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Chapter 8

Introduction to quantitative research

Geri LoBiondo-Wood

Learning outcomes

After reading this chapter, you should be able to do the following:

- Define research design.
- Identify the purpose of a research design.
- Define control and fidelity as it affects research design and the outcomes of a study.
- Compare and contrast the elements that affect fidelity and control.
- Begin to evaluate what degree of control should be exercised in a study.
- Define internal validity.
- Identify the threats to internal validity.
- Define external validity.

The word *design* implies the organization of elements into a masterful work of art. In the world of art and fashion, design conjures up images that are used to express a total concept. When an individual creates a structure such as a dress pattern or blueprints for a house, the type of structure depends on the aims of the creator. The same can be said of the research process. The framework that the researcher creates is the design. When reading a study, you should be able to recognize that the literature review, theoretical framework, and research question or hypothesis all interrelate with, complement, and assist in the operationalization of the design (Fig. 8.1). The degree to which there is a fit between these elements and the steps of the research process strengthens the study and also your confidence in the evidence's potential for applicability to practice.

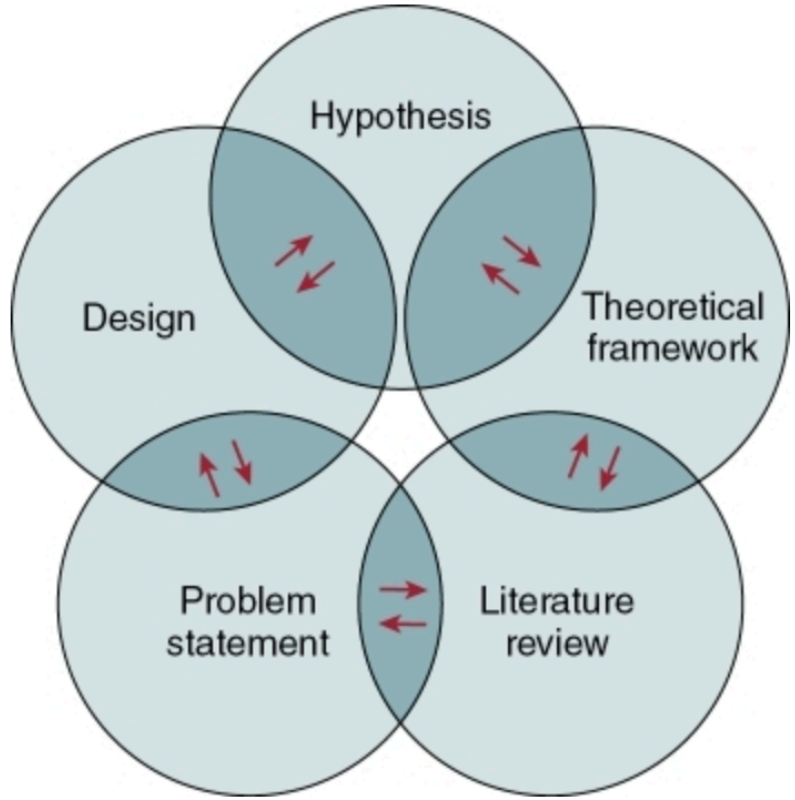


FIG 8.1 Interrelationships of design, problem statement, literature review, theoretical framework, and hypothesis.

How a researcher structures, implements, or designs a study affects the results of a study and ultimately its application to practice. For you to understand the implications and usefulness of a study for evidence-based practice, the key issues of research design must be understood. This chapter provides an overview of the meaning, purpose, and issues related to quantitative research design, and Chapters 9 and 10 present specific types of

quantitative designs.

Research design—purpose

Researchers choose from different design types. But the design choice must be consistent with the research question/hypotheses. Quantitative research designs include:

- A plan or blueprint
- Vehicle for systematically testing research questions and hypotheses
- Structure for maintaining control in the study

The design coupled with the methods and analysis provides control for the study. **Control** is defined as the measures that the researcher uses to hold the conditions of the study consistent and avoid possible potential of **bias** or error in the measurement of the **dependent variable** (outcome variable). Control measures help control threats to the validity of the study.

