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Research Designs and Methodologies Related to Pharmacy Practice

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Learning Objectives

- Discuss the value of pharmacy practice research to evidence-based practice and policy.
- Describe the classifications and types of study designs commonly used in pharmacy practice research.
- Discuss the concepts and structure of common study designs used in pharmacy practice research including experimental, quasi-experimental, observational, qualitative, and mixed method designs.
- Discuss the important considerations for conducting pharmacy practice research in terms of study design, data collection, data analyses, and ethical considerations.

Introduction to Research Methodologies Used in Pharmacy Practice

The mission of pharmacy profession and the role of pharmacists in healthcare have evolved toward patient-centered care in the last few decades. Pharmacists with their expertise in drug therapy and accessibility to the public have unprecedented opportunities to assume increasing responsibility for direct patient care (Bond, 2006). New cognitive pharmaceutical services and new roles for pharmacists continue to emerge.

In the era of evidence-based practice and health services, it is not just adequate to propose those new pharmacy services or new roles without evidence of their benefit (Awaisu and Alsalimy, 2015; Bond, 2006). New pharmacy services and new roles must be proven to be feasible, acceptable, cost-effective, and increase health outcomes. Pharmacy practice research provides such evidence and can confirm the value of a new service, inform policy, and result in practice changes (Bond, 2006; Chen and Hughes, 2016). Research evidence should be used to identify new areas for improved health service delivery and rigorously

evaluate new services. The research used to generate such evidence should be grounded in robust and rigorous methodologies (Chen and Hughes, 2016). Traditionally, common quantitative and qualitative methods such as randomized controlled trials, cohort study, case control study, questionnaire-based surveys, and phenomenology using qualitative interviews have been used in pharmacy. However, in recent years, novel and more complex methods are being developed and utilized. Pharmacy practice researchers need to know how these old and new methodological approaches should be selected, applied, and interpreted in addressing research problems.

Various study designs, including, but not limited to experimental, quasi-experimental, observational, qualitative, and mixed method designs, have been used in pharmacy practice research. Furthermore, different classification systems (e.g., quantitative vs. qualitative, experimental vs. observational, descriptive vs. analytical study designs) have been used in the literature. The choice of a study design to answer a research question in pharmacy practice research is driven by several factors, including the type of the research question or the research hypothesis, expertise of the investigator, availability of data, and funding opportunities. Pharmacy practice researchers need to be competent in the selection, design, application, and interpretation of these methodological and analytical approaches. Today, many of the research methods used in pharmacy practice research have been adapted from fields such as sociology, anthropology, psychology, economics, and other disciplines. This paradigm shift has led to a greater emphasis on the appropriate choice of a specific research design or method to answer a specific research question (Chen and Hughes, 2016). Consequently, pharmacy practice researchers should place an emphasis on the reliability of the methods selected, the correct interpretation of their findings, the testing of a specific hypothesis, and the internal validity of their data, among other considerations. Novice and early career researchers should be familiar and have sound foundation in a variety of methods applied in pharmacy practice research, which will be covered in this chapter and other chapters in this Encyclopedia. We do believe that more experienced researchers should focus on certain methods in order to advance research in our discipline.

Core Quantitative and Qualitative Approaches Used in Pharmacy Practice Research

Traditionally, core quantitative approaches used in pharmacy practice research include nonexperiments, quasi-experimental designs, and true experimental designs such as prospective randomized controlled intervention trials. Nonexperiments also include observational study designs that are often described as pharmacoepidemiologic study designs such as case–control study, cohort study, nested case–control study, and cross-sectional study (Etminan, 2004; Etminan and Samii, 2004). In recent years, conventional qualitative approaches and their philosophical paradigms are increasingly been used in pharmacy. These include the five qualitative approaches to inquiry: narrative research, phenomenology, grounded theory, ethnography, and case study. These qualitative methods are often difficult for pharmacy practice researchers to comprehend, and researchers tend to describe the methods of data collection such as individual interviews and focus group discussions as qualitative methods of inquiry. These data collection methods are briefly described later in this chapter, among others. Furthermore, there is an increasing importance on the appropriate selection and use of mixed method approach (Hadi et al., 2013; Hadi and Closs, 2016a, 2016b), which are often designed and applied wrongly. Finally, it is worthwhile to be familiar with novel research methodologies such as discrete choice experiments, Delphi techniques, simulated client technique, and nominal group techniques, which fall between quantitative and qualitative approaches, often with no clear differentiation on where they belong. Although called "novel" in the context of this chapter, these methods are not new in other relevant disciplines, but new and not commonly used in pharmacy practice research.

Research Question and Selection of Study Design

Pharmacy practice researchers begin by conception of a research idea or identifying a research question and defining a hypothesis based on the question. The researcher then selects a study design that will be suitable to answer the research question. The study design should be appropriately selected prior to initiation of any research investigation. Selecting an inappropriate study design may potentially undermine the validity of a study in its entirety. Investigators are encouraged to critically think about the possible study designs to ensure that the research question is adequately addressed and should be able to adequately justify their choice. These study designs have been variously classified and one common classification system is quantitative vs. qualitative study designs. Study designs play a major role in determining the scientific value of research studies. Inappropriate choice of a study design is impossible to correct after completion of the study. Therefore, thorough planning is required to avoid unconvincing results and invalid conclusions. Good understanding of basic study design concepts will aid researchers in conducting robust and rigorous practice-based research. This chapter introduces the structure and the fundamentals of common study designs used in pharmacy practice research and discusses the important considerations for conducting pharmacy practice research in terms of study design, data collection, data analyses, and ethical considerations.

