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How to Statistically Process and Interpret Data

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About Dr. Wickham

10+ years of work experience in USA and China:

Senior Managing Editor,Integrative Zoology
2014 – present

Visiting Professor, Institute of Chemistry,
Chinese Academy of Sciences
2010 – 2017

Assistant Professor, Institute of Zoology,
Chinese Academy of Sciences
2017 – 2021

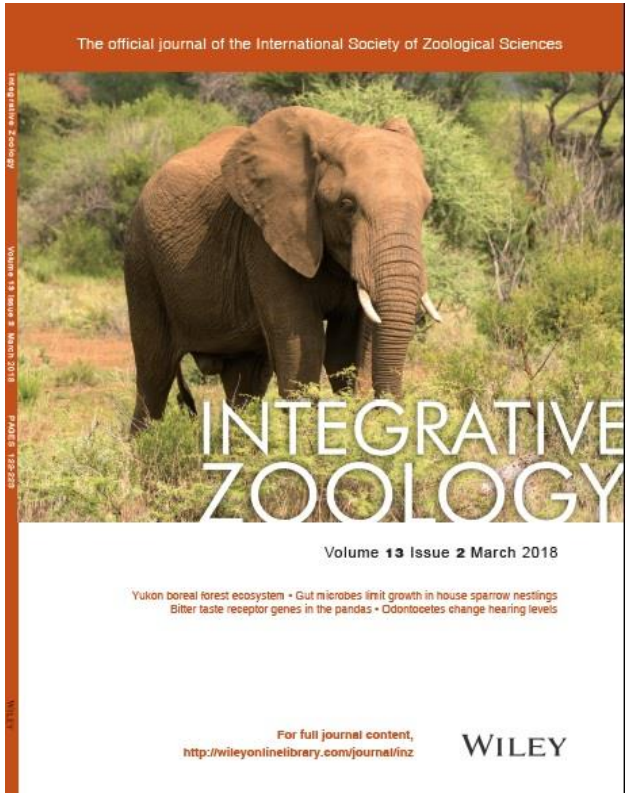
Adjunct Professor, Rutgers University
2016 – present

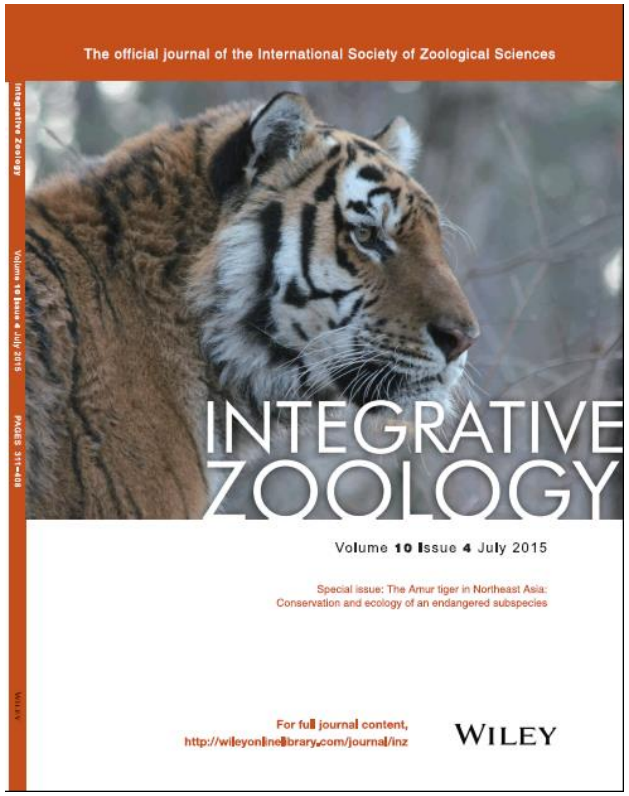
Senior Researcher, Severstov Institute of Ecology and Evolution, Russian Academy of Sciences
2022 - present

ISZS International Society of Zoological Sciences

INTEGRATIVE ZOOLOGY

INSTITUTE OF ZOOLOGY CAS





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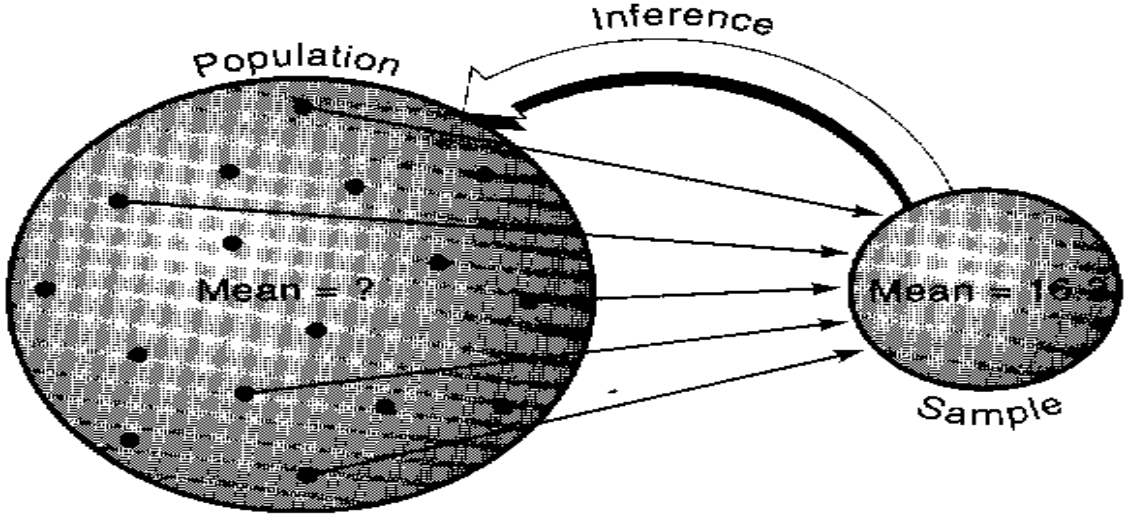
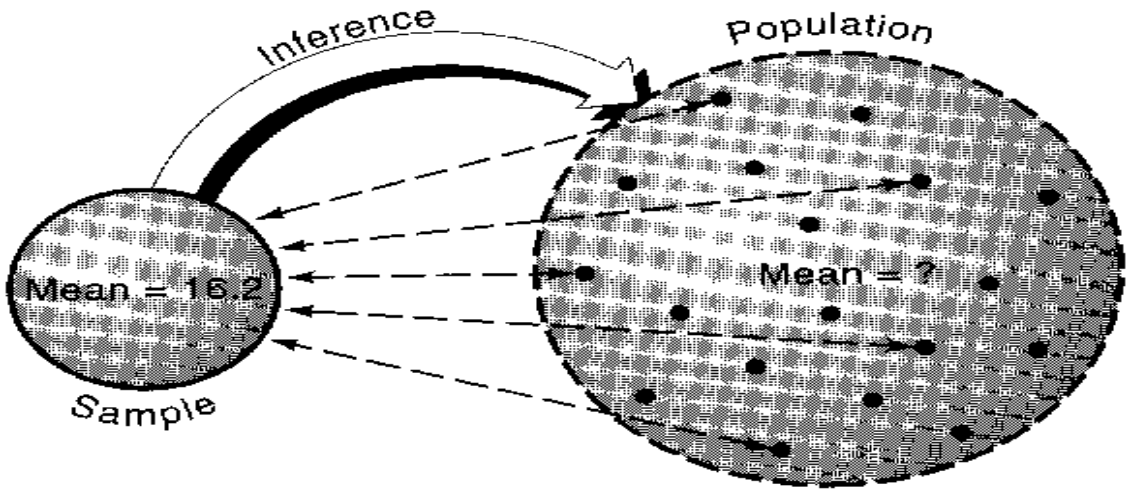


(a) Sampling from a tangible population



(b) Creation of an abstract population to fit an existing sample

FIGURE

Two questions asked at the end of a study

- Validity the study results?

