**Evidence-Based Practice Guidelines for the
Management of Communication Disorders in
Neurologically Impaired Individuals:
Project Introduction**

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Preamble

Introduction

As an outgrowth of the 1997 Joint Leadership Conference, co-sponsored by **Division 2** (Neurophysiology and Neurogenic Speech and Language Disorders) of the American Speech-Language-Hearing Association (ASHA) and the **Academy of Neurologic Communication Disorders and Sciences** (ANCDS), the Executive Board of ANCDS agreed to undertake the development and publication of "evidence-based practice guidelines" for the management of communication disorders associated with neurological conditions. The leadership of these organizations recognized the growing trend in contemporary health care toward referencing research evidence to support clinical decision-making for management of medical conditions---a practice now commonly referred to as "evidence-based medicine" (EBM) or "evidence-based practice" (EBP). In response to this trend, the leadership of ANCDS agreed to initiate a project that examines research support for procedures used to treat communication disorders in neurologically impaired individuals. This project supports the purposes of the ANCDS.

Project Goal

The goal of this project is to improve the quality of services to individuals with neurologic communication disorders by assisting clinicians in decision-making about the management of specific populations through "guidelines" based on research evidence. The main activities of the project included conducting literature reviews that were exhaustive, balanced, and inclusive, so as to encompass a broad range of the available research evidence and expert opinion and disseminate that information to clinicians in practice. An equally important purpose of this project was to delineate those areas where additional research is needed, because advancement of any specialty rests upon continuing clinical research (Rosenfeld, 2001).

Co-Sponsorship Acknowledgements

Following the initiation of this project, ANCDS obtained co-sponsorship and funding support from the ASHA and the Steering Committee of Division 2. Additionally, co-sponsorship and funding support were received from the Department of Veterans Affairs (DVA).

ANCDS, ASHA, and the DVA are distinct bodies, with separate incorporations. Collectively, these bodies encompass virtually all of the clinically certified, board-certified, or licensed speech-language pathologists working with neurologic communication disorders in the United States.

Practice Standards, Practice Guidelines, Practice Patterns, Common Sense and Patient Self-Determination

Practice guidelines are recommendations intended to assist in making clinical decisions about the management of specific populations based on the available research evidence and prevailing expert opinion. These recommendations serve to insure equality of service and to decrease variations in practice. They are intended to improve the quality of services, identify the most cost-effective intervention, prevent unfounded practices, and stimulate needed research (Johnston, Maney, & Wilkerson, 1998). Any practice recommendation drawn from literature reviews is subject to the same criticism often made with about a meta-analysis of research: it is influenced by the existing body of literature. For that reason, the present project is intentionally focused on the development of evidence-based practice **guidelines**, as compared to practice **standards**. According to the Quality Standards of the Subcommittee of the American Academy of Neurology (Miller, 1999) practice standards are recommendations for patient management that reflect a high degree of certainty based on Class I or very strong Class II evidence.

> **Practice guidelines are recommendations on procedures for patient management that reflect at least a moderate degree of clinical certainty, usually based on Class II, or a strong consensus from Class III evidence** (Miller, 1999. p. 1313)**.**

Evidence-based practice guidelines are just that: guidelines for decision-making. These guidelines do not define the "best practices"---as the body of research literature may be inadequate to make that determination. Practice guidelines are not intended to encompass or describe the therapeutic relationship in clinical practice. In clinical decision-making, patient self-determination and the clinician's common sense may override any evidence-based guideline or standard.

In their discussion of the development of practice standards for care of the patient with amyotrophic lateral sclerosis, Miller et al. (1999) emphasize, "High priority should be placed on patient self-determination and autonomy as an underlying assumption in the therapeutic relationship" (p. 1311). Rosenfeld (2001) reminds us, "Common sense dictates that when research is lacking the other components of EBM---patient preference and clinical expertise---drive management decisions" (p. 123). Ultimately, evidence-based practice guidelines should result in changes in **clinician behavior** that reflect more tested, proven, and cost-effective procedures and a global improvement in *practice patterns* without sacrificing either common sense or the patient's right to self-determination.

