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Pharmacy 476
Selecting a Study Design

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Objectives

- Discuss the process of selecting a study design
- Address project-specific questions about study design

Study Designs

Most Common Study Designs
Number of Contacts with the Study Population

- Three different perspectives to consider:
  - number of contacts with the study population
  - duration of study or the length of the study period
  - the type of investigation

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Study Design
Based on the Number of Contacts

- Study design based on the number of contacts falls into one of three groups:
  - cross-sectional
  - before-and-after
  - longitudinal

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Study Design

Cross-sectional Study Design

- Takes a "snap-shot" in time
  - takes a "cross-section" of a population
  - can be prospective or retrospective
- Best suited for:
  - finding out the prevalence of a disease or phenomenon
- Is simple in design
  - identify the study population
  - select a sample
  - acquire data

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Cross-sectional Study Design

- Examples
  - the attitude of the elderly towards pharmacists
  - the socioeconomic-demographic characteristics of teenagers with STDs
  - the relationship between the home environment and the incidence of asthma in children
- These studies involve only one contact with the study population

Study Design
Before-and-After Study Design

- Measures change
  - It's the most appropriate design for measuring the impact or effectiveness of an intervention or program:
    - can be two-cross sectional studies
    - can be prospective or retrospective
    - "impact" or "effect" on a study population

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Before-and-After Study Design

- Examples
  - The impact of specialty board certification on the quality of pharmacy services
  - The effectiveness of pharmacy-based management of hypertension
  - The impact of an antibiotic restriction program on hospital drug costs

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Before-and-After Study Design

- Advantages
  - measures change and/or impact/effectiveness
- Disadvantages (depends on type of study)
  - requires the collection of two (rather than one) data sets from the same study population
  - time between measures may result in attrition of study population or can skew its demographics (e.g., pediatrics)
  - measures *total change*- you can't ascertain whether other variables contribute to the change in your measure
  - "intervention" may condition study population
  - study population attitudes can be influenced over time

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Study Design
Longitudinal Study Design

- Used to study patterns of change over time
  - to study the proportion of people adopting a program in relation to time
  - you can collect data on a continuing basis and measure trends
- Study population is sampled numerous times
  - a series of repetitive cross-sectional studies

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Longitudinal Study Design

- Advantages
  - allows for the measure of changes in patterns over time on a regular or continuous basis
    - effect of propranolol on blood pressure using a continuous blood pressure monitoring device
- Disadvantages
  - conditioning effect

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Most Common Study Designs

Duration of the Study

- Three different perspectives to consider:
  - number of contacts with the study population
  - duration of study or study period
  - the type of investigation

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Study Design
Based on Study Length

- Study design based on the duration of the study or the length of the study period falls into one of three groups:
  - retrospective
  - prospective
  - retrospective-prospective

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Study Design
Retrospective

- Retrospective studies investigate a phenomenon or problem that has happened in the past
  - fact-finding, preliminary, hypothesis-generating
  - important event that occurred in the past

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Study Design
Prospective

- Prospective studies refer to the future
  - to determine the impact or an effect of an intervention on a future event

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Study Design
Retrospective-Prospective

- These studies use past trends to study future events
  - measurement of an intervention without having a control group (e.g., use of historical controls)
  - before-and-after studies can be retrospective-prospective
    - part of the data are collected before an intervention from existing records then the same group is studied following an intervention