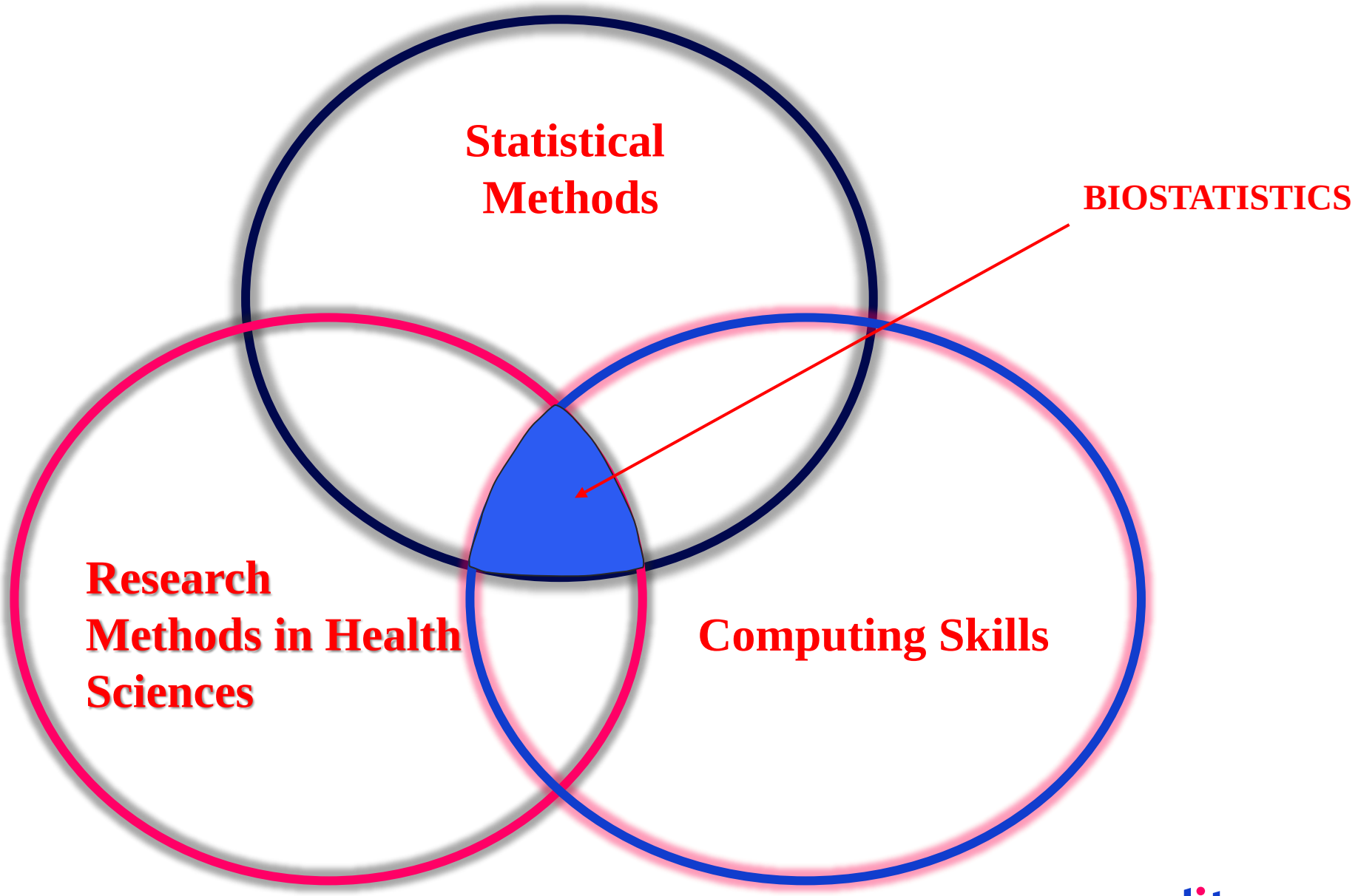
- Reliability of the study results?

Validity and Reliability of both : Measurements, and Study result

- Validity :
  - Asking - Are we measuring/estimating what we think we are meaning?

- Reliability :
  - Asking - How reproducible is the value/study result ?

STATISTICAL METHODS, IF USED PROPERLY, PROVIDES VALID AND RELIABLE RESULTS


Statistical Methods
BIOSTATISTICS
Research Methods in Health Sciences
Computing Skills

Statistical Methods

I. Design Stage

- Sample Size
- Sampling/Randomization
- Data Management Plan
- Data Analysis Plan

II. Analysis Stage

- Descriptive Analysis
- Inferential analysis

III. Interpretation & Publication

Statistical Methods (Analysis)

I. Descriptive Methods :

Tables

Diagrams

Summary : **Univariable,**

Bivariable strength

Multivariable

II. Inferential Methods :

- **Estimation**
- Point Estimation
  Mean / proportion
  etc.
- Interval Estimation
  i.e. Confidence interval of point estimate

- **Hypotheses Testing**
  - Comparison between the treatments
  - Association
  - Etc.

Five Important Terms

- Outcome
- Exposures
- Bias
- Confounder(s)
- Chance factor

Functional Relationship	Measurement/Analysis		
	Categorical	Quantitative	Time to an event
Outcome	√	√	√
Exposure	√	√	X
Other factors • Confounder/s • Effect modifier/s • Interaction	√ √ √	√ √ √	x x x

Descriptive Analysis

- **One variable (uni-variable)**
  - Qualitative
  - Quantitative
  - Time to an event
- **Two variables (Bivariable)**
  - Qualitative vs Qualitative
  - Qualitative vs Quantitative
  - Quantitative vs Quantitative
- **More than two variables (Multivariable)**

- The observed statistical association between a certain outcome and the hypothesized exposure could be the result of systematic errors in collection of data (sampling, disease and exposure ascertainment) or its interpretation
  - role of bias

