Design Decisions in Research

1. Learning Objectives

After reviewing this chapter readers should be able to:

- Describe the steps of the research process and key components of designing a study.
- Explain that the conceptual phase, including a conceptual or theoretical framework, underpins and organizes any research study, quantitative or qualitative.
- Recognize that the study design and methods are further determined by the problem to be examined, purpose of the study, and questions to be answered.
- Understand that rigorous methodological specification, implementation, and control of extraneous variables are necessary for valid and reliable statistical conclusions.
- Recognize that the processes and outcomes of research should be disseminated to appropriate audiences of professionals, policy makers and consumers in order to advance knowledge.

2. Introduction

Health professionals rely on research to improve the delivery and outcomes of health care for individuals, families, and communities. Research must be thoughtfully designed and rigorously conducted to produce accurate and generalizable results. Therefore, it is important for those conducting research to develop expertise in the design and conduct of research.

> The purpose of this chapter is to provide an overview on design decisions to consider when planning a study.

The reader is referred to research textbooks for greater detail on specific designs or methodological challenges pertinent to a particular design (Aday & Cornelius, 2006; Burns & Grove, 2004; Hulley et al., 2006; Pedhazur & Smelkin, 1991; Polit & Beck, 2009).

2. Introduction

Overview of the Research Process

Designing research requires careful consideration of the entire research process, from the development of a research question to dissemination of the results. Polit and Beck (2004) describe 5 phases to the research process: the conceptual phase, the design and planning phase, the empirical phase, the analytic phase, and the dissemination phase (Table 1). This chapter will focus on the first two phases, conceptualizing and planning a study; however, all phases will be described. Design features of quantitative, qualitative, and mixed method research will be addressed.

Table 1: Overview of Research Process

Research Phase	Definition
The Conceptual Phase	Formulating the clinical problem, reviewing the literature, and determining the research purpose
The Design and Planning Phase	Selecting a research design, developing study procedures, determining the sampling and data collection plan
The Empirical Phase	Collecting data and preparing data for analysis
The Analytic Phase	Analyzing the data and interpreting the results
The Dissemination Phase	Communicating results to appropriate audience

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3. The Conceptual Phase

The conceptual phase is the initial phase of research and involves the intellectual process of developing a research idea into a realistic and appropriate research design. This phase can be time-consuming, depending on the level of expertise of the investigator. During this phase, time is spent critiquing the literature on the topic of interest, continually refining and narrowing down the topic until a succinct research problem and purpose have been determined.

A thorough review of the literature needs to be conducted to fully understand:

- The scope and significance of the problem;
- The state of the science; and
- Gaps in the literature.

The existing research on the topic of interest should be critically evaluated for strengths and limitations. Often it is helpful to discuss research ideas with experts in the field too. Reviewing the literature and discussing research ideas with experts will help guide the design of the study. If very little is known about the topic, a descriptive study (qualitative or quantitative) will need to be undertaken. For example, little is know about African American women's beliefs about mental illness. Therefore, a qualitative study to identify African American women's beliefs, coping behaviors, and barriers to seeking mental health services was conducted (Ward, Clark, & Heidrich, 2009). Results of this study have the potential to inform clinical assessment or development of an intervention to address identified barriers.

3. The Conceptual Phase

If there is considerable evidence, but evidence is conflicting or lacks synthesis, an integrative or systematic review may be necessary. For example, numerous health technologies are available for persons with type 1 and type 2 diabetes. A systematic review was conducted to determine the effectiveness of self-monitoring devices related to diabetes, which has the potential to guide practice and future research (Russell-Minda et al., 2009).

The review of the literature will also help to identify the theoretical or conceptual framework of the study. The theoretical framework informs the study organization and allows for results to be generalized to other groups and settings beyond those of the study (Polit & Beck, 2009). Theoretical frameworks are implicit or explicit and identify study variables, propose relationships to be tested, and can guide the intervention protocol for an experimental study (Polit & Beck, 2004). In a study evaluating a coping skills training program for youth with type 1 diabetes, the Adaptation to Chronic Illness model guided the study design by specifying mediating, moderating, and outcome variables (Grey et al., 2009). It is important to mention that qualitative studies are not usually guided by a theoretical framework because the purpose of qualitative research is to describe a phenomenon without a preconceived perspective (ie., phenomenology) or to develop explanatory theory (ie., grounded theory).

