

# Training Guide



## Understanding Research Design and Implementation



# Experimental Design and Methodologies

## Learning Objectives

1. Explain the scientific method in six steps
2. Identify the three types of study variables
3. Discuss sampling techniques to conduct research
4. Differentiate types of studies and survey instruments
5. Determine how to establish causation
6. Compare the uses of statistics in health-related fields

## Overview

This section will show how to set up your experiment by discussion variables, the scientific method, sampling strategies, types of data collection, study design, and statistics in health research.

## Variables

To begin the ideal experiment, scientists define and measure variables. A variable changes in an experiment while other conditions hold constant.<sup>3</sup> These conditions hold constant because they serve as stable forces within the experiment. Variables help run an experiment to determine changes and effects. Scientists carefully select the best variables with effective manipulation. The three types of variables are:

- Independent
- Dependent
- Control<sup>3</sup>

Figure 1 illustrates the relationship between the dependent variable and independent variable. The dependent variable responds to the independent variable. Another term for the dependent variable is the responding variable and the independent variable is the manipulated variable.<sup>3</sup>

## Independent Variable

The manipulated, or independent variable, determines if the change in behavior will occur.<sup>3</sup> The *experimenter* changes the variable and its varying levels of intensity. For example, increasing the intensity of a sound will cause more people to respond to the sound. Other examples include the brightness of a lamp, the loudness of a tone, or the number of sweets given to a child. The amount of the independent variable to the exposed marks the intensity level.<sup>3</sup>

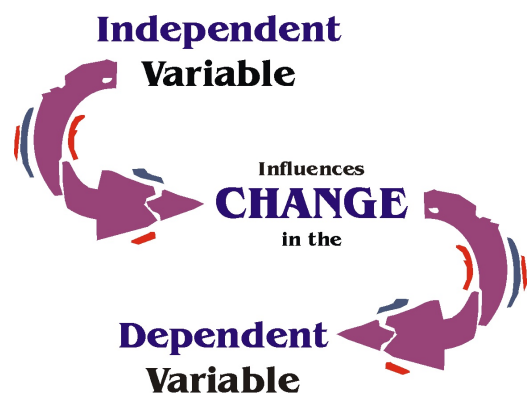


Figure 1. Independent variables influence the dependent variable.

Independent variables control the amount of change within an experiment, in this case behavior.<sup>3</sup> If the independent variable cannot control the behavior, this is a null result. A null result *does not support the hypothesis*. There are two common reasons to have null results. First, the researcher may have assumed the incorrect independent variable. If this is not the case, researchers may have poorly manipulated the independent variable. Adequate manipulation is necessary to produce a range of effects. There are other reasons for null results, however, the discussion continues in the dependent and control variables which will be discussed next.<sup>3</sup>

## Dependent Variable

The next variable is the dependent variable which is observed and recorded by the experimenter.<sup>3</sup> Examples of dependent variables include the time it takes to press a switch and the speed of an animal crawling through a maze. A suitable dependent variable must be reliable and consistent. Reliability depends on how frequent an experiment repeats and still receives the same result. Reliability bases itself on consistency or standardized conditions to insure reliability. Unreliable experiments stem from poor measurements of the dependent variable.<sup>3</sup>

As mentioned with the independent variable, dependent variables may cause null results.<sup>3</sup> Null results in the dependent variable are results that do not support the hypothesis of the experiment. A hypothesis is an educated “guess” based on past theories and evidence to predict a certain outcome. One of the reasons for null results to occur in the dependent variable includes restricted or limited range of the dependent variable, like the independent variable. An additional reason includes statistical error. This error may be the *Type 2 Error* which is failing to reject the null hypothesis when it was correct to reject the null hypothesis. When experimenters conduct research, the null hypothesis is that the experimental and control groups do not differ. A Type 2 error is when the experimental and control groups DO differ, but the experiment wrongly determined that the groups do not differ.<sup>3</sup>

## Control variable

The control variable is the constant in an experiment.<sup>3</sup> It acts as an independent variable, but it does not change intensity levels. Control variables are essential to limit outside effects or extraneous variation. Experimenters will try to control for as many factors small in effect compared to the main independent variable of the experiment. For example, temperature and time controls a person’s studying efficiency because varying day and room conditions affect people differently.<sup>3</sup>

Null results for control variables attribute to insufficient control of other factors and the confounding effect.<sup>3</sup> *Confounding* occurs when unintended effects influence the interpretation of the experiment. When experimenters conduct studies outside of a laboratory or other controlled space, these results often occur in these environments because of the lack of control.<sup>3</sup> Look to the planting figure two to apply what was learned about independent, dependent, and control variables in the next section.

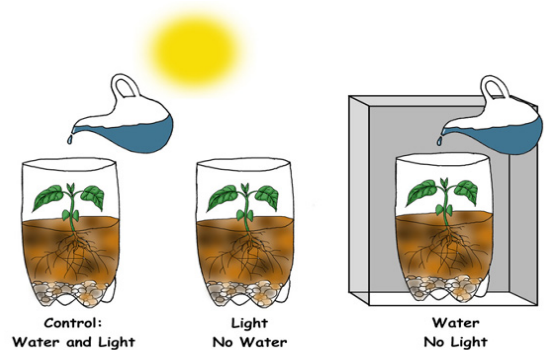


Figure 2. Can you identify the independent, dependent, and control variable in this scenario?

