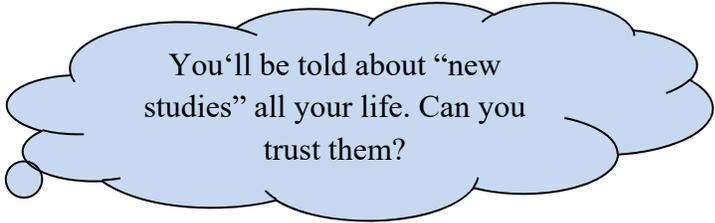
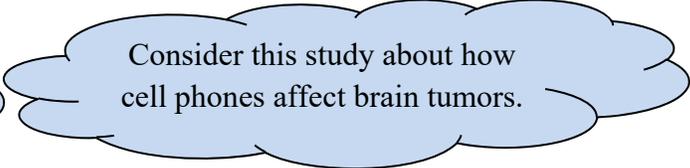


Observational Studies versus Designed Experiments (Section 1.2)



You'll be told about "new studies" all your life. Can you trust them?

You'll hear that coffee or wine reduces heart disease. You'll hear cell phones cause cancer. You'll hear breastfeeding improves IQ. We'll study these observational studies and designed experiments to determine if we can trust them.



Consider this study about how cell phones affect brain tumors.

**EXAMPLE: Cellular Phones and Brain Tumors**

Researchers Joachim Schüz and associates wanted "to investigate cancer risk among Danish cell phone users who were followed for up to 21 years." To do so, they kept track of 420,095 people whose first cell phone subscription was between 1982 and 1995. In 2002, they recorded the number of people out of the 420,095 people who had a brain tumor and compared the rate of brain tumors in this group to the rate of brain tumors in the general population. They found no significant difference in the rate of brain tumors between the two groups. The researchers concluded "cellular telephone was not associated with increased risk for brain tumors." (Source: Joachim Schüz et al. "Cellular Telephone Use and Cancer Risk: Update of a Nationwide Danish Cohort," *Journal of the National Cancer Institute* 98(23): 1707-1713, 2006)

**Definitions: Explanatory and Response Variables:** Remember a variable is just some characteristic of the individuals in the population, like age or cell phone use or cancer rate. The **explanatory variable** is the characteristic that we think may influence another characteristic, which is the **response variable**.

expl 1: In the above study, what is the explanatory variable? What is the response variable?

The above study is an example of an **observational study**. The researchers simply observed the participants. They did not intervene in their subjects' lives and instruct them to do anything differently. Here is another group of researchers approaching the same problem.

### **EXAMPLE: Cellular Phones and Brain Tumors**

Researchers Joseph L. Roti and associates examined “whether chronic exposure to radio frequency (RF) radiation at two common cell phone signals—835.62 megahertz, a frequency used by analogue cell phones, and 847.74 megahertz, a frequency used by digital cell phones—caused brain tumors in rats. The rats in group 1 were exposed to the analogue cell phone frequency; the rats in group 2 were exposed to the digital frequency; the rats in group 3 served as controls and received no radiation. The exposure was done for 4 hours a day, 5 days a week for 2 years. The rats in all three groups were treated the same, except for the RF exposure. After 505 days of exposure, the researchers reported the following after analyzing the data. “We found no statistically significant increases in any tumor type, including brain, liver, lung or kidney, compared to the control group.” (Source: M. La Regina, E. Moros, W. Pickard, W. Straube, J. L. Roti Roti. “The Effect of Chronic Exposure to 835.62 MHz FMCW or 847.7 MHz CDMA on the incidence of Spontaneous Tumors in Rats.” Bioelectromagnetic Society Conference, June 25, 2002.)

This is an example of a **designed experiment**. Unlike an observational study, the researcher in an experiment *manipulates* the explanatory variable to determine how varying the explanatory variable will affect the response variable.

### **Which is better? An observational study or designed experiment?**

They both have advantages and disadvantages.

### **EXAMPLE: Observational Study or Designed Experiment? Do Flu shots Benefit Seniors?**

Researchers wanted to determine the long-term benefits of the influenza vaccine on seniors aged 65 years and older. The researchers looked at records of over 36,000 seniors for 10 years. The seniors were divided into two groups. Group 1 were seniors who chose to get a flu vaccination shot, and group 2 were seniors who chose not to get a flu vaccination shot. After observing the seniors for 10 years, it was determined that seniors who get flu shots are 27% less likely to be hospitalized for pneumonia or influenza and 48% less likely to die from pneumonia or influenza. (Source: Kristin L. Nichol, MD, MPH, MBA, James D. Nordin, MD, MPH, David B. Nelson, PhD, John P. Mullooly, PhD, Eelko Hak, PhD. “Effectiveness of Influenza Vaccine in the Community-Dwelling Elderly,” *New England Journal of Medicine* 357:1373–1381, 2007)

