Study designs for assessing risk factors & effectiveness of interventions

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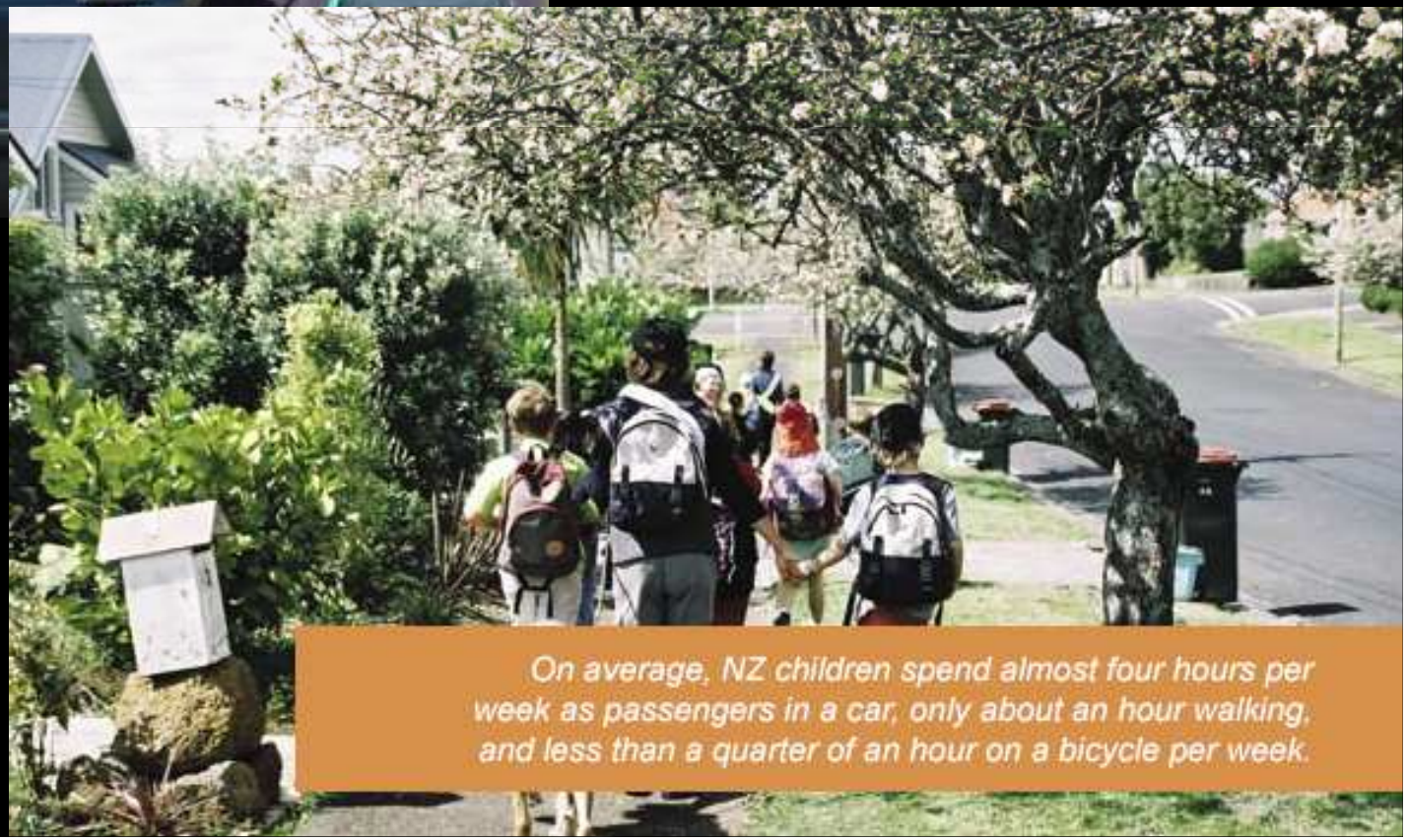
What NOT to do!



