not mandatory. All the clinical trials being carried out in India need to be registered in the Clinical Trials Registry of India (*www.ctri.in*) which is hosted by the Indian Council of Medical Research. Alternatively, researchers may register their trials in one of the following trial registries: *http://www.actr.org.au*; *http://www.clinicaltrials.gov*; *http://isrctn.org*;*http://www.trialregister.nl/trialreg/index.asp*; and http://www.umin.ac.jp/ctr. Funding information may be specified in the methodology section, though majority of the journals require a separate declaration regarding funding to be furnished during manuscript submission.

Population, Sample and Participant Characteristics

Authors must describe the population from which they have chosen the participants of the study. A description of how the participants were selected *i.e.* the type of sampling technique used (*e.g.* simple random, stratified, cluster, convenience) is also important. Subjects for the research may be patients, laboratory samples, animals, hospital records, *etc*. Similarly, for a systematic review or meta-analysis, the subjects will be clinical studies like randomized controlled trials (RCTs). In case of trials, provide details regarding process of randomization and allocation of subjects to the different groups. Specify the methods of allocation concealment and blinding wherever applicable. One should avoid labeling the different groups with alphabets (groups A,B) or numbers (groups 1,2); rather stick to names *e.g*. Immunized group and unimmunized group, to minimize confusion to the readers [20].

In comparative studies like Case-control studies and Controlled trials, there is a group of subjects that does not receive an intervention, receives a placebo or receives a different intervention. It is equally essential to describe the comparison or the control group characteristics as the main study group. The manuscript must incorporate the criteria for selection of controls and the methodology used for allocation of groups that was used to ensure comparability. The authors must give criteria used for matching, the method of randomization (simple, stratified, block, *etc*.), and technique of allocation concealment and blinding, wherever applicable [2].

Specify the detailed criteria (*e.g*. age, sex, well-defined disease condition) which make the participant eligible to be included in the study. Studies usually also have some exclusion criteria – parameters that make a subject ineligible to be a part of the study even after

TABLE I REPORTING GUIDELINES FOR DIFFERENT TYPES OF STUDY DESIGNS (Available from *http://www.equator-network.org/*) [9-17]

Type of Study	*Reporting Guidelines*	*Website*
Randomized trials	CONSORT (**CON**solidated**S**tandards **o**f **R**eporting **T**rials)	*www.consort-statement.org*
Observational studies	STROBE (**St**rengthening the **R**eporting of **Ob**servational Studies in **E**pidemiology)	*http://strobe-statement.org/,*
	RECORD (**Re**porting of studies **C**onducted using **O**bservational **R**outinely-collected health **D**ata) [10]	*http://www.equator-network.org/reporting-guidelines/record/*
Systematic review & Meta-analysis	PRISMA(**P**referred **R**eporting **I**tems for **S**ystematic Reviews and **M**eta-**A**nalyses)	*http://prisma-statement.org/*
Case reports	CARE (**Ca**se **RE**ports)	*http://www.care-statement.org/*
Qualitative research	SRQR (**S**tandards of **R**eporting **Q**ualitative Research) [11]	*http://www.equator-network.org/reporting-guidelines/srqr/*
	ENTREQ(**EN**hancing**T**ransparency in **RE**porting the synthesis of **Q**ualitative research) [12]	*http://www.equator-network.org/reporting-guidelines/entreq/*
	COREQ (**CO**nsolidated criteria for **RE**porting**Q**ualitative research) [13]	*http://www.equator-network.org/reporting-guidelines/coreq/*
Diagnostic/ Prognostic studies	STARD 2015 (**STA**ndards for **R**eporting **D**iagnostic accuracy studies) [14]	*www.stard-statement.org/*
	TRIPOD(**T**ransparent **R**eporting of a multivariable prediction model for **I**ndividual **P**rognosis **O**r **D**iagnosis) [15]	*http://www.equator-network.org/reporting-guidelines/tripod-statement/*
Quality improvement studies	SQUIRE (***S**tandards for **Qu**ality **I**mprovement **R**eporting **E**xcellence*)	*http://www.squire-statement.org/*
Economic evaluations	CHEERS (**C**onsolidated **H**ealth **E**conomic **E**valuation **R**eporting **S**tandards) [16]	*http://www.equator-network.org/reporting-guidelines/cheers/*
Study protocols	SPIRIT (**S**tandard **P**rotocol **I**tems: **R**ecommendations for **I**nterventional **T**rials) [17]	*http://www.spirit-statement.org/*

