Solutions for Health Psychology An Interdisciplinary Approach 3rd Edition by Ragin

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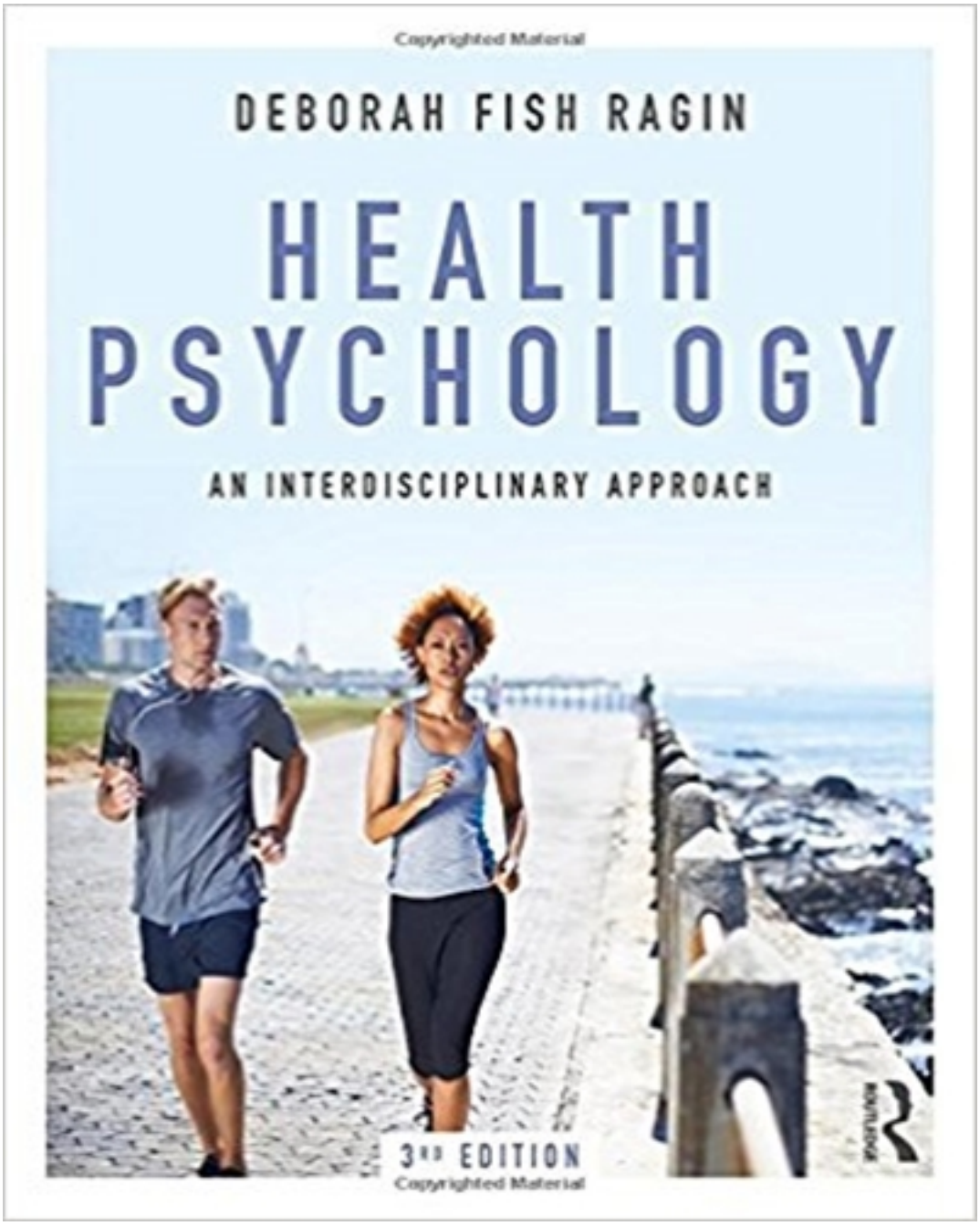

Solutions

CHAPTER 2: RESEARCH METHODS

CHAPTER AT A GLANCE

MEASURING HEALTH

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Incidence, Prevalence and Relative Risk
Proximal vs. Distal Causes of Illness

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Qualitative Studies

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RESEARCH ETHICS AND POLICY

Reactions to the Word 'Research'
The Tuskegee Syphilis Study
The Nuremberg Code of 1947
Study of Interpersonal Dynamics (Stanford Prison Experiment)
Research without Informed Consent

CHAPTER OBJECTIVES

After studying this chapter, students will be able to:

1. Identify and describe the five classic indicators of health.
2. Explain proximal and distal causes.
3. Identify and describe non-experimental research designs.
4. Explain the relevance of non-experimental designs for health research.
5. Identify and describe experimental designs.
6. Explain the relevance of experimental designs for health research.
7. Describe intervention studies.
8. Explain the relevance of intervention studies for health research.
9. Identify historical events leading to the establishment of the Nuremberg Code of Conduct, the Declaration of Helsinki and the U.S. National Research Act.
10. Describe IRBs, their role and their function.
11. Identify and explain the two principal violations of research ethics in the Tuskegee Study.
12. Identify and explain the psychological harm to participants in the Stanford Prison Experiment.
13. Explain the concept "research without informed consent".

