

**A
GUIDE
TO
REHABILITATION**

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and

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CHAPTER 9B

Research Design and Statistics: A Practical Guide to Reading Research Literature and Practice Guidelines¹

by

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SCOPE

This chapter will introduce you to the skills necessary to effectively read, dissect, and interpret published research literature and practice guidelines. Basic research methodology for the life care planner will be presented and, by the end of this explanation, you will find you will be able to glean far more information out of each resource you tap into throughout the planning process. If you have traditionally been afraid of basic research or statistical terminology, relax. This chapter will take you step by step through what you need to know to make getting through the literature enjoyable, informative and rewarding for you and your patient.

Consider this statement: “. . . realizing the practical benefits of a scientific approach to knowledge in rehabilitation counseling is contingent upon the ability of rehabilitation counselors to translate scientific principles and research-based findings on their practice?”

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(Bellini & Rumrill, 1999). This applies equally to any health-related professional who finds it necessary to make effective use of research literature in their day to day practice.

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§ 9B.15 References**§ 9B.01 Theory Development**

The ultimate goal of science is to develop theories that explain relationships between traits or variables and predict how they interact. A theory is a model of the interaction between variables. Theory development is a goal and a tool of research relied upon to identify related variables, explain how they are related, and to determine why they are related. Theories are developed from methodically testing the various components of the model according to a hypothesis about the characteristics of a particular component. A hypothesis is an educated speculation about a characteristic of a particular element of the model. Research is the process of testing hypotheses to obtain information. Theories arise out of the data accumulated from multiple hypotheses tests. Hypotheses enable the researcher to operate within a framework of knowledge while examining how well it explains and predicts empirical data, while theories summarize and order existing knowledge regarding a particular area of study.

[1] What Research Is

A comprehensive review of the principles of research are beyond the scope of this chapter and most practitioners will have completed introductory coursework in basic research designs and concepts. The following points attempt to highlight some of the more important characteristics of scientific research:

- The aim of research is to contribute to the development of theories, general principles, and descriptions of a research problem;
- Research is directed toward the solution of a problem

(Best, 1970);

- Research is built upon the premise that knowledge is generated from methodical investigation, experience, and objective observation;
- Research is guided by carefully designed procedures governing sample selection, instrumentation, data collection, data analysis, and interpretation of results;
- Research is based upon what is already “known” about the problem under investigation;
- Research is based upon accurate, objective observation and description;
- Research is based upon a chain of reasoning;
- Research utilizes quantitative measurements, valid and reliable instruments, and psychometrics to record, calculate, and analyze data;
- Research involves systematic definition of all related terminology, limitations are acknowledged and procedures are described in detail;
- Research demands well-documented references, accurate data retrieval and record-keeping, and carefully considered conclusions;
- The body of research within a field of study is self-correcting. Misinformation, ill-founded conclusions, and aberrant results are discredited and, over time, replaced by more accurate and precise knowledge;
- Scientific methodology controls and verifies the procedures and conclusions which can be reasonably asserted by the researcher.
- Scientific methods are used to test and encourage the proposal of alternative hypotheses.

[2] What Research Is Not

Researchers, and consumers of research, should be aware of the limitations of scientific study and should be able to recognize faulty methodology in the work of others.

The purpose of research is not to “prove” hypotheses:

- ❖ Research is not merely a reorganization or restatement of what has been published in the scientific literature regarding a

specific topic (Best, 1970);

- ❖ Research is not simply information retrieval (Best, 1970);
- ❖ Research is not unsystematic, inconsistent, or spontaneous;
- ❖ Research is not persuasive or aimed at “proving” personal convictions;
- ❖ Research is not based entirely upon what is accepted by a culture or discipline as being “true”;
- ❖ Research is not conducted clandestinely, but is open to public review and critique.

One of the primary assumptions made by research scientists is that events in nature follow an ordered, lawful sequence which can be identified through experimentation. In other words, it is accepted that within a definite set of circumstances, certain events may be expected to occur. What does this mean for life care planners?

Life care planners must turn to the research literature when making recommendations regarding the future needs of patients. Science is guided by the aim of identifying causal relationships through probability and theory, while life care planning involves analysis of patient-specific information to identify the most likely course of disability within reasonable rehabilitation probability as documented in the research literature.

§ 9B.02 Elements of a Research Report

The American Psychological Associations (APA) *Publication Manual* (2001) provides the report format, which is followed by most researchers in rehabilitation and the social sciences. When reviewing research articles published in peer-reviewed journals, it is likely that most will comply with APA guidelines and will contain the following elements: Title, Abstract, Introduction, Method, Results, Discussion, and References.

[1] Title

While this element of a research report may seemingly require no explanation, it is important to understand that most indexing and categorization systems identify key words within the title as a basis for grouping articles by topic area. Further, most search systems allow

users to search for articles of interest according to key words as they appear in the title.

The APA (2001) suggests a title of 12-15 words which accurately and concisely identify the topic of the research report, the variables studied, and key concepts of the project. Authors should be mindful of indexing procedures when selecting the most effective title in leading others to their article. Extraneous words and phrases should be avoided to allow for both general and specific search queries to retrieve the article.

[2] Abstract

The abstract provides a potential reader with a “detailed summary” of the research article. It summarizes the purpose or research problem and question, hypotheses, objectives, sample demographics, methodology, variables, and results so that readers can determine whether the parameters of the study meet their particular needs. For example, an abstract might specify that all subjects were under the age of 18 years. This may, or may not, influence whether the results of the study will be of benefit to the potential reader.

Many journals have begun publishing abstracts of articles online so that researchers are better able to ascertain the contents of specific reports without having to physically locate the journal and review the abstract in print. This saves the researcher a great deal of time, but is also a critical consideration of the author. The abstract must accurately and succinctly communicate the essential elements of the research project.

Life care planners should consider the title and abstract of a research article, but must read further in order to fully appreciate the scope of the study. It is not enough to simply report the findings documented in the abstract as a basis for plan recommendations. The theoretical perspective, procedure, methods, normative population, and interpretation must also be considered.

[3] Introduction

The introduction of the research report broadly discusses the topic of the research project and describes the underlying theories, concepts, and developments within the field from which the present study evolved. The research problem is discussed in detail and serves as an

orientation to the components of the project. The introduction helps to clarify the relationship between what is already known in the field and what remains to be discovered. After reading this explanation, the reader should be in a better position to understand the importance of the current study, how it contributes to the general knowledge of the field, and why the findings of the study are relevant to the overall theory or practice of interest. What is, and is not, known in the field is encompassed by a review of the body of published literature. A review of the literature establishes the need and the rationale for the current investigative study.

[4] Literature Review

A review of the relevant literature in the field provides a foundation for the present study and builds upon the collective knowledge accumulated by other professionals and researchers. Previous research studies which contribute directly, and perhaps indirectly, to the present research question, hypotheses, and methodology are described. This section of the article leads the reader through the reasoning process exercised by the researcher in conceptualizing the current project.

After reading the literature review, the reader should be able to independently arrive at the same logical connections and draw the same conclusions as were determined by the researcher. The literature review helps the reader to understand why the present study was designed, executed, and analyzed in the ascribed manner.

The literature review puts the current study into perspective, defines the field, describes what has been effective/ineffective in the past, and helps the reader (and researcher) to interpret the significance of the results obtained from the study.

Unfortunately, the Literature Review sections of published research reports are often edited in journals in order to conserve space. For professionals familiar with the theoretical suppositions from which the study was developed, this does not pose an especially critical problem. For those seeking to build an understanding of all aspects of a problem, or are unfamiliar with the underlying theory of the discipline, this poses a challenge. Additional reading and attention may be required to fully appreciate the foundations of the reported study. Journal articles that present reviews of the literature give a comprehensive summary of the knowledge in the area of interest and can be a useful tool for the novice in the field.

The researcher typically concludes the literature review (or begins the Methodology section) with hypotheses statements regarding the expected outcomes of the study. Based upon the previous findings in the literature, the researcher asserts the expected relationships among the variables measured in the study. For example, a hypothesis may read: "High school students who participate in a Work-Study program will obtain competitive employment at a higher rate upon graduation than those who do not participate in a Work-Study program."

[5] Methods

This section of the report describes how the study was conducted in such detail that it could be replicated by another researcher. In most cases, the Methods section includes the following information:

- **Participants or Subjects:** The total number of subjects, how subjects were selected, and demographics (*i.e.*, gender, age, ethnicity, disability, age of onset of disability, *etc.*) or other characteristics of interest within the study.
- **Variables:** The operationalized definitions of all study variables are provided. Operationalized definitions specify how the constructs of interest will be identified and measured. In the example cited in the previous section, "Work-Study programs" may be defined as year-long courses offered to high school students during their senior year which provide direct instruction of employability skills. The "higher rate" of employment may be determined by administering a follow-up questionnaire/survey six months after graduation to students who participated in the program and comparing those results to a random sample of students who did not participate in a Work-Study program.
- **Instrumentation:** All instruments, standardized assessments, surveys, *etc.* used at any point during the study (*e.g.*, sampling, follow-up) must be identified. The instruments are thoroughly described in terms of the number of test items, mode of administration and response, method of scoring, and the associated reliability and validity. The author should clearly describe how each instrument relates to the variables of interest in the study and why the chosen instruments were more effective measures than other test alternatives.
- **Materials:** All of the items necessary to replicate the study

should be specified. Examples include written instructions, tools, software, equipment, supplies, and other materials used by the subjects and researchers in gathering, analyzing, and interpreting data.

- **Research Design:** The research design connects the hypotheses to the scientific procedure of investigation and describes how the results of the study were analyzed and interpreted. Because the design of the project greatly influences the type and depth of information that can be extracted from the results, researchers must clearly communicate the theoretical basis of analysis.
- **Procedures:** The author describes the sequence of tasks accomplished throughout the study in such detail that the procedure may be replicated by others. From the beginning of the sampling process through the final stages of interpretation, the researcher explains how each step of the project was completed.

[6] Results

The Results portion of the report includes all findings derived from the research data. Depending upon the research design, some authors may choose to divide results into two statistical analysis categories: descriptive (*i.e.*, means, standard deviations, *etc.*) and inferential (*i.e.*, analysis of variance, multiple regression analysis, *etc.*). Results are limited only to those findings derived from the present data; no attempt to interpret the data is included in this section.

Authors may include tables and charts or graphs to visually display data and allow readers to more fully appreciate the results obtained. Ethically, all results should be reported, whether significance was achieved or not, but some authors may not report the results that failed to achieve a level of significance. Therefore it is important that readers be able to ascertain all the results that *should have* been derived from the data collected and recognize omissions.

[7] Discussion

The Discussion section of the report allows the researcher to contextualize findings, speculate as to the effects of unforeseen challenges and link the present study back to the research literature existing

in the field. Most authors cite the limitations of the study (*e.g.*, subjects limited to one geographic location), speculate how those limitations may have impacted the results and offer suggestions for future research.

[8] References

All references cited within the body of the text should be specified so that a reader may locate the original sources utilized by the researcher in developing the study.

[9] The Tone of Technical Writing

Simple, concise sentence structures are used to communicate the contents of a research article. Rather than load sentences with adverbs, adjectives, and extraneous phrases, authors attempt to use direct and uncomplicated language.

§ 9B.03 Critiquing Research Articles

Life care planners have a wealth of rehabilitation and medical information available, but must be able to discern which studies are of merit. Refer to research information from your own library and develop a critique form you can use to evaluate research articles.

Consider each of the primary sections within a research report (*i.e.*, title, abstract, introduction, including the literature review, methods, results, discussion) and the questions which should be asked within each section. Create your document for use in your practice to guide you in consistently reviewing research articles. Here are some suggestions:

[1] The Title

- Did the title adequately describe the study?
- Would appropriate keyword searches retrieve this article from an indexing system?
- Was the title concise and free of extraneous words/phrases?

[2] The Abstract

- Did the abstract summarize the purpose, methodology, and findings of the study?
- Did the abstract specify the independent and dependent variables?
- Were all primary findings mentioned in the abstract?
- Did the abstract provide enough information for a reader to determine whether the article was relevant to his/her research efforts?
- What type of research design most accurately describes this study?

[3] The Introduction: The Research Problem

- Was the research problem or question clearly defined?
- Is the problem important enough to warrant investigation?
- Was the problem logically deduced from a particular theory, or set of theories?

[4] The Literature Review

- Does the literature review logically lead to both the hypothesis to be tested and the Methods selected to test it?
- Are the hypotheses and research questions clearly stated and indicate the anticipated findings?
- Identify the independent variable(s).
- Identify the dependent variable(s).

[5] The Method: Procedure

- Are the procedures thoroughly described in chronological order?
- Were the treatments and/or data collecting methods described so that you could replicate the study?
- Were the treatments administered so that extraneous sources of error were either held constant for all treatments and control groups or randomized among subjects

within groups?

[6] The Method: Design

- Was the research design explicitly identified?
- Was an appropriate research design selected in the analysis of the problem?
- Was the population clearly defined?
- Were the sampling methods clearly described?
- Was a control or comparison group chosen in the same manner and from the same population as the sample?
- Were the treatments randomly assigned to the groups?

[7] The Method: Sample

- Is the sample clearly described in terms of size and demo-graphics?
- Is inclusion and exclusion criteria explicitly stated?
- Was the sample appropriately identified by the researcher, based on the purpose of the study?
- How were individuals assigned to treatment groups?
- What, if any, incentives were offered to subjects to enroll them in the study?
- If incentives were offered, were they sufficiently compelling as to compromise the subject's *voluntary* consent to participate in the research?

[8] The Method: Instrumentation

- Are the instruments described in the study appropriate measures of the variables being investigated?
- Did the author include the relevant psychometric properties (*i.e.*, validity, reliability) of the instruments used throughout the study?
- Are all of the materials listed and clearly described?

[9] The Results: Measurement

- Is the Results section clearly written and logically organized?

Is the analytical procedure appropriate to the research design and hypotheses of the study?

- Do the reported results address all aspects of the hypotheses/ research questions?
- Was any evidence of reliability of the measurements given?
- Was any evidence of the validity of the measurement given?
- Were tables, charts and graphs easily interpreted and helpful to the reader in conceptualizing the results?

[10] The Discussion

- Were the conclusions consistent with the obtained results?
- Were the generalizations confined to the population from which the sample was drawn, and not extrapolated to other populations?
- Were the study's limitations and their implications clearly discussed?
- Are findings discussed in terms of the purpose of the study, the research problem and hypotheses?
- Are suggestions for future research provided?
- Are the implications of the results of the current research to the field of study discussed?

