Clinical Research Methods
in Speech-Language Pathology
and Audiology

Third Edition
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Preface

This book is intended for speech-language pathology and audiology students as well as practicing professionals who wish to learn more about conducting clinical research and its application to the professions. In line with first and second editions of this text, more speech-language pathologists and audiologists are being asked to conduct research due to increased interest in evidence-based practice and demands for accountability.

Revisions to the Third Edition

As with the first and second editions of this text, many of the chapters include a general orientation to research design and statistical analysis, followed by specific discussion of various types of research methods and conclude with a chapter focusing on the acquisition of research grants. Furthermore, the utilization of discussion questions at the end of each chapter functions as a guide to focus learning and prompt further inquiry for the reader.

Major changes for the third edition include the following: (1) includes many references to and quotations from the ASHA and AAA Codes of Ethics (ASHA, 2016 and AAA, 2018); (2) updated list of databases and sources for research in communication sciences and disorders (CSD); (3) examples to follow regarding integration of citations into a literature review; (4) updated discussion of types of qualitative research currently being used; (5) additional and updated examples of qualitative research published in speech-language pathology; (6) expanded discussion of the generalizability of qualitative research; (7) expanded discussion of types of mixed method designs; (8) additional and updated examples of mixed method designs published in speech-language pathology; (9) additional review of textbooks regarding evidence-based practice published in CSD; (10) expanded discussion of the levels of measurement and specific scales of measurement, including the importance of reliability and validity in research; and (11) more than 15 new references regarding grants acquisition and related topics (grant seeking, grant proposal writing, and grant management).
Acknowledgments

The authors of this book thank the publishers who granted with a waiver or reduction in the fees to publish the materials in this book. The authors also want to acknowledge the wonderful mentoring and motivation for this book, Dr. Mary Pannbacker, CCC-SLP, ASHA Fellow. Dr. Pannbacker gave many people the inspiration to achieve above and beyond for the professions of speech-language pathology and audiology. Many of the chapters continue to include her work and ideas. The authors would like to thank the family of Dr. Pannbacker who granted the rights to publish her work in this edition. The staff at Plural Publishing, particularly Nicole Hodges and Valerie Johns, have been very supportive and helpful in the production of and assistance with this third edition of our book.

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Jennifer Whited, PhD, CCC-SLP
# Introduction to Research

## Chapter Outline

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References
Upon completion of this chapter, the reader will be able to:

- Discuss the importance of research to clinical practice
- Describe the historical evolution of research in the professions
- Briefly describe the sources of knowledge used in the professions
- Describe descriptive research including strengths and weaknesses
- Describe exploratory research including strengths and weaknesses
- Describe experimental research including strengths and weaknesses
- Describe survey research including strengths and weaknesses
The vitality and endurance of a profession are dependent on the quantity and quality of its ongoing research programs. The curricula of speech-language pathology and audiology programs traditionally have reserved the study of research methods and responsibilities for advanced graduate training. By that time, students may have developed an attitude of apprehension about research. Sometimes, these attitudes develop into sheer terror. Some academic advisors in programs having a thesis option rather than a requirement have difficulty persuading entering graduate students to consider pursuing a thesis project. By the time the students become informed and confident about doing research, they are so far along in their graduate programs that doing a thesis would delay graduation.

The purpose of this text is to remove the mystery surrounding research by teaching basic principles and providing practice in gathering and summarizing data. It is hoped that this information will be conveyed to students early in their training in an effort to increase the number of research projects conducted by speech-language pathology and audiology students. Once students have developed research skills under the direction of productive faculty, they are more likely to continue the practice as they move into varied professional settings.

There are a number of reasons for doing research in communication sciences and disorders. Short-term or survival objectives for doing research include doing projects to complete one's education or to improve one's job security in an academic setting where tenure and promotion depend on research productivity.

More important reasons for doing research include contributing to the professional pool of knowledge about treatment of clients presenting a variety of communication disorders and maintaining quality clinical services while realizing a sense of professionalism by active involvement in learning through discovery. For the person who enjoys receiving professional recognition along with the opportunity to be creative, satisfy curiosities, and engage in problem solving with a team of colleagues having similar interests, research provides numerous secondary rewards (Pannbacker & Middleton, 1991–1992).

A profession's image is readily enhanced by the integration of research along with the provision of clinical services. This has become more important with an increased emphasis on the use of evidence-based practice. Such practice increases professionalism, accountability to clients and other professionals, and the social relevance of the health services delivered in an economy with increased costs and decreased resources. Clinical research may readily integrate into the assessment, planning, intervention, and evaluation phases of clinical management (Portney & Watkins, 2009). Findley and DeLisa (1990) stress the importance of integrating clinical and research activities for the following reasons. The best clinicians and strongest research are providing clinical services and conducting research. Furthermore, staff training and awareness about new procedures and technology followed by improved client
care are direct results. Both lead to the establishment of a rewarding, stimulating professional environment that contributes to improved staff recruitment and retention.

There is also an ethical reason for accepting the challenge of doing research. The speech-language pathologist or audiologist is frequently asked by clients or their relatives, “Does this treatment really work?” or “Is this hearing aid going to make a difference?” These questions are very difficult to answer ethically and truthfully without controlled research to substantiate an affirmative response. Ferketic (1993) stated, “We can’t ignore the challenge to promote efficacy research. There are many questions to be answered. We all have something to offer and we need to work together to answer the questions. It’s an opportunity to strengthen our professional credibility and viability” (p. 12). Collaboration between researchers and clinicians has been identified as a priority by the American Speech-Language-Hearing Foundation (ASHF) (http://www.ashfoundation.org) and the National Institute on Deafness and Other Communication Disorders (http://www.nidcd.nih.gov). Many members of the American Speech-Language-Hearing Association (ASHA) now utilize the Practice Portal to have an evidence-based resource for assessing and treating a variety of communication disorders (http://find.asha.org/asha?q=Practice%20portal&sort=relevancy). Distinguishing two terms at this point is important. In research, efficacy is the benefit of an intervention plan as compared to a control or standard program. This type of research lets us examine theory and draw generalizations to large populations. Effectiveness in research is defined as the benefits and use of the procedure under “real-world” conditions. Effectiveness involves the expectation that when researchers apply treatments, they do so without being able to control all circumstances (Portney & Watkins, 2000). Understanding the distinction and also the relationship between these two terms helps researchers ask answerable questions that meet the rigor of scientific methods and produce usable results.

**Historical Evolution of Research in Communication Disorders**

During the academic year, 1968 to 1969, Dr. Elaine Pagel Paden began to write a history of the ASHA. In 1970, Paden authored a book that covered the years from 1925 to 1958. This is a summary of the early efforts by the membership to compile completed projects and continue research in speech disorders.

A small group interested in speech disorders met, beginning in 1919, at the annual meeting of the National Association of Teachers of Speech (NATS) and continuing until 1925. Lee Edward Travis reported a study in which he described the effects on phonatory pitch of stutterers and nonstutterers following the firing of a blank pistol at close range without warning. The teachers of public address (public speaking) in attendance were outraged at such inhumane treatment of subjects under investigation. Following this incident, it was decided that a separate organization for individuals interested in researching speech disorders should be established.

In December 1925, the American Academy of Speech Correction was organized by 11 individuals, 5 men and 6 women. Conducting research about speech dis-
orders was one of the three minimal requirements for membership. From the very beginning, the group emphasized the importance of a working, productive organization. The projects initially assigned to the membership were all research in nature. They included establishing the classifications and terminology for the field, summarizing thesis projects in progress, developing bibliographies on topics in speech correction, and investigating topics including stuttering, foreign accent problems, and phonetic description of “careless speech.” Realizing the need for a vehicle for publishing studies in speech correction, the group initially mimeographed 28 studies and made them available for $3.00 each. Having made money on the project, the group continued the practice. The *Journal of Speech Disorders* was established in 1935. The University of Illinois library has in its collection the early issues of this journal.

In the first issue of the new journal, published in 1936, three articles appeared covering the topics of foreign dialect, cleft palate, and stuttering. Also a bibliography covering speech, voice, and hearing disorders was included. Gradually, the journal became less devoted to news items and increasingly dedicated to quality scholarly content. The camaraderie and friendships established among the young energetic contributors with similar professional interests remained. Eventually, the *Journal of Speech Disorders* was renamed the *Journal of Speech and Hearing Disorders*. The majority of articles that appeared in the journal for the first 20 years covered topics on stuttering followed by articles on general topics and therapy and “audiometry.” Also, between 1936 and 1949, the articles were more clinically oriented. In 1950, the journal’s focus shifted to articles with a research orientation, until 1957 when the reverse trend began.

With the explosion of submitted research, the *Journal of Speech and Hearing Research* (JSHR) began publication in 1958. This journal adopted a research orientation, whereas the *Journal of Speech and Hearing Disorders* (JSHD) published research with clinical application. Because individuals working in school settings were interested in clinical applications and felt that neither journal served their needs, another ASHA journal, *Language, Speech, and Hearing Services in Schools* (LSHSS), began publication in 1970.

In an effort to increase the relevance of the ASHA journal program to all members, in 1990, the *Journal of Speech and Hearing Disorders* was divided into two separate publications, and its title was discontinued. Two new journals were initiated. The *American Journal of Audiology: A Journal of Clinical Practice* and the *American Journal of Speech-Language Pathology: A Journal of Clinical Practice* were first published in the fall of 1991. With these changes, both audiologists and speech-language pathologists have subject-specific periodicals in which to publish clinical and experimental research. Supporting research by the ASHA will continue to evolve as the needs of the professions change. In 2004, ASHA took action to develop the Advisory Committee on Evidence-Based Practice (ACEBP). This committee has been charged to address several issues relative to EBP in communication disorders. According to Mullen (2005), ASHA has also established the National Center for Evidence-Based Practice in Communication Disorders (N-CEP). Mullen (2005) stated that ASHA “members will be introduced to the basic principles of EBP and provided with the necessary
support tools to assist them with integrating quality evidence into their practice” (p. 1). Duchan (2006) has developed a website that documents the history of speech-language pathology during the 19th and 20th centuries. The historical review contains numerous references and efforts of various fields on the evolution of research in speech-language pathology. These fields include phonetic studies, brain studies, technology, testing, and child study.

The American Academy of Audiology (AAA) was founded in January 1988 when a group of audiology leaders met. The purpose of the study group was to establish an independent freestanding national organization run by and for audiologists. The AAA published the first edition of the *Journal of the American Academy of Audiology* (JAAA) in 1990 (http://www.audiology.org).

**Sources of Knowledge**

Information used by clinicians and other types of researchers can come from a variety of sources. As consumers of research, we may accept some findings based on tradition, authority, trial and error, and logical reasoning (deductive and inductive). For a summary of these sources, one should consult Portney and Watkins (2009). Each of these sources of knowledge may be limited by a lack of empirical research principles, an unsystematic use of variables, lack of control for critical variables, or stifling of new knowledge and thought.

Research is conducted to answer questions, and it is an increasingly important component in speech-language pathology and audiology, because both basic and clinical questions remain unanswered. In an effort to determine cause-and-effect relationships, researchers conscientiously apply scientific methodology to carefully control variables. Kerlinger (1973) defined the scientific approach as a systematic, empirical, controlled, and critical examination of hypothetical propositions about the association among natural phenomena. Portney and Watkins (2000) assert that the element of control is “the most important characteristic that sets the scientific method apart from the other sources of knowledge” (p. 11). It is important for any researcher to attempt to control factors that are directly related to the variables in question.

Lieske (1986) described the systematic study of a problem or question as a cyclical process beginning with an unanswered question followed by a clear statement of the problem, development of appropriate hypotheses, data collection, and finally interpretation of the information gathered in an effort to accept or reject hypotheses.

Portney and Watkins (2009) caution researchers that the scientific method may have limitations when applied to human behavior. Because humans are unique and capacities vary widely, there will always be some uncertainty regarding the interpretation and generalization of data. It is almost impossible to control for all variables in clinical research. This does not mean that clinicians should allow for less control, but rather that they should recognize that other variables may be happening that could influence results.

**Types of Research**

Classification of research into specific categories is not easy because there are
There is also a lack of agreement about these categories as well as overlap among the various types of research so that specific research projects may fit more than one classification (Ventry & Schiavetti, 1986). Portney and Watkins (2009) view research on a continuum and describe the major categories: descriptive, exploratory, and experimental. Figure 1–1 shows how these types of research may be viewed along a continuum and that some share properties with all three categories (e.g., survey research), whereas others are specific to a particular category (e.g., randomized controlled trials).

**Figure 1–1.** A continuum of research. Adapted with permission from *Foundations of Clinical Research* (2nd ed.) by L.G. Portney and M. P. Watkins, p. 13, Upper Saddle River, NJ: Pearson Education. Copyright 2000 Pearson Education, Inc.
Descriptive Research

Descriptive research is designed to systematically describe situations or events as they naturally occur, in other words, the status of phenomena of interest as they currently exist (Polit & Beck, 2010). It is a type of research in which the distributions of selected dependent variables is observed and recorded (Hegde, 2003). Descriptive research is used to study group differences, developmental trends, and relationships among variables (Schiavetti, Metz, & Orlikoff, 2011). Sometimes this type of research is called normative or developmental research (Hegde, 2003). Developmental research that focuses on changes over time may be cross-sectional, longitudinal, or semi-longitudinal (Maxwell & Satake, 2006; Portney & Watkins, 2009; Schiavetti, Metz, & Orlikoff, 2011; Shearer, 1982). Not all research is developmental in the maturational sense; it may be designed, for example, to study the course of progress for a pathology.

Cross-Sectional Research

Cross-sectional research involves selecting subjects from various age groups and observing differences between the behavior and characteristics of the group. This approach has several advantages: (a) it is less costly and less time consuming than longitudinal research and (b) it is relatively immune to subject attrition. The greatest disadvantage is the possibility that results could be attributable to biased selection of the cross-sectional groups. A variety of terms are used to describe cross-sectional research: disease, frequency, survey, and prevalence study (Rosenfeld, 1991).

Longitudinal Research

Many consider longitudinal research stronger than cross-sectional research because the same group of subjects is followed over time. This approach has the disadvantages of being expensive, time consuming, and vulnerable to subject attrition. Because of these problems, only a small number of subjects can be studied. Synonyms for longitudinal research include cohort study, follow-up study, incidence study, and perspective study (Rosenfeld, 1991).

Semilongitudinal Research

The semilongitudinal approach is a compromise designed to maximize the strengths and minimize the weaknesses of the cross-sectional and longitudinal approaches. This involves dividing the total age span to be studied into several overlapping age spans, selecting subjects whose ages are at the lower edge of each new age span, and following them until they reach the upper age of the span (Schiavetti, Metz, & Orlikoff, 2011; Shearer, 1982).

Historical Research

Historical research, sometimes referred to as archival or library research, is a type of research aimed at establishing facts and relationships about past events (Bordens & Abbott, 1988; Portney & Watkins, 2000). It may summarize a specific topic, sometimes in a type of review article entitled “State of the Art” or “Tutorial.” Tutorial papers have been published about a variety of topics in communication disorders: facilitated communication (Duchan, 1993); and hearing loss, speech, and hearing aids (Van Tassell,
Such papers are often written at the request of a journal editor who wants to present a summary from the viewpoint of a recognized scholar (Shearer, 1982). Shearer (1982) pointed out that “nearly every example of published research contains a miniature library study as part of the introductory section that refers to related research. More extensive reviews of the literature commonly comprise the second chapter of theses and dissertations” (p. 17).

The following characteristics of historical research were identified by Isaac and Michael (1987):

1. Historical research depends on data observed by others rather than the investigator.
2. Historical research must be rigorous, systematic, and exhaustive. Much “research” claiming to be historical is an undisciplined collection of inappropriate, unreliable, or biased information.
3. Historical research depends on two kinds of data: primary sources where the author was a direct observer of the recorded event, and secondary sources where the author reports the observation of others and is one or more times removed from the original event.
4. Two basic forms of criticism weight the value of the data: external criticism, which asks, “Is the document or relic authentic?” and internal criticism, which asks, “If authentic, are the data accurate and relevant?” This critical evaluation of the data is what makes true historical research so vigorous—in many ways more demanding than experimental methods (p. 45).

Case Study Research

Case study research is an intensive study of the background, current status, or environmental interactions of an individual, group, institution, or community (Isaac & Michael, 1987). Most case studies are descriptive studies that examine relationships among different variables or trends over time (Maxwell & Satake, 2006; Polit & Beck, 2010).

The primary strength of case study research is that it may be the only method available for studying some phenomena when few subjects are available or when financial restrictions preclude the use of other types of study (Schiavetti, Metz, & Orlikoff, 2002). In some instances, case studies should be considered pilot studies because they need to be combined with appropriate follow-up studies using larger numbers of subjects having the same phenomena and focusing on specific hypotheses (Isaac & Michael, 1987). Table 1–1 presents several case studies that have been done in communication disorders.

Case studies also have weaknesses. Because of their narrow focus on a few subjects, case studies are limited in their generalizability. Also, case studies are vulnerable to subjective bias. This may happen because the subjects were selected because of dramatic or atypical attributes.

Secondary Analysis

Secondary analysis involves research that uses previously gathered data (Polit & Beck, 2010). It may involve examining unanalyzed variables, testing unexplored relationships, focusing on a specific subsample, or changing the unit of analysis.

Because secondary analysis uses existing data, it has the advantage of reducing
time and cost. It has the disadvantage of little or no control over data collection (Hearst & Hulley, 1988). There is also the possibility that the data are inaccurate.

### Evaluation Research

Evaluation research involves collection and analysis of information related to the effects of a program, policy, or procedure (Hegde, 2003; Polit & Beck, 2010). Four types of evaluation research have been described in the literature: process or implementation evaluation, outcome and impact evaluation, cost-benefit analysis, and comprehensive evaluation. This type of research can be used to ensure compliance with quality assurance policies and third-party payers such as Medicare and Medicaid.

Process or implementation evaluation is designed to answer questions about the function of a program or policy (Polit & Beck, 2010). Typically, this type of research involves intensive examination of a program and often involves collection of both qualitative and quantitative data gathered through interviews.
with clients and staff, observation of the program in operation, and analysis of records related to the program.

A process or implementation evaluation may focus on improving a new or ongoing program. Such an evaluation is sometimes referred to as a formative evaluation. In other instances, the evaluation may be designed primarily so that the program can be replicated by others (Polit & Hungler, 1999).

Outcome and impact evaluation is concerned with the effectiveness of a program. The purpose is to determine whether a program should be discontinued, replaced, modified, continued, or replicated. The evaluation may be referred to as a summative evaluation. An outcomes evaluation is fairly descriptive but does not utilize a vigorous experimental design (Polit & Beck, 2010). Such an evaluation documents the extent to which the goals of the program are achieved and the extent to which positive outcomes result.

Impact evaluation is designed to identify the impact(s) of an intervention, in other words, the impact(s) that can be attributed to the intervention rather than to other factors. Polit and Hungler (1999) believe that impact evaluation usually involves “an experimental or quasi-experimental design, because the aim of such evaluations is to attribute a casual influence to the specific intervention” (p. 200). Hegde (1994) agrees to an extent because he feels that “in some ways, an impact evaluation resembles experimental research. However, in practice, appropriate experimental methods are not used in impact evaluation” (p. 101).

Evaluations that determine whether the benefits of the program outweigh the cost are referred to as cost-benefit analyses. Such analyses are often done in conjunction with impact evaluations (Polit & Beck 2010).

Evaluation research combines process and outcome-impact evaluations, which were previously described. Hegde (2003) believes that comprehensive evaluation is the only truly useful type of evaluation research, because the usefulness of process or impact evaluation is limited. A comprehensive model of evaluation, which includes multiple types of evaluation, was described by Isaac and Michael (1987) and is presented in Figure 1–2. The greatest problem with evaluation research is that it can be threatening to individuals. Even though the focus of evaluation research is on a program, procedure, or policy, people develop and implement the entity. Some people think they or their work are being evaluated. It can also be difficult to determine goals of the program (Polit & Beck, 2010). Often, the objectives of a program are multiple and diffuse.

Exploratory Research

An exploratory researcher examines how one event or events relate to other factors. Correlational research is used to determine possible relationships among factors (Portney & Watkins, 2009). Examples of correlational research include studying the role of home literacy practices and children’s language and emergent literacy skills (Roberts, Jurgens, & Burchinal, 2005), frequency processing in listeners with hearing impairment (Healy, Kannabiran, & Bacon, 2005); and frequency discrimination and literacy skills for children with mild to moderate
sensorineural hearing loss (Halliday & Bishop, 2005).

Correlational Research

Portney and Watkins (2000) state that “predictive research studies are designed to predict a behavior or response based on the observed relationship between that behavior and other variables” (p. 278). For example, predictive studies can be used to study the scores achieved on standardized tests (e.g., Graduate Record Examination) and performance in a graduate program. Predictive research is being used more often in outcomes for making clinical decisions. For example, Daniels, McAdam, Brailey, and Foundas (1997) studied whether risk factors detected in the clinical examination approximated the videofluoroscopic swallow study in the identification of dysphagia severity. They studied six clinical features: dysphonia, dysarthria, abnormal volitional cough, abnormal gag reflex, and cough after an oropharyngeal evaluation, and a clinical swallowing examination.

Case-Control Studies

Case-control studies are done when individuals are selected, whether they have a
particular disorder or not. Cases have the disorder or disease being studied, and controls are chosen because they do not have the disorder or disease (Portney & Watkins, 2009). The researcher may utilize a variety of techniques, including interviews, questionnaires, or chart review, to determine why an individual may or may not have a disorder/disease based on exposure factors. Tallal et al. (2001) conducted a case-control study in which the current language-related ability of all biological, primary relatives (mother, father, siblings) or probands with specific language impairment was studied and compared to matched controls.

Portney and Watkins (2000) suggest that “one advantage of case-control design is that samples are relatively easy to gather. Therefore, case-control studies are useful for studying disorders that are relatively rare, because they start by finding cases in a systematic manner” (p. 325). Case-control studies are typically done for diseases or disorders that have a long latency period.

Cohort Studies

A cohort study is where the “researcher selects a group of subjects who do not yet have the outcome of interest and follows them to see if they develop the disorder” (Portney & Watkins, 2000, p. 328). Cohort studies allow the researcher to follow the temporal sequence of factors that may have impacted the development of a disorder. Grievink, Peters, van Bon, and Schilder (1993) examined the relationship between early otitis media with effusion (OME) and later language ability in a group of children systematically documented with bilateral OME. The children in this study received tympanometry every 3 months, between the ages of 2 and 4, and at age 7, three groups participated in language testing.

Cohort studies can be either prospective or retrospective. If a researcher determines that subjects have already been exposed to risk factors, then the study would be retrospective. If the researcher contacts the subjects before they develop the disorder but after exposure to risk factors, then it would be prospective (Portney & Watkins, 2000).

Experimental Research

In experimental research, the independent variable is controlled to measure its effect on the dependent variables (Shearer, 1982). In other words, experimental research is used to examine possible cause-and-effect relationships by exposing one or more experimental groups to one or more conditions and comparing the results to one or more control groups (Isaac & Michael, 1987). This type of research has also been referred to as the cause-and-effect method, the pretest-posttest control group design, and the laboratory method (Leedy, 1989). The distinguishing feature of experimental research is the experiment and control of the main variables; other types of research do not involve an experiment (Hegde, 2003; Shearer, 1982). Experimental research is considered by many to be the best or most powerful research design, but it is not the only acceptable type of research (Hegde, 2003; Ottenbacher, 1990; Portney & Watkins, 2009). Shearer (1982) points out that the most appropriate type “of research is the one that best fits the problem and the situations available” (p. 10).

The three characteristics of experimental research described by Polit and
Hungler (1999) were: (1) "manipulation—the experimenter does something to at least some of the subjects in the study; (2) control—the experimenter introduces one or more control over the experimental situation, including the use of a control group and (3) randomization—the experimenter assigns subjects to a control or experimental group on a random basis" (p. 152).

Isaac and Michael (1987) have outlined the steps in experimental research (Table 1–2). This outline is useful in understanding experimental research and knowing the procedures that a researcher might utilize.

Hegde (2003) stated, "The strengths of experimental research are the strengths of science itself" (p. 170). It is the most appropriate method for testing hypotheses of cause-and-effect relationships between variables. Experimental research offers greater corroboration than any other type of research in that if the independent variable is manipulated in a certain way, then certain consequences in the dependent variable may be expected to ensue.

### Table 1–2. Seven Steps in Experimental Research

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>1.</td>
<td>Survey the literature relating to the problem.</td>
</tr>
<tr>
<td>2.</td>
<td>Identify and define the problem.</td>
</tr>
<tr>
<td>3.</td>
<td>Formulate a problem hypothesis, deducing the consequences and defining basic terms and variables.</td>
</tr>
<tr>
<td>a.</td>
<td>Identify all nonexperimental variables that might contaminate the experiment, and determine how to control them.</td>
</tr>
<tr>
<td>b.</td>
<td>Select a research design.</td>
</tr>
<tr>
<td>c.</td>
<td>Select a sample of subjects to represent a given population, assign subjects to groups, and assign experimental treatment to groups.</td>
</tr>
<tr>
<td>d.</td>
<td>Select or construct and validate instruments to measure the outcome of the experiment.</td>
</tr>
<tr>
<td>e.</td>
<td>Outline procedures for collecting the data, and possible conduct a pilot or &quot;trial run&quot; test to perfect the instruments or design.</td>
</tr>
<tr>
<td>f.</td>
<td>State the statistical or null hypothesis.</td>
</tr>
<tr>
<td>5.</td>
<td>Conduct the experiments.</td>
</tr>
<tr>
<td>6.</td>
<td>Reduce the raw data in a manner that will produce the best appraisal of the effect which is presumed to exist.</td>
</tr>
<tr>
<td>7.</td>
<td>Apply an appropriate test of significance to determine the confidence one can place on the results of the study.</td>
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</table>

Experimental research has several weaknesses. First, there are many situations in which experimental research cannot be conducted because of ethical or practical considerations (Polit & Beck, 2010; Portney & Watkins, 2009). Another problem with experimental research is the Hawthorne effect. This refers to the effect on the dependent variable caused by changes in subjects' behavior because they know they are participating in a study (Huck, Cormier, & Bounds, 1974; Portney & Watkins, 2000). Despite problems inherent in research, Hegde (2003) believes none of the “weaknesses of experimental research seem to be valid” (p. 169).

**Randomized Controlled Trial**

The basic structure of an experiment involves the pretest-posttest design (Portney & Watkins, 2009). Some researchers (Portney & Watkins, 2009) regard the “gold standard” for clinical research to include the randomized controlled trial (RCT). This involves the experimental group receiving the variable of interest and the control group not receiving any form of treatment. The differences between the two groups, with all other factors being equal or constant, are due to the impact of the experimental variable. In RCT, the assignment of subjects to groups is randomized. An example for the use of RCT by speech-language pathologists includes Roy, Weinrich, Gray, Tanner, Stemple, and Sapienza (2003), who studied three treatments for teachers with voice disorders. Cohen et al. (2005) used RCT when studying 77 children between the ages 6 and 10 and the effects of computer-based intervention through acoustically modified speech (i.e., Fast ForWord; Scientific Learning Corporation, 1998). Portney and Watkins (2009) assert that this design is strong in internal validity, and selection bias can be controlled through random assignment of subjects.

**Quasi-Experimental**

Variations of “true” experimental research are considered quasi-experimental because they have the same degree of experimental control or inferential confidence (Ottenbacher, 1990). This type of research is sometimes referred to as pseudoexperimental or preexperimental (Huck, Cormier, & Bounds, 1974). Quasi-experimental research, like experimental research, involves manipulation of an independent variable but does not have a comparison group or randomization (Polit & Beck, 2010). The two characteristics of quasi-experimental research identified by Isaac and Michael (1987) are: “(1) quasiexperimental typically involves applied setting where it is not possible to control all the relevant variables but only some of them; and (2) the distinction between true and quasiexperimental research is tenuous, particularly where human subjects are involved” (p. 54).

**Sequential Clinical Trials**

The use of sequential clinical trials (SCTs) addresses two concerns often seen with experimental designs. First, an SCT does not require a fixed sample size before the study can begin. Subjects can be added to the study as they become available or develop a disease. Second, a SCT allows for the analysis of data to occur when the subject has completed the trial. Other forms of experimental research
require the collection of the data from the entire sample before data analysis begins (Portney & Watkins, 2009). The use of SCTs has application to the field of speech-language pathology and audiology because it allows for the comparison of a “new” treatment to an “old” treatment. This may address the ethical concerns of true experimental designs being used in clinical research.

**Single-Subject Designs**

Single-subject designs focus on the behavior of one or a few subjects. These designs are also referred to as applied behavioral analysis designs or behavioral analysis, idiographic designs, single-subject experimental designs, single-case designs, intrasubject replication designs, small N-approach, and within-subjects designs. It is misleading to consider any design that uses one or a few subjects as a single-subject design. Designs that use single subjects also can be classified as case studies or single-subject designs (Warren, 1986). Single-subject designs are experimental designs that attempt to establish cause-and-effect relationships (Hegde, 2003).

**Meta-Analysis**

Meta-analysis is similar to secondary analysis, because it also uses previously gathered data. In meta-analysis, statistical techniques are used to compare results across previous studies (Bordens & Abbott, 1988; Cooper, 1993). Meta-analysis by speech-language pathologists and audiologists has included various topics such as clinical outcomes in the treatment of aphasia (Robey, 1998), the efficacy of treatment for children with developmental speech and language delay/disorder (Law, Garrett, & Nye, 2004), and otitis media and language development (Casby, 2001).

Meta-analysis provides a method for integrating and synthesizing research studies and theory development. It involves: (a) identification of relevant variables, (b) location of relevant research to review, and (c) conduction of the meta-analysis (i.e., comparing or combining results across studies) (Bordens & Abbott, 1988). Cooper (1993) identified several problems in meta-analysis, including publication bias, missing information, reliability, independent effect sizes, correlated moderators, and interpreting of effect sizes.

**Survey Research**

Survey research can be used with descriptive, exploratory, and experimental research. Survey research, which is often called sample survey, is designed to provide a detailed inspection of the prevalence of conditions, practices, or attitudes in a given environment by asking people about them rather than observing them directly. Surveys can be classified by the method by which data are obtained: controlled observation, mail questionnaire, panel, personal interview questionnaires, and telephone interviews (Kerlinger, 1973). The most powerful type of survey data is collected through personal interview (Polit & Beck, 2010). This method has the advantage of encouraging subject cooperation, which results in good response rates and a better quality of data (Polit & Beck, 2010). Table 1–3 gives several other advantages. Personal interviews, however, have limitations: they are rather costly and considerable time is required to conduct the interviews. A variety
of formats is used for questionnaires: fill in the blank, multiple choice, true/false, and selecting a number to indicate strength of agreement or disagreement with a specific term. There are a variety of methods that can be used to distribute surveys, including the Internet (e.g., http://www.surveymonkey.com).

The most important component of any survey, regardless of how it is distributed, is the response rate. High response rates are important for at least three reasons: (a) they increase sample size and statistical power, (b) they tend to produce a more representative sample, and (c) they reduce wasted time and materials (Dodd, Boswell, & Litwin, 1988). A response rate of 50% is considered adequate, a response rate of at least 60% is considered good, and a response rate of 70% or more is very good (Babbie, 1973). Shewan (1986) suggests pretesting questionnaires so that potential problems can be identified prior to disseminating them. Answers to the following questions are requested:

- How long did it take you to complete the questionnaire?
- Did you understand the instructions?
- What, if anything, was unclear?
- Did you ever feel forced to make a choice that did not fit your particular situation? If so, on which question(s), and why?
- Were the questions reasonable and appropriate? How, in your judgment, could the questions be improved?

A cover letter should accompany all questionnaires (electronic or paper) briefly explaining the purpose of the survey, conveying researcher's thanks and appreciation for the reply, that the survey has been approved by the appropriate committee or advisor, and offering to provide a summary of the results. Contact information for the researcher should be listed such as telephone number, e-mail, and fax number. A self-addressed envelope should be enclosed for paper questionnaires. There are several resources for conducting surveys (Dillman, 1978;
Surveys have been used to study a variety of topics in speech-language pathology and audiology. Garcia, Chambers, and Molander (2005) surveyed the practice patterns of speech-language pathologists in their use of thickened liquids. Zipoli and Kennedy (2005) utilized a questionnaire to examine attitudes of 240 speech-language pathologists toward use of thickened liquids. Hoffman et al. (2005) utilized the results from a Medicare Current Beneficiary Survey to determine how many respondents over 65 years of age were categorized by level of communication disability.

The use of surveys makes it possible to obtain a great deal of information from a large population (Kerlinger, 1973). Surveys are also economical because of the amount and quality of information they yield. Surveys, however, have a number of weaknesses. First, survey research tends to be relatively superficial; in other words, it does not usually penetrate much below the surface (Kerlinger, 1973; Portney & Watkins, 2000). Second, survey research does not permit cause-and-effect conclusions because of a lack of experimental manipulations (Hegde, 2003; Portney & Watkins, 2000). A third weakness is that surveys tend to be demanding of time and other resources and tend to focus on “soft” (i.e., opinions) dependent variables (Hegde, 2003).

**Summary**

This chapter has provided an introduction to the research process, historical overview of how it evolved during the early years of the professions, review of various sources of knowledge when making clinical decisions, and overview of the scientific method and various types of research. It is important for all readers to understand that this chapter is not complete and exhaustive of all aspects related to research. In subsequent chapters, more information is discussed in greater detail. Although many research projects ask very important and viable questions, it is important to remember: The best research project is one that is done and properly disseminated. Subsequent chapters are designed to guide students through this process so that they can complete a research project that adheres to standards and answers important questions for the professions of speech-language pathology and audiology.

**Discussion Questions**

1. What might be personal, professional, and ethical reasons to conduct research?
2. Differentiate between efficacy and effectiveness. What is used in speech-language pathology and audiology?
3. How did research evolve in the speech-language pathology and audiology professions?
4. What are some sources of knowledge? What might be some problems with these sources?
5. Describe the scientific method. Why is the issue of experimental control difficult for some studies in clinical practice?
6. What are three major types of research? How can these be viewed along a continuum?
7. What is developmental research?
8. Compare cross-sectional, longitudinal, and semilongitudinal research.
9. What are some problems with doing historical research? How might these problems be controlled or resolved?
10. Under what circumstances do researchers tend to use case studies?
11. What are some types of evaluation research? Why might this research be difficult to conduct?
12. Give some examples of exploratory research in speech-language pathology and audiology.
13. What has ASHA done to collect more data using EBP?
14. Compare case-control and cohort studies.
15. What is the distinguishing aspect of experimental research according to Portney and Watkins (2000)?
16. What is considered the “gold standard” for experimental research? Why?
17. Why might sequential clinical trials be valuable to a researcher involved in clinical practice for speech-language pathology or audiology?
18. What are some advantages and weaknesses of meta-analysis?
19. Surveys can be in various formats. Describe the pros and cons of each format.
20. What is considered an “adequate,” “good,” and “very good” response rate to a survey?
21. Describe why a questionnaire should be tested with some subjects prior to dissemination.
22. What are some weaknesses associated with surveys?

References


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2

Ethics of Research in Speech-Language Pathology and Audiology

CHAPTER OUTLINE

Need for Ethical Guidelines
Historical Background
Research Misconduct
Issues in Research Ethics
Planning Research
Confidentiality
Health Insurance Portability and Accountability Act
Informed Consent
Deception
Institutional Approval
Control Groups
Conflict of Interest
Mentoring
Documentation
Referencing Sources
Copyright
Authorship
Peer Review
Publication Correction
Evidence-Based Practice
American Academy of Audiology
American Speech-Language-Hearing Association
Sanctions for Ethical Misconduct
Institutional Review Board
Teaching Research Ethics
Content
Methods
Current and Future Issues
Summary
Discussion Questions
References
Appendix 2–A
Appendix 2–B
Upon completion of this chapter, the reader will be able to:

- Explain the need for ethical research
- Trace the historical background of ethics in research
- Define responsible conduct of research and research misconduct
- Apply ethical principles to research
- Identify and avoid research misconduct
- Compare the AAA and ASHA Codes of Ethics related to research
- Identify content and methods for teaching ethics
- Explain current and future issues related to research ethics
Research requires knowledge about scientific methods as well as the responsible conduct of research. The proliferation of research in speech-language pathology and audiology has increased interest in research ethics. Research requires careful consideration of ethical issues. The American Academy of Audiology (AAA) and American Speech-Language-Hearing Association (ASHA) provide information about the responsible conduct of research. Both the AAA (2018) and ASHA (2016) Codes of Ethics have guidelines, principles, and rules related to research in ethics. The Codes of Ethics for these organizations are in Appendices 2–A and 2–B.

This chapter discusses the major ethical issues related to research.

Historical Background

There is a long history of research misconduct. Meline (2006) described ethical abuse as early as the first century BC. There has been considerable interest in research ethics since the Nazi medical experiments of the 1930s and 1940s. The Nazi research used prisoner of war and “racial enemies” in studies to test the limits of human endurance and human response to disease and untested drugs. The studies were unethical because “participants” were exposed to permanent physical harm, even death, and not given an opportunity to refuse participation (Polit & Beck, 2010).

There have been numerous reports about unethical research involving humans in the United States. This research has involved surgical experiments, exposure to pathogens, disease, radiation, chemicals, drugs, and psychological experiments. A historical summary of this research is in Table 2–1. There is limited information about the long-term adverse effects of this research; there is limited information about unethical research in speech-language pathology and audiology except for the Tudor study in 1939. It was not until the 1970s and beyond that researchers in the United States considered informed consent and the risks and benefits of research (Horner & Minifie, 2011a). Limited attention has been given to the use of animals in research (Horner & Minifie, 2011a). Relevant issues included the emergence of humane treatment of animals, animal welfare versus animal rights, and evolving regulations and guidelines for animal research. It is noteworthy that the ASHA Code of Ethics did not include protection of animals until 2003.

Need for Ethical Guidelines

Research has not always been conducted ethically. Also, there has been inadequate training in the responsible conduct of research. Currently, ethical issues related to research have high visibility because of past ethical transgressions, such as lack of informed consent, unfavorable risk-benefit ratio, and use of vulnerable populations, such as children, students, and prisoners. Furthermore, ethical standards have changed over time. Previously, specific protection of human subjects did not exist, and ethical standards were considerably more lax than today. Last, ethical considerations have not always been given adequate attention. In the following section, the historical reasons for the development of ethical guidelines are considered.
### Table 2–1. Chronologic Listing of Unethical Research in the United States 1840–1972

<table>
<thead>
<tr>
<th>Year(s)</th>
<th>Investigators/Site</th>
<th>Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgical Experimentation:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1840s</td>
<td>Dr. J. Marion Sims</td>
<td>Surgical experiments on enslaved African women without anesthesia; operated on one woman 30 times</td>
</tr>
<tr>
<td>1874</td>
<td>Dr. Robert Barthlow Good Samaritan Hospital</td>
<td>Treated Irish women servant for cancer; cut open head and inserted needle electrodes into exposed brain</td>
</tr>
<tr>
<td>1896</td>
<td>Dr. Arthur Wentworth Boston Children’s Hospital</td>
<td>Performed spinal taps on 29 children without parental consent</td>
</tr>
<tr>
<td>1913–1951</td>
<td>Dr. Leo Stanley San Quentin Prison</td>
<td>Experiments on 100s of prisoners; many involved testicular implants</td>
</tr>
<tr>
<td><strong>Pathogens, Disease, and Biological Agents:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1880s</td>
<td>California physician Hawaii Hospital for Lepers</td>
<td>Injected 12 young girls under 12 with syphilis</td>
</tr>
<tr>
<td>1895</td>
<td>Dr. Henry Heiman</td>
<td>Infected two mentally disables boys, 4 and 16, with gonorrhea</td>
</tr>
<tr>
<td>1900</td>
<td>U.S. Army doctor Philippines</td>
<td>Infected 5 prisoners with bubonic plague; induced beriberi in 29 prisoners</td>
</tr>
<tr>
<td>1906</td>
<td>Professor Richard Strong Harvard University</td>
<td>Infected 24 Filipino prisoners with cholera; all became sick and 13 died</td>
</tr>
<tr>
<td>1908</td>
<td>3 Researchers St. Vincent Hospital, Philadelphia</td>
<td>Infected dozens of children with TB causing permanent blindness or painful lesions and inflammation of eyes</td>
</tr>
<tr>
<td>1909</td>
<td>C. Knowles</td>
<td>Infected 2 children at orphanage</td>
</tr>
<tr>
<td>1911</td>
<td>Dr. Hideyo Noguchi Rockefeller Institute for Medical Research</td>
<td>Injected 146 patients, some children, with syphilis</td>
</tr>
<tr>
<td>1932–1972</td>
<td>U.S. Public Health Service Tuskegee, AL</td>
<td>400 improvised black males with untreated syphilis</td>
</tr>
<tr>
<td>Year(s)</td>
<td>Investigators/Site</td>
<td>Subjects</td>
</tr>
<tr>
<td>---------</td>
<td>-------------------</td>
<td>----------</td>
</tr>
<tr>
<td>1941</td>
<td>Dr. Francis and Jonas Salk University of Michigan</td>
<td>Infected patients at several hospitals with influenza virus</td>
</tr>
<tr>
<td>1941</td>
<td>Dr. William C. Black</td>
<td>Inoculated 12-month-old with herpes</td>
</tr>
<tr>
<td>1943–1970</td>
<td>Statesville Penitentiary Joilet, IL University of Chicago Medical School U.S. Army and State Department</td>
<td>Effects of malaria on 441 prisoners</td>
</tr>
<tr>
<td>1944–1946</td>
<td>Dr. Alf Alving University of Chicago Medical School</td>
<td>Infected psychiatric patients with malaria</td>
</tr>
<tr>
<td>1946</td>
<td>Guatemala U.S. Public Health Service National Institute of Health Pan American Health Sanitary Bureau</td>
<td>Used prostitutes to infect prisoners, psychiatric patients, and Guatemalans with syphilis and other sexually transmitted diseases</td>
</tr>
<tr>
<td>1950</td>
<td>U.S. Navy</td>
<td>Sprayed large quantities of bacteria over San Francisco, CA; numerous pneumonia-like illnesses; killed at least one.</td>
</tr>
<tr>
<td>1950</td>
<td>Dr. Joey Stokes University of Pennsylvania</td>
<td>Infected 200 female prisoners with viral hepatitis</td>
</tr>
<tr>
<td>1952</td>
<td>Chester M. Southam Sloan-Kettering Institute</td>
<td>Injected live cancer cells into prisoners at the Ohio State Prison, half were black, other half were not</td>
</tr>
<tr>
<td>1955</td>
<td>CIA</td>
<td>Released whooping cough bacteria from boats outside Tampa Bay, FL, caused epidemic: killed at least 12</td>
</tr>
<tr>
<td>1956–1957</td>
<td>U.S. Army</td>
<td>Released millions of infected mosquitoes on Savannah, GA, and Avon Park, FL; hundreds affected</td>
</tr>
</tbody>
</table>

*continues*
### Table 2–1. continued

<table>
<thead>
<tr>
<th>Year(s)</th>
<th>Investigators/Site</th>
<th>Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>1962</td>
<td>Chester M. Southam</td>
<td>22 elderly patients injected with live cancer cells</td>
</tr>
<tr>
<td></td>
<td>Jewish Chronic Disease Hospital Brooklyn, NY</td>
<td></td>
</tr>
<tr>
<td>1966</td>
<td>U.S. Army</td>
<td>Released <em>Bacillus globigis</em> into subways of New York and Chicago</td>
</tr>
</tbody>
</table>


There has been little discussion of ethical misconduct in speech-language pathology and audiology except for the Tudor study, which was conducted in 1939 at the University of Iowa. Twenty-two normally fluent children were taught to stutter (Annett, 2001; Dyer, 2001; Yairi & Amrose, 2001). These children were orphans at the Soldiers and Sailors Orphan’s Home in Davenport, Iowa. The study was a master’s thesis conducted by a graduate student, Mary Tudor, and directed by Wendell Johnson. Ambrose and Yairi (2002) reviewed the Tudor study and concluded that there were “fundamental flaws in its design and execution” (p. 201). They also indicated that their assessment of related ethical issues “should be viewed within the common standards of the period that there is no evidence of intent to harm, and that the objective in increasing disfluent speech should not be confused with instilling chronic stuttering in normally fluent children” (p. 201). Obviously, such a study would not be permitted under current ethical standards. Ambrose and Yairi (2002) believe that “in spite of the controversy regarding the Tudor thesis, there is no question that Johnson’s contribution to the study of stuttering remains very significant in many positive ways” (p. 201). Conversely, Silverman (1988a) reviewed the study and stated that “The implications of the findings seem clear—asking a child to monitor his speech fluency and attempt to be more fluent can lead to increased disfluency and possibly stuttering” (p. 231). Goldfarb (2006) edited a comprehensive review of the Tudor study and current ethical issues in clinical research. Johnson stated that the Tudor study ethics compare favorably not only to the standards of its own time in 1939 but to those of 2000 as well.

It is also important to know about the history of the responsible conduct of research. Horner and Minifie (2011a) provided a detailed chronology of the major documents relevant to the responsible conduct of research pertaining to human and animal experimentation.
Research misconduct is relatively rare in speech-language pathology and audiology, although it has increased over the past several years. Horner and Minifie (2011c) noted that “the actual prevalence of misconduct is unknown.” Data from the Office of Research Integrity (2007, 2010) indicate an increase in research misconduct among public health service researchers. A possible increase in research misconduct may be related to a number of factors, such as greater attention to responsible conduct of research, awareness and knowledge of research misconduct, and the publish or perish culture. It is possible that junior employees may bear the burden for sanctions for scientific misconduct.

Research misconduct in any form not only threatens to undermine the progress and public support for science, but it also has the potential to cause harm to those who receive the erroneous treatment. Those involved in research must specifically address these issues (Society for Clinical Trials, 2004).

Research misconduct involves fabrication, falsification, or plagiarism in proposing, performing, reviewing, or reporting research. It does not include honest error or differences of opinion. Fabrication is making up data or results and recording or reporting data for experiments that were never conducted. Falsification of data is probably rare (Knapp & Van de Creek, 2006). It involves manipulating research materials, equipment, or processes, or altering data or results, such that the research is not accurately represented in the research record. The research record includes, but is not limited to, research proposals, laboratory records, progress reports, abstracts, theses, dissertations, oral presentations, and journals. Plagiarism is the use of another person’s ideas, procedures, results, or words without giving appropriate credit. It has been further defined as stealing someone else’s work and using it for personal gain. Plagiarism can relate to the theft of ideas as well as text (Association of American Medical Colleges, 1994). In recent years, plagiarism has become more problematic because of the proliferation of documents available on the Internet (Knapp & Van de Creek, 2006). Furthermore, some sources offer to sell papers on specific topics or prepare them for a fee.

Self-plagiarism is duplicate submission or publication. Duplicate/previous submission means that the manuscript is simultaneously being considered for publication elsewhere. It is essentially publication of the same content by the same author(s) (Bennett & Taylor, 2003; JAMA, 2006).

Research misconduct is a significant failure to adhere to prevailing, professional standards, and is considered a violation of the AAA (2018) and ASHA (2016) Codes of Ethics. Seriousness of research misconduct ranges from obvious to subtle. Several forms about research misconduct have been identified (ASHA, 2008; Bailar, 1995; Sales & Lavin, 2000). Examples of research misconduct are listed in Table 2–2.

Reporting research misconduct is the responsibility of every speech-language pathologist and audiologist. This is a responsibility of both practicing professionals and students. However, students may be in an especially awkward situation for fulfilling this responsibility. Practicing professionals and students should be aware of AAA (2018) and ASHA
Ethical issues and problems related to research were identified and discussed by Hoit (2005). These three issues were self-plagiarism, conflict of interest, and authorship. For each ethical dilemma, a resolution was provided, also issues and Ethical Principle and Rule, and concept. Ethical misconduct in audiology and speech-language pathology has increased. This can be verified by reviewing the ASHA Leader which published sanctions for ethical misconduct of its members. According to the Office of Research Integrity (2010), ethical misconduct among Public Health Service research has increased from 163 in 1993 to 286 in 2010. Reynolds (2004) reported that “junior employees may bear the burden of sanction for scientific misconduct” (p. 509). The most frequent sanction was the requirement for a plan of supervision. Furthermore, research misconduct frequently involved all members of the

<table>
<thead>
<tr>
<th>Table 2–2. Examples of Research Misconduct</th>
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</thead>
<tbody>
<tr>
<td>Arbitrary or biased selection of data</td>
</tr>
<tr>
<td>Bias in manuscript</td>
</tr>
<tr>
<td>Censorship</td>
</tr>
<tr>
<td>Coercion</td>
</tr>
<tr>
<td>Conflict of interest</td>
</tr>
<tr>
<td>Cyber-cheating</td>
</tr>
<tr>
<td>Data recycling</td>
</tr>
<tr>
<td>Deception</td>
</tr>
<tr>
<td>Duplicate publication</td>
</tr>
<tr>
<td>Dual relationships</td>
</tr>
<tr>
<td>Exploitive supervision</td>
</tr>
<tr>
<td>Failure to comply with guidelines for handling research misconduct</td>
</tr>
<tr>
<td>False representation of manuscript</td>
</tr>
<tr>
<td>Forging of academic documents</td>
</tr>
<tr>
<td>Fragmented publication</td>
</tr>
<tr>
<td>Ghost authorship</td>
</tr>
<tr>
<td>Honorary authorship</td>
</tr>
<tr>
<td>Improprieties of authorship</td>
</tr>
<tr>
<td>Inadequate maintenance of records</td>
</tr>
</tbody>
</table>
research team and not solely those at the doctoral level.

Research misconduct in any form threatens not only to undermine scientific progress and public support for science, but also to cause harm to those who use the possible erroneous outcome(s) of this research. Those involved in research must specifically address this issue (Society for Clinical Trials, 2004).

Three types of legal perspectives have influenced selection of sanctions for research misconduct: (a) quasicontractual legal remedy of restitution; (b) philosophy of “just desserts” or retribution based on an intuitive idea that the individual who engages in criminal conduct deserves punishment; and (3) deterrence of misconduct (Dresser, 1993).

Consequences for research misconduct include article retraction, private lawsuits, adverse personal actions, and administrative, civil, and criminal sanction. The names of individuals guilty of research misconduct are listed in a federal database and published in federal print materials (Horner & Minifie, 2011c).

**Planning Research**

Speech-language pathologists and audiologists design, conduct, and report research in accordance with recognized standards for ethical conduct of research. Research is planned so as to minimize the possibility that results will be misleading. Planning ethically responsible research involves application of basic ethical principles (beneficence, respect, and justice) to research activities, which are described in Table 2–3 (Sieber, 1992). In planning research, speech-language pathologists and audiologists consider the AAA (2018) and ASHA Code of Ethics (2016). If an ethical issue is unclear, speech-language pathologists and audiologists seek to resolve the issue through consultation with institutional review boards, the AAA and ASHA Boards of Ethics, or other resources, such as the Publication of the American Psychological Association Manual (APA, 2010). Speech-language pathologists and audiologists take reasonable steps for ethical treatment of all those associated with the research: human and animal subjects, collaborators, assistants, students, and employees.

Ethical issues that may arise during a study should be considered early; that is, these issues should be considered before writing the research proposal (Creswell, 2003). These issues relate to all phases of research and include research sites and potential readers.
Confidentiality

Speech-language pathologists and audiologists have the ethical responsibility to maintain confidentiality in research activities including mentoring, reviewing manuscripts or research grants, consulting, or participating in research (Knapp & Van de Creek, 2006; Lansing, 2002; Lansing & Moss, 2003). Upholding participants’ rights to confidentiality and anonymity is a central tenet of research. Speech-language pathologists and audiologists should also be aware of situations where they have access to confidential ideas, such as hearing ideas during an informal conversation. Maintaining confidentiality in peer review is an ethical responsibility, because a manuscript is a privileged communication and represents confidential information (Macrina, 1995c). Reviewers of manuscripts have the ethical responsibility to maintain confidentiality. Speech-language pathologists increasingly are using the Internet for online experimentation, and chat rooms, and e-mail for collecting research data. This raises new issues of confidentiality and informed consent that will probably require further consideration of existing codes of ethics (Meline, 2006).

Confidentiality is included in the ASHA (2016) Code of Ethics and is mentioned in Principle of Ethics 1, Rule P, which states, “Individuals shall protect the confidentiality of any professional or personal information about persons served.
professionally or participants involved in research and scholarly activities and may disclose confidential information only when doing so is necessary to protect the welfare of the person or the community, is legally authorized, or is otherwise required by law” (p. 5). The AAA (2018) Code of Ethics also addresses confidentiality in Principle 3, “Members shall maintain the confidentiality of the information and records of those receiving services or involved in research” (p. 1).

The Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act (HIPAA) has had an impact on research practices (Horner & Wheeler, 2005). Research involving the use of protected health information must adhere to both HIPAA’s privacy rule and the U.S. Department of Health and Human Services’ Common Rule. Information about both of these documents can be found in the U.S. Code of Federal Regulations.

HIPAA protects health coverage for workers and their families, provides standards for transmission of health care records and identification of providers, health care plans, and employer. It also addresses security and privacy (confidentiality of health care data). Although the Act was passed in 1996, the regulations (standards) were not implemented until 1999 (Cornett, 2007).

Many aspects of HIPAA are relevant to research. The standards related to research are privacy, security, de-identification, and enforcement.

The Privacy Rule is intended to prevent using or disclosing individually identified health information without consent (Horner & Wheeler, 2005). Ness (2007) believes the intent of the Privacy Rule is “to strike a balance between protecting the privacy of individual’s identifiable health information and prescribing the legitimate use and disclosure of this information” (p. 2164).

The Privacy Rule addresses the use and disclosure of all protected health information, including paper and electronic, that is related to the individuals' past, present, and future health conditions, treatment for these conditions, and financial history related to health care. A covered entity is a health plan, a health care clearinghouse, or a health care provider that transmits any health care information electronically in connection with a covered transmission (Horner & Wheeler, 2005). HIPAA compliance is required for all covered entities (Romanow, 2011).

Researchers are required to disclose certain information to all research participants. This information includes the following:

- Description of protected health information to be used or disclosed, identifying information in a meaningful, specific way
- Names or other detailed identification of the person(s) authorized to make the requested use of disclosure
- Names or other detailed identification of the person(s) to whom the covered entity can make a requested use or disclosure
- Description of every purpose of the requested use or disclosure
- Authorization expiration date
- Signature of participants and date (Horner & Wheeler, 2005)
The Security Rule applies only to the protection of electronic health care information. It requires covered entities to meet three standards. The standards for compliance are administration, physical, and technical (Wikipedia, n.d.). Administrative standards are related to policies and procedures designed to describe how the entity complies with HIPAA. Physical refers to controlling physical access to content against inappropriate access to protected health information. Technical standards involve controlling access to computer systems and enabling covered entities to protect communication containing protected health information transmitted electronically over open networks from being intercepted by anyone other than the intended receiver.

De-identification of health information refers to individually identified information in which all individually identified information is removed. As an alternative to removing all individual identifiers, a researcher may use statistical methods to reduce the possibility that information will identify research participants (Horner & Wheeler, 2005).

The Enforcement Rule became effective in 2006. This rule established penalties for HIPAA violation related to civil violations and compliance. These violations and penalties are shown in Table 2–4.

There are possible changes in HIPAA related to privacy, business associates, and enforcement (Romanow, 2011). The privacy changes are related to the covered entity making a reasonable effort to resolve payment issue(s) prior to sending protected health information to the health plan. Business associates would be required to enter into a contract or their agreements with a subcontractor(s) to protect the security of electronic pro-

<table>
<thead>
<tr>
<th>Violation</th>
<th>Minimum Penalty</th>
<th>Maximum Penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual unknowingly violated HIPAA</td>
<td>$100 per violation</td>
<td>$50,000 per violation</td>
</tr>
<tr>
<td></td>
<td>$25,000 annual maximum</td>
<td>$1.5 million annual maximum</td>
</tr>
<tr>
<td>Reasonable cause, not due to willful neglect</td>
<td>$1,000 per violation</td>
<td>$50,000 per violation</td>
</tr>
<tr>
<td></td>
<td>Annual maximum</td>
<td>$100,000 for repeated violations</td>
</tr>
<tr>
<td></td>
<td>$100,000 for repeated violations</td>
<td></td>
</tr>
<tr>
<td>Willful neglect but violation corrected within required time period</td>
<td>$10,000 per violation</td>
<td>$50,000 per violation</td>
</tr>
<tr>
<td></td>
<td>$250,000 annual maximum</td>
<td>$1.5 annual maximum</td>
</tr>
<tr>
<td>Willful neglect not corrected</td>
<td>$50,000 per violation</td>
<td>$50,000 per violation</td>
</tr>
<tr>
<td></td>
<td>$1.5 million annual maximum</td>
<td>$11.5 million annual maximum</td>
</tr>
</tbody>
</table>

tected health information. The proposed enforcement change addresses civil penalties, complaints, and compliance review. The civil monetary penalty will make a covered entity liable for acts of business associates, which may require covered entities to conduct due diligence. Penalty(s) will also consider previous indications of violations, not just previous violation(s). The secretary of health and human services will attempt to resolve complaints when possible, but (Romanow, 2011) may directly proceed to formal enforcement without attempting informal resolution.

HIPAA has had considerable impact on research. Several obstacles have been identified in the peer-reviewed literature (Dunlop, Graham, Leroy, Glanz, & Dunlop, 2007; Horner & Wheeler, 2005; Ness, 2007; Nosowsky & Giordano, 2006; O’Herrin, Fost, & Kudon, 2004; Wipke-Tevis & Pickett, 2008; Wolf & Benett, 2006). These obstacles to research include but are not limited to time, delay, cost, subject recruitment and retention, less user friendly, informed consent, and restricted use of databases. Some of the obstacles can be reduced by better education about HIPAA; researchers are working more closely with health care providers, and considering the role of researchers in health care (Gunn et al., 2004; Nosowsky & Giordano, 2006). Furthermore, Gunn and associates (2004) provided suggestions for reducing the negative impact of HIPAA on research. These suggestions include using de-identified health information or a limited dataset; requiring the covered entity to develop authorization forms for requesting protected health information; if authorization is impractical, seeking an institutional review board/privacy board waiver; and/or being famil-
the ASHA (2005), the key components of informed consent are respect for participants, benefits, and justice.

Informed consent requires that prospective participants sign a consent form. Obtaining informed consent may be complicated for several reasons: the most appropriate method of obtaining informed consent may not be clear, the competency of the patient is in doubt, participants are vulnerable because they are not competent to make an informed decision about participation, and circumstances make participants feel that free choice is constrained, or circumstances increase their risk for harm. Children, adults with diminished cognitive ability, and individuals residing in institutions (nursing homes or prisons) are especially vulnerable. A major barrier to informed consent is problems with reading comprehension. Almost half the population in the United States reads at or below the eighth-grade level, and some have little or no reading skills (Meline, 2006). Furthermore, special accommodations are needed for participants from different cultures, ethnic, and socioeconomic groups to avoid misunderstanding. In addition, special accommodations are needed for individuals who are blind, deaf, or hard-of-hearing to ensure comprehension of informed consent.


Informed consent is usually considered as a means for protecting the rights of research participants (Silverman, 1998b). It also protects the rights of researchers and the institutions where the research is done. Informed consent provides researchers and institutions with some protection from research participants of alleged physical or mental harm.

Deception

One ethical issue that has been debated is the appropriateness of using deception (Mertens, 2005). The justification for deception is that the results of the study should be compromised without it because participants would modify their behavior if they knew what was being studied. Deception is supposed to be reduced by debriefing, misrepresentation, guaranteeing privacy, and obtaining fully informed consent.

Institutional Approval

Speech-language pathologists and audiologists should obtain prior approval for conducting research and provide accurate information about their research proposals (APA, 2010). The research should be conducted consistent with the approved research protocol and consultation with the Institutional Review Board (IRB) as needed. Many journals require information about the IRB status of a research report, including the name of the IRB and approval number.

Control Groups

The use of control groups has been a long-standing ethical issue. The most effective design for determining the effect of treatment is to compare subjects who
receive treatment with those who receive no treatment or a sham treatment (Portney & Watkins, 2009). It is unethical to withhold treatment, that is, the control group should receive treatment (French, Reynolds, & Swain, 2001). Waiting list control groups are selected from persons on the waiting list for treatment. Furthermore, there is no basis for assuming that no treatment and waiting list control groups are equivalent (Lum, 2002).

Conflict of Interest

ASHA’s Board of Ethics (ASHA, 2011) defines conflict of interest as

A situation in which personal and/or financial considerations have the potential to influence or comprise judgment in any clinical service, research, consultation, instruction, administration, or any other professional entity (e.g., clinical service, research, consultation, instruction, administration, etc.), or where the situation may appear to provide the potential for professional judgment to be compromised. (p. 1)

Both the AAA (2018) and ASHA (2016) Codes of Ethics address conflicts of interest. The AAA (2018) Code, Rule 4c, indicates that “Individuals shall not participate in activities that constitute a conflict of professional interest.” ASHA’s Code of Ethics (2016) states that speech-language pathologists and audiologists “shall avoid engaging in conflicts of interest whereby personal, financial, or other considerations have the potential to influence or compromise professional judgment and objectivity.” Speech-language pathologists and audiologists should also avoid the appearance of a conflict of interest, although there may not be an ethical violation. Appearance of a conflict of interest can damage the professional reputation of an individual and adversely affect his or her practice and profession (Diefendorf, 2003).

Conflicts of interest involve bias or influencing professional judgment or practice. Some conflicts of interest are obvious, whereas others may be subtle. These conflicts can be intellectual (non-financial) or financial and interfere with research conduct or reports. Examples of intellectual conflicts in interest include, but are not limited to, ego, professional advancement, and beliefs (Ludlow, 2001). Financial conflicts include support for research, large honorariums, patents, agreements with industry, and product-oriented research. Scientific conflicts of interest are the use of position to influence publication of manuscripts and review of grant applications (Bradley, 1995).

Conflict of commitment is another aspect of conflict of interest. Also referred to as dual loyalty or dual commitment, it refers to conflicting demands or speech-language pathologists and audiologists who have obligations to their patients and to others, including students and other professionals (Beyrer, 2003). Multiple roles also can contribute to conflicts of interest (Sales & Lavin, 2000). Multiple roles are not unethical as long as they are not reasonably expected to have adverse effects. Speech-language pathologists and audiologists should be cautious about multiple roles. Guidelines and procedures for addressing personal and professional loyalty, Dual Loyalty and Human Rights in Health Professional Practice, have been developed by the International Dual Loyalty Working Group (2002).
Disclosure is often cited as the key to managing conflicts of interest (Association of American Medical Colleges, 1994; Korn, 2000). ASHA journals require disclosure of any real or potential conflict of interest that could be seen as having an influence on the research, such as financial interests in a test or procedure, and funding by an equipment or materials manufacturer for efficiency research. In 2012, submission for the ASHA convention required a disclosure statement.

There are new disclosure requirements for presentation of courses offered for ASHA continuing education credits (ASHA, 2012). These requirements are as follows:

- Presenters must disclose financial or nonfinancial interest
- Focus on one method or device must indicate if information given about similar products
- Focus must be on science or contemporary practice, not on sales or promotion
- Should not favor or use, promote, or purchase product
- Acknowledge if presenting limited or no information about similar products or services
- Disclose relevant financial and nonfinancial relationships or lack of attendees in each session

Accurate outcome research aimed at assessing the efficacy of clinical services is essential to speech-language pathology and audiology. Product-oriented research increases the risk for conflict of interest (Sininger, March, Walden, & Wilber, 2004). Responsibility for conducting product efficacy research should be independent of the development and production of these products.

**Mentoring**

Mentoring is an important part of teaching research. Mentees not only learn scientific expertise from their mentors, but also learn about the reasonable conduct of research, preparing grant applications, interacting with colleagues, and preparing manuscripts for publication (Association of American Medical Colleges, 1994). Unfortunately, sometimes the roles and responsibilities of mentees and mentors are misunderstood. On one hand, the mentee may believe his or her role is passive, not active, and the mentors are responsible for the work. On the other hand, the mentor may view the mentee as inexperienced labor. Therefore, it is important to understand the roles and responsibilities of both mentees and mentors.

Students usually select their mentor based primarily on which faculty member has research interests that most closely relate to their interests. Other factors that may be considered in selecting a mentor include the publication record of the faculty member, extramural financial support, national recognition, productivity of the department, atmosphere within the department, current positions of graduates, and opportunities for professional growth (Association of American Medical Colleges, 1994; Macrina, 1995a).

Both mentees and mentors should know what to expect from each other. It is reasonable for mentees to have expectations about the support and advice a mentor can provide. Mentors also have expectations, such as the mentee will work independently and will be enthusiastic about the work.

Supervision is essential to maintaining and facilitating research integrity. Speech-language pathologists and audiologists often have dual roles as both
mentor and supervisor to students whom they also teach in class. It has been suggested that misunderstanding can be avoided by written agreement outlining the responsibilities of both mentor and mentee. The agreement should also include authorship consideration, as well as the amount and type of supervision. It has been suggested that mentors set up periodic and specific meetings to provide mentees feedback, and maintain a record of supervision, including meeting times, issues discussed, and duties assigned.

