MONASH University

MONASH
PUBLIC HEALTH AND
PREVENTIVE MEDICINE

Doing the Advanced Training Research Project (or Research) - for Occupational & Environmental Medicine Trainees

Professor Karen Walker-Bone BM, FRCP, PhD, Hon FFOM
Director, Monash centre for Occupational and Environmental Health

Plan

- Advanced Training Research Project
- Clinical Audit
- Systematic Review
- Research on human subjects, populations or communities and laboratory research
  - Research question and study methodology
  - Literature search and protocol
  - Research write-up
  - Bias and confounding
  - Time management

Advanced Training Research Project (ATRP)

- A project that you have significant involvement in designing, conducting, and data analysis
- Enables gaining of experience in:
  - Research methods
  - Interpretation of research literature
  - Participation in research
  - Developing quality improvement skills
- Should be “broadly relevant” to your area of specility

The ATRP submission

- Provides evidence of the skills of:
  - Considering and defining research problems
  - The systematic acquisition, analysis, synthesis and interpretation of data
  - Effective written communication
- “Acceptable” research projects
  - Research in human subjects, populations and communities or laboratory research
  - Audit
  - Systematic review

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Clinical audit

- Assessment of ACTUAL practice against the “gold standard” or evidence-based guideline
- In OEH, few published evidence-based guidelines or protocols so it can be a guideline /best practice approach that is widely used in the discipline (check with your supervisors)
- e.g. **Management of low back pain**: notes-based assessment of recording of: asked about sphincter disturbance; red flags and yellow flags; provision of written educational materials; recommendation of exercise and self-management; not requesting first-line imaging; not prescription of medication as first-line; aim for early return-to-work; safety netting

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Systematic Review

- Highly systematic approach to exploring literature around a delineated topic
- DELINEATED – not 1000s of papers to screen and synthesise but NOT too few either..
- Create a PROTOCOL and consider registration in PROSPERO

https://www.prisma-statement.org/prisma-2020-checklist

Systematic Review: PICO

- Define PI(E)CO
  - Population
  - Intervention /Exposure
  - Control
  - Outcome
- E.g. Amongst **workers attending for pre-employment screening**, what is the evidence that assessment of range of motion of shoulders using goniometry is superior to non-assessment of range of motion in predicting workers at risk of shoulder pain or injury within 12 months of commencing work

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Systematic Review: Process

- Defined **search strategy** with carefully chosen research terms
- Usually 4-5 on-line databases searched on a defined day: make decisions about languages included and time period for search. RARE things longer time period..
- Information scientist /librarian
- Have in mind 2-3 relevant papers and make sure your strategy finds them
- Each database yield will have some overlap – delete duplicates
- Helpful to import abstracts into a software tool like **Covidence** for screening

Systematic Review: Screening

- Screen titles and abstracts for inclusion /exclusion
- Screen full-texts for inclusion /exclusion
- Ideally both screening phases have two independent observers and check those in which there is disagreement together (Covidence helps with this)

Systematic review: data extraction

- Final pool of papers – systematic data extraction
- Used pre-developed proforma
- Ideally two observers do first 2-3 papers independently then review and if necessary refine proforma
- Complete data extraction for all included papers

Systematic review: quality assessment

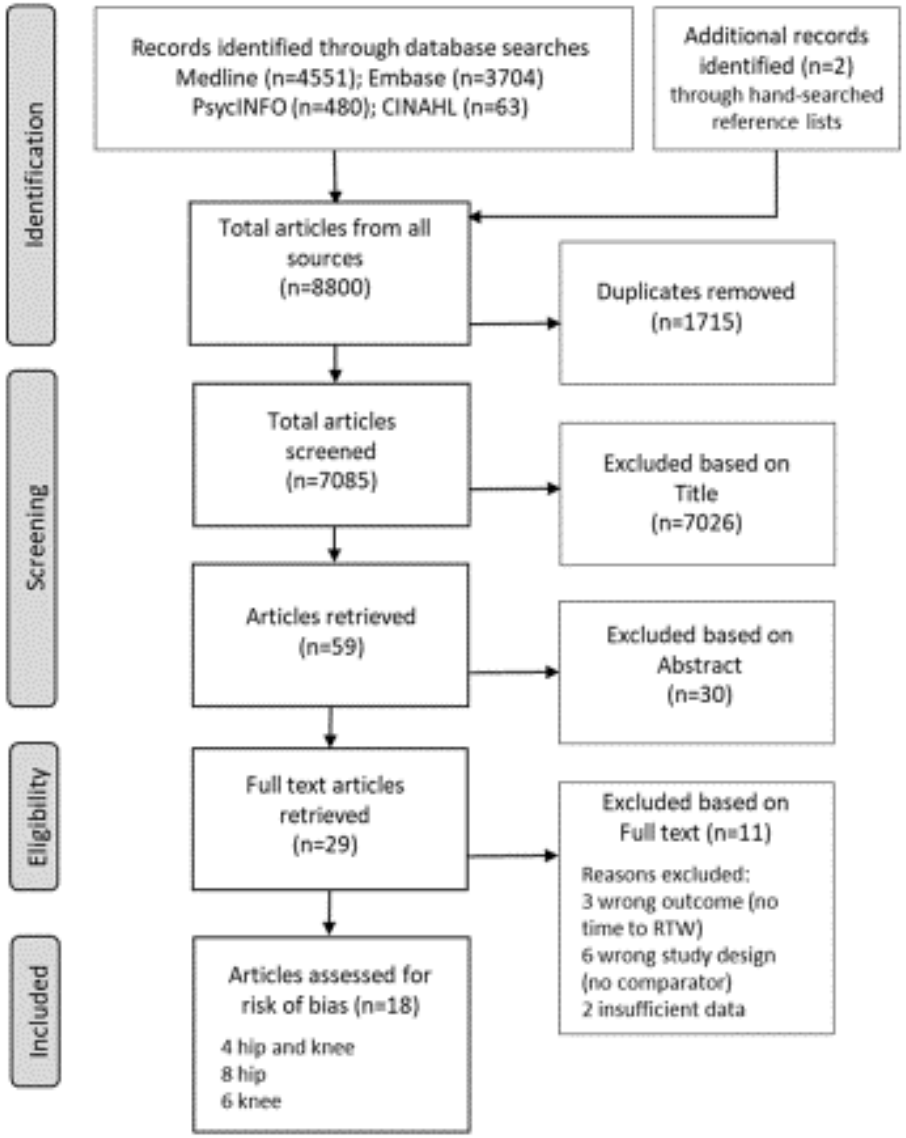
- Undertake risk of bias /quality assessment of included papers
- Variety of different tools available
- May need to be “personalised” for your review topic
- E.g. return to work

Cochrane library
JBI tools
Scottish Intercollegiate Network (SIGN)

Systematic Review: Synthesis

- Synthesise your extracted data for reporting
- PRISMA flow-chart (Covidence)
- Tables of included papers (& excluded papers with reasons)
- Narrative synthesis of your results

Systematic review of factors which impact the time taken to return to work after lower limb arthroplasty - PRISMA



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Research in human subjects, populations and communities or laboratory research

- First step: define a RESEARCH QUESTION

Research question

- The most important part of any study
- Leads to the appropriate study design for the research
- Should be as SPECIFIC as possible
- Should be clearly laid out in any paper you are reading
- PICO /PECO
  - Population
  - Intervention or Exposure
  - Control
  - Outcome

Study Methodology

- Dependent upon the question…

….. And some other practicalities:

- Time and urgency
- Resources
- Ethical considerations

Research question dictates study design

• Prevalence /frequency	**Cross-sectional**
• Hypotheses about possible causes	**Ecological**
• Causes/risk factors	**Case-Control**
• Harm (or causes)	**Cohort**
• Lived experience of illness	**Qualitative**
• Efficacy (harm)	**RCT**

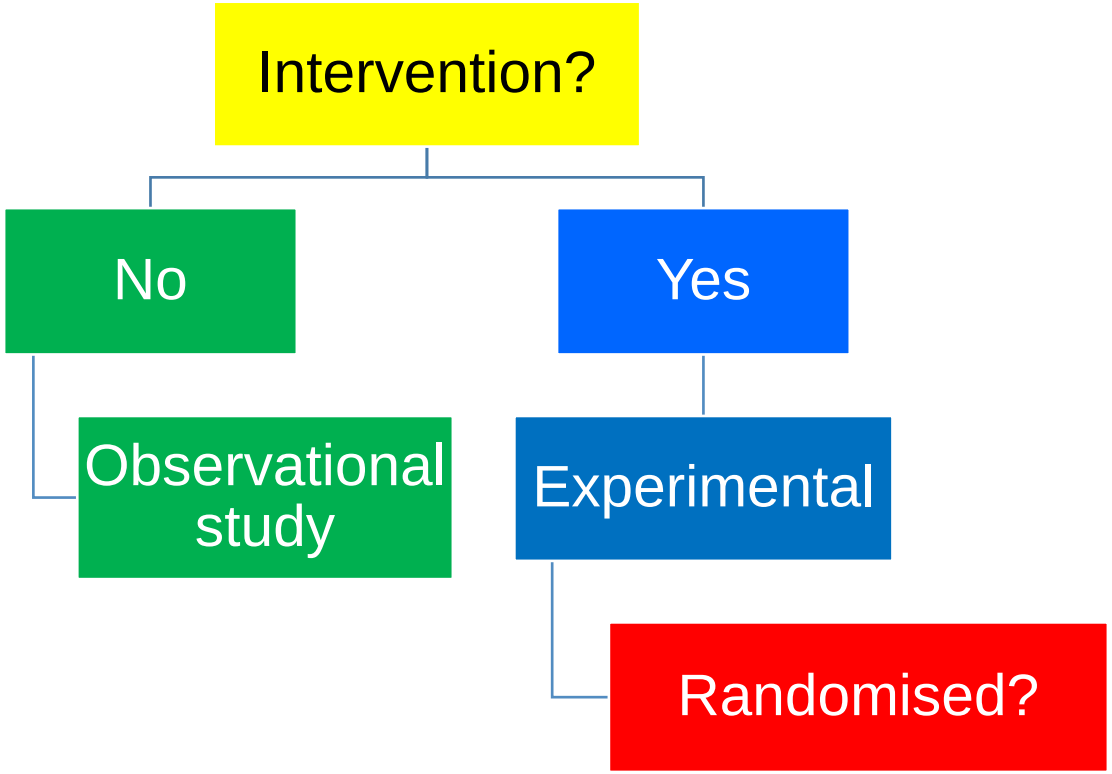
Qualitative research

- Perceptions, beliefs and experiences
- Valuable for answering questions about best approaches to planning and delivering interventions
- Can be included as part of quantitative research: “mixed methods”

Qualitative studies: methods of data collection and analysis

- Data collection methods
  - Observation
  - Interviews
  - Focus groups
  - Diaries
- Data analysis
  - Themes/Contexts/Categories

Types of quantitative research studies



Which study to use when?

