Chapter 7

Data Ethics

Lecture Slides

Case Study: Data Ethics 1

Does alcohol increase our perception of the attractiveness of members of the opposite sex?

Researchers at the University of Bristol in England recruited 42 male and 42 female students.

Andrew Watson/Photolibrary/Getty Images

Students were randomly assigned to receive either a strong alcoholic drink (vodka, tonic water, and lime cordial) or a placebo (tonic water and lime cordial).
They were given 15 minutes to consume their drink.

Case Study: Data Ethics 2

The students were asked to rate the facial attractiveness of 20 male and female faces.

Researchers compared the ratings of those receiving the alcoholic drink with those receiving the placebo.

Is having subjects consume a strong alcoholic drink so that their judgment is impaired ethical?

By the end of this chapter you will have learned the principles that will help you answer this question.

First principles 1

The production and use of data, like all human endeavors, raise ethical questions.

Using deception or publishing fake data is clearly unethical.

Other situations are not so cut and dried.

Just how honest must researchers be about real, unfaked data?

Example: Missing details 1

Papers reporting scientific research are supposed to be short, with no extra baggage. Brevity can allow the researchers to avoid complete honesty about their data.

Did they choose their subjects in a biased way?

Did they report data on only some of their subjects?

Did they try several statistical analyses and report only the ones that supported what the researchers hoped to find?

Example: Missing details 2

The statistician John Bailar screened more than 4000 medical papers in more than a decade as consultant to the New England Journal of Medicine.

He says, “When it came to the statistical review, it was often clear that critical information was lacking, and the gaps nearly always had the practical effect of making the authors’ conclusions look stronger than they should have.”

The situation is no doubt worse in fields that screen published work less carefully.

First principles 2

The most complex issues of data ethics arise when we collect data from people (but research with animals also raises ethical issues).

The ethical difficulties are more severe for experiments that impose some treatment on people than for sample surveys that simply gather information.

There are some basic standards of data ethics that must be obeyed by any study that gathers data from human subjects, whether sample survey or experiment.

First principles 3

The organization that carries out the study must have an **institutional review board** that reviews all planned studies in advance in order to protect the subjects from possible harm.

All individuals who are subjects in a study must give their **informed consent** before data are collected.

All individual data must be kept **confidential**. Only statistical summaries for groups of subjects may be made public.

First principles 4

If subjects are children then their consent is needed in addition to that of the parents or guardians.

Many journals have a formal requirement of explicitly addressing human subjects issues if the study is classified as human subjects research.

The law requires that studies funded by the federal government obey these principles. But neither the law nor the consensus of experts is completely clear about the details of their application.

Institutional Review Boards 1

The purpose of an **institutional review board** (often abbreviated IRB) is to protect the rights and welfare of human subjects.

The IRB does not decide whether a study will produce valuable information or is statistically sound.

The board reviews the plan of the study and can require changes. It reviews the consent form to ensure that subjects are informed about the nature of the study and about any potential risks. It then monitors progress at least once a year.

Institutional Review Boards 2

The most pressing issue concerning IRBs is whether their workload has become so large that their effectiveness in protecting subjects drops.

When the government temporarily stopped human-subject research at Duke University Medical Center in 1999 due to inadequate protection of subjects, more than 2000 studies at Duke were in progress.

Projects that involve only minimal risks to subjects, such as most sample surveys, have shorter review. It can be tempting to put more proposals in the minimal-risk category to speed the work when overloaded.

Informed consent

Both words in the phrase “informed consent” are important, and both can be controversial.

Subjects must be informed in advance about the nature of a study and any risk of harm it may bring.

In the case of a sample survey, physical harm is not possible. The subjects should be told what kinds of questions the survey will ask and about how much of their time it will take.

Subjects must consent, usually in writing.

Example: Who can consent? 1

Are there some subjects who can't give informed consent?

It was once common to test new vaccines on prison inmates who gave their consent in return for good-behavior credit. Now we worry that prisoners are not really free to refuse, and the law forbids medical experiments in prisons.

Children can't give fully informed consent, so the usual procedure is to ask their parents.

Example: Who can consent? 2

A study of new ways to teach reading is about to start at a local elementary school, so the study team sends consent forms home to parents.

Many parents don't return the forms. Can their children take part in the study because the parents did not say "No," or should we allow only children whose parents returned the form and said "Yes"?

Example: Who can consent? 3

What about research into new medical treatments for people with mental disorders?

What about studies of new ways to help emergency room patients who may be unconscious or have suffered a stroke? In most cases, there is no time even to get the consent of the family.