Several problems related to mentoring have been identified by Horner and Minifie (2011b). Among these problems were continued dependency, disparities of power, inadequate accountability, vulnerable subordinates, and failure to give appropriate credit. Recommendations for improving mentoring have been described by Shamoo and Resnick (2003). These recommendations included acknowledging mentors for effective mentoring, developing guidelines for amount and types of responsibilities and intellectual property, ensuring appropriate response to whistleblowing, establishing procedures for evaluating mentees, promoting adverse and non-discriminatory environment safe from harm, and providing mentors with time for mentoring.

Documentation

Documentation is crucial to research (Macrina, 1995b). Documentation includes IRB approval, informed consent forms on all participants, participant encounters, research protocol, data collection and analysis, and research reports. Confidentiality is a major consideration in creating, storing, accessing, transferring, and disposing of records. According to the AAA (2018) Code of Ethics, “Individuals shall maintain accurate documentation of services rendered, according to acceptable medical, legal, and professional standards and requirements.” The ASHA (2016) Code of Ethics also addresses maintenance of records in Principle of Ethics I Rule O (see Appendix 2–B).

Referencing Sources

The AAA (2018) Code of Ethics has no specific reference to publication credit or authorship. The 2016 ASHA Code of Ethics states, “Individuals shall reference the source when using other person’s ideas, research, presentations, or products in written, oral, or any other media presentations or summary.”

Accurate and appropriate referencing of information even in slides and handouts prevents the appearance of plagiarism. Referencing of sources in ASHA journals is based on recommendations and guidelines of the Publication Manual of the American Psychological Association (APA, 2010). Speech-language pathologists and audiologists must accept the ethical responsibilities for appropriate referencing of sources.

Stealing ideas, plagiarism, or both, is an issue at all levels of education and has increased over the past 10 years (Young, 2003). Plagiarism is not giving credit to someone’s ideas, results, or words. Plagiarism can take many forms and ranges from very obvious to very subtle. Some plagiarism involves direct verbatim copying of text or the text can be modified in ways that are not immediately recognizable from the source material (Association of American Medical Colleges, 1994). Other forms of plagiarism
include lazy writing and redundant or duplicate publications. Lazy writing or patchwork plagiarism involves overreliance on direct quotations. Duplicate of self-plagiarism is repeated publication of previous results (Benninger, 2002). Duplicate publication is also inappropriate, because ASHA journals require that submitted manuscripts have neither been previously published nor are currently under review elsewhere. In addition, information about any previous presentation of the data, whether at a professional meeting or in conference proceedings, book chapters, websites, or related media must be disclosed. Duplicate publications may also contribute to misrepresentation of publication credit, that is, a distorted in accurate record. Failure to acknowledge the contributions of colleagues, collaborators, or others, whether deliberate or not, can be viewed as a form of plagiarism (Association of American Medical Colleges, 1994). The widespread use of the Internet makes using information without acknowledging the source(s) easier. Cyber-cheating or online plagiarism enables cut and paste plagiarism and online paper mills. Plagiarism frequently occurs as a result of ignorance about appropriate referencing. Ignorance is not an excuse for plagiarism. This can be avoided by learning and using guidelines for referencing sources such as the Publication Manual of the American Psychological Association (APA, 2010). Suspected plagiarism can be identified by Google’s search engine for scholarship (http://scholar.google.com).

Copyright

Copyright is a legal concept protecting exclusive rights, usually for a limited time, of the creator of intellectual work. The American Medical Association (1998) defined copyright as providing “for the protection of rights of parties involved in the creation and dissemination of intellectual property” (p. 115). The Copyright Act of 1976 is a comprehensive law related to permission for quoting, reproducing, or adapting published or unpublished information (American Psychological Association, 2010). Requirements for obtaining copyright permission vary. It is the author’s responsibility to find out if permission is required from the copyright holder.

Exceptions from copyright permission are fair use and public domain (Blessing & Forister, 2012). Fair use provides for limited use of copyrighted materials. According to Horner and Minifie (2011b) fair public domain applies to materials that can be used without permission but must be acknowledged. Additional information about copyright is available in Silverman’s (1999) Professional Issues in Speech-Language Pathology and Audiology.

Copyright infringement is the use of published or unpublished information without permission. In other words, it is unauthorized use of information, which includes computer software and programs published since 1976 (Blessing & Forister, 2012). Illegal copying of materials is not uncommon in educational and clinical activities. Test forms are often duplicated without authorization.

Authorship

Authorship is the basis by which university faculty are evaluated for employment, promotion, and tenure. Those faculties who do not publish may not be promoted or tenured. Therefore, these
faculties may feel pressure to publish. Some faculty, however, believe publishing detracts from teaching and that resources and time are not available for publishing.

In addition to promotion and tenure, there are other advantages in publishing research, such as staying current in professionally obtaining funds for research, networking, and collaborating with other professionals.

Authorship credit can be a problem because of the prevalence of honorary and ghost authorship as well as academia's competitive “publish or perish” (Bennett & Taylor, 2003; Macrina, 1995c; Mowatt et al., 2002). The different types of irresponsibilities are described in Table 2–5.

Several studies have confirmed that a substantial portion of authors listed in multiauthored publications did not meet criteria for authorship (Bennett & Taylor, 2003; Goodman, 1994; Mowatt et al., 2002; Shapiro, Wagner, & Shapiro, 1994). Some individuals who do not meet the criteria for authorship may be included, or individuals who should be included as authors are omitted. Honorary or courtesy authorship is naming as an author an individual who does not meet authorship criteria. Ghost authorship is failure to name as an author an individual who has made substantial contribution that merits authorship or an unnamed individual who participated in writing the manuscript. Students are at greater risk for not being given credit.

### Table 2–5. Irresponsible Authorship: Types and Definitions

<table>
<thead>
<tr>
<th>Types</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coercion</td>
<td>Use of intimidation or bullying to gain authorship. The white bull effect.</td>
</tr>
<tr>
<td>Courtesy</td>
<td>Author who does not meet authorship criteria. Same as Gift, Guest, or Honorary.</td>
</tr>
<tr>
<td>Denial</td>
<td>Failure to include or acknowledge individual(s) who should be included as author. Same as Ghost or Silent author.</td>
</tr>
<tr>
<td>Duplicated</td>
<td>Publishing the same paper more than once. Sometimes referred to as self-plagiarism.</td>
</tr>
<tr>
<td>Gift</td>
<td>Same as Courtesy, Guest, or Honorary</td>
</tr>
<tr>
<td>Guest</td>
<td>Same as Courtesy, Gift or Honorary</td>
</tr>
<tr>
<td>Honorary</td>
<td>Same as Courtesy, Gift, or Guest.</td>
</tr>
<tr>
<td>Mutual support</td>
<td>Agreement by two or more authors to place each other’s name on publication to give appearance of higher productivity. May or may not meet authorship criteria. Depending on the later may be a type of Courtesy, Gift, Guest, or Honorary.</td>
</tr>
<tr>
<td>White bull</td>
<td>Coercion or intimidation to obtain authorship</td>
</tr>
</tbody>
</table>

for authorship. Furthermore, students should be the principal author on any multiple-authored presentation or publication that is substantially based on the student’s thesis or dissertation (Knapp & Van de Creek, 2006). Mere possession of an institutional position, such as Department Chair, does not justify authorship (APA, 2010). AAA's (2005a) guidelines for ethical practice address issues related to authorship in publication and presentation of research, such as disclosure to avoid potential conflicts of interest and determination of authorship. ASHA’s (2016) Code of Ethics provides some guidance about authorship: “Individuals shall assign credit only to those who have contributed to a publication, presentation, or product. Credit shall be assigned in proportion to the contribution and only with the contributor’s consent” (ASHA 2016, P-IV, R-J). The ASHA journal requires corresponding authors to affirm that all individuals listed in the byline have made appropriate contributions for authorship, have consented to the byline order, and have agreed to the submission of the manuscript in its current form. These contributions are outlined in Table 2–6.

The American Medical Association (2006) specifies three criteria for authorship: (a) substantial contributions to conception and design or acquisition of data, or analysis or interpretation of data; (b) drafting or revising the manuscript; and (c) final approval of the version to be published. Other responsibilities of an author include critical review and revision of manuscript; statistical expertise; administrative, technical, or material support, and study supervision (Mowatt et al., 2002; Yedidia et al., 2003).

The order of authorship also warrants consideration, because disagreement about authorship can be very bitter and even result in legal action (Gabard & Martin, 2003; Kwok, 2005). Order of authorship should be in descending order based on level of contribution, with the greatest contribution(s) made by the first author. However, the order of authors may be considered relative to an author’s university affiliation, because some universities only consider first-author publications in determining promotion, tenure, and merit increases.

Journals do not have uniform criteria for designating authorship. For example, the ASHA (2011) requires that a statement about authorship accompany manuscript submission. Specifically, this affirms that all of the authors have made contributions appropriate for authorship. Furthermore, “the primary author is responsible for assuring that the list of authors includes all and only those persons who have played significant roles in writing the manuscript, designing the study, preparing and executing the plan for data collection, and or interpreting the results in preparation for publication” (p. 4).

Some journals, such as the Journal of the American Medical Association, pub-

<table>
<thead>
<tr>
<th>Table 2–6. Author Contributions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study concept and design</td>
</tr>
<tr>
<td>Acquisition data</td>
</tr>
<tr>
<td>Analysis and interpretation of data</td>
</tr>
<tr>
<td>Drafting of the manuscript</td>
</tr>
<tr>
<td>Critical revision of the manuscript for important intellectual content</td>
</tr>
<tr>
<td>Obtained funding</td>
</tr>
<tr>
<td>Administrative, technical, or material support</td>
</tr>
<tr>
<td>Study supervision</td>
</tr>
</tbody>
</table>
lished the author contribution between the last section of a paper or report and the references.

**Peer Review**

Peer review has been a part of the scientific process for over 300 years, and researchers probably have complained about its shortcomings for nearly as long (Laine & Murlow, 2003). Peer review is the process by which the quality of research is assessed, and it involves multiple activities (Association of American Medical Colleges, 1994). First, there is the peer review of research proposals to assess the scientific merit of grant applications, that is, funding decisions based on peer review. Second, professional journals and other publications use peer review to assess the quality of manuscripts, namely, publication decisions based on peer review. Thus, it is obvious that peer review is an essential component of research. High-quality reviews are those that provide constructive and substantiated comments about the importance and originality of the research, strengths, and weaknesses, and an interpretation of results (Laine & Murlow, 2003).

Issues related to peer review include, but are not limited to, bias on the part of authors, editors, and reviewers; confidentiality; and plagiarism or theft of ideas (Macrina, 1995c; Olson et al., 2002; Scheetz, 2001). Reviewers and editors may be tempted to solicit the opinion of friends and colleagues with expertise in a particular area about a manuscript, which may be a breach of confidentiality. The Scientific Research Society (1986) described several problems related to reviewers and editors. Among the reviewer problems were obtaining a secondary citation for one's own publication in the guise of improving the manuscript; pirating the topic of the manuscript; providing criticism on a subsequent review; excessively delaying review without explanation; and losing manuscript. Another problem is peer review failure that occurs when a peer-reviewed paper contains several errors. Most journals do not have a policy for peer-review failures other than “Letter to the Editor.” Therefore, it becomes the individual reader's responsibility to identify and seek resolution of these failures in the form of a letter to the editor. The author of a quantitative paper usually has the option of publishing a reply to the Letter to the Editor. Peer review is such an important issue that there have been five International Congresses on Peer Review to discuss efforts to systematize reviews and improve reports of research. The first International Congress was in 1989 in Chicago, the second was in 1993 in Chicago, the third in 1999 in Prague, the fourth in 2001 in Spain (Rennie, 2002), and the fifth in 2005 in Chicago. The topics of presentation included authorship, conflicts of interest, journal guidelines and policies, ethical concerns, peer review process, scientific misconduct, publication bias, and quality of journal articles.

**Publication Correction**

Research reports may be flawed because of errors in methodology, selective reporting of results, or overuse of or vague citation of references (Altman, 2002). Critical review of published reports and letters to the editor about inaccurate published reports are essential to the
integrity of research (Getzsch, Delamothe, & Goodlec, 2010). Authors are sometimes reluctant to respond to critical reviews of their work. Editors should insist that the authors respond to criticism of their work. Speech-language pathologists and audiologists also have ethical obligations when their research is published. If authors discover or learn of errors in the published data, they are ethically obligated to promptly take reasonable steps to correct the error, retract the error, or use other appropriate publication means (APA, 2010).

Reports also may be retracted or withdrawn because of unsubstantiated or irreproducible data. According to Scheetz (2001), since 1992 findings of scientific misconduct have resulted in 63 revisions to the literature.

Several problems related to mentoring have been identified by Horner and Minifie (2011b). Among these problems were continued dependency, disparities of power, inadequate accountability, vulnerable subordinates, and failing to give credit. Recommendations for improving mentoring have been described by Shamoo and Resnik (2003). These recommendations include acknowledge mentors for effective mentoring, develop guidelines for amount and type of responsibilities and intellectual property, ensure appropriate response to whistleblowers, establish procedures for evaluating mentees, promote a diverse and nondiscriminatory environment, secure an environment safe from harm, and provide mentors with time for mentoring.

More subtle issues of research ethics were identified by Rosenthal (1999). These issues were related to inadequacy in research design, hyperclarity, data dropping, outlier rejection, self-censoring, and external censoring. Hyperclarity is suggesting that research is likely to achieve what it is unlikely to achieve. Closely related to hyperclarity, it is the tendency to imply a caused relationship when none has been established. Rosenthal (1999) believes bad science makes for bad ethics.

Reasons for retraction of a report include misconduct or presumed misconduct, significant reporting errors, and inability of author(s) to replicate (Horner & Minifie, 2011c). If there are significant errors or ethical misconduct, published papers should be retracted, and citation of retracted papers should not occur.

Evidence-Based Practice

Gupta (2003) believes there has been limited consideration of the ethical issues related to evidence-based practice. Ethical considerations are involved in evidence-based practice as well as in not practicing it. There are several areas for ethical concern. One concern is the potential for patient care to be manipulated by administrators to deprive persons of certain health services. Another area of concern is the effect that evidence-based practice has on the authority and power of health care providers. Evidence-based practice prioritizes certain types of research and, thus, increases the pressure for this research to be funded. There may be publication bias, that is, the publication of positive and statistically significant results. Another area for ethical concern is the uncritical and permissive attitude of evidence-based practice toward private funding of research. Other issues are related to control groups, random-
ization, need for research or treatment, meaning outcomes, setting (location) of research treatment, strategies for which evidence is not available, and determining risks and benefits. Additional information about evidence-based practice is presented in Chapter 13.

American Academy of Audiology

The AAA (2018) Code of Ethics contains several specific statements related to research (see Appendix 2–A). AAA also has guidelines for ethical research; authorship in publication and presentations; adequacy of research design; security of data; and conflicts of interest in product-oriented outcome research (Sininger et al., 2004).

Sanctions for Ethical Misconduct

Three types of legal perspectives influence selection of sanctions for ethical misconduct: (a) quasicontractual legal remedy of restitution; (b) philosophy of “just desserts” or retribution based on an intuitive idea that the individual was engaged in criminal activity deserving punishment; and (c) detection of misconduct (Dresser, 1993).

Sanctions for ethical misconduct have been described by both AAA (2018) and ASHA (2016). Part II of the AAA (2011) Code of Ethics includes “procedures for the management of alleged noncompliance.” The sanctions are educative letter, reprimand, probation of suspension, suspension of membership, and revocation of membership.

The fundamental purposes of ASHA (2012) are: (a) penalize the person in violation; (b) serve as a mechanism to educate and rehabilitate; (c) protect the public; and (d) inform other ASHA
members and certificate holders that the Association enforces its ethical standards and alert them that there are penalties for engaging in professional misconduct. Typically, more serious misconduct receives harsher sanctions. The sanctions from least to most severe are reprimand; censure; revocation of membership, certification, or both; suspension of membership, certification, or both; withholding of membership, certification, or both; and cease and desist.

### Institutional Review Board

An IRB is a committee mandated by the National Research Act, Public Law 93-348, to be established within each institution that conducts research involving human and animal subjects and needs federal funding for research (Sieber, 1992). The IRB is a group of individuals who are affiliated with an institution who meet to review research proposals and monitor ongoing research relative to ethical standards. Responsibilities of the IRB include the following:

- Protecting the rights and welfare of subjects
- Ensuring protocols are presented by the sponsor(s)
- Ensuring sponsor(s) of a protocol disclosure(s) including areas of concern such as appearance of a conflict of interest and financial interests
- Reviewing, monitoring, and approving research protocols

<table>
<thead>
<tr>
<th>Title</th>
<th>Authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research integrity in communication sciences and disorders</td>
<td>Moss (2011)</td>
</tr>
<tr>
<td>Research integrity in communication sciences and disorders: Preface</td>
<td>Horner &amp; Minifie (2011a)</td>
</tr>
<tr>
<td>Research ethics I: Responsible conduct of research (RCR)—History and contemporary issues pertaining to human and animal experimentation</td>
<td>Horner &amp; Minifie (2011a)</td>
</tr>
<tr>
<td>Research ethics II: Mentoring, collaboration peer review and data management and ownership</td>
<td>Horner &amp; Minifie (2011b)</td>
</tr>
<tr>
<td>Research ethics III: Publication practices and authorship, conflict of interest, and research misconduct</td>
<td>Horner &amp; Minifie (2011c)</td>
</tr>
<tr>
<td>Responsible conduct of research in communication sciences and disorders: Faculty and student perceptions</td>
<td>Minifie et al. (2011)</td>
</tr>
<tr>
<td>Ethical principles associated with the publication of research in ASHA's scholarly journals: Importance and adequacy of coverage</td>
<td>Ingham et al. (2011)</td>
</tr>
</tbody>
</table>

Table 2–7. ASHA’s Research Integrity Supplement in JSLHR
Ensuring that rights including privacy and confidentiality are protected

Ensuring that all research is conducted within current federal and state guidelines (Pozar 2012)

The term “research ethics review board,” not IRB, has been suggested because the focus is on ethics rather than the institution. HIPAA has had significant impact on IRB (see the HIPAA discussion earlier in this chapter).

IRBs are often viewed negatively by researchers because of delays and requirements that provide limited protection of subjects (Azar, 2002). However, delays and revisions can be reduced by using understandable language in the consent form, explicitly describing the research protocol submitted to the IRB, and submitting all required documents (Sharp, 2001). Furthermore, many of the ethical problems related to research are resolved in the course of the IRB review, that is, appropriate risk-to-benefit rating, details about informed consent, and appropriateness of compensation (Jonsen, Siegler, & Winslade, 2006).

The IRB is responsible for making decisions about research plans at convened meetings. In making decisions, the following are considered: scientific merit, competence of the investigator(s), risk to subjects, feasibility based on identified reasons, procedures for selecting subjects, voluntary informed consent based on complete understandable descriptions, and confidentiality. The required elements of informed consent are listed in Table 2–8. In addition, the informed consent must be written in lay language; that is, the language must be clear and basic so that it can be understand by the average participant (Portney & Watkins, 2009). Many believe that informed consent makes research ethical; however, informed consent is neither necessary nor sufficient for ethical research.

IRB members must be able to adequately review research proposals. The IRB must be composed of at least five members and may not consist entirely of males, females, or members of one profession. At least one IRB member must be primarily concerned with nonscientific areas; many are lawyers, clergy, or ethicists. One member may not be affiliated with the institution where the research is to be conducted or be a member of the immediate family of a person who is affiliated with the institution (Polit & Beck, 2010; Sales & Folkman, 2000).

Many research plans require a full review by the IRB. For a full review, the IRB must meet with a majority of the members present. In order for the research plan to be approved, it must receive approval of the majority of IRB members present at the meeting.

IRBs are often viewed negatively by researcher and administrators. The major reasons for these negative views are increased delays, added costs, and limited protection of subjects. There have also been complaints about differences between federal regulations and IRBs (Azar, 2002). Several strategies have been suggested for improving IRBs. One strategy is modifying the local independent IRB system and replacing with a central IRB plus local option out. Education and dissemination of guidelines about IRBs have also been suggested (Green, Lowery, Kowalski, & Wyszwianski, 2006). Delays and revisions of research protocol can be reduced by using understandable language in the consent form, providing
specific descriptions of the research methodology, and submitting all associated documents (Sharp, 2001). Last, many problems are resolved in the course of the IRB review. These problems include risk to benefit, details about informed consent, and suitability of compensation (Jonsen, Seglar, & Winslade, 2006).

Some research plans qualify for expedited review or exempted status. For certain types of research involving no more than minimal risk, the research plan may be expedited. An expedited review is conducted by the IRB chair or another IRB member designated by the chair. The advantage of an expedited review is that it usually is completed in less time than a full review.

Research plans may be exempted from full review if there is no apparent risk. Surveys, interviews, or studies of existing records may be exempt from full review if data are collected so that subjects cannot be identified and the study does not involve sensitive issues such as criminal activity, drug abuse, or sexual behavior (Portney & Watkins, 2009).

Before implementing a study, the researcher must submit a research proposal to the IRB. An IRB can approve the proposed research plan, require restriction(s), or disapprove the plan.

### Table 2–8. Elements of Informed Consent

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Clear explanation of research and its importance reason for selecting individual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures</td>
<td>Clear explanation of what will be done to or by individual</td>
</tr>
<tr>
<td>Risks and discomforts</td>
<td>Truthful and inclusive statements</td>
</tr>
<tr>
<td>Benefits</td>
<td>Description of potential benefits to individual, general knowledge, or future of health care</td>
</tr>
<tr>
<td>Alternative to participation</td>
<td>Description of reasonable alternative procedures that might be used in treatment with treatment is being started</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>Statement of procedures used to ensure anonymity for collecting, storing, and reporting information and who (persons or agencies) will have access to information</td>
</tr>
<tr>
<td>Request for more information</td>
<td>Statement that individuals may ask questions about or discuss study participation at any time, naming an individual to contact</td>
</tr>
<tr>
<td>Refusal or withdrawal</td>
<td>Statement that individual may refuse to participate or discontinue participation at any time without prejudice</td>
</tr>
<tr>
<td>Injury statement</td>
<td>Description of measures to be taken if injury occurs as direct result of research activity</td>
</tr>
<tr>
<td>Consent statement</td>
<td>Confirmation that individual consents to participation</td>
</tr>
<tr>
<td>Signatures</td>
<td>Participants; patient or guardian, assent of minor over age 7; witness</td>
</tr>
</tbody>
</table>
The main requirements governing IRB decisions are summarized in Table 2–9.

Recent issues about IRB include the cost of operation, local versus central IRB, and characteristics of IRB members. It was reported that high-volume IRBs were more expensive than low-volume IRBs but more economically efficient. The potential savings of large IRBs may encourage small IRBs to merge, which could reduce local review, control, and oversight. Christian and associates (2002) advocate both central and local IRBs. Central IRBs review large national multicenter clinical studies, whereas local IRBs continue to be a key component of the review system. This approach preserves local autonomy and responsibility for local matters, reduces the workload of local IRBs, and eliminates duplication of effort. McWilliams and associates (2003) believe that there are serious differences in the review process between local and central IRBs for multicenter studies. Conversely, Rose (2003) opposed central IRBs and suggested that reviews by local IRBs could be improved by education, consultation, and funding. Campbell and associates (2003) studied the characteristics of medical school faculty members serving on IRBs. Faculty members serving on IRBs have research experience and knowledge, but almost half of all faculty IRB members were consultants to industry, which raises the possibility of the potential for conflict of interest.

### Teaching Research Ethics

Professional ethics begin on the college campus (DeRussy, 2003). Therefore, higher education has a critical role in teaching ethics. Furthermore, ASHA’s certification standards for speech-language pathology and audiology require training in research and ethics (ASHA, 2009, 2010). This involves integrating ethical principles into research. This requires that students in speech-language pathology and audiology be able to understand and integrate ethical principles into research. Educational training programs must have curricula and experiences in the ethical conduct of research. This section addressed topics related to teaching research ethics. First, content is considered, and then methods for teaching about ethics in research. Goals for teaching ethics are listed in Table 2–10. Their goals should also be reviewed periodically by practicing speech-language pathologists and audiologists.

The goal of teaching research ethics is to apply ethical principles in making decisions about research.

### Table 2–9. Major Requirements Governing IRB Decisions

<table>
<thead>
<tr>
<th>Requirement</th>
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<tbody>
<tr>
<td>Risks to participants minimized</td>
</tr>
<tr>
<td>Risks to participants reasonable in relation to anticipated benefits, if any, and importance of knowledge that may reasonable be expected to result</td>
</tr>
<tr>
<td>Equitable selection of participants</td>
</tr>
<tr>
<td>Informed consent appropriately documented</td>
</tr>
<tr>
<td>Adequate provisions for monitoring research to ensure safety of participants</td>
</tr>
<tr>
<td>Appropriate provisions to protect privacy or participants and confidentiality of data</td>
</tr>
<tr>
<td>When vulnerable subjects involved, appropriate additional safeguards to protect their rights and welfare</td>
</tr>
</tbody>
</table>

[Note: The table is not fully visible in the image provided.]

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Emanuel, Wendler, and Grady (2000) identified seven requirements for evaluating the ethics of research studies: (a) value—enhancement of health or knowledge must be derived from the research; (b) validity—methodological rigor; (c) fair subject selection—scientific objectives, not privilege or vulnerability, and potential for and distribution of risks and benefits should determine selection; (d) risk-benefit ratio within context of standard clinical practice and the research plan, risks must be minimized, potential benefits enhanced, and potential benefits to individual and knowledge gained for society must outweigh the risks; (e) independent review—unaffiliated individuals must review the research and approve, amend, or terminate it; (f) informed consent—individuals should be informed about the risks and provide voluntary consent; and (g) respect for enrolled subjects—subjects should have confidentiality protected, opportunity to withdraw, and their well-being monitored.

Content

The teaching of ethics cannot be separated from the Codes of Ethics of AAA (2018) and ASHA (2016), which contain several references to ethics in research (see Appendixes 2–A and 2–B). There is a wide range of information about the responsible conduct or research, such as: (a) topic related to conduct and reporting of research; (b) ethical dilemmas presented by certain types of research; and (c) responses to research misconduct. Ingham and Horner (2004) identified 11 core areas for teaching the responsible conduct of research. These core areas are listed in Table 2–11.

In addition to the AAA (2018) and ASHA (2016) Codes of Ethics, it is helpful to beware of the ethical issues that may arise during a research study. These issues are usually related to specifying the research problem; identifying a purpose statement and research questions; and collecting, analyzing, and writing up the results of the study (Creswell, 2003). By anticipating these issues in advance, ethical problems may be prevented or reduced. There is also need for information about research ethics in dissertations. Krellstrom, Ross, and Fridland (2011) reported that ethical concerns about dissertations are often related to inadequate supervision. It was suggested that ethical issues be emphasized in graduate and postgraduate studies.

<table>
<thead>
<tr>
<th>Table 2–10. Goals for Teaching Research</th>
</tr>
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<tbody>
<tr>
<td>Examine and make distinctions between ethical concepts such as beneficence, nonmaleficence, justice, fidelity, respect. Patient rights, confidentiality</td>
</tr>
<tr>
<td>Know that ethical certainty is often impossible but ethical reasoning about choice can be precise.</td>
</tr>
<tr>
<td>Serious consideration of personal and professional ethics</td>
</tr>
<tr>
<td>Identify ethical dilemmas and seek resolution of these dilemmas</td>
</tr>
</tbody>
</table>
Topics about conducting and reporting research are presented in Table 2–12. The second classification is related to ethical dilemmas associated with certain types of research that could become the focus of public debate. These topics included the use of humans and animals in research. The third area addressed is recognizing and responding to research misconduct, such as plagiarism and fabricating or falsifying research data. This involves institutional policies and guidelines for the responsible conduct of research and guidance from the AAA (2018) and ASHA (2016) Codes of Ethics. The American Medical Association (Iverson et al., 1998) has guidelines for ethical and legal considerations in publishing papers. These topics and subtopics are listed in Table 2–13.

There is a need for information about ethical issues related to specific populations and work settings. Moss (2011) and Jakubowitz (2011) described ethical research practices in pediatric populations. Work settings such as the schools (Watson, Byrd, & Moore, 2011), and health care settings (Kummer & Turner, 2011; Larsen & McMillin, 2011) considered ethical research in multidisciplinary clinics. A comprehensive survey of students and faculty in communication sciences and disorders by Minifie and associates (2011) found that students were not receiving adequate information about mentoring, research collaboration, conflicts of interest, and humane treatment of animals in research. These findings provide a basis for including and expanding this information.

There is also a need for continuing education about research ethics. Speech-language pathologists and audiologists need to periodically review and monitor

---

**Table 2–11. Core Instructional for the Responsible Conduct of Research**

| Ethics and morality                      |
| Research misconduct                      |
| Human subjects protection                |
| Publication practices and responsible authorship |
| Peer review                              |
| Mentor/trainee relationships             |
| Conflict of interest and commitment      |
| Data acquisition, management, sharing, and ownership |
| Collaborative research                   |
| Animal subjects protection               |
| Guidelines and regulation                |

information about professional ethics. The quality of instruction in ethics should be considered.

Ethical consultations are being used more frequently to resolve ethical dilemmas (Schneiderman et al., 2003). Lo (2003) suggests that ethics consultation fosters more effective education, because it may identify areas needing improvement such as misunderstandings about ethics or limitations in communicating with patients and families. Kenny, Lincoln, and Balandin (2010) found that experienced speech-language pathologists more frequently used informal support networks to resolve ethical dilemmas than consulting work-based committees or their professional associates.

### Methods

There is literature available about a variety of methods for teaching ethics. These methods include role-playing, discussion groups, mentoring, case studies, self-directed learning, and computerized reference searches (ASHA, 2002; Association of American Medical Colleges, 1994; Bulger, 2001; Bulger, Heitman, & Reiser,
<table>
<thead>
<tr>
<th>Table 2-13. Ethical and Legal Considerations in Publishing</th>
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</thead>
<tbody>
<tr>
<td><strong>Authorship Responsibility</strong></td>
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<tr>
<td>Authorship criteria</td>
</tr>
<tr>
<td>Guest and ghost authors</td>
</tr>
<tr>
<td>Unsigned editorials</td>
</tr>
<tr>
<td>Number of authors</td>
</tr>
<tr>
<td>Order of authorship</td>
</tr>
<tr>
<td>Group/collaborative authorship</td>
</tr>
<tr>
<td><strong>Acknowledgments</strong></td>
</tr>
<tr>
<td>Permission to name individuals</td>
</tr>
<tr>
<td><strong>Duplicate Publications</strong></td>
</tr>
<tr>
<td>Secondary publication</td>
</tr>
<tr>
<td>Editorial policy or preventions/handling allegations of duplicate publication</td>
</tr>
<tr>
<td><strong>Scientific Misconduct</strong></td>
</tr>
<tr>
<td>Misrepresentation</td>
</tr>
<tr>
<td>Misappropriation</td>
</tr>
<tr>
<td>Editorial policy for scientific misconduct</td>
</tr>
<tr>
<td><strong>Conflict of Interest</strong></td>
</tr>
<tr>
<td>Author’s disclosure</td>
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<tr>
<td>Peer reviewer’s disclosure</td>
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<tr>
<td>Editor’s disclosure</td>
</tr>
<tr>
<td>Editorial policy for failure to disclose financial interest</td>
</tr>
<tr>
<td><strong>Copyright</strong></td>
</tr>
<tr>
<td>Ownership and control of data</td>
</tr>
<tr>
<td>Copyright</td>
</tr>
<tr>
<td>Types of works; copyright duration</td>
</tr>
<tr>
<td>Copyright assignment or licensure</td>
</tr>
<tr>
<td>Copyright notice/resignation</td>
</tr>
<tr>
<td>Copying, reproducing, adapting</td>
</tr>
<tr>
<td>Publishing discussions from symposia, conferences</td>
</tr>
<tr>
<td><strong>Reprint permissions, Intellectual Property</strong></td>
</tr>
<tr>
<td>Standards for reprints</td>
</tr>
<tr>
<td>Standards for licensed international editors</td>
</tr>
<tr>
<td><strong>Ownership rights, Management</strong></td>
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<tr>
<td>International copyright</td>
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<tr>
<td>Moral rights</td>
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<tr>
<td>Patent</td>
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<tr>
<td>Trademark</td>
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<tr>
<td>Peer review</td>
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<tr>
<td>Allegation of scientific misconduct</td>
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<tr>
<td><strong>Confidentiality</strong></td>
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<tr>
<td>Selecting editors, editorial board members</td>
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<tr>
<td>Legal petitions, claims privileged information</td>
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<table>
<thead>
<tr>
<th>Table 2–13. continued</th>
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<tbody>
<tr>
<td>Protecting Individual’s Rights in Publication</td>
</tr>
<tr>
<td>Informed consent</td>
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<td>Patient’s rights</td>
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<tr>
<td>Rights to publish reports</td>
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<tr>
<td>Defamation Libel</td>
</tr>
<tr>
<td>Living persons, existing entities</td>
</tr>
<tr>
<td>Public, private figures</td>
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<tr>
<td>Statements of opinion</td>
</tr>
<tr>
<td>Editorials, letters, reviews</td>
</tr>
<tr>
<td>Works of fiction</td>
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<tr>
<td>Republication, news reporting</td>
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<tr>
<td>Defense against libel</td>
</tr>
<tr>
<td>Other liability concerns</td>
</tr>
<tr>
<td>Editorial Freedom and Integrity</td>
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<tr>
<td>Policy on editorial freedom</td>
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<tr>
<td>Editorial Responsibilities, Procedures, Policies</td>
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<tr>
<td>Editor’s responsibilities</td>
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<tr>
<td>Rejection</td>
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<tr>
<td>Acknowledging manuscript receipt</td>
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<tr>
<td>Revisions</td>
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<tr>
<td>Manuscript assessment</td>
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<tr>
<td>Peer review</td>
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<tr>
<td>Acceptance</td>
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<tr>
<td>Correspondence column, corrections</td>
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<tr>
<td>Disclosure of practices</td>
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<tr>
<td>Audits, reviews</td>
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<tr>
<td>Quality reviews</td>
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<tr>
<td>Advertisements, Suppliers Sponsored Supplements</td>
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<tr>
<td>Advertisements</td>
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<tr>
<td>Criteria of advertisement</td>
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<tr>
<td>Advertorials</td>
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<tr>
<td>Sponsored suppliers</td>
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<tr>
<td>Advertising, sponsorship</td>
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<tr>
<td>Release of information to public</td>
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<tr>
<td>Embargo</td>
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<tr>
<td>Dealing with news media</td>
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<tr>
<td>News release</td>
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</tbody>
</table>

2. ETHICS OF RESEARCH IN SPEECH-LANGUAGE PATHOLOGY & AUDIOLOGY

2002; Canter, Bennett, Jones, & Nagy, 1999; Davies 1999; Hamilton, 2002; Huffman, 2003; Jefferies & Bauer, 2003; Macrina, 1995a; Moss, 2010; Nagy, 2000). The National Institutes of Health have online training for the protection of human subjects at no cost (http://cme.cancer.gov/clinical trials/learning/humanparticipants/protection.csp). Analysis and discussion about cases and situations are essential to teaching the responsible conduct of research (Heitman, 2002). Ethics courses and programs in many professions, including speech-language pathology and audiology, use the case study method to illustrate ethical issues in the field and to teach a system for ethical decision-making professional practice.

Another approach to teaching research ethics is on-site observation of ethical misconduct. This can be modified and based on role-playing or case-based observations (Oberman, Bosh-Missimov, & Ash, 2011).

Other resources for teaching research ethics are online print syllabi. McCarthy, Poole, and Solomon (2007) developed a model for teaching professional issues in university audiology and speech-language pathology training programs. The issues included ethical conduct and dilemmas and professional writing. Activities for these issues were based on Bloom's taxonomy ranging from one (knowledge) to seven (evaluation). A syllabus for research ethics committee training was developed by Cairoli and associates (2011). Training needs and competencies were identified. Funding for this training was reported to be a major problem. The University of Pittsburgh designed, implemented, and evaluated an institution with Web-based training for the responsible conduct of research (Barnes et al., 2006). The AAA (2012) also has a Web-based instruction based on the Ethics Green Book.

Current and Future Issues

There are several unresolved issues related to the responsible conduct of research. These issues should be recognized and appropriate strategy for resolution be developed. Two surveys have identified relevant issues (Ingham et al., 2011; Minifie et al., 2011). Ingham and associates (2011) completed a two-part survey of ASHA members about research principles of publishing research. Several of the topics considered important were included in ASHA policy documents, although some topics were not adequately addressed; recommendations were to have ASHA develop a single comprehensive publication policy document, implementation and enforcement of the policy, formal procedures for processing alleged ethical misconduct, and collaboration of communication sciences and disorders programs to design and implement long-term educational programs about research ethics. Minifie and associates (2011) used a Web-based survey to assess the perceptions of students and faculty about the responsible conduct of research in communication science and disorders. Coverage of eight topics related to the responsible conduct of research was rated as adequate fabrication: falsification, reporting research misconduct, interpreting and reporting findings, confidentiality, protecting vulnerable subjects, alternative treatments, and data accuracy. Two topics did not receive adequate coverage: protection of electronic research information, recognizing and disclosing conflicts of interest. This information should be useful for
improving instruction about the responsible conduct of research.

In a comprehensive review about research ethics, Minifie and associates (2011) identified “a host” of ethical issues. These issues were balance between risk and benefit; vulnerability and protection of subjects; conducting research with deceased subjects; protection of children; adequacy of federal regulations; appropriate limits of consent by parents and other legally authorized representatives; waive consent in intensive care; appropriate limitation of coercion and deception; representation of minorities; ethical and legal responsibilities of researchers; nature of research setting; social behavioral protection of subjects; harmful effect of randomization; and access to experimental pharmaceutical devices or alternative treatments when studies show no benefits.

Continuing education for speech-language pathology or audiology licensure in Texas requires completion of two continuing education hours as part of the 20-hour minimum for 2 years (ASHA, 2011). Ingham and associates (2011) believe that “improved education of all aspects” of research ethics is needed (p. 394).

There is a need for professional universities and professional organizations to develop a consensus on the best ethical practices (Steneck & Bulger, 2007). There is also a need to assess the quality of ethical instruction and the effect of training.

Ethical training of students and professionals may be a way to decrease the need for regulation (Body & McAllister, 2009). Therefore, there should be increased self-assessment and monitoring.

Case studies should be detailed enough to provide meaningful ethical decisions but general enough for students to analyze from their own knowledge and experience. The goal of case studies is to determine an ethical resolution to the problem(s) pertinent to the case and to define appropriate action for resolving the problem(s). The basic steps of case study and analysis are outlined in Table 2–14. Yin (2003a, 2003b) provided extensive guidelines about the designing case studies. Case studies in research ethics are available in the Association of American Medical Colleges (1994), Hamilton (2002), Heitman (2002), Jonsen et al. (2006), and Macrina (1995a).

Table 2–14. Steps for Case Study

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>1.</td>
<td>Recognize and identify issues and specific ethical problems in the case.</td>
</tr>
<tr>
<td>2.</td>
<td>Identify key facts, establish important definitions, and obtain other necessary information.</td>
</tr>
<tr>
<td>3.</td>
<td>Identify professional ethical principles, standards or practice, and law relevant to ethical issues of the case.</td>
</tr>
<tr>
<td>4.</td>
<td>Identify possible alternative courses and action, ethical arguments for and against implementation, and the likely outcome.</td>
</tr>
<tr>
<td>5.</td>
<td>Choose the course of action best supported by the preceding analysis.</td>
</tr>
<tr>
<td>6.</td>
<td>Evaluate the actions taken and the subsequent outcome.</td>
</tr>
</tbody>
</table>

Summary

Speech-language pathologists and audiologists face multiple ethical issues in planning, designing, and implementing research. There is a need for ethical guidelines, because research has not always been conducted ethically. There are three major types of research misconduct: (a) fabrication, (b) falsification, and (c) plagiarism. The Code of Ethics of AAA (2018) and ASHA (2016) have several standards related to responsible conduct of research and scholarly activities. The role and scope of the Institutional Review Board (IRB) and HIPAA are considered.

This chapter also included discussions of ethical issues related to research: (a) planning research, (b) confidentiality, (c) informed consent, (d) deception, (e) control group, (f) institutional approval, (g) conflicts of interest, (h) mentoring, (i) referencing of sources, (j) authorship, (k) copyright infringement and plagiarism, (l) peer review, (m) publication correction, and (n) evidence-based practice. Last, content and methods for teaching the responsible conduct of research and current and future issues are considered.

DISCUSSION QUESTIONS

1. Define the responsible conduct of research.
2. Explain the need for ethical guidelines.
3. Trace the historical background of research conduct.
4. What is the impact of research misconduct?
5. How does research misconduct affect professional status?
6. Describe the major types of research misconduct.
7. Define fabrication, falsification, and plagiarism.
8. Explain ASHA’s (2003b) ethical standards for reporting and publishing research.
9. Describe the ethical bases for the responsible conduct of research.
10. Why is confidentiality related to research?
11. Why does peer review fail?
12. How can confidentiality be maintained in research?
13. Why can obtaining informed consent be difficult?
14. How do professional codes of ethics address informed consent?
15. Define conflict of interest.
16. How can conflict of interest affect research?
17. What can be done to minimize conflicts of interest?
18. What factors should be considered in selecting a mentor?
19. Why should research records be maintained? For how long should they be maintained?
20. How can and why should plagiarism be avoided?
21. Why can authorship be a problem?
22. What is irresponsible authorship?
23. Describe the types of irresponsible authorship.
24. What is peer review?
25. What issues are related to peer review?
26. What should be done if authors discover or learn of errors in their published reports?
27. What guidelines for research are in the AAA (2011) Code of Ethics?
29. What is IRB?
30. What are major responsibilities of an IRB?
31. What are the essential elements of informed consent?
32. What requirements affect IRB decisions?
33. What are the types of IRB reviews?
34. Discuss recent issues related to IRB.
35. How could these issues be resolved?
36. How can the ethics of research studies be evaluated?
37. What issues affect the content of teaching ethics?
38. Discuss the major topics related to conducting and reporting research.
40. How can case study and analysis be used to teach ethics?
41. What is the procedure for case study and analysis?
42. How can peer review fail?
43. What can be done to eliminate or resolve failed peer reviews?
44. What is copyright? Copyright infringement?
45. Why should and how can copyright infringement be avoided?
46. What is HIPAA?
47. How are HIPAA regulations enforced?
48. What are the penalties for violating HIPAA regulations?
49. List and briefly describe the three major HIPAA rules.
50. What is Protected Health Information?
51. How has HIPAA affected research?
52. What are the reasons for “Letter to the Editors”?
53. What are the current issues relative to the responsible research?
54. How can these issues be resolved?

References


Getzsch, P. O., Delamothe, T., & Goodlec, T. (2010). Adequacy of authors replies to critical or unfriendly electronic letters to the editor. *British Medical Journal, 3*.


Appendix 2–A
American Academy of Audiology (AAA)
Code of Ethics 2018

CODE OF ETHICS OF THE AMERICAN ACADEMY OF AUDIOLOGY

PREAMBLE
The Code of Ethics of the American Academy of Audiology specifies professional standards that allow for the proper discharge of audiologists’ responsibilities to those served, and that protect the integrity of the profession. The Code of Ethics consists of two parts. The first part, the Statement of Principles and Rules, presents precepts that members (all categories of members including Student Members) effective January 1, 2009 of the Academy agree to uphold. The second part, the Procedures, provides the process that enables enforcement of the Principles and Rules.

PART I. STATEMENT OF PRINCIPLES AND RULES

PRINCIPLE 1: Individuals shall provide professional services and conduct research with honesty and compassion, and shall respect the dignity, worth, and rights of those served.

Rule 1a: Individuals shall not limit the delivery of professional services on any basis that is unjustifiable or irrelevant to the need for the potential benefit from such services.

Rule 1b: Individuals shall not provide services except in a professional relationship and shall not discriminate in the provision of services to individuals on the basis of sex, race, religion, national origin, sexual orientation, or general health.

PRINCIPLE 2: Individuals shall maintain the highest standards of professional competence in rendering services.

Rule 2a: Members shall provide only those professional services for which they are qualified by education and experience.

Rule 2b: Individuals shall use available resources, including referrals to other specialists, and shall not give or accept benefits or items of value for receiving or making referrals.

Rule 2c: Individuals shall exercise all reasonable precautions to avoid injury to persons in the delivery of professional services or execution of research.

Rule 2d: Individuals shall provide appropriate supervision and assume full responsibility for services delegated to supportive personnel. Individuals shall not delegate any service requiring professional competence to unqualified persons.

Rule 2e: Individuals shall not knowingly permit personnel under their direct or indirect supervision to engage in any practice that is not in compliance with the Code of Ethics.

Rule 2f: Individuals shall maintain professional competence, including participation in continuing education.

PRINCIPLE 3: Individuals shall maintain the confidentiality of the information and records of those receiving services or involved in research.

Rule 3a: Individuals shall not reveal to unauthorized persons any professional or personal information obtained from the person served professionally, unless required by law.

PRINCIPLE 4: Individuals shall provide only services and products that are in the best interest of those served.

Rule 4a: Individuals shall not exploit persons in the delivery of professional services.

Rule 4b: Individuals shall not charge for services not rendered.

Rule 4c: Individuals shall not participate in activities that constitute a conflict of professional interest.

Rule 4d: Individuals using investigational procedures with human participants or prospectively collecting research data from human participants shall obtain full informed consent from the participants or legal representatives. Members conducting research with human participants or animals shall follow accepted standards, such as those promulgated in the current Responsible Conduct of Research by the U.S. Office of Research Integrity.

PRINCIPLE 5: Individuals shall provide accurate information about the nature and management of communicative disorders and about the services and products offered.

Rule 5a: Individuals shall provide services to persons served with the information a reasonable person would want to know about the nature and possible effects of services rendered or products provided or research being conducted.

Rule 5b: Individuals may make a statement of prognosis, but shall not guarantee results, mislead, or misinform persons served or studied.

Rule 5c: Individuals shall conduct and report product-related research only according to accepted standards of research practice.

Rule 5d: Individuals shall not use their services or products in a manner that constitutes an invasion of privacy or that fails to inform persons fully about the nature and possible effects of these activities, affording all persons informed free choice of participation.

Rule 5e: Individuals shall maintain accurate documentation of services rendered according to accepted medical, legal, and professional standards and requirements.

PRINCIPLE 6: Individuals shall comply with the ethical standards of the Academy with regard to public statements or publication.

Rule 6a: Individuals shall not misrepresent their educational degrees, training, credentials, or competence. Only degrees earned from regionally accredited institutions in which training was obtained in audiology, or a directly related discipline, may be used in public statements concerning professional services.

Rule 6b: Individuals shall not use professional or commercial affiliations in any way that would limit services to or mislead patients or colleagues.

Rule 6c: Individuals’ public statements about professional services, products or research results shall not contain representations or claims that are false, misleading, or deceptive.

PRINCIPLE 7: Members shall honor their responsibilities to the public and to professional colleagues.

Rule 7a: Individuals shall not use professional or commercial affiliations in any way that would limit services to or mislead patients or colleagues.

Rule 7b: Individuals shall inform colleagues and the public in an objective manner consistent with professional standards about products and services they have developed or research they have conducted.

PRINCIPLE 8: Individuals shall uphold the dignity of the profession and freely accept the Academy’s self-imposed standards.

Rule 8a: Individuals shall not violate these Principles and Rules nor attempt to circumvent them.

Rule 8b: Individuals shall not engage in dishonesty or illegal conduct that adversely reflects on the profession.

Rule 8c: Individuals shall inform the Ethical Practices Committee when there are reasons to believe that a member of the Academy may have been in noncompliance with the Code of Ethics.

Rule 8d: Individuals shall fully cooperate with reviews being conducted by the Ethical Practices Committee in any matter related to the Code of Ethics.

Signature: ___________________________ Date: ___________________________
PART II.
PROCEDURES FOR THE MANAGEMENT OF ALLEGED NONCOMPLIANCE

INTRODUCTION
Members of the American Academy of Audiology are obligated to uphold the Code of Ethics of the Academy in their personal conduct and in the performance of their professional duties. To this end, it is the responsibility of each Academy member to inform the Ethical Practice Committee of possible noncompliance with the Ethics Code. The processing of alleged noncompliance with the Code of Ethics will follow the procedures specified below in an expeditious manner to ensure that behaviors of noncompliant ethical conduct by members of the Academy are halted in the shortest time possible.

PROCEDURES

1. Suspected noncompliance with the Code of Ethics shall be reported in letter format, giving documentation sufficient to support the alleged noncompliance. Letters must be addressed to:
   
   American Academy of Audiology
   Chair, Ethical Practices Committee
   11480 Commerce Park Dr. Suite 220
   Reston, VA 20191

2. Following receipt of a report of suspected noncompliance, at the discretion of the Chair, the Ethical Practices Committee will request a signed Waiver of Confidentiality from the complainant indicating that the complainant will allow the Ethical Practice Board to disclose his/her name and complaint details should this become necessary during investigation of the allegation.

   a. The Committee may, under special circumstances, act in the absence of a signed Waiver of Confidentiality. For example, in cases where the Ethical Practice Committee has received information from a state licensure board of a member having his or her license suspended or revoked, then the Ethical Practice Committee will proceed without a complainant.

   b. The Chair may communicate with other individuals, agencies, and/or programs for additional information as may be required for Committee review at any time during the deliberation.

3. The Ethical Practice Committee will convene to review the merit of the alleged noncompliance as it relates to the Code of Ethics

   a. The Ethical Practice Committee shall meet to discuss the case, either in person, by electronic means, or by teleconference. The meeting will occur within 60 days of receipt of the Waiver of Confidentiality, or of notification by the complainant of refusal to sign the waiver. In cases where another form of notification brings the complaint to the attention of the Ethical Practice Committee, the Committee will convene within 60 days of notification.

   b. If the alleged noncompliance has a high probability of being legally actionable, the case may be referred to the appropriate agency. The Ethical Practice Committee will postpone member notification and further deliberation until the legal process has been completed.

4. If there is sufficient evidence that indicates noncompliance with the Code of Ethics has occurred, upon majority vote, the member will be forwarded a Notification of Potential Ethics Concern.

   a. The circumstances of the alleged noncompliance will be described.

   b. The member will be informed of the specific Code of Ethics principle(s) and/or rule(s) that may conflict with member behavior.

   c. Supporting AAA documents that may serve to further educate the member about the ethical implications will be included, as appropriate.

   d. The member will be asked to respond fully to the allegation and submit all supporting evidence within 30 calendar days.

5. The Ethical Practices Committee will meet either in person or by teleconference:

   a. within 60 calendar days of receiving a response from the member to the Notification of Potential Ethics Concern to review the response and all information pertaining to the alleged noncompliance, or

   b. within sixty (60) calendar days of notification to member if no response is received from the member to review the information received from the complainant.

6. If the Ethical Practice Committee determines that the evidence supports the allegation of noncompliance, the member will be provided written notice containing the following information:

   a. The right to a hearing in person or by teleconference before the Ethical Practice Committee;
b. The date, time, and place of the hearing;
c. The ethical noncompliance being charged and the potential sanction
d. The right to present a defense to the charges.

At this time the member should provide any additional relevant information. As this is the final opportunity for a member to provide new information, the member should carefully prepare all documentation.

7. Potential Rulings.
   a. When the Ethical Practices Committee determines there is insufficient evidence of ethical noncompliance, the parties to the complaint will be notified that the case will be closed.
   b. If the evidence supports the allegation of Code noncompliance, the Code(s)/Rule(s) will be cited and the sanction(s) will be specified.

8. The Committee shall sanction members based on the severity of the noncompliance and history of prior ethical noncompliance. A simple majority of voting members is required to institute a sanction unless otherwise noted. Sanctions may include one or more of the following:
   a. Educative Letter. This sanction alone is appropriate when:
      1. The ethics noncompliance appears to have been inadvertent.
      2. The member’s response to Notification of Potential Ethics Concern indicates a new awareness of the problem and the member resolves to refrain from future ethical noncompliance.
   b. Cease and Desist Order. The member signs a consent agreement to immediately halt the practice(s) that were found to be in noncompliance with the Code of Ethics
   c. Reprimand. The member will be formally reprimanded for the noncompliance with the Code of Ethics.
   d. Mandatory continuing education
      1. The EPC will determine the type of education needed to reduce chances of recurrence of noncompliance.
      2. The member will be responsible for submitting documentation of continuing education within the period of time designated by the Ethical Practices Committee.
      3. All costs associated with compliance will be borne by the member.
   e. Probation of Suspension. The member signs a consent agreement in acknowledgement of the Ethical Practice Committee decision and is allowed to retain membership benefits during a defined probationary period.
      1. The duration of probation and the terms for avoiding suspension will be determined by the Ethical Practice Committee.
      2. Failure of the member to meet the terms for probation will result in the suspension of membership.
   f. Suspension of Membership.
      1. The duration of suspension will be determined by the Ethical Practice Committee.
      2. The member may not receive membership benefits during the period of suspension.
      3. Members suspended are not entitled to a refund of dues or fees.
   g. Revocation of Membership. Revocation of membership is considered the maximum consequence for noncompliance with the Code of Ethics.
      1. Revocation requires a two-thirds majority of the voting members of the EPC.
      2. Individuals whose memberships are revoked are not entitled to a refund of dues or fees.
      3. One year following the date of membership revocation the individual may reapply for, but is not guaranteed, membership through normal channels, and must meet the membership qualifications in effect at the time of reapplication.

9. The member may appeal the Final Finding and Decision of the Ethical Practice Committee to the Academy Board of Directors. The route of Appeal is by letter format through the Ethical Practice Committee to the Board of Directors of the Academy. Requests for Appeal must:
a. be received by the Chair of the Ethical Practice Committee within 30 days of the Ethical Practice Committee notification of the Final Finding and Decision,

b. state the basis for the appeal and the reason(s) that the Final Finding and Decision of the Ethical Practice Committee should be changed,

c. not offer new documentation.

The EPC chair will communicate with the Executive Director of the Academy to schedule the appeal at the earliest feasible Board of Director’s meeting.

The Board of Directors will review the documents and written summaries and deliberate the case.

The decision of the Board of Directors regarding the member's appeal shall be final.

10. In order to educate the membership, upon majority vote of the Ethical Practice Committee, the circumstances and nature of cases shall be presented in Audiology Today and in the Professional Resource area of the AAA website. The member’s identity will not be made public.

11. No Ethical Practice Committee member shall give access to records, act or speak independently, or on behalf of the Ethical Practice Committee, without the expressed permission of the members then active. No member may impose the sanction of the Ethical Practice Committee or interpret the findings of the EPC in any manner that may place members of the Ethical Practice Committee or Board of Directors, collectively or singly, at financial, professional, or personal risk.

12. The Ethical Practice Committee Chair and Staff Liaison shall maintain electronic records that shall form the basis for future findings of the Committee.

CONFIDENTIALITY AND RECORDS

Confidentiality shall be maintained in all Ethical Practice Committee discussion, correspondence, communication, deliberation, and records pertaining to members reviewed by the Ethical Practice Committee.

1. Complaints and suspected noncompliance with the Code of Ethics are assigned a case number.

2. Identity of members involved in complaints and suspected noncompliance cases and access to EPC files is restricted to the following:
   a. EPC members
   b. Executive Director
   c. Agent/s of the Executive Director
   d. Other/s, following majority vote of EPC

3. Original records shall be maintained at the Central Records Repository at the Academy office in a locked cabinet.
   a. One copy will be sent to the Ethical Practice Committee Chair or member designated by the Chair.
   b. Redacted copies will be sent to members.

4. Communications shall be sent to the members involved in complaints by the Academy office via certified or registered mail, after review by Legal Counsel, as needed.

5. When a case is closed,
   a. The Chair will forward all documentation to the Staff Liaison to be maintained at the Academy Central Records Repository.
   b. Members shall destroy all material pertaining to the case.

6. Complete records generally shall be maintained at the Academy Central Records Repository for a period of 5 years.
   a. Records will be destroyed five years after a member receives a sanction less than suspension, or five years after the end of a suspension, or after membership is reinstated.
   b. Records of membership revocations for persons who have not returned to membership status will be maintained indefinitely.
Appendix 2–B
American Speech-Language-Hearing Association
Code of Ethics 2016

CODE OF ETHICS
ASHA Code of Ethics

PREAMBLE

The American Speech-Language-Hearing Association (ASHA; hereafter, also known as “The Association”) has been committed to a framework of common principles and standards of practice since ASHA’s inception in 1925. This commitment was formalized in 1952 as the Association’s first Code of Ethics. This Code has been modified and adapted as society and the professions have changed. The Code of Ethics reflects what we value as professionals and establishes expectations for our scientific and clinical practice based on principles of duty, accountability, fairness, and responsibility. The ASHA Code of Ethics is intended to ensure the welfare of the consumer and to protect the reputation and integrity of the professions.

The ASHA Code of Ethics is a framework and focused guide for professionals in support of day-to-day decision making related to professional conduct. The Code is partly obligatory and disciplinary and partly aspirational and descriptive in that it defines the professional’s role. The Code educates professionals in the discipline, as well as students, other professionals, and the public, regarding ethical principles and standards that direct professional conduct.

The preservation of the highest standards of integrity and ethical principles is vital to the responsible discharge of obligations by audiologists, speech-language pathologists, and speech, language, and hearing scientists who serve as clinicians, educators, mentors, researchers, supervisors, and administrators. This Code of Ethics sets forth the fundamental principles and rules considered essential to this purpose and is applicable to the following individuals:

- a member of the American Speech-Language-Hearing Association holding the Certificate of Clinical Competence (CCC)
- a member of the Association not holding the Certificate of Clinical Competence (CCC)
- a nonmember of the Association holding the Certificate of Clinical Competence (CCC)
- an applicant for certification, or for membership and certification

By holding ASHA certification or membership, or through application for such, all individuals are automatically subject to the jurisdiction of the Board of Ethics for ethics complaint adjudication. Individuals who provide clinical services and who also desire membership in the Association must hold the CCC.

The fundamentals of ethical conduct are described by Principles of Ethics and by Rules of Ethics. The four Principles of Ethics form the underlying philosophical basis for the Code of Ethics and are reflected in the following areas: (I) responsibility to persons served professionally and to research participants, both human and animal; (II) responsibility for one’s professional competence; (III) responsibility to the public; and (IV) responsibility for professional relationships. Individuals shall honor and abide by these Principles as affirmative obligations under all conditions of applicable professional activity. Rules of Ethics are specific statements of minimally acceptable as well as unacceptable professional conduct.

The Code is designed to provide guidance to members, applicants, and certified individuals as they make professional decisions. Because the Code is not intended to address specific situations and is not inclusive of all possible ethical dilemmas, professionals are expected to follow the written provisions and to uphold the spirit and purpose of the Code. Adherence to the Code of Ethics and its enforcement results in respect for the
professions and positive outcomes for individuals who benefit from the work of audiologists, speech-language pathologists, and speech, language, and hearing scientists.

**TERMINOLOGY**


**advertising** – Any form of communication with the public about services, therapies, products, or publications.

**conflict of interest** – An opposition between the private interests and the official or professional responsibilities of a person in a position of trust, power, and/or authority.

**crime** – Any felony; or any misdemeanor involving dishonesty, physical harm to the person or property of another, or a threat of physical harm to the person or property of another. For more details, see the “Disclosure Information” section of applications for ASHA certification found on www.asha.org/certification/AudCertification/ and www.asha.org/certification/SLPCertification/.

**diminished decision-making ability** – Any condition that renders a person unable to form the specific intent necessary to determine a reasonable course of action.

**fraud** – Any act, expression, omission, or concealment—the intent of which is either actual or constructive—calculated to deceive others to their disadvantage.

**impaired practitioner** – An individual whose professional practice is adversely affected by addiction, substance abuse, or health-related and/or mental health–related conditions.

**individuals** – Members and/or certificate holders, including applicants for certification.

**informed consent** – May be verbal, unless written consent is required; constitutes consent by persons served, research participants engaged, or parents and/or guardians of persons served to a proposed course of action after the communication of adequate information regarding expected outcomes and potential risks.

**jurisdiction** – The “personal jurisdiction” and authority of the ASHA Board of Ethics over an individual holding ASHA certification and/or membership, regardless of the individual’s geographic location.

**know, known, or knowingly** – Having or reflecting knowledge.

**may vs. shall** – May denotes an allowance for discretion; shall denotes no discretion.

**misrepresentation** – Any statement by words or other conduct that, under the circumstances, amounts to an assertion that is false or erroneous (i.e., not in accordance with the facts); any statement made with conscious ignorance or a reckless disregard for the truth.

**negligence** – Breaching of a duty owed to another, which occurs because of a failure to conform to a requirement, and this failure has caused harm to another individual, which led to damages to this person(s);
failure to exercise the care toward others that a reasonable or prudent person would take in the circumstances, or taking actions that such a reasonable person would not.

**nolo contendere** – No contest.

**plagiarism** – False representation of another person’s idea, research, presentation, result, or product as one’s own through irresponsible citation, attribution, or paraphrasing; ethical misconduct does not include honest error or differences of opinion.

**publicly sanctioned** – A formal disciplinary action of public record, excluding actions due to insufficient continuing education, checks returned for insufficient funds, or late payment of fees not resulting in unlicensed practice.

**reasonable or reasonably** – Supported or justified by fact or circumstance and being in accordance with reason, fairness, duty, or prudence.

**self-report** – A professional obligation of self-disclosure that requires (a) notifying ASHA Standards and Ethics and (b) mailing a hard copy of a certified document to ASHA Standards and Ethics (see term above). All self-reports are subject to a separate ASHA Certification review process, which, depending on the seriousness of the self-reported information, takes additional processing time.

**shall vs. may** – Shall denotes no discretion; may denotes an allowance for discretion.

**support personnel** – Those providing support to audiologists, speech-language pathologists, or speech, language, and hearing scientists (e.g., technician, paraprofessional, aide, or assistant in audiology, speech-language pathology, or communication sciences and disorders).

**telepractice, teletherapy** – Application of telecommunications technology to the delivery of audiology and speech-language pathology professional services at a distance by linking clinician to client/patient or clinician to clinician for assessment, intervention, and/or consultation. The quality of the service should be equivalent to in-person service.

**written** – Encompasses both electronic and hard-copy writings or communications.

### PRINCIPLE OF ETHICS I

Individuals shall honor their responsibility to hold paramount the welfare of persons they serve professionally or who are participants in research and scholarly activities, and they shall treat animals involved in research in a humane manner.

### RULES OF ETHICS

A. Individuals shall provide all clinical services and scientific activities competently.  

B. Individuals shall use every resource, including referral and/or interprofessional collaboration when appropriate, to ensure that quality service is provided.
C. Individuals shall not discriminate in the delivery of professional services or in the conduct of research and scholarly activities on the basis of race, ethnicity, sex, gender identity/gender expression, sexual orientation, age, religion, national origin, disability, culture, language, or dialect.

D. Individuals shall not misrepresent the credentials of aides, assistants, technicians, support personnel, students, research interns, Clinical Fellows, or any others under their supervision, and they shall inform those they serve professionally of the name, role, and professional credentials of persons providing services.

E. Individuals who hold the Certificate of Clinical Competence may delegate tasks related to the provision of clinical services to aides, assistants, technicians, support personnel, or any other persons only if those persons are adequately prepared and are appropriately supervised. The responsibility for the welfare of those being served remains with the certified individual.

F. Individuals who hold the Certificate of Clinical Competence shall not delegate tasks that require the unique skills, knowledge, judgment, or credentials that are within the scope of their profession to aides, assistants, technicians, support personnel, or any nonprofessionals over whom they have supervisory responsibility.

G. Individuals who hold the Certificate of Clinical Competence may delegate to students tasks related to the provision of clinical services that require the unique skills, knowledge, and judgment that are within the scope of practice of their profession only if those students are adequately prepared and are appropriately supervised. The responsibility for the welfare of those being served remains with the certified individual.

H. Individuals shall obtain informed consent from the persons they serve about the nature and possible risks and effects of services provided, technology employed, and products dispensed. This obligation also includes informing persons served about possible effects of not engaging in treatment or not following clinical recommendations. If diminished decision-making ability of persons served is suspected, individuals should seek appropriate authorization for services, such as authorization from a spouse, other family member, or legally authorized/appointed representative.

I. Individuals shall enroll and include persons as participants in research or teaching demonstrations only if participation is voluntary, without coercion, and with informed consent.

J. Individuals shall accurately represent the intended purpose of a service, product, or research endeavor and shall abide by established guidelines for clinical practice and the responsible conduct of research.

K. Individuals who hold the Certificate of Clinical Competence shall evaluate the effectiveness of services provided, technology employed, and products dispensed, and they shall provide services or dispense products only when benefit can reasonably be expected.

L. Individuals may make a reasonable statement of prognosis, but they shall not guarantee—directly or by implication—the results of any treatment or procedure.

M. Individuals who hold the Certificate of Clinical Competence shall use independent and evidence-based clinical judgment, keeping paramount the best interests of those being served.