To be scientifically meaningful, all variables in a study should be part of a theoretical framework that defines the variable and specifies relationships with other variables (Pedhazur & Schmelkin, 1991).

3. Different Methods

The final step in the conceptual phase of the research process is to specify the research purpose, research questions, and research hypothesis if appropriate. The purpose of a study is a declarative statement that identifies the focus of the study, variables of interest, and the targeted population. There are times that a study may have an overarching purpose with several aims or research questions that will be investigated.

Table 2: Example of Research Purpose

	Example
Research Purpose	To understand the process of integrating type 2 diabetes treatment recommendations into an existing lifestyle.
Research Questions	What are the challenges to integrating type 2 diabetes treatment recommendations into an existing lifestyle? What is the process that adults go through as they attempt to integrate type 2 diabetes treatment recommendations into an existing lifestyle?

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The overall goal of the conceptual phase of the research process is to articulate an important research question that can be developed into a feasible, important, valid, and ethical study design (Hulley et al., 2006).

Stephen Turner, PhD, discusses this phase in more detail in the chapter Theory Development.

4. The Design and Planning Phase

When designing a study, many methodological decisions need to be made that influence the overall quality of the study and the ability to generalize results to other populations. The study design, the sampling plan, data collection procedures, and the data analysis plan all have implications for the quality of the study. Strategies to ensure the ethical conduct of research must also be incorporated into the research plan.

Validity

In quantitative research, validity is a quality criterion that indicates the degree of accuracy of study conclusions (Polit & Beck, 2004). It is important to recognize that numerous variables, in addition to the variables examined in a study, may be influencing the results and thereby posing threats to the validity of conclusions (Pedhazur & Schmelkin, 1991). Anticipating and controlling threats to validity requires careful consideration when designing a quantitative study.
Types of validity include: internal validity, external validity, construct validity, and statistical conclusion validity.

Table 3: Validity Standards in Quantitative Research

	Example
Internal Validity	Extent to which the effects detected in the study are a true reflection of reality rather than the result of some other extraneous factor
External Validity	Extent to which the study findings can be generalized beyond the sample of the study
Construct Validity	The fit between what an instrument is intended to measure and what the instrument actually measures
Statistical conclusion validity	Whether conclusions about relationships or differences drawn from statistical analysis are an accurate reflection of reality

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4. The Design and Planning Phase

Validity

Internal validity, or the degree to which study results are true and can be attributed to the variables measured, is the most important consideration in designing a quantitative study. There are many research strategies to enhance internal validity, including (Pedhazur & Schmelkin, 1991):

- Random selection of study participants;
- Random assignment of participants to groups;
- Inclusion of a control group;
- Modifying sampling criteria; or
- Using statistical analyses to control confounding variables.

For example, in a study in which depressive symptoms may influence the results, the investigator may want to exclude participants who are depressed or the investigator may want to include participants who are depressed and statistically control for this effect on the outcome variable. Both of these strategies would enhance the internal validity of the study.

4. What's Wrong

Maximizing control of the sample, setting, and procedures will enhance internal validity; however, increasing internal validity will limit external validity or the ability to generalize study results to other populations (Pedhazur & Schmelkin, 1991). For example, results of study with a highly homogenous sample may not be generalizable to a sample with different characteristics. Thus, implications of design decisions are considered when planning a study. Is it more important to have a highly controlled study with high internal validity? Or will such a highly controlled study produce results that will not be relevant to clinical practice? An investigator needs to determine if internal validity is of the highest priority or if external validity should also be considered. More on instrument validity is found in the chapter Observational Studies by Richard Berk, PhD.

