COMMENTARY

No Research Versus Research With Compromised Results: A Study of Validation Therapy

SUSANNE S. ROBB • CHARLES E. STEGMAN • MARY OPAL WOLANIN

Experimental designs have become the cornerstone of experimental research in the health sciences. Control of extraneous variables and threats to internal and external validity are well-known attributes of this research (Cook & Campbell, 1976). Unfortunately, in many instances such methodological rigor cannot be achieved, and serious design problems follow (Flay & Best, 1982). One of these instances may be found in institutional care settings serving elderly resident populations.

One extreme solution to these problems is to not conduct research. Perhaps this solution is one reason that gerontological research is infrequently performed in institutions. However, were everyone to adopt this strategy, nurses would practice in a research-based vacuum.

Agencies engaged in long-term care of the elderly tend to adopt programs without valid information about their effectiveness. Resources required to implement them, in the context of controlled trials, are rarely available. The programs begin, run for a while, and then vanish. Only the developers who market them are clear beneficiaries! Geriatricians and gerontologists are years away from curing problems that the programs attempt to alleviate. Closer-to-ideal research environments in long-term care are even further away. It is debatable whether evaluations, done under ideal conditions, will produce programs that can be readily adopted in suboptimal settings.

This article reports a study of validation therapy, a popular program that is threatening to surface in many long-term care facilities in the absence of research-based information about its effectiveness. By the time this study was completed, it was so flawed that the results were severely compromised. The real value in publishing this report rests in its potential to encourage others to evaluate validation therapy, using flawed designs if necessary, so that a body of valid information can emerge, based on conceptual generality.

Replication to achieve conceptual generality has been a fundamental tenet of science. Replication is not as simplistic as repeating an experiment the same way. The science of physics is not advanced by having students perform the same classical experiments over and over again; these students are learning about experimentation, not increasing core scientific knowledge. Replication entails the ability of ideas or results to hold up under generalized conditions. Hendrick and Jones (1972) argued that the basic premise of conceptual generality is that when the same results are found with different subjects, situational factors, and other variations in study procedures, the aggregate results are accepted with greater confidence than the results from any single study. The idea of conceptual generality represents a potential solution to the problem of obtaining valid results from studies that lack methodological rigor because they focus on human behavior in complex health care environments.

Research Background: Reality orientation (Taulbee & Folsom, 1966) achieved acceptance as a therapy for the severely disoriented elderly before a number of important questions were answered, such as whether the process or content was responsible for the effects produced. One major objection to reality orientation concerns the degree to which emphasis on orienting residents in long-term care settings to time, place, and person reflects the realities and demands of the institutional environment (Bernstein & Dvorkin, 1978; Carroll & Gray, 1981). For example, is it functionally adaptive to be continually aware of time within an institutional setting characterized by the absence of activities to fill time? Johnson (1980), Mitchel (1980), and Zepelin,

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Wolfe, and Kleinplatz (1981) all questioned the benefit of reality orientation for severely disoriented aged persons.

Feil (1967) proposed an alternative therapy after she observed that severely disoriented elderly clients failed to respond to orientation therapy. Her treatment, generally referred to as validation therapy, is based on the premise that there is logic behind all behavior, even disoriented behavior. Awareness of reality is not the goal of this therapy; the goal is to help the individual relate behaviors to logical meanings. The therapist employs principles of empathic listening and group work to discover the severely disoriented person's inner reality in order to reach the individual (Wetzler & Feil, 1978). Specific procedures and techniques are described by Feil in a number of sources (E. Feil, 1972, 1978; N. Feil, 1982a, 1982b). This therapy had been evaluated only by its developers using mostly female subjects. Their evaluation methods have not been published, however, and their results are therefore based primarily on clinical experiences and impressions.

Despite the possibility that validation therapy might not prove useful for severely disoriented elderly persons with neurological damage (N. Feil, personal communication, June 6, 1980) and might need to be used up to 3 years to produce results (Feil & Wetzler, 1979, p. 43), staff were eager to try the therapy. To facilitate the process, a research hypothesis was developed: A validation therapy group would show less decline when compared to a control group on the following variables: mental status, morale, and social behavior. Records were kept to permit description of the program, as well as time and monetary expenses, session content, length, and frequency.