N. Individuals who hold the Certificate of Clinical Competence shall not provide clinical services solely by correspondence, but may provide services via telepractice consistent with professional standards and state and federal regulations.

O. Individuals shall protect the confidentiality and security of records of professional services provided, research and scholarly activities conducted, and products dispensed. Access to these records shall be
allowed only when doing so is necessary to protect the welfare of the person or of the community, is legally authorized, or is otherwise required by law.

P. Individuals shall protect the confidentiality of any professional or personal information about persons served professionally or participants involved in research and scholarly activities and may disclose confidential information only when doing so is necessary to protect the welfare of the person or of the community, is legally authorized, or is otherwise required by law.

Q. Individuals shall maintain timely records and accurately record and bill for services provided and products dispensed and shall not misrepresent services provided, products dispensed, or research and scholarly activities conducted.

R. Individuals whose professional practice is adversely affected by substance abuse, addiction, or other health-related conditions are impaired practitioners and shall seek professional assistance and, where appropriate, withdraw from the affected areas of practice.

S. Individuals who have knowledge that a colleague is unable to provide professional services with reasonable skill and safety shall report this information to the appropriate authority, internally if a mechanism exists and, otherwise, externally.

T. Individuals shall provide reasonable notice and information about alternatives for obtaining care in the event that they can no longer provide professional services.

**PRINCIPLE OF ETHICS II**

Individuals shall honor their responsibility to achieve and maintain the highest level of professional competence and performance.

**RULES OF ETHICS**

A. Individuals who hold the Certificate of Clinical Competence shall engage in only those aspects of the professions that are within the scope of their professional practice and competence, considering their certification status, education, training, and experience.

B. Members who do not hold the Certificate of Clinical Competence may not engage in the provision of clinical services; however, individuals who are in the certification application process may engage in the provision of clinical services consistent with current local and state laws and regulations and with ASHA certification requirements.

C. Individuals who engage in research shall comply with all institutional, state, and federal regulations that address any aspects of research, including those that involve human participants and animals.

D. Individuals shall enhance and refine their professional competence and expertise through engagement in lifelong learning applicable to their professional activities and skills.

E. Individuals in administrative or supervisory roles shall not require or permit their professional staff to provide services or conduct research activities that exceed the staff member’s certification status, competence, education, training, and experience.

F. Individuals in administrative or supervisory roles shall not require or permit their professional staff to provide services or conduct clinical activities that compromise the staff member’s independent and objective professional judgment.
G. Individuals shall make use of technology and instrumentation consistent with accepted professional guidelines in their areas of practice. When such technology is not available, an appropriate referral may be made.

H. Individuals shall ensure that all technology and instrumentation used to provide services or to conduct research and scholarly activities are in proper working order and are properly calibrated.

### PRINCIPLE OF ETHICS III

Individuals shall honor their responsibility to the public when advocating for the unmet communication and swallowing needs of the public and shall provide accurate information involving any aspect of the professions.

### RULES OF ETHICS

A. Individuals shall not misrepresent their credentials, competence, education, training, experience, and scholarly contributions.

B. Individuals shall avoid engaging in conflicts of interest whereby personal, financial, or other considerations have the potential to influence or compromise professional judgment and objectivity.

C. Individuals shall not misrepresent research and scholarly activities, diagnostic information, services provided, results of services provided, products dispensed, or the effects of products dispensed.

D. Individuals shall not defraud through intent, ignorance, or negligence or engage in any scheme to defraud in connection with obtaining payment, reimbursement, or grants and contracts for services provided, research conducted, or products dispensed.

E. Individuals’ statements to the public shall provide accurate and complete information about the nature and management of communication disorders, about the professions, about professional services, about products for sale, and about research and scholarly activities.

F. Individuals’ statements to the public shall adhere to prevailing professional norms and shall not contain misrepresentations when advertising, announcing, and promoting their professional services and products and when reporting research results.

G. Individuals shall not knowingly make false financial or nonfinancial statements and shall complete all materials honestly and without omission.

### PRINCIPLE OF ETHICS IV

Individuals shall uphold the dignity and autonomy of the professions, maintain collaborative and harmonious interprofessional and intraprofessional relationships, and accept the professions’ self-imposed standards.

### RULES OF ETHICS

A. Individuals shall work collaboratively, when appropriate, with members of one’s own profession and/or members of other professions to deliver the highest quality of care.

B. Individuals shall exercise independent professional judgment in recommending and providing professional services when an administrative mandate, referral source, or prescription prevents keeping the welfare of persons served paramount.
C. Individuals’ statements to colleagues about professional services, research results, and products shall adhere to prevailing professional standards and shall contain no misrepresentations.

D. Individuals shall not engage in any form of conduct that adversely reflects on the professions or on the individual’s fitness to serve persons professionally.

E. Individuals shall not engage in dishonesty, negligence, fraud, deceit, or misrepresentation.

F. Applicants for certification or membership, and individuals making disclosures, shall not knowingly make false statements and shall complete all application and disclosure materials honestly and without omission.

G. Individuals shall not engage in any form of harassment, power abuse, or sexual harassment.

H. Individuals shall not engage in sexual activities with individuals (other than a spouse or other individual with whom a prior consensual relationship exists) over whom they exercise professional authority or power, including persons receiving services, assistants, students, or research participants.

I. Individuals shall not knowingly allow anyone under their supervision to engage in any practice that violates the Code of Ethics.

J. Individuals shall assign credit only to those who have contributed to a publication, presentation, process, or product. Credit shall be assigned in proportion to the contribution and only with the contributor’s consent.

K. Individuals shall reference the source when using other persons’ ideas, research, presentations, results, or products in written, oral, or any other media presentation or summary. To do otherwise constitutes plagiarism.

L. Individuals shall not discriminate in their relationships with colleagues, assistants, students, support personnel, and members of other professions and disciplines on the basis of race, ethnicity, sex, gender identity/gender expression, sexual orientation, age, religion, national origin, disability, culture, language, dialect, or socioeconomic status.

M. Individuals with evidence that the Code of Ethics may have been violated have the responsibility to work collaboratively to resolve the situation where possible or to inform the Board of Ethics through its established procedures.

N. Individuals shall report members of other professions who they know have violated standards of care to the appropriate professional licensing authority or board, other professional regulatory body, or professional association when such violation compromises the welfare of persons served and/or research participants.

O. Individuals shall not file or encourage others to file complaints that disregard or ignore facts that would disprove the allegation; the Code of Ethics shall not be used for personal reprisal, as a means of addressing personal animosity, or as a vehicle for retaliation.

P. Individuals making and responding to complaints shall comply fully with the policies of the Board of Ethics in its consideration, adjudication, and resolution of complaints of alleged violations of the Code of Ethics.

Q. Individuals involved in ethics complaints shall not knowingly make false statements of fact or withhold relevant facts necessary to fairly adjudicate the complaints.

R. Individuals shall comply with local, state, and federal laws and regulations applicable to professional practice, research ethics, and the responsible conduct of research.

S. Individuals who have been convicted; been found guilty; or entered a plea of guilty or nolo contendere to (1) any misdemeanor involving dishonesty, physical harm—or the threat of physical
ASHA Code of Ethics

harm—to the person or property of another, or (2) any felony, shall self-report by notifying ASHA Standards and Ethics (see Terminology for mailing address) in writing within 30 days of the conviction, plea, or finding of guilt. Individuals shall also provide a certified copy of the conviction, plea, nolo contendere record, or docket entry to ASHA Standards and Ethics within 30 days of self-reporting.

T. Individuals who have been publicly sanctioned or denied a license or a professional credential by any professional association, professional licensing authority or board, or other professional regulatory body shall self-report by notifying ASHA Standards and Ethics (see Terminology for mailing address) in writing within 30 days of the final action or disposition. Individuals shall also provide a certified copy of the final action, sanction, or disposition to ASHA Standards and Ethics within 30 days of self-reporting.
# Chapter 3

## Research Problems

![Balance Scale](image)

### CHAPTER OUTLINE

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LEARNING OBJECTIVES

Upon completion of this chapter, the reader will be able to:

- Define and provide examples of independent and dependent variables
- Describe how variables and confounding factors may be controlled in a research project
- Describe how a topic can be selected for a research problem
- Discuss how to state a research problem, null hypothesis, and alternative hypothesis
- Describe what factors should be considered regarding the feasibility of a research project
- Discuss the six phases of budget preparation for a research project
- List the factors that may be included in a Charge Master
Science is the search for knowledge. Schiavetti, Metz, and Orlikoff (2011) described the scientific method as a method of efficiently or methodically generating knowledge by recognizing a problem capable of objective study, collecting data by observation or experimentation, and drawing conclusions based on analysis of the data. Silverman (1998) further described the scientific method as a set of rules used for describing, explaining, and predicting “events” that are observable and occur over time.

The scientific method is an effective tool for answering the types of questions that it was designed to answer. However, as Siegel (1987) points out, some questions in communication disorders (e.g., those involving social or personal values and attitudes) cannot be answered using pure methods of science.

Theoretically, studies can be classified as basic or applied experimental research. Basic research focuses on answering important questions or deciphering the laws of nature (Hegde, 2003; Shearer, 1982). Applied research employs the answers to basic questions of future research to practical problems, such as questions involving clinical practice.

Questions involving clinical management are answered using clinical or applied research models. Furthermore, clinical research may be experimental or descriptive. Experimental studies involve the use of rigorous design in which variables are carefully controlled. Experimental research in speech-language pathology and audiology is often weakened somewhat statistically because some variables cannot be controlled (Shearer, 1982).

Variables are capable of change or modification and may vary in quality or quantity. Examples of qualitative variables might include the gender of an individual, the disorder of speech or language with which an individual has been diagnosed, or the type of clinical management selected for particular patients. Quantitative variables such as intelligence can be measured quantitatively or numerically. Discrete quantitative variables are not expressed in decimals or fractions. Examples include the number of subjects in a study, scores on some tests, or the number of times a treatment is administered. Continuous quantitative variables can be expressed in any numerical value, including fractions. Examples include the age of subjects (i.e., 1.5 or 1½ years), scores on some tests that allow results to be expressed in whole numbers or in fractions, or subjects’ height and weight data. Variables describe the population investigated by a study. Variables that do not change from individual to individual (such as a diagnosis of stuttering) are called constant variables.

Research in speech-language pathology and audiology is designed to investigate the cause(s) of specific communication disorders and the effect(s) of various phenomena on behaviors associated with communication disorders. Dependent variables, sometimes called outcome variables, are the effect of unknown etiology(ies). An example of a dependent variable is a hyperfunctional voice disorder characterized by a rough voice quality and accompanied by frequent upper respiratory infections, coughing, allergies, and laryngitis. The dependent variable must be described in operational terms so that it is clear how the variable will be identified and measured.
for a particular study (Hegde, 1994). An operational definition should have sufficient detail so that another researcher(s) can replicate the procedure or condition (Portney & Watkins, 2009). Independent variables explain the dependent variables. For example, an individual’s vocal habits (talking frequently, loudly, and with excessive laryngeal tension) along with behaviors associated with a medical condition (laryngitis) might constitute identified independent variables explaining the dependent variable (a voice disorder defined according to description and accompanying medical condition). By manipulating independent variables, an investigator may change dependent variables involving disorders of communication. For example, reducing abusive vocal habits and medically testing the laryngitis may successfully affect a change in voice characteristics to a smooth, more relaxed, and pleasant voice production.

Hegde (2003) described three types of independent variables in communication disorders research, those that:

1. Explain the cause of normal parameters of communication;
2. Explain the development of abnormal communication; or
3. Identify treatment techniques that create optimal changes in communication.

The independent variables that can be manipulated (e.g., vocal habits and medical condition of the larynx and surrounding tissues) are active variables (Hegde, 2003). Some independent variables may be impossible to change (e.g., a predisposition for laryngeal vulnerability to abusive vocal habits). These are called assigned variables (Hegde, 2003). They may play a role in determining outcome but cannot be controlled by the researcher. The experimental researcher attempts to rule out assigned variables. For example, if both patients identified as having a predisposition or vulnerability to some voice problems and patients identified as having no predisposition or vulnerability to some voice problems improve by changing vocal habits and receiving medical intervention, the vulnerability variable may be ruled out, as the assumption that it causes hyperfunctional phonation is reduced.

**Control of Variables**

According to Portney and Watkins (2009), “an extraneous variable is any factor that is not directly related to the purpose of the study, but may affect the dependent variable” (p. 153). When extraneous variables are not controlled, they can have a confounding influence on the independent variable. For example, if a patient has a history of sinus congestion and drainage, then this extraneous variable could influence vocal quality.

Complete control of all confounding variables is usually not possible, which may lead to results that are inconclusive and difficult to interpret. Portney and Watkins (2009) suggest several methods that may help control for extraneous or confounding variables, such as random assignment of subjects, use of a control group, a well-defined research protocol, and blinding.

Random assignment of subjects means that each subject has an equal chance of being assigned to any group and ensures that assignments will be independent of personal judgment or bias. However, clinical research in speech-language pathol-
ogy and audiology often involves using small numbers of subjects, and randomization can result in groups with disparate differences on critical variables. Researchers may use statistical means of comparing groups on initial values in regard to the dependent variable to determine if the influence of any extraneous variable did balance out (Portney & Watkins, 2009). Control groups are frequently used by researchers to rule out the influence of extraneous variables. In a classic experimental design, subjects in a control group receive no form of treatment. This is in contrast to the experimental group, which is targeted to receive the “new” treatment. This type of design strategy would lead the researcher to safely assume that if the treatment group is significantly different from the control group, then that is probably attributable to the influence of the “new” treatment. Portney and Watkins (2000) state that “the use of a control group is often unfeasible in clinical situations, for practical or ethical reasons” (p. 157). Because of such reasons, clinical researchers have a control group receive a “standard” form of treatment with the experimental group receiving a “new” form of treatment. Without comparison of these two groups, it is difficult to conclude that any form of treatment is actually responsible for an observed change.

A well-defined research protocol usually ensures that many extraneous variables have been considered and controlled. The protocol needs to have each procedure explained and detailed in order for another researcher to critically analyze what was done, for an Institutional Review Board (IRB) to make decisions, and to improve reliability. Research protocols should also include a description of all limitations in the study. Limitations would not prevent a study from being conducted, but may help to recognize that other variables may not have been controlled, which may have influenced the obtained results.

It is preferable that blinding be used in studies whenever possible to avoid the possibility of consciously or subconsciously influencing the performance of a subject or the recording of data by a researcher. According to Portney and Watkins (2000), double-blind studies are “where neither the subjects nor the investigators are aware of the identity of the treatment groups until after the data are collected” (p. 159). In some cases, single-blind studies can be conducted where only the investigator or research team is blinded. A further discussion about how these aspects of research control might influence the validity and reliability of studies occurs later in this chapter.

Figure 3–1 demonstrates a model of the research process. Phases need to be completed in a sequential manner. This model is referenced in other parts of this text.

**Selecting a Topic**

Selecting a topic for a research project is influenced by many factors. First, it may be that a researcher or group of researchers share(s) a curiosity about a given topic. Second, it may be that a student must choose one topic to complete an academic requirement for a course or a degree. Third, a topic may be selected because clinical experiences have led a clinician to ask questions about the impact of various treatment protocols. Whatever the reason for selecting a topic, it is important that it be something the researcher(s) is/are very interested
3. RESEARCH PROBLEMS

in doing. Intrinsic motivation and the willingness to know why or how something occurs will drive other decisions in the problem-solving process. There are numerous topics that may be selected, and it may be challenging to determine which problem needs to be addressed first. Discussion with other researchers, faculty, and students should provide productive decision-making.

Topics provide a general foundation to determine which area may be researched, but this then must be narrowed into a research question. A research question is usually answered in a single study (Portney & Watkins, 2000). It may start out very broad, but it does require refinement so that specific variables may be defined. The process of narrowing the research question can be facilitated by a review of the literature or “landmark” studies. Frequently, a review of studies relevant to the topic can provide good examples of the questions that have previously been asked and investigated.

The role of clinical experience may influence the type of research question that is asked (Maxwell & Satake, 2006). Clinicians often encounter situations with patients that are not easily explained. The clinician may believe that it is important to explain unexpected results to the patient and/or family. Research questions have been generated based on everyday clinical experiences.

Research questions may also result from working with different patient populations. For example, a clinician may find that a particular treatment protocol is very effective with one group of patients but does not have a similar impact on another group of patients. These situations can lead a clinician to question which variables differentiate the patients and necessitate the need to modify procedures.

Research is conducted to answer questions and is an increasingly important component of the field of communication sciences and disorders. In an effort to determine cause-and-effect relationships, researchers conscientiously apply scientific methodology to carefully control variables. Because of federal laws governing the education of disabled children and the importance of documenting outcome measures for treatment, it is imperative that the scientific method be implemented in basic and applied research projects.

Johnson (2006) proposed that, when posing an answerable question, a key starting point for evidence-based practice (EBP), the method known as PICO should be used: $P = \text{patient/population}$, $I = \text{intervention/treatment/exposure}$, $C = \text{comparison}$, and $O = \text{outcome}$. Johnson (2006) stated that “The following is a PICO question of possible relevance to childhood speech-language disorders: ‘Does group, as compared with individual, language intervention result in greater expressive language growth for preschool children with delays in language production?’” (p. 23). For this example, Johnson identified the following: “$P = \text{preschool children with delays in language production}; I = \text{group language intervention}; C = \text{individual language intervention}, and O = \text{expressive language growth}” (p. 23).

Clinical theory is often used as a resource for developing research questions. Theories will guide and sometimes
explain relationships between variables. In addition, they also may enhance the prediction of outcomes based on certain information (Portney & Watkins, 2009). However, it should be noted that research will not “prove” that a theory is or is not correct. Research either will or will not support the theoretical principles. Therefore, it is important that researchers carefully word the findings of a study in order to have any consumer of the research understand that nothing has been “proven” but can only support or refute a clinical theory.

**Hypotheses and Theories**

Hypotheses are often formulated for the purpose of testing theories that explain a phenomenon, event, or condition. Questions may be stated in the form of a formal or working hypothesis. The formal or null hypothesis to be accepted or rejected by a study is stated in negative terms. A null hypothesis states that there is “no statistically significant difference” or “no statistically significant relationship” between groups or variables. For example, to test the theory that phonological errors may be caused by the presence of a hearing loss, a null hypothesis attempts to eliminate bias from the hypothesis by declaring that no relationship exists between the variables (Hegde, 2003). Thus, the researcher attempts to reject the null hypothesis that there is no relationship between phonological development and the presence of a hearing loss. Hegde (2003) cautions, however, that the null hypothesis does not eliminate or control for examiner bias. Objective interpretation of the results of a study requires objective, ethical research practices by a researcher with research education and experience, preferably initially in collaboration with experienced, objective researchers.

A working hypothesis, sometimes known as a research hypothesis, may simply ask a question: “Is there a difference” or “Is there a relationship” between groups or variables? When a researcher states in a hypothesis that there will be a change or describes a relationship in a certain direction, this is known as a directional hypothesis. For example, if the hypothesis states that “there is a high relationship” or “there is a low relationship,” this would indicate that the researcher would believe the results of the study will not only be statistically significantly different, but also in a certain direction.

Research hypotheses should include the description of the independent and dependent variables (Portney & Watkins, 2000). A simple hypothesis includes one independent variable and one dependent variable, while a complex hypothesis contains more than one independent and dependent variables.

The acceptance or rejection of hypotheses (null, nondirectional, directional, simple, or complex) based on the results of one study are always interpreted as tentative. The findings of current studies may be replaced or expanded by future findings based on new theories, different clinical practice procedures, or changes in research methods. Like the records set by athletes, research findings often do not withstand expansion and changes in the knowledge bases. As Silverman (1998) stated, “The final aspect of the scientific approach is being aware of the tentative nature of answers and hypotheses because it indicates that no answer to a question or test of a hypothesis is final. Thus, the language used to convey
the conclusions reached by a researcher conducting any study revolves around the words ‘suggest,’ ‘support,’ or ‘refute’ rather than ‘prove.’”

**Feasibility of a Research Project**

The feasibility of a research study needs to be considered very early in the research process (Portney & Watkins, 2000). Any research project that is worthy of investigating and investing of time and resources must undergo a “feasibility” test. The researcher may need to consider several factors when determining feasibility (Johnson, 2004):

- What previous experience does the researcher have with this topic?
- What are the risks/benefits for the subjects?
- What is the duration of the project?
- Does a “pilot study” need to be conducted? If so, will subjects require screening?
- Will an IRB approve the protocol?
- Will the consent form need to be translated for non-English speakers?
  What about consent for subjects with mental disabilities or learning disabilities?
- Can the research protocol be adequately integrated with routine standards of care?
- Is specialized equipment required? If so, how will it be calibrated and maintained?
- Is outside personnel required to conduct special procedures or efficacy measures?
- What are the frequency and severity of an adverse event (AE)?
- Are the inclusion/exclusion criteria reasonable to meet anticipated subject enrollment?
- Will the following factors impede subject enrollment: age, duration of participation, frequency of visits, and procedural discomfort?
- Will extended hours be required? If so, is current staffing adequate to conduct the protocol?
- Will personnel requirements compete with other research projects?
- How much funds will be necessary to conduct the project? Who will pay for them? What about personnel time? What if there is a long time lag between receiving budgetary funds and initiating the study? Will subjects need to be paid for their time?

Feasibility of a research study needs to be carefully discussed with all involved parties during the planning phase. After several discussions with key personnel, a “go/no go” decision is made by all parties. The next phase involves the development of a budget, which encompasses several phases.

**Budgetary Considerations and Preparation**

Rowell (2004) suggests that there are six phases when developing a research budget (Figure 3–2). Phase one is the preparation phase. During this time, the researcher(s) should have a good idea of what they can and cannot do, know the costs of services that will be necessary to complete the project, and develop a “charge master.” It is important to determine start-up costs by considering the
following: IRB fees, IRB preparation, protocol review time, copies, equipment (and any upgrades), chart reviews, database reviews, pre-study visits, any pharmacy and lab setups, administrative oversight, and regulatory requirements.

When considering the per-patient cost, it important to determine direct cost (what will be involved with direct subject contact), variable costs (charges that depend on items that the subject may or may not require), and time for the researcher to conduct the experiment. Rowell (2004) states that time is the most underestimated value when considering per-patient costs. This may not only include researcher salary, but fringe benefits that must be paid for a researcher. In addition, close-out costs need to be considered and include administrative costs, closing out records, and long-term storage of records.

Phase two involves the protocol review phase. It is important that the principal investigator (PI) choose realistic timelines for completion of the study. Time is one variable that can be easily under- or over-estimated. During this phase, it is important to consider the amount of time for the following:

- Consent process—may take approximately 45 minutes to 1 hour, including a discussion about the Health Insurance Portability and Accountability Act (HIPAA);
- Screening failure compensation—if a subject does not meet the criteria.

![Diagram of the six phases of a research site budget.](image-url)

**Figure 3–2.** The six phases of a research site budget. From Rowell, J. (2004). *Clinical research workshop.* ISU School of Medicine, Division of Research and Department of Pediatric/Section on Clinical Pharmacology. Copyright 2004 LSUHSC-Shreveport. Adapted with permission.
for inclusion in the study, how is the subject compensated?

- Payments for unscheduled procedures such as adverse events, tests, and failures;
- Advertising for subjects, including print and electronic media;
- Costs that may be necessary if the study runs longer than expected;
- Time for the “coordinator” or someone who has administrative oversight of the project, which includes protocol revisions, meetings, consent or re-consent, audits, training, travel, faxing, and preparing source documents.

Phase three includes the budget submission to the funding source. There are various ways this may be done, including flat rate (nonnegotiable), small up-front payments, competitive bidding, high performance, and speedy enrollment performances. Rowell (2004) suggests requesting more funding than may be expected is possible. However, any sponsor or supporter of the research may require a single cost figure per patient and justification for each cost.

Phase four includes budget negotiation. In some instances, a sponsor or funding source may allow for some negotiation before support will be provided. It is important that, during negotiation, the sponsor understand the commitment of the researcher toward the project. Enthusiasm and dedication can lead a sponsor or funding agency to support the project at the level required to be successful. If adjustments are necessary by the researcher, it is important that they be carefully considered so as not to jeopardize the completion of the protocol or violate IRB rules and regulations.

Phase five of the process includes the review and acceptance of the budget. During this time, be sure to use your Charge Master (spreadsheet) to determine that all charges are accurate. Carefully review the contract and seek legal counsel when necessary. Does the contract state a startup date? How will the contract be paid? What are the milestones for payment? Payment method can vary, but it may include one-fourth of the budget to cover start-up and screening costs or payment when one-half of the enrollment target is completed.

Phase six is also called the “post-study” phase of the budget. This phase takes place when all obligations have been met and all payments have been received. At this time, the researcher(s) should review the Charge Master to see if it was indeed accurate, asking, for example, the following questions: Did the budget reflect the work performed? Have all fees been paid? Were there extra procedures that were not requested in the original budget?

Budgetary issues should not be an afterthought. Careful planning of time commitment, supplies, administrative costs, and site preparation need to be included early when discussing the feasibility of a study. Failure to carefully consider these issues could result in some projects being initiated but not completed, thus resulting in a waste of time and resources. Furthermore, all subjects should clearly understand any type of compensation that is due and what is not to be paid.

### Summary

By the time a research project is published, it has been organized and presented in an established, straightforward format. However, the actual process of conducting research is not as organized
as one might think after reading numerous published articles that have been repeatedly edited. Hegde (2003) described a formative view of research as an evolving process. After much discussion and pondering, numerous false starts, and repeated attempts, a project may emerge and develop. However, many worthy projects are abandoned in the process. Braddom (1990) provides an in-depth outline or guide to assist in the identification of specific omissions or errors in the major sections of a completed research project.

Some significant findings in science over the years have been based on accidental discoveries. Hegde (2003) refers to serendipity in research as evidence that worthwhile projects are not always carefully planned. Accidental discoveries may be the reward for flexibility and a creative sense of inquiry on the part of observers when conducting a research project.

**DISCUSSION QUESTIONS**

1. What is an *independent variable*? Provide an example of it in research.
2. What is a *dependent variable*? Provide an example of it in research.
3. What is meant by *experimental control*? What are some examples of things that can be controlled in a research project?
4. What is the purpose of a *control group*? Why might it be difficult to have a control group involved in clinical research?
5. How might a researcher decide on a *general topic for inquiry*? How might the researcher decide on a *specific problem to study*?
6. What is the difference between a *null hypothesis* and a *research hypothesis*? Provide an example of each.
7. Why would a conclusion that forms a hypothesis only "suggest" rather than "prove" something?
8. What are some variables to consider when determining the *feasibility of a study*? When is feasibility determined? Who makes the decision for "go/no go"?
9. What are the *six phases of planning a budget*?
10. What is a *Charge Master*? What variables might be included in it?


Locating, Accessing, and Assessing Information

CHAPTER OUTLINE

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LEARNING OBJECTIVES

Upon completion of this chapter, the reader will be able to:

- Discuss the methods involved in a successful literature search
- Describe speech-language pathology and audiology journals that allow online access
- List some commonly used databases
- Describe the content of critical appraisal of topic or paper (CAT or CAP)
- List the advantages and disadvantages of using a CAT or CAP
**Introduction**

Locating information for a research project can be done efficiently and effectively if the speech-language pathologist or audiologist applies some basic principles regarding literature searches. Furthermore, after the literature is obtained, it is important that assessment of the research reports involves a systematic approach to summarizing and organizing the evidence. Critical appraisal topics or papers (CATs or CAPs) are the preferred format for organizing evidence-based information. This chapter provides information about locating, accessing, rating, classifying, and reporting levels of evidence that can be used for clinical practice. It also provides an example of a CAT.

**Locating Information**

Speech-language pathologists (SLPs) and audiologists (AUDs) should utilize a variety of methods when locating information for research and consumer health materials. As computers and various databases are now available for professionals to utilize, it is not possible to know all information that has been published. For example, the Cumulative Index to Nursing and Allied Health Literature (CINAHL) has a Subject Heading List of over 11,000 headings, of which 4,526 terms are unique, covering nursing and allied health topics (https://www.ebscohost.com/nursing/products/cinahl-databases/the-cinahl-database). According to Portney and Watkins (2009), there are numerous sources such as indexes and abstracts that provide bibliographic listing of several thousand articles and conference proceedings.

Clinicians and students conducting research are busy and need strategies to locate and access critical information. Furthermore, more researchers are expecting full-text online articles after completing the bibliographic search. It is important that a researcher utilize all sources of information when locating sources. A reference librarian at a university library is a very valuable resource in learning to conduct effective and informative literature searches. The reference librarian will help guide literature searches and provide instruction about using the various databases that include research in health sciences. It is important that any researcher have a topic and utilize the strategies presented in Chapter 3 to determine a topic of interest. Specificity about a topic facilitates any literature search and provides the reference librarian with key word information.

In Figure 4–1, CINAHL (2001) provides a strategy for a successful literature search that should be used when locating resources. Figure 4–1 emphasizes the importance of using a logical sequence when conducting literature searches. Subject headings need to be carefully worded utilizing key words that will allow the search process to specifically pull articles, abstracts, or books relevant to the topic. If a literature search utilizing an online system is not successful in retrieving information, then it may require rephrasing the heading or reconsidering the topic (CINAHL, 2001).

**Databases**

Numerous databases can assist the researcher when locating information. These databases may include literature
from around the globe, and some allow for online access. Johnson (2006) also provides a list of databases that may be utilized regarding children with speech and language disorders. Table 4–1 lists some commonly used indexes and databases for references and abstracts in science and related areas.
### Table 4–1. Commonly Used Indexes and Databases for References and Abstracts in Science and Related Areas

<table>
<thead>
<tr>
<th>Database</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic Search Premier</td>
<td>A multidisciplinary database that covers scholarly journals in biomedical fields, social sciences, humanities, education, physical sciences, and engineering.</td>
</tr>
<tr>
<td>ASHAWire</td>
<td>A collection of research, publications, and other publications from the American Speech-Language-Hearing Association at <a href="https://pubs.asha.org/index.aspx">https://pubs.asha.org/index.aspx</a></td>
</tr>
<tr>
<td>CINAHL: Cumulative Index to Nursing &amp; Allied Health Literature</td>
<td>Available from several vendors, CINAHL indexes journals in nursing and allied health. Some versions provide full text of many articles.</td>
</tr>
<tr>
<td>Clinical Research Education (CREd) Library</td>
<td>The newest addition to ASHA Wire, the CREd Library hosts a dynamic collection of resources on topics critical to the conduct and advancement of high-quality clinical practice research in the communication sciences and disorders (CSD) domain.</td>
</tr>
<tr>
<td>Cochrane Library</td>
<td>The Cochrane Library is a collection of databases created to supply evaluated, high-quality information in support of evidence-based medicine. Although its focus is necessarily broader, it does contain material relevant to communication disorders.</td>
</tr>
<tr>
<td>Dissertation Abstracts</td>
<td>A bibliographic database that indexes doctoral dissertations and master’s theses from about 1,000 graduate schools and universities. About 47,000 new dissertations and 12,000 new theses are added annually.</td>
</tr>
<tr>
<td>EBSCO Information Services</td>
<td>EBSCO offers library resources to customers in academic, medical, K–12, public library, law, corporate, and government markets. Its products include EBSCONET, a complete e-resource management system, and EBSCOhost, which supplies a fee-based online research service with 375 full-text databases, a collection of 600,000-plus e-books, subject indexes, point-of-care medical references, and an array of historical digital archives. In 2010, EBSCO introduced its EBSCO Discovery Service (EDS) to institutions, which allows searches of a portfolio of journals and magazines.</td>
</tr>
<tr>
<td>ERIC (Educational Resources Information Center)</td>
<td>ERIC indexes information from education journals, including articles on communication disorders in an educational context.</td>
</tr>
</tbody>
</table>

*continues*
Table 4–1. continued

<table>
<thead>
<tr>
<th>Database</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>JSTOR</td>
<td>A series of full-text archives covering scholarly journals. Subscriptions are available for discipline-specific or multidisciplinary subsets of the archive, some of which contain journals relevant in communication disorders.</td>
</tr>
<tr>
<td>Linguistics &amp; Language Behavior Abstracts</td>
<td>This database indexes and provides summaries of journal articles in the language sciences, including communication disorders as well as broader subjects such as linguistics.</td>
</tr>
<tr>
<td>PsycINFO</td>
<td>PsycINFO contains over two million citations and abstracts of journal articles, book chapters, books, and dissertations. More than 65,000 new records are added each year.</td>
</tr>
<tr>
<td>PubMed</td>
<td>PubMed, produced by the National Library of Medicine and available to the public without charge, indexes about 4,000 journals covering all aspects of the health sciences. Much of this content is also licensed to commercial vendors for use on their database platforms for a fee.</td>
</tr>
<tr>
<td>Web of Science</td>
<td>A bibliographic database that covers many scholarly journals in the sciences.</td>
</tr>
</tbody>
</table>

Data Mining

Data mining, generally, is the process of analyzing data from different perspectives and discovering new patterns from large data sets involving the intersection of several areas of science procedures and related databases (“Data mining,” 2012). This term is also called data fishing and data snooping.

Technically, data mining can be used to find correlations or patterns in field in large relational databases. Data mining can be conducted in a variety of different ways with the use of more advanced software and machine learning. In general, the relationships are sought among the following areas: (1) Classes: stored data in predetermined groups. For example, a researcher may be concerned with the variables of individuals with stuttering and perceptions that potential employers have toward such individuals. (2) Clusters: data items are grouped according to logical relationships and determine potential markets. For example, an audiologist may be interested in determining which groups are best for dispensing hearing aids. (3) Associations: data can be used to identify associations such as the relationship between hearing loss and the development of phonological development in children. (4) Sequential patterns: data are used to anticipate behavior patterns and trends. For example, a researcher may study the identification of hearing loss and how many batteries are purchased in a month by various clients (Frand, 2012).

The use of data mining methods in communication sciences and disorders is
4. LOCATING, ACCESSING, AND ASSESSING INFORMATION

an emerging field of interest. A study by Danubianu, Pentiuc, Tobolcea, and Schipor (2010) has utilized the association portion of data mining with a case study. The authors used associative data mining with a method of speech-language treatment. They used the database developed from a single-subject case study to answer the following questions: What is the predicted final state for a child or what will his or her state be at the end of various stages of therapy? Which are the best exercises for each case? Which factors might be associated with certain family characteristics and the success of therapy? In general, the authors determined that associative data mining can be used in communication sciences and disorders. However, more research is needed to explore the use of data mining in the use of finding effective assessment and treatment procedures.

The application of data mining has occurred frequently in business with WalMart pioneering massive amounts of data sets to transform its supplier relationships. Data mining is also being used in sports, gaming, and health care. The more data being processed and the more complex the queries to do data mining are require a more powerful system (Frand, 2012).

Online Journals

Online journals may or may not be free. The American Speech-Language-Hearing Association (ASHA) offers online access to its membership (http://www.asha.org). Access to online journals is sponsored by ASHA, and some date back from 1980 to the present. These include American Journal of Audiology (AJA); American Journal of Speech-Language Pathology (AJSLP); Journal of Speech, Language, and Hearing Research (JSLHR); Language, Speech, and Hearing Services in the Schools (LSHSS); and ASHA Leader Online (more information can be found at https://pubs.asha.org/). “CiteTrack” provides e-mail alerts when new content is published that matches specific selected parameters, quick and advanced searches from http://www.highwire.org, improved “Googling,” and personal folders (ASHA Leader, 2006). The American Academy of Audiology (AAA) allows access to the Journal of the American Academy of Audiology online at http://www.audiology.org, and it does not require membership in AAA.

Many journals are subject to a publication embargo. This means that access to the full text becomes available only after a specified period: generally 6 to 12 months, but up to 2 years for a few journals (LSUHSC, 2014). Most databases that contain free journal access online are identified by the “free” icon.

Use of the World Wide Web

The World Wide Web (WWW) is frequently one of the first sources that researchers and/or consumers of health information utilize when locating information. Although, the WWW provides an excellent source of information, it “must be recognized that this resource cannot replace the quality materials accessible from professional organizations, peer reviewed health care journals, the Cochrane Library, etc.” (Levy, 2002, p. 1).

O’Brien (2001) made the point that “information on the WWW needs to be evaluated because, while some of it is
accurate, some of it can be potentially dangerous as there can be a lack of peer review or regulation and because the information can be inaccurate and misleading" (p. 42). Levy (2002) provides a credibility checklist that can be utilized when evaluating research on the WWW.

The checklist includes the following:

- Look at the URL. These include .gov for government sites, .edu for educational sites, or .org for not-for-profit organizations (O’Brien, 2001).
- Look for information from trained and licensed health professionals. Cooke (1999) suggests that affiliations be noted.
- The mission and objectives of any organization should be given at the website so conflicts of interest and advertising can be considered (Cooke, 1999; O’Brien, 2001).
- Statements about any website limitations, scope, or purpose should be carefully considered (Cline & Haynes, 2001).
- Be certain that the information has been peer reviewed. Review the credentials of the reviewers and determine if conflicts of interest might be present (Levy, 2002).
- Although the website may look professional, be sure that references and sources are clearly listed. Also, check when the site was last updated.

It is important for researchers and consumers of health care research to understand that the acceptance rate on the WWW for information is probably 110%. Therefore, all information should be carefully scrutinized when reviewing information from any website. The use of the WWW may be one of the first resources used, but it certainly should not be the only one.

### Interlibrary Loan

Interlibrary loan is one method of obtaining information that may not be available in electronic format or books that may have limited editions. A reference librarian can help when making requests for an interlibrary loan. Charges for the interlibrary loan may or may not exist depending on the agreement the libraries have with each other. Many libraries allow for online requests for interlibrary loan through the ILLiad system. Many loans can be delivered to the user’s desktop, depending on the delivery method used by the library that filled the request (LSUHSC, 2005).

### Manual Searches

Manual searches involve going to the periodical sections of a library and reviewing articles that are bound into annual issues. This method may seem somewhat antiquated compared to the use of computerized databases, but it still provides an excellent method to review literature. Probably the most useful aspect of a manual search includes the review of more “classic” studies and other types of research that have not been transferred to electronic formats. Furthermore, photographs and other types of visual information that may not be available in online searches can be reviewed during a manual search. It is
important that any researcher not be limited to publications that are available only in electronic format. According to Galvan (2006), landmark studies and theorists with historical importance in developing an understanding of a topic or problem can be achieved by utilizing a manual research.

Social Media

The use of social media, such as e-mail, message boards, Skype, and Facebook, is developing a method for expanding research. The use of these methods for communication has increased dramatically within the last few years. Quinnell (2011) discussed that using social media for research and researcher development allows for collection of data from a wide range of stakeholders. This author conducted interviews using asynchronous message boards, Skype, and e-mail conversations. In addition, this author was able to network with other policy-makers and organizations on a variety of topics and related issues. There are ethical and logistical issues associated with the use of these types of social media that must be considered.

Evaluating Research

Evaluating research evidence is important for several reasons. First, sources of evidence are heterogeneous; in other words, not all sources or evidence are equal. Second, the quality of clinical services is related to evidence and the manner in which it was obtained and presented. Third, application of research to clinical practice is related to the level of evidence (Finn, Bothe, & Bramlett, 2005). Last, the use of high-level evidence in making clinical decisions is an ethical responsibility; that is, evidence-based practice is fundamental to ethical practice.

There is a need for SLPs and AUDs to utilize evidence-based results to make clinical decisions. Unfortunately, this is not always the case. Zipoli and Kennedy (2005) found that SLPs used clinical experiences and opinions of colleagues more frequently than research studies or clinical practice guidelines to make clinical decisions. Utilization of research reports can be facilitated by a step-by-step process. These steps include: (a) asking a question, (b) finding the highest level of evidence, (c) critically appraising the evidence, (d) integrating the evidence with clinical experience and client values, and (e) evaluating the decision-making process (Boswell, 2005; Johnson, 2006; Kully & Langeven, 2005). Evaluating research reports requires critical analyses. Methods of evaluating research reports can be classified as traditional, evidence based (levels of evidence), and criterion based in distinguishing between science and pseudoscience. Critically appraised topics or papers (CATs or CAPs) are a format for organizing evidence-based information.

Several systems have been developed for classifying levels of evidence (Agency for Healthcare Research and Quality, 1999; ASHA, 2004; Hadorn, Baker, Hodges, & Hicks, 1996; Ottenbacher, 2002; Queensland Center, 2002). The systems are generally based on levels of evidence according to quality and credibility from highest/most credible to lowest/least credible.
Rating the level of evidence is challenging (Yorkston et al., 2001). Hadorn and associates (1996) believe that it is not clear as to what counts as evidence, and even less clear what weight to assign to different types of evidence. Four questions are usually considered in evaluating the literature for strength of evidence. These questions and more description of the criteria are in Table 4–2 (Yorkston et al., 2001). Chambless and Hollon (1998) rated the level of evidence based on guidelines of the American Psychological Association. Three questions were considered: (a) Has the treatment been shown to be beneficial in controlled research? (b) Is the treatment useful in applied clinical settings and, if so, with what patients and under what circumstances? and (c) Is the treatment efficient in the sense of being cost-effective relative to other alternative treatments? Dawes et al. (1999) also described questions that are important when reviewing a paper on treatment. These questions are listed in Table 4–3.

Table 4–3. Important Questions When Reviewing a Paper on Treatment

<table>
<thead>
<tr>
<th>Question</th>
</tr>
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<tbody>
<tr>
<td>Did the authors answer the question(s)?</td>
</tr>
<tr>
<td>Were groups of patients randomized?</td>
</tr>
<tr>
<td>Are the comparison groups similar?</td>
</tr>
<tr>
<td>Were patients “blinded”?</td>
</tr>
<tr>
<td>Was it placebo-controlled?</td>
</tr>
<tr>
<td>Was evaluation of efficacy “blinded”?</td>
</tr>
<tr>
<td>Was the length of study appropriate?</td>
</tr>
<tr>
<td>What was the follow-up rate?</td>
</tr>
<tr>
<td>Are there clear measures of outcomes?</td>
</tr>
</tbody>
</table>

Table 4–2. Four Questions Used in Evaluating Literature for Strength of Evidence

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>How well were the subjects described?</td>
</tr>
<tr>
<td>How well was the treatment described?</td>
</tr>
<tr>
<td>• Rationale for treatment</td>
</tr>
<tr>
<td>• Replication of treatment</td>
</tr>
<tr>
<td>What measures of control were used in the study?</td>
</tr>
<tr>
<td>• Reliability and stability of outcome measures (inter- or intrarater reliability, dispersion of scores)</td>
</tr>
<tr>
<td>• Support for internal validity (outcome measures obtained with or without treatment; improved performance with treatment in progressive disorders)</td>
</tr>
<tr>
<td>• Presence of comparison or control group</td>
</tr>
<tr>
<td>Are the consequences of the treatment well described?</td>
</tr>
<tr>
<td>• Outcome measures at levels of impairment, activity limiting, restriction in participation</td>
</tr>
<tr>
<td>• Risks and complication of treatment</td>
</tr>
</tbody>
</table>
It is important to recognize the level of evidence in evaluating research. Typically, research evidence is classified according to levels based on the type and quality of research (ASHA, 2004). The earliest evidence scale was published in 1994 by the American Academy of Neurology. This evidence scale has a hierarchy of three levels of evidence. These levels of evidence are on a continuum of hierarchy, based on study design; that is, evidence based on opinion of respected authorities, evidence from case-controlled studies, and evidence from randomized controlled clinical trials. Class III, the lowest level of evidence, is evidence provided by expert opinion, case studies, case reports, and studies with historical controls. Class II evidence is that provided by at least one or better designed observational, clinical studies with concurrent controls, that is, single case control or cohort control studies. Class I, the highest level of evidence, is provided by at least one well-designed, randomized controlled clinical trial (ASHA 2005; Wertz, 2002).

Hadorn and associates (1996) described a hierarchy of seven levels of evidence based on study design (Table 4-4). The seven levels of evidence were collapsed into three levels: A, B, and C. “A” level evidence consisted of levels one through three, “B” level evidence consisted of levels four through six, and “C” level evidence was seven or expert opinion. “A” is most rigorous, and “C” is least rigorous. Four levels (A–D) of evidence for intervention were described by Ottenbacher (2002). Minor and major flaws were identified for eight aspects of study methodology: selection of patients, allocation of patients to treatment group, treatment regimen, study administration, withdrawal from the study, patient blinding (randomized clinical trials only), outcome measurement, and statistical analysis. Minor flaws include deviations from good practice that do not create a potential for bias large enough to cast doubt on the validity of a study. Major flaws create a potential for bias large enough to question a study’s results.

Unfortunately, published papers can have flaws that may occur anywhere along the publication process (Dawes et al., 1999). Critical appraisal is important in examining the rigors with which a study was conducted, and thus the amount of confidence placed in the findings. SLPs and AUDs should read and critique the literature to stay current on prevailing clinical research findings, and apply what is known to clinical practice (Frat tali & Worrall, 2001). Critical appraisal involves the application of knowledge about research design to the literature (Gallagher, 2001).

A critical appraisal topic or paper (CAT or CAP) is a summary of a critical review of the best evidence on a specific topic (Worrall & Bennett, 2001). It is a written outcome of the evidence-based practice (EBP) process. A CAT begins with a declarative title and then indicates a “clinical bottom line,” which describes the clinical action that results from the report (Sackett, Strauss, Richardson, Rosenberg, & Haynes, 2000). There are five major types of CATs: (a) diagnosis/screening; (b) progress; (c) evaluating
Table 4–4. Hierarchy of Seven Levels of Evidence Based on Study Design

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1.    | Supportive evidence from well-conducted randomized controlled trials that included over 100 patients or more.  
|       | a. Evidence from a well-conducted multicenter trial  
|       | b. Evidence from a meta-analysis that incorporated quality ratings in the analysis and included a total of 100 patients in its estimates of effect size and confidence intervals. |
| 2.    | Supportive evidence from well-conducted randomized controlled trials that included fewer than 100 patients.  
|       | a. Evidence from a well-conducted trials at one or more institutions  
|       | b. Evidence from a meta-analysis that incorporated quality ratings in the analysis and included fewer than 100 patients in its estimate of effect size and confidence intervals |
| 3.    | Supportive evidence from well-conducted cohort studies  
|       | a. Evidence from a well-conducted prospective cohort study or registry  
|       | b. Evidence from a well-conducted retrospective cohort study  
|       | c. Evidence from a well-conducted meta-analysis of cohort studies |
| 4.    | Supportive evidence from a well-conducted case-control study |
| 5.    | Supportive evidence from poorly controlled or uncontrolled studies  
|       | a. Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results  
|       | b. Evidence from observational studies with high potential for bias (such as case studies with comparison to historical controls)  
|       | c. Evidence from case studies or case reports |
| 6.    | Conflicting evidence with the weight of evidence supporting the recommendation |
| 7.    | Expert opinion |


risk and harm in case-controlled studies; (d) evaluating risk and harm in a control study; and (e) intervention (treatment, prevention, and screening) (Law, 2002). An example of a CAT on treatment of voice problems of teachers is shown in Table 4–5. Another example of a critical review–based format is presented in Table 4–6. Johnson (2006) suggests the development of collaborative working groups to develop a system for developing a large database of CATs. For more
Table 4–5. Example of a Critically Appraised Topic (CAT) on Treatment of Teachers with Voice Problems

<table>
<thead>
<tr>
<th>Clinical Bottom Line:</th>
<th>Amplification for teachers with voice problems yield better outcome than vocal hygiene instruction for six weeks.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Question:</td>
<td>Which is more effective for treatment of teachers with voice problems, voice amplification (VA) or vocal hygiene (VH) instruction?</td>
</tr>
<tr>
<td>Search Terms:</td>
<td>Voice disorders, treatment, teachers, voice amplification, vocal hygiene.</td>
</tr>
<tr>
<td>Design:</td>
<td>Prospective, randomized control group.</td>
</tr>
</tbody>
</table>

Table 4–6. Example of a Critical Review-Based Format

<table>
<thead>
<tr>
<th>Study</th>
<th>Class I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Title:</td>
<td>Voice amplification versus vocal hygiene instruction for teachers with voice disorders: A treatment outcomes study.</td>
</tr>
<tr>
<td>Authors:</td>
<td>Roy, N., Weinrich, B., Gray, S. D., Tanner, K., Toledo, S.W., Dove, H., Corbin-Lewis, K., &amp; Stemple, J. C.</td>
</tr>
<tr>
<td>Year of Publication:</td>
<td>2002</td>
</tr>
<tr>
<td>Design:</td>
<td>Prospective, randomized clinical trial</td>
</tr>
<tr>
<td>Subjects:</td>
<td>44 voice disordered teachers randomly assigned to one of three groups: voice amplification (VA, n = 15); vocal hygiene (VH, n = 15), nontreatment control group (n = 14).</td>
</tr>
<tr>
<td>Treatment:</td>
<td>VA consisted of using Chatter Box portable amplifier. VH program was adapted from Morrison et al.'s (1994) program</td>
</tr>
<tr>
<td>Duration and Intensity of Treatment:</td>
<td>6 weeks</td>
</tr>
<tr>
<td>Outcome Measures:</td>
<td>Voice Handicap Index; voice severity self-rating scale; audio recording for later acoustic analysis</td>
</tr>
<tr>
<td>Analysis:</td>
<td>Descriptive statistics</td>
</tr>
<tr>
<td>Results:</td>
<td>Clearly support clinical validity of amplification as alternative for treatment of voice disorders in teachers</td>
</tr>
</tbody>
</table>
examples of CATs, see http://www.otcats.com/ (Johnson, 2006).

Critical appraisals are not without critics. Several problems have been identified that warrant discussion (Woolf, 2000; Yorkston et al., 2001). First there is frequent reliance on a single indicator of study quality, that is, marked emphasis on one type of research, randomized controlled trials. Second, individuals are strikingly heterogeneous despite common diagnostic categories. Third, there is an incomplete base of evidence; that is, the research literature is not sufficiently current and complete to answer all clinical questions; there are important gaps in evidence. Fourth, not all sources of information are readily available through electronic searches. Excessive and inadequate critical appraisal can lead to premature adoption or abandonment of treatment and result in overlooking potential harms of more effective treatment alternatives. In addition, critical appraisal can do harm if valid evidence is rejected. Last, critical appraisal lacks systematic application. Criteria to determine which studies are rated “bad” or “good” should be specific and consistent.

Another criticism is the amount of time to write and apply CATs. Worrall and Bennett (2001) suggested that CATs can be undertaken by groups of speech-language pathologists and audiologists. Students and practicing professionals are involved with interest groups and journal clubs. Resources and expertise can be shared in developing CATs. CATs can be the product of one individual or a small group of individuals, and may be subject to error, bias, and other limitations inherent in non-peer-reviewed materials (Law, 2002). CATs can also be flawed because of the speed in which they are created.

Summary

Locating, accessing, and assessing the evidence is an essential part of evidence-based practice. Appropriate clinical decisions require systematic evaluation and integration of evidence from published research reports. It is important to summarize the results of critical appraisal and share information with SLPs and AUDs.

**DISCUSSION QUESTIONS**

1. Describe the strategy for a successful search.
2. Discuss how databases are utilized for literature searches.
3. What are some of the types of data mining being used for research? How might these be used for communication sciences and disorders?
4. Discuss some use of social media that can be used for research and researcher development.
5. What are some journals that are available online? Are these always free?
6. Who is the person in a library who will probably help the
most when doing a literature search?

7. Why is rating the level of evidence from a body of literature difficult?

8. What are some key questions to ask when rating the strength of evidence?

9. How can evidence be classified?

10. What is a critical appraisal?

11. What are the key components of a critically appraised topic or paper?

12. Discuss the relative advantages and disadvantages of using CATs

**References**


Sciences and Disorders (pp. 29–45). Sarasota, FL.
Louisiana State University Health Sciences Center, Shreveport Medical Library. (2005). Library information for new faculty. Shreveport: LSUHSC Medical Library.
5

Literature Review

CHAPTER OUTLINE

- Organizing Literature Reviews
- Background Literature Reviews
- Formulating Questions for Literature Reviews
- Narrative Reviews
- Systematic Reviews
  - Difference Between Narrative and Systematic Reviews
- Meta-Analysis
- Best-Evidence Synthesis
- Clinical Practice Guidelines
- Summary
- Discussion Questions
- References
Upon completion of this chapter the reader will be able to:

- Prepare and organize various types of literature reviews
- Explain the limitations of narrative reviews
- Know the difference between narrative and systematic reviews
- List and describe the parts of a systematic review
- Explain why meta-analysis is a strong basis for clinical decisions
- Define best evidence synthesis
- Be aware of the limitations of practice guidelines
- Select best available practice guidelines
Literature reviews are at the heart of any research. There are two broad types of literature reviews. First, they can be completed in order to guide primary, original research (Mertens, 2005). This category of literature reviews can be completed to ensure a research project is focused and relevant. This first type of research is typically referred to as a “review of the literature” and is integrated with the introduction of most research articles. A literature review of this nature might also be referred to as a background literature review. The second broad type of literature reviews are those that can be research in and of themselves. These include: narrative or traditional; systematic; meta-analysis, best evidence synthesis; and practice guidelines. All have potential limitations, many of which can be overcome by using an evidence-based approach. The more rigorous the method of reviewing the literature and the quality of the primary research that is reviewed, the more evidence-based the review is likely to be (Cook, Mulrow, & Haynes, 1997).

Reviewing the literature involves consideration of potential biases related to publication practices, variable quality of the studies involved in the review, and inclusion-exclusion criteria (Mertens, 2014). For example, there is a tendency for research with statistically significant results to be published. Conversely, research studies that show no difference are published less frequently because they either are not submitted or are rejected more frequently. Literature reviews can be biased by data exclusion that is methodologically questioned, or subjective selection of studies for inclusion in the review. Watching for these biases is a necessary part of reviewing literature for any reason.

In this chapter, we will first discuss general principles that apply to organizing any type of literature review, how to conduct a review of the literature or background literature review, and will finish with a description of literature reviews that are research in and of themselves: narrative review, systematic review meta-analysis, best-evidence synthesis review, and clinical practice guidelines.

A number of steps are involved in preparing and organizing a literature review as summarized in Figure 5–1. As the figure shows, after identifying potential sources, references need to be located and screened for relevancy to the topic being reviewed. References that seem appropriate are read, notes are taken, and inappropriate references are discarded.

As mentioned in the previous chapter, one reference may provide citations to several other relevant references. After all relevant references have been reviewed; they are organized, analyzed, and synthesized. Organization facilitates analysis of the topic or evidence and synthesizes the literature. Information can be organized into four categories based on relevance: A-pile: highly relevant; B-pile: somewhat relevant; C-pile: might be relevant; and X-pile: not relevant (DePoy & Gitlin, 2011). Also, there are several ways literature can be organized to provide a visual summary of research and is typically represented as a table or figure (Creswell, 2003).

One approach to organizing and integrating the literature is a chart summarizing each study (DePoy & Gitlin, 2011).
Discard irrelevant or inappropriate references

Formulate and refine primary and secondary questions

Devise search strategy (e.g., select databases, identify keywords, etc.)

Search for, identity, and retrieve potential primary source materials

Screen sources for relevant appropriateness

Read source materials

Abstract, encode information from the studies

Critique/Evaluate studies

Analyze, integrate information, search for themes

Prepare synthesis/critical summary

Identify new reference, new leads

Document search decisions and actions

Figure 5–1. Steps in preparing a literature review. From Nursing Research: Principles and Methods (p. 105), by D. F. Polit and C. T. Beck, 2004, Philadelphia, PA: Lippincott Williams & Wilkins. Reprinted with permission from Lippincott Williams & Wilkins.
These charts are sometimes referred to as evidence tables (Golper et al., 2001). A chart is used in considering the literature as a whole, as well as critically evaluating and identifying research gaps. An example of a literature review table is presented in Table 5–1.

Another approach to organizing the literature is a concept/construct matrix in which information is organized by key concept (x-axis) and source (y-axis). A matrix helps in identifying specific concepts that need to be discussed in the written report (DePoy & Gitlin, 2011). This approach can be a preliminary step in developing a concept map which is described in Chapter 11.

### Background Literature Reviews

Literature reviews that serve as a background for research papers are an important part of any research project. Background literature reviews are also referred to as “reviews of the literature” in speech language pathology. They are typically part of the introductory section of any research article, and they serve three main purposes. The first purpose is that they report on research that has been previously done on a topic to ensure a specific project focuses on the best aspect of a particular issue. The second purpose is to describe the theoretical and conceptual background of the research project. The third reason for a review of the literature is to demonstrate the purpose and significance of the research project.

Prior to beginning a search for literature to serve as background for a research project, it is recommended to establish a topic area by creating a working title to the research project (Creswell, 2014). When creating a title it is helpful if a researcher can finish the statement: “my study is about . . .” (Creswell, 2014). For example, if a researcher wanted to study early childhood literacy issues, an initial statement could be, “my study is about early childhood literacy.” After more information is gathered from a search based on these terms, a statement such as this could then lead to the development of a working research project title that includes more specific information such as, “An ethnography: Preschool education teachers’ early childhood literacy knowledge.”

Individuals writing a literature review as part of reporting the results of a research project should review and include all relevant research on a topic area,

<table>
<thead>
<tr>
<th>Type of Study</th>
<th>Primary Focus</th>
<th>Number of Subjects</th>
<th>Measures</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized Clinical Trials</td>
<td>Voice amplification resonance therapy</td>
<td>6+</td>
<td>Voice Handicapped Index</td>
<td>Voice resonance therapy group improved</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Voice Severity Self-Rating</td>
<td></td>
</tr>
</tbody>
</table>

Table 5–1. Literature Review Table
as well as cite sources that help them explain to the reader the reasons the study needed to be conducted in the first place. It should be noted that once an article related to the overall topic is found, the references cited in that article can serve as a launch point to collect other relevant information to include in the research project literature review.

Additionally, prior to conducting a review of this nature, the researcher should form a question (discussed previously) (Creswell, 2014). Once a working title is formed, it will be easier to form a tentative research question. Based on the previous example, a good question to pose under the working title of “An ethnography: Early childhood literacy knowledge of preschool education teachers,” would be: “What is the knowledge base of preschool education teachers regarding early childhood literacy?” A question of this nature would allow the researcher to investigate the knowledge base and understanding of the teacher-participants.

After a question is formed, there are various recommended sequences to conducting the literature review. Creswell (2014) recommends a 7-step process:

1. Identify a few key words. You can begin by selecting some of the terms used in your working title. Initial readings about your topic area may also yield a few useful key words.
2. Go the library and search both onsite and online sources using the key words you have identified.
3. Try to acquire a minimum of 50 resources either in the form of articles or books that support your topic area.
4. Narrow the number of resources down to the most relevant.
5. Once you have identified the most useful literature, form a literature map, or a visualization (of your choosing), of the types of research you have so that you can begin categorizing it.
6. Write summaries of the articles that you know you will use. These summaries will start to form the first written draft of the literature review portion of your article. While you are engaged in this process, it is recommended that you begin a citation or reference list using the guidelines of the American Psychological Association (APA, 2010).
7. Construct your literature review in written form. It should be organized according to themes or relevant concepts. It should not be organized by authorship of the articles you are reviewing.

There are certain criteria when it comes to the organization and completeness of a background literature review. McMillan (2012) provides several criteria that guide the researcher in both critiquing and creating a strong literature review:

1. A review of the literature should cover all previous research thoroughly and adequately.
2. A review of the literature should actually describe the results of other research studies. It should not simply report opinions of others on a specific topic.
3. A review of the literature should be current. The studies that are included should be fairly recent. If
the majority of the studies cited are from the 1980s in a paper written in 2017, that literature review would not be considered up to date.

4. A review of the literature should both summarize and analyze the studies it reviews. When an author includes a study in the literature review, she should not just report findings, but discuss their quality and value to the current study.

5. A review of the literature should be organized by most relevant topic. In other words, paragraphs should cover overall issues and include a few articles in each paragraph to illuminate that issue. The review of the literature should not be organized into paragraphs that simply report on each article that has been chosen for the review of the literature.

6. When summarizing articles, talk about minor studies minimally, and go into more detail on the major studies that have been conducted on your topic area.

7. There should be a clear reason to conduct the research project based on the studies described in the review of literature.

8. The theoretical background of the study should be well described in a review of the literature. All strong research projects identify and describe the guiding theory that helps to shape the purpose and overall design of the study. The review of literature should clearly describe this aspect of the project.

Table 5–2 contains excerpts from a research project that studied how typically developing siblings of children with autism spectrum disorders mediated social interaction for the sibling with the communication impairment (Abendroth, 2011). These excerpts provides examples of how resources are woven into the introduction/review of the literature portion of a published research article to accomplish several of the above recommended criteria.

As previously mentioned, this chapter addresses several types of literature reviews. The one just described serves the purpose of providing background to a research project. The following sections apply primarily to narrative reviews, systematic reviews, meta-analysis, best-evidence synthesis reviews and clinical practice guidelines, though some aspects of the following section of this chapter may be adapted for background literature reviews.

**Formulating Questions for Literature Reviews**

It should be noted that this section applied to literature reviews that are research in and of themselves, or literature reviews such as narrative review, systematic review, best evidence synthesis, etc. For these types of literature reviews, formulating a question is the first step in a literature review. This involves determining the type of question it is, background or foreground. Background questions ask for general information about a condition or process, who, what, when, and so forth. Foreground questions focus on specific information about clinical decisions or recommendations. Background questions are usually asked because of the need for basic information.
The first step in evidence-based practice and systematic reviews is formulation of clinical guidelines questions. Two methods for formulating clinical questions have been described in the literature. PICO and PESICO. Each letter in the acronyms stands for its components.

PICO stands for population, intervention, comparison, and outcome. Descriptions for each component are listed in Table 5–3.

It was first described in 1995 by Richardson, Wilson, Nishikawa, and Haywood. PICO has been used in evidence-based medicine and has been adopted for use in speech-language pathology.

The adequacy and stability of PICO was evaluated by Huang, Lin, and Demner-Fushman (2006). It was reported that PICO primarily focused on questions and was less suitable for clinical questions related to diagnosis, prognosis, and etiology. A web-based tutorial for understanding PICO and answering questions, accessing and assessing the evidence, was developed by LaRue, Draus, and Klem (2009). PICO can be used to answer clinical questions such as:

1. What intervention was studied?
2. What outcome is measured?
3. What is studied?
4. Who are the researchers?
5. What are the results?
6. What is the final analysis/practical application?

PESICO was described by Schlosser, Koul, and Costello (2007). The six components of PESICO are person, environments, stakeholders, intervention, comparison, and outcomes. Table 5–4 summarizes the PESICO framework.

There are differences between PICO and PESICO. PICO is the more frequently used framework for formulating questions. PESICO has two additional components: environments and stakeholders. It may be that PICO does not include these two components because it is based on a medical model that focuses less on environmental and stakeholder issues (Schlosser et al., 2007). See the Schlosser et al., 2007 article for excellent PESICO examples.

The templates described in this section are especially useful when conducting literature reviews for the purpose of finding the best available evidence for practice in speech-language pathology and for writing systematic reviews of literature. It should be noted that PICO and PESICO frameworks weren’t initially designed to inform background literature.

### Table 5–3. Description of PICO Components

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Population</td>
<td>Patient population or disorder of interest</td>
</tr>
<tr>
<td></td>
<td>Age</td>
</tr>
<tr>
<td></td>
<td>Gender</td>
</tr>
<tr>
<td></td>
<td>Ethnicity</td>
</tr>
<tr>
<td>Intervention</td>
<td>Intervention or range of interventions</td>
</tr>
<tr>
<td></td>
<td>Exposure to disorder</td>
</tr>
<tr>
<td></td>
<td>Prognostic factors</td>
</tr>
<tr>
<td></td>
<td>Risk(s)</td>
</tr>
<tr>
<td>Comparison</td>
<td>Comparison of intervention</td>
</tr>
<tr>
<td></td>
<td>No disorder</td>
</tr>
<tr>
<td></td>
<td>Placebo or no intervention</td>
</tr>
<tr>
<td></td>
<td>Prognosis</td>
</tr>
<tr>
<td></td>
<td>Absence of risk factor(s)</td>
</tr>
<tr>
<td>Outcome</td>
<td>Outcome of interest</td>
</tr>
<tr>
<td></td>
<td>Risk of disorder</td>
</tr>
<tr>
<td></td>
<td>Accuracy of diagnosis</td>
</tr>
<tr>
<td></td>
<td>Rate of occurrence of adverse outcome</td>
</tr>
</tbody>
</table>

reviews (discuss earlier). However, it should be noted that they can be adapted for this purpose if necessary.