An example that demonstrates how the design can aid in the solution of a research question and maintain control is illustrated in the study by Nyamathi and colleagues (2015; Appendix A), whose aim was to evaluate the effectiveness of peer coaching, and hepatitis A and B vaccine completion in subjects who met the study's inclusion criteria were randomly assigned to one of the three groups. The interventions were clearly defined. The authors also discuss how they maintained **intervention fidelity** or constancy of interventionists, data-collector training and supervision, and follow-up throughout the study. By establishing the sample criteria and subject eligibility (inclusion criteria; see Chapter 12) and by clearly describing and designing the experimental intervention, the researchers demonstrated that they had a well-developed plan and were able to consistently maintain the study's conditions. A variety of considerations, including the type of design chosen, affect a study's successful completion and utility for evidence-based practice. These considerations include the following:

- Objectivity in conceptualizing the research question or hypothesis
- Accuracy
- Feasibility (Table 8.1)
- Control and intervention fidelity
- Validity—internal
- Validity—external

TABLE 8.1

Pragmatic Considerations in Determining the Feasibility of a Research Question

Factor	Pragmatic Considerations
Time	A question must be one that can be studied within a realistic time period.

Subject availability	A researcher must determine if a sufficient number of subjects will be available and willing to participate. If one has a captive audience (e.g., students in a classroom), it may be relatively easy to enlist subjects. If a study involves subjects' independent time and effort, they may be unwilling to participate when there is no apparent reward. Potential subjects may have fears about harm and confidentiality and be suspicious of research. Subjects with unusual characteristics may be difficult to locate. Dependent on the design, a researcher may consider enlisting more subjects than needed to prepare for subject attrition. At times, a research report may note how the inclusion criteria were liberalized or the number of subjects altered, as a result of some unforeseen recruitment or attrition consideration.
Facility and equipment availability	All research requires equipment such as questionnaires or computers. Most research requires availability of a facility for data collection (e.g., a hospital unit or laboratory space).
Money	Research requires expenditure of money. Before starting a study, the researcher itemizes expenses and develops a budget. Study costs can include postage, printing, equipment, computer charges, and salaries. Expenses can range from about $1000 for a small study to hundreds of thousands of dollars for a large federally funded project.
Ethics	Research that places unethical demands on subjects is not feasible for study. Ethical considerations affect the design and methodology choice.

There are statistical principles associated with the mechanisms of control, but it is more important that you have a clear conceptual understanding of these mechanisms.

The next two chapters present experimental, quasi-experimental, and nonexperimental designs. As you will recall from Chapter 1, a study's type of design is linked to the level of evidence. As you appraise the design, you must also take into account other aspects of a study's design and conduct. These aspects are reviewed in this chapter. How they are applied depends on the type of design (see Chapters 9 and 10).

Objectivity in the research question conceptualization

Objectivity in the conceptualization of the research question is derived from a review of the literature and development of a theoretical framework (see Fig. 8.1). Using the literature, the researcher assesses the depth and breadth of available knowledge on the question (see Chapters 3 and 4), which in turn affects the design chosen. **Example:** ➤ A research question about the length of a breastfeeding teaching program in relation to adherence to breastfeeding may suggest either a correlational or an experimental design (see Chapters 9 and 10), whereas a question related to coping of parents and siblings of adolescent cancer survivors may suggest a survey or correlational study (see Chapter 10).

IPE **HIGHLIGHT**

There is usually more than one threat to internal and external validity in a research study. It is helpful to have a team discussion to summarize specific threats that affect the overall

strength and quality of evidence provided by the studies your team is critically appraising.

Accuracy

Accuracy in determining the appropriate design is aided by a thoughtful theoretical framework and literature review (see Chapters 3 and 4). Accuracy means that all aspects of a study systematically and logically follow from the research question or hypothesis. The simplicity of a research study does not render it useless or of less value. You should feel that the researcher chose a design that was consistent with the research question or hypothesis and offered the maximum amount of control. Issues of control are discussed later in this chapter.

Many research questions have not yet been researched. Therefore, a preliminary or **pilot study** is also a wise approach. A pilot study can be thought of as a beginning study in an area conducted to test and refine a study's data collection methods, and it helps to determine the sample size needed for a larger study. **Example:** ➤ Patterson (2016) published a report of a pilot study that tested the effect of an emotional freedom technique on stress and anxiety in nursing students. The key is the accuracy, validity, and objectivity used by the researcher in attempting to answer the question. Accordingly, when consulting research, you should read various types of studies and assess how and if the criteria for each step of the research process were followed.

