Research Essentials

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sydney.edu.au/sydney-informatics-hub





Slides available here



Acknowledging SIH



- All University of Sydney resources are available to researchers free of charge. The use of the SIH services including the Artemis HPC and associated support and training warrants acknowledgement in any publications, conference proceedings or posters describing work facilitated by these services.
- The continued acknowledgment of the use of SIH facilities ensures the sustainability of our services.

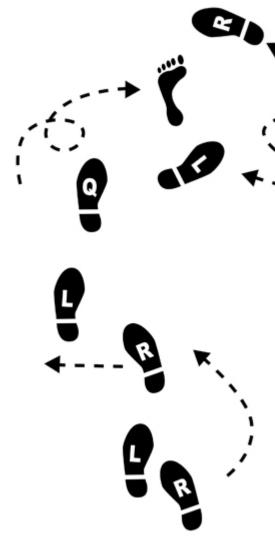
Suggested wording for use of workshops and workflows:

 "The authors acknowledge the Statistical workshops and workflows provided by the Sydney Informatics Hub, a Core Research Facility of the University of Sydney." What is a workflow?

- Every statistical analysis is different, but all follow similar paths. It can be useful to know what these paths are.
- We have developed practical, step-by-step instructions that we call 'workflows', that can you can follow and apply to your research.
- We have a general research workflow that you can follow from hypothesis generation to publication.
- And statistical workflows that focus on each major step along the way (e.g. experimental design, power calculation, model building, analysis using linear models/survival/multivariate/survey methods).

Statistical workflows

- Our statistical workflows can be found within our workshop slides.
- Statistical workflows are software agnostic, in that they can be applied using any statistical software.
- To access these statistical workflows and more, visit our <u>Workshops and Workflows</u> page.



Software workflows



- There may also be accompanying software workflows that show you how to perform the statistical workflow using particular software packages (e.g. R or SPSS). We won't be going through these in detail during the workshop. If you are having trouble using them, we suggest you attend our monthly <u>Hacky Hour</u> where SIH staff can help you.
- Our software workflows contain:
 - R code and comments.
 - SPSS syntax as well as screenshots of the point and click procedures and written methods.
 - Screenshots of the point and click procedures and written methods for other bespoke software.

During the workshop



 Ask short questions or clarifications during the workshop (either by Zoom chat or verbally). There will be breaks during the workshop for longer questions.



- Slides with this blackboard icon are mainly for your reference, and the material will not be discussed during the workshop.



- Challenge questions will be encountered throughout the workshop.

Research Essentials workshop overview

8-step general research workflow and other resources

- Where does this Workshop fit into the research process?
- Where does it fit in with other SIH training and support on offer?

Setting up your data for most analyses:

- Step 3: Collect and store data
- Step 4: Cleaning data

Workflow examples for common analyses – brief introduction to:

- Step 5: Exploratory data analysis
- Step 6: Inferential analysis

8-step general research workflow

General research workflow

- 1. Hypothesis Generation (Research/Desktop Review)
- 2. Experimental and Analytical Design (Sampling, power, ethics approval)
- 3. Collect/Store Data
- 4. Data cleaning
- 5. Exploratory Data Analysis (EDA)
- 6. Data Analysis aka inferential analysis
- 7. Predictive modelling
- 8. Publication















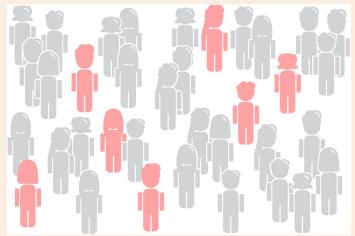






6. Statistical Inferential analysis – from sample to

population



Statistical inference:

"The theory, methods, and practice of forming judgments about the parameters of a population, usually on the basis of random sampling."

Collins English Dictionary

7. Predictive modelling – Inferential predictive statistics versus machine learning predictive analytics

 Inferential predictive statistics



Predicting temperature rise in climate change.

Machine learning/predictive analytics





Very accurately verify fingerprint to unlock a mobile phone.



Ecosystem of SIH statistical training

| Workflow step | Other training |
|------------------------------|--|
| 1. Hypothesis generation | Research Essentials |
| 2. Study design | Experimental Design Power and Sample Size Design and Analysis of Surveys 1 + Design and Analysis of Surveys 2: Advanced Topics Statistical Model Building |
| 3. Collect/store data | Research Essentials |
| 4. Data cleaning | Research Essentials |
| 5. Exploratory data analysis | Research Essentials |
| 6. Inferential analysis | Linear Models 1 to 3 + Statistical Model Building Introduction to Survival Analysis Meta-Analysis: An Introduction Design and Analysis of Surveys 1 + Design and Analysis of Surveys 2: Advanced Topics Multivariate Statistical Analysis 1: Dimension Reduction |
| 7. Predictive modelling | [Predictive analytics: Introduction to machine learning in R/Python (SIH Data Science)]: From 26th August |
| 8. Publication | |

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SIH training

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Different offerings, in person, online, and hybrid content in a variety of formats from webinars to interactive workshops.



Attendees at all career levels, from undergraduate students to senior professors, and representation from every Faculty and School.



Partnerships with national organisations like Australian BioCommons:

biocommons.org.au/training-cooperative.



Find out more on our training calendar:

sydney.edu.au/informaticshub/training. Or stay up to date with our newsletter.





| Statistics | Data Science | Research Computing | Bioinformatics | Events |
|--------------|-----------------------------------|----------------------------------|------------------------------------|----------------------|
| Fundamentals | Machine Learning | High Performance Computing | 'omics Techniques | Hacky Hour |
| Modelling | Visualisation | Cloud Computing | Reproducible Pipelines | Summer Schools |
| Specialist | Natural Language Processing | Containers | Data Analytics | Coding Challenges |
| | Geospatial Analysis | Workflows | National Compute Infrastructure | |



Ecosystem of other USyd training

| Workflow step | Other training |
|------------------------------|--|
| 1. Hypothesis generation | Library research support: <u>Literature and systematic review</u> |
| 2. Study design | |
| 3. Collect/store data | RedCap- Various trainings for survey data from introduction to advanced Research Data Management modules and techniques |
| 4. Data cleaning | |
| 5. Exploratory data analysis | SIH: EDA in R |
| 6. Inferential analysis | |
| 7. Predictive modelling | |
| 8. Publication | Library research support: Publishing |

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Research Data Consulting

Research Integrity & Ethics Administration

digital.research@sydney.edu.au

Book a consultation



- eNotebook
- RedCap
- •Research data store
- •OneDrive (Office 365)

Supported platforms

- Google Drive
- Survey Monkey
- •Portable Drives e.g. USB

Do not use



<u>University-supported research data</u> platforms: Features and comparisons

Research data that is managed optimally improves research efficiency and reach, as well as ensuring its integrity and security, and meeting legislative/policy/funding/publishing requirements.

The Research Data Consulting team assists researchers to enhance their research productivity and improve data management practices. They provide:

- Short consultations to integrate digital tools and data management into your research.
- Training and functional support for university supported tools/platforms.



Research Computing





Commercial



National



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Hacky Hour

For researchers who code or analyse data



- A monthly meetup where anyone from the University students, staff and university affiliates can collaborate and get support e.g., swap notes, get help, or learn new techniques in programming and data science.
- Experts & mentors from SIH and across the University will be available to advise and answer questions on coding, data analytics or digital tools.
- Come join us on zoom the 3rd Wednesday of every month, 2 - 3pm!
- sydney.edu.au/informatics-hub/hacky-hour

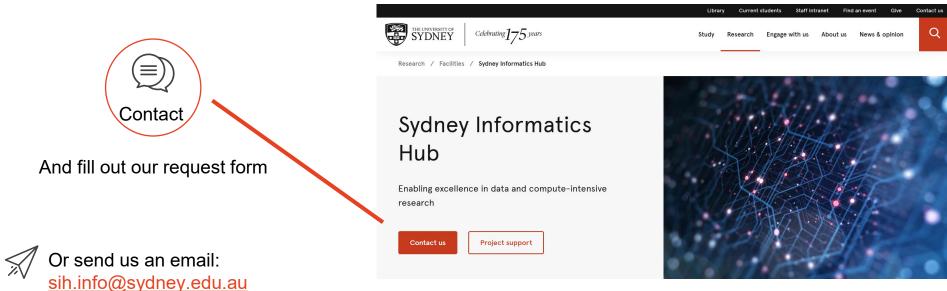


How to engage with us





sydney.edu.au/informatics-hub



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General research workflow

- 1. Hypothesis Generation (Research/Desktop Review)
- 2. Experimental and Analytical Design (Sampling, power, ethics approval)
- 3. Collect/Store Data
- 4. Data cleaning
- 5. Exploratory Data Analysis (EDA)
- 6. Data Analysis aka inferential analysis
- 7. Predictive modelling
- 8. Publication





















The first question: Which car will you take?













The first question: Which car will you take?

Getting from step 3 to step 8 will involve using software. Will it be:

Graphical User Interface
(GUI) – like an automatic car
Interactive, point and click and
Menu driven
Easier to get started



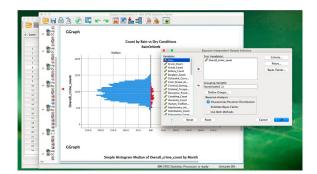
Command line interface (CLI) – like a manual car Writing code Easier to handle complex and/or large data sets



Software choice as the first question: GUI versus CLI

- Which software are you more familiar or comfortable with?
- How do you record your analysis for reproducible research?
- By documenting, you should always be able to re-run your analysis from start to finish (and get the same result)!
- If using interactive processing, you should keep track of the commands you run.

Graphical User Interface (GUI) SPSS



Command line interface (CLI) R code

```
R>
R> lm(Sepal.Length ~ Species, data = iris)

Call:
lm(formula = Sepal.Length ~ Species, data = iris)

Coefficients:
(Intercept) Speciesversicolor Speciesvirginica
5.006 0.930 1.582
```



Statistical software used at USyd

- A variety of statistical software options are supported at USyd, and what you use may depend on your lab or faculty or school.
 - The main two we see in our statistical consulting are R (CLI) and SPSS (GUI).
 - We also consult with clients using jamovi, SAS, Stata, Graphpad Prism, Python and Genstat.
- To access these and more:
 - As a student you may need to access via the citrix workspace:
 <u>Student IT: Apps</u>
 - As a researcher (with valid staff ID): What software is available to University staff?

3. Collect/store your data

- A. Research data management
- B. Organise your data for input into statistical software

A. Research data management

- Data storage
- Back up EVERYTHING including original data collection forms or raw data (images, electrical signals, DNA sequences, whatever).
- Data entry will you be using manual data entry?
- Ideally double-data entry followed by comparison.
- Be wary of spreadsheets especially entering, editing analysing in the same sheet.
- Statistical software generally doesn't allow easy editing once you have entered your data.