**Narrative Reviews**

Traditional narrative reviews are nonsystematic reviews of the literature. At one time, narrative reviews were the most prevalent approach to synthesizing the speech-language pathology and audiology literature. However, this has changed in recent years. Systematic reviews are much more prevalent (e.g. Fisher 2017; Rudolph, 2017). There are three major disadvantages of narrative reviews: (1) the sources and identification of

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person or problem</td>
<td>Age</td>
</tr>
<tr>
<td></td>
<td>Gender</td>
</tr>
<tr>
<td></td>
<td>Ethnicity</td>
</tr>
<tr>
<td></td>
<td>Risk</td>
</tr>
<tr>
<td></td>
<td>Diagnosis or classification</td>
</tr>
<tr>
<td></td>
<td>Sensory status</td>
</tr>
<tr>
<td></td>
<td>Motor status</td>
</tr>
<tr>
<td></td>
<td>Cognitive status</td>
</tr>
<tr>
<td></td>
<td>Communication competence</td>
</tr>
<tr>
<td>Environments</td>
<td>Current</td>
</tr>
<tr>
<td></td>
<td>Future</td>
</tr>
<tr>
<td></td>
<td>Communication</td>
</tr>
<tr>
<td>Stakeholders</td>
<td>Direct (person)</td>
</tr>
<tr>
<td></td>
<td>Secondary (others)</td>
</tr>
<tr>
<td></td>
<td>Perception of problem</td>
</tr>
<tr>
<td>Intervention</td>
<td>Comparison of options</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Effectiveness (acquisition, generalization maintenance of skills)</td>
</tr>
<tr>
<td></td>
<td>Efficiency</td>
</tr>
<tr>
<td></td>
<td>Communication partners</td>
</tr>
<tr>
<td></td>
<td>Self-determination</td>
</tr>
<tr>
<td></td>
<td>Quality of life</td>
</tr>
<tr>
<td></td>
<td>Stakeholders</td>
</tr>
</tbody>
</table>

studies are not described; (2) the search terms are not specified; and (3) the criteria for including and excluding studies are not specific (Schlosser, 2000). In addition, narrative reviews do not provide a detailed description of each study. Typically, narrative literature reviews are at risk for subjectivity in selecting, evaluating, and interpreting studies.

A more systematic alternative to narrative review has been developed called the scoping review (Arskey and O’Malley, 2005). The Canadian Institutes of Health research defined the scoping review as “an exploratory project that systematically maps the literature available on a topic, identifies key concepts, theories, sources of evidence and gaps in research” (n.d.). Overall, the scoping review examines the information that is available on a topic and helps to determine if a full systematic review should be initiated, it summarizes findings, and ultimately, the scoping review identifies gaps that may exist in the available research on a specific topic (Arskey & O’Malley, 2005). Overall, the scoping review is more systematic and specific variation of a narrative review.

### Systematic Reviews

Melnyk and Fineout-Overholt (2015) define systematic reviews as “a scientific approach to summarize, appraise, and communicate the results and implications of several studies that may have contradictory results” (p. 126). Systematic reviews are the basis of evidence-based practice (Pring, 2004). These reviews are a source of evidence to guide practice and identify the need for further research (Bannigan, Droogan, & Entwistle, 1997). In addition, systematic reviews have the potential for facilitating the transfer of research evidence into clinical practice and for helping readers understand generalization and consistency of research findings (McCauley & Hargrove, 2004). Parts of a systematic review are listed in Table 5–5. It should be noted that a challenge often encountered in systematic reviews is a type of literature referred to as gray literature (Hartling et al., 2005). Gray literature includes unpublished studies or services that are not published in peer-reviewed journals (Portney & Watkins, 2009). Gray literature is difficult to locate or retrieve by using electronic databases. The gray literature is heterogeneous and varies substantially in design and quality. Gray literature should be explicitly identified and reported as such in the written portion of any systematic review.

Additionally, a systematic review can be a method for locating, appraising, and synthesizing evidence (Petticrew, 2001). A number of steps are involved in preparing a systematic review as summarized in Table 5–5. The initial steps are related to finding evidence and later steps focus on using evidence. These are essentially the same steps that are involved in development of meta-analysis and evidence-based guidelines.

The last step of conducting a systematic review is writing a report. The report should be concise, conform to standards for professional writing, and provide a critical analysis/synthesis of current information related to the topic. Additionally, the report should identify gaps in knowledge and research needs. It should not simply list what research has been done on the topic. The report should provide the confirming and contradictory evidence about possible explanations of
findings (APA, 2010; DePoy & Gitlin, 2011; Polit & Beck, 2010).

There are several reasons for undertaking a systematic review. Among them are to: (1) summarize large amounts of information; (2) provide decision makers with synthesized information; (3) explain consistency and inconsistency of data; (4) identify conflicts; (5) increase power and precision in estimates of risk or effect size; (6) identify gaps in knowledge; and (7) improve treatment (Seers, 1999).

Systematic reviews vary in quality and should be critically appraised. Some systematic reviews are misleading because the quality of the review is poor or biased. In other words, a systematic review may not present accurate analysis/synthesis of research reports. Criteria for evaluating and making recommendations about systematic reviews are presented in Tables 5–6 and 5–7. Mathuna and Fineout-Overholt (2015) suggest a rapid checklist for appraising a systematic review, which consist of three questions: (1) are the results of the review valid? (2) what were the results? and (3) will the results assist me in caring for clients?

Systematic reviews are available from the websites of the Academy of Neurologic Communication Disorders and

**Table 5–5. Systematic Review Template**

<table>
<thead>
<tr>
<th>Abstract</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Purpose</td>
</tr>
<tr>
<td>• Method</td>
</tr>
<tr>
<td>• Conclusion</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Introduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Background/Need</td>
</tr>
<tr>
<td>• Purpose/Question</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method (Source Selection)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Inclusion Criteria</td>
</tr>
<tr>
<td>• Exclusion Criteria</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Electronic databases</td>
</tr>
<tr>
<td>• Key words</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Number of Sources Identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Number of sources excluded</td>
</tr>
<tr>
<td>• Number of sources included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Quantitative analysis</td>
</tr>
<tr>
<td>• Qualitative analysis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Criterion-based recommendations</td>
</tr>
<tr>
<td>• Limitations</td>
</tr>
<tr>
<td>• Clinical Implications</td>
</tr>
<tr>
<td>• Future Research</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>References</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Tables</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Table 1 Reference levels</td>
</tr>
<tr>
<td>• Table 2 Evidence table (appraisal summary of studies)</td>
</tr>
</tbody>
</table>

**Table 5–6. Steps in Conducting a Systematic Review**

<table>
<thead>
<tr>
<th>Problem Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information search and retrieval</strong></td>
</tr>
<tr>
<td>• Search terms (Key words)</td>
</tr>
<tr>
<td>• Search electronic and manual</td>
</tr>
<tr>
<td>– Level of evidence</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Analysis and synthesis of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Grades for recommendation of use</td>
</tr>
</tbody>
</table>

| Report results |

Sciences, American Academy of Audiology, American Speech-Language-Hearing Association, and the Cochrane collections. These reviews can also be located by manual searches of professional journals. Systematic reviews have been published in a variety of journals in speech-language pathology and audiology. ASHA’s National Center of Evidence-Based Practice in Communication Disorders (N-CEP) has made available systematic reviews of several areas of research in the field of speech-language pathology. Additionally, ASHA has developed guidelines help in the critical appraisal and application of systematic reviews such as the criteria described in Tables 5–7 and 5–8.

Systematic reviews about speech-language treatment have been criticized. Pring (2004) believes many researchers do not follow appropriate procedures for clinical outcomes research. In addition, many studies on which systematic reviews are based have methodological problems and often fail to adequately describe treatment, thereby making it impossible to evaluate or compare different types of treatment.

Garrett and Thomas (2006) responded to Pring’s (2004) “Ask a silly question: Two decades of troublesome trials” by stating that systematic reviews using qualitative and/or statistical methods for combining studies can be completed within or across any phase of outcome research. Furthermore, systematic reviews can be informative because they help bring together what is, and what is not, known, and suggest treatments that may be beneficial or in need of further research.

Pring (2006) replied to Garrett and Thomas (2006) by stating that “systematic reviews are essential to evidence-based practice” (p. 208). Three advantages of systematic reviews were identified by Pring: (1) they can provide an overall effect size for treatment of a client group;

<table>
<thead>
<tr>
<th>Grade Recommendations</th>
<th>Criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Good evidence for inclusion</td>
<td>There is good peer-review evidence supporting consideration of use for the treatment</td>
</tr>
<tr>
<td>B. Fair evidence for inclusion</td>
<td>There is fair peer-review evidence supporting consideration of use for the treatment</td>
</tr>
<tr>
<td>C. Insufficient evidence</td>
<td>There is insufficient peer-review evidence for inclusion supporting consideration of use for treatment although recommendations for use are possible on other grounds</td>
</tr>
<tr>
<td>D. Fair evidence for exclusion</td>
<td>There is fair peer-review evidence supporting that the treatment should be excluded from consideration of use</td>
</tr>
<tr>
<td>E. Good evidence for exclusion</td>
<td>There is good peer-review evidence supporting that the treatment should be excluded from consideration</td>
</tr>
</tbody>
</table>

(2) where different types of treatment have been provided, systematic reviews can compare the effect sizes to determine which treatment is more effective; and (3) the influence of experimental design on the overall effect size can be determined. Furthermore, methodological problems associated with systematic reviews “serve as a further reminder that primary research must be both systematic in its development and rigorous in its procedures” (p. 110).

It should be noted that a valuable resource when searching for quality systematic reviews is The Cochrane Collaboration. This organization prepares, maintains, and disseminates systematic reviews. The Cochrane Collaboration requires that systematic reviews address: specific decision points; objectives; criteria for considering studies; types of studies; types of participants; types of intervention; types of outcome measures; search strategy; methods for selection of studies; awareness of methodological quality; data management; and data synthesis (Douglas, Brown, & Barry, 2004).

**Table 5-8. Examples of Outcomes from Systematic Reviews**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the review address a focused clinical question?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were tables used to show key features and to facilitate comparisons of studies?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were the criteria used to select articles for inclusion appropriate?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is it unlikely that important relevant studies were missed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the validity of the included studies appraised?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were assessments of the studies reproducible?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were the results similar from study to study?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are the results of a systematic review clear?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are the results precise?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can the results be applied to my client care?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were all clinically important criteria considered?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are the benefits worth the harms and costs?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were potential conflicts of interest disclosed?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


**Differences Between Narrative and Systematic Reviews**

There are major differences between a regular narrative review of the literature
and a systematic review. Narrative reviews may lack the objectivity, rigor, and comprehensiveness of systematic reviews (Johnson, 2006). Systematic reviews use more specific search strategies and criteria for inclusion. These and other differences are compared in Table 5–9. Overall, systematic reviews are considered superior to narrative reviews for synthesizing research (Meline, 2006b).

Meta-analysis

Meta-analysis is a systematic review in which a statistical summary is provided (Bradley & Law, 2014). It is a relatively recent approach to quantitative synthesis of previous studies which should not be confused with traditional reviews of the literature. In other words, meta-analysis is a statistical approach for combining studies about the same problem to determine the efficacy of a procedure or treatment (Haynes & Johnson, 2009).

Steps in developing and completing a meta-analysis are listed in Table 5–10.

### Table 5–10. Steps of a Meta-Analysis

- Selection of a research hypothesis
- Definition of eligibility criteria for inclusion and exclusion
- Development of a search strategy
- Identification of studies for inclusion
- Conversion of study statistic to common effect-size metric
- Complete summary effect and interpret its meaning

### Table 5–9. Differences Between Narratives and Systematic Reviews

<table>
<thead>
<tr>
<th>Feature</th>
<th>Narrative Review</th>
<th>Systematic Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question</td>
<td>Broad, general question</td>
<td>Focused or hypothesis to be tested</td>
</tr>
<tr>
<td>Sources and Search</td>
<td>Usually unspecified, risk for bias; do not usually attempt to locate all relevant literature</td>
<td>Comprehensive sources; specific search strategy</td>
</tr>
<tr>
<td>Selection</td>
<td>Usually unspecified risk for bias</td>
<td>Criterion-based selection, uniform application; limit selection bias</td>
</tr>
<tr>
<td>Appraisal</td>
<td>Variable; do not consider differences in study method or quality</td>
<td>Rigorous systematic critical appraisal; investigate potential biases and sources of heterogeneity</td>
</tr>
<tr>
<td>Synthesis</td>
<td>Qualitative</td>
<td>Quantitative</td>
</tr>
<tr>
<td>Inferences</td>
<td>Sometimes evidence-based; do not differentiate between sound and unsound studies</td>
<td>Usually evidenced-based; base conclusions on most methodologically sound studies</td>
</tr>
</tbody>
</table>

A preliminary step in meta-analysis is selection of a model of analysis. There are two analysis models: fixed effects and random effects. Fixed effects analysis is appropriate when most of the primary studies are obtained, and are reasonably homogeneous. Random effects analysis is appropriate when primary studies have random samples or are heterogeneous (Robey, 1999; Robey & Dalebout, 1998).

Meta-analysis can provide evidence, especially if it includes several randomized controlled trials (RCT), although it is influenced by the evidence available in the literature (Golper et al., 2001). The highest evidence ratings are assigned to meta-analysis studies of RTCs (ASHA, 2004a). Thus, RTCs are considered the gold standard for evidence, but they are not infallible (Hartling et al., 2005).

Meta-analysis can provide information about treatment results if it includes an average effect size that is considered clinically important and provides evidence that statistical power is adequate to detect and affect. Maxwell and Satake (2006) define effect size as “the degree to which the null hypothesis is false” (p. 511). That is, meta-analysis provides an average effect size to estimate whether a null hypothesis can be rejected, or the treatment has no influence on outcome.

Some meta-analyses have instigated criticism in speech-language pathology. For example, J. R. Johnston (2005) voiced concerns about the meta-analysis of treatment for children with developmental speech and language delay/disorder by Law, Garrett, and Nye (2004). These concerns were related to limitations in content, exclusion of practice sections, focus on very young children, and lack of sufficient attention to duration or methods of treatment. Law, Garrett, and Nye (2005) replied that “one person’s narrowing is another person’s strength” (p. 118). The concern about lack of information about treatment was valid.

To address some of the issues that may arise in utilization of meta-analysis, Maxwell and Satake (2006) developed a worksheet for meta-analysis review that is shown in Table 5–11. Another approach for reviewing meta-analysis is a series of questions, which are presented in Table 5–12. Critical review of meta-analysis reporting is important because of limitations associated with this type of analysis. Among these limitations are invalid primary studies, overemphasis on statistical significance, heterogeneous data, overestimation of treatment effectiveness, concern with whole populations rather than individual’s, and technical skill required for meta-analysis (Law & Philip, 2002; Maxwell & Satake, 2006; Robey, 1999). Furthermore, meta-analysis may or may not have specific criteria for selection of studies. The criteria for inclusion and evaluation of studies may not be as specific as the criteria should be. Ultimately, it should be noted that meta-analysis reviews warrant critical appraisal.

Best-evidence synthesis is an alternative to meta-analysis. It is a review of both qualitative and quantitative studies which are selected according to specific criteria (McMillan, 2012). Best-evidence synthesis utilizes the strongest evidence to support conclusions. This means that it does not only include gold standard randomized control trials or “high quality” research in the review (Slavin, 2009).
Table 5-11. Meta-Analysis Review

<table>
<thead>
<tr>
<th>Check one:</th>
<th>☐ Assessment article</th>
<th>☐ Intervention article</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purpose Statement:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Studies:</td>
<td>_____</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Seems inappropriate</td>
<td>Appropriate</td>
<td>Appropriate</td>
</tr>
<tr>
<td>No rationale</td>
<td>Limited rationale</td>
<td>Useful rationale</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time Range for Inclusion:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Seems inappropriate</td>
<td>Appropriate</td>
<td>Appropriate</td>
</tr>
<tr>
<td>No rationale</td>
<td>Limited rationale</td>
<td>Useful rationale</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Types of Designs Included:</td>
<td>Check all applicable:</td>
<td></td>
</tr>
<tr>
<td>☐ Large randomized controlled trials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Small randomized controlled trials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Repeated randomized single-case designs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Non-randomized study with control group(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Single-case design using alternating treatments or multiple baseline methods</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Case control study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Case reports</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Seems inappropriate</td>
<td>Appropriate</td>
<td>Appropriate</td>
</tr>
<tr>
<td>No rationale</td>
<td>Limited rationale</td>
<td>Useful rationale</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Criteria for Inclusion in Meta-Analysis:</td>
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<td></td>
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<tr>
<td>Comments:</td>
<td></td>
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Table 5–11. continued

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<table>
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<th>Main Points/Strategies Found to be Effective:</th>
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<tr>
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<table>
<thead>
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<table>
<thead>
<tr>
<th>Interpretation of Results:</th>
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</thead>
<tbody>
<tr>
<td>Interpretation beyond data</td>
</tr>
<tr>
<td>Some extension of interpretation beyond data</td>
</tr>
<tr>
<td>Data related tied to past research</td>
</tr>
<tr>
<td>Comments: __________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Credibility of Source:</th>
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</thead>
<tbody>
<tr>
<td>Source unknown</td>
</tr>
<tr>
<td>Trade journal or self-published/reported</td>
</tr>
<tr>
<td>Peer-reviewed edited publication</td>
</tr>
<tr>
<td>Peer-reviewed professional journal</td>
</tr>
<tr>
<td>Comments: __________________________</td>
</tr>
</tbody>
</table>


Table 5–12. Criteria for Meta-Analysis Studies

- Was the method for accumulating results from individual studies clear and appropriate?
- Were the methods for combining study effects appropriate?
- Were the data tested for heterogeneity and an appropriate statistic model utilized for the analysis?
- Where the data inspected for possible moderate variables?
- Were interpretation and conclusions consistent with the results?
- Were implications for future research discussed?

For example, if a review of available research on approaches to phonological disorders revealed that there were no randomized control trial studies available, a best-evidence synthesis would proceed and include lower tiered studies such as case studies and semi-experimental studies in its review of the evidence. In contrast to a meta-analysis, best-evidence synthesis will produce conclusions based on BEST evidence available and will even state the fact that not enough evidence has been generated in order to draw conclusions (Slavin, 2009).

**Clinical Practice Guidelines**

The types of literature review discussed in this chapter are ways of ensuring that the speech-language pathologist is utilizing the best evidence available to guide their steps—either for conduction of research or for everyday treatment of individuals with swallowing or communication impairment. There is a specific type of literature review called a clinical practice guideline (CPG). It should be noted that most practice guidelines are a combination of clinician experience, expert opinion, and research evidence (Cook, Greengold, Elrod, & Weingarten, 1997). However, CPGs provide a more scientific, evidence-based way to approach the process of finding the best clinical practice for clients (Hargrove, Griffer, and Lund, 2008).

It should be noted that all practice guidelines are not equal. Some are based on expert opinion/consensus and/or evidence-based practice. The former are variable from high quality and credible to low quality, that is, biased and even deceptive and misleading, the latter are explicit statements that assist speech-language pathologist, audiologists and their clients to make informed decisions about appropriate care for specific speech-language-hearing problems. Furthermore, practice guidelines should be current, that is, developed, reviewed, or revised within the last 5 years (Johnson, 2006). Some practice guidelines may be outdated and need to be updated because of advances on clinical practice (Shojania, Sampson, Doucette, & Moher, 2007).

Determining when to develop guidelines should be considered carefully because of the amount of resources, skill, and time required (Slutsky, 2005). Criteria used to develop guidelines include:

- Potential to change outcomes or costs
- Availability of evidence on which to develop guidelines
- Topic clinically important
- Topic complex enough to initiate debate about recommendations
- Variation between actual and appropriate care
- No existing or relevant guidelines available to use
- Evidence available to support evidence-based development
- Recommendations acceptable to potential users
- Implementation of guidelines feasible.

Evidence-based guidelines are based on the best available evidence and professional judgment. Melnyk and Fineout-Overholt (2005) describe evidence-based practice guidelines as “... specific practice recommendations that are based on a methodologically rigorous review of the best evidence on a specific topic” (p. 587). ASHA has also defined practice
guidelines as part of its preferred practice patterns for speech-language pathology and audiology (ASHA, 2004b). These guidelines “define generally applicable characteristics of activities directed toward individual patients/clients and that addresses structural requisites of the practice, processed to be carried out, and expected outcomes (ASHA, 2004b).

There are three types of clinical practice guidelines based on evidence: traditional clinical practice guidelines (TCPs), systematic reviews (SR) (previously described in this chapter), and evidence-based practice guidelines (EBPCPGs) (Hargrove, Griffer, & Lund, 2008). Differences between these clinical practice guidelines are listed in Table 5–13.

There is a hierarchy of clinical practice guidelines with traditional-narrative reviews being the lowest rank (meeting the fewest criteria). Traditional reviews met only two of seven criteria. According to Hargrove, Griffer, and Lund (2008) evidence-based reviews differ

\[ \ldots \] from systematic reviews primarily in the quality of the evidence that is considered. Systematic reviews generally only consider only higher quality evidence, whereas evidence-based practice guidelines consider evidence from a variety of levels, including case studies and even expert opinions. (p. 290).

This information is useful in making decisions about using and recommending clinical practice guidelines. The National Evidence-Based Center of ASHA (2011) uses the Appraisal of Guidelines for Research and Evaluation (AGREE) for evaluating and recommending systematic reviews. These reviews are highly

<table>
<thead>
<tr>
<th>Evidence Criteria</th>
<th>TCP</th>
<th>SR</th>
<th>EBCPG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on a comprehensive, methodical review of the literature</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Based on the consensus of a panel of experts</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Can include expert opinion</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Identifies evidence that supports recommendations</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Evaluates the quality of the literature used to support the recommendations</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Expertise of the expert or group of experts is disclosed</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Can include case studies, retrospective, nonrandomized research designs</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

recommended, recommended with reservations, or not recommended.

The Academy of Neurologic Communication Disorders and Sciences (ANCDS) as developed evidence-based practice guidelines (EBPG). These EBPGs focus on five areas: aphasia, acquired apraxia, cognitive dysarthria, and communication disorders related to traumatic brain injury and dementia.

Obviously, there is some variation in reporting clinical practice guidelines. Some practice guidelines do not meet the criteria for systematic review and are narrative rather than systematic. There may be limited information about the outcome measures used the literature search strategy or key words used, and no inclusion/exclusion criteria for the studies reviewed. Thus, it is important for speech-language pathologists and audiologists to critically appraise practice guidelines. Finding appropriate guidelines depend on being able to critically evaluate the reliability of a guideline because guidelines do not always confirm the best practice (Slutsky, 2005). Criteria for evaluating guidelines include: validity; reliability and reproducibility; clinical applicability; clinical flexibility; clarity; documentation; development by a multidisciplinary program; and plans for review. Additional information about practice guidelines is provided in Chapter 13.

**Summary**

There are several types of literature reviews with which graduate students and practicing professionals should be familiar. Reviews of the literature or background literature reviews serve to introduce and define the purpose of a research project. Narrative reviews unsystematically review available research and are utilized infrequently in the field of speech-language pathology. Systematic reviews and meta-analysis reviews are being utilized more frequently in recent years and provide a rigorous, systematic review of quality research in the field of speech-language pathology.

A major aspect of evidence-based practice and literature reviews is the formulation of a question. Two strategies for formulating questions are available for use: PICO and PESICO. Finally, clinical practice guidelines (CPGs) are a useful tool utilized in the field speech-language pathology that not only present available research on a topic, but make recommendations for practice. It is often difficult to make sense of the information on a specific topic and the various types of literature review presented here can assist graduate students and practicing professionals in accomplishing that goal.
DISCUSSION QUESTIONS

1. Discuss the purposes of a review of the literature.
2. Outline the steps for performing and organizing any type of literature review.
3. What are the differences between narrative and systematic reviews?
4. What are the major components of a systematic review?
5. Define meta-analysis and discuss its use in speech-language pathology and audiology.
6. What are the steps in conducting a meta-analysis?
7. What is a best-evidence synthesis?
8. Explain the importance of practice guidelines.
9. How are practice guidelines developed?
11. What is the difference between systematic review and an evidence-based clinical practice guideline?
12. How can clinical practice guidelines be used for making clinical decisions?
13. Why should the use of clinical practice guidelines be encouraged?
14. Describe PICO. Describe PESICO. What are the differences between PICO and PESICO?
15. What are the differences between clinical practice guidelines, systematic reviews, and evidence-based clinical practice guidelines?

References


Measurement

CHAPTER OUTLINE

<table>
<thead>
<tr>
<th>Scales of Measurement</th>
<th>Validity of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal Level of Measurement</td>
<td>Reliability of Measurement</td>
</tr>
<tr>
<td>Ordinal Level of Measurement</td>
<td>Summary</td>
</tr>
<tr>
<td>Interval Level of Measurement</td>
<td>Discussion Questions</td>
</tr>
<tr>
<td>Ratio Level of Measurement</td>
<td>References</td>
</tr>
</tbody>
</table>
# LEARNING OBJECTIVES

Upon completion of this chapter, the reader will be able to:

- Define nominal, ordinal, interval, and ratio levels of measurement
- Provide an example of each level of measurement
- Describe differences in the levels of measurement
- Define validity and reliability
- Describe the various subtypes of validity and reliability
- Describe the importance of reliability and validity in research
Measurement of relevant variables is important in any research project. Scales of measurement provide a means of assigning numbers to events or objects according to prescribed rules, and preparing numerical data according to these rules permits the use of statistical treatment. Four scales or levels of measurement are used to categorize data. In hierarchical order, they are nominal, ordinal, interval, and ratio scales (Table 6–1).

Measurement scales may be based on clearly observable events or subjective impressions. An example of a precise, clearly observable scale is the metric ruler, which is composed of millimeters and centimeters. An example of a scale based on subjective impressions is a scale of listener clarity for different regional dialects. This kind of scale might be constructed simply by asking a group of subjects to assign numbers (scale values) to each dialect in a survey. The lowest number might represent the least clear dialect and the highest number the most clear dialect. Scales that attempt to quantify a relationship between subjective (psychological) sensations and physical quantities are called psychophysical scales. Hearing scientists have used both simple and complex scales of measurement to quantify various loudness-intensity and pitch-frequency relationships. There are four types of measurement scales: nominal, ordinal, interval, and ratio (Lass & Woodford, 2007).

**Nominal Level of Measurement**

The nominal (lowest) level of measurement classifies an event or object into a category. Examples of such categories

<table>
<thead>
<tr>
<th>Scale of Measurement</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratio</td>
<td>Equal intervals; true meaningful zero; possesses properties of all other scales</td>
<td>Age, IQ, weight; many personality and educational tests</td>
</tr>
<tr>
<td>Interval</td>
<td>Equal intervals; no meaningful zero; possesses properties of ordinal and nominal scale</td>
<td>Temperature</td>
</tr>
</tbody>
</table>
| Ordinal              | Ranked data; possesses properties of nominal scale | Heaviest-lightest  
Sweetest-sourest  
Tallest-shortest |
| Nominal              | Named or counted data; classification of labeling | Color Label: male or female |

may include gender, medical chart number, individuals who do and do not stutter, individuals with and without a history of voice problems, hearing sensitivity (normal or abnormal), etiology of hearing loss (conductive or sensorineural or mixed), as well as language development (normal or abnormal). A subject is measured at this level by assigning the individual to one of the established categories. Some variables at the nominal level are naturally measured as numerics (e.g., medical chart number). In addition, other variables are coded numerically (e.g., 1 = normal, 2 = abnormal, etc.). The numbers assigned represent differences and are not used mathematically for addition, subtraction, multiplication, or division functions which would be meaningless at this level.

According to Portney and Watkins (2009), nominal categories are mutually exclusive; that is, no object or person can logically be assigned to more than one category. Use of the nominal data category also assumes that the rules for classifying a set of attributes are exhaustive; that is, every subject can be accurately assigned to only one category. For example, classifying blood type would follow these rules.

Nominal scales represent the simplest type of measurement scales. They are constructed by placing various scale items into different categories, but no attempt is made to order the items. Many studies dealing with loudness and pitch use nominal scales of measurement. For example, these scales address our ability to discriminate between two auditory stimuli. The question asked in these studies is: “What is the smallest physical (acoustic) difference between two auditory stimuli that the listener can detect?”

For example, if studying loudness discrimination,

- Various pairs of auditory stimuli differing only in their intensities (with frequency the same) are presented to the listener.
- Many different combinations would be presented and listeners would have to make judgments for each pair: Do the stimuli sound equally loud? Do the stimuli sound different in loudness?
- Listeners have two choices from which to choose, and they assign one of the choices to each pair to which they listen (e.g., yes/no, same/different) (Lass & Woodford, 2007).

### Ordinal Level of Measurement

The ordinal level of measurement shows the position of one variable relative to another, but intervals between variables are not equal. Examples of variables at the ordinal level include college classification (freshman, sophomore, junior, or senior), teacher ranks (instructor, assistant professor, associate professor, or professor), and severity of a disorder (mild, moderate, or severe). Examples of the ordinal categories for the variable of hearing sensitivity include normal, mild, moderate, and severe. As with the nominal level of measurement, variables at the ordinal level are frequently coded numerically (e.g., 1 = freshman, 2 = sophomore, 3 = junior, and 4 = senior). However, mathematical or numeric operations (addition, subtraction, multiplication, and division) remain meaningless with ordinal measures. Nonparametric
statistical methods are used to examine ordinal data.

Ordinal scales of measurement are somewhat more complex than nominal scales, because the scale items are arranged in order with respect to some common feature. Therefore, ordinal scales may be constructed by procedures requiring the subject to rank order various items presented. For example, in a study of listener “clarity” for 10 accented English speech stimuli, each of the 10 accents could be presented to subjects, and they are asked to rank each accent from 1 to 10, with “10” being the most clear accent and “1” the least clear accent. No two accents could occupy the same rank. This is an ordinal scale of measurement because items would be arranged in order with respect to clarity of accent. However, it would be impossible to determine absolute differences between accents using this type of scale. Thus, it could not be determined whether the accent ranked “10” was actually twice as “clear” as the accent ranked “5,” or that the accent ranked “5” was five times as “clear” as the accent ranked “1,” and so on (Lass & Woodford, 2007).

Ordinal scales of loudness and pitch sensation may be constructed in much the same manner as the previous example of clarity of accents of English. For example, a study designed to rank listeners’ perceived loudness discomfort produced by various types of aircraft as they fly over homes adjacent to an airport. Six different planes might be considered for study and placed in rank order from “1” to “6,” with “6” representing the plane whose loudness was most uncomfortable to hear, and a rank of “1” would represent the plane with the least uncomfortable noise level. As in the previous example, no two planes could share the same rank. Since the scale of measurement is ordinal, it would only be possible to determine the relative ranks among aircraft. However, it would not be possible to determine from this scale whether one plane sounded twice as uncomfortable as another plane or planes, or to determine any other ratio among individual aircraft (Lass & Woodford, 2007).

Interval Level of Measurement

Interval scales are used when there are equal intervals between values but no absolute zero. For a numeric operation to yield meaningful results, it is necessary to have equal intervals between adjacent numerical values. For example, the difference between 3 and 5 should be the same as the difference between 28 and 30, or 41 and 43, or 79 and 81, and so on. In both interval and ratio levels of measurement, there are constant differences in data entries.

According to Portney and Watkins (2009), the interval scale does not allow for comparison of absolute magnitude of an attribute, because an absolute is not zero (as in ordinal measurement). Examples of variables at the interval level include the following:

1. numerical ratings of vocal quality on a 5- or 7-point interval scale;
2. numerical ratings reflecting attitudes of individuals who stutter based on a 5-point Likert-type rating scale; and
3. standard or scaled scores on a language test or IQ scores.

Parametric statistics are used if the following criteria are met: (a) the subjects
represent a “normal” population distribution; (b) the sample is sizable, usually more than 30; and (c) information is derived using the interval or ratio level of measurement (Ventry & Schiavetti, 1986). Thus, parametric statistical methods are used to examine equal interval data.

**Ratio Level of Measurement**

*Ratio scales* are interval scales with an absolute zero. Thus, it is assumed that the attribute being measured may not be present. This measure is more frequently appropriate for studies involving natural science than for studies in areas of social science. However, if the dependent variable is the frequency of events (such as frequency of moments of stuttering), has time measures (such as the latency period between seeing a printed word and saying it), involves a measured distance (such as measurement of the space constituting a velopharyngeal gap during phonation in patients with velopharyngeal incompetence), and so on, the ratio level may be appropriate. Height, weight, chronologic age, hearing level in decibels, and fundamental frequency of a complex wave are additional examples of variables that can be measured at the ratio level (Lass & Woodford, 2007).

The differences between interval and ratio measurements are that multiples are meaningful at the ratio level (e.g., a 6-mm velopharyngeal gap is twice as large as a 3-mm gap), and the units of the variables measured at the ratio level can be changed by simple multiplication (e.g., feet are converted into inches by multiplying by 12). These properties do not hold true for measurements at the interval level. For example, a person with an IQ of 100 is not twice as intelligent as someone with an IQ of 50. All numbers at the ratio level of measurement have mathematical properties, thus allowing parametric statistics to be employed to examine ratio and interval level data (Lass & Woodford, 2007).

Ratio scales of measurement contain all properties of nominal, ordinal, and interval scales. That is, they are capable of:

1. *classification* (like nominal scales);
2. *ordering* (like ordinal scales); and
3. *determination of exact differences* (like interval scales).

In addition, ratio scales also have the property of determining exact ratios between scale items. Since ratio scales have *true zero points*, numbers on ratio scales reflect actual ratios between items. An example of a ratio scale of measurement is the common metric ruler. On a metric ruler, 8 mm is exactly twice as long as 4 mm, and 50 m is exactly half as long as 100 m. The exact ratio between any two scale items can be derived on a ratio scale because it has a nonarbitrary, *absolute zero point*. For example, 0 mm is the total absence of distance (“zero distance”). Ratio scales represent the most precise scale type (Lass & Woodford, 2007).

In summary, in ratio scales, variables are treated as categorical (e.g., gender, age, disorder) or quantitative (e.g., height, weight, IQ, frequency of occurrence). It is important that categories for variables be classified so that each subject fits into only one category.

Quantitative variables usually are measured in discrete units (e.g., frequency, pounds, milliseconds, and millimeters), and these units must be carefully recorded.
as the data are collected. Table 6–2 shows hypothetical data for vocal fundamental frequency utilizing all types of measurements.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Ratio Measure</th>
<th>Interval Measure</th>
<th>Ordinal Measure</th>
<th>Nominal Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>220</td>
<td>4</td>
<td>3</td>
<td>High</td>
</tr>
<tr>
<td>B</td>
<td>198</td>
<td>5</td>
<td>2</td>
<td>Medium</td>
</tr>
<tr>
<td>C</td>
<td>137</td>
<td>8</td>
<td>1</td>
<td>Low</td>
</tr>
<tr>
<td>D</td>
<td>235</td>
<td>3</td>
<td>4</td>
<td>High</td>
</tr>
</tbody>
</table>


Validity of Measurement

When analyzing the accuracy of the results of a study, the investigator objectively attempts to answer questions of validity and reliability. When assessing the validity of a study, the primary question involves determining whether the obtained information actually contributes to answering the research question (Schiavetti, Metz, & Orlikoff, 2011). For example, if the investigator identifies phonatory quality using a Visi-Pitch analysis with an inappropriate frequency range for some of the subjects, perturbation data might be questioned.

Hegde (1994) differentiates between the validity of the data defining the dependent variables and the validity of the experiment itself. Accuracy of the information about the phonation attributes of the subjects is an example of establishing the validity of data defining the dependent variable(s). The design of a study, including control methods for observing, collecting, and recording data and control of the variables that might have an impact on the outcome of the study, contributes to the validity of the experiment. For example, consistent tracking of relevant phonatory habits and phonatory attributes of all subjects would contribute to the validity of the experiment.

Both internal and external validity are important to establish when analyzing the results of a research study. To establish internal validity, the experimenter determines if the experimental manipulation really made a difference (Kerlinger, 1973) by ensuring that extraneous factors that could influence the results are carefully controlled (Schiavetti, Metz, & Orlikoff, 2011). To establish internal validity, the design of a study should effectively rule out all variables that might affect the dependent variable so that it can be concluded that the independent variable was ultimately responsible.
for any change in the dependent variable (Doehring, 1988).

Portney and Watkins (2009) cited several factors that affect internal validity. Some of these are the effectors of prior events: maturation, attrition, testing effects by repeated testing, instrumentation, statistical regression (regression toward the mean), compensatory rivalry, and resentful demoralization of respondents receiving less desirable treatments. In summary, internal validity involves answering the question of whether the experimental treatments actually made a difference in the study (Isaac & Michael, 1987).

For the voice study cited previously, internal validity could be established by demonstrating voice improvement using Visi-Pitch data and a comparison of pre- and post-experimental perceptual analyses of the quality of subjects' voices. In addition, internal validity could be further established by reporting that: (a) the VisiPitch equipment was properly set and calibrated; (b) subjects with phonatory disorders related to preexisting laryngeal conditions were not selected; (c) all perceptual judgments were made by the same speech-language pathologists whose perceptual judgments were calibrated to the same criteria in training sessions administered by the experimenter; (d) all subjects received the same training in identifying poor vocal habits and establishing good vocal habits; and (e) all received the same medical diagnosis and treatment.

External validity is the extent to which the results of a study satisfy representativeness or generalizability (Kerlinger, 1973) or can be generalized to the population as a whole (Schivettti, Metz, & Orlikoff, 2011). Practical clinical use of findings is determined by establishing external validity. The extent to which effects of independent variables on dependent variables apply to the natural setting must be determined to establish external validity (Doehring, 1988). Hegde (1994) cites effects of treatment during a study and knowledge of expected results by subjects as factors that may influence the external validity of a study. Isaac and Michael (1987) concluded that questions about external validity involving what populations, settings, treatment variables, and measurement variables to which an effect can be generalized may not be completely answerable. The researcher must attempt to control all variables as well as possible.

For the voice study, establishing external validity could be done by showing that: (a) the individuals selected for the study were typical in age, sex, and occupation to those generally reported in the literature as having chronic voice problems related to vocal abuse and/or inflammatory laryngeal conditions; (b) standard treatment information was given to all subjects about identification and reduction of vocal abuses; (c) typical medical management was used for the conditions' diagnoses; and (d) it was established that the data provided by the Visi-Pitch and pre- and postperceptual analyses by examiners are typical of that collected by certified speech-language pathologists in varied clinical settings.

Three types of validity should be considered when using a test or questionnaire to measure an individual's knowledge or attitudes. These are content validity, criterion-related (including predictive and concurrent) validity, and construct validity. Content validity concerns whether the substance or content of a measure adequately represents the
universe of content of the attribute being measured or how well the content of the attribute being measured or how well the content of a test reflects the subject matter from which conclusions will be drawn (Isaac & Michael, 1987; Kerlinger, 1973; Portney & Watkins, 2009). Kerlinger (1973) further explained that content validation is basically judgmental in that each item is judged for its pertinence or applicability to the property or characteristic being measured.

Schiavetti, Metz, and Orlikoff (2011) further described content validity as a subjective means of logically explaining and evaluating test items to determine how well they reflect the characteristics to be measured. Content validity is concerned with adequately assessing all the aspects of the behaviors to be measured. For example, to assess IQ, the research usually assesses quantitative and verbal abilities, because both have been shown to correlate with intelligence. For example, the content validity of a test of language development would be determined by identifying the important behaviors that reflect good or poor language performance, then determining whether the content of the test items reflects those behaviors or skills.

Schiavetti, Metz, and Orlikoff (2011) define criterion-related validity as a test of whether a test (or measure) correlates with a known indicator (validating criterion) of the behavior (characteristic) being measured. Two types of criterion-related validity include concurrent and predictive validity (Kerlinger, 1973). Kerlinger (1973) further described concurrent criterion-related validity as involving the ability to check a currently administered measuring instrument against an outcome occurring now. Predictive criterion-related validity involves the ability to check a currently administered measuring instrument against a future outcome. For example, future achievement is predicted by aptitude tests (predictive), and present (concurrent) and future (predictive) achievement are predicted by achievement tests. Present and future ability to learn and solve problems are predicted by IQ tests (Kerlinger, 1973). Therefore, it is difficult to separate the predictive and concurrent components of criterion-related validity.

Criterion-related validity involves a test's ability to predict current or future performance. This may involve using correlation measures to compare test scores with criteria known to identify the same skills as the proposed test (Isaac & Michael, 1987). In fact, criterion-related data may be collected concurrently with the test to ascertain whether the test involves criteria-related procedures (Isaac & Michael, 1987).

The major difficulty in establishing criterion-related validity is determining whether criteria exist to predict a specific skill or performance, such as teaching effectiveness. The question of what constitutes appropriate criteria to measure teaching effectiveness has long been proven to be very controversial.

Construct validity involves scientific inquiry by testing a hypothesized relationship and validating a test and the theory behind it (Kerlinger, 1973). By investigating the qualities that a test measures, the degree to which the concepts or theory behind the test account for performance on the test may be determined (Isaac & Michael, 1987). Thus, construct validity is concerned with the extent to which a test or questionnaire measures what it is supposed to measure by
reflecting the theory, behavior, or characteristic to be measured (Schiavetti & Metz, 2002). The scores on a test are correlated with other accepted measures of the same behavior. If subjects’ scores on a new test are strongly correlated with their scores on an established test, then construct validity has been established.

**Reliability of Measurement**

*Reliability* refers to the consistency of a rater or of a measurement. Several words have been used to define reliability: dependability, predictability, consistency, credibility, and stability. In research, reliability refers to the consistency or correlation among repeated measures or observations. However, reliability does not ensure accuracy or validity. Thus, it is very possible that observations can be consistent without being accurate. For example, children’s responses to audiometric screening in a noisy environment might very well be consistent but certainly would not be considered accurate or valid indicators of their hearing sensitivity.

Three types of reliability: *intraexaminer* (intrarater or intrajudge), *interexaminer* (interrater or interjudge), and *test-retest* reliability should be assessed when establishing the reliability of the results of a study. Strong *intraexaminer reliability* implies that in repeated observations of the same subject, the same examiner gets similar results. *Intraexaminer reliability* is usually not difficult to establish. However, *interexaminer reliability* implies agreement among different observers measuring the same phenomenon. Interexaminer reliability is considered a crucial measure of objectivity and is a necessary element to subjecting a study to scientific review (Hegde, 2003). *Test-retest reliability* involves how well subjects perform on one set of measurements as compared to their performance on a second evaluation of the same measurements.

The relationship between validity and reliability is shown in Figure 6–1A.

Measurement may be very reliable but not very valid. However, a measurement with random error is usually considered neither reliable nor valid (Figure 6–1B). It should be noted that if a measurement has only a small amount of error, then it is possible to have relatively valid and reliable measurements (Figure 6–1C). If a measurement has no variance and is consistently reliable and valid, then the confidence in those measurements is high (Figure 6–1D).

**Summary**

Measurement of variables includes the control of factors that may influence reliability and validity. The level of measurement may be nominal, ordinal, interval, or ratio. It is important that the level of measurement used fits the study so that appropriate analysis of the data can be used. Moreover, it is important for all researchers to understand that validity and reliability are interrelated. Various types of factors may influence internal and external validity as well as different forms of reliability.
Figure 6–1. Representation of targets to illustrate the relationship between reliability and validity. 

A. Scores are highly reliable, but not valid, demonstrating systematic error. 

B. Scores are neither reliable nor valid, demonstrating random error. 

C. Reliability had improved but is still low; scores are somewhat valid. 

D. Scores are both reliable and valid. 

DISCUSSION QUESTIONS

1. Describe nominal and ordinal levels of measurement. What are the major properties that distinguish these two levels of measurement?
2. Provide an example of interval level of measurement. Does it have an absolute zero?
3. Ratio level of measurement allows for what type of mathematical operations? Why is this advantageous?
4. What is the difference between content and construct validity? Provide an example of each.
5. Differentiate between internal and external validity. Provide an example of each.
6. What is reliability? How does reliability relate to validity?
7. Can a study have good reliability and poor validity? If so, provide an example.
8. Differentiate between inter-judge reliability and intrajudge reliability. When might each of these be used during clinical research?

References

Research Design and Strategy

CHAPTER OUTLINE

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<td>Advantages and Disadvantages of Group Designs</td>
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LEARNING OBJECTIVES

Upon completion of this chapter, the reader will be able to:

- Describe several group designs for between-subjects and within-subjects
- Discuss single-subject designs related to clinical practice
- Describe the basics of sequential clinical trials
- Describe the basics of the Statistical Package for Social Sciences
- Discuss the advantages and disadvantages of group, single subject, and sequential clinical trials designs
Introduction

All types of research have a strategy or design that permits statistical analysis of differences between and within groups of subjects (Doehring, 1988; Maxwell & Satake, 2006; Portney & Watkins, 2009). Several types of research were described in previous chapters. Research strategy and design refer to the plans for answering research questions and testing research hypotheses. Some authorities differentiate between these terms; others do not. The strategy or design of a study indicates the methods and procedures used in the investigation. There are essentially two types of research designs: group designs and single-subject designs. Group designs include between-subject, within-subject designs, and mixed group designs. Single-subject designs include case studies, within-subject experimental designs, multiple baseline, and multiple treatment designs. Group research designs and single-subject designs are compared in Table 7–1.

Characteristics of a Good Design

Good research design may be described in terms of a number of characteristics. Understanding that systematic changes are the result of the experiment being conducted involves the use of “the researcher's ability to manipulate and control variables and measurements, so that rival hypotheses are ruled out as a possible explanation for the observed response” (Portney & Watkins, 2000, p. 153). Essentially, there are two types of extraneous variables: (a) intrinsic and (b) extrinsic (Polit & Hungler, 1999; Portney & Watkins, 2000). Intrinsic variables are variables associated with subjects of an investigation, such as age, gender, socioeconomic status, and marital status. There are a number of ways to reduce intrinsic variability, such as randomization (each subject has an equal chance of being assigned to any group), homogeneity (choosing only subjects who have the same characteristics), blocking (building extraneous variables into the design by using them as independent variables), using the subject as his or her own control, and analysis of covariance (selecting a covariate and adjusting scores statistically to control for differences on the extraneous variable) (Portney & Watkins, 2009). Extrinsic variables are variables associated with the research situation or environment. The variables are related to the place and time the research was conducted and adherence or not to the research specification or protocols. The most effective method of controlling external factors is directly related to the consistency of conditions under which an investigation is performed, that is, the conditions under which data are collected should be as similar as possible for every subject.

The second characteristic of good research design is that it should be appropriate for the question(s) being asked. Third, the design should not result in data that are biased. A fourth characteristic of good research design is precision, which can be accomplished by the use of a well-described protocol. Research designs differ considerably in the sensitivity with which statistically significant results can be detected. A fifth characteristic is the power of the design or its ability to detect relationships among variables. According to Portney and Watkins...
Table 7–1. Comparison of Group-Research Designs and Single-Subject Designs

<table>
<thead>
<tr>
<th>Group Designs</th>
<th>Single-Subject Designs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compare at least 2 groups from a target population</td>
<td>Compare within-subject performance for 1 subject or a small group of subjects.</td>
</tr>
<tr>
<td>Minimum number of subjects: 10</td>
<td>Minimum number: 1</td>
</tr>
<tr>
<td>Outcome measures collected infrequently; usually only pretest/post-test.</td>
<td>Performance repeatedly measured over a period corresponding to requirements of design.</td>
</tr>
<tr>
<td>Unnecessary to run subjects more than once under each experimental condition</td>
<td>Necessary to run subject more than once under each experiment.</td>
</tr>
<tr>
<td>Little or no subject feedback; emphasis on outcome.</td>
<td>Subject feedback monitored; emphasis on process and outcome.</td>
</tr>
<tr>
<td>Inflexible; changes not permitted once intervention is introduced.</td>
<td>Flexible, permits addition or elimination.</td>
</tr>
<tr>
<td>Standardized measurement procedures and comparisons between subjects.</td>
<td>Measurement procedures flexible, individualized.</td>
</tr>
<tr>
<td>Generalization</td>
<td>Limited generalization.</td>
</tr>
<tr>
<td>Expensive</td>
<td>Inexpensive</td>
</tr>
<tr>
<td>Statistical procedures well developed.</td>
<td>Statistical procedures relatively new.</td>
</tr>
<tr>
<td>Relatively easy to control for order and sequence effects.</td>
<td>Difficult to control for order and sequence effects.</td>
</tr>
</tbody>
</table>


The power of a statistical test addresses the ability of a test to reject the null hypothesis, that is, “to document a real relationship between independent and dependent variables” (p. 164). The appropriateness of research designs must also be considered relative to the current state of the art. Portney and Watkins (2000) suggested six critical questions that should be considered when choosing a specific design:

1. How many independent variables are being tested?
2. How many levels do each independent variable have, and are these controlled?
levels experimental or control conditions?
3. How many groups of subjects are being tested?
4. How will subjects be selected, and how will they be assigned to groups?
5. How often will observation of responses be made?
6. What is the temporal sequence of interventions and measurements?

**Group Design**

Group designs permit comparison of the average or typical performance of a group to other groups or other conditions (Warren, 1986). Several terms are used for this design: between-groups design, between-subjects designs, correlational design, preexperimental design, quasiexperimental design, and true experimental design (Bordens & Abbott, 1988; Portney & Watkins, 2009). Hegde (1999) indicates that the basic method for implementing group designs is to initially have two or more comparable groups that represent the populations from which they were drawn (especially when the random procedure is used); at least one of the groups receives a treatment (experimental group) and another group does not (control group).

**Between-Subjects Designs**

A classic design for exploring cause-and-effect relationships includes the pretest/posttest randomized control group (Patten, 2005). Figure 7–1 illustrates the classic design, which assumes that all groups are equal except that one received an experimental treatment and the other did not. Patten (2005) states that the advantage of using a pretest is that it will allow a researcher to determine how much each group has gained or changed, not just whether they are different at the end of the experiment.

If a researcher is concerned that a pretest might make subjects more sensitive to what is being studied, an alternative is to implement the posttest-only design (Portney & Watkins, 2009). A researcher would have used random assignment of subjects, and the groups would be comparable. The posttest-only design is most successful when the groups are large so the probability of balancing interpersonal characteristics is increased (Portney & Watkins, 2009).

<table>
<thead>
<tr>
<th>Assign subjects at random to groups</th>
<th>Group A: (Experimental group)</th>
<th>Pretest</th>
<th>Experimental Treatment</th>
<th>Posttest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group B: (Control group)</td>
<td>Pretest</td>
<td>Control condition</td>
<td>Posttest</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 7–1.** Classic design for cause-and-effect relationship. Adapted from Patten, M. L. (2005). *Understanding research methods* (5th ed.). Glendale, CA: Pyrczak Publishing.
Multiple control group design is a variation of the single-factor, multiple group design. This design uses multiple control groups, because a single control group is inadequate for assessing the impact of each potentially confounding factor of the dependent variables. Multiple control groups can be included in both parametric and nonparametric designs (Bordens & Abbott, 1988; Portney & Watkins, 2009).

Factorial designs manipulate two or more independent variables; one group in the design accounts for each possible combination of the levels of the independent variables. A factorial design is usually described according to its dimensions so that a two-way or two-factor design has two independent variables and a three-way or three-factor design has three independent variables. These designs can be described as a 2 × 2 design, which would pair two independent variables with two different levels. For example, if a researcher utilized two independent variables (types of speech sample) for connected speech and single word articulation production and manipulated the environment (child’s home and another sample in the clinic), this would be designated as a 2 × 2 factorial design. Again, all subjects would be assigned to one of four groups receiving a combination of connected or single-word articulation speech sample in a home or clinic setting. A factorial design has two or more independent variables, which are manipulated simultaneously; it permits analysis of the main effects of the independent variables separately and the interaction effects of these variables. Each main effect is a single-factor experiment, and the interaction addresses the question of the effect of one variable at different levels of the second variable (Portney & Watkins, 2009).

Multivariate designs involve two or more dependent variables, and provide information about the effect of the independent variable on each dependent variable and on a composite dependent variable formed from a weighted combination of the individual independent variables. In a multivariate design, Gutierrez-Clellen and Heinrichs-Ramos (1993) examined the referential cohesion of the narratives of Spanish-speaking children.

The validity of between-subjects experimental designs can be confounded or damaged by a variety of sources, such as nonrandomization randomization, experimenter bias, and poor planning and execution of experimental conditions. Confounding can be avoided by randomization, use of blinding, and careful planning and execution of a research protocol. Double-blinding is where neither the subjects nor the investigators are aware of the identity of the treatment groups until after data are collected (Portney & Watkins, 2000). Single-blinding of a study involves only the investigator(s) not knowing which treatment is used. It is often difficult to offer a placebo for studies involving rehabilitation procedures; therefore, single-blinding is more often used to try new or experimental procedures.

Within-Subjects Designs

In within-subjects designs, every subject in the experiment is exposed to all of the experimental or treatment conditions. Fewer subjects are required for this design than for an equivalent between-subjects design. Sometimes referred to as a repeated measures design, within-
subjects designs are a group of designs that incorporate the same basic structure, that is, using the same subjects in all conditions (Bordens & Abbott, 1988; Patten, 2005; Portney & Watkins, 2009). Within-subjects designs are classified or described similar to between-subjects designs and include two treatments, single-factor, multilevel, factorial, multiple control group, and multivariate designs.

The advantages of within-subjects designs include fewer subjects required, matching of subject factors, and power in detecting effects of dependent variables. Disadvantages include less power than equivalent between-subject designs if the dependent variable is only weakly related to subject differences, and possible carryover effects when exposure to one treatment influences behavior in a subsequent treatment. Carryover can be reduced by randomizing the order of presentation of levels of the independent variable. More frequently, counterbalancing is used in which individual subjects are exposed to the treatments in different orders. Utilizing treatment order as an independent variable makes it possible to determine whether carryover effects are present and, if so, their magnitude and direction. Despite the advantages of making treatment order an independent variable, there are disadvantages. The primary disadvantage is that every treatment order requires a separate group of subjects who must be tested under every treatment condition. This is expensive in terms of number of subjects and the time required testing them. Chapman, Sindberg, Bridge, Gigstead, and Hesketh (2006) utilized a repeated measure design when studying the effect of memory support and elicited production of new words by adolescents with Down syndrome.

**Mixed-Group Designs**

Mixed designs combine within-subjects and between-subjects designs and are used to investigate the effects of treatment for which carryover effects would be a problem while repeatedly sampling behavior across time or trials. Warren (1986) and Portney and Watkins (2009) consider mixed designs both descriptive and experimental. Three advantages of mixed designs are ease of implementation, generalizability of findings, and availability of statistical techniques. Frequent misinterpretation and overinterpretation of the results are the primary disadvantages. Altenberg and Ferrand’s (2006) study about the attitudes of monolingual English, bilingual Cantonese-English, and bilingual Russian-English speakers toward individuals with voice disorders utilized a mixed experimental design.

The *nested design* is a variation of the mixed group design that combines within-subjects and between-subjects designs. It involves more than one task for each level of the independent variable. For example, assume that you were conducting an experiment on the ability to write diagnostic reports. The between-subjects factor might be difficulty (low, moderate, and high). Under each level of difficulty, two sets of diagnostic data would be included, with all subjects in each level of difficulty completing both sets of reports. By demonstrating the effect of item difficulty with different tasks, effects are not limited to a specific type of problem. This design is useful when subjects must be tested in groups rather than individually. It also has the advantage of increasing the generality of results (Bordens & Abbot, 1988; Portney & Watkins, 2009).
Clement and Wijner (1994), in a study of vowel contrasts, analyzed their data utilizing a “three way ANOVA, with factors subject group, vowel, and subject (nested under subject group)” (p. 86). It is important to note that subjects are always nested under subject group. An example of a nested design, with speech-language pathologists nested within states, follows.

A group of six speech-language pathologists, two each from Louisiana, Oklahoma, and Texas, were discussing the treatment of patients with spasmodic dysphonia. The speech-language pathologists from Louisiana decided that Botox injections were the best means of treatment; therefore, their patients were injected, received voice management for 3 months, and then were reevaluated to determine the amount of improvement. The speech-language pathologists in Texas decided that voice management was the best means of treatment; therefore, their patients received voice management for 3 months and then were re-evaluated to determine amount of improvement. All data were then analyzed statistically.

Further information about nested designs may be found in Portney and Watkins (2009).

### Advantages and Disadvantages of Group Designs

Advantages and disadvantages of group designs are summarized in Table 7–2 and

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reliability of data</td>
<td>Assumption of homogeneity of group members</td>
</tr>
<tr>
<td>Availability of statistical procedures</td>
<td>Subject attrition</td>
</tr>
<tr>
<td>Generalization from sample to population</td>
<td>Availability of subjects</td>
</tr>
<tr>
<td>Established population characteristics</td>
<td>Typical subject may not be typical</td>
</tr>
<tr>
<td>Control order or sequence of effects</td>
<td>Generalizability of results</td>
</tr>
<tr>
<td>Quantitative information</td>
<td>Ethical considerations</td>
</tr>
</tbody>
</table>

discussed briefly here. Group designs have several advantages. Statistical procedures for determining reliability are available for group designs. Another advantage is that it is possible to control order or sequence effects because a relatively large number of subjects permits randomization (Portney & Watkins, 2009; Silverman, 1998). Group designs also allow generalization of results from samples of subjects to the population as a whole (Doehring, 1988; Portney & Watkins, 2009). Another advantage is the ability to demonstrate causal relationships (Patten, 2005; Portney & Watkins, 2000).

Despite the advantages of group designs, there are several disadvantages. First is the assumption of homogeneity of group members, that is, that all members of a group respond similarly to an experimental condition. Related to this is subject attrition, which can affect results because loss of group members may disrupt group equivalency (Portney & Watkins, 2009; Warren, 1986). A second disadvantage is related to availability of subjects; in group designs, more subjects may be required than are available (Silverman, 1998). Third, the typical subject may not be typical; in other words, the mean or average of the group may not accurately reflect differences in individual performance (Patten, 2005; Portney & Watkins, 2009; Silverman, 1998). Fourth, it may be difficult to generalize results because of the possibility of uncertain validity (Portney & Watkins, 2009; Silverman, 1998). Another disadvantage is related to limitations of quantitative information (Doehring, 1988). Last, there are ethical considerations about group designs because of concern about withholding treatment for research projects (Portney & Watkins, 2009; Warren, 1986).

Single-subject designs focus on the behavior of one or a few subjects. These designs are also referred to as applied behavioral analysis designs or behavioral analysis, idiographic designs, single-subject experimental designs, single-case designs, intrasubject replication designs, small N-approach, and within-subjects designs. The use of the term is confusing, because it is also used to refer to a variety of group designs (Hegde, 1999). Cardon and Azuma (2011) describe the use of single-subject research designs for individuals with autistic spectrum disorders (ASD). These authors stated that individuals with ASD are a rather heterogeneous group to study; therefore, single-subject research designs may be very helpful when describing the impact of various types of clinical treatment.

It is misleading to consider any design that uses one or a few subjects as a single-subject design. Designs that use single subjects also can be classified as case studies or single-subject designs (Warren, 1986). Single-subject designs are experimental designs that attempt to establish cause-and-effect relations. According to Portney and Watkins (2000), “Single-subject designs are structured around two core elements that distinguish them from a case study or group studies; repeated measurement and design phases” (p. 224). Single-subject designs can be used to study comparison between several types of treatment or between treatment and no treatment (Portney & Watkins, 2000). Bordsens and Abbott (1988) described four characteristics of single-subject designs:

1. Individual subjects are observed intensely under each of several
treatment conditions; these observations provide a baseline against which any future change induced by the independent variable can be evaluated.

2. All incidental variables that may affect the dependent variable are controlled as rigidly as possible.

3. Each subject is observed under all treatment conditions, and each treatment is repeated at least twice during the course of the experiment. This repetition of intrasubject replication shows the reliability of the findings. Subjects usually remain in each treatment of the experiment until the behavioral measure meets a stability criterion.

4. If more than one subject is used, the additional subjects are included to evaluate the generality of findings across subjects. This intersubject replication establishes whether the results obtained with one subject are similar or dissimilar to those obtained with other subjects. (p. 263)

There are many types of single-subject designs, but two basic categories of single-subject designs known as baseline designs and discrete trials designs have been identified (Bordens & Abbott, 1988; Portney & Watkins, 2009). 

*Baseline designs* include designs that manipulate a single independent variable (single-factor designs), those that manipulate two or more independent variables (multifactor designs), and those that measure several dependent variables (multiple baseline designs). In baseline designs, the variable, also known as the target behavior, is measured prior to the experimental treatment of intervention.

*Single-factor designs* include a baseline condition (A) during which a baseline of subject performance is established and a treatment or intervention condition (B) in which the effect of the treatment or intervention is observed. There are several types of these designs, including AB, ABA, ABAB, ABAC, and BAB (Portney & Watkins, 2009; Silverman, 1998). These symbols are designed as follows:

A = baseline,

B = first treatment or intervention,

and

C = second treatment or intervention different from the first.

*Multifactor baseline designs* include more than one independent variable and require that different combinations of the independent variable be tested across the study. The effects of the independent variables and their interactions can be assessed. A factorial design may be used or specific combinations may be evaluated (Portney & Watkins, 2000). These designs can be very time consuming, because each treatment is evaluated at least twice for intrasubject replication.

*Multiple baselines designs* involve observation of different behaviors and establishing baselines for each. Thus, several behaviors are observed within the experimental context to provide multiple baselines. Treatment is considered effective if the level of each behavior changes after the treatment is applied to it.

In *single-subject discrete trial designs*, individual subjects receive each treatment condition of the experiment dozens of times. Each treatment or trial produces one data point for each dependent variable measured. Extraneous variables
that could introduce unwanted variability in the dependent measure are rigidly controlled. If possible, the order of treatments is randomized or counterbalanced to control order effects. Intrasubject replication is established by comparing the behavior of individual subjects undergoing the same treatment.

The advantages and disadvantages of single-subject designs are summarized in Table 7–3. Single-subject designs often are frequently used to determine treatment efficacy (Hegde, 1999; Portney & Watkins, 2009). These designs are economical in terms of time, because single-subject research frequently can be conducted during regular clinical hours and during regularly scheduled treatment sessions (Gillam & Gillam, 2006). Furthermore, single-subject designs are similar in form to the design of therapy and are the best, if not the only, appropriate strategy to advance clinical knowledge and make use of evidence-based practice. Table 7–4 provides examples of studies using single-subject designs in ASHA journals between 2002 and 2006.

### Sequences Clinical Trials

Group studies often require a fixed sample size prior to starting an experiment (Portney & Watkins, 2009). An alternative to group studies and single-subject designs includes sequential clinical trials (SCTs). Instead of waiting until the end of an experiment for data analysis, the SCT allows for analysis when each subject is tested and can be stopped at any point, as the evidence is there to determine a significant difference between treatments (Portney & Watkins, 2009).

---

**Table 7–3. Advantages and Disadvantages of Single-Subject Designs**

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control of error variance</td>
<td>Limited generalization</td>
</tr>
<tr>
<td>Establish causal relationships</td>
<td>Control of extraneous variables</td>
</tr>
<tr>
<td>Identify individual differences</td>
<td>Control of order and sequence effects</td>
</tr>
<tr>
<td>Flexibility</td>
<td>Limited availability of statistical procedures</td>
</tr>
<tr>
<td>Small number of subjects (as few as 1)</td>
<td></td>
</tr>
<tr>
<td>Focus on actual behavioral outcomes</td>
<td></td>
</tr>
<tr>
<td>Practical clinical application</td>
<td></td>
</tr>
<tr>
<td>Can be done during scheduled treatments</td>
<td></td>
</tr>
<tr>
<td>Economical</td>
<td></td>
</tr>
</tbody>
</table>

SCT can be used to compare two treatments such as an “old” or standard treatment to a “new” experimental treatment. Once the parameters of the study have been adequately defined, then the first eligible subject can be enrolled. The patient is assigned to either the standard or experimental treatment by some randomization process. When the next eligible patient is enrolled, that patient is enrolled in a condition that is the opposite of the first patient.

Portney and Watkins (2000) stated that it is often “convenient to evaluate the relative effectiveness of two treatments by collecting a series of qualitative preferences in favor of one or the other” (p. 205). The preference by the subject is defined on the “basis of clinically meaningful differences between two treatments” (p. 205).

There are four possible outcomes for classifying preference. First, both subjects could indicate “improvement.” Second, both subjects could indicate “no improvement” with their treatment. Third, one subject could indicate “improvement,” and the other subject could show “no improvement.” Fourth, the situation could be reversed in which the first subject showed “no improvement” and the other subject showed “improvement.” For further discussion about data collection and analysis, one should consult Portney and Watkins (2009). Table 7–5 describes advantages and limitations for SCTs.

### Table 7–4. Examples of Studies Using Single-Subject Designs in ASHA Journals Between 2002–2006

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davidow, Bothe, &amp; Bramlett (2006)</td>
<td>Stuttering treatment research and evaluation and assessment tool (STREAT)</td>
</tr>
<tr>
<td>Gillam &amp; Gillam (2006)</td>
<td>Evidence-based decisions about child language intervention in schools</td>
</tr>
<tr>
<td>Inglehart (2004)</td>
<td>Speech perception by students with cochlear implants using sound-field systems in classrooms</td>
</tr>
<tr>
<td>Kiran &amp; Thompson (2003a &amp; 2003b)</td>
<td>Semantic complexity in treatment of naming deficits in fluent aphasia</td>
</tr>
<tr>
<td>Lund &amp; Light (2003)</td>
<td>Effectiveness of grammar instruction with AAC users</td>
</tr>
</tbody>
</table>
Whether using group or single-subject research designs, a researcher should make use of the technology available when conducting data analysis. Group designs usually involve more inferential statistics, because a researcher is interested in making inferences from a sample to a population (Pyrczak, 2004). Descriptive statistics can be used with a variety of research designs (group, single-subject, SCTs) and would include information about, but not limited to, the mean, standard deviation, mode, median, and correlations.