[11] The References

- Are the citations sufficiently current?
- Are "classic" studies within the body of literature of the discipline referenced?
- Do the works cited represent a comprehensive review of the existing literature within the discipline?

[12] General (Your Opinion)

- Was the article well-written and well-organized?
- What did you learn from the article?
- Did the study address an important issue affecting individuals with disabilities or catastrophic injuries?

- What are the strengths of this study?
- How could this study have been improved?
- Was the study important? Why?

These questions were adapted from:

Bellini, J. & Rumrill, P. (1999). *Research in Rehabilitation Counseling: A Guide to Design, Methodology, and Utilization*. Springfield, IL: Charles C. Thomas, (1999).

Farquar, W., & Krumboltz, J. *A Checklist Evaluating Experimental Research in Psychology and Education*. *Journal of Educational Research*, 52, 353-54 (1959).

§ 9B.04 Fundamentals of Measurement — Basic Scientific Research Methodology

[1] Introduction

Basic scientific research can be applied to achieve the goals of demonstrating the reliability, validity and relevancy of life care planning as a tool for case management of the patient with severe disabilities. In order to do that, we need an understanding of scientific methodology.

[2] Hypothesis-Driven Research

Basic scientific research is driven by the testing of hypotheses. The hypothesis is our best supposition of what we think is happening under a given set of circumstances. While the development of a working hypotheses is applicable to individual client assessment (Reid, 1997) and is employed in daily clinical practice, it can also be applicable to a larger field in general, such as life care planning.

Each scientific study or experiment is designed to ask a particular question about the hypothesis. The results of each study or experiment have the potential to either lend support to the truth of the hypothesis or to disprove and challenge the hypothesis. As the evidence in support of a hypothesis accrues, the hypothesis may become a well-accepted theory on how things work. This does not imply that life care planning is a theory. It is certainly not a theory, but rather a very useful tool. So how might we develop hypotheses about life care planning to test scientifically?

[a] Hypothesis Testing

Traditionally, hypotheses develop from careful observations of a phenomenon or reviews of the published literature in an area leading to a rational assessment of the field. Once an idea is intellectually formed of how things might be working, then a research question can be posed to test whether the hypothesis is true. A scientific study sets forth specific aims and objectives to answer the research question. The specific aims define the response variable that will be recorded as the outcome of the investigation. In the instance of research for validation of life care planning, the body of published literature is only now emerging. For a comprehensive anthology, see the appendix to the *Amicus Curiae Brief* (Countiss, 2002) and *The Bibliography of Life Care Planning and Related Publications* (Weed, Berens & Deutsch 2002), as well as Hamilton's state of the science paper (1999).

The issues arising from the United States Supreme Court ruling in *Daubert v. Merrill Dow* (1993), serve as an impetus for scientific studies to validate the life care planning process. The ruling has asked three important questions as to whether life care planning, in all its aspects, are:

- (1) reliable;
- (2) valid; and
- (3) relevant to each specific patient's case.

Therefore, our hypothesis is that life care plans are indeed (1) reliable, (2) valid, and (3) relevant to each specific patient's case.

[3] The Research Process

A single hypothesis can generate many research questions. In a research study, the research question is addressed by development of specific aims and the research objectives through which the specific aims are going to be accomplished. The specific aims identify the response variables to be analyzed.

Next, the study protocols and procedures are developed. The protocols and procedures detail the methods to be employed to assure consistent collection of reliable data. After the data is gathered, it must be statistically analyzed. To be meaningful, the results must be interpreted in context of the current state of the profession and its future directions.

[4] The Design of Research Studies

The research process is captured within the overall design of the proposed study. Whatever the hypothesis, design the best possible study to *disprove* it. Results gathered in this manner have the strongest impact.

A major distinction in design can be made between descriptive and analytical study designs, (Bellini & Rumrill, Ch. 6, 1999). *Descriptive studies* are non-experimental or “cohort” studies, while *Analytical studies* test hypotheses.

[a] Descriptive Studies

Descriptive studies gather data of interest about a certain population, a “cohort.” A cohort is a sub-population of patients that share particular characteristics, (e.g., HIV infection or hemiplegia). The outcome of a descriptive study might be a determination of the prevalence of disability within a certain population. After analyzing the results of a descriptive study statistically and making some inference about the meaning of the data, a hypothesis may be generated that can be tested analytically. For example, in a cohort of insulin-resistant type II diabetics, the prevalence of hearing loss might be determined and compared to hearing loss in a population of non-diabetics sharing the same basic demographic characteristics (e.g., age, race, gender, socioeconomic level) as the insulin-resistant type II diabetic group. If it turns out that hearing loss is more prevalent in the diabetic group than in the non-diabetic control group, then we might hypothesize that insulin-resistant type II diabetes plays a role in causing the hearing loss and design an analytical study to test our hypothesis.

The *individual case report* and *case series* are always descriptive studies, usually of a singular, interesting nature. These studies can provide a provocative observation justifying a larger, descriptive cohort study.

[b] Analytical Studies

Descriptive studies can inform the design process for an analytical

study. A *retrospective case review* groups similar cases as cohorts and collects specific data about them. They can be either descriptive or analytical. An example of an analytical case review study to test the hypothesis developed above might be the comparison of the medical histories of insulin-resistant type II diabetics with hearing loss to insulin-resistant type II diabetics without hearing loss. If some characteristic in the medical histories differed significantly between the two groups, support for the hypothesis would be obtained. Another example of a retrospective case review study would be the comparison of life care plans that were updated five to seven years after implementation to determine the predictive validity of the initial life care plans.

Prospective longitudinal studies are more powerful than retrospective case reviews. They always test hypotheses by following a particular endpoint over time in a specially enrolled patient population. If, in the retrospective case review study mentioned above, the prevalence of hearing loss in insulin-resistant type II diabetics were found to correlate to prolonged periods of hyperglycemia, a new hypotheses might be developed and tested by experimental intervention in a prospective longitudinal study (Elwood, 1998, Ch. 2; Piantadosi, 1997, Ch. 4). A sample hypothesis might be that prolonged periods of hyperglycemia contribute to hearing loss in insulin-resistant type II diabetics. This hypothesis could be tested prospectively by randomly assigning insulin-resistant type II diabetics to either the treatment arm or the control arm of the prospective longitudinal study and monitoring the two groups over time for changes in hearing acuity. The control arm would be offered the standard of care for controlling hyperglycemia while the treatment arm would be offered more aggressive monitoring and control of hyperglycemic episodes. A lesser degree of hearing loss experienced by the treatment group compared to the control group would lend support to the hypothesis that prolonged episodes of hyperglycemia in insulin-resistant type II diabetics contributes to hearing loss. The reverse result would refute the hypothesis. No significant difference in hearing loss between the groups might be interpreted as a inconclusive, or that the study did not have the statistical power to detect the difference that was actually present.

[5] Statistical Design and Power Analysis

Importantly, statistical consultation should be a part of the study de-

sign process. Because the data must ultimately be analyzed statistically to be meaningful, it is extremely helpful to consult with a statistician in the design stage of the study. The final methods of analysis should be determined before data collection begins.

After the data collection has been completed, statistical analysis will indicate whether the outcome is significant. However, the qualitative parameters for deciding what is significant must be chosen before data collection begins. The level of the difference detected must be set very low to minimize the chance of identifying a false positive effect, known as a Type I error.

[a] Type I Error

A Type I error occurs when the difference detected in the study is accepted as a true result when it is not. In other words, a false positive result is identified by the study as being true. Conventionally, the level of significance is set at $p < 0.05$, so that the probability of a Type I error is less than 5%. In contrast to the parameter for the Type I error rate, the parameter for the Type II error rate should be set very high.

[b] Type II Error

A Type II error occurs when no difference is detected, but a difference actually does exist. In other words, a false negative result is identified by the study as being true. The Type II error probability is frequently set as high as 80% - 90% (Bellini & Rumrill, 1999, Ch. 3; Friedman, Friedman, Furberg, & DeMets, 1998, Ch. 7; Piantadosi, 1997, Ch. 4).

[c] Power Analysis

Statisticians can also help determine whether the proposed study is feasible. This is done by power analysis. "Power" refers to whether the study has the capability to detect a significant difference in the response variables given the levels set for the qualitative parameters discussed above. Power comes from the number (N) of participants included in the study and the magnitude of the effect of interest.

If a sufficient number of cases are not available to power the study adequately, then it is not feasible to conduct the study because no mean-

ingful results can be detected. The N required for the study to detect a difference can be calculated from the expected effect size and the expected variation in the data. If the effect size is small, or the variation large, then the N must be large.

The circular question is "How can the effect size from a study that has not been completed be determined?" The answer is that it cannot be determined, only estimated. Published reports of similar effects or preliminary studies, which are small studies that were not "powered" and may not have detected a difference in outcomes, can inform us about estimating the effect size and the range of variation in the effect (Bellini & Rumrill, 1999, Chap. 6; Friedman, Furberg, & DeMets, 1998, Chap. 7; Senn, 1997, Chaps. 4 & 13.).

[d] Inclusion/Exclusion Criteria

Inclusion/exclusion criteria define the study's target population, (Bellini & Rumrill, 1999; Piantadosi, 1997, Ch. 8). The baseline characteristics considered by the study are described by the inclusion/exclusion criteria, including any baseline exams the study might deem important to control of potential extraneous confounding variables.

[e] Confounding Variables

A confounding variable, or bias, is some factor that accounts for an effect identified in the study, but masks a true effect. Some commonly identified confounding variables include baseline characteristics of the cohort such as gender, age, cultural background and socioeconomic level. Other confounding variables could be identified as pre-existing medical conditions with pathology similar to the pathology of interest in the study age or with pathology that exacerbates the severity or progression of the pathology of interest in the study.

[i] Controlling for Confounding Variables

One way to control for confounding variables is to set the inclusion/exclusion criteria to limit their presence within the study population. For example, it might be reasonable in a study on the effects on I.Q. of HIV-Associated Dementia (HAD) to exclude those patients with a pre-existing closed head trauma or cerebral stroke. In the same study,

age might be limited to young adults aged 21-35 to control for the normal age effects on intellect seen in immature and geriatric populations. The inclusion/exclusion criteria serve as an assessment of eligibility, or checklist, for participant enrollment to the study.

[ii] Stratification

Another way to control for confounding variables is to include the confound in the study population, but stratify the study by the levels of the confounding variable. For example, socioeconomic effects are commonly stratified by level of education achieved and earned income. Gender might be an interesting confound within the same study of HAD effects on intelligence, not because males and females have essentially different IQ's, but because the HIV disease state underlying the observed pathology may progress differently in males and females due to their intrinsically different immune systems. Stratifying for a confounding variable has the potential to identify important and sometimes unanticipated effects.

[iii] Stratification and Hypothesis Testing

Stratification can also be used to test hypotheses. Consider the following analytic retrospective case review study: The response variable, (*i.e.*, recommended level of nursing care for a patient with C5 tetraplegia), may be stratified by some factor of interest to test a hypothesis. In order to test for intra-planner reliability, members of the cohort from a single practitioner's caseload may be grouped according to the purpose and source of referral. Three groups may include:

- (1) development of a life care plan referred by defense counsel;
- (2) development of a life care plan referred by plaintiff counsel; or
- (3) an independent medical examination.

The mean response variables may then be compared and group differences identified. In this study the inclusion/exclusion criteria would be set to limit the population to a single life care planner's caseload and to specifically include patients referred from all three sources.

§ 9B.05 Types of Research

The purpose of this section is to present an overview of the types of research designs most commonly utilized in the rehabilitation and medical sciences. As consumers of research literature, it is important that life care planners are equipped to critique journal articles and to determine whether study findings are relevant to the patients with whom we are working. Recommendations in the life care plan must be supported by research data and based upon the documented course of disability and patient-specific variables over time.

The manner in which a researcher designs a study determines the type and depth of information that can be concluded from the project. For this reason, researchers spend a significant amount of time considering the most effective design in addressing the topic of interest. First, a researcher determines the purpose of the study. Are they seeking to:

- ♦ **Explore or Describe a Research Problem?** If so, then a descriptive research design such as a survey, a developmental study or a case study or qualitative design study may be most appropriate.
- ♦ **Explain or Predict Relationships Between Variables?** A relational or associational research design may be most effective for this purpose. These designs include correlational and *ex post facto* studies.
- ♦ **Control, Establish Cause and Effect, or Induce a Result?** In this case, experimental or quasi-experimental designs are likely to yield the most useful results.

[1] Descriptive Research

Descriptive research designs are most effectively applied to studies aimed at gathering additional information, learning more about an area of interest, or becoming more familiar with a topic. Researchers interested in identifying the prevalence or incidence of a disability or in describing the distribution and characteristics of a group of patients may adopt a descriptive research design.

[a] Survey Research

The purpose of conducting survey research is to explore and/or describe an area of interest in greater detail. Typically, a researcher gathers information from a large group of participants either by mail, interactive online site, telephone interview, or personal interview.

Results from this type of study will produce a "snapshot" of the current state of the research issue. A survey does not investigate relationships between variables, patient-specific characteristics, or generalize findings to all members of a population. In other words, the purpose of survey research is not to establish cause and effect relationships. Most individuals have completed a survey of some type, whether a public opinion questionnaire, customer service form, or community investment poll.

[b] Developmental Studies

Developmental studies generally follow a group of participants over time and document changes in status. These types of studies may be referred to as trend, cohort, or panel designs. In most cases, researchers collect data at specific points in time which are used as a basis of comparison and analysis.

Narrative or documentary-style reports may result from this type of design, but conclusions cannot be applied to other members of the target population. Developmental studies are useful in describing phenomena longitudinally and may be used as the foundation for further investigation.

[c] Case Study or Qualitative Designs

The purpose of this type of research is the same as pursued by survey and developmental designs, but generally involves much smaller sample sizes. Rather than gathering information from a large group of people, as in survey designs, the researcher is interested in gaining deeper insights into a fewer number of subjects. This form of inquiry typically involves personal interview or direct observation throughout the data collection process. Examples of this type of design may be a study based on the relationships and interpersonal dynamics of a specific family, documenting experiences of a small group of patients with

traumatic brain injury in a rehabilitation facility, or observing the interactions of selected toddlers in a preschool setting.

[2] Relational or Associational Research

The purpose of relational or associational research is to identify the relationship or association between two or more variables.

[a] Correlational Studies

Correlational studies are appropriate when comparing two or more characteristics within the same group of participants (Ary, Jacobs, & Razavieh, 1999). The purpose is not to establish cause and effect but to:

- ≈ demonstrate how specific characteristics vary together; and
- ≈ assess the degree to which one characteristic can be predicted when another is known.