- The disease of interest is a rare condition?

  Case-control study
- We want to assess multiple outcomes?

  Cohort study
- There is a cost/time constraint?

  Case-control study
- We want to know prevalence?

  Cross-sectional

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Literature search

- Detailed and comprehensive
- Really understand the literature
- Do NOT need a systematic strategy and multiple databases but does need to be comprehensive and best practice to define years, language, databases used
- Lots of references will need to be read and filtered to find the **at least 30** which set the backdrop
- Mostly will be peer-reviewed papers and reviews NOT textbooks, occasionally definitive websites..

Protocol

- After defining the research question and selection of the appropriate methodology
- Create a structured protocol
  - Background from Literature Review– what do we know on this topic and what do we not? Why is YOUR research needed?
  - Methods – what are you going to do, on whom, how will you find them and recruit them? How will you get their consent? What will you ask them, do to them or measure? How? How often?
  - What will you do to analyse your results? (May be statistical analysis plan)

Protocol: key headings

- Title page – title, names of researchers, version number, date
- Background
- Study design
- Justification of sample size
- Inclusion/Exclusion criteria
- Participants recruitment
- Interventions
- Randomisation
- Study Outcomes
- Bias and Confounding
- Data Management
- Quality assurance and control procedures
- Data analysis
- Study timelines
- Signature of PI

Clinical governance and ethics

- Most research involving human participants requires ethical approval from a Human Research Ethics Committee (HREC)
- Most HRECs use on-line forms (often with protocol required)
- Submission will require any patient-facing materials e.g. explanatory statement, questionnaire being used (or script for qualitative research)
- Consent process, data storage and destruction, confidentiality and privacy considerations
- Ethical to undertake research for your own education ONLY??

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Research: Write-up

- Abstract
- Background
- Methods
- Results
- Discussion

Abstract

- A brief synopsis of your project
- Absolute prerequisite for many applications in medicine
- E.g. Conference presentations, theses or prizes
- Format proscribed by journals /conferences but usually: Background; Methods; Results: Discussion
- Often 250 or 300 words OR LESS
- It is a SKILL and needs practice

Background

- First part of your write-up: Set the scene..
- Must lead the reader to understand why you have chosen this research topic, why it is important, to whom, and what the essential gaps are that your research will fill (based on EVIDENCE and critical evaluation of evidence)
- Broadly like a background in a published paper:
  - General introduction to the topic – common disease? Rare disease with severe implications or impact? Treatable or not treatable? Disabling? Public or personal health effects? Costly to society?
  - What are the gaps in knowledge?
  - Why do they matter?
  - What difference could filling them make? Practice /Policy?
  - Therefore the aims of your research were.. (with /without a hypothesis)

Reading papers critically

- Research question (PICO or PECO)
- Research methodology
- Selection of the participants for study
- Selection of the controls (if relevant) for study
- How is exposure assessed –is it reliable and valid?
- Is there blinding of the participants? Researchers?
- How are the data analysed? Is it appropriate?
- What are the outcome(s) – how well are they assessed?
- Have bias and confounding been considered fully and discussed?

Evidence-based medicine

Decreasing bias

Eminence-based medicine

Methods

- What you actually DID (i.e. a recipe to follow)
- Factual
- Past tense
- What questions were included, where they came from (validated?)
- What analysis was performed (which statistical package? Which statistics?)
- Include all developments of your methods – pilot studies / developing experiments etc

Results

- What you actually FOUND
- Analysed and presented appropriately
- Graphs / Tables and Figures
- Presentation important
- Every Table /Figure needs well-structured careful description avoiding repetition. Do NOT need to highlight all results but do need to draw attention to those that are important or unexpected

Discussion

- EVERY “new” researcher struggles here
- Do NOT leave to last minute – most likely place to fail if superficial
- Need to contextualise your key findings with what you hypothesised – what was expected? What was unexpected?
- ALSO: what are the implications.. For policy? For practice?
- What are the STRENGTHS of your research and importantly what are the WEAKNESSES (bias, confounding, recruitment) and what impact might the weaknesses have had on your findings? Over estimated? Under estimated?
- Healthy worker effect

Discussion

- How does your project ‘fit’ with the literature
- What did your research contribute?
- Did you get what you expected?
- If not, why not?
- What were the strengths and weaknesses of your study?
- What do your findings MEAN?
- What other work is now required?

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Associations

Exposure ?→ Outcome

Have you considered

- Chance
- Bias
- Confounding

Bias

- Any process at any stage of study that produces results that depart from the truth
- Two main types:
  - Selection
  - Information

Selection bias

- Identification of subjects into study biased
  - e.g. non responders in a survey? are they the same as responders
- Case control studies
  - Where choice of cases or controls is dependent on exposure
- Cohort studies
  - ‘healthy worker’ in occupational studies

Information bias

- Measurement
  - systematic differences in the way information on exposure or disease is collected between groups
- Observer
  - awareness of exposure affects assessment of disease or vice versa
- Subject
  - recall - patient with disease maybe more likely to remember exposure than control group

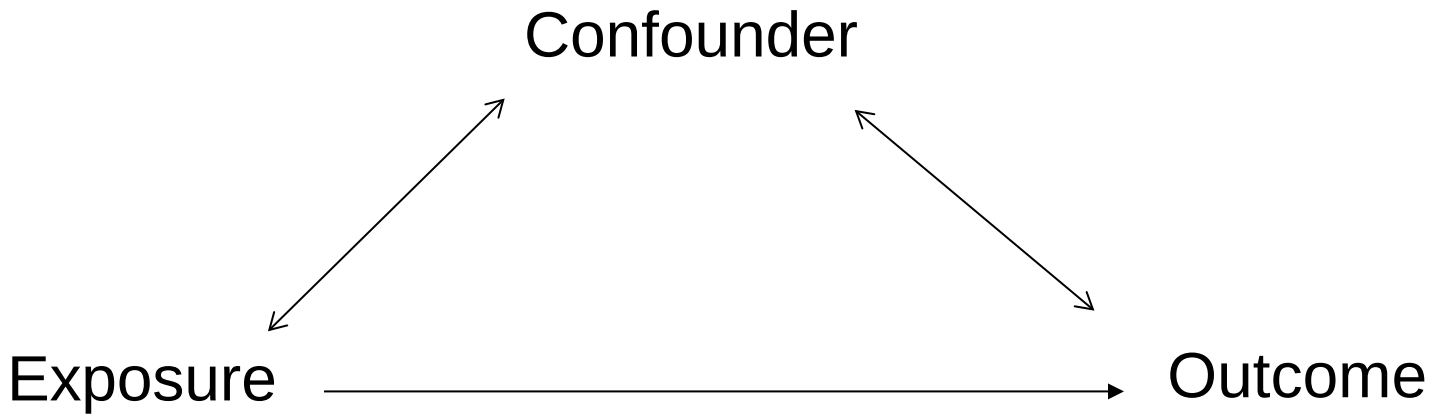
How to deal with bias in research

- Get design as good as possible
- Statistical analysis cannot compensate for design flaws
- Take care in:
  - Selection of cases and controls
  - Assessment of exposures and outcome
  - Follow-up: aim to maximise

GOOD epidemiology relies upon acknowledgement and recognition of bias

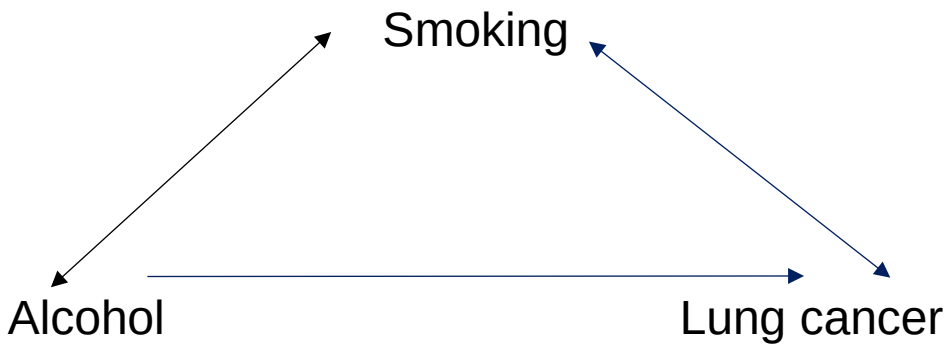
Confounding

- A confounder is a factor that is independently associated with both exposure and outcome



- It provides an alternative explanation for an observed association between exposure and outcome

An example of confounding



How to take confounding into account

- Consider potential confounders
- Design:
  - matching (age/sex)
  - randomisation
- Analysis:
  - stratification
  - multivariate analysis
  - standardisation (usually age sex)

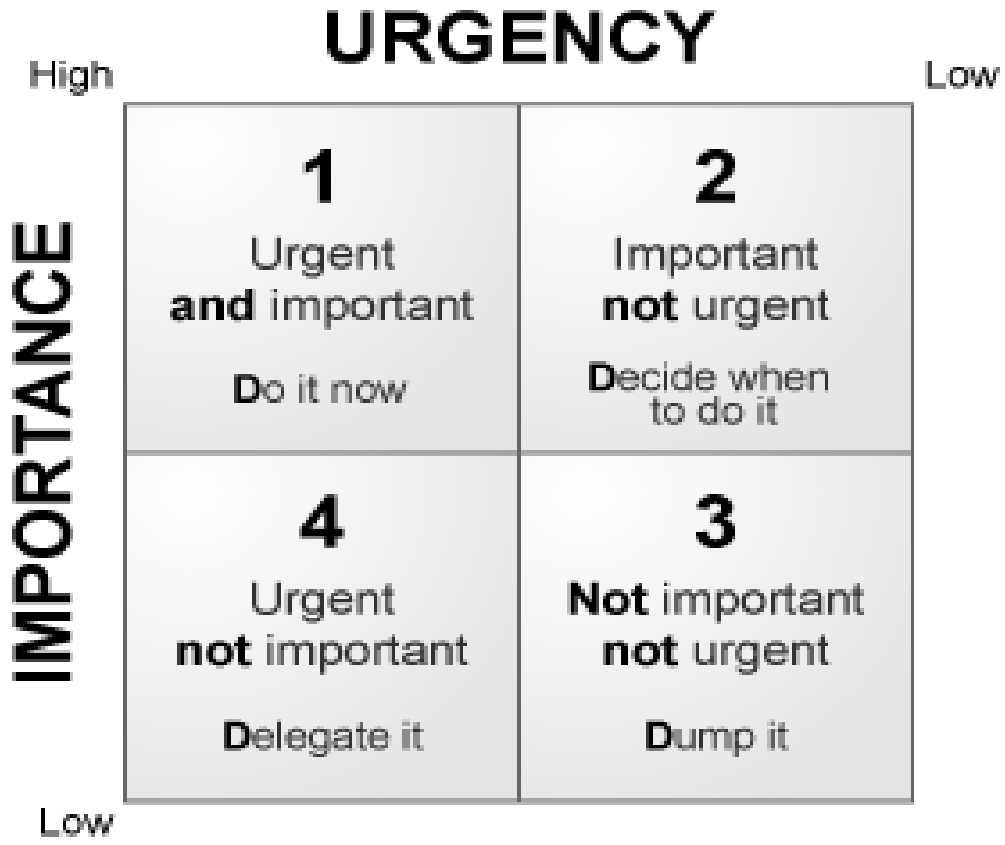
Research does not always go smoothly..