Method: *Study Setting:* The setting was a 400-bed long-term care division of a large Veterans Administration Medical Center. Based on a 1981 census of the 398 residents, the population was essentially all male, and the following functional status problems were prevalent: confusion (56%), wandering (15%), mobility impairment (80%), and incontinence (61%). Thirty-six percent of the residents were 75 years of age and older (Robb, 1981).

Sample. Questions about adequate sample size and selection procedures are often difficult. In long-term care settings, the number of residents who meet study criteria is usually smaller than the researcher would prefer to attain high statistical power. Instead of randomly selecting an appropriate number of subjects from a large population, the researcher generally has to choose between studying 100% of a numerically inadequate volunteer sample or conducting the study in several different settings. This latter strategy introduces the risk of confounding setting with either treatment or subjects, especially when the treatment is psychosocial in nature and thus highly dependent on those who provide and receive the intervention.

An interrupted time–series design with switching replications represents one solution to the problem of inadequate numbers of subjects. Although there are several sources of invalidity within this design (Cook & Campbell, 1976), a major problem concerns the drain on staff resources imposed by repeated measurement. This burden can also affect subjects who are tested repeatedly using the same measures.

Available resources for the validation therapy study were not sufficient to support any more than single pre- and postmeasurements. Therefore, in the current study, a pretest–posttest, two group (control and experimental) design was initially planned with random assignment to each group.

The study group included all residents who were (a) 60 years and older, (b) moderately to severely disoriented (but not disoriented due to documented neurological disorders including Alzheimer's disease, Pick's disease, Huntington's chorea, or a cerebrovascular accident within the past 6 months), and (c) unlikely to be discharged during the next 12 months. Head nurses and physicians were asked independently to nominate all residents who met the study criteria. Of the 398 residents, 60 were nominated; 36 met the eligibility criteria.

Willingness to participate was obtained by assent, rather than written consent. In this study, assent was defined as the absence of verbal or nonverbal objection to possible participation in a program involving group discussions of past experiences and answering test questions. This procedure was approved by the human rights committee only because of the minimal risk inherent in the program and study procedures and difficulty experienced in locating relatives or guardians. The committee realized that serious legal and ethical questions existed concerning the use of "assent" in place of actual written consent. When the revised code of Federal Regulations, concerned with protection of human subjects (National Research Act, 1983), was adopted in 1983, the code did not include a section dealing with research on the elderly and/or mentally infirm and, in effect, did not sanction the procedure.

Control Conditions: Ideally, subjects in control and experimental groups are treated exactly the same except for the program that is being evaluated. In this study, the treatment involved a much greater attention-giving component than other kinds of programs such as medications, where double-blind and placebo procedures can be used.

In such psychosocial studies, three-group designs are often required. However, the setting did not contain enough subjects for three groups and the resources (staff, time, and money) did not exist to provide an attention-type placebo.

Initially, 16 subjects were randomly assigned to the control group and 20 to the experimental group. Randomization does not guarantee group equivalency, especially for small sample sizes. Fortunately, the two groups in this study had similar mean ages (80 and 81 years), and 12 and 13 members, respectively, had diagnoses indicative of dementia. The experimental group had a slightly less favorable mean mental status score (11 vs. 13 points) and a longer mean length of stay (3.8 vs. 2.8 years).

Attrition: Subject loss, due to illness and death, is to be expected in elderly populations. Researchers often oversample to compensate for this type of attrition. But, when all eligible subjects are included in a study, oversampling is impossible and the researcher has no control over the final sample size. Such was the case for this study; 9 subjects were unavailable for the posttest because of death ($n = 8$) or acute illness ($n = 1$). Twelve subjects remained in the con-

trol group (loss of 4) and 15 subjects (loss of 5) in the experimental group.

