# Phil/LPS 31 Introduction to Inductive Logic Lecture 18

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# **Topics**

- Causal Inference
- Observational Studies (No intervention)
  - Case-control studies: Retrospective Studies
  - Cohort studies: Prospective Studies
- Experimental Studies (Intervention)
  - Randomized Control Studies
- Evaluating Studies

#### Hume and Causal Inference

▶ Recall that in his *A Treatise of Human Nature*, David Hume (1711 - 1776) called into serious question the thesis that we have any logical or rational basis for inductive reasoning about causality, i.e., reasoning of the form *A* causes *B*.

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#### Hume and Causal Inference

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- More generally, since Hume was what philosophers call an empiricist, Hume's question was: what empirical justification do we have to validate inferences, like causal inference, which extend our empirical knowledge beyond pre-existing empirical knowledge?
- ► The answer he wanted was that the only empirical justification was custom and habit. But before he could say that this was the only empirical justification, he had to show that no other non-empirical justification was possible!

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- It is fair to say that Hume's arguments, which raised the problem of induction, are sound. The problem of induction (what is the rational justification for good rules of inductive inference?) is still an open problem.
- ▶ But what does modern science have to say about causation (bracketing the issue of the metaphysics and the rational justification of causal inference as a form of inductive inference)?
- Let us spend the next two lectures discussing that.

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- We shall see more distinguishing features of these two major kinds of studies when we look at each more closely below, starting with observational studies.

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- ▶ For each of these kinds of observational studies, I want you to know: (1) what it is; (2) what are the key measures looked for by scientists; (3) what are the advantages and drawbacks of each kind of study.

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- Researchers select subjects at the onset of the study and then determine whether they have the risk factor or have been exposed.
- All subjects are then followed over a certain period to observe the effect of the risk factor or exposure. Because the events of interest transpire after the study is begun, these studies are sometimes called prospective studies.

# An Example of a Cohort Study

▶ The Framingham Study, began in 1948, followed up a sample of 5,209 men and women residing in Framingham, Mass. with the use of clinical examinations, conducted every 2 years, and continuous surveillance of morbidity and mortality. On each examination a variety of characteristics were measured, including blood chemistry values and blood pressure; an electrocardiogram is taken; and a thorough cardiovascular evaluation is made after obtaining a routine history and physical examination.

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- ▶ Their results showed that persons at high risk of cardiovascular disease can be effectively identified from a measurement of their serum cholesterol and blood pressure, a smoking history, an electrocardiogram and a determination of glucose intolerance.

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- Cohort studies are the design of choice for studying the risk factors of a condition, the course of a disease because they are longitudinal and follow a group of subjects over a period of time.
- Causation generally cannot be proved with cohort studies because they are observational and do not involve interventions. However, because they follow a cohort of patients forward through time, they possess the correct time sequence to provide strong evidence for possible causes and effects.

#### Draw-backs of Cohort Studies

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- Cohort studies that require a long time to complete are especially vulnerable to problems associated with patient follow-up, particularly patient attrition (patients stop participating in the study) and patient migration (patients move to other communities).

## Observational Studies: Case-control Studies

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- ► The cases in case—control studies are individuals selected on the basis of some disease or outcome; the controls are individuals without the disease or outcome.
- ► The history of both cases and controls are analyzed in an attempt to identify a characteristic or risk factor present in the cases' histories but absent the controls' histories.

# An Example of a Case-Control Study

Margaret A. Olsen and colleagues (2003) studied data obtained in patients between 1996 and 1999 who had undergone laminectomy or spinal fusion. Forty-one patients with surgical site infections (SSI) or meningitis were identified, and data were compared with those acquired in 178 uninfected control patients. For patients with SSI the postoperative hospital length of stay was significantly longer than that in uninfected patients. The study concluded that postoperative incontinence, posterior approach, surgery for tumor resection, and morbid obesity were independent risk factors predictive of SSI following spinal surgery. Interventions to reduce the risk for these potentially devastating infections need to be developed.

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- They are generally the quickest and least expensive studies to undertake and are ideal for investigators who need to obtain some preliminary data prior to writing a proposal for a more complete, expensive, and time-consuming study.
- They are also a good choice for someone who needs to complete a clinical research project in a specific amount of time.

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- Of all study methods, they have the largest number of possible biases or errors, and they depend completely on high-quality existing records.
- One of the greatest problems in a case—control study is selection of an appropriate control group. The cases in a case—control study are relatively easy to identify, but deciding on a group of persons who provide a relevant comparison is more difficult.