- Do not bury your head in the sand
- It is not possible to pass the ATRP by doing nothing until last minute..
- The examiner knows how much/little time you have spent
- Time management and planning is essential
- Not every project will run to the same deadlines – if you cannot collect data immediately, get ahead with your reading and drafting your Background and Methods

Time management

- One of your most important assets
- Ability to plan ahead and organise
- Anticipate deadlines and times of pressure
- Do what you can to get ahead
- Particularly if you are doing stage B exams

Time management



Conclusions

- To be an excellent OEM specialist you do not need to be a researcher
- BUT you do need to be able to commission and use research and read published papers critically
- A field where there not many lights on..
- Often extrapolating from what few facts there are..

You never know, you just might “love” it..

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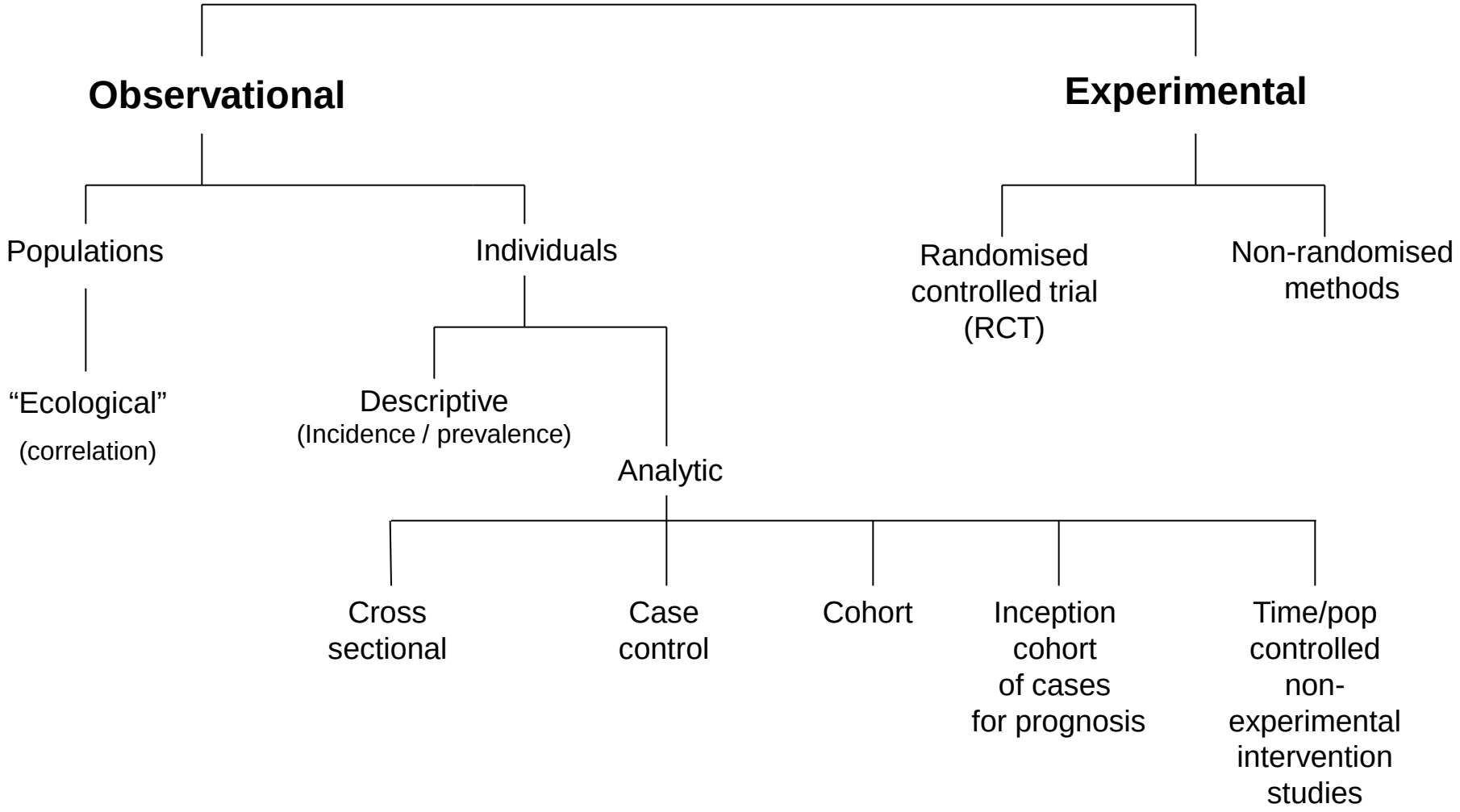
THANK YOU