The program was offered twice a week for the 9 months from September through May. Six subjects who were originally assigned to the experimental group did not attend most of the scheduled sessions because of episodic acute illnesses ($n = 5$) or extremely disruptive behavior during group meetings ($n = 1$). This partial treatment group was not the same as the control or treatment groups. Some researchers opt to drop such a group entirely. Others include these subjects with the control group or, worse yet, count them as treatment subjects. The solution favored here was to include them as a special subgroup. Thus, data analysis included 12 persons in the control group, 9 in the experimental group, and 6 who had been randomly assigned to the experimental group, but who failed to attend a majority of the meetings. Compared to persons who remained in the experimental or the control group, those who dropped out were older, had longer lengths of stay in the facility, and demonstrated lower mental status scores.

Measures: The selection and/or development of appropriate measurement procedures are vitally important to behavioral science research. And yet, in many institutional settings there is little support for this type of research. In these cases, researchers are often forced to use ill-defined subjective measures of program effectiveness from existing measures that may or may not be adaptable to the current situation. Scarce personnel resources, lack of suitable instruments, and finite subject tolerance for testing also limit the number of dependent variables that can be considered in any study. Theory and previous research dictate the important variables to consider.

Of all the treatment effects reported by Feil and Wetzler (1979) and Wetzler and Feil (1978), three were selected for study. Mental status, morale, and social behavior were chosen because of the researchers' beliefs that change might occur more rapidly in these areas. Also, these variables could be quickly measured with few disruptions to the residents and the nursing staff. The developers and sole evaluators of validation therapy had not used procedures with established reliability, validity, and sensitivity. Therefore, tools with at least partly established reliability and validity were selected to measure each variable. Mental status of the subjects was measured by the Mental Status Questionnaire (MSQ) developed by Fishback (1977). Morale was measured with the Philadelphia Geriatric Center Morale Scale (PGCMS) developed by Lawton (1975). The Minimal Social Behavior Scale (MSBS) by Farina, Arenberg, and Guskin (1957) was used to evaluate social behavior.

The MSQ (Fishback, 1977) is a 36-item questionnaire that combined the Kahn, Goldfarb, Pollack, and Peck (1960) and Pfeiffer (1975) mental status questionnaires to give greater latitude and accuracy in determining degrees of senile dementia. Some degree of validity had been established in that "scores correlate highly with clinical findings" (actual coefficient not reported) (Fishback, 1977, p. 167). Reliability was not established for the combined instrument, but Pfeiffer's Short Portable Mental Status Questionnaire (SPMSQ) had test–retest correlations of .82 and .83 for two groups tested at 4-week intervals. In terms of validity, the SPMSQ was significantly, $p \leq .001$, correlated with clinical diagnosis of organic brain syndrome in two study groups. The MSQ was found to be "highly related to psychiatrists' clinical evaluations of the presence and degree of chronic brain syndrome" (actual coefficient not reported) (Kahn et al., 1960, p. 328).

The PGCMS is a 17-item, 3-factor scale (tranquility, attitude-toward-own-aging, and lonely–dissatisfaction) that yields an overall measure of morale. Reliability statistics were as follows: KR 21 = .81 (matched items); $r = .75$ test–retest (5 weeks). Validity studies indicated a moderate correlation with interviewers' life satisfaction ratings ($4 = .57$) (Lawton, 1972, 1975), as well as high correlations with other morale scales: LSIA = .74; Dean = .57; Kutner = .73; LSIZ = .79; and LISA-A = .77 (Lohman, 1977, p. 74).

The MSBS is a 32-item instrument that taps habit patterns that are disrupted only in the extremes of pathology. The scale can be administered quickly and without previous acquaintance with the client. Interrater reliability between two raters scoring the same sample of behavior was .96 ($N = 15$) (Farina et al., 1957). A test–retest correlation of .87 ($N = 13$) was obtained after a 7-week interval. The scale was able to detect at a statistically significant level (actual significance level not reported), changes that presumably resulted from a promazine treatment program. The scale was found to differentiate, $p \leq .001$, four groups of clients with varying levels of psychopathology (Farina et al., 1957).

