

## Chapter 2 Methods Section

Based on the IMRaD (Introduction, Methods, Results and Discussion) format discussed previously, the second section of a scientific research paper is the methods. The purpose of the methods section is to provide a comprehensive picture of the methodological approach of the study in a straightforward and transparent manner. Broadly, the methods section should allow the readers to understand the dataset under consideration and the analytical steps undertaken in the study, and give a sense of reproducibility of the study (1,2).

### 2.1 The “Bridge”

Following the introduction section, the methods section connects the previously developed research question to the results section and equips the readers with all methodological details necessary to interpret the findings that will be presented in the next section. As such, the methods section is the “bridge” between the introduction and the results section. Typically, the main elements of a methods section are: study design and data collection; setting, analytic sample and variables; data and statistical analysis.

Furthermore, breaking the methods section into sub-sections can be a helpful way to present the methodological approach in an organized fashion. The main elements of the methods section can be presented as sub-sections.

1. **Statement of study design and data collection:** the study design (e.g. cohort study, cross-sectional study, etc) and other key elements of the study design should be mentioned early in the methods. The data source(s) and how data was collected should be detailed.
  - a. **Sampling strategy:** for cross-sectional studies, it is recommended to describe the sampling design for the data source.
2. **Setting, analytic sample and variables:** if relevant, the setting, locations and timeframe (e.g. recruitment, follow-up, data collection) can be described. For the analytic sample, how it was obtained from the target population should be clearly described, including inclusion and exclusion criteria. The key outcome and explanatory variables should be defined, including case definitions or algorithms. You can also present the details of methods of measurement or assessment if they are relevant, or if they are derived from other variables or measures. It is important to identify which covariates were included and why they were included or not included (variable selection).
  - a. For the **study population**, if there are any differences between people who were included in the study population compared to those who were excluded from the source population, these differences should be described.
  - b. **Ethics approval:** a statement about ethics approval from a research ethics board or other ethical considerations should be included.
3. **Data/statistical analysis:** all statistical methods used for descriptive and inferential analyses should be described, including the methods used to control for confounding. If

you have conducted sensitivity analyses, these should be described. The methods section should contain descriptions of statistical approach used for all findings presented in the results section. In general, the statistical program or software and the packages used are also stated in this section.

When writing a scientific paper in epidemiology or in population and public health, the STROBE checklist (3) can be a helpful tool to ensure that you are reporting all necessary components in the methods section. Below we will have a look at two examples of papers presenting survey-based analysis with the STROBE checklist.

## 2.2 Examples

### 2.2.1 Example 1

This example is taken from Nikiforuk et al. (4), which was based on the NHANES data.

Table 1: A study about chronic hepatitis C infection and monocyte-to-platelet ratio

Elements	Location in the methods section	Comments
Study design	The sub-section titled “data, design and study population”	The authors outline briefly this was a cross-sectional study.
Setting		The data source for the study, NHANES, is described including the target population, location, timeframe and sampling design.
Participants	The second paragraph of the sub-section titled “analytic sample and variable selection”	The authors describe how the analytic dataset was created from the data source. Exclusion criteria is also included. Figure 1 in the paper illustrates who were excluded at each stage and helps readers to understand potential sources of selection bias and how these might affect the generalizability.
Variables	The first and second paragraphs of the sub-section titled “analytic sample and variable selection”	The exposure and outcome variables of interest are clearly defined, including the explanation of how the outcome variable “monocyte-

		<p>to-platelet ratio” was derived from two variables, complete blood count measures of monocyte count and platelet count. The authors include an additional file for more detailed description.</p> <p>The authors also provide the justification of how covariates were identified, with a directed acyclic graph included as an additional file.</p>
Data sources/measurement	The sub-sections titled “analytic sample and variable selection”	The authors provide information on how the key variables were measured, and further provide a reference for additional information on the data source, NHANES.
Bias	Throughout the sub-section titled “statistical analysis”	The authors described all methods applied to adjust for any potential confounding, such as in the sub-section “transformation of the monocyte-to-platelet ratio” and other methods including missing data and propensity score analyses.
Study size	Figure 1	Figure 1 clearly presents all people who were excluded at each stage and the remaining study sample size.
Quantitative variables	The sub-sections titled “analytic sample and variable selection” and “statistical analysis”	The authors describe how the continuous variables were derived for the outcome variable, and further, how the resulting outcome variable was dichotomized.
Statistical methods	Throughout the sub-section titled “statistical analysis”	The authors provide adequate information about descriptive, inferential, missing data and sensitivity analyses, including the

		statistical software and packages. The level of information provided ensures the reproducibility of the results if needed. The authors also include citations for relevant methods or analyses.
--	--	---

### 2.2.2 Example 2

This example is taken from Nethery et al. (5), which was based on the CCHS data.

Table 2: A study about the household income and contraceptive methods

Elements	Location in the methods section	Comments
Study design	The sub-section titled “data source, design and study population”	The authors state that this was a cross-sectional study.
Setting		The data source for the study, CCHS, is described including the target population, location, timeframe, response rates and sampling design.
Participants	The sub-section titled “analytic sample”	The authors describe how the analytic dataset was drawn from the CCHS data including the inclusion and exclusion criteria. As in the first example, the authors include a flowchart as Figure 1 to illustrate who were included/excluded at each stage, resulting in the analytic sample.
Variables	The sub-sections titled “outcome variables” and “exposure variable”	The definitions of outcome and exposure variables are stated clearly. The authors provide additional details on the outcome variables, including some potential sources of bias, which enhances the readers ability to interpret the findings. The authors also explain how the