A. Research data management

- Have you got a Research data management plan according to University policy?
 - What is a Research Data Management Plan (RDMP)?
 - What are the university supported tools for data collection and storage?
 - What is an eNotebook?
 - Where can I store my data?
- Consider appropriate folder/directory structure, file naming and version control for your project, or at least your part of it.
 - Good enough practices for scientific computing
 - <u>Best practices for data management and sharing in experimental</u> biomedical research



A. Research data management

Guide to storing and managing your projects research data Unsuitable as Prohibited for primary protected University supported and licenced platforms storage for research data research data Other cloud Highly Australian Research Data OneDrive Teams Protected Local storage, tools (e.g. Platform/Tool eNotebook REDCap (Enterprise) (Enterprise) SharePoint Google Drive Service (AIS) (Enterprise) Dropbox) survey and data networked data chat. removable imaging electronic capture, storage, large collaboration, function cloud storage collaboration, epository and media, local cloud storage files, HPC notebook including cloud storage cloud storage analytics storage Clinical trials access suitable for data 0 0 classification ~ ~ ~ **~** ~ ~ stored in Australia various external collaborator **~ ✓** ~ **~** access context and ~ × × **~** commentary n/a supported syncing with local ~ ~ n/a n/a n/a сору unlimited 25TB max available storage unlimited unlimited 5TB 2TB+ unlimited (default 2TB) (default 2TB) backup and disaster **✓** recovery audit trail/version **~ ~** control ~ versioning retained manual up to 60 days 7 years 7 years 7 years





highly protected
 highly protected data needs additional file encryption
 protected
 public

Highly Protected data may require additional encryption depending on some platforms.

Protected data may benefit from encryption.

For more information about research data classifications, go to https://sydney.edu.au/research-data-classifications

For research data management enquiries, please contact digital.research@sydney.edu.au

Version control – keeping track of your files

- Use a separate directory for each discrete analysis.
- When processing data and intermediate files save with a new name.
 - Use a good <u>file naming convention</u> to keep track of files.
- Save frequently so if you lose a version, you do not have to redo too much work.
- For collaborative research consider using eNotebook or other version control systems, e.g. <u>Git</u> (free) or <u>GitHub</u>.
- Create a log file in the same directory and use version control (e.g. name sequentially, date/time stamp, for example:
 - "20230208 stats101 workshop v2.0.xlsx" (orders files chronologically).

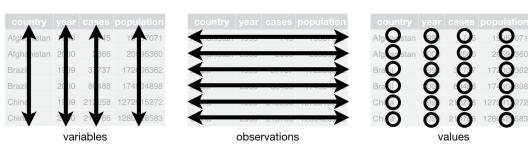
Version control – keeping track of your files

Example of a version log file in Excel:

| File name | Description | # Obs | # Vars |
|------------------------|--|-------|--------|
| Mydata_v1_30102022.csv | Original data entry by KS, 1 record per person | 250 | 34 |
| Mydata_v2_01112022.csv | Eligible records only based on study inclusion criteria with new variables created for analysis: BMI calculated from recorded height and weight; babies age processed to be consistently in months instead of days and weeks as well; number of pets categorised (none, 1-2, 3+) | 204 | 37 |

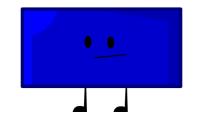
Data formats – tidy data

- Depending on the design of your experiment/survey you may have a mix of demographic data on each individual, and measurements.
 - You may need multiple tables and a unique ID for each individual to link them, or just have the demographic data repeated when transforming to long format
- Wide and long can become relative terms especially if you have clusters of subjects.
- Tidy data is a consistent way to should have:
 - One variable in each column
 - One observation per row
 - One value per cell



R for Data Science: 12 Tidy data

B. Organising a dataset for analysis



- Most programs read in data in a rectangular format:

- E.g. A text file you can read it in Notepad or any text editor or Excel, csv etc.
- A header including column names in the first row.
- Each row thereafter being the data itself (often corresponding to a single unit of interest e.g. person, animal, plant, plot, farm, machine, business, school, hospital etc).
- Each column represents one variable.
 - ID variable identifies the subject.
 - Demographic variable characteristics of the subject. including their treatment.
 - Measurement variable some observation on the subject.
- A delimiter between each column (comma .csv and tab .tsv/.tab/.txt).
- Do a quick skim of your dataset and look at the corners to see if it is actually rectangle.

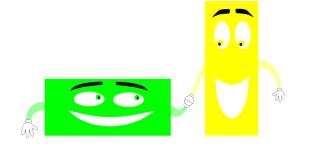
Pitfalls when coming from Excel

- Watch out for:
 - Merged cells
 - Cell comments
 - Colour coding
 - Blank rows
 - Data in multiple sheets
 - Particular coding of missing data/blanks/non-applicable
- Deal with the above in Excel before exporting to text. Sometimes these have been added to annotate the data, or make it easier to read. Other times, annotations must be represented in text file.
- A good summary of these pitfalls is provided in this paper.
- Check your data once it is imported into the statistical software.

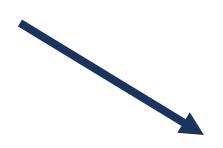


B. Data formats – transformations

| Patient ID | Time 1 | Time 2 | Time 3 |
|---------------|--------|--------|--------|
| 1 | 50 | 55 | 60 |
| 2 | 47 | 49 | 50 |
| | | | |



Wide/unstacked format



| Patient ID | Time | Body weight |
|------------|------|-------------|
| 1 | 1 | 50 |
| 1 | 2 | 55 |
| 1 | 3 | 60 |
| 2 | 1 | 47 |
| 2 | 2 | 49 |
| 2 | 3 | 50 |
| | | |

Long/stacked format

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B. Organising a dataset for statistical analysis – data coding

- Specify type of variable: ensure your analysis software knows whether a variable is numeric (continuous or discrete), or categorical/factor/string/character (text).
- Label variables, either within the software or by keeping your own record (e.g. Age = Age at interview in years).
- Label variable values/'levels' within categorical variables. While numerical codes are
 often displayed when you extract survey data, e.g. from your REDCAp project, the data
 may come without label definitions, so keep track of these, e.g. 1 = "Male", 2 = "Female",
 3 = "Non-binary".
- Correctly code missing values according to software program: ensure your analysis software knows that the data is missing and not '0' or some other value (e.g. 999, 777, 99, 77).

4. Data cleaning



Data cleaning: data wrangling and data dictionary

A simple example of a data dictionary:

| 4 | А | С | D |
|---|---------------|------------|-----------|
| 1 | | | |
| 2 | Questions | Categories | Code used |
| 3 | Q1_Age(years) | 20-30 | 1 |
| 4 | | 31-40 | 2 |
| 5 | | 41-50 | 3 |
| 6 | | 51-60 | 4 |
| 7 | | >60 | 5 |
| 8 | Q2_Gender | male | 1 |
| 9 | | female | 2 |

- Data cleaning involves examining* the variables in the dataset and creating new variables for analysis by recoding/processing variables as required.
- Use short but informative variable names; it's a good idea to have a data dictionary.
- Names should keep track of transformations/recoding, e.g.
 - age = original data in years.
 - age_c2 = age categorised into two categories (young vs old).

^{*} More on how to examine, i.e. describe the distribution of variables later in this workshop.



Data cleaning: data wrangling and data dictionary

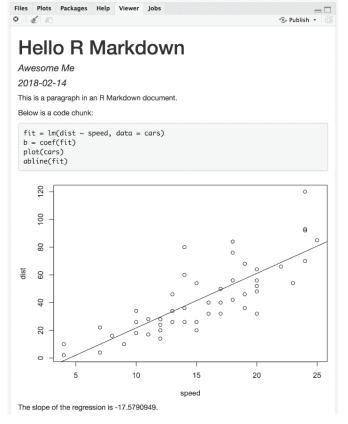
- If you are using R, the janitor package is great for cleaning up variable names.
 - janitor: Simple Tools for Examining and Cleaning Dirty Data
- Regardless of your software choice, below are some suggested styles for naming your variables:

| Case Style | Argument (in R) | Example | |
|----------------------|--|-------------|--|
| Snake case | "snake" | employee_id | |
| Lower camel case | "lower_camel" | employeeld | |
| Upper camel case | "upper_camel" | Employeeld | |
| Screaming snake case | "screaming_snake" | EMPLOYEE_ID | |
| Lower case | "lower" | employeeid | |
| Upper case | "upper" | EMPLOYEEID | |
| Title case | "title" | Employee Id | |
| Sentence case | "sentence" | Employee id | |
| Pascal case | "pascal" (alias for "upper_camel") | Employeeld | |
| Small camel case | "small_camel" (alias for "lower_camel") | employeeld | |

Keep track of analyses

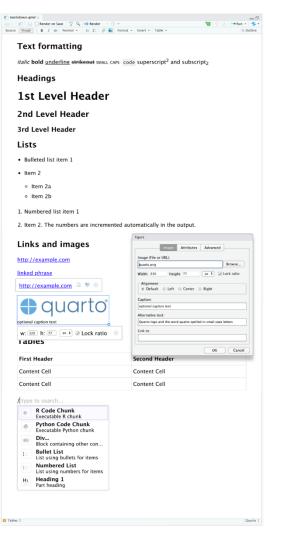
- Remember you should be able to repeat analysis from the start, to demonstrate/enable reproducibility.
- For statistical programming languages:
 - Name the program file logically.
 - Use structure, work in blocks or 'chunks' of code for different sections, e.g. 'descriptive analyses' do it for all predictors in one go.
 - Log file same name as program file, different extension VERY important as record for interactive mode!
 - Use functions to avoid repetition.
 - Use appropriate level of comments, e.g. key steps and results.
 - Consider using an Rmarkdown/Quarto notebook if using R.
- Also covered in <u>Good enough practices in scientific computing</u>.

Example R Markdown and Quarto files



R for Data Science: Chapter 27 R Markdown

> R for Data Science: Chapter 28 Quarto



Data cleaning in action

| . Motivated Resident esearch Project | | | | vvn | at | are so | me c | bvi | ous | thin | gs abo | out th | nis file that | need updatin | ıg? | |
|---|--------------|--------|--------------------------|-----------|----|--------------|-----------|----------|----------|-----------|-----------|----------|------------------------|----------------------------|-------------|------------|
| tudy_id dob | Race | Sex | Hispanic | | A | dmission GFR | Day 1 gfr | DAY2 | GFR' (| day 3 GfR | Day 4 GFR | DAY5 GFR | diagnosis | sediment | HD catheter | . NV fistu |
| . 11/11/19 | 67 White | Male | Hispanic | | | 17 | 1 | 12 | 10 | 22 | 34 | 4 | 1 hypotension | many granular casts | Yes | lo |
| 11/12/19 | 90 Caucasian | Female | Not Hispanio | | | 21 | 1 | 17 19 bu | t poor c | 12 | 19 | 2 | sepsis | muddy brown casts | Yes | lo |
| 3 may 5 19 | 0 White | Male | Hispanic | | L | 32 | - | 20 | 45 | 11 | 15 | 2 | bleeding out | many epithelial cell casts | No | lo |
| 3-Jun- | 81 Other | Female | Not Hispanio | | | 11 | | 9 | 6 | 5 | 9 | 1 | 3 norovirus diarrhea | muddy brown casts | YES | YES |
| 7/06/19 | 84 Af-Am | Male | Not Hispanio | | | 15 | - | 12 | 9 | 8 | 11 | . 1 | 1 sepsis | muddy brown casts | YES | lo |
| 9/04/19 | 80 Black | Female | Н | X4 | n | percent | valid | d_per | rcent | 26 | 38 | 4 | 1 liver failure | many epithelial cell casts | No | lo |
| 13/01/19 | 85 White | Female | Hispani | F | | 0.08 | | .0952 | | | 39 | 4 | 3 pneumonia sepsis | many granular casts | No | lo |
| 7 15/11/19 | 68 Asian | F | Hispani | | | | | | | 38 | 47 | 5 | 1 line sepsis | many epithelial cell casts | No` | IO |
| 22/04/19 | 82 Mixed | Male | Not His | F | 1 | 0.04 | | . 0476 | | 33 | 36 | 4 | 1 C diff diarrhea | many epithelial cell casts | No | lo |
| 12/10/20 | 03 White | 11 | Not His F € | nale | 7 | 0.28 | 0. | . 3333 | 33333 | 3 9 | 11 | . 1 | 1 NSAID tox | muddy brown casts | Yes | IO |
| 1. 6/11/19 | 82 White | F | NH | М | 3 | 0.12 | 0. | .1428 | 85714 | 4 29 | 36 | 4 | 1 burns | muddy brown casts | Yes | es |
| 12 9/07/19 | 79 Caucasian | 11 | Not His | | 1 | 0.04 | | .0476 | | 0.7 | 44 | . 4 | B pyelo | many epithelial cell casts | No | llo |
| 13 5=11-198 | 4 Black | F | NH | | _ | | | | | 33 | 39 | 4 | 1 urethral obstruction | many epi cell casts | Yes | lo |
| 1 7/04/20 | 04 Af-Am | 11 | Hispani | 4ale | ь | 0.24 | | . 2857 | | 4. | 44 | 4 | GI bleed | many granular casts | No | lo |
| 1 8/03/19 | 90 Asian | 11 | NH | Sex | 1 | 0.04 | 0. | . 0476 | 5190! | 36 | 39 | 4 | 3 sepsis | rare gran casts | No | llo |
| 15 6/09/19 | 83 WHITE | Male | Not His | <na></na> | 4 | 0.16 | | | N/ | 39 | 47 | 5 | 1 salmonella | many granular casts | No | llo |
| 1 11/07/19 | 86 WHITE | Female | Not His pan n | | • | 33 | | J2 | 57 | 34 | 48 | 5 | 2 sepsis | rare granular casts | No | IO |
| 1) 9/06/19 | 87 Black | Male | Hispanic | | | 22 | 2 | 20 | 24 | 24 | 39 | 4 | B esophageal varices | many epithelial cell casts | Yes | lo |
| 2) 29/03/19 | 79 Caucasian | Female | Hisspanic | | | 232 | 1 | 19 | 15 | 18 | 28 | 3 | B dehydration | many granular casts | No | lo |
| 2 11/08/19 | 78 Caucasian | Female | Not Hispanio | | | 177 | 1 | 14 | 12 | | 28 | 3 | 5 high ostomy output | muddy brown | Yes | lo |

