Evaluating Research

AAID Asia Maxicourse®

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Evaluating Research

- Experimental studies

  -assignment is under control of investigator
- Can be randomized
- Provides a better foundation for statistical procedures

Types of Experimental Studies

a. **Randomized Controlled Clinical Trial (RCT)**

-uses primary data generated in the clinical environment

b. **Randomized Cross-Over Clinical Trial**

-uses primary data generated in the clinical environment

c. **Randomized Controlled Laboratory Study**

-uses primary data generated in the laboratory environment

Observational Studies

- NOT under the control of the investigator
- Combinations are self-selected
- "experiments of nature"
- Provide weaker empirical evidence
- Symmetry of unknown confounders cannot be maintained

Types of Observational Studies

a. **Cohort (Incidence, Longitudinal Study) Study**

-primary data from a follow-up period of a group that have or will have the exposure of interest

b. **Case-Control Study**

-based on secondary data

-cases with risk factors are compared to the proportion of control with same risk factors

Types of Observational Studies

c. Ecologic (Aggregate) Study

-based on aggregated secondary data

d. Cross-Sectional (Prevalence Study) Study

-study of relationship between diseases and other factors at one point in time

e. Case Series

-series of cases describing the manifestations, clinical course, and prognosis of a condition

f. Case Report

-anecdotal evidence

Validity vs. Bias

- Validity: Truth

a. External Validity (Generalizability)

-truth beyond a study

b. Internal Validity

-truth within a study

c. Symmetry Principle

-keeping all things between groups similar except for the treatment of interest

Confounding

- Distortion of the effect of one risk factor by the presence of another
- Occurs when another risk factor for a disease is associated with the one being studied but acts separately
- Age, breed, gender, and production levels are risk factors

Bias (Systematic Error)

- Process or effect at any stage of a study that produces results or conclusions that differ systematically from the truth
- Almost all studies have bias, to varying degrees
- Question is whether or not the results could be due to bias, making the conclusions invalid

Types of Biases

a. **Confounding Bias**

-due to failure to account for the affect of one or more variables that are related to both the casual factor being studied and the outcome and are not distributed the same between the groups being studied

Types of Biases

b. **Ecological (Aggregation) Bias (Fallacy)**

-occurs when the nature of an association at the individual level is different from the association observed at the group level

Types of Biases

c. **Measurement Bias**

-occurs when the measurement methods are consistently different between groups in the study

- ✓ **Screening Bias**: occurs when the presence of a disease is detected earlier during its latent period by screening tests but the course of the disease is not changed by earlier intervention

Types of Biases

d. **Reader Bias**

-errors of interpretation made during inference by the user or reader of clinical information

e. **Sampling (Selection) Biases**

-occurs when the study comparisons are between groups that differ with respect to the outcome of interest for other reasons

Types of Biases

f. **Zero Time Bias**

-occurs in a prospective study when individuals are found and enrolled in such a fashion that unintended systematic differences occur between groups at the beginning of the study

Bias Effect

a. **Non-differential Bias**

   -opportunities for bias are equivalent in all study groups

b. **Differential Bias**

   -opportunities for bias are different in different study groups

Study Objective, Direction and Timing

1. **Analytic (Explanatory) Study**
   -make casual inferences about the nature of hypothesized relationships between risk factors and outcome
2. **Descriptive Study**
   -describe the distribution of variables in a group
3. **Contemporary (Concurrent) Comparison**
   -between two groups experiencing the risk factor or treatment at the same time

Study Objective, Direction and Timing

4. Historical (Non-concurrent) Comparison

   -of the same or different groups at different times that are not experiencing the risk factor or the treatment at the same time

5. Prospective Study (Data)

   -data collection and the events of interest occur after individuals are enrolled

6. Retrospective Study (Data)

   -have already occurred and data are generated from historical records and from recall

Other Terms

1. **Baseline:** health state of individuals at beginning of a prospective study
2. **Blinding (Masking):** to reduce bias by preventing observers from knowing the hypothesis being investigated

    -Placebo: shame treatment used in a control group in place of the actual treatment

