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METHODS OF CLINICAL EXPERIMENTATION TO IMPROVE PATIENT CARE

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METHODS OF CLINICAL EXPERIMENTATION TO IMPROVE PATIENT CARE

To the memory of SIR RONALD A. FISHER

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Foreword

This publication of a text on Clinical Experimental Method (CLEM as the authors call it) comes at a fortuitous time in the history and development of professional nursing. While early nursing research most often focused on the nurse as the provider of care, modern nursing research needs to evaluate the effectiveness of clinical nursing practice as measured by outcomes in the health status of clients. This requires controlled clinical trials with replication to test the generalizability of findings.

We, as nurse educators, practitioners, and researchers can no longer—indeed, if ever we could—afford the luxury of long, germinating stages of development, based primarily on attitude surveys and descriptive studies of existing practice. Such studies have value, but they are insufficient as the sole basis for professional growth in developing nursing leaders of the future. We are challenged today to be accountable for the effectiveness of our interventions as well as their efficiency, economy, and humaneness. The authors present CLEM as a paradigm for testing the effectiveness of existing practice and future innovations.

This publication is unique in its emphasis on replication, theory building, and inductively deriving general research principles from specific examples. The novice researcher is offered basic information about research terminology, techniques, and strategies. The more experienced researcher is provided with a sophisticated examination of the issues involved in articulating research with clinical practice and general theory. The Glossary and the Outline of Strategies and Techniques summarize the material in a way that enhances the value of the book as a reference source. The wide experiences of the authors in the study of nursing care problems, and the association they have enjoyed with faculty and students in schools of nursing, provide a broad background of knowledge about nursing and expertise in conceptualizing problems of intervention. Their advice to researchers is based on actual experiences in conducting clinical experiments, and it takes into account the organization of nursing services, political issues of interdisciplinary collaboration, and the complexities and compromises required by "the everyday flux of ongoing clinical settings."

viii Foreword

The emphasis of the examples chosen is on manipulation of psychosocial aspects of nursing practice in hospital settings, since these affect both psychological and physiological aspects of the patient's welfare. This focus reflects the nature of the history of clinical experimentation in nursing and the authors' own experiences. However, as the authors point out, the methodologic techniques and principles they discuss are generalizable to the more physically oriented aspects of nursing interventions and to the practice of other professional groups (such as social workers, hospital administrators, and physicians). The intent of the authors is to promote a holistic approach in which all aspects of professional practice can be studied in terms of their effects on achieving health care goals.

Interdisciplinary approaches involving health practitioners and scientists of all kinds are needed in order to realize the full potential of CLEM as a research paradigm for improving patient care. Such research demands an organizational environment conducive to interdisciplinary research and to the conduct of research by practicing clinicians and teachers, in order to promote transfer of technology through enlightened administrative and educational practice. At the University of Rochester, we believe that the unification of nursing practice, education, and research offers an unusually favorable climate for improving patient care through clinical nursing research. We have been fortunate to have students, faculty, and staff work closely with Professor Wooldridge, whose contributions to the development of CLEM have evolved in part from his experience here. Through publication of this book, many of the benefits we at the University of Rochester have experienced from that association are now available to the profession at large.

Loretta C. Ford, R.N., Ed.D.

Dean, School of Nursing and Director of Nursing, University of Rochester

November 1977

Preface

This book was written to help promote the use of clinical experiments for testing patient care procedures and developing general principles of more effective practice. It is a companion volume to our *Behavioral Science*, *Social Practice and the Nursing Profession*,* which analyzed the relation between behavioral science and nursing, with emphasis on the development of clinical nursing theory. The relation between such theory development and clinical research was briefly sketched in one chapter. This book completes that sketch by presenting a paradigm for Clinical Experimental Method (which we refer to as CLEM).