IMPORTANT TERMS

adverse event

atrial septal defect

baseline measures

Belmont report

case study

cause and effect relationship

closed-ended questions

cohort

community-based study

control group

correlational studies

cross-sectional study design

Declaration of Helsinki

dependent variable

distal cause of illness

E. coli 0157:H7 bacterium

eligibility criterion

encephalitis

epidemiology

experimental group

experimental study

focus group

Framingham Heart Study

longitudinal study design

morbidity

mortality

negative correlation

nonexperimental study

null hypothesis

Nuremberg Code

Office of Human Research Protection (OHRP)

one-on-one interviews

open-ended questions

Pearson correlation coefficient *(r)*

positive correlation

post-test

predisposing factor

pre-post-post-test design

pre-posttest studies

pretest-posttest studies

prevalence

prevalence rates

proximal cause of illness

qualitative studies

qualitative data

quasi-experimental design

hexamethonium

hypertension

incidence

Incidence rates

Independent variable

Infant mortality rate

Latent stage

Longitudinal study design

morbidity

mortality

mortality rates

random assignment

random sample

randomized clinical trial

rates

raw data

relative risk

research hypothesis

research without informed consent

retrospective analysis

Stanford Three Community Study

Study of Interpersonal Dynamics (Stanford Prison Experiment)

Tuskeegee Syphyllis Study

LECTURE OUTLINE

I. ***Measuring Health***

A. *Borrowing from Epidemiology*

1. Health psychology borrows some concepts from the field of **epidemiology**, the study of factors which determine the health status of population groups. **Epidemiologists** can be thought of as medical detectives who determine the origins of disease by examining the earliest known human infected and the agent causing the infection. From there, they work to determine the risk of the disease to current and future populations.

B. *Mortality versus Morbidity*

1. **Mortality** (deaths) and **morbidity** (diseases that may contribute to mortality) are two important measures of the health of a population.

2. Health researchers use two types of data when reporting mortality and morbidity statistics: **raw data** (actual numbers) and **rates** (the calculation of the number affected in a given time period for a specific population, divided by the total population). Raw data can be misleading because they do not allow us to determine the overall percentage of the population affected. More importantly it does not allow us to determine the magnitude of the problem nor does it allow us to compare the magnitude of the problem in a different population.

3. **Infant mortality rates** are considered an important measure of the overall health of a community. For example, the leading causes of infant death in the U.S. in 2007 were birth defects, disorders related to prematurity, and sudden infant death syndrome. Since the main causes of birth defects are lack of prenatal care and

substance abuse (maternal factors), infant death rates are also indicators of maternal health.

C. *Incidence, Prevalence and Relative Risks*

1. **Incidence** refers to the number of new cases of a disease. When expressed as rates, **incidence rates** allow us to see how quickly a disease is spreading through a population.

2. **Prevalence** is the total number of cases (old and new) of a specific disease. When expressed as rates, **prevalence rates** allow us to compare the magnitude of the disease in different populations that may have vastly different population sizes.

3. **Relative risk** is an estimate of the risk of acquiring a disease by persons who are members of a particular group, compared to members of another group. For example, IV drug users have about a 60% higher relative risk of contracting HIV, as compared to non-IV drug users.

D. *Proximal vs. Distal Causes of Illness*

1. **Proximal** (immediate) and **distal** (remote in time) causes of illness may include individual, situational, or environmental factors. For example, in an outbreak of gastrointestinal illnesses, a proximal factor may be the **e-coli 0157:H7 bacterium** in a particular food or restaurant. Distal causes may predate an illness by months or even years. For example, heart disease can be caused by genetic or congenital defects, hypertension, and other (distal) **predisposing factors**.

II. *Methodology*

A. *Qualitative Studies*

1. Qualitative studies are used to gather rich, contextual, largely non-statistical data that help to explain a behavior or outcome in the environment in which it occurs.

2. **Case studies** are used to gather in-depth information on a relatively small group of individuals.

3. **Focus groups** bring together small groups of people in discussions that are facilitated by a moderator. The four main functions of focus groups are: to gather information, generate insight, explore a decision-making process, and encourage interactions that create new insights.

4. **Interviews** are an in-person data collection method that uses **closed-ended** (yes or no) and **open-ended** questions to elicit a range of responses.

B. *Quantitative Studies*

1. **Correlational studies** allow researchers to examine whether or not there is a relationship between two or more variables, and how strong the relationship may be. For example, the correlation between height and weight in a population of children can tell us how healthy these children are.

a. An important limitation of correlational research is that it does not imply causation (e.g., changes in height do not *cause* changes in weight).

2. **Experimental studies** allow researchers to determine whether or not there is a cause and effect relationship between variables. There are several key components to experimental studies.

a. **Independent variables** are the variables that the researcher manipulates, and **dependent variables** are the outcome variables. For example, in a study of the effects of exercise on stress, exercise would be the independent variable and stress would be the dependent variable.

b. Experimental studies include at least two groups of participants: **the experimental group** (the test group) and the **control group** (the group

that either receives no special treatment or a treatment that will have a neutral effect on the dependent variable).

c. Experimental studies use **random sampling** to select a group of participants that is representative of the population. These studies also use **random assignment** to the experimental versus the control group (each participant has an equal chance of being assigned to either group).

d. Experimental studies may be **longitudinal** (following the same group of participants over time) or **cross-sectional** (measuring several different groups of participants at the same time). Longitudinal studies yield important data, but they are time-consuming, costly, and have problems with attrition.

i. A famous example of a longitudinal study is the **Framingham Heart Study,** which was the first to identify risk factors for heart disease. This study, which began in 1949, examined a **cohort** of 5,127 men and women over many years, linking key risk factors with the later development of heart disease. This study still continues today, and is now examining a third generation of offspring from the original group to explore genetic, environmental, and individual contributions to heart disease.

3. **Intervention Studies** test the extent to which a particular program or treatment improves health outcomes. Participants are given a **pre-test** to obtain baseline measures of their knowledge, performance, or physical and mental status. Following the intervention, a **post-test** is given to determine the outcome. These studies may be experimental or quasi-experimental, depending on whether or not a control group is used.

a. A good example of an intervention study is the **Stanford Three Community Study**. This study examined the effects of mass media campaigns and intensive individual instruction on risk reduction for heart disease. Three communities in California were studied: one served as a control condition, one received mass media communication intervention, and the third received both mass communication intervention and individualized instruction. The study found that mass media intervention was more effective than individualized instruction or no intervention at all in reducing cardiac risk.