Several problems became apparent when these instruments were used with the validation study population. For example, to score the MSQ (Fishback, 1977), researchers had to know whether residents actually had dentures, where those dentures were located, and the names of the resident's mother and father. Because of deficiencies in written records and inaccessibility to significant others, correct answers for some items were unknown. Given the high rate of mobility deficits among subjects, many were not able to pick up a pencil from the floor or draw a four-sided figure with diagonals, tasks required in the MSBS (Farina et al., 1957). Admittedly, trial administration (Fox & Ventura, 1983) of these instruments would have revealed some of these problems. However, pretesting would have meant postponing the study to allow for further instrument development.

Internal consistency reliabilities for these instruments were acceptable in this study. The Cronbach alphas computed at both pre- and posttest exceeded .75.

Results and Discussion: Differences between the pre- and posttest scores on mental status, morale, and social behavior measures for the three study groups, proved nonsignificant, $p \geq .05$. Given the limitations of the sample sizes and the lack of normative information on the variables for elderly populations, the use of parametric statistical procedures is highly questionable. However, given the use of random assignment to the two main groups, the use of nonparametric procedures under a randomization model is more justifiable (Lehmann, 1975). There was little difference between pretest–posttest results or the posttest results between the groups on the three measures (Table 1). The experimental dropout group scored consistently lower on all three variables. However, using the Kruskal–Wallis one-way ANOVA on the posttest, scores revealed no significant differences at the .05 level between the groups.

Salaries for personnel involved in conducting the validation therapy program were the greatest costs incurred. Space was available for comparatively small groups of 10 to 12 persons to meet. Most supplies were available by donations from program staff and volunteers. No money was paid to staff persons who conducted the program, apart from their regular salaries. However, unlike space and supplies that did not represent losses to another program, time spent by the nurses and social workers represented a loss to the larger programs for which they were responsible. In addition, some preparation was done during off-duty time.

Conducted as a small-group therapy in a centralized location, validation therapy was labor-intensive, and, thus, expensive. A major problem with the centrally located program involved escort services required to bring participants to and from sessions. This responsibility was assigned to nursing personnel because program team members were busy greeting participants and conducting the sessions. Volunteer escorts would have required considerable support to retain beliefs that the program was worthwhile and, thus, continue to offer their services. The program staff did not have sufficient time to support volunteer escorts.

For the program to continue as a discrete entity, additional personnel would be needed. However, a full-time validation therapist might be limited in ability to provide effective programming. The nature of the therapy is such that one person might become extremely bored with conducting more than two or three sessions a day for 4 or 5 days each week, or with conducting the therapy for 9 to 12 months.

The empathic model used in validation therapy placed unusual demands on the members/leaders who needed to be constantly active—physically and mentally—during sessions. On occasion, leaders found themselves unable to elicit responses from the men or involve them in the task at hand. Frustrated leaders relied heavily on each other for support. A second source of frustration occurred when other personnel implied the therapy team was making a "futile" effort to assist a "helpless" group.

Costs could possibly be reduced by shifting the program to clinical units, particularly those with large proportions of the kinds of residents believed by Feil and Wetzler (1979) to benefit from the therapy: severely confused, "old–old," and without definite neurological deficits.

If validation therapy were conducted by all personnel as an integral part of clients' treatment plans, no additional staff would be required. However, costs would then shift to cover the extensive and ongoing continuing education program required to teach the therapy to all program personnel.