## Activity to identify variables

A gardener wants to determine whether light or water has a greater effect on plant growth. The gardener will use light and water as traditionally used in gardens and have two additional plants, a watered plant and a sun-sheltered plant, to determine which method has a greater effect. Name the variables.

*Independent:* No Light or water

*Dependent variable:* Growth of plant

*Control variables:* Light and water combination

The independent variable is the manipulated variables of light and water. These two conditions determine the outcome of the experiment. The dependent variable is the growth of the plant because the plant's growth responds to the abundance or lack of light and water. The control variables are the light and water combination which is the general controlled condition of this experiment.

## Scientific Method

The scientific method provides a framework to conduct standardized research based on theories and empirical evidence.<sup>3</sup> Experience leads empirical evidence instead of faith as the source for knowledge. Scientists use the scientific method to answer what is happening, why this is happening, what will happen, and to show what will happen.<sup>4</sup> In other words, scientists identify a question and then gather data related to that question. After tedious literature reviews and documents observations, scientists form a hypothesis.<sup>5</sup> After the hypothesis formation, the scientists test hypothesis, and then based on whether the hypothesis is rejected or not, the new data will improve the scientific discoveries.

### Step 1: Observations and asking questions

The first step to scientific discovery includes *observations and asking questions*.<sup>5</sup> Evidence, acquired from previous research studies, guides the questions. Evidence informs theories and data. From this information, questions build on asking how, what, when, who, which, why or where observations occur.<sup>5</sup> Questions meet the standards of being measurable and determining whether objectives are met. Measurable indicates the question is quantifiable through numbers.

### Step 2: Form the Hypothesis

The following step expands on observations and asking questions. Step two of the scientific method *forms the hypothesis*.<sup>5</sup> As mentioned previously, scientists base hypotheses on past studies to make a prediction. Extensive reviews of the literature surrounding the topic, inform the direction of the study and formulate the hypothesis. Through these literature searches, it is essential to determine the research gap. The research gap states the significance of the study. As the term implies, a research gap indicates that there is not enough research in the area so more studies need to be done to advance science. Research gaps inform funding. If there is no research gap, funding institutions will fund a project that does. Research gaps found in the conclusion section of scientific articles determine suggestions for future research during literature reviews. The most basic question is: Are there unanswered questions? This will direct the study.

### Step 3: Test the Hypothesis

After extensive research and formulation of hypotheses, the next step includes *testing the hypothesis*.<sup>5</sup> Assuming the research received a research grant, the most basic rules to remember are to keep the experiment fair and repeatable.<sup>3</sup> A fair experiment only changes one factor and maintains the other conditions of the experiment or study the same. In regards to repeatability, the experiment must repeat across multiple groups to increase generalizability. This is especially important in reliability and external validity. Reliability, as mentioned, is being able to repeat experiments with the same results. *External validity* or generalizability means application of the experiment's results expands to the general public, which why representation and sampling of research participants are foundational for a successful and informative experiment.<sup>3</sup>

## Step 4: Collect Data

While the experiment runs, tools, like statistical software, *analyze and observe descriptive data* to run tests to draw conclusions.<sup>4,5</sup> The data collected will then display in a bar graph and tables. The following questions are important when collecting data:

- Why are data collected?
- What data needs a look at?
- What purpose does the data serve?

Graphs and tables illustrate data. Tables are numerical and graphs are visual displays of data.

## Step 5: Interpret Data

At this step, scientists *interpret data* through various softwares.<sup>5</sup> The hypothesis is revisited once again and it is determined as to whether the data support the findings. If the hypothesis supports the data, the next step is to test in a new setting to increase the findings' generalizability. If the findings do not support the hypothesis, a new hypothesis needs to be formed.<sup>4,5</sup> Although this may be discouraging, the data are still useful for other findings.<sup>3</sup> Using statistical formulas and other tools of measurement, the data will be statistically significant or not. In statistics, showing that the results are numerically showing a relationship is significant. This means significance is quantitative and measurable, not subjective based on opinion, which is an alternate definition commonly used.<sup>6</sup>

Once scientists collect, illustrate, and determine data, scientists *draw conclusions and discussions*.<sup>4</sup> This portion of the scientific method suggests future directions for the research.<sup>3</sup> These directions guide the research gap for future researchers and inform practitioners for use in practical settings.



Figure 3. Quantitative data are often represented through graphs.

