RMJ research series: How to write-up research methodology

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MY EXPERIENCES:

I had never been involved in writing research before my fifth year of medical school. I was motivated but also knew that it required skills and experience that I did not have at the time. However, after attending a global health course which contained a topic on research methodology I was encouraged and felt that I could plan and start doing my undergraduate research. An initial problem I had was that, when reading research articles, I could not understand why the authors decided upon using a certain methodology, and what they based that decision on. I consulted my colleagues who had graduated in medicine to help me understand research methodology, and ultimately it was my supervisor that helped me understand how to design the methodology for my study.

While writing up the project I used a standard format, starting with what was already known (literature review), and progressing to describe the format by which we would investigate the unknown.

The methodology is a systematic recipe which includes all the steps taken in carrying out the research, from data collection to data analysis. Clearly stating our methods not only helps us as researchers to focus on the best approach to answering our research question, but allows others to assess the quality of our study design and replicate it if needed.

In this article we continue with our Research Series to support researchers in conducting and writing about research [1], focusing on Methods, as part of the standard IMRAD (Introduction, Methods, results, and Discussion) structure to writing an original research paper [2].

> ***TIP:*** *The key is to ask yourself; "Could another scientist repeat my study using my description of the methods used?"*

Methodology – the most important section of a research write-up?

The Methods section gives a clear and comprehensive overview of study procedures. There should be enough information that readers can evaluate the persuasiveness of the study for themselves and replicate the study if needed [2], [3].

This section is a crucial section of any manuscript and is where those who appraise your study will look to decide the validity of your results and conclusions [4]. The methodology section convinces the reader of a number of things:

1. Your method of gathering data is suitable to answer your research question

2. Data has been managed and analyzed appropriately

3. You have accounted for sources of bias (systematic error (issues) with obtaining data that alter results, confounding (outside factors that cause false statistical associations), and error to ensure internal and external validity

4. That the research performed was ethical

> ***TIP:*** *Describe fully the steps undertaken, but be wary of excessive detail that would not be required to "repeat the study". The write-up should be concise [5]*

Writing style

The language you use should always be accurate, concise, clear and objective. Use correct English throughout, ensuring that spelling, punctuation and grammar are correct.

Tense: The present tense should be used for known and established facts, whereas the past tense should be used to describe your experiment and the results you collected. Grammar: In the methods section of your research paper, unlike the rest, you should use the passive voice (for example: "the data were collected" instead of "we collected the data"). Be concise by eliminating redundant words or phrases, but avoid contractions or little-known abbreviations. If you use an abbreviation often, write it out the first time it appears in your paper, such as "World Health Organization (WHO)". Sentences should be kept short, with one piece of information conveyed per sentence.

Box - Key sections to be included and considered in the methodology write-up

Study Type
Study population

Internal and external validity
Inclusion and exclusion criteria
Recruitment & enrollment of participants
Selection bias
Describe cases and controls, exposed and non-exposed
Randomization and blinding
Study setting and location:
Setting, location, time
Multi-center studies
Sample size (power calculation):
Variables and outcomes:
Objective measurement of variables
Primary and secondary outcomes
Data management
Study pitfalls
Random error
Bias
Confounding
Statistical analysis
Which statistical tests were used to analyse the data
Hypothesis testing
Standardization
Ethics/study oversight
Risk to subjects (including safeguards to mitigate these risks):
Funding & Sponsors
Potential conflict of interest
Confidentiality
Informed consent
Incentives for subjects
Institutional review board (IRB) approval/date

Study type:
Describe the type of study that was undertaken. If your study design is well known and an accepted form of research methodology (see Figure 1) you need not explain it at length, but merely note how you have implemented it; however, if your study design is more complex, novel, or qualitative it is good to describe the study in sufficient detail that it could be replicated [5].

Consider why you have chosen a certain methodology and be prepared to justify your choice and acknowledge the specific risks of error and confounding inherent in your study [4].