Auckland School Travel Plan, 2004

Outline

- A common (generic) epidemiological approach to investigating contribution of risk factors and interventions to injury outcomes
- Risk factor studies
- Intervention research designs
- Some implications for RTIRN

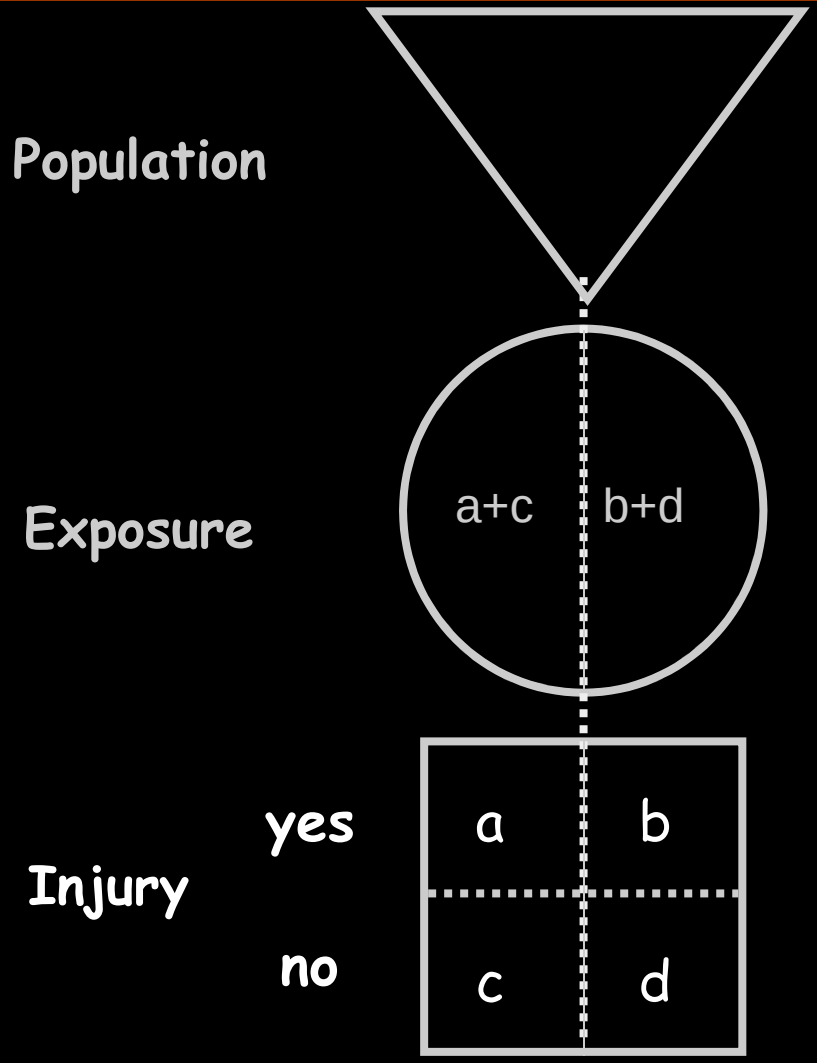
Epidemiological approach

- Epidemiology studies the distribution and determinants of health events (eg, injury) and applies results to control the health problem
- Focuses on populations (rather than individuals) to compare frequency of injuries in groups with different ‘exposures’

- Risk factor studies: Exposures - presumed risk factors. Almost always ‘observational’ studies
- Intervention studies: Exposures – interventions.

  Often ‘experimental’ (or investigator-controlled)

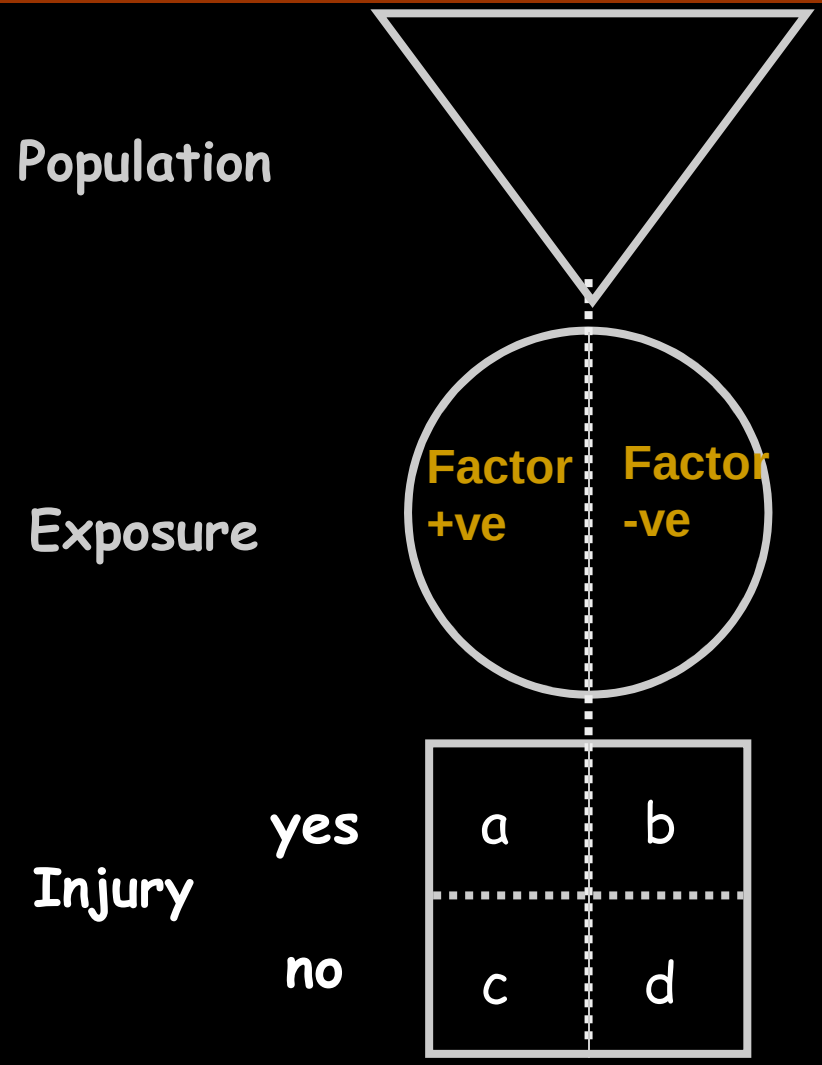
Epidemiological Study Design: Basic (generic) plan



Relative Risk

$$\frac{a / (a + c)}{b / (b + d)}$$

Risk factor studies investigate measurable factors associated with higher probability of injury