4. **Ethical considerations in Experimental Design**

a. **Randomized clinical trials** are an important type of experimental design used in health research to determine the effects of a new medication, therapeutic approach, or treatment apparatus. Because of the possible risk to participants, the U.S. Food and Drug Administration requires new drugs to undergo several stages of testing, beginning with laboratory trials with animals. The process can take years. Ethical concerns arise when clinical trials require control groups, and the participants in the control groups have delayed access to the potential benefits of new drugs (e.g., potentially life-saving HIV/AIDS drugs or the potentially new Ebola vaccine). There is a need to balance ensuring that new drugs are effective and safe against the time needed to complete testing and provide access to the drugs timely to save lives.

i. One way to address this problem is to use a **pre-post-post-test** design where as soon as the control group finishes the post-test, the participants are given a trial of the new drug, thus minimizing delay.

5. **Quasi-experimental Intervention Studies** allow researchers to examine independent variables that cannot be controlled or manipulated (e.g., gender, age, and ethnicity). Quasi-experimental intervention studies also do not have control groups. The price to pay for the lack of these controls is that cause-effect relationships cannot be established.

The following table from the textbook lists the pros and cons of the above research methods.

TABLE 2.2
SAMPLE RESEARCH METHODS
FOR HEALTH PSYCHOLOGY RESEARCH

DESIGN	PURPOSE	STATISTIC	PROS (P) AND CONS (C)
Non-experimental			
Qualitative	Explore phenomenon in context	Minimal or no statistical data Analyze content of responses	(P) In-depth analysis of response (C) Cannot examine cause–effect relationships
Case	In-depth exploration of person, place, situation	Minimal or no statistical data Analyze content of responses	(P) In-depth exploration of rare/unique events (C) Cannot examine cause–effect relationships
Focus Groups	Gather information Generate Insight Explore decision making Encourage interactions	Minimal use of descriptive data Analyze content of responses	(P) Generate new information, insights (P) Interactive approach (C) Cannot examine cause–effect relationships
Correlational Studies	Describe relationship between two variables	*Pearson Correlation Coefficient (r)* *Range =–1.00 to +1.00*	(P) Identifies relationship between two variables (C) Cannot determine casual relationship
Experimental			
Experimental Studies	Detect cause–effect relationship between variables.	*Central tendency (mean, median, mode)* *Student's t* *Analysis of Variance (ANOVA)* *Multiple Analysis of Variance (MANOVA)* *Linear, multiple or logistic regression (R^2)*	(P) Causal explanation of effects of one or more variables on outcomes (P) Direct control of causal variables (C) Not suitable for all studies (C) No in-depth analysis
Intervention Studies	*Measure effect of intervention usually with pre-post-test format*	*Central tendency (mean, median, mode)* *Student's t* *Analysis of Variance (ANOVA)* *Multiple Analysis of Variance (MANOVA)* *Linear, multiple or logistic regression (R^2)*	(P) Direct measure of effectiveness of intervention (P) Causal explanation of effects (C) Not suitable for all studies (C) No in-depth analysis
Quasi-experimental			
Quasi-experimental	Detect cause-effect relationship between two variables with limitations	*Central tendency (mean, medial, mode)* *Student's t* *Analysis of Variance (ANOVA)* *Multiple Analysis of Variance (MANOVA)* *Linear, multiple or logistic regression (R^2)*	(P) Limited cause–effect relationship (P) Control of some causal variables (C) Pre-existing conditions not be controlled

Intervention Studies	*Measure effect of intervention usually with pre-post-test format*	*Central tendency (mean, median, mode)* *Student's t* *Analysis of Variance (ANOVA)* *Multiple Analysis of Variance (MANOVA)*	(P) Measure intervention effect on single group (P) Limited subject variance (C) Limited inference of causality without control groups

III. ***Research Ethics and Policy***

A. *Reactions to the Word "Research"*

1. What do you think of when you hear the word "research"? Some people associate this word with positive thoughts about new scientific discoveries. Others think of "human guinea pigs" and the mistreatment of subjects. Unfortunately, both views hold some truth.

2. Mistreatment of subjects in several famous studies has led to important regulations over health research.

B. *Tuskegee Syphilis Study*

1. This infamous longitudinal study was conducted in the U.S. from 1932 through 1972. Researchers from the U.S. Public Health Service (USPHS) sought to observe the effects of **latent** (non-contagious) syphilis on different races, based on conflicting clinical findings suggesting differences. They studied approximately 400 men who tested positive for syphilis, compared with a 201-member control group. However, instead of telling the former group that they had tested positive for syphilis, they simply told them they had "bad blood", a southern term for general ailments. This was a serious deception because the men did not know that untreated, their illnesses would result in death. When penicillin became available as an effective treatment for syphilis, the men were not given this drug. In 1966 Peter Buxtun, an investigator with the USPHS, raised moral and ethical concerns about the study, and the CDC convened a panel to review the issues. Incredibly, the decision was to continue the study without treating the men. Only after Buxton reported the study to the Associated Press was the study ended in 1972.

2. In addition to the deception and deliberate withholding of life-saving treatment of these men, the Tuskeegee study had serious consequences for their spouses and unborn children, some of whom were infected with the disease.

3. More disturbing still, this study continued in spite of the fact that in 1947. The U.S. and other Western European allies developed and signed a Nuremberg Code, a formal document defining the rules of conduct for research involving human subjects. The Tuskegee Experiment was in clear violation of that international Code.

4. Other alarming health studies in the mid to late 1800s were done on African American slaves.

5. The Tuskegee study demonstrates the critical need to regulate and monitor research involving human subjects.

C. *The Nuremberg Code of 1947*

1. At the end of World War II, when survivors of the concentration camps were released, it was discovered that people in the camps were subjected to medical experiments in the name of science. These included procedures to change eye color by injecting chemicals into eye sockets, forced sterilization, and the effects of starvation on the liver. A U.S. military tribunal convened an international court known as the Nuremburg trial. In addition to prosecuting the people responsible for these experiments, an outcome of the trials was the **Nuremberg**

Code of 1947, a list of 10 conditions that comprised the first formal document regulating the use of human subjects in research.