## Step 6: Communicate Findings

After all the gathering of information and experimental processes, *communicate the results*.<sup>5</sup> Scientific journal publish findings. Publishing in a journal builds reputation and is accessible directly to scientists. Each scientific journal has an impact factor which determines how many scientists will read the journal. The higher the impact factor, the more influence it has in the scientific community.<sup>3</sup> Publications generally take several years after experiments are conducted so the next best way to disseminate information is through scientific meetings like conferences. Conferences hold recent data and is much more personal because of its face-to-face structure. Scientists receive immediate feedback this way. Another method of distribution is to the community through newspapers, the internet science websites, and books for a lay audience. Research combines varying levels of expertise. The most foundational reason for research is to advance public knowledge.<sup>3</sup>

## Key Points for Scientific Method

In conclusion, the scientific method standardizes the approach to scientific discoveries. Before this segment of this module concludes, there are a few pieces of the scientific method that need mentioning. The graphic simplifies how observations lead to scientific theory. Starting from the hypothesis, it must be able to be proven false.<sup>4</sup> This determines its falsifiability. Also in the scientific process, deductive and inductive reasoning occurs. Deductive reasoning stems from general theories to specific observations. Inductive reasoning applies observations to theories. These terms work together when forming scientific theories. In addition to building theories, strong inferences build theories. Inferences are conclusions and are based on scientific evidence. Strong inferences are only possible if there are no alternative reasons for the conclusions. Within the scientific method are variables.<sup>3</sup>

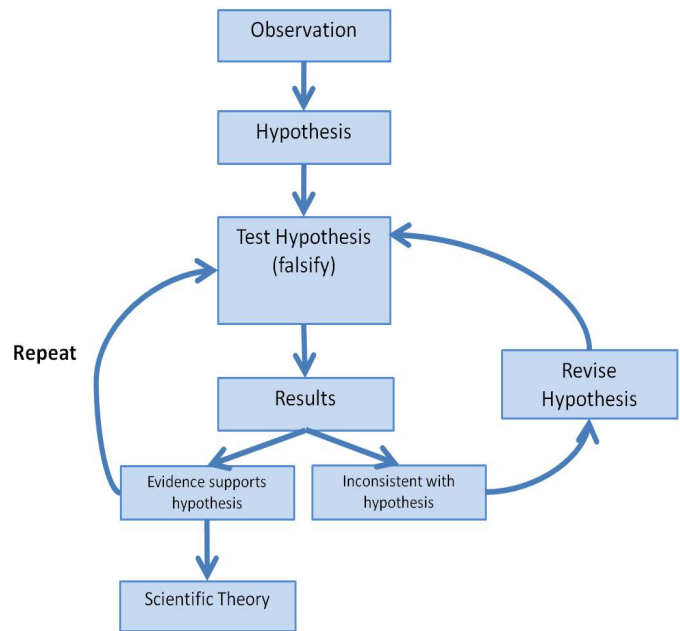


Figure 4. Steps to the scientific method

To reiterate variables within the scientific process:

- Dependent variables - These are the responding variables, which means that the responses collect the data.
- Independent variables - These do not change during the experiment, but manipulated by the study.

To add, experimental groups and control groups based from the same concept as variables. The experimental group receives the independent variable which means they experience the treatment of interest and the defining factor of the experiment. The control group is the untreated subjects or the group unexposed to the condition, however, they are different from the control variable. A control group is not exposed to certain conditions that the experimental group experiences while a control variable are individual factors held constant during an experiment. In short, control groups control for changes that may occur whether or not any particular variable is introduced into the situation.<sup>3</sup>

## Sampling

Sampling is the way we choose the people or things that will be tested with the hypothesis we formed from step 3 of the scientific method.<sup>3</sup> Sampling is important because it allows for conclusions to become generalized. So, say we are interested in a population with a certain characteristic, we would want to take a small group from the total population to test our hypothesis. However, the way you choose this small group matters because it determines if you can generalize your findings. Another way to look at this is by imagining the population of interest as a

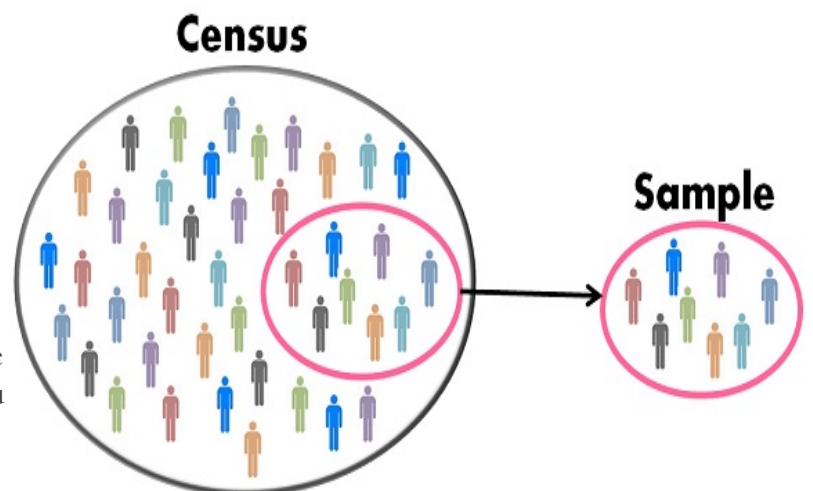


Figure 5. Census vs sample

census which includes everything or everyone of interest for the study. The individual things that make up this census are elements, and choosing many elements makes up your sample. In general, there are two kinds of sampling: probability sampling and nonprobability sampling. *Probability* sampling happens when you know the chances of an individual participant in the sample from the target population. If you don't know the chances, then you're doing *nonprobability* sampling.<sup>3</sup>

## Sample Size

How large should my sample be? In general, large samples mean you can generalize your conclusions, but sometimes it's hard to get a large sample.<sup>7</sup> So, the sample size depends on your study *and* your resources. You need to think about many factors such as whether participants have the time to be in your study. You might also need to think about if your participants are different from each other. When participants in your sample are different, this means they have a large variability. In this case, you need to have a lot of people because you won't be able to find any conclusions.<sup>7</sup> These are just two examples of factors to be considered when choosing a sample size.