Exercise 1: Internal and External Validity in Design Decisions

There is often a trade-off between internal validity and external validity with many important design decisions.

1. A researcher plans to recruit a sample of patients by hanging flyers and distributing brochures in a numerous clinical and community settings.

Increase INTERNAL validity | Increase EXTERNAL validity

2. A researcher believes anxiety may have some effect on a treatment for bipolar disorder so she controls for high levels of anxiety in her analyses.

Increase INTERNAL validity | Increase EXTERNAL validity

3. A researcher randomly selects doctors from a physician directory in her city to conduct a survey about external interferences with patient care.

Increase INTERNAL validity | Increase EXTERNAL validity

4. A researcher trains clinicians to provide a behavioral intervention rather than hire a clinician to implement study protocols.

Increase INTERNAL validity | Increase EXTERNAL validity

5. A researcher decides that it is very important to measure blood pressure using sophisticated technology not typically used in the practice setting.

Increase INTERNAL validity | Increase EXTERNAL validity

6. A researcher replicates a study of depression in adults in a different geographical area with a different targeted population.

Increase INTERNAL validity | Increase EXTERNAL validity

4. The Design and Planning Phase

In qualitative research, there are different quality criterion, reflective of naturalistic inquiry aimed at holistically describing or understanding a phenomenon. The most frequently cited validity standards in qualitative research include: credibility, dependability, confirmability, and transferability.

Table 4: Validity Standards in Quantitative Research

	Example
Credibility	Confidence in the truth of the data and interpretations.
Dependability	Stability of data over time and conditions.
Confirmability	Potential for congruence of interpretation between two or more persons.
Transferability	Extent to which findings can be transferred to other settings or groups.

Table previously published in: Whittemore, R. & Melkus, G. (2008). Designing a research study. The Diabetes Educator, 34, 201-216.

The overall goal of qualitative research is to be “descriptively accurate and explicit” and “interpretively rich and innovative” (Polit & Beck, 2004, p. 492). Numerous strategies to enhance validity during sampling, data collection, and data analysis have been proposed (Polit & Beck, 2004; Whittemore et al., 2001). For example, persistent observation will help to ensure exploration of a phenomenon or process in depth, enhancing accuracy or credibility of results. Investigator triangulation, whereby two investigators independently code and analyze data can also enhance credibility. Thus, decisions made in the design and planning phase of qualitative research are also intended to enhance the validity of results.

4. The Design and Planning Phase

The Research Design

The research design is the overall plan for conducting a study that will optimize the ability to achieve the study purpose and obtain accurate results.

Quantitative designs require control, precise measurement, and numerical data to describe, predict, or determine the cause and effect of relationships. Different designs are used depending on the research problem and purpose of the study.

Nonexperimental designs typically describe a phenomenon, compare characteristics of two or more groups, or examine relationships among variables. Methodological research to develop or refine questionnaires often uses nonexperimental designs. In contrast, **quasi-experimental or experimental designs** are used to determine the effect of an intervention and if rigorous in design, provide strong evidence to guide clinical practice (Melnyk & Fineout-Overhold, 2005).

5. The Design and Planning Phase

Qualitative designs examine the subjective experience of a phenomenon or process holistically and thoroughly when little is known about the topic (Polit & Beck, 2004). Different philosophical perspectives have specific methodologies that are employed depending on the research question and investigator preference.

Table 5: Common Qualitative Research Designs

	Example
Phenomenology	To understand the lived experiences of persons.
Grounded Theory	To understand the social and psychological processes that characterize an event or situation.
Ethnography	To describe and interpret cultural behavior.
Critical Theory	To understand how people communicate and how they develop meaning within society; To evaluate how political, cultural, and social orders influence phenomenon; To give voice to oppressed.
Generic	To describe a phenomenon, experience, or situation.

Table previously published in: Whittemore, R. & Melkus, G. (2008). Designing a research study. The Diabetes Educator, 34, 201-216.