CLEM is grounded in more than a hundred small-sample clinical experiments, which we have designed in collaboration with nurses and other social practitioners, beginning in the early 1960's and continuing to the present. In the first two sections, generalizations about methodology and theory building are derived from examples chosen from these experiences, in order to ensure that they will be directly relevant to the situations a beginning clinician-researcher might face. These sections begin by assuming as little as possible about knowledge of methodology, statistics, and theory building. However, they go on to develop and present advanced material, which should be useful even to experienced researchers. This is particularly true of the third section, which deals with general issues of philosophy, methodology, and application.

The majority of the experiments we discuss were conducted at a single institution between 1960 and 1966. This choice permits us to address issues of replication and historical continuity that are essential to the understanding of research as a process. These example experiments typically involved small samples of patients, with one or two nurse clinicians conducting the research, and with a short time between manipulation of one or two independent variables and measurement of the dependent variables. Basic designs of this kind are emphasized for the following reasons: (1) they are the best starting

^{*}This book is currently out of print. Our forthcoming Behavioral Science and Nursing Theory will contain a revised and expanded version of this material.

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point for learning about experimental research; (2) small-sample experimentation is one of the most efficient strategies for exploring new dimensions of patient care; and (3) the simplicity of such designs makes it possible to explore in depth selected issues of measurement, theoretical inference, and data analysis.

Using CLEM to improve patient care does not require a large investment in new facilities or education. It does require four elements: (1) a skilled and thoughtful clinician with an idea for a new procedure to test; (2) access to a setting where the procedure can be tested; (3) availability of statistical and methodologic consultation; and (4) knowledge of clinical experimental methodology and an appreciation of its feasibility and desirability. The first three are already available in most health care facilities. The material in this book is designed to provide the fourth element.

For the clinician, experimental research has major advantages over questionnaire surveys or other kinds of nonexperimental research, since it is a natural extension of the problem-solving and documentation that are the essence of thoughtful clinical practice. To improve patient care through experimentation requires clinical expertise in performing the procedures whose effectiveness are to be tested, assessing the validity of the results, and generalizing about potential applications to other settings. Clinicianresearchers often find it useful to consult research methodologists, statisticians, and (perhaps) computer experts; but this does not mean that they can delegate all the responsibility for designing the study and analyzing the data to such consultants. For optimal results, the clinician should know enough about research and theory building to collaborate actively in the design and data analysis, and the methodologist should know enough about the patient care area to collaborate actively in planning the intervention and data collection procedures. This strategy was used in designing and carrying out the research on which CLEM is based, and it is the strategy that we recommend for its application. The improvement of patient care is a goal the clinician and methodologist share, and experimental research is essential to achieving that goal.

The nurse-researchers and other clinicians with whom we have collaborated over the past 17 years have contributed in many ways to the development of the ideas presented in this book. In addition to those whose contributions are cited in the text, Margaret G. Arnstein, Donna K. Diers, Virginia A. Henderson, Ida J. Orlando, Florence S. Wald, and Donald B. Trow deserve specific acknowledgment. We would also like to acknowledge the general contributions of all the other students and faculty who discussed clinical research with us at Yale University, the University of Rochester, the University of Iowa, the University of Western Ontario, the University of Arizona, Case Western Reserve University, and the Medical College of Ohio at Toledo.

We very much appreciate the help received in preparing and editing the

manuscript. Jill H. Wooldridge shared the major responsibility for editing the final draft with a compulsive perfectionism that was needed and appreciated. Pat Stannard made essential editorial contributions at a crucial point in the early writing stages. Elsie Gardner, Jean Jacobson, and Lenore Bookless cheerfully typed and retyped multiple drafts of illegible scrawls.

Special acknowledgments are due to Raymond V. Bowers, who suggested the Latin term "ceteris fortuitous"; to members of the School of Nursing Committee for Research Involving Human Subjects at the University of Rochester—Madeline Schmitt, Elizabeth Speegle, Dorothy Taylor, and Mack Lipkin, Jr.—who contributed to the development of the position on research ethics discussed in Chapter 8; and Trev Leger, for his early encouragement and support.

> P. J. Wooldridge R. C. Leonard J. K. Skipper, Jr.

