Clinical Research in Communication Disorders

PRINCIPLES AND STRATEGIES

Fourth Edition

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Preface to the First Edition

I am a student and an instructor of philosophy and methodology of science and research. In my teaching of science and research, I have found it necessary to supplement information from a variety of sources. I knew that several of my colleagues who taught courses on research and science were doing the same to make their courses more relevant and useful to graduate students. To me, this meant that we did not have a comprehensive textbook on science and research. This book is an effort to fulfill that need.

My own teaching experience and discussions with many of my colleagues suggested that a book on science and research should address the following concerns. The first deals with the basic concepts of science and scientific methods. That is, the book should point out the need to study science and research methods and summarize the basic concepts of science and research. It should describe the true and lively process of research, not an idealized and frighteningly formalized process that typically discourages the beginning student from a further study of science and research. The book should give an adequate description of the different kinds of research that are conducted in communication disorders. A discussion of observation and measurement, which are the basic tools of science, must be provided.

The second concern is clinical research designs. Most books on research designs tend to be statistically oriented. The enormously prestigious analysis of variance is constantly confused with experimental designs. A book on designs should present experimental designs, not methods of data analysis under the guise of research designs. Furthermore, the book should address both group and single-subject designs. Generally speaking, most books that offer information on research designs focus almost exclusively on group designs. Clinically more relevant single-subject designs are not well represented in those books. On the other hand, there are some books that focus exclusively on single-subject designs. There are not many books that present adequate information on both design strategies. Regardless of one's own methodologic preference and practice, a critical user and producer of research must have a knowledge of group as well as single-subject design approaches. It was thought that a single source that offered descriptions and comparative evaluations of both strategies would be useful to students and researchers alike.

The third concern is the discussion of some important philosophic issues that are an inexorable part of science and research. Research is based on methodology as well as philosophy. There is a tremendous lack of appreciation of the philosophic bases of research. Therefore, it was thought that this book should at least raise the issue of philosophy of research to stimulate further discussion in the discipline.

The fourth concern is the practical aspect of performing, writing, reporting, and evaluating research. Students need suggestions on where to find research

questions, how to find current research trends, how to search the literature, how to refine research questions, and how to select designs that help answer those questions. They also need information on how to get started on theses and dissertations. A major problem instructors and students alike face is writing style and writing skills. It was thought that this book should offer basic information on principles of good writing.

The fifth concern is the ethics of research. Science and research are an ethical activity. From the beginning, science and research must be taught with due regard for the ethical principles that restrain research. A textbook on research should summarize ethical principles that govern research activities.

I have written this book with those five concerns as the guiding principles. An overall concern was to make a book on science and research especially relevant to clinical research in communication disorders and write it in a less formal, and I would hope, more readable style. It is thought that such a style would also reflect the process of research more accurately than the typical style that formalizes research to an unnatural extent.

My wife Prema and my son Manu have been a part of all of my writings. This book, which I began to write soon after completing *Treatment Procedures in Communicative Disorders,* would not have been finished without their full support.

I thank all of my former students at both the undergraduate and graduate levels who have been generous in their support and encouragement. My students have always tolerated and often appreciated my unlimited passion to teach science and research anytime and anywhere. Many students in my graduate seminar on research methods have offered excellent comments on earlier versions of several chapters in this book.

Preface to the Fourth Edition

Since its first publication in 1987, many instructors have adopted this book as the main text in various courses on research methods and designs in communication disorders. Most of these instructors have offered their gracious and positive comments on the book. The instructors have suggested that the comprehensive treatment of issues and methods of research is a strength of this book. The new fourth edition retains that strength.

I am glad to have Dr. Anthony Salvatore of the University of Louisiana at Lafayette as my coauthor of this fourth edition, published after 30 years of its first edition. Together we have extensively revised and updated each chapter. In the chapter on research ethics, we have included web-based sources that monitor research fraud and recalled studies.

The chapter on writing and reporting research papers includes the reporting standards for experimental studies, qualitative research, and meta-analyses published by various organizations.

The chapter on types of research includes new sections on translational research, qualitative research, and mixed-methods research. A critical and comparative analysis of these types of research has been included.

The new edition contains a new chapter on statistical analysis of research data. This chapter covers quantitative analysis of both group- and single-subject study results. We have outlined both parametric and nonparametric tests for analyzing research data. In addition, the chapter covers such contemporary topics as narrative reviews, systematic reviews, and meta-analyses of both group- and single-subject design data.