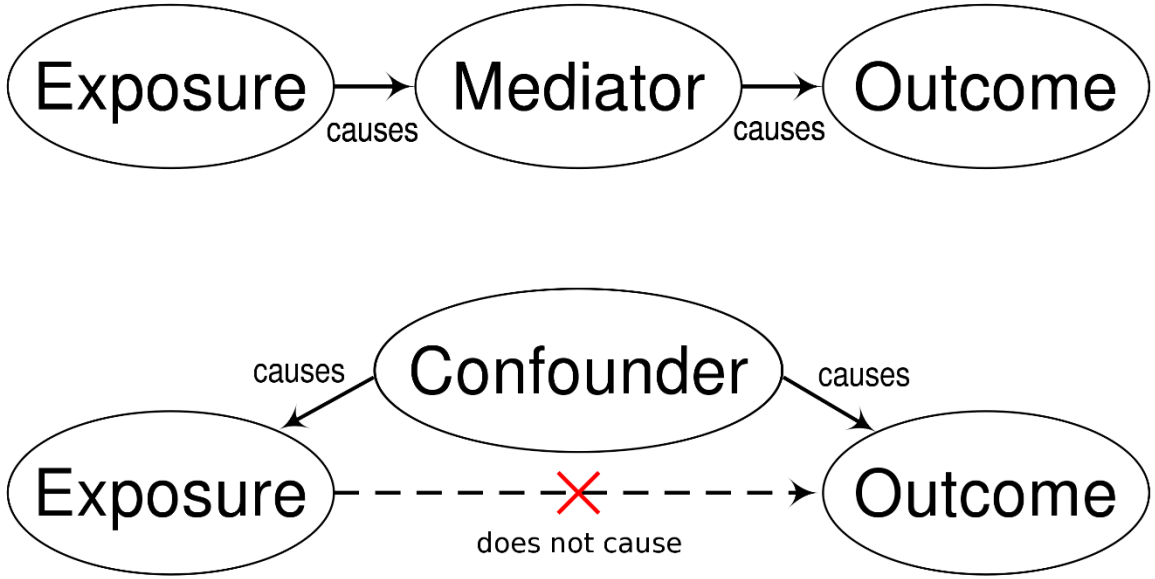
- Or it could be due to the effect of additional variables that might be responsible for the observed association
  - role of confounding variable(s)

- Or it could be just a matter of chance

- Or it could be a real association

THE DIFFERENCE BETWEEN BIAS AND CONFOUNDING

- Bias creates an association that is not true,
- Confounding describes an association that is true, but potentially misleading.
- By definition, a **confounder** (also **confounding variable**, **confounding factor**, **extraneous determinant** or **lurking variable**) is a variable that influences both the independent and dependent variable



Whereas a mediator is a factor in the causal chain (above), a confounder is a spurious factor incorrectly implying causation (bottom)

Figure Credit: Wikipedia Confounding - Wikipedia

EXAMPLES OF RANDOM ERROR, BIAS, MISCLASSIFICATION AND CONFOUNDING IN THE SAME STUDY:

Cohort study: babies of women who bottle feed and women who breast feed are compared,

it is found that the incidence of gastroenteritis, as recorded in medical records, is lower in the babies who are breast-fed.

Knowledge on statistics

Knowledge of statistics is important right through the project:

- Sample size
- Blinding
- Randomisation procedure
- Inclusion/exclusion criteria
- Outcomes
- Type of statistical test used
- Interpretation of data
- Type of control group
- Data management
- Missing data
- Confounding factors
- Data safety monitoring

Hypothesis

- **Hypothesis**: Local Remedy X has an effect on plasma glucose levels
- **Null hypothesis**: Local Remedy X has no effect on plasma glucose levels

- **Trial designs:**
  - The investigational drug (new drug) is better than or superior to the standard, control drug or placebo (superiority trial design)
  - New drugs perform as good as the standard treatment (equivalence trial design)
  - New drug is less effective than the standard treatment (inferiority trial design)

The p-value

- P = **probability value** shows us whether the difference observed is just due to chance, or if it's statistically significant.
- If P>0.05, accept the null hypothesis (i.e. there IS NOT a statistically significant difference)
- If P<0.05, reject the null hypothesis (i.e. there IS a statistically significant difference)

Study bias

- This is an error associated with the study design, conduct, analysis and publication that exaggerates or underestimates the effectiveness of the investigational product

Study bias

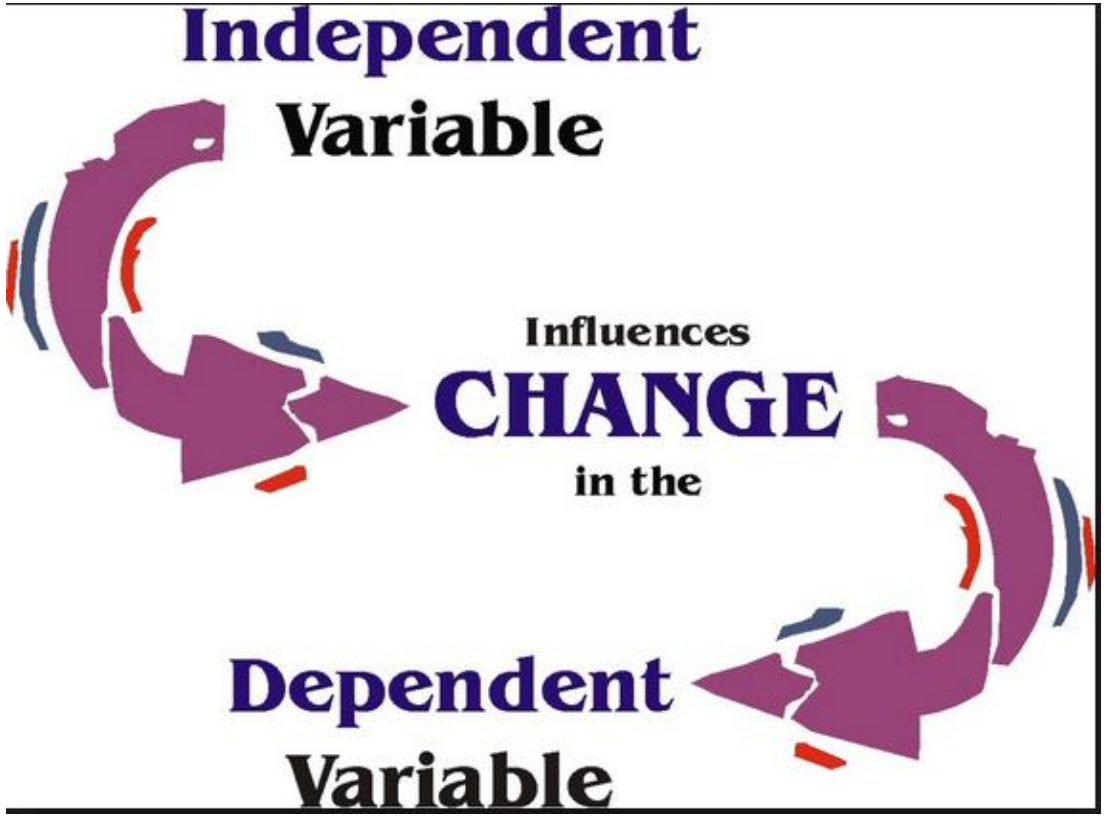
Randomisation and blinding are important ways to minimise some types of bias. Why do you think we randomise and blind participants?