Other Terms

3. **Case Definition:** set of history, clinical signs and laboratory findings used to classify an individual as a case or not for an epidemiological study
4. **Cohort:** individuals identified on the basis of a common experience
5. **Experimental Unit, Unit of Concern (EU):** randomly selected or allocated to a treatment

Sample Selection/ Allocation Procedures

1. **Matching:** cases are matched with individual controls that have similar confounding factors
2. **Restriction (Specification):** restrictions, such as age, for entry into an analytic study
3. **Census:** sample that includes every individual in a population or group

Sample Selection/ Allocation Procedures

4. **Haphazard, Convenience, Volunteer, Judgmental Sampling:** sampling not involving a truly random mechanism
5. **Consecutive (Quota) Sampling:** sampling individuals with a given characteristic as they are presented until enough with that characteristic are acquired
6. **Random Sampling:** each individual has a known probability of being included in the sample obtained from the group

Sample Selection/ Allocation Procedures

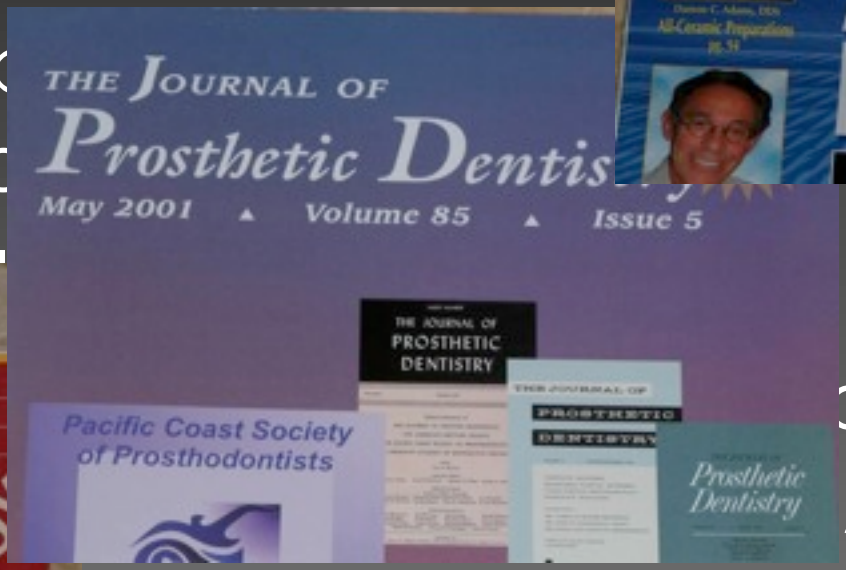
7. **Simple Random Sampling/ Allocation:** conducted such that each eligible individual has the **same** chance of being selected or allocated to a group
8. **Stratified Random Sampling:** the sample to be taken first is stratified on the basis of an important characteristic related to the problem at hand

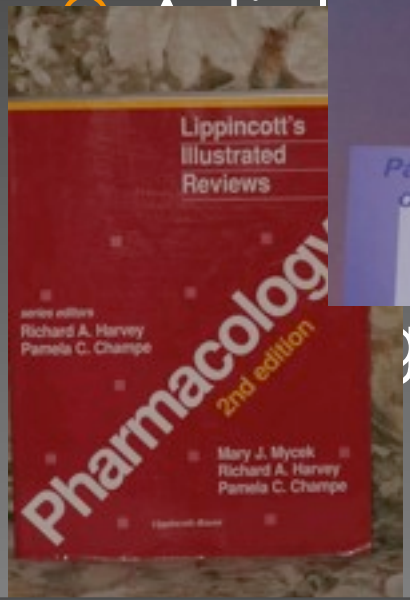
Sample Selection/ Allocation Procedures

9. **Cluster Sampling:** staged sampling in which a random sample of natural groupings of individuals are selected and then sampling all the individuals within the cluster
10. **Systematic Sampling:** from a random start in first n individuals, sampling every nth animal as they are presented at the sampling site

Literature Hierarchy

- Published peer revie
  scientific journals
- Text b
  by Sc
- A





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