Karen.Walker-Bone@Monash.edu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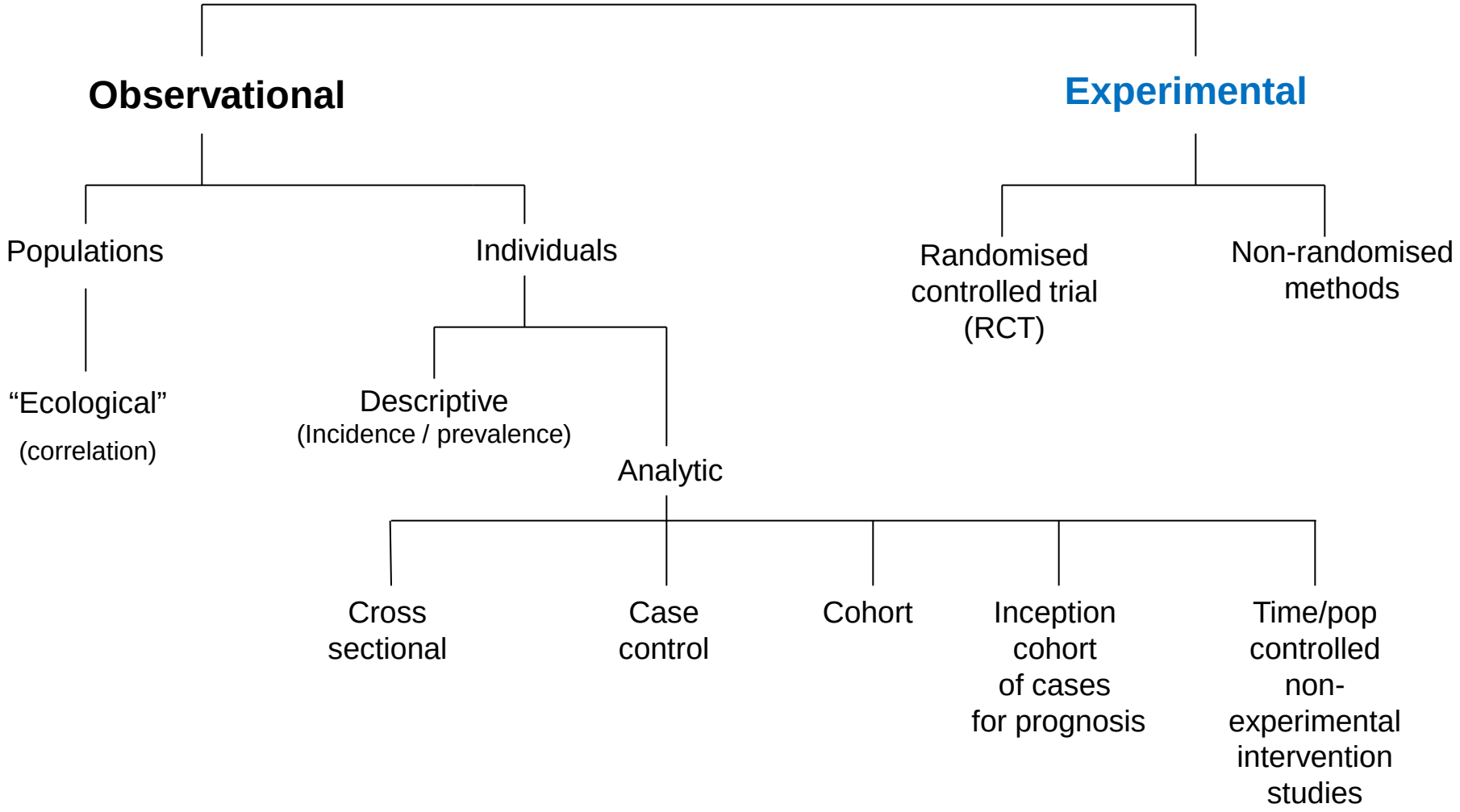
Time/pop controlled non-experimental intervention studies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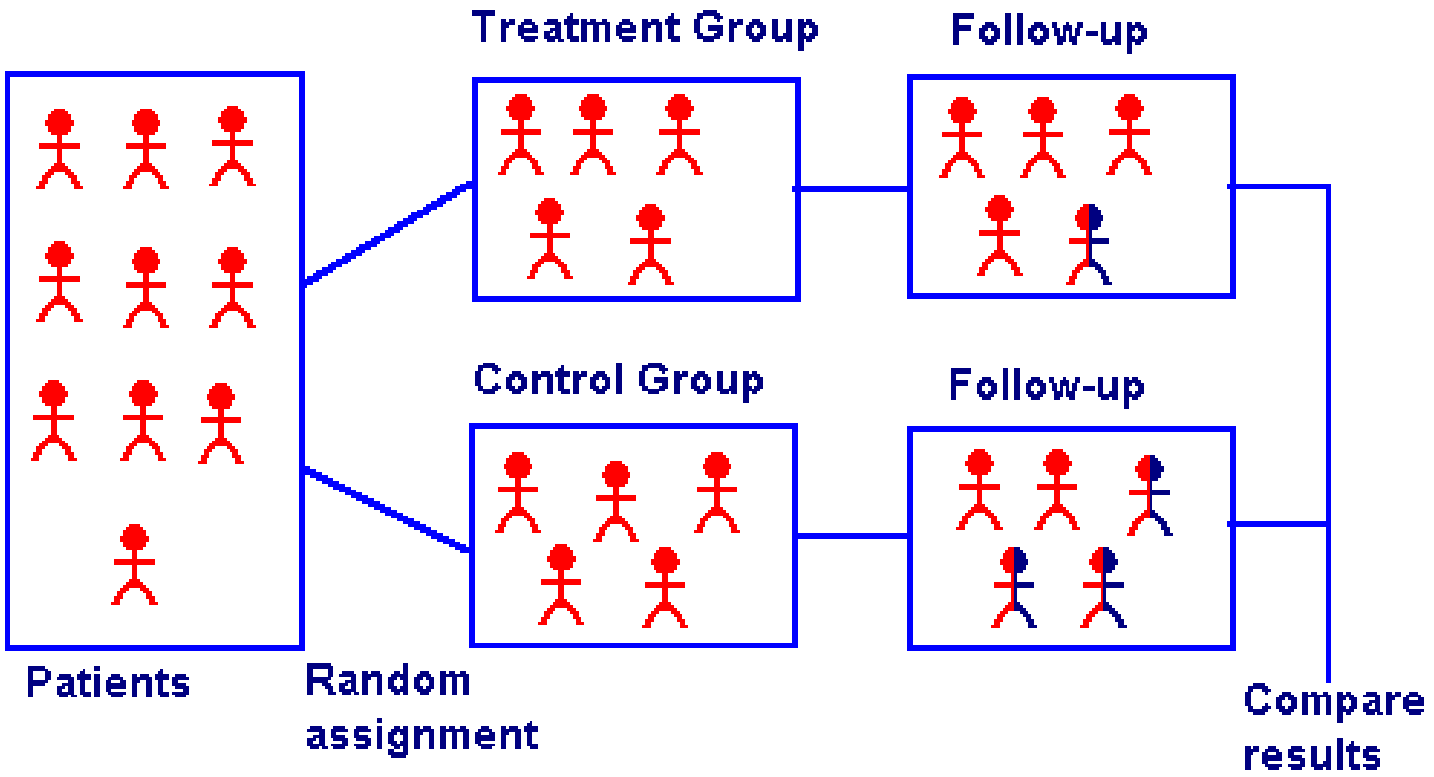
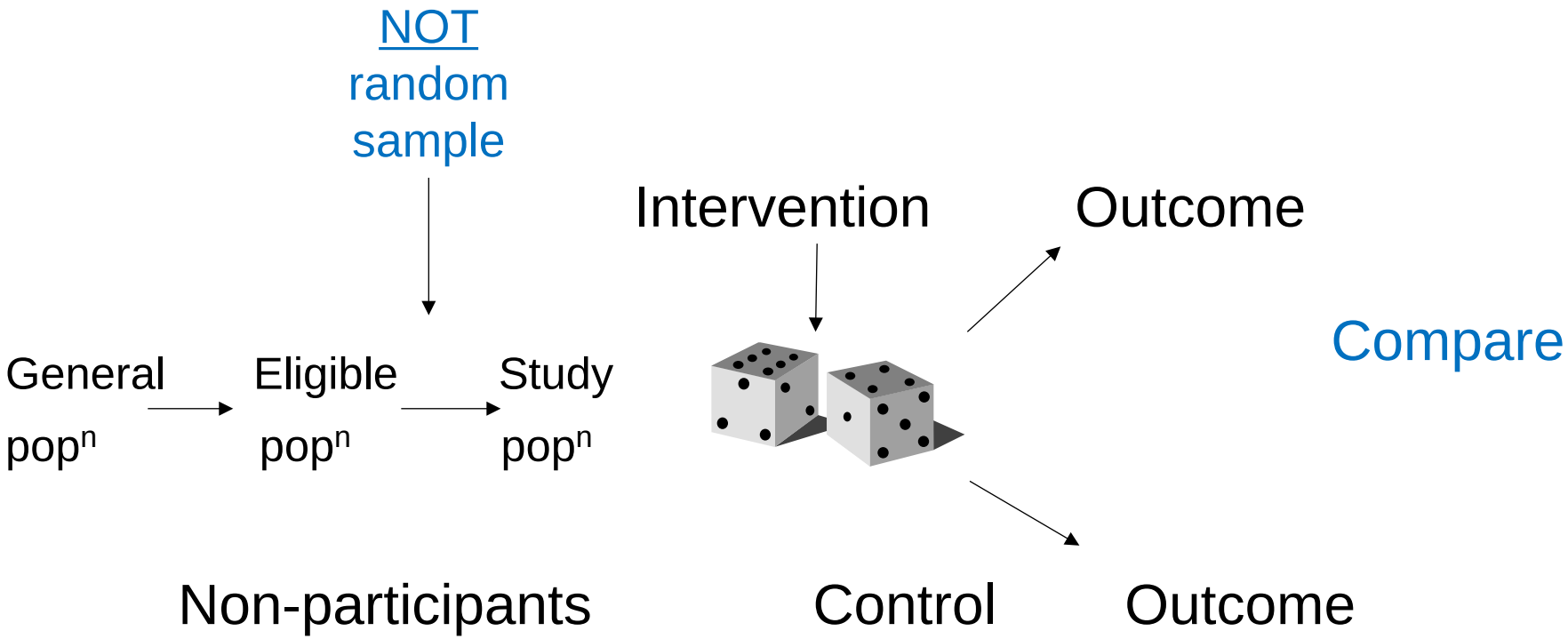
Experimental studies

- If participants are assigned to the intervention randomly then its a randomised controlled trial (RCT)
- If NOT randomly assigned, can be quasi-experimental or ‘open label’

A randomised controlled trial



The randomised controlled trial



Randomised controlled trial

Advantages:

- unbiased distribution of known & unknown confounders
- blinding more likely to be possible
- randomisation facilitates statistical analysis

Randomised controlled trial

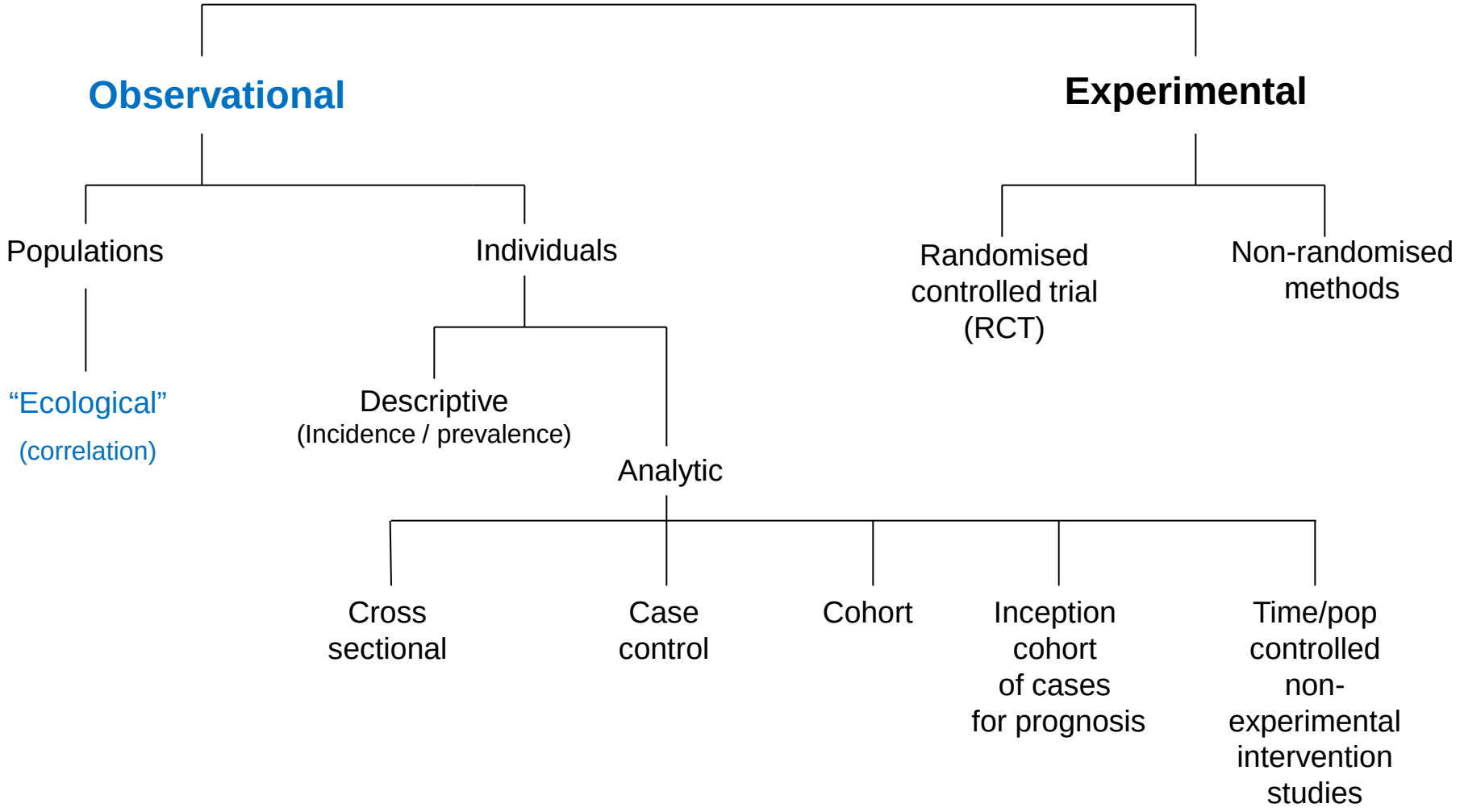
Disadvantages

- expensive: time and money
- volunteer bias
- ethically problematic at times
- recruitment difficulty-clinician /patient
- may not be appropriate method as inappropriate for the question, timescales too long to reach answer, no clinical uncertainty

What questions cannot be answered with a randomised controlled trial?

- How common is pneumoconiosis in coalminers? **Prevalence Incidence**
- Is there more occupational disease amongst migrant workers? **Inequalities**
- Is there more silicosis among stone benchtop workers? **Risk factors**
- Is mesothelioma increasing or decreasing? **Time trends**
- What is the prognosis of melanoma? **Long term outcomes Risk factors**
- What factors influence prognosis?