> > December 1977

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Section I

BASIC CONCEPTS AND PRINCIPLES

Section I demonstrates how methodologists think about clinical experimentation and causal theory building. Chapter 1 describes the history of an actual clinical experiment. Methodologic concepts, terms, and principles are then introduced and are illustrated by applying them to the analysis of this example.

Technical terms and methodologic principles are important because they help in thinking about how research results relate to theoretical principles and to the improvement of patient care. It is most important to understand the way these terms are used and the methodological problems on which they focus, rather than to become overly concerned with memorizing their definitions. However, without learning something of the language that methodologists use, it is almost impossible to read and understand discussions about research; thus, in Chapter 1 considerable emphasis is placed on introducing and defining basic terms. Each term is italicized when it is introduced in the text and is followed by a brief definition and an illustrative application to the example experiment. Major terms are also included in a glossary at the end of the book. Methodologic principles are also presented in italics.

It is, of course, possible to do sound experiments without knowing all of these terms and principles. The basic notion of field experimentation is simple, and common sense might warn the researcher to avoid many of the problems discussed. The beginning researcher may feel that technical matters are better left to more experienced researchers. However, the experienced researcher is likely to avoid serious problems in doing research because of previous encounters with similar studies. It is the beginning researcher who has the greater need to be familiar with technical terms and methodologic principles as reminders of the issues being addressed.

Methodologic concepts and principles form a special language—a language designed particularly for thinking about the problems of doing sound

research and making valid theoretical inferences. In learning any language, one first learns about the terms superficially by seeing how they are used and only learns their full meaning through using them in thinking, talking, and writing. This takes time, so it may be necessary to reread the early sections of this book to help understand later sections. This is part of the process of learning to think systematically about how research can be used to test theory and improve clinical practice.

Chapter 2 introduces the reader to the fundamentals of making theoretical interpretations from data. Theoretical interpretations explain, in terms of general principles that can be applied to many different kinds of patient care situations, why a research result was obtained. Theoretical interpretations are the basis of valid generalization, and they help connect the research results to the results of other studies. Consequently, they play a very important part in the development of a scientifically based practice. However, theoretical interpretations go beyond what was actually established by the research, so there is always a possibility that the interpretations are incorrect.

Clinical diagnosticians must consider alternative interpretations in weighing the evidence of a clinical test in support of a given diagnosis. Similarly, the theoretician must consider other possible interpretations of research results in weighing the evidence in support of a given theoretical principle. The clinican reaches a valid conclusion by using a wide variety of clinical tests and by repeating the same tests under different conditions. The theoretician is also likely to improve the validity of interpretations by using a variety of measures in testing an experimental result and by replicating (repeating) the experiment under different conditions. Just as the essence of clinical judgment lies in making differential diagnoses, the essence of theoretical judgment lies in distinguishing between competing theoretical interpretations. A theory building technique called "causal modeling" is used to show how alternative interpretations can be identified and how multiple measures and replication can be used to help distinguish between alternatives.

While these first two chapters set the stage, they do not present the illustrative studies in sufficient detail to show the wide variety of technical procedures of design and data analysis from which the researcher chooses in attempting to minimize threats to valid interpretation. These topics are covered in greater detail in Section II. The initial two chapters also say very little about nonexperimental design, the history of clinical experimentation, ethical issues in designing experiments, or difficulties in putting experimental results to use on a broad scale to improve clinical practice. These topics are examined in Section III.

CHAPTER 1

Elements of clinical experimentation

Who has not thought, "There must be a better way to do this?" How to find a better way and how to know with some certainty that it is better is what clinical experimentation is about. Everyday clinical experience is a rich source of ideas about how to improve patient care, and such ideas can best be tested in this same clinical setting. One clinician with a good idea can do a valuable study; the essential ingredients are clinical competence and knowledge of the basic concepts and principles of experimental research.

In this chapter, a simple clinical experiment is recounted without the use of technical terminology. Basic methodologic concepts and principles are then defined and illustrated by applying them to the example experiment. Finally, an overview of the logic of clinical experimental design and data analysis is presented, using the terms and principles that have been defined.