The sections on single-subject research analysis includes guidelines on visual analysis and assessment of quality indicators. We have reviewed the effect size statistics for single-subject data and have included nonoverlap techniques and *d*-statics.

Finally, the new chapter contains a discussion of statistical versus clinical significance of treatment research evidence. We have given an overview of quantitative and qualitative measures of clinical significance.

The widespread use of this book as a text in classrooms over 30 years across the country and beyond has strengthened our belief that instructors of research designs in communication disorders would welcome a text that represents both the single-subject and group design strategies along with issues of measurement; philosophy of science; ethics of research; and planning, conducting, and reporting research. We wish to express our appreciation to all those instructors who have found this book an effective teaching device and have taken time to offer their thoughtful comments.

—M. N. H.

PART I

Science and the Scientific Methods

1

Why Study Science and Research Methods?

Chapter Outline

- Evaluation of Research
- The Need to Study Scientific Methods
- The Need to Produce In-House Knowledge
- Why Research by Clinicians Is Limited
- Problems Associated With Certain Research Practices
- Problems Associated With the Education and Training Models
- Summary
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Communication disorders is both an academic discipline and a clinical profession. As an academic discipline, communication disorders seeks to study and understand normal and disordered communication. As a clinical profession, it is concerned with the methods of assessing and treating various disorders of hearing, speech, language, voice, and fluency. An academic discipline can research practical problems without applying the information it generates. For example, a biochemist who develops a new drug that can be used in treating a particular disease may not treat patients with that disease. In communication disorders, researchers who develop new information or technology also may apply that information in the treatment of disordered communication. In this sense, communication disorders is simultaneously concerned with both scientific and professional matters.

As the discipline of communication disorders emerged and developed, the professional aspects, rather than the scientific bases, received greater attention. This is understandable because the starting point of the discipline was a professional concern to understand and treat speech problems, especially stuttering and speech sound disorders. The profession had to begin providing clinical services without the benefit of a history of controlled experimental research to support clinical practice. Borrowing from several basic and applied disciplines, the speech-language pathologist of earlier days began to treat communication disorders. Historically, the emphasis has been on expanding clinical services rather than conducting experimental research to produce a scientific basis for those clinical services.

An unfortunate historical lesson of many human service professions, including that of communication disorders, is that clinical services can continue to be offered without a strong experimental database. Such services may be supported by subjectively solidified clinical experience, uncontrolled observations, anecdotes widely circulated by "authorities" in the field, descriptive research, and speculative theories. Systematic experimental evaluation of treatment techniques may be lacking. As a result, clinical services the profession offers may not be based on controlled research evidence. However, this may not deter a profession from offering services, partly because of practical exigencies and partly because something better is not available.

The problem with such a history is that the clinical practice does not change quickly when experimental research information begins to flow. The clinical practice of established clinicians may continue to be based on old and unverified assumptions. Typically, it takes several years to affect clinical practice on a wide scale because the research information must be incorporated into the training of new clinicians.

Evaluation of Research

Evaluation of old and new research is about as important as the creation of new in-house knowledge. Professionals who cannot evaluate research data and theories also cannot make effective use of information. Critical evaluation of research should be a part of the clinician's repertoire, and such an evaluation requires the same knowledge needed to do meaningful research.

The process of evaluating research data follows the same logical steps as

the process of designing experiments. Therefore, evaluation of research is possible only when clinicians understand how research is done. Clinicians who are not knowledgeable in science and methods of investigation in their field of study are likely to have difficulty in judging the relevance of the questions their colleagues research, the validity and reliability of observations, the relation between results and conclusions, the transition from evidence to theory, and the distinction between theory and speculation.

Furthermore, clinicians who are not sophisticated in the philosophy of science may not see logical and empirical mistakes in study designs. In such cases, clinicians who read research uncritically accept the author's interpretations. However, bad interpretations are about as prevalent as bad designs, and clinicians who cannot detect inconsistent relations between interpretations and results cannot separate data from conclusions. Data that are based on sound methods are always more valuable and durable than the author's interpretations imposed on them. Future clinicians and researchers may keep the sound data while rejecting faulty interpretations.