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Data cleaning in action

| 4 | Α | В | С | D | Rem | ember to h | ave t | idv red | ctangl | e data | BEFORE vo | u import into | vour | Р |
|-----|-------------|---|---------------|------------|---------------------------|-------------------------|--------|------------|---------|---------|-------------------------|----------------------------|--------|---------------|
| 1 Δ | | y Injury (AKI) | | | | | | | | | | • | | |
| | . Motivated | | Jeauy | | cnose | en software | , SO 1 | irst de | elete r | 0WS 1 | to 4 and 2/ t | o 28. Then, or | nce in | |
| | esearch Pr | | | | | r chasen a | £4 | wa ala | | ah wa | richle column | a ana at a time | . b | |
| 4 | 2524101111 | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | | you | r chosen so | ontwa | ire, cie | ean ea | cn va | riable columi | n one at a time | e by | |
| 5 s | tudy_id | dob | Race | Sex | Hispani | | | lookin | a at th | nair di | istribution. | | | er AV fistula |
| 6 | | 11/11/1967 | White | Male | Hispani | | | IOOKIII | y at ti | ieli ui | istribution. | | | No |
| 7 | 2 | 11/12/1990 | Caucasian | Female | Not Hispanic | 21 | 17 19 | but poor c | 12 | 19 | 26 sepsis | muddy brown casts | Yes | No |
| 8 | 3 | may 5 1970 | White | Male | Hispanic | 32 | 20 | 15 | 11 | 15 | 24 bleeding out | many epithelial cell casts | No | No |
| 9 | 3 | 3-Jun-81 | Other | Female | Not Hispanic | 11 | 9 | 6 | 5 | 9 | 13 norovirus diarrhea | muddy brown casts | YES | YES |
| 10 | 4 | 7/06/1984 | Af-Am | Male | Not Hispanic | 15 | 12 | 9 | 8 | 11 | 14 sepsis | muddy brown casts | YES | No |
| 11 | 5 | 9/04/1980 | Black | Female | Н | 33 | 23 | 17 | 26 | 38 | 44 liver failure | many epithelial cell casts | No | No |
| 12 | 6 | 13/01/1985 | White | Female | Hispannic | 26 | 24 | 19 | 33 | 39 | 43 pneumonia sepsis | many granular casts | No | No |
| 13 | 7 | 15/11/1968 | Asian | F | Hispanic | 43 | 21 | 26 | 38 | 47 | 51 line sepsis | many epithelial cell casts | No' | NO |
| 14 | 8 | 22/04/1982 | Mixed | Male | Not Hispanic | 55 | 24 | 28 | 39 | 36 | 41 C diff diarrhea | many epithelial cell casts | No | No |
| 15 | 8 | 12/10/2003 | White | M | Not Hispanic | 23 | 11 | 6 | 9 | 11 | 14 NSAID tox | muddy brown casts | Yes | NO |
| 16 | 11 | 6/11/1982 | White | F | NH | 18 | 17 | 24 | 29 | 36 | 41 burns | muddy brown casts | Yes | Yes |
| 17 | 12 | 9/07/1979 | Caucasian | M | Not Hispanic | 21 | 20 | 28 | 37 | 44 | 48 pyelo | many epithelial cell casts | No | No |
| 18 | 13 | 5=11-1984 | Black | F | NH | 19 | 20 | 23 | 33 | 39 | 44 urethral obstruction | many epi cell casts | Yes | No |
| 19 | 14 | 7/04/2004 | Af-Am | M | Hispanic | 26 | 28 | 32 | 41 | 44 | 49 GI bleed | many granular casts | No | No |
| 20 | 15 | 8/03/1990 | Asian | M | NH | 36 | 322 | 28 | 36 | 39 | 43 sepsis | rare gran casts | No | No |
| 21 | 16 | 6/09/1983 | WHITE | Male | Not Hispanic | 27 | 24 | 29 | 39 | 47 | 51 salmonella | many granular casts | No | No |
| 22 | 17 | 11/07/1986 | WHITE | Female | Not Hispanic | 39 | 32 | 37 | 34 | 48 | 52 sepsis | rare granular casts | No | NO |
| 23 | 19 | 9/06/1987 | Black | Male | Hispanic | 22 | 20 | 24 | 24 | 39 | 43 esophageal varices | many epithelial cell casts | Yes | No |
| 24 | 20 | 29/03/1979 | Caucasian | Female | Hisspanic | 232 | 19 | 15 | 18 | 28 | 33 dehydration | many granular casts | No | No |
| 25 | 21 | 11/08/1978 | Caucasian | Female | Not Hispanic | 177 | 14 | 12 | | 28 | 35 high ostomy output | muddy brown | Yes | No |
| 26 | | | | | | | | | | | | | | |
| 27 | | Note data co | ollected from | March to J | une 2022 while rotating t | through the Gastonia VA | | | | | | | | |
| 28 | | Permission f | rom Attendir | ng doctor | | | | | | | | | | |

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Variable types are important!



Why worry about variable types?

- Variable types determine the appropriate statistical methods for analysis.
- You need to know what data type your variable is AND how it is recorded in your dataset.
- You may need to convert a numeric variable to a categorical variable depending on its distribution.

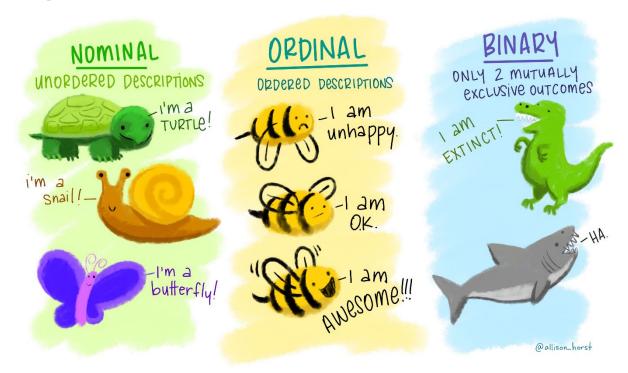
A. Identify variable types Continuous (with decimals) Discrete (whole numbers) Variable Ordinal (ordered)

Variable types





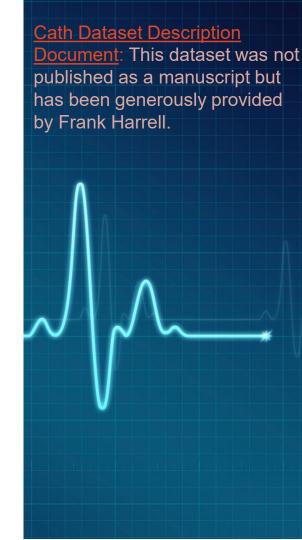
Variable types



Variable types – Example Cath dataset

- Dataset from the Duke University
 Disease Databank an observational cohort study.
- Patients were referred to the clinic for chest pain and cardiac catheterisation was performed to diagnose and open blockages in the arteries, followed by stenting to keep them open.

- 3504 participants



Variable types – Example Cath dataset

Cath Dataset Description
Document: This dataset was not published as a manuscript but has been generously provided by Frank Harrell.

Codebook

| variable | position | Variable_Label | units | Codes | type |
|----------|----------|--|--------------------------------|-------------------------|--------|
| sex | 1 | Gender | | 0 = male, 1 = female | double |
| age | 2 | Age | years | | double |
| cad_dur | 3 | duration of cadiac symptoms | days | | double |
| choleste | 4 | Serum Cholesterol | milligrams per deciliter | | double |
| sigdz | 5 | Significant Coronary Artery Disease Found on Cardiac Cath | | 0 = no, 1 = yes | double |
| tvdlm | 6 | Three Vessel or Left Main Disease Found on Cardiac Cath | | 0 = no, 1 = yes | double |

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B. Descriptive analysis for individual variables

Categorical variables

Graphical summaries

- Bar charts

Tabular summaries

- Frequency tables

Numerical variables

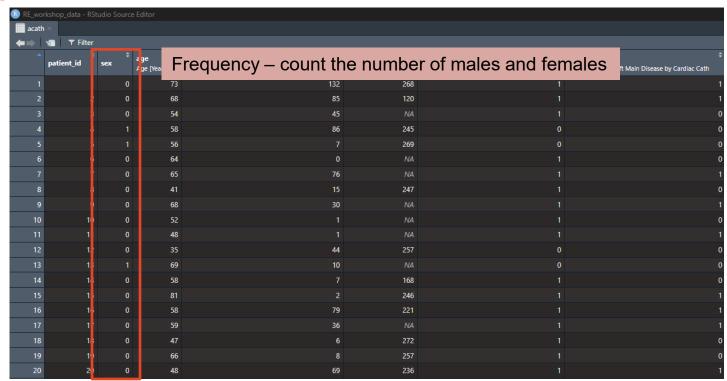
Graphical summaries

- Histogram
- Boxplots

Tabular summaries

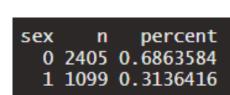
 Numerical summary statistics of centre (mean, median mode) and spread (quartiles, percentiles, sd)

Cath Dataset
Description
Document: This
dataset was not
published as a
manuscript but has
been generously
provided by Frank
Harrell.