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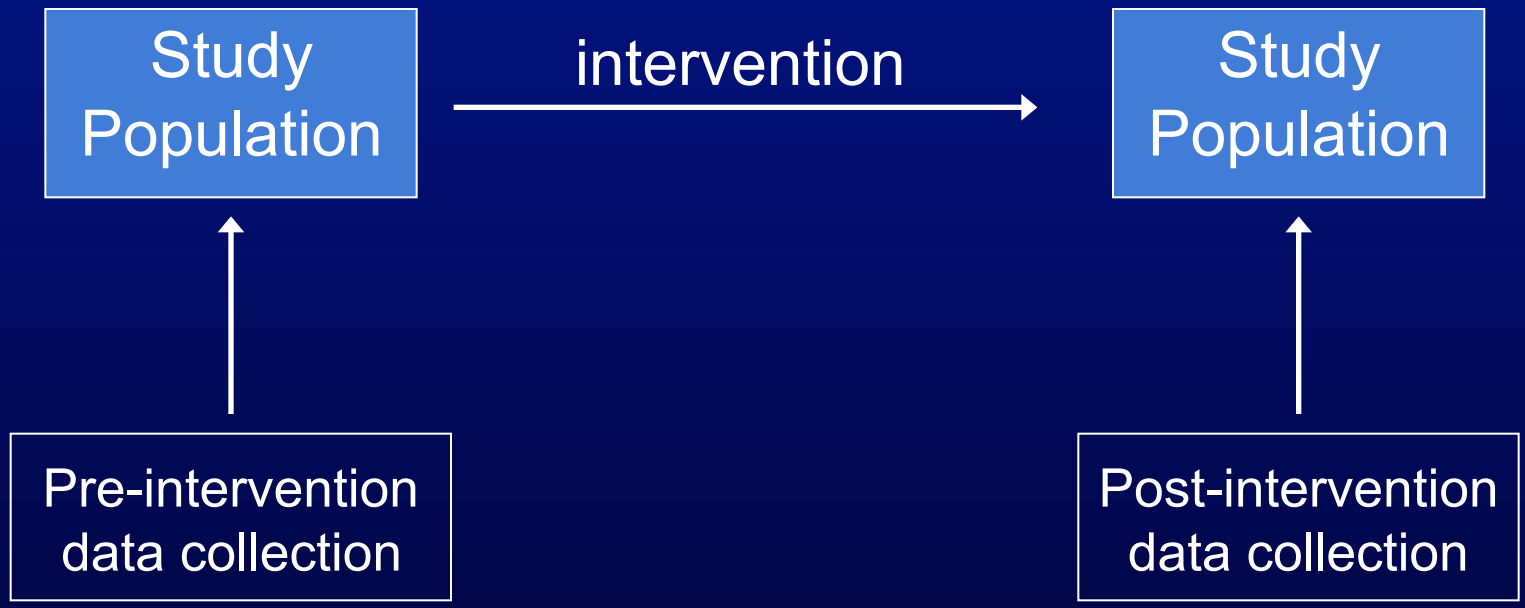
Randomization

- Experimental studies can be further classified on whether the study population is randomly assigned to different treatment groups
  - the intent is that potentially confounding variables will be equally distributed between the groups
  - can be used in any experimental design