4. The Design and Planning Phase

Qualitative designs are flexible and can be changed to optimize the collection of rich and relevant data. Across methodologies, qualitative designs typically include a small sample in order to gain an in-depth understanding of the phenomenon or process of interest. Data collection consists of interviews or field observations and often occurs concurrently with data analysis to inform subsequent sampling and data collection. Rigorous qualitative research can provide important insights into the perspective of persons or the context in which processes occur. David Silverman, PhD, discusses this topic in depth in the chapter Qualitative Methods.

Table 6: Common Qualitative Research Designs

	Definition	Major Characteristics
Non-experimental	Descriptive – describe and/or compare characteristics or prevalence Correlational – to examine relationships among variables Methodological – to develop the reliability and validity of instruments .	Collection of data without any intervention
Quasi-Experimental	To examine the effects of an intervention.	Manipulation (intervention) Missing Characteristic: Control (control or comparison group) AND/OR Randomization (assignment to intervention or control group randomly)
Experimental	To examine the effects of an intervention.	To describe and interpret cultural behavior.

Table previously published in: Whittemore, R. & Melkus, G. (2008). Designing a research study. The Diabetes Educator, 34, 201-216.

4. The Design and Planning Phase

Mixed method research is recognized as another major research approach along with qualitative and quantitative research (Johnson et al., 2007). Mixed method research combines qualitative and quantitative approaches into the methodology of a single study. Mixed method research considers multiple perspectives, collecting data on processes and experiences along with objective data (Teddlie & Tashakkori, 2008). One initial decision in mixed method research is to determine whether the qualitative and quantitative approaches will assume equal status or whether one approach is dominant (Johnson et al., 2007) (See Table 6).

Table 7: Mixed Method

	Definition
Design Status	**Equal status** – each method has equal status in sampling, data collection, and data analysis **Dominant status** – one method is dominant, with the other method providing supplemental data to enhance overall understanding
Design Timing	**Concurrent** – conduct of qualitative and quantitative methods at the same time **Sequential** – conduct of study in 2 phases where one method is completed prior to undertaking the second method

(Johnson et al., 2007)

For example, in a mixed method study evaluating the translation of a diabetes prevention program to primary care, the dominant method was quantitative, evaluating outcomes in an experimental design (Whittemore et al., 2009). Qualitative data were also collected from providers and participants to understand the process of implementation; however, this was not the primary aim of the study (Whittemore et al., 2010). Another design decision of mixed method research is to determine how each method will be implemented, sequentially or

concurrently (See Table 5). In the aforementioned study, quantitative and qualitative data were collected concurrently.

4. The Design and Planning Phase

Identify the population to be studied

In behavioral and social science research, the population to be studied is derived based on the context and problem that will be examined. The population is the entire group of individuals about whom the researcher is interested in gaining knowledge. Because of the multiple background and contextual factors that characterize any given population, the specificity of the research questions delineates the identification of the study population or participants. For example, in a study of urban ethnic minority women, the researcher could delimit the population to a certain ethnic group or if the research problem was one that was related to a broader topic such as gender roles, then perhaps a more diverse group of study participants would be identified. The process of study population delineation and specification leads to the identification of characteristics needed for participation. This is referred to as inclusion and exclusion criteria, which in turn stipulates for whom the results of the study can be generalized (Polit & Beck, 2004).

Exercise 2:

The research purpose should drive decisions about what type of design is used. For each of the following research purposes, determine which design type might be most appropriate.

	Non-Experimental/ Qualitative	Mixed	Experimental
1. A researcher wishes to develop a screening instrument for colorectal cancer and then evaluate its reliability and validity.	☐	☐	☐
2. A researcher wants to determine if a new surgical procedure is more effective than existing ones.	☐	☐	☐
3. A researcher wishes to identify barriers to implementing a new behavioral intervention for treatment of anxiety.	☐	☐	☐

	Non-Experimental/ Qualitative	Mixed	Experimental
4. A researcher plans to evaluate the ability to implement a diabetes prevention program in primary care, examining processes of implementation and outcomes of intervention efficacy.	☐	☐	☐
5. A researcher wants to examine the health behaviors and health outcomes of overweight adolescents over time as they transition to young adults.	☐	☐	☐
6. A researcher wants to understand the experience of older adults when they move to an assisted living community.	☐	☐	☐

4. The Design and Planning Phase

Developing a Sampling Plan

Identification of the study population and related inclusion and exclusion criteria are key components needed for the development of a sampling plan. Because it is impossible to collect data from an entire population of interest, data is collected from a subset of the target population who will be representative of the whole population.