Definitions

This project proceeded within the framework of the following definitions:

Outcome is a natural result; a consequence; or, generally, a comparison of an observation at a later point in time with an observation made earlier (Wertz and Irwin, 2001). Unless specific conditions are met, outcome does not index the efficacy, effectiveness, or efficiency of a treatment administered between pre- and post-treatment observations. Thus, outcome is a broadly defined term that refers to change, or the lack of it, that may occur as a result of time, treatment, or both.

Efficacy is the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under **ideal** conditions of use (Office of Technology Assessment, 1978). The definition implies constraints—inference about a treatment's efficacy is applicable to a population, not an individual; the population and the treatment are clearly specified; and the conditions under which efficacy is determined are optimal (Robey and Schultz, 1998). Thus, efficacy indicates the possible benefits of a treatment and not the actual benefits of a treatment.

Effectiveness is the probability of a benefit to individuals in a defined population from a medical technology applied for a given medical problem under **average** conditions of use (Office of Technology Assessment, 1978). Thus, effectiveness is determined when an efficacious treatment is employed in actual conditions of clinical practice (Chambless and Hollon, 1998). Essentially, efficacy indicates whether a treatment **can** work, and effectiveness demonstrates whether the treatment **does** work. Robey and Schultz (1998) propose tests of a treatment's effectiveness should be conducted only **after** the treatment has been demonstrated to be efficacious.

Efficiency implies acting or producing effectively with a minimum of waste, expense, or unnecessary effort, essentially, exhibiting a high ratio of output to input (Wertz and Irwin, 2001). Thus, the efficiency of a treatment that has been demonstrated to be efficacious and effective might be compared with another treatment to determine which yields a better outcome. Or, the intensity and duration of an efficacious and effective treatment might be examined by determining whether the same outcome could be attained with less intensity or a shorter duration.

Cost-Effectiveness, Cost-Benefit, and Cost-Utility are terms employed to relate the expense of providing a treatment to the outcome attained. Sackett et al. (1997) observe, "Some fear that evidence-based medicine will be highjacked by purchasers and managers to cut the cost of health care. This would not only be a misuse of evidence-based medicine but suggests a fundamental misunderstanding of its financial consequences" (p. 4). Clinicians who practice evidence-based medicine will identify and provide the most efficacious treatments to maximize their patients' quality and quantity of life. This may raise rather than lower the cost of care. Chambless and Hollon (1998) and Frattali (1998) provide the following definitions to illustrate how costs may be examined.

- **Cost-Effectiveness** relates monetary cost to improvement of direct health outcomes such as the cost of providing a treatment related to extending life and decreasing mortality or the cost savings in preventing additional expenses (e.g., readmission to the hospital).

- **Cost-Benefit** compares the monetary cost of the treatment with the monetary benefit of the outcome measured in length of survival, increased income, improved leisure time, etc.

- **Cost-Utility** compares the monetary cost of the treatment with quality of life outcome. Thus, cost-utility considers the treatment's influence on improving the patient's quality of life rather than the length of survival or reduction in mortality.

Outcomes Research

A variety of data is obtained by employing a variety of research designs to collect information about outcome. Operationally, outcome measures provide evidence for answering questions about clinical practice and patient care (Robey, 2001). Robey and Schultz (1998) have described a five-phase outcome research model that is employed by most scientific disciplines. The model represents a systematic method for developing a treatment; testing its efficacy; testing its effectiveness; examining its efficiency; and determining its cost-effectiveness, cost-benefit, and cost-utility. Specific research designs are appropriate for each phase in the model, and the evidence about a treatment's outcome, as tested in each phase, can be rated by a level, or quality, of evidence scale. While all phases in the model provide information about outcome, efficacy, effectiveness, efficiency and cost-analyses are tested in specific phases. A brief summary of each phase, adapted from Robey and Schultz (1998), follows.

Phase I: The objectives are to develop the hypothesis about a treatment that will be tested in later phases; to establish the safety of the treatment; and to demonstrate whether the treatment is active—patients who receive it improve. Phase I studies are brief, employ small sample size, and do not require external controls. Thus, single-subject experiments and small, single group experiments are appropriate. Essentially, Phase I is a time of discovery.