## Sampling Errors

In general, there are two types of errors: systematic error and random error.<sup>3</sup> Systematic error occurs when you the researcher has done something wrong. Random error occurs when the sample you get does not represent the target population *by chance*. While systematic error should not happen, random error is expected in small amounts.<sup>3</sup>

## Random Sampling

There are two types of random sampling: simple random sampling and stratified random sampling.<sup>3</sup> *Simple random sampling* means there are equal chances of being selected. This method defines the population narrowly and can be costly. The other type of random sampling is stratified random sampling. *Stratified random sampling* means you know the probability of someone's selection because you group people into groups called strata based on similar characteristics. This method is useful if representation of the population is important or you want to compare groups. However, this method requires more effort on your part because you need to think of how you want to group people, but this way is more likely to accurately represent the population.<sup>3</sup>

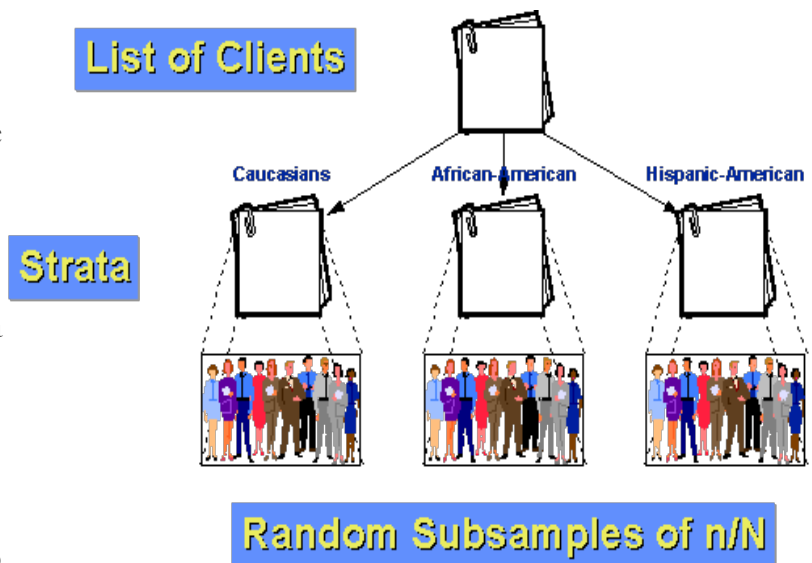


Figure 6. Stratified sampling by race/ethnicity

## Systematic Sampling



Figure 7. Systematic sampling example of every third choice selected for sample

Systematic sampling means you pick your sample based on a fixed interval.<sup>3</sup> This method is easy to implement because it simplifies picking the sample, but it is prone to biases when compared to random sampling. If you're doing systematic sampling, you would want to make sure that your sample groups represent the population you're trying to study.<sup>3</sup>

## Convenience Sampling

A convenience sample is a *nonprobability sample*

meaning you don't know the chances of an individual being selected for the study.<sup>3</sup> These are quick, cheap, and convenient - as the name implies. While these are easier to implement than the previous sampling methods. The findings are less generalizable or applicable to the general population.<sup>3</sup> However, if you don't need to generalize your conclusions, then this might not be a problem. You just need to know what you want to do with your study.

## Randomization

When conducting an experimental study, you will want to eliminate the influence of confounding variables on your experimental group as much as possible. One way to do this is through randomization.<sup>3</sup> *Randomization* is the practice of assigning subjects to either a treatment or control group in a completely random manner. This act increases the likelihood that extraneous elements will have a similar effect on one experimental group as on the other group.<sup>3</sup>

## Blinding

*Blinding* used during randomization to prevent either the investigator(s) and/or the participant(s) from knowing the assignment of subjects to each group throughout the time of the experiment or gathering of data. This practice prevents the investigators from showing bias during the experiment.

A *double-blind trial* is a trial in which both the investigator(s) and the subject(s) are unaware of the assignments into groups.

## Types of Data Collection

Once we have our sample groups, we need to know how to collect data from them. Three general types of data collection methods are case studies, interviews, and questionnaires.

## Case Studies

A *case study* is just an analysis of a single individual or sample of one. Your analysis is usually a qualitative interpretation, and may include the individual's history, characteristics, and behaviors. Case studies are useful because they often highlight a rare, unusual, or noteworthy experience.



## Interviews

An *interview* is just a conversation guided by questions you have thought of before to explore at a specific topic in-depth. Interviews are useful in understanding how your study groups think.

### Types of Interviews

There are three types of interviews: face-to-face interviews, telephone interviews, and focus groups. *Face-to-face* interviews are one-on-one conversations with both people in the same room while *telephone interviews* are the same thing except the conversation takes place over the phone. *Focus groups*, on the other hand, are group conversations guided by a moderator who asks questions from a script.