Relative Risk

$$\frac{a / (a + c)}{b / (b + d)}$$

A risk factor would result in RR > 1

Types of risk factors

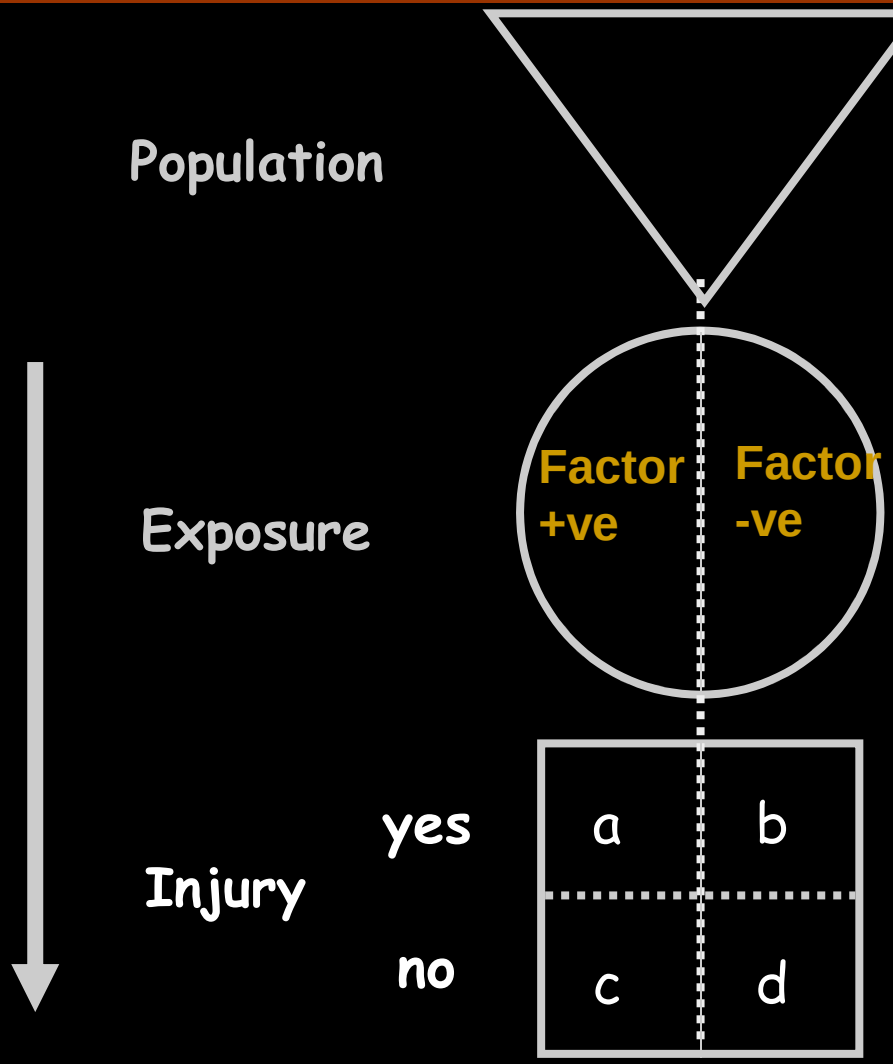
Potentially modifiable
Less modifiable in short-term
Non-modifiable

- Personal characteristics
  - age, gender, poverty, disability (eg,vision)
- Behavioural / lifestyle factors
  - alcohol / drug use, mobile phone use, speeding
- Environmental factors
  - Road engineering features, curbs, footpaths, lighting, separating road users
- Vehicle characteristics
  - size, safety features (‘pedestrian-friendly’)

Limitations of Risk Factor studies

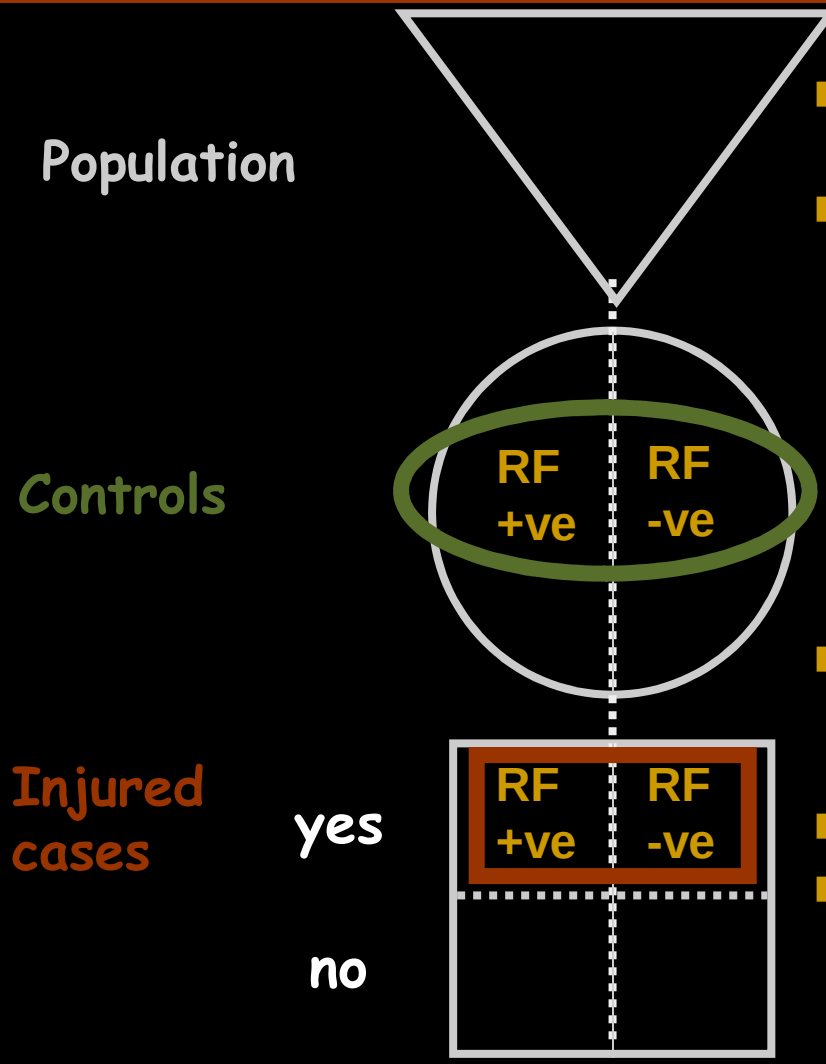
- Many factors typically contribute to injuries, and some cluster together
- Difficult to prove that one factor causes injury – risk of **confounding ('mixing of effects')**
- As it is not possible to ensure other factors are balanced in comparison groups without doing randomised studies (not practical or ethical), researchers aim to reduce confounding by carefully designed studies

