MedicalBiostatistics.com

TIPS FOR THESIS WRITING AND PREPARING RESEARCH PAPERS

Initial parts of a manuscript
- Choice of TITLE
- Providing AUTHORSHIP credits
- Selection of KEY WORDS
- Structure of the ABSTRACT

Main body of the report
- Contents of INTRODUCTION
- Describing the METHODS
- Stating RESULTS
- Writing DISCUSSION

End features of a report
- Ethics of ACKNOWLEDGMENTS
- Framing KEY MESSAGES
- Writing REFERENCES
- Need of a BIBLIOGRAPHY
- Contents of APPENDIX

For an updated version, see
Basic Methods of Medical Research, Fourth Edition
by A. Indrayan (http://indrayan.weebly.com)
AITBS Publishers, Delhi
(Phones: 011-22009084) (available also at amazon.com)
email: aitbsindia@gmail.com, aitbs@bol.net.in

Describing METHODS

Credibility of a research depends to a great extent on the appropriate methodology. Describe it as accurately as possible: not just the planned one but also the one actually followed with justification of variation, if any. Consult the protocol because that can provide substantial help in preparing Methods section. The focus should be to describe why this study was done in that particular way. Specifically, include in this section the setting in which the study was carried out, the types of group of cases and controls studied, and the design adopted. Include justification of each.

Specify the setting. This could be a general community, a primary health centre, a referral or a general hospital (in-patients or out-patients), a private clinic, or any such facility. This helps readers to determine the applicability of the results to their own setting. If the source

of data is records, specify that clearly. Also describe the steps taken to preserve the quality of the study.

All applicable elements of design should be stated. In particular state what groups were covered and why that many subjects were studied in each group, and how were they selected. Explain the inclusion and exclusion criteria and state the period of recruitment. State the statistical power and justify the difference you considered medically important. State whether the study is prospective, retrospective or cross-sectional if observational; or therapeutic, prophylactic, diagnostic, or screening if a trial. Describe the design in details using Figure as a guide. Justify the choice of controls. State matching criteria if applicable. Lay out such as cross-over or repeated measures, and one-way, two-way, or factorial, etc., should be specified. Actual implementation of the intricacies such as randomisation, blinding and matching should be fully explained. In case the study involves medical predictions, describe about validation methods used. The reader should understand from Methods section about all potential sources of bias and how were they controlled. Sometimes a diagram of flow of research helps in achieving clarity.

Fully specify the intervention if any including the dosage and the duration. For drugs and chemicals, include their generic name, route of administration, etc. Explain ethical considerations. State the mechanism of follow-up and its duration, clearly specifying the censoring (incomplete observations because of the design) if any. The percentage of subjects who dropped out should be stated separately from those who had to be withdrawn because of adverse effects. Any deviation from protocol and its reasons should be highlighted.

Specify the instrumentation and provide references that describe them. Give details of any new method or apparatus used, including its testing. Justify the variation, if any, you used from the standard practice. Give as much details as necessary for the reader to replicate the study. Demonstrate that your instruments are valid and reliable, and that you were able to use them properly.

Clearly define antecedent and outcome measures, and establish their relevance to the study objectives. Explain how you operationalised the research variables. In case you have used categories such as mild, moderate and severe, clearly specify how such categorization was derived. For continuous quantitative variables, categories are not desirable but if you still use categories for reasons such as easy interpretation, explain the rationale. If scores are used, give complete methodology or a reference to the source that describes it fully. Also comment on the validity and reliability of the scoring system. If your research is on developing a scoring system, provide details of its theoretical justification and state how you plan to assess its adequacy.

For the number of subjects, begin with how many were potentially eligible, how many examined for eligibility, how many actually found eligible, how many included in the study for data collection, how many dropped out and how many completed the study, how many were followed up for different durations, how many were excluded from analysis for reasons such as outlying values, and how many actually analysed in each group. A flow diagram may be helpful such as CONSORT for trials. Give reasons for dropouts at each stage.

State also about the possibilities you envisioned of contamination in data and how did you cleaned up the data. This should include the remedial steps you took for handling missing data, if any. The second distinct possibility is error in measurement. This occurs all the time but must remain within tolerance limit. Your report must indicate to the reader that you were alive

to such errors and were able to manage them with proper instrumentation and their adequate handling. In case multiple observers or raters are used, include how they were trained for standardized readings and how inter-rater reliability was assessed. For your own safety, raise a red flag at the time of drafting a report whenever you find possibility of sloppiness. Resolve them adequately in final draft.

Identify the confounders and state how they were tackled. Limitations of the methods should be stated without inhibition including how these limitations might affect the results. Such a statement would tell the readers that you are aware of these gaps, and would help them to evaluate the utility of results more realistically in the context of their own setting.

State the statistical methods you have used to analyse the data in sufficient detail to permit replication. Explain how these methods are appropriate for the kind of data in hand, and how will they achieve the stated objectives of research. Cite reference if the method is not well-known. The procedure must conform to the research design, and the models and hypotheses you started with. Also state the methods you used to control for confounding bias. Also describe methods used to examine subgroups and interactions, and how the missing data were addressed. Specify the computer software used. Remember some software are not reliable and different software can give different results depending upon the algorithm used. State the confidence level and the level of significance wherever applicable. Whereas 95 percent confidence and 5 percent level of significance tend to be accepted without question, any other level is expected to be accompanied by its justification. Describe any validation method you used such as sensitivity analysis.

As always, methods section should also be precise yet should provide details for any one to repeat the investigation for confirmation. Do not do methodological overkill. Only new methods should be stated fully; for others just give reference. The reader should be convinced that the methodology is adequate to ensure reasonable reliability and validity of conclusions.