There are two types of correlational studies; concurrent and predictive. Concurrent correlational studies involve assessment of the relationship between characteristics that were collected by the researcher at the same point in time. For example, a researcher may be interested in assessing the relationship between patients' emotional well-being and levels of impairment when beginning a vocational rehabilitation program.

Predictive correlational studies may be utilized when a researcher is interested in determining whether knowing a previously documented characteristic (or set of characteristics) can lead to the prediction of a later characteristic (or set of characteristics). For example, a researcher may record patients' emotional well-being when beginning a vocational rehabilitation program and then again after 60 days of job placement to ascertain whether earlier data was predictive of later data.

[b] Ex Post Facto Studies

Ex post facto, or "after the fact", designs, attempt to identify a natural impetus for specific outcomes without actually manipulating the independent variable. This type of design is often utilized when it is not possible to control the experience, exposure, or influences which may affect participants.

[3] Experimental or Quasi-Experimental Research

The purpose of experimental or quasi-experimental research is to establish a cause and effect relationship between two variables. The researcher deliberately manipulates a treatment (or independent variable) and measures how it affects the behavior or reaction of subjects (the dependent variable). In order for this research design to be appropriately utilized, the researcher must be able to:

- ⊗ randomly select subjects;
- ⊗ randomly assign subjects to intervention and control groups;
- ⊗ randomly assign treatment to intervention groups; and
- ⊗ to control the treatment (or independent variable) and any extraneous variables which may have an effect upon the dependent variable.

As may be apparent from the description, this type of design is very difficult to utilize when working with human subjects. Consider the ethical problem of withholding pharmaceutical treatment from a control group for the purpose of determining the drug's effectiveness. In order for the drug to be approved for distribution to the general public, it is necessary to establish its efficacy as a treatment or prophylactic for a given indication. However, there exists the potential for harm to individuals who participate in the project, whether receiving the drug or not.

While efficacy studies occur, and *must* occur if advances in therapeutic interventions and prophylaxis are to be realized, there are many safeguards, supervisory and administrative requirements, and limitations imposed upon studies involving human subjects. For this reason, quasi-experimental designs are commonly used in medical and allied health fields of study.

Note:

Causality can only be established by true experimental designs, so the term "cause" (or derivatives) should not be used in association with any other design type.

Quasi-experimental designs are used when the researcher is unable to control for a necessary variable, or set of variables, but follow string-

gent guidelines for controlling error. For example, trials for an experimental pharmaceutical may utilize a quasi-experimental design to ascertain the effectiveness of a specific medication. Subjects are carefully pre-tested and monitored as the independent variable (the medication) is manipulated. Assuming that it was not possible to randomly select or randomly assign subjects to treatment/control groups, a quasi-experimental design (or pre-experimental design) must be adopted.

Life care planners will analyze a variety of research data when developing plans to meet patient-specific needs and should be familiar with the basic assumptions and limitations of each design. After reviewing several research articles, discussing your thoughts with other professionals, and considering the practical applications of various studies, you will gain a level of comfort in evaluating research literature.

[4] References for Further Reading on Research

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§ 9B.06 Reliability and Validity for Life Care Planners

Why are we, as clinical practitioners, interested in research aimed at validating the process of life care planning? There are multiple answers. Through research we can improve the process, raise standards, help to answer ethical questions and resolve ethical dilemmas. Perhaps most importantly, we protect the patient's access to life enhancing care through this very useful case management tool.

Ensuring the future of life care planning is essential to protecting the catastrophically injured patient's access to quality of life enhancing care through visionary case management practices. In light of the recent challenges presented by the *Daubert* rulings, the future of life care planning as a forensic tool is dependent upon validating the Life Care Planning process in the eyes of the courts (Countiss & Deutsch, 2002).

We can do this through definitive research attesting to consistent methodology employed by life care planning professionals that is reliable, valid and relevant to the individual patient's case. Because we intend to objectively validate the utility of life care planning as a tool in case management, let's first consider the facets of reliability that are prerequisite to validation of life care planning.

[1] Issues Related To Reliability

Demonstrating the reliability of life care planning as a case management tool is at the heart of validating life care planning as a specialty area of practice. Reliability is comprised of the dependability and consistency of the life care planning process to yield similar results under similar conditions. In other words, life care plans (LCPs) are reproducible. If life care planning is a reliable tool in case management and the provision of patient care, then the results of a given LCP can be consistently replicated. We can convincingly demonstrate reliability of life care planning by appropriately designed research studies. First we need to discriminate between two aspects of reliability: *intra*-planner and *inter*-planner reliability (Bellini & Rumrill, 1999, Ch. 3).

[a] Intra-Planner Reliability

Intra-planner (a.k.a., *Intra -rater*, or *Intra -observer*) reliability provides internal consistency to the process much like "test-retest." Intra-planner reliability attests to the consistent application of an individual life care planner's processes and the reliability of the results of that process. Given similar circumstances, the process of developing the LCP recommendations and cost estimates are the same. Certainly, similar forms and procedures would be used for collecting the information needed for similar cases. But intra-planner reliability goes beyond that type consistency.

Because the LCP is a document that makes recommendations for case management and estimates the costs of those recommendations, it will produce similar recommendations and cost estimates given patients with similar disabilities and life circumstances. Differences between the individual patients, their families, and geographic locations would be appropriately noted as modifying factors in the comparisons. For example, the basis for establishing the skill level involved in the provision of care for a C-5 tetraplegic should remain consistent regardless of geographic location and irrespective of subsequent development of cost data. What is being validated is the basis for establishing need for care, level of care, and availability of care. Costs are incidental to these issues. It does not vary depending upon the geographic locale or any other predisposing factor for bias.

The significance of intra-planner reliability is that a given life care planner will produce the same life care plan whether it is produced in Indiana or California, whether it is produced as an Independent Medical Examination (IME), or as a forensic tool of the defense or plaintiff, or even whether funding is available to implement the recommendations.

[b] Inter-Planner Reliability

Inter-planner (a.k.a., *Inter -rater*, or *Inter -observer*) reliability provides external consistency to the process. Inter-planner reliability indicates that life care planning is a standardized process, consistently applied by life care planners across the country in a similar manner. Given similar patient disabilities and circumstances, life care planners, in general, present similar recommendations and cost estimates. Wide discrepancies do not occur between plans generated by different life

care planners for the same patient.

For example, what if Dr. Smith who always works for the plaintiff, always gets his cost estimates for custom modification of a vehicle to accommodate a wheelchair from Jaguar, Porsche, and Mercedes? Dr. Smith could show a tight range of costs, and his results would be consistent and dependable over time for each and every LCP he develops.

On the other hand, his colleague, Dr. Jones, only accepts defense work. Dr. Jones consistently gets his cost estimates from Bubba's Junkyard, Billy Bob's Pre-Owned Palace, and Honest Eddie's. (Honest Eddie's motto is "*We'll beat any deal or give it to you for free,*" so Dr. Jones always checks with him last.) Dr. Jones's results are also consistent and dependable over time, for each and every LCP he develops. However, reliability between the LCPs provided by Dr. Smith and Dr. Jones does not exist. The results vary depending upon which life care planner writes the LCP!

[2] Validity is Case Specific

Dependability and consistency in applying the life care planning process will reliably yield similar results under similar conditions. While general reliability is necessary to establish validity, it is not entirely sufficient. Validity is case specific. A standard, "valid" life care plan for all people who are infected with HIV does not exist. Each LCP must be valid for the individual for whom it was developed. If life care planning is a valid process, then a good LCP will accomplish its mission: to decrease the frequency and severity of medical complications for a particular patient, avoiding case management by crisis intervention, and improving the patient's overall quality of life. Establishing the validity of the life care planning process shows that the basic tenets of life care planning are sound.

[3] Issues Related to Validity

Validity has four major aspects:

- (1) face validity;
- (2) content validity;
- (3) criterion-related validity; and
- (4) construct validity.

These four aspects can be used as lenses through which to view validity. For validity to be established, evidence of each of the four aspects should be demonstrated (Bellini & Rumrill, 1999, Ch. 3).

(1) Face Validity. Face validity in life care planning refers to whether the LCP “looks like” it appropriately details the disability-related needs of a given individual. Although face validity is not evidence of whether or not the LCP accurately presents an individual’s needs, it is still important to life care planners.

Because the LCP is a tool for educating people about disability-related needs, if it does not appear to represent those needs accurately, then family members, judges, juries, insurance adjusters, etc. may not accept it as a useful instrument. The establishment of face validity speaks to the lay audience.

(2) Content Validity. Content validity relates to whether the elements included in the LCP actually address all the disability-related needs of an individual with a particular disability and set of circumstances for enhancing their life across their life span. The specific LCP should address all of a particular patient’s needs without providing for extraneous treatments.

For example, an annual urological exam would be an important part of the LCP for a person with a spinal cord injury, but not for an individual who has had her leg amputated. Furthermore, to find a meaningful and useful life, the patient’s needs could reasonably be expected to extend beyond medical care. These needs may include vocational education and retraining.

One approach to examining content validity is to have a group of recognized experts come to consensus about which items are most appropriate. Relating your recommendations to published treatment protocols and standards of care could help you to demonstrate the content validity of elements in your life care plan. An excellent reference is *Outcomes Following Traumatic Spinal Cord Injury: Clinical Practice Guidelines for Health-Care Professionals* issued by the Consortium for Spinal Cord Medicine (July 1999).

(3) **Criterion-Related Validity.** Criterion-related validity is the gold standard of validity. Evidence of criterion-related validity is presented when a relationship exists between the LCP's recommendations and estimated costs and some outside measure, or criterion, relevant to those recommendations and estimated costs. There are three types of criterion-related validity: concurrent validity, predictive validity, and convergent and divergent validity.

Concurrent Validity

Concurrent validity refers to the relationship between elements of the LCP and objective findings available at the time the plan was developed, (*concurrent* "at the same time").

If the client fits the demographic profile and circumstances of individuals studied in *Aging With Spinal Cord Injuries* (Whiteneck, Charlifue, Gerhart, *et al.*, 1993), it should be possible to demonstrate similarity between the LCP's recommendations and the recommendations made for the individuals in that published study. As medical research and education advance, the standards of practice for life care planning must necessarily evolve to keep pace. Demonstrating concurrent validity shows that the specific LCP meets the current standards of practice and is not obsolete.

Predictive Validity

Predictive validity is of greatest interest to those utilizing the LCP for reserve setting, budgeting, or in a forensic setting. Demonstrated predictive validity answers these questions:

- (1) Do the recommendations and cost estimates accurately predict the services that will be needed by the individual for whom the plan was written, and at what cost?
- (2) If the LCP's recommendations are implemented in full, and the LCP predicts they will help reduce the incidence, frequency, severity, and duration of complications, will the research study demonstrate a difference from the occurrence of those complications in patients with similar injuries but without LCPs?
- (3) If projections of life expectancy are included in the LCP, are those projections accurate?

Predictive validity examines the quality and quantity of follow-up on patients with whom LCPs have been completed. The goal is to re-examine these patients and update the plans later in time to establish predictive validity.

Convergent and Divergent Validity

Convergent and divergent validity are specific types of criterion-related validity. They could be addressing either concurrent or predictive variables. Essentially, if you have evidence that two things that should be similar to each other, are similar to each other (converge) you have evidence of convergent validity. Likewise, if two things that should be different from each other, actually are different from each other (diverge), you have evidence of divergent validity.

Evidence of convergent validity is demonstrated when the recommendations in a LCP for an individual who has lower extremity paralysis are similar, in some ways, to those in a plan for an individual who has lower extremity amputation. On the other hand, the recommendations for an individual who has congestive heart failure would be expected to differ from those of an individual who has a hearing impairment. If the life care plans for these two individuals are not different, then the divergent validity of the two plans is not demonstrated.

(4) Construct Validity. Construct validity is the essential validity to establishing that the basic tenets of life care planning are sound and are evolving contemporaneously with related health care fields. Construct validity might best be understood as theoretically related validity. Evidence of construct validity is presented when a theory or hypothesis predicts a particular finding, and the results of an analytical study correspond to that prediction.

Although life care planning is not a theory *per se*, many of the underlying tenets of life care planning could be considered theoretical propositions. For example, we operate under the assumption that the development and implementation of a good LCP will decrease the incidence of medical complications, and increase an individual's quality of life. To test that assumption, we could compare the rate of complications for people who have implemented a LCP with those who did not have a LCP. We could also interview individuals with implemented LCPs and individuals without such plans, and ask them

questions about their quality of life.

Consideration of construct validity leads us to conclude that validation must be an on-going process. There are many different aspects of validity most of which change with time. The large number of variables involved in LCP complicates the process of researching reliability and validity relative to life care planning. The only solution is to reduce the number of variables in any given research project and increase the number of projects being conducted.

No single study will conclusively validate life care planning once and for all. Every research study provides another piece of evidence establishing life care planning as a valid case management tool. We need to begin collecting elements that contribute to establishing the validity life care planning's place in the management of the catastrophically injured patient's case.

§ 9B.07 Threats to Validity

It is extremely difficult, if not impossible, to control for all of the possible complications and events which may affect subjects participating in a research project. However, responsible, ethical methodology dictates that all threats to the validity of a study must be considered and accounted for throughout the design process. While a researcher is expected to account for all of the possible influences which may have altered the results, some are reluctant to do so fearing that the such acknowledgment may discredit their work. Life care planners must be aware of these threats so that we may independently evaluate the efficacy of research studies and draw alternative conclusions from the data where appropriate.

The validity of a research design is evaluated in two ways: (1) the internal validity of the study; and (2) the external validity of the study.

[1] Internal Validity

Internal validity evaluates the extent to which extraneous factors, rather than the treatment, may have produced the outcomes of the study. When a researcher designs the methodology to be employed throughout the project, careful consideration is given all factors which may exert an unintended effect and cause subjects to respond differently than they would have otherwise. Internal validity seeks to answer the question:

■ **Was the treatment responsible for the results of the study or was it something else?**

☞ **Sample Selection:** Consider the fundamental differences between the control group and the treatment group, or between the subjects who are being compared. There may have been significant differences between these groups from the conception of the project.

How were these groups selected? If subjects were randomly selected and randomly assigned to groups, the threat is decreased. A researcher may administer a pre-test to all subjects then compare the responses of the groups to ensure that they are similar before introducing the treatment or intervention.

☞ **History:** Events may occur during the course of a study that impact the responses of the subjects. For example, a national news story which is closely related to the topic of the study, or a natural disaster occurring in an area where many of the subjects reside may influence their responses to the treatment or intervention.