Control and intervention fidelity

A researcher chooses a design to maximize the degree of **control**, fidelity, or uniformity of the study methods. Control is maximized by a well-planned study that considers each step of the research process and the potential threats to internal and external validity. In a study that tests interventions (randomized controlled trial; see Chapter 9), **intervention fidelity** (also referred to as **treatment fidelity**) is a key concept. *Fidelity* means trustworthiness or faithfulness. In a study, intervention fidelity means that the researcher standardized the intervention and planned how to administer the intervention to each subject in the same manner under the same conditions. A study designed to address issues related to fidelity maximizes results, decreases bias, and controls preexisting conditions that may affect outcomes. The elements of control and fidelity differ based on the design type. Thus, when various research designs are critiqued, the issue of control is always raised but with varying levels of flexibility. The issues discussed here will become clearer as you review the various designs types discussed in later chapters (see Chapters 9 and 10).

Control is accomplished by ruling out mediating or intervening variables that compete with the independent variables as an explanation for a study's outcome. An **extraneous**, **mediating**, or **intervening variable** is one that occurs in between the independent and dependent variable and interferes with interpretation of the dependent variable. An example would be the effect of the stage of cancer and depression during different phases of cancer treatment. Means of controlling mediating variables include the following:

- Use of a homogeneous sample

- Use of consistent data-collection procedures
- Training and supervision of data collectors and interventionists
- Manipulation of the independent variable
- Randomization

OSEN EVIDENCE-BASED PRACTICE TIP

As you read studies, assess if the study includes an intervention and whether there is a clear description of the intervention and how it was controlled. If the details are not clear, it should make you think that the intervention may have been administered differently among the subjects, therefore affecting bias and the interpretation of the results.

Homogeneous sampling

In a smoking cessation study, extraneous variables may affect the dependent variable. The characteristics of a study's subjects are common extraneous variables. Age, gender, length of time smoked, amount smoked, and even smoking rules may affect the outcome in a smoking cessation study. These variables may therefore affect the outcome. As a control for these and other similar problems, the researcher's subjects should demonstrate **homogeneity**, or similarity, with respect to the extraneous variables relevant to the particular study (see Chapter 12). Extraneous variables are not fixed but must be reviewed and decided on, based on the study's purpose and theoretical base. By using a sample of homogeneous subjects, based on inclusion and exclusion criteria, the researcher has implemented a straightforward method of control.

Example: ➤ In the study by Nyamathi and colleagues (2015; see Appendix A), the researchers ensured homogeneity of the sample based on age, history of drug use, homelessness, and participation in a drug treatment unit. This step limits the **generalizability** or application of the findings to similar populations when discussing the outcomes (see Chapter 17). As you read studies, you will often see the researchers limit the generalizability of the findings to similar samples.

HELPFUL HINT

When critiquing studies, it is better to have a "clean" study with clearly identified controls that enhance generalizability from the sample to the specific population than a "messy" one from which you can generalize little or nothing.

If the researcher feels that an extraneous variable is important, it may be included in the design. In the smoking example, if individuals are working in an area where smoking is not allowed and this is considered to be important, the researcher could establish a control for it. This can be done by comparing two different work areas: one where smoking is allowed and one where it is not. The important idea to keep in mind is that before data are collected, the researcher should have identified, planned for, or controlled the important extraneous variables.

Constancy in data collection

A critical component of control is constancy in data collection. **Constancy** refers to the notion that the data-collection procedures should reflect a cookbook-like recipe of how the researcher controlled the study's conditions. This means that environmental conditions, timing of data collection, data-collection instruments, and data-collection procedures are the same for each subject (see Chapter 14). Constancy in data collection is also referred to as **intervention fidelity.** The elements of intervention fidelity (Breitstein et al., 2012; Gearing et al., 2011; Preyde & Burnham, 2011) are as follows:

- *Design:* The study is designed to allow an adequate testing of the hypothesis (or hypotheses) in relation to the underlying theory and clinical processes
- *Training:* Training and supervision of the data collectors and/or interventionists to ensure that the intervention is being delivered as planned and in a similar manner with all the subjects
- *Delivery:* Assessing that the intervention is delivered as intended, including that the "dose" (as measured by the number, frequency, and length of contact) is well described for all subjects and that the dose is the same in each group, and that there is a plan for possible problems
- *Receipt:* Ensuring that the treatment has been received and understood by the subject
- *Enactment:* Assessing that the intervention skills of the subject are enlisted as intended

The study by Nyamathi and colleagues (Appendix A; see the "Interventions" section) is an example of how intervention fidelity was maintained. A review of this study shows that data were collected from each subject in the same manner and under the same conditions by trained data collectors. This type of control aided the investigators' ability to draw conclusions, discuss limitations, and cite the need for further research. When interventions are implemented, researchers will often describe the training of and supervision of interventionists and/or data collectors that took place to ensure constancy. All study designs should demonstrate constancy (fidelity) of data collection, but studies that test an intervention require the highest level of intervention fidelity.

Manipulation of independent variable

A third means of control is manipulation of the **independent variable**. This refers to the administration of a program, treatment, or intervention to one group within the study and not to the other subjects in the study. The first group is known as the **experimental group** or **intervention group,** and the other group is known as the **control group**. In a control group, the variables under study are held at a constant or comparison level. **Example: ➤** Nyamathi and colleagues (2015; see Appendix A) manipulated the provision of three levels of peer coaching and nurse-delivered interventions.

Experimental and quasi-experimental designs are used to test whether a treatment or intervention affects patient outcomes. Nonexperimental designs do not manipulate the

independent variable and thus do not have a control group. The use of a control group in an experimental or quasi-experimental design is related to the aim of the study (see Chapter 9).

HELPFUL HINT

The lack of manipulation of the independent variable does not mean a weaker study. The type of question, amount of theoretical development, and the research that has preceded the study affects the researcher's design choice. If the question is amenable to a design that manipulates the independent variable, it increases the power of a researcher to draw conclusions—that is, if all of the considerations of control are equally addressed.

Randomization

Researchers may also choose other forms of control, such as randomization. **Randomization of subjects** is used when the required number and type of subjects from the population are obtained in such a manner that each potential subject has an equal chance of being assigned to a treatment group. Randomization eliminates bias, aids in the attainment of a representative sample, and can be used in various designs (see Chapter 12). Nyamathi and colleagues (2015; see Appendix A) randomized subjects to intervention and control groups.

Randomization can also be accomplished with questionnaires. By randomly ordering items on the questionnaires, the investigator can assess if there is a difference in responses that can be related to the order of the items. This may be especially important in longitudinal studies where bias from giving the same questionnaire to the same subjects on a number of occasions can be a problem.

Quantitative control and flexibility

The same level of control or elimination of bias *cannot* be exercised equally in all design types. When a researcher wants to explore an area in which little or no literature and/or research on the concept exists, the researcher may use a qualitative method or a nonexperimental design (see Chapters 5 through 7 and 10). In these types of studies, the researcher is interested in describing a phenomenon in a group of individuals.

Control must be exercised as strictly as possible in quantitative research. All studies should be evaluated for potential variables that may affect the outcomes; however, all studies, based on their design, exercise different levels of control. You should be able to locate in the research report how the researcher maintained control in accordance with its design.

QSEN EVIDENCE-BASED PRACTICE TIP

Remember that establishing evidence for practice is determined by assessing the validity of each step of the study, assessing if the evidence assists in planning patient care, and assessing if patients respond to the evidence-based care.

Internal and external validity

When reading research, you must be convinced that the results of a study are valid, are obtained with precision, and remain

faithful to what the researcher wanted to measure. For the findings of a study to be applicable to practice and provide the foundation for further research, the study should indicate how the researcher avoided bias. Bias can occur at any step of the research process. Bias can be a result of which research questions are asked (see Chapter 2), which hypotheses are tested (see Chapter 2), how data are collected or observations made (see Chapter 14), the number of subjects and how subjects are recruited and included (see Chapter 12), how subjects are randomly assigned in an experimental study (see Chapter 9), and how data are analyzed (see Chapter 16). There are two important criteria for evaluating bias, credibility, and dependability of the results: internal validity and external validity. An understanding of the threats to internal validity and external validity is necessary for critiquing research and considering its applicability to practice. Threats to validity are listed in Box 8.1, and discussion follows.