Classification of Research Methodologies Used in Pharmacy Practice

Various classifications for research designs and methods used in pharmacy practice have been used in the literature. The following are some of the approaches for the classification of research designs:

1. Classification based on time orientation: Retrospective vs. prospective designs

a. Retrospective design—A retrospective study design observes what has happened in the past. It begins and ends in the present. This design involves a major limitation as it looks to collect information about events that occurred in the past. An example of this design is retrospective case-control study.
Case example: Investigators were looking for the association between acute myocardial infarction and smoking status, type of tobacco, amount of smoke, etc. (Teo et al., 2006). Another example of a case–control study from published literature is the study investigating the association between the use of phenylpropanolamine and the risk of hemorrhagic stroke (Kernan et al., 2000).
b. Prospective design—A prospective study design begins in the present and progresses forward, collecting data from subjects whose outcomes lie in the future. An example of this design is prospective cohort study.
Case example: Investigators were interested to determine the long-term effectiveness of influenza vaccines in elderly people; they recruited cohorts of vaccinated and unvaccinated community-dwelling elderly (Nichol et al., 2007).

2. Classification based on study purpose: Descriptive vs. analytical designs

a. Descriptive design—A descriptive study describes a population/sample in terms of distribution of the variables, and frequency of outcomes of interest. Unlike analytical studies that include control (comparison) group, descriptive studies do not include a comparison group. Descriptive studies include case reports, case series reports, cross-sectional studies, surveillance studies, and ecological studies.
Case example: A case report was written by a physician who contracted Severe Acute Respiratory Syndrome (SARS) during an outbreak in Hong Kong (Wu and Sung, 2003). Another example is an ecological study examining diet and sunlight as risks for prostate cancer mortality (Colli and Colli, 2006). Chim et al. conducted a large population-based survey in Australia to determine what community members think about the factors that do and should influence government spending on prescribed medicines (Chim et al., 2017).
b. Analytical design—An analytical study identifies risk factors, associated factors, mediating factors, etc. Analytical studies are either experimental or observational. Case–control and cohort studies are types of observational studies.
Case example: A group of investigators carried out a study to establish an association between the use of traditional eye medicines (TEM) and corneal ulcers. In this case, both case–control and cohort study designs are applicable. In an example of a case control study, Archibugi et al. aimed to investigate the association between aspirin and statin exclusive and combined and pancreatic ductal adenocarcinoma occurrence (Archibugi et al., 2017). Another example of a cohort study is a study carried out by Wei et al. in which they investigated whether or not acid-suppression medicines increased the risk of bacterial gastroenteritis (Wei et al., 2017).

3. Classification based on investigator orientation: Experimental vs. quasi-experimental vs. observational designs

a. Experimental design—In experimental design (also known as interventional design), the investigator performs an intervention and evaluates cause and effect relationships.
Case examples: Investigators conducted a study about the newer versus older antihypertensive agents in African hypertensive patients (NOAAH) trial (nct01030458) to compare the efficacy of single-pill combinations of newer versus older antihypertensive agents (i.e., a single-pill combination of newer drugs, not involving a diuretic, with a combination of older drugs including a diuretic) (Odili et al., 2012). In a crossover design, a group of investigators evaluated the effect of spironolactone on nonresolving central serous chorioretinopathy (Bousquet et al., 2015).
b. Quasi-experimental design—The quasi-experimental design is very similar to the true experimental design described above and it involves an intervention. The design has been employed when randomization is inappropriate or impossible, especially when implementing complex interventions.
Case examples: Prashanth et al. aimed to understand if (and how) a package of interventions targeting primary health centers and community participation platforms affect utilization and access to generic medicines for people with noncommunicable diseases using quasi-experimental design approach (Prashanth et al., 2016).
c. Observational design—It involves only observation of natural phenomena and does not involve investigator intervention. Typically, this study design investigates associations and not causation. Examples include cohort study and case–control study. These studies can explore an association between a pharmacologic agent and a disease of interest. Case examples: Please see previous examples of these.

4. Classification based on question orientation: Quantitative vs. qualitative vs. mixed method designs

a. Quantitative design—This is based on measurement of quantity and it is applicable to phenomenon that can be quantified (i.e., expressed in terms of numbers).
Case examples: Please see experimental studies, and case–control and cohort study designs.
b. Qualitative design—Qualitative research is concerned with qualitative phenomenon (i.e., a phenomenon relating to or involving quality).
Case examples: Investigators in Canada explored the lived experiences of youth who are prescribed antipsychotics by conducting interpretative phenomenology study (Murphy et al., 2015).

c. Mixed method designs—Mixed method design brings together qualitative and quantitative methodologies within a single study to answer or understand a research problem (Hadi et al., 2013).
Case examples: Shiyanbola et al. combined focus group discussion with a survey tool to investigate patients' perceived value and use of quality measures in evaluating and choosing community pharmacies (Shiyanbola and Mort, 2015).

5. Classification of pharmacoepidemiologic study designs
Below is a brief description of traditional and novel pharmacoepidemiologic study designs. Several examples of pharmacoepidemiologic study designs are provided above. Some descriptive studies including case reports, case series, and ecological studies will not be described in this chapter.

a. Case–control studies—In this design, patients (those who develop the disease or outcome of interest) are identified and control patients (those who do not develop the disease or outcome of interest) are sampled at random from the original cohort that gives rise to the cases (Etminan and Samii, 2004; Newman et al., 2013). The distribution of exposure to certain risk factors between the cases and the controls is then explored, and an odds ratio (OR) is calculated.
b. Cohort studies—This can be described as a study in which a group of exposed subjects and a group of unexposed subjects are followed over time and the incidence of the disease or outcome of interest in the exposed group is compared with that in the unexposed group (Etminan and Samii, 2004; Hulley et al., 2013).
c. Case-crossover studies—The case-crossover may be considered comparable to a crossover randomized controlled trial in which the patients act as their own control (Etminan and Samii, 2004). Pattern of exposure among the cases is compared between event time and control time. The between-patient confounding that occurs in a classic case-control study is circumvented in this design. Tubiana et al. evaluated the role of antibiotic prophylaxis and assessed the relation between invasive dental procedures and oral streptococcal infective endocarditis, using a nationwide population-based cohort and a case-crossover study design (Tubiana et al., 2017).
d. Case–time control studies—This design is an extension of the case-crossover design, but includes a control group (Etminan and Samii, 2004). A group of researchers assessed medication-related hospitalization. They used the case–time control study design to investigate the associations between 12 high risk medication categories (e.g., antidiabetic agents, diuretics, benzodiazepine hypnotics) and unplanned hospitalizations (Lin et al., 2017).
e. Nested case–control studies—In this design, a cohort of individuals is followed during certain time periods until a certain outcome is reached and the analysis is conducted as a case–control study in which cases are matched to only a sample of control subjects (Etminan, 2004). de Jong et al. examined the association between interferon-β (IFN-β) and potential adverse events using population-based health administrative data in Canada (De Jong et al., 2017).
f. Cross-sectional studies—In this type of study, the investigator measures the outcome of interest and the exposures among the study participants at the same time (Hulley et al., 2013; Setia, 2016b). It provides a snapshot of a situation for a particular period.

Quantitative Research Designs in Pharmacy Practice

A wide range of quantitative methods are commonly applied in pharmacy practice research. These methods are widely used in published pharmacy practice literature to explore appropriateness of medicines use, appropriateness and quality of prescribing, and medication safety, through analyzing existing datasets, direct observation, or self-report (Green and Norris, 2015). Pharmacy practice research questions also seek to determine the knowledge, behaviors, attitudes, and practices of pharmacists, other healthcare providers, patients, policy-makers, regulators, and the general public. Quantitative methods are also used in evaluating the effect of new pharmacy services and interventions to improve medicines use. These practice research projects provide valuable insights about how medicines are used, and how to maximize their benefits and minimize their harmful effects. In the context of this chapter, quantitative study designs will be broadly classified into three: (1) observational, (2) experimental and quasi experimental, and (3) other designs.

Observational Study Designs

Pharmacoepidemiology is a "relatively new science that explores drug efficacy or toxicity using large observational study designs" (Etminan, 2004; Etminan and Samii, 2004). These study designs explore drug use studies that usually cannot be answered using randomized controlled trials or other experimental designs. In several instances, experimental study designs may not be suitable or feasible; in such circumstances, observational study designs are applied (Cummings et al., 2013). As the name implies, observational studies involve merely observing the subjects in a noncontrolled setting, without investigator intervention or manipulating other aspects of the study. Therefore, observational studies are nonexperimental. The observation of the variables of interest can be prospective, retrospective, or current depending on the type of the observational study.

In pharmacoepidemiology and other areas of pharmacy practice, researchers are often interested in measuring the relationships between exposure to a drug and its efficacy, toxicity, or other outcomes of interest using observational study designs. It is worthwhile to note that observational study designs investigate association, but, in most cases, not causation. Here, we provide descriptions of some commonly used study designs in pharmacoepidemiology and pharmacy practice research in general.

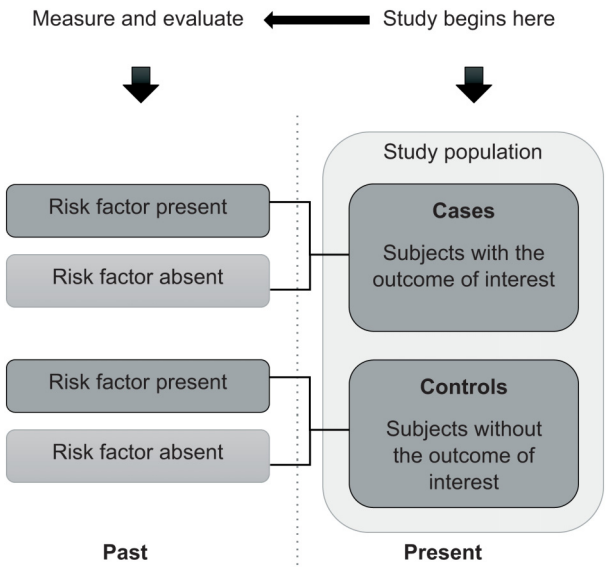

Figure 1 Case–control study design.

Case–Control Studies

Case–control study design is used to determine association between risk factors or exposures and outcomes. It is a useful design to study exposures in rare diseases or diseases that take long time to develop (Newman et al., 2013). It investigates exposures in individuals with and those without the outcome of interest. Nevertheless, case–control studies can help to identify harmful or beneficial exposures. Furthermore, the outcome of interest can be undesirable (e.g., mortality) or desirable (e.g., microbiological cure). As the name suggests, in a case–control study design, there are two groups of subjects: (1) cases (individuals with the outcome of interest) and (2) controls (individuals without the outcome of interest) (Newman et al., 2013). Cases are randomly selected based on prespecified eligibility criteria from a population of interest. Appropriate representative controls for the cases selected are then identified. The researchers then retrospectively investigate possible exposures to the risk factor. **Fig. 1** represents a schematic diagram of a case–control study.

Case–control studies are relatively inexpensive, less time-consuming to conduct, allow investigation of several possible exposures or associations, and are suitable for rare diseases. Selection of the control group is a critical component of case–control studies. Case–control studies have several drawbacks: confounding must be controlled, subject to recall, observation, and selection biases.

OR is the measure of association used for the analysis of case–control studies. This is defined as the odds of exposure to a factor in those with a condition or disease compared with those who do not have the condition or disease.

Cohort Studies

Similar to case–control studies, cohort studies determine an association between exposures/factors and development of an outcome of interest. As previously described, a cohort study is a study in which a group of exposed subjects and a group of unexposed subjects are followed over time to measure and compare the rate of a disease or an outcome of interest in both groups (Etminan and Samii, 2004; Hulley et al., 2013). A cohort study can be prospective (most common) or retrospective. While a case–control study begins with patients with and those without the outcome of interest (e.g., diseased and nondiseased patients), a cohort study begins with exposed and unexposed patients (e.g., patients with and those without certain risk factor) (Hulley et al., 2013; Setia, 2016a). In a cohort study, both the exposed and the unexposed subjects are members of a larger cohort in which subjects may enter and exit the cohort at different periods in time (Etminan and Samii, 2004; Hulley et al., 2013).

Typically, a cohort study should have a defined time zero, which is defined as the time of entry into the cohort (Etminan and Samii, 2004). The cohort (a group of exposed and unexposed subjects, who are free of the outcome at time zero) is followed for a certain period until the outcome of interest occurs. In addition, information or data related to all potential confounders or covariates should also be collected as failure to account for these can bias the results and over- or underestimates the risk estimate. There are two types of cohort studies: retrospective cohort and prospective cohort studies.

Retrospective cohort study, also known as historical cohort study, begins and ends in the present, while looking backward to collect information about exposure that occurred in the past (**Fig. 2**). Historical cohort studies are relatively less time-consuming and less expensive than prospective cohort studies (Etminan and Samii, 2004; Hulley et al., 2013; Setia, 2016a). In addition, there is no loss to follow-up and researchers can investigate issues not amenable to intervention study designs. However, these studies are only as good as the data available, the investigator has limited control of confounding variables, and it is prone to recall bias.

On the other hand, prospective cohort study, also known as longitudinal cohort study, begins in the present and progresses forward, collecting data from enrolled subjects whose outcomes fall in the future (Etminan and Samii, 2004; Hulley et al., 2013;

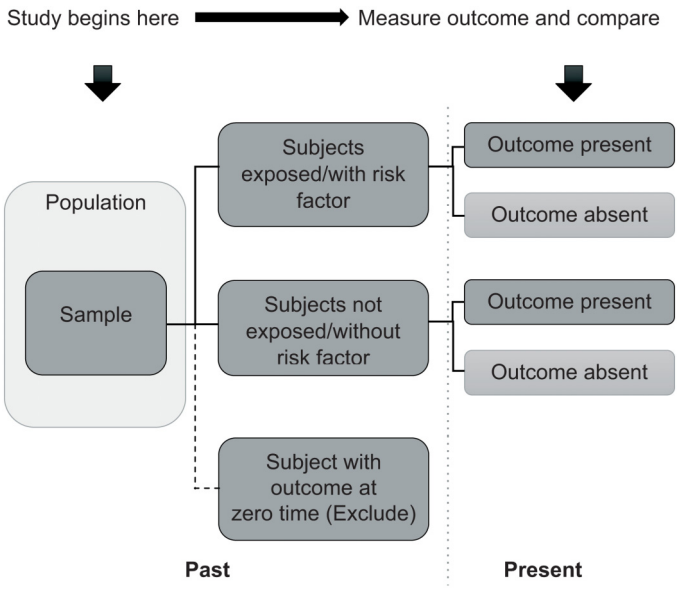

Figure 2 Retrospective (historical) cohort study design.

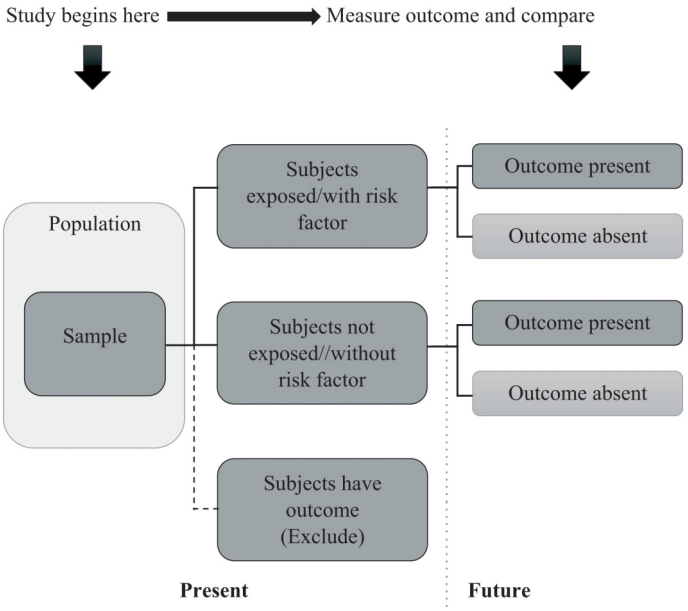

Figure 3 Prospective (longitudinal) cohort study design.

Setia, 2016a) (**Fig. 3**). Prospective cohort studies are easier to plan for data collection, have low recall bias, and the researcher has a better control of confounding factors. On the other hand, it is difficult to study rare conditions; they are more prone to selection bias, more time-consuming, expensive, and loss of subjects to follow-up is common.

Relative risk (RR) is the measure of association used for the analysis of a cohort study. This is defined as the risk of an event or development of an event relative to exposure (i.e., the risk of subjects developing a condition when exposed to a risk factor compared with subjects who have not been exposed to the risk factor).

Case-Crossover Studies

This is a relatively new design in the field of epidemiology in which the patients act as their own controls (Maclure, 1991). In this design, there is a case and a control element both of which come from the same subject. In other words, each case serves as its own control. It can be considered equivalent to a crossover RCT with a washout period (Etminan and Samii, 2004). Pattern of exposure to the risk factor is compared between the event time and the control time (Etminan and Samii, 2004). Case-crossover study design is useful to investigate triggers within an individual. For instance, it is applicable when studying a transient exposure or risk factor.

However, determination of the period of the control and case components is a crucial and challenging aspect of a case-crossover study design. Since the patients serve as their own controls, the interindividual variability that is inherent in classic case–control studies is eliminated. This is important in studies involving progressive disease states in which disease severity may differ between patients such as multiple sclerosis. OR is estimated using techniques such as Mantel–Haenszel statistics and logistic regression.

Cross-Sectional Studies

Cross-sectional studies also known as prevalence studies identify the prevalence or characteristics of a condition in a group of individuals. This design provides a snapshot of the prevalence or the characteristics of the study subjects in a single time point. The study investigator measures the outcomes and the exposures in the study subjects simultaneously (Etminan and Samii, 2004; Hulley et al., 2013; Setia, 2016b). Hence, cross-sectional studies do not follow up patients to observe outcomes or exposures of interest. Data are often collected through surveys. Cross-sectional design cannot provide cause and effect relationships between certain exposures and outcomes of interest.

Experimental and Quasi-Experimental Study Designs

In a typical experimental study design, the investigator assigns subjects to the intervention and control/comparison groups in an effort to determine the effects of the intervention (Cummings et al., 2013). Since the investigator has the opportunity to control various aspects of the experiment, this allows the researcher to determine the causal link between exposure to the intervention and outcome of interest. The researcher either randomly or conveniently assigns the subjects to an experimental group and a control group. When the investigator performs randomization, the study is considered a true experiment (see Fig. 4). On the other hand, if subjects are assigned into groups without randomization, the study is considered a quasi-experiment (refer to Fig. 5). As with experimental designs, quasi-experimental designs also attempt to demonstrate a causal link between the intervention and the outcome of interest. Due to the challenges of conducting a true experimental design, the quasi-experimental study designs have been consistently used in pharmacist intervention research.

RCTs are considered the gold standard of experimental study designs in pharmacy practice and evidence-based research (Cummings et al., 2013). The investigator randomly assigns a representative sample of the study population into an experimental group and a control group (Fig. 4). Randomization in RCT is to minimize confounding and selection bias; it enables attainment of similar experimental and control groups, thereby isolating the effect of the intervention. The experimental group receives the treatment or intervention (e.g., a new drug or pharmaceutical care for treatment of a certain disease), while the control group receives a placebo treatment, no treatment, or usual care treatment depending on the objective of the study (Cummings et al., 2013). These groups are then followed prospectively over time to observe the outcomes of interest that are hypothesized to be affected by the treatment or intervention. The result of the study is considered to have high internal validity if significant changes on the outcome variable occur in the experimental group, but not the control group. The investigator can infer that the treatment or intervention is the most probable cause of the changes observed in the intervention group. The unit of randomization in RCTs is usually the patient, but can sometimes be clusters to circumvent the drawbacks of contamination.

RCTs are very challenging to undertake and pharmacy practice researchers should ensure design of robust experiments, while considering all essential elements and adhering to best practices. For instance, to determine the impact of a cognitive pharmaceutical service, the selection of a representative sample of the population is a prime consideration in an RCT. Moreover, RCTs are expensive, labor-intensive, and highly prone to attrition bias or loss to follow-up.

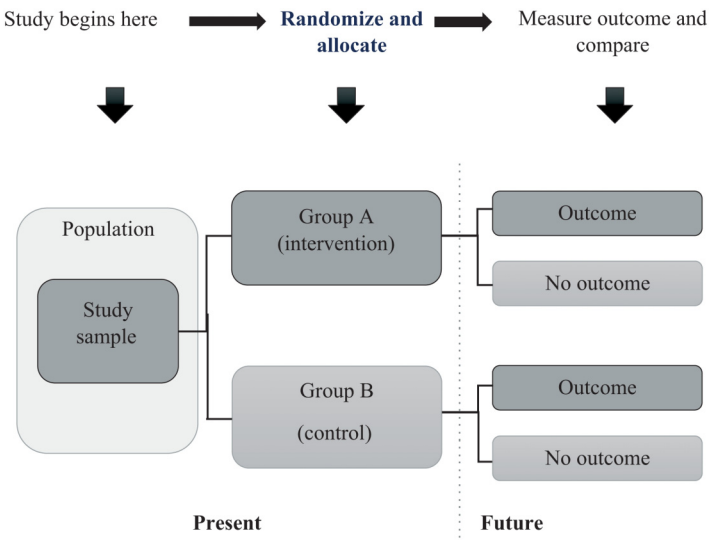

Figure 4 True experimental study design.

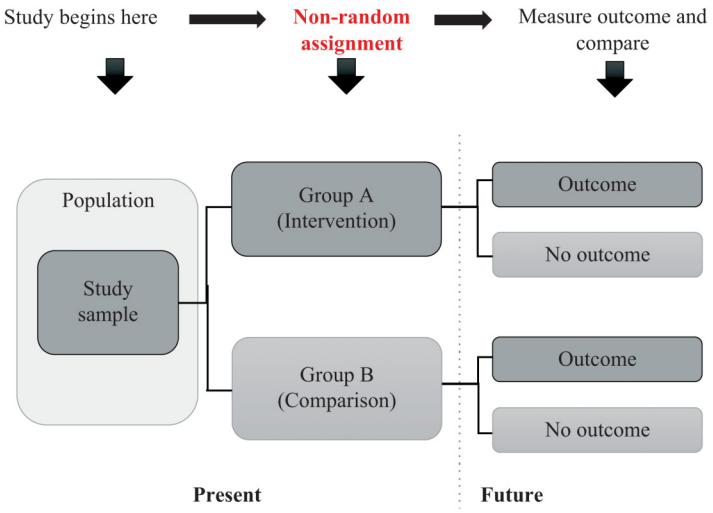

Figure 5 Quasi experimental study design.

In pharmacy practice research, it is often difficult to comply with the stringent requirements of true experimental designs such as RCTs, due to logistic reasons and/or ethical considerations (Grady et al., 2013; Krass, 2016). Whenever true experimental models are not feasible to be applied in pharmacy practice research, the researcher should endeavor to use a more robust quasi-experimental design. For instance, when randomization is not feasible, the researcher can choose from a range of quasi-experimental designs that are non-randomized and often noncontrolled (Grady et al., 2013; Krass, 2016). Quasi-experimental studies used in pharmacy literature may be classified into five major categories: (1) quasi-experimental design without control groups (i.e., one group pre–posttest design); (2) quasi-experimental design that use control groups with no pretest; (3) quasi-experimental design that use control groups and pretests (i.e., nonequivalent control group design with dependent pretests and posttests) (see **Fig. 5**); (4) interrupted time series and; (5) stepped wedge designs (Brown and Lilford, 2006; Grady et al., 2013; Harris et al., 2006).

The one group pretest posttest design and the nonequivalent control group design (**Fig. 5**) are the most commonly applied quasi-experimental designs in practice-based research literature. These designs have been commonly used to evaluate the effect of pharmacist interventions in medications management in general and specific disease states management. The lack of randomization and/or the lack of control group is a major weakness and a threat to internal validity in quasi-experimental designs (Grady et al., 2013). The observed changes could be due to some effects other than the treatment.

Other Quantitative Study Designs

In addition to the common observational, experimental, and quasi-experimental designs described above, there are other designs that are used in pharmacy. These research methods include, but are not limited to, simulated client technique, discrete choice experiments, and Delphi techniques. These methods, which are considered relatively new to pharmacy, are now commonly used in pharmacy practice research. In this chapter, we briefly describe these methods and their application in pharmacy. However, a more detailed description of their components and the nitty gritty of their application in pharmacy practice are available elsewhere within this textbook.

Simulated Client Method

The use of simulated client or simulated patient (mystery shopper) method to assess practices or behaviors in pharmacy practice has received much attention in recent times (Watson et al., 2004, 2006). "A simulated patient is an individual who is trained to visit a pharmacy (or drug store) to enact a scenario that tests a specific behavior of the pharmacist or pharmacy staff" (Watson et al., 2006). A review by Watson et al. demonstrated the versatility and applicability of this method to pharmacy practice research in both developing and developed countries (Watson et al., 2006). The investigators also identified some important characteristics that should be taken into consideration in designing studies that use this technique.

This method can be used to assess wide range of cognitive pharmacy services including counseling and advice provision, treatment of minor ailments, provision of nonprescription medicines, and public health pharmacy, among other things. This method can be a robust and rigorous method of assessing pharmacy practice if used appropriately (Watson et al., 2006; Xu et al., 2012). More recent developments have documented that the simulated patient methods have been used to provide formative feedback in addition to assessing practice behavior of pharmacists and their staff (Xu et al., 2012).

In a case example, a group of investigators evaluated Qatari pharmacists' prescribing, labeling, dispensing, and counseling practices in response to acute community-acquired gastroenteritis (Ibrahim et al., 2016). In another example, the investigators documented the state of insomnia management at community pharmacies in Pakistan (Hussain et al., 2013).

Discrete Choice Experiments

Evidence in healthcare suggests that understanding consumers' preferences can help policy-makers to design services to match their views and preferences (Ryan, 2004). Traditionally, studies to understand patients' and consumers' preferences for pharmaceutical services used opinion or satisfaction survey instruments. Nevertheless, such satisfaction surveys lack the ability to identify the drivers of satisfaction or the relative importance of the different characteristics of the service (Vass et al., 2016). Discrete choice experiments are a novel survey-based method in pharmacy that are predicated on economic theories that allow systematic quantification of preferences to help identify which attributes of a good or service consumers like, the relative value of each attribute, and the balance between the different attributes (Naik Panvelkar et al., 2010; Ryan, 2004; Vass et al., 2016). In-depth description of this method and its essential elements are described in another chapter in the Encyclopedia.

Qualitative Research Designs in Pharmacy Practice

Qualitative research methodology is applied to investigate a problem that has unmeasurable variables, to get a comprehensive understanding of the topic, through discussing it with the involved individuals, and to recognize the natural context in which the investigated issue takes place (Creswell, 2013). The use of qualitative research methodology is becoming increasingly common across diverse health-related disciplines, including pharmacy practice. This is because of its ability to describe social processes and behaviors associated with patients or healthcare professionals, which strengthen the research impact (McLaughlin et al., 2016). Therefore, pharmacy researchers and practitioners need to be better oriented to qualitative research methods (Behar-Horenstein et al., 2018).

In the following section, interpretative frameworks and philosophical orientations, methodologies, data collection and analysis methods, approaches to ensure rigor, and ethical considerations in qualitative research are briefly discussed (Cohen et al., 2013; Creswell, 2013).

Interpretative Framework and Philosophical Assumptions of Qualitative Research

Interpretative Frameworks

Interpretative frameworks are the conceptual structures for comprehension, which form researcher's reasoning and views of truth and knowledge (Babbie, 2015). Different scholars have categorized qualitative research paradigms or interpretative frameworks differently. The following are examples of interpretative framework categories that are used in health science research based on the categorization of Creswell (2013): (1) social constructivism (interpretivism) framework; (2) post-positivism framework; (3) transformative, feminist, critical frameworks and disabilities theories; (4) postmodern frameworks; (5) pragmatism frameworks.

Philosophical Assumptions

Philosophical assumptions are theories and perspectives about ontology, epistemology, axiology, and methodology, which underpin the interpretative frameworks selected by qualitative researchers (Cohen et al., 2013). As with interpretative framework, there are numerous means to categorize the philosophical assumptions that are folded within interpretative framework. The following are explanations of philosophical assumptions based on the categorization of Creswell (2013):

1. Ontological assumptions, which define the nature of reality
2. Epistemological assumptions, which clarify means for knowing reality
3. Axiological assumptions, which explain the role and influence of researcher values
4. Methodological assumptions, which identify approaches to inquiry

It is important that a qualitative researcher understands how interpretative frameworks (e.g., social constructivism, post-positivism, and pragmatic interpretative frameworks) are differentiated because of their underpinning philosophical assumptions (i.e., ontological, epistemological, axiological, and methodological assumptions).