To not influence the results – even unconsciously

trial is double blinded: neither the investigator or the patient will know whether they're receiving remedy X or not.

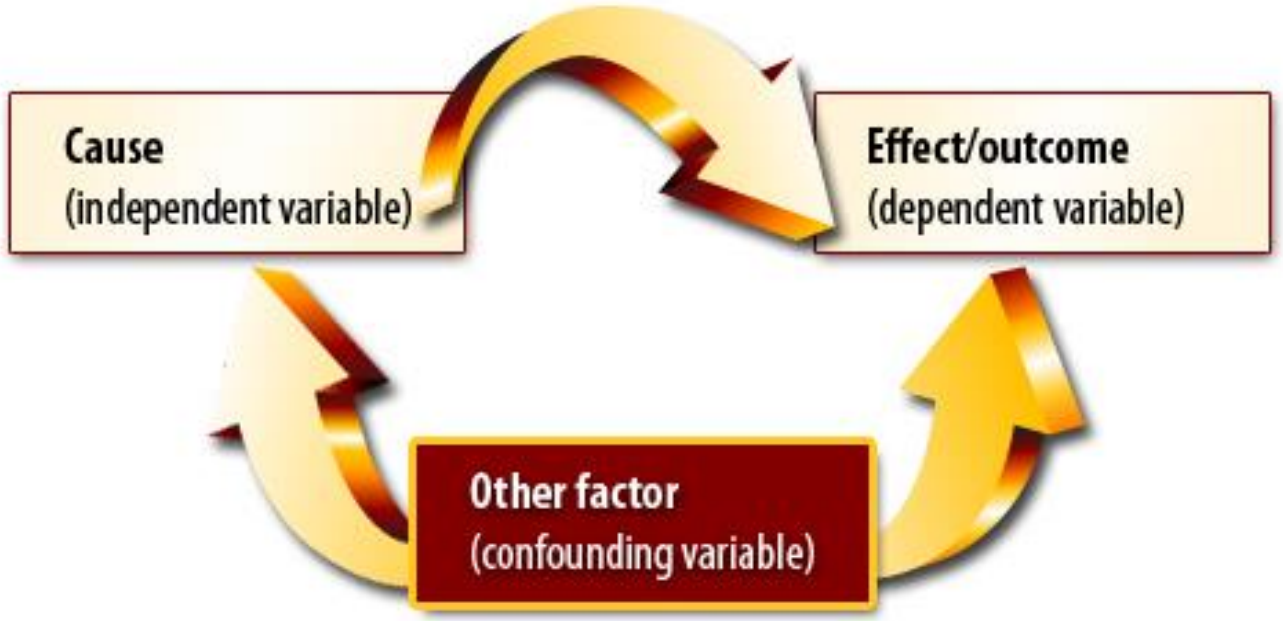
Variables

- The Independent variable is the characteristic that, when changed or modified, will influence the outcome which is observed.
- The Dependent variable is a manifestation or outcome that is achieved by manipulating the independent variable. So the dependent variable ‘depends’ on the value of the independent variable.

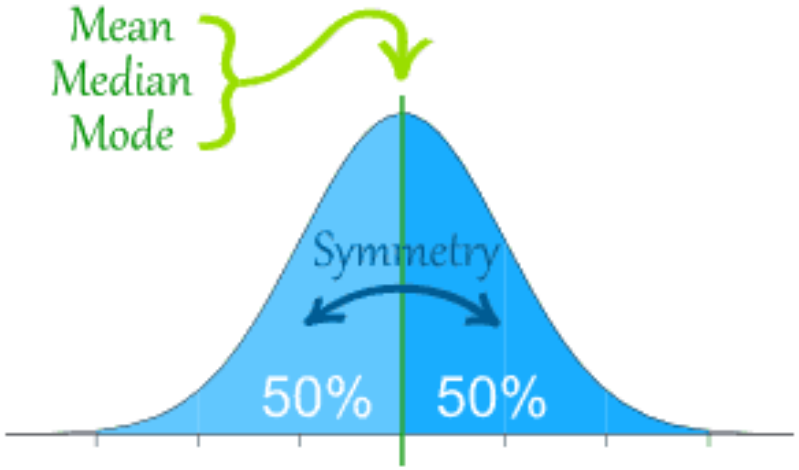


Confounding variables

These are factors that are not normally measured during the study, but may be accountable for the effects observed in research.



Distribution of data



A normal distribution has the same mean, median and mode, and symmetry around the centre, with 50% above and 50% below the mean.

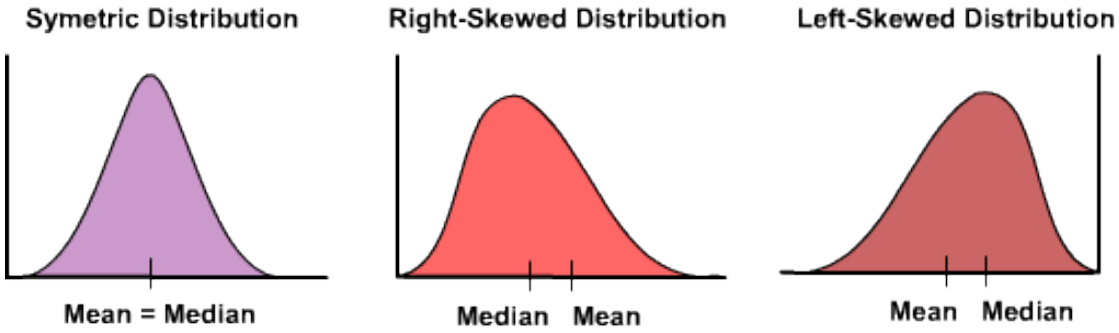
Why does it matter?

Expectation of your data distribution impacts the statistical tests you could use to analyse the data.

How does distribution affect choice of analysis?

- Normally distributed data:
  - Parametric statistical testing
    - Simple mean
    - standard deviations
    - coefficient of variation
    - t-test
    - F –test (ANOVA)
    - correlation
    - regression analyses

- Not expected to have normal distribution:
  - Mann-Whitney test
  - Wilcoxon Signed-Rank test
  - the Kruskal-Wallis test
  - Friedman test



Types of errors in analyses

Type 1

the incorrect rejection of a null hypothesis which is actually true (a "false positive")

Type 2

the failure to reject a false null hypothesis (a "false negative").

