Epidemiology 101

Types of Study Designs

Overview

• When determining the type of study design, the first issue is to identify the research question. There are 3 overall goals:
  – Identify significant associations that can be used to prevent disease.
  – Evaluate intervention programs
  – Determine the effectiveness of medical treatments and procedures.

Two overall types of epidemiological studies

• Descriptive
  – Observational
• Analytical
  – Observational
  – Intervention

• Different types of study designs fall under these categories and there can be some overlap.
• Epidemiologists progress through study designs as they answer questions.

Understanding study design

DES and Vaginal Cancer: an overview of study design

Our story begins in the 1960s.

Determine if there is a problem

• Case Study
  – Example of vaginal cancer among young women*
    • In the 1960s, there were seven cases of vaginal cancer occurring in young women 15 to 22 years of age reported. Six sought medical advice because of abnormal bleeding, which was assumed to be due to anovulation.

Case reports/series

• Case reports
  – Accounts of a single occurrence of a noteworthy event or a small collection of events
• Case Series
  – Larger collection of cases of disease

• They often serve to alert the medical community to a potential problem.

Cross-sectional studies

- Individuals are enrolled as representatives of a certain population
- Not dependent on disease or exposure
- Information on exposure and disease is collected at the same time
- May be done for more common conditions but was not used in the vaginal cancer study
  - Asthma

Facts about vaginal cancer

- Rare disease
- Makes up less than 3% of all gynecological cancers
- Risk factors
  - Smoking
  - Age > 50
  - History of cervical cancer, or genital warts from HPV
  - Past hysterectomy
  - Past pelvic radiation
- These cases were very unusual, an epidemic

Identify the cause

- No one knew why these girls had vaginal cancer
- Need to compare the girls with vaginal cancer with those who did not have the disease
- Look for differences between the two groups
- Case-control study

Case Control Study in 1971

- Sudden and unexpected appearance of 8 cases of vaginal cancer in young women
- Epidemiologists needed to find out the cause
- Interviewed the mothers of 8 women with cancer and the mothers of 32 women without cancer to see if they could determine any differences.
- They found that seven of the eight mothers of these patients had been treated with diethylstilbestrol (DES) during pregnancy compared to none of 32 other mothers.
- This is called a case-control study as women are picked by having or not having a disease and asked about the past.

Step 3

- If we know that DES use during pregnancy leads to vaginal cancer, what might we also want to know?
Step 3: Establishing other health risks of DES use in pregnancy

- Set up a study in which women with DES exposure while in utero were compared to women without DES exposure in utero.
- This is called a cohort study
  - Women are identified by exposure
  - They are followed over time to look at many outcomes

Des exposure

- No DES exposure

Step 5: Further study

- Evaluated the health risks for men exposed to DES while they were in utero.

Health effects of DES on men

- Confirmed
  - Some genital abnormalities
    - Benign epididymal cysts
- Suspected
  - Testicular cancer
  - Infertility
  - Prostate cancer (mouse studies)
- Third generation effects

Ecological studies

- Study that is done on large groups and not individuals
- Not done on DES
- Study of seat belt laws and motor vehicle injury rates
Health interventions

• Once a link is established, the goal is to prevent further disease.
• Possible actions include:
  – Developing a health message
  – Identify a screening practice
  – Identify treatments
• These could result in evaluation studies or randomized clinical trials.

Randomized clinical trial

• Study to determine the effect of a treatment on a disease
• People with a disease are enrolled
  – They are randomly put into groups
  – Some get treatment
  – Some get placebo
  – They do not know which they get
  – Outcomes are compared

Health intervention studies

• Evaluation research
• Try to determine if certain health interventions improve outcomes
  – People may be randomized into groups
  – Usually know what group they are in
  – Often done in larger communities

Overview of study designs

• Case reports/case series
• Cross-sectional design
• Case-control study
• Cohort study
• Ecological studies
• Randomized clinical trials
• Evaluation research