BOX 8.1

Threats to Validity

Internal validity

- History
- Maturation
- Testing
- Instrumentation
- Mortality
- Selection bias

External validity

- Selection effects
- Reactive effects
- Measurement effects

Internal validity

Internal validity asks whether the *independent variable* really made the difference or the change in the *dependent variable*. To establish internal validity, the researcher rules out other factors or threats as rival explanations of the relationship between the variables—essentially sources of bias. There are a number of threats to internal validity. These are considered by researchers in planning a study and by clinicians before implementing the results in practice (Campbell & Stanley, 1966). You should note that threats to internal validity can compromise outcomes for all studies, and thereby the overall strength and quality of evidence of a study's findings should be considered to some degree in all quantitative designs. How these threats may affect specific designs are addressed in Chapters 9 and 10. Threats to internal validity include history, maturation, testing, instrumentation, mortality, and selection bias. Table 8.2 provides examples of the threats to internal validity. Generally, researchers will note the threats to validity that they encountered in the discussion and/or limitations section of a research article.

TABLE 8.2

Examples of Internal Validity Threats

Threat	Example

History	A study tested an exercise program intervention in a cardiac care rehabilitation center at one center and compared outcomes to those of another center in which usual care was given. During the final months of data collection, the control hospital implemented an e-health physical activity intervention; as a result data from the control hospital (cohort) was not included in the analysis.
Maturation	Hernandez-Martinez and colleagues (2016) evaluated the effects of prenatal nicotine exposure on infants' cognitive development at 6, 12, and 30 months. They noted that cognitive development and intelligence are clearly influenced by environment and genetics and not just by nicotine exposure.
Testing	Nyamathi and colleagues (2015) discussed the lack of treatment differences found in terms of vaccine completion rates possibly due to the bundled nature of the program (see Appendix A).
Instrumentation	Lee and colleagues (in press) acknowledged in a study of obesity and disability in young adults that "our measures of disability are not directly comparable to more traditional measures of disability used in studies of older adults."
Mortality	Nyamathi and colleagues (2015) noted that more than one-quarter (27%) did not complete the vaccine series, despite being informed of their risk for HBV infection (see Appendix A).
Selection bias	Nyamathi and colleagues (2015) controlled for selection bias by establishing inclusion and exclusion participation criteria for participation. Subjects were also stratified using a specific procedure that ensured balance across the three groups (see Nyamathi et al., 2015, Appendix A, Fig. 1).

History

In addition to the independent variable, another specific event that may have an effect on the dependent variable may occur either inside or outside the experimental setting; this is referred to as **history**. An example may be that of an investigator testing the effects of a research program aimed at young adults to increase bone marrow donations in the community. During the course of the educational program, an ad featuring a known television figure is released on television and Facebook about the importance of bone marrow donation. The release of this information on social media with a television figure engenders a great deal of media and press attention. In the course of the media attention, medical experts are interviewed widely, and awareness is raised regarding the importance of bone marrow donation. If the researcher finds an increase in the number of young adults who donate bone marrow in their area, the researcher may not be able to conclude that the change in behavior is the result of the teaching program, as the change may have been influenced by the result of the information on social media and the resultant media coverage. See Table 8.2 for another example.

Maturation

Maturation refers to the developmental, biological, or psychological processes that operate within an individual as a function of time and are external to the events of the study. **Example:** ➤ Suppose one wishes to evaluate the effect of a teaching method on baccalaureate students' achievement on a skills test. The investigator would record the students' abilities before and after the teaching method. Between the pretest and posttest, the students have grown older and wiser. The growth or change is unrelated to the study and may explain the differences between the two testing periods rather than the experimental treatment. It is important to remember that maturation is more than change resulting from an age-related developmental process, but could be related to physical changes as well. **Example:** ➤ In a study of new products to stimulate wound healing, one might ask whether the healing that occurred was related to the product or to the natural occurrence of wound healing. See Table 8.2 for another example.

Testing

Taking the same test repeatedly could influence subjects' responses the next time the test is completed. **Example:** ➤ The effect of taking a pretest on the subject's posttest score is known as **testing**. The effect of taking a pretest may sensitize an individual and improve the score of the posttest. Individuals generally score higher when they take a test a second time, regardless of the treatment. The differences between posttest and pretest scores may not be a result of the independent variable but rather of the experience gained through the testing. Table 8.2 provides an example.

