

Chapter 5 Introduction to Study Design

Open session 04/08/25

04/015/25 mid term exam

04/22/2025 project work time

04/29/2025 presentation

5.1 Introduction to Etiologic Research

Epi Hypotheses

1. Studies should address defined research hypothesis or research question
2. Hypotheses must be based on sound causal mechanisms in specific terms that can be tested
3. Hypotheses are refined as new information becomes available

Hypothesis Statement

Needs a broad question that you want answer

Selected elements of an epi research question

1. Source Population
2. Exposure variable
3. Disease variable
4. Confounding variables
5. Dose response
6. Time response sample size

Variable Yaz Example

Confounders

Ethics: Studying Human Subjects

Institutional review board review if humans who engage are protected.

Informed Consent is important

The Belmont Report is a guideline for human case study

Casualties are bad

Data Safety Monitoring Board checks if outcomes are good or bad, or outweighs goal

Equipoise

Equipoise is balanced doubt

Cannot expose a participant to harm, like smoking

Cannot withhold known benefit to subjects

Selected Study Design Elements

Referent Group Only judge effects of an exposure relative to the baseline determined by referent or control group

Experimentation

How was exposure assigned?

Experimental study is an assignment or

Observational study classify

Unit of Observation

Longitudinal v X-Sectional

Longitudinal follows a group over time

Chapter 7

7.1 Introduction

Needs cohort study

Classify as exposed or non-exposed

Retro spective cohort studies

Correlation does not equal causation

Cross section studies cannot conclude causality

Birth Cohort mimics birth cohorts

Cohort studies

Classify exposed and non exposed

Follow them over time

compare risk or rate of disease

Chapter 8

Longitudinal refers to time line

Case-Control

Comparing diseased and non diseased

Looking at groups of people and check their history

Case control studies are always retrospective

Identify cases in source population

Select random non cases from same source population

Check what exposure was or reason

R_0 not available, so odds are used in case control studies

Source Population A Seattle Area HMO

175 Histologically confirmed prostate cancer cases, must be clinically confirmed

258 Similar aged men selected at random for source population (controls)

Exposure

Identifying Cases

Incidence cases are preferred

Prevalent cases

Sources of cases

Typically control population surveillance or valid ways such as hospitals, death cert, health records, pharmacy

Maximum efficiency of 1 control to 1 case

Good Information

Quality of study depends on garbage in garbage out

Gather information for cases and controls in identical manners, blinded review is best to avoid bias

Data collection forms

It should be done simply

Data should be collected consistently