Approaches to Inquiry (Methodology)

It is important that qualitative researchers understand the differences between the characteristics of the five qualitative approaches to inquiry, in order to select an approach to inquiry and attain methodological congruence (Creswell, 2013). The five approaches to qualitative research inquiry are:

a. Narrative research: Describes participants' written and spoken stories about their experiences with a phenomenon being investigated, while considering the chronological connection of the phenomenon's series of events (Anderson and Kirkpatrick, 2016; Creswell, 2013; Czarniawska, 2004).
b. Phenomenological research: Describes the essence of participants' common experiences of a phenomenon, so that the description is a general essence rather than an individual experience (Creswell, 2013; Giorgi, 1997; Moustakas, 1994).

c. Grounded theory research: Aims to generate a theory grounded in participants' data that conceptually explain a social phenomenon, which could involve social processes, or actions or interactions (Creswell, 2013; Strauss and Corbin, 1990; Woods et al., 2016).
d. Ethnographic research: Involves describing the shared patterns of values, behaviors, and beliefs of culture-sharing participants (Creswell, 2013; Harris, 1968; Rosenfeld et al., 2017).
e. Case study research: Provides an in-depth examination of a real-life contemporary phenomenon that researchers cannot change over time, to illustrate the significance of another general topic (Baker, 2011; Creswell, 2013; de León-Castañeda et al., 2018; Mukhalalati, 2016; Yin, 2014).

Data Collection and Analysis Methods in Qualitative Research

1. Data collection methods
   Data collection tools in qualitative research can be categorized into the following fundamental categories (Creswell, 2013):
   a. Observation
   b. Documents
   c. Individual semi-structured interviews
   d. Focus groups (FGs)
   e. Audio-visual materials
   f. Emails chat rooms, weblogs, social media, and instant messaging.
2. Common elements and steps in conducting individual interviews and focus groups
   a. Topic guides: Topic guides guide the discussions in focus groups and individual interviews, and contain open-ended questions and probes, to enable the researcher to understand the complete picture, based on participant views and experiences. They are developed based on the literature review, aim and objectives, research questions, and propositions (Kleiber, 2004).
   b. Audio recording of FGs and interviews: Audio recording of discussions that take place in interviews and FGs is essential for managing and analyzing data, and for increasing the accuracy of data collection and analysis, and ultimately enhancing the dependability and credibility of the research (Rosenthal, 2016; Tuckett, 2005).
   c. Transcription of FGs and interviews recording: Verbatim transcription refers to the word-for-word conversion of oral words from an audio-recorded format into a scripted text format. Transcribing data is considered as the first data reduction step because it generates texts that can be examined and rechecked (Miles et al., 2014; Grossoehme, 2014).
3. Data analysis
   Data analysis comprises several fundamental steps, including reading the transcribed text, arranging data, coding data deductively based on prefigured themes or inductively to produce emergent themes, and then summarizing the codes into themes, and finally presenting the analyzed data as results (Cohen et al., 2013; Crabtree and Miller, 1999; Pope et al., 2000).
   The most commonly used data analysis methods in health science research are:
   a. Thematic analysis
      Thematic analysis is characterized by identifying, analyzing, and reporting themes that are available in the data (Braun and Clarke, 2006; Castleberry and Nolen, 2018).
   b. Content analysis
      Content analysis comprises systematic coding followed by quantification of the analyzed data in a logical and unbiased way (Berelson, 1952; Vaismoradi et al., 2013).
   c. Discourse analysis
      Discourse analysis emphasizes the core format and the structure of texts to examine the assumptions and concealed aspirations behind discourses (Brown and Yule, 1983; Gee, 2004).

Quality Perspectives in Qualitative Research

Qualitative research validation involves ensuring the rigor of the utilized data collection, management, and analysis methods, by utilizing approaches to ensure the quality. In pharmacy practice research, Hadi and Closs (2016a, 2016b) argued that quality in qualitative research topic has not been discussed widely in the literature, and therefore Hadi and Closs (2016a, 2016b) suggested using several trustworthiness criteria to ensure the rigor of qualitative study. The trustworthiness criteria for ensuring quality in qualitative research (Lincoln and Guba, 1985) are:

1. The trustworthiness criteria
   a. Credibility
      This criterion aims to ensure that the results are true and increases the possibility that the conclusions are credible (Cohen and Crabtree, 2008).

b. Dependability
This criterion aims to indicate that the research results are repeatable and consistent, in order to support the conclusions of the research (Cohen and Crabtree, 2008).
c. Confirmability
This criterion aims to confirm the neutrality in interpretation by ensuring that the perspectives of participants, not the bias of researchers, influence the results (Krefting, 1991).
d. Transferability
This criterion involves identifying the contexts to which the study results can be generalized, and indicating if the study conclusions can be applied in similar setting (Yin, 2014).

2. Reflexivity in qualitative research
Reflexivity implies revealing and evaluating the effect and biases that researchers can possibly bring to research process, by explaining the researcher's opinion, feelings, and experience with the phenomenon in question, and explaining the influence of this experience on research methods, findings, and write-ups (Creswell, 2013; Krefting, 1991; Lincoln and Guba, 1985).

Ethical Considerations

Obtaining an ethical approval from the Institutional Review Board (IRB) is required before conducting the qualitative research (Creswell, 2013). The key ethical issues that need to be considered are:

a. Informed consent and participant information leaflet
Informed consent refers to the decision taken by a competent individual to voluntarily participate in a research, after adequately understanding the research. Participant information leaflet is usually distributed to participants before they consent to participate in the research to clarify them the voluntary nature of research participation, the aim and objectives of the research, the rights of the respondents and the potential risks and harms, the data collection, management and storage conditions, and the right of participants to withdraw from the research (Jefford and Moore, 2008).
b. Anonymity and confidentiality
The anonymity is usually ensured by not disclosing names of participants and by utilizing a code system to identify them during data collection, management, analysis, and in the writing up of the research. The confidentiality of participants and data is ensured by using a code system to identify participants, and by storing all data in a locked cabinet and a password-protected computer for a specified period of time (Creswell, 2013).
c. Power relations in qualitative research settings
Power imbalance is caused by the fact that participants have the experience about the investigated phenomenon, and researchers need to obtain information about these experiences. The power imbalance is usually associated with interaction between the researcher and participants during recruitment stage, and during data collection, analysis, interpretation, and validation stages. Hence, researchers should take suitable measures at each stage to decrease the influence of possible power imbalance, and should enhance trust with participants (Karnieli-Miller et al., 2009; Yardley, 2000).