Practical approaches to data analysis

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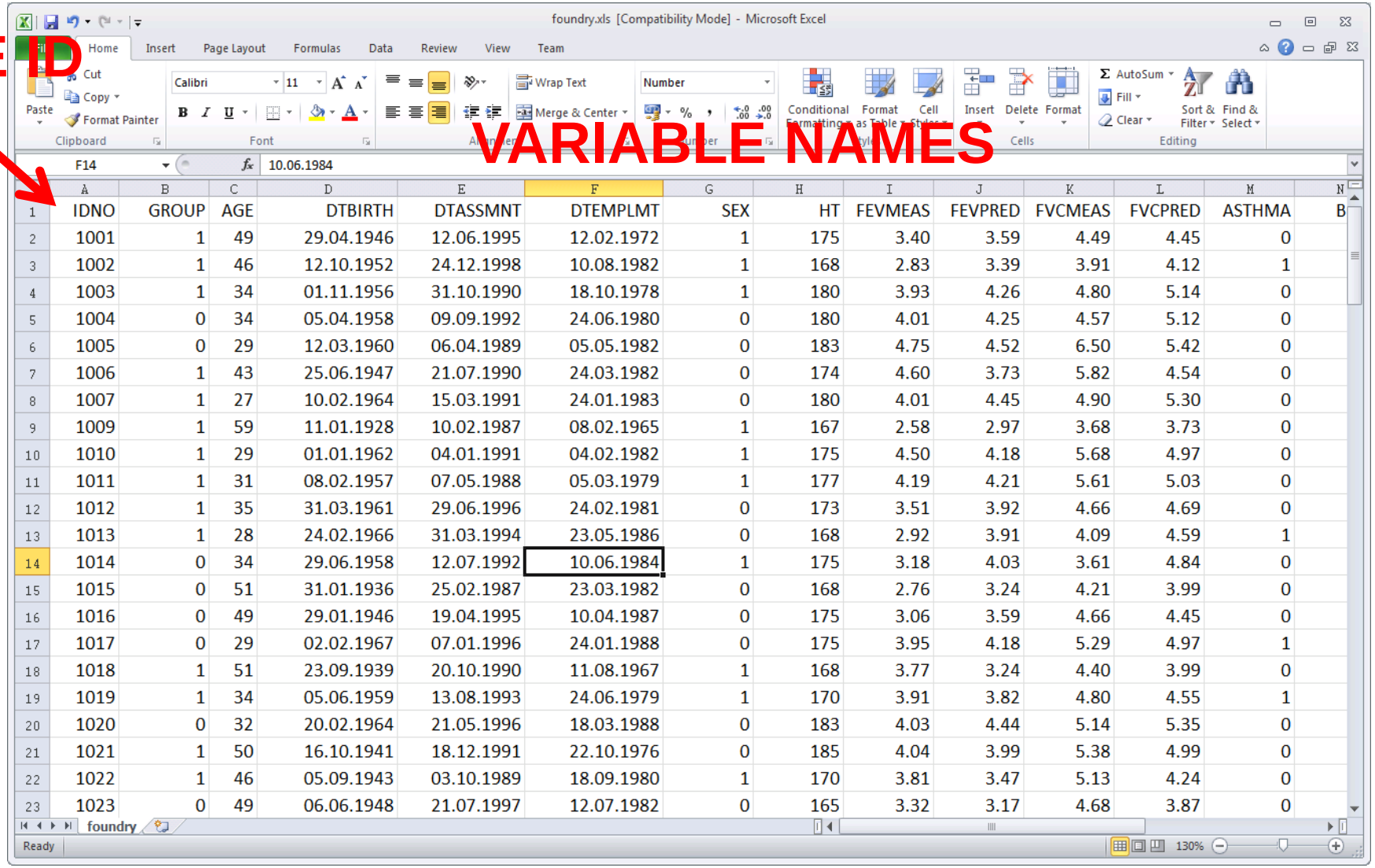
Entering data

- Data should usually be entered into a single worksheet.
- Use one row for each ‘subject’ (patients, participants, laboratory sample).
- Each column should then be a particular piece of information or “variable” for all subjects.
  - If one patient can have multiple values, code as separate yes/no columns
- The first row of the spreadsheet should contain the variable names.
  - Something short, no spaces or punctuation (except “_”)
- Where the subjects are divided into several groups don’t split into several spreadsheets.
  - Enter all data onto one sheet.
  - Add a variable with a numeric code for each group.