2. The Nuremberg Code was later incorporated into the Declaration of Human Rights, approved by the United Nations. This document was broadened by the World Medical Society in 1964 to comprise **The Declaration of Helsinki**: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects. This document has been revised several times, most recently in 2000.
3. In 1953, the U.S. National Institutes of Health (NIH) established an Institutional Review Board (IRB), a system of national and local research review boards responsible for protecting human subjects.
4. In 1958, the American Psychological Association (APA) developed a set of ethical standards for psychologists, which includes protections for human subjects in research studies.

D. *Study of Interpersonal Dynamics (Stanford Prison Experiment)*

1. 1971, Philip Zimbardo designed an experiment to examine the impact of an institutional environment on human behavior. He randomly assigned 24 male Stanford University student volunteers to one of two roles: prison warden or prisoner. Arrangements were made for them to live in a mock prison for two full weeks, with the wardens working eight-hour shifts "guarding" the prisoners. However, the study was terminated after the sixth day because the prisoners showed extreme psychological trauma due to the increasingly hostile and abusive behavior of the wardens. The study clearly demonstrated that a "bad situation" can lead otherwise "good" people to behave in uncharacteristically disturbing ways. It also shed light on situations such as the atrocities performed in concentration camps during World War II.
2. The results of this study were shocking. At the time the study was planned, the potential for harm to the research participants was unforeseen. Fortunately, Zimbardo acted ethically by discontinuing the experiment. Today, this type of research would not be allowed, and IRBs would take steps to predict and safeguard against potential risk to participants.

E. *Research Without Informed Consent*

1. Research can be performed on people without their consent only if they have **diminished mental capacity** (e.g., the person is unconscious due to cardiac arrest).
2. This type of research is typically done in emergency situations, and regulations state that conditions must be met: 1) the patient is experiencing a life-threatening condition for which existing treatments are deemed unsatisfactory or unproven, 2) further evidence is needed to determine an experimental treatment's safety or efficacy, 3) the participant is incapable of consent due to his/her medical condition, 4) intervention is necessary before an authorized representative can be consulted, and 5) researchers have observed a number of special protections including "community consultation" (a rather vaguely defined and hotly contested condition).

F. **In conclusion**, partly due to serious past abuses, important steps have been taken by various agencies to protect human subjects in health research. The vast majority of studies today pose little physical or psychological risk to the participants. The first responsibility for ethical conduct begins with the researcher.

LECTURE LAUNCHERS

Medical Detectives

We learned in this chapter that epidemiologists can be thought of as medical detectives who determine the origins of disease by examining the earliest known human who was infected and the agent causing the infection. Consider the case of Gaetan Dugas, "Patient Zero," who was identified as a key figure initiating the spread of the HIV virus in the gay community in the U.S. In 1982, the CDC tracked down Dugas, who was a French-Canadian flight attendant. His travel patterns and multiple partners allowed him to spread the virus to a large number of people very quickly. By the time he learned he was contagious, he had been carrying HIV for two years. After interviewing Dugas and obtaining the names of his sexual partners, CDC researchers were able track the spread of a large number of cases of HIV in the San Francisco and New York City gay communities. Dugas died in 1984, after having AIDS for 4 years. He did not stop having sex, even after knowing he was contagious with a deadly disease.
(Source: Shiltz, R. (1987) *And the band played on: Politics, people, and the AIDS epidemic*. NY: St. Martin's Press.)

Present this case of Patient Zero to your class, and discuss the ethical issues associated with this case. Once an individual is identified as carrying an infectious disease that seems to be rapidly spreading and life-threatening, how does one balance individual freedom with protection of the community? Compare this example to other recent outbreaks, such as the H1N1 virus ("swine flu") and the case of Andrew Speaker who had drug resistant tuberculosis and traveled internationally by plane in 2007 before being detained (See Chapter 3). Consider also how during the 19th and 20th centuries, outbreaks of tuberculosis led to many states and communities in the U.S. requiring people to be quarantined in sanatoriums (see Chapter 3). When it is unclear how dangerous an illness may be, how quickly should health officials step in with preventive measures (e.g., mandatory vaccines, quarantines)?

What is the Best Measure of the Health of a Population?

Epidemiologists and other health researchers commonly use infant mortality rates as a measure of the global health of a population. Ask students why they think this is a good measure and what it reflects about the given population or country. Refer to Appendix II, which lists Infant Mortality Rates for Selected Countries (2007). Note that the U.S. has a higher infant mortality rate than Canada, and many European countries. Ask students why they think this is (e.g., higher rates of premature births; less access to prenatal care). Note also that this chart from the U.S. Census Bureau shows life expectancy rates for each country. Ask students which measure of health is a better measure and why. What do their opinions reflect about the values a society places on women, children, and aging? How are infant mortality rates and life expectancy rates intertwined? Students may be alarmed to see the low life expectancies in countries such as Angola, India,, and South Africa. How can these life expectancies be so low, given the health care technology available in the 21st century? What explanations can students offer for fact that Australia, Hong Kong, Japan, and Singapore, to name a few, have higher life expectancies than the U.S.?

Correlation Verses Causation: The Hot Dog Question

Psychology instructors agree that one of the key concepts we hope our students will grasp in any psychology course is the distinction between correlation and causation. Although at first glance it appears easy to understand, it often takes repeated exposure to a variety of examples for a full understanding to sink in. Especially, since the media continually reports health and other psychology research in a way that misleadingly implies causation.

A few years ago, reports appeared in the media linking the consumption of hot dogs with various forms of childhood cancer. Several newspaper articles declared that parents should stop feeding their children hot dogs. You will find that if you have older students who are parents, when you tell them about these reports they will gasp and say that they feed their children hot dogs all the time (especially because they are on a limited budget!)