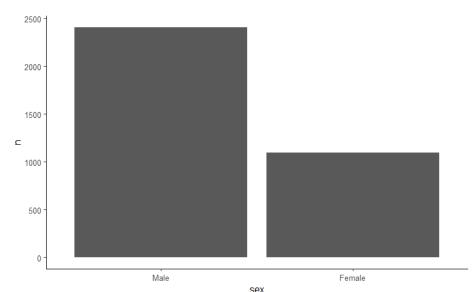


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- Frequency – count the number of males and females



Where 0 = male, and 1 = female



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Example Cath dataset – How to summarise numerical

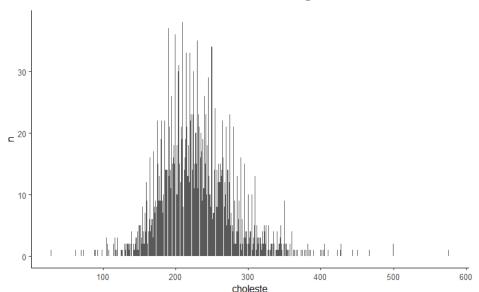
variables?

- Serum cholesterol (mg per dl) of the participants who provided a response
- A frequency table would be long and messy. Not a great summary!

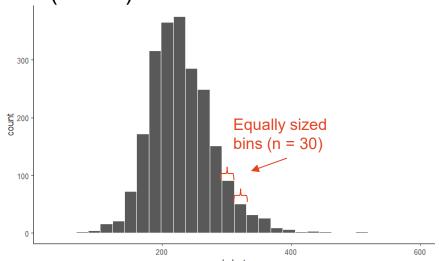


| | choleste ‡ | | percent [‡] | valid_percent ‡ |
|-----|------------|------|----------------------|-----------------|
| 234 | 353 | | 0.0005707763 | 0.0008857396 |
| | 354 | | 0.0002853881 | 0.0004428698 |
| 236 | 356 | | 0.0002853881 | 0.0004428698 |
| | 358 | | 0.0005707763 | 0.0008857396 |
| 238 | 360 | | 0.0011415525 | 0.0017714792 |
| | 363 | | 0.0002853881 | 0.0004428698 |
| 240 | 364 | | 0.0002853881 | 0.0004428698 |
| 241 | 366 | | 0.0002853881 | 0.0004428698 |
| 242 | 368 | | 0.0002853881 | 0.0004428698 |
| 243 | | | 0.0002853881 | 0.0004428698 |
| 244 | 375 | | 0.0002853881 | 0.0004428698 |
| 245 | 378 | | 0.0002853881 | 0.0004428698 |
| 246 | 380 | | 0.0002853881 | 0.0004428698 |
| 247 | 382 | | 0.0005707763 | 0.0008857396 |
| 248 | 384 | | 0.0002853881 | 0.0004428698 |
| 249 | 386 | | 0.0002853881 | 0.0004428698 |
| | 390 | | 0.0002853881 | 0.0004428698 |
| | 400 | | 0.0002853881 | 0.0004428698 |
| | 402 | | 0.0002853881 | 0.0004428698 |
| | 404 | | 0.0002853881 | 0.0004428698 |
| 254 | 405 | | 0.0005707763 | 0.0008857396 |
| | 410 | | 0.0002853881 | 0.0004428698 |
| 256 | 423 | | 0.0002853881 | 0.0004428698 |
| | 427 | | 0.0002853881 | 0.0004428698 |
| 258 | 428 | | 0.0005707763 | 0.0008857396 |
| | 444 | | 0.0002853881 | 0.0004428698 |
| 260 | 451 | | 0.0002853881 | 0.0004428698 |
| | 467 | | 0.0002853881 | 0.0004428698 |
| | 500 | | 0.0005707763 | 0.0008857396 |
| | 576 | | 0.0002853881 | 0.0004428698 |
| 264 | NA | 1246 | 0.3555936073 | NA |

- Serum cholesterol (mg per dl) of the participants who provided a response
- A bar chart isn't the best either! (3)

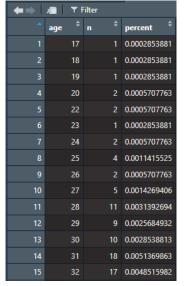


- Serum cholesterol (mg per dl) of the participants who provided a response
- A histogram of cholesterol, with frequency shown with equally sized bins (n = 30).





- Age (years) of the participants who provided a response
- A frequency table would be long and messy. Not a great summary!



| | age ‡ | n ‡ | percent |
|----|-------|-----|--------------|
| 16 | 33 | 15 | 0.0042808219 |
| 17 | 34 | 30 | 0.0085616438 |
| 18 | 35 | 30 | 0.0085616438 |
| 19 | 36 | 34 | 0.0097031963 |
| 20 | 37 | 46 | 0.0131278539 |
| 21 | 38 | 56 | 0.0159817352 |
| 22 | 39 | 61 | 0.0174086758 |
| 23 | 40 | 63 | 0.0179794521 |
| 24 | 41 | 84 | 0.0239726027 |
| 25 | 42 | 76 | 0.0216894977 |
| 26 | 43 | 90 | 0.0256849315 |
| 27 | 44 | 102 | 0.0291095890 |
| 28 | 45 | 95 | 0.0271118721 |
| 29 | 46 | 130 | 0.0371004566 |
| 30 | 47 | 111 | 0.0316780822 |

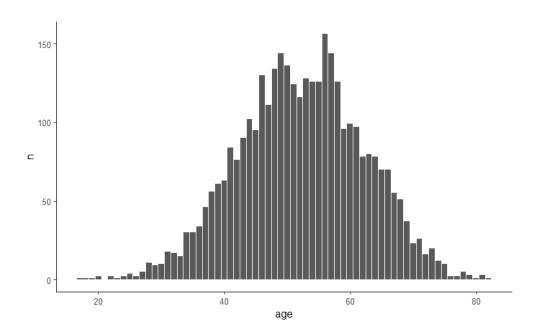
| | age ‡ | n ‡ | percent |
|----|-------|-----|--------------|
| 31 | 48 | 134 | 0.0382420091 |
| 32 | 49 | 144 | 0.0410958904 |
| 33 | 50 | 136 | 0.0388127854 |
| 34 | 51 | 124 | 0.0353881279 |
| 35 | 52 | 116 | 0.0331050228 |
| 36 | 53 | 128 | 0.0365296804 |
| 37 | 54 | 126 | 0.0359589041 |
| 38 | 55 | 126 | 0.0359589041 |
| 39 | 56 | 156 | 0.0445205479 |
| 40 | 57 | 144 | 0.0410958904 |
| 41 | 58 | 126 | 0.0359589041 |
| 42 | 59 | 96 | 0.0273972603 |
| 43 | 60 | 99 | 0.0282534247 |
| 44 | 61 | 97 | 0.0276826484 |
| 45 | 62 | 78 | 0.0222602740 |
| | | | |

| | age ‡ | n ‡ | percent ‡ |
|----|-------|-----|--------------|
| 46 | 63 | 80 | 0.0228310502 |
| 47 | 64 | 78 | 0.0222602740 |
| 48 | 65 | 70 | 0.0199771689 |
| 49 | 66 | 70 | 0.0199771689 |
| 50 | 67 | 55 | 0.0156963470 |
| 51 | 68 | 51 | 0.0145547945 |
| 52 | 69 | 37 | 0.0105593607 |
| 53 | 70 | 23 | 0.0065639269 |
| 54 | 71 | 26 | 0.0074200913 |
| 55 | 72 | 16 | 0.0045662100 |
| 56 | 73 | 20 | 0.0057077626 |
| 57 | 74 | 12 | 0.0034246575 |
| 58 | 75 | 10 | 0.0028538813 |
| 59 | 76 | 2 | 0.0005707763 |
| 60 | 77 | 2 | 0.0005707763 |

| | age ‡ | n ‡ | percent [‡] |
|----|-------|-----|----------------------|
| 61 | 78 | 5 | 0.0014269406 |
| 62 | 79 | 3 | 0.0008561644 |
| 63 | 80 | 1 | 0.0002853881 |
| 64 | 81 | 3 | 0.0008561644 |
| 65 | 82 | 1 | 0.0002853881 |

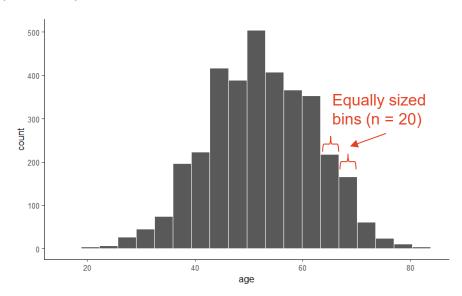


- Age (years) of the participants who provided a response
- A bar chart isn't the best either!

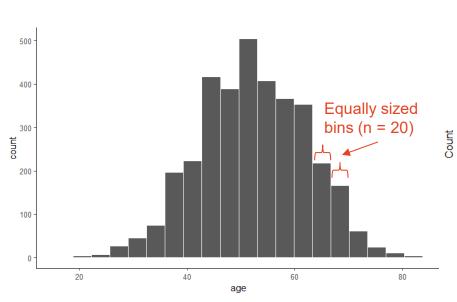




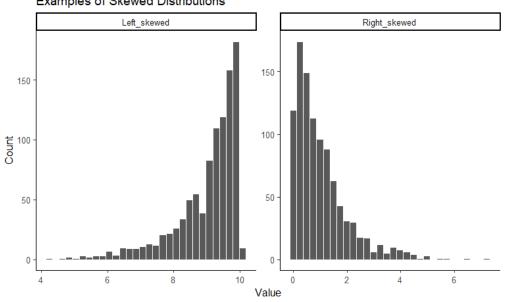
- Age (years) of the participants who provided a response
- A histogram of age, with frequency shown with equally sized bins (n = 20).



Shapes of the distribution





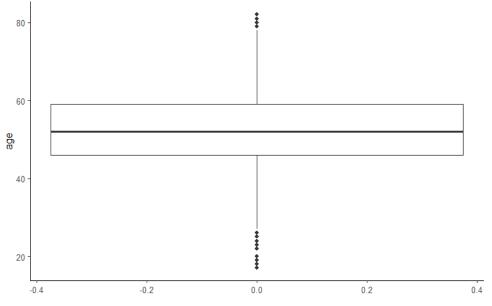


Symmetric distribution

Asymmetric distribution

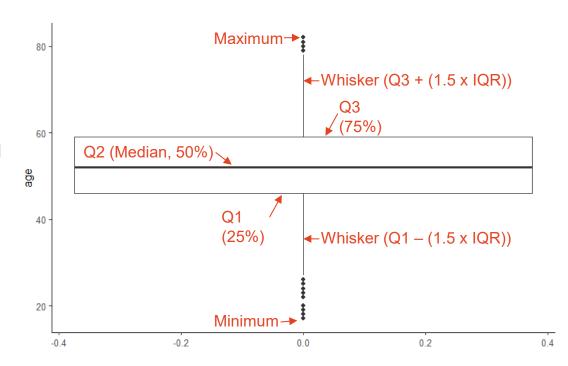
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- Another way to summarise a numerical variable is through a boxplot.