Phase II: If outcomes in Phase I studies are promising, Phase II studies are initiated. The purposes of Phase II studies are to: refine the primary research hypothesis and develop an explanation for why a treatment may be efficacious and effective, specify the target population by establishing study-patient selection criteria, standardize the treatment protocol, demonstrate the validity and reliability of the outcome measures, and optimize the dosage. As in Phase I, studies are brief, employ small sample sizes, and do not require external controls. Thus, single-subject designs and small, single group experiments are appropriate. Phase II is a time for determining what is **ideal**—the treatment, the study patients, the outcome measures, the intensity and duration, clinician training, the environment, etc.

Phase III: In Phase III, the efficacy of the treatment developed in Phases I and II is tested under **<u>ideal</u>** conditions—ideal study patients, ideal clinicians, ideal treatment, ideal intensity and duration, and ideal outcome measures. The typical Phase III experiment is the randomized controlled trial (RCT) in which patients who meet selection criteria are assigned randomly to treatment or no-treatment. Large samples are required to achieve acceptable statistical power. And, to obtain the large samples, especially when rigid study patient selection criteria are employed, efficacy studies are conducted in multiple sites (i.e., a multi-center RCT).

Phase IV: If the efficacy of the treatment is established in Phase III, it is appropriate to proceed to Phase IV studies that test the treatment's effectiveness. The primary purpose of effectiveness research is to test an efficacious treatment's outcome under **<u>average</u>** conditions—typical patients, typical clinicians, typical intensity and duration, etc. Large samples are required; however, external control (e.g., no-treatment) is not. Thus, single-subject experiments with multiple replications and large, single group designs are appropriate. Additional purposes in Phase IV effectiveness research include examining variations in the population definition employed in the Phase III efficacy study, variation in the dosage (intensity and duration), and variation in the level of clinician training.

Phase V: Effectiveness research continues in Phase V, and it may include exploration of efficiency, cost-effectiveness, cost-benefit, and cost-utility. Included in these studies may be examination of patient and family satisfaction with the treatment and influence of the treatment on the patients' quality of life. Large samples are necessary, and these may be acquired by single-subject designs with multiple replications or large, single group designs. Usually, there is no need for an external control.

<u>**Research Evidence**</u>

Controlled Experimentation

Clinicians seek treatments that do more good than harm and that are worth the efforts and costs of using them (Sackett et al., 1997). Typically, a treatment is selected based on the available evidence, ideally coming from controlled experimentation, that supports its use. Evidence is provided by a variety of treatment research designs employed to answer specific questions: is the treatment **active** (Phase I and II research); is the treatment **efficacious** (Phase III research); is the treatment **effective** (Phase IV research); and is the treatment **cost-effective**, or is there a **cost-benefit**, or what is the **cost-utility** (Phase V research). In clinical decision-making, one looks to RCTs, the "gold standard," or highest level of evidence available, and when necessary, one "backs up" to the next level of evidence to support decisions. It is often necessary and preferable to take into consideration the full weight or range of research evidence available and, to the extent that higher levels of evidence are not available, to appreciate that any level of evidence should be viewed as a valid platform upon which to base treatment decisions (Rosenfeld, 2001).

In controlled experimentation, specific treatment research designs are employed to answer specific questions. Some of these designs and the questions they are qualified to answer are described below.

Single-subject designs. A variety of single-subject designs exist. All seek an answer to the question **is a specific treatment active in a single patient** (e.g., does the patient display a positive change in behavior from pre- to post-treatment?) Thus, single-subject designs are appropriate in Phase I and II research to establish the treatment's activity. In addition, if a treatment has been demonstrated to be efficacious in Phase III research, single-subject designs with multiple replications (employed with a variety of patients) are appropriate in Phase IV, effectiveness studies, and Phase V, efficiency and cost-effectiveness studies. Because "efficacy is a property of a treatment delivered to a population and inference to a population requires a group experiment" (Robey and Schultz, 1998, p. 805), single-subject designs do not and cannot index efficacy.