AN EXAMPLE CLINICAL EXPERIMENT

Consider the following, only somewhat fictionalized, history of a clinical experiment.¹ A clinician had the idea that patients who were emotionally distressed preoperatively were more likely to vomit in the recovery room. She got this idea from experience as a student nurse, when she was assigned responsibility for taking care of the emesis basins in the recovery room. To know which patients were more likely to vomit and need the emesis basins was useful to her. In that particular hospital she would see the patients preoperatively and then also would see them in the recovery room. It seemed to her that she could tell in advance which patients were more likely to need the basins. Knowing about the association between preoperative emotional distress and emesis in the recovery room made her own job easier.

¹The knowledgeable reader may recognize that the clinical experiment described in this chapter is based on Rhetaugh Dumas' early experiments on postoperative vomiting. The account is accurate enough in most respects, and some of Dumas' published and unpublished work has been quoted. However, modifications have been made in a number of places in order to avoid complications. The reader should therefore *not* consider this to be a substitute for reading Dumas' work. See instead Dumas (1963); Dumas and Leonard (1963); Dumas et al. (1965); and Dumas and Johnson (1972).

4 Basic concepts and principles

To be able to tell in advance when problems are likely to occur helps the clinician prepare for them. It is even more useful to be able to prevent the problem from occurring. In fact, this became the next step in this clinician's experience. She began to think about how she might relieve patients' emotional distress preoperatively and thus reduce vomiting in the recovery room. This idea developed some years after the first experience—this time when she was studying social interaction theory. She analyzed her interaction with patients and developed a general idea of how to talk to them in order to relieve emotional distress.

She came to believe that she could help patients define and accept their hospitalization by (1) discussing their worries and fears about their operations, (2) providing information about the operations, and (3) correcting misconceptions. Patients would then be more confident and would experience less emotional distress when they actually underwent surgery. Her earlier experience with postoperative vomiting suggested that this approach would also reduce the incidence of postoperative vomiting. She was not sure it would all work out that way; but if it did, it would be new knowledge about how nurses could help surgical patients. It would be important because postoperative vomiting is a potentially dangerous complication and because emotional distress can lead to other serious problems.

In her clinical practice she attempted to identify and help patients she thought were anxious about their operations. It seemed to her that their anxiety was decreased and that they were less likely to vomit than she would have expected from her past experience. But she could not be sure that she was right. Perhaps she was fooling herself in believing that the patients became less anxious. And perhaps the patients would not have vomited anyway. Informally trying her idea out in her practice made her feel even surer that she was right. But a more rigorous test was needed. In consultation with a research methodologist, she designed a simple clinical experiment to test her prediction that she would be able to reduce postoperative vomiting by talking to patients about their worries and fears.

First, she thought about the kinds of patients who would be most likely to have their postoperative vomiting reduced by her approach. If she were going to try to reduce postoperative vomiting, then she must find a place to do her research and determine the kind of patient in whom postoperative vomiting was likely. If she were going to reduce the patients' anxieties and fears by talking to them, then she should choose patients likely to have anxieties and fears. Finally, she would like the patients to be as similar as possible on other things that might influence vomiting. She decided to use only patients scheduled for gynecologic surgery under general anesthesia. She did this to make all the patients comparable in terms of sex, surgical procedure, and type of anesthesia, since she knew from a study of hospital records that postoperative vomiting rates were associated with these factors. She chose

females undergoing gynecologic surgery with general anesthesia because they had the highest postoperative vomiting rates and because she was convinced from her earlier experiences that they often have anxieties and fears about surgery.