Reports from nursing staff indicated no changes in participants' self-

Table 1. Differences in Mean Scores and Standard Deviations for Three Subject Groups Between Pre- and Posttest on Three Measures

Dependent Variable	Group[a]	Pretest $\bar{X}$	Pretest *SD*	Posttest $\bar{X}$	Posttest *SD*	Mean Change	
Mental status	C	14.4	3.1	13.3	6.6	−1.1	↓
	D	9.3	7.2	9.3	6.6	0.0	—
	E	12.1	3.0	12.8	6.0	+0.7	↑
Morale	C	8.1	5.0	7.2	4.4	−0.9	↓
	D	8.6	4.6	4.3	3.4	−4.3	↓
	E	8.4	3.5	8.6	3.0	+0.2	↑
Social behavior	C	21.9	4.5	19.2	6.9	−2.7	↓
	D	14.2	9.3	14.6	2.1	+0.4	↑
	E	22.0	4.4	18.2	6.6	−3.8	↓

NOTE. Higher scores = better status.
[a]C = Control ($n = 12$), D = Dropped ($n = 6$), E = Experimental ($n = 9$).

care abilities (such as dressing, toileting, or bathing). However, many of the residents did demonstrate changes in their social behaviors. Increased demands on the nursing staff for cigarettes, conversation, and so forth prompted at least one nurse to comment, "If these men keep returning so riled up, we'll just have to increase their tranquilizers." In many instances, staff retained negative attitudes despite having received materials describing the therapy and its potential benefits. Part of this problem stemmed from differences in goals held by the therapy team versus goals held by the staff. The latter group expected bowel and bladder continence to be restored, but the therapy team was satisfied with subjects' gains in social behavior or recognition of feelings.

Implications: Before results of this study can be used for decision-making, they should be integrated with those from other evaluations. Given the limitations imposed on doing research in long-term care facilities, it is doubtful if any single study will ever sufficiently control the threats to internal and external validity to warrant making final decisions about the worth of a new treatment program.

A question that researchers must face as they design their studies is, "At what point does inability to control threats to internal and external validity render the research worthless?" In adapting true experimental designs to fit the situational realities of long-term facilities, a number of compromises are often made. Each of these must be acknowledged in reports and the results discussed in light of these limitations. Although the researcher may not be justified in making causal inferences based on the study, the results can still inform decision-makers about some aspects of the phenomenon studied and point the way to better studies. The accumulation of results through techniques like meta-analysis (Glass, McGraw, & Smith, 1981; Slavin, 1983) may also lend strength to the conceptual generality of the results. Results are reported here in an effort to facilitate such comparisons. NR

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CALENDAR OF RESEARCH EVENTS

Announcements of coming research events should be submitted at least 3 months in advance of issue date.

April 9–10, 1986
"Riskbusters: Discovering Hazards in the Nurses' Workplace," cosponsored by the Mid-Atlantic Regional Nursing Association (MARNA), National Student Nurses Association, and Nurses Environmental Health Watch, will be held in Pittsburgh, PA (April 9) and New York, NY (April 10). For information contact: MARNA, Teachers College, Box 146, Columbia University, 525 W. 120 St., New York, NY 10027; (212/678-3988).

April 11, 1986
"Applying Ethical Principles in Continuing Care," sponsored by the Catholic Health Association, will be held in Boston, MA. For information contact: Department of Meetings, Catholic Health Association, 4455 Woodson Rd., St. Louis, MO 63134-0889; (314/427-2500).

April 16, 1986
"Nursing Practice Today: Legal/Ethical Conflicts," cosponsored by the Mid-Atlantic Regional Nursing Association (MARNA) and State University of New York/Downstate, College of Nursing, will be held in Brooklyn, NY. For information contact: MARNA, Teachers College, Box 146, Columbia University, 525 W. 120 St., New York, NY 10027; (212/678-3988).

April 17–18, 1986
The 2nd National Traumatic Brain Injury Symposium, "The Road to Recovery," sponsored by the Speech-Communication Disorders Program, Maryland Institute for Emergency Medical Service Systems, University of Maryland, will be held in Baltimore, MD. For information contact: Roberta Schwartz, MIEMSS, 22 S. Greene St., Baltimore, MD 21201; (301/528-6101).

April 17–18, 1986
The 22nd Annual Clinical Nursing Conference, "Traumatic Stress: The Healing Journey," hosted by the Cleveland Veterans Administration Medical Center—Nursing Service, will be held in Independence, OH. For information contact: Marva L. Gordon, PhD, RN, Veterans Administration, 10701 East Blvd., Cleveland, OH 44106; (216/526-3030, ext. 6522).