One of the most often used statistical programs in behavioral and social sciences is the Statistical Package for Social Sciences (SPSS) published by Prentice Hall, a division of Pearson Education, Inc. (available at http://www.prenhall.com). Student versions of SPSS are available that typically provide sufficient capacity for studies involving up to 50 variables and 1,500 data entries. Holcomb (2006) describes that SPSS can be used with a variety of levels of measurement in research including nominal, ordinal, interval, and ratio.

When utilizing SPSS, it is important that a researcher understand there are many methods that can be used for the collection of data (e.g., pencil-paper, direct observation, etc.), but SPSS assists during the analysis of the data. Initially, all data must be entered into the SPSS program in which the researcher defines the variables to be entered and analyzed. After defining variables, the next step involves data input that follows the system developed within SPSS (Holcomb, 2006).

SPSS supports the researcher by saving data to a file that can be analyzed and graphically displayed in a variety of ways. This includes, but is not limited to, descriptive statistics, t-tests, ANOVA, linear regression, correlations, and multiple linear regressions (SPSS, 2006). There are useful tools to support a researcher when making decisions about statistical

### Table 7–5. Advantages and Limitations for Sequential Clinical Trials (SCTs)

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixed sample size not needed to start</td>
<td>Only compare 2 treatments</td>
</tr>
<tr>
<td>Can analyze data as subjects complete trials</td>
<td>Do not explore multiple or interaction effects</td>
</tr>
<tr>
<td>Subjects can be enrolled once eligible</td>
<td>Control extraneous variables only with randomization of pairs</td>
</tr>
<tr>
<td>Statistical technique can be done without computer</td>
<td>If a pair doesn’t state preference those data are discarded</td>
</tr>
<tr>
<td>Holds much potential in rehabilitation research</td>
<td>Effects of treatment should be soon so time is limited</td>
</tr>
</tbody>
</table>

Group research designs require the formation of two or more groups. Single-subject designs are based on an individual subject's performance under different conditions. Although group designs are often used, they do not meet the practical needs of speech-language pathologists and audiologists to evaluate treatment. These designs were described as if they were mutually exclusive, but this is not so. Some studies use designs that generate both types of data. Different study designs have different strengths and weaknesses. It is important to remember that research designs that are appropriate today may not be in the future. Technology supports the analysis of data used with a variety of research designs but still requires the researcher to make decisions regarding the appropriate application of the technology, data analysis, and interpretation.

**Discussion Questions**

1. Distinguish between strategic planning and research design.
2. Distinguish between group and single-subject designs. What are the advantages and disadvantages of each?
3. When would a between-subjects design be appropriate? When would a within-subjects design be used?
4. Why might there be ethical concerns with certain types of research designs?
5. Why should single-subject designs be used by clinicians?
6. Are single-subject designs used by clinicians on a daily basis in some form? Explain your answer.
7. When would sequential clinical trials be used? Why are SCTs not frequently seen in rehabilitation literature?
8. What is SPSS? How would SPSS help a researcher? When is a SPSS not helpful to a researcher?
9. Explain to your faculty advisor that the program needs to invest in SPSS.
10. Choose one of the single-subject designs listed in Table 7–4. Describe the statistical analysis that was used. What did you find interesting about it?
References


Quantitative Research

CHAPTER OUTLINE

Characteristics of Quantitative Research
Advantages and Disadvantages of Quantitative Research
Quantitative Research Designs
Nonexperimental Designs
Preexperimental Designs
Quasiexperimental Designs
Single-Subject Designs

True Experimental Designs
Quantitative Analysis
Descriptive Statistics
Inferential Statistics
Multivariate Statistics
Meta-Analysis
Summary
Discussion Questions
References
LEARNING OBJECTIVES

Upon completion of this chapter, the reader will be able to:

- Describe characteristics of quantitative research
- Identify various types of quantitative research
- Select an appropriate statistic
- Explain different methods of descriptive statistics
- Describe methods used for inferential statistics
- Apply special methods such as meta-analysis
- Evaluate quantitative research
Research can be classified as either qualitative or quantitative. The latter involves investigation of phenomena that lend themselves to precise measurement and quantification, often under controlled conditions that can be subject to statistical analysis (Maxwell & Satake, 2006; Polit & Beck, 2010). This chapter describes various aspects of quantitative research including descriptive and inferential statistics.

### Characteristics of Quantitative Research

Quantitative research is a type of research in which objective data are gathered and analyzed numerically (McMillan & Schumacher, 2010). The emphasis is on numbers, measurement, deductive logic, control, and experimentation. Characteristics of quantitative research are shown in Table 8–1 and Figure 8–1.

### Advantages and Disadvantages of Quantitative Research

Historically, quantitative research has been the gold standard for research, that is, superior to other types of research. A major strength of quantitative research is its credibility, which is the extent to

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Quantitative</th>
<th>Qualitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>Explain and predict</td>
<td>Describe and explain</td>
</tr>
<tr>
<td></td>
<td>Conform and validate</td>
<td>Explore and interpret</td>
</tr>
<tr>
<td></td>
<td>Test theory</td>
<td>Build theory</td>
</tr>
<tr>
<td>Process</td>
<td>Focused</td>
<td>Holistic</td>
</tr>
<tr>
<td></td>
<td>Known variables</td>
<td>Unknown variables</td>
</tr>
<tr>
<td></td>
<td>Established guidelines</td>
<td>Flexible guidelines</td>
</tr>
<tr>
<td></td>
<td>Predetermined methods</td>
<td>Emerging methods</td>
</tr>
<tr>
<td></td>
<td>Somewhat context free</td>
<td>Context bound</td>
</tr>
<tr>
<td></td>
<td>Detached view</td>
<td>Personal view</td>
</tr>
<tr>
<td>Researcher's role</td>
<td>Detached</td>
<td>Observer or participant</td>
</tr>
<tr>
<td>Data collection</td>
<td>Statistical analysis</td>
<td>Search for themes and categories</td>
</tr>
<tr>
<td></td>
<td>Stress objectivity</td>
<td>Acknowledgment of subjectivity and bias potential</td>
</tr>
<tr>
<td></td>
<td>Deductive reasoning</td>
<td>Inductive reasoning</td>
</tr>
<tr>
<td>Communication of findings</td>
<td>Numbers</td>
<td>Words</td>
</tr>
<tr>
<td></td>
<td>Statistics, aggregated data</td>
<td>Narrative, individual quotes</td>
</tr>
<tr>
<td></td>
<td>Formal voice, scientific style</td>
<td>Personal voice, literary style</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Associated terms or phrases</th>
<th>Positivist*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Experimental</td>
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<tr>
<td></td>
<td>Hard data</td>
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<td></td>
<td>Statistical</td>
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<tr>
<td>Key concepts</td>
<td>Variable</td>
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<td></td>
<td>Operationalized</td>
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<td></td>
<td>Controlled</td>
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<tr>
<td></td>
<td>Reliable</td>
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<tr>
<td></td>
<td>Statistically significant</td>
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<tr>
<td></td>
<td>Replicated</td>
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<tr>
<td></td>
<td>Hypothesized</td>
</tr>
<tr>
<td>Goals</td>
<td>Test theory</td>
</tr>
<tr>
<td></td>
<td>Establish facts</td>
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<tr>
<td></td>
<td>Show relationships</td>
</tr>
<tr>
<td></td>
<td>Predict</td>
</tr>
<tr>
<td></td>
<td>Statistically describe</td>
</tr>
<tr>
<td>Design</td>
<td>Structure</td>
</tr>
<tr>
<td></td>
<td>Predetermined</td>
</tr>
<tr>
<td></td>
<td>Formal</td>
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<tr>
<td></td>
<td>Specific</td>
</tr>
<tr>
<td>Sample</td>
<td>Large</td>
</tr>
<tr>
<td></td>
<td>Representative</td>
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<tr>
<td></td>
<td>Random selection</td>
</tr>
<tr>
<td></td>
<td>Control group</td>
</tr>
<tr>
<td></td>
<td>Stratified</td>
</tr>
<tr>
<td>Data</td>
<td>Quantities</td>
</tr>
<tr>
<td></td>
<td>Count</td>
</tr>
<tr>
<td></td>
<td>Measures/instruments</td>
</tr>
<tr>
<td></td>
<td>Numbers</td>
</tr>
<tr>
<td></td>
<td>Statistics</td>
</tr>
<tr>
<td>Techniques or methods</td>
<td>Experiments</td>
</tr>
<tr>
<td></td>
<td>Quasiexperiments</td>
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<tr>
<td></td>
<td>Structured observations</td>
</tr>
<tr>
<td></td>
<td>Structured interviews</td>
</tr>
<tr>
<td></td>
<td>Surveys</td>
</tr>
<tr>
<td>Data analysis</td>
<td>Deduction</td>
</tr>
<tr>
<td></td>
<td>Statistical</td>
</tr>
</tbody>
</table>

**Figure 8–1.** Characteristics of quantitative research. (*Positivist or post-positivism is based on the assumption that phenomena should be studied objectively; the goal is obtaining a single true reality, or at least within known probabilities.*) Adapted from McMillan, J. H. (2004). *Educational research*. Boston, MA: Pearson.
which the data and conclusions are believable and trustworthy. Other advantages are objectivity, standardization, replication, and limited bias. There is no uniform agreement about disadvantages. The disadvantages that have been identified are superficial/oversimplification, unrelated to the real world, too intense, focus on hard data, and unnatural environment (French, Reynolds, & Swain, 2000).

Quantitative Research Designs

There are major differences in the credibility of nonexperimental and experimental designs. Quantitative designs may be viewed on a continuum. True experimental designs are at one end of the continuum (highest), and nonexperimental studies are at the other end (lowest). Five major categories of research designs have been identified: nonexperimental, preexperimental, quasiexperimental, experimental (true experimental), and single subject.

Nonexperimental Designs

Nonexperimental or observational designs are the weakest of all designs because they do not involve randomization, manipulation, or use of control groups. Furthermore, casual relations cannot be established (Maxwell & Satake, 2006). This type of research includes descriptive research and correlational studies. The advantages of nonexperimental research are its: (a) appropriateness for studying problems not amenable to experimental research, and (b) efficiencies and effectiveness for studying a large amount of information about a problem. The disadvantages are the failure to describe casual relationships and faulty interpretation on selection of groups and self-selection.

Nonexperimental research includes descriptive and correlational studies (Polit & Beck, 2010). Descriptive studies provide descriptive information about population parameters and relationships among subjects. Correlational studies describe relationships among variables (DePoy & Gitlin, 2011).

Nonexperimental research is undertaken when: (a) a number of independent variables such as gender and height are not amenable to randomization, (b) some variables cannot be ethically manipulated, (c) there are practical constraints to manipulating variables, and (d) avoiding manipulation achieves a more realistic understanding (Polit & Beck, 2010). There are a variety of nonexperimental research designs, which are summarized in Table 8–2.

Preexperimental Designs

Preexperimental designs are sometimes referred to as pseudo-experimental designs, because they do not meet at least two of the three criteria for true experiments: randomization, manipulation, or control. Furthermore, preexperimental studies are limited to describing outcomes because appropriate statistical analysis cannot be performed. Thus, the goal of such studies is to explore or describe phenomena rather than explain their causes. Currently, the use of preexperimental designs is limited due to inadequate control of numerous extraneous variables. Maxwell and Satake (2006) noted that preexperimental designs “give the impression of constituting credible
Table 8–2. Nonexperimental Quantitative Research Designs

<table>
<thead>
<tr>
<th>Name of Design</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case Study</td>
<td>In-depth analysis of single individual, a few individuals, or an institution.</td>
</tr>
<tr>
<td>Case control</td>
<td>Retrospective comparison of case and a matched control.</td>
</tr>
<tr>
<td>Case series</td>
<td>Three or more cases in a case study.</td>
</tr>
<tr>
<td>Cohort</td>
<td>Focuses on specific subpopulation from which different samples are selected at different points in time.</td>
</tr>
<tr>
<td>Correlational</td>
<td>Study of interrelationships among variables on interest without any active intervention of inferring causality.</td>
</tr>
<tr>
<td>Descriptive</td>
<td>Summarizes status on phenomena, that is, characteristic and/or frequency with which certain phenomena occur.</td>
</tr>
<tr>
<td>Ex post facto</td>
<td>Presumed cause that occurred in the past. Also called causal comparison.</td>
</tr>
<tr>
<td>Retrospective</td>
<td>Begins with outcome and looks back in time for antecedent caused.</td>
</tr>
<tr>
<td>Prospective</td>
<td>Begins with examination of presumed causes and then goes forward in time for its effect.</td>
</tr>
<tr>
<td>Natural experiments</td>
<td>Comparison of groups in which one group is affected by a seemingly random event.</td>
</tr>
<tr>
<td>Path analysis</td>
<td>Uses correlation of several variables to study causal patterns</td>
</tr>
<tr>
<td>Causal comparison</td>
<td>Dependent variable already occurred so its relationship to other variables can only be studied. Also called ex post facto.</td>
</tr>
<tr>
<td>Structural equation modeling</td>
<td>Relatively new method, more powerful than path analysis for studying correlations to identify causal patterns.</td>
</tr>
<tr>
<td>Surveys</td>
<td>Focuses on obtaining information about activities, beliefs, preferences, attitudes, by direct questioning.</td>
</tr>
<tr>
<td>Cross-sectional survey</td>
<td>Survey given at one time.</td>
</tr>
<tr>
<td>Longitudinal survey</td>
<td>Same or similar subjects surveyed over time.</td>
</tr>
</tbody>
</table>

scientific studies but are characterized by numerous sources on invalidity” (p. 204). These designs were described as “fools gold” because of the “misleading impressions of belonging to more rigorous and powerful kinds of experimental methodologies” (p. 203). Schiavetti and Metz and Orlikof (2011) pointed out that these designs are weak in both internal and external validity.

There are four types of preexperimental designs: single group pretest only, single group pretest-posttest, time series design, and nonequivalent groups posttest only. These designs are summarized in Figure 8–2.

The weakest of the preexperimental designs is the one-group postdesign, which is also known as the single group posttest only or one-shot case study. This design involves study of the presumed effect of an independent variable in one group of subjects by administering a posttest after some treatment.

The single or one-group pretest-posttest design, also known as a before-after design, compares pretest and posttest data subsequent to treatment. There is inadequate control for internal and external validity, because there is no control group.

The time series design involves repeated measures before and after treatment using the same instruments with the same or similar subjects over an extended period of time. McMillan (2005) believes this is “a good design for frequently occurring measures of the dependent variable at regular intervals” (p. 218). There is some confusion about the classification of time series designs. This design is classified by some as preexperimental (McMillan, 2005; Mertens 2005) and by others as quasiexperimental (DePoy & Gitlin, 2011; Maxwell & Satake, 2006; Meline, 2006; Polit & Beck, 2010). The next section on quasiexperimental designs provides further information about time service designs.

Nonequivalent groups; posttest-only design has a comparison control group, both of whom are tested after treatment and not before treatment. Another type of preexperimental design is the static group comparison in which the performance of two groups is compared. One group receives treatment, and the other does not (Maxwell & Satake, 2004).
Quasiexperimental Designs

These designs are commonly used in speech-language pathology and audiology research (Maxwell & Satake, 2004; Meline, 2006). Quasiexperimental are sometimes referred to as nonrandomized. These designs are sometimes called controlled times without randomization. These designs are almost true experiments but not quite because of the lack of randomization and a control group, that is, subjects are not randomly assigned to groups. Quasi or semi-experimental designs combine some of the characteristics of both experimental and nonexperimental research (Kumar, 1996). These designs are used when true experiments are impractical or impossible.

Quasiexperiments are not as powerful as true experiments in establishing relationships between treatments and outcomes (Polit & Beck, 2010).

The nonequivalent group pretest-posttest design involves the use of two nonrandomized comparison groups, both of whom are tested before and after treatment. The most serious threat to validity of this design is that subjects are not randomly assigned to these groups (DePoy & Gitlin, 2001). This design is similar to the nonequivalent groups posttest-only design and static group comparison, except for the addition of a pretest (Maxwell & Satake, 2006; McMillan, 2005). Single-subject designs are classified as quasiexperimental (Maxwell & Satake, 2006) or experimental (McMillan, 2005). They have been described as a special application of experimental research. These designs are described in more detail in Chapter 7.

Single-Subject Designs

Single-subject designs can be used to study one subject or a small number of subjects for an extended period of time before and after treatment. This design involves a variation of several group designs (repeated measures; time series). Single-subject designs are classified as quasiexperimental (Maxwell & Satake, 2006) or experimental (McMillan, 2005). They have been described as a special application of experimental research. These designs are described in more detail in Chapter 7.

True Experimental Designs

True experimental designs or randomized controlled trials (RCTs) are considered by many as the gold standard, that is, the strongest of the research designs (Maxwell & Satake, 2006; Polit & Beck, 2010). Randomization, also called random assignment, is the selection of a sample of subjects so that each member of a population has an equal probability of being selected (Polit & Beck, 2010). Random assignment is randomization of subjects to experimental and control groups so that the groups are compara-
ble at the onset of the experiment. Control is the process of holding constant confounding influences of the dependent variable under study. This usually means a control group of subjects who do not receive treatment. These designs can provide information about cause-and-effect relationships among independent and dependent variables.

A true experimental design is characterized by manipulation (treatment or intervention), randomizations or random assignment (equal chance of being represented), and control. If a research design does not meet these three criteria, it is probably a quasiexperimental design. There are several types of experimental designs. Some of the more common designs are summarized in Table 8–3. Additional information about experimental designs is available in Blessing and Forester (2012) and Isaac and Michael (1987), and Vogt (2006).

**Quantitative Analysis**

Quantitative or statistical analysis is the organization and integration of quantitative data according to systematic mathematical rules and procedures. Statistical analysis is guided by and dependent on all previous steps of the research process, including the research problem, study, design, number of study variables, sampling procedures, and number of subjects. Each of these steps should lead to the selection of appropriate statistical analysis (DePoy & Gitlin, 2011). Statistical analysis and statistic warrant definition. Statistical analysis is concerned with summarizing $m =$ numerical data, assessing its reliability and validity, determining the nature and magnitude and relationships among sets of data, and making generalizations from current to future events (Nicolosi, Harryman, & Kresheck, 2004). Statistic according to Maxwell and Satake (2006), “is a number derived by counting or measuring sample observations drawn from a population that is used in estimating a population parameter” (p. 529). DePoy and Gitlin (2011) described statistic as a “number derived from a mathematical procedure as part of the analytic process experimental type research” (p. 324).

**Descriptive Statistics**

Descriptive statistics are used to describe and synthesize data. Table 8–4 summarizes the different types of descriptive statistics. The most basic statistic is frequency distribution, which is a systematic arrangement of values from lowest to highest with a count of times each value was obtained.

Graphs can be used to display frequency or relative frequency of percentages. The most frequently used graphs are histograms (bar graphs) and frequency polygons (line graphs). Other graphs for displaying distributions include pie graphs and trend charts.

Pie charts are used to represent the proportion of data falling into certain categories in the form of a circle containing segments, which are also called slices, sections, or wedges. These graphs are useful in illustrating percentages in relation to each other and to the whole (Nicol & Pexman, 2003). They are also referred to as pie charts, pie diagrams, cake charts, circle graphs, percentage graphs, or 100% graphs. An example of
<table>
<thead>
<tr>
<th>Name of Design</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between-subjects</td>
<td>Comparison of groups treated differently on some independent variable.</td>
</tr>
<tr>
<td>Counterbalance</td>
<td>Variation of experimental design in which more than one treatment is tested and the order of participation in each treatment is manipulated.</td>
</tr>
<tr>
<td>Factorial (ANOVA)</td>
<td>Any design in which more than one treatment factor is investigated.</td>
</tr>
<tr>
<td>Latin square</td>
<td>Repeated measures design in which presentation of conditions is counterbalanced so that each occurs in each sequential position of a block.</td>
</tr>
<tr>
<td>Parallel</td>
<td>Experiments that generally have at least two randomly assigned independent groups of participants, each of whom receive only one of the treatments (independent variables) under investigation.</td>
</tr>
<tr>
<td>Posttest only (after only)</td>
<td>Data collected from subjects only after treatment. Most basic of the experimental designs</td>
</tr>
<tr>
<td>Pretest-posttest (before-after)</td>
<td>Data collected from subjects both before and after treatment. Most commonly used true experimental design.</td>
</tr>
<tr>
<td>Randomized block</td>
<td>Involves two or more factors (independent variables), only one of which is experimentally manipulated.</td>
</tr>
<tr>
<td>Repeated measures (crossover)</td>
<td>One group of subjects is exposed to more than one condition or treatment in random order.</td>
</tr>
<tr>
<td>Randomized clinical trial (RCT)</td>
<td>Experimental test of a new treatment, involving random assignment to treatment groups; typically a large and diverse sample. Also known as a phase III clinical trial.</td>
</tr>
<tr>
<td>Solomon four group</td>
<td>Uses a before-after design for one pair of experimental and control groups, and after only design for a second pair.</td>
</tr>
<tr>
<td>Split plot</td>
<td>Uses both within-subject and between-subject design elements of statistical analysis of treatment effects.</td>
</tr>
<tr>
<td>Within-subjects</td>
<td>Comparison within same subjects under circumstances in which they were exposed to two or more treatment conditions.</td>
</tr>
</tbody>
</table>

### Table 8-4. Descriptive Statistics

<table>
<thead>
<tr>
<th>Type of Analysis</th>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shape of distribution</td>
<td>Skewed</td>
<td>Asymmetric distribution</td>
</tr>
<tr>
<td>Positively skewed</td>
<td></td>
<td>Asymmetric distribution tail points to right (positive) side because frequency of low scores greatly outnumber high scores</td>
</tr>
<tr>
<td>Negatively skewed</td>
<td></td>
<td>Asymmetric distribution; tail points left (negative) side because frequency of high scores greatly outnumbers low scores</td>
</tr>
<tr>
<td>Modality</td>
<td></td>
<td>Describes number of peaks, values with high frequencies.</td>
</tr>
<tr>
<td>Unimodal</td>
<td></td>
<td>Distribution of values with one peak (high frequency)</td>
</tr>
<tr>
<td>Bimodal</td>
<td></td>
<td>Distribution of values with two peaks</td>
</tr>
<tr>
<td>Multimodal</td>
<td></td>
<td>Distribution of values with more than one peak.</td>
</tr>
<tr>
<td>Leptokurtic</td>
<td></td>
<td>Too peaked</td>
</tr>
<tr>
<td>Platykurtic</td>
<td></td>
<td>Too flat</td>
</tr>
<tr>
<td>Central tendency</td>
<td>Mode</td>
<td>Value that occurs most frequently</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>Point in distribution where 50% above and 50% below; mid-score</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>Arithmetic average</td>
</tr>
<tr>
<td>Variability</td>
<td>Range</td>
<td>Difference between lowest and highest score</td>
</tr>
<tr>
<td></td>
<td>Interquartile range</td>
<td>Range of middle 50% of scores</td>
</tr>
<tr>
<td></td>
<td>Semiquartile</td>
<td>Same as interquartile range</td>
</tr>
<tr>
<td></td>
<td>Sum of squares</td>
<td>Difference between each score and the mean</td>
</tr>
<tr>
<td></td>
<td>Variance</td>
<td>Mean of squares deviation from the mean</td>
</tr>
<tr>
<td></td>
<td>Standard deviation</td>
<td>Square root of the variance; indicates average deviation of scores around the mean</td>
</tr>
</tbody>
</table>

*continues*
<table>
<thead>
<tr>
<th>Type of Analysis</th>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bivariant</td>
<td></td>
<td>Two-dimensional table that illustrates frequencies of responses for two or more nominal or quantitative variables</td>
</tr>
<tr>
<td>Correlation</td>
<td></td>
<td>Describes relationship between two or more variables</td>
</tr>
<tr>
<td>Pearson's product moment correlation</td>
<td></td>
<td>Uses interval or ratio data; yields a score between −1 and +1</td>
</tr>
<tr>
<td>Spearman's rho</td>
<td></td>
<td>Uses ordinal data; yields a score between −1 and +1; preferable to product moment for numbers under 20 nonparametric equivalent of Pearson r</td>
</tr>
<tr>
<td>Kendall's tau</td>
<td></td>
<td>Used with ordinal data; yields a score between −1 and +1; preferable to rho for numbers under 10</td>
</tr>
<tr>
<td>Point biserial</td>
<td></td>
<td>To examine relationship between a nominal variable and an internal level measure; yields lower correlation than r and much lower than r big</td>
</tr>
<tr>
<td>Phi coefficient</td>
<td></td>
<td>Describes the relationship between two dichotomous variables</td>
</tr>
<tr>
<td>Terrachoric correlation coefficient</td>
<td></td>
<td>Used when both variables are artificial dichotomies</td>
</tr>
<tr>
<td>Cramer's V</td>
<td></td>
<td>Describes relationship between nominal level data; used when contingency table to which it is applied is larger than 242</td>
</tr>
<tr>
<td>Contingency coefficient</td>
<td></td>
<td>Two dichotomous variables on a nominal scale; closely related to chi square</td>
</tr>
<tr>
<td>Multiple correlation</td>
<td></td>
<td>One single variable and some combination of two or more other variables</td>
</tr>
<tr>
<td>Partial correlation</td>
<td></td>
<td>Two variables studied; influence of their or several other variables held constant. Also called first order correlation</td>
</tr>
</tbody>
</table>

a pie chart is in Figure 8–3. The pie to the right is an exploded pie chart that emphasizes the proportion of time devoted to research (Bordens & Abbott, 1988). The major advantage of pie charts that people typically think of as a circle encompassing 100%.

*Trend charts* also can be used to illustrate frequencies or percentages of change in a data set that is organized in a developmental or temporal order. A trend chart is shown in Figure 8–4.

**Shapes of Distributions**

Data can be described relative to shape. Several shapes have been described and are illustrated in Figure 8–5 and defined in Table 8–4. Some distributions occur so frequently that they have special names. The *normal curve* or *normal distribution* is a symmetrical bell-shaped curve that has a concentration of scores in the middle of the distribution with fewer scores to the right and left sides of the distribution (Figure 8–6). An important characteristic of the normal curve is that predictable percentages of the population are within any given portion of the curve (Leedy & Ormrod, 2010b). About two-thirds (68.2%) of the population fall within plus or minus one standard deviation of the mean, 96% fall within plus or minus two standard deviations of the mean, and 99% of the population fall within plus or minus three deviations of the mean.

**Central Tendency**

*Measures of central tendency* provide statistics that indicate an average or typical value of a set of scores. There are three measures of central tendency, *mode*, *median*, and *mean*, which are described in Table 8–4.

**Variables**

*Measures of variability* or dispersion are the degree of dispersion or the difference among scores. These measures include the *range*, *interquartile range*, *sum of squares*, *variance*, and the *standard deviation*. See Table 8–4 for definitions of these measures.

![Figure 8–3. Pie chart and exploded pie chart.](image-url)
Figure 8–4. Trend chart showing distribution of average hearing levels for children with OME in years 1, 2, and 3. Data are presented according to hearing level (HL) categories in decibels (dB). Four-frequency (500, 1000, 2000, and 4000 Hz) average values displayed were derived by categorizing each participant’s mean hearing levels across each study year. Reprinted by permission from Gravel, J. S., & Wallace, I. F. (2000). Effects of otitis media with effusion in the first 3 years of life. *Journal of Speech, Language, and Hearing Research, 43*, 638. Copyright 2000 by American Speech-Language-Hearing Association. All rights reserved.

Figure 8–6. Normal distribution curve. From *Test Service Notebook #148*. Copyright 1980 by Harcourt Assessment, Inc. Reproduced with permission. All rights reserved.

Bivariate Descriptive Statistics

Bivariate descriptive statistics are a data reduction approach for describing relationships between two or more variables (DePoy & Gitlin, 2011). There are two methods: contingency tables and correlational analysis. A contingency table is a two-dimensional frequency distribution in which the frequencies of two nominal or ordinal level variables are cross-tabulated (Polit & Beck, 2010). Contingency tables are also used with nominal or ordinal data.

Correlation

Correlation is a statistical method for measuring the relationship between two or more quantitative variables for ordinal, interval, or nominal levels of measurement. This means that the value of one variable can be predicted by knowing the value of the other (McMillan, 2005). Scatter plots or diagrams can be used to graphically illustrate the relationship between two variables. Scatter plots indicating correlation of variables are shown in Figure 8–7.

A correlation coefficient is a measure of the direction and strength of the relationship between variables, usually ranging from 1.00 (perfect positive) through zero (no relationship) to −1.00 (perfect negative) relationships (Polit & Beck, 2010). The higher the value of the coefficient, the stronger is the relationship. Correlation coefficients between 0.10 and 0.30 are small or low relationships, 0.40 to 0.60 are moderate relationships, and 0.70 and above are high relationships.

There are several types of correlation coefficients, as summarized in Table 8–4. The most frequently used correlation coefficient is the Pearson product moment correlation coefficient or Pearson’s r.

There are several issues related to correlation: cause and effect, coefficient of determination, outliers, linearity, independence, and relationship strength. Correlation coefficients cannot be used to establish cause and effect. In other words, correlations should not be interpreted to imply a cause-and-effect relationship. A coefficient of determination is determined by squaring the raw correlation coefficient. This suggests that the raw correlation coefficient (the value of r not squared) exaggerated the relationship between variables.

Outliers are scores that are outside the range of most scores. Outliers can cause the size of a correlation coefficient to under- or overestimate the strength of relationship between two variables.

A correlation coefficient is appropriate if the two variables have a linear relationship but not if there is a curvilinear relationship. A linear relationship requires that the path of data points be straight. If there is a curvilinear relationship, the correlation coefficient will underestimate the strength of the relationship between the variables.

Correlation coefficients indicate the extent to which two measuring instruments are independent. Independence exists to the extent that r is close to zero, that is, high correlations suggest lack of independence, whereas low correlations imply independence (Huck, 2004). There are no widely accepted criteria for describing the strength of relationship between two variables (correlation) (Portney & Watkins, 2009).

The relationship strength may be misinterpreted because of subjective interpretation for defining relationships as weak, moderate, or strong. Furthermore,
there may be bias in selecting adjectives to describe results because of preconceived ideas about outcome.

**Inferential Statistics**

*Inferential statistics* are a type of statistics used to make inferences about whether relationships observed in a sample are likely to occur in the larger population, that is, infer characteristics about a population based on data from a sample. Inferential statistics are used to compare differences between groups (Mertens, 2005). Tables 8–5 and 8–6 provide descriptions of inferential statistical methods.

Statistical inference consists of two major approaches: estimating parameters and testing hypothesis. *Parameter estimation* is used to estimate a single parameter such as a mean. Estimates can take two forms: point estimates or intervals estimation. *Point estimation* is calculated by dividing the observed values from the sample by the size of the sample, that is, a single statistic to estimate the population parameter. Point estimation is described as an educated guess on the basis of the sample data about the unknown value of the population.

**Table 8–5. Summary of Statistical Methods**

<table>
<thead>
<tr>
<th>Level of Independent Measurement</th>
<th>Methods of Analyzing Relationships</th>
<th>Methods for Analyzing Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal Test for Samples</td>
<td>Contingency</td>
<td>Cochran Q Test</td>
</tr>
<tr>
<td>Ordinal</td>
<td>Spearman Rank-Order Correlation Coefficient (Rho)</td>
<td>Two Samples Wilcoxon Matched Pairs Signed-Ranks Test (T)</td>
</tr>
<tr>
<td>ANOVA</td>
<td></td>
<td>More Than Two Samples Friedman Two-Way ANOVA</td>
</tr>
<tr>
<td>Interval or Independent Ratio</td>
<td>Pearson Product-Moment Correlation Coefficient (r)</td>
<td>Two Samples t-test for correlated groups z-Ratio</td>
</tr>
<tr>
<td></td>
<td>Multiple Regression Analysis</td>
<td>More Than Two Samples ANOVA (F) ANCOVA (F) MANOVA (T², A, F)</td>
</tr>
</tbody>
</table>

Table 8–6. Inferential Statistics

<table>
<thead>
<tr>
<th><strong>Parametric Statistics</strong></th>
<th><strong>Description</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>ANOVA</td>
<td>Comparison of three or more treatment groups or conditions or the simultaneous manipulation of two or more independent variables</td>
</tr>
<tr>
<td>ANCOVA</td>
<td>Used to compare two or more treatment groups while controlling effect of one or more extraneous variables (covariables)</td>
</tr>
<tr>
<td>Factor Analysis</td>
<td>Used to examine structure within a large set of variables and to determine underlying dimensions that exist within that set of variables</td>
</tr>
<tr>
<td>Pearson’s $r$</td>
<td>Determine relationship between two variables</td>
</tr>
<tr>
<td>Structural equation models</td>
<td>Examines correlation among a number of variables to identify possible causal relationships. Includes methods such as path analysis and confirmatory analysis</td>
</tr>
<tr>
<td>t-test</td>
<td>Used for comparing two means. Also called student t-test</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Nonparametric Statistics</strong></th>
<th><strong>Description</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chi square</td>
<td>Compares observed frequencies within categories to frequencies expected by change. Computed for nominal, ordinal, inferential, or ratio data</td>
</tr>
<tr>
<td>Fishers exact t-test</td>
<td>Used with small samples to test significance of difference in proportions</td>
</tr>
<tr>
<td>Kendall’s tau</td>
<td>Measure of association or ordinal measuring</td>
</tr>
<tr>
<td>Kruskal-Wallis</td>
<td>Compares more than two independent groups representing levels of one independent variables; nonparametric counterpart of ANOVA</td>
</tr>
<tr>
<td>Mann-Whitney U test</td>
<td>Compares two independent groups; nonparametric counterpart of t-test</td>
</tr>
<tr>
<td>McNemar test</td>
<td>Used for nominal level measures to correlated samples: For Chi square test</td>
</tr>
<tr>
<td>Median test</td>
<td>Compares median values of two independent groups to determine if groups are from populations with different medians</td>
</tr>
<tr>
<td>Odds ratio</td>
<td>Estimate of relative risk by a case control study</td>
</tr>
<tr>
<td>Phi coefficient</td>
<td>Used to estimate relationship between two dichotomous variables</td>
</tr>
<tr>
<td>Spearman’s rho</td>
<td>Correlation coefficient indicates magnitude of relationship between ordinal level measures</td>
</tr>
<tr>
<td>Wilcoxon signed rank test</td>
<td>Compares two correlated samples (repeated measures); nonparametric counterpart of t-test</td>
</tr>
</tbody>
</table>

Internal estimation is a statistic that indicates the upper and lower limits of a range of values within which the parameter has a given probability of occurring, that is, the confidence intervals or the range of values within which a population parameter is estimated to lie. Confidence intervals are used to indicate the degree of confidence to which the data reflect the population’s mean (Mertens, 2005). Confidence limits are the upper and lower limits of the confidence level (Polit & Beck, 2010).

Huck (2004) provided four cautionary statements about point and intervals estimation. First, the second of two numbers separated by a plus and minus sign may or may not be the numerical value of the estimated standard error. Second, sample data permit estimation of the standard error, not definitive determination of the standard error. Third, the sample statistic will always be located between the upper and lower limits of the confidence interval but will not always be located halfway between the interval’s end points. Fourth, estimation requires that the data used for inference come from a random sample.

Hypothesis Testing

Hypothesis testing is concerned with making objective decisions based on statistical analysis of differences between groups or relationships of values. The null hypothesis is a statement that there is no difference or no relationship between variables, that is, the statistical hypothesis (Portney & Watkins, 2009). Rejection of the null hypothesis lends support to the hypothesis, whereas not rejecting the null hypothesis indicates that the observed difference is not due to chance. There are two types of errors in testing hypothesis: rejecting a true null hypothesis (Type I) or accepting a false null hypothesis (Type II). Conversely, there are two possible correct decisions: accepting a true null hypothesis and rejecting a false null hypothesis. Figure 8–8 summarizes these decisions.

A Type I error occurs if the null hypothesis is rejected when it is true, namely, that a relationship exists when it does not. A Type II error is when the null hypothesis is accepted when it is false, namely, that no relationship exists when it does (Polit & Beck, 2010).

<table>
<thead>
<tr>
<th>Status of null hypothesis</th>
<th>Null hypothesis is true</th>
<th>Null hypothesis is false</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accept null hypothesis</td>
<td>Correct decision</td>
<td>Type II error</td>
</tr>
<tr>
<td>Reject null hypothesis decision</td>
<td>Type I error</td>
<td>Correct decision</td>
</tr>
</tbody>
</table>

The risk of being wrong is rejecting the null hypothesis (Type I error) and is called the level of significance or limit of confidence (Schiavetti et al., 2011). The level of significance is indicated with the small letter \( p \) (probability) or by the Greek letter \( \alpha \). The most frequently used levels of significance are 0.05 and 1.1. This means that the probability of making a Type I error is 0.05 (5 chances in 100) or 0.01 (1 chance in 100). This means at the 0.01 level, the null hypothesis would be rejected when it should have been accepted in only 1 out of 100 samples.

The level of significance is affected by three factors (McMillan, 2005): (a) the differences between the groups being compared—the greater the difference, the smaller is the \( p \)-value; (b) the degree of sampling and measurement error—the lower the error, the smaller is the \( p \)-value; and (c) the sample size—the \( p \)-value will be smaller for a very large sample, that is, if a small sample size is used.

### One- and Two-Tailed Tests

A one-tailed (directional) test of statistical significance is one in which only values at one extreme (tail) of a distribution are considered in testing significance (Polit & Beck, 2004). A one-tailed test may be appropriate if there is a strong basis for a directional hypothesis, which is a hypothesis that makes a specific prediction about the direction and nature of the relationship between two variables. The use of one-tailed tests is controversial, because differences found with two-tailed tests are more significant than those found with a one-tailed test (Schiavetti, Orlikoff, & Meta et al., 2002).

Two-tailed (nondirectional) tests are usually preferred. These tests involve both ends of the sampling distribution to determine improbable values (Polit & Beck, 2010). Two-tailed tests are more strict or credible than one-tailed tests; that is, a greater difference between groups may be significantly different when using a two-tailed test (Schiavetti et al., 2011). Conversely, a smaller difference may not be significant with a two-tailed test but may be significant with a one-tailed test.

### Parametric and Nonparametric Statistics

Parametric (distribution bound) statistics involve the estimation of at least one parameter: the use of interval or ratio measures, normal distribution, and a fairly large sample. The sample has a central high point and is not seriously skewed, that is, leptokurtic. Parametric statistics are more powerful (more sensitive to differences and relationships) than nonparametric statistics and are usually preferred. Nonparametric statistics are sometimes called distribution-free statistics because they do not involve rigorous assumptions about the distribution. They are used most often with nominal or ordinal measures. Tables 8–5 and 8–6 list parametric and nonparametric statistical methods.

### Between- and Within-Subjects Tests

There are between-subject tests (test for independent groups) for comparing separate groups of subjects and within-subject test (test for dependent groups) for comparing a single group of subjects under different conditions or at different points in time (Polit & Beck, 2010).
Steps in Hypothesis Testing

The steps of hypothesis testing are basically the same starting with stating a hypothesis and ending with a decision about the hypothesis. The sequence of these steps is illustrated in Figure 8–9. These steps are described as follows:

1. State the hypothesis. The null hypothesis is a statement of no difference between or among groups. The alternative hypothesis is a hypothesis that is different from the one being tested and usually different from the null hypothesis (Polit & Beck, 2010).

2. Select the test statistic. The following factors are usually considered: type of groups (independent, dependent, repeated measures, matched groups, randomized blocks, or mixed groups); the number of independent and dependent variables; the scale of measurement; and whether parametric tests are appropriate. DePoy and Gitlin (2011) developed a series of seven questions to consider in selecting appropriate statistical tests. These questions are presented in Table 8–7.

3. Establish level of significance. The level of significance for accepting or rejecting the null hypothesis is established before analyzing the data. The level of significance is usually set at 0.05 or less.

4. Choose sample size. The sample size influences the power of a statistical test. A larger sample usually results in a more powerful test of the null hypothesis (Meline, 2006). Small samples are at greater risk for Type II error.

Figure 8–9. Steps in hypothesis testing.

risk for a Type II error, that is, accepting the null hypothesis when it is false.

5. Select a one- or two-tailed test.
   Usually a two-tailed test is selected.

6. Compute test statistic. Calculate a test statistic using a computational formula or a computer. The test statistic is a standard score such as z- or t-statistic (Meline, 2006). The test statistic is computed using the formula in Figure 8–10.

7. Calculate degrees of freedom.
   Degrees of freedom are the number of values within a distribution that are free to vary, given restrictions on the data; often n-I (Portney & Watkins, 2009).

8. Obtain tabled value for the statistical tests. All test statistics have theoretical distributions. By examining these distributions, it can be determined whether obtained values of the test statistic are beyond the range of what is probable if the null hypothesis is true. A table is consulted for the appropriate test statistic to obtain the critical value corresponding to the degree of freedom and significance level (Polit & Beck, 2010).

9. Compare the test statistic with the tabled value. If the test statistic is smaller than the tabled value, the results are nonsignificant. If
the computed value is larger, the results are statistically significant.

10. Make decisions about the hypothesis. The final step involves making a decision about rejecting or not rejecting the null hypothesis. If the null hypothesis is rejected, the alternative hypothesis is supported but not proven (Meline, 2006).

Evaluating Inferential Statistics

McMillan (2005) suggested eight criteria for evaluating inferential statistics. These criteria were as follows: (a) basic descriptive statistics are needed to evaluate the results of inferential statistics; (b) inferential analyses refer to statistical, not practical or clinical, significance; (c) inferential statistics do not indicate external validity; (d) inferential statistics do not indicate internal validity; (e) the results of inferential tests depend on the number of subjects; (f) appropriate statistical tests should be used; (g) the level of significance should be interpreted correctly; and (h) be cautious of statistical tests with small numbers of subjects in one or more groups or categories.

Multivariate Statistics

The preceding statistical procedures were univariate or bivariate because one or two dependent variables were analyzed. Multivariable statistics analyze all the dependent variables in a single procedure; this is important in understanding the relationship between dependent variables (McMillan, 2005). Multivariate statistical procedures are being used more often in speech-language pathology and audiology research to study complex relationships among three or more dependent variables. Most outcomes in speech-language pathology and audiology are fundamentally multivariable regardless of whether or not the study is designed for multivariable statistics.

Commonly used multivariable statistical procedures are multiple regressions, analysis of covariables, discriminate analysis, and factor analysis. Multiple regressions analysis is the most widely used multivariable statistical procedure (Polit & Beck, 2010). These and other multivariable statistical procedures are summarized in Table 8–8. Multivariable analyses are usually done by computer because computations are complex.

Meta-Analysis

Meta-analysis statistically combines the results of two or more studies, that is, conclusions are made about other researchers’ statistical analyses. It is a specialized quantitative synthesis of the results of existing research. The major advantages of meta-analysis are (a) increased power by increasing sample size; (b) improved estimated effect; (c) resolution of uncertainty about conflicting results; and (d) improved generalizability of findings.
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<td>MA-NOVA (multivariable analysis of covariables)</td>
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<td>Survival analysis</td>
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Effect size is an important concept in meta-analyses. The *effect size* is a standardized scale-free measure of the relative size of the effect of an intervention (Turner & Bernard, 2006). Effect sizes are interpreted in two ways: (a) common benchmarks of small, medium, and large; or (b) by comparing reported effect size to those reported in prior studies of a similar nature. Schuele and Justice (2006) believe that authors should both report and interpret effect size. It has practical, clinical implications for speech-language pathologists and audiologists who are interested in estimating the effects of treatment; there are several methods for determining effect size (Maxwell & Satake, 2006; Turner & Bernard, 2000). For further discussion about meta-analysis, see Chapter 5.

The statistics methods used in meta-analyses vary widely and depend, in part, on the research designs used in the studies being analyzed (Leedy & Ormrod, 2010b). For example, correlated studies require different meta-analytic procedures that do experimental studies.

### Summary

In this chapter, quantitative research was discussed relative to design and analysis. Quantitative research uses procedures for collection of data that can be subjected to statistical analysis. There are several types of qualitative research designs: nonexperimental, preexperimental, quasiexperimental, single subject, and experimental. Major differences between these designs are related to control, manipulation, and intervention (treatment). Quantitative analysis can be classified as descriptive statistics, inferential statistics, multivariable statistics, and meta-analysis. Guidelines for evaluating quantitative were also described.

### DISCUSSION QUESTIONS

1. Define quantitative research.
2. Why is quantitative considered to be the sole standard for research?
3. Why must one be cautious when interpreting results from a quasiexperiment?
4. Compare the between-subjects, within-subjects, and single-subject designs.
5. What are the strengths and limitations of single-subject design?
6. What are the major characteristics of single-subject design? How can it be used in speech-language pathology and audiology research?
7. Why is it important to graph data?
8. What factors would affect your decision about which measure of central tendency to choose?
10. What is the difference between cross-sectional and longitudinal studies?
| 11. | What are the advantages and disadvantages of quantitative research? |
| 12. | Why is it necessary to use descriptive statistics? Inferential statistics? |
| 13. | How is the null hypothesis used in inferential statistics? |
| 14. | What is the difference between Type I and Type II errors? |
| 15. | What is the difference between parametric and nonparametric statistics? |
| 16. | What are the major characteristics of quantitative research? |

| 17. | What are the major characteristics of qualitative research? |
| 18. | What is the difference between quantitative and qualitative research? |
| 19. | Why is randomization an important consideration in choosing a statistical test? |
| 20. | What can be done when the basic assumptions for parametric inferential statistics are not met? |
| 21. | How can quantitative research be evaluated? |

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**References**


Qualitative Research

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LEARNING OBJECTIVES

Upon completion of this chapter, the reader will be able to:

- Describe qualitative research
- Understand the major issues surrounding qualitative research
- Explain qualitative research designs
- Describe methods for collecting qualitative data
- Describe methods for analyzing qualitative data
- Critique qualitative research
Qualitative research is "a variety of analytic procedures designed to systemically collect and describe authentic, contextualized, social phenomena with the goal of interpretive adequacy" (Damico & Simmons-Mackie, 2003, p. 132). In the field of speech-language pathology, qualitative research can be a valuable resource in helping practitioners understand complicated real-life phenomena and establish functional, contextualized speech and language therapy.

Qualitative research is often starkly contrasted with quantitative or experimental research. For example, qualitative research is often described as non-numerical, while quantitative research is described as numerical. Further, qualitative research is at times described as subjective, while quantitative research is described as objective. While these statements may hold some truth, discussion of these differences does not help us understand the nature of qualitative research. In fact, this type of comparison creates a false dichotomy (Damico & Simmons-Mackie, 2003). A stark comparison does not provide us with an understanding of the relationship between quantitative and qualitative research, it also does not help us understand that qualitative research is simply attempting to ask different questions in different ways. One type is not inferior to the other. Ultimately, it is more accurate and beneficial to recognize that qualitative research often merges interpretive description with numerical data to form a clear picture of a phenomenon (Damico & Simmons-Mackie, 2003). This process can be initiated to support quantitative studies and can also be fully integrated into the research plan to create mixed methods studies, which is discussed in the next chapter.

Until recently, research in speech-language pathology and audiology was dominated by quantitative methods. This trend was apparent in both textbooks and scholarly journals. Although most studies continue to be quantitative, a greater number of qualitative studies have been published in the last several years. Damico and Simmons-Mackie (2003) identified some reasons for this trend: (a) increasing recognition of a need to focus on complexity of communication in the context in which it occurs; (b) concentration of consumer-based issues, that is, efficacy, clinical outcomes, and impact of services on quality of life; (c) response to social and economic conditions and trends; (d) social diversification; and (e) recognition of the relationship between clinical practice and research.

It is important to note that qualitative research is an essential part of establishing evidence-based practice (EBP). Often the first stage of EBP involves qualitative methods (Johnson, 2006). Therefore, the purpose of this chapter is to describe the characteristics of qualitative research, qualitative research design, data collection and analysis, and evaluation of qualitative research.

**Characteristics of Qualitative Research**

The primary characteristic of qualitative research is that it focuses on understanding real-life events or situations. Qualitative research is more concerned with subjective, narrative information and is typically obtained under less structured conditions than quantitative research (Portney & Watkins, 2009). Qualitative
research involves insight into the participant's personal experiences, the possibility of unexpected findings, understanding of individual needs and requirements, and continued development of the therapeutic relationship (French, Reynolds, & Swain, 2001).

Other characteristics of qualitative research have been described ( Creswell, 2014; McMillan & Schumacher, 2010). The following are some of these characteristics.

Natural setting. Individuals who conduct qualitative research collect data from natural environments, such as classrooms, homes, playgrounds, or therapy rooms. It is necessary to collect data for qualitative studies in natural, everyday environments, because one of the goals of qualitative research is to richly describe how or why human behavior occurs. This cannot be accomplished in an unnatural, lab-like environment.

Researcher as key instrument. The qualitative researcher collects data via personal interaction, observation, video recording, and so on. The researcher is typically always present and does not rely on questionnaires or surveys. This is necessary because qualitative research relies on accurate interpretation of the researcher's perception and experience with the participants and setting. The researcher must be present if this is to occur.

Multiple sources of data. Qualitative researchers, under almost any tradition of inquiry (case study, ethnography, etc.), utilize several different types of data. They may collect interviews, journal entries, or participant observation for analysis. The researcher would then code the data and look for themes or categories that can be organized to reveal a higher level of understanding of the topic under investigation.

Emergent design. Qualitative research seeks to deeply understand a particular topic. Therefore, the specific procedures and design should not be fixed or predetermined, rather they must be emergent. As data are collected, further questions will be revealed that need to be answered by various additional means of data collection. The qualitative research project may take multiple turns and change data collection methods several times before the questions it poses are answered.

Participant view. Throughout an entire qualitative research project, the investigator is interested in what the participants perceive about the topic of interest. Qualitative research is highly concerned with uncovering and making sense of the participants' personal experiences. Therefore, ensuring that the researcher is not superimposing only his or her own views, but rather, is taking the perspective of the participant is vital in qualitative research.

A further description of qualitative research can be seen in some basic criteria set forth by Simmons-Mackie and Damico (2003): (a) Social phenomenon is studied. Qualitative research is concerned with social, human interaction. (b) Data collection is contextualized and authentic. Qualitative research data collection must take place in the original, natural context that is the subject of inquiry. It should not be recreated in a lab or clinic room. (c) Data collection is systematic. Qualitative research is inherently flexible and emergent. However, each data collection technique utilized should be defensible and clearly explained. (d) Results are well described. When a researcher is studying social phenomena, it is not advantageous to simply use numerical data that can reduce and simplify behavior into broad categories. Rather, it is necessary to also thoroughly
describe the social behavior under investigation so that inherently rich, complex meaning can be derived. Any numerical data resulting from the investigation should align with thick, rich, narrative description and interpretation of the researcher.

### Issues in Qualitative Research

Qualitative research presents specific advantages to researchers who are willing to embrace complexity, rather than control variability. As mentioned previously, the primary advantage of qualitative research is its focus on phenomena that occur in natural settings. For example, Damico and Simmons-Mackie (2009) have studied aphasia treatment via video transcripts of actual therapy sessions in both individual and group settings and have revealed significant therapeutic implications for clinicians who treat individuals with aphasia.

In addition, qualitative research may bridge the gap between research and clinical practice and involve studying these phenomena in all their complexity (Maxwell & Satake, 2006). There is often a large gap between what the research says about what we should do in therapy and what we actually do in the treatment room, and qualitative research can provide support for this problem. For example, Page and Howell (2015) studied the nature of the clinical practice of speech-language pathologists (SLPs) who treated individuals with aphasia. They worked from the premise that little is known about the actual, current practices of speech-language pathologists who work with individuals with aphasia (Page & Howell, 2015). Given that there is often a gap between research evidence and practice, the researchers sought, via interviews, to establish a theory regarding the state of current practice in aphasia treatment. The study revealed that SLPs had a process of establishing the best therapy plan for their clients that involved creating a relationship with them as they developed treatment strategies. It also revealed that SLPs do, in fact, struggle to implement evidence-based practice in the treatment of individuals with aphasia, and that this struggle is often due to time constraints (Page & Howell, 2015). This study provided some relevant information to researchers explaining why the gap between research and practice exists.

It is important to note that even though there has been an increase in use of qualitative methods in the last few years, qualitative research is often seen as inferior to quantitative research. This may occur because even well-designed nonexperimental studies rank low on any hierarchy of evidence-based practice, below quasiexperimental designs, randomized controlled studies, and even meta-analysis. This conception of a hierarchy of validity in research, which permeates both publication and peer review, fails to consider that researchers are asking and answering different questions when they select qualitative or more experimental methods. That question, more than anything else, centers on whether the researcher feels comfortable embracing the complexity of social phenomena or seeks to restrict it to a few isolated variables.

In any discussion of advantages and disadvantages of qualitative research, there are concerns with reliability, validity, and generalizability in qualitative
research, and whether or not there is enough power or strength in the results of a qualitative study. It is true that the best research method is the one that is most appropriate, singly or combination, to the problem and will produce credible information. Qualitative studies should be designed from this perspective—not from the perspective that one research paradigm is superior to the other.

Despite the advantages of qualitative research, there are limitations. First is perceived issues with credibility, which is based primarily on the concepts of validity and reliability (McMillan, 2005). It is important to note here that because the focus of qualitative research is entirely different than quantitative research, the concepts of validity and reliability mean different things in the context of qualitative research. We discuss the issue of generalizability next and revisit the issues of validity and reliability later in this chapter.

One of the weaknesses mentioned by many is that qualitative research is not: (a) randomized or (b) controlled or (c) involves manipulation of variables (the three criteria for experimental research) and, therefore, is often not applicable to a wider population. This perspective of qualitative research is based on a view of generalization that is rooted in the probability theory—the idea that predictions can be made or extrapolated from a smaller set of data if the data are randomized, controlled, and include manipulated variables (Ball & Damico, 2010). However, Ball and Damico propose two additional perspectives of generalizability that help explain the relevancy and the generalizability of qualitative research in the field of speech-language pathology. The first type is analytic generalization. This view purports that qualitative research methods study the underlying human processes of the behavior in question. Therefore, results of these analyses are applicable to a wider population because they were derived from basic, systematic human processes that are common to all humans (Ball & Damico, 2010). In other words, generalizability is not determined by high statistical probabilities, but rather, via a deep understanding of the fundamental entities of which human social behavior is comprised (Ball & Damico, 2010).

The second type of generalizability is case-to-case transfer. Case-to-case transfer occurs when a reader consumes a published qualitative study and decides to apply the findings to a client he or she is seeing. In this case, the reader of the research is responsible for making the decision regarding generalization rather than the researcher. It is, therefore, important for the researcher to engage in thorough, rich, thick description of the topic under investigation to ensure later application of the result is valid and warranted.

There are a wide variety of qualitative research designs or traditions of inquiry. Tesch (1990) listed 46 different qualitative designs. It should be noted that there is often a great deal of overlap between these designs (Damico & Simmons-Mackie, 2003). There are a few research designs that are relatively common in the field of speech-language pathology, and those designs are discussed in this chapter. These include case study, ethnography, ground theory, phenomenol-
ogy, and conversation analysis. Other designs, such as critical theory, heuristic, life history, and narrative, are less common. These designs differ in several ways: purpose, focus, data collection, and analysis. Table 9–1 provides a summary of qualitative designs.

### Case Study

One of the most frequently used qualitative research designs is the case study. A case study is a retrospective research method involving detailed analysis of one or more individuals, groups, institutions, programs, or other entities (McMillan, 2012; Polit & Beck, 2010; Tetnowski, 2017). A case study may be an expansion of an earlier case study. Typically, a case study is a detailed qualitative analysis of a single entity and utilizes various qualitative data collection methods. Case studies, however, may be quantitative and occasionally combine quantitative and qualitative methods (McMillan, 2012).

Case studies have several purposes. Among these purposes are understanding unusual patients and conditions; providing examples of creative or innovative treatments; generating and testing theory; and providing implications for further research (Portney & Watkins, 2009). It should be noted that there has been an increase in the use of case studies in the field of speech-language pathology.

The following is an example of how a case study can be utilized to understand issues in our field. Daniels (2016) studied one school-age child who stuttered. This child had previously been treated using speech modification techniques only (an

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<td>Case study</td>
<td>A detailed qualitative analysis of a single entity. Utilizes various qualitative data collection methods.</td>
</tr>
<tr>
<td>Ethnography</td>
<td>Studies complex and contextually sensitive aspects of social interaction and culture. Allows the researcher to investigate aspects of social action or patterns of human behavior in a natural, original context.</td>
</tr>
<tr>
<td>Phenomenology</td>
<td>Focuses on the subjective, lived experiences of individuals. Typically conducted via interviews that are loosely structured with open-ended questions.</td>
</tr>
<tr>
<td>Grounded theory</td>
<td>A general methodology for developing theory that is grounded in data systematically gathered and analyzed.</td>
</tr>
<tr>
<td>Conversation analysis</td>
<td>Created to reveal how individuals accomplish social action within conversation. Involves detailed analysis of video transcripts.</td>
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approach that focuses only on “fixing” nonfluent speech). The child was admitted for treatment at a university clinic. Over three semesters, speech modification techniques were taught as well as strategies for how to manage emotions that surround stuttering. This study was necessary due to the fact that many approaches to stuttering focus only on modifying the stuttering behavior while ignoring a widely proven fact that stuttering is the result of many factors, one of which involves psychosocial aspects. Addressing emotions within therapy is widely recommended. Since there is a disparity between the recommendations of research and actual practice, a case study that demonstrates the benefit of such an approach was warranted. This study found that successful therapy outcomes were achieved with a broad therapeutic focus that included both stuttering modification and strategies that help the child who stutters overcome the psychosocial barriers he or she encounters (Daniels, 2016).

This case study is an example that demonstrates how case studies can be used to explain the impact of a specific therapeutic approach on one person or group. It is just one way that case studies can be used in the field of speech-language pathology.

Ethnography

Ethnography was born in the field of anthropology, which is the study of the aspects of life that make us human. It has been adapted by various disciplines such as psychology and education, and it is not used the same by everyone (Damico & Simmons-Mackie, 2003). At its core, ethnography is a research design that studies complex and contextually sensitive aspects of social interaction and culture (Damico & Simmons-Mackie, 2003). This research design allows the researcher to investigate aspects of social action or patterns of human behavior in a natural, original context. Additionally, ethnography gives the researcher an opportunity to utilize various forms of data collection such as observation, interviewing, and collection of artifacts as needed (Damico & Simmons-Mackie, 2003). Therefore, it is a natural, often very useful tool to study communication disorders. Finally, ethnography is driven by discovery (Damico & Simmons-Mackie, 2003). When discovery is part of the decision-making process, the researcher changes the approach to data collection methods based on the themes that emerge from analysis. For example, if data collected from interviews indicates that the participants should be observed in their natural environment, the researcher can change course and include that type of data in the collection plan.

Cohen (2011) utilized ethnography to explore and describe teacher-student interaction in classrooms wherein children with specific learning difficulties were learning English as a second language. This study had the aim of understanding how second-language learning was facilitated within the social interaction in a classroom. The researchers spent time observing in the classroom, recording those observations and videotaping (for later transcription). Analysis of the data collected revealed that teachers had the most success in the classroom when they deviated from a traditional initiate-response-feedback style and instead used a style of questioning and facilitation that promoted participation and opportunities for learning (Cohen,
In this example, ethnography was employed by utilizing various forms of data collection to study the culture of a classroom in order to explain intricate interaction patterns. The results of this ethnographic study yielded important information that practicing speech-language pathologists can utilize.

Ethnography holds promise for the field of speech-language pathology as the call for more functional, real-world treatment options increases. Ethnography has the potential to thoroughly explain human behavior in context so its ability to describe the impact of treatment, the nature of therapeutic relationships, and the real lives of individuals with communication disorders is significant.

Phenomenology

Phenomenological research focuses on the subjective, lived experiences of individuals (Mertens, 2014). This research is typically conducted via interviews that are loosely structured with open-ended questions. These interviews are intended to reveal the thoughts, feelings, and overall perceptions individuals have of a particular phenomenon (Mertens, 2014). It should be noted that the researcher is not concerned with any form of objective reality that exists outside of the person being interviewed (Mertens, 2014). Rather, that person’s lived experience is the sole focus of a phenomenological project.

Fencel and Mead (2017) conducted a phenomenological study to investigate how speech-language pathology interns perceived the relationship with their supervisor while in graduate school. Graduate students were interviewed to record their perceptions of what contributed to a positive or negative relationship with a graduate supervisor. Results indicated that respect, clear expectations, constructive feedback, positive praise, and structured clinical guidance contributed to a positive relationship. However, a lack of these attributes contributed to a negative supervisor/supervisee relationship (Fencel & Mead, 2017). This study utilized interviews to investigate graduate students’ lived experiences in order to understand how they perceived their relationships with their supervisors. This is an example of how phenomenology can be used to provide useful information to guide the quality of clinical teaching in our field.

Grounded Theory

Grounded theory research was created for the purpose of bringing a more systematic approach to the field of qualitative research. Grounded theory can be best described as “a general methodology for developing theory that is grounded in data systematically gathered and analyzed” (Strauss & Corbin, 1994, p. 273). The key characteristic of grounded theory is that there is no theoretical orientation stated at the outset of the project. Rather, theory emerges as data are collected and analyzed (Mertens, 2014).

As in the case of previously discussed qualitative designs, data are collected through various methods. These data are then analyzed using procedures that have been specifically developed to reveal aspects of the theory that the researcher goes on to generate and explain (Simmons-Macke & Damico, 2003). The analytic process is a transactional one wherein the researcher observes the data
and codes the data in a way that allows for comparisons to be made between various data sets. Then, the researcher asks a variety of questions about the data (Damico & Simmons-Mackie, 2003). The answers to these analytic questions then lead the researcher to be able to ask generative (or productive) questions that link and describe the different sets of data that have been collected (Damico & Simmons-Mackie, 2003). Another term for this type of data analysis procedure is the constant comparative method (Damico & Simmons-Mackie, 2003; Mertens, 2014). The constant comparative method gave rise to what we now call triangulation in a general sense (Damico & Tetnowski, 2014). Triangulation involves uncovering and interpreting themes from the coded data, and then collecting more data from additional, different sources by way of confirming interpretation (Damico & Tetnowski, 2014). This continues in a cyclical, iterative process until conclusions are credible and sound. The final product of grounded theory research is a new theory that is based on or “grounded” in the data.

For example, Marshall et al. (2017) explored the experiences of parents of children with language delays who were navigating various intervention systems. The researchers sought to understand, via interviews with 20 parents, what primary issues arise in this sometimes very complicated process. The results revealed that parents must demonstrate advocacy and engagement throughout a rigorous process of recognizing the delay, getting assessment results, and finally enrolling in the needed services for their children (Marshall et al., 2017). This rigorous process presented many challenges for the parents, and the study ultimately concluded with a recommendation that program planners should facilitate a more streamlined, timely response to the issues faced by these parents (Marshall et al., 2017). These results were grounded in the words of the individuals. That is, the conclusions were directly tied to the statements produced by the parents in the interviews (Marshall et al., 2017). Grounded theory was used in this case to investigate how professionals could better assist parents of individuals with disabilities.

**Conversation Analysis**

Conversational analysis (CA) is a qualitative research design that was created to reveal how individuals accomplish social action within conversation (Goodwin, 1995). According to Damico and Simmons-Mackie (2003), CA “is intended to determine and understand how speakers produce their own behaviors in conversation and how they interpret the conversational behaviors of others.” In order to achieve this goal, CA uses methodologies that assist the researcher in determining the interactional devices a speaker uses to accomplish a communicative goal within a conversation. Goodwin used CA to reveal how an individual with aphasia achieved success in conversation (Goodwin, 1995). He found that the speaker used his limited vocabulary (which included the words and, yes, and no) as well as several other interactional devices such as gestures and collaboration with a fluent speaker to maintain competency within conversation (Goodwin, 1995).

Damico and Simmons-Mackie (2005) report that there are three basic assump-
tions of conversation analysis: (a) All aspects of social action have organized patterns of stable, identified structural features. (b) Conversation tends to be sequentially organized. In other words, speakers will respond or produce an utterance based on what the previous speaker did or said. (c) CA must be grounded empirically during the data analysis and data interpretation portion of the research project. Researchers must utilize a specific set of procedures to analyze the data, and any decisions that are made based on that data are grounded or directly derived from the data.

Conversation analysis has been used extensively to understand how individuals with aphasia negotiate meaning in conversation. This can be especially helpful when trying to design plans for therapy that focus on real-life interaction. Damico and Simmons-Mackie (2009), in particular, studied how engagement is facilitated in group therapy. Engagement is an essential component of therapy, especially in a group, because some individuals may not participate as frequently if they are not confident or fluent, thereby missing out on the therapeutic impact of group therapy. Damico and Simmons-Mackie (2009) videotaped group therapy sessions and transcribed them. They then studied those transcripts using conversation analysis procedures to reveal that clinician behaviors were important aspects of engaged group therapy with individuals with aphasia. Clinicians’ body orientation, mirroring, and shared laughter, among other things, played a significant part in establishing engagement (Damico & Simmons-Mackie, 2009).