> The **sampling plan** specifies how the sample will be selected and the sample size. Inclusion and exclusion criteria are identified to stipulate the exact characteristics that must be met for a participant to be eligible for inclusion in a study and what exact characteristics would exclude a given participant for study eligibility.

For example, if the purpose of the study is to examine emotional distress in mid-life women who have a new diagnosis of breast cancer, the inclusion criteria would stipulate that potential participants must be within a certain age range that constitutes mid-life and have a new diagnosis based on a defined time frame. More information on sampling is found in the chapter Sample Surveys by Sarah Nusser, PhD and Mike Larsen, PhD.

4. The Design and Planning Phase

The **sampling plan** specifies how the sample will be selected and the sample size. Inclusion and exclusion criteria are identified to stipulate the exact characteristics that must be met for a participant to be eligible for inclusion in a study and what exact characteristics would exclude a given participant for study eligibility.

The same principles apply for specifying inclusion and exclusion criteria whether a researcher is interested in conducting an exploratory, cross sectional descriptive study or a larger prospective repeated measures study.

Often in exploratory, descriptive studies of an understudied phenomenon or population, inclusion/exclusion criteria are more broadly defined in order to understand the factor/s of interest and define for whom and under what conditions it is expressed or exists.

The degree to which there are narrowly defined criteria or broader criteria depends on the nature of the study purpose and research questions to be answered.

4. The Design and Planning Phase

Sampling plans and sample sizes for qualitative and quantitative research designs are very different.

In general, sampling plans for qualitative research are based on identifying persons who would be good informants of the phenomenon under investigation. Sample sizes are typically small (<40) and are based on the principle of data redundancy or saturation. In contrast, quantitative samples are much larger. Samples in quantitative research are determined by a power analysis, which calculates the minimum sample size needed to detect a significant effect with a particular level of confidence (if a significant relationship or difference exists). For longitudinal studies, sample size estimates also need to factor in the potential for attrition over time.

In both qualitative and quantitative designs, considerable thought must go into the determination of the recruitment procedures to obtain the proposed sample. Multiple, culturally relevant recruitment strategies are often necessary, particularly in reaching vulnerable populations (Newlin et al., 2006). Data on recruitment methods, the number of eligible subjects approached, the number enrolled, and the number that completed each phase of the study need to be reported. This information has important implications for data interpretation and is now required when reporting results from randomized clinical trials. The CONSORT (CONsolidated Standards of Reporting Trials) Statement provides recommendations for the reporting of study participants from study entry to completion and a flow chart that illustrates such (Moher, 1998; Consort Statement, 2010).

4. The Design and Planning Phase

Specify data collection methods.

The next aspect of the design and planning phase of a research study is to specify the data collection and analysis procedures. In qualitative research, data sources typically include field observation, interviews, and/or document analysis. The specific research question and the qualitative methodology will direct the qualitative data collection approach. For example, a generic qualitative study on the stressors and meaning of a type 2 diabetes in elders may consist of semi-structured interviews or focus groups. An ethnographic study of barriers and facilitators to healthy food choices in an urban setting among adolescents may involve field observations at schools, homes, and neighborhoods as well as semi-structured interviews with adolescents, parents, and school administrators. As previously mentioned, data collection and data analysis often occur simultaneously so that the data analysis process can guide the sampling and data collection plans (Polit & Beck, 2004). Stephen Woodland discusses this process in detail in the chapter Social Survey Data Collection.