Does the principle of informed consent bar realistic trials of new treatments for unconscious patients? These are questions without clear answers. Reasonable people differ strongly on all of them. There is nothing simple about informed consent.

Confidentiality 1

Ethical problems do not disappear once a study has been cleared by the review board, has obtained consent from its subjects, and has actually collected data about the subjects.

It is important to protect the subjects' privacy by keeping all data about individuals **confidential**.

The report of an opinion poll may say what percentage of the 1500 respondents felt that legal immigration should be reduced, but it may not report what you said about this or any other issue.

Confidentiality 2

Confidentiality is not the same as **anonymity**.

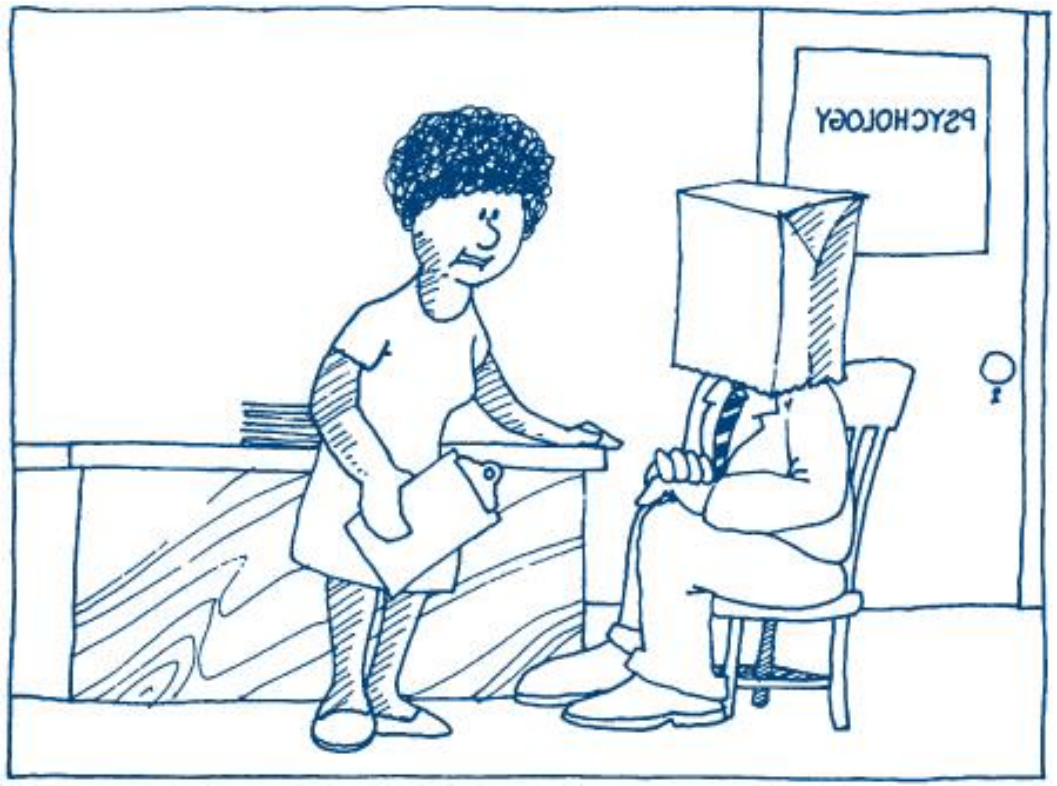
Anonymity means that subjects are anonymous—their names are not known even to the director of the study. It is not possible to determine which subject produced which data.

Anonymity is rare in statistical studies.

Even where anonymity is possible (mainly in surveys conducted by mail), it prevents any follow-up to improve nonresponse or inform subjects of results.

Confidentiality 3

A picture illustrating an interesting problem with anonymity…



"I realize the participants in this study are to be anonymous, but you're going to have to expose your eyes."

Moore/Notz, *Statistics: Concepts and Controversies*, 9e, © 2017 W. H. Freeman and Company

Example: Use of government databases

Citizens are required to give information to the government. The government needs these data for administrative purposes—to see if we paid the right amount of tax and how large a Social Security benefit we are owed when we retire.

Some people feel that individuals should be able to forbid any other use of their data, even with all identification removed. This would prevent using government records to study, say, the ages, incomes, and household sizes of Social Security recipients. Such a study could well be vital to debates on reforming Social Security.

Clinical trials 1

Clinical trials are experiments that study the effectiveness of medical treatments on actual patients.