This is a great opportunity to point out the distinction between correlation and causation, along with several other common flaws of correlational research. Just because the parents of the children who had cancer reported having fed them more hot dogs, this does not mean the hot dogs caused their cancer. There are third variable explanations (e.g., less than optimal general nutrition, poverty, even the mustard or yellow dye in the mustard). Also, there may be recall bias. (Parents whose children are tragically afflicted with cancer may be searching for a culprit to explain what caused the cancer.)

Ask students to give other examples of health research that they have read or heard about in the media that misleadingly suggest causation instead of correlation. Encourage students to bring in examples from the newspapers and online news sources.

CLASSROOM ACTIVITIES

How to Design a Health Research Study

This activity is designed to help students apply material regarding the various health research methods. Divide students into groups and ask them to consider how to design a research study investigating condom use among teenagers. Give them the handout in Appendix 2.2 to record their answers to the questions. Following their group discussion, ask them to share their answers with the class as a whole. This will spark an interesting discussion of research flaws and the pros and cons of various methods.

Identifying Types of Research Studies

If you are in a wired classroom or if students have access to the internet on their phones or laptops, ask them to find examples of health research in several different categories: longitudinal, experimental, correlational, and qualitative. If you want to save time, divide them into groups and ask each group to find a different category of research and report on it. Alternatively, bring copies of health psychology journals and ask the students to look through them and find examples. Then have them briefly summarize the methodology, results, and limitations of the studies.

Debates

Randomly assign students to teams debating the pros and cons of the following topics. Note that students who are assigned a stance that is in opposition to their actual opinion will find this to be a particularly enlightening learning opportunity, as it will allow them to consider the relative merits of their opponents' points of view.

Be clear with students that mere opinions will not be sufficient to form their arguments. Require them to cite specific research studies supporting their claims, and to submit copies of the journal articles they use. This will also help students to become familiar with the research process and with current studies in health psychology. See the Preface to this Instructor's Manual for an example of specific instructions to give to students.

Possible Topics:

- Health-related research on animals is unethical and should be outlawed.
- The use of potentially life-saving vaccines which have not completed all clinical trials should not be available for use in the United States.

Appendix 2.1

Infant Mortality Rates for Selected Countries (2017)

Country	Infant mortality[1]	Life expectancy[2]
Albania	12.0	78.0
Angola	75.0	56.0
Australia	4.0	82.0
Austria	3.0	82.0
Bahrain	9.0	79.0
Bangladesh	32.0	73.0
Brazil	17.0	74.0
Canada	5.0	82.0
Chile	7.0	79.0
China	12.0	76.0
Costa Rica	8.0	79.0
Cuba	4.0	79.0
Denmark	4.0	80.0
Egypt	19.0	73.0
Finland	3.0	81.0
France	3.0	82.0
Germany	3.0	81.0
Greece	5.0	81.0
Hong Kong	3.0	83.0

Country	Infant mortality[1]	Life expectancy[2]
Japan	2.0	85.0
Korea, North	22.0	71.0
Korea, South	3.0	82.0
Kuwait	7.0	78.0
Mexico	12.0	76.0
Netherlands	4.0	81.0
New Zealand	4.0	81.0
Norway	2.0	82.0
Panama	10.0	79.0
Peru	18.0	74.0
Poland	4.0	78.0
Portugal	4.0	79.0
Saudi Arabia	13.0	75.0
Singapore	2.0	85.0
South Africa	31.0	64.0
Spain	3.0	82.0
Sweden	3.0	82.0
Switzerland	4.0	83.0
Thailand	9.0	75.0

Iceland	2.0	83.0
India	39.0	69.0
Ireland	4.0	81.0
Israel	3.0	83.0
Italy	3.0	82.0

United Kingdom	4.0	81.0
United States	6.0	80.0
Venezuela	12.0	76.0

1. Infant deaths per 1,000 live births.
2. Life expectancy at birth, in years, both sexes.

Source: U.S. Census Bureau, International Database.

Appendix 2.2

Design a Study of Condom Use in Teenagers

1. What might be the advantages of doing a **qualitative study** to investigate this health behavior?
2. Which would be the most effective qualitative research method for this issue: **case studies** or **focus groups**? Why?
3. What kinds of **closed ended questions** would you want to ask? Why? **Open-ended questions**?
4. Why would it be important to get a **random sample** for this study? If the study consists of volunteers, how might this bias the results (i.e. what might be the characteristics of teens who volunteer/do not volunteer)?
5. Could an **experimental study** be done on this question? Why/why not?
6. If you wanted to do a **correlational study,** what might be some of the variables you would hypothesize might correlate with condom use? Why?
7. How would you design a **longitudinal study** on this question? How easy/difficult would this be to do? Why? What kinds of information could you get from a longitudinal study that you could not get from other methods?
8. How would you design an **intervention study** in this area? Would it be appropriate to have a control group? Why or why not?

Health Psychology

3rd edition

Deborah Fish Ragin

Chapter 2

Research Methods

Chapter Themes

- I. Measuring Health
- II. Methodology
- III. Research Ethics & Policy

Measuring Health

- Borrowing from Epidemiology
- Summary

Measuring Health

- *Borrowing from epidemiology*
  - Epidemiology
    - The study of the etiology (causes) and spread of health status or events
    - The application of that knowledge to control the health diseases and related problems
  - Epidemiologists
    - Study the impact of diseases on prior generations
    - Determines the potential risk of disease to current & future generations