- all very important questions for health services, prevention efforts and policy makers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Ecological studies

- Exposure and disease measured at population/group level not at individual
  - Alcohol consumption and RTA
  - Staffing levels health centres and vaccination rates
  - Water fluoridation and hip fracture
- Correlate exposure and disease
- Often these studies use routine data collected for other purpose

Ecological studies

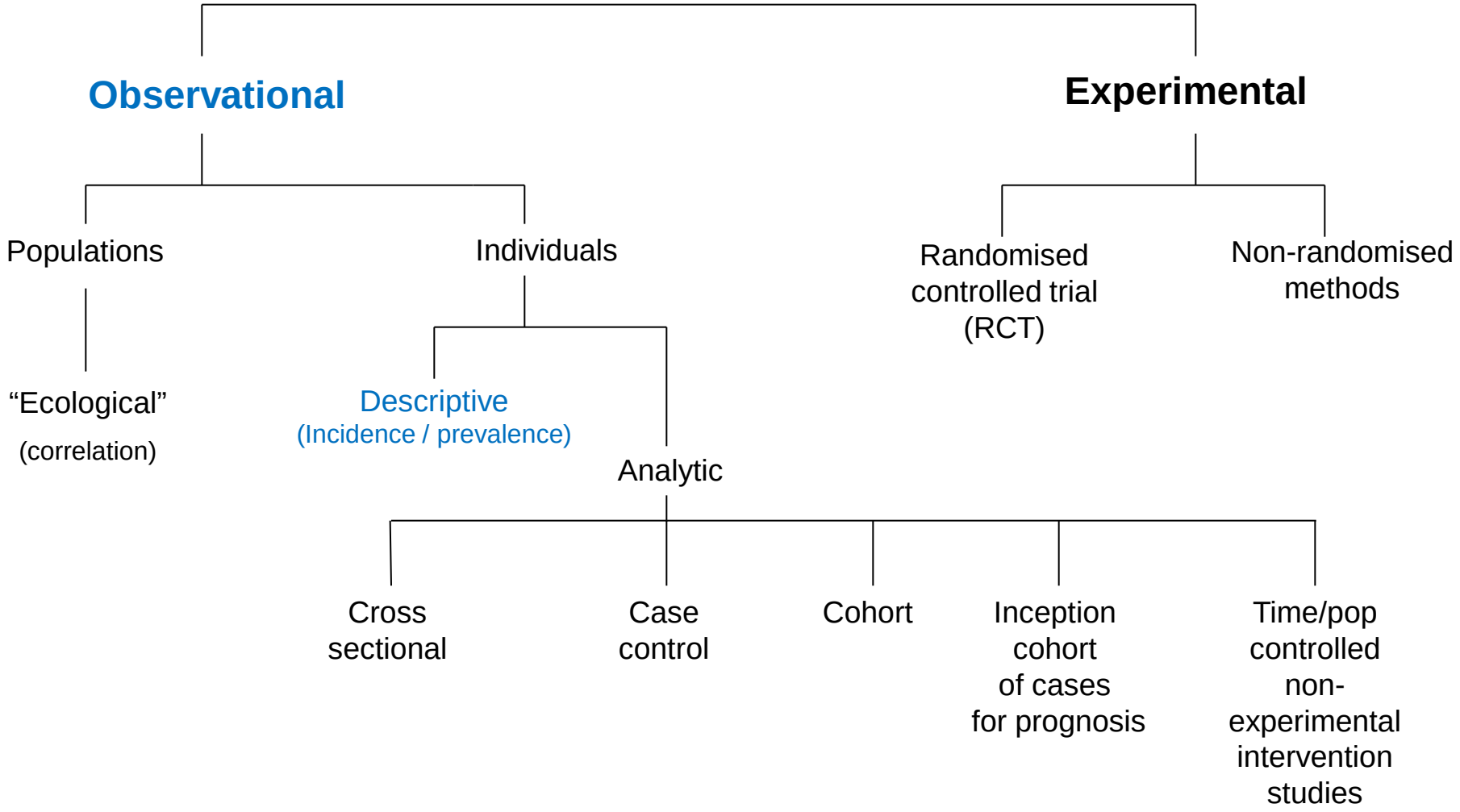
Advantages

- Relatively cheap
- May be only feasible way to evaluate effects of health care programmes where individual data unavailable
- Results obtained quickly
- Can generate interesting hypotheses
- Can be used to investigate outcomes and exposures that show a variety of trends over time

Ecological studies

Disadvantages

- NO causality
- Ecological fallacy
  - The bias that may occur because an association observed between variables on a group level does not necessarily represent the association that exists at an individual level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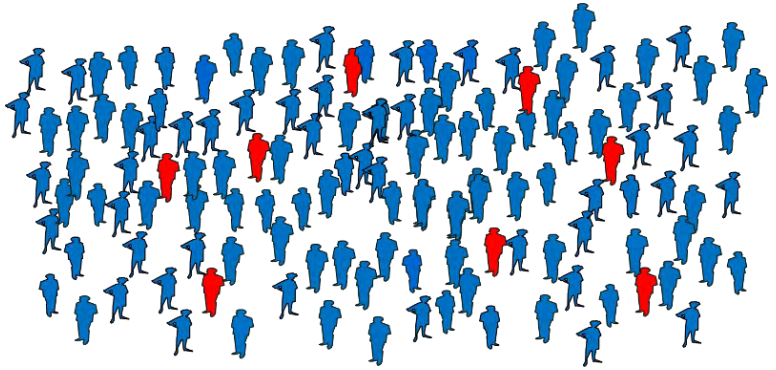
Prevalence

- Prevalence is the proportion of a population who have a specific characteristic in a given time period
- Point prevalence (today, now, at a point in time)
- Period prevalence (cases in last week, month, year, lifetime..)
- Expressed as % (5%, 10%, 90%) or as number of cases per 10,000 or 100,000 per head of population



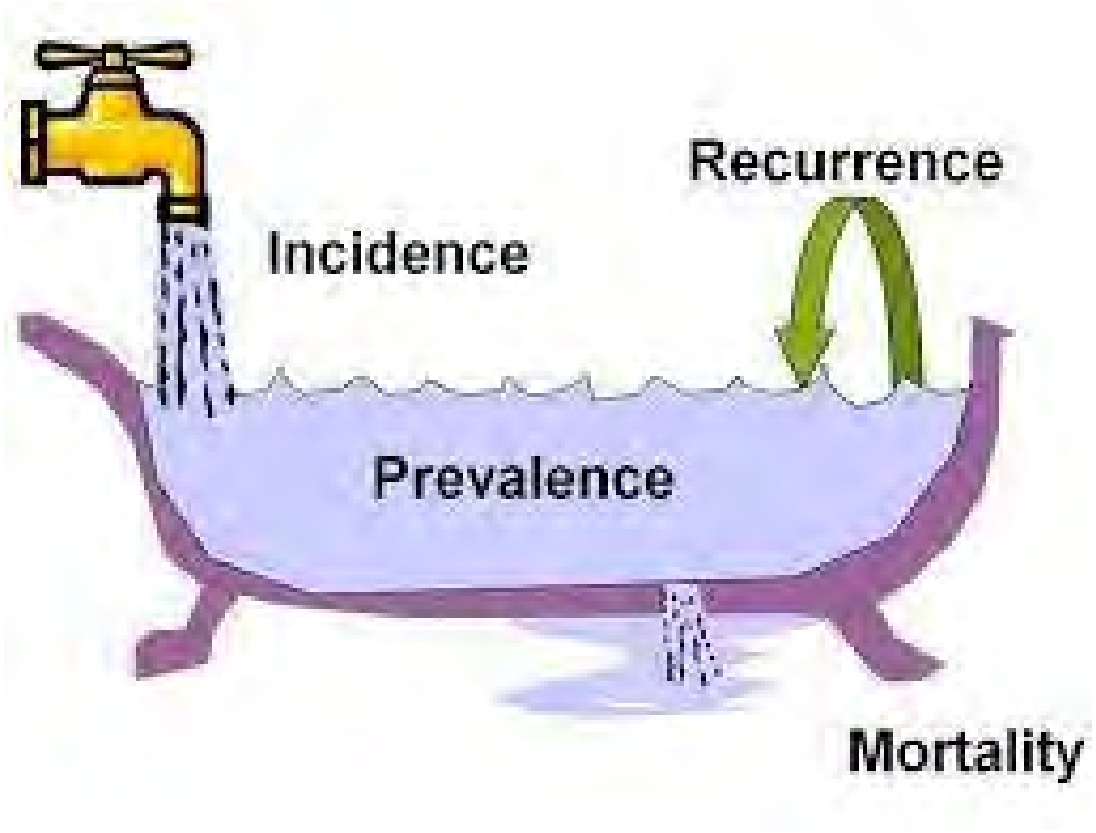
Incidence

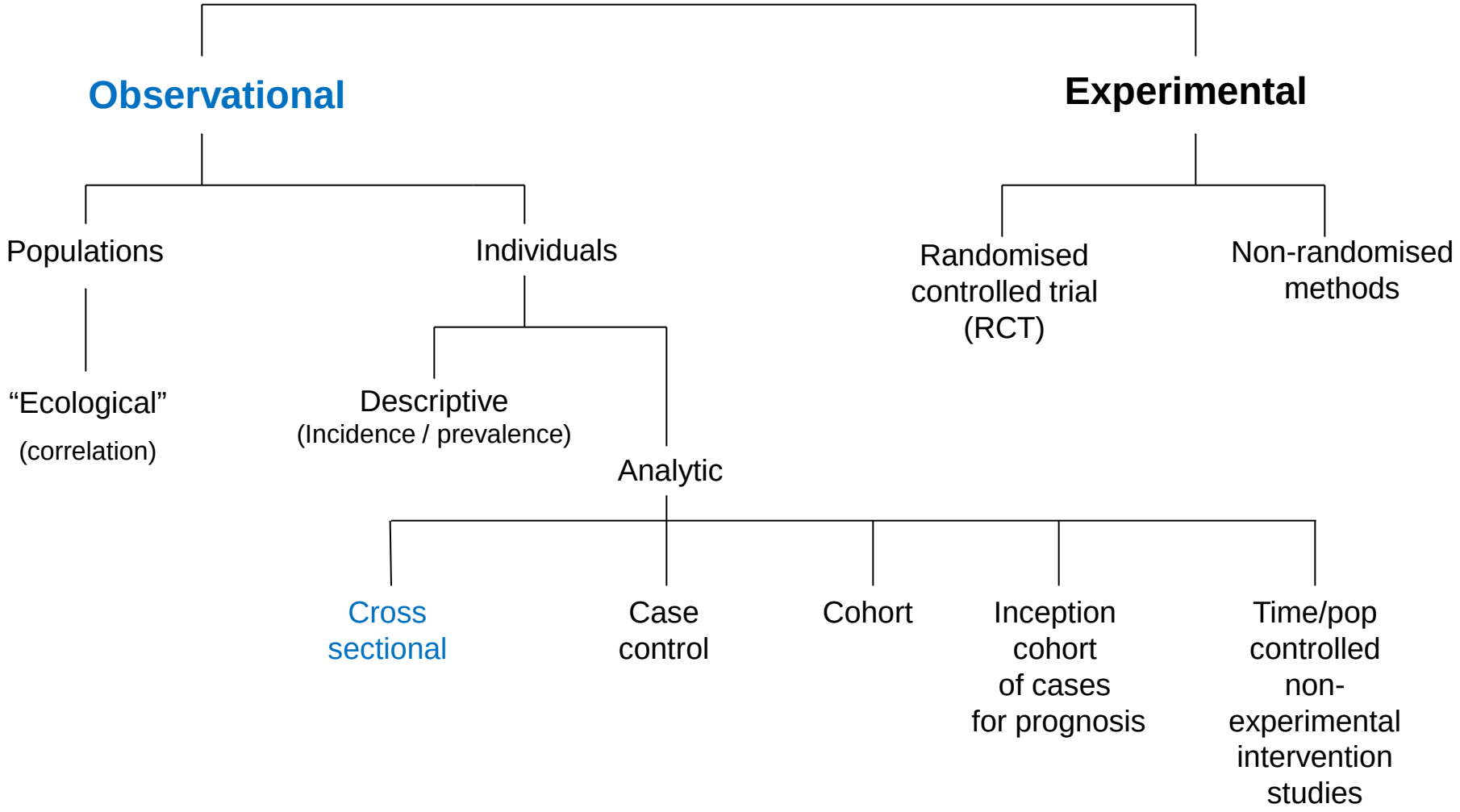
- Incidence is NEW cases over a specified period of time
- Estimated as:

$$\frac{\textbf{Number of new cases of carpal tunnel syndrome over one year}}{\textbf{Total population at risk over one year}}$$

Could be general population
Could be people at work in e.g. meat processing factory
(Total number of person-years of observation)

Epidemiologist's bathtub

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Cross-sectional studies

- Usually a **survey** of a ‘population’ of interest
- Measure exposure and/or disease at **one point in time**
- Measures **prevalence** not incidence
- No temporal relation of exposure and disease so not good for investigating causal relations
- Widely used for biochemical, pathophysiological, lifestyle measures

Cross-sectional studies

- Descriptive: frequency and distribution of health related exposures or outcomes
  - **Survey (prevalence of silicosis amongst stone benchtop workers in Victoria)**
- Analytical: Measure association between exposure to risk factors and outcome
  - **Association between ever working in aluminium production and prevalence of mesothelioma**

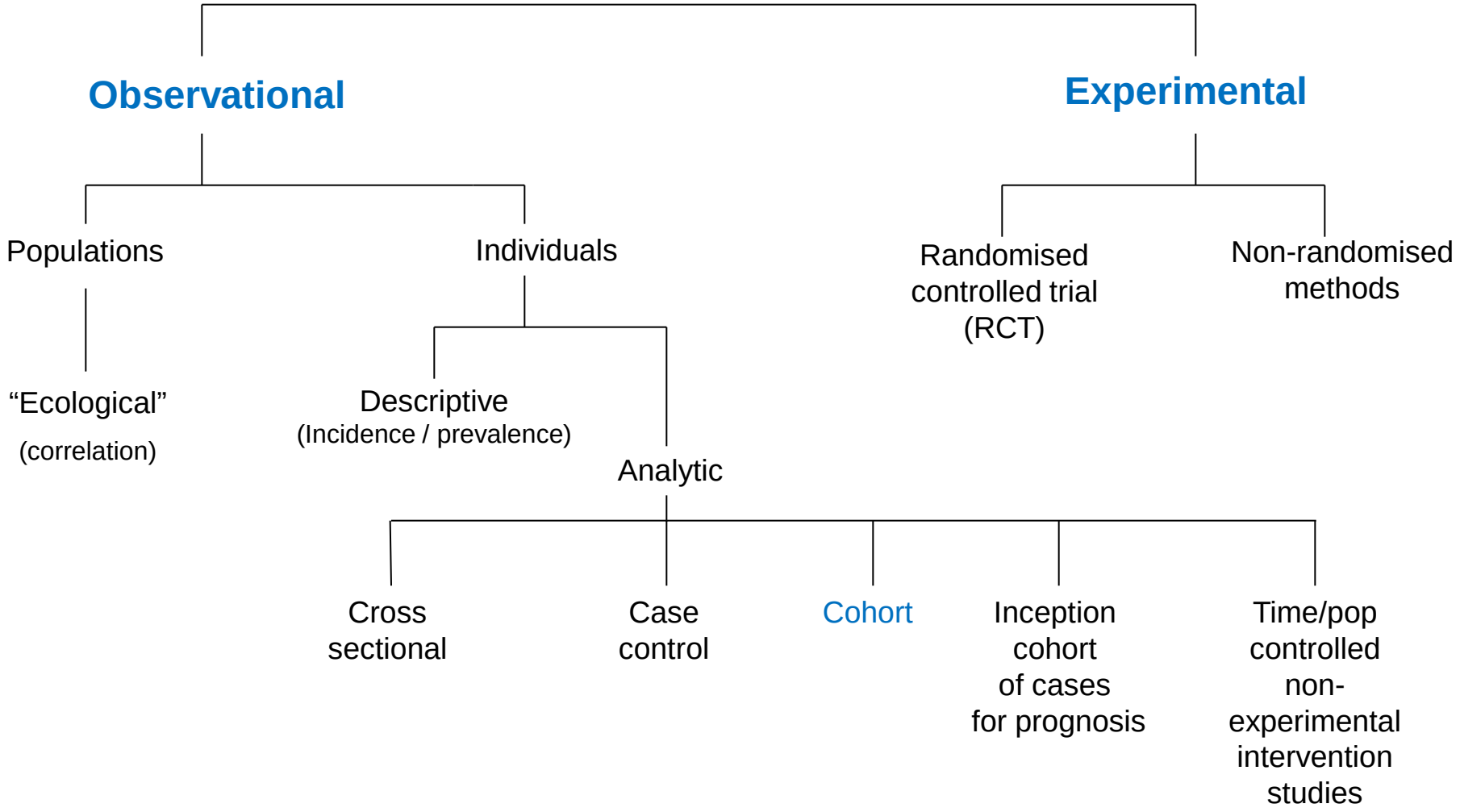
Cross sectional studies

STRENGTHS

- Relatively quick and easy (cheap)
- Useful for measuring prevalence of disease, risk factors for disease and patterns of disease in a population
- Repeated studies can provide data on change in disease or risk factors over time
- Hypothesis generation
- Ethically safe

WEAKNESSES

- Establishes association at most, not causality
- Retrospective exposure so risk of **recall bias**
- Non-response to survey
- Single measures (chronicity?)
- Measures prevalent rather than incident cases
- Prevalent cases are survivors
  - may miss acute fatal illnesses
  - or those with not recovered or more severe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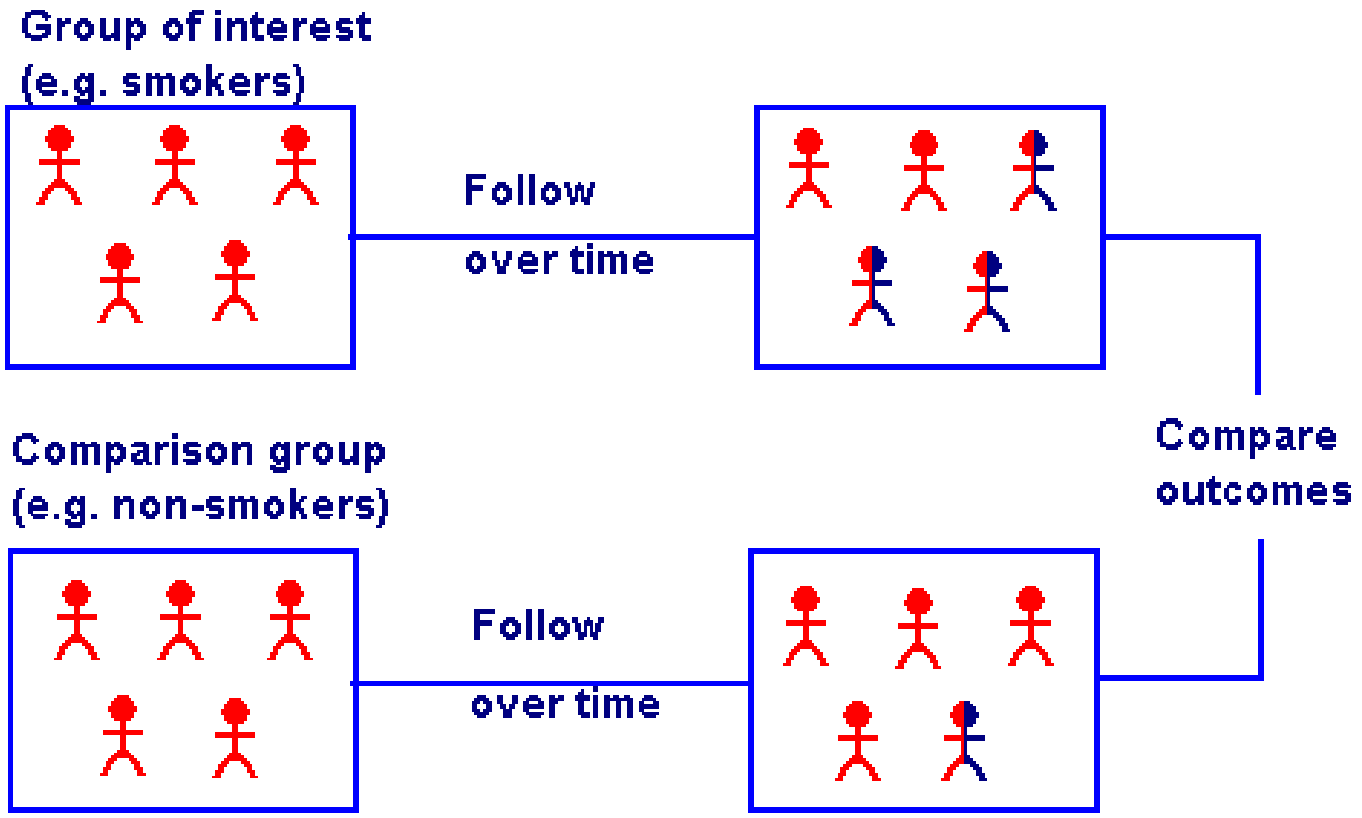
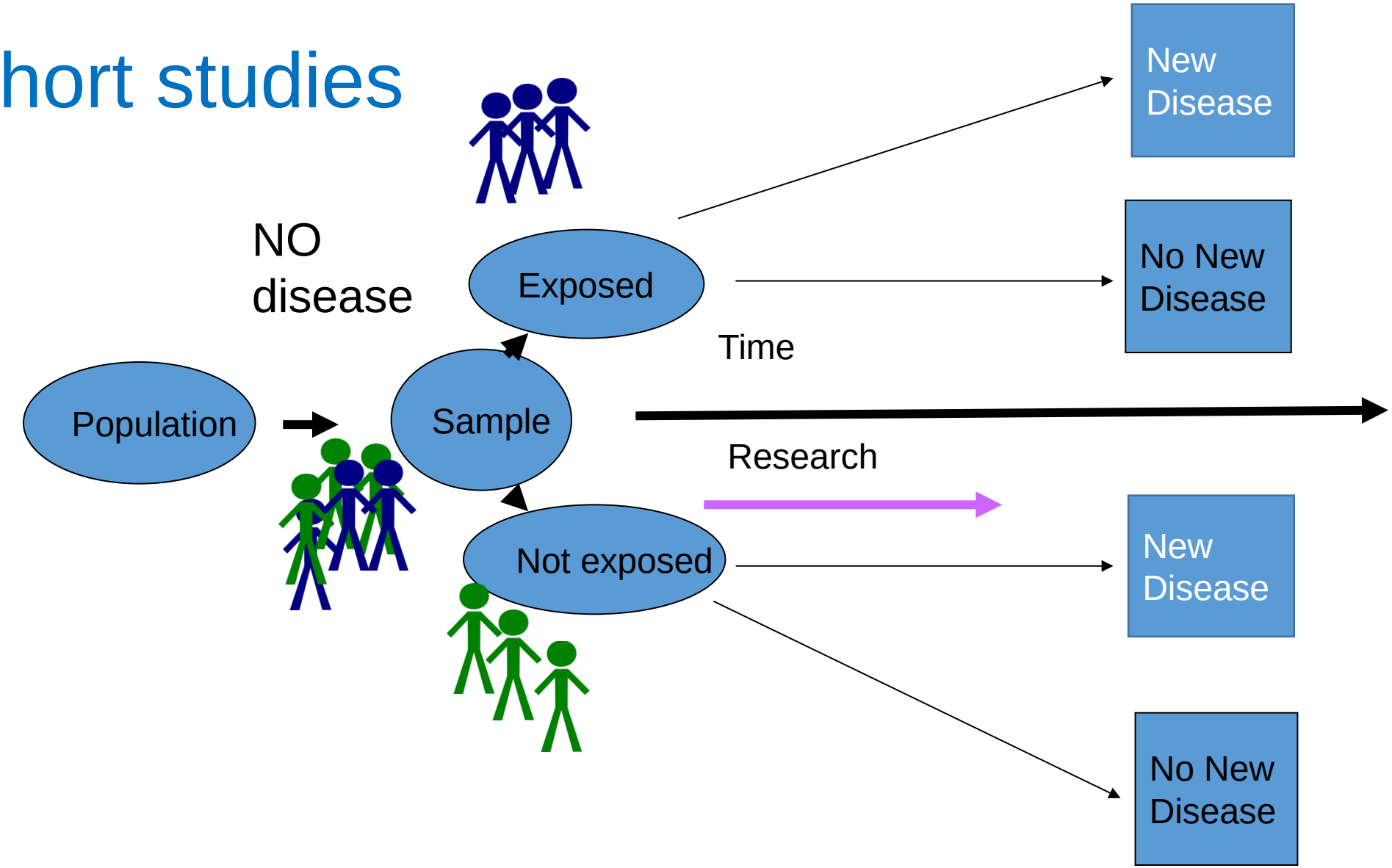


