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Evidence-based systematic review: Oropharyngeal dysphagia behavioral treatments. Part I—Background and methodology

Tobi Frymark, MA;[1*] Tracy Schooling, MA;[1] Robert Mullen, MPH;[1] Karen Wheeler-Hegland, PhD;[2] John Ashford, PhD;[3] Daniel McCabe, DMA;[4] Nan Musson, MA;[2] Carol Smith Hammond, PhD[5–6]
[1]American Speech-Language-Hearing Association, Rockville, MD; [2]Malcom Randall Department of Veterans Affairs Medical Center (VAMC), Gainesville, FL; [3]Tennessee State University/Vanderbilt University, Nashville, TN; [4]Davenport and Taylor Memorial Hospital, Bath, NY; [5]Durham VAMC, Durham, NC; [6]Duke University, Durham, NC

Abstract—Evidence-based systematic reviews (EBSRs), in conjunction with clinical expertise and client values, are invaluable tools for speech-language pathologists and audiologists. This article provides an overview of the levels-of-evidence scheme used by the American Speech-Language-Hearing Association (ASHA) to conduct systematic reviews. The goal of ASHA reviews is to provide a tool to help clinicians determine the best treatment course for their clients. We present a collaborative project between ASHA's National Center for Evidence-based Practