Validity of epidemiological studies

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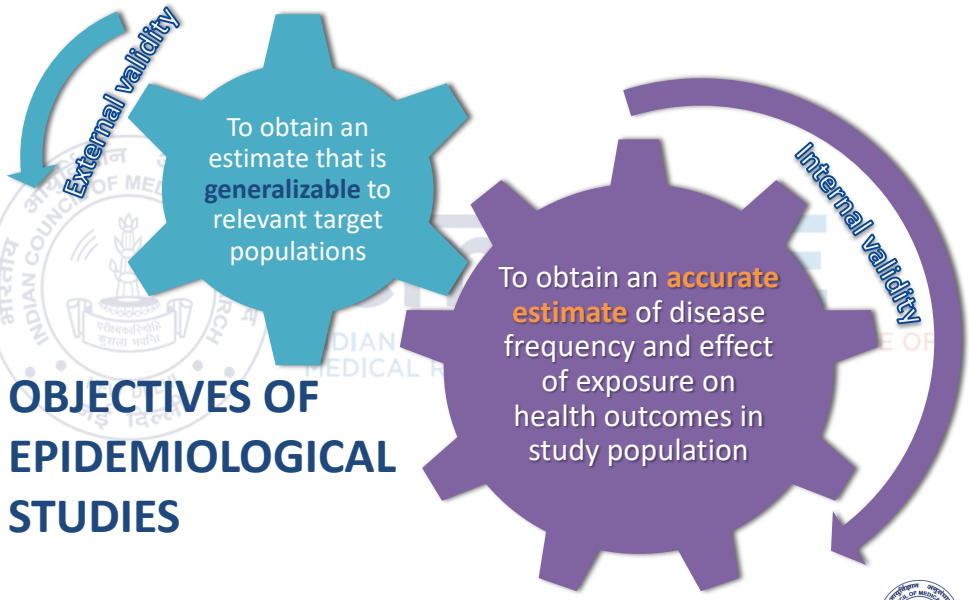
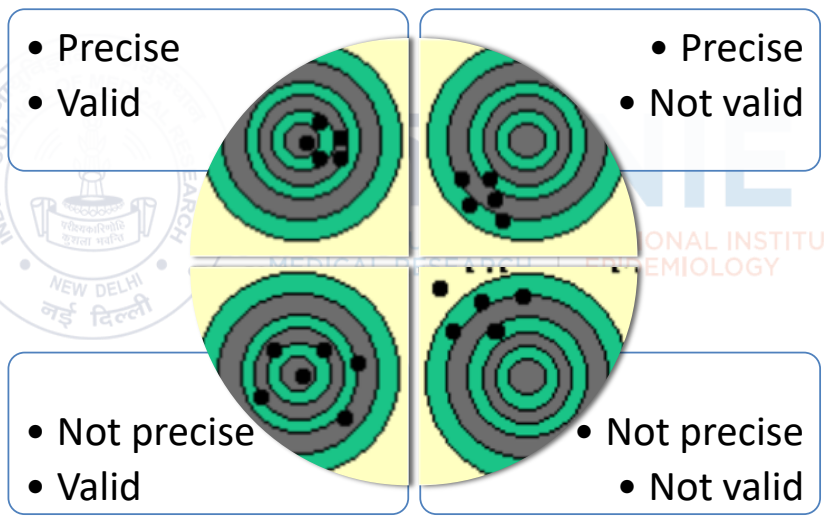
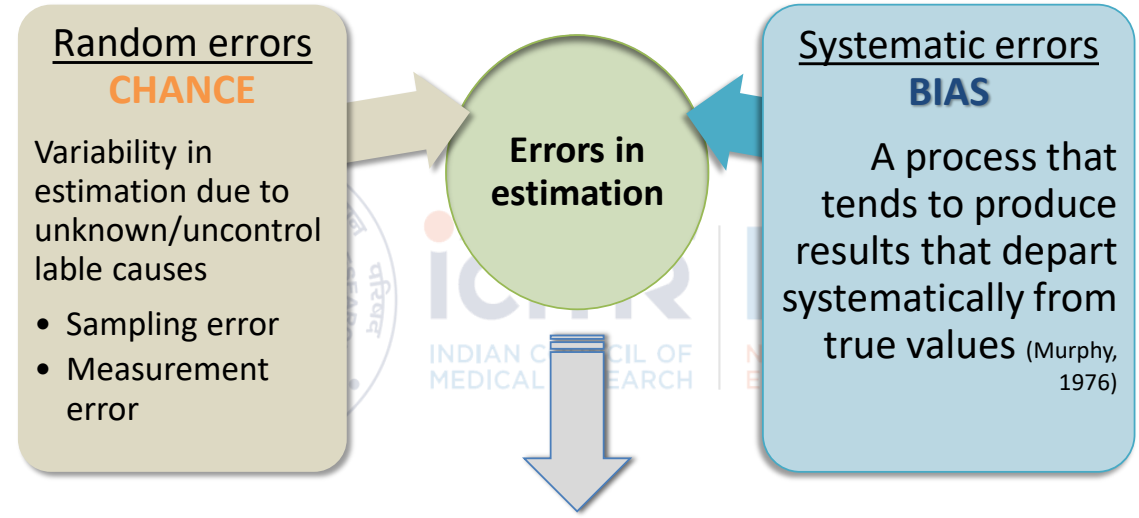
OBJECTIVES OF EPIDEMIOLOGICAL STUDIES



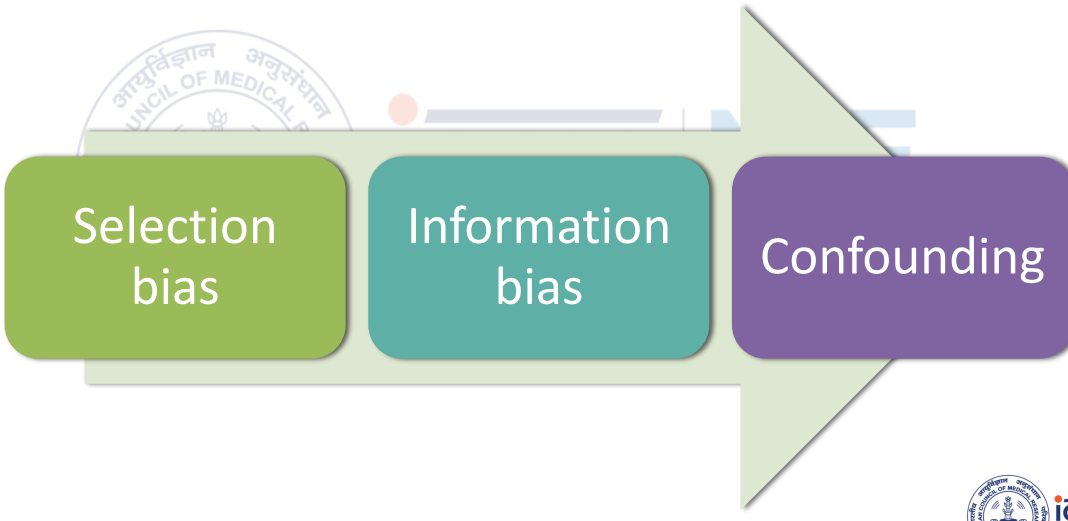
Accuracy = Precision and Validity





Association between exposure and outcome among the study participants differs from the causal association in the population

Threats to validity in epidemiologic studies



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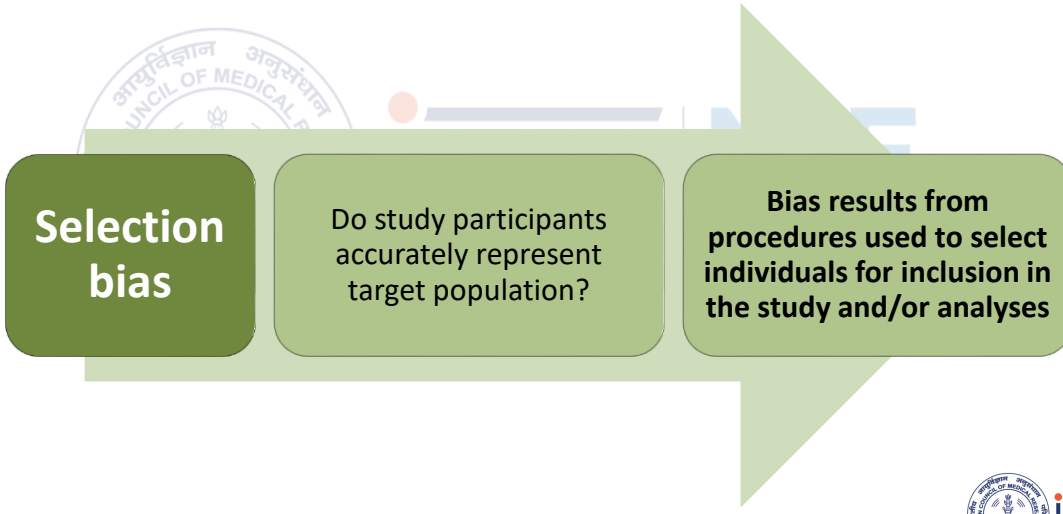

Selection bias in epidemiological studies

- **Surveillance** - Systematic notification of exposed cases
- **Screening / diagnosis** - Systematic case search among exposed
- **Admission to health care facilities** - Systematic admission of:
  - Case-patients exposed / unexposed
  - Control-subjects exposed / unexposed
- **Selective survival** - Systematic inclusion of cases who survived and who may be more or less exposed
- **Non response / loss to follow up** - Systematic inclusion of subjects more likely to participate who may be:
  - More or less exposed
  - More or less at risk

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Dealing with selection bias

Designing stage of a study

- Use incident cases, not prevalent cases
- Case control studies
  - Use population-based design
  - Apply same eligibility criteria for selecting cases and controls
  - Both cases and controls undergo the same diagnostic procedures and intensity of disease surveillance

Dealing with selection bias

Data collection stage of the study

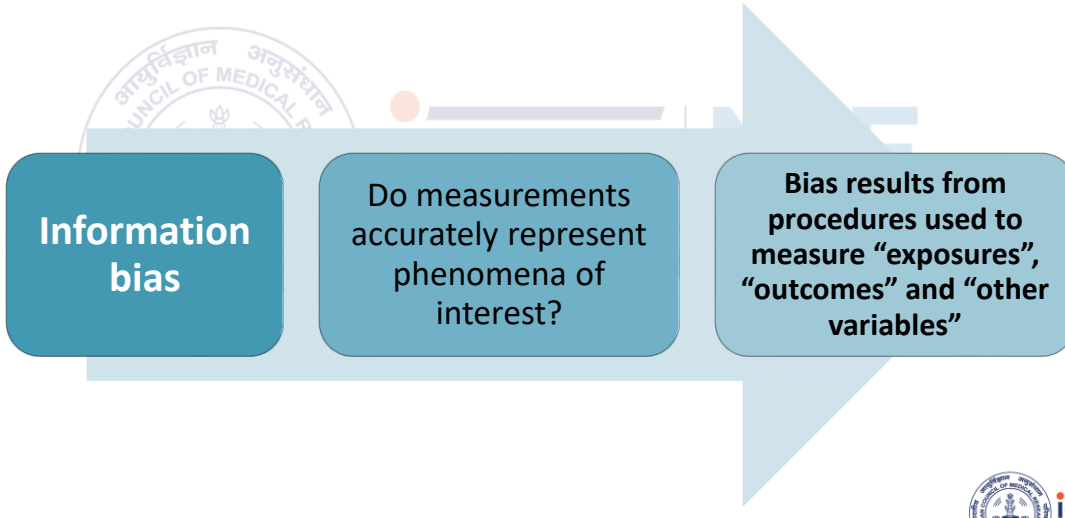
- Minimize nonresponse, nonparticipation and loss to follow-up (Cohort studies)
- Keep a record of all losses and collect baseline data on them
- Make sure that diagnosis of disease is not affected by exposure status (blinding)

Dealing with selection bias

Analysis stage of study

- Compare non-responders/dropouts with responders/non-dropouts with respect to baseline variables
  - Large differences strongly suggest selection bias
  - Small differences do not rule out selection bias
- Use study results and external information to deduce the direction of biases and assess magnitude of biases
  - Do sensitivity analysis

Threats to validity in epidemiologic studies



Information bias in epidemiological studies

- **Case control study**
  - Collection of information leaning towards specific exposure status
  - Recall - Cases may recall exposure more than controls
  - Better exposure data available on cases compared to controls
- **Cohort study**
  - Collection of information leaning towards specific outcome status
  - Better outcome data available on exposed compared to unexposed

- **Investigator** - Systematic collection of information supporting expected conclusions (Unconsciously or Consciously)
  - May be examined in the analysis
- **Prevarication** - Systematic distortion of the truth by subjects

Dealing with information bias

- Precise operational definitions of variables
- Detailed measurement protocols
- Repeated measurements on key variables
- Training, certification and re-certification
- Data audits (of interviewers, of data centers)
- Data cleaning – visual, computer
- Re-running all analyses prior to publication

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Threats to validity in epidemiologic studies

Confounding

"confusion of effects"

The apparent effect of the exposure of interest is distorted because the effect of extraneous factors is mistaken for – or mixed with – the actual exposure effect

Confounding in epidemiological studies

May simulate an association that does not exist

May hide an association that does exist

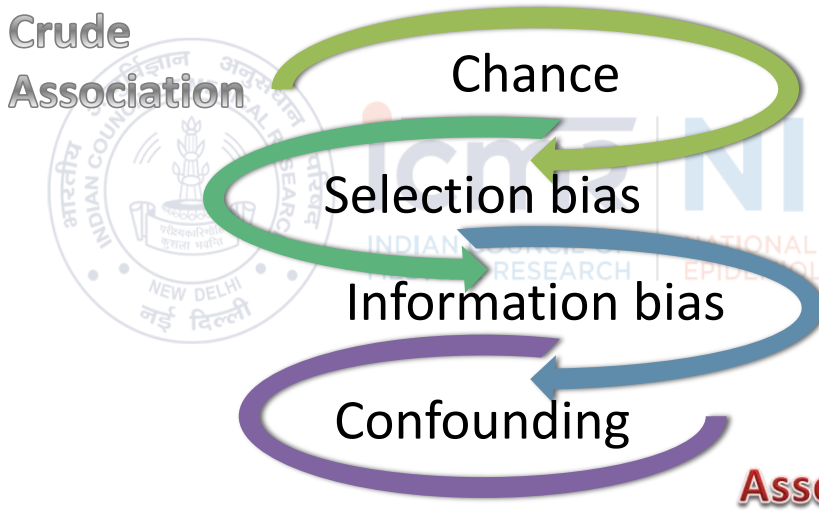
May change the direction of an effect

May increase or decrease the strength of the association

Dealing with confounding

- Design stage
  - Restriction
  - Matching
  - Randomization
    - Experimental studies
- Analysis stage
  - Stratification
  - Multivariate analysis

How to evaluate associations?



Does coffee increase risk of heart attack?

- Truth in Universe
- Population: All Adults
- Actual Coffee intake
- Actual heart attack (MI)

Selection bias

Information bias

- Truth in Study
- Sample:
  Consenting adults
  Low participation rate
  Hospital patients
- Reported Coffee intake
- Reported/misdiagnosed heart attack (MI)

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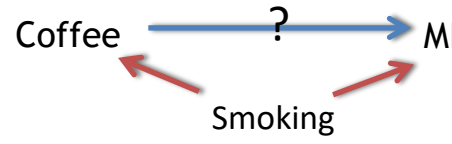
Does coffee increase risk of heart attack?

- Was the association between coffee and MI due to **CONFOUNDING** by smoking?
  - "A confounder is associated with both the exposure (coffee) and the outcome (MI)."
  - Smoking in
    - coffee (+) 86%
    - coffee (-) 27%
    - MI (+) 80%
    - MI (-) 40%



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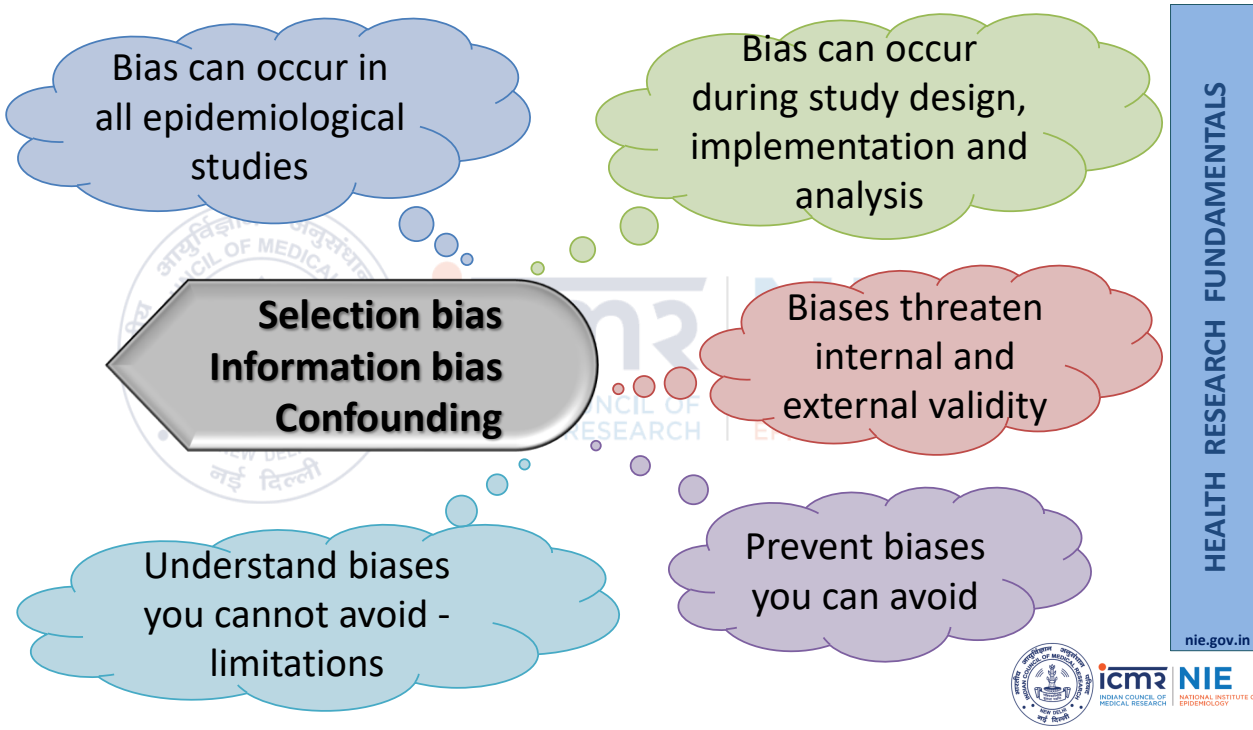

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Thank you

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