Even when many practitioners do treatment-related research, a majority of clinicians will read research papers mostly to improve their practice. The popular phrase "clinicians are consumers of research" has a ring of validity in that most clinicians will be users, not producers, of research. It is well known that naive consumers are victims of bad products. Similarly, clinicians who are naive in the methods and philosophy of science are likely victims of bad research; unfortunately, in a clinical science such as communicative disorders, individuals who receive services also become victims.

It is thus clear that clinicians who do not do research still need to understand science and research methods. Even if there is much research that cannot be applied, clinicians will have to keep reading and evaluating research because that is the only way they can find out what is useful and what is not. Those who avoid reading the research literature because some of it is irrelevant to clinical practice are sure also to miss what is relevant to them. Meanwhile, when research practices improve, and clinically relevant studies begin to be routinely published, clinicians will be unaware of them and unprepared to apply them in their practice. For detailed information on evaluating research, see Chapter 15.

The Need to Study Scientific Methods

It is now widely recognized that communication disorders needs to strengthen the scientific bases of its clinical practice. The need to place our clinical practice on an experimental foundation is growing because of many legal, social, professional, and scientific reasons.

Legal and Social Considerations

An increasing number of federal and state laws influence professional practices in communication disorders. A major source of influence is a set of federal laws related to the education of children with disabilities. The original Education for all Handicapped Children Act of 1977 (P.L. 94-142) had a significant effect on public school special education services, including those

of communication disorders. The law was amended in 1986, retitled Individuals With Disabilities Education Act (P.L. 101-476) in 1990 and reauthorized periodically. The latest reauthorization was in 2004 and ammended in 2015. (Many federal laws are periodically reauthorized and amended to address new concerns; therefore, the reader should consult the latest versions of the laws of interest.)

Some of the most significant requirements under these laws are that special education services must be oriented to the individual child and his or her family and the service programs must have specific procedures, objectives, and evaluative criteria. The laws place considerable emphasis on clinician accountability in that the effects of treatment programs must be documented objectively so that they can be verified by independent observers. Such documentation requires that changes in student (client) behaviors be measured systematically and continuously. As we shall see shortly, these and other mandates of the laws are in harmony with the principles of scientific clinical practice.

Other kinds of legal concerns necessitate a more objective and scientific clinical practice. Third-party payment for clinical speech, language, and hearing services is common now. Various government agencies and private insurance firms that pay for the services demand more and more systematic documentation of the need, the procedures, and the outcome of such services. Uniform and objective means of evaluating treatment effects are being encouraged by agencies that pay for services.

Many social concerns are also leading us in the direction of clinical practice based on scientific methods. The profession continues to take steps to increase public awareness of speech and language problems and the services that are available to individuals with those problems. Consequently, an increasing number of individuals and families are seeking and paying for services in private clinics and hospitals. At the same time, many people who are seeking services are also inclined to question the effectiveness of those services. Inevitably, widespread social awareness of speech, language, and hearing problems combined with higher demands for services and increasing cost of service delivery will result in a thorough scrutiny of professional practices.

Professional and Scientific Considerations

Regardless of the legal and social requirements, there are professional reasons for developing a scientifically sound clinical discipline. Much concern surrounds the professional standing of communication disorders in the community of clinical professions and scientific disciplines. There is a growing concern that the profession of communication disorders does not have high social visibility. The profession may not be well recognized by other established or recently developed professions, such as medicine or clinical psychology.

A profession can try to draw attention to itself by various means. It may seek better legal recognition and protection by more effective lobbying efforts. Extensive public relations and public awareness campaigns may be launched. Services may be more aggressively publicized through advertisements in local and national media. Since all professions have a business side, most of these efforts are fiscally necessary. Indeed, all professions find it necessary to market their

services ethically. Such efforts may yield somewhat quick results; however, to build a lasting and more solid reputation, the profession, in addition to taking all those steps, must put its practice on a scientific footing. In the long run, no amount of public relations campaign can compensate for questionable and subjectively evaluated clinical practice. In fact, public awareness—which is generally beneficial—can expose the inherent and widespread weaknesses of a profession.

Scientifically based and technologically competent professions enjoy good reputations and higher visibility. A profession can make significant progress when its concepts are scientific and its methods are evaluated objectively. The ideal to strive for is a solid scientific discipline and a clinical profession with a single identity. This ideal, when achieved, will help ensure the quality of speech and hearing services offered to persons with communication disorders.