What did the subjects experience during the course of the study? A researcher may ask all participants to complete the study in an isolated setting or to keep a diary detailing the event of their lives throughout the project. If the subjects were randomly assigned to groups, theoretically, extraneous factors will influence the groups equally.

☞ **Mortality:** Some of the subjects may drop out of the project, move, or be unreachable for follow-up evaluation. This may present difficulty for the researcher if mortality affects groups at different rates. For example, in a two-group study of 50 participants each, if 15 drop out of Group A and only two drop out of Group B the groups may no longer be suitable for comparison. A researcher must try to identify the cause for attrition.

How many subjects dropped out of the study? A researcher may

attempt to re-establish contact with subjects or rely upon statistical procedures designed to account for missing data (Campbell & Stanley, 1966).

➤ **Location:** Consider the location and circumstances under which the first sets of data were gathered as compared to the location or circumstance under which the second set of data were gathered. If the situations were different, the setting or circumstance under which data was collected may have influenced the response of subjects (rather than the treatment or intervention).

What were the circumstances under which all sets of data were collected? A researcher should consider the quality of testing environments, similarity among sites, and describe the general testing circumstance.

➤ **Instrumentation:** Changes in the calibration of the testing instruments or equipment, or changes in observers or scorers may affect the data. Life care planners should be aware of the conditions under which measurement instruments were normed, how they should be administered, and the purpose for which they were developed. There is also the possibility of scorer bias, whether conscious or unconscious.

Were the measurement instruments correctly used? A researcher may randomly assign scorers to participant groups, or employ masked or double-blinded data collection techniques. A researcher may train and then pre-test scorers so that all are clear as to what is/is not to be tabulated and how the scores should/should not be derived. These pretests can be analyzed for inter-rater reliability and intra-rater reliability before scorers are given the responsibility of data collection.

➤ **Testing:** The “practice effect” of pretesting may influence the outcome of posttests, particularly when the contents of these assessments are closely related. In addition, the contents of a pretest may make subjects more sensitive or responsive to the treatment or intervention.

What effect might the pretest have exerted upon the results of

the posttest? A researcher may choose not to administer a pretest. Theoretically, and if the sample size is large enough, this threat should equally affect all groups if the subjects were randomly assigned. Alternatively, a sufficient period of time may be allowed to elapse between the pretest and posttest to allow the "practice effect" to extinguish and no longer be a concern. This "washout" period, if used, is always established scientifically.

☉**Maturation:** Particularly in a longitudinal study, changes over the course of the study may be attributable to the effects of time, rather than the intervention or treatment. For example, first graders may respond to project assessments much differently at the end of the school year simply due to maturation effects, rather than the intervention applied over several months. In another example, improvements in cognitive functioning may be a result of natural, biological processes rather than the rehabilitation program instituted by therapists.

Were the effects due to the intervention or to maturation? A researcher may select subjects who are relatively mature or exhibit stability on measures of interest. Also, the duration of the experiment may be limited to control for the effects of maturation, fatigue, or physical changes. Theoretically, if subjects were randomly selected this threat should affect all groups equally.

☉**Attitude of Subjects:** The approach and mindset of study participants can affect the outcome of the project. For example, subjects may put forth exceptional effort because they know their performance will be evaluated. Or, subjects may feel insulted based upon how they perceive the group of which they were assigned, particularly if the groups are being treated differently beyond the administration of the independent variable. When evaluating research, life care planners should consider whether results were affected by the

experience of subjects in the experimental condition or whether results reflect only the influence of the treatment or intervention.

Do the results reflect the subjects' reaction to the experimental condition or the treatment? A researcher should make a conscious effort to treat all groups the same, aside from the administration of the treatment. Unobtrusive measures may be selected so that scorers are able to observe subjects' behavior without disrupting the natural circumstances of the environment or calling attention to their task.

➤ **Implementation:** This threat occurs when implementers of the treatment or intervention use different methods in instructing or implementing the independent variable. An implementer may like one intervention better than the others and do a better job of implementing it. For example, if a study was designed to examine the effects of a new teaching method, an implementer who preferred the traditional method may not teach the experimental method as well.

Could the implementer have influenced the results of the study? A researcher may randomly assign implementers to groups (when possible), monitor the administration of the trials, or use the same implementer for all groups.

➤ **Regression:** Groups selected because of unusually high or low scores on pretests (or similar measures) will tend to score closer to the mean on subsequent assessments (Ary, Jacobs, & Razavieh, 1996). This threat occurs when groups are selected on the basis of scores that are not representative of their true performance. For example, a researcher tests all patients in a rehabilitation facility with the same level and type of injury on measures of psychological adjustment. The lowest (*i.e.*, those who show the most significant psychological difficulties in adjusting to their disability) are selected to participate in a six week intervention program. At the end of the program, all subjects are re-tested, the scores are compared, and the

scores of the experimental group improved.

Actually, two extraneous variables may have influenced the results of this study. First, most patients will experience greater ease in psychological adjustment over time, particularly if counseling support is available in a rehabilitation setting such as the one referenced in this example. Second, there is a tendency for extreme scores to move closer to the mean on subsequent measures.

Is movement in scores over time due to the effects of the intervention or to regression to the mean? A researcher may attempt to control for this threat by eliminating extreme scores from participation in the study or by randomly assigning individuals to groups (theoretically, regression to the mean should occur equally in both groups). By analyzing the raw data for aberrant scores which make extreme moves, a researcher may conclude that this effect is not typical, but a result of measurement error.

➤ **Statistical Conclusion Validity:** This threat occurs when analytical errors are made and these produce invalid results. There are numerous statistical errors that can corrupt the data such as the reliability of measurement instruments, violations of the assumptions of the statistical tests used, or even selecting the wrong statistic for data analysis. Sample size is important to consider, particularly if very few or very many subjects were used in the study. Statistical analysis may produce invalid results by being over-sensitive (if the sample size is large) or under-sensitive (if the sample size is small) to differences attributed to the treatment. In other words, when sample sizes are very large statistical analysis may detect positive effects that do not exist. That is, a false positive or type I error occurs. When sample sizes are very small, statistical analysis may not be sensitive enough to detect the differences that exist; so, even though the treatment did have an effect, it is not recognized. In this instance, a false negative or type II error occurs. (Ary, Jacobs, &

Razavieh, 1996).

Are the results based on what truly occurred throughout the study, or are they due to statistical errors? A researcher often consults with statisticians during the course of the study to insure that all analytical errors are prevented. Life care planners should be familiar enough with basic statistical analysis to determine whether the conclusions reached by the researcher are plausible.

[2] External Validity

External validity refers to the extent to which the results of a study generalize to the target population and/or other groups of individuals. In evaluating the external validity of a study, life care planners must consider how well the sample, administration of the treatment, and all related factors match the “real world” experience of those with whom we work. Threats to external validity include the following:

☞ **Influence of Testing:** If all of the participants in the study were pretested, it may or may not be possible to generalize the findings to others. In real world applications, it may not be possible to pretest patients, so *to what degree* can the results of the study be generalized to others? And, *to whom* can the results be generalized?

In order to control for this threat, a researcher may not pretest subjects or may use a research design such as a “Solomon Four-Group design.” This procedure randomly assigns subjects to each of four groups; two are pretested, two are not. One non-pretested group and one pretested group receive treatment and all four groups are post-tested (Campbell & Stanley, 1966). This design allows the researcher to analyze the effects of pretesting.

☞ **Influence of Selection:** If subjects self-select or volunteer to participate in the study, an unusual sample may result; one which is not representative of the target population. Consider whether data reflects the effects of the treatment or the desire of participants to cooperate

cooperate with and please the researcher.

In order to control for this threat, a researcher may randomly assign subjects from the target population, if possible. In clinical studies, this option is not often possible. Therefore, many researchers utilize the most appropriate design available to them, publish the results, and call upon others to replicate the study for further corroborate findings.

➤ **Reactive Effects:** The fact that subjects realize that they are participating in a study may effect the results and limit the degree to which results can be generalized. The observed effects may be due to the fact that subjects are, consciously or unconsciously, “performing” in a way which is inconsistent with their typical behavior. Subjects may simply be reacting to the novelty and experience of participation/observation. This is similar to what occurs when subjects are given placebo drugs in pharmaceutical trials exhibit improvement in measured symptoms, even though no treatment was administered.

This is a difficult threat for researchers to control, particularly when issues of informed consent, human subjects restrictions, and ethical responsibilities limit the degree to which covert observation/experimentation can occur. There are statistical techniques which may be useful in detecting “false” behaviors by comparing early subject-specific data to later subject-specific data. In many cases the reactive effect of participation decreases and subjects resume typical behaviors, but this is difficult to control for within a large sample. Results simply have to be replicated over a variety of conditions.

➤ **Multiple Treatment Interference:** Subjects who have participated in other studies, particularly ones of similar design or treatment, may be performing as a function of previous participation experiences, rather than as a function of the treatment. Previous treatment effects cannot be eradicated. Also, if subjects were exposed to

multiple treatments throughout the course of the study, the accumulated effects of repeated testing may influence results. It may be problematic to generalize findings from this type of study when all other members of the target population (*i.e.*, those who were not involved in the study) are not similarly exposed to multiple treatments.

A researcher may minimize the effects of multiple treatment interference by choosing the most appropriate research design to control for this threat, calling for replication, and considering the most appropriate sample selection process (Campbell & Stanley, 1966).

☉ **Interaction of Time and Treatment Effects:** Results from a study may not be appropriate for generalization to the target population or other groups if they cannot be sustained over time. While initial posttests may indicate an improvement in a specific measure, the effects of treatment may decrease over time. For example, subjects may lose weight by participating in an experimental intervention program; therefore, the researcher concludes that the intervention was successful. If, after six months, most participants regained what they had lost, is the intervention still considered to be successful? The answer depends upon how the results were reported and how the data was used in relation to the target populations and other groups of individuals.

A researcher may administer posttests for a specified length of time in order to ascertain the duration of the alteration in behavior that occurred in subjects as a result of the intervention.

☉ **Posttest Sensitization:** The administration of a posttest to subjects may actually provide a means of solidifying, clarifying, and facilitating the acquisition of concepts instructed through the applied intervention (Ary, Jacobs, & Razavieh, 1996). In other words, by completing a posttest, subjects are given an opportunity to reflect upon their experience, engage in problem-

solving which may serve as an extension of the intervention. Life care planners must consider whether the administration of a posttest may influence results and whether conclusions may be reasonably applied to the target population.

If after considering all of the potential threats to the validity of research, one may wonder how this literature can be relied upon to inform any life care planning decisions. This discussion was presented in order to raise the awareness of those consulting research and to caution professionals from unquestioningly accepting the conclusions asserted by authors.

Even in disciplines beyond your field of professional practice, you must be able to critique the design, implementation, and results reported by the researcher. Scientific inquiry encourages consumers of research to evaluate the relevance and accuracy of what is purported to be “known” within a discipline. By becoming familiar with research design and statistics, life care planners will be in a much better position to identify the information most beneficial to the specialty.

§ 9B.08 Statistical Methods

Statistical analysis provides researchers with a means of translating data collected from a sample into numerical expressions that represent the characteristics of the sample. Mathematical principles are applied to data in an effort to objectively determine whether change occurred as a result of intervention or treatment. For many rehabilitation professionals, the study of statistics is a “necessary evil” and is generally the least favored coursework of those enrolled in graduate or continuing education programs.

For the purposes of this chapter, an overview of basic statistical methods will be helpful to life care planners in understanding how research conclusions were reached and how findings may, or may not, relate to a specified area of interest. This section will familiarize you with the

basic statistical methods commonly utilized in rehabilitation and medical research. The two types of statistical analyses generally applied to research data are descriptive and inferential statistics.

[1] Descriptive Statistics

Descriptive statistics help researchers to organize, summarize, and visualize the data collected from samples. At first, researchers are interested in learning how the response variable(s) are distributed.

- ⊗ **Distribution.** The set of scores or data collected from subjects is referred to as the “distribution.” Distribution of data may be displayed creating an ordered list of scores (*i.e.*, from high scores to low scores), creating a frequency distribution (*i.e.*, tally of the raw scores), or creating a histogram (*i.e.*, bar graph) to visually summarize the data. Once the distribution has been established, additional descriptive analyses may occur.
- ⊗ **Measures of Central Tendency.** Measures of central tendency simply calculate the mean (*i.e.*, the average performance of all subjects), median (*i.e.*, the central score of all subjects which divides scores into equal parts), and mode (*i.e.*, the most frequently attained score observed in all subjects). Each value provides the researcher with slightly different information, but all describe the “central tendency” of the participants. For example, the mean is affected by extreme scores so in distributions having many extreme values, the median may be a more accurate measure of central tendency (*i.e.*, the median is not affected by extreme scores). If the distribution of scores is absolutely normal (*i.e.*, a “bell curve”), the mean, median, and mode will be identical.
- ⊗ **Shape.** A normal distribution produces a bell curve when scores are graphically displayed. Life care planners should note that this “normal” distribution is a mathematical model and is rarely produced by most studies. Many descriptive and inferential statistics are based upon this model of normal distribution, but specific correction techniques may be employed to account for a certain degree of abnormality. In reality, the shape of distributions may be bimodal, asymme-

rical, skewed, flat, or otherwise dissimilar from a bell-shaped curve.

⊗ **Measures of Variability.** Range and standard deviation describe the extent to which scores are dispersed across the distribution. The *range* is a rough measure of difference between the highest and lowest scores. The resulting number is not informative enough, however, so researchers calculate the *standard deviation*, which is the square root of the variance and reflects the average deviation of each individual score from the mean score. In short, the mean and the standard deviation of a distribution help the researcher to identify the average scores and the average variability of scores from the mean.

Imagine a normal distribution; a bell-shaped curve. Draw a line directly in the center of the “bell” at the highest point of the curve. This represents the mean where 50% of the scores fall below and 50% of the scores fall above. Now, continue dividing the “bell” into equal parts; four parts above the mean, and four parts below the mean. Label each of the dividing lines as illustrated below:

SD: 4	-3	-2	-1	0	+1	+2	+3	+4
%-.1%	2%	16%	50%	84%	98%	99.9%	--	

Theoretically speaking (*i.e.*, in a normal distribution) 68% of the scores lie within plus and minus one standard deviation of the mean; 95% of the scores lie within plus and minus two standard deviations of the mean.

Note:

Keep in mind that the normal distribution is not a fact of nature, but is a mathematical model, only!