### Face-to-Face Interviews

Face-to-face interviews allow for flexibility as you can go back and repeat questions if the person did not hear you, wants to answer later, or needs to explain their answers. More importantly, though, you can see nonverbal behavior as you ask your questions and they answer. This gives you another kind of data to record on top of the respondent's answers. Finally, since they are in the room with you, you can make sure you complete the interview. However, respondents always have the option to refuse or stop answering interview questions. However, there are a few negatives in using face-to-face interviews. These reasons are as follows:

- If used, incentives are expensive to distribute.
- Face-to-face interviews are time consuming because of numerous interview questions and conversational
- They may be scheduling conflicts.
- There is lack of anonymity, meaning the respondent will be able to recognize their face



Figure 8. Face-to-face interviews are useful for nonverbal behaviors.

nature.  
knows you

### Telephone Interviews



Telephone interviews, in certain circumstances, offer some key advantages over face-to-face interviews. You do not have to be in the same room and can take less time and they may be less costly because the respondent does not have to come to you. But there are also problems with telephone interviews that were not present for face-to-face interviews. You cannot see nonverbal behavior so researchers must pay closer attention to the tone in their voice.

### Focus Groups

Figure 9. Telephone interviews are not ideal for noticing nonverbal behaviors.

Focus groups are just interviews with a lot of people and allow you to observe more people to get information. And since there are more people, when you ask open-ended questions, other's responses might inspire people to speak or provide new information. Also, these people are in the room, so you can view their nonverbal behavior while receiving specific information like the other interview types. However, there are disadvantages because there are more people. There may be less structure because everyone will talk in any order and conversation might continue past the moderator's planned time. Then, just like face-to-face interviews there is a certain lack of anonymity because everyone



Figure 10. Focus groups allow the opportunity for more responses to be collected in the same time frame.

can see one another's faces.

## Questionnaires/Surveys

A *questionnaire* is a written list of questions that allows respondents to write their answers out. In this sense, a questionnaire is a kind of *survey* or way of collecting information to represent a population. Compared to interview methods, a survey is easier to implement in a whole community.

YRBS Questionnaire Content 1991 – 2017														
Standard and National High School Questionnaire Content														
Question and Response Options	1991	1993	1995	1997	1999	2001	2003	2005	2007	2009	2011	2013	2015	2017
During the past 12 months, how many times did you actually attempt suicide? A. 0 times B. 1 time C. 2 or 3 times D. 4 or 5 times E. 6 or more times	Q21	Q26	Q24	Q24	Q25	Q26	Q26	Q26	Q26	Q26	Q27	Q29	Q29	Q28
If you attempted suicide during the past 12 months, did any attempt result in an injury, poisoning, or overdose that had to be treated by a doctor or nurse? A. I did not attempt suicide during the past 12 months B. Yes C. No	Q22	Q27	Q25	Q25	Q26	Q27	Q27	Q27	Q27	Q27	Q28	Q30	Q30	Q29
<a href="#">[Back to table of contents]</a>														
<b>Tobacco Use</b>														
Have you ever tried cigarette smoking, even one or two puffs? A. Yes B. No	Q23	Q28	Q26	Q26	Q27	Q28	Q28	Q28	Q28	Q28	Q29	Q31	Q31	Q30

Figure 11. Youth Risk Behavior Surveillance<sup>2</sup>

## Questionnaire Example

Figure 11 shows an example from the Youth Risk Behavior Surveillance System survey. Surveys can have lots of different looks, so this is just one example. Your survey might look a lot different. Surveys range from multiple choice questions, short answer/essay format, to ranked statements.

## Three Types of Surveys

There are three kinds of surveys: case study surveys, sampled surveys, and census surveys. Case study surveys build on what we have learned about case studies and just applies a survey to that one case. For example, you might be studying a single community, by giving a sample that might not represent the whole community a survey, you are doing a case study

survey. Sampled surveys, however, given out to a sample that is representative of the community, so you can generalize your findings to the whole community without surveying every individual. Lastly, scientists distribute census surveys to every single person in the community or population. This method provides the most accurate information about the group, but it can be difficult and resource consuming if there are lot of people.

## Types of Questions

In general, there are two kinds of questions: *open-ended* and *closed-ended* questions. Open-ended questions are questions that make the respondent give an answer that is longer than two words to tell a story. Close-ended questions are questions that have defined answers such as yes or no and numbers such as age. An example of an open-ended question may be how is your current state of health. An example of a close-ended question may be, “Do you eat the recommended amount of vegetables?”

## Question Structures

Questions can take many forms such as free response, multiple choice and Likert scale. Free response is just fill in the blank. Multiple choice questions make respondents choose their answer from a list of options made by you the researcher. A Likert scale is type of multiple choice question. With these questions, the respondent answers the question by choosing the option that they think describes them. Looking at figure 12, imagine a statement like, “It is cold outside today.” The interviewers would ask the respondent if they strongly agree, agree, are neutral, disagree, or strongly disagree. Notice how the scale moves from one extreme another.