Instrumentation

Instrumentation threats are changes in the measurement of the variables or observational techniques that may account for changes in the obtained measurement. **Example:** ➤ A researcher may wish to study types of thermometers (e.g., tympanic, oral, infrared) to compare the accuracy of using a digital thermometer to other temperature-taking methods. To prevent instrumentation threat, a researcher must check the calibration of the thermometers according to the manufacturer's specifications before and after data collection.

Another example that fits into this area is related to techniques of observation or data collection. If a researcher has several raters collecting observational data, all must be trained in a similar manner so that they collect data using a standardized approach, thereby ensuring interrater reliability (see Chapter 13) and intervention fidelity (see Table 8.2). At times, even though the researcher takes steps to prevent instrumentation problems, this threat may still occur and should be evaluated within the total context of the study.

Mortality

Mortality is the loss of study subjects from the first data-collection point (pretest) to the second data-collection point (posttest). If the subjects who remain in the study are not similar to those who dropped out, the results could be affected.

The loss of subjects may be from the sample as a whole or, in a study that has both an experimental and a control group, there may be differential loss of subjects. A differential loss of subjects means that more of the subjects in one group dropped out than the other group. See Table 8.2 for an example.

Selection bias

If the precautions are not used to gain a representative sample, **selection bias** could result from how the subjects were chosen. Suppose an investigator wishes to assess if a new exercise program contributes to weight reduction. If the new program is offered to all, chances are only individuals who are more motivated to exercise will take part in the program. Assessment of the effectiveness of the program is problematic, because the investigator cannot be sure if the new program encouraged exercise behaviors or if only highly motivated individuals joined the program. To avoid selection bias, the researcher could randomly assign subjects to groups. In a nonexperimental study, even with clearly defined inclusion and exclusion criteria, selection bias is difficult to avoid completely. See Table 8.2 for an example.

HELPFUL HINT

More than one threat can be found in a study, depending on the type of study design. Finding a threat to internal validity in a study does not invalidate the results and is usually acknowledged by the investigator in the "Results" or "Discussion" or "Limitations" section of the study.

EVIDENCE-BASED PRACTICE TIP

Avoiding threats to internal validity can be quite difficult at times. Yet this reality does not render studies that have threats useless. Take them into consideration and weigh the total evidence of a study for not only its statistical meaningfulness but also its clinical meaningfulness.

External validity

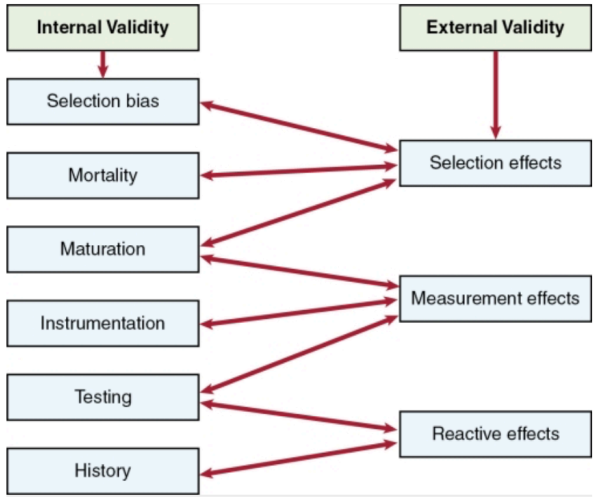
External validity concerns the generalizability of the findings of one study to additional populations and other environmental conditions. External validity questions under what conditions and with what types of subjects the same results can be expected to occur.

The factors that may affect external validity are related to selection of subjects, study conditions, and type of observations. These factors are termed *selection effects, reactive effects,* and *testing effects*. You will notice the similarity in the names of the factors of selection and testing to those of the threats to internal validity. When considering internal validity threats factors as internal threats, you should assess them as they relate to the testing of *independent* and *dependent* variables within the study. When assessing external validity threats, you should consider them in terms of the *generalizability* or use outside of the study to other populations and settings. The internal validity threats ask if the independent variable changed or was related to the dependent variable or if was affected by something else. The Critical Thinking Decision Path for threats to validity displays the way threats to internal and external validity can interact

with each other. It is important to remember that this decision path is not exhaustive of the type of threats and their interaction. Problems of internal validity are generally easier to control. Generalizability issues are more difficult to deal with because they indicate that the researcher is assuming that other populations are similar to the one being tested.