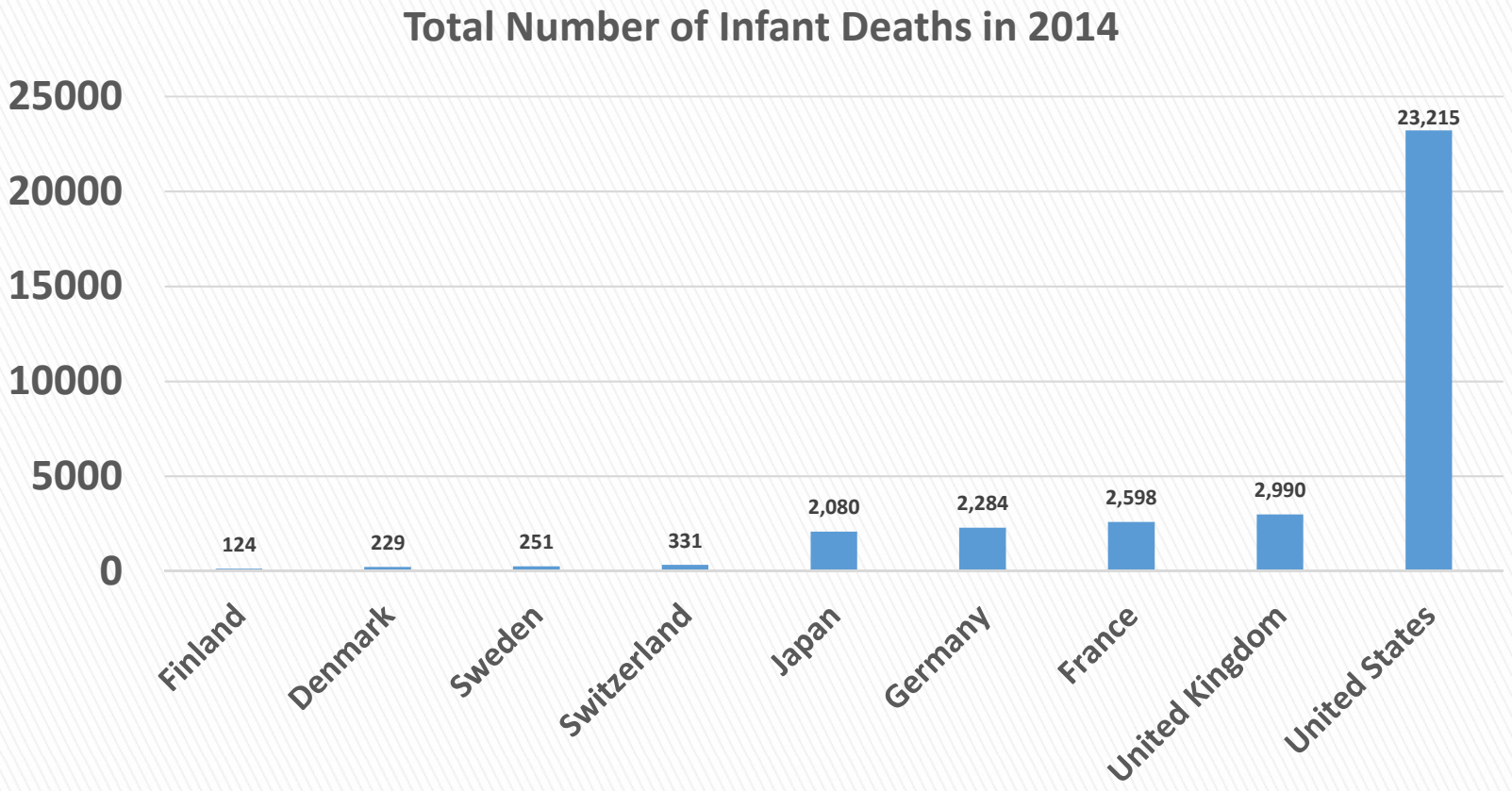
Borrowing from Epidemiology

Mortality vs. Morbidity	***Mortality vs. Morbidity Rates***
Raw Statistic: total number of cases for specific death/illness	Rates: raw statistic adjusted for population and time frame

- *Mortality:* number of deaths
- *Morbidity:* number of persons with specific illness that may contribute to mortality

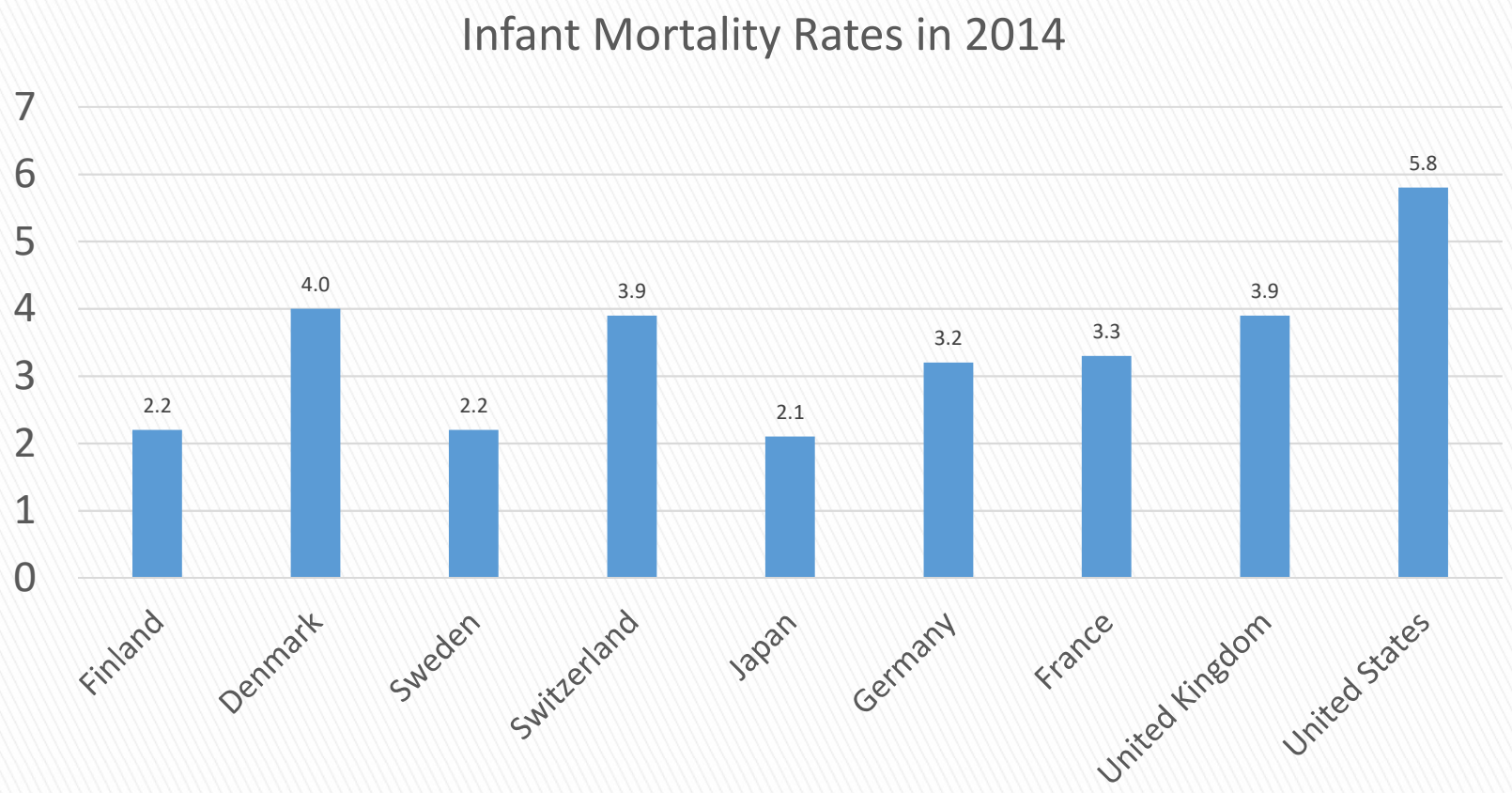
- *Mortality rate:* death in a population during a specific time period
- *Morbidity:* specific illness that may contribute to mortality in a population during a specific time period