## Guidelines for Organizing Questions

When you are questionnaire want to put first or earlier, your answer the questions later. Make

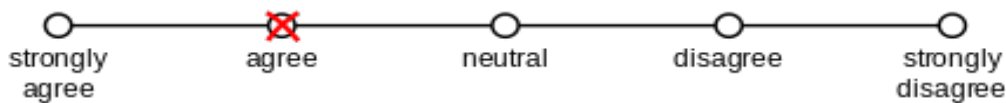


Figure 12. Likert scales are commonly used to show rankings of strongly agreeable to strongly disagreeable statements.

making your or survey, you easy questions so you can prepare respondents to more difficult that may show up sure to place

your questions in an order that makes sense and group similar questions together, so the respondent can keep thinking about the same topic. There are few things you want to avoid though. For one, if you are asking about sensitive issues, try to word your questions in a way that does not offend respondents. You should also avoid words that provoke bias or make the respondents feel uncomfortable. These problems might make the respondents give partial responses.

## Methods of Distributing Surveys

Once a survey is constructed, there are several methods for distributing it to the priority population.

Direct mail - Surveys mailed to individuals either at their home or business address. This mode of distribution is inexpensive and allows the researcher to contact a large population in a short amount of time. One drawback to this method is the relatively low response rate from participants. Also, if the individual has any questions or concerns about the survey, it is harder for them to reach the researcher for assistance.

Phone Surveys - Researchers can administer surveys to potential subjects through the telephone. This distribution method is also inexpensive and allows the researcher to choose the exact time of day that the subject receives the survey.

With telephone calls, participants can provide an immediate report of their current environment, activities, or emotions, as well as have direct contact with the researcher to ask any questions or concerns they may have regarding the survey.

Drop boxes - Surveys distributed in the drop boxes of companies or large corporations that have frequent contact with clients. Drop boxes can provide a good source point for administering a survey to a specific population who is in contact with that agency.

Media Distribution - A researcher can distribute a survey to the general population by attaching it to a local newspaper or newsletter.

Convenience Sampling - This distribution method is a form of nonprobability sampling that occurs in a public setting and requests the participation of any individual passing by within proximity to the distributor. This method can assist with getting exposure to the study/research, but introduces the risk of bias because the location may not provide an accurate representation of the population.

Group Administration - Surveys distributed at large group gatherings or meetings held by an organization or community (ex: classroom, clinic, town hall meeting, etc.).

An investigator may choose to use one or a combination of these distribution methods.<sup>8,9</sup>

## Study Design

There are two types of analytical study designs, *experimental* and *observational*. Experimental studies occur when the researcher intervenes with the study to produce an intended outcome. Scientists conduct observational studies without intervention by the researcher, and observe intended outcomes in natural circumstances. Observational methods will be explained in further detail in the following sections.<sup>10</sup>

## Observational Methods

Experiments where the investigator simply observes the natural course of events by taking note of who is exposed or unexposed to a behavior change, called *observational studies*. There are three main types of observational studies: cross-sectional studies, case/control studies, and cohort studies. Each of these types will be discussed in further detail in the following sections.<sup>10</sup>

## Cross-sectional Study

In a cross-sectional study, a defined population is surveyed by simultaneously classifying individuals per their *exposure* and *disease* status. This observation method occurs during a single period of observation and estimates the prevalence of disease, risk factors, exposure, and more. One negative aspect of this study design is that it does not account for temporality - the issue of causation between the exposure and disease outcome. An example of a cross-sectional study method is distributing a questionnaire that asks about obesity and amount of sleep an individual gets each night. This study could provide insights into whether weight gain and sleep deprivation are associated. From this example, it is not known if obesity causes lack of sleep or if lack of sleep causes obesity.<sup>10,11</sup>

## Case/Control Study

Scientists conduct a case/control study when a random sample of individuals with the observed condition (*cases*) when compared to a random sample of individuals who do not have the observed condition (*control*). When selecting

participants for this study design, the case and control groups are chosen from the same population that yielded the observed disease/behavior. Each subject's exposure status is examined retrospectively to determine what factors lead to their current outcome, and then the exposure status of the different groups is compared. Although researchers can hypothesize causation of the disease, this design method cannot prove causation alone. To prove causation, investigators must conduct additional studies to confirm their hypotheses. Case/control studies are used for rare cases/situations. An example of a case/control study is examining factors associated with cervical cancer in women by identifying women with cervical cancer and comparing them to women without cervical cancer.<sup>10</sup>

## Cohort Study

In a cohort study, investigators select a cohort to observe. A *cohort* observes many subjects who do not already have the outcome of interest. For this study method, scientists classify the cohort by exposure to one or more specific risk factors for the outcome of interest. The cohort is then observed to determine the rates at which the disease develops in each group. There are two types of cohort studies: prospective cohort study and retrospective cohort study.<sup>10</sup>

## Prospective vs. Retrospective

There are two types of cohort studies: prospective and retrospective. Scientists conduct *Prospective cohort studies* by taking two classified groups of participants, an exposure group and a non-exposure group. The exposure group consists of participants who have been exposed to the studies risk factors. The non-exposure group contains individuals of similar characteristics to those in the exposure group, but who have not been exposed to the disease/health issue of interest. These two groups are then followed into the future and observed to