Cohort studies

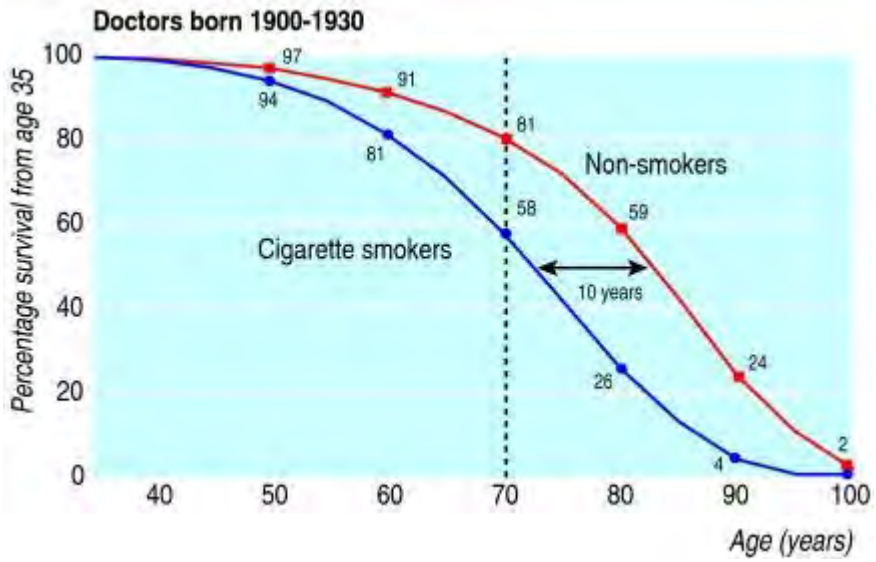
- Define population group with a common characteristic e.g. workers from a factory/individuals without outcome of interest
- Measure exposure then follow-up over time to see who gets disease
- Can be prospective or retrospective (esp occupational/clinical)
- Exposure can be an intervention
- Cohort can be people with disease followed to determine prognostic factors
- Good for rare exposures
- NB Healthy worker effect need to be careful in occupational cohort studies

Cohort studies



Famous cohort study

Hazards of cigarette smoking in a cohort of nearly 35,000 British doctors 1951 onwards



Survival from age 35 for continuing cigarette smokers and lifelong non-smokers among UK male doctors born 1900-1930, with percentages alive at each decade of age

Doll R, et al. Mortality in relation to smoking: 50 years' observations on male British doctors BMJ 2004;328:1519

Cohort studies

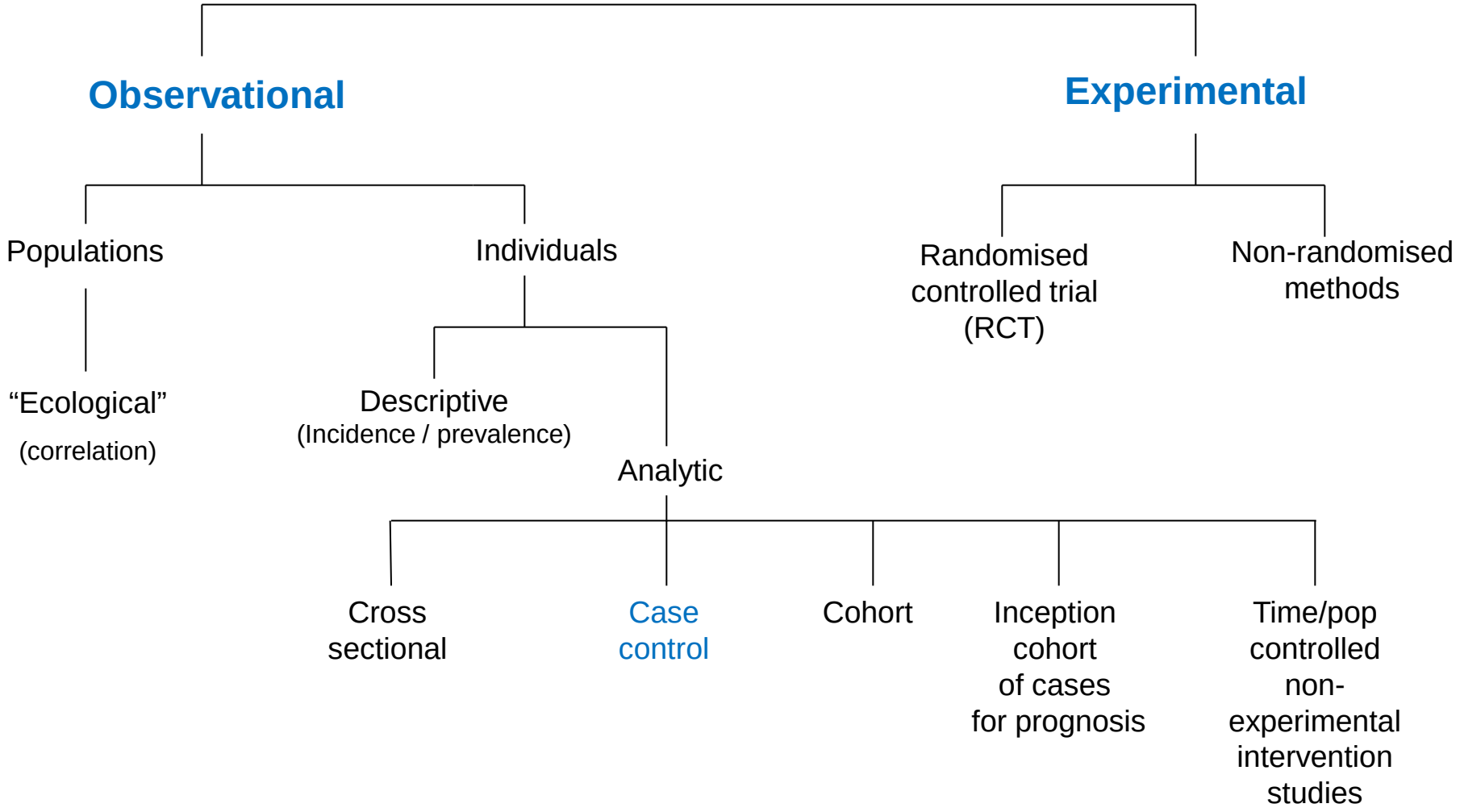
Advantages

- Rare exposures can be studied
- Multiple outcomes can be studied for one exposure
- Retrospective cohorts can produce relatively quick results on longer term outcomes
- Time sequence of intervention and outcomes can be measured
- Can measure incidence and prevalence