UNIQUE ID

VARIABLE NAMES

SUBJECTS

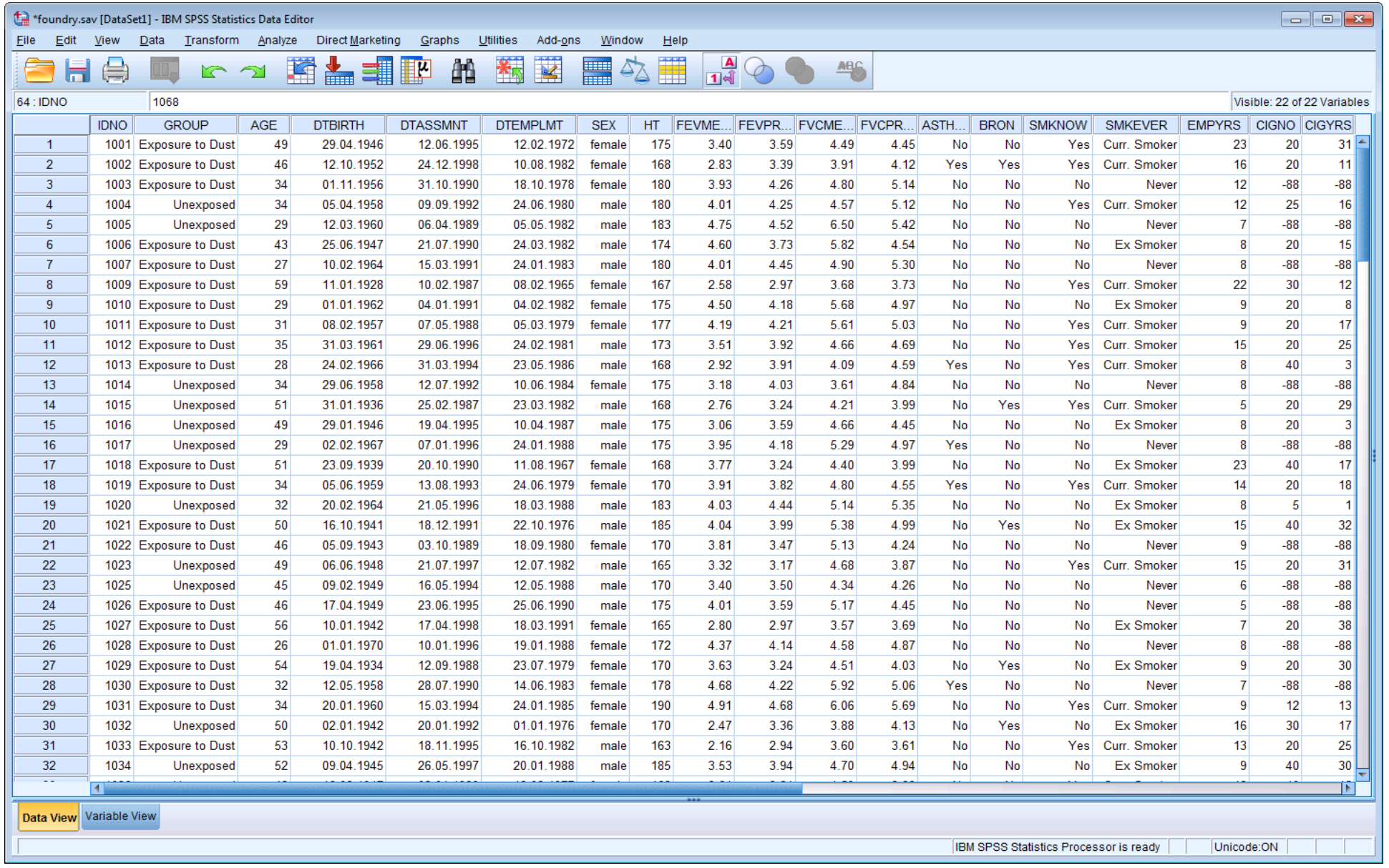


	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	IDNO	GROUP	AGE	DTBIRTH	DTASSMNT	DTEMPLMT	SEX	HT	FEVMEAS	FEVPRED	FVCMEAS	FVCPRED	ASTHMA	B
2	1001	1	49	29.04.1946	12.06.1995	12.02.1972	1	175	3.40	3.59	4.49	4.45	0	
3	1002	1	46	12.10.1952	24.12.1998	10.08.1982	1	168	2.83	3.39	3.91	4.12	1	
4	1003	1	34	01.11.1956	31.10.1990	18.10.1978	1	180	3.93	4.26	4.80	5.14	0	
5	1004	0	34	05.04.1958	09.09.1992	24.06.1980	0	180	4.01	4.25	4.57	5.12	0	
6	1005	0	29	12.03.1960	06.04.1989	05.05.1982	0	183	4.75	4.52	6.50	5.42	0	
7	1006	1	43	25.06.1947	21.07.1990	24.03.1982	0	174	4.60	3.73	5.82	4.54	0	
8	1007	1	27	10.02.1964	15.03.1991	24.01.1983	0	180	4.01	4.45	4.90	5.30	0	
9	1009	1	59	11.01.1928	10.02.1987	08.02.1965	1	167	2.58	2.97	3.68	3.73	0	
10	1010	1	29	01.01.1962	04.01.1991	04.02.1982	1	175	4.50	4.18	5.68	4.97	0	
11	1011	1	31	08.02.1957	07.05.1988	05.03.1979	1	177	4.19	4.21	5.61	5.03	0	
12	1012	1	35	31.03.1961	29.06.1996	24.02.1981	0	173	3.51	3.92	4.66	4.69	0	
13	1013	1	28	24.02.1966	31.03.1994	23.05.1986	0	168	2.92	3.91	4.09	4.59	1	
14	1014	0	34	29.06.1958	12.07.1992	10.06.1984	1	175	3.18	4.03	3.61	4.84	0	
15	1015	0	51	31.01.1936	25.02.1987	23.03.1982	0	168	2.76	3.24	4.21	3.99	0	
16	1016	0	49	29.01.1946	19.04.1995	10.04.1987	0	175	3.06	3.59	4.66	4.45	0	
17	1017	0	29	02.02.1967	07.01.1996	24.01.1988	0	175	3.95	4.18	5.29	4.97	1	
18	1018	1	51	23.09.1939	20.10.1990	11.08.1967	1	168	3.77	3.24	4.40	3.99	0	
19	1019	1	34	05.06.1959	13.08.1993	24.06.1979	1	170	3.91	3.82	4.80	4.55	1	
20	1020	0	32	20.02.1964	21.05.1996	18.03.1988	0	183	4.03	4.44	5.14	5.35	0	
21	1021	1	50	16.10.1941	18.12.1991	22.10.1976	0	185	4.04	3.99	5.38	4.99	0	
22	1022	1	46	05.09.1943	03.10.1989	18.09.1980	1	170	3.81	3.47	5.13	4.24	0	
23	1023	0	49	06.06.1948	21.07.1997	12.07.1982	0	165	3.32	3.17	4.68	3.87	0	

Coding Data

- A statistical package will treat the text “Yes” “YES” and “yes” as different categories.
- Use numerical codes for categories so they can be entered as numbers rather than as text to simplify data entry.
  - E.g. Use “0” and “1” for “yes” and “no” or “male” and “female” .
- Use the software:
  - Search and replace in Excel to check and change data
  - Define a set of value codes, or drop-down boxes
- Don’t mix text with numbers in the same variable
  - Can code missing (eg as 999) and tell SPSS this is missing
  - Leaving blank in Excel will also work for missing values
  - Avoid “<“ and “>” and essays (comment columns can be useful)

Data (Foundry example SPSS)