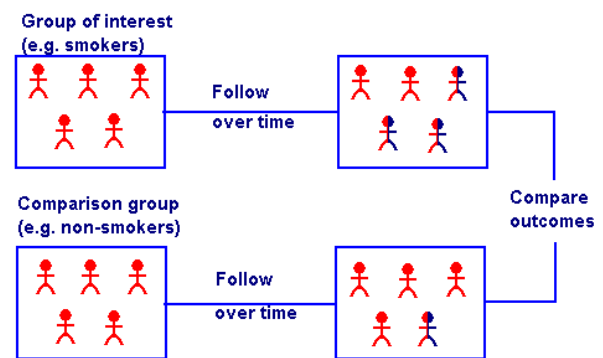


Figure 13. Prospective Study<sup>1</sup>

measure the differences in health outcomes.<sup>10</sup>

A *retrospective cohort study* shares a similar design to that of the prospective study, but instead, this study uses collected data from past. With this design, the exposure to disease and the health outcome have already occurred; participants already enrolled have the studied condition. Researchers must look back in past through medical records or through conducting questionnaires to measure participants' previous exposure and outcome statuses. This type of study can only be observational because the researcher is unable to alter past results.<sup>10</sup>

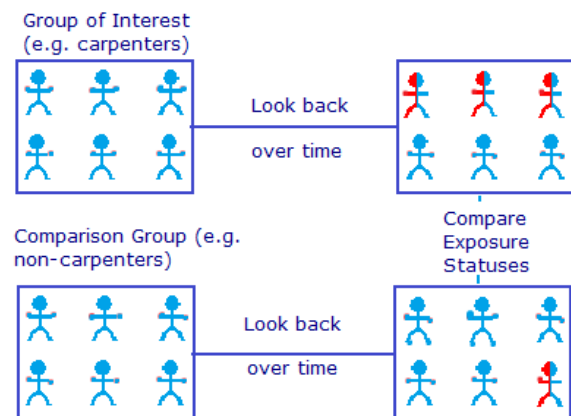


Figure 14. Retrospective Study

## Criteria for Causation

It is often difficult for researchers to identify whether exposure to a certain risk factor is truly associated with the development of a disease. This idea introduces the concept of *causation*, which asks the question: does contact with one variable directly cause the development of an intended outcome? For

example, if researchers found an association between increased physical activity and decreased rates of stomach cancer, that does not necessarily mean that working out will eliminate all chances of developing stomach cancer.

In 1965, researcher Austin Bradford Hill developed five criteria that he recommends before scientists can assume causality.

- *Strength* - How strong is the association between the exposure and the disease?
- *Consistency* - Has the association been reported in a variety of people exposed to a variety of settings? Are the results repeatable?
- *Specificity* - Is the disease associated with the exposure the only health problem that results from that exposure?
- *Temporality* - Does the exposure always precede the disease?
- *Biological plausibility* - Does the suspected causation make sense with what we know about science and previous medical knowledge?<sup>10</sup>

## Statistics in Health Research

When conducting a study, researchers are interested in collecting both qualitative and quantitative data. Quantitative data is usually easier to measure and displays more observable forms of change when compared to qualitative information. This section will provide a brief overview of important measures that scientists can take to collect quantitative data in the form of rates and other health statistics.

### Statistics in Health - Rates

A *rate* is the number of events that occur in each population during a given period. Rates provide an appropriate description of the health status of a certain community and allow researchers to understand the extent of disease present. There are several rates that describe births, cases of disease, or deaths within a community in regards to a specific health condition. The main rates that will be discussed in further detail include natality/birth rate, morbidity rate, mortality/fatality rate, attack rate, incidence rate, and prevalence rate.<sup>10,12</sup>

There is a brief description of each rate and calculations that coincide with each rate in the following section. When discussing population rates of a community, *natality/birth rate* is the number of live births divided by the total population. *Morbidity rate* discusses the number of people who are sick within the total population of individuals who are at risk of exposure to the disease. The opposite of natality/birth rate is *mortality/fatality rate*, which calculates the number of deaths within a total population. Incidence, attack, and prevalence rate are all in regards to the health condition within a population. *Incidence rate* is the number of new health-related events or cases of disease divided by the total number of individuals in the population who are at risk. Similarly, an *attack rate* is when an incidence rate is calculated for a population for a single disease outbreak. This rate expressed as a percentage, shows the percent of the total community that is at risk exposure to a single disease. Lastly, *prevalence rate*, which is often confused with incidence rate, is the number of new *and old* cases of a disease in a population in a given period of time, divided by the total number in that population.<sup>10</sup>

## Statistics in Health - Rate Calculations

**Natality (birth) Rate** =  $\frac{\text{\# of live births}}{\text{total population}}$

**Incidence Rate** =  $\frac{\text{\# of new health-related events or cases of a disease}}{\text{total number in the population at risk}}$

**Morbidity Rate** =  $\frac{\text{\# of people who are sick}}{\text{total population at risk}}$

**Attack Rate** =  $\frac{\text{cumulative incidence of infection in a group during an epidemic}}{\text{\# of people exposed}} \times 100$

**Mortality/Fatality Rate** =  $\frac{\text{\# of deaths in a population}}{\text{total population}}$

**Prevalence Rate** =  $\frac{\text{\# of new and old cases of a disease in a population in a given period of time}}{\text{total number in that population}}$

## Statistics in Health -Rates

There are three different forms of incidence and prevalence rates which are crude, adjusted, and specific rates. *Crude rates* calculate in which the denominator includes the total population. When discussing a total population in regards to a certain characteristic, *adjusted rate* expresses a population that is statistically adjusted for that characteristic (i.e. age). *Specific rate* narrows down the studied population even more by calculating a rate for a particular population subgroup, such as for a particular disease (i.e. disease-specific) or for a particular age of people (i.e. age-specific).<sup>10</sup>

## Measurements of Health Status

There are several other measurements that help display the health status of a whole population, including life expectancy, years of potential life lost (YPLL), disability-adjusted life years (DALYs), and health-adjusted life expectancy (HALE).<sup>10</sup> Each of these health indicators are used by epidemiologists to summarize and understand quality of life in terms of years.