Cohort Studies



- Exposure status determined and people followed-up for occurrence/not of injury
- Strengths: exposure – outcome time sequence preserved ('natural experiment'); can look at many outcomes and exposures
- Problem: Injuries are relatively 'rare' - so need large and often expensive cohort studies
- Difficult to study 'transient' or 'acute' risk factors

Case-control studies



- Well-suited for injury RF studies (1961 pedestrian study by Haddon)
- General method:
  - all cases from a defined population recruited to study
  - Cases' exposure characteristics compared with those of a control group which aims to represent population from which cases arose
- Can be very efficient (feasibility and cost); can examine transient & acute factors and distal factors
- But only one outcome per study
- Threats to validity: care with control selection, recall bias, and response rates (esp controls)

Auckland Child Pedestrian Injury Study – I Roberts, R Norton, et al

- Personal characteristics: age, gender, ethnicity, socio-economic status (including family access to car), single-parent families
- Environmental factors: More likely to be injured if walking on streets
  - With higher density of traffic
  - Higher average traffic speeds
  - More curb-side parking
- Children who were of Maori or Pacific ethnicity, poor, and had limited access to cars crossed x2-4 times as many streets as those not in these ‘high risk’ groups
- Importance of recognising social and contextual factors, particularly relating to exposure to risk

Case-crossover studies

- Variant of case-control study where cases serve as their own controls to investigate transient or intermittent risk factors (e.g., mobile phone use) where same individual is sometimes exposed and other times not.
- Participants' exposure status at relevant time before injury cf. exposure status at a control period
- No potential for confounding by measured and un-measured 'fixed' characteristics of individual (e.g., socio-economic status)