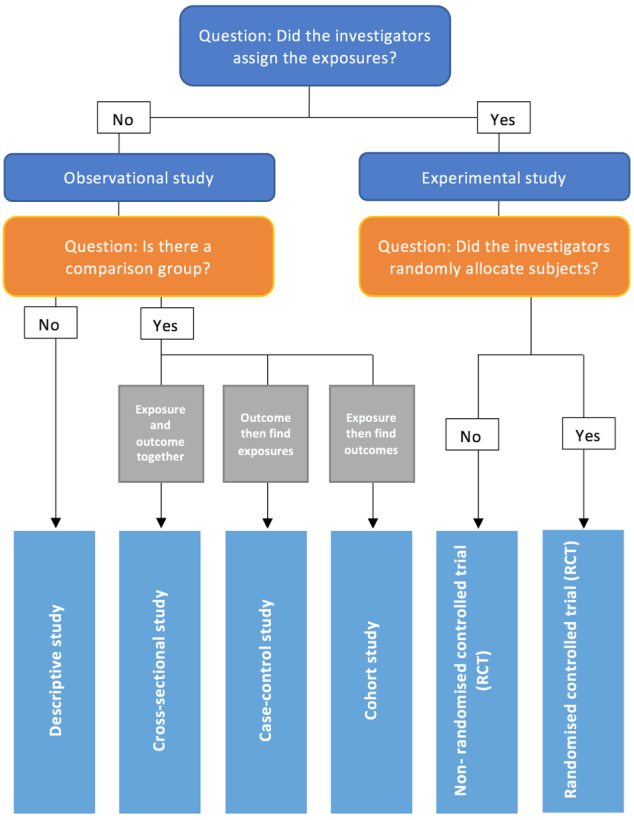

Figure 1: Classification of common research methodologies [6].

Study type:

Study population
A full description of the study population should be given.

Internal and external validity: Describe what steps were taken to gain a population that was both internally and externally valid. Internal validity is decreased by poorly controlled experiments that allow confounders to alter results. External validity refers to how well results can be generalized to "external" populations of interest, and is related to the characteristics of the population being studied.

Inclusion and exclusion criteria: Study subject selection should be guided by predefined inclusion and exclusion criteria to keep enrolment consistent and objective. Describe fully any criteria that are required for a subject to be enrolled. Describe any criteria that would exclude the subject from enrolment; however, do not just state the opposites of the inclusion criteria.

Recruitment & enrollment of participants: Give a clear description of how you recruited and enrolled subjects who meet the above inclusion and exclusion criterion. Was it opportunistic, continuous sampling etc.

Guarding against selection bias: Study subject selection should be done carefully to guard against selection bias. The approach to and location of study selection can lead to certain characteristics influencing observations and outcomes among the study population. Describe what steps you took to avoid selection bias, e.g. random sampling.

Determine cases and controls, exposed and non-exposed: In relevant studies it is important to describe which subjects are cases (have the condition being studied) or controls (do not have the condition), exposed or non-exposed. Describe how was each group of subjects was identified and enrolled.

Randomization and blinding procedures (where relevant): In a controlled trial, randomization (random assignment to intervention and non-intervention groups) and blinding (hiding group status from patients and investigators to avoid bias) should be planned before the study. Several strategies can be used. If you have performed a randomised and/or blind trial don't merely state it was "randomised" or "blind", a full description of how patients were randomised and/or blinded needs to be given. This allows the reader to make their own judgment on whether your methods were robust enough to minimise biases.

Study setting and location:

The setting and location in which your study takes place will have an impact on the validity of your study or the conclusions you have drawn. Your study may be urban or rural, clinic, hospital or lab-based, over a brief period of time or over years, and it is good practice to mention the specific circumstances under which you conducted your study. These factors will have an important bearing on the external validity of the results. Therefore these need to be described fully so that the reader can determine if the results are relevant to subjects in their own population.

Multicenter studies present a particular challenge; for these, be sure to describe how coordination occurred between cites to ensure consistency.

Sample size (power calculation):

A key way to reduce the impact of "random error" on your study results is by increasing the sample size. With larger sample sizes one can be more certain that results are due to an effect, rather than chance. If a study is "under powered" (i.e. it didn't have enough subjects) then any "non-significant" results (i.e. p-value >0.05) are not relevant as there may in fact be a true difference between the groups, but your groups were not large enough to find the difference between them. Therefore a brief description of the sample-size calculation will help the reader know that the study is adequately powered to make valid conclusions [7].

Variables and outcomes:

In order to minimize information bias it is important to identify and objectively classify different categories in your experiment. These may be exposures, controlled or uncontrolled variables, or your primary outcomes of interest. It is useful here to make use of known and validated appraisal tools, such as staging systems, objective tests (such as blood investigations), and to consider the ways in which these categorization schemes may be undermined or invalidated. Having objective measurement tools as opposed to subjective measures not only makes your data more valid, but it makes the study easier to replicate.