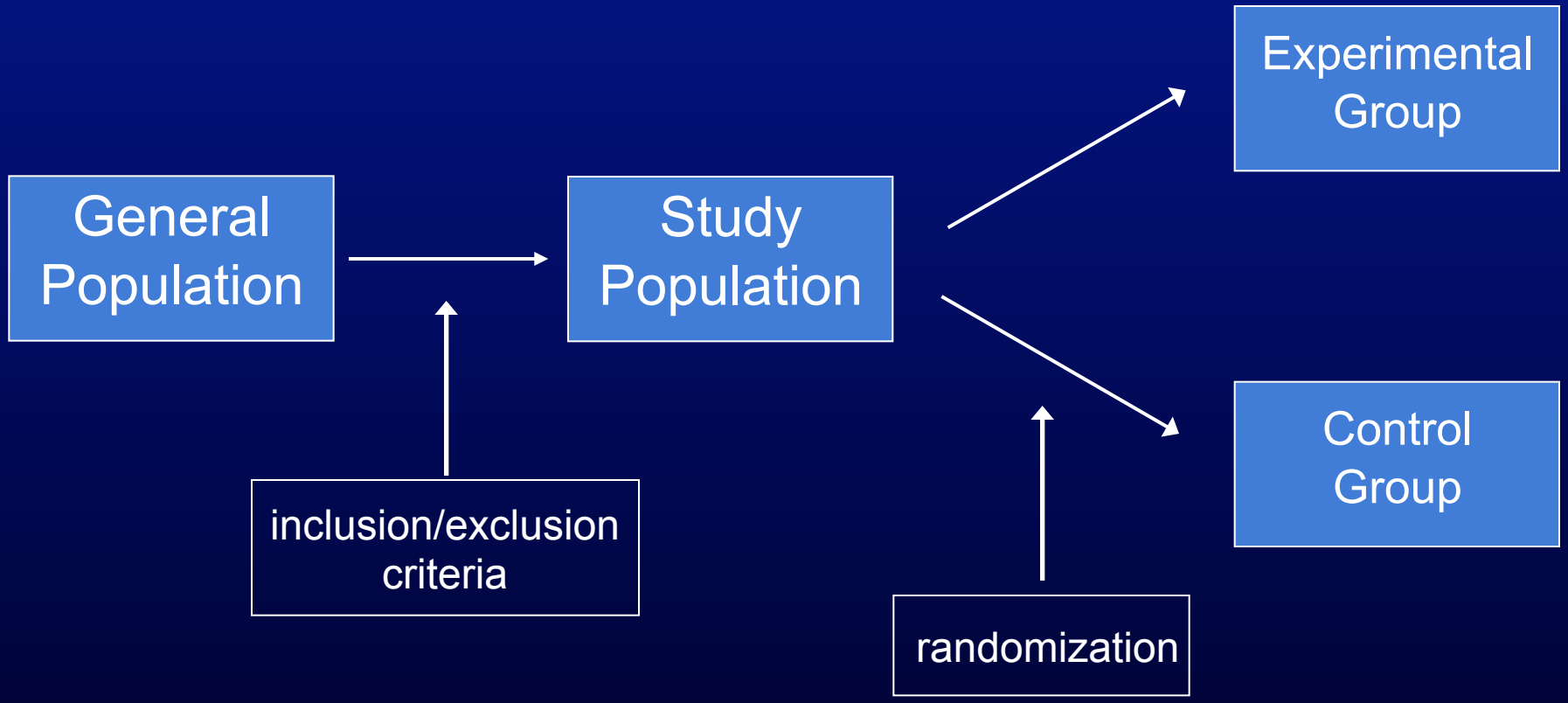
Study Design
Experimental

- before-and-after design



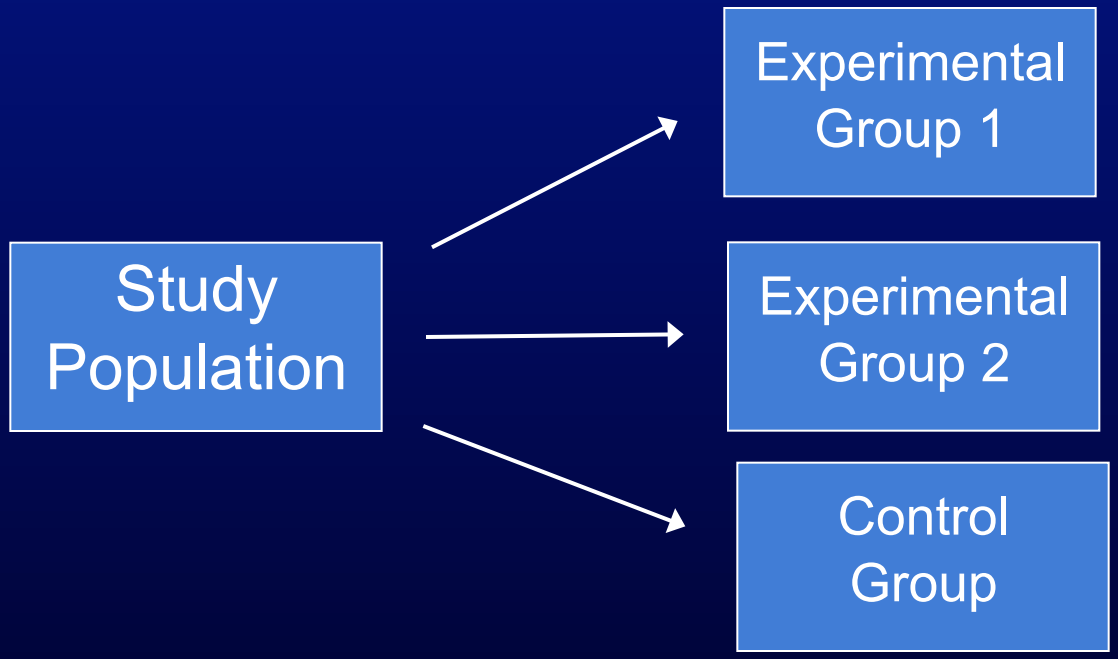
Study Design
Experimental

- Addition of inclusion/exclusion criteria, randomization and control groups