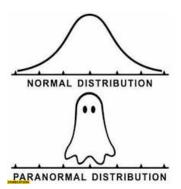
Example Cath dataset – Summarising the boxplot

- A numerical distribution can be summarised by giving descriptions of:
- Its shape
 - Symmetric, right or left skewed
- Its centre
 - Measures of central value or location
- Its spread
 - Measures of spread or dispersion



JAMA Guide to Statistics and Methods: Nonparametric Statistical Analysis

Parametric versus Nonparametric stats

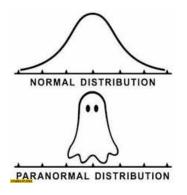


- Parametric
- Based on assumptions about data distribution and shape.
 - Normality
 - Though quite robust in large samples due to the central limit theorem.
 - Homogeneity of variance.
- Mean and standard deviation reported.
- Suitable for larger samples, with a normal distribution. More powerful if assumptions met.
- Examples:
 - 2-sample t-test
 - General linear model (GLM, One-way Anova, Least squares regression)

- Nonparametric
- Not based on assumptions about data distribution and shape.
- Median and percentiles/quartiles/max and min reported.
- Suitable for smaller samples, skewed data or ordinal variables.
- Examples:
 - Mann-Whitney U
 - Kruskal-Wallis
 - Spearman correlation

With the rise of GLMs and other more flexible parametric methods, such as distributional regression, quantile regression and generalised additive models, nonparametric methods are becoming less useful (and are now less of a requirement for publication).



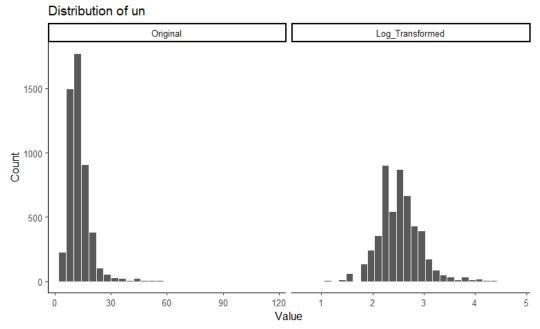


- Why check the distribution?
- Helps us understand skewness and any extreme values in the raw data.
- Common transformations: log, square root, inverse, Box-Cox.
 - We cannot take a log of 0, so if the raw data contains values of 0, add a constant to the variable before taking the log.
 E.g. log(x + 1).

- Best practice in statistics: The use of log transformation
- Checking the raw data is an important part of EDA. However, when fitting linear models, we assess distributional assumptions using the residuals, not the raw data. See the <u>Linear Models 1</u> workshop for more information.



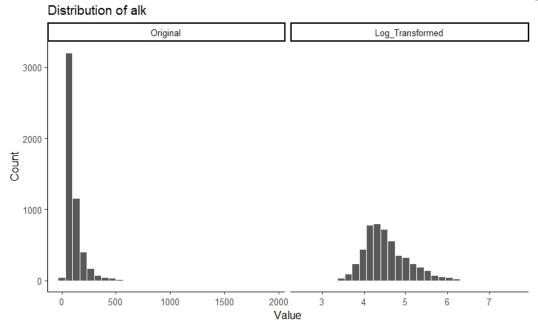
- **UN:** Blood Urea Nitrogen. Numeric. Range: 2-118. 53 missing values.



<u>Thiomon Dataset Description Document</u>: This dataset is from Akbar K. Waljee and Peter D. Higgins, who de-identified data on CBC and chemistry testing at the University of Michigan for development of a machine learning algorithm to predict response to thiopurine medications in IBD patients.



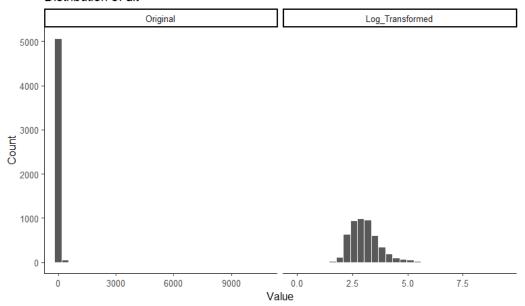
- **ALK:** Alkaline phosphatase. Numeric, range 13-1938, 0 missing values.



<u>Thiomon Dataset Description Document</u>: This dataset is from Akbar K. Waljee and Peter D. Higgins, who de-identified data on CBC and chemistry testing at the University of Michigan for development of a machine learning algorithm to predict response to thiopurine medications in IBD patients.



- **ALT:** Alanine Transaminase. Numeric, range 1-10666, 18 missing values.



<u>Thiomon Dataset Description Document</u>: This dataset is from Akbar K. Waljee and Peter D. Higgins, who de-identified data on CBC and chemistry testing at the University of Michigan for development of a machine learning algorithm to predict response to thiopurine medications in IBD patients.

What is a systematic approach to conduct descriptive analyses for individual variables?

Categorical variables

Graphical summaries

- Bar charts

Tabular summaries

- Frequency tables

Don't forget to check for missing data/NAs!

For formatting tips, check your target journal's instructions to authors or recent publications in that journal!

Numerical variables

Graphical summaries

- Histogram
- Boxplots

Tabular summaries

- Symmetric?
 - Mean, standard deviation, minimum and maximum.
- Asymmetric?
 - Median, quartiles, minimum and maximum.

Variable types are important for describing the distribution of each variable and checking/cleaning each individual variable, but....



What about my research question and analysis?



Formulating your research question

- Your research question should clearly detail the problem that is being addressed in your study. It should be a focused and answerable question that guides the content of your study.
- Start by identifying a gap in existing knowledge, and then refine your research question to be specific, measurable and relevant to your field.
- Depending on your research field, there may be a specific framework to follow when developing your research question. E.g. the <u>PICO</u> <u>framework</u> which helps structure clinical research questions by breaking them down into: Population, Intervention, Comparison and Outcome.

Back to the basics: guidance for formulating good research questions

What's Your Problem? Writing Effective Research Questions for Quality Publications

What is the research question?

Depending on who taught you statistics, your discipline, stats software or textbook, you may have come across some of these terms and more!

- For any analysis we need to be clear what the functional classification of the variables in the dataset is, e.g. we want to investigate the effect of smoking on lung disease:



Smoking (yes/no)

Predictor, explanatory variable, risk factor, independent variable*

*This term is frequently used, but we don't promote it as predictors may be correlated and hence are not independent.

Lung disease (yes/no) Response, outcome, dependent variable

Other functional classifications for variable types

- Covariate: a measured predictor (numerical predictor variable).
- <u>Factor:</u> (a categorical predictor variable).

Experimental design variables:

- <u>Design variables:</u> Based on the physical design of the experiment. They are often included in the analysis even if not 'significant' e.g., correctly partition the variance e.g., Block (batch of reagent, source of lab mice), subject ID, etc.
- <u>Treatment:</u> Variables of interest, e.g., diet, drug treatment, intervention etc. NB: The 'levels' of a 'treatment variable' might include 'control (placebo)', 'treatment 1 (drug 1)', 'treatment 2 (drug 2)'.

More information on design variables in our **Experimental Design** workshop!

What is the outcome variable?

- Review study aim and objectives

- E.g., vaccine RCT daily morbidity outcome data could be analysed as:
 - mean daily rate (average numerical).
 - cumulative morbidity (sum numerical).
 - peak morbidity (maximum numerical).
 - outbreak presence/absence (binary group categorical).
 - time to infection/disease outbreak (time to binary event data
 survival analysis).

More data processing

- Assess all variables for missing observations if many missing consider analysing with and without that predictor.
- Check the distribution of all variables individually (previous step).
- Numerical predictors: handle as numerical or categorical?
- Categorical: may have to combine categories if there are low frequency counts (if it makes sense to do so).
- Multi-level (clustered) data
- Each observation/row uniquely identified? E.g., herd, animal, ID.
- Evaluate hierarchical structure of your data: Average/range of observations at one level in each higher level?
- E.g., mean, min, max of students/class; mean, min, max of classes/school.

A quick primer to Step 5: EDA

Your variable types will dictate the type of statistical analysis you perform

- The type of outcome and explanatory variables you have will dictate the type of EDA and inferential analysis you can do, so it is crucial to think about this and your research question before you collect your data!
 - Is your outcome numerical or categorical?
 - Are your explanatory variables numerical or categorical?
 - Do you have one or multiple outcomes and/or explanatory variables?
- Choosing the wrong analysis can violate statistical assumptions and often won't run properly in your statistical software. Even worse, the incorrect analysis could lead to erroneous results and therefore conclusions or policy!

Step 5: Exploratory data analysis (EDA)

7

It will depend on the analysis and variables involved.



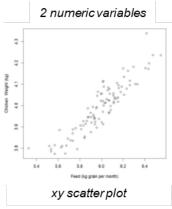
Basic EDA is where you plot the relationship of each predictor with the outcome, and you may need to reconsider data processing. E.g. Do I need to merge more categories together?

Two categorical variables

- Contingency table
- Side-by-side bar chart

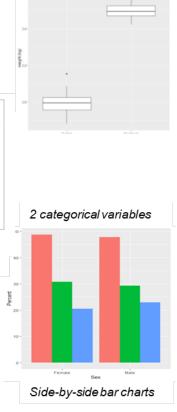
A categorical and a numerical variable

- Tabulate summary statistics by groups
- Box-and-whisker plot by groups



Two numerical variables

Scatter plot and correlation coefficient r



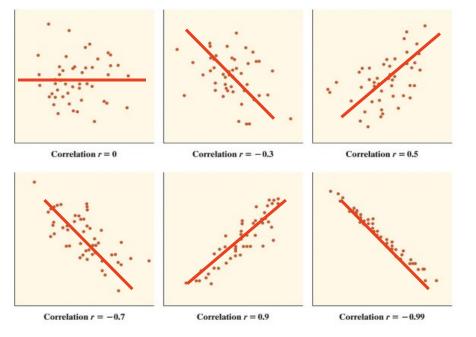
1 categorical variable; 1 numeric variable

XY scatterplot and Pearson's correlation coefficient (r)

A quick review of correlation coefficient r to describe the relationship of two numerical variables in a scatter plot; r = 0 means no relationship – data points in

a random scatter.

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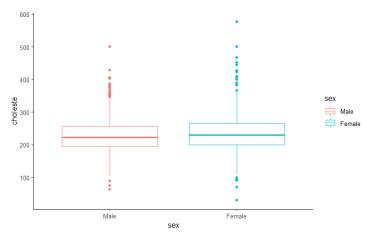
Examples for reporting descriptive analyses:

- Plotting gives a quick visual summary during EDA and highlights any issues.
- Tables are more publication friendly as they save space!
 - This step of the statistical analysis process is often seen in Table 1 of your manuscript.
 - See this paper for more information: Who is in this study, anyway? Guidelines for a useful Table 1.

Examples for reporting descriptive analyses: Cath dataset

Table 1. Summary statistics for the variables in a study of patients undergoing cardiac catheterisation, split according to sex.

| | Male (N=2405) | | Overall (N=3504) | |
|---|-------------------|-------------------|---------------------|--|
| Age [Year] | | | | |
| Mean (SD) | 51.6 (9.83) | 53.8 (9.99) | 52.3 (9.93) | |
| Median [Min, Max] | 52.0 [17.0, 82.0] | 54.0 [20.0, 81.0] | 52.0 [17.0, 82.0] | |
| Duration of Symptoms of Coronary Artery Disease | | | | |
| Mean (SD) | 43.0 (58.1) | 43.0 (58.3) | 43.0 (58.2) | |
| Median [Min, Max] | 17.0 [0, 416] | 20.0 [0, 404] | 18.0 [0, 416] | |
| Cholesterol [mg %] | | | | |
| Mean (SD) | 227 (47.3) | 237 (56.9) | 230 (50.6) | |
| Median [Min, Max] | 223 [63.0, 500] | 230 [29.0, 576] | 225 [29.0, 576] | |
| Missing | 836 (34.8%) | 410 (37.3%) | 1246 (35.6%) | |
| Significant Coronary Artery Disease | | | | |
| No | 533 (22.2%) | 637 (58.0%) | 1170 (33.4%) | |
| Yes | 1872 (77.8%) | 462 (42.0%) | 2334 (66.6%) | |
| Three Vessel or Left Main Disease | | | | |
| No | 1463 (60.8%) | 909 (82.7%) | 2372 (67.7%) | |
| Yes | 941 (39.1%) | 188 (17.1%) | 1129 (32.2%) | |
| Missing | 1 (0.0%) | 2 (0.2%) | 3 (0.1%) | |



Cath Dataset Description

Document: This dataset was not published as a manuscript but has been generously provided by Frank Harrell.