	IDNO	GROUP	AGE	DTBIRTH	DTASSMNT	DTEMPLMT	SEX	HT	FEVME...	FEVPR...	FVCME...	FVCPR...	ASTH...	BRON	SMKNOW	SMKEVER	EMPYRS	CIGNO	CIGYRS
1	1001	Exposure to Dust	49	29.04.1946	12.06.1995	12.02.1972	female	175	3.40	3.59	4.49	4.45	No	No	Yes	Curr. Smoker	23	20	31
2	1002	Exposure to Dust	46	12.10.1952	24.12.1998	10.08.1982	female	168	2.83	3.39	3.91	4.12	Yes	Yes	Yes	Curr. Smoker	16	20	11
3	1003	Exposure to Dust	34	01.11.1956	31.10.1990	18.10.1978	female	180	3.93	4.26	4.80	5.14	No	No	No	Never	12	-88	-88
4	1004	Unexposed	34	05.04.1958	09.09.1992	24.06.1980	male	180	4.01	4.25	4.57	5.12	No	No	Yes	Curr. Smoker	12	25	16
5	1005	Unexposed	29	12.03.1960	06.04.1989	05.05.1982	male	183	4.75	4.52	6.50	5.42	No	No	No	Never	7	-88	-88
6	1006	Exposure to Dust	43	25.06.1947	21.07.1990	24.03.1982	male	174	4.60	3.73	5.82	4.54	No	No	No	Ex Smoker	8	20	15
7	1007	Exposure to Dust	27	10.02.1964	15.03.1991	24.01.1983	male	180	4.01	4.45	4.90	5.30	No	No	No	Never	8	-88	-88
8	1009	Exposure to Dust	59	11.01.1928	10.02.1987	08.02.1965	female	167	2.58	2.97	3.68	3.73	No	No	Yes	Curr. Smoker	22	30	12
9	1010	Exposure to Dust	29	01.01.1962	04.01.1991	04.02.1982	female	175	4.50	4.18	5.68	4.97	No	No	No	Ex Smoker	9	20	8
10	1011	Exposure to Dust	31	08.02.1957	07.05.1988	05.03.1979	female	177	4.19	4.21	5.61	5.03	No	No	Yes	Curr. Smoker	9	20	17
11	1012	Exposure to Dust	35	31.03.1961	29.06.1996	24.02.1981	male	173	3.51	3.92	4.66	4.69	No	No	Yes	Curr. Smoker	15	20	25
12	1013	Exposure to Dust	28	24.02.1966	31.03.1994	23.05.1986	male	168	2.92	3.91	4.09	4.59	Yes	No	Yes	Curr. Smoker	8	40	3
13	1014	Unexposed	34	29.06.1958	12.07.1992	10.06.1984	female	175	3.18	4.03	3.61	4.84	No	No	No	Never	8	-88	-88
14	1015	Unexposed	51	31.01.1936	25.02.1987	23.03.1982	male	168	2.76	3.24	4.21	3.99	No	Yes	Yes	Curr. Smoker	5	20	29
15	1016	Unexposed	49	29.01.1946	19.04.1995	10.04.1987	male	175	3.06	3.59	4.66	4.45	No	No	No	Ex Smoker	8	20	3
16	1017	Unexposed	29	02.02.1967	07.01.1996	24.01.1988	male	175	3.95	4.18	5.29	4.97	Yes	No	No	Never	8	-88	-88
17	1018	Exposure to Dust	51	23.09.1939	20.10.1990	11.08.1967	female	168	3.77	3.24	4.40	3.99	No	No	No	Ex Smoker	23	40	17
18	1019	Exposure to Dust	34	05.06.1959	13.08.1993	24.06.1979	female	170	3.91	3.82	4.80	4.55	Yes	No	Yes	Curr. Smoker	14	20	18
19	1020	Unexposed	32	20.02.1964	21.05.1996	18.03.1988	male	183	4.03	4.44	5.14	5.35	No	No	No	Ex Smoker	8	5	1
20	1021	Exposure to Dust	50	16.10.1941	18.12.1991	22.10.1976	male	185	4.04	3.99	5.38	4.99	No	Yes	No	Ex Smoker	15	40	32
21	1022	Exposure to Dust	46	05.09.1943	03.10.1989	18.09.1980	female	170	3.81	3.47	5.13	4.24	No	No	No	Never	9	-88	-88
22	1023	Unexposed	49	06.06.1948	21.07.1997	12.07.1982	male	165	3.32	3.17	4.68	3.87	No	No	Yes	Curr. Smoker	15	20	31
23	1025	Unexposed	45	09.02.1949	16.05.1994	12.05.1988	male	170	3.40	3.50	4.34	4.26	No	No	No	Never	6	-88	-88
24	1026	Exposure to Dust	46	17.04.1949	23.06.1995	25.06.1990	male	175	4.01	3.59	5.17	4.45	No	No	No	Never	5	-88	-88
25	1027	Exposure to Dust	56	10.01.1942	17.04.1998	18.03.1991	female	165	2.80	2.97	3.57	3.69	No	No	No	Ex Smoker	7	20	38
26	1028	Exposure to Dust	26	01.01.1970	10.01.1996	19.01.1988	female	172	4.37	4.14	4.58	4.87	No	No	No	Never	8	-88	-88
27	1029	Exposure to Dust	54	19.04.1934	12.09.1988	23.07.1979	female	170	3.63	3.24	4.51	4.03	No	Yes	No	Ex Smoker	9	20	30
28	1030	Exposure to Dust	32	12.05.1958	28.07.1990	14.06.1983	female	178	4.68	4.22	5.92	5.06	Yes	No	No	Never	7	-88	-88
29	1031	Exposure to Dust	34	20.01.1960	15.03.1994	24.01.1985	female	190	4.91	4.68	6.06	5.69	No	No	Yes	Curr. Smoker	9	12	13
30	1032	Unexposed	50	02.01.1942	20.01.1992	01.01.1976	female	170	2.47	3.36	3.88	4.13	No	Yes	No	Ex Smoker	16	30	17
31	1033	Exposure to Dust	53	10.10.1942	18.11.1995	16.10.1982	male	163	2.16	2.94	3.60	3.61	No	No	Yes	Curr. Smoker	13	20	25
32	1034	Unexposed	52	09.04.1945	26.05.1997	20.01.1988	male	185	3.53	3.94	4.70	4.94	No	No	No	Ex Smoker	9	40	30

Data Cleaning

Once your data is entered ….

- Check it for sense
  - Summary parameters – mean values, range
  - Plots – histograms, scatterplots
  - Cross-tabulations
- Don’t remove data without a good reason
  - But check suspicious values at source and confirm
  - If results depend on a few extreme values report sensitivity analyses
  - Non-parametric?
  - With and without the aberrant points

Data Analysis

- Appropriate to your study question
- Hypothesis tests and p-values are not compulsory
  - Audit is about counting
  - Many research studies are about describing groups of patients and their outcomes
  - Hypothesis tests are about comparisons
- Descriptive statistics are good statistics

- Keep it simple – use tests you have met before – but know their limitations
- Use the Stats clinics (and Piazza) for advice

Over-the-counter statistics

- **Comparing groups – measurement a real number**
  - T-test; Mann-Whitney U test
  - Paired t-test; Wilcoxon test if paired
  - Oneway ANOVA; Kruskal-Wallis test
- **Comparing groups – measurement categorical**
  - χ^2 test; Fishers Exact test
  - Relative risk, Odds ratios
- **Relationship between two variables– measurement real numbers**
  - Linear regression (both numbers)
  - Correlation (Pearson or Spearman)
- **Diagnostic tests**
  - Sensitivity, specificity, predictive value

Which test do I pick off the shelf?

- Many crib sheets for over-the-counter methods
  - eg in the notes for the statistical software labs

	Plausibly Continuous and Normal	**Ordinal or Ordered Categorical**	**Binary and Unordered Categories**
Comparison of Independent Two Groups	Box-plot Independent groups t-test	Box-plot or Cross-tabulation of ordered categories Mann-Whitney U-test	Cross-tabulation Chi-squared test Fisher's exact test
Comparison of more than Two groups	Analysis of variance (ANOVA)	*Kruskal Wallis analysis of Variance**	Cross-tabulation Chi-squared test
Comparison of two related outcomes	Paired samples t-test	Wilcoxon Matched Pairs	McNemar's Test
Relationship between a dependent variable and one or more independent variables	Scatter plot Regression *Pearson's correlation coefficient*	*Spearman correlation or Kendall's correlation coefficient*	*Phi coefficient* *Logistic Regression*

- Use with caution – if in doubt consult a statistician

Prescription Only Statistics

- Survival Analysis (Time to event)
- Logistic regression
- Multiple regression
- Two-way ANOVA
- Measurement studies
  - Agreement – Kappa, Bland-Altman

Interpretation - What does it mean?

- Effect Estimates
  - Absolute difference

    = $Risk^A$ – $Risk^B$ / $Mean^A$ – $Mean^B$/Linear regress

    = e.g. 2% - 0.5% = 1.5%

  - Relative difference

    = $Risk^A$ / $Risk^B$ or $Odds^A$/$Odds^B$ or logistic regress

    = e.g. 2% / 0.5% = 4

    Odds – Ratio of event occurring vs not occurring

- Statistically Sig (P-val≤0.05) vs Clinically Sig
- Confidence Interval (95% C.I.) = accuracy!

Is it all it seems?