fulfilling the inclusion criteria. The exclusion criteria are generally outlaid to avoid bias or due to some feasibility or ethical issues. There should not be any overlap in the inclusion and exclusion criteria. In other words, the exclusion criteria can be applied only on the subjects who already fulfill the inclusion criteria. For example, in a study on prevalence of celiac disease in adolescents with anemia, inclusion criteria could be:

"*All adolescents (age 10-19 years) residing in a particular community, and having hemoglobin values below the cut-offs (Hb<12g/dL in 10-19 y girls and 10-14 y boys and Hb<13g/dL in 15-19 y boys*)[Reference]."

Exclusion criteria for this study could be:

"*Those having received a blood transfusion or hematinics in preceding 4 weeks, those with acute illness* (*e.g. fever, diarrhea, respiratory tract infection) or known chronic disease (e.g. chronic liver disease, chronic kidney disease, thalassemia*)."

Take care not to write: age <10 years or >19 years or Hb>13 g/dL as exclusion criteria as these subjects already do not fulfill the inclusion criteria.

Procedure, Intervention and Outcome Measures

The procedure may be just recording an observation, recording the response to a questionnaire, carrying out a diagnostic test or doing an intervention which may be preventive or therapeutic. Mention the exact details of the intervention applied to the participants in case of trials; description of the drug, device or educational

program being tested, including the exact dosage, formulation, schedule and duration. For trials as well as for observational studies, discuss about the process of collecting information and data for analysis. Give description of the variables analyzed, technique and the instruments used in the study. Give the reference if the technique used in the study has been published previously or is a well-established, standardized one. If that is not the case, ensure to describe it well with the exact temporal sequence. Similarly, one must give the manufacturer's name and place in parenthesis if a novel apparatus has been used. For example,

"Fasting blood sample was collected to measure HbA1c by HPLC (BIO-RAD Germany) and lipid profile (enzymatic method). The GE-Lunar DPX Pro (GE Healthcare, Wisconsin, USA) was used to measure body compositin [21]."

Outcome measures or study end points are the parameters which will fulfill the objectives of the study and are classified as primary and secondary. Primary outcome, which is generally single, is the parameter on which the study hypothesis is based and is the main objective of research. The other outcomes of interest, which may be more than one, are designated as secondary outcomes. These all should be clearly defined while writing a manuscript. For example,

"The primary outcome was CPAP failure, defined as need for intubation and mechanical ventilation within 72 hours of initiation of respiratory support.…..… The secondary outcomes related to respiratory support were duration of CPAP support, duration of supplementary oxygen requirement, maximal flow, PEEP and oxygen requirement, incidence of air leaks and Broncho-pulmonary dysplasia. Other outcomes included incidence of patent ductus arteriosus, intraventricular hemorrhage.…..."[22].

Statistical Analysis

The data management strategy and statistical analysis technique used for a study must always be provided in sufficient detail, to the extent that any skilled person having access to the original data set is able to reproduce the results. The manuscript must include an account of sample size calculation with its justification as well as literature citation as appropriate. The computer software used for data analysis should also be mentioned. The authors should avoid using generalized statements and must write statements specific to that study parameters and outcome variables. The statistical tests and the comparisons must be specified. Common statistical methods may just be mentioned but advanced or unusual methods must be described or cited with an appropriate reference. Description of statistical analysis of the primary outcome must precede that of secondary outcome(s) [20].

WHAT NOT TO WRITE IN METHODS

Methodology must be described in a complete but concise manner avoiding any unnecessary detail that is irrelevant to the readers. Methods section should include only that information that was available at the time of planning of the study, whereas any information that was collected while carrying out the study should be a part of the Results [4]. Avoid giving any explanatory information in this section like background and rationale for using a particular methodology for a particular study that may be covered under the section on discussion. Methods section must include only the proposed sample size and not what was actually achieved. The account of the subjects who were selected by sampling till the ones who were eventually analyzed, including details like refusal to give consent, exclusion based on exclusion criteria must also be covered under the Results and not Methods [3].