Single treatment group design. This design involves assessing performance of a group of subjects pretreatment, administering the treatment, and reassessing performance post-treatment. Comparison of pre- and post-treatment performance provides inference about outcome; for example, the group improved, remained the same, or became worse. A single treatment group design is appropriate in Phase I and II research to determine whether the treatment is active. It is also appropriate in Phase IV and V effectiveness, efficiency, and cost-effectiveness research if, **and only if**, the treatment being examined has been demonstrated to be efficacious in a Phase III study.

Comparison of treatments design. A comparison of treatments, or parallel-groups, design involves assigning study patients (usually randomly) to two or more treatment groups. Performance of patients in each group is assessed pretreatment, the specified treatment is administered, performance of patients in each group is reassessed post-treatment, and improvement is compared between or among groups. Comparison of treatment designs will provide information about outcome; for example, one group improved more than the other (or others) or there was no difference in improvement between or among groups. Comparison of treatments designs are appropriate in Phase I and II research to determine which of two or more treatments is/are most active. Also, a comparison of treatments design is appropriate for Phase IV and V effectiveness, efficiency, and cost-effectiveness studies if, **and only if**, one or more of the treatments being compared has been demonstrated to be efficacious in Phase III studies. Comparison of one or more treatments of unknown efficacy will only indicate whether the outcome of one is the same as, better than, or worse than the other(s).

Randomized controlled trial (RCT). Randomized controlled trials are epidemiological studies in which a direct comparison is made between two or more treatment groups, one of which serves as a control for the other. Thus, the comparison of treatments design, discussed above, constitutes a RCT if study-patients are assigned randomly to two or more treatments. The virtue of randomization is that it avoids bias by eliminating baseline (pretreatment) differences (known or unknown) between or among groups. The classical RCT is random assignment to one or more treatment groups and a no-treatment

group. The no-treatment, control group, whether simply randomized to no-treatment or randomized to deferred treatment (will be treated later), provides a control for time— improvement from maturation, spontaneous recovery, or unknown influences. That control is not present when comparing only two or more treatments of unknown efficacy. Thus, the RCT that employs random assignment to treatment and no-treatment groups is the "gold standard" for demonstrating efficacy in Phase III outcomes research.

Meeting the "gold standard" comes at a cost. Sufficiently large samples are required to achieve adequate statistical power, conventionally at least .80 (Cohen, 1988). Moreover, the Phase III, efficacy research criterion that dictates the study be conducted under **ideal** conditions places limitations on obtaining the large samples of **ideal** study patients— those who meet rigid selection criteria. As discussed earlier, some authors (Chambless and Hollon, 1998; Rosenfeld, 2001) object to restricting efficacy evidence to RCTs that include a randomly assigned no-treatment control group. They argue that there are ethical issues in withholding treatment and that the controlled conditions in a RCT make it difficult to apply the results to routine clinical practice. Others (Robey and Schultz, 1998; Wertz and Irwin, 2001) suggest ethical issues should include not advocating treatments of unknown efficacy, and the purpose of Phase IV effectiveness research, discussed earlier, is to determine whether the results of an RCT designed to demonstrate efficacy under **ideal** conditions apply in **average** clinical practice.

Certainly, one would not want to restrict outcome research evidence to RCTs that employ a randomly assigned no-treatment control. Other designs provide evidence to support practice guidelines; however, if one seeks evidence about a treatment's **<u>efficacy</u>**, there is no substitute for the RCT treatment versus no-treatment comparison.

Self-selected and other controls. A variety of other designs provide evidence about treatment outcome. A cohort study, for example, might compare a group of patients who receive treatment with a selected cohort of patients who did not receive treatment for a variety of reasons (i.e, subjects elected not to receive treatment because severity was mild, they could not afford the expense of treatment, they resided where treatment was not available, etc.)   These designs provide Phase I and II evidence regarding a treatment's "activity;" however, they do not control for selection bias and differences between treated and untreated groups that may exist at baseline (pretreatment).