Medical treatments can harm as well as heal, so clinical trials spotlight the ethical problems of experiments with human subjects.

Clinical trials 2

Randomized comparative experiments are the only way to see the true effects of new treatments.

Clinical trials produce great benefits, but most of these benefits go to future patients. We must balance future benefits against present risks.

Both medical ethics and international human rights standards say that “the interests of the subject must always prevail over the interests of science and society.” The quoted words are from the 1964 Helsinki Declaration of the World Medical Association.

Example: Tuskegee Syphilis Study 1

In the 1930s, syphilis was common among black men in the rural South of the United States, a group that had almost no access to medical care.

The Public Health Service recruited 399 poor black sharecroppers with syphilis and 201 others without the disease in order to observe how syphilis progressed when no treatment was given. Beginning in 1943, penicillin became available to treat syphilis. However, the study subjects were not treated, even after penicillin became a standard treatment for syphilis.

Example: Tuskegee Syphilis Study 2

The Public Health Service tried to prevent any treatment until word leaked out and forced an end to the study in 1972.

The Tuskegee study is an extreme example of investigators following their own interests and ignoring the well-being of their subjects. In 1997, President Clinton formally apologized to the surviving participants in a White House ceremony.

The Tuskegee study helps explain the lack of trust that lies behind the reluctance of many blacks to take part in clinical trials.

Example: Placebo controls 1

Are placebo controls ethical? You are testing a new drug. Is it ethical to give a placebo to a control group if an effective drug already exists?

Yes: The placebo gives a true baseline for the effectiveness of the new drug. Every clinical trial is a bit different, and not even genuinely effective treatments work in every setting. The placebo control helps us see if the study is flawed so that even the best existing drug does not beat the placebo. Sometimes the placebo wins, so the doubt about the efficacy of the new and the existing drugs is justified. Placebo controls are ethical except for life-threatening conditions.

Example: Placebo controls 2

Are placebo controls ethical? You are testing a new drug. Is it ethical to give a placebo to a control group if an effective drug already exists?

No: It isn't ethical to deliberately give patients an inferior treatment. We don't know whether the new drug is better than the existing drug, so it is ethical to give both in order to find out. If past trials showed that the existing drug is better than a placebo, it is no longer right to give patients a placebo. A placebo group is ethical only if the existing drug is an older one that did not undergo proper clinical trials or doesn't work well or is dangerous.

Behavioral and social science experiments 1

When we move from medicine to the behavioral and social sciences, the direct risks to experimental subjects are less acute, but so are the possible benefits to the subjects.

Consider, for example, the experiments conducted by psychologists in their study of human behavior.

Example: Keep out of my space 1

Psychologists observe that people have a “personal space” and get annoyed if others come too close to them. We don’t like strangers to sit at our table in a coffee shop if other tables are available, and we see people move apart in elevators if there is room to do so.

Americans tend to require more personal space than people in most other cultures. Can violations of personal space have physical, as well as emotional, effects?

Example: Keep out of my space 2

Investigators set up shop in a men's public restroom. They blocked off urinals to force men walking in to use either a urinal next to an experimenter (treatment group) or a urinal separated from the experimenter (control group).

Another experimenter, using a periscope from a toilet stall, measured how long the subject took to start urinating and how long he kept at it.

Behavioral and social science experiments 2

This personal space experiment illustrates the difficulties facing those who plan and review behavioral studies.

- There is no risk of harm to the subjects, although they would certainly object to being watched through a periscope. What should we protect subjects from when physical harm is unlikely? Possible emotional harm? Undignified situations? Invasion of privacy?

Behavioral and social science experiments 3

This personal space experiment illustrates the difficulties facing those who plan and review behavioral studies.

- What about informed consent? The subjects in the personal space experiment did not even know they were participating in an experiment. Many behavioral experiments rely on hiding the true purpose of the study. The subjects would change their behavior if told in advance what the investigators were looking for. Subjects are asked to consent on the basis of vague information. They receive full information only after the experiment.

Behavioral and social science experiments 4

The “Ethical Principles” of the American Psychological Association require consent unless a study merely observes behavior in a public place.

They allow deception only when it is necessary to the study, does not hide information that might influence a subject’s willingness to participate, and is explained to subjects as soon as possible.

The personal space study of the previous example (from the 1970s) does not meet current ethical standards.

Statistics in Summary

• Data ethics begin with some principles that go beyond just being honest. Studies with human subjects must be screened in advance by an **institutional review board**.

• All subjects must give their **informed consent** before taking part.

• All information about individual subjects must be kept **confidential.**