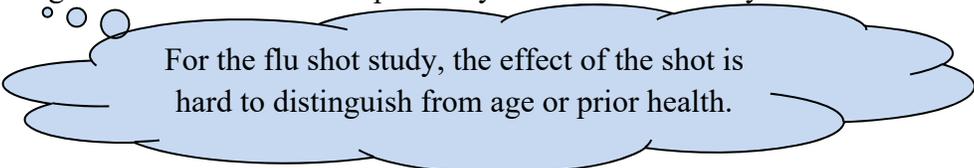
expl 2: Can you think of any other factors that could affect the response variable of hospitalization rate or death rate? Do you think the researchers took them into account?

## An important distinction: Observational studies versus Designed experiments:

**Observational studies do *not* allow a researcher to claim causation**, only association. It is wrong to take the above study's findings and say that flu shots *caused* the decrease in hospitalization and death. Designed experiments, which we will look into further, can be used to show that one thing *causes* another.

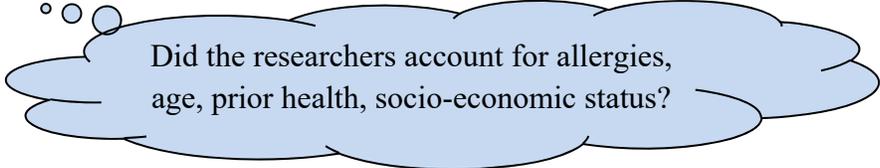
**Definitions: Confounding** in a study occurs when the effects of two or more explanatory variables are *not* separated. Therefore, any relation that may exist between an explanatory variable and the response variable may be due to some other variable or variables *not* accounted for in the study.

A **confounding variable** is an explanatory variable that was considered in a study whose effect cannot be distinguished from a second explanatory variable in the study.



For the flu shot study, the effect of the shot is hard to distinguish from age or prior health.

A **lurking variable** is an explanatory variable that was *not* considered in a study, but that affects the value of the response variable in the study. In addition, lurking variables are typically related to any explanatory variables considered in the study.



Did the researchers account for allergies, age, prior health, socio-economic status?

### Worksheet: Variables:

This worksheet details a study, using it to investigate our new vocabulary. We look at terminology such as explanatory, response, and lurking variables.

### Three Types of Observational Studies:

**1. Cross-sectional Studies** Observational studies that collect information about individuals at a specific point in time, or over a very short period of time.

**2. Case-control Studies** These studies are **retrospective**, meaning that they require individuals to look back in time or require the researcher to look at existing records. In case-control studies, individuals who have certain characteristics are matched with those who do not.

**3. Cohort Studies** A cohort study first identifies a group of individuals to participate in the study (the cohort). The cohort is then observed over a long period of time. Over this time period, characteristics about the individuals are recorded. Because the data is collected over time, cohort studies are **prospective**.

expl 3: Determine which type of observational study each of the following is.

a.) Researchers wanted to assess the long-term psychological effects on children evacuated during World War II. They obtained a sample of 169 former evacuees and a control group of 43 people who were children during the war but were not evacuated. The subjects' mental states were evaluated using questionnaires. It was determined that the psychological well being of the individuals was adversely affected by evacuation. (Source: Foster D, Davies S, and Steele H (2003) The evacuation of British children during World War II: a preliminary investigation into the long-term psychological effects. *Aging & Mental Health* (7)5.)

b.) A total of 974 homeless women in the Los Angeles area were surveyed to determine their level of satisfaction with the healthcare provided by shelter clinics versus the healthcare provided by government clinics. The women reported greater quality satisfaction with the shelter and outreach clinics compared to the government clinics. (Source: Swanson KA, Andersen R, Gelberg L (2003) Patient satisfaction for homeless women. *Journal of Women's Health* (12)7.)

c.) The Cancer Prevention Study II (CPS-II) is funded and conducted by the American Cancer Society. Its goal is to examine the relationship among environmental and lifestyle factors on cancer cases by tracking approximately 1.2 million men and women. Study participants completed an initial study questionnaire in 1982 providing information on a range of lifestyle factors such as diet, alcohol and tobacco use, occupation, medical history, and family cancer history. These data have been examined extensively in relation to cancer mortality. Vital status of study participants is updated biennially (every two years). Cause of death has been documented for over 98% of all deaths that have occurred. Mortality follow-up of the CPS-II participants is complete through 2002 and is expected to continue for many years. (Source: American Cancer Society)

**Definition: Census:** As opposed to a sample, a **census** is a list of *all* individuals in a population along with certain characteristics (the variables of interest) of each individual.