For each outcome and variable you must say how it was classified and measured. Clearly describe collection tools like interviews, physical examination findings, questionnaires, case notes, results of investigations, readouts from measurement devices and data collected in other studies.

You should describe your "primary outcome". The primary outcome is the main outcome under study and relates directly to your research question.

Data management: Your data management includes how you collected, stored, and accessed your data as well as any means of quality control you applied. These steps function to ensure accurate translation of information gathered into an up-to-date error-free secured database. Describe the procedures you took to ensure the security and confidential handing of your data, such as password protections on electronic databases and physical barriers to hardcopy data. Describe any computer programs used for data entry and access. Any software used pre-analysis, such as for stratification or randomization, according to and matching of confounding factors, should also be noted.

Statistical analysis:

Detail all the different statistical tests you have applied to your data; often there are appropriate tests for the type of study conducted (see table 1).

Table 1: A guide to test selection for epidemiological data [8]

Type	Specification	Test to use if data is	
		Normally distributed	Skewed / Ordinal
Comparing between:	The averages (means) of two independent groups	Independent t-test	Mann-Whitney test Wilcoxon rank sum
	The averages (means) of 3+ independent groups	One-way ANOVA	Kruskal-Wallis test
	The difference between the averages (means) of two paired samples	Paired t-test	Wilcoxon signed rank test
	>3 measurements on the same subject	Repeated measured ANOVA	Friedman test
Testing the association between:	2 continuous variables	Pearson's correlation coefficient	Spearman's correlation coefficient
	Continuous variables and any other type of variable	Simple linear regression	Transform the data
	Categorical variables and any other type of variable	Logistic regression	
	2 categorical variables		Chi-squared test

Ethics/study oversight:

You should report the ethical considerations and approval of your study.

- **Risk to subjects:** Include a full breakdown of all the risks within your study, as well as any measures you have taken to safeguard your participants against those risks. Categorize the risks according to type: physical risks, social risks, emotional risks, legal risks and financial risks
- **Funding & Sponsors:** Detail any sponsors or funders that have supported your study
- **Potential conflict of interest:** Disclose all relationships that could be construed as giving rise to a conflict of interest
- **Confidentiality:** You must detail how you have handled sensitive or confidential information.
- **Informed consent:** You must detail how you enlisted your participants and sought their informed consent (and assent for minors).
- **Incentives for subjects:** If you have incentivized participation in your study in any way you must mention it.
- **Institutional review board (IRB):** If the study was approved by an IRB (as all human research should be) then detail by which board and give a reference number.

TIP: CRITICAL APPRAISAL

One of the best ways to improve your methodology is to use an "EBM critical appraisal tool". These are freely available from many sources

1. Centre of Evidence Based Medicine (CEBM): Oxford University (click here)
2. Critical Appraisal Skills Programme (CASP): Institute of Health Science, Oxford. (click here)
3. The Joanna Briggs institute: University of Adelaide (click here)
4. Faculty for medical and health sciences: University of Auckland (click here)

REFERENCES:

[1] C. Page, C. Nsanzabaganwa, T. Walker, and P. Cartledge, "RMJ Research Series: literature searching," Rwanda Med. J., vol. 74, no. June, pp. 21–24, 2017.

[2] I. D. Cooper, "How to write an original research paper (and get it published)," J. Med. Libr. Assoc., vol. 103, no. 2, pp. 67–68, 2015.

[3] G. M. Liumbruno, C. Velati, P. Pasqualetti, and M. Franchini, "How to write a scientific manuscript for publication," Blood Transfus., vol. 11, no. 2, pp. 217–226, 2013.

[4] E. Marshall and E. Boggis, "The statistics tutor's quick guide to commonly used statistical tests," Statstutor Community Proj., vol. 49, no. 10, pp. 1229–1232, 2016.

[5] R. H. Kallet, "How to write the methods section of a research paper.," Respir. Care, vol. 49, no. 10, pp. 1229–1232, 2004.

[6] D. a Grimes and K. F. Schulz, "Epidemiology 1: An overview of clinical research: the lay of the land.," Lancet (London, England), vol. 359, no. 9300, pp. 57–61, 2002.

[7] S. R. Jones, "An introduction to power and sample size estimation," Emerg. Med. J., vol. 20, no. 5, pp. 453–458, 2003.

[8] E. Marshall, "The statistics tutor's quick guide to commonly used statistical tests," Statstutor Community Proj., 2016.