Infant Mortality Raw Data



- Number of Infant Deaths in Nine Industrialized Countries

Infant Mortality Rates



- Rates of Infant Deaths in Nine Industrialized Countries

United Nations (2016) Population & Vital Statistics Report. Technical Notes. Table 3: Live births, deaths and infant deaths. Latest Year available. http://unstats.un.org/unsd/demographic/products/vitstats/

Borrowing from Epidemiology

- Four Leading Causes of Infant Deaths
  - Birth Defects
  - Premature Births
  - Sudden Infant Death Syndrome (SIDS)
  - Maternal Health Factors (e.g., lack of prenatal care, mother's substance use)

Borrowing from Epidemiology: Raw Statistics

Gross Measures of Population Health Status: Raw Statistics

- Incidence
  - number of new cases of disease
- Prevalence
  - total number of cases of disease
- Relative Risk
  - risk to members of exposed group of acquiring disease

Borrowing from Epidemiology: Rates

Rate	Illness/Cause	Sample Calculation
Mortality	Automobile Accident	Automobile fatalities in 2005 in U.S. / U.S. Population in 2005 X 100,000
Morbidity	Hypertension	Hypertension in 2005 in U.S. / U.S. Population in 2005 X 100,000
Incidence	HIV in Ukraine	New HIV Cases in 2004 in Ukraine / Ukrainian Population in 2004 X 100,000
Prevalence	HIV in Ukraine	All HIV Cases in 2004 in Ukraine / Ukrainian Population in 2004 X 100,000
Relative Risk	HIV in Ukraine	HIV Cases in 2004 of drug users in Ukraine / HIV Cases in 20004 of non-drug users in Ukraine X 100,000

Borrowing from Epidemiology

- *Gross Measures of Etiology (cause)*
  - ***Proximal***: immediate, precipitating causes of health & illness
    - e.g., gastrointestinal distress caused by food poisoning
  - ***Distal***: Remote in time, predisposing causes of health & illness
    - e.g., hypertension caused by atrial septal defect (hole in wall of heart)
  - Proximal and Distal causes may include individual, situational, or environmental factors
  - Explains timing of illness and probable cause

II. Methodology

- Qualitative Studies
- Correlational Studies
- Experimental Studies
- Intervention Studies
- Ethical Considerations in Experimental Design
- Quasi-experimental Intervention Studies

Qualitative Studies

- *Qualitative Studies*
  - Method for gathering largely non-statistical data
    - help explain behaviors or outcomes
  - Provides rich contextual data
  - Allows for in-depth exploration of issue

Qualitative Studies

- *Methodology*

- ***Case Studies***
  - In-depth analysis of rare or unique events
- ***Focus Groups***
  - Gather information and generate insight through interaction by small group of informants
- ***Interviews***
  - Structured and unstructured questions administered face-to-face.
  - Structured: closed-ended (e.g., yes/no) responses
  - Unstructured: open-ended (e.g., descriptive), unrestricted responses

Correlational Studies

- *Correlational Studies*

- Examines relationship between two interval-level variables
  - Do two variables share something in common?
  - Correlation does not imply causality
  - Correlation does not test for cause and effect.

Correlational Studies

- ***Pearson Correlation Coefficient (r)***
  - Test statistic measuring strength and direction of relationship
  - Positive correlation: as one variable increases in value, so does second variable
  - OR, as one variable decreases in value, so does second
  - Negative correlation: as one variable increases in value, the second *decreases.*

Correlational Studies

- *Strength of Correlation*
- Determined by value of *r* and by p-value associated with the statistic
- *General " Rule of Thumb"*
  - *r* values greater than .60 = strong correlations
  - *r* values between .40 – .59 = moderate correlations
  - *r* values between .21 – .39 = weak correlations
  - *r* values between .00 – .20 = no correlation

Experimental Studies

- *Tests for a cause-and-effect relationship between two variables*
- Test a hypothesis or research question
  - *Null Hypothesis:* assumes no relationship between variables.
    - Research assumes null hypothesis is valid until shown otherwise
  - *Research Hypothesis:* assumes a relationship between variables.
    - Must be shown by outcome of research