The number of years that a person from a specific cohort is projected to live from a given point in time is known as *life expectancy*. *Years of Potential Life Lost (YPLL)* is defined as the number of years that are lost when death occurs before the age of 65 or 75. This measurement is calculated by subtracting a person's age at death from a predefined standard age for that cohort. Another measurement of health status is *Disability-Adjusted Life Years (DALYs)*, which measures for the burden of disease that also considers premature death and loss of health life resulting from disability. The opposite of the DALYs measurement is the *Health-Adjusted Life Expectancy (HALE)* which is the number of years of healthy life that are expected, on average, in each population. All of these calculations offer the average quality of life that can be expected for an individual who resides within the population of interest.<sup>10</sup>

## Conclusions

In conclusion, there are several main concepts to keep in mind. The steps to the scientific method are as follows:

*1) Make observations, 2) formulate a hypothesis, 3) test hypothesis, 4) collect and analyze data, 5) form conclusions, and 5) communicate findings.*

The scientific method standardizes the process of finding new information. Independent, dependent, and control variables are the general variables included within experiments. In this module, there are three sampling methods, which are *random, systematic, and convenience sampling*. *Cross-sectional, case-control, and cohort studies* are types of *observational* studies used in research. Instruments used to collect data include *case study, sampled, and census surveys*. Scientists distribute these to specific people (i.e. mail) or the general population (i.e. newspaper). There are five

criteria to establish causation: *strength, consistency, specificity, temporality, and biological plausibility*. Health statistics uses *rates* and *proportions* to determine quantitative data.

## Additional Resources

For some tips and tricks when practicing the scientific method, sampling technique, or any other topics discussed in this module, please consult the following sources:

- [http://www.sciencebuddies.org/science-fair-projects/project\\_scientific\\_method.shtml](http://www.sciencebuddies.org/science-fair-projects/project_scientific_method.shtml)
- <https://www.healthypeople.gov/2020/about/foundation-health-measures/General-Health-Status>
- <http://epiville.ccnmtl.columbia.edu/>
- Research methods in psychology by Elmes (4th edition)
- [https://www.youtube.com/watch?v=sdFYHSxq\\_qo](https://www.youtube.com/watch?v=sdFYHSxq_qo)

## References

1. Andale. Prospective study: Definition, examples. 2016; <http://www.statisticshowto.com/prospective-study/>.
2. Centers for Disease Control and Prevention. YRBS questionnaire content - 1997-2017. In: National Center for HIV/AIDS, STD, and TB Prevention, ed: Division of Adolescent and School Health; 2016:1.
3. Elmes, D. G., Kantowitz, B. H., & Roediger, H. L., III. (1992). Research methods in psychology (4th ed.): Brooks/Cole Publishing.
4. "Science & the scientific method: A definition." LiveScience. Purch, 30 Mar. 2015. Web. 18 May. 2016.
5. Science Buddies. (2008, September). Steps of the Scientific Method. Retrieved from <http://jackson.ifas.ufl.edu/4-h/files/2012/01/Scientific-Method.pdf>.
6. Yale University. Tests of Significance. 1998; <http://www.stat.yale.edu/Courses/1997-98/101/sigtest.htm>.
7. Nayak, B. K. (2010). Understanding the relevance of sample size calculation. Indian Journal of Ophthalmology, 58(6), 469–470. <http://doi.org/10.4103/0301-4738.71673>. Retrieved February 28, 2017, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2993974/>.
8. KU Work Group for Community Health and Development. Chapter 3, Section 12: Conducting Interviews. In: Kansas Uo, ed. Community Tool Box: Community Tool Box; 2016: <http://ctb.ku.edu/en/table-of-contents/assessment/assessing-community-needs-and-resources/conduct-interviews/main>.
9. KU Work Group for Community Health and Development. Chapter 3, Section 13: Conducting Surveys. In: Kansas Uo, ed. Community Tool Box Community Tool Box; 2016: <http://ctb.ku.edu/en/table-of-contents/assessment/assessing-community-needs-and-resources/conduct-surveys/main>.
10. McKenzie JF, Pinger RR. *An Introduction to Community and Public Health*. Eighth ed: Jones & Bartlett Learning; 2015.
11. Friis RH, Sellers TA. *Epidemiology for Public Health Practice*. Fifth ed: Jones & Bartlett Learning; 2014.
12. Cottrell RR, Girvan JT, McKenzie JF, Seabert D. *Principles and Foundations of Health Promotion and Education*. Sixth ed: Pearson Education, Inc.; 2015.