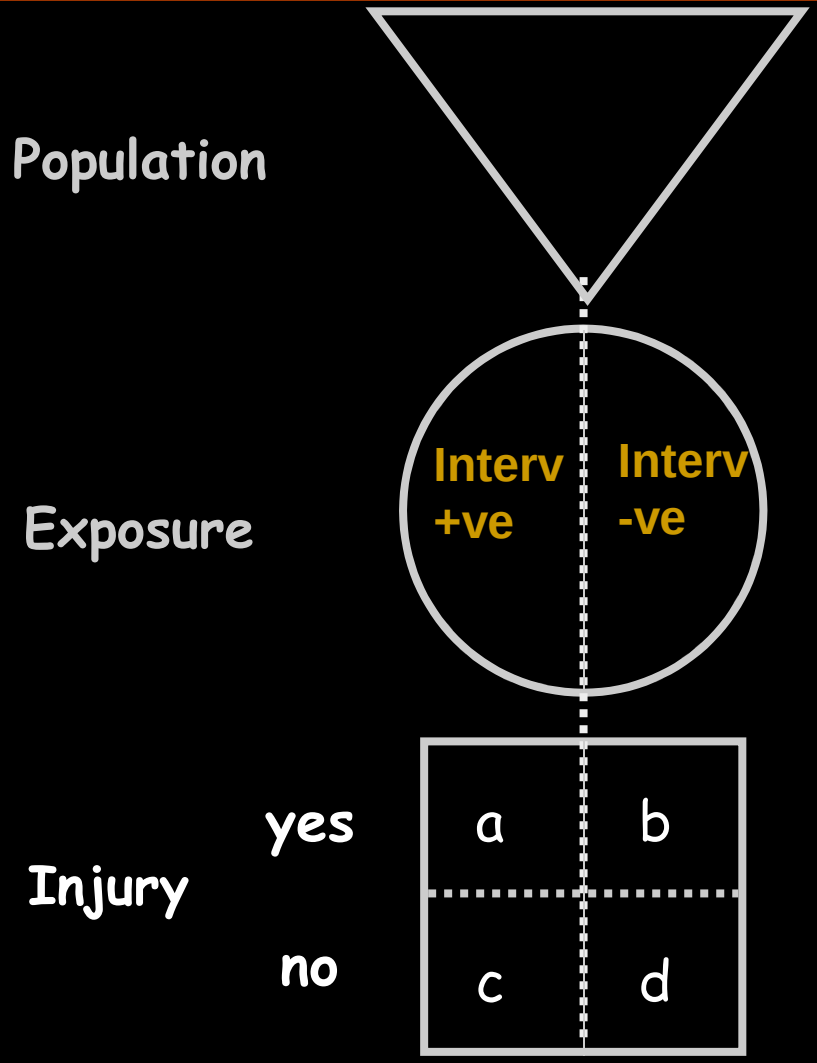
Important issues in interpretation

- Establishing an **association** between an exposure and injury outcome (e.g., by finding significant relative risk or odds ratio) **does not imply causality**
- Need to consider influence of chance, confounding, and possibility of different effects in some groups
- Several approaches to dealing with problem of confounding (not elaborated today)
  - Restriction
  - Matching
  - Controlling in multivariable analyses (adjustment)
  - Stratification

Population Attributable Risk (PAR)

- Proportion by which injury would be reduced if population was entirely un-exposed to risk factor
  - Helps consider relative importance of different risk factors for the same injury outcome and prioritise interventions at the policy level
  - PARs are not usually generalisable from one context to another as these are directly linked to the prevalence of risk factors in community

Studies investigating interventions designed (or expected) to reduce probability of injury