With all qualitative research, data collection procedures need to specify not only the data collection method but also how data will be documented or recorded (ie., audiotaped) and made accessible for analysis (ie., transcribed verbatim).

4. The Design and Planning Phase

In quantitative research, variables of interest are determined from the theoretical or conceptual framework. Data sources that are quantifiable, objective, precise, consistent and reproducible need to be defined. Biophysical data, self-report questionnaires, or observational data is often utilized. The study design will determine the frequency of measures to be collected. For example, if the purpose of a study is to determine the effect of a behavioral intervention for diabetes self-management, specific outcome variables and the frequency of data collection must be specified (D'Eramo Melkus et al., 2010). A biophysical variable may be glycemic control that will be determined by measures of HbA1c using a DCA 2000 auto-analyzer, or column chromatography collected at baseline and following the behavioral intervention at specified time intervals. Similarly, a psychosocial outcome variable may be diabetes-related emotional distress that can be determined by a Likert-type questionnaire such as the Problem Adjustment in Diabetes (PAID) scale (Welch, Weinger, Anderson, & Polonsky, 2003).

Multiple measures of a data source or variable may be obtained, particularly with variables that are difficult to quantify (ie., dietary intake) to insure statistical conclusion validity. This process referred to as **triangulation** is when two or more methods are used to measure a variable.

4. The Design and Planning Phase

All instruments must have evidence of adequate reliability and validity. Instrument reliability refers to the extent to which an instrument consistently measures an attribute, variable or construct. Instrument validity refers to the extent to which the instrument measures what it is intended to measure. The process of instrument validation often requires several sequential studies, which often includes comparison with another similar instrument. For example, a valid questionnaire of physical activity should be highly associated with actual physical activity measured by an actigraph physical activity monitor. Researchers can find reliable and valid instruments that measure variables of interest for a particular study using computer searches and published compendiums (Bradley, 1994; Glasgow, 1997; Jones, 1996; Salek, 1999).

Table 8: Mixed Method

	Definition	Statistical Test
Reliability	The degree of consistency or dependability with which an instrument measures what it is designed to measure.	Reliability coefficient (a correlation coefficient that range from 0 to 1.0) For psychosocial measures, a reliability coefficient of .70 or higher is recommended. For physiological measures, a higher reliability coefficient is recommended.
Validity	The degree to which an instrument measures what it is intended to measure.	Not a single statistical test Numerous techniques are used (ie., evaluating the correlation coefficient of the instrument with a gold standard or testing the instrument in groups anticipated to score high or low on the instrument) Usually takes years to establish validity of an instrument.

Table previously published in: Whittemore, R. & Melkus, G. (2008). Designing a research study. *The Diabetes Educator*, 34, 201-216.

4. The Design and Planning Phase

Finalize the research plan.

Upon completion of the research plan, it is reviewed by any combination of collaborators, consultants, funding agencies, and institutional review boards for scientific merit and ethical procedures. It is imperative that all research involving human subjects be examined by an objective ethical review board whose purpose is to safeguard the welfare of study participants. All participants will need to review and complete an informed consent, documenting their understanding of all procedures, risks, and potential benefits of the study. Protection against coercion that may be used in recruitment strategies is critical, particularly as it may pertain to vulnerable populations such as the elderly; persons with mental illness; women and children; gay, lesbian and transgendered persons; and racial and ethnic minorities to name a few groups. The researchers must also provide rationale for the study population to the extent that it does or does not include women, children, and racial and ethnic minorities.

Ethical conduct and the protection of participant involvement in any study extend to data storage wherein confidentiality and anonymity should be maintained. All study investigators and key personnel should complete the Human Participant Protections Education for Research course offered by the National Institutes of Health, Office of Human Subject Research and also be in compliance with the Health Insurance Portability and Accountability Act (HIPAA).

Sometimes a pilot study is conducted to evaluate potentially difficult aspects of the design and methods, such as how participants are able to complete data collection procedures (examining participant burden) or how an intervention is delivered to make sure that all aspects of the study are feasible and acceptable (O'Donnell et al., 2007).