To conclude, the section on methods is the foundation stone of any research being planned or written; hence it must be clear and elaborate. It should also be sufficiently described for easy reproducibility as JC Jones said, "*Methodology should not be a fixed track to a fixed destination but a conversation about everything that could be made to happen*." Laying the strong foundation of a robust Methods section will pave the way for smooth writing of the rest of the paper. The next write-up in this series will lead the readers about intricacies in presenting your Results.

Happy Writing!

Contributors: DS conceptualized the review. SKA and DS searched for literature and drafted the manuscript. DS revised the manuscript. SKA and DS approved the final manuscript.
*Funding***:** None; *Competing interests:* None stated

REFERENCES

1. Dewan P, Gupta P. Writing the title, abstract and introduction: looks matter! Indian Pediatr. 2016;53:235-41.
2. Azevedoa LF, Canário-Almeidaa F, Almeida Fonsecaa J, Costa-Pereiraa A, Winckb JC, Hespanholb V. How to write a scientific paper - writing the methods section. Rev Port Pneumol. 2011;17:232-8.
3. Shah D. Material and methods: How will I do it? *In*: Gupta P, Singh N, editors. How To Write the Thesis and Thesis Protocol. New Delhi: Jaypee Brothers; 2014. p. 75-82.
4. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. Available from: *www.icmje.org/recommendations/*

Accessed February 25, 2016.
5. Kallestinova ED. How to write your first research paper. Yale J Biol Med. 2011;84:181-90.
6. Maxwell JA. Methods: what will you actually do? *In*: Maxwell JA, editor. Qualitative Research Design: An Interactive Approach, 2nd ed. Thousand Oaks, CA: Sage; 2005. p. 79-104.
7. Röhrig B, du Prel JB, Wachtlin D, Blettner M. Types of study in medical research. DtschArztebl Int. 2009; 106: 262-8.
8. Porta M, Greenland S, Last JM, editors. A Dictionary of Epidemiology. 5thed. New York: Oxford University Press; 2008.
9. EQUATOR Network. Oxford: EQUATOR Network. Available from: *www.equator-network.org/reporting-guidelines/*. Accessed February 25, 2016.
10. Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, et al; RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. PLoS Med. 2015;12:e1001885.
11. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89:1245-51.
12. Tong A, Flemming K, McInnes E, Oliver S, Craig J. Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ. BMC Med Res Methodol. 2012;12:181.
13. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007;19:349-57.
14. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig L, *et al*., For the STARD Group. STARD 2015: An updated list of essential items for reporting diagnostic accuracy studies. BMJ. 2015;351:h5527.
15. Collins GS, Reitsma JB, Altman DG, Moons KG. Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD): The TRIPOD statement. Ann Intern Med. 2015;162:55-63.
16. Husereau D, Drummond M, Petrou S, Carswell C, Moher D, Greenberg D, *et al*. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. Eur J Health Econ. 2013;14:367-72.
17. Chan A, Tetzlaff JM, Altman DG, Laupacis A, G¸tzsche PC, Krleþa-Jeriã K, *et al*. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. Ann Intern Med. 2013;158:200-7.
18. World Medical Association. World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects. JAMA. 2013;310:2191-4.
19. Ethical guidelines for biomedical research on human participants. New Delhi: Indian Council of Medical Research; 2006. Available from: *http://icmr.nic.in/ethical_guidelines.pdf*. Accessed March 17, 2016.
20. Wenzel V, Dünser MV, Lindner KH. A step by step guide to writing a scientific manuscript. Available from: *www.aaeditor.org/StepByStepGuide.pdf*. Accessed February 23, 2016.
21. Parthasarthy L, Chiplonkar S, Khadilkar V, Khadilkar A. Association between metabolic control and lipid parameters in Indian children with type 1 diabetes. Indian Pediatr. 2016;53:39-41.
22. Goel S, Mondkar J, Panchal H, Hegde D, Utture A, Manerkar S. Nasal mask versus nasal prongs for delivering nasal continuous positive airway pressure in preterm infants with respiratory distress: a randomized controlled trial. Indian Pediatr. 2015;52:1035-40.