Experimental Studies

- *Independent versus Dependent Variables*
  - Independent (IV):
    - Variable manipulated or controlled by investigator
    - Examine possible effect of variable on study's outcome
    - May have more than one IV
  - Dependent (DV):
    - The outcome variable
    - May be influenced by IV

Experimental Studies

- *Experimental versus Control Groups*
  - Experimental group:
    - Test group receiving special treatment or condition
  - Control Group:
    - Group receiving no special condition
    - OR group receiving neutral treatment (i.e., would not affect dependent variable)

Experimental Studies

- *Random Sampling*
  - Random Sampling:
    - Method of participant selection
    - Ensures all have equal chance of participating
    - Aims:
      - Study sample to be representative of population to be studied
      - Minimize possibility of experimenter bias
  - Random Assignment:
    - Methodology of group assignment
    - Ensures every person has equal chance of being assigned to either experimental or control condition

Experimental Studies

- *Longitudinal versus Cross-Sectional Design*
  - Longitudinal
    - Study phenomenon over extended timeframe using same participants (e.g. Framingham Heart Study)
    - Pro: Helps control variability
    - Con: Time-consuming and costly
  - Cross-Sectional
    - Study phenomenon across different participants sampled only once
    - Pro: Shorter duration and less cost
    - Con: Multiple groups introduce more variability

Intervention Studies

- *Experimental Intervention*
  - Test possible effect of intervention program, treatment or training on health outcomes
  - Procedure includes, in order:
    - Pretest (baseline measure)
    - Intervention
    - Post-test
  - Experimental design requires control group

Ethical Considerations in Experimental Design

- *Randomized clinical trial studies*
- Goal: tests safety and/or efficacy of new drugs/procedures
  - 1+ experimental group and 1 control group
- Problem: Time needed to complete testing delays distribution of potential life-saving drugs/procedures

Ethical Considerations in Experimental Design

- *Modified Intervention Design*

- Pre-post-post-test design:
  - Experimental and control groups receive treatment but at different times
  - Preserves scientific approach
  - Preserves ability to test drug's/procedure's safety and efficacy
  - Ensures both groups get potentially life-saving treatment with minimal delay.

Quasi-Experimental Intervention Studies

- *Quasi-experimental design*

- Adjusts for researchers' lack of total control
  - e.g., cannot control who experiences heart disease, asthma
  - e.g., cannot control demographic variables
  - Lack of control compromises ability to demonstrate cause and effect

- May not include control groups
  - Cannot demonstrate causal effect of intervention on outcome

III. Research Ethics and Policy

- Reactions to the Word ‘research’
- The Tuskegee Syphilis Study
- The Nuremberg Code of 1947
- Study of Interpersonal Dynamics (Stanford Prison Experiment)
- Research without Informed Consent

Reactions to the Word ‘research’

- *Reactions to the Word ‘research’*

- Positive: life-saving discoveries
- Negative: abusive, using people as human “guinea pigs”

- Views of research influenced by first-hand experiences, books, movies or life-saving scientific discoveries

- Some views influenced by violation of research ethics

Tuskegee Syphilis Study

- *Brief History*
- Conducted in United States from 1932–1972
- Example of Breech of Research Ethics
- Researchers' goal: observe effects of syphilis on different races
- Hypothesis: syphilis affected the cardiovascular system for blacks, and the neurological systems for whites
- Problem: test required autopsy
  - i.e. person must die from complications of syphilis

Tuskegee Study (cont.)

- *Multiple Ethical Problems*
  - *Deception*
  - "Volunteers" were misled
    - Misinformed of true goal of study
    - Misled about health condition: not informed of diagnosis of syphilis
    - Misinformed about treatment efficacy: would not cure syphilis
    - Not provided with cure for syphilis when available
    - Not informed that untreated syphilis could cause death
    - Not informed that spouses and children at risk for contracting untreated syphilis
  - ***Flagrant disregard of rights and welfare of study participants***

Tuskegee Study

- *What Did We Learn from the Tuskegee Study?*
  - Belmont Report: Three fundamental ethical principles for the protection of human subjects
    - 1) Respect for persons
    - 2) Beneficence
    - 3) Justice
  - National Research Act of 1974
    - "Require the (then) Health, Education and Welfare Department to [formalize and regulate] its policy for the protection of humans subjects …"

Nuremburg Code of 1947

- *Brief History*
- A product of the Nuremburg Trials, an International Court to address abuse of and welfare of human beings
- Trials charged doctors & others for subjecting detainees of concentration camps to inhuman treatment as subjects in medical experiments
- Purpose of the trial:
  - Try the doctors and others responsible for conducting such research
  - Establish Nuremburg Code of 1947, a list of 10 conditions that regulated the use of human subjects in research

Nuremburg Code of 1947 (cont.)

- *Trial Outcomes*
  - Document defining rules of conduct for research involving human subjects
  - Declaration of Human Rights
  - Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research
  - Establish Institutional Review Board (IRB) in U.S. to monitor research
  - American Psychological Association (APA) joined efforts to protect the rights of volunteers in research
- In spite of guidelines, occasionally unethical studies are conducted

Study of Interpersonal Dynamics (Stanford Prison Experiment)

- *Can social contexts influence, shape, transform human behavior?* Phillip Zimbardo (1971)

- Study design
  - Two-week study
  - Stanford University volunteers randomly assigned to role of prison warden or prisoner (males only)
  - Prisoners confined in mock prison
  - Wardens worked 8-hour shifts guarding prisoners

- Study terminated after 6 days
  - Prisoners experienced extreme psychological trauma
  - Wardens displayed increasingly hostile and abusive behavior toward prisoners

Research without Informed Consent

- *Is Research without Informed Consent permissible?*

- Yes, if satisfying one of following conditions:
  - Physical/mental condition prevents a patient's informed consent
  - Patient experiencing life-threatening condition
  - Further evidence needed to determine safety or efficacy of experimental treatment
  - Participant incapable of consent due to medical condition
  - Intervention necessary before an authorized representative can be consulted
  - Researchers observed special protections including "community consultation"