Meta-analysis. A meta-analysis is a mathematical means for synthesizing research results that are scattered throughout a body of literature. It provides an average effect size to estimate whether a null hypothesis (e.g., treatment has no influence on outcome for a given disorder) can be rejected (Robey, 1998). The results of a meta-analysis may imply that treatment, in general, results in favorable outcomes. Or, when a sufficient body of data exists, specific statements may be made about specific treatments (such as, patient characteristics, acute versus chronic status, or intensity and duration). A meta-analysis provides excellent evidence, especially if it includes several RCTs; however, it is influenced by the body of evidence existing in the literature.

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<u>Classification of Evidence</u>

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Classification of research evidence is discussed as "levels" or "classes." Typically, a rating system is employed; for example: **Grade A**---supported by one or more randomized controlled trials; **Grade B**---supported by one or more retrospective, prospective, or outcome study(ies) with an internal control or comparison group; **Grade C**--- supported by case series of outcome studies without a control or comparison group; and **Grade D**--- supported by expert opinion without explicit appraisal or by "bench research" (Centre for Evidence-Based Medicine, 1999). For purposes of the present project, where classifications have been referenced, the writing committees have used the following categories, provided by the Quality Standards Subcommittee of the American Academy of Neurology, Miller et al., 1999:

- **Class I.** Evidence provided by one or more well-designed, randomized controlled clinical trials (RCTs).
- **Class II.** Evidence provided by one or more well-designed, observational clinical studies with concurrent controls (such as with single case control or cohort control studies).
- **Class III.** Evidence provided by expert opinion, case series, case reports, and studies with historical controls.

Evaluation of Empirically Supported Therapies

In addition to considering classes, levels or grades of research evidence, Chambless and Hollon (1998) propose a system for evaluating empirically supported treatment research related results. This system includes consideration of the following:
- How well were the subjects described?
- How well was the treatment described?
- What measures of control were imposed in the study?
- Were the consequences of the intervention well described?

Classification of Clinical Management Recommendations

For purposes of classifying management recommendations, the following usage, after that described by Miller et al. (1999), was applied:

- **Standard**. A recommendation for patient management that reflects a high degree of certainty based on Class I or very strong Class II evidence.
- **Guideline**. A recommendation for patient management reflecting moderate clinical certainty, usually based on Class II, or a strong consensus from Class III evidence.
- **Option**. A strategy for patient management for which the evidence is inconclusive or when there is some conflicting evidence or opinion.

Description and Work Plan of the Project

Oversight and Direction

This project is directed by the *ad hoc Practice Guidelines Coordinating Committee* of ANCDS. The *ad hoc* committee is composed of the current President of ANCDS, recent past presidents, and the chairs of each of the writing committees. This committee reports to the Executive Board of ANCDS and prepares periodic progress reports for the co-sponsoring bodies: the ASHA's Executive Board, the Steering Committee of Division 2 of the ASHA, and the DVA's National Speech Pathology Organization.

Scope

The scope of the practice guidelines includes examination of practices related to: dysarthria; aphasia; apraxia of speech; and the cognitive and communication disorders associated with traumatic brain injury (TBI); dementia; and right hemisphere brain damage (RHD). Treatment research reviews and the development of a series of publications in each of these areas have been, or will be, reviewed by "writing committees," consisting of small panels of recognized experts in a specialty area. The reviews and guidelines that are developed may vary in format, focus, or content, depending on the topic areas examined. Some guidelines will deal with specific procedures (e.g., the use of botulinum toxin or surgical interventions with spasmodic dysphonia and related conditions). Others address management of a particular disorder or condition (e.g., velopharyngeal incompetency).

Composition of the Writing Committees

Development of practice guidelines can be viewed as a process of translating evidence from research literature and expert opinion into recommendations for treatment options. The strength of the recommendations from "standard," to "guideline," to "option" rests with the reviewers' abilities to assess the strength of the prevailing evidence. Consequently, it is essential that reviewers have both an excellent familiarity with the body of research specific to a given disorder, procedure, or area of clinical practice and have a good sense of the prevailing consensus, expert opinion, as it applies to a specialty area.