⊗ **Measures of Correlation.** Measures of correlation describe the extent to which two variables are related, or co-vary with one another. Correlation statistics indicate the magnitude (*i.e.*, strength) and direction (*i.e.*, positive or negative relationship) between two variables. Correlation coefficients range from -1.0 to +1.0 with +1.0 indicating a perfect relationship (*i.e.*,

an increase in one variable is accompanied by a proportional increase in the other variable). When graphed on a scatterplot or statistically analyzed (*i.e.*, contingency tables), the measure of correlation (*i.e.*, the correlation coefficient) is an index of the *linear* relationship of the variables.

A common example of correlation is when height and weight are considered. In most cases, individuals who are taller also weigh more than those who are shorter. Of course there are exceptions, so there is not a +1.0 correlation between these variables. The actual observed relationship is +0.8; less than perfect, but a strong linear relationship (Bellini & Rumrill, 1999).

The correlation coefficient does not tell the researcher whether statistical significance has been achieved, it only serves to quantify the strength of the relationship that exists.

[2] Inferential Statistics

Inferential statistics are based on probability theory and are used to calculate the degree to which results derived from the sample can be generalized to the target population. Empirical data is translated into probability statements which are used to *infer* the relationship between variables within a target population (based upon what was observed in the sample). Put another way, tests of statistical significance determine the probability that the findings produced by the sample are also true within the target population.

A Note About Inferential Statistics

Statistical tests do not confirm that the research hypotheses are true.
Statistical tests do not guarantee that the same results will be obtained if replicated (Cohen, 1990)

⊗ **Statistical Significance.** In the social sciences, statistical significance is typically determined when the probability (*i.e.*, the *p* value) of an occurrence is less than 5%, or 0.05. When a *p* value is reported as being less than or equal to 0.05, the researcher interprets it to mean that there is likely to be a statistically significant relationship between the variables under investigation within the target population. Conversely, when a *p* value is found to be more than 0.05, the researcher

concludes that there is likely to be no statistical relationship between the variables within the target population.

In other words, a statistically significant result (at the $p < .05$ level) means that there is a 95% probability that results reflect what truly occurs between the variables within the target population.

Researchers may set the p value at any value, but most are at 0.05 or 0.01 for a more stringent test, or .10 for a less stringent test of significance. Determining the statistical significance of the data provides researchers with a means and level of confidence when identifying whether the results of the study were due to *chance* or to the treatment.

A Note About Inferential Statistics:

The only way to know for certain the actual nature of the relationship between these variables in population of interest is to sample every member of the population, an impossible task in nearly every instance of research (Bellini & Rumrill, 1999).

⊗ **Effect Size.** Sample size (*i.e.*, the number of subjects participating in a study) has an enormous effect on tests of statistical significance. If the sample size is large, statistical tests may detect significance very small correlations simply because the number of subjects causes the calculation to *appear as though* results were not due to chance, but to the treatment. As may be imagined, this fact has created a great deal of confusion and misinterpretation in the research literature. Life care planners should be aware of this fact and critically review the conclusions drawn from large sample sizes (Cohen, 1990; Hunter & Schmidt, 1990).

Hunter and Schmidt (1990) propose the following exercise:

Imagine that you reviewed all of the research studies regarding a specific counseling technique or therapy and tallied the number of studies that concluded that the intervention "worked" and those that concluded that the intervention did not "work." After reading these conflicting reports a student may determine that the evidence in favor of the intervention is inconclusive and does not have merit. Is the student correct? Possibly, but upon closer review the student recognizes that the studies used samples of varying sizes and probabilities of varying values. Should this change the

student's mind?

Limitations in the sensitivity of significance tests and the practice of using them as the only measure of results has led to the development of alternatives such as "effect size measures." Effect size refers to the proportion of variance in one variable (or a set of variables) that is accounted for by another variable (or set of variables) (Cohen, 1988). A *d* statistic is a measure of effect size and may be reported by researchers comparing the mean difference in standard deviations between two groups. Basically, the *d* statistic allows research findings of various sample sizes and outcome measures to be directly evaluated. Researchers may report the *d* statistic of the data to facilitate cross-study comparisons (Bellini & Rumrill, 1999).

[3] Methods of Statistical Analysis

There are many statistical techniques by which data are analyzed. Bellini and Rumrill (1999) note, "Methods are tools, and the methods of statistical analysis are meaningful only when they are applied within an appropriately designed study and interpreted within the theoretical context of the research question."

The following statistical tests are commonly utilized in rehabilitation and social sciences:

- ❖ The t-test;
- ❖ Analysis of variance (ANOVA);
- ❖ Multiple regression; and
- ❖ Multivariate analysis.

Each of these tests may *sound* complicated, but are readily understood when the assumptions are known.

[a] t-Test

One of the least complicated statistical analyses to perform is the t-test. This statistic measures the mean differences between two groups, usually between the experimental and control groups. The t-test is one method used by researchers to determine whether the mean differences between groups is large enough to be considered "significant" or whether the results were likely due to chance.

Consider the following scenario which is typical of research studies in rehabilitation sciences:

Mary has developed a twelve-week vocational adjustment and training program for adults who have sustained a physical injury requiring them to locate employment outside of their field of expertise. She wants to test her program to ascertain whether the individuals who complete it will exhibit higher levels of psychological adjustment than those who participated in the traditional program.

Mary gains the cooperation and consent of a group of individuals seeking vocational assistance, and randomly assigns them to two groups. One group will participate in Mary's twelve-week program and the others will receive traditional vocational counseling and guidance. The study is initiated and after twelve weeks, all participants complete a self-report questionnaire.

Mary expects that the mean psychological adjustment scores of the individuals who participated in her vocational program will be higher than those who completed the traditional program.

Mary looks at *between-group differences* because she believes that the mean scores of these two groups will be unequal due to the benefits of her vocational adjustment program. She also realizes that individuals within each group will be different from one another (this is a fact of most research studies) so she must analyze the data for *within-group differences*.

The t-test will provide an analysis of the ratio of between-group differences to within-group differences. If the ratio of these differences is large enough, statistical significance is achieved. In other words, the t-test is applied to the data in an effort to determine whether the ratio of between-group differences and within-group differences is large enough that a researcher is able to attribute these differences to a treatment or intervention, rather than to chance.

In reality, the t-test identifies significance by analyzing three factors:

1. the vehemence of the treatment or intervention (between-group difference);
2. the degree of variance within each group (within-group difference); and
3. the sample size.

The best scenario for a researcher hoping for statistical significance is when the effect of the treatment/intervention is large (substantial be-

tween-group scores), when there is little variability among individual scores within each group, and when a large sample has been obtained.

[b] Analysis of Variance

An analysis of variance (ANOVA) is very similar to a t-test, as may be inferred by the name, but is used when more than two groups are involved in the study. Referring back to the previous example, if Mary were to have developed two different vocational programs that she wanted to test, Group 1 may participate in Program A, Group 2 may participate in Program B, and Group 3 would participated in the traditional program.

Just like the t-test, the ANOVA determines the mean deviations within and between all three (or more) groups. An additional type of test, the post hoc (or “after the fact”) test, is used to obtain more information about the mean differences of the three groups. For example, Mary would likely be interested in knowing how each of her vocational programs compared with the traditional program, and which of the two may have been “better” than the other.

Post hoc tests allow researchers to compare the mean differences of Group 1 to Group 2, Group 2 to Group 3, and Group 1 to Group 3. This way, researchers are better able to determine the relative effectiveness of each group as compared to the others.

By performing a factorial analysis of variance, or *factorial ANOVA*, researchers are able to analyze the separate as well as the interactive effects of two or more categorical (*i.e.*, differing in *kind*, not amount or degree) variables.

Consider the following scenario which is based upon an actual study conducted by Leierer, et al. (1996):

John is a rehabilitation counselor who has worked with individuals with physical disabilities for many years and has noticed certain patterns in consumer behavior. Upon case closure or termination, consumers are asked to complete an evaluation of their counselor.

Several counselors on staff at his agency have physical disabilities themselves and John wonders whether consumers prefer to discuss issues involving the challenges related to disability with counselors who also have a disability may personally identify with some of their difficulties. On the other hand, he

wonders whether consumers feel comfortable discussing general concerns unrelated to disability issues with any of the counselors on staff, whether with or without a disability.

He defines the following parameters:

- (1) John also knows that one of the most important skills counselors possess is the ability to actively attend to the concerns of consumers and is a benchmark for *professional competence*. This will be one of the variables.
- (2) John hypothesizes that there is a relationship between *counselor's disability status* (whether they have a disability) and the consumer's satisfaction ratings (the dependent variable) of their counselors. This will be a second variable.
- (3) In addition, this relationship is influenced by the *nature of the issues discussed* with the counselor (consumers may prefer discussing disability-related issues with a counselor who has a disability, but has no preference when issues unrelated to the disability are being discussed). This will be a third variable.

By performing an ANOVA, John will be able to parcel out the effect of the status variables (counselor's disability, professional competence rating) and independent variable (nature of the issues discussed) to identify the main effect. The *main effect* demonstrates the effect that an independent variable has on a specific dependent variable without being influenced by the other variables under study. The ANOVA will also enable him to analyze the influential effects of the combinations of independent variables, or *interactive effects*, of all of the elements under investigation.

[c] Multiple Regression

Multiple regression is similar to the factorial ANOVA but may be used to *predict* and identify *causal* explanations, rather than to simply identify relationships. Multiple regression analyzes the multiple relationships between a *set* of independent variables and *one* dependent variable. In other words, this statistic is used as a means of predicting an outcome based upon a combination of two or more variables. Multiple regression is more flexible than ANOVA, which is limited to cate-

gorical variables. Multiple regression techniques can analyze multiple continuous, dichotomous, or categorical variables.

For example, a researcher may want to identify the variables which best predict return to work success following physical injury. Based upon what is known in the field of vocational rehabilitation, the researcher may select the following variables: age of onset, previous work history, severity of physical impairment, marital status, etc., believed to influence vocational outcome. Multiple regression analysis allows the researcher to identify the combination of factors most likely to predict whether individuals successfully return to work after sustaining physical injuries.

[d] Multivariate Analysis

According to Bellini and Rumrill (1999), multivariate analysis is less commonly utilized in rehabilitation sciences than multiple regression, but may be useful depending upon the research design of a particular study. Rather than one method, multivariate analysis refers to a group of statistical techniques which analyze the effects of *one or a set* of variables on a *set* of continuous variables.

[3] Statistical Significance v. Practical Significance

Life care planners need to be familiar enough with statistical methods in order to determine the difference between the *statistical significance* of a study, and the *practical significance* of a study. While statistical significance is the yardstick by which research findings are measured, it may not always be a useful criterion for determining whether the results have any practical importance affecting the welfare of individuals with disabilities.

Knowing the effect of a large sample size on probability (*i.e.*, large sample sizes tend to detect significance when it may not be truly present), the life care planner should pay close attention to the reported *actual differences* among group means and other indicators of *magnitudes* of relationships.

Bellini and Rumrill (1999) assert:

Evaluating the practical significance of research findings also involves reassessing the status of the theoretical proposition following the empirical test, as well as the heuristic and

practical value of the theoretical proposition relative to the goals, activities, and procedures of the particular agency or program.

Recall that the purpose of scientific inquiry is to develop theories that guide a discipline's philosophy and practice. Research does not "prove" or "disprove" facts, but support or refute current hypothetical propositions, several of which taken together can give rise to a theory. Bellini and Rumrill (1999) continue, "it is the theory, confirmed by research findings, that provides rehabilitation practitioners with tools for understanding the relationships among personal values, beliefs about disability, and subsequent adjustment of persons with acquired disabilities.

§ 9B.09 Methodology of Data Collection

Protocols and procedures establish the reliability and reproducibility of the study's results. They set forth who will collect the data and how they will be trained. Have a written protocol for how data is collected, then follow the same procedure all the time. Do not be tempted to make "adjustments" to the protocol as the study proceeds even if better ways of operating are identified. Without adherence to the study's protocols and procedures, the data will be meaningless. Any change in the protocol invalidates the results because inconsistency in how they are attained destroys their dependability (Piantadosi, 1997, Ch. 4).

The person collecting or analyzing the data should be "masked" or "blinded" to the identity of the groups being compared. Masking is an important aspect of data collection and analysis in experimental research so that the outcomes are not biased by the researcher's expectations (Friedman, *et al.*, 1998, Ch. 6). All the data must be collected in a consistent and dependable manner by a blinded investigator to obtain a reliable answer to the study's research question.

[1] Statistical Analysis and Inference

Data analysis is always done statistically. The research question and experimental design determine, in advance of data collection, how the data will be analyzed statistically. However, the process cannot be entirely anticipated until the data is available for analysis. In the conventional comparative research design using parallel groups, initial statistical tests comparing the two primary groups of interest are made even if the groups are stratified by other factors such as gender or age. If an overall, or main effect, is detected between the main groups, then the subgroups can be tested *post hoc* to determine the exact location of the effect within the study population's strata.

The limitation of this type of study design is that interaction between effects cannot be determined. This is a problem particularly if the effect in one subgroup runs counter to the overall, main effect of interest such that the effect in the subgroup negates the main effect. The factorial study design adjusts for this possibility by allowing statistical analysis for main effects as well as the interaction of effects (DeMuth, 1999).

From statistical analysis, inferences can be made about the results of the study but, to have meaning, the results of the study should be interpreted in light of the current times and the state of the art and what it may mean for the future. If an effect is detected by the study, then the various possible explanations of the effect can be considered. Interpretation of why or how an effect may have occurred is an issue that can be covered within the Discussion section of the published report.

[2] Reading and Interpreting the Life Care Planning Literature

Ultimately, the professional should be prepared to critically evaluate a study reported in the literature and apply that new knowledge to their professional practice and future investigative endeavors. The reader should read and interpret the published literature in the professional field to determine for themselves what to take away from the reading rather than accepting *carte blanche* the conclusions presented by the research investigators.

The research concepts presented in this text offer a foundation for

developing a general appraisal. Some critical questions a reader might ask of a published report include:

- A. How does the research design, methodology and statistical analysis affect outcome?
- B. Has the study been powered appropriately
- C. What is the period of observation? If comparisons between LCPs were made after 5 months and the updated LCPs were completely congruous with the original LCPs, the meaningfulness might be suspect. However, if the window of observation were extended to 5 years, and the same result obtained, it might be meaningful.
- D. Was the research protocol appropriate and was adherence to it stringent?
- E. How credible, ethical and moral is the investigator?
- F. Does this researcher hold reputable credentials and is the work supported by a research institution?
- G. Has the author addressed the points that a study needs to address?

Elwood (1998, Chaps. 10-15) presents guidelines for critically evaluating and interpreting specific types of research studies.