Second, she described how and when she would talk to the patients and how she would determine whether or not each patient had vomited after the operation. She would first observe and talk to the patient, watching for any indication of distress. If she noticed anything in the patient's behavior that indicated distress, she would explore her observations with the patient in order to see if she was right and, if so, to find out what was causing the distress and what she might do to help. Then she would try to help the patient in any way that seemed appropriate, such as providing information, reinforcing the patient's desire to talk about fears, and helping the patient adjust to the hospitalization in whatever way seemed best. She would then explore further with the patient to see if she had relieved the distress and, if not, would provide further help. In other words, the clinician would enlist the patient's cooperation in determining the patient's needs, the course of action best suited to meet those needs, and whether the action taken had been successful 2

Finally, the nurse decided that postoperative vomiting would be documented by her own observation in the recovery room. If any amount of stomach content was ejected through the mouth by the patient during her stay in the recovery room, she would be recorded as having "vomited"; otherwise she would be recorded as having "not vomited."

Now the nurse was ready to test her theory. She began with two patients selected from the gynecologic surgery schedule. She tossed a coin to decide which of the two patients to talk to preoperatively and which patient not to talk to. In addition, both patients would receive the ordinary preparation specified by the very high, but physically oriented, standards of this university medical center. In the recovery room she observed the patients and recorded whether or not each vomited and, if so, how much. She went back another day and repeated with 2 other patients. She continued this for a total of 5 operating days, 2 patients per day. At the end of those 5 days, the results were as follows: none of the patients to whom she had talked vomited in the recovery room; in contrast, 3 out of the 5 patients to whom she had not talked vomited.

With as few as 10 patients she still couldn't be confident that her talking with the patients was reducing the postoperative vomiting rate. However, the results were certainly very encouraging. The experiment was repeated until there were 50 gynecologic patients in the study. Of 25 patients talked to by

²This is essentially the "deliberative" nursing process as described by Orlando (1961). The substantive emphasis on cognitive structuring as a means of reducing emotional distress for surgical patients is related to hypotheses proposed by Janis (1958).

the research clinician, only 4 (16%) vomited. In contrast, 14 (56%) of the 25 comparison patients who received only the regular, physically oriented, preparation vomited. This was a difference of 40 percentage points in the postoperative vomiting rate. It was very unlikely that the nurse could have found such encouraging results unless she were really reducing vomiting. However, there was still the possibility that in spite of her care in documenting the postoperative vomiting rate, she might have been influenced by knowing which patients were experimental and which were control. The last fifteen pairs in the experiment ruled out this possibility by documenting postoperative vomiting through an observer who did not know which patients had received the extra preoperative preparation.

This is close to the true story of one clinician who had the satisfaction of seeing an original idea from her clinical experience as a student turn into a nursing procedure with demonstrated usefulness in preventing postoperative vomiting. It also produced important implications for patient care in general. Her general result has been supported by experimental research with patients having other kinds of surgery and with pediatric and obstetric patients. (For example, see Bender, 1963; Moran, 1963; Egbert, 1964; Healy, 1968; Skipper and Leonard, 1968; Schmitt and Wooldridge, 1973; Wolfer and Visitaner, 1976.)

RESEARCH CONCEPTS AND TERMINOLOGY

The previously discussed case history of a research project was written without using formal research terminology. Once one has a feel for the basic logic of clinical experimentation, it is easier to understand the meaning of the terms used to talk about research. Just as knowledge of clinical concepts helps in thinking about patient care, knowledge of research concepts helps in thinking about research. Clinical concepts and terminology provide a systematic framework for evaluating and treating illness. Research concepts and terminology provide a systematic framework for evaluating and for drawing valid conclusions from research data.

The previous discussion of an example experiment included the methodologic concepts associated with the following research terms: variable, category, variation, covariation, hypothesis, operationalizing, theory, cause-effect, manipulation, temporal order, prediction, spuriousness, holding constant, random assignment, probability test, replication, and blind measurement. These are some of the basic methodologic terms used to discuss research, experimentation, and theory building. They are not necessary for a nontechnical discussion of an experimental study; but they clarify the methodologic and theoretical issues that are only implicit in such a discussion, and they are needed to formulate general methodologic principles that can be applied to other studies. In the following sections, we will introduce, define, and illustrate these research terms.