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