5. The Empirical Phase

The next phase of the research process is the empirical phase. This involves the collection of data and the preparation of data for analysis. A data collection plan needs to be developed specifying:

- What data will be collected;
- How the data will be collected (i.e., in person, over the phone);
- Who will collect the data;
- How data collectors will be trained; and
- The data collection procedure (i.e., what order forms are filled out, what the interview questions are).

Considerable attention to detail is required in the data collection phase of any research study in order to decrease the introduction of bias and to ensure complete data sets for all participants.

5. The Empirical Phase

If the study design is experimental, data collectors should be **blinded** to participant group assignment to avoid the potential for bias. The researcher also needs to have procedures in place if participants become upset or have any problems with the data collection procedure (particularly when interviewing study participants on potentially difficult experiences).
Often, investigators create an operations manual that describes in detail all study procedures including the data collection plan as well as the sampling plan and recruitment procedures (Bowman, Wyman, & Peters, 2002). An experimental design will also require an intervention protocol that describes the intervention in detail (components, procedures, dosage, and timing), who will deliver the intervention, the training of the interventionist, and procedures to evaluate treatment fidelity. The development of study protocols will allow for a standard approach to the conduct of research within a particular study, enhancing internal validity.

6. The Analytic Phase

In all research, the analytic phase is closely aligned with the empirical phase. After data are collected, the data is prepared for analysis. Quantitative data is typically entered into a statistical software program and qualitative data is often transcribed verbatim to facilitate data analysis. Numerous software programs are available to facilitate qualitative data analysis. Procedures must be in place to ensure the accuracy of this process. For example, quantitative data may be double-entered into two separate databases so that the databases can be compared to identify any errors in the data entry process. Qualitative data is often evaluated for accuracy by comparing audiotapes to transcriptions. For all types of data, data entry and management procedures must also be in place to protect the private health information of participants.

In the analytic phase of all research, patterns and relationships in the data are identified and the research question is answered through the synthesis of numerical and/or narrative data. Descriptive statistics are used to describe the sample characteristics which enhances the interpretation of other analyses. It is important to evaluate the outcome of the sampling plan and determine whether study participants are representative of the larger population in quantitative research and whether participants provided rich data in qualitative research.

6. The Analytic Phase

For quantitative analysis, instruments are evaluated for reliability and validity. Assumptions of statistical tests also need to be evaluated before inferential statistics are completed (Munro, 2004). Often, researchers seek statistical consultation with experts to facilitate data analysis procedures.

For qualitative analysis, transcripts or field notes are reviewed and entered into a database. While different qualitative methodologies specify different data analysis methods; in general, the qualitative data analysis includes reducing data by coding significant statements, identifying themes, and drawing conclusions (Miles & Huberman, 1994). Comparing codes within and across participants, noting patterns and discrepancies, and drawing conceptual maps to examine relationships between themes may also be completed (Polit & Beck, 2004).

Once data is analyzed, results need to be interpreted to determine the meaning and importance of findings. Investigators need to have a critical eye as they interpret study results as all studies have strengths and weaknesses that affect the accuracy of results and the strength of conclusions. Interpretation of research also involves determining clinical, research, and policy implications. More on analysis can be found in the chapter Cluster Unit Randomized Trials by Allan Donner, MSc, PhD.

7. The Dissemination Phase

The last phase of the research process is to prepare research reports in order to communicate findings to the appropriate audience. Similar to review of a final research plan, noted previously, dissemination reports should also be peer-reviewed from independent colleagues in the same field of research who have not participated in the conduct of the study. The peer-review process of completed reports will ensure objectivity and increase likelihood of a valid and reliable report. To be most effective, a dissemination plan should be developed prior to the completion of the study, identifying the strategies for dissemination and the targeted audience. Resources are available that outline creative and effective dissemination plans (Research Utilization Support & Health, 2001). Research reports or presentations may be disseminated to other investigators, health professionals, policymakers, or consumers. A brief research report can also be submitted to professional organizations or the media. Press releases should also be considered, as this offers an efficient mechanism for dissemination. Communicating study results to participants is based on the principle of respect for persons and although not required, is increasing in practice (Shalowitz & Miller, 2008). The stipulation of sending a research report is often included in the consent form that participants sign upon entry to a study. This is an ethical consideration given the time and effort participants contribute to the conduct of a study.