The purpose of the published literature is to inform the public in general and future research efforts in particular. Therefore, it is paramount that future investigators and readers are equipped to read the work and parse out for themselves the strengths and weaknesses of the research, to enable the specialty practice of Life Care Planning to move forward into the future.

[3] Developing a Research Study Proposal

Inexperience does not preclude a professional from entering the arena of scientific research. All investigators were once novices. In developing a research study proposal, seasoned mentors serve an important function for experienced as well as novice investigators. They can guide the researcher through the investigative process and give key direction. Sometimes the key direction is an introduction to the person who can help at a particular impasse. Sage mentoring is an indispensable resource to support the professional who embarks upon the scientific course of investigation.

A second essential resource to facilitate research efforts is database

accessibility. Access to larger caseloads may be obtained through research institutions such as The Foundation for Life Care Planning Research. This foundation's purpose is to help develop research proposals, provide opportunities for mentoring, and access to significant databases. For the professional who is developing a research study proposal, The Foundation for Life Care Planning Research offers important support.

[4] References for Further Reading: Instrumentation and Data Collection

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§ 9B.10 Ethics in Research

As practitioners and researchers we have a responsibility to protect the research subject from potential harms including psychological harm. This responsibility includes preserving the privacy and confidentiality of the patient's information. Federal regulations aimed at assuring these safeguards govern research.

The design and execution of descriptive and analytical research

studies must uphold the three ethical principles of respect, beneficence and justice. The principle of respect requires investigators to treat study subjects as autonomous individuals. Respect is exercised in obtaining voluntary, informed consent of the subject to participate in the study and in minimizing harm to the subject. The principle of beneficence requires that the benefits of research are proportional to the risks the study subjects assume by their participation. The results of research should be generalizable to the population from which the study subjects are drawn and the design of the study should protect the subjects from unnecessary harm. Justice is provided by distributing the benefits and burdens of research equally among those who stand to benefit from the study. This is addressed especially with vulnerable populations such as the severely disabled when they are neither excluded from research, nor over represented in the study. That the ethical principles of research are adhered to is the primary duty of Institutional Review Boards (IRBs). Informed consent instruments and publication of research findings are two major tools in meeting ethical research standards (Brody, 1998).

Maintaining the security of the research databank is a separate concern; that only ethical research is conducted using the information in the databank. The data should not be available for "junk" or unscrupulous scientific endeavors. Finally, the conduct of research carries with it the ethical mandate to make public the findings of the scientific study, (Bellini & Rumrill, 1999, Ch. 4; Brody, 1998; Dunn & Chadwick, 1999; Piantadosi, 1997, Ch. 3)

[1] Privacy and Confidentiality

One way to assure the confidentiality of the patient's records is to remove the identifiers from the records. Alternatively the identifiers can be dissociated from the records and the key to the dissociation process kept under lock and key as privileged information. These safeguards notwithstanding, informed consent for the study should be obtained from the study's subjects as part of the eligibility of subjects for inclusion in the study.

[2] Informed Consent

Subjects, who are vulnerable to manipulation and abuse such as the very young or old, the impoverished, the sick or disabled, etc., are owed special protection by medical researchers (Brody, 1998; Chs. 2 &

6; Dunn & Chadwick, 1999, Ch. 6). By definition, all subjects involved in studies validating the life care planning process are vulnerable and therefore owed special protection. The informed consent process informs the subject of the purpose of the study and the risks to the subject. The informed consent document requires the subject's acknowledgement and is important in assuring privacy and confidentiality to the study's research subjects.

Unscrupulous or junk science is never in the best interest of society as a whole. The databank available within the many caseloads of Life Care Planners should only be available to competent, ethical researchers who will produce credible research studies. Academic institutions or private research foundations can function as gatekeepers in permitting access to databanks held in their trust for appropriately designed and executed research studies.

[3] Institutional Review Boards

The Institutional Review Board (IRB) of the research conducting institution is charged with administering research according to the Federal regulations. Some types of research are exempt from Federal regulation, however, the exemption must be certified by the IRB. The IRB provides ethical review of research protocols and informed consent forms, primarily to assure the protection of the subjects, but also to assure quality control of the research itself. This process also essentially limits access to data banks to authorized researchers (Brody, 1998, Ch. 2; Dunn & Chadwick, 1999, Ch. 6; Piantadosi, 1997, Chs. 3 & 4).

IRBs provide two other services. Administrative IRBs are established to review proposals for research, applications for grant funding to perform research and contractual arrangements to conduct research with the institution. Other IRBs exist to provide for the peer review process in publication of research study results.

[4] Publication of Results

Publication of results is ethically mandated. Whether the results of a study are negative or positive, the mandate holds. Research uses valuable societal resources and the information garnered is held to be public domain. If results are not published, then the study may be repeated needlessly by other researchers, thus wasting scarce research

resources. The most wanton waste is the unavailability of the research resources to move the scientific knowledge base forward (Dunn & Chadwick, 1999, Ch. 7).

§ 9B.11 Introduction to Clinical Practice Guidelines

Life care planners must base recommendations upon reasonable, ethical, and appropriate analyses of patient-specific needs. How are these analyses generated? Where can life care planners obtain such information? What is meant by “clinical practice guidelines?”

[1] Definition

Definitions of clinical practice guidelines vary slightly from one another, but are very similar in intent. For example:

Practice guidelines are statements that are systematically developed to assist practitioner and patient decisions about appropriate healthcare for certain clinical diagnoses. They are intended to be flexible: deviations are expected, acceptable and justified depending upon individual characteristics and circumstances. (Callender, 1999)

“ . . . systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific circumstances.” (Institute of Medicine, 1990)

The Joint Commission of Accreditation of Healthcare Organizations (2000) defines clinical practice guidelines as: descriptive tools or standardized specifications for care of the typical individual in the typical situation, developed through a formal process that incorporates the best scientific evidence of effectiveness with expert opinion. Synonyms include clinical criteria, parameter, protocol, algorithm, review criteria, preferred practice pattern and guideline.

The American Medical Association (Hirshfeld, 1990) has not yet formulated a universally accepted definition of clinical practice guidelines, but has defined what it refers to as “practice parameters.” These parameters have been established as, “recommendations for patient management that may identify a particular management strategy or a range of management strategies.”

Wyer (2002) asserts that clinical practice guidelines are not:

- A. Decision rules

- B. Computerized support systems
- C. Decision analyses
- D. Cost-effectiveness analyses.

Oetgen and Wiley (1996) note that the development of formal practice guidelines were initiated in the 1980s as a result of three primary forces:

1. Health care costs assumed by the federal government were expanding at an ever-increasing rate. With Medicare expenditures soaring, Congress became interested in developing a methodology for analyzing physician services for medical necessity and effectiveness.
2. A wider database which incorporated medical outcomes research findings was being utilized more efficiently by health care professionals and health policy administrators.
3. As more data was amassed, it became apparent that inappropriate care practices were going unchecked and causing harm to patients. In addition, inequalities in access to care and necessary treatment were recognized.

While most definitions of clinical practice guidelines are similar, not all organizations and fields of expertise are in agreement regarding the appropriate use of guidelines in practice.

[2] The Purpose of Clinical Practice Guidelines

The Joint Commission of Accreditation of Healthcare Organizations (JCAHO, 2000) and MacLean (2002) assert that the purpose of clinical practice guidelines are to:

- To improve outcomes and quality of care provided to patients;
- To reduce undesirable variations in care and treatment by providing continuity of care;
- To reduce inflation of healthcare costs and identify the most effective practices considering costs and resources expended (money, effort, and risk);
- To manage quality by setting measurable standards.

Amon (2000) points out that the notion of established clinical practice guidelines is not a new concept but, "What is new is the emphasis placed on systematic, evidence-based guidelines and the

structure, process, and incentives that support their effective use and as a mechanism of internal assessment of such guidelines.”

Ultimately, clinical practice guidelines serve as recommendations for patient care and injury/disability management. The purpose of these recommendations is to guide the decision-making process of professionals contemplating the most beneficial medical and therapeutic interventions.

[3] Policymakers and Clinical Practice Guidelines

Policymakers sometimes have a slightly different perspective regarding the purpose and utility of clinical practice guidelines. In general, policymakers are interested in:

- Reducing the incidence of inappropriate care;
- Minimizing wide variations in level of care and/or therapy;
- Maximizing the value of each health care dollar spent toward recovery and rehabilitation.

If these purposes appear to be similar to those espoused by JCAHO and MacLean, they are. However, the ways in which each group determines that it will accomplish its goal may differ enormously. The same set of clinical practice guidelines used to treat and rehabilitate patients may also be used to determine “medical necessity,” “cost-effective” treatment, and to establish standardization of care. In order for life care planners to better appreciate the capacity of clinical practice guidelines, the scientific data upon which they are based and the process by which they are developed must be understood.

[4] Development of Clinical Practice Guidelines

Clinical practice guidelines have been developed through the collaborative efforts of many committees, organizations, and federal agencies.

[a] Agency for Healthcare Research and Quality

In 1999 former President Clinton reauthorized the Agency for Healthcare Research and Quality (AHRQ), which is a branch of the U.S. Department of Health and Human Services Agency. The follow-

ing statement was extracted directly from the Agency's website (<http://www.ahcpr.gov/about/ahrqfact.htm>):

The legislation also positions the Agency as a "science partner," working collaboratively with the public and private sectors to improve the quality and safety of patient care.

Under the legislation AHRQ will:

- Meet the information needs of its customers' patients and clinicians, health system leaders, and policy-makers so that they can make more informed health-care decisions.
- Build the evidence base for what works and doesn't work in healthcare and develop the information, tools, and strategies that decision-makers can use to make good decisions and provide high-quality healthcare based on evidence.
- Develop scientific knowledge in these areas but will not mandate guidelines or standards for measuring quality.

[b] Health Insurance Companies

For many years health insurance companies have been utilizing practice guidelines as a way of making claims decisions and selecting care providers. Over time, the guidelines referenced by health insurance companies have become more well defined and, in some cases, more reflective of clinical input from physician organizations.

[c] Other Sources of Development

Amon (2000) notes that more than 35 medical groups, physician organizations, and specialty associations have developed clinical practice guidelines, including the American Medical Association and the Council of Medical Specialty Societies. In addition, independent and academic research centers, such as the RAND Corporation and the Institute of Medicine, are working to establish protocols for the development of guidelines.

[5] The Validity of Clinical Practice Guidelines

As you read about the following classifications of practice guide-

lines, consider each category with respect to the discussion of validity. The validity of a specific set of clinical practice guidelines depends upon the methodology utilized by the developers in identifying appropriate components of the final document. Further, the purpose for which the developers created the practice guidelines should be considered. If the foundations (*i.e.*, methodology and purpose) are faulty, little credibility may be invested in the product.

[6] Classification of Development Methodologies

Amon (2000) describes a classification system consisting of four categories:

1. informal consensus development;
2. formal consensus development;
3. evidence-based guideline development; and
4. explicit guideline development.

[a] Informal Consensus Development

Informal consensus development is the simplest, most commonly employed method of developing practice guidelines. In most cases, a panel of field experts meets to discuss the relevant issues and form a consensus through discussion and debate. There are positive aspects to this method in that the process is uncomplicated and decisions may be made in a brief period of time.

However, there are several disadvantages to this method. Many times, consensus opinion is reached without providing an explanation to others as to how recommendations were reached, without explicitly linking knowledge within the field (scientific, clinical, or otherwise), and without documenting the methodology utilized to arrive at the summative consensus.

Amon (2000) provides an example of such non-disclosure by explaining that insurance companies often utilize sophisticated methods of analyses, but because of proprietary concerns, they will not disclose the analytical methodology relied upon to develop guidelines. Unfortunately, when life care planners do not have access to such information significant limitations may be imposed upon the practical usefulness of these guidelines.

[b] Formal Consensus Development

The primary difference between informal and formal consensus development is that the latter typically involves structured workshop sessions held over several days and efforts are made to document the methodology applied throughout the process. In general, formal procedures include detailed literature reviews, debate, and votes by a panel of experts recognized in the field.

While it is a more structured attempt to define practice guidelines, this method of development is, nonetheless, based upon expert opinion and the “tools” with which they choose to evaluate the relevant issues. For example, if a group of experts in the health insurance industry were to perform in-depth literature reviews, analyze claims data, debate, vote, and publish practice guidelines, should life care planners deem the product valid? Consider the fact that research literature may be flawed or irrelevant and that insurance claims data is often erroneous. As with an informal process, expert opinion ultimately determines the form of the guidelines.

[c] Evidence-based Guideline Development

The evidence-based approach emphasizes the need to distinguish between guidelines derived from a scientific foundation, and those based upon expert opinion. This method includes a formal evaluation and analysis of scientific evidence, an exchange of information among panel members, and open forums that seek to reach a wide audience.

While this process increases the scientific rigor of practice guideline development methodology, it may be limited by the lack of acceptable “evidence” reported in the research literature. Anon (2000) reports that a very small percentage (only about 10 percent) of current medical interventions have been validated through well-designed clinical studies. Because of this, neutral recommendations may be made but are not likely to be useful for large numbers of practitioners.

[d] Explicit Guideline Development

Professionals employing this method of development outline the benefits, harms, and costs of potential interventions then calculate explicit numerical probabilities of each outcome. Estimates may be generated using scientific evidence, mathematical models, or expert opin-

ion, but the sources of each recommendation are distinctly cited.

Amon (2000) describes a "balance sheet" which is created to display the alternatives to interested parties (*i.e.*, patients, families, physicians, payers, *etc.*). This "objective" data is then compared with the preferences and desires of the patient in order to arrive upon decisions.

This approach is becoming more popular, but because it is still a relatively new method of guideline development, published reviews and critiques are limited.

[7] Are Clinical Practice Guidelines Helpful or Harmful?

The manner in which clinical practice guidelines should best be utilized is somewhat controversial and depends in large part upon the goals of the particular group stating a position on the issue.

[a] The Medical Community

Physicians groups have expressed concerns that practice guidelines may be encouraging reliance upon "cookbook medicine," rather than sound clinical judgments based upon patient-specific factors (Amon, 2000). Some view the advocacy of practice guidelines as an effort to standardize care which is an obstacle in providing individualized care to patients within a specific demographic or practice setting.

