**MODULE 1: FUNDAMENTAL CONCEPTS**

**Module 1.3: Study designs**

**Learning Objectives**
- Describe the basic research study designs used in public health
- Compare and contrast experimental and observational designs

**Study design**

In conducting a study, we examine the effect of an exposure on an outcome. Most research study designs fall under two categories:

1. **Experimental**
2. **Observational studies**

**Note:** The choice of a study design mainly depends on the research question(s) and type of research conducted (experimental or observational).
Experimental Studies

The investigator controls the experimental environment in which the hypothesis is tested. The randomized double-blind clinical trial is the gold standard.

- **Purpose:** To obtain the most definitive evidence that a "treatment" causes a "response", often to test "Cause-Effect" hypotheses.
- Can be done in Lab or Field settings
- Differ from observational studies whose sole purpose is to estimate population parameters.

Observational design (non-experimental)

Observed without any interference by the investigator. The researchers are not manipulating any variable (e.g., giving a drug or placebo)

- For example, in a study to see the effect of smoking, it is impossible for an investigator to assign smoking to the subjects. Instead, an investigator can study the effect of smoking by choosing a control group who do not smoke and a comparable group who do smoke to find the cause and relation effect. The "effect" of smoking is not being experimentally manipulated (assigning one group to smoke and the other to abstain) but is just being observed in those who already smoke and those who do not.
- Examples of Observational Study designs
  - Cross-sectional study
  - Cohort study
  - Case-control study

Cross-sectional Study

- Both the exposure and outcome are assessed at the same time

- Ex. Have 1,000 people complete a survey and ask if they smoke and if they have lung cancer
Case-control Study

- Select participants whether they have the outcome of interest (an outcome is usually a disease)
- Ask those with the disease and those without the disease about previous exposures
- Ex. Select 400 people who do not have lung cancer and 400 people who have lung cancer and ask about their smoking habits

Cohort Study

- Select participants who have the exposure of interest and follow them to see if they have the outcome
- Ex. Select 5,000 people who do not smoke and 5,000 people who smoke and follow them for 20 years to see how many develop lung cancer