Traditional research reports include:

- an introduction;
- a description of the method;
- results;
- discussion of major findings; and
- clinical, research and/or policy implications.

Brief research or policy reports should provide a concise and interesting description of the results with key points highlighted. Press releases should also be brief with recommendations clearly specified.

7. The Dissemination Phase

Exercise 3:

Identify in which phase each of the following research activities or decisions should occur by selecting the appropriate box.

	Phases				
	Conceptual	Design and Planning	Empirical	Analytic	Dissemination
Telephone interviews will be conducted, with data recorded by the phone interviewer through an electronic data entry form.	☐	☐	☐	☐	☐
A recently published report provides evidence that diets high in fiber result in lowering of cholesterol levels in older adults.	☐	☐	☐	☐	☐
A theoretical model of behavior change comprising appraisal, motivation, and self-efficacy will guide the testing of a diabetes behavioral self-management intervention.	☐	☐	☐	☐	☐
A prospective randomized clinical trial will test hypotheses using comparison groups, alternative treatment conditions and repeated measures.	☐	☐	☐	☐	☐
Consensus panels of experts provide feedback on content of instruments to be used to collect data on health beliefs and attitudes of migrant workers seeking healthcare.	☐	☐	☐	☐	☐
Preliminary findings of a novel treatment for anxiety presented at a national research conference generated much enthusiasm and interest.	☐	☐	☐	☐	☐
Pilot testing of a new therapeutic modality requires a homogenuous sample that meets strict inclusion and exclusion criteria.	☐	☐	☐	☐	☐

8. Summary

An understanding of the research process can guide novice investigators in designing and planning a research study.

All design decisions need to be carefully considered to enhance the overall quality of the research and the applicability of results to healthcare practice or policy.

This chapter provides an overview of the phases of research design, with an emphasis on the first two phases:

- The Conceptual Phase
- The Design and Planning Phase
- The Empirical Phase
- The Analytic Phase
- The Dissemination Phase

This chapter addressed research methodologies including:

- Qualitative
- Quantitative
- Mixed Methods

Further reading on specific designs and methodological challenges is recommended. Many of the topics and methodologies discussed here are discussed in great detail throughout the rest of this anthology.

9. References

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10. Author Biographies

Robin Whittemore, PhD, APRN, FAAN is an Associate Professor at Yale School of Nursing. She has conducted translational research on type 2 diabetes management and prevention. She has additional expertise in the development and testing of internet interventions for youth with type 1 diabetes and youth at risk for type 2 diabetes. Dr. Whittemore also has written numerous methodological papers. She received her BSN from the University of Bridgeport in 1978, a MSN from the University of Connecticut in 1991, and a PhD in nursing from Boston College in 2000.

Dr. Gail Melkus, EdD, C-ANP, FAAN, is the Florence and William Downs Professor in Nursing Research and Director of the Muriel & Virginia Pless Center for Nursing Research at New York University College of Nursing. Dr. Melkus is a nationally recognized expert in diabetes nursing care and research. Her sustained interest in eliminating health disparities among vulnerable populations earned her a reputation as a leader in the development and testing of culturally competent models of diabetes care. Dissemination, replication and translation of her work have contributed to reshaping the delivery of diabetes care. In collaboration with the Diabetes Research & Training Center of the Albert Einstein College of Medicine in New York, Dr. Melkus developed and implemented the first specialty concentration in diabetes care for advanced practice nurses in the country. Dr. Melkus received her undergraduate degree from the University of Bridgeport, masters degree in Community Health from SCSU, and doctoral degree from Teacher's College Columbia University. She is the former Independence Foundation Professor of Nursing at the Yale University School of Nursing.