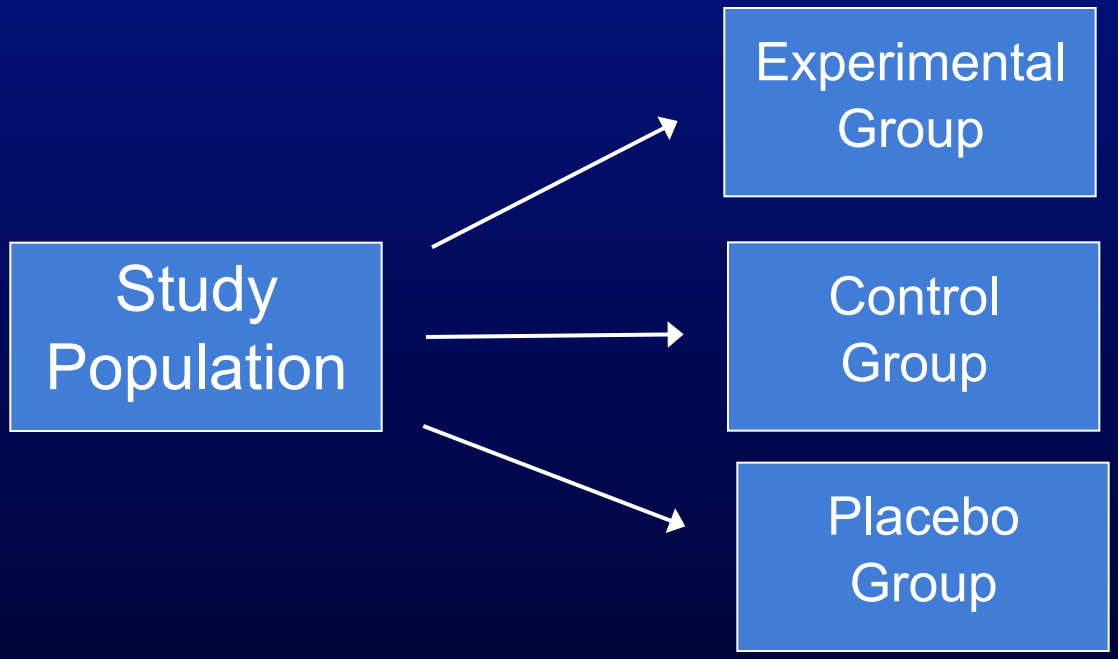
Study Design
Experimental

- Can have more than one experimental and/or control groups
  - may also have more than one treatment or intervention (arms)
  - this will be dictated by your hypothesis and your specific aims