 Translating practice guidelines into improved practice patterns requires linking an application of better practices, as suggested by the research literature and expert opinion, with the clinical "realities" of service delivery to given populations. This linkage necessitates engaging a panel of recognized experts within a specialized area who are willing to conduct a rigorous review and who can place recommendations into the contexts of clinical practice. The chairs of the writing committees were selected based on their expertise and previous scholarly work within a given area and their ability to select writing committees who can undertake comprehensive, balanced reviews of the research literature and use that information to make relevant clinical recommendations.

Procedural Sequence

Each writing committee set its own timeline for completing its writing project. Generally, this was eighteen months from the initial planning meeting through submission of the technical or clinical report document for publication. The writing processes included the following:

- A writing committee, or panel of experts, was convened for designated subspecialty areas of management in neurologic communication disorders;
- Each committee held a face-to-face meeting during which basic assumptions about good clinical practices were clarified and pertinent questions were identified;
- Tasks were listed, and an exhaustive literature search related to a specific population, procedure, or area of management was conducted using electronic data bases and other sources;
- Pertinent articles were retrieved and reviewed;
- A "Table of Evidence" was prepared, based on the reviews, to provide a matrix of information about the studies reviewed and their relevant outcomes;
- A summary of recommendations based on the literature reviews was prepared, and, in some cases, decision algorithms were prepared for illustration;
- The initial draft document was sent for widespread peer reviews and targeted reviews by experts with interests in neurologic communication disorders;
- The comments and recommendations from that review were considered by the writing committee and revisions were incorporated into the manuscript;
- A journal publication version of the guidelines was submitted to the Editor of the *Journal of Medical Speech-Language Pathology,* and any additional editorial peer reviews were incorporated into the document;
- Upon acceptance for publication and notice of a publication date, a summary document was prepared by the *ad hoc Practice Guidelines Coordinating Committee* and submitted to the co-sponsoring organizations for their consideration for endorsement and/or distribution to their memberships via website posting and other mechanisms; and
- After completion of their writing tasks through publication and distribution, each writing committee set a date for the future review and revision of its document.

Searches

Some or all of the following electronic databases was a part of the literature search: CARL, Cochrane, EMBASE, PsycInfo, PubMed, MEDLINE, OVID MEDLINE, OVID Excerpta Medica, OVID BIOETHICSLINE, and CINAHL. In addition to these electronic searches, hand searches of relevant edited books and chapters related to a specific topic and ancestral searches of extant references (e.g., studies cited within an article or chapter) were conducted.

Tables of Evidence

Evidence tables were prepared to provide matrix summaries across articles reviewed and evaluated according to a scheme similar to one developed by the American Psychological Association (Chambless & Hollon, 1998), as described above.

Dissemination of Products

The initial, comprehensive, technical summaries or clinical reports from the writing committees will be published in the *Journal of Medical Speech-Language Pathology.* Additional clinical publications generated by the writing committees for journal format may appear in *JMSLP*, the *American Journal of Speech-Language Pathology (AJSLP), Journal of the International Neuropsychological Society (JINS),* or similar publications. The summary reports appearing on the websites of the ANCDS, the DVA, the ASHA, and Division 2 of ASHA will direct the reader to the refereed publications. In addition, the writing committees will be presenting results and reports of the status of their work at professional meetings, such as: the International Neuropsychological Society meetings; the American Heart Association's Stroke Conferences; the ASHA's Annual Convention; the ANCDS' Annual Scientific and Educational Programs; Clinical Aphasiology Conferences; Motor Speech Disorders Conferences; etc. to ensure ease of access and the widest possible dissemination to clinicians and researchers.

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Web Resources

CARL. http://uncweb.carl.org/
Cochrane. http://www.updateusa.com/clibhome/clib.htm
EMBASE. http://www.healthgate.com/embase/search-embase-pre.shtml
Eric. http://ericir.syr.edu/Eric/
Medline. http://medlineplus.gof/
Psychinfo. http://www.apa.org/psychinfo/
PubMed. http://www.nci.nlm.nih.gov/entrez/query.fcgi

Attachments: Summaries of the Technical Reports in Order of