

Analyzing and Reporting for Clinical Research

*What you need to know in 60
minutes or less*

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Working with acquired data

- Benefits
 - Data do not need to be captured = time savings
 - Efficiency – not all studies require acquisition of new data
- Limitations
 - No control over acquisition of data
 - Instruments used to capture the data
 - Population studied
 - Must be considerate of extensive work needed to capture the data (co-authorship, acknowledgement)

Major Roadblocks/ common errors

- Not understanding the context in which data were acquired
 - Population, cohort phenomenon, etc.
- Ensure ethical approvals for the analyses done/investigators

Major Roadblocks/ common errors

- Not scrutinizing hypotheses based on available data
 - Reconsider the most appropriate questions to meet your needs that can be understood with the data
- Poor external validity
 - Instruments used may not be most appropriate for clinical settings and may not translate to this setting

Step 1 – Understanding the data

- Where do the data come from?
 - Study title, investigators, funding agencies
 - What were the primary aims that led to data acquisition?
 - How were subjects recruited?
 - Who was left out of the final analysis?

Step 2 – Understanding the problem

- What is known about the question you are interested in?
- Has a similar study been conducted – if so, what did they find
- If not, has a similar study been conducted in a different disease/population? What can be learned about it?
- Consider the broader disease – what is known?

Step 2 – Understanding the problem

- Literature review
 - Using PubMed to understand the literature
 - Focused reviews
 - Use of a librarian to help develop a formal review
 - Reporting the information
 - Annotated bibliography
 - Using Endnote/shared documents within the lab
 - Formatting for journals
 - Review of journal specific requirements – getting citation template from the internet

Step 3 – Defining how the information was acquired

- What is the timeline under which the data were acquired?
- What other variables were acquired at the same time? Consider those important as predictors, outcomes, and covariates
- Are there other factors that will influence the study?

Step 4 - Hypotheses

- State your primary and secondary hypotheses
- Critical need to state these before you begin analyses
 - Risk for false discoveries; risk for multiple comparisons
- Make the hypotheses as specific as possible

Step 4 - Hypotheses

- Translate these hypotheses into precisely how they will be managed in the statistical analysis
 - Which variable will be used to define the major predictors, outcomes, and covariates
- Is your analysis feasible? – what is the likelihood that you will have meaningful power to answer this question?

Step 5 – Define your statistical methodology

- List:
 - What program will you use/version #?
 - How will you compare groups to be studied?
 - Consider distribution of the variables for parametric vs. non-parametric approaches
 - How will you test your main hypothesis?
 - Be specific – include covariates; clearly state what is primary and what is exploratory

Step 6 – Describe accrual and timeline

- Define when and how the subjects were recruited
- Define inclusion and exclusion criteria
- Define drop-outs and excluded cases that impact your data

Key: Understand and write something that would allow another person to reproduce your study based on the description you give

Step 7 – Demographics and clinical variables

- Compared groups to be studied
 - What variables are critical to compare: age, education, CD4, treatment, etc.
 - Do the two groups differ?
 - Prepare a table (Table 1 of most papers)
 - Keep in mind the distribution of the data

(p-values are easy to get – but, are the model assumptions met?)

Step 8 - Complete and present your major analyses

- Use graphs and tables liberally
- Do not limit yourself to those figures that will be used in presentation – in descriptive areas, be open minded.

Step 8 - Complete and present your major analyses

- Visually demonstrate what you found and summarize it in succinct sentences
- Use appropriate error estimates in graphs so that individuals can easily see the certainty in the data
- Use appropriate range for x and y axis (don't artificially make your data look better than they are)

Step 9 – Summarize your major findings

- Use 2-3 paragraphs to state:
 - What you found
 - Why it is important
 - What gaps (limitations) are there in your analysis
 - Where this research can take us mechanistically
 - What are the next steps?

Step 10 – Present your data to an audience

- Conferences
 - What is the best venue/audience?
 - What is feasible?
 - Be sure to know your audience
 - When a small crowd, acknowledge accomplishments of the crowd
 - Be humble!
 - Be comfortable saying “I don’t know” – but don’t say it too quickly.

Step 10 – Present your data to an audience

- Publication
 - What journal publishes similar work?
 - What audience do you want to target?
 - Where will the work have the greatest impact?
 - Other considerations:
 - What is the impact factor of the journal?
 - Is the journal referenced on PubMed?

Good Luck