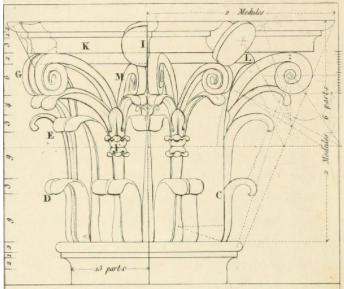
Propensity Score-Based Methods for Causal Inference

Module 3: Implications of the Study Design



**I. Module Objectives**

After we define the research question in terms of potential outcomes and a causal effect, we need to develop a strategy for data collection. Often times, we think about study design more for randomized trials and consider observational data in terms of “whatever we collected”. However, study design represents an equally critical, and even more complex, component of observational designs. As stated by Rubin (2008), “For objective causal inference, design trumps analysis”. In other words, no amount of sophisticated statistical analysis can save a poorly designed study. This module describes the key considerations for observational study design that are necessary before even considering causal inference.

By the end of this module, you will be able to:

1. Describe the concept of confounding in observational studies
2. Describe strengths and weaknesses of randomized trials for estimating causal effects
3. Critique possible data sets for evaluating your research question

**II. Module Assignments**

As with some of the videos and assignments in the previous modules, these videos were developed specifically for comparative effectiveness research and comparison of treatments or interventions, rather than more general assessments of causal effects from some exposure. However, most of the points made in these videos apply very generally to assessing causality of any exposure.

**Optional Assignment to gain further prerequisite knowledge (before starting the Required Assignment):**

There are many available resources for identifying and describing the different components, and strengths and weaknesses of possible study designs. For those without the prerequisite course in fundamental epidemiologic methods, you may want to take either a for-credit course, or an online course, or study a textbook, such as *Epidemiology: An Introduction* (Rothman, 2012). Chapter 7 of that textbook is particularly relevant to this module.

For another useful reference on study design (which is somewhat specific to comparative effectiveness research, but also serves as a useful discussion on issues necessary for causal inference), see the Agency for Healthcare Research and Quality document: Velentgas, P., Dreyer, N. A., Nourjah, P., Smith, S. R., & Torchia, M. M. (Eds.). (2013). *Developing a protocol for observational comparative effectiveness research: a user's guide*. Chapter 2. Government Printing Office.

**Required Assignments: (~56 minutes)**

Since the strengths and limitations of observational designs are most easily described in terms of how they differ from randomized, trials, begin by watching Slides 1-15 of Lesson 2 (on history and basic elements of RCTs) from the [UC-Davis CER Lessons](https://cpeonline.ucdavis.edu/courses/1874/pages/Lessons). (**~20 minutes**) You can also watch the remaining 17 slides, but they are more specific to drug treatment trials.

For an introduction to some basic observational designs and related issues for planning the statistical analysis plan, watch Modules 7a (**~13.5 minutes**) and 7b (**~22.5 minutes**) from [Category 3 (on data integrity and rigorous analyses) from the PCORI Methodology Standards Academic Curriculum](https://www.pcori.org/research-results/about-our-research/research-methodology/methodology-standards-academic-curriculum-1).

**Optional Assignment: (~1.5 hours)**

For further reinforcement of the topics of confounding and bias, watch Lesson 14 (on Observational Studies for CER. How can they be made as good as RCTs?) from the [UC-Davis CER Lessons](https://cpeonline.ucdavis.edu/courses/1874/pages/Lessons). (**~53 minutes total**) Although this lesson is labeled specifically for CER, the discussion is generally applicable to other exposures.

For more information about guidelines for collecting and reporting observational data, and differences between primary versus secondary data, watch the videos for Module 3 and Modules 5a-5b from PCORI Methodology Standards Academic Curriculum under the [Category 3: Standards for Data Integrity and Rigorous Analysis](https://www.pcori.org/research-results/about-our-research/research-methodology/methodology-standards-academic-curriculum-1). (**~40 minutes total**)

**III. Project Exercises**

Create a copy of this Google Doc or download the Module onto your computer and review the material offered above under Module Assignments before beginning these workbook exercises.

Thinking about what you learned in this module so far, begin developing the analysis plan for your project by answering the following questions:

1. Based on the strengths and weaknesses of the observational data sets you considered in the Module 2 exercises, and what you learned about study designs in the Module 3 assignments, either A) select a data set to use for your analysis or B) plan a new data collection effort.

***Please note*** that we will not actually work through the analysis in this online course, but instead will focus on developing analysis plans (so it’s ok if you will not actually be able to collect the data during your timeline for taking this course.

1. Describe the variables that you intend to use or collect to define your analysis population and control for confounding in your analysis.
2. Describe the temporal associations between those variables and the exposure and outcome(s) of interest.

[Link to go back to the Course Overview Document](https://docs.google.com/document/d/1UDTkp3rbhqdun7jvSvktaZmTtoUWOz_VUDQw3HIsElg/edit?usp=sharing)