An observational study is an empiric investigation of effects caused by treatments when randomized experimentation is unethical or infeasible. The quality and strength of evidence provided by an observational study is determined largely by its design. Excellent methods of analysis will not salvage a poorly designed study.

The line between design and analysis is easier to draw in practice than it is in theory. In practice, the design of an observational study consists of all activities that precede the examination or use of those outcome measures that will be the basis for the study’s conclusions. Unlike experiments, in some observational studies, the outcomes may exist as measurements prior to the design of the study; it is their examination and use, not their existence, that separates design from analysis. Aspects of design include the framing of scientific questions to permit empirical investigation, the choice of a context in which to conduct the investigation, decisions about what data to collect, where and how to collect it, matching to remove bias from measured covariates, strategies and tactics to limit uncertainty caused by covariates not measured, and sample splitting to guide design using individuals who will not be included in the final analysis. In practice, design ends and analysis begins when outcomes are examined for individuals who will be the basis of the study’s conclusions. An observational study that begins by examining outcomes is a formless, undisciplined investigation that lacks design.

In theory, design anticipates analysis. Analysis is ever present in design, as any goal is ever present in any organized effort, as a goal is necessary to organize effort. One seeks to ask questions and collect data so that results will be decisive when analyzed. To end well, how should we begin?

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