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- ➤ The first fundamental feature is that the researchers manipulate, or systematically vary, the level of the independent variable. For example, drug vs. placebo; exposure to sunlight vs. no exposure to sunlight.
- ► The second fundamental feature of an experiment is that the researcher exerts control over, or minimizes the variability in, variables other than the independent and dependent variable.

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- ► They manipulate the independent variable by systematically changing its levels and control other variables by holding them constant.
- ▶ The manipulation of an independent variable must involve the active intervention of the researcher. Comparing groups of people who differ on the independent variable before the study begins is not the same as manipulating that variable.
- ► The active manipulation of the independent variable is crucial for eliminating potential alternative explanations for the results.

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- ▶ However, sometimes greater insights can be gained by adding more conditions to an experiment. When an experiment has one independent variable that is manipulated to produce more than two conditions it is referred to as a single factor multi-level design.

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- ▶ Extraneous variables make it difficult to detect the effect of the independent variable in two ways. One is by adding variability or "noise" to the data (in a non-systematic way across different levels of the independent variable) The other way is by confounding (which is systematic variation, on average, across the different levels of the independent variable due to that extraneous variable)

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- ➤ To confound means to confuse, and this effect is exactly why confounding variables are undesirable. Because they differ systematically across conditions just like the independent variable they provide an alternative (causal) explanation for any observed difference in the dependent variable. See Simpson's Paradox later.

► For example, in almost all experiments, participants' intelligence quotients (IQs) will be an extraneous variable. But as long as there are participants with lower and higher IQs in each condition so that the average IQ is roughly equal across the conditions, then this variation is probably acceptable (and may even be desirable). This is "noise".

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- What would be bad, however, would be for participants in one condition to have substantially lower IQs on average and participants in another condition to have substantially higher IQs on average. In this case, IQ would be a confounding variable.

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- But this approach is not always desirable because of potential bias. A second and much more general approach is random assignment to conditions.
- ▶ This is the basis of randomized control studies.

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- ► In medicine, randomized control experiments that involve humans are called randomized clinical trials because their purpose is to draw conclusions about a particular procedure or treatment.
- ▶ If participants in the treatment arm end up better off than participants in the control arm, then the researcher can conclude that the treatment is effective.

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- ► The best way to ensure that the groups are treated similarly is to plan interventions for both groups for the same time period in the same study. In this way, the study achieves concurrent control.
- ➤ To reduce the chances that subjects or investigators see what they expect to see, researchers can design double-blind trials in which neither subjects nor investigators know whether the subject is in the treatment or the control group. When only the subject is unaware, the study is called a blind trial.

# An Example of a Randomized Control Study

The Physicians' Health Study (Steering Committee of the Physicians' Health Study Research Group, 1989) investigated the role of aspirin in reducing the risk of cardiovascular disease. One purpose was to learn whether aspirin in low doses reduces the mortality rate from cardiovascular disease. Participants in this clinical trial were over 22,000 healthy male physicians who were randomly assigned to receive aspirin or placebo and were followed over an average period of 60 months. The investigators found that fewer physicians in the aspirin group experienced a myocardial infarction during the course of the study than did physicians in the group receiving placebo.

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- ► The randomized control study provides the greatest justification for concluding causality and is subject to the least number of problems or biases.
- Randomized clinical trials are the best type of study to use when the objective is to establish the efficacy of a treatment or a procedure.

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- Although clinical trials provide the greatest justification for determining causation, obstacles to using them include their great expense and long duration.
- Another potential obstacle to using clinical trials occurs when certain practices become established and accepted by the medical community, even though they have not been properly justified.

# **Evaluating Studies: Internal Validity**

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- Experiments are high in internal validity because the way they are conducted with the manipulation of the independent variable and the control of extraneous variables (such as through the use of random assignment to minimize confounds) provides strong support for causal conclusions.
- In contrast, non-experimental research designs (e.g., correlational designs), in which variables are measured but are not manipulated by an experimenter, are low in internal validity.

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- As a general rule, studies are higher in external validity when the participants and the situation studied are similar to those that the researchers want to generalize to.

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- Operationalization is how researchers convert the research question into an experimental design to answer it.

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- When considering the proper type of test, researchers must consider the scale of measure their dependent variable was measured on (ratio/interval, nominal, ordinal) and the design of their study.
- ► Further, many inferential statistics tests carry certain assumptions (e.g., the data are normally distributed) and statistical validity is threatened when these assumptions are not met but the statistics are used nonetheless.