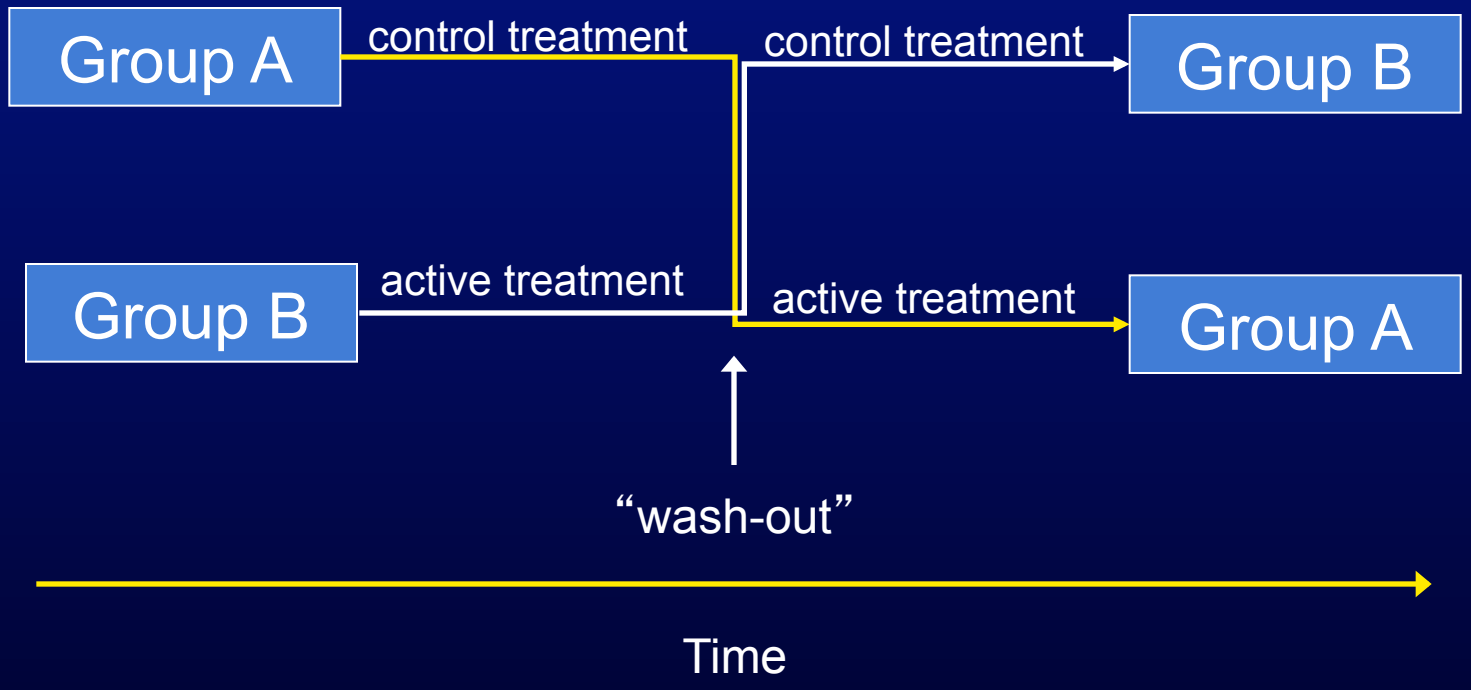
Study Design
Experimental

- Control groups can consist of an active control, a placebo control or both



Study Design
Experimental

- Other designs
  - Cross-over



Study Design

- **Case control study-** characteristics of patients with a condition are compared with those without. What's the cause?
- **Cohort study-** group of patients with a specific disease or characteristic are followed over a period of time to detect complications or new events. Can be retrospective or prospective.
- **Cross-sectional-** presence or absence of exposure to possible risk factor measured at one point in time. Obtains prevalence.

Study Design

- Blinding
  - limits bias in the conduct of research and the interpretation of data
  - bias influences recruitment, enrollment, group allocation, decision-making, data analysis and assessment
  - Types: double-blind, single-blind
- Unblinded or open label

Study Design
The Devil's in the Details

- Identify the study design you will use to test your hypothesis and *achieve* your aims
- Expand to include more details
  - inclusion/exclusion criteria (avoid redundancy)
  - treatment regimens or interventions
    - what *exactly* are you going to test?

Study Design

- Define your patient population
  - who (gender, age, ethnicity etc)
  - disease state (specific criteria)
  - setting (inpatient, outpatient)
- These parameters are what you'll use to define your inclusion/exclusion criteria
- You need to provide enough detail so your reviewer knows what you plan to do

Study Design

- Method details
  - describe drug regimen (if applicable)
    - what?
    - how much (and frequency)?
    - how long?
  - treatment arms
  - specifics of intervention

Measurements

- On Monday we'll talk about outcomes, variables and measurements
  - these are also aspects of your study design
- Individual assignment #2
  - due TOMORROW via Ctools assignments

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