Mixed Methods in Pharmacy Practice Research

Research studies in pharmacy practice usually utilize single-method research designs. However, often these report numerous limitations and may not adequately answer the research question. Therefore, the combination of more than one research method to answer certain research questions has become increasingly common in pharmacy practice research (Ryan et al., 2015). Mixed methods research design is now a popular and widely used research paradigm in pharmacy practice research fields (Hadi et al., 2013, 2014; Hadi and Closs, 2016a, 2016b; Ryan et al., 2015). Mixed methods research allows the expansion of the scope of research to offset the weaknesses of using either quantitative or qualitative approach alone (Creswell et al., 2004; Hadi et al., 2013; Hadi and Closs, 2016a, 2016b; Pluye and Hong, 2014). Typically, qualitative and quantitative data are collected concurrently or sequentially in order to increase the validity and the comprehensiveness of the study findings (Creswell et al., 2004; Hadi et al., 2013; Hadi and Closs, 2016a, 2016b; Pluye and Hong, 2014; Ryan et al., 2015). The mixed method approach provides an expanded understanding of phenomenon under investigation through the comparison between qualitative and quantitative data (Hadi et al., 2013; Hadi and Closs, 2016a, 2016b; Pluye and Hong, 2014).

This section provides an overview and application of mixed method research in pharmacy practice. However, considerations in selecting, designing, and analyzing mixed methods research studies as well as the various typologies of mixed methods research are discussed elsewhere. Johnson et al. (2007) proposed the following definition for mixed methods research: "The type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purpose of breadth and depth of understanding and corroboration."

Mixed methods design allows the viewpoints of participants to be reflected, enables methodological flexibility, and promotes multidisciplinary teamwork (Ryan et al., 2015). Furthermore, the approach allows a more holistic understanding of the research

question. However, its major limitations include: need for wide range of research expertise across the research team members, highly labor-intensive, and the complexity of data integration.

Scholars believe that it is challenging to provide researchers with a step-by-step guide on how to undertake a mixed methods study and that this is driven by the specific research question (Ryan et al., 2015). Nevertheless, the investigator should precisely determine the type of qualitative and quantitative methods to be employed, the order of data collection to be undertaken, the data collection instruments to be used, and the method of data analysis (Ryan et al., 2015). This approach encompasses a synthesis of findings from both quantitative and qualitative components, which is achieved through integration of the findings from each approach (Hadi et al., 2013; Hadi and Closs, 2016a, 2016b; Pluye and Hong, 2014).

Different models or typologies for mixed methods research have been described in the literature. The most common typologies used in pharmacy practice and health services research include: concurrent or convergent parallel design, exploratory sequential design, explanatory sequential design, and the embedded design (Hadi et al., 2013; Pluye and Hong, 2014). Scholars believe that there are several factors to consider when selecting the typology or model of mixed methods research to use. These factors include: the order of qualitative and quantitative data collection (concurrent vs. sequential); priority of data (i.e., which type of data has priority between quantitative and qualitative data); purpose of integration of the data (e.g., triangulation); and number of data strands (Hadi et al., 2013; Pluye and Hong, 2014). In mixed methods research, integration of qualitative and quantitative findings is critical, and this research approach does not simply involve the collection of these data (Ryan et al., 2015).

Summary and Take-Home Messages

- In the era of evidence-based practice, it is not sufficient to propose new pharmacy services or roles without evidence of their benefit.
- New pharmacy services and new roles must be proven to be feasible, acceptable, beneficial, and cost-effective.
- Practice-based research provides such evidence and can inform policy, confirm the value of the new service, and change practice.
- Various study designs, including, but not limited to experimental, quasi-experimental, observational, qualitative, and mixed-methods designs, have been used in pharmacy practice research.
- Pharmacy practice researchers need to be competent in the selection, design, application, and interpretation of these methodological and analytical approaches.
- The choice of any study design in pharmacy practice research is driven by the expertise of the investigator, type of research question or hypothesis, data availability, time orientation, ethical issues, and availability of funding.

Conclusion

There is a great demand for innovation and quality in pharmacy practice. These can be achieved partly through robust and well-designed pharmacy practice research. Pharmacy students, practitioners, educators, and policy-makers are exposed to a variety of research designs and methods. We need to have the best evidence (e.g., in policy, regulation, practice) for making decisions about the optimal research design that ensures delivering an ultimate pharmacy practice and a quality patient care.

Glossary

Pharmacy practice research The Canadian Pharmacists Association defines pharmacy practice research as a component of health services research that focuses on the assessment and evaluation of pharmacy practice (Koshman and Blais, 2011).
Quantitative research Is simply defined as "a research in which things are counted." These things might be people, medicines, opinions, behaviors, etc. "While qualitative research is very useful for describing phenomena in depth (particularly motivations, feelings, understandings), quantitative research can tell us how common and widespread the phenomena are" (Green and Norris, 2015).
Qualitative research Qualitative research within the health sciences has developed as a means to gather an in-depth understanding of human behavior, as well as to find the underlying reasons, attitudes, and motivations that govern such behavior (Kaae and Traulsen, 2015).
Mixed methods research A mixed methods research typically involves both the components of qualitative and quantitative research approaches embedded within a single study or research program for the broad purpose of breadth and depth of understanding and corroboration (Creswell et al., 2004; Johnson et al., 2007; Tashakkori and Creswell, 2007).
Observational studies Observational studies involve merely observing the study subjects in a noncontrolled setting, without investigator intervention or manipulating other aspects of the study in order to determine an association between an exposure and an outcome of interest.

Experimental studies In experimental design (also known as interventional design), the investigator performs an intervention and evaluates cause and effect relationships between exposure to the intervention and an outcome of interest (Cummings et al., 2013). Subjects are typically randomly assigned into experimental and control groups.

Quasi-experimental studies Quasi-experimental designs are studies that aim to evaluate interventions, but that do not use randomization and at times noncontrolled (Harris et al., 2006; Krass, 2016). Similar to true experimental studies, quasi-experiments aim to determine causality between an intervention and an outcome of interest.

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