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Methodology Matters

Design, analysis, and conclusions: Telling a consistent causal story

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ABSTRACT

Pharmacy educators are dedicated to providing the best education to student pharmacists and post-graduate trainees. This involves developing and evaluating new educational approaches or activities, as well as working to understand better other factors that may affect student and program outcomes. Although we may not realize it, the idea of causality, or the presence of a cause-and-effect relationship, is embedded in much of what we do when engaging in pharmacy educational scholarship. Saying that an educational intervention is effective at improving test scores implies that the intervention caused the increase. Perhaps more subtly, a cause-and-effect relationship is implied when identifying poor interviewing skills as a factor that reduces the likelihood that a student will obtain a pharmacy practice residency. The extent to which causal claims can be made depends on appropriate study design and analysis. Similarly, the language used to present these claims is related to study design and analysis. Unfortunately, study designs used when evaluating educational approaches do not always align with the language used to report the results. This review provides a brief overview of current thinking related to causal inference. The role of study design and analysis in causal inference is also discussed along with recommendations for study design and analysis to facilitate making appropriate causal claims. After reading this article, readers should be able to select a study design that best aligns with their particular research question and report their findings in ways that are faithful to the strengths of the study design.

My situation

One common question asked in educational scholarship is, "Did this new activity I implemented in my class work?" This is a question that is near and dear to most of our hearts as educators since we are constantly striving to provide the best education possible to our students. Other questions may be framed as, "What are the effects of increased time spent working on academic performance?" One recurring issue I have noticed as a peer reviewer for several journals is that the language used in the conclusions is not always consistent with the study design and data analysis used. After pointing out that the language used in the conclusions was directly causal (e.g., the activity resulted in improved knowledge) but the study design did not support that (e.g., a one-group pretest-posttest was used), I have sometimes gotten the response that the intent of the study was not to demonstrate causality since the study did not use random assignment or only used one group. As Pearl stated, "[t]he central aim of many studies in the physical, behavioral, social, and biological sciences is the elucidation of cause-effect relationships among variables or events."[1] While this may not be our primary intention, it is still present in many of the questions we ask as pharmacy education scholars, so we must keep issues of causality and causal inference in mind as we design and report our educational scholarship efforts. The purpose of this article is to review basic principles of causal inference and to provide recommendations for study design and analysis to support making causal conclusions.

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Methodological literature review

Causality is a concept that is common in our everyday thinking. We intuitively know (or at least expect) that turning the key in the ignition will cause a car engine to start. Using common graphical notation,[1] this relationship could be represented as *Turn the ignition key → Car engine starts*. We also use causal language to explain or justify our actions, as in "I was not able to get any work done because somebody cut me off in my morning commute, which put me in a bad mood" (i.e., *Somebody cut me off → My mood deteriorated → I could not get any work done*). In the realm of science, causation has been the source of a considerable amount of debate, both philosophically and methodologically. These debates have ranged from simply defining what constitutes a cause and an effect to describing how and when one can determine that a causal relationship exists to delineating acceptable evidence in support of causation.[2–5] To make matters more confusing, causal language in research is notably inconsistent.[6] As one example, epidemiology is largely focused on identifying the determinants, or causes, of diseases in populations, yet it lacks a single, agreed-upon definition of causation.[7–9] Travers went so far as to advocate for doing away with the word *cause* altogether in order to "bring educational research out of the middle ages."[10] As an added source of confusion, many different disciplines or areas of study have their own perspectives on causality (e.g., psychometrics, qualitative inquiry, epidemiology). This review focuses primarily on the experimental and epidemiologic perspectives of causality. The notion of causality is important in many applied research contexts, such as education and health care, since there is a focus on explaining why phenomena occur, determining whether interventions "work," examining the effects of various exposures, and gathering information to support evidence-based practice.[3,5,11] Before reviewing causal thinking and causal inference, two preliminary issues should be addressed: study design terminology and making comparisons with epidemiology.