The typical argument supporting a more scientific orientation is made on the basis of the legal, social, and professional requirements described so far. Such requirements are compelling, and anything that forces a more scientific orientation is welcome. However, a profession need not be driven entirely by such requirements. Professionals need not face legal, social, and professional image-oriented reasons and requirements to strive to be more scientific. Although the statement may sound tautological, science itself is a good reason to be scientific. The logical beauty, methodological elegance, and practical benefits of science antecede legal, social, and professional pressures.

Had the profession heeded the call of science from its inception, it is possible that most of the legal and social pressures would have become superfluous. Clinicians who by training and practice follow the methods of science do not need a push from public laws to write treatment targets in measurable terms. For such clinicians, the requirement that changes in client behaviors must be documented objectively will not come as news or as a legal nuisance. Their personal history of training and education will suffice for such purposes. Surely, social and legal demands can force clinicians to be systematic and objective in their clinical work, but those with a strong scientific background are inclined to be so regardless of such demands. Concerns regarding bad professional image may not necessarily drive clinicians to conduct or evaluate controlled treatment research. Well-trained clinicians have better reasons, including science itself. Scientifically competent clinicians are unlikely to be overly concerned with image; nevertheless, they are probably better for the profession's image than those who are concerned with public reactions but continue to offer questionable services.

These comments should not be construed as a negative evaluation of legal, social, and professional reasons to be more scientific. In fact, governments, social groups, and professional bodies have an obligation to protect the rights of people who seek and then financially support professional services. Societal and regulatory forces are necessary for smooth and socially beneficial operations of professions as well as sciences. Such regulatory forces have helped all professions and sciences move in the right direction, as we shall see in Chapter 17. The comments are meant to underscore an additional and often neglected reason to be more systematic, responsible, and objective in clinical work: the philosophy and methodology of science that

are capable of providing unsurpassed safeguards for both the profession and the public. Besides, science provides an unlimited and exciting opportunity to make significant advances in all areas of professional endeavor.

The Need to Produce In-House Knowledge

During the time when service delivery, not scientific research, is the urgent business, the profession is dependent on other disciplines for a knowledge base. Communication disorders historically has depended on some nonclinical disciplines such as linguistics, experimental psychology, and child psychology. It also has depended on clinical professions such as medicine and basic sciences such as physiology and physics.

Communication disorders has been a borrower for a long time, perhaps too much of a borrower and too little of an innovator. It borrowed not only basic or applied information but also conceptual frameworks, theories, paradigms, models, and methods of investigation and data analysis. Therefore, the slowly developing traditions of research in communication disorders have been extensively influenced by other disciplines that have offered methods and theories of varying degrees of validity, reliability, relevancy, and applicability.

It is true that certain scientific approaches, concepts, and methods are common to many scientific disciplines and professions. Nonetheless, unless a discipline quickly begins to produce its own experimental database, it will continue to borrow theories and methods that may or may not be appropriate for studying its subject matter. The only way some professions can begin to generate their own databases is to train their practitioners to do research. Professions such as medicine have the luxury of receiving a large and varied amount of custom-produced research information from outside their professions. Medicine has chemists, biochemists, physiologists, anatomists, biologists, geneticists, bioengineers, and a variety of technologists and technical product manufacturers (including global pharmaceutical companies) who do research dedicated to medicine and supply theoretical information and practical technology. There are not comparable bands of researchers and technicians supplying information and technology to communication disorders. Much of the information and technology the discipline borrows is not produced for it; its relevance may be incidental and, in some unfortunate cases, mistaken.

Specialists in communication disorders should produce their own knowledge base and technology, but this does not mean that they should not selectively borrow from other disciplines. Like other professions, communication disorders will continue to borrow what is relevant and useful. Many fields of knowledge are interrelated. Therefore, the fields benefit from each other's research. Nonetheless, what is urgently needed is a systematic effort to increase the in-house knowledge base and technology. A discipline cannot always expect other specialists to produce the basic scientific information necessary to understand its subject matter. A profession cannot always expect others to produce a relevant and effective technology.

The most significant problem with increasing the amount of in-house knowledge is the scarcity of research institutions and sustained research programs in communication disorders. Many univer-

sity programs in communication disorders are not research oriented, and large institutions that specialize in research are few or nonexistent. Producing a systematic body of reliable and valid scientific information is a slow process even under the best possible conditions. Therefore, under the existing conditions, the accumulation of valid knowledge in communication disorders will be a prolonged process. There seems to be no easy or quick solution to this problem. Several steps are necessary to increase the amount of research; for example, the discipline can seek more government and private research funds, increase the number of theses produced by master's degree candidates, accelerate research efforts at existing research and teaching institutions, and establish new programmatic research.