Other examples for reporting descriptive analyses:

Midurethral Sling vs OnabotulinumtoxinA in Females With Urinary Incontinence

| | No. (%) | | |
|--|--|----------------------------|--|
| Characteristic | OnabotulinumtoxinA (n = 71) ^a | Midurethral sling (n = 66) | |
| Age, mean (SD) [range], y | 59.1 (11.4) [27-78] | 59.0 (11.7) [33-87] | |
| Race ^b | | | |
| Asian | 2 (2.8) | 0 | |
| Black/African American | 10 (14.1) | 10 (15.2) | |
| Native Hawaiian or Other Pacific Islander | 1 (1.4) | 1 (1.5) | |
| White | 55 (77.5) | 54 (81.8) | |
| Unknown/not reported | 3 (4.2) | 1 (1.5) | |
| Hispanic/Latina ethnicity, No./total (%) ^c | 15/71 (21.1) | 6/65 (9.1) | |
| Education, highest level obtained was greater than high school, No./total (%) | 46/68 (64.8) | 32/63 (48.5) | |
| Currently smoking | 7 (9.9) | 9 (13.6) | |
| No. of vaginal deliveries, median (IQR) | 2 (1-3) | 2 (1-3) | |
| Total No. of deliveries, median (IQR) | 2 (1-3) | 2 (2-3) | |
| Menopausal status | | | |
| Pre | 7 (9.9) | 14 (21.2) | |
| Post | 56 (78.9) | 49 (74.2) | |
| Not sure | 8 (11.3) | 3 (4.5) | |
| Currently using estrogen by prescription | 21 (29.6) | 18 (27.3) | |
| BMI, mean (SD) ^d | 34.3 (8.3) | 35.0 (7.6) | |
| Type of urinary incontinence ^e | | | |
| Stress predominant | 3 (4.2) | 4 (6.1) | |
| Urge predominant | 7 (9.9) | 10 (15.2) | |
| Balanced | 61 (85.9) | 52 (78.8) | |
| Baseline incontinence episode daily frequency, mean (SD) | 7.1 (4.1) | 7.4 (4.0) | |
| Time from baseline visit to treatment, mean (SD), df | 59.0 (38.5) | 56.8 (43.4) | |
| Median (IQR) | 49 (36-75) | 46 (27-76) | |
| Treatment >90 d after baseline | 7 (9.9) | 10 (15.2) | |
| Baseline UDI scores, mean (SD) ^q | | | |
| Total | 187.6 (38.2) | 180.9 (36.5) | |
| Irritative | 75.7 (16.6) | 77.3 (15.4) | |
| Stress | 86.6 (18.4) | 80.3 (21.9) | |

Abbreviations: BMI, body mass index; UDI, Urogenital Distress Inventory.

and stress urinary incontinence (SUI) ten "Do you experience urine leakage related to physical activity, cougling or sneezing? If yes, how much does it bother you?" Greater bother reported on the UII item is classified as urge predominant, greater bother reported on the SUI item is classified as stress predominant, and equal bother reported is disasified as balanced.

If issedimer refers to the time of the first UID assessment completion, which is used to determine eligibility. Participants were expected to receive treatment.

 $^{\rm B}$ The UDI total score ranges from 0 to 300, and the UDI irritative and stress scores range from 0 to 100, with higher scores indicating greater symptom severity.

within 91 days of completing their baseline UDI.

Immunogenicity and Safety of Influenza and COVID-19 Multicomponent Vaccine in Adults ≥50 Years

| | Age ≥65 y | | Age 50-64 y | | |
|--|-------------------------|--------------------------------------|-------------------------|--------------------------------------|--|
| | mRNA-1083 (n = 2011) | HD-IIV4 + mRNA-1273 (n = 2006) | mRNA-1083 (n = 1993) | SD-IIV4 + mRNA-1273 (n = 2005) | |
| Age, y | | | | | |
| Mean (SD) | 70.9 (5.0) | 70.7 (4.7) | 57.5 (4.3) | 57.4 (4.2) | |
| Median (IQR) | 70 (67-74) | 70 (67-74) | 58 (54-61) | 58 (54-61) | |
| Age group, No. (%) | | | | | |
| 50-64 y | 2 (<0.1)b | (<0.1) ^b 0 | | 2004 (99.9) | |
| 65-74 y | 1593 (79.2) | 1591 (79.3) | 1 (<0.1)b | 0 | |
| ≥75 y | 416 (20.7) | 415 (20.7) | 1 (<0.1) ^b | 1 (<0.1) ^b | |
| Sex, No. (%) | | | | | |
| Male | 933 (46.4) | 908 (45.3) | 837 (42.0) | 811 (40.4) | |
| Female | 1078 (53.6) | 1098 (54.7) | 1156 (58.0) | 1194 (59.6) | |
| Race, No. (%) ^c | n = 2000 | n = 1994 | n = 1978 | n = 1981 | |
| American Indian or Alaska Native | 9 (0.5) | 12 (0.6) | 12 (0.6) | 13 (0.7) | |
| Asian | 25 (1.3) | 36 (1.8) | 50 (2.5) | 39 (2.0) | |
| Black or African American | 370 (18.5) | 370 (18.6) | 517 (26.1) | 552 (27.9) | |
| Native Hawaiian or Other Pacific Islander | 1 (0.1) | 4 (0.2) | 3 (0.2) | 5 (0.3) | |
| White | 1577 (78.9) | 1565 (78.5) | 1373 (69.4) | 1343 (67.8) | |
| Multiple | 14 (0.7) | 4 (0.2) | 19 (1.0) | 21 (1.1) | |
| Other | 4 (0.2) | 3 (0.2) | 4 (0.2) | 8 (0.4) | |
| Ethnicity, No. (%) | | | | | |
| Hispanic or Latino | 283 (14.1) | 275 (13.7) | 392 (19.7) | 381 (19.0) | |
| Not Hispanic or Latino | 1688 (83.9) | 1689 (84.2) | 1576 (79.1) | 1603 (80.0) | |
| Unknown or not reported | 40 (2.0) | 42 (2.1) | 25 (1.3) | 21 (1.0) | |
| BMI | | | | | |
| Mean (SD) | 30.3 (6.2) | 30.1 (6.1) | 31.1 (7.1) | 31.6 (7.3) | |
| Median (IQR) | 29.4 (25.9-33.8) | 29.2 (25.7-33.6) | 30.2 (26.2-34.9) | 30.5 (26.6-35.4) | |
| BMI group, No. (%)d | n = 1995 | n = 1984 | n = 1963 | n = 1980 | |
| <30 | 1077 (54.0) | 1096 (55.2) | 951 (48.4) | 927 (46.8) | |
| ≥30 | 918 (46.0) | 888 (44.8) | 1012 (51.6) | 1053 (53.2) | |
| Comorbidity group, No. (%) | | | | | |
| High risk ^e | 1312 (65.2) | 1292 (64.4) | 1233 (61.9) | 1264 (63.0) | |
| Low risk | 699 (34.8) | 714 (35.6) | 760 (38.1) | 741 (37.0) | |
| Influenza vaccine received since Sept 2022, No. (%) | 1019 (50.7) | 1016 (50.6) | 783 (39.3) | 784 (39.1) | |
| COVID-19 vaccine received since Sept 2022, No. (%) | 853 (42.4) | 854 (42.6) | 632 (31.7) | 611 (30.5) | |

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); HD-IIV4, high-dose quadrivalent inactivated influenza vaccine; SD-IIV4, standard-dose quadrivalent inactivated influenza vaccine.

- ^a The safety population included all participants who were randomized and received the study vaccination. Participants were included in the vaccine group corresponding to the vaccine they received.
- b Due to misrandomization, 2 participants aged 50-64 years were enrolled in the ≥65 years cohort and 3 participants aged ≥65 years were enrolled in the 50-64 years
- ^c Race and ethnicity of participants was self-reported according to multiple categories. The total number of participants with a reported race (excluding participants with race unknown or unreported); percentages are based on this total.
- ^d The total number of participants with a reported BMI group (excluding participants with unknown BMI group); percentages
- are based on this total.

 *High-risk comorbidity included having any medical history of autoimmune/immune-mediated disease, blood disorders, cardiac disorders, nervous system disorders, disbetes mellitus, kidney disorders, hepatic disorders, mental impairment disorders, pulmonary disorders, or metabolism and nutritional disorders. Comorbidities based on self-report or review of productions of the company of the control of the company of

^a The primary analysis population is defined as all participants who received any treatment and have postbaseline efficacy data, regardless of randomized treatment.

b Race categories were self-reported using check all that apply and specific closed options, including an unknown/not reported selection.

^c Ethnicity categories were self-reported using select only one, specific closed option, including an unknown/not reported selection.

^d BMI calculated as weight in kilograms divided by height in square meters.

^o The type of urinary incontinence is defined by responses at baseline on the UDI to the urgency urinary incontinence (UUI) item "Do you experience urine leakage related to a feeling of urgency? If yes, how much does it bother you?"

Tips from the consulting room



- Have your research question in mind, as well as a clear idea of what your publication goals are. Think about your 'story'.



- If you're planning to publish your work, be sure to review the journal's "Instructions for authors" and browse recent articles to guide your layout and presentation!



- Consider who will be reading your work and present your findings in a way that's easy for them to understand.
 - Is it clinicians? Is it industry? Is it other researchers? Is it a broad audience/lay people?
 - Try and make things as readable and accessible as possible.

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How to present your results in an accessible way

- Ensure that each figure or table you include can be understood independently, without needing to refer to the main text.
- Don't overload the reader remember any additional information can be provided in your Appendix/Supplementary Materials and there will be maximum word counts for most journals.
- Group and order your information logically.
- Be consistent in your terminology throughout the manuscript and always provide the units of analysis. E.g. always call it "Intervention group" not "Intervention group" in one part and "Treatment group" in another, or "numerical predictor" in one part and "continuous predictor" in another.
- Consider colourblind friendly colour palettes and ensure high contrast between graph elements (e.g. lines, points).

Best-practice reporting guidelines



- The Equator Network (Enhancing the QUAlity and Transparency Of health Research) is a centralised platform for researchers to access a wide range of reporting guidelines.
 - Seeks to improve the reliability and value of published health research by promoting transparent, standardised and accurate reporting.
- There are guidelines for different study types to help you with your manuscript writing.
 - Provides you with a check-list of information required so that your manuscript can be easily understood by the reader and reproduced by other researchers.