In this example, the researchers utilized the data methodology of conversation analysis to reveal how engagement was achieved in the moment-to-moment interaction in the conversational, informal dynamic of a group session. This is one of the ways in which conversation analysis can be used to reveal the intricacies of interaction that help individuals accomplish social action. Since speech-language pathology is highly interested in helping individuals communicate to their fullest potential, conversation analysis is a valuable tool in the study of communication disorders.

Data Collection Procedures

Qualitative research is inherently emergent. Therefore, data collected to answer the questions posed in a qualitative research project must be ongoing, interactive, and flexible. As data are collected, data are analyzed, and more data are then collected, if necessary. This section discusses general guidelines that should be in place prior to data collection as well as describes specific types of data collection. More discussion regarding data analysis is provided in the following section.

When a qualitative researcher begins a study, he or she must first set general, flexible boundaries for the study, collect information through various data collection methods that are further discussed in this section, and if necessary, create a protocol for recording and keeping a permanent record of the data (Creswell, 2014). When creating general boundaries, selection of participants or site of data collection is necessary (Creswell, 2014). It is also necessary to choose the participants or site that will best answer
the question. This is in contrast to quantitative research wherein random selection of participants is valued in order to fulfill the requirement of supposed generalizability (that if participants are selected randomly, there is greater likelihood that the results will be applicable to others). Rather, a solid qualitative research design selects participants in order to best understand the problem at hand.

A common issue that arises in qualitative research is the question of how many participants to include in the study (Creswell, 2014). There are no set criteria for numbers of participants in qualitative research. However, the recommendation is to follow a general rule of thumb: phenomenological studies typically have 3 to 10 participants, grounded theory usually has 20 to 30, ethnography investigates one single cultural group (children with autism, internationally adopted children, etc.), and case studies can include anywhere from one to five cases (Creswell, 2014). Another way of thinking about numbers of participants comes from the grounded theory literature (Charmaz, 2006), and this is the idea of saturation. When a researcher stops getting fresh, new information from the data, he or she has likely collected enough (Creswell, 2014). The researcher has reached a level of saturation in the amount of data collected and can move on to interpretation.

A variety of methods for collecting qualitative data have been identified: observation, interviews, qualitative documents, and qualitative audio and visual information. Furthermore, multiple versions of methods are often used for any single study (Damico & Simmons Mackie, 2003; Silverman, 2014).

Data collection and analysis occur in overlapping phases. While there is a significant amount of flexibility in qualitative research, there are five general phases of data collection: (a) planning, (b) beginning data collection, (c) basic data collection, (d) closing data collection, and (e) completion. Phases 2 through 4 involve actual data collection. The last phase (e) focuses on data analysis, including development of tables and figures (McMillan & Schumacher, 2010). These phases help give structure to the data collection process, but it is not necessary to strictly follow these phases.

Observation

Observation is comprehensive because it is continuous and total (McMillan, 2012). Observations can vary in the degree of structure from totally unstructured to highly structured (French, Reynolds, & Swain, 2001). In unstructured observation, there is no attempt to manipulate the situation. Events are observed as they occur naturally and encompass the entire situation. Semistructured observation is more concerned with some aspects of the situation than others. In structured observation, what to observe is decided in advance, and there is an observational schedule. A single observation may involve all of these methods of observation. Unstructured and semistructured observations tend to be time consuming and labor intensive. These methods are most frequently associated with qualitative research.

There are several types of observational methods, which are based on the degree of participation and involvement
of the researcher, ranging from complete participation at one end to complete observer at the other end (McMillan, 2012). A participant observer is when the researcher is an active participant in the activity being studied, that is, the researcher participates as a member of the group and is not known as the researcher. According to Meline (2004), participant observation “is more demanding than direct observation because the researcher must acclimate to the situation and become an accepted member in the scene” (p. 79). A complete observer or passive participant is detached from the group being studied and is known as the researcher.

Observation as a data collection technique is particularly well suited to speech-language pathology and audiology. Speech-language pathologists and audiologists are in an advantageous position to observe the behaviors and activities of clients and their families. Moreover, speech-language pathologists and audiologists, if trained, may be very reliable observers. Many speech-language-hearing problems are well suited to an observational approach.

There are, however, disadvantages, including possible ethical consideration, distorted behavior of the person being observed if the observer is conspicuous, a high refusal rate, and observer bias (Polit & Beck, 2010). Creswell (2004) believes “first and foremost the researcher has an obligation to respect the rights, needs, values, and desires of the informant(s)” (p. 201). Observation is vulnerable to observation bias for a number of reasons (Polit & Beck, 2010). Among these reasons are emotions, prejudices, attitudes, and values of observers; personal interest and commitment; preconceived ideas about what is to be observed; and inappropriate decisions about data collection.

Interviewing

Interviewing is the most common method of data collection in qualitative research (Llewellyn, 1996). The interview is a form of data collection in which questions are asked orally and participants’ responses are recorded (Maxwell & Satake, 2006). Interviews are conducted face-to-face, by telephone, or electronically. Some general guidelines for interviewing are provided in Table 9–2.

Additional information about interviewing can be found in French, Reynolds, and Swain (2001); Haynes and Pin-

<table>
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<th>Table 9–2. Guidelines for Conducting Qualitative Research</th>
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<tr>
<td>• Identify questions in advance</td>
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<td>• Make interviews representative of the group</td>
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<td>• Obtain written permission</td>
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<tr>
<td>• Establish and maintain rapport</td>
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<tr>
<td>• Focus on actual rather than abstract or hypothetical</td>
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<tr>
<td>• Do not put words in people’s mouths</td>
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<tr>
<td>• Record responses verbatim</td>
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<tr>
<td>• Keep your reaction(s) to yourself</td>
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<tr>
<td>• Remember you are not necessarily obtaining the facts</td>
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<tr>
<td>• When conducting a focus group, consider group dynamics</td>
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Interviews have both advantages and disadvantages. Advantages are related to rapport with the participants, which can enhance motivation and results in obtaining information that might not otherwise be obtained: clarification of participants’ questions; follow-up on leads or probing; use with many different types of persons (illiterate or too young to read or write); and higher return of results (McMillan, 2012). Face-to-face interviews also have additional advantages, such as observation of nonverbal behavior, and a tendency to reduce no and unknown answers or neutral responses.

The disadvantages of interviews are cost, time, small sample size, possible subjectivity, or the training and experience of the interviewer. It is important that questions not be leading or suggest a specific response (McMillan, 2012).

Interviews may be structured, semi-structured, or unstructured. **Structured interviews** are often used in telephone interviews (Maxwell & Satake, 2006). Structured interviews have the advantage of efficient use of time and allow some flexibility (Llewellyn, 1996). **Semi-structured interviews** are predetermined, but the participants are not predetermined. Rather, the questions are open-ended but specific, which permits individual responses. **Unstructured interviews** are sometimes referred to as informal conversation or in-depth interviews, because they are open ended and flexible. This type of interview is especially useful for understanding individual behavior over time. The disadvantages of unstructured interviews are the time involved and resources needed to analyze the data obtained.

**Focus Groups**

**Focus groups** are a method of interviewing a group of individuals about a specific topic or issue. The same format used for individual interviews is used for focus groups: structured, semi-structured, or unstructured. The advantages of focus groups are that multiple responses can be obtained in a relatively short period of time, observation of interaction between focus group members, and some people feeling more comfortable talking in a group than alone (Leedy & Ormrod, 2010). Disadvantages are related to possible domination of the group by one or more members. Furthermore, if the facilitator of the focus group is not skilled in group processes and interviewing methods, this will adversely affect the responses of others (Law, 2002).

**Analyzing Qualitative Data**

As data are being collected, the data analysis portion of the study can begin. It is important to note again that data analysis is an integral part of data collection. As the data are collected, it is necessary to start the analysis process so that further data collection can be modified, if need be. If, for example, a study involving interviewing is being conducted, it would be a good idea to read over and code the first interview as the interviews are being collected to help shape the content of the subsequent interviews (Creswell, 2014).

Data collection, in qualitative research, can lead to a copious amount of information and potential details to unravel.
It is easy as a novice (or even seasoned) qualitative researcher to get lost in the wealth of information and struggle to focus on the most relevant aspects of the data. Then, it becomes necessary to go through a process of “winnowing” the data (Creswell, 2014). This involves choosing to only look at the aspects of data that are most relevant to the questions and purpose of the qualitative study. It should be noted that this is in contrast to quantitative research, wherein all data are necessary to fulfill the requirements of the study, and missing data are replaced if at all possible (Creswell, 2014).

There are a variety of methods of analyzing qualitative data ranging from objective and systematic to subjective and interpretive (Maxwell & Satake, 2006). One helpful step-by-step process seen in the literature by Creswell (2014) is the following:

Step 1. Data collected should be prepared and organized for analysis. This involves transcribing interviews, videos of therapeutic interaction, typing up observation field notes, and so on.

Step 2. Look at all of the data. This will assist the researcher in getting an overall picture of the information. When an overall picture is achieved, it is then possible to reflect on specific issues that may need to be areas of focus.

Step 3. Begin the coding process. Coding is a process wherein all of the individual units of data are assigned a name of some type. For example, when coding transcripts, each utterance or conversational turn would be given an interpretive label. The researcher then takes those individual codes and brackets them into larger chunks or units of meaning to derive a broad theme for interpretation.

Step 4. The coding process leads to description of the setting or participants. This description arises from the broad categories or themes that are generated from the coding process. When each theme is thoroughly and richly described, a detailed picture of the participants or setting will emerge. All description should include quotes and many examples from the data to back up any narrative description. This ensures that the broader themes stay tied to the original data.

Step 5. Decide how themes and description of those themes will be represented in the finished product. Most researchers rely on narrative writing to share the findings of a qualitative study. This narrative is often supported by tables or graphs that represent the data.

Step 6. The final step in data analysis is to interpret the data. This is accomplished by asking and answering the questions: “what does this mean?” or “what lessons can be learned from this investigation?”

Validity and Reliability

In any discussion of data analysis in qualitative research, it is necessary to address the issues of validity and reliability. Similar to the issue of generalizability
discussed earlier in this chapter, validity and reliability do not mean the same things in qualitative research that they mean in quantitative research. Rather, in qualitative research, validity indicates that the researcher has ensured accuracy of findings by implementing specific, necessary procedures. Additionally, qualitative research reliability indicates that the researcher has maintained consistency of approach across all researchers involved and methodologies utilized (Creswell, 2014).

To ensure that a qualitative study is valid, Creswell (2014) describes eight strategies:

1. **Triangulation.** The researcher should utilize multiple forms of data collection to verify the meanings of the themes that emerge from data analysis. If each theme is backed up by multiple examples and data points, it will have much stronger validity.

2. **Member checking.** This is accomplished by taking some of the descriptions of the themes that were established back to the participants for discussion of their accuracy. Member checking is often done in interviews, wherein the final results of a study are presented and discussion is held to establish whether or not the findings are accurate and realistic.

3. **Rich, thick description.** The researcher should provide highly detailed description to the point that readers may feel that they are in the setting or know the participants. Providing descriptions of different viewpoints and perspectives is also very helpful. By thoroughly describing the setting, participants, and findings, it is possible to achieve a higher level of validity in qualitative research.

4. **Be clear about author bias.** One characteristic of qualitative research is that it is interpretive. Therefore, the writer/researcher will inevitably integrate his or her own experience and perspective as they are interpreting the results. It is necessary, from the beginning of the study, for the researcher to be reflective and to write clearly about his or her own theoretical orientation and background. This will help the consumer of qualitative research to be aware of the overall perspective of the researcher and how it influences the outcome of the study.

5. **Present contradicting evidence.** In most every qualitative study, there will be data that do not agree with one or more of the themes the researcher has established. This is common and realistic. Therefore, it is necessary for the researcher to be honest about these issues. Reporting contradicting evidence will increase the validity of the study.

6. **Spend a significant amount of time in the field.** When a researcher spends a lot of time with the participants in the setting under investigation, it increases his or her understanding of the entire larger picture. This ultimately will lead to more accurate, realistic interpretation of findings and, thus, validity of the study.

7. **Peer debriefing.** It is helpful to share the written product and findings with a peer. This will give the researcher a perspective other
than his or her own to ensure that the findings resonate with a wider audience. This also ensures validity of interpretation.

8. **External auditor.** The researcher should also consider asking someone completely external to the project (has had no part in constructing the study or collecting the data) to review every aspect of the study. This will help identify weaknesses and clarify interpretation.

Additionally, ensuring reliability, which is the concept that the research design is consistent across researchers and methodologies, is essential in qualitative research. There are several ways to ensure reliability of a qualitative study (Gibbs, 2008):

- Checking transcripts to ensure that there are no obvious mistakes in transcription.
- Constantly comparing data that have been coded to ensure that there is no drift in the meaning of the codes that have been assigned.
- Conducting regular meetings between those doing the coding to ensure interpretation and meaning are being maintained.
- Ensuring intercoder agreement by cross-checking codes through a process of comparing results that have been interpreted independently.

Data analysis in qualitative research is an intense, often long process that can yield deep, useful, and wide-reaching results. If done appropriately, following the above guidelines, it is possible to achieve outcomes in a qualitative study that are generalizable, valid, and reliable.

This checklist is one of many that can be utilized to critique qualitative research. However, it is key to this process to remember that the specific design and data collected must be well suited and specific enough to investigate the phenomenon in question.

**Criteria for Evaluation of Qualitative Research**

Qualitative research requires different criteria for evaluation because of differences in design and data. Several authors have described criteria for evaluation of qualitative research (Creswell, 2014; French, Reynolds & Swain, 2001; Leedy & Ormrod, 2016; Silverman, 2014; Trochim, 2001). A checklist for evaluation of qualitative research by Silverman (2014) is as follows:

- Are the methods of research appropriate to the nature of the question being asked?
- Is the connection to an existing body of knowledge or theory clear?
- Are there clear accounts of the criteria used for the selection of cases for study, and of the data collection and analysis?
- Does the sensitivity of the methods match the needs of the research question? Were the data collection and record keeping systematic?
- Is reference made to accepted procedures of analysis?
- How systematic is the analysis?
- Is there adequate discussion of how themes, concepts, and categories were derived from the data?
- Is there adequate discussion of the evidence for and against the researcher's arguments?
- Is a clear distinction made between the data and their interpretation?
Qualitative research is a valuable way to approach complex issues worthy of study in the field of speech-language pathology. The increasing popularity of qualitative research in speech-language pathology and audiology is evident in the growing number of qualitative studies reported in the past few years. In speech-language pathology, the demand for real-life, functional therapy outcomes is high. Due to the fact that the main focus of qualitative research is to richly describe complex phenomena as they occur in a natural context, this approach to research is vital to the further development of our field.

**References**


Daniels, D. E. (2012). Treatment of stuttering in a school-age child: A description of a...


Chapter Outline

- Characteristics of Multimethod Research
- Advantages and Disadvantages of Multimethod Research
- Sequencing Research Designs
- Examples of Mixed Method Design in Speech-Language Pathology
- Evaluating Multimethod Research
- Summary
- Discussion Questions
- References
Upon completion of this chapter, the reader will be able to:

- Describe the sequences for combining qualitative and quantitative research
- Understand designs for multimethod research
- Acknowledge advantages and disadvantages of multimethod research
- Evaluate multimethod research
Multimethod or mixed research combines quantitative and qualitative research methods to ideally use the best of both methods. According to Creswell and Clark (2007), “the use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone” (p. 5). Speech-language pathologists and audiologists should understand multimethod research, because a significant amount of clinical research combines quantitative and qualitative research methods.

Characteristics of Multimethod Research

Multimethod research is a growing trend that resulted from discussion and controversy regarding quantitative and qualitative research. These arguments gave rise to a new approach in order to solve some of the issues that arose. Multimethod or mixed method research combines both quantitative (outcome) and qualitative (process) features in design, data collection, and analysis (McMillan, 2012; Mertens, 2014). The steps in multimethod research, from determining the feasibility of the study through data collection to reporting the results, are shown in Figure 10–1. Similar steps have been described by Creswell (2014), McMillan (2012), and McMillan and Schumacher (2010).

Creswell (2014) further describes and defines mixed method research in a comprehensive sequence of points:

- Collection of both quantitative and qualitative research.
- Analysis of both types of data.
- Data collection and analysis conducted with rigor.
- The two forms of data are either connected, merged or embedded.
- The procedures are integrated into a new, distinct, mixed methods design that has a distinct timing of data collection and a specific emphasis on either qualitative or quantitative research (equal versus unequal).

Additionally, a number of publications describe methods for combining research (Creswell, 2009; Mertens, 2014; Polit & Beck, 2010; Tashakkori & Teddlie, 2010). The Handbook of Mixed Methods in Social and Behavioral Research (Tashakkori & Teddlie, 2010) and Designing and Conducting Mixed Methods Research (Creswell & Clark, 2007) are comprehensive publications about issues related to combining quantitative and qualitative research. Additionally, there are a number of journals that emphasize mixed method research specifically, such as Field Methods, the International Journal of Multiple Research Approaches, and Journal of Mixed Methods Research. The increased singular focus of these journals on mixed methods indicates a significant shift and increased use of mixed method research in academia.

Despite the increasing popularity of mixed method research, there is considerable debate (Adamson, Gooberman-Hill, Woolhead, & Donovan, 2004). These two methods of research are different, and the results may be reported separately. Also, it may be difficult to combine quantitative and qualitative methods because of technical problems or conflicts between theoretical perspectives about research (Morgan, 1998).

Until recently, research in speech-language pathology and audiology has
been dominated by quantitative studies. However, qualitative studies gained considerable attention during recent years. Another trend is the blending of quantitative and qualitative data. Multimethod studies are now published in a greater number of speech-language pathology and audiology journals.


There are both advantages and disadvantages in multimethod research. The major advantage is that by combining...
qualitative and quantitative methods, the weaknesses of one may be reduced or avoided; that is, there is the potential for one to offset the other's weaknesses (Polit & Beck, 2010).

There are other advantages to multimethod research, such as: (a) providing comprehensive data analysis, both objective (quantitative) and subjective (qualitative); (b) permitting study of both process and outcome; (c) allowing for different types of research questions; (d) compensating for use of a single type of research method; and (e) enhancing credibility of findings (Abusabha & Wel fel, 2003; McMillan & Schumacher, 2010). In addition, a multimethod approach may lead to theoretical insight that might be possible without combining methods.

Different methods are more appropriate for different phases of research; that is, qualitative methods are appropriate for exploration of hypothesis generation, and quantification is needed later for verification. Multiple and complementary types of data can improve the validity of results. When there are conflicting findings, careful review of the discrepancies between qualitative and quantitative data can provide new insights and enhance theoretical understanding.

There are also disadvantages and limitations in combining qualitative and quantitative research. Depoy and Gitlin (2011) believe mixed method research should not be viewed with skepticism and as nontraditional because of its inconsistency. Polit and Beck (2010) identified five limitations: (a) cost, (b) biases, (c) research training, (d) analytic challenges, and (e) publication biases. First, multimethod research is usually expensive. Second, there are extreme preferences; some prefer quantitative research, whereas others prefer qualitative re- search. Third, training can be a challenge because multimethod research requires knowledge and understanding of both qualitative and quantitative research. Furthermore, many training programs offer training in only one method or the other, but not both. Fourth, there are analytic challenges related to combining numeric (quantitative) and narrative (qualitative) data, and resolving and interpreting inconsistent or contradictory results. In addition, writing the report and formatted conclusions can be challenging (McMillan & Schumacher, 2010). The fifth limitation is a possibility of publication biases. Some journals prefer qualitative research; however, typically more journals prefer quantitative research. There is also the possibility of a mismatch or bias between the theoretical perspectives of the reviewers and the authors—that is, quantitative researchers serving as reviewers for qualitative research (Belgrave, Zablotsky, & Guadagno, 1998). According to Meline (2006), “it is somewhat popular to indicate that research has both components, even though one of the two methods is only used superficially” (p. 288). Other issues identified by Tashakkori and Teddlie (2003) are related to overreliance on one method alone and the need for an alternative to mixed methods designs. The former involves going beyond mixing at the method level only. The latter suggests that mixed studies go beyond the mixing of methods to include combining other stages of the research cycle. Related to the disadvantages are several myths and misunderstandings that Creswell and Clark (2007) identified. The more common myths are that: (a) multimethod research is just qualitative research, (b) it is a method that has always been used, and (c) multimethod
research is universally accepted. Acceptance ranges from minimal to major/most (Table 10–1).

### Sequencing

Typically, multimethod research is sequential. An explanatory design may be the most common type of mixed methods research. Quantitative data are collected first, and qualitative data are collected in the second phase—that is, qualitative follows quantitative. Another type of mixed methods research is an explanatory design in which qualitative data are collected first and then followed by a quantitative phase—that is, quantitative follows qualitative. The other type of mixed methods research is a mixed design in which the phases are simultaneous. The third type of mixed methods research is a process design in which multiple methods are used in a single study.

<table>
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<tr>
<td>_______  Special issue of a journal focusing on the use of mixed methods in the profession</td>
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<td>_______  Publication of mixed methods studies in top professional journals</td>
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<td>_______  Course on mixed methods research as part of graduate training programs</td>
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<th>Moderate Acceptance</th>
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<tr>
<td>_______  Leaders in the profession advocate for use of mixed methods research</td>
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<td>_______  Workshops on mixed methods research forums dedicated to the profession</td>
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<td>_______  Funding agencies supporting mixed methods research</td>
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<td>_______  Methodological discussions of mixed methods in journals devoted to the profession</td>
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<th>Minimal Acceptance</th>
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<tr>
<td>_______  Awareness within the profession of qualitative research</td>
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<tr>
<td>_______  Publication of actual mixed methods studies in professional journals</td>
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<td>_______  Graduate students using mixed methods in dissertation research</td>
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<td>_______  Discussions in journals about need for mixed methods</td>
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<td>_______  Mixed methods research discussed at professional conferences</td>
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Table 10–1. Levels of Acceptance for Mixed Methods Studies

of multimethod study is the triangulation design in which both qualitative and quantitative data are collected simultaneously (McMillan, 2012). Mixed methods research can also be described relative to the stage in which the methods occur (Tashakkori & Teddlie, 2010).

In equal status (equivalent) mixed methods designs, both quantitative and qualitative methods are used about equally. Dominant–less dominant mixed methods designs refer to studies in which one method is dominant and a small part of the study evolves from the other method. Qualitative and quantitative data are collected and analyzed simultaneously in parallel/simultaneous mixed methods designs.

**Research Designs**

The choice of research methods is frequently associated with a specific theoretical orientation (Adamson et al., 2004). There are, however, specific criteria for selection of appropriate mixed method designs (Creswell, 2009). These criteria are related to: (a) implementation for data collection (concurrent or sequential), (b) priority or equal weight given to quantitative or qualitative approach, (c) phase of research in which the two methods are combined, and (d) identification of theoretical orientation used in the study.

A checklist of questions may help in designing a mixed methods study. Such a checklist is presented in Table 10–2. Mixed method designs have been described in various ways. This chapter discusses three designs and later describes advanced designs that integrate the three basic designs described in this section. We describe convergent, explanatory, and exploratory designs in this section, with attention to detail in the areas of overall description, data collection, data analysis, and interpretation.

Convergent parallel mixed method design is the most common of all the mixed method designs (Creswell, 2014). This type is conducted by implementing both qualitative and quantitative methods simultaneously. The data are then analyzed separately and compared to identify whether or not there is agreement (Creswell, 2014). There are some issues with data analysis. Two types of data analysis are suggested. The first is to analyze the data side-by-side in an effort to compare and discuss. The second is to convert the qualitative data into quantitative data (via Likert scales, etc.) The two forms of data are then merged into table or graph format to present in visual form (Creswell, 2014).

In convergent parallel mixed method designs, after data are collected, analyzing involves searching for either convergent or divergent findings between the two types of data (Creswell, 2014). When divergence occurs, it is very important to report on it and to explain it rather than ignore it.

An example of convergent parallel mixed method design can be found in a study wherein the researchers investigated aspects of driver safety in older adults in order to establish an intervention program for older drivers (Classen et al., 2008). The researchers used the national crash data set numbers along with interviews that acquired the participants’ perspectives, goals, and needs in order to be safe drivers (Creswell, 2014).
The second type of mixed methods research is explanatory sequential mixed methods design (Creswell, 2014). This design involves two phases. The first implements quantitative methods in order to inform the second phase of qualitative methods. For example, a survey might be given to explore a specific topic to get quantitative data on the characteristics of a given population. Then, qualitative interviews could be designed specifically for that population (Creswell, 2014).

The two phases of research in explanatory sequential designs must be planned carefully (Creswell, 2014). The quantitative phase must be rigorous and specifically designed to identify the factors most relevant for study by the later occurring qualitative methods. One of the main ideas of this design is that the qualitative phase builds directly on the quanti-
tative phase (Creswell, 2014). Data analysis involves analyzing the results of both phases separately. The results of the quantitative phase are used to plan the qualitative phase (Creswell, 2014).

Banyard and Williams (2007) conducted a mixed method design that was explanatory in nature to study issues surrounding the recovery process of childhood sexual abuse in women. They formed a questionnaire to acquire quantitative data regarding the nature of resilience and the correlates of resilience. They used the data from these interviews to build interviews for a smaller set of participants to investigate their life history, recovery, resilience, and coping abilities.

The final design we discuss is the exploratory sequential mixed methods design. This design is a reverse of the explanatory sequential approach to research. The researcher begins the study by researching a specific topic thoroughly utilizing qualitative methods (Creswell, 2014). Then, the researcher initiates the second phase of the project using quantitative methods that are built on the results of the qualitative phase (Creswell, 2014).

In an exploratory sequential mixed methods design, qualitative data can be coded to acquire a set of themes that can then be used to group items on a psychometric test, for example. This method can be used to develop scales for assessment (Creswell, 2014). If the qualitative data are thorough and sound, the construct validity of a measurement scale for assessment will be much stronger (Creswell, 2014).

An example of exploratory sequential mixed methods design can be found in the 2011 study by Betancourt et al. This study sought to understand how to adapt and evaluate a specific intervention for mental health problems in HIV-affected children living in Rwanda. The investigators chose to begin with an exploration of personal issues of the children and their caregivers via in-depth interviews. They analyzed this qualitative data and utilized these themes to develop survey instruments to be used as pretest and posttest measures for the intervention program they would later implement. This study used qualitative measures to develop an instrument that was later used to acquire quantitative data.

**Examples of Mixed Method Design in Speech-Language Pathology**

Mixed method research is used in a variety of health-related fields of study. As can be seen in the examples given so far, it can be a useful tool to accomplish a wide variety of different objectives in research. We now turn our attention to how mixed method research has been used in the field of speech-language pathology by sharing two specific examples.

The first example is a pilot study that investigated the perceptions of speech-language pathology student clinicians regarding individuals who stutter (Koutsodimitropoulos, Buultjens, Louis, & Monfries, 2016). These researchers used a convergent parallel design to administer the Public Opinion Survey of Human Attributes–Stuttering (POSHA-S) as the quantitative component of their study...
as well as semistructured interviews as the qualitative component. Through the POSHA-S results, they were able to quantify their students’ attitudes and compare them to a national average. They also were able to describe more in-depth themes that emerged from the interviews of these students about their attitudes and beliefs about stuttering.

The second example is a study conducted to investigate the difficulties encountered by Hispanic students who struggle with developing adequate writing skills (Perry, 2017). This is a complex issue that is often related to cultural and linguistic differences. Perry conducted a variation of exploratory sequential methods design, which was more embedded. Perry implemented a qualitative analysis of expository essays in order to develop an understanding of the overall structural issues that occur in this type of writing. Then, an intervention was implemented to address these issues and see if they improved after intervention—this was the quantitative portion of the study.

Questions for evaluating multimethod research were described by Creswell and Clark (2007). These questions reflect relatively general standards, such as basic knowledge of multimethod research, rigor of the research, and advanced knowledge of specific designs. The questions are as follows: (a) Is the study a multimethod study? (b) Does the study show rigorous multimethod research? (c) Does the study include advanced multimethod features consistent with multimethod design? and (d) Does the study show sensitivity of some of the challenges of using the design?

The questions in Table 10–3 may be used to analyze methods research. These questions refer to issues related to quality, which would be referred to as credibility or trustworthiness in qualitative terms or validity in quantitative research. Mertens (2005) also described questions for analyzing mixed methods research that are in Table 10–3. The questions require narrative answers.

Summary

Multimethod research is an approach to research that combines quantitative and qualitative methods to answer complex questions. It is a valuable tool in speech-language pathology and is gaining momentum in our field. It is important to remember that multimethod studies follow a specific sequence depending on the problem under investigation. Convergent parallel, explanatory sequential and exploratory sequential designs can be used to best address issues under investigation. It is true that combining qualitative and quantitative data collection and analysis has several barriers. However, reducing these barriers is worth the time and effort. The truth is that most clinical activities combine qualitative and quantitative research, that is, are multimethod research. Therefore, using this method to study issues in the field of speech-language pathology could be the answer to barriers we face in bridging the gap between research and practice.
Table 10–3. Questions for Analyzing Mixed Methods Research

- What are the purposes and questions that justify the use of a mixed-methods design?
- Has the researcher matched the purposes and questions to appropriate methods?
- To what extent has the researcher adhered to the criteria that define quality for the quantitative portion of the study?
- To what extent has the researcher adhered to the criteria that define quality for the qualitative portion of the study?
- How has the researcher addressed the tension between potentially conflicting demands of paradigms in the design and implementation of the study?
- Has the researcher appropriately acknowledged the limitation associated with data that were collected to supplement the main data collection of the study?
- How has the researcher integrated the results from the mixed methods? If necessary, how has the researcher explained conflicting findings that resulted from different methods?
- What evidence is there that the researcher developed the design to be responsive to the practical and cultural needs of specific subgroups on the basis of such dimensions as disability, culture, language reading levels, gender, class, and race or ethnicity?


DISCUSSION QUESTIONS

1. What is multimethod research?
2. What are its characteristics?
3. Why should speech-language pathologists and audiologists understand multimethod research?
4. Describe the major categories of multimethod research.
5. What are the advantages and disadvantages of multimethod research?
6. Identify the different types of component designs.
7. What are the different types of mixed methods designs?
8. Why should a mixed method design be used?
9. How can multimethod research be evaluated?
References


Perry, V. (2017). A mixed methods study of expository paragraph writing in English-proficient Hispanic, middle school students with writing weaknesses. Perspectives of the ASHA Special Interest Groups, 2(1), 151–167


CHAPTER OUTLINE

Reasons for Reporting Research
Myths and Facts About Research Reports
Time Management for Reporting Research
Procrastination
Formats of Research Reports
Abstracts
Key Words (Indexing Terms)
Author Contributions
Tables and Figures
Diagrams and Maps
Writing Styles
APA Format
References
Personal Pronouns
Avoid Bias
Permissions
Rewriting and Revising
Translating Research Reports to Published Papers

Types of Research Reports
Journal Articles
Selecting a Journal
Categories of Reports in ASHA Journals
Theses and Dissertations
Textbooks
Presentations at Professional Meetings
Oral Reports
Poster Presentations
Visual Supplements
Evaluating and Reviewing Research Reports
CATs
Summary
Discussion Questions
References
Upon completion of this chapter, the reader will be able to:

- Identify reasons for reporting research
- Correct misconceptions about research reporting
- Avoid misconceptions about research reports
- Effectively manage time for reporting research
- Maintain a research log
- Develop a schedule for reporting research
- Use appropriate professional writing style
- Request permission for copyright materials
- Understand rewriting and revision
- Translate research reports into manuscript
- Identify different types of research reports
- Select a journal to submit a manuscript
- Evaluate and review reports
Reporting and disseminating research studies are essential to the advancement of science in speech-language pathology and audiology. Students and practicing professionals are often not prepared to write and publish research reports. What distinguishes the unpublished from the published is a matter of attitude, training, and perseverance. First is a positive attitude of confidence and determination that suggests, “I can and I will publish.” Second is the probability that those who do not publish do not know how to publish. Throughout schooling, students have had to write and have been graded on writing, but they have not been taught how to write for publication. Irwin, Pannbacker, and Kallail (1992) suggest that “university faculty should instruct students about the process of publishing in a journal” (p. 122). Third, an unpublished paper is often one that someone gave up on. Fourth, many people think they have good writing skills but few do; good writers edit and rewrite, again, and again (Henson, 1993).

The purpose of this chapter is to: (a) describe common myths about research reports, (b) identify reasons for reporting the results of research, (c) discuss managing time to report research, (d) describe the organization and style of research reports, (e) explain research reports at professional meetings, (f) classify and describe visual supplements, and (g) explain submission and review of research reports.

### Reasons for Reporting Research

There are numerous reasons for reporting research, including ethical responsibility, improving clinical service, academic survival, and personal and group recognition. Hegde (2003) believes “dissemination or research findings are an ethical responsibility” (p. 560). According to the American Speech-Language-Hearing Association’s Code of Ethics (ASHA, 2016), speech-language pathologists and audiologists have ethical responsibilities related to “dissemination of research findings and scholarly activities” (p. 3). In *A History of the American Speech and Hearing Association 1925–1958*, Paden (1970) stated, “one of the chief reasons for the existence of a profession or learned society is the sharing of knowledge on the field among its members” (p. 21). ASHA provides many opportunities for disseminating research, including its scholarly journals, teleseminars, and annual meetings.

Reporting research is fundamental to the advancement of diagnosis and treatment of speech, language, and hearing problems. Silverman (1998) pointed out that if clinical speech-language pathologists and audiologists do not formally disseminate clinical outcome research, the potential to help persons with speech-language-hearing problems is restricted to their caseload and those of colleagues with whom they communicate.

Academic survival is related to understanding “publish or perish.” Publication has a significant impact on academic survival and promotion, tenure, and merit salary raises (Anderson, 1992; Boyes, Happel, & Hogen, 1984; Holcomb & Roush, 1988; Schilling, 2005; Sininger, March, Walden, & Wilber, 2003). Publishing makes a difference to speech-language pathologists and audiologists employed in colleges or universities. Those who are promoted have published more than those who have not been promoted. For these reasons, there is tremendous pressure to publish among academicians
(Luey, 1987). Academic survival (graduation) of students is also related to completing a thesis or dissertation requirement (Cone & Foster, 2006; Davis & Parker, 1979; Rudestam & Newton, 2001. There are also several other reasons for reporting, which are listed in Table 11–1. These reasons are institutional as well as individual.

Reasons for not reporting research also warrant consideration. Two of the most frequently cited reasons are lack of time and negative attitudes (Bennett & Taylor, 2003; Meline, 2006). Time management for reporting research is discussed in the next section. Some speech-language pathologists and audiologists do not report research because of the fear of rejection, revisions, or self-censorship (Meline, 2005). In recent years, ASHA journals rejected between 39% and 66% of the manuscripts that were submitted (Table 11–2). Moreover, one or more revisions were usually required before any manuscript was accepted for publication (ASHA, 2000). Avoiding peer review may also be seen as a related response. Reports based on opinion and testimonials lack significant credibility and are not accepted for publication in peer-reviewed journals. Therefore, peer review is avoided, and such reports are presently directed toward the public and others (Finn, Bothe, & Bramlett, 2005).

Table 11–1. Reason for Reporting Research

<table>
<thead>
<tr>
<th>Reason for Reporting Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethical responsibility</td>
</tr>
<tr>
<td>Advancement of clinical practice</td>
</tr>
<tr>
<td>Academic survival; promotion, tenure</td>
</tr>
<tr>
<td>Graduation requirement (theses or dissertation)</td>
</tr>
<tr>
<td>Stimulate further research</td>
</tr>
<tr>
<td>Peer approval</td>
</tr>
<tr>
<td>Personal sense of achievement</td>
</tr>
<tr>
<td>Evidence of intellectual effort</td>
</tr>
<tr>
<td>Entry to professional networks</td>
</tr>
<tr>
<td>Quality indicator of group/program/institution</td>
</tr>
</tbody>
</table>

Table 11–2. Acceptance and Rejection Rates for ASHA Journals

<table>
<thead>
<tr>
<th>Journal</th>
<th>Accept</th>
<th>Reject</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Journal of Audiology</td>
<td>58 63</td>
<td>37 39</td>
<td>95</td>
</tr>
<tr>
<td>American Journal of Speech-Language Pathology</td>
<td>81 35</td>
<td>158 66</td>
<td>230</td>
</tr>
<tr>
<td>Language, Speech and Hearing Services in Schools</td>
<td>106 42</td>
<td>148 58</td>
<td>256</td>
</tr>
<tr>
<td>Journal of Speech-Language-Hearing Research</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Speech</td>
<td>50</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Language</td>
<td>42</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>Hearing</td>
<td>48</td>
<td>52</td>
<td></td>
</tr>
</tbody>
</table>
Despite attempts to debunk the myths surrounding research reports, there continue to be several common misconceptions, which Sternberg (1993) identified in his book, *The Psychologist’s Companion: A Guide to Scientific Writing for Students and Researchers*. These myths are described in Table 11–3. Identification and understanding of these myths should facilitate more accurate and realistic concepts about reporting research.

According to Leedy and Ormrod (2010), the first step is the development of a reasonable writing schedule and sticking to it. Additionally, suggestions are identification of small accomplishable goals within the project; setting reasonable dates for completing each goal; rewarding yourself each time you meet a goal; seeking regular feedback; and building time into the schedule for at least two or three rewrites.

From the beginning, a target date should be set for completion of the research report. A personal deadline should preempt some time before the actual deadline. The research report should be organized so that it can be completed. If delayed by unavoidable influences, it is necessary to work twice as hard the next day or week, or to work over the weekend to stay on schedule. Robertson (2004) described strategies for managing time that may be helpful, such as setting personal goals, using a master list, organizing work space, and being proactive. It is helpful to develop a timetable of activities required to plan, write, and submit a research report (DePoy & Gitlin, 2011; Polit & Beck, 2010). Table 11–4 provides a list of activities and a schedule for completing a research report. Several activities overlap, and some involve little time; others are more time consuming. The identification and scheduling of tasks to complete the report should facilitate completion of the report within a reasonable period of time. In developing a schedule, several factors should be considered: available resources such as technology support and personnel will influence the amount of time required. Other activities that will take time include securing necessary permission and holding meetings or communicating with co-authors.
<table>
<thead>
<tr>
<th>Myth</th>
<th>Facts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinicians are not researchers.</td>
<td>Clinicians should be researchers.</td>
</tr>
<tr>
<td>Writing the research report is the most routine, least creative aspect of research, requiring much time but little creativity.</td>
<td>Writing the research report requires both time and creativity.</td>
</tr>
<tr>
<td>The important consideration is what is said rather than how it is said.</td>
<td>How it is said (professional writing style) is an important consideration.</td>
</tr>
<tr>
<td>Longer papers are better, more papers also better.</td>
<td>Concise papers are better, quality of papers is more important than quantity of papers.</td>
</tr>
<tr>
<td>The main purpose of a research paper is presentation of facts, whether newly established (experimental research) or established (literature review, tutorials).</td>
<td>Research papers have several purposes: analysis/synthesis of past and current research, drawing conclusions, and providing suggestions for future research.</td>
</tr>
<tr>
<td>The difference between scientific writing and advertising is that the purpose of the former is to inform and the latter is to persuade.</td>
<td>Scientific writing and advertising may both inform and persuade.</td>
</tr>
<tr>
<td>An acceptable way to gain acceptance of a theory is to refute another theory.</td>
<td>An acceptable way to gain acceptance of a theory is to provide credible evidence.</td>
</tr>
<tr>
<td>Negative results which fail to support a hypothesis are as valuable as positive results that do not support the hypothesis.</td>
<td>Both negative and positive results can improve knowledge and understanding.</td>
</tr>
<tr>
<td>Logical development of ideas in a research paper reflects historical development of ideas.</td>
<td>Logical development of ideas in a research paper may not reflect the historical background.</td>
</tr>
</tbody>
</table>
Table 11–4. Steps and Schedule for Writing a Research Report

<table>
<thead>
<tr>
<th>Steps</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prewriting/planning stage</td>
<td></td>
</tr>
<tr>
<td>Review requirement for submitting report</td>
<td></td>
</tr>
<tr>
<td>Obtain permission(s) to use previously published material(s)</td>
<td></td>
</tr>
<tr>
<td>Decide on authorship and order of authors</td>
<td></td>
</tr>
<tr>
<td>Determine level of evidence relevant to topic</td>
<td></td>
</tr>
<tr>
<td>Assemble materials needed to write report</td>
<td></td>
</tr>
<tr>
<td>Writing first draft</td>
<td></td>
</tr>
<tr>
<td>Title page</td>
<td></td>
</tr>
<tr>
<td>Abstract</td>
<td></td>
</tr>
<tr>
<td>Key words</td>
<td></td>
</tr>
<tr>
<td>Introduction (background)</td>
<td></td>
</tr>
<tr>
<td>Statement of problem (purpose)</td>
<td></td>
</tr>
<tr>
<td>Method</td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td></td>
</tr>
<tr>
<td>Discussion</td>
<td></td>
</tr>
<tr>
<td>Conclusions</td>
<td></td>
</tr>
<tr>
<td>Author contributions</td>
<td></td>
</tr>
<tr>
<td>Contact information</td>
<td></td>
</tr>
<tr>
<td>References (all references cited both in text and list)</td>
<td></td>
</tr>
<tr>
<td>Tables and figures</td>
<td></td>
</tr>
<tr>
<td>Documentation of informed consent</td>
<td></td>
</tr>
<tr>
<td>Documentation of IRB approval</td>
<td></td>
</tr>
<tr>
<td>Resources and environment</td>
<td></td>
</tr>
<tr>
<td>Review and revision</td>
<td></td>
</tr>
<tr>
<td>Revise first draft and subsequent revisions</td>
<td></td>
</tr>
<tr>
<td>Editing</td>
<td></td>
</tr>
<tr>
<td>Review and revise the last complete draft</td>
<td></td>
</tr>
<tr>
<td>Final editing and proofreading</td>
<td></td>
</tr>
<tr>
<td>Prepare final report</td>
<td></td>
</tr>
<tr>
<td>Submit manuscript and cover letter</td>
<td></td>
</tr>
<tr>
<td>Assemble report copies and accompanying materials</td>
<td></td>
</tr>
</tbody>
</table>

Source: Reprinted from Writing and Publishing in Medicine, by E. J. Huth, 1999, Baltimore, MD: Lippincott Williams & Wilkins. Copyright 1999, with permission from Elsevier.
Efficient use of computer technology can increase productivity because of its speed and accuracy. Computers are used for a variety of research tasks: searching the literature, sampling, recording observations, and qualitative and quantitative data analysis (Maxwell & Satake, 2006; McMillan, 2004; Polit & Beck, 2010).

In addition, some types of research are less time consuming than others (Hegde, 2003; Maxwell & Satake, 2006; Meline 2006). Single-subject research designs require less time because clinical service can be integrated with experimental evaluation. Use of single-subject designs can provide answers to many clinically relevant questions. As Connell and McReynolds (1988) concluded, “individual contact with a client over an extended time interval is the basic requirement for implementation of single-subject experimental designs” (p. 1062). This also helps dispel the myth that there is a division between clinical and research activities.

Procrastination

Related to time management is procrastination or needless delay in beginning or completing a research project. Procrastination may include discomfort, anxiety, busyness, or binging (Boice, 1989). It may reflect a fear of failure or success. And/or it may reflect a need to rebel. Carter-Scott (1989) refers to procrastination as the manana syndrome and describes it as “the precise behavior which keeps you from meeting deadlines, doing what you say you will do, and reinforcing the fact that you’re not up to the challenges” (p. 21). Several strategies have been described to reduce procrastination, such as cognitive behavioral orientation, reprogramming negative attitudes, prioritization, contingency management, procrastination support groups, and time slots. Roth (1989) suggested maintaining a research log or journal from the beginning to the end of a research project, including the completed research report and submission of the report for presentation and/or publication (Table 11–5). This information can also be used to determine authorship contributions.

Several professional journals request that authors disclose their contributions (American Medical Association [AMA], 2006; Bates et al., 2004). The log can also be used to verify supervision.

Table 11–5. Research Log Example

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of entry</td>
<td>Record time; stop and start</td>
<td>Specify what was done.</td>
</tr>
<tr>
<td>3/18/06</td>
<td>10:00–11:45 AM</td>
<td>Computer references search; located articles of interest; requested interlibrary load for journal articles not available.</td>
</tr>
<tr>
<td>3/19/06</td>
<td>1:00–2:30 PM</td>
<td>Reviewed articles.</td>
</tr>
<tr>
<td>3/21/06</td>
<td>9:30–11:00 AM</td>
<td>Drafted outline and working title.</td>
</tr>
</tbody>
</table>
Research reports contain most, if not all, of the sections listed in Table 11–6. Further description of selected parts of research follows in this section: abstracts, key words, author contributions, and tables and figures. Sometimes the results and discussion sections are combined. The format of research is fairly consistent across different types of reports, such as thesis, dissertations, journal articles, and papers for professional meetings (Polit & Beck, 2010). Extensive discussions of the format for written reports can be found in the Publication Manual of the American Psychological Association (2010a), the American Medical Association Manual of Style (AMA, 2007), Schiavetti, Metz, and Orlikoff (2010), and Silverman (1998).

### Abstracts

An abstract is a brief comprehensive summary of a report (APA, 2016). The

<table>
<thead>
<tr>
<th>Table 11–6. Format for Research Report</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title page</strong></td>
</tr>
<tr>
<td>Title, name of authors, and institutional affiliation</td>
</tr>
<tr>
<td><strong>Abstract</strong></td>
</tr>
<tr>
<td>Summary including methods, results, implications</td>
</tr>
<tr>
<td><strong>Key words</strong></td>
</tr>
<tr>
<td>Short list of words for indexing</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
</tr>
<tr>
<td>Untitled; begins body of paper; review of relevant literature, theoretical foundations and rationale, purpose/research questions or hypothesis</td>
</tr>
<tr>
<td><strong>Method</strong></td>
</tr>
<tr>
<td>Design of study, subjects, sampling techniques, controls, equipment or test materials, experimental procedures, rationale for choice of statistics</td>
</tr>
<tr>
<td><strong>Results</strong></td>
</tr>
<tr>
<td>Summary and evaluation of relevant data, tables, and figures</td>
</tr>
<tr>
<td><strong>Discussion</strong></td>
</tr>
<tr>
<td>Comparison of findings to previous research, limitations, implications for clinical practice, and future research</td>
</tr>
<tr>
<td><strong>Author information</strong></td>
</tr>
<tr>
<td>Contains information</td>
</tr>
<tr>
<td><strong>Author contributions</strong></td>
</tr>
<tr>
<td>Disclose of contributions to report</td>
</tr>
<tr>
<td><strong>Acknowledgments</strong></td>
</tr>
<tr>
<td>Recognition of support from individuals and/or organizations</td>
</tr>
<tr>
<td><strong>References</strong></td>
</tr>
<tr>
<td>All cited sources of information</td>
</tr>
<tr>
<td><strong>Tables and figures</strong></td>
</tr>
<tr>
<td>Visual presentation of information</td>
</tr>
<tr>
<td><strong>Appendix</strong></td>
</tr>
<tr>
<td>Contains information that cannot be integrated in text; usually contains unpublished information</td>
</tr>
</tbody>
</table>
abstract may be the most important part of a report, because it may be the only part that many people read. Most professional journals use structured abstracts, because they provide more detailed and consistent information. In addition, structured abstracts make literature searches easier (Editors, 2004).

There are two types of structured abstracts. The first is for original reports, and the second is for review or tutorial reports. The primary information for these abstracts is summarized in Table 11–7. No information should be reported in the abstract that does not appear in the text of the paper (AMA, 2006).

ASHA journals use a modified abstract, which includes the following sections: purpose, method, results, and conclusions. The Annals of Internal Medicine (Editors, 2004) added a section on Limitations located immediately before Conclusions. The Limitation section reduced the risk of overgeneralization, overinterpretation, or overexplaining of the evidence. It also helps readers understand how one report differs from another on the same topic.

Table 11–7. Information Required for Structured Abstract

<table>
<thead>
<tr>
<th>Original Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Objective: exact question(s) addressed by the report</td>
</tr>
<tr>
<td>2. Design: the basic design of the study</td>
</tr>
<tr>
<td>3. Setting: the location and level of clinical care</td>
</tr>
<tr>
<td>4. Patients or participants: the manner of selection and number of patients or participants who entered and completed the study</td>
</tr>
<tr>
<td>5. Interventions: the exact treatment or intervention, if any</td>
</tr>
<tr>
<td>6. Main outcome measures: the primary study outcome measure as planned before data collection began</td>
</tr>
<tr>
<td>7. Results: the key findings</td>
</tr>
<tr>
<td>8. Conclusions: key conclusions including direct clinical applications</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Purpose: the primary objective of the review paper</td>
</tr>
<tr>
<td>2. Data sources: a succinct summary of data sources</td>
</tr>
<tr>
<td>3. Study selection: the number of studies selected for review and how they were selected.</td>
</tr>
<tr>
<td>4. Data extraction: rules for abstracting data and how they were applied</td>
</tr>
<tr>
<td>5. Results of data synthesis: the method of data synthesis and key results</td>
</tr>
<tr>
<td>6. Conclusions: key conclusions, including potential applications and research needs.</td>
</tr>
</tbody>
</table>

Key Words (Indexing Terms)

Most journals include a list of key words or indexing terms that represent content of the report, including words in the title or abstract. They are placed on the abstract page following the abstract. These words assist in locating research reports in computer databases such as Medline and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) (DePoy & Gitlin, 2011; McMillan, 2005; Silverman, 1998). Medline is the database most commonly used in health care and is one of the largest in the world. CINAHL focuses on publications from the allied health professions.

Author Contributions

Several professional journals require that authors disclose their contributions to a report. Each author specifies their contributions, which are published before the acknowledgement section. Some examples are as follows:

- Study concept and design
- Acquisition of data
- Analysis and interpretation of data
- Drafting of the manuscript
- Critical revision of the manuscript for important intellectual content
- Statistical analysis
- Obtaining funding
- Administrative, technical, or material support
- Study supervision

All authors of a group should have full access to all of the data in the report and be responsible for the integrity and accuracy of the report.

Tables and Figures

A wide variety of tables and figures have been described that are used to present complex information in a concise, visual format. Tables generally present exact numerical values, and the data are arranged in an orderly display of columns and rows (APA, 2010). A figure is any kind of graphic illustration other than a table.

Harris (1999) defined and illustrated more than 400 tables and figures. Among the most frequently used figures are pie charts, bar graphs, scatter plots, and curves (DePoy & Gitlin, 2011). Less frequently used figures are concept maps and V-diagrams. Curves refer to any line on a figure used to represent a set or series of data (Harris, 1999).

Computer software is available for the preparation of tables and figures. Among the available programs are IBM SPSS, Microsoft Excel, Adobe Photoshop, Adobe Illustrator, PowerPoint, and Corel Draw.

Tables and figures should be clear enough to stand alone without explanation in the text (Blessing & Forister, 2012). General guidelines for tables and figures are listed in Tables 11–8 and 11–9.

Diagrams and Maps

There are several reasons for using diagrams and maps to display research data. Among the reasons are to: (a) simplify complex information, (b) summarize or enhance certain findings, (c) illustrate complicated results, and (d) demonstrate
trends or redundancies in research (Nicol & Pexman, 2003).

According to the APA (2010) manual, both diagrams and maps are types of figures. The main types of diagrams are graphs and charts. The former are described as “typically displaying the relationship between two quantitative indices, or between a continuous quantitative variable” and the latter are “gen-

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**Table 11–8. Guidelines for Preparing Tables**

- Select a clear and specific table
- Number tables consecutively
- Use subheadings for columns and rows
- Only include information related to the title
- Do not explain table in text it should stand alone
- Use consistent format that confirms to publisher’s guidelines. Refer to instructions to Authors.
- Avoid excessive lines. Usually vertical lines are not needed
- Use appropriate units of measure

Source: From Research and Medical Literature, by J. D. Blessing and J. G. Forister, 2012, Burlington, MA: Jones and Bartlett.

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**Table 11–9. Guidelines for Preparing Figures**

- Labeling table as a figure not a table
- Select appropriate type of figure based on data, statistical analysis and readability
- Title should be self-explanatory
- Refer to figure in text; number consecutively
- Check spelling and plotting of data
- Review publisher’s guidelines for overall size, resolution and specification: See instruction for authors
- Include legends if necessary, define abbreviations
- Update permission from copyright holder

Source: From Research and Medical Literature, by J. D. Blessing and J. G. Forister, 2012, Burlington, MA: Jones and Bartlett.
erally displays of quantitative information such as the flow of subjects through a process” (APA, 2010, p. 150). Maps usually present spatial information (APA, 2010).

Diagrams and maps are often created by using available computer programs, such as Microsoft Word and Microsoft Excel. There are a variety of diagrams and maps for displaying information. A V-diagram consists of 12 elements and is provided in Figure 11–1. Information Graphics by Harris (1999) is a comprehensive 448-page illustrated reference book. Yau (2011) has step-by-step guidelines for graphics from start to finish.

<table>
<thead>
<tr>
<th>CONCEPTUAL/THEORETICAL</th>
<th>METHODOLOGICAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FOCUS/RESEARCH:</strong></td>
<td><strong>VALUE CLAIMS:</strong></td>
</tr>
<tr>
<td><strong>WORLD VIEW:</strong></td>
<td></td>
</tr>
<tr>
<td>The general belief system motivating and guiding the inquiry.</td>
<td>Statements based on knowledge claims declare the worth or value of the inquiry.</td>
</tr>
<tr>
<td><strong>PHILOSOPHY:</strong></td>
<td><strong>KNOWLEDGE CLAIMS:</strong></td>
</tr>
<tr>
<td>The beliefs about the nature of knowledge and knowing guiding the inquiry.</td>
<td>Statements that answer the focus or research question(s) and are reasonable interpretations of the transformed records (or data) obtained.</td>
</tr>
<tr>
<td><strong>THEORY:</strong></td>
<td><strong>TRANSFORMATIONS:</strong></td>
</tr>
<tr>
<td>The general principles guiding the inquiry that explain why events or objects exhibit what is observed.</td>
<td>Tables, graphs, concept maps, statistics, or other forms of organization of records made.</td>
</tr>
<tr>
<td><strong>PRINCIPLES:</strong></td>
<td><strong>RECORDS:</strong></td>
</tr>
<tr>
<td>Statements of relationships between concepts that explain how events or objects can be expected to appear or behave.</td>
<td>The observations made and recorded from the events/objects studied.</td>
</tr>
<tr>
<td><strong>CONSTRUCTS:</strong></td>
<td><strong>EVENTS AND/OR OBJECTS:</strong></td>
</tr>
<tr>
<td>Ideas showing specific relationships between concepts, without direct origin in events or objects.</td>
<td>Description of the events(s) and/or object(s) to be studied in order to answer the focus/research question.</td>
</tr>
<tr>
<td><strong>CONCEPTS:</strong></td>
<td></td>
</tr>
<tr>
<td>Perceived regularity in events or objects (or records of events or events or objects) designated by a label.</td>
<td></td>
</tr>
</tbody>
</table>

These guidelines are for visualizing patterns over time, proportions, relationship differences, and spatial relationships.

The following guidelines for diagrams and maps have been described by Nichol and Pexman (2003):

- They must be referred to in the text.
- Information should be as simple as possible.
- Only relevant information should be included.
- Labels should be consistent.
- Use of color should be avoided because most print information is black and white.

General guidelines for evaluating diagrams and maps have been described by Nichol and Paxman (2003). These criteria are as follows: text diagrams and maps use a simple format, font sizes in diagrams and maps do not vary by more than four fonts, captions are typed double spaced on a separate page, lines are thick enough to be clear after reduction, similar diagrams or maps within the same manuscript should have a similar appearance, and diagrams and maps are referred to in the text using the same number(s) as in the caption(s). Detailed strategies for evaluating V-diagrams and concept maps have been developed by Gowin and Alvarez (2005).

### APA Format

All publications of the American Speech-Language-Hearing Association (ASHA) follow the style of the American Psychological Association that is in the *Publication Manual of the American Psychological Association* (2010a). A training supplement to the APA publication manual (APA, 2010b) is available.

The *Publication Manual of the American Psychological Association* (2010a) provides information about content and organization of research reports as well as rules for citing references and organizing a reference list. The manual also includes guidelines about punctuation, spelling, capitalization, headings, quotations, numbers, tables, and figures.

### References

All parts of every reference should be checked against the original publication. Every reference cited in the text should be listed; conversely, every reference listed should be cited in the text.

Mistakes in referencing are too common. These mistakes are usually related to plagiarism, use of secondary sources, and not reading the source.
is sometimes unintentional—that is, the author did not intend to plagiarize (DePoy & Gitlin, 2011). To avoid this potentially devastating mistake, one should be aware of the standards for referencing. All work written by another person, even if not directly quoted, must be cited. The use of secondary sources is not acceptable; that is, only primary sources should be cited. Another common error is the use of citations that have not been read.

**Personal Pronouns**

The use of personal pronouns, such as “I,” “my,” “you,” and “we,” should be avoided in research reports because of the appearance of subjectivity. However, several journals are beginning to break with this tradition (Polit & Beck, 2010).

**Avoid Bias**

Research reports should be objective and free from bias about gender, individuals, and groups (APA, 2010a; Hegde, 2010). APA (2010a) has specific guidelines to reduce bias in language: (a) describe at the appropriate level of specificity, (b) be sensitive to labels, and (c) acknowledge participation.

Racism and sexism are probably most common. Racist expressions should be avoided in describing participants and discussing results. Hegde (2003) advises that “if it is necessary to identify participants as belonging to a particular ethnic or cultural group, terms that are nonevaluative should be used. The best practice is to select the terms the group use to refer to themselves” (p. 479). Expressions such as culturally deprived or disadvantaged are also biased and imply that one culture is the standard against which other cultures are evaluated.

Sexism in language has a long history and may not be easily recognized. It is inherently discriminatory and suggests an unjustified bias against an individual or a group, usually women, but sometimes men (Schneider & Soto, 1989). Sexist language should be avoided in speaking and writing. There is nothing more out of contact with reality than believing women are not equal to men. One of the most misused personal pronouns is *he*, which is frequently used to refer to someone of unidentified gender, such as a child, client, customer, or student (Hegde, 2003). Indiscriminate use of personal pronouns may suggest that all authors, bankers, deans, department heads, doctors, editors, executives, fire fighters, lawyers, police officers, presidents, or professors are male. The noun *man* is often inappropriately used in ways that also imply sexism. For example, *chairman* of a department or organization. *Chairperson* or simply *chair* is appropriate. Apparently, there is some truth in Barzun's (1986) statement that “sex is a source of chaos in language generally, as it is in life” (p. 37).

In 1979, the ASHA Committee on Equality of Sexes adopted the American Psychological Association Guidelines for Unbiased Language. These guidelines provide specific suggestions and examples for gender-free writing. ASHA (1993) also provided guidelines for gender equality in language usage, which includes “being specific about gender when inclusion of this information is relevant and avoids generalization which may lead to stereotyping” (p. 42). Other useful references are *The Handbook of Nonsexist Writing* by Miller and Swift.

“Person-first” language should be used to describe individuals with disabilities; that is, put the person first, not the disability. According to APA (2010a), “the guiding principle for nonhandicapping language is to maintain the integrity of individuals as human beings” (p. 76). Table 11–10 provides a list of person-first phrases and those that should be avoided. Folkins (1992) described five principles for determining language used to describe individuals with disabilities. These principles are: (a) use person-first language, (b) determine disability versus handicap, (c) remember that everyone likes to think of themselves as normal, (d) avoid terms that project unnecessary negative connotations, and (e) do not overdo it.

There are other words that are misused. Huth and Shreen (1984) described some words as dehumanizing, for example, *case* and *patient* or *client*. Case is an episode or example of illness, injury, or disease. Patient or client is the person cared for by the speech-language pathologist or audiologist. Patients or clients are cared for, not cases. Another misused word is *subject* or *participant*. The term *participants* should be used because it acknowledges that participants have an active role in research studies (APA, 2010a).

### Permissions

The legal reason for seeking appropriate permission when using previously published materials is related to copyright law (APA, 2010a; Huth, 1999). Most publications are copyrighted; legal ownership is vested to the copyright holder. Permission for reproduction of published material must be obtained from the copyright holder, or the writer and publisher are at risk for legal action because of copyright infringement for unauthorized use of published materials. When in doubt about the need for permission, it is probably better to request it. Permission should be sought well in advance. Figure 11–2 provides an example of a letter requesting permission to

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**Table 11–10. Person First Language**

<table>
<thead>
<tr>
<th>Preferred</th>
<th>Avoid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children with cleft palate</td>
<td>Cleft palate children</td>
</tr>
<tr>
<td>Persons who stutter</td>
<td>Stutterers</td>
</tr>
<tr>
<td>Adults with aphasia</td>
<td>Aphasic adults</td>
</tr>
<tr>
<td>The lawyer who has dyslexia</td>
<td>The dyslexic lawyer</td>
</tr>
<tr>
<td>The client with hearing impairment</td>
<td>The hearing-impaired client</td>
</tr>
</tbody>
</table>

Source: Adapted from *The Language Used to Describe Individuals with Disabilities*, by J. Folkins. Available from http://www.asha.org/about/publications/journal-abstracts/submission/person_first.htm#one. Copyright 1992 by the American Speech-Language-Hearing Association. All rights reserved.
use copyrighted material. Most publishers have form letters or online forms for requesting permission to use copyrighted material. Additional information about permission is available elsewhere (APA, 2010a; Huth, 1999).

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Rewriting and revision are an important part of writing, because authors are usually asked to make revisions (Portney & Watkins, 2009). For most, even those who are experienced writers—writing is hard work. The first or rough draft should not be the final draft. Even experienced writers revise manuscripts several times. Often, the final draft is much different from the first or original draft (Hegde, 2003). Editing and rewriting are the steps to good writing. These steps are listed in Table 11–11.

Rewriting is not easy for several reasons. Self-editing is difficult, because it requires critical evaluation of one’s own writing (Hegde, 2003). Rewriting requires much focused attention to details and usually reorganization of the paper (Meline, 2006). Lack of time may also prevent revision of a paper. Another

<table>
<thead>
<tr>
<th>Table 11–11. Steps in Writing and Revising Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Write first draft</td>
</tr>
<tr>
<td>Hold first draft 1–2 weeks, then revise</td>
</tr>
<tr>
<td>Second draft</td>
</tr>
<tr>
<td>Distribute copies to co-authors and to colleagues</td>
</tr>
<tr>
<td>willing to critically review</td>
</tr>
<tr>
<td>Read draft, make notes on needed revisions</td>
</tr>
<tr>
<td>Get written recommendations for revisions from</td>
</tr>
<tr>
<td>co-authors and colleagues</td>
</tr>
<tr>
<td>Third draft same sequences as second</td>
</tr>
<tr>
<td>Later drafts</td>
</tr>
<tr>
<td>Continue reading to co-authors</td>
</tr>
<tr>
<td>Concentrate on content and structure</td>
</tr>
<tr>
<td>When satisfied with content, revise style</td>
</tr>
<tr>
<td>Review and revise large elements first</td>
</tr>
<tr>
<td>Paragraph lengths</td>
</tr>
<tr>
<td>External and internal sequence of paragraphs</td>
</tr>
<tr>
<td>Consider sentences: length; variety</td>
</tr>
<tr>
<td>Elements of sentences: clarify and phrasing;</td>
</tr>
<tr>
<td>modifying word choices</td>
</tr>
<tr>
<td>Read the revised text to identify and correct</td>
</tr>
<tr>
<td>“overlooked flaws”</td>
</tr>
</tbody>
</table>

problem is related to co-authors who may not be able to respond with suggestions for revision(s) (Huth, 1999). Rewriting and revising increased the likelihood of acceptance, although it is no guarantee. Some writers revise content, structure, and style of a paper at the same time; others revise content and structure first and then style. The content of a paper is more likely to determine whether it is accepted for publications than style. Writing style includes paragraph length and structure, paragraph linkage, sentence variety, and word choices. Further detailed information about writing style is available in Huth's (1999) *Writing and Publishing in Medicine*, *The Publication Manual of the American Psychological Association* (APA, 2010a), and the *American Medical Association Manual of Style* (AMA, 1998). Strategies for improving writing styles are writing from an outline, putting the first draft aside for a week or two before revising, and having colleagues critically review the draft (APA, 2010a; Huth, 1999).

### Translating Research Reports to Published Papers

Most research presented at professional meetings (platform presentations and poster presentations) is not subsequently published in peer-reviewed journals. There are two reasons for this failure to complete a full manuscript and submit it to a peer-reviewed journal. First, research accepted for presentation at a professional meeting might not stand up under peer review because it is flawed. Second, preparing a manuscript can be overwhelming, especially for beginning presenters.

Many of the reasons for a manuscript rejection can be avoided. Therefore, it is useful to be aware of reasons for rejecting manuscripts. Among the reasons are inappropriate or incomplete statistics, overgeneralization of results, inappropriate or substandard instrumentation, sample too small or biased, writing style flaws, insufficient problem statement, inaccurate or inconsistent data, and inadequate tables or figures (Pierson, 2004).