In sociobehavioral research, the term *observational study* may be used interchangeably with the term *quasi-experimental study*.[2,12] This may cause concern for those with a health sciences background since "observational study" typically refers to epidemiologic designs (e.g., case-control, cohort, or cross-sectional). These epidemiologic designs are conceptually similar to *ex post facto* or correlational research described in many social science research methods textbooks.[3,13] For the purposes of clarity in this article, non-experimental studies will refer to those studies using an observational or epidemiologic approach, which aligns with language in existing texts[4,14] and recent recommendations for educational research.[15] From a study design reporting standpoint and given pharmacy education's location within the health sciences literature, I recommended that the term *observational study* be reserved for those situations when epidemiologic designs are used rather than quasi-experimental designs. When reporting study methods, however, it is important to be specific and state the particular research design used (e.g., case-control study or non-equivalent control group) rather than providing a more generic term (e.g., observational study or quasi-experimental design).

In this review, various references and comparisons are made to methods for causal inference used in epidemiology. Many pharmacy educators likely have a working understanding of general epidemiologic principles since these are often included in pharmacy and health sciences curricula. This can be helpful since other areas investigating causal inference (e.g., economics or education) use terminology and methods that may be less familiar to those with health sciences backgrounds. Beyond this pre-existing familiarity, there are many additional similarities between scholarly inquiry in epidemiologic and educational contexts. To a large extent, the two disciplines are concerned with both the how *and* why of causality (i.e., causal explanation) rather than simply determining if some factor is causal (i.e., causal description). In both disciplines, research may take a case-oriented or population-oriented approach.[16] The case-oriented approach focuses on a particular case, whether that be an individual patient, an individual student on an advanced pharmacy practice experience (APPE), or a particular class that a faculty member teaches. The population-oriented approach focuses on the average-treatment effect of a factor or intervention in a larger target population of interest (e.g., all patients with diabetes or all pharmacy students in general). While the notion of determining causality is important in both approaches, one key difference is the potential or desire for generalization—low potential/desire in the case-oriented approach vs. high potential/desire in the population-oriented approach. The scholarship of teaching and learning could be framed as a case-oriented approach while educational research uses a more population-oriented approach. Both education and epidemiology investigate issues related to human behavior where context is a vital component. This is more than just context as it relates to generalizability, but in terms of how contextual and situational factors may affect the outcomes of interest. In epidemiology, this is seen in the host-agent-environment relationship. In education, this is achieved through recognizing the way in which students are embedded within and inextricably linked to their particular social, political, environmental, and educational context. Both disciplines are concerned with the potential for finding areas where action can be taken (e.g., to reduce the risk of a heart attack or improve students' patient counseling skills). Although intervention and manipulation may be offer notable methodological advantages in both education and epidemiology, it is not always possible. Even if manipulation is possible, random assignment may not be feasible or even desirable for ethical or legal reasons. In epidemiologic and educational studies, manipulation often takes the form of higher level programmatic or systemic initiatives that affect in-tact groups (e.g., changing policies about required vaccinations or implementing a new assessment approach for all students within a program) rather than manipulation at the level of the individual person.

There are many criteria that have been proposed to guide the evaluation of identified relationships for potential causality (i.e., whether the relationship is indeed causal). The criteria set forth by John Stuart Mill are commonly used as a general framework for evaluating potential causal relationships: X causes Y (or $X \rightarrow Y$) if and only if (1) the cause (X) preceded the effect (Y), (2) the cause was related to the effect, and (3) there are no plausible alternative explanations of the effect other than the cause.[2] The first criterion speaks to the importance of a temporal sequence, and the second conveys the idea of meaningful covariation (i.e., statistical correlation or association). While this may seem unsettling to some given the mantra "correlation is not causation," it is important to note that a statistical association is a necessary part of causation. In addition to Mill's criteria, Scriven suggests that causal