Another tactic is to recruit practitioners into the kind of research that does not detract from clinical activities. That is, the field can make an effort to increase research by practicing clinicians. Since the majority of persons in the field are clinicians, even a slight increase in the number of clinicians doing research may have an appreciable effect. This is the kind of in-house knowledge base that can have immediate and simultaneous clinical and theoretical significance.

Why Research by Clinicians Is Limited

It is well known that a majority of clinicians do not do research. After all, they are busy serving their clients. There are many reasons why clinicians typically do not engage in research. For example, most clinicians do not have the needed extra time for research. Besides, when research is thought of as something unrelated to clinical service, the clinicians obviously cannot do research. Also, the client scheduling may be good for clinical work but bad for research; when clients are seen twice weekly for a few minutes each time, collecting in-depth data may be difficult.

Most clinical settings do not support or encourage research. Many public schools and hospitals do not require research from clinicians and may not encourage it. Much research, both good and bad, is done when research is required or valued in a given setting. It also may be noted that bad research can be done even when someone "wanted" to do research while it was not required to achieve promotions or pay raises. In many settings, research often is done over and above one's regular duties. When it is not required for professional advancement, the administration is unlikely to support research to any great extent.

It also is possible that clinicians themselves assume that: (a) they are not well prepared to do research and (b) research does not necessarily help them, their colleagues, or their clients. Both of these assumptions may be valid to a degree. The first assumption may be due to many practitioners' limited training and experience in research methods. To do research, one should also maintain currency in the slowly-but-surely changing field of knowledge in the discipline. The pressures of day-to-day professional practice may not be conducive to spending the needed amount of time and energy on reading the literature. Though significant advances in communication disorders have been few and far between, there has been an information explosion in recent years. It takes time just to keep up with published research. Because they do not have this time, many clinicians may think

that they lack the technical knowledge of scientific procedures and current information needed to do research.

The second assumption—that research does not necessarily help clinical practice—may be based on experience. There is some question regarding the extent to which research affects day- to-day clinical practice. Douglas, Campbell, and Hinckley (2015) stated that a treatment procedure that has support based on 20 years of research may still remain unused by the clinicians. With all the emphasis on evidence-based practice, there is no evidence to support that a majority of clinicians use treatment procedures that are known to be effective. In treating clients, clinicians are likely to depend upon their past training and clinical experience. Practitioners across professional settings do not automatically apply experimentally but unsupported theories, and recent trends without substance have a greater influence on clinical practice than do technical research reports.

Workshops, presentations, discussions with colleagues, and lectures on the "latest" techniques and "hot topics" may affect clinical practice more than experimental evidence does. However, even those who give frequent workshops often think that clinicians rarely apply exactly what the workshops offered. For example, some individuals who frequently attend workshops agree equally well with totally contradictory approaches, and clinicians assimilate what they hear (or read) with their past experience and apply new techniques in modified ways. Such modifications are not necessarily bad. The only problem is that unspecified and varied modifications of published techniques make it difficult to identify successful techniques. In any case, the disturbing situation remains: Controlled and technical research does not affect clinical practice to the extent it should.

The belief that research does not necessarily help clinical practice is partially true. We are *not* just referring to basic research, which is not expected to give immediate solutions to practical problems; we are referring to the kinds of research that are expected to solve clinical problems. Purported clinical research on assessment or treatment of communication disorders also may frustrate clinicians. Clinicians who read and evaluate such research to sharpen their clinical skills may be disillusioned about the usefulness of all kinds of clinical research. In essence, certain research practices may generate a justifiable skepticism regarding the relevance of research to clinical practice.

Problems Associated With Certain Research Practices

There are multiple modes of clinical research, and not all of them are equally helpful to the clinician in solving current practical problems. In Chapters 4 and 5, we will describe different types of research in some detail. Here it may be noted that clinical-experimental research is likely to produce results that help solve immediate practical problems clinicians face. Many other types of research, although essential, may lead to solutions to practical problems but only in the future.

Clinical usefulness is not the only criterion by which the value of research is determined. Basic research often does not have immediate practical significance. However, it is valuable because it might help explain a phenomenon, put unrelated observations in a single perspective, suggest new lines of experimental analy-