### Types of Research Reports

The organization and style of research reports are fairly consistent across different types of reports, although there is some variation. This section describes the major types of research reports: journal articles, theses and dissertations, textbooks, and presentations at professional meetings. Other types of research reports, systematic reviews, and reports to funding agencies are described elsewhere in Chapters 5 and 14, respectively.

### Journal Articles

Publication in a journal ensures wide circulation of research findings. Research reports are often substituted for publication after presentation at a professional meeting or they may be reduced reports of research findings from theses and dissertations. Many manuscripts are now submitted online. Manuscripts submitted to ASHA are submitted online via ASHA manuscript central, online manuscript submission, and review center (http://
When submitting a manuscript, it must include a cover letter requesting that the manuscript be considered for publication. The following information should be included in the cover letter:

- Request that the manuscript be considered for publication
- Verification that all authors have made contributions that justify authorship
- Affirmation of compliance with ethical considerations for protection of human and animal subjects in research
- Copy of permission granted to reproduce or adapt any copyright material
- Verification that the manuscript has not been previously published in the same, or essentially the same, form
- Notice that the manuscript is not currently under review elsewhere
- Disclosure of any real or potential conflicts of interest
- Author's professional address, telephone and fax numbers, and e-mail address

An example of a cover letter is shown in Figure 11–3.

Manuscripts submitted for publication in peer-review journals are reviewed and evaluated by peers who are experts in the subject area. Non-peer-reviewed journals do not require a critical review of manuscripts by peers with relevant expertise. There is a greater likelihood that the former contribute to the scientific knowledge base in speech-language pathology and audiology and have clinical relevance and credibility.

Journals in speech-language pathology and audiology publish several types of articles, which are described in the next section. ASHA journals provide descriptions of types of articles, at the end of each issue. Additional information about types of articles is also available in the American Medical Association Manual of Style (Iverson et al., 1993), AMA Information for Authors (2006), and the Publication of the American Psychological Association (APA, 2010a).

**Selecting a Journal**

Selecting a journal to submit a manuscript to is important and should be an early step in planning a paper. Steps in publishing a paper and possible outcomes are shown in Figure 11–4. In addition to ASHA journals, there are several other journals that publish information about speech-language pathology and audiology. Maxwell and Satake (1999) suggested the following questions be considered in selecting a journal:

1. Is the topic of the proposed paper within the scope of the journal?
2. Is the topic reported in the journal frequently or only rarely?
3. Would the journal be the best match of readers with that topic?
4. What formats does the journal accept?
5. Does the journal publish an “information for authors” page or issue similar information online?

Information relevant to these questions can usually be found on a journal's information-for-authors page in the journal or at its website. Huth (1999) suggests if one is uncertain about selecting the right journal, “then write or call the journal's editor” (p. 16). This should probably be
avoided, because many editors of journals do not encourage such questions because the information is usually available elsewhere, that is, in the instructions for authors.

It also may be helpful to consider the quality of the journals. This can be based on citation analysis, which is an examination of the frequency and patterns of citations of print materials. Citation analysis reflects the quality of journals in print. The impact factor is also used as an indicator of quality. It is the number of times a report is cited in a
given year divided by the total number of reports published. Higher values suggest greater credibility and greater and higher impact. There has been criticism about the impact factor relative to its use to evaluate individuals rather than journals and distribute research funds (Hirschbok, 2011; Schutte & Svec, 2007).

Black (2001) reported that the most important journals in communication disorders were the following:

- *Journal of Speech, Language, and Hearing Research*
- *Journal of the Acoustical Society of America*
- *Brain and Language Journal of Fluency Disorders Ear and Hearing Services in Schools*
- *Journal of Communication Disorders*

![Figure 11-4. Steps in publishing a paper.](image-url)
Categories of Reports in ASHA Journals

ASHA publishes original research reports, reviews, tutorials, special forums, letters to the editor, and general other categories of articles in their journals, namely, American Academy of Audiology, American Journal of Speech-Language Pathology, Journal of Speech-Language and Hearing Research, and Language, Speech and Hearing Services in Schools. Topics include subjects related to communication sciences and to the clinical practice of speech-language pathology and audiology.

Research reports are based on data, descriptive, ethnographic, or experimental studies. They also include case studies, which follow case study designs and require information about the reliability of the data reported. Reviews and tutorials are reports of interest to speech-language pathologists and audiologists that cover recent literature, clinical implications, and the need for further research. Special forums focus on a specific topic. Letters to the editor provide readers an opportunity to respond to recently published papers. Conversely, the author(s) of the report is given the opportunity to respond to a letter to the editor.

Theses and Dissertations

Some master's programs and most doctoral programs in speech-language pathology and audiology require completion of a written thesis (masters) or dissertation (doctoral). Theses and dissertations usually document a research project. Most universities have a required format for theses and dissertations. Examples of typical formats can be found in the APA Manual (2010a), Cone and Foster (2006), Davis (1997), and Polit and Beck (2010). A written research proposal, or prospectus, is a prerequisite for approval of either a thesis or dissertation (Maxwell & Satake, 2006). Prior to writing a prospectus, an advisor and a committee with relevant expertise are selected. A prospectus is important, because it is an action plan for the proposed research and may prevent future criticisms of the research by committee members. The content of theses and dissertations is often appropriate for publication, but the format and content usually require extensive revisions (ASHA, 2000). The format of theses and dissertations is similar to a book. The content is very detailed and more comprehensive than required for publication. In other words, the length must be reduced for publication. Some suggestions for reducing length are to narrow the focus to a specific topic, be specific in reporting the results, avoid problems common to beginning authors, omit information that is not appropriate for journal articles, and be selective in the use of references. The only requirement for publication is that enough information is provided to replicate the study.

The best time to publish data from a thesis or dissertation is when the information is “fresh” (Davis, 1999). It is easier to prepare a manuscript while the data are new, because it becomes increasingly difficult to do so as time passes. Furthermore, the impact of the research will be limited if not submitted for publication. For these reasons, some advisory committees suggest that the thesis or dissertation be in the format of a journal article or articles.
Textbooks

There are five types of publishers for textbooks: professional associations, trade publishers, university-affiliated centers, university presses, and vanity presses. Publishers differ in the review process, types of manuscripts published, marketing strategies, and contractual arrangements with authors (Luey, 1987).

Some professional associations, including ASHA, publish books. ASHA’s first book was published in 1954 (Paden, 1970).

There are two types of trade publishers: (a) general trade publishers who target nonfiction of interest to the general public and (b) specialized or professional publishers who focus on specific professional groups. Frequently, universities publish books in their specialty areas, although these publications are sometimes limited to research sponsored by the university. University presses are the primary outlet for book-length scholarly reports. They vary greatly in size; some publish hundreds of books a year, others publish less than one a year. Some university presses publish on a variety of subjects; others focus on a few areas. Vanity or subsidy publishers charge money to publish; in other words, if the author pays, the vanity press publishes the book. Obviously, there is no peer review. Therefore, publications by a vanity press carry no prestige and no merit for academic promotion or tenure.

The primary issue in selecting a publisher is whether they publish information about issues related to speech-language pathology and audiology. A book proposal or manuscript submitted to a publisher should be in proper form for the publisher. The author should obtain guidelines for preparing proposals and manuscripts from the publisher to which they plan to submit their manuscript.

University presses and trade houses usually base their publishing decisions on the opinions of reviewers. When a publisher receives a manuscript, it is read by an editor to determine if it is appropriate for the publisher and to assess the quality of the writing. A manuscript may be rejected on the basis of the editor’s reading, or it may be sent out to reviewers or referees. Publishers often request that reviewers complete questionnaires similar to the forms used for evaluating research reports. A manuscript may be accepted with revisions, or rejected.

Presentations at Professional Meetings

ASHA, AAA, state speech-language-hearing associations, and other professional organizations have meetings at which research is presented, either through oral reports or poster presentations. Presentation at a professional meeting is often linked with publication of similar information in a journal article. That is, oral reports or poster presentation may precede development of a manuscript for publication. Organizing and planning a presentation for a professional meeting and preparing a manuscript are similar up to a point. Presentations of research at professional meetings have several advantages: (a) there is usually less time between completion of the research and dissemination of the findings; (b) one receives immediate feedback; (c) it is interactive, that is, interaction between the author and audience; and (d) it allows networking with others who have similar interests and possible future research (Maxwell & Satake,
Presentations at professional meetings are less valued as scholarly products. Table 11–12 provides a comparison about oral reports and poster presentations. Submitting a presentation for a meeting is somewhat simpler than for submitting a manuscript to a journal. ASHA requires electronic submissions through the ASHA website. Some state organizations also require electronic submission, although others continue to use mail-in submission.

Usually, the professional organization announces a “Call for Papers” on its website or written materials (newsletter, journals) about 6 to 9 months before the meeting. The announcement includes instructions/requirements and deadlines for submission. If the submission is accepted, the author is required to appear at the meeting to make the presentation. Regardless of the type of proposed presentation, it must meet certain criteria to be accepted. ASHA’s program committee selects proposals based on the following criteria: strength of theoretical rationale, originality of research, strength of research design, credibility of data, integration of findings, and overall clarity.

**Table 11–12. Comparison of Oral Reports and Poster Presentation**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Oral Reports</th>
<th>Poster Presentations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials</td>
<td>Slides, computer, notes</td>
<td>Poster, Velcro</td>
</tr>
<tr>
<td>Subject</td>
<td>Justify objectives, refer to literature, support; methods and results</td>
<td>Justify objectives; refer to literature, support methods and results</td>
</tr>
<tr>
<td>Preparation</td>
<td>Formal speech to adhere to time limits</td>
<td>Answers to expected questions</td>
</tr>
<tr>
<td></td>
<td>Prepare early; practice, review, revise</td>
<td>Prepare early, construct posters, review, revise</td>
</tr>
<tr>
<td>Style</td>
<td>More formal; contact one to many</td>
<td>Relatively informal; contact one to one or a few</td>
</tr>
<tr>
<td></td>
<td>Speaker standing, audience seated</td>
<td>Both speaker and audience standing</td>
</tr>
<tr>
<td>Moderator</td>
<td>Moderator introduces, buffer audience, keep time</td>
<td>No moderator, direct control, no buffer</td>
</tr>
<tr>
<td>Time</td>
<td>Limited</td>
<td>Flexible</td>
</tr>
<tr>
<td>Audience</td>
<td>Captive, not likely to leave</td>
<td>Free, only interested stay</td>
</tr>
<tr>
<td>Discussion</td>
<td>Declamation from speaker with short questions</td>
<td>Chiefly questions and answer or conversational discussion</td>
</tr>
<tr>
<td>Handouts</td>
<td>Possible</td>
<td>Helpful</td>
</tr>
</tbody>
</table>

Oral Reports

Oral reports usually last between 10 and 15 minutes and are followed by a question-and-answer period. These presentations frequently use slides and occasionally handouts. Organization of oral reports is similar to that of a journal article (Silverman, 1998). However, there are differences related to length, less detail because of limited time, style, less formal and more redundant, and language—less formal and more conversational.

General characteristics of an oral report are presented in Table 11–12. Additional guidelines include do not “wing it” or read the paper, and whenever possible, use appropriate visual supplements to present complex information (APA, 2010a). In addition, the skilled presenter: (a) captures the audience’s attention at the very beginning; (b) clearly states the objectives of the presentation; (c) concentrates on concepts, not confusing details; (d) presents important concepts in different ways; (e) uses slides or less complexity than published tables and figures; and (f) prepares for a question-and-answer period.

A first-time presenter is usually more anxious than an experienced presenter. Also to be considered is the size of the audience, typically as the larger the audience, the greater the anxiety. Presenters should also be aware of other factors that affect oral presentations. These factors include the:

- quality of the presenter's speech and manner;
- physical or nonverbal aspects of the presenter (appearance, eye contact, facial expression, gesture enthusiasm, dress, grooming);
- confidence and poise; and
- knowledge of information related to effective presentations (Goldfarb & Serpanos, 2009).

Poster Presentations

Poster sessions have become a major format for presenting research at a professional meeting. A poster session at a professional conference consists of several simultaneous visual displays of research studies. Attendees circulate around the posters during the session (Polit & Beck, 2011). Poster presentation may be formal or open. In formal poster presentations, the author presents an overview of the poster with a moderator who guides discussion about each poster in a symposium format. The author is present at an open session to answer attendee's questions. Most organizations have specific instructions for poster presentations. Generally, the title is at the top followed by author(s) and affiliation. The introduction is in the upper left corner and the conclusions in the right lower corner. Traditional posters have the advantage of permitting simultaneous sessions within the same time period. Poster presentations allow participants to select information of interest, receive substantial information within a short period of time, and avoid posters dealing with topics of less interest to them. For some presentations, poster presentations are less threatening (Maxwell & Satake, 2006). Traditional poster presentations also have disadvantages. First, preparing posters requires more effort and expense than preparing for an oral report. Second, posters, like wedding dresses, are often not used subsequently. Third, a presentation can be seriously disadvantaged if placed in an awkward, crowded location or in poor lighting conditions (Simmonds,
1984). It might be best, if possible, to check the room in advance when doing a poster presentation (Deep & Sussman, 1990). Problems identified early may be resolved. An example involves placing posters on a crowded stage, which was inaccessible to participants in wheelchairs or on crutches. Fourth, posters at times can be difficult to transport (Bordens & Abbott, 1988).

In recent years, more poster presentations have been electronic. The primary differences between traditional and electronic poster presentations are related to the presence of an author and attendees. These and other differences are compared in Table 11–13.

General guidelines for posters according to Blessing and Forister (2011) are as follows:

- Keep the poster simple.
- Include only enough information to support the conclusions.
- Use tables and figures; less text is better.

Templates are available for preparing posters as well as computer-generated programs such as Power Point, Microsoft Excel, and Statistical Programs for the Social Sciences (SPSS). Leedy and Ormrod (2010) provided detailed descriptions of Microsoft Excel and SPSS. Nichol and Pexman (2003) provided guidelines for the content and style of posters. Considerations related to content were to consider the main point, key points of information for attendees, crucial details, methodology, the most important results, and realistic conclusions. Style was related to available space: one large poster or a poster consisting of small panels.

### Visual Supplements

Visual supplements are essential to oral presentations and posters. A visual supplement is any illustration used to clarify and analyze information in written reports and oral presentations. The most common visual supplements are

| Table 11–13. Characteristics of Traditional and Electronic Poster Presentations |
|---------------------------------|-----------------|
| **Access**                      | **Live**        |
| **Audience**                    | **Restricted**  |
| **Schedule**                    | **Fixed**       |
| **Frequency**                   | **Nonrepeatable**|
| **CEUs**                        | **Inconsistent**|
| **Duplication**                 | **Impossible**  |
| **Author and audience**         | **Present**     |
| **Access**                      | **Direct**      |
| **Electronic**                  | **Remote**      |
|                                | **Widespread**  |
|                                | **Flexible**    |
|                                | **Repeatable**  |
|                                | **Consistent**  |
|                                | **Possible**    |
|                                | **Not present** |
|                                | **Indirect or direct** |
tables and figures, which were discussed earlier in the chapter under the section on Format of Research Reports. Handouts may be used to supplement oral reports and poster presentations. They should include the title of the report, the authors' name and affiliation, and where and when presented. PowerPoint slides or a mini poster are frequently used as handouts. It is recommended that handouts for oral reports be distributed prior to the presentation, not while the presentation is occurring. Instead of, or in addition to handouts, some presenters distribute diskettes containing information about the presentation (Nichol & Pexman, 2003). However, this can be expensive.

Guidelines for visual supplements are listed in Table 11–14. Criteria for visuals are simplicity, legibility, unity, quality, and feasibility. Visuals should be cohesive and uniform with other visual supplements and with the written or spoken words. Production and presentation of visual supplements should be possible with available materials, facilities, and time (Davis, 1997). The Publication Manual of the American Psychological Association (2010a) provides extensive guidelines about traditional tables and figures.

### Evaluating and Reviewing Research Reports

Research reports should be read critically; just because a report has been published does not ensure its quality. The published research varies in both quality and value. Peer-reviewed journals ensure that reports “have received scrutiny by experts, and it maximizes the likelihood that serious errors of fact, reasoning, or method will be detected and eliminated” (ASHA, 2000). Another consideration is the impact factor, which indicates how many times a journal's paper is cited in other journals (Huth, 1999). Some journals provide this information at the end of reports.

Readers are responsible for critically reviewing research reports and deciding their value. Critically evaluating and reviewing research reports is a skill that requires knowledge and experience. The most important considerations are scientific relevance, soundness of methodology, and the author(s). Several guidelines for evaluating research reports are available (APA, 2010a; Hegde, 2010; Polit & Beck, 2010; Schiavetti, Metz, & Orlikoff, 2010; Silverman, 1998). These guidelines can also be used to evaluate oral reports and poster presentations.

### Table 11–14. Guidelines for Visual Supplements

- Make them simple
- Make the images or letters large enough to be seen clearly
- Make a trial run long enough before the presentation to permit you to revise the visual aids if needed
- Coordinate the visual aids with the oral report or written text so that the audience is not distracted and the visual aid is relevant to the oral report or text
- Prior to a presentation that uses visual aids, be sure that any needed equipment is available and operational

Evidence-based practice uses specific criteria to evaluate the quality of evidence. The criteria differ according to whether the evidence is related to decisions about diagnosis or treatment (ASHA, 2005).

These guidelines can also be used to evaluate oral presentation and posters. There are also guidelines with specific focus, such as the type of research, qualitative or quantitative (Leedy & Ormrod, 2010; McMillan, 2004), clinical services, diagnosis or treatment (ASHA, 2005), and level of evidence (Haynes & Johnson, 2009; Jewell, 2011).

Dollaghan (2007) developed brief summaries of evidence for a variety of topics:

- **CATE**—Critical Appraisal of Treatment Evidence
- **CADE**—Critical Appraisal of Diagnostic Evidence
- **CASM**—Critical Appraisal of Systemic Review or Meta-Analysis
- **CAPE**—Checklist for Appraising Patient/Practice Evidence
- **CAPP**—Checklist for Appraising Patient Preferences

Answers to questions can be used for evaluating reports (Blessing & Forister, 2011). These questions are listed in Table 11–15.

**Table 11–15. Questions to Ask and Answer About Research**

- What is the source of the report?
- Was the publication peer-reviewed?
- Who are the authors and their affiliations?
- What was the main subject of the study?
- What was the problem(s) investigated?
- What was the purpose or rationale for the study?
- Who or what constituted the sample or populations?
- What was the design?
- What statistical analyses were used?
- Are the results clear?
- Did the results answer the identified question(s)?
- Are the conclusions consistent with the design and analysis?
- Are the results consistent or contradictory with the results of similar studies?
- What do the results mean relative to clinical practice, and patients?
- Can the results be applied to your research or clinical practice?

Source: From Research and Medical Literature, by J. D. Blessing and J. G. Forister, 2012, Burlington, MA: Jones and Bartlett.

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CATs

Two methods have been suggested for brief critical reevaluations of the literature. Critically Appraised Topics (CATS) and Evidence-Based Communication Assessment and Intervention (EBCAI) structure appraisal abstracts.

A CAT is a brief summary of clinical quality and appraisal of the evidence that typically begins with a clinical bottom line that is a recommendation about use and application (Polit & Beck, 2010). There are several templates for CATs available online. CATS have two distinguishing characteristics: (a) based on specific clinical questions and developed
by using the PICO format and (b) inclusion of the bottom line or conclusions about the value of the findings. The major advantage of CATs is the potential to improve patient care. Other advantages include a standard format, specific/focused questions, brevity, and possibly reducing the amount of time for critical review. Disadvantages are short-term use as new evidence becomes available, limited access to the literature, based on only one or two studies, and variable skills and methods of analysis (EBCAI). Structured appraisal abstracts can be used to evaluate evidence (Lackey & Ogletree, 2012). These abstracts are published in the peer-review journal, Evidence-Based Communication Assessment and Intervention. EBCAI abstracts can be used to evaluate credibility and determine the potential for application to clinical practice.

**Summary**

There are several reasons for reporting research. Among these reasons are ethical responsibility to contribute and disseminate professional information as an indicator of institutional quality as well as recognition and academic survival.

It is difficult to report research without effective time management. Research is frequently not reported because of failure to make time to write and revise reports. There are, however, several strategies that can facilitate managing time for reporting research.

Research is incomplete until the reports have been disseminated at a professional meeting, as a written report, or both. The form and content of oral and written research reports are similar, although there are differences primarily in manner of presentation and length. Written reports are usually longer. There are different types of written reports: journal articles, theses and dissertations, and textbooks. Evaluating and reviewing research reports is an important professional responsibility. Critical review and evaluation of research reports are an integral part of evidence-based practice, which emphasizes the application and use of research evidence to make clinical decisions.

**DISCUSSION QUESTIONS**

1. What distinguishes the unpublished from the published writer?
2. What are the reasons for reporting research?
3. Define “publish or perish.”
4. Why is research not reported?
5. Explain the myths about research reports.
6. Why and how can these myths be eliminated?
7. How can time management facilitate research productivity?
8. What is the difference between “busyness” and binging?
9. Why should a timetable be developed and implemented for reporting research?
10. How can computer technology be used to increase productivity?
11. Why do single-subject research designs require less time?
12. Describe procrastination.
13. How can procrastination affect research?
14. How can procrastination be avoided or reduced?
15. How can a research log be used to determine order of authorship?
16. List and briefly describe the major sections of research reports.
17. What is a structured abstract?
18. Compare structured abstracts for original and review of tutorial reports.
19. Why are key words important?
20. Why do professional journals require the authors to disclose their contributions to a report?
21. What is the difference between tables and figures?
22. Why are tables and figures valuable to research reports?
23. What is meant by writing style?
24. How is writing style developed?
25. What is APA format?
26. Why are mistakes in referencing so common?
27. How can mistakes in referencing be eliminated or reduced?
28. What is biased language? How can it be avoided?
29. What is person-first language?
30. When and why should one request permission to use previously published materials?
31. What are the steps in rewriting and revising a report?
32. Why are rewriting and revising challenging?
33. List and briefly describe the types of research reports.
34. What is a cover letter? What information is included in a cover letter?
35. Define peer review. Why is peer review important?
36. How does one select an appropriate journal to submit a manuscript?
37. What types of articles are published in ASHA journals?
38. Briefly describe the different types of textbook publishers.
39. What is a vanity press? What are the limitations?
40. What are the advantages and disadvantages of presenting research at professional meetings?
41. What is a “call for papers”?
42. What are the advantages and disadvantages of poster presentations?
43. What are the differences between traditional and evidence-based poster presentations?
44. How can visual supplements be used in written reports and oral presentations?
45. Why should published research reports be evaluated and reviewed?
46. How can research reports be reviewed?
47. Which ASHA journal has the highest rate of acceptance for manuscripts submitted? The lowest? What are the implications?
48. What are the guidelines for tables and figures? Why is it important to be familiar with these guidelines?
49. What are the advantages and disadvantages of presenting research findings at professional meetings?
50. What are the major components of a V-diagram?
51. What information should be included in a cover letter when submitting a manuscript?
52. What factors can affect presentation of research findings at professional meetings?
53. What are CATs? What are the different types of CATs?
54. How can research be evaluated?
55. Why should research be evaluated?
56. What factors influence poster presentation?
57. Compare traditional and electronic poster presentation. Which would have the most advantages? Why?

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Chapter Outline

- Evaluation Issues
- Tests
- Treatment
- Summary
- Discussion Questions
- References
LEARNING OBJECTIVES

Upon completion of this chapter, the reader will be able to:

- Understand reasons for evaluating tests and treatments
- Distinguish between decisions based on evidence and opinions
- Apply specific criteria to evaluation of tests and treatments
- Define terms related to testing: true/false negative, true/false positive, specificity, and sensitivity
- Distinguish between the types of treatment outcome research
The evaluation of tests and treatments involves both qualitative and quantitative research—that is, multimethod research. In speech-language pathology and audiology, data are collected about individuals for diagnosis and treatment. Options for data collection include tests, checklists, quality-of-life measuring, observation, and various documents (case history, medical charts, and educational records). Evaluating diagnostic tests and treatment outcomes is a type of research relevant to the clinical practice of speech-language pathology and audiology. This type of research involves

- being skeptical,
- considering the source of the information,
- distinguishing between cause and effect,
- differentiating observation from inference,
- ensuring that describing a product is not only to sell it, and
- recognizing that an example is not evidence for what is claimed (Lum, 2002).

Evidence-based practice and ethics are important in evaluating tests and treatments. It is a method of using the highest available level of evidence to make clinical decisions.

Evidence-based tests and treatments are an ethical responsibility. The present Code of Ethics of the American Speech-Language-Hearing Association (ASHA, 2016) contains several related references to ethical research. Moreover, selection of tests and treatments is significant in terms of cost and benefit.

Speech-language pathologists and audiologists should be discerning consumers of diagnostic and treatment resources. A test or treatment should be selected on the best available evidence. Obsolete and outdated evaluation and treatment methods should be discarded. New diagnostic and treatment products constitute a growing market that may be heavily promoted because of high profit margins (Lum, 2002).

### Evaluation Issues

Speech-language pathologists and audiologists should assume responsibility for critical review of diagnostic tests and treatment materials to avoid sham products being used, because there is great variability in the quality of tests and treatments. With any test or treatment, speech-language pathologists and audiologists should always ask, “What is the evidence?”

An evaluation of diagnostic tests and treatment methods based on opinion is incompatible with evidence-based practice. All sources of evidence are not equal—that is, bad to poor evidence that is low (weak) to high (strong) level. Opinion is considered to be weak evidence (Reilly, 2004). Unfortunately, many speech-language pathologists more frequently use clinical experience and opinion than research or clinical practice guidelines to make clinical decisions (Zipoli & Kennedy, 2005). Several trends have decreased the emphasis on general psychometric checklists for evidence about sensitivity and specificity of tests (Pena, Spaulding, & Plante, 2006). Opinion and blind acceptance should not be the basis for making clinical decisions. Speech-language pathologists and audiologists
should be skeptical and admit to not knowing unless there is sound evidence (Lum, 2002).

Tests

Tests are used by speech-language pathologists and audiologists for a variety of reasons. They may be used to establish whether or not someone has a speech-language-hearing problem, to monitor response to treatment, to make informed treatment decisions, to assess progress, or to assess the risk of developing a speech-language-hearing problem (Mart, 1999).

The primary purpose of any test is to determine whether or not someone has a speech-language-hearing problem. A good test is one that can correctly detect that a problem is really present (true positive) or that someone does not have a problem (true negative). Test results can be misleading if there is a high false-negative or false-positive result (Mart, 1999). In other words, low false-positive and false-negative results are more accurate.

Haynes and Pindzola (1998) believe uncritical acceptance of tests is “probably the rule rather than the exception” (p. 83). Test accuracy is based on sensitivity and specificity. The sensitivity of a test is the proportion of people who actually have the problem who had a true positive test—that is, accuracy of the test in identifying people with the problem. It is further defined as the probability of a diagnostic test finding a problem among those who have the problem and those people who do not (Dollaghan, 2004). Sensitivity and specificity can be calculated as follows (Portney & Watkins, 2009):

\[
\text{Sensitivity} = \frac{\text{true positives}}{\text{true positives} + \text{false negatives}}
\]

\[
\text{Specificity} = \frac{\text{true negatives}}{\text{false negatives} + \text{true positives}}
\]

The composition of normative groups should be considered in interpreting test scores and making diagnostic decisions. Pena, Spaulding, and Plante (2006) reviewed descriptions of the normative groups for 32 child language tests. If the normative group includes a mixed sample of normal and language-impaired children, measurement precision decreases for absolute score interpretation but may increase for relative interpretations.

Thus, clinicians should be aware of two principles: (a) determine if test characteristics are appropriate for interpretation and (b) a single test may not support multiple diagnostic purposes.
Another consideration in evaluating tests is the **predictive value**. The predictive value of a test has practical implications for predicting actual clinical outcome based on test results (Maxwell & Satake, 2006). There are two major components or predictive values of a diagnostic test: (a) predictive value positive and (b) predictive value negative. Predictive value positive ($PV^+$) is the probability that a person has a problem given the test result is positive. Predictive value negative ($PV^-$) is the probability that a person does not have a problem given that the test result is negative. These values are calculated as (Portney & Watkins, 2009):

\[
PV^+ = \frac{\text{true positives}}{\text{true positives} + \text{false negatives}}
\]

\[
PV^- = \frac{\text{true negatives}}{\text{true positives} + \text{false negatives}}
\]

Many tests have tables for converting raw scores into age and/or grade equivalent scores. These scores, according to Haynes and Pindzola (1998), “are the least useful and most dangerous scores to be obtained from standardized tests because they lead to gross misinterpretation of a client’s performance” (p. 72). Age- and grade-equivalent scores are the least useful types of scores, because they tend to distort performance and lead to misinterpretations by both consumers and professionals. Nonetheless, these scores are often used to interpret test performance and make diagnostic decisions. Furthermore, many state departments of education mandate the use of age-equivalent scores for making decisions about eligibility for services (Haynes & Pindzola, 2012).

There are two basic types of review for evaluating diagnostic tests and treatment methods: traditional and evidence based. There are major differences between traditional and evidence-based reviews. The former tend to be subjective and have vague criteria. The latter involve application of specific criteria for evaluation, diagnosis, and treatment. This reduces the risk for bias. ASHA (2018) has provided examples of levels of evidence hierarchies for both diagnosis and treatment as presented in Tables 12–1 and 12–2.

Some evaluation strategies have multiple purposes. For example, ASHA (2006) has a series of questions for evaluation, treatment procedures, purchasing a product, or attending an educational program. These questions can also be used for evaluating tests. Table 12–3 lists ASHA’s questions.

Another method of evaluation is to differentiate between science and pseudoscience characteristics of a test or treatment. These criteria are shown in Table 12–4. Several authors have described criteria for evaluating tests (Haynes & Pindzola, 2012; Hutchinson, 1996; Lum, 2002; Mertens, 2005; Shipley & McAfee, 2009; Stein & Cutler, 1996). Basically, these criteria are related to the test manual, descriptive statistics, and normative sample. Hutchinson presented a series of 20 questions to consider in reviewing a test manual.

Haynes and Pindzola (1998) suggested obtaining a test for evaluation, because test brochures and catalogs may not provide adequate information. Furthermore, “if possible, order a test for appraisal, and pay for it only if you are satisfied with its psychometric adequacy and what it will actually tell you about a client” (p. 77). Therefore, psychometric adequacy should be evaluated on the basis of identifiable criteria.
### Table 12–1. Examples of Levels-of-Evidence Hierarchies for Diagnostic Studies

<table>
<thead>
<tr>
<th>Level</th>
<th>Type of Diagnostic Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>Systematic review or meta-analysis of 1c studies (high-quality trials)</td>
</tr>
<tr>
<td>1b</td>
<td>Independent replication of a 1c study</td>
</tr>
<tr>
<td>1c</td>
<td>A diagnostic study having a representative and consecutive sample and appropriate reference standard (e.g., gold-standard test) in an independent blind comparison demonstrating validated specificity and sensitivity that are almost absolute</td>
</tr>
<tr>
<td>2a</td>
<td>Systematic review or meta-analysis 2b diagnostic studies</td>
</tr>
<tr>
<td>2b</td>
<td>A cohort study with a good reference standard</td>
</tr>
<tr>
<td>3a</td>
<td>Systematic review or meta-analysis 3b studies</td>
</tr>
<tr>
<td>3b</td>
<td>A diagnostic study having a nonconsecutive sample or a consistently applied reference standard</td>
</tr>
<tr>
<td>4</td>
<td>One or more case-control study</td>
</tr>
<tr>
<td></td>
<td>Expert opinion without explicit critical appraisal</td>
</tr>
</tbody>
</table>

*Note:* Levels 1 through 3b could be further fractioned by experimental precision. For example, level 2a could become 2a(+) and 2a(−) for grouping high- and low-precision experiments respectively.


### Table 12–2. Examples of Levels-of-Evidence Hierarchies for Treatment Studies

<table>
<thead>
<tr>
<th>Level</th>
<th>Type of Treatment Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>Systematic reviews or meta-analyses of high-quality randomized controlled trials</td>
</tr>
<tr>
<td>1b</td>
<td>High-quality randomized controlled trials</td>
</tr>
<tr>
<td>2a</td>
<td>Systematic reviews or meta-analyses of high-quality nonrandomized controlled trials</td>
</tr>
<tr>
<td>2b</td>
<td>High-quality nonrandomized controlled trials</td>
</tr>
<tr>
<td>3a</td>
<td>Systematic reviews of cohort studies</td>
</tr>
<tr>
<td>3b</td>
<td>Individual cohort study or low quality randomized controlled trials</td>
</tr>
<tr>
<td>4</td>
<td>Clinical outcome studies</td>
</tr>
<tr>
<td>5a</td>
<td>Systematic review of case-control studies</td>
</tr>
<tr>
<td>5b</td>
<td>Individual case-control studies</td>
</tr>
<tr>
<td>6</td>
<td>Case-series</td>
</tr>
<tr>
<td>7a</td>
<td>Expert opinion without explicit critical appraisal</td>
</tr>
</tbody>
</table>

### Table 12–3. ASHA’s Questions for Evaluating Treatments, Procedures, Products, or Programs

| Stated uses: | What are the stated uses of the procedure, product, or program? |
| Population: | To which client/patient population does it apply? Is there documented evidence that it is valid for use with a specific population? |
| Generalization: | To which other populations does it claim to generalize? |
| Outcomes: | Are outcomes clearly stated? |
| Publications: | Are there publications about this procedure, product, or program? Is the information published in a peer-reviewed journal? Is promotional material the only published source of information? |
| Peer-reviewed: | Is there peer-reviewed research that supports or contradicts research: the stated outcomes or benefits? |
| Developers: | What is the professional background of the developers of the procedure/product/program? |
| Availability: | Are there similar procedures, products, or programs currently and cost: available? How do they compare in performance and cost? |
| Experience: | Have you talked with others who have experience with this product, procedure, or program? What was their expertise? Have you considered posting a query on ASHA’s interactive member forum on its website? |
| Scope of Practice: | Is it within my profession’s Scope of Practice? Is it within my personal scope of practice (i.e., personal training, competence, experience) to use this procedure, product, or program? |
| Information/ Policies: | Have you checked to see if there are any ASHA statements or guidelines on this topic? |
| Cost: | Based on the factors above, is the cost reasonable and justifiable? |

Dollaghan (2004) described criteria from the evidence-based practice literature to use in evaluating diagnostic tests, which are presented in Table 12–5. Three evidence-based propositions were considered:

- The opinions of expert authorities, singly or in groups, such as consensus panels, should be viewed with skepticism and discounted entirely when they contradict evidence from rigorous scientific studies.
- Not all research is relevant to decisions about clinical practice.
- Being judgmental about evidence is a goal, not a character flaw.

Another consideration is reporting diagnostic findings that involve both quantitative and qualitative data, namely,
multimethod research. A worksheet for organizing and interpreting diagnostic findings is shown in Figure 12–1. The worksheet can be used as the final report or as the prerequisite to a narrative report. The worksheet serves as a reminder that diagnosis of communication disorders is a type of research that combines both quantitative and qualitative data.

Table 12–5. Checklist of Questions for Evaluating Evidence of a Diagnostic Measure

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
| ☐   | ☐  | Was the measure compared to a gold standard (GS)?
| ☐   | ☐  | Was the gold standard valid, reliable, and reasonable?
| ☐   | ☐  | Were both measures administered to all participants?
| ☐   | ☐  | Were participants identified prospectively?
| ☐   | ☐  | Did participants include individuals with and without the disorder of interest?
| ☐   | ☐  | Did participants exhibit a range of severity levels?
| ☐   | ☐  | Did participants include some with confusible symptoms?
| ☐   | ☐  | Were the two measures administered independently, by different examiners?
| ☐   | ☐  | Were examiners blinded to performance on the other test?
| ☐   | ☐  | Were examiners blinded to other patient information?
| ☐   | ☐  | Was the positive likelihood ratio in at least the intermediate range ($\geq 4.0$)?
| ☐   | ☐  | Was the negative likelihood ratio in at least the intermediate range ($\geq 0.4$)?
| ☐   | ☐  | Was the confidence interval reasonable narrow?
| ☐   | ☐  | Is the new measure feasible in usual clinical practice?
| ☐   | ☐  | Does the new measure offer a significant advantage over the gold stand?  

Treatment outcome is a broadly defined term that refers to change, or the lack of it, that may occur as a result of time, treatment, or both (Golper et al., 2001). Moreover, treatment outcomes are generalized, maintained, indirect, and clinically valid results of treatment (Hegde, 2003). A distinction is frequently made between efficacy, effectiveness, and efficiency of treatment. The following questions can be used to make this distinction:

- Has the treatment been shown to be beneficial in controlled research, that is, ideal conditions (efficacy)?
- Is treatment useful in applied clinical settings (average conditions), and if so, with what patients and under what circumstances (effectiveness)?
Is treatment efficient (minimal waste, expense, and unnecessary effort) in the sense of being cost effective relative to other alternative interventions (efficiency) (Golper et al., 2001; Maxwell & Satake, 2006).

There are major differences between various types of treatment research. Uncontrolled or nonexperimental research is designed to document improvement such as case studies (Hegde, 2003). Controlled treatment research, or experimentation, is designed to establish a cause-and-effect relationship between treatment (independent variable) and positive changes (dependent variable). Controlled treatment research is used to determine effectiveness. It requires either a single subject or group experimental design. Directly replicated research or experimentation is designed to determine if results (improvement or effects) in an uncontrolled or controlled study can be replicated when there is no change in treatment, setting, or clinicians; the only change is new clients.

Two other variations of treatment studies warrant consideration: retrospective (past) and prospective (current) (Lum, 2002). Retrospective studies involve examination of existing case records, which has limitations if the records are incorrect or inaccurate. Retrospective studies can be completed quickly and economically because they are based on existing data (Maxwell & Satake, 2006). Prospective means the data needed for study are determined before they are collected. In prospective studies, current information is used to predict future status.

Silverman (1998) provided a series of questions for evaluating treatment that focused on space and time. These questions are listed in Table 12–6. To assess treatment outcomes with a single client,

<table>
<thead>
<tr>
<th>Table 12–6. Questions for Evaluating Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>— What are the impacts of the treatment on specific behaviors that contribute to a client's speech-language problem at given points in time?</td>
</tr>
<tr>
<td>— What are the effects of the treatment on other aspects of a client's speech-language at given points in space-time?</td>
</tr>
<tr>
<td>— What are the effects of the treatment on a client other than those directly related to speech-language at given points in space-time?</td>
</tr>
<tr>
<td>— What are the client's attitudes about the treatment and its impact on his or her speech-language and other behaviors at given points in space-time?</td>
</tr>
<tr>
<td>— What are the attitudes of a client's clinician, family, friends, and others toward the treatment and toward its effect on the client's speech-language and other attributes of behavior in space-time?</td>
</tr>
<tr>
<td>— What investment is required of client and clinician at given points in space-time?</td>
</tr>
<tr>
<td>— What is the probability of relapse following termination of treatment?</td>
</tr>
</tbody>
</table>

Lum (2002) described a number of factors to consider in evaluating treatments, as presented in Table 12–7. These factors utilize elements related to single-subject research design. Robey and Schulz (1998) and Robey (1998, 2004) described a five-phase outcome model for clinical outcome research that involves developing a treatment; testing its efficacy; testing its effectiveness; examining its efficacy; and determining its cost effectiveness, cost benefit, and cost utility. The model is presented in Figure 12–2.

Additional measures of treatment outcome include traditional instrumental and behavioral data, cost-benefit analysis, and quality-of-life scales. Integrated data systems linking these data produce comprehensive reports that provide better information about treatment outcomes. Further information related to treatment outcome research is available in books edited by Frattali (1998), Law (2002), and Schlosser (2003).

**Table 12-7. Factors to Consider in Evaluating Treatment**

<table>
<thead>
<tr>
<th>Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>— Specify the nature of the client’s problem</td>
</tr>
<tr>
<td>— Deciding on the time frame for evaluation</td>
</tr>
<tr>
<td>— Selecting the behaviors to be changed</td>
</tr>
<tr>
<td>— Deciding on control and treatment behaviors and tasks</td>
</tr>
<tr>
<td>— Deciding on the format of the treatment tasks</td>
</tr>
<tr>
<td>— Deciding on the content of the treatment task items</td>
</tr>
<tr>
<td>— Deciding on the staging of treatment</td>
</tr>
<tr>
<td>— Deciding on the strategy for changing behavior</td>
</tr>
<tr>
<td>— Deciding which tasks to use to measure performance</td>
</tr>
<tr>
<td>— Deciding on the length of the baseline phase</td>
</tr>
<tr>
<td>— Deciding on the number of data measurements</td>
</tr>
<tr>
<td>— Deciding whether to use probes or continuous measurement</td>
</tr>
<tr>
<td>— Defining time intervals for reassessment and maintenance</td>
</tr>
<tr>
<td>— Stating predictions about generalization effects</td>
</tr>
<tr>
<td>— Developing treatment tasks</td>
</tr>
<tr>
<td>— Documenting decisions in treatment and obtaining the client’s response</td>
</tr>
</tbody>
</table>

DISCUSSION QUESTIONS

1. What type/s of research is/are involved in evaluating tests and treatments?
2. Why should speech-language pathologists and audiologists be discerning consumers of tests and treatments?
3. Why are clinical decisions based on opinion(s) incompatible with evidence-based practice?
4. How can false-negative and false-positive results affect clinical decisions?
5. Explain the importance of specificity and sensitivity to test accuracy.
6. What is the difference between positive and negative predictive values?
7. Differentiate between traditional and evidence-based review for evaluating tests and treatments.
8. How do science and pseudoscience differ?
9. What are the criteria for pseudoscience?
10. What are the primary criteria for evaluating tests?
11. What are the evidence-based criteria for evaluating tests?
13. Describe the major differences between various types of treatment research.
14. What is the difference between retrospective and prospective studies?
15. What factors should be considered in evaluating treatment with a single client?
16. Describe a five-phase model for clinical outcome research.

Summary

Careful evaluation of tests and treatments is a fundamental responsibility for justifying clinical services. There are a variety of methods for evaluating tests and treatments, either individually or collectively. Clinical decisions are too often made on the basis of opinion rather than critical review and the best available research evidence. Clinical services are enhanced by evidence-based decisions as opposed to beliefs and opinions.

References


# Evidence-Based Practice: Application of Research to Clinical Practice

## CHAPTER OUTLINE

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<thead>
<tr>
<th>Defining Evidence-Based Practice</th>
<th>Developing and Implementing Evidence-Based Practice</th>
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</thead>
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<td>Evidence-Based Practice: Terms and Definitions</td>
<td>Organizational Support for Evidence-Based Practice</td>
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<td>Resources for Evidence-Based Practice</td>
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<tr>
<td>Information Literacy</td>
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<tr>
<td>Clinical Trials</td>
<td>Communicating Evidence</td>
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<td>Advantages and Disadvantages of Evidence-Based Practice</td>
<td>Ethical Considerations</td>
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<td>Myths About Evidence-Based Practice</td>
<td>Control Groups</td>
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<tr>
<td>Quality of Evidence: Levels and Grades of Evidence</td>
<td>Risks and Benefits</td>
</tr>
<tr>
<td>Knowledge and Skills Needed for Evidence-Based Practice</td>
<td>Fidelity</td>
</tr>
<tr>
<td></td>
<td>Summary</td>
</tr>
<tr>
<td></td>
<td>Discussion Questions</td>
</tr>
<tr>
<td></td>
<td>References</td>
</tr>
</tbody>
</table>
Upon completion of this chapter the reader will be able to:

- Define evidence-based practice, research utilization, and information literacy
- Recognize myths surrounding evidence-based practice
- Evaluate quality and credibility of ethic communicative evidence to patients and other professionals
- Describe the clinical issues related to evidence-based practice
- Describe clinical traits
- Identify barriers to evidence-based practice
- Locate resources for evidence-based practice
- Recognize the knowledge and skills needed for evidence-based practice
Evidence-based practice (EBP) is the application of research data to clinical decisions. Speech-language pathologists and audiologists, who base their practice on the best available evidence, use a systematic approach to selecting assessment and treatment procedures (Cornett, 2001). The most compelling reason for speech-language pathologists and audiologist to be evidence-based practitioners is to ensure that clients receive the best possible services (Johnson, 2006).

Speech-language pathologists and audiologists in all work settings should be aware of the advantages of evidence-based practice or research-based practice. Meline (2006) believes evaluating research for its application to clinical practice is one of the most important resources available for ensuring best clinical practice in speech-language pathology and audiology. There is growing interest in developing an evidence-based practice through research that is used in making clinical decisions.

During the past 15 years, changes in education and research have led to an awareness of the need for a better evidence base for the clinical practice of speech-language pathology and audiology. Most training programs have modified their curricula to include evidence-based practice and critical analysis of the research literature. Moreover, standards for the Certificate of Clinical Competence (CCC) in Speech-Language Pathology (ASHA, 2014) require “knowledge of processes used in research and integration of research principles into evidence-based clinical practice.” Standards for the CCC-Audiology (ASHA, 2012) also required research and its association to make clinical decisions. There has also been an increased focus on research related to clinical practice. Both students and practicing professionals need hands-on, interactive, practical experience in translating research into clinical practice (Gallagher, 2001). In 2005, ASHA issued a positive statement about evidence-based practice in communication science and disorders. Additional information about this statement is in the section, Knowledge and Skills Needed for Evidence-Based Practice.

There are other factors that may account for the increasing use of evidence-based practice. Among these factors are the development of strategies for efficiently finding evidence, systematic clinical practice guidelines, electronic databases, and continuing education (Sackett, Strauss, Richardson, Rosenberg, & Haynes, 2001). In spite of these developments, there have not been major changes in research utilization among clinicians; underutilization of research continues to be a problem. Research evidence is not routinely used in making clinical decisions about assessment and treatment. Unfortunately, too many clinicians continue to make clinical decisions in the absence of evidence, and on the basis of opinion, testimony, and/or advertisements. Opinions, singly or in groups, even from respected authorities, should be viewed with skepticism (Dollaghan, 2004a). In this chapter, various aspects of evidence-based practice are discussed.

**Defining Evidence-Based Practice**

Evidence-based practice utilizes the best available research to make clinical decisions about patient care. It is based on critical appraisal of research findings and applying what is known to clinical
practice (Frattali & Worrall, 2001). Research utilization is the application of some aspect of research to clinical practice. Polit and Beck (2004) described research utilization as a continuum ranging from direct application of research findings to clinical practice (instrumental utilization) through situations in which research findings are ignored or not used. Research utilization is a matter of degree; clinicians even with limited effort can accomplish some degree of evidence-based practice (Schlosser, 2004). In essence, evidence-based practice is the utilization of research findings to make decisions about patient care.

The major steps in using evidence-based practice are as follows:

- Selecting a topic or problem (Schlosser & O’Neil-Pirozzi, 2006)
- Assembling and evaluating evidence (Law & Plunkett, 2000; Meline, 2006)
- Assessing for potential implementation (Nye & Harvey, 2006)
- Developing or identifying evidence-based practice guidelines or protocols (Law & Plunkett, 2000)
- Implementing the treatment
- Evaluating outcomes (Bernstein-Ratner, 2006; Herder, Howard, Nye, & Vanryckegehem, 2006)
- Deciding to adopt or modify the treatment or revert to prior practice (Konnerup & Schwartz, 2006)

Evidence-Based Practice: Terms and Definitions

Evidence-based practice is utilization of the best available research to make clinical decisions about patient care. It is based on critical appraisal of research findings and applying what is known to clinical practice (Frattali & Worrall, 2001).

Other terms related to evidence-based practice are as follows:

- Clinical expertise: proficiency of clinical skills and abilities, informed by continually expanding knowledge that individual clinicians develop through experience learning and reflection about their professional practice.
- Cost-effectiveness, Cost benefit, Cost utility: terms that compare cost of service to outcome.
- Effectiveness: extent to which an intervention or service produces a desired outcome under usual conditions.
- Efficacy: extent to which an intervention or service produces a desired outcome under ideal conditions.
- Efficiency: extent to which an intervention produces an outcome with a minimum of waste, expense, or unnecessary effort.
- Evidence: any empirical observation about apparent relations between events constitutes potential evidence.
- Evidence-based designs: emphasizes the importance of using credible evidence.
- Evidence-based management: evaluation of best evidence for making decisions.
- Fidelity: truthfulness; degree to which administration of a test or treatment corresponds to the prototype.
- Intent to treat: analysis based on initial treatment intent.
- Outcome: result.
- Randomized controlled trial (RCT): experimental study in which
patients meeting specific criteria are randomly assigned to treatment and no-treatment groups. (Golper et al., 2001; Jewell, 2011; Kaderavek & Justice, 2010).

Research Utilization

Research utilization is the application of research to clinical practice. Polit and Beck (2010) described research utilization as a continuum ranging from direct application of research to clinical practice (instrumental utilization) through situations in which research is ignored or not used. Therefore, research utilization is a matter of degree; clinicians even with minimal effort can use research to some degree to make clinical decisions that are based on evidence or evidence-based practice.

Audiologists and speech-language pathologists’ use of research to make clinical decisions is limited (Guro, Bain & Miller, 2008; Kloda & Bartlett, 2009). Zipoli and Kennedy (2005) reported that speech-language pathologists most often consult colleagues and do not use scholarly journals for clinical information.

Information Literacy

Information literacy is the ability to recognize when information is needed and the ability to locate, critically review, and effectively use information (Cobus, 2008). Many audiologists and speech-language pathologists have inadequate information-seeking abilities (Guro, Bain, & Miller 2008; McCurtin & Roddam, 2012; Moodle et al., 2011; Nail-Chiwetalu & Rattner, 2006). There is a need for information literacy instruction in the university curriculum and continuing education for practicing audiologists and speech-language pathologists (Nail-Chiwetalu & Rattner, 2007). It was suggested that librarians work with audiology and speech-pathology training programs to integrate a high level of information into the curriculum and that librarians provide continuing education activities focusing on information literacy for practicing professionals.

Information literacy is essential for evidence-based practice (Nail-Chiwetalu & Rattner, 2006). Five standards for information literacy have been identified (Nail-Chiwetalu & Rattner, 2006):

1. Determine the nature and extent of information needed
2. Access needed information effectively and efficiently
3. Evaluate information and sources critically, and incorporate selected information into a knowledge-based and values system
4. Individually, or as a member of a group, use information effectively to accomplish a specific purpose
5. Understand the economic, legal, and social issues about the use of information, and access and use ethically and legally

Clinical Trials

Clinical trials are typically associated with evidence-based practice. Sometimes referred to as clinical research trials or outcome measures, clinical trials are research designed to study the safety, efficacy, effectiveness, efficiency, and cost-benefit of an assessment or treatment (DePoy & Gitlin, 2011; Polit & Beck, 2010).
Clinical trials are classified according to purpose (Portney & Watkins, 2009). The six purposes are: (a) prevention, (b) screening, (c) diagnostic, (d) treatment, (e) quality of life, and (f) compassionate use.

There are six hierarchical phases of clinical trials ranging from the preclinical phase to the lowest or highest phase that involves cost-effectiveness, and cost-benefit. These phases are listed and described in Table 13–1. Each phase provides information about assessment or treatment.

A major limitation of phase III is related to RCTs. According to Polit and Beck (2009), RCTs are not relevant to real-life situations. Moreover, there is the ethical dilemma of having a treatment and no treatment group and blinding or masking, which are typically needed for a control group—that is, withholding treatment. Therefore, the focus is on practical information that can be used in routine clinical practice. Another problem related to audiology and speech-language pathology is that most studies in audiology and speech-language pathology do not adequately address assessment and treatment relative to setting or condition. Other problems are related to extremely limited information from Phase IV treatment in audiology and speech-language pathology.

### Advantages and Disadvantages of Evidence-Based Practice

Evidence-based practice has the potential to improve assessment and treatment of children and adults with communication disorders, increase resources for clinical services, and enhance the perception of the professionals of speech-language pathology and audiology (Mullen, 2007).

Disadvantages include limited or no evidence about some clinical practices, evidence unrelated to routine clinical practice, conflicting evidence, increased

### Table 13–1. Phases of Clinical Trials

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-clinical</td>
<td>Exploratory to determine safety under laboratory conditions.</td>
</tr>
<tr>
<td>I</td>
<td>Develop questions to be considered in later phases.</td>
</tr>
<tr>
<td>II</td>
<td>Refine primary hypothesis and develop plan for evaluating efficacy and effectiveness of assessment or treatment.</td>
</tr>
<tr>
<td>III</td>
<td>Efficacy under ideal conditions: typically a randomized controlled trial.</td>
</tr>
<tr>
<td>IV</td>
<td>Efficacy under average conditions</td>
</tr>
<tr>
<td>V</td>
<td>Study of efficiency, cost effectiveness, cost benefit, or cost utility.</td>
</tr>
</tbody>
</table>

cost bias, conflict of interest, erroneous concepts, and overemphasis on randomized controlled trials. (Mullen, 2007)

There is also the possibility the evidence is wrong (Dodd, 2007). There are other issues; one is the limited discussion of settings and conditions in many research reports. Another is the limited information about the rule of instituting in evidence-based practice (Dodd, 2007).

Several myths surrounding evidence-based practice should be considered. Table 13–2 lists those myths that contribute to misunderstanding evidence-based practice and may make it difficult, if not impossible, to implement evidence-based practice.

### Table 13–2. Evidence-Based Practice: Myths and Facts

<table>
<thead>
<tr>
<th>Myth</th>
<th>Evidence-based already exists.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fact</td>
<td>Many clinicians use opinions not evidence to make clinical decisions.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Myth</th>
<th>Evidence-based practice is impossible to initiate.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fact</td>
<td>It impossible to initiate with minimal time.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Myth</th>
<th>Clinical experience is not relevant to evidence-based practice.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fact</td>
<td>Clinical experience is relevant to evidence-based practice.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Myth</th>
<th>Cost is not an important consideration.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fact</td>
<td>Cost-benefit is an important consideration.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Myth</th>
<th>Expert opinion is the highest level of evidence.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fact</td>
<td>Expert opinion is not considered credible evidence.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Myth</th>
<th>All research is related to clinical decisions.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fact</td>
<td>Basic research is not related to clinical decisions, but applied research is related to clinical decisions.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Myth</th>
<th>Evidence-based on opinion is best.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fact</td>
<td>Evidence-based empirical research is best.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Myth</th>
<th>Textbooks contain high levels of evidence.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fact</td>
<td>Textbooks contain low levels of evidence copying.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Myth</th>
<th>Clinical practice guidelines are not detailed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fact</td>
<td>Some clinical practice guidelines are detailed.</td>
</tr>
</tbody>
</table>

based practice. Eliminating or reducing these misconceptions increases the likelihood of using evidence-based practice to support clinical decision-making.

**Barriers to Evidence-Based Practice**

A major disadvantage of evidence-based practice is related to barriers that prohibit or impede its implementation. Barriers should be considered so that strategies can be developed to reduce or eliminate these barriers, thereby facilitating research use and evidence-based practice. A major barrier to evidence-based practice is failure to integrate research and clinical activities. There have also been delays between the completion of a research study and the time the results were reported, which might make the results no longer applicable to clinical practice.

The evidence base itself is frequently cited as a barrier (Mullen, 2005a, 2005b). Barriers to evidence-based practice were also identified by Woraell and Bennett (2001). These barriers were:

- limited access and ability to use databases,
- all related literature not listed,
- frequently a lack of evidence about the topic,
- level of evidence not high,
- evidence not matching the reality of clinical services, and
- no database of published CATs.

Nonexistent, conflicting, or irrelevant evidence is considered to be a formidable problem. Overreliance on RCTs is also a source of controversy (Elman, 2006). Sackett, Rosenberg, Gray, Haynes, and Richardson (1996) believe that evidence-based practice is not restricted to RCTs and meta-analysis, and it should involve finding the best available evidence to answer clinical questions.

Other barriers to EBP are related to bias about funding, publication, consumer-research mismatch, and reduced clinical applicability (Elman, 2006). There are limited research funds and a trend to allocate funds on the basis of evidence. There is a tendency for positive trials to be published more than once and the possibility of subjective publication decisions. Also, there may be a mismatch between the treatments that are researched and those that are desired or prioritized by consumers. Reduced clinical applicability results from a trade-off between subject selection criteria and clinical applicability. Clients with severe problems or comorbidities may be underrepresented in clinical trials that have a homogeneous subject selection.

The type of evidence also warrants consideration. The RCT is considered the gold standard or highest level of evidence, although the information needed to understand human problems is not necessarily amenable to RCT (DePoy & Gitlin, 2011). A related limitation is that RCTs are not the only valid design. RCTs may not be appropriate for evaluating treatment provided to heterogeneous populations that have a wide range of differences, such as, aphasia, dysphagia, and developmental language disorders. For many types of speech-language disorders, RCTs cannot be used at this time (Dodd, 2007).

Additional barriers to EBP include research utilization and information literacy, negative attitudes about research, resistance to change, and limited col-
collaboration and communication between researchers and clinicians. Some speech-language pathologists and audiologist do not read research journals or do not critically review published research findings. Lack of knowledge about how to access and critically review research evidence has also been identified as a barrier to using research evidence in clinical practice. Research is sometimes reported in a way that makes findings inaccessible for clinicians. Complex statistical information and dense research jargon may pose barriers to acquiring knowledge about evidence-based practice (Polit & Beck, 2010). Some speech-language pathologists and audiologists do not attend professional conferences where research is reported. Another consideration is that researchers sometimes ignore the research needs of clinicians.

Other barriers are related to time and change. Sometimes, clinicians are overwhelmed or overstretched because they believe they do not have enough professional time for evidence-based practice (Frattali & Worrall, 2001; Meline & Paradiso, 2003; Mullen, 2005a, 2005b; Zipoli & Kennedy, 2005). Sometimes, clinicians are resistant to change because it requires retraining and reorganization. Some clinicians may lack administrative support to implement evidence-based practice (Rose & Baldac, 2004). Both time and cost are reported as barriers to EBP by some speech-language pathologists (Mullen, 2005; Upton & Upton, 2006). Critical appraisal of research is fundamental to evidence-based practice, yet it may be difficult for some speech-language pathologists and audiologists.

Other barriers to evidence-based practice are related to the shortage of PhD-level researchers in speech-language pathology and audiology (ASHA, 2002; Justice & Fey, 2004). There are problems associated with the PhD shortage: (a) almost half of new PhDs choose non-academic positions, which are probably nonresearch positions; and (b) an aging faculty is facing imminent retirement (Meline & Paradiso, 2003).

Last, there are barriers related to organizations and the professions. Professional organizations may be reluctant to expend resources for teaching and/or using evidence-based practice. The professionals may also have barriers related to a shortage of role models for evidence-based practice or may carry historical baggage that causes them to perceive themselves as not being capable of doing research or recommending changes based on research results (Polit & Beck, 2010).

### Quality of Evidence: Levels and Grades of Evidence

Assessment of the quality of evidence is essential to evidence-based practice. Levels of evidence refer to a hierarchy for evaluating the quality and credibility of evidence. There are several methods for determining levels of evidence.

ASHA (2004) modified the levels of evidence from the Scottish Intercollegiate Guidance Network (Table 13–3). The levels of evidence hierarchical model is based on research design and ranges from highest/most credible or strongest to lowest/least credible or weakest. Randomizing and controlling are considered within research design. Tickle-Degnen and Bedell (2003) criticized this model, because “it is wrong when applied in a manner that excludes the use of all relevant valid, and available research
ASHA’s Advisory Committee on Evidence-Based Practice and the National Center for Evidence-Based Practice developed a system for levels of evidence (Mullen, 2007). This system is shown in Table 13–4. The system involves four processes: (a) appraising the quality of studies; (b) identifying the research stage of each study; (c) assessing the quality relative to the stage of the research; and (d) synthesizing the information into a single table. Eight factors were identified for evaluation.

The type of clinical study, diagnostic or treatment oriented, can be used to determine the level of evidence. ASHA (2005) described hierarchies of evidence for diagnosis and treatment. In addition to these levels of evidence, studies are graded with recommendations about use for making clinical decisions (Figure 13–1). The grades range from A (highly recommended) to D (not recommended).

Regardless of the criteria used for evaluation of the quality of evidence, five common themes were identified by ASHA (2004). These themes are: (a) independent confirmation and converging evidence, (b) experimental control, (c) avoidance of subjectivity and bias, (d) effect sizes and confidence intervals, and (e) relevance and feasibility.

### Knowledge and Skills Needed for Evidence-Based Practice
Audiologists and speech-language pathologists should understand that evidence-based practice utilizes the best available evidence in research and clinical practice. Research utilization and information literacy are basic perquisites to evidence-based practice. ASHA’s (2005) position statement about evidence-based practice

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<table>
<thead>
<tr>
<th>Level</th>
<th>Creditability Description</th>
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</thead>
<tbody>
<tr>
<td>Ia</td>
<td>Well-designed meta-analysis of &gt;1 randomized controlled trial</td>
</tr>
<tr>
<td>Ib</td>
<td>Well-designed randomized controlled study</td>
</tr>
<tr>
<td>Ila</td>
<td>Well-designed controlled study without randomization</td>
</tr>
<tr>
<td>Iib</td>
<td>Well-designed quasi-experimental study survey</td>
</tr>
<tr>
<td>III</td>
<td>Well-designed nonexperimental studies, i.e., correlational and case studies</td>
</tr>
<tr>
<td>IV</td>
<td>Expert committee report, consensus conference, clinical experience of respected authorities</td>
</tr>
</tbody>
</table>

### Table 13–4. ASHA’s (2007) Levels of Evidence

<table>
<thead>
<tr>
<th><strong>Study Design</strong></th>
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<tbody>
<tr>
<td>• Controlled Trial</td>
<td></td>
</tr>
<tr>
<td>• Cohort Study</td>
<td></td>
</tr>
<tr>
<td>• Single-Subject Design or Case Control Study</td>
<td></td>
</tr>
<tr>
<td>• Cross-Sectional Study or Case Series</td>
<td></td>
</tr>
<tr>
<td>• Case Study</td>
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<table>
<thead>
<tr>
<th><strong>Blinding</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Assessors blinded</td>
<td></td>
</tr>
<tr>
<td>• Assessors not blinded or not stated</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Sampling</strong></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>• Random sample adequately described</td>
<td></td>
</tr>
<tr>
<td>• Random sample inadequately described</td>
<td></td>
</tr>
<tr>
<td>• Convenience sample/hand-picked sample or not stated</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Subjects</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Groups comparable at baseline on important factors (between subject design) or subject(s) adequately described (within subject design)</td>
<td></td>
</tr>
<tr>
<td>• Groups/subjects not comparable at baseline or comparability not reported or subject(s) not adequately described</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Outcomes</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• At least one primary outcome measure is valid and reliable</td>
<td></td>
</tr>
<tr>
<td>• Validity unknown, but appears reasonable; reliable</td>
<td></td>
</tr>
<tr>
<td>• Invalid and/or unreliable</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Significance</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• p value reported or calculable</td>
<td></td>
</tr>
<tr>
<td>• p value neither reported nor calculable</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Precision</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Effect size and confidence interval reported or calculable</td>
<td></td>
</tr>
<tr>
<td>• Effect size or confidence interval, but not both reported or calculable</td>
<td></td>
</tr>
<tr>
<td>• Neither effect size nor confidence interval reported or calculable</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Intention to Treat</strong></th>
<th>(controlled trials only)</th>
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<tr>
<td>• Analyzed by intention to treat</td>
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<tr>
<td>• Not analyzed by intention to treat or not stated</td>
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outlines the skills needed for evidence-based practice. Audiologists and speech-language pathologists should:

- Recognize the needs, abilities, values, preferences, and interests of patients and families and combine this information with best current research evidence and clinical expertise.
- Acquire and maintain knowledge and skills necessary to provide high-quality professional service, including knowledge about evidence-based practice.
- Evaluate clinical services and procedures for cost-effectiveness using recognized appraisal criteria described in the evidence-based literature.
- Evaluate efficacy, effectiveness, and efficiency of clinical and research protocols using criteria described in the evidence-based literature.
- Evaluate the quality of evidence in journal reports, textbooks, continuing education newsletters, advertisements, and web-based products.
- Monitor and apply new and high-quality evidence.

Haynes and Johnson (2009) provided a detailed discussion for each of these skills. The discussion was related to skills for both students and practicing professionals. In addition, audiologists and speech-language pathologists should:

- Use scientific criteria for making decisions about research and clinical practice (Finn, Bothe, & Bramlett, 2005)
- Effectively communicate about evidence to patients, families, and other professions

Figure 13–1. Outcomes from systematic review. Reprinted with permission from Justice, L. M., and Fey, M. E. (2004.) Evidence-based practice in schools: Integrating craft and theory with science and data. ASHA Leader, 9(4–5), 30–32. Copyright by American Speech-Language-Hearing Association. All rights reserved.
Determine level of evidence for clinical and research studies (ASHA, 2004; Mullen 2007)

Educate students and other professionals about the use and application of evidence-based practice

Evaluate effectiveness and outcomes of education and training about evidence-based practice

Develop and implement strategies to reduce barriers to evidence-based practice

Dispel the myths and misconceptions about evidence-based practice

Create an evidence-based environment

Document fidelity

To utilize EBP, speech-language pathologists and audiologists must: (a) discount the opinions of authorities when there is counterevidence; (b) focus on research relevant to clinical practice, and (c) use rigorous criteria to evaluate the quality of evidence, including validity, importance, and precision (Dollaghan, 2004a).