Professionals in the health industry are concerned that practice guidelines may:

- ⊞ ·Interfere with their ability to exercise clinical judgement;
- ⊞ ·Cite unreasonable recommendations, particularly when prepared by non-practitioners, payers, or those unfamiliar with clinical practice;
- ⊞ ·Be used to deny coverage of physician recommended procedures;
- ⊞ ·Be inappropriately used to rate physician competence;
- ⊞ ·Serve as evidence in malpractice cases;
- ⊞ ·Threaten specialty areas of practice through intervening guidelines of other groups;
- ⊞ ·Become compulsory standards;
- ⊞ ·Obstruct physicians' attempts to obtain malpractice insurance unless they are compliant with all guidelines.

[b] The Health Insurance Coverage Community

There is little doubt that rising costs of health insurance coverage, emergency/trauma treatment, acute medical care, and rehabilitation certainly provides a powerful motivation for considering alternatives to the system currently utilized.

As mentioned earlier, some health insurance companies will not disclose the methodology employed to analyze and develop practice guidelines because of proprietary concerns.

[c] The Patient Community

Even when pleased with their medical professionals of choice, patients often seek reassurances that the care and treatments they are receiving from their personal providers are, indeed, appropriate and comparable to the treatments prescribed by other professionals. Practice guidelines may provide some level of comfort to patients and families and allow for improved communication, education, and compliance with recommended interventions.

However, patients also recognize that practice guidelines may be inappropriately applied to their specific case and used as a basis for denial of claims, provider groups, or coverage. Practice guidelines developed to maximize outcomes for a target population may not adequately meet the needs of individual patients within that group.

[8] Enforcement and Litigation

Some groups believe that the underlying impetus for rising health care costs rests with physicians. Following this logic, these groups seek to develop enforcement policies which penalize physicians (through denial of reimbursement for services, pre-certifications, or reasonable malpractice coverage) who do not comply with the established guidelines. Further, physicians failing to comply with guidelines may be subjected to medical review and/or confront challenges when acquiring licensure, specialty practice re-certification, and hospital privileges (Amon, 2000).

Many physician's groups object to the publication of practice guidelines because of the probability that they will be submitted as evidence in litigated cases against professionals who have exercised clinical judgments beyond the stated guidelines. They are concerned that

deviations from the practice guidelines will be argued to constitute substandard care or negligence.

Oetgen and Wiley (1996) report that no jurisdictions have allowed guidelines to be submitted as the sole piece of evidence regarding standards of care. In fact, Oetgen and Wiley (1996) state that the presentation of practice guidelines in most jurisdictions necessitates the appearance of an expert witness who must explain the guidelines to the jury/judge, discuss their validity and relevance, and participate in cross-examination, if requested by the opposing counsel.

While physicians should not be expected to comply with erroneous guidelines, professionals who administer inappropriate care must be identified and prevented from harming patients. Consider the notion that although guidelines may not be entirely valid in every patient's circumstance, they may provide a limited measure of professional competency in cases where obvious infractions are committed.

[9] Limitations of Clinical Practice Guidelines

There are three primary areas in which clinical practice guidelines are limited (Amon, 2000):

- (1) Medical science is not able to unequivocally define "optimal" care, even with advancing technologies and an ever-growing databank of knowledge. For example, a review of research literature in nearly any aspect of disability will result in few studies involving minority groups, patients who do not fit the "stereotypical" profile, or those from rural communities.

As discussed previously, it is very difficult to design true experimental research studies (*i.e.*, multiple randomized clinical trials with large numbers of participants) involving human subjects. Most studies are inherently limited in their ability to offer undisputed results, validity, practical significance, and generalizability. Certainly, the existing body of research may be used to determine the most probable benefits of interventions, it is not possible to state that practice guidelines, based upon these studies, are indisputably accurate and appropriate for all patients.

- (2) The methodology of practice guideline development is questionable. While efforts are made to perform thorough

reviews of the existing literature and to integrate objective expert opinion, the resulting recommendations cannot be deemed to be "right" or to accurately reflect optimum care; these guidelines continue to represent what experts identify as being the best course of action.

- (3) Patients are unique individuals with factors distinguishing them from the average subject as defined within a set of practice guidelines. The recommended course of action for the average patient with a given diagnosis may be inappropriate and/or harmful to a specific patient with a unique medical and rehabilitation history, comorbidities, and lifestyle.

Patients respond differently to treatments and interventions which requires physicians to make necessary adjustments in recommendations. In addition, patients have unique preferences, motivations, and tolerances for certain types of treatment and may/may not have adequate support to maintain recommended interventions over time.

[10] Utility of Clinical Practice Guidelines

While clinical practice guidelines cannot account for all of the individual variations patients represent, they can serve as a foundation for initial care and treatment. Amon (2000) asserts:

Limitations of practice guidelines are not a problem, as long as they are communicated honestly in the working of the recommendations and rational. Honest uncertainty is communicated in the rationale by stating clearly which parts of the recommendations are based on science and the quality of the evidence, and which recommendations are based on opinion and how that opinion was gathered.?

When reviewing clinical practice guidelines, life care planners must actively question:

- a) The goals of the group who developed them;
- b) The methodology of development;
- c) The language within the document (flexible or absolutist?)

- d) The degree to which inherent limitations are acknowledged;
- e) The degree to which the guidelines apply to an individual patient

Clinical practice guidelines serve as one of the resources to be considered when developing a life care plan. Like any other source, professionals must view all practice guidelines with a critical eye, question the validity of the recommendations, and recognize the limitations of the development methodology. Most importantly, life care planners must determine whether specific practice guidelines are applicable and appropriate for the individual with whom we are working.

§ 9B.12 Introduction to Evidence-based Practice

For more than two decades, clinical practice guidelines have been a source of interest for health insurance carriers and government providers (Medicare, Department of Veterans Affairs, etc.) seeking to reduce health care/pharmaceutical costs, improve quality assurance measures, and to reduce wide variations between clinical practice settings.

Wyer (2002) asserts that while clinical practice guidelines offer direction for practice and decrease variations between practitioners, evidence-based medicine integrates research findings and clinical evidence that ultimately supports or refutes the current principles of care.

[1] Definition

Sacket, Rosenberg, Gray, Haynes, and Richardson (1997) define evidence-based medicine as:

. . . the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

The Evidence-based Medicine Resource Center (New York Academy of Medicine and American College of Physicians, 2002) states:

Evidence-based medicine's ultimate application is at the level of the individual clinician's decisions about managing patients. It is an explicit approach to problem solving and continual professional learning which requires the use of current best evidence in making medical decisions about individual patients. To achieve evidence-informed decisions, the health practitioner should:

- ◆ ·Develop a focused clinical question concerning the patient's problem(s);
- ◆ ·Search the primary literature and secondary databases for relevant articles;
- ◆ ·Access the validity and usefulness of those articles;
- ◆ ·Judge the relevance to the individual patient;
- ◆ ·Implement the findings in patient care."

Evidence-based medicine is not a "new" concept in the field, but may be an effective methodology for evaluating and developing clinical practice guidelines and evaluating research literature within healthcare fields. Rather than relying solely upon one's personal clinical experience, professionals are encouraged to consult research literature when making patient recommendations.

The evidence-based approach is consistent with the basic tenets and methodologies of life care planning which state that plan recommendations must have a basis in research literature which is relevant to the specific patient for whom the plan is developed. This approach is also consistent with other health care entities and is sometimes referred to as "evidence-based health care" or "evidence-based practice."

O'Rourke (1997) points out that the evidence-based approach parallels clinical practice in that both:

- ▽ Are about *using* rather than *doing* research;
- ▽ Aim at improving healthcare delivery and raising standards;
- ▽ Consider the use of resources;
- ▽ Focus on the range of outcomes by insisting on explicit end points;
- ▽ Are tools for delivering education;
- ▽ Are useful for setting standards.

[2] Professional Skills

Most professionals coming to the specialty of life care planning will have had experience reviewing and critiquing research articles as one component of undergraduate/graduate preparatory academic programs. Continuing education, professional development activities, and continuous research literature review are essential responsibilities of life care planners. The American Medical Association (1992) delineates the following skills as being necessary in order to fully utilize research literature:

- * Precisely define a patient problem;
- * Determine what information is necessary in order to resolve the problem;
- * Conduct an effective search of the research literature;
- * Select the most relevant studies, consider in patient-specific information;
- * The validity of research studies;
- * Communicate the findings of research studies, strengths and limitations, and relevance to others;
- * Apply research data to the patient problem.

Life care planners attend to the pathophysiology of injury as well as the cognitive, emotional, and interpersonal consequences of long-term disability. When referencing clinical practice guidelines and research literature, life care planners must also take these factors into consideration.

[3] Evidence-Based Methodology and Life Care Planning

By applying an evidence-based approach to research involving patient-specific plan recommendations, life care planners may conduct successful literature reviews. This can be conducted in a four step process.

Step One: Identify the Patient Problem

Patient Characteristics and Demographics. The more precisely you are able to define the patient and his/her limitations, the more productive your literature search will prove to be. Many of the data points will be identified through a review of patient records and the clinical interview and history.

Functional Limitations. In addition to the patient's specific medical diagnoses, life care planners should assess the *functional limitations* (physical, emotional, cognitive, interpersonal, vocational) imposed by the disability. Both the medical diagnosis (*e.g.* Projected EvalEvaluations, Therapeutic Modalities, Medications, *etc.*) and the functional limitations (Aids for Independent Functioning, Home Furnishings and Accessories, Recreation and Leisure, *etc.*) are addressed in the life care plan.

Focus of Research. The State University of New Yor (SUNY) Downstate Medical Center (2000) provides an excellent online introductory course to the basic methodology of the evidenced-based approach. It is suggested that, in addition to patient-specific data, the patient's problem should clearly defined before beginning a literature search. The following classifications were extracted from the Center's website (<http://servers.medlib.hscbklyn.edu/ebmdos/toc.html>):

Therapy. Therapy problems are questions about what treatment, if any, to give a patient, and what the outcomes of different treatment options might be.

Diagnosis. Diagnosis problems are questions about the degree to which a particular test is reliable and clinically useful, generally asked in order to decide whether a patient of yours would derive sufficient benefit from the test to justify having it done. Most articles on diagnosis compare the results of the diagnostic test being studied to the results of another standard test that is regarded as being definitive. A definitive test is sometimes referred to as a "gold standard" test.

Prognosis. Prognosis problems are questions about a patient's future health, life span, and quality of life in the event that s/he chooses a particular treatment option. For instance, how do the life span and quality of life of an elderly patient undergoing surgery for prostate cancer compare with those for a similar patient who chooses not to undergo the surgery?

Harm. Harm problems are questions about the relationship between a disease and a possible cause. For example, does a diet rich in saturated fats increase the risk of heart disease, and if so, by how much?

Most of the questions asked by life care planners would be considered to be prognosis oriented since our work focuses on the long-term needs of patients.

Be cautious, however, that you do not attempt to make recommendations which are beyond your area of licensure/certification. The

purpose of performing patient-specific research is not to make an independent assessment or diagnosis of the patient's condition, but to illustrate the basis for your recommendations. When reporting the conclusions of research, life care planners should make certain that it is presented as an *educational component* of the process, not as a *prescription* for specific medical treatments or interventions for which you are not qualified to make.

Step Two: Review the Published Literature

Using reliable Internet sites for statistics/data, current texts, peer-reviewed journals, and other sources, your first choice in locating articles is to find those which employ randomized, controlled (true experimental or quasi-experimental) designs which address the needs of the patient with whom you are working. Experimental research designs are preferable to others because they represent the research design types having the highest degree of control. Unfortunately, for most of the topics in which life care planners are interested randomized controlled trials are excluded for ethical reasons.

When true/quasi-experimental studies are not available within your particular area of interest, carefully evaluate the designs of those you chose to review. Recall that each research design type and methodology has benefits and limitations which may impact the validity of results.

Consider the Relevance of the Study

Are the participants similar to your patient? If so, to what extent?

Can the results of the study be generalized to your patient?

Is the treatment/intervention feasible and/or available to your patient?

Consider the Validity of the Study

As life care planners, we are seeking articles which provide the best possible evidence to guide our recommendations; we are seeking validity in the research design, methodology, analysis, and interpretation.

Are subjects randomly assigned to the different treatment groups?

Random assignment allows for the most stringent control of factors (*i.e.*, age, sex, co-morbid conditions, investigator bias, *etc.*) because they are, theoretically equally distributed among

the participants in all groups.

Do the subjects, researchers, and data analyzers know which treatment was given to a particular individual?

Were all the study subjects accounted for at the end of the study?

How meaningful are the results? Within the body of literature, there are many studies reporting statistically significant, but clinically irrelevant results.

Step Three: Evaluate the Research Evidence

Strategies for evaluating the information provided in published research studies have been presented through-out this chapter. Identifying whether a specific study is valid and practically significant is absolutely necessary, but not sufficient to determine whether it is of use to you; *its relevance to the patient is paramount*. Without relevance, the results of the study are meaningless to the outcomes of the patient with whom you are working.

Life care planners must make use of their knowledge of research design, methodology, data collection, analysis, and interpretation in order to answer the question: Is this study relevant to my patient?

The following questions were extracted from the SUNY Downstate Medical Center (2000) website:

(1) Are the People in the Study Like My Patient?

You want a study in which the patients are as like your patient as possible, in terms of variables such as:

- Age;
- General State of Health;
- Type and Severity of Disease Process;
- Time in the course of the disease.

You will rarely find a study with patients exactly like yours, but if they are too different you may want to spend some time looking for another study.

(2) Did the Study Cover All Aspects of the Problem?

Most medical problems have many different aspects to consider when deciding on a treatment or course of action for a patient. Look for studies that deal with all the aspects that are of importance to your patient. For instance, a study may show that a treatment is effective for a certain condition, but it does not address the treatment's side effects or adverse events. Or a study may indicate that one treatment provides

patients better pain relief than another, but may not identify which of the treatments most effectively treats the underlying condition.

In cases like these, you will want to look for other studies that answer the questions which were not addressed by the first study. If you are unable to locate such articles, be aware that you need to fill in the gaps using your own judgment or the recommendations of members of the treatment team.

(3) Were the Groups Selected in an Impartial Way?

The paper should describe in detail how the groups were selected, and the method should be designed so that the groups are as similar as possible in every way except for the one being studied.

If this is not done, then any results of the study could just be due to the initial differences between the groups. For instance, a group of physicians studied air pollution levels and mortality in six U.S. cities (Dockery, Pope, Spengler, Ware, Fay, Ferris, and Speizer, 1993. *An Association Between Air Pollution and Mortality in Six U.S. Cities*. *New England Journal of Medicine*, 329, 1753-59). They went into enormous detail on measurements of mortality and pollution levels and obtained some extremely impressive results. However, they never said anywhere in the paper how or why they selected those six cities. So, for all the reader knows, they just looked through the atlas and selected only those cities that had high pollution levels and poor life expectancies, or low pollution levels and good life expectancies, and ignored the rest. The results would have been much stronger if they had studied all cities within a certain region (even in less detail) and/or explained clearly why they selected the cities they did.