April 17–18, 1986
"Microcomputer Jungle: Impact on Health Care," sponsored by the University of Kansas Medical Center, will be held in Overland Park, KS. For information contact: Carol Rosen, University of Kansas Medical Center, Office of Continuing Education, 39th and Rainbow Blvd., Kansas City, KS 66103; (913/588-4480).

April 22–23, 1986
"Emergency Nursing: Maternal Child Health," sponsored by the University of Kansas Medical Center, will be held in Kansas City, KS. For information contact: Carol Rosen, University of Kansas Medical Center, Office of Continuing Education, 39th and Rainbow Blvd., Kansas City, KS 66103; (913/588-4480).

April 30, 1986
The 8th Annual Nursing Research Day, sponsored by the Pittsburgh Veterans Administration Medical Center, will be held in Pittsburgh, PA. For information contact: Karen Olson, RN, Veterans Administration Medical Center, University Drive C, Pittsburgh, PA 15240; (412/683-3000, ext. 306).

May 1, 1986
"Nursing and Human Values: Ethical and Legal Dimensions," symposium sponsored by the Alpha Omicron Chapter of Sigma Theta Tau, will be held in Chicago, IL. For information contact: Darlene O'Callaghan, MSN, RN, Saint Xavier College, 3700 W. 103 St., Chicago, IL 60655; (312/779-3300).

May 3, 1986
The 4th Annual Research Papers Day, sponsored by University of South Alabama College of Nursing and Zeta Gama Chapter of Sigma Theta Tau, will be held in Mobile, AL. For information contact: Alice S. Ward, EdD, RN, University of South Alabama, College of Nursing, EGLB, Rm. 244, Mobile, AL 36688; (205/460-7130).

May 5, 1986
Nursing Research Symposium, sponsored by the University of Kansas, will be held in Kansas City, KS. For information contact: Helen R. Connors, MSN, RN, University of Kansas College of Health Sciences, School of Nursing/Divsion of Continuing Nursing Education, 2011 Eleanor Taylor Building, Kansas City, KS 66103.

May 13–14, 1986
"Infection Control: How Do We Live with AIDS?" sponsored by the University of Kansas Medical Center, Office of Continuing Education, will be held in Kansas City, KS. For information contact: Carol Rosen, Office of Continuing Education, University of Kansas Medical Center, 39th and Rainbow Blvd., Kansas City, KS 66103; (913/588-4480).

May 14, 1986
"Perinatal Nursing: Challenges for the Future," sponsored by the Hospital of the University of Pennsylvania, School of Nursing Center for Continuing Education, will be held in Philadelphia. For information contact: Rita Nemchik, MS, RN, Center for Continuing Education, University of Pennsylvania School of Nursing, 420 Service Dr., Philadelphia, PA 19104; (215/898-4522).

May 15, 1986
"Research: 86," Annual Research Day, sponsored by the University of South Carolina, College of Nursing, will be held in Columbia, SC. For information contact: Mary Ann Schroeder, PhD, Assistant Dean, Nursing Research, College of Nursing, University of South Carolina, Columbia, SC 29208; (803/777-6510).

June 4–7, 1986
Research Institute, sponsored by Clemson University, will be held in Clemson, SC. For information contact: Dee Evers, Director of Continuing Education, College of Nursing, Clemson University, Clemson, SC 29634-1715, (803/656-3078).

June 8–10, 1986
"Nursing and Feminism: Implications for Health Care, sponsored by Delta Mu Chapter of Sigma Theta Tau and Yale University School of Nursing, will be held in New Haven, CT. For information contact: Dean's Office, Yale School of Nursing, 855 Howard Ave., New Haven, CT 06510; (203/785-2393.

June 22–28, 1986
The 4th Western Network Institute for Nurse Executives, sponsored by the the Western Network for Education in Health Administration and the National League for Nursing, will be held in Berkeley, CA. For information contact: Western Network for Education in Health Administration, School of Public Health, Warren Hall, 4th Floor, University of California, Berkeley, CA 94720.