# Environmental Epidemiology - Study Designs

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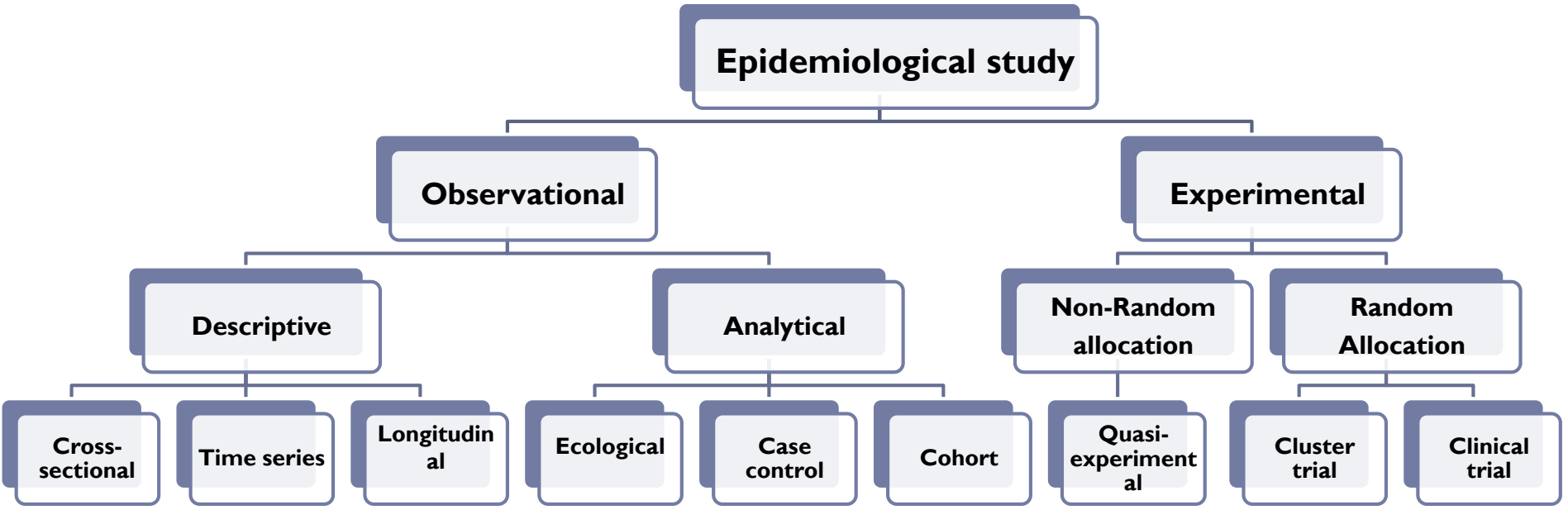
# Example study questions

- Descriptive
  - What is the health burden (specific diseases) of air pollution in India?
  - Is climate change happening in India?
- Analytical
  - Is air pollution related to cases of asthma in the country?
  - Is climate change responsible for variations in vector-borne diseases?
- Experimental
  - How will change to CNG/Delhi Metro impact health in Delhi

# Classification of Study Designs



# Cross-sectional study

- Measures the **prevalence** of health outcomes or environmental exposure or both, in a population at a point in time or over a short period.
- Such information can be used to explore aetiology but associations must be interpreted with caution.
- Advantages
  - Easy to do, low cost, fast
  - Can study multiple exposures and outcomes
- Disadvantages
  - Bias may arise because of selection into or out of the study population.
  - Is difficult to establish what is cause and what is effect, because cause and effect are measured at the same point in time.
- Can also be converted to a case-control study and measure prevalence odds ratio.

# Other descriptive designs

- **Longitudinal**
  - A population of individuals followed up over time and measures health outcomes of interest.
  - **Incidence** of malaria in a population
  - Usually expressed as incidence rate in person-year terms.
  - Survival Analysis

- **Time Series**
  - Repeated Cross-sectional studies or reported statistics
  - Analysis of variation in health events, such as daily/monthly/yearly counts of deaths or hospital admissions, in relation to exposures measured at similar temporal frequency.
  - Look at variations in trend using appropriate statistical approaches.

# Ecological studies

- An ecological (ecologic) study is one where both the outcome and the exposure information is collected on a group rather than on individuals.
- Example - persons living in a geographic area such as a census tract, county, or state. For each group or region, therefore, we know the average exposure level or distribution and the disease rate,
- For example, temperature for a population obtained from a single weather station (proxy for average levels of exposure in in individuals.) and death rates or hospital admissions
- Hypothesis generation and testing.
- Many important individual-level risk factors for disease simply do not vary enough within populations to enable their effects to be identified or studied.
- Some important risk factors for disease genuinely operate at the population level. Climate only operates at the population level.
- Usually done on secondary datasets.

# Cohort Study

- A cohort or follow-up study is a longitudinal design of a specified population in which exposure status is measured for all subjects at the start of follow-up (baseline) and possibly during follow-up to divide into exposed and unexposed group.
- The entire study population-typically persons who are free of the index disease at baseline are followed for detection of all incident cases or deaths of interest.
- Cohort studies may be entirely prospective, or entirely retrospective or a combination of them.
- Example – maternal smoking and birth weight
- Advantages
  - Quite similar to an experiment except randomization
  - Temporality well established
  - Less likelihood of selection and measurement biases
- Disadvantages
  - Long time period – cost and operational issues
  - Attrition and loss-to follow-up

# Case-control study

- In a case-control study, patients who have developed a disease are identified and their past exposure to a certain risk factor is compared with that of controls who do not have the disease.
- This permits estimation of odds ratios (but not of risks).
- Allowance is made for potential confounding factors by measuring them and matching or making appropriate adjustments in the analysis.
- The choice of controls is very important and must be done to minimise bias.
- Could be population based or hospital based
- Advantages
  - Easy to do, multiple exposures
  - Possible to study rare diseases
- Disadvantages
  - Possibility of selection and measurement bias

# Quasi-experimental

- Quasi-experiments are studies that aim to evaluate interventions but that do not use randomization.
- Quasi-experimental studies can use both pre-intervention and post-intervention measurements as well as non-randomly selected control groups.
- These designs are frequently used when it is not logistically feasible or ethical to conduct a randomized controlled trial.
- Policy and program interventions
- Advantages
  - Easy to do
  - Only options for some interventions
- Disadvantages
  - Selection Bias
  - Existing time trend, maturation of intervention

# Trials

- Randomized controlled trials have not been widely embraced by environmental health researchers and comprise less than 1% of research publications in the field.
- From a public health perspective, programs that reduce pollution emissions and exposure among large populations will always be preferable to interventions that attempt to reduce exposure at the individual or household level after the pollutants have been widely distributed.
- Example
  - Total Sanitation Campaign (TSC) on the availability of improved sanitation, open defecation behaviors, water quality, and childhood diarrheal and gastrointestinal illnesses. Villages randomized to the intervention group received the TSC, while control group villages received the TSC after the trial was completed.
- Issues
  - Ethical
  - Blinding
  - Time-scale (cancer – study intermediate outcomes)

# Implications for choosing study designs

- Experimental studies–
  - Ability to randomize
  - individual versus group
  - Contamination versus similarity
- Observational Studies
  - Collection of primary data Vs secondary data

# Difficulty in proving causality in Environmental studies

- Exposure
  - Occurs at population level and not individual level
  - Diffuse and low
  - Long latent period
  - Problem of Confounding and bias
  - May change over time
- Outcomes
  - Multiple outcomes
  - Rare events

# Choice of Strategy : 1

| Basis | Cohort | Case-control | Cross-sectional |
|---|---|---|---|
| Rare condition | Not practical | Best | NA[a] |
| To determine a precise risk | Best | Only estimate possible | Gives relative prevalence, not incidence |
| To determine whether exposure preceded disease | Best | NA | NA |
| For administrative purposes | NA | NA | Best |

[a] NA = not appropriate

[b] If attrition is more than 30 %, conclusions will be suspect

# Choice of Strategy : 2

| Basis | Cohort | Case-control | Cross-sectional |
|---|---|---|---|
| If attrition is a serious problem[b] | NA | Attrition is usually minimal | Attrition may have occurred before the study |
| If selective survival is a problem | Best | NA | NA |
| If all factors are not known | Best | NA | Less appropriate |
| Time and money | Most expensive | Least expensive | In between |

[a] NA = not appropriate

[b] If attrition is more than 30 %, conclusions will be suspect

# Key Messages

- 1. Epidemiological studies answer three types of questions – who, where, when what occurred? (descriptive), is there an association between an exposure and an outcome? (analytical) and what is the effect of an intervention? (Experimental).

- 2. The final choice of study design depends on the study question, resources including time available and a good understanding of strengths and weaknesses of different study designs.

- 3. Because of the fact that environmental exposures are shared by a group of people, ecological study designs and cluster trials are often used in environmental studies.

# Essential Reading


1. Bonita R., Kjellstrom T. Basic epidemiology. World Health Organization.
2. Morgenstern H., Thomas D. Principles of Study Design in Environmental. Epidemiology. Environmental Health Perspectives Supplements Volume 101, Supplement 4, December 1993.
3. Sari Kovats. The good, the bad and the ugly - How to read and understand climate-health studies. NCAR Colloquium. 2006
4. Ryan W. Allen, Prabjit K. Barn, and Bruce P. Lanphear Randomized Controlled Trials in Environmental Health Research: Unethical or Underutilized? PLoS Med. 2015 Jan; 12(1): e1001775.
5. Checkoway H., Pearce N., Kriebel D. Selecting appropriate study designs to address specific research questions in occupational epidemiology. Occup Environ Med. 2007 Sep; 64(9): 633–638.


# Effects of occupational heat exposure on female brick workers in West Bengal, India.

- **OBJECTIVE:** This study aims **to evaluate the effect of workplace heat exposure on the well-being, physiological load, and productivity of female brickfield workers in India.**
- **DESIGN:** A questionnaire study (n=120), environmental temperature, and weekly work productivity analyses were evaluated **for 8 months** in the brickfields.
- **RESULTS:** The subjects experience summer for about 5 months with additional heat stress radiating from the brick kiln. The weekly productivity data show a linear decline in productivity with increased maximum air temperature above 34.9°C. The brick carriers adapted to hotter days by decreasing their walking speed.

Sett M, Sahu S. Glob Health Action. 2014 Feb 3;7:21923.

# Forecasting incidence of dengue in Rajasthan, using time series analyses.

- **AIM:** To develop a prediction model for dengue fever/dengue haemorrhagic fever (DF/DHF) using time series data over the past decade in Rajasthan and to forecast monthly DF/DHF incidence for 2011.
- **MATERIALS AND METHODS:** Seasonal autoregressive integrated moving average (SARIMA) model was used for statistical modeling.
- **RESULTS:** During January 2001 to December 2010, the reported DF/DHF cases showed a cyclical pattern with seasonal variation. The proportion of variance explained by the model was 54.3%. Adequacy of the model was established through Ljung-Box test (Q statistic 4.910 and P-value 0.996), which showed no significant correlation between residuals at different lag times. The forecast for the year 2011 showed a seasonal peak in the month of October with an estimated 546 cases.

Bhatnagar S[1], Lal V, Gupta SD, Gupta OP. Indian J Public Health. 2012 Oct-Dec;56(4):281-5.

# Community-based control of Aedes aegypti by adoption of eco-health methods in Chennai City, India.

- **BACKGROUND:** This intervention study was aimed at **establishing the efficacy** as well as the favouring and limiting factors relating to a community-based environmental intervention package to control the dengue vector Aedes aegypti.
- **METHODS:** A **cluster randomized controlled trial** was designed to measure the outcome of a **new vector control package**. Ten randomly selected intervention clusters were paired with ten control clusters on the basis of ecological/entomological indices and sociological parameters collected during baseline studies. In the intervention clusters, Aedes control was carried out using a community-based environmental management approach like provision of water container covers through community actors, clean-up campaigns, and dissemination of dengue information through schoolchildren. The main outcome measure was reduction in pupae per person index in the intervention clusters compared to the control clusters.
- **RESULTS:** A total of 1000 houses and 4639 inhabitants received the intervention while the 1000 houses and 4439 inhabitants received only the routine government services and some of the project IEC materials. After 10 months of intervention, the pupae per person index was significantly reduced to 0.004 pupae per person from 1.075 (P = 0.020) in the intervention clusters compared to control clusters. There were also significant reductions in the Stegomyia indices: the house index was reduced to 4.2%, the container index to 1.05%, and the Breteau index to 4.3 from the baseline values of 19.6, 8.91, and 30.8 in the intervention arm.

Arunachalam N et al. Pathog Glob Health. 2012 Dec;106(8):488-96.