Reporting guidelines for main study types

| Randomised trials | <u>CONSORT</u> | Extensions | | | |
|----------------------|----------------|-------------------|--|--|--|
| <u>Observational</u> | | | | | |
| <u>studies</u> | STROBE | <u>Extensions</u> | | | |
| Systematic reviews | <u>PRISMA</u> | Extensions | | | |
| Study protocols | <u>SPIRIT</u> | PRISMA-P | | | |
| Diagnostic/prognost | <u>ii</u> | | | | |
| <u>c studies</u> | STARD | TRIPOD | | | |
| Case reports | CARE | Extensions | | | |
| Clinical practice | | | | | |
| <u>guidelines</u> | <u>AGREE</u> | RIGHT | | | |
| Qualitative research | SRQR | COREQ | | | |
| Animal pre-clinical | | | | | |
| <u>studies</u> | <u>ARRIVE</u> | | | | |
| Quality improvemen | <u>t</u> | | | | |
| <u>studies</u> | <u>SQUIRE</u> | <u>Extensions</u> | | | |
| <u>Economic</u> | | | | | |
| <u>evaluations</u> | <u>CHEERS</u> | <u>Extensions</u> | | | |



Best-practice reporting guidelines



Key Reasons for Adopting Reporting Guidelines

| | Key Reasons for Adopting Reporting Guidelines |
|----------|--|
| Ω | STANDARDIZED REPORTING Reporting guidelines provide a standardized framework for documenting and reporting experimental procedures, methods, and results. They ensure consistent capture of essential information. |
| | ENHANCING REPRODUCIBILITY Complete and transparent reporting enables other researchers to replicate and verify study findings, minimizing ambiguity and increasing reproducibility of results. |
| | TRANSPARENCY AND TRUSTWORTHINESS Transparent reporting instills confidence, allowing readers to critically evaluate research methodology and identify limitations, biases, or sources of error. |
| | FACILITATING DATA SHARING AND REUSE Reporting guidelines promote data sharing and facilitate the integration of existing research, accelerating scientific progress and fostering collaboration. |
| | IMPROVING DATA INTERPRETATION Detailed reporting helps readers accurately interpret and understand presented data by providing essential contextual information and avoiding misinterpretation. |
| | CONSISTENCY AND COMPARABILITY Reporting guidelines ensure consistency and comparability within a field, aligning experiments with accepted practices and facilitating meta-analyses and literature reviews. |
| | IDENTIFICATION OF METHODOLOGICAL BIASES Transparent reporting enables identification of biases or methodological flaws that may impact reliability and validity, aiding critical assessment of the study's limitations. |
| • | COMPLIANCE WITH ETHICAL AND REGULATORY STANDARDS Reporting guidelines incorporate ethical and regulatory considerations, ensuring adherence to legal, ethical, and safety obligations in biomedical experimentation. |

Best practices for data management and sharing in experimental biomedical research



Statistical analysis plans (SAPs)



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- SAPs as well as study protocols are a great tool to improve communication and collaboration between you and other researchers.
- They should include information on:
 - Objectives and hypotheses
 - Primary and secondary outcomes
 - Study design
 - Data collection methods
 - Data management
 - Statistical analysis including handling of missing data and sensitivity analyses
 - Reporting of findings
- Australian Clinical Trials Alliance: Statistical analysis plan
- Guidelines for the Content of Statistical Analysis Plans in Clinical Trials
- A template for the authoring of statistical analysis plans
- Developing a Quantitative Data Analysis Plan for Observational Studies

A cautionary tale...

When inexperience meets bad statistical advice

This is based on a true story from the consulting room highlighting the importance of Research Essentials...

A client approached me for a stats consult with a manuscript due in one week. The whole paper was written, and they just needed confirmation of one results section. The client had relied on a collaborator to analyse the data (who had now left), and they were also under pressure to submit, trusting that the work completed was sound. Whilst sharing their screen and reading through their manuscript and r code, alarm bells started ringing in my head. There were a variety of statistical issues, highlighting a lack of statistical literacy, reproducibility and academic integrity from the collaborator.



A cautionary tale...

When inexperience meets bad statistical advice

Data import & cleaning: Raw REDCap .csv imported directly with no data cleaning prior to analysis. **Outlier handling:** Plausible 'outlier' minimum values were removed before analysis, without justification or

sensitivity analyses.

Variable coding: Variable types not defined so all predictors were treated as numeric. Categories did not match data dictionary, making interpretation unclear.

Exploratory data analysis: Limited EDA, histograms plotted, but for categorical variables coded as numeric. **Statistical terminology:** "Multivariate" incorrectly used instead of "multivariable".

Model specification: Models violated assumptions, had sparse cell counts, and were overly complex and not parsimonious.

Reproducibility: Participant data altered or omitted, and summary tables could not be replicated.

Data management: Files were missing or poorly named in the data folders and multiple result versions were shared with the client.

P-value focus: Heavy reliance on arbitrary p-value thresholds, with little attention to effect size or clinical relevance.

Final advice: Client was advised to include a disclaimer that results should be interpreted with caution as they may be unreliable.

A cautionary tale...

Due diligence matters!

- Even if you are not the primary one analysing the data, if your name is on the paper, then you are also responsible for the academic integrity of the work.
- Many journals now require author contribution statements, making clear who did what, but nonetheless, shared accountability still applies.
- Basic statistical checks (e.g. data types, summary tables and EDA) are often enough to uncover major issues early on and will save you time down the track.
- Don't overlook the simple stuff, as it can catch what complex analysis might obscure.
- Start simple → get complex.

Some analysis examples

- 5. Exploratory data analysis (EDA)
- 6. Inferential analysis

Data analysis workflow: 4 examples

- **A.** Linear models examples Simple regression, ANOVA, ANCOVA, Repeated measures.
- **B.** Extended linear models example Survival analysis.
- **C.** Extended linear models example Generalised linear model (Binary logistic regression).
- **D.** Multivariate analysis Confirmatory factor analysis (CFA).

Your variable types will dictate the type of statistical analysis you perform

- Examples using the generalised linear model framework:
 - 2-sample t-test = binary explanatory variable and numerical outcome.
 - ANOVA = multi-categorical explanatory variable and numerical outcome.
 - Simple linear regression = numerical explanatory variable and numerical outcome.
 - Binary logistic regression = numerical or categorical explanatory variable and binary outcome.
- For more information on the type of statistical test to run, see the slide entitled "Statistical inferential analysis roadmap" later on in this workshop!

Example A: Linear models examples

Scenario: We are interested in studying a numerical (continuous) outcome variable, e.g. weight gain (kg) or blood cell count (cells/µL).

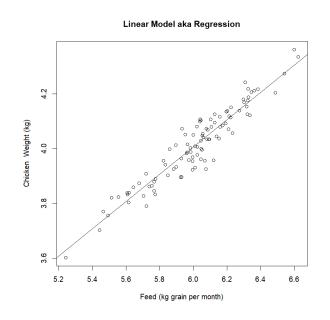
- 1. Simple linear regression one numerical predictor variable.
- 2. ANOVA (control vs. treatment) for 2 groups = 2 sample ttest = simple linear regression with one binary predictor variable.
- 3. ANCOVA ANOVA with a covariate predictor.

For more detail on how to do these analyses including R code, attend our SIH <u>Linear Models 1: Linear Regression</u>, <u>ANOVA</u>, <u>ANCOVA and Repeated Measures (a Simple Mixed Model)</u> workshop!

Example A1: Linear models – Simple linear regression

Step 5: EDA – Plot the data in a scatterplot.

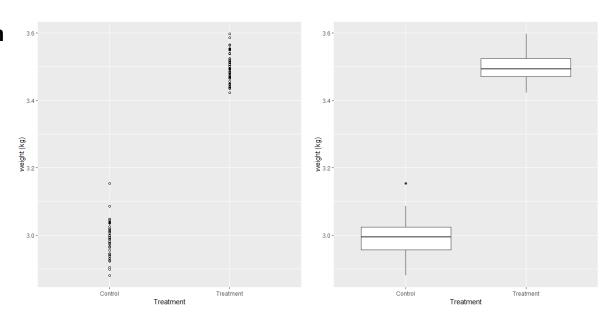
Step 6: Inferential analysis – fit a linear regression line and test if the slope is different from 0; P < 0.001; report slope/regression estimate and 95% CI.



Example A2: Linear models – Control vs. treatment experiment

Step 5: EDA – Plot the data with grouped boxplots.

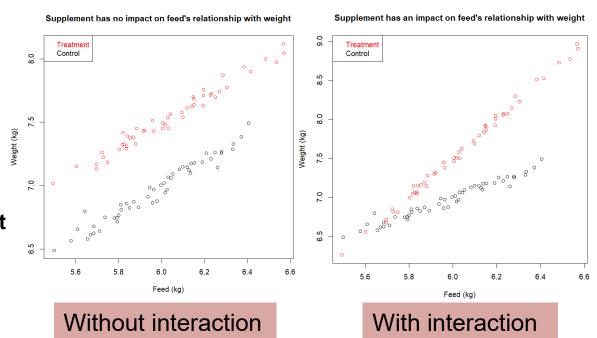
Step 6: Inferential analysis – ANOVA/2-sample t-test; P < 0.001; report predicted means and 95% CIs.



Example A3: Linear models – ANCOVA (ANOVA with a numerical covariate)

Step 5: EDA – Plot the data (differentiate categories of the treatment variable).

Step 6: Inferential analysis – ANCOVA or multivariable regression; P < 0.001; report predicted means with or without interaction and 95% CIs.

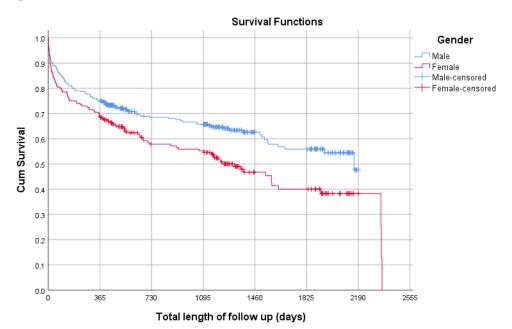


Example B: Survival analysis

- Scenario: Worcester Heart Attack Community Surveillance Study (WHAS)
- **Aim:** To examine time trends in the incidence rate of acute heart attacks.
- **Objective:** Investigate if different demographic and clinical. factors are associated with the time to a heart attack.
- **Data:** Longitudinal, observational data.
- Outcome: Heart attack time to event.
- **Predictors:** Demographic and clinical data.
- **Key feature:** Data is censored see our Introduction to Survival Analysis WS.

Example B: Survival analysis

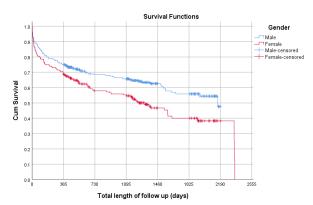
Step 5: EDA – Kaplan Meier curve is the EDA plot for survival analysis.



Example B: Survival analysis

Step 6: Inferential analysis – <u>The logrank test</u> to compare the survival curves of two or more groups.

- There is a significant difference in survival between males and females (by log-rank test).
 - Median survival for males: 2160 days [95%CI: not calc].
 - Median survival for females: 1317 days [95% CI 970-1664].



Example C: Binary logistic regression

- **Scenario:** Survey responses of 32 long-term smokers to determine the association between smoking status and lung-cancer diagnosis.
- Outcome: Lung cancer (no/yes)
- **Predictors:** Years smoking, BMI
- Primer on binary logistic regression

For more detail on how to do these analyses including R code, attend our SIH <u>Linear Models 2: Logistic and Poisson/Count Regression - An Introduction to Generalised Linear Models</u> workshop!

Example C: Binary logistic regression

Step 5: EDA – Log odds of the outcome (lung cancer) vs. numerical predictor (years of smoking) to check the linearity assumption.

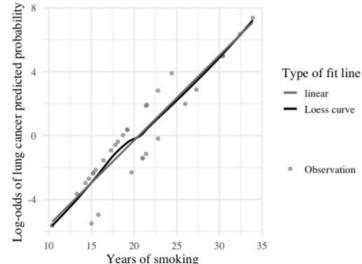


Figure 2

Checking the linearity assumption graphically.