Education and training are the foundation for developing and implementing evidence-based practice. The December 2009 issue of Evidence-Based Communication Assessment and Intervention focused on teaching evidence-based practice to speech-language pathologists. Table 13–5 is a list of the authors and titles of these reports.

The decision-making process can be used to implement and develop evidence-based practice. Boswell (2005) and Kully and Langeven (2005) described similar procedures for evidence-based decision-making. The steps were: (a) asking a clear, focused question; (b) finding the best evidence; (c) critically appraising the evidence; (d) integrating the evidence with clinical judgment and clinical values; and (e) evaluating the decision-

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### Table 13–5. Teaching Evidence-Based Practice from December 2009 Evidence-Based Communication Assessment and Intervention

<table>
<thead>
<tr>
<th>Author</th>
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<tr>
<td>Klee and Stringer</td>
<td>Teaching evidence-based practice to speech and language therapy students in the United Kingdom</td>
</tr>
<tr>
<td>McCabe, Purcell, Baker, Madill, and Trembath</td>
<td>Case-based learning: One route to evidence-based practice</td>
</tr>
<tr>
<td>Proxy and Murza</td>
<td>Building speech-language pathologists capacity for evidence-based practice: A unique graduate course approach</td>
</tr>
<tr>
<td>Raghavendra</td>
<td>Teaching evidence-based practice in a problem-based course in speech-language pathology</td>
</tr>
<tr>
<td>Schlosser and Sigafoos</td>
<td>Teaching evidence-based practice: An impetus for further curricular innovation and research</td>
</tr>
</tbody>
</table>
making process. According to Schlosser, Koul, and Costello (2007) the first step in EBP is asking well-built questions. However, this is often difficult for clinicians. To facilitate well-built questions, the PESICO template was proposed. PESICO stands for person (problem), environments, stakeholders, intervention, comparison, and outcome. Johnson, (2006) provided specific examples for making evidence-based decisions about childhood speech-language disorders.

 Threats (2002) suggested the World Health Organization's International Classification of Disorders for developing evidence-based practice that could bridge the gap between research and clinical practice by providing a common framework and language. The purposes were to: (a) collect statistical data about functioning and disability, such as in population studies; (b) conduct clinical research, such as measurement of outcomes, quality of life, or impact of environmental factor on disability; (c) use for clinical needs assessment, matching treatments with specific conditions, program outcome evaluation, and rehabilitation documentation; and (d) use for social policy, such as social security planning, governmental oversight of disability programs, and policy decision-making.

 There are several strategies for implementing and developing evidence-based practice. Some of these strategies include the following:

- Create a culture for evidence-based practice (Fingout-Overholt & Melnyk, 2009)
- Provide evidence-based practice training and experience for both students and practicing professions
- Develop critical thinking skills (Finn, 2011)
- Integrate evidence-based practice into speech-language pathology and audiology curriculum (Forrest & Miller, 2001)
- Eliminate dichotomy between research and clinical practice
- Develop awareness of misconceptions about evidence-based practice
- Provide high levels of research evidence
- Encourage collaboration of researchers and clinicians
- Use systematic reviews to introduce evidence-based practice (McCauley & Hargrove, 2004; Mullen, 2005b)
- Communicate research results widely and clearly
- Specify clinical implications of research
- Expect evidence that a diagnosis or treatment procedure is effective
- Practice in a journal group
- Form collaborative work groups (Johnson, 2006)
- Use ASHA's registry of evidence-based practice guidelines and systematic reviews (Evidence-Based Practice Tool Available, 2006; Mullen, 2006)
- Indicate level of evidence in professional presentations and publications, and continue education
- Seek professional environment that supports evidence-based practice
- Identify and eliminate sources of bias about EBP (Elman, 2005)
- Volunteer to participate in clinical research trials (Logemann & Gardner, 2005)
- Audit the degree and extent of research utilization
- Form on-site or online journal clubs (Betz, Smith, Melnyk, & Rickey, 2005)
- Provide multidisciplinary evidence-based practice courses
Use formats for case presentations and critical reviews such as those suggested by Dollaghan (2004a, 2004b), Frattali and Worrall (2001), Threats (2002), and Worrall and Bennett (2001).

Evidence-based practice is a process by which the current best evidence is critically appraised, clinical expertise considered, and a course of action selected. Several decisions may be made. For example, what is the best and most current research evidence? How can the evidence be integrated with clinical expertise and client preferences?

Because of the relative newness of evidence-based practice in speech-language pathology and audiology, little evidence exists to guide identification of the best strategies for implementing evidence-based practice. Some strategies are successful in some settings and with some professional groups but not with other settings or groups (Cilisla, DeCenso, Melynk, & Stetler, 2005).

Organizational Support for Evidence-Based Practice

Professional organizations have supported evidence-based practice. Among these organizations are the Academy of Neurological Communication Disorders and Sciences, American Academy of Audiology, American Speech-Language-Hearing Association, Australian Speech and Hearing Association, and the Canadian Speech and Hearing Association.

ASHA has devoted considerable effort to increase research utilization through evidence-based practice. The major activities include a website for evidence-based practice (ASHA, 2004b), a position statement (ASHA, 2005a), levels of evidence (2005b), a technical report (ASHA, 2005b), and evidence maps for amyotrophic lateral sclerosis, aphasia, autism, cerebral palsy, cleft lip and palate, dementia, head and neck cancer, Parkinson's disease, traumatic brain injury-adult, and traumatic brain injury-children (National Center for Evidence-Based Practice, 2012). In addition to ACEBP, ASHA has established the National Center for Evidence-Based Practice in Communication Disorders. The center has a registry of clinical practice guidelines and systematic reviews (Mullen, 2006). Only guidelines and reviews with an overall rating of highly recommended or recommended with provisions are included in the registry. ASHA also has several practice guidelines, which provide information to assist clinicians in making decisions based on available research evidence and prevailing expert opinion. The purpose of such guidelines is to improve the quality of service, identify the most cost-effective treatment, prevent unfounded practices, and stimulate research (Golper et al., 2001).

ASHA also established the Communication Sciences and Disorders Clinical Trials Research Group (CSDRG), which is devoted solely to the development and conduct of clinical trials by audiologists, speech-language pathologists, and speech, language, and hearing scientists (Baum, Logemann, & Lilienfeld, 1998; Logemann, 2004; Logemann & Gardner, 2005). CSDRG's clinical trials involve dysarthria, dysphagia, and language stimulation.

ASHA's Research and Scientific Affairs Committee had a series of reports about research concepts and their application to speech-language pathology and audiology (Feeney, 2006). Topics include

In addition, two ASHA journals have had issues focusing on EBP. *Communication Issues in Communication Services and Disorders* (CICSD) (2006) described the specific task(s) needed to conduct a systematic review and meta-analysis that would facilitate EBP. The other journal, *Language, Speech, and Hearing in Schools* (LSHSS), discussed making evidence-based decisions for speech sound disorders, reading problems, and child language intervention.

The American Academy of Audiology emphasized EBP in a special 2005 issue of the Academy's journal, the *Journal of the American Academy of Audiology*. These papers focused on the effectiveness of hearing rehabilitation.

ANCDS applied the principles of evidence-based practice to the development of practice guidelines with support of ASHA’s Special Interest Division, Neurophysiologic and Neurogenic Speech and Language Disorders (Golper et al., 2001). “The purpose of such guidelines is to improve and assure the quality of care by reducing unacceptable variation in its provisions” (p. 2). The practice guidelines were completed when research evidence was available in the literature.

There are three types of clinical practice guidelines based on evidence: traditional or narrative (TPG), systematic reviews (SR), and evidence-based practice (Hargrove & Gruffer, 2008). Differences between these clinical practice guidelines were described in Chapter 5.

There is hierarchy of clinical practice guidelines with tradition-narrative reviews lowest (meeting the fewest criteria) and evidence-based reviews highest (meeting the most criteria). Specifically, traditional reviews met only two of seven criteria, systematic reviews met five of seven criteria, and evidence-based reviews met all seven criteria. This information is useful in making decisions about using and recommending clinical practice guidelines.

The National Evidence-Based Center of ASHA (2011) uses the Appraisal of Guidelines for Research and Evaluation (AGREE) for evaluating and recommending systematic reviews. These reviews are highly recommended, recommended with reservations, or not recommended. The Academy of Neurologic Communication Disorders and Sciences (ANCDS) has developed evidence-based practice guidelines (EBPG). These EBPGs focus on five areas: aphasia, acquired apraxia, cognitive dysarthria, and communication disorders related to traumatic brain injury and dementia.

Obviously, there is a variation in reporting clinical practice guidelines. Shiffman and associates (2003) developed and standardized a format for reporting clinical practice guidelines which is based on 15 factors and is followed by systematic reviews by writing committees within ANCDS (Golper et al., 2001; Yorkston et al., 2001a). These guidelines reflected a moderate degree of clinical certainty and are usually based on Class II evidence or strong consensus from Class III evidence (Golper et al., 2001).

The Canadian Association of Speech Language Pathologists and Audiologists (CASLPA) have promoted evidence-based practice in classrooms, clinics, and research (Orange, 2004). In 1996, CASLPA affiliated with the Canadian Cochrane Network and Center. Evidence-based practice has been
incorporated into the academic coursework, clinical practice, and thesis research at the University of Western Ontario.

The Australian Speech Pathology Association published a series of reports about clinical practice (Baker, 2005). The first in this series of articles was “What Is the Evidence for Oral Motor Therapy” by Bowen (2005). Reports about evidence-based practice have continued to be published in the association’s journal.

Resources for Evidence-Based Practice

Finding evidence is a fundamental aspect of evidence-based practice. Electronic searches can be an efficient way to locate evidence (Dollaghan, 2007). There are several electronic databases related to evidence-based practice: PubMed, Cumulative Index of Nursing and Allied Health (CINHAL), and the Cochrane Collection. The American Speech-Language-Hearing Association (n.d.) developed evidence-based maps related to clinical expertise/expert opinion, external scientific evidence, and client/patient/caregiver perspectives. There are evidenced-based maps for amyotrophic lateral sclerosis, autism, spectrum disorders, Parkinson’s disease, and traumatic brain injury in children and adults.

Several books are available that focus on evidence-based practice in communication disorders:

- Evidence-Based Practice in Speech Pathology (Reilly, Douglas, & Oates, 2004)
- The Efficacy of Augmentative and Alternative Communication: Toward Evidence-Based Practice (Schlosser, 2000)
- The Handbook for Evidence-Based Practice in Communication Disorders (Dollaghan, 2007)
- Understanding Research and Evidence-Based Practice in Communication Disorders (Haynes & Johnson, 2009)
- Introduction to Communication Disorders: A Lifespan Evidence-Based Perspective (Owens, 2012)
- Evidence-Based Practice in Audiology: Evaluating Interventions for Children and Adults with Hearing Impairment (Wong & Hickson, 2012).
- Evaluating Research in Communication Disorders (Orlikoff, Schiavetti, & Metz, 2015).

In addition, there are two journals exclusive to evidence-based practice:

- Evidence-Based Communication: Assessment and Intervention is published four times per year by Psychology Press. This journal brings together professionals from several different disciplines to facilitate evidence-based services for children and adults with communication disorders. These professionals include speech-language pathologists, special educators, regular educators, applied behavior analysts, clinical psychologists, physical therapists, and occupational therapists.
- Evidence-Based Practice Briefs in Speech-Language is a combination electronic and print peer-reviewed journal. It began publication in 2006 by Pearson.

Evidence-based practice guidelines integrate evidence about a single topic (Polit & Beck, 2010). The evidence is
summarized and evaluated from previous studies for use in clinical practice. Systematic reviews, meta-analyses, and clinical practice guidelines are useful resources for evidence-based practice.

**Communicating Evidence**

Communication is important for implementing and developing evidence-based practice. Communicating evidence to clients and others improves understanding, involvement in decisions, and outcomes (Epstein, Alper, & Quill, 2004). Speech-language pathologists and audiologists should discuss possible options, including relevant research evidence, and risks and benefits. The goal is to provide sufficient information to the client and/or family so that an informed decision can be made (Johnson, 2006).

Tickle-Degnen (2002) described four steps for effectively communicating information: (a) identify the relative role or the decision maker relative to the clinician, (b) identify the decision that the decision maker will make with the clinician, (c) locate and interpret which evidence is related to the information need of the decision maker and the clinician, and (d) translate the evidence in a comprehensive communication that facilitates informed delegating with the decision maker so that decisions can be made and action taken.

Methods for communicating evidence include visual supplements, tables and groups, decision aids, graphic representation, and quantitative translation of clinical evidence. Systematic reviews and clinical practice guidelines can be used to communicate evidence for clinical decision-making among professionals, third-party payees, and policy makers.

Another approach for communicating evidence among professionals is the peer-reviewed journal *Evidence-Based Communication Assessment and Intervention* (EBCAI) (Taylor & Francis Group, 2006). The primary aims of EBCAI are: (a) promoting EBP in communication assessment and treatment, (b) appraising the latest evidence in communication evaluation and treatment, (c) providing a forum for discussions that advance EBP, and (d) disseminating EBP research.

Critically appraised topics (CATs) have also been used to communicate information among professionals (Worrall & Bennett, 2001). CATs were described in Chapter 11.

**Ethical Considerations**

There are several ethical principles and practices especially pertinent to evidence-based practice: beneficence, nonmaleficence, justice, autonomy, control groups, risks-benefits, and fidelity (Chabon, Morris, & Lemoncello, 2011). Beneficence is doing good or kindness, seeking to maximize benefits for study participants and prevent harm (Polit & Beck, 2010). Nonmaleficence means do no harm, in other words, avoiding harm to subjects or patients (Aiken, 2002). Justice is fairness to equitable distribution of risks and benefits (Portney & Watkins, 2009). Autonomy is independence or freedom to make decisions.

**Control Groups**

The use of control groups (RCTs) has been criticized because withholding treatment is wrong; therefore, many studies have only experimental groups
and not control groups. These studies are considered to be weak. RCTs are considered to be the gold standard for evidence (Brown & Golper, 2012; Golper & Brown, 2007).

**Double Blinding**

Double blinding is possible in audiology and speech-language pathology research but is rarely used because of ethical issues related to withholding treatment from a control group (Dodd, 2007).

**Risks and Benefits**

Risks and benefits are an ethical principle with an element of informed consent in which risks and benefits are compared and related to outcomes. Studies are compared to the benefits of the study outcome (Portney & Watkins, 2009). Essentially, the question is, do the benefits outweigh the risks?

**Fidelity**

Fidelity is the extent to which a clinical procedure is administered according to the author’s instructions. It is an important but neglected concept that can affect clinical research findings. Fidelity can be enhanced by using a detailed unified protocol so that the procedure can be delivered consistently, is producible, and is independent of style; provide training and monitoring through observation or review of audio or video recordings; and provide training compliance (DePoy & Gitlin, 2011).

**Summary**

There has been progress in implementing evidence-based practice in speech-language pathology and audiology, although this process has been slow. It does not seem that clinicians have increased their recognition of the need for evidence-based practice, or research utilization.

Several organizations have undertaken efforts to facilitate implementation and development of evidence-based practice. Among these organizations are ASHA, ANCDS, CASLPA, and ASPA.

There are barriers to evidence-based practice. The primary barriers are related to the evidence base itself, time, and resistance to change. There are a number of strategies to implement evidence-based practice that may improve the extent to which research is used for making clinical decisions. Information about evidence in audiology and speech-language pathology must be communicated to decision makers—that is, patients, third-party payees, and other professionals. Several ethical issues are especially related to evidence-based practice: use of control groups, risks-benefits, and blinding.
DISCUSSION QUESTIONS

1. What are evidence-based practice, research utilization, and information literacy?
2. What factors may account for the increased interest in evidence-based practice?
3. How do speech-language pathologists and audiologists make decisions about assessment and treatment?
4. Why is the research underutilized? Why is the poorest evidence overutilized?
5. How can research utilization be improved?
6. What is meant by the statement that “research utilization is on a continuum”?
7. How do speech-language pathologists and audiologists make clinical decisions?
8. Why should levels of evidence be considered in making clinical decisions?
9. What are the myths about evidence-based practice? How do these myths affect clinical decisions?
10. What activities has ASHA undertaken to facilitate implementation of evidence-based practice?
11. What is CSDRG?
12. Define clinical trials. What are the phases?
13. What is blinding or masking?
14. What are the indications and contradictions for blinding?
15. What are the steps in making evidence-based decisions?
16. What are the barriers to evidence-based practice? How can these barriers be reduced or eliminated?
17. What can be done to develop and implement evidence-based practice?
18. How can evidence be communicated to patients? Other professionals?
19. How have professional organizations supported evidence-based practice?
20. What resources are available for evidence-based practice?
21. What are the major ethical issues related to evidence-based practice?

References

13. EVIDENCE-BASED PRACTICE: APPLICATION OF RESEARCH


McCauley, R. J., & Hargrove, P. (2004). A clinician’s introduction to systematic reviews in communication disorders: The course review paper with muscle. Issues in Com-


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Research Grants

CHAPTER OUTLINE

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LEARNING OBJECTIVES

Upon completion of this chapter, the reader will be able to:

- Identify the three phases of the grants acquisition process
- Identify reference sources available for the seeking of grants from federal and private agencies
- List general principles of the grant-seeking process
- Discuss preliminary considerations in grant proposal writing
- Identify the major sections of a research grant proposal
- List and define the major categories in the budget section of a research grant proposal
- Differentiate direct costs and indirect costs associated with a research grant proposal
- Discuss the sources of ideas/problems for research projects
- Identify basic principles of grant proposal writing
- List some suggestions for grant proposal writing
- Identify the characteristics of a fundable research grant proposal
- Describe the grant proposal review process
Introduction

There is a strong association between research activities and grants. Without grants from the government and private sector, much of the research in communication disorders (and, for that matter, in many fields) would not be possible. In addition to any available internal funds, for those involved in research, it is essential to locate a specific external source(s) of support for their activities. For example, a university professor or hospital audiologist or school speech-language pathologist who has an interest in a specific communication disorder and wishes to pursue a research project to learn more about the disorder, may find that funds are not available within her/his agency to support the necessary personnel, equipment, materials, travel, and other items that are needed to conduct the research. The only feasible approach for obtaining funds for the research may be through external sources (such as the federal government or private foundations), and the only way to obtain external support is to write a grant proposal to a particular funding agency. Moreover, the importance of grants is further accentuated in academia, where support for research activities is essential for conducting research, and conducting research is essential for publications in scholarly journals, which, in turn, are essential for the awarding of tenure, which is essential for maintaining one’s position in a university. Therefore, grants may be the mechanism for job stability and may play a major role in the “publish or perish” philosophy in institutions of higher education.

The Grants Acquisition Process

Acquiring grant support may appear to the uninitiated as somewhat “mystical” in nature. However, in reality, there is nothing magical about the grants acquisition process. In fact, it is a systematic process that can be considered in three phases: grant seeking, grant proposal writing, and grant management. First, the investigator seeks sources of support whose mission and interests coincide with the goals and nature of his or her project. Next, the investigator writes a grant proposal following the guidelines established by the sponsoring agency. Finally, if a grant is awarded, the investigator manages the research project, including the expenditure of awarded funds.

Grant Seeking

Grant seeking involves searching for a source of funding for a specific research project, thus matching the nature of the topic with the objectives of the support source. There are various sources of external support for research projects, the largest being the federal government. In addition, national organizations and private corporations are potential sources for competitive grants.

Foundations are another major source of support in the private sector. A foundation is a nongovernmental, nonprofit organization whose funds and programs are managed by its own trustees or directors and established to maintain or aid educational, charitable, or other activities
serving the common welfare, primarily through the awarding of grants. There are different types of foundations, but the type that serves as the primary source of support for research projects is the independent foundation.

In addition to extramural (outside the institution) funding sources, colleges and universities provide support for research in the form of relatively small grants as “seed money” for starting new research projects. These intramural (in-house) funds, although relatively small, are essential for collecting preliminary data and providing the foundation for external funding. They can be a very important component in the decisions for funding made by outside agencies.

Numerous references are available to locate potential funding sources in both the public and private sectors. Much of this information can be found online, most of it free and some fee-based. The following are representative samples of references available for grant-seeking purposes.

- **Catalog of Federal Domestic Assistance** (CFDA) (http://www.cfda.gov) is a valuable reference source to learn about relevant federal programs, eligibility requirements, and application deadlines. It provides access to a database of all available federal programs that can be searched in a number of ways, including key words, agency, applicant eligibility, type of assistance, and several other factors. There is a category specifically for finding grants that would be of most relevance to seekers of support for research activities. There is also a CFDA User Guide that can be downloaded.

- **Foundation Center** (http://www.foundationcenter.org) collects, organizes, and communicates information on U.S. philanthropy; provides education and training on the grant-seeking process; and allows public access to information and services through its website, print, and electronic publications, library/learning centers, and a national network of Cooperating Collections. Included on its website are general and specialized information retrieval tools.

- **Foundation Directory Online** (https://fconline.foundationcenter.org) developed by the Foundation Center, is part of an online subscription set of databases providing access to information on grant makers and their giving interests. Searches include text-based foundation searches, grant searches, and IRS 990 searches. (IRS 990 forms are the tax forms completed by foundations that contain information on awarded grants, including recipients and titles of projects funded, which could be very useful information to grant seekers.)

- **infoEd Global’s Sponsored Programs Information Network (SPIN)** (http://www.infoedglobal.com) is a computer database containing information on grant opportunities from federal and private sponsoring agencies. The database is targeted primarily to institutions of higher education. infoEd Global, the company that maintains the SPIN database, also offers an alert service called SMARTS, which sends e-mail messages whenever there is a match between the grant seeker’s choice of key words and the funding programs...
in the SPIN funding opportunities database. This website indicates that their database is the world’s largest database of sponsored funding opportunities (over 40,000 opportunities from more than 10,000 global sponsors). Subscription required.

- **Grants.Gov** (http://www.grants.gov), a central storehouse for information on grant programs offered by federal grant-making agencies, allows grant seekers to electronically find and apply for competitive grant opportunities from these federal agencies. Those interested in research grants can: (a) register for e-mail notification of grant opportunities; (b) access, download, complete, and submit active grant application packages; and (c) check the status of grant applications submitted via Grants.gov.

- **GrantSelect** (http://www.grantselect.com) provides an extensive list of funding opportunities from state and federal government agencies (including National Institutes of Health [NIH], National Science Foundation [NSF], Centers for Disease Control and Prevention [CDC], and others), corporations, foundations, research institutes, and other nonprofit organizations. Grant seekers can subscribe to the entire research grants database or choose from customized segments, including Arts and Humanities, Biomedical and Health Care, Children and Youth, Community Development, International Programs, and others.

- **Guidestar** (http://www.guidestar.org) allows grant seekers to search for information on nonprofit organizations, including foundations. It provides general information as well as specifics, including foundations’ current IRS Form 990, income range, contact information, mission, programs, goals, boards of directors, grants awarded, and other relevant information.

- **Pivot** (formerly **Community of Science**) (http://pivot.cos.com) is a resource for hard-to-find information critical to scientific research and other projects across all disciplines. It provides grant seekers the opportunity to search a comprehensive resource for funding opportunities. It also contains prepopulated scholar profiles worldwide to match a given institution’s profiles against funding opportunities and to find potential collaborators from among the scholar profiles.

- **Society of Research Administrators (SRA) International** (http://www.srainternational.org/sra03/grantsweb/index.cfm) is a source for finding funds available from local, state, federal, and international governments. It also contains information to locate private funding for projects, including links to foundations, nonprofit centers, and charities.

- **GrantsNet** (http://www.hhs.gov/grantsnet) is an Internet application tool created by the Department of Health and Human Services (HHS) for finding and exchanging information about HHS and other federal grant programs. In support of its mission, HHS is the largest grant-awarding agency in the federal government.

- **Ed.Gov** (http://www.ed.gov), the website of the U.S. Department of Education (ED), contains answers to frequently asked questions about funding opportunities; information on and instructions
for completing grant application packages; application packages for ED grant competitions that are currently open; announcements of grant competitions; all programs and competitions under which ED has invited or expects to invite applications for new awards; deadlines for the submission of applications; and the *Guide to ED* Programs, which describes all programs administered by ED (including the National Institute on Disability and Rehabilitation Research [NIDRR]). It also provides a search tool to find ED programs relevant to grant seekers’ interests.

- **National Science Foundation** (http://www.nsf.gov/) is an independent federal agency created by Congress “...to promote the progress of science; to advance the national health, prosperity, and welfare; to secure the national defense.” This website includes information about research projects that NSF has funded since 1989 by searching the *Award Abstracts* database. The information includes abstracts that describe the research as well as names of principal investigators and their institutions. The database includes both completed and current research projects.

- **National Institute on Deafness and Other Communication Disorders (NIDCD)**, a member of the National Institutes of Health (NIH), is mandated to conduct and support behavioral and biomedical research and research training in the normal and disordered processes of voice, speech, language, balance, smell, and taste. The Institute also conducts and supports: research and research training related to special behavioral and biomedical problems associated with people who have communication impairments or disorders; and efforts to create devices which substitute for lost and impaired communication and sensory functions. The extramural program funds research and training opportunities at universities, medical centers, and other institutions throughout the United States and abroad through research grants, career development awards, and other mechanisms.

- **American Speech-Language-Hearing Association** (http://www.asha.org) contains information on research grants offered by the American Speech-Language-Hearing Foundation (http://www.ashfoundation.org) and federal agencies (including the National Institutes of Health, Agency for Healthcare Research and Quality, Department of Education, National Science Foundation, Centers for Disease Control and Prevention, and U.S. Department of Veterans Affairs) as well as private foundations and organizations (http://www.asha.org/research/grants-funding/Funding-for-Researchers.htm). Also included on this website is information and suggestions on the grants acquisition process, including grant seeking and grant proposal writing. A bimonthly subscription to the *ASHA Access Academics and Research E-Newsletter* (http://www.asha.org/publications/enews/accessacademics.htm), which serves the specific needs of researchers, including information, resources, services, educational opportunities, as well as funding, research, and grant opportunities, is available at this website.
American Academy of Audiology (AAA) (http://www.audiology.org) contains information on research grants offered jointly by the Academy (AAA) and the Academy of Audiology Foundation (AAF) (http://www.audiology.org/about/foundation) to support research, education, and public awareness in audiology and hearing science, as well as other sources, including federal agencies, private foundations, and national organizations in hearing and balance. (http://www.audiology.org/education/research/funding/Pages/default.aspx) In support of this goal, the AAA and the AAF provide research funding through the Research Grants in Hearing & Balance Program and the New Investigator Program.

The American Academy of Audiology Foundation and the American Academy of Audiology will make grants for research projects with a duration of one year. Grants of up to $10,000 will be made based on the merit of the research project. In addition, grants may be made for basic research or clinical/applied research. Applicants must have been granted a doctoral degree in audiology (Au.D.) or hearing science (Ph.D.) within the past five years of their application for funding and must be formally associated (faculty, staff, or otherwise) with a non-profit public or private institution in the United States or Canada, with no significant source of research funding (e.g., no federal funding from NIH or NSF), and a mentor with expertise in the research area to be investigated and who will be prepared to foster the advancement of the grantee in the development and conduct of the research.

American Hearing Research Foundation (http://american-hearing.org) funds research in hearing and balance disorders. It awards an average of five to ten research projects per year, with an average grant of approximately $20,000. Priority is given to investigators early in their careers who need seed funds to generate results and data that can be used to support later applications for larger grants (e.g., NIH or NSF grants) in the future. This site has links to a research grant application as well as a list of former recipients and their research topics from 1996 through the present.

Capita Foundation (http://www.capitafoundation.org) is dedicated to the support of cutting-edge innovative auditory research worldwide. The majority of Capita Foundation grants fund early stage research and projects by early career research scientists, allowing them to produce the preliminary results needed to secure grants from the NIH and other major funders. Grant applications are welcomed from scientists conducting research in line with the Foundation’s mission statement to “support innovative research that works toward the prevention and cure of hearing disorders.”

Federal Grants and Contracts (http://www.federalgrantsandcontracts.com/about.aspx) is a comprehensive biweekly review of the latest funding opportunities across all federal agencies. It covers relevant grant opportunities announced each week, provides information on upcoming grant initiatives, and offers news on standing cyclical grant competitions.
It researches many online and print channels of federal information and resources, and provides specific information on scope, deadline, funds, eligibility, and contact needed to start the grant application process.

- **The Grantsmanship Center** (http://www.tgci.com) offers training programs that include information, resources, best approaches, tips, and insights to avoid trial-and-error learning. These training programs provide an overview of the entire proposal development process, highlighting the key elements that make proposals competitive. Also addressed is an understanding of federal application guidelines and design of a proposal development work plan.

Other reference sources on research grants include the following directories. Information on their availability can be obtained via online searches (e.g., Google) as well as at other websites (e.g., Amazon.com).

- **Annual Register of Grant Support.**
  A directory of grant and fellowship programs of foundations, governmental agencies, as well as business, professional, and other organizations.

- **Directory of Biomedical and Health Care Grants.**
  Includes U.S. and international grant programs of governmental agencies, foundations, corporations, and professional organizations.

- **Directory of Research Grants.**
  Contains a listing of grant opportunities from federal agencies as well as U.S. and international foundations, corporations, government agencies, and other organizations. Included are grants for fellowships, basic research, equipment, building construction/renovation, and other program types.

- **Taft Foundation Reporter.**
  Provides comprehensive profiles and gives analyses of America’s major private foundations in annual grants to nonprofit organizations. It contains information on corporate foundations and direct giving programs.

### General Principles of Grant Seeking

The following are some general principles applicable to the grant-seeking process:

- Search databases of existing grants from relevant funding agencies
- Know a funding agency's mission and what types of topics of research that it wishes to fund
- Match an agency whose goals fit your research project topic
- Contact the contact person (program officer) to discuss your proposed project in order to determine its feasibility for support. Additional information on the grant-seeking process is provided by Bauer (2017) and Licklider (2012).

### Grant Proposal Writing

#### Preliminary Considerations

Once the grant-seeking phase has been completed and the agency located as a potential funding source for the proposed research project, the next major step is to write the grant proposal. However, before the writing begins, there are some preliminary considerations:
1. Obtain an application from the sponsoring agency’s website.
2. Carefully review the agency’s guidelines (located in the application material) for the relevant grants program, which should contain the following important information:
   - suggested format for the proposal,
   - any necessary appendices,
   - deadline dates,
   - any applicable cost-sharing requirements for the applicant,
   - allowable indirect cost rates,
   - criteria used to judge each proposal
   - relative weighting of each factor in the criteria.

The guidelines should be followed exactly as specified. If any of the above information is missing from the guidelines, or if there are questions about the guidelines, the sponsoring agency’s contact person (whose name, e-mail and/or postal address, as well as, and telephone number are listed in the application material) should be contacted for clarifications.

The Grant Proposal

The grant proposal usually contains the following major sections:

- Introduction
- Problem Statement (Needs Assessment)
- Objectives
- Methodology
- Budget

Writing a research grant proposal is somewhat similar to writing a manuscript for publication in a journal or a master’s thesis or a doctoral dissertation, because all include a review of the pertinent literature, a statement of purpose of the research, and a description of the methodology to study a proposed purpose or problem. However, since a research grant proposal is written before the proposed research is conducted, it includes a budget section requesting funds to conduct the research.

The Budget

The major categories of the budget usually include the following:

- **Personnel**—the people who will be working on the project, including the principal investigator and other personnel, as well as the amount of time they will be working on the project.
- **Fringe Benefits**—whenever grant funds are used to pay salaries and wages, associated fringe benefits must also be charged to the grant. The fringe benefit rate and percentage usually includes social security, unemployment/worker’s compensation, retirement, and health insurance. It is a percentage of the base salary of the persons working on the research project and will vary from institution to institution.
  
  Once the salary amount is determined, fringe benefits are calculated as a percentage of the total salary for each individual or category of employee. These percentages are intended to provide adequate funding to cover the actual fringe benefit costs that will be charged to sponsors.
- **Travel**—funds to travel to professional meetings to present the findings of the research project and,
depending on the nature of the research, may include funds to travel to collect data and other related research activities.

- **Equipment**—any necessary instrumentation to conduct the research. For many organizations, equipment is defined as any item with a unit acquisition cost of $5,000 or more and a life span of two or more years (NIH) [or a lifespan useful for more than one year (NSF)].

- **Supplies**—needed supplies and materials.

- **Contractual**—any necessary contractual agreements with other agencies or individuals as part of the research project.

- **Other**—other items not covered in the previous six categories.

- **Total Direct Costs**—the sum of the seven budget categories previously listed.

- **Indirect Costs**—expenditures not included directly in any of the budget categories previously listed, such as the cost of heating/cooling; electricity; maintenance; security of facilities used for the research project; the processing of paperwork for purchases associated with the project; administrative costs; and other related expenses.

- **Total Project Costs**—the total cost of the research project, including all direct and indirect costs.

It should be noted that grant proposals need not include all seven budget categories previously listed. Only budget items that can be justified because they relate directly to the methodology should be included in the proposed budget for the research project.

### The Idea/Problem

A fundable proposal includes a good idea/problem that is expressed well and with an appropriate plan for implementation. The idea/problem for a research grant proposal should ask an important theoretical or applied question(s) capable of being systematically studied. A few questions to ask and answer about the idea/problem for a research study are as follows:

- Is it important (regarding discovery, improvement, or application of knowledge)?
- Is it timely today?
- Is it capable of being investigated (regarding the availability of personnel, expertise, techniques, instrumentation, facilities, etc.)?

Ideas/problems for a research project come from various sources, including the following:

- the applicant's previous experiences (e.g., teaching, research, clinical practice, administration, etc.);
- the applicant's literature reading and familiarity with the area of investigation;
- unresolved problems in the applicant's field of study;
- potential applications of previous research findings; and
- priority areas for funding established by sponsoring agencies.

### Unsolicited and Solicited Proposals

An *unsolicited proposal* is one that is written without any specific guidelines
provided by a sponsoring agency and is not in response to a particular need or problem expressed by a sponsoring agency. Instead, it originates from a need perceived by the applicant who tries to find a sponsor to support the proposal. Unsolicited proposals have no specific deadline dates for submission and usually are reviewed and accepted by sponsoring agencies at any time rather than at specified dates each year.

On the other hand, solicited proposals originate with a sponsoring agency that recognizes a need for something to be done or learned. Solicited proposals are usually announced by a Request for Application (RFA) or Request for Proposal (RFP), which identifies problem areas and may include specific objectives to be met.

Basic Principles of Grant Proposal Writing

- The grant proposal should contain clear, concise writing, with definitions/explanations for all appropriate terms. (Grants cannot be awarded for projects that are not understood by a sponsoring agency’s reviewers.)
- All factual statements should be documented with cited references to support them.
- An objective and strong case for funding should be provided, with sufficient empirical evidence presented to support the investigator’s position.
- The idea/problem for funding should be relevant, feasible, important, and contemporary.
- The methodology proposed should be well-designed for accomplishing the objectives of the project.
- The project personnel should be shown (via their vitae or resume) to be qualified to conduct the research.
- The budget should be realistic by containing only items that are justifiable and relevant to the proposed project.

A knowledge of grant application deficiencies is helpful. Some common deficiencies are inadequate control of relevant variables, deficiency in methodology, research design problem(s), poor conceptualization of problem(s), and inappropriate statistical analyses.

Suggestions for Grant Proposal Writing

- Read and follow the sponsoring agency’s guidelines.
- Begin writing early, well in advance of the submission deadline.
- Set a deadline to complete each section of the grant proposal.
- Define a specific, focused problem.
- Develop procedures to study the problem.
- Draft the body (narrative) of the proposal.
- Develop a realistic budget, with valid justifications for all items in the budget.
- Add any required additional components to the proposal (e.g., relevant assurance forms).
- If possible, share a draft of the proposal with colleagues for their review and comments.
Revise the proposal based on any relevant comments and suggestions before submitting the finalized proposal.

Characteristics of a Fundable Research Grant Proposal

In summary, a fundable research grant proposal, one that should receive serious consideration for funding, should contain the following features which have been expressed by numerous investigators who have been cited earlier:

- A clearly established need for the proposed research, preferably with supporting data.
- Clear objectives of the project.
- A detailed schedule of activities for the project, with realistic timelines.
- If relevant, commitment of all involved agencies/consultants verified with letters of commitment in the appendix.
- Any relevant cost-sharing is included in the proposal.
- All budget items are justifiable and consistent with the proposed purpose and procedures of the research project. All budget explanations/justifications provide an adequate basis for the dollar figures used in the budget section.
- All major items included in the funding agency's guidelines are addressed in the proposal.
- All appropriate assurance forms are completed, indicating that all governmental and non-governmental agency requirements have been fulfilled.
- All sections of the proposal contain sufficient details and address all relevant issues.
- All directions in the funding agency's guidelines have been followed.
- Appropriate appendices have been included to provide evidence of careful planning of the research project.
- The writing style is clear and concise.
- The length of the proposal does not exceed the funding agency's guidelines.
- The qualifications of project personnel are clearly indicated (via resumes, curriculum vitae, etc.) in the proposal.


The Grant Proposal Review Process

Although the specific process of reviewing research grant proposals may vary from one funding agency to another, there are some commonalities applicable to all reviews. Proposals usually are reviewed by the investigator's peers,
generally colleagues at other institutions or laboratories who are knowledgeable about the topic of the proposal. Sponsoring agencies base their decisions about the awarding of grants on reviewers’ comments. Usually, reviewers are required to follow specific criteria and use some type of rating scale established by the sponsoring agency to judge the merits of each proposal. Moreover, some agencies, like the National Institutes of Health (NIH), have a specific rating system for all proposals and a face-to-face meeting of a panel of peers to arrive at decisions for funding proposals. Additional information on the peer review process can be found online at the websites of various funding agencies (e.g., https://public.csr.nih.gov).

**Grant Management**

Each grant usually has one principal investigator (project director) who is responsible for all activities and expenditures associated with the grant. Once a grant is awarded, there needs to be competent management of the funds, because the grantee is held accountable for all expended funds. In addition, there are reporting requirements, frequently annual reports to the sponsoring agency delineating progress in research activities and fund expenditures. However, some agencies require more than an annual report. The award notification letter or an addendum to the letter should specify all reporting requirements.

Usually, funds awarded in a grant are specified and earmarked for particular budget categories (e.g., personnel, equipment, travel, etc.). However, on occasion, because of unexpected expenses or unexpected increases in approved budget items, there is a need to modify the existing approved budget. Most sponsoring agencies have an established rule of allowing the transfer of no more than a specific percentage of the entire budget from specific line items to other specific line items without the need for prior approval from the sponsoring agency. However, in cases that exceed this maximum percentage, the principal investigator must make a written request to transfer funds from one budget category to another and must receive approval in writing from the person at the sponsoring agency who is authorized to do so. In addition, the same is true for other necessary nonmonetary changes in the research project: the principal investigator must make a request in writing and must receive approval in writing from the appropriate authorized representative of the sponsoring agency.

Thus, once a grant is awarded, the grantee’s responsibilities begin. In addition to conducting the proposed research, the principal investigator is responsible for the expending of funds approved by the sponsoring agency (and in the amounts approved) as well as for any fiscal and programmatic reporting requirements.

**Summary**

Grants are essential for conducting research. The process of grants acquisition involves three phases: grant seeking, grant proposal writing, and grant management. Grant seeking is searching for funds from internal as well as external sources, including governmental agencies, private foundations, corporations, and national organizations. Grant
proposal writing involves the preparation of a proposal that makes a strong case for financial support and follows the guidelines established by the sponsoring agency. Grant management involves conducting the research project and expending funds associated with the project as delineated in the grant proposal and approved by the sponsoring agency. In addition, it involves the preparation of fiscal and programmatic reports to the sponsoring agency. Detailed information and suggestions concerning each phase of the grants acquisition process are presented in this chapter.

DISCUSSION QUESTIONS

1. What are the three phases associated with the grants acquisition process?
2. What are some available online and hard copy reference sources for locating information on research grant opportunities from federal and private agencies?
3. What are some preliminary considerations in writing a research grant proposal?
4. What are the major sections of a research grant proposal?
5. What are the major categories in the budget section of a research grant proposal?
6. What is the difference between direct costs and indirect costs associated with a research grant?
7. What are some sources of ideas/problems for research projects?
8. List some basic principles of grant proposal writing.
9. List some suggestions for research grant proposal writing.
10. What are the characteristics of a fundable research grant proposal?
11. Who reviews research grant proposals and makes recommendations for funding?
12. What are the responsibilities of the principal investigator in the management of a research grant?

STUDY EXERCISES

1. Locate 10 online (and/or hard copy) research grant references and prepare a brief summary of one entry from each reference. Select five sources of federal grants and five sources of foundation grants. Include in each summary the following:
   - the title of the entry and
   - a brief description of the funding program.
2. Obtain a grant application online or by contacting an appropriate federal agency (or obtain one from the sponsored programs office at your institution or agency). Read it thoroughly, and indicate whether or not each of the following items is included in the application:

- legislation relevant to the federal agency’s research grants program;
- eligibility requirements for grantees;
- priorities (topics/areas) for funding in a particular fiscal year;
- restrictions (if any) on topics/areas to be funded;
- amount of funds available for grant awards for a particular fiscal year;
- maximum dollar amount (or range) to be awarded per grant;
- cost-sharing requirements (if any);
- indirect cost rate restrictions (if any);
- cover page and instructions for completion;
- budget sheets and instructions for completion;
- assurance forms and instructions for completion;
- instructions for completion of narrative section of grant application;
- page limitations for the narrative section of the grant application;
- deadline date(s) for submission of the grant application;
- criteria to be used to judge each grant proposal for funding, including any relative weighting of each criterion;
- any necessary appendices; and
- name, e-mail address, and telephone number of contact person.

3. Read two funded grant proposals, one by a governmental agency and one by a foundation (these may be obtained from your institution or funding agency or else contact the sponsoring agency) and prepare a brief abstract of each proposal. Include in the abstract the following information:

- title of proposal,
- agency to which submitted,
- purpose/objectives,
- methodology, and
- budget summary.

References


A-B design: single-case design with two phases: A represents the baseline phase, and B represents the intervention phase.

A-B-A design: a single-case withdrawal design in which a second baseline phase is introduced.

Abstract: brief description of a paper, usually located at the beginning of an article.

Analytic generalization: A view of generalization that purports that qualitative research methods study the underlying human processes of the behavior in question. Results of these analyses are applicable to a wider population because they were derived from basic, systematic human processes that are common to all humans.

Applied research: research that seeks to answer practical questions such as those pertaining to prevention and management of communication disorders; also known as clinical research.

Assurance forms: standardized forms completed by the applicant agency to assure the funding agency that the applicant agency meets all requirements to qualify for funding.

Baseline measure: measurement of dependent variable before experimental intervention.

Basic research: research that is often theoretical; designed to seek answers that explain and/or predict phenomena.

Between-subject design: design that uses two groups of subjects, each group assigned to a different level of the independent variable.

Bias: any influence that affects results.

Bivariate statistics: test used to analyze significance of the relationship between two variables simultaneously, for example, correlation.

Blinding: process of preventing those involved in a study (subjects, clinicians, data collectors) from having information that could bias. Same as masking.
CADE: critically appraised topic of diagnostic evidence.
CAPE: checklist for appraising patient/practice evidence.
CAPP: checklist for appraising evidence on patient preference.
CASM: critical appraisal of systematic review or meta-analysis.
CATE: critical appraisal of treatment evidence.
Case-control studies: when individuals are selected whether they have a particular disorder or not.
Case-to-case transfer: A type of generalization that occurs when a reader consumes a published qualitative study and decides to apply the findings to a client he/she is seeing. The reader of the research is responsible for making the decision regarding generalization rather than the researcher.
Case study research: intensive study of the background, current status, or environmental interactions of an individual, group, institution, or community.
Charge master: a spreadsheet that is part of the budgetary process and includes all expenses related to the implementation of a research study.
Class I level of evidence: the highest level of evidence provided by at least one well-designed, randomized controlled clinical trial.
Class II level of evidence: evidence provided by at least one or better designed observational, clinical studies with concurrent controls, that is, single case control or cohort control studies.
Class III level of evidence: the lowest level of evidence; provided by expert opinion, case studies, case reports, and studies with historical controls.
Clinical research: research designed to generate knowledge to guide the clinical practice in speech-language pathology and audiology; also known as applied research.
Clinical trial: study designed to investigate outcome.
Cohort study: follows the temporal sequence of factors that may have impacted the development of a disorder.
Complementary design: the result of the dominant research method being enhanced or clarified by results from the findings of the other type of research.
Complex hypothesis: the hypothesis contains more than one independent and dependent variable.
Concept maps: require selecting important relevant concepts to add to the map and identifying salient cross links; and indicating relationships between concepts in different sections of the map.
Confidence interval: an inferential statistic for estimating range of values within which a population parameter lies.
Confirmability: refers to sharing findings with participants by informant checks or feedback sessions to confirm view of the person being studied.
Conflict of commitment: conflicting demands on professionals who have obligations to their patients and to others including students and other professionals.
Conflict of interest: situations where personal and/or financial consider-
ations compromise judgment in any professional activity.

**Consent process**: involves meeting with a potential subject, finding out whether he or she is capable of giving consent, and discussing the purpose, risks, and benefits of participation.

**Constant variable**: variables that describe the population investigated by a study; variables that do not change from individual to individual (such as a diagnosis of stuttering).

**Construct validity**: the extent to which a test or questionnaire measures what it is supposed to measure.

**Content validity**: a logical examination of all behaviors that need to be measured in order to adequately answer the question.

**Continuous variable**: a quantitative variable that can theoretically take on values along a continuum.

**Control group**: a group that does not receive treatment; equivalent to the experimental group in age, sex, and so on.

**Convenience sampling**: using the most readily available persons as participants, sometimes called accidental sampling.

**Coordinated substudies**: qualitative studies that are part of a larger program project or long-term study.

**Correlation**: tendency for variation in one variable to be related to variation in another variable; an interrelation between two or more variables.

**Correlation coefficient**: a measure of the direction and strength of the relationship between variables usually ranging from +1.00 (perfect positive) through zero (no relationship) to −1.00 (perfect negative) relationships.

**Correlational research**: used to determine possible relationships among factors.

**Cost-benefit analysis**: an evaluation comparing financial costs with financial gains attributed to a program or intervention.

**Cost-sharing requirements**: expenses associated with a grant that are to be incurred by the applicant agency to share the expense of the research project with the funding agency.

**Cover letter**: typically includes the purpose, conveys appreciation to the participant, states that the survey has been approved by the appropriate committee or advisor, and offers to provide a summary of the results.

**Credibility**: the extent to which data are believable and trustworthy, that is, confidence in the truth of the data.

**Criterion-related (predictive) validity**: the measure of an attribute to predict future performance.

**Critical Appraisal Topic/Paper (CAT/CAP)**: a summary of a critical review of the best evidence on a specific topic; a written outcome of the evidence-based practice (EBP) process.

**Cross-sectional research**: involves selecting subjects from various age groups and observing differences between the behavior and characteristics of the group.

**Database**: information accessed by using electronic hardware.

**Deception**: deliberate withholding of information or misinformation

**Dependability**: the qualitative equivalent to reliability of quantitative research.

**Dependent variable**: variable that is the effect of unknown etiology(ies) and must be described in operational terms.

**Descriptive research**: designed to systematically describe situations or events as they naturally occur, in other words,
the status of phenomena of interest as they currently exist.

**Descriptive statistics:** procedures for describing and analyzing quantitative data.

**Design:** the structure of a study organized for the purpose of revealing cause-and-effect relationships by controlling variables, comparing groups, or analyzing specific characteristics of individuals or groups.

**Direct costs:** expenses related to personnel, fringe benefits, travel, equipment, supplies, and contractual matters.

**Directional hypothesis:** when a researcher states there will be a change or describes a relationship in a certain direction (i.e., high or low; positive or negative; etc.).

**Discrete variable:** a variable that can only be measured in separate units and that cannot be measured in intervals less than 1.

**Dissertation:** research project/paper typically associated with a doctoral degree.

**Double-blind studies:** a study in which the investigator and the subject do not know group assignment.

**Editing analysis:** involves interpretation of the data on which categorization is used for coding, sorting, and organizing the data.

**Effect size:** a statistical expression of the magnitude of difference between two treatments or the magnitude of a relationship between two variables.

**Effectiveness:** in research is defined as the benefits and use of the procedure under “real world” conditions.

**Efficacy:** in research is the benefit of an intervention plan as compared to a control or standard program.

**Evaluation research:** the collection and analysis of information related to the effects of a program, policy, or procedure.

**Evidence-based practice:** such practice increases professionalism, accountability to clients and other professionals, and the social relevance of the health services delivered in an economy with increased costs and decreased resources; utilization of the best available research to make clinical decisions about patient care.

**Expansion design:** involves using different methods for different components for a multimethod research project.

**Experimental research:** examines possible cause-and-effect relationships by exposing one or more experimental groups to one or more conditions and comparing the results to one or more control groups.

**Experimental treatment:** utilizes the principles of experimental research investigating the use of new or novel treatment.

**Exploded pie chart:** emphasizes the proportion of time devoted to a topic or area that is displayed in a pie chart.

**Exploratory research:** examines how one event or events relate to other factors.

**External validity:** degree results of a study can be generalized to persons or settings outside the experimental situation.

**Extramural funding:** funding for research projects provided by agencies outside the researcher’s institution.

**Extraneous variable:** a variable that confounds the relationship between the independent and dependent variable.

**Extrinsic variables:** variables associated with the research situation or environment; related to the place and
time the research was conducted and adherence (or not) to the research specification or protocols.

**Fabrication:** making up data or results and recording or reporting data for experiments never conducted.

**Factorial designs:** manipulating two or more independent variables; one group in the design accounts for each possible combination of the levels of the independent variables.

**Feasibility test:** a researcher reviews factors that could influence the possibility of a study being conducted.

**Fidelity:** maintaining integrity in use of test or treatment.

**Focus groups:** a method of interviewing a group of individuals about a specific topic or issue.

**Foundation:** a nongovernmental, nonprofit organization whose funds and programs are managed by its own trustees or directors and established to maintain or aid educational, charitable, or other activities serving the common welfare, primarily through the awarding of grants.

**Frequency polygon:** a graphic display of a frequency distribution; created by drawing a straight line between the success midpoints of class intervals.

**Fringe benefits:** an item in the budget section of a grant proposal that usually includes social security, workmen’s compensation, health insurance, unemployment compensation, and a retirement plan. It is a percentage of the base salary of personnel on a funded research project and will vary from institution to institution.

**Ghost authorship:** failure to name as an author an individual who has made substantial contribution that merits authorship or an unnamed individual who participated in writing the manuscript; also known as honorary authorship.

**Gold standard:** An instrument that is considered a valid measure and that can be used as the standard for assessing validity of other instruments.

**Grant seeking:** the process involved in searching for a source of funding for a specific research project, thus matching the nature of the topic with the objectives of the support source.

**Grants acquisition process:** the process for securing a funding source that involves three phases: grant seeking, grant proposal writing, and grant management.

**Group designs:** design involving comparison of average or typical performance of a group to other groups or conditions; includes between-subject designs, within-subject designs, and mixed group designs.

**Health Insurance Portability and Accountability Act of 1996 (HIPAA, Title II):** required the Department of Health and Human Services (HHS) to establish national standards for electronic health care transactions and national identifiers for providers, health plans, and employers. It also addresses the security and privacy of health data.

**Histogram (graph):** graphic display of frequency distribution data in which scores (often in group intervals) are plotted on the x-axis and frequency (or percent of cases) is plotted on the y-axis.

**Hyperclarity:** suggesting that research is likely to achieve what it is unlikely to achieve.

**Hypothesis:** statement concerning the relationship between variables; formulated to test theories.

**Immersion method:** a form of qualitative data analysis that involves total
immersion in the problem; considered to be an insider's perspective.

**Impact evaluation**: to determine whether a program should be discontinued, replaced, modified, continued, or replicated.

**Independent variable**: variable with known qualities that explains the dependent variable; may be manipulated to determine effect on dependent variable.

**Indirect costs**: costs such as heating/cooling, electricity, maintenance, security, and administrative costs.

**Inferential statistics**: statistics used to test hypotheses by drawing inferences or generalizations from small groups to larger groups.

**Informed consent**: requires obtaining the consent of the individual to participate in a study based on full prior disclosure of risks and benefits.

**Institutional Review Board (IRB)**: a group of diverse individuals who review research proposals to protect human and animal subjects through analysis of risks and benefits.

**Interaction effect**: combined effect of two or more independent variables on a dependent variable.

**Interexaminers reliability**: implies agreement among different observers measuring the same phenomenon.

**Internal estimation**: a statistic that indicates the upper and lower limits of a range of values in which the parameter has a given probability of occurring.

**Internal validity**: degree of relationship between independent and dependent variables is free from the impact of extraneous/confounding variables.

**Interquartile range**: difference between the first and third quartiles in a distribution.

**Interval scale**: level of measurement in which values have equal intervals, but no true zero point.

**Interview**: a form of data collection in which questions are asked orally and participants' responses are recorded; may be structured, semi-structured, or unstructured.

**Intraexaminer reliability**: implies that in repeated observations of the same subject, the same examiner gets similar results.

**Intramural funding**: in-house funds used to support research projects.

**Intrinsic variables**: variables associated with subjects of an investigation such as age, gender, socioeconomic status, and marital status.

**Level of significance**: significance level selected to reject the null hypothesis established before statistical analysis to reduce the risk of making a Type I or Type II error; also known as limit of confidence.

**Longitudinal research**: the same group of subjects is followed over time; sometimes known as cohort study, follow-up study, incidence study, or perspective study.

**Main effect**: separate effect of one independent variable in a multifactor design.

**Mañana syndrome**: procrastination; frequently results in missing deadlines.

**Mean**: simple arithmetic average.

**Measures of central tendency**: measures representing the average or typical score in a distribution (mean, median, mode).

**Median**: a statistic describing the central tendency of scores in an ordinal scale; the midpoint in a set of values (same number of values as above and below the median).
**Meta-analysis**: a technique for quantitatively combining results of several studies on a given topic.

**Mixed group design**: combines within subjects and between-subjects designs to investigate effects of treatment for which carryover effects would be a problem while repeatedly sampling the behavior.

**Mode**: the most frequently occurring value in a distribution.

**Multifactor baseline designs**: include more than one independent variable and require that different combinations of the independent variable be tested across the study.

**Multimethod or mixed research**: combines both quantitative (outcome) and qualitative (process) features in the design, data collection, and analysis.

**Multivariate designs**: two or more dependent variables; provides information about the effect of the independent variable on each dependent variable and on a composite dependent variable.

**Multivariate statistics**: statistical procedures used to study the relationships between three or more variables.

**Narrative review**: nonsystematic review of the literature that synthesizes particular topics of interest; also known as a "review of the literature" in most research proposals.

**Nominal scale**: level of measurement for classification variables; values are assigned based on mutually exclusive and exhaustive categories with no inherent rank order.

**Nonequivalent groups posttest-only design**: a comparison between an experimental and control group both of whom are tested after treatment and not before treatment.

**Nonparametric statistics**: a type of inferential statistics that does not involve rigorous assumptions about the parameters of the population from which the sample was drawn; used for nominal and ordinal measures.

**Null hypothesis**: statement that there is no relationship between variables under study.

**One-group postdesign**: a type of pre-experimental design; involves study of the presumed effect of an independent variable in one group of subjects by administering a posttest after some treatment.

**One-tailed (directional) test**: a test of statistical significance in which only values at one extreme (tail) of a distribution are considered in testing significance.

**Online**: data that are accessed by the user who interacts directly with the electronic program to retrieve desired information.

**Ordinal scale**: level of measurement in which scores are ranked.

**Outliers**: scores that are outside the range of most scores.

**Parallel designs**: involve qualitative methods such as case studies, focused ethnographic observation, multiple linked in-depth interviews, or some combination of time in combination with other methods.

**Parameter estimation**: used to estimate a single parameter such as a mean.

**Parametric statistics**: a type of inferential statistics that involves making assumptions about the parameters.
of the population from which the research sample was drawn; used for interval measures.

**Participant observer:** when the researcher is an active participant in the activity being studied, that is, the researcher participates as a member of the group and is not known as the researcher.

**Passive participant:** is detached from the group being studied and is known as the researcher.

**Peer review:** the process by which the quality of research is assessed; involves multiple activities.

**PESICO:** framework for asking question. 
- **P** = person or problem, **E** = environment, **S** = stakeholder, **I** = intervention, **C** = comparison, **O** = outcome.

**PICO:** **P** = patient/population, **I** = intervention/treatment/exposure, **C** = comparison, and **O** = outcome; a method used in evidence-based practice/research.

**Pie charts:** used to represent the proportion of data falling into certain categories in the form of a circle containing segments that are also called slices, sections, or wedges.

**Plagiarism:** use of another person’s ideas, processes, results, or words without giving appropriate credit.

**Predictive value:** the degree to which a test or instrument can determine an outcome.

**Predictive value negative (PV−):** the probability that a person does not have a problem, given that the test result is negative.

**Predictive value positive (PV+):** the probability that a person has a problem, given the test result is positive.

**Pre-experimental designs:** sometimes referred to as pseudo-experimental designs because they do not meet at least two of the three criteria for true experiments: randomization; manipulation; or control.

**Principal investigator (PI):** the project director of a research grant who is responsible for all expenditures and programmatic issues associated with the grant.

**Priorities:** topics/areas for research support that have been established by a funding agency for a particular fiscal year.

**Point estimation:** calculated by dividing the observed values from the sample by the size of the sample.

**Power:** the probability of a statistical test to reject the null hypothesis when in fact it is false.

**Primary source:** firsthand data that the researcher obtains directly from the source.

**Prospective study:** researcher contacts the subjects before they develop the disorder, but after exposure to risk factors.

**Protected health information:** related to HIPAA privacy rule about individual’s past, present and future health conditions, treatment for conditions and financial history related to health care.

**Publish or perish:** academic requirement of publishing to obtain or maintain position or be promoted.

**Qualitative research:** research designed to investigate real-life events or situations without reference to hypothesis or theory, allowing researchers’ subjective point of view; also known as field research, hermeneutic, naturalistic inquiry, phenomenological research, symbolic interactionism, descriptive research, interpretive research, and ethnographic study.
Quantitative or statistical analysis: the organization and integration of quantitative data according to systematic mathematical rules and procedures.

Quantitative research: research that generates data capable of being organized in graphs and descriptive statistical forms; stresses numbers, measurement, deductive logic, control, and experiments.

Quasi-experimental research: like experimental research, involves manipulation of an independent variable but does not have a comparison group or randomization; also known as preexperimental and pseudo-experimental.

Quasi-statistical analysis: involves preconceived ideas about the analysis that has been specified in a code book, and then using these ideas (codes) to sort the data; also known as manifest analysis.

Randomization: a method of selecting subjects that ensures that everyone in the population has an equal chance of being included in the study.

Randomized control trial (RCT): involves the experimental group receiving the variable of interest and the control group not receiving any form of treatment; also known as the “gold standard” for clinical research.

Range: distance between the lowest and highest value in a distribution.

Ratio scale: The highest level of measurement, in which there are equal intervals between score units and a true zero point.

Reliability: repeatability, consistency among repeated measures or observations.

Research hypothesis: the question being asked by an investigator; sometimes known as the working hypothesis.

Research utilization: the application of some aspect of research to clinical practice.

Retrospective study: researcher determines subjects have already been exposed to risk factors.

Risk-benefit: comparison of relative cost and benefit.

Scales of measurement: a means of assigning numbers to events or objects according to prescribed rules. Nominal, ordinal interval or ratio.

Scatter plot: a graphic display of the relationship between two variables; also known as scatter diagram or scattergram.

Scientific approach: a systematic, empirical, controlled, and critical examination of hypothetical propositions about the association among natural phenomena.

Scientific method: a method of efficiently or methodically generating knowledge by recognizing a problem capable of objective study, collecting data by observation or experimentation, and drawing conclusions based on analysis of the data.

Secondary analysis: involves research that uses previously gathered data; examining unanalyzed variables, testing unexplored relationships, focusing on a specific subsample, or changing the unit of analysis.

Secondary sources: secondhand documentation based on what is seen or heard by someone else, or a summary of primary information.

Seed money: funds provided by colleges and universities to support research in the form of relatively small grants for starting new research projects in the hope that this intramural support will help secure extramural funding.
**Self-plagiarism:** involves duplicate submission or publication: duplicate/previous submission means that the manuscript is simultaneously being considered for publication elsewhere.

**Self-reports:** a method of collecting data that involves a direct report of information by the person being studied.

**Semi-longitudinal approach:** compromise designed to maximize the strengths and minimize the weaknesses of the cross-sectional and longitudinal approaches; selecting subjects at the low end of designated age spans and following them until they reach the upper limits of that age span.

**Semi-structured observation:** a method used in qualitative research that is more concerned with some aspects of the situation for the participants than others.

**Sensitivity:** a measure of validity based on the probability that someone with a disease or condition will test positive.

**Sequential clinical trials (SCTs):** does not require a fixed sample size before the study can begin; can be used to compare two treatments such as an “old” or standard treatment to a “new” experimental treatment.

**Simple hypothesis:** the hypothesis includes one independent variable and one dependent variable.

**Single-blind studies:** a study in which only the investigator does not know the assignment of a subject to a group.

**Single or one group pretest-posttest design:** compares pretest and posttest data subsequent to treatment.

**Single-subject discrete trial designs:** individual subjects receive each treatment condition of the experiment dozens of times.

**Single-subject research:** focuses on the behavior of one or a few subjects; applied behavioral analysis designs or behavioral analysis; idiographic designs; single-subject experimental designs; single-case designs; intrasubject replication designs; small approach; and within-subjects designs.

**Snowball sampling:** selection of participants by nomination or referral from earlier participants in a study.

**Solicited proposals:** grant proposals that originate with a sponsoring (funding) agency that recognizes a need for something to be done or learned; usually are announced by a Request for Application (RFA) or Request for Proposal (RFP), which identifies problem areas and sometimes includes specific objectives to be met.

**Specificity:** a measure of validity of a procedure based on the probability that a person who does not have a disease will test negative.

**Standard deviation:** a variability measure of the degree to which each value deviates from the mean.

**Statistic:** a number derived by counting or measuring sample observations drawn from a population that is used in estimating a population parameter.

**Statistical Package for Social Sciences® (SPSS):** statistical program used in behavioral and social sciences published by Prentice-Hall, a division of Pearson Education, Inc.; can be used for qualitative and quantitative research analyses.

**Structured observation:** a method used in qualitative research; what to observe is decided in advance and there is an observational schedule.

**Sum of squares:** a measure of variability in a set of data, equal to the sum of squared deviations for a distribution; used in analysis of variance as
the basis for partitioning between groups and within-groups variance components.

**Survey research**: designed to provide a detailed inspection of the prevalence of conditions, practices, or attitudes in a given environment by asking people about them rather than observing them directly.

**Synthesis**: collecting, analyzing and integrating information.

**Systematic review**: a summary of the evidence typically conducted by an expert or expert panel that uses a rigorous process for identifying, appraising, and synthesizing studies to answer a particular question or draw a conclusion.

**Template analysis**: involves the development of a template or analysis guide to sort the data.

**Test-retest reliability**: how well subjects perform on one set of measurements as compared to their performance on a second evaluation of the same measurements.

**Theoretical sampling**: selection of participants based on emerging findings as the study progresses so adequate representation of important themes is ensured; also known as purposeful sampling.

**Thesis**: research project/paper typically associated with a master’s degree.

**Time series design**: involves repeated measures before and after treatment using the same instruments with the same or similar subjects over an extended period of time.

**Total project cost**: total cost of a research project, including all direct and indirect costs.

**Transferability**: the extent to which findings from a qualitative study can be transferred to similar circumstances.

**Treatment outcome**: a broadly defined term that refers to change, or the lack of it, that may occur as a result of time, treatment, or both.

**Trend chart**: illustrates frequencies or percentages of change in a data set which is organized in a developmental or temporal order.

**Triangulated designs**: both quantitative and qualitative methods are used to study the same entity or concept with a focus on convergence (similarities) and increased validity.

**Triangulation**: refers to the use of multiple methods to improve the credibility of findings or the truth and it may involve comparison of data from different sources or analyses to reduce or eliminate bias and errors.

**True experimental design**: characterized by manipulation (treatment or intervention), randomizations, and use of a control group.

**Two-tailed test**: test of a hypothesis using both ends of the distribution to determine a range of improbable values.

**Type I error**: incorrectly rejecting the null hypothesis.

**Type II error**: incorrectly accepting the null hypothesis.

**Unsolicited proposals**: grant proposals written without any guidelines provided by a sponsoring (funding) agency and are not in response to a particular need or problem expressed by the agency; originate from a need perceived by the applicant who tries to find a sponsor to support the proposal.

**Unstructured observation**: a method used in qualitative research when there is no attempt to manipulate the situation.

**Variable**: a trait capable of change or modification.
Variance: a measure of variability equal to the square of the standard deviation.

V diagrams: used to diagram the components of knowledge and clarify their relationships.

Within-subjects designs: a design in which every subject in the experiment is exposed to all the experimental conditions.
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