CRITICAL THINKING DECISION PATH

Potential Threats to a Study's Validity



EVIDENCE-BASED PRACTICE TIP

Generalizability depends on who actually participates in a study. Not everyone who is approached actually participates, and not everyone who agrees to participate completes a study. As you review studies, think about how well the subjects represent the population of interest.

Selection effects

Selection refers to the generalizability of the results to other

populations. An example of selection effects occurs when the researcher cannot attain the ideal sample. At times, the numbers of available subjects may be low or not accessible (see Chapter 12). Therefore, the type of sampling method used and how subjects are assigned to research conditions affect the generalizability to other groups, the external validity.

Examples of selection effects are reported when researchers note any of the following:

> • "There are several limitations to the study. At 1 and 3 months' post-death, parents were in early stages of grieving. Thus these findings may not be applicable to parents who are later in their grieving process" (Hawthorne et al., 2016, Appendix B).
> • "The sample size was small, which could have limited the power and obscured significant effects that may have been revealed with a larger sample" (Turner-Sack et al., 2016, Appendix D).

These remarks caution you about potentially generalizing beyond the type of sample in a study, but also point out the usefulness of the findings for practice and future research aimed at building the research in these areas.

Reactive effects

Reactivity is defined as the subjects' responses to being studied. Subjects may respond to the investigator not because of the study procedures but merely as an independent response to being studied. This is also known as the Hawthorne effect, which is named after Western Electric Corporation's Hawthorne plant, where a study of working conditions was conducted. The researchers developed several different working conditions (i.e., turning up the lights, piping in music loudly or softly, and changing work hours). They found that no matter what was done, the workers' productivity increased. They concluded that production increased as a result of the workers' realization that they were being studied rather than because of the experimental conditions.

In another study that compared daytime physical activity levels in children with and without asthma and the relationships among asthma, physical activity and body mass index, and child report of symptoms, the researchers noted, "Children may change their behaviors due to the Hawthorne effect" (Tsai et al., 2012, p. 258). The researchers made recommendations for future studies to avoid such threats.

Measurement effects

Administration of a pretest in a study affects the generalizability of the findings to other populations and is known as **measurement effects**. Pretesting can affect the posttest responses within a study (internal validity) and affects the generalizability outside the study (external validity). **Example:**
➤ Suppose a researcher wants to conduct a study with the aim of changing attitudes toward breast cancer screening behaviors. To accomplish this, an education program on the risk factors for breast cancer is incorporated. To test whether the education program changes attitudes toward screening behaviors, tests are given before and after the teaching intervention. The pretest on

attitudes allows the subjects to examine their attitudes regarding cancer screening. The subjects' responses on follow-up testing may differ from those of individuals who were given the education program and did not see the pretest. Therefore, when a study is conducted and a pretest is given, it may "prime" the subjects and affect the researcher's ability to generalize to other situations.

HELPFUL HINT

When reviewing a study, be aware of the internal and external validity threats. These threats do not make a study useless—but actually more useful—to you. Recognition of the threats allows researchers to build on data, and allows you to think through what part of the study can be applied to practice. Specific threats to validity depend on the design type.

There are other threats to external validity that depend on the type of design and methods of sampling used by the researcher, but these are beyond the scope of this text. Campbell and Stanley (1966) offer detailed coverage of the issues related to internal and external validity.

Appraisal for evidence-based practice quantitative research

Critiquing a study's design requires you to first have knowledge of the overall implications that the choice of a design may have for the study as a whole (see the Critical Appraisal Criteria box).

When researchers ask a question they design a study, decide how the data will be collected, what instruments will be used, what the sample's inclusion and exclusion criteria will be, and how large the sample will be, to diminish threats to the study's validity. These choices are based on the nature of the research question or hypothesis. Minimizing threats to internal and external validity of a study enhances the strength of evidence. In this chapter, the meaning, purpose, and important factors of design choice, as well as the vocabulary that accompanies these factors, have been introduced.

Several criteria for evaluating the design related to maximizing control and minimizing threats to internal/external validity and, as a result, sources of bias can be drawn from this chapter. Remember that the criteria are applied differently with various designs (see Chapters 9 and 10). The following discussion pertains to the overall appraisal of a quantitative design.