Example C: Binary logistic regression

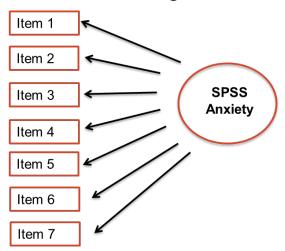
Step 6: Inferential analysis – binary logistic regression to examine association between lung cancer (y/n) and years smoking (numerical), if linearity assumption is met.

For every additional year of smoking, the odds of lung cancer are approximately 1.98 times higher (95% CI 1.36 to 3.86).

- **Scenario:** To test if a factor model 'SPSS statistical software Anxiety' explains the common variance among 7 questionnaire items:
 - 1. I dream that Pearson is attacking me with correlation coefficients.
 - 2. I have little experience with computers.
 - 3. All computers hate me.
 - 4. I have never been good at mathematics.
 - 5. My friends are better at statistics than me.
 - 6. Computers are useful only for playing games.
 - 7. I did badly at mathematics at school.

Example adapted from <u>A Practical Introduction to Factor Analysis: Confirmatory Factor Analysis</u> from the UCLA: Statistical Consulting Group.

- **Scenario:** Confirm SPSS Anxiety as a factor explaining the common variance among the 7 items.

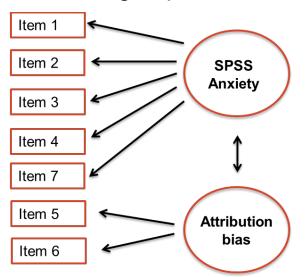


Example adapted from <u>A Practical Introduction to Factor Analysis: Confirmatory Factor Analysis</u> from the UCLA: Statistical Consulting Group.

Step 5: EDA – scatter plots + Pearson's correlation coefficient r; correlation matrix.

| | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 |
|----|-------|-------|------|------|------|------|----|
| Q1 | 1 | | | | | | |
| Q2 | -0.34 | 1 | | | | | |
| Q3 | 0.44 | -0.38 | 1 | | | | |
| Q4 | 0.40 | -0.31 | 0.40 | 1 | | | |
| Q5 | 0.22 | -0.23 | 0.28 | 0.26 | 1 | | |
| Q6 | 0.31 | -0.38 | 0.41 | 0.34 | 0.51 | 1 | |
| Q7 | 0.33 | -0.26 | 0.35 | 0.27 | 0.22 | 0.30 | 1 |

Step 6: Inferential analysis – to test if a 2-factor model 'SPSS statistical software Anxiety' and 'Attribution bias' explains the common variance among 7 questionnaire items.





Final notes on Step 6: Inferential analysis

- We only showed some common examples of statistical analyses there are many different types of analyses you can consider:
 - Other Linear Models extensions such as Poisson regression and more complex mixed models - see our SIH <u>Linear Models 2:</u> <u>Logistic and Poisson/Count Regression - An Introduction to</u> <u>Generalised Linear Models</u> workshop.
 - Survival Analysis for 'time-to-event' outcome data see our SIH Introduction to Survival Analysis training!
 - Survey Data analysis see our <u>Design and Analysis of Surveys 1</u> and <u>Design and Analysis of Surveys 2: Advanced Topics</u>.
 - Other Multivariate Analyses for example PCA, Factor Analysis see our <u>Multivariate Statistical Analysis 1: Dimension Reduction</u>.
 - And more more workshops!



Final notes on Step 6: Inferential analysis

- Start simple and increase complexity step-by-step.
- Always consider/check the test/model assumptions.
- Report 95% CIs for estimates, e.g., predicted means/ probabilities/rates.
- For basic analyses consider more powerful (parametric) analyses first and use less powerful tests if assumptions are violated. e.g.:
 - Use a 2-sample t-test with equal or unequal variance for means, before a Mann-Whitney test.
 - Use a chi-squared test to compare proportions before a Fisher's exact test.
- Use knowledge of variable types to guide you through the systematic roadmap on the next slide!

Statistical inferential analysis roadmap

How many outcome(s)?

What type of outcome(s)?

How many predictor(s)?

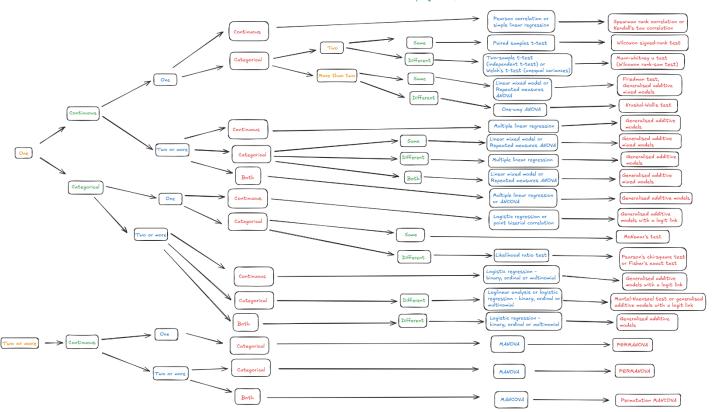
What type of predictor(s)?

If a categorical predictor, how many categories?

If a categorical predictor, do categories represent repeated measures (same sampling units) or independent measures (different sampling units)?*

All assumptions of linear model met? Use GLM (parametric) framework. Assumptions of linear model partially or fully unmet? Use semiparametric or nonparametric.





Where possible, if the assumptions are met, use the parametric test as it has more statistical power to detect differences than the nonparametric test equivalent.

*If you are unsure of the units in your study, see our Experimental
Design workshop for more information!



Final notes on Step 6: Inferential analysis

- Univariate/univariable
 involving one variable,
 e.g. one outcome per analysis; analysis with one predictor variable.
- Multivariate multiple outcomes in the same analysis/model.
- Multivariable multiple explanatory variables in the same analysis/model.

- Linear models (LM numerical outcome).
- Generalised linear models (GLM categorical outcomes, e.g. binary, ordinal, multinomial (for nominal outcome data) or Poisson/negative binomial regression (for count/rate outcome data).
- General linear models
 (GLM numerical
 outcome and any type
 of explanatory variable
 (categorical or
 numerical).
- Mixed models (i.e. LM or GLM with a random effect = LMM or GLMM) where data are clustered in space or time, e.g. repeated measures/longitudinal data.

Further R resources

- There is a large online community of R users contributing to free 'packages' with data analysis functions, which leads to many ways of coding your analysis in R. This can be confusing. We recommend using tidyverse packages and tidy-centric code.
- See our SIH helpful links for guides on using R and Rstudio.
- <u>LinkedIn Learning: R courses</u>
 - Including Learning the R Tidyverse (2024), Complete Guide to R: Wrangling, Visualizing, and Modelling Data, and Cleaning Bad Data in R.
- RLadiesSydney: RYouWithMe

Other resources



Books on R

- R for Data Science by Hadley Wickham.

Statistical blogs and websites

- The Analysis Factor
 - Seven Steps for Data Cleaning
 - Best Practices for Organizing your Data Analysis
 - Best Practices for Data Preparation
 - Preparing Data for Analysis is (more than) Half the Battle
 - Four Weeds of Data Analysis That are Easy to Get Lost In

Further assistance at The University of Sydney



SIH

- <u>Statistical Resources</u> website: containing our workshop slides and our favourite external resources (including links for learning R and SPSS).
- Hacky Hour: an informal monthly meetup for getting help with coding or using statistics software.
- 1on1 Consults can be requested on our website or here (click on the big red 'contact us' link).

SIH Workshops

- Create your own custom programs tailored to your research needs by attending more of our Statistical Consulting workshops. Look for the statistics workshops on our training page or on our <u>Training</u> <u>calendar</u>.
- Sign up to our mailing list to be notified of upcoming training.

Other

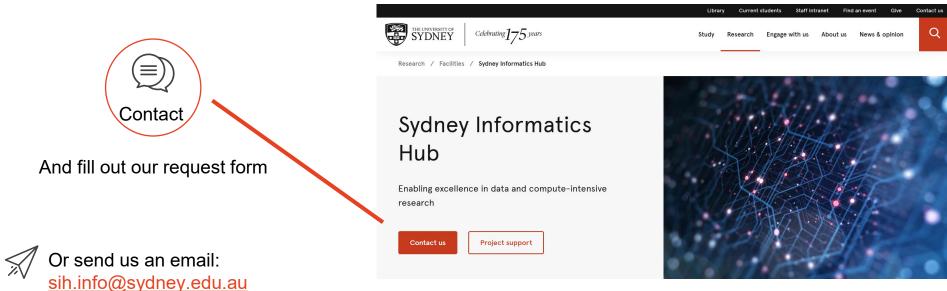
- Open Learning Environment (OLE) courses
- Linkedin Learning

How to engage with us





sydney.edu.au/informatics-hub



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How to use our workshops



- Workshops developed by the Statistical Consulting Team within the Sydney Informatics Hub form an integrated modular framework. Researchers are encouraged to choose modules to create custom programs tailored to their specific needs. This is achieved through:
 - Short 90-minute workshops, acknowledging researchers rarely have time for long multi day workshops.
 - Providing statistical workflows appliable in any software, that give practical step by step instructions
 which researchers return to when analysing and interpreting their data or designing their study e.g.
 workflows for designing studies for strong causal inference, model diagnostics, interpretation and
 presentation of results.
 - Each one focusing on a specific statistical method while also integrating and referencing the others to give a holistic understanding of how data can be transformed into knowledge from a statistical perspective from hypothesis generation to publication.

For other workshops that fit into this integrated framework, refer to our training link page under statistics, found below:

Workshops and training

Online statistical consulting resources

Sydney Informatics Hub

SIH Statistical Resources

Collapse All | Expand All



- ☐ Welcome
- Workshops and Workflows
- The Statistical Consulting Unit
- Helpful Links



Sydney Informatics Hub: Statistical Resources

Workshops and Workflows: Download all our workshops with their step-by-step workflows on how to do analysis.

References: 1-3 Curated links on a variety of common statistical concepts and tests e.g.. Basic Theory, Meta Analysis, Software, etc. *A great place to start looking for help!!*

Statistical Consulting Unit/What to expect in a consult: For tips on how to get the most out of your consult.

(You may need to click "Expand all" on the Sites sidebar to get an overview of the available pages). We recommend our experimental design and sample size workshops

Experimental design workshop

- Far too many researchers think they know all they need to in this area. We commonly see designs that could be substantially improved for stronger causal inference and improved results which leads to publication in higher impact journals (amongst other benefits).
- Even if you have already collected your data, it is well worth attending since it may improve your write up and analysis. E.g., we had a client who didn't realise they had a very strong before/after control/impact (BACI) design.

Power and sample size workshop

- Shows the steps and decisions researchers need to make when designing an experiments to ensure sufficient sample e.g., power, minimum sample required to fit the necessary model, etc.
- Also, how much power the study has, i.e., does it have sufficient power to detect the effects you expect to see, or is your study a complete waste of time and resources?

A reminder: Acknowledging SIH



- All University of Sydney resources are available to researchers free of charge.
- The use of the SIH services including the Artemis HPC and associated support and training warrants acknowledgement in any publications, conference proceedings or posters describing work facilitated by these services.
- The continued acknowledgment of the use of SIH facilities ensures the sustainability of our services.

Suggested wording for use of workshops and workflows:

- "The authors acknowledge the Statistical workshops and workflows provided by the Sydney Informatics Hub, a Core Research Facility of the University of Sydney."

We value your feedback



- We want to hear about you and whether this workshop has helped you in your research. What worked and what didn't work.
- We actively use the feedback to improve our workshops.
- Completing this survey really does help us and we would appreciate your help! It only takes a few minutes to complete (promise!)
- You will receive a link to the anonymous survey by email.