(4) Was the Follow-up of Sufficient Duration and Complete?

Conditions under study regarding "Prognosis" and "Harm" often take a long while to run their course. For example, sometimes it can take decades between initial exposure to a carcinogen and full-blown cancer. So a study whose follow-up is not long enough can underestimate risk and ignore clinically important effects.

On the other hand, the longer the study, the greater the number of patients who may be lost to follow-up. Patients who are lost to follow-up tend to have a different prognosis from those who stay in a study. Some may be lost because they die, while others may have lost interest in the health care system, possibly to the point that they are no longer taking care of themselves. The study results should indicate how many

patients were lost to follow-up, under what circumstances, and whether the rate of attrition could materially affect the results of the study.

Step Four: Apply the Conclusions to Practice

Ideally, the processes of research, education, professional development and practice should be integrated.

(1) Does it Suggest a Clear and Useful Plan of Action?

The most useful studies are those that suggest a useful plan to improve your patient's state of health. Studies that help clarify a patient's prognosis may also be helpful to the patient in making life decisions. Studies that don't do either of these are of little or no interest to you. A lot of very valuable preliminary research falls into this category. It is not that the research is not good, it's just that it hasn't yet reached the point of being able to provide clear-cut clinical recommendations.

(2) Cautiously Reference Clinical Practice Guidelines

Consider the discussion regarding the validity of development methodologies relied upon in creating clinical practice guidelines. Life care planners must be cautious when citing a set of clinical practice guidelines as the sole substantiation for specific plan recommendations.

In addition, consider the fact that most clinical practice guidelines do not address the effects of aging with disability or specify factors influencing long-term support and care needs. Even the most well-developed guidelines fall short of offering recommendations relative to the interaction of the aging process and disability management. As stated, life care planners are primarily interested in using prognosis-oriented research literature and practice guidelines to build a foundation for the projected needs of an individual patient.

The link between research literature, clinical practice guidelines, and future needs must be clearly demonstrated within the narrative report and the life care plan. Patients, family members, and other professionals should be able reach the same conclusions represented in a life care plan when given a comprehensive explanation of the methodology and resources used to develop the recommendations.

[4] Suggestions for Further Research — Evidence Based Practice

Center for Health Evidence:

<http://www.cche.net/usersguides/main.asp>

Evidence-Based Medicine:

<http://hsc.usf.edu/CLASS/Gene/ebm.htm#Source>

<http://hsc.usf.edu/CLASS/Gene/Presentation/sld001.htm>

(Power Point)

Netting the Evidence:

(databases) <http://www.shef.ac.uk/~scharr/ir/netting/>

(journals) <http://www.shef.ac.uk/~scharr/ir/netting/>

SUNY Downstate Medical Center Evidence Based Medicine Course:

<http://servers.medlib.hscbklyn.edu/ebmdos/toc.html>

University of Illinois at Chicago:

<http://www.uic.edu/depts/lib/lhsp/resources/ebm.shtml>

University of Missouri-Kansas City:

<http://www.umkc.edu/lib/HSL/biostats.html#web>

The Wisdom Centre:

<http://www.shef.ac.uk/uni/projects/wrp/seminar.html#EBP>

§ 9B.13 Locating Practice Guidelines

The citations within this section are provided as a starting point for life care planners interested in reviewing the clinical practice guidelines of several specialty practice areas. It is not possible to provide a comprehensive list of references, however, because each patient presents a unique set of circumstances and the practice guidelines that you consult as part of your plan development will depend upon the specific needs of the individual with whom you are working.

[1] Beginning the Search

When seeking clinical practice guidelines specific to the patient with whom you are working, you may begin your search in the following ways:

- ¶ **Literature Review.** In reviewing the research literature related to a patient's case, it is likely that authors will have referenced clinical practice guidelines within their articles. This not only saves you time in locating the documents, but provides you with insight when evaluating the validity of the findings of studies which relied heavily upon the guidelines as a basis for their methodology.
- ¶ **The Internet.** Many professionals find that the Internet is one of the most efficient ways to locate information if, of course, you are able to hit upon an effective search methodology. In addition to referencing the databanks provided within this chapter, you may search the websites of national organizations, state agencies, credentialing bodies, and similar associations. When utilizing practice guidelines provided on an organization's website, it is a good idea to actually contact the organization to verify that they have posted the most current document. If not explicitly stated in the guidelines, you should ask for information regarding the development methodology.
- ¶ **The Treatment Team.** Ask members of the treatment team or other professional contacts for information regarding the practice guidelines that exist within their specialty area or profession. These individuals will likely save you time in locating the guidelines and may be able to provide a specific citation.
- ¶ **State and National Organizations.** Contact state and national organizations directly and request a copy of their clinical practice guidelines. In speaking with representatives, you will have an opportunity to learn more about the group and about the guideline development methodology.

Databases

Agency for Healthcare Research and Quality

Agency for Healthcare Research and Quality (AHRQ) maintains an extensive website and may be helpful to life care planners seeking clinical practice guidelines. The following information was extracted directly from the Agency's website.

The AHRQ is "The health services research arm of the U.S. Department of Health and Human Services (HHS), complementing the

biomedical research mission of its sister agency, the National Institutes of Health. It is home to research centers that specialize in major areas of health care research:

- Quality improvement and patient safety;
- Outcomes and effectiveness of care;
- Clinical practice and technology assessment;
- Health care organization and delivery systems;
- Primary care (including preventive services);
- Health care costs and sources of payment.

A major source of funding and technical assistance for health services research and research training at leading U.S. universities and other institutions.

A science partner, working with the public and private sectors to build the knowledge base for what works and does not work in health and health care and to translate this knowledge into everyday practice and policymaking.

In examining what works and does not work in health care, AHRQ's mission includes both translating research findings into better patient care and providing policymakers and other health care leaders with information needed to make critical health care decisions.?

The National Guideline Clearinghouse

The National Guideline Clearinghouse (NGC) provides a comprehensive databank of evidence-based clinical practice guidelines and other relevant documents. The following information was extracted directly from the Clearinghouse's website.

The National Guideline Clearinghouse (NGC) is a comprehensive database of evidence-based clinical practice guidelines and related documents produced by the Agency for Healthcare Research and Quality (AHRQ) (formerly the Agency for Health Care Policy and Research [AHCPR]), in partnership with the American Medical Association (AMA) and the American Association of Health Plans (AAHP).

The NGC mission is to provide physicians, nurses, and other health professionals, health care providers, health plans, integrated delivery systems, purchasers and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation and use.

The National Guideline Clearinghouse will promote widespread access to clinical practice guidelines through a comprehensive database of clinical practice guidelines. Data on each guideline will include:

1. A structured abstract containing information about the guideline and its development;
2. A comparison of guidelines covering similar topics, showing areas of similarity and difference; and
3. The full-text of the guidelines (when available) or links to the full-text (when not) and ordering details for the full guideline.

In addition, the National Guideline Clearinghouse will provide an electronic forum for exchanging information on clinical practice guidelines, their development, implementation and use.?

Association and Agency Sites

Even though the AHRQ and NGC attempt to maintain comprehensive databases, not all organizations are currently included in these sources. The following citations are provided so that you may add them to your research databank:

American Academy of Neurology:

<http://www.aan.com/professionals/practice/guidelines.cfm>

American Academy of Pediatrics:

<http://www.aap.org/policy/paramtoc.html>

American College of Cardiology:

<http://www.acc.org/clinical/topic/topic.htm#guidelines>

National Heart, Lung, and Blood Institute:(Hypertension)

<http://www.nhlbi.nih.gov/guidelines/hypertension/index.htm>

Note:

Although the paths may change as webmasters improve these websites, it is likely that the clinical practice guidelines will remain posted. Most all of these guidelines appear as links from the homepages of the associations. Alternately, perform a keyword search on the site for "practice guidelines" or "guidelines," or view the site map for a link to the information.

Searching MedlinePlus®

Locating clinical practice guidelines on MedlinePlus® is simple. From the homepage (<http://medlineplus.gov/>), enter a search for "prac-

tice guidelines.”

You will be linked to a page with all topics and references related to your search. From this page, select areas of interest. The primary limitation with this method of searching is that you may only be directed to pages containing the phrase you typed into the search, rather than to the actual practice guideline for which you are seeking.

Searching Medscape®

Registration for this site is free of charge (<http://www.medscape.com/>) and contains a great deal of information useful to life care planners. By entering a search for “practice guidelines” from the homepage, you will be linked to all topics and references related to your search.

Note that directly underneath the “Search” box, you may link to Medline®. In doing so, you will be led to a screen entitled, “Search Medline.” From here you can tailor your search to your specific needs. For example, when “practice guidelines” is typed into the “Search Query” box (with no other parameters defined), 200 references are returned. The limitation of this site, however, is that not all articles are available for full-text viewing but citations are provided so that you may locate the publication elsewhere.

Searching PubMed®

From the PubMed® homepage (<http://www.ncbi.nlm.nih.gov/PubMed/>) you may search the site for “practice guidelines” to retrieve all of the references related to the topic. For example, when this phrase was entered as a search, 1,075 references were cited. As with Medscape®, not all articles are available for full-text viewing but citations are provided so that you may locate the publication elsewhere.

Searching Online Journals

Another option for locating clinical practice guidelines is to go directly to an online journal and perform an internal search of the publication. In some cases, even journals that do not provide full-text articles online will allow users to search the abstracts.

For example, when the *American Journal of Medicine* (<http://www.medicinedirect.com/journal/journal'sdid=5195>) is searched for the phrase, “practice guidelines” in all fields, 122 results are returned.

Once you have located the clinical practice guidelines of interest, be certain to review the development methodology and find out as much as you can in order to evaluate the validity and relevance of the guidelines to your patient.

It is important to network, continually update your reference and contact files, and establish an efficient databank.

[2] References — Locating Practice Guidelines

Agency for Healthcare Research and Quality: <http://www.ahrpr.gov/>

American Journal of Medicine: <http://www.amjmed.org/>

MedlinePlus: <http://medlineplus.gov/>

Medscape: <http://www.medscape.com/>

National Guideline Clearinghouse: <http://www.guideline.gov/>

PubMed: <http://www.ncbi.nlm.nih.gov/PubMed/>

§ 9B.14 Sources of Research Information

There are numerous resources available to life care planners, but professionals need to know where information exists and how it may be accessed.

[1] Peer Reviewed Journals

Peer-reviewed journals accept submissions based upon a “blind” critique of the contributor’s article. In a sense, the peer review process serves as a quality control measure to minimize the distribution of misinformation based upon poorly designed research or theoretical assertions. Peer reviewers are typically experts in a specified field of practice charged with the responsibility of evaluating the scientific merit of a paper or research report.

For this reason, life care planners should rely primarily upon information appearing in peer-reviewed journals. This is not to say that the findings are “correct,” or that the studies included in these publications are as well-designed as they could be. Simply, in order to have been included in the journal, the article was subjected to a review of peers within the field.

There are many valuable journals and, depending upon a professional’s background and issues specific to individual patients, some publications may be of greater use than others. The following journals

are suggested resources:

[2] Journals of Rehabilitation and Psychology

- ❖ *Rehabilitation Counseling Bulletin*
- ❖ *Journal of Applied Rehabilitation Counseling*
- ❖ *Rehabilitation Psychology*
- ❖ *Journal of Rehabilitation Administration*
- ❖ *Journal of Vocational Rehabilitation*
- ❖ *Vocational Evaluation and Work Adjustment Bulletin*
- ❖ *Journal of Job Placement and Development Work*
- ❖ *Journal of Counseling and Development*
- ❖ *Journal of Counseling Psychology*
- ❖ *Measurement and Education in Counseling and Development*
- ❖ *Journal of Disability Policy and Studies*
- ❖ *Journal of Applied Behavior Analysis*
- ❖ *Psychological Bulletin*
- ❖ *Teaching Exceptional Children*
- ❖ *Journal of Life Care Planning*
- ❖ *RehabManagement*
- ❖ *Journal of Rehabilitation Research and Development*
- ❖ *The Case Manager*
- ❖ *The Rehabilitation Professional*
- ❖ *Psychosomatics*
- ❖ *Psychology, Public Policy, and Law*

[3] Journals of Medicine and Allied Health

- ❖ *Archives of Physical Medicine and Rehabilitation*
- ❖ *Journal of the American Medical Association*
- ❖ *Topics in Spinal Cord Injury Rehabilitation*
- ❖ *British Medical Journal*
- ❖ *Annals of Long-Term Care*
- ❖ *Home Health Care Consultant*
- ❖ *Spine*
- ❖ *Rehabilitation Nursing*
- ❖ *Journal of Head Trauma Rehabilitation*
- ❖ *Brain*

- ❖ *Neurology*
- ❖ *American Journal of Physical Medicine and Rehabilitation*
- ❖ *Pain*
- ❖ *The Clinical Journal of Pain*
- ❖ *Spinal Cord*
- ❖ *American Journal of Occupational Therapy*
- ❖ *SCI Nursing*
- ❖ *Journal of Pediatrics*
- ❖ *Physical Therapy*
- ❖ *Respiratory Research*
- ❖ *Health Psychology*
- ❖ *Journal of Prosthetics and Orthotics*
- ❖ *Journal of Spinal Cord Medicine*
- ❖ *Ear & Hearing*
- ❖ *Journal of Occupational Medicine*
- ❖ *Journal of Physical Therapy Science*
- ❖ *Journal of Neurorehabilitation*

[4] Locating Journals of Interest

In most cases, life care planners will need to access peer-reviewed journals through the nearest university library. Journals are typically located in the reference section of the library and cannot be borrowed for long-term use, so most volumes will be available for review and photocopying. Most library systems allow members of the community to utilize reference sources, though some may require an identification badge or security check.

Many publishers have begun to transmit issues electronically or provide website access for those who subscribe to the journal. Subscriptions vary widely in cost, beginning at approximately \$25 per year and escalating into the hundreds of dollars per year. In some cases, a journal subscription is included as a benefit of association membership. For example, a subscription to the *Journal of Life Care Planning* is included in the annual membership fee of the International Association of Life Care Planners.

Many journals provide the table of contents and/or the abstracts for articles appearing in recent issues. There are also journals providing full text of articles free of charge or at a nominal fee, online. Networking with other planners and practitioners, attending seminars and continuing education workshops, and joining professional listserve

discussion groups may provide additional sources of useful information.

§ 9B.15 References

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