- **Confounding**
  - A third variable which has the potential to affect both the measurement and the variable being assessed.
  - Eg case mix; time periods (before/after)….
  - Identify and demonstrate confounding (or lack of it)
  - May be able to adjust statistically (ask for help!)
- **Is the sample representative?**
  - Inclusion/exclusion?
  - Selectively missing data?
  - Setting?
  - Power?
- **Hawthorne effect**
  - People behave differently if they know they are being observed

Red Flags

- No clear hypothesis or parameter to be estimated
- Multiple measurements (of the same thing) on the same people
- Multiple hypothesis tests
- Incompletely observed outcomes
    - Survival or time to event which hasn’t always happened
- Non-random sampling
- Potential confounding
- Missing data (…)

Missing data

- Try to avoid it!
- Acknowledge it
- Describe it
  - Who/what is missing?
- Think about the reasons and consequences
  - Why missing?
- Explore the consequences
  - How big a difference could it make?

EXAMPLE OF RANDOM ERROR

By chance, there are more episodes of gastroenteritis in the bottle-fed group in the study sample, producing a type 1 error. (When in truth breast feeding is not protective against gastroenteritis).

Or, also by chance, no difference in risk was found, producing a type 2 error (When in truth breast feeding is protective against gastroenteritis).

EXAMPLE OF RANDOM MISCLASSIFICATION

Lack of good information on feeding history results in some breast-feeding mothers being randomly classified as bottle-feeding, and vice-versa.

If this happens, the study finding *underestimates* the true RR, whichever feeding modality is associated with higher disease incidence, producing a type 2 error.

EXAMPLE OF BIAS

The medical records of bottle-fed babies *only* are *less complete* (perhaps bottle fed babies go to the doctor less) than those of breast fed babies, and thus record fewer episodes of gastro-enteritis in them only.

This is called bias because the observation itself is in error.

EXAMPLE OF CONFOUNDING

The mothers of breast-fed babies are of higher social class, and the babies thus have *better hygiene, less crowding* and perhaps other factors that protect against gastroenteritis.

Less crowding and better hygiene are truly protective against gastroenteritis, but we mistakenly attribute their effects to breast feeding. This is called confounding because the observation is correct, but its explanation is wrong.

What to compute? **Objective(s)**

Primary **Secondary**

Study Designs

Burden **Hypothesis generation**

Cross-Sectional

Prevalence, mean ***Prevalence of Relative Frequencies & Measures of Assoc.***

Measures outcomes and exposures of the study subjects at the same time. It is described as taking a "snapshot"

Association **Hypothesis generation**

Case-Control

Prevalence of Relative Frequencies in Case-Control & Measures of Assoc.

Study design is called **observational** because the researcher does not control the assignment of a subject to one of the groups, unlike in a planned experimental study.

Cause-Effect **Hypothesis generation**

Cohort

Incidence of outcome(s), Measures of Assoc.

A **cohort study** is a type of **observational study** that follows a group of participants over a period of time. Its primary goal is to examine how certain factors (such as exposure to a specific risk factor) influence their health outcomes. Here are the key points about cohort studies:

Cause-Effect **Hypothesis generation**

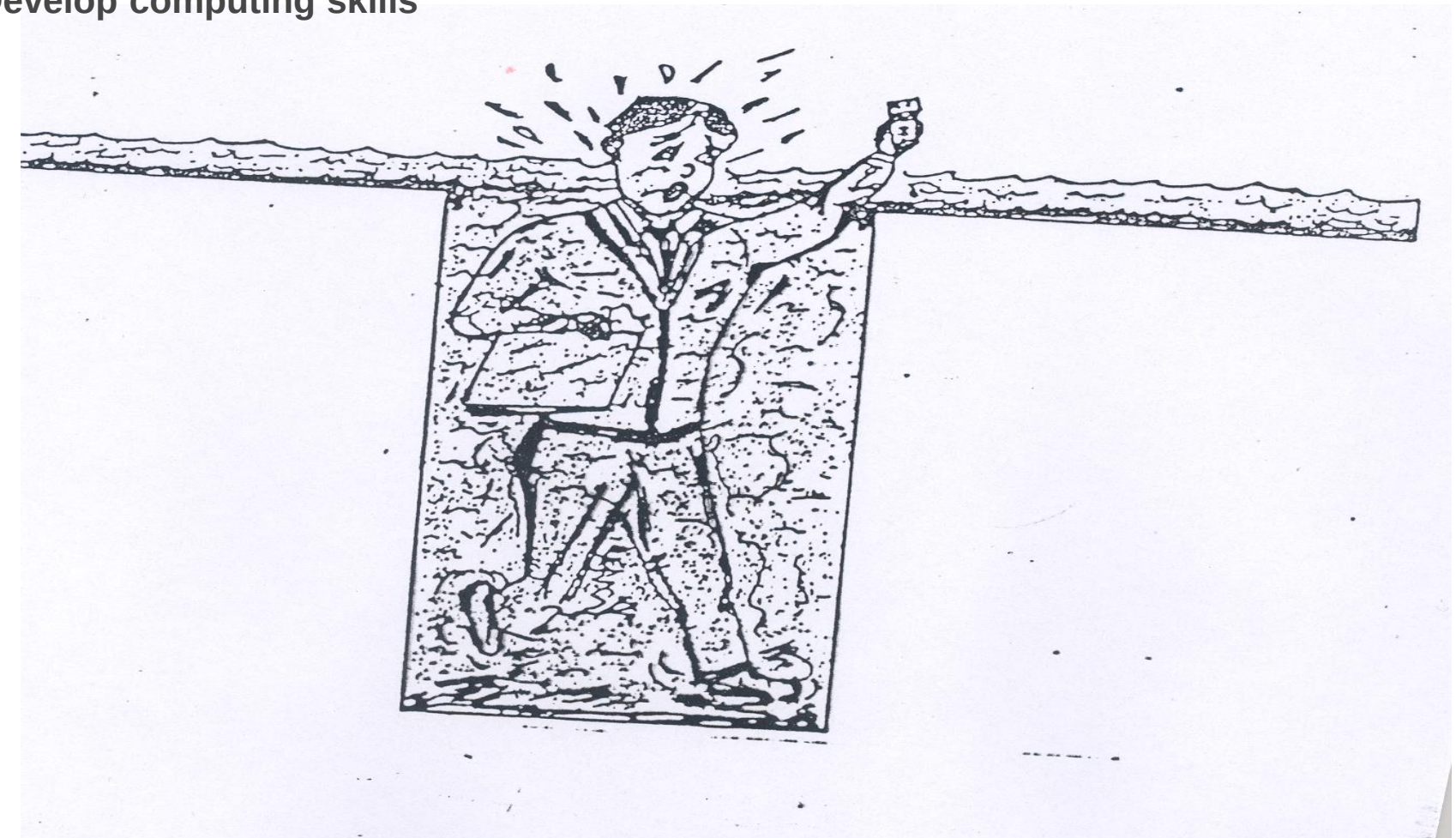
Clinical Trial

Incidence of outcome(s), Measures of Assoc.

A properly designed clinical trial can provide strong evidence supporting cause-effect relationships and form the basis for clinical and public health policy.

- **Statistical Analysis is a computing problem: Avoid Such a thinking**
- **Prevention is Cost-Effective: Also true for Biostatistics**
- **Preventive measures:**

1. **Must have knowledge of Principles of Research Methods & Biostatistics.**
2. **Develop computing skills**



Thank You

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A CACTUS Solution