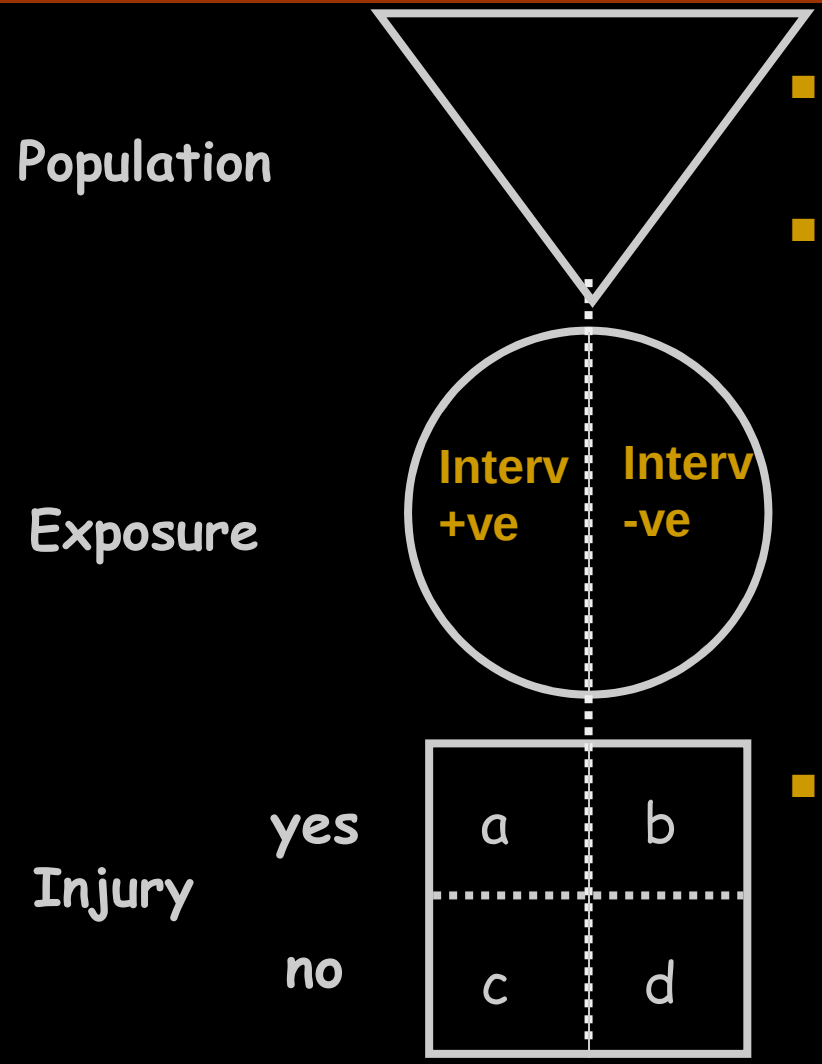


Relative Risk

$$\frac{a / (a + c)}{b / (b + d)}$$

An effective intervention results in a RR < 1

Studies investigating interventions designed (or expected) to reduce probability of injury



- Theoretically, has potential to be fully or partly investigator-controlled
- Level of Evidence: Quality of intervention research is often judged by the extent to which study design can
  - support confidence regarding causal relationship between the intervention and effect on injury by overcoming problem of residual confounding
  - Well conducted Randomised controlled trials (RCTs) are generally considered best positioned for this
  - Systematic reviews collate information from many studies
- Challenges: feasibility, natural experiments, cost, ethics, generalisability to 'real-life' and field situations

Examples of designs

- **RCT or Cluster RCT:** Individuals or groups of individuals (eg, classes, communities) randomly allocated to receive or not receive intervention; followed to document injury outcome (or proxy)
- **Quasi-experimental designs:** studies where investigator lacks full control over allocation or timing of interention but conducts an analysis as if it was an experiment
  - Time series design: multiple observations of injury outcomes before & after implementation, separated in time & space
  - Non-equivalent control group design: injury outcomes in one or more groups before/after intervention compared with injury outcomes of one or more groups that do not receive intervention
- **Observational studies:** case-control and cohort designs
- **Laboratory studies:** eg, experiments on visibility enhancing materials

Cochrane Collaboration

- Major benefits: Time saver, systematic appraisal
- Several published reviews on pedestrian injuries, including pedestrian skills education, traffic calming, visibility enhancing materials, and school travel plans
- Increasing global representation in numbers of contributors and reviewers
- Increasing efforts to incorporate evidence from research in LMICs but accessing information from ‘grey literature’ remains a major challenge compounded by publication and language biases

Challenges and Calls to Action!

- Many innovative injury prevention strategies being implemented globally. Employ rigorous methods to assess effectiveness and publish findings (positive & negative) in peer-reviewed literature.
- Increasing attention to sustainable transportation policies; prioritise strategies that promote active modes of travel and mitigate risks for ‘vulnerable road users’
- Many studies look at changes in knowledge, attitudes, skills and behaviours as primary outcomes. Ensure such outcomes translate to changes in injury outcomes.
- Undertake cost-effectiveness studies
- Identify and describe issues encountered in developing, implementing and scaling up effective interventions (formative, process and outcome evaluations)
- Investigate issues relating to opportunities for and barriers to implementation. These are likely to be context-specific and require robust qualitative and mixed-methods studies
- Engaging with relevant sectors, policy & decision-makers is important; engaging communities is vital.

References

McClure R, Stevenson M, McEvoy S (Eds). *The Scientific Basis of Injury Prevention and Control*. IP Communications, Melbourne, 2004

- Chapter 9: Connor J. Risk factor identification: the role of epidemiology
- Chapter 12: Ameratunga S. Developing injury interventions

Cochrane Collaboration (www.cochrane.org)