		exposure variable was dichotomized.
Data sources/measurement		The authors outline specific questions from the CCHS (data source) that were used to derive the outcome and exposure variables.
Bias	The sub-sections titled “statistical analysis” and “sensitivity analysis”	<p>The authors describe some of the methods that were used to mitigate potential confounding (e.g. use of survey weights, multiple imputation, sensitivity analyses).</p> <p>The authors also provide the explanation behind the selection of confounders, providing background references.</p>
Study size	Figure 1	As in the first example, Figure 1 presents all people who were excluded at each stage and the remaining analytic sample size.
Quantitative variables	N/A	The key outcome and explanatory variables in this study were binary. In the “statistical analysis” sub-section, it is mentioned that the “age” variable is included as a confounder, and it isn’t clear whether this was a continuous or a categorical variable. However, this is neither key outcome nor explanatory variable, so the level of detail is perhaps not required.
Statistical methods	The sub-sections titled “statistical analysis” and “sensitivity analysis”	The authors provide details on the descriptive, inferential, missing data and sensitivity analyses, including the

		statistical software and packages.
Other	The sub-section titled “ethics approval”	The ethics approval for the use of data source is stated briefly.

### 2.3 Significance of the methods section in population and public health research paper

In population and public health, the methods section of the research paper should enable readers to assess the internal and external validity of the study. It should provide all the necessary information to understand in which ways the authors have made efforts to try to address their research question as accurately as possible. As Rothman et al. describes, generally the goal of epidemiologic research is to “*obtain a valid and precise estimate of the frequency of a disease or of the effect of an exposure on the occurrence of a disease in the source population of the study*” (6). In addition, as the introduction section would have described the importance of the research question in relation to the population and public health, researchers often aim to generalize the study findings to the relevant population groups. By providing clear and adequate information about the target population and how the study sample was selected from the source population, the methods section allows the readers to assess the generalizability of the study findings.

As such, a well-written methods section in a research paper in population and public health should contain necessary information about the analytical steps undertaken in the study, and sufficient description of the study design and target population to enable readers to understand what some of the potential sources of bias in the study are, and what measures were taken to minimize the bias. This allows the readers to interpret the internal and external validity of the study. A well-written methods section provides credibility and validity of the results and conclusions of the study.

After reading the methods section, the readers should have an understanding of the dataset which is under consideration in the study, who the target population was, how the data was collected, and how the analytic data was created (who are included and excluded). Based on the analytic steps described in the methods section, the readers should also be able to understand how the results and conclusions in the next sections of the paper derive from the statistical analyses. Finally, the readers should be able to replicate the study if needed and reproduce the results if they had access to the data source.

### 2.4 Common pitfalls

- Common pitfalls in the methods section can largely arise from not reviewing the key elements of the methods section carefully and missing some of the elements in consequence.

- Missing crucial elements providing information on the potential sources of selection or information bias can result in losing the reviewers' and editors' confidence in the validity and credibility of the study findings.
- Another common problem is not providing any explanations regarding the variable selection (i.e. how the covariates were included or not included in the model).
- Be mindful about plagiarism and self-plagiarism, especially if you are using the same data source or similar methods from previously published work.

## 2.5 Tips

- As in the introduction section, excessive and unnecessary details are discouraged. Unless the focus of your paper is the methodological approach, only discuss enough details to enable reproducibility and to highlight the elements that are relevant for the interpretation of the results. We talked about presenting the research as a “story”, any detail that are unnecessary or redundant to understanding this story should be avoided.
- The methods section should also include a statement on the ethical approval or any other ethical considerations.
- It's often a good idea to include a citation for the statistical test or method, if this is relatively unknown to the readers. This can also increase the credibility of the methods presented.
- Some journals focused on patient-oriented research encourage researchers to include any processes or efforts that were made to include patients or the community members during research. If patients or community members were involved in the study at any step, it can be a good idea to describe what their involvement was.

## References

1. Annesley TM. Who, what, when, where, how, and why: The ingredients in the recipe for a successful methods section [Internet]. Vol. 56, Clinical Chemistry. Oxford Academic; 2010 [cited 2021 Sep 19]. p. 897–901. Available from: <https://academic.oup.com/clinchem/article/56/6/897/5622467>
2. Kotz D, Cals JWL. Effective writing and publishing scientific papers, part IV: Methods [Internet]. Vol. 66, Journal of Clinical Epidemiology. Elsevier; 2013 [cited 2021 Sep 19]. p. 817. Available from: <http://www.jclinepi.com/article/S089543561300019X/fulltext>
3. Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: Guidelines for reporting observational studies. PLoS Med. 2007 Oct;4(10):1623–7.
4. Nikiforuk AM, Karim ME, Patrick DM, Jassem AN. Influence of chronic hepatitis C infection on the monocyte-to-platelet ratio: data analysis from the National Health and Nutrition Examination Survey (2009–2016). BMC Public Health [Internet]. 2021 Jul 13 [cited 2021 Sep 19];21(1):1–11. Available from: <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-11267-w>
5. Nethery E, Schummers L, Maginley KS, Dunn S, Norman W V. Household income and

contraceptive methods among female youth: a cross-sectional study using the Canadian Community Health Survey (2009–2010 and 2013–2014). *Can Med Assoc Open Access J* [Internet]. 2019 Oct 1 [cited 2021 Sep 19];7(4):E646–53. Available from: <https://www.cmajopen.ca/content/7/4/E646>

6. Rothman KJ, Greenland S, Lash TL. Validity in epidemiologic studies. In: *Modern Epidemiology: Third Edition*. 3rd ed. Lippincott Williams & Wilkins; 2011. p. 128–47.