The research design should reflect that an objective review of the literature and establishment of a theoretical framework guided the development of the hypothesis and the design choice. When reading a study, there may be no explicit statement regarding how the design was chosen, but the literature reviewed will provide clues as to why the researcher chose the study's design. You can evaluate this by critiquing the study's theoretical framework and literature review (see Chapters 3 and 4). Is the question new and not extensively researched? Has a great deal of research been done on the question, or is it a new or different way of looking at an old question? Depending on the level of the question, the investigators make certain choices.

Example: ➤ In the study by Nyamathi and colleagues (2015), the researchers wanted to test a controlled intervention; thus they developed a randomized controlled trial (Level II design). However, the purpose of the study by Turner-Sack and colleagues (2016) was much different. The Turner-Sack study examined the relationship between and among variables. The study did not test an intervention but explored how variables related to each other in a specific population (Level IV design).

CRITICAL APPRAISAL CRITERIA

Quantitative Research

1. Is the type of design used appropriate?
2. Are the various concepts of control consistent with the type of design chosen?
3. Does the design used seem to reflect consideration of feasibility issues?
4. Does the design used seem to flow from the proposed research question, theoretical framework, literature review, and hypothesis?
5. What are the threats to internal validity or sources of bias?
6. What are the controls for the threats to internal validity?
7. What are the threats to external validity or generalizability?
8. What are the controls for the threats to external validity?
9. Is the design appropriately linked to the evidence hierarchy?

You should be alert for the means investigators use to maintain control (i.e., homogeneity in the sample, consistent data-collection procedures, how or if the independent variable was manipulated, and whether randomization was used). Once it has been established whether the necessary control or uniformity of conditions has been maintained, you must determine whether the findings are valid. To assess this aspect, the threats to internal validity should be reviewed. If the investigator's study was systematic, well grounded in theory, and followed the criteria for each step of the research process, you will probably conclude that the study is internally valid. No study is perfect; there is always the potential for bias or threats to validity. This is not because the research was poorly conducted or the researcher did not think through the process completely; rather, it is that when conducting research with human subjects there is always some potential for error. Subjects can drop out of studies, and data collectors can make errors and be inconsistent. Sometimes errors cannot be controlled by the researcher. If there are policy changes during a study, an intervention can be affected. As you read studies, note how each facet of the study was conducted, what potential errors could have arisen, and how the researcher addressed the sources of bias in the limitations section of the study.

Additionally, you must know whether a study has external validity or generalizability to other populations or environmental conditions. External validity can be claimed only

after internal validity has been established. If the credibility of a study (internal validity) has not been established, a study cannot be generalized (external validity) to other populations. Determination of external validity of the findings goes hand in hand with sampling issues (see Chapter 12). If the study is not representative of any one group or one event of interest, external validity may be limited or not present at all. The issues of internal and external validity and applications for specific designs (see Chapters 9 and 10) provide the remaining knowledge to fully critique the aspects of a study's design.

Key points

- The purpose of the design is to provide the master plan for a study.
- There are many types of designs.
- You should be able to locate within the study the question that the researcher wished to answer. The question should be proposed with a plan for the accomplishment of the study. Depending on the question, you should be able to recognize the steps taken by the investigator to ensure control, eliminate bias, and increase generalizability.
- The choice of a design depends on the question. The research question and design chosen should reflect the investigator's attempts to maintain objectivity, accuracy, and, most important, control.
- Control affects not only the outcome of a study but also its future use. The design should reflect how the investigator attempted to control both internal and external validity threats.
- Internal validity must be established before external validity can be established.
- The design, literature review, theoretical framework, and hypothesis should all interrelate.
- The choice of the design is affected by pragmatic issues. At times, two different designs may be equally valid for the same question.
- The choice of design affects the study's level of evidence.

Critical thinking challenges

- How do the three criteria for an experimental design, manipulation, randomization, and control, minimize bias and decrease threats to internal validity?
- Argue your case for supporting or not supporting the following claim: "A study that does not use an experimental design does not decrease the value of the study even though it may influence the applicability of the findings in practice." Include examples to support your

rationale.

- IPE Have your interprofessional team provide rationale for why evidence of selection bias and mortality are important sources of bias in research studies. As you critically appraise a study that uses an experimental or quasi-experimental design, why is it important for you to look for evidence of intervention fidelity? How does intervention fidelity increase the strength and quality of the evidence provided by the findings of a study using these types of designs?

Go to Evolve at http://evolve.elsevier.com/LoBiondo/ review questions, critiquing exercises, and additional search articles for practice in reviewing and critiquing.

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