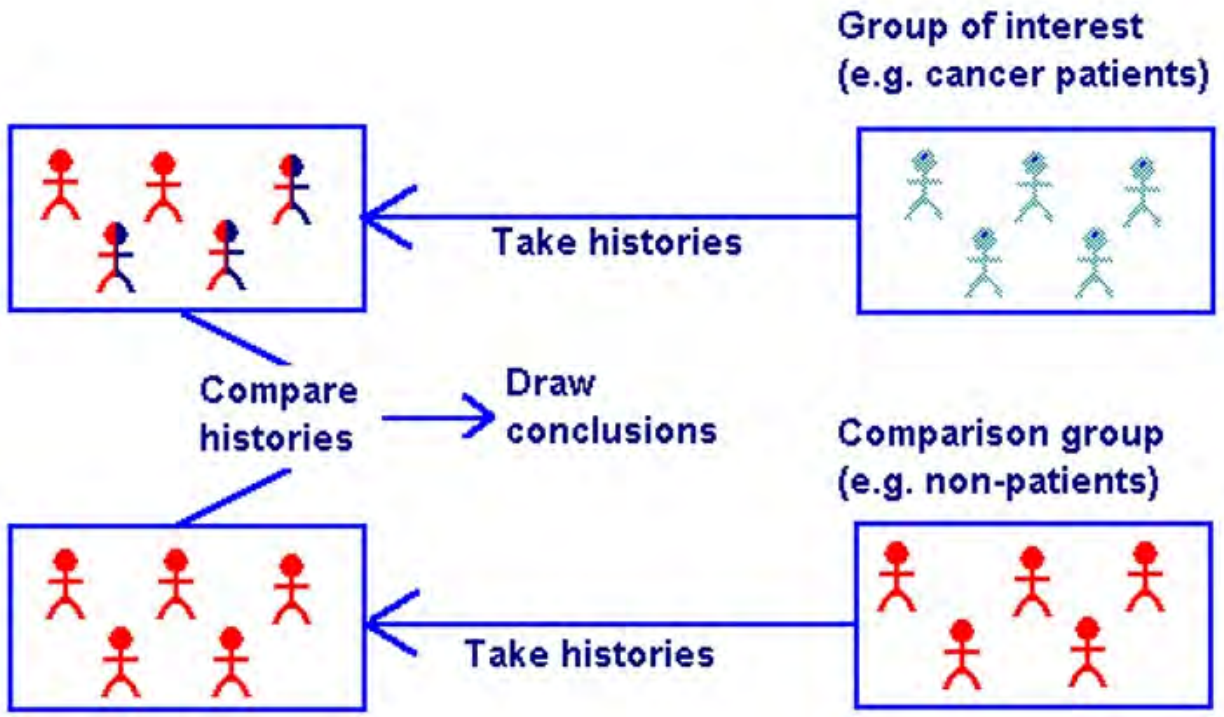
Cohort studies

Weaknesses

- Loss to follow up can cause bias- if drop out is related to outcome
- Observation bias a problem if exposure status known by person assessing outcome
- No mechanism to deal with unknown confounders
- Need large number of participants especially if disease is rare
- Cost of data collection and of long duration of follow up

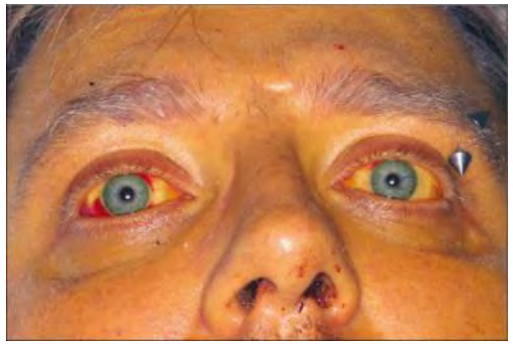

Observational
Experimental
Populations
Individuals
Randomised controlled trial (RCT)
Non-randomised methods
"Ecological"
(correlation)
Descriptive
(Incidence / prevalence)
Analytic
Cross sectional
Case control
Cohort
Inception cohort of cases for prognosis
Time/pop controlled non-experimental intervention studies

Case-control studies

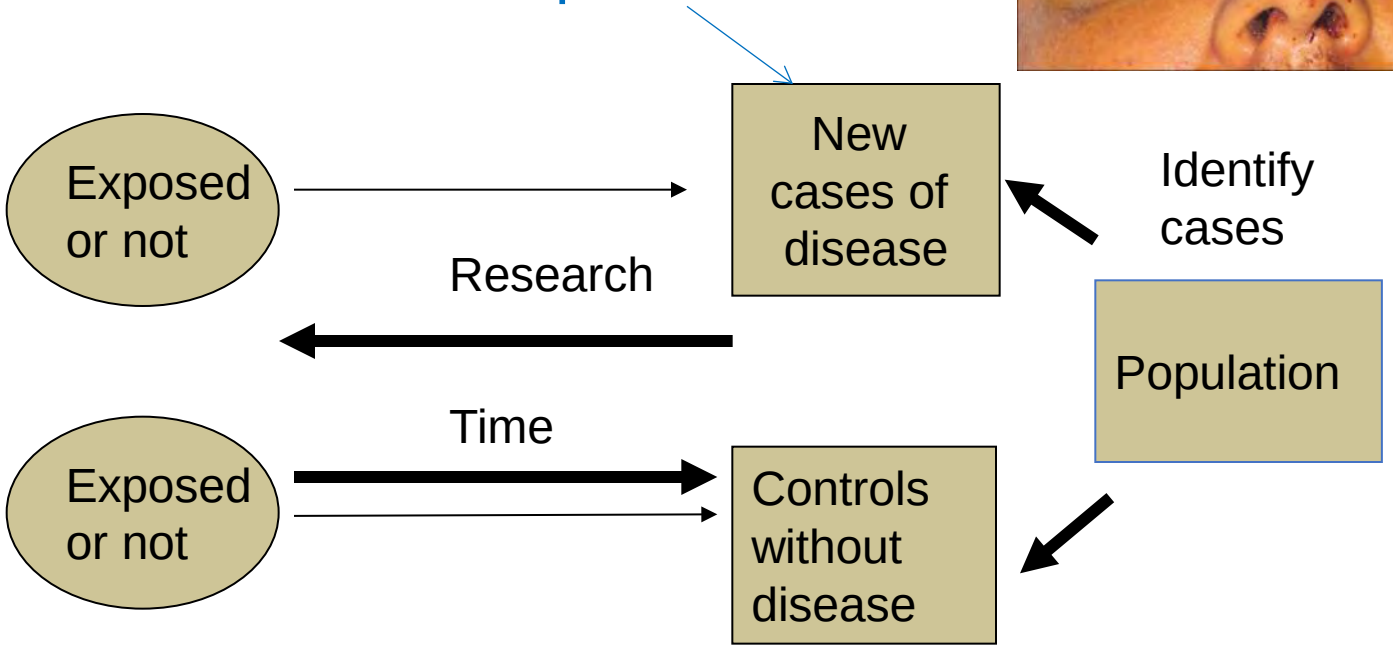


Case-control studies

- Study population defined by outcome not exposure
  - find new cases of disease
- Then find controls with no disease
- Cases compared to controls to assess whether they are different in terms of their historical exposure to particular risk factors



Case definition:
Incident/prevalent



Case-control studies

Advantages

- Quicker and cheaper than cohort studies
- Good for study of rare diseases
- Can be used to study multiple risk factors/exposures
- Can be used as initial study to establish an association

Case-control studies

Disadvantages

- Recall bias
- Selection bias especially controls
- Observer bias (especially if unblinded)
- Not good at investigating rare exposures
- Only one outcome can be investigated
- Cannot be used to estimate incidence
- Reverse causality ensure risk factor occurred before disease diagnosis (particularly if long latent period)

Case-control studies

Disadvantages

- Recall bias
- Selection bias especially controls
- Observer bias (especially if unblinded)
- Not good at investigating rare exposures
- Only one outcome can be investigated
- Cannot be used to estimate incidence
- Reverse causality ensure risk factor occurred before disease diagnosis (particularly if long latent period)

Hospital controls vs community controls

Convenient, cheap, available (in bed)

More likely to participate

BUT: they are ill

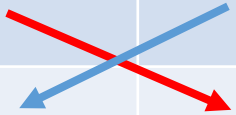
More likely biased sample

May not be representative of the study sample

Beware if similar risk factors e.g. COPD and lung cancer cases..

Measuring “risk” (odds ratio)

	Hand dermatitis	No hand dermatitis
Wears latex gloves at work	A	B
Does not wear latex gloves at work	C	D



$$OR = \frac{\text{Odds that a case was exposed } (A/C)}{\text{Odds that a control was exposed } (B/D)} = \frac{A \times D}{B \times C}$$

Measuring “risk” (odds ratio)

	Hand dermatitis	No hand dermatitis
Wears latex gloves at work	25	25
Does not wear latex gloves at work	250	500

$$\text{OR} = \frac{\text{Odds that a case was exposed (A/C)}}{\text{Odds that a control was exposed (B/D)}} = \frac{25 \times 500}{25 \times 250} = \frac{12500}{6250} = 2.0$$

Relative risk

	Hand dermatitis	No hand dermatitis	
Wears latex gloves at work	A	B	A + B
Does not wear latex gloves at work	C	D	C + D

$$\text{Relative risk} = \frac{A / (A+B)}{C / (C+D)} = \frac{\text{Incidence of disease with exposure}}{\text{Incidence of disease without exposure}}$$

Measurement of the **strength of the association** of the outcome for the exposure

Relative risk

	Hand dermatitis	No hand dermatitis	
Wears latex gloves at work	25	25	50
Does not wear latex gloves at work	250	500	750

$$\text{Relative risk} = \frac{25 / 50}{250 / 750} = \frac{0.5}{0.333} = 1.5$$

Standardised incidence rate ratio (SIR)

- SIR is an estimate of the number of disease cases in a given population compared to what might be “expected” based on a comparison with the disease experience in a larger population.
- It is the ratio of the number of disease cases observed compared to the number expected

	Lung cancer	Person-years without lung cancer
Coalmine worker	60	51477.5
Never coalmine worker	30	54308.7

The rate in those who worked in coalmines was 60 / 51477.5 = 116.6 per 100,000 person-years

The rate in those NOT working in coalmines was 30 / 54308.7 = 55.2 per 100,000 person-years.

= SIR 2.1

Standardised mortality rate (SMR)

- SMR describes whether a specific population (e.g. people who worked in petrochemical industry) are more, less or equally as likely to die than a standard/ reference population (e.g. general population of Australia)
- It is the ratio of the number of observed deaths over the number of expected deaths

$$\frac{\text{The number of observed deaths}}{\text{The number of expected deaths}}$$

SMR < 1.0 indicates there were fewer than expected deaths in the study population
SMR = 1.0 indicates the number of observed deaths equals the number of expected deaths in the study population
SMR >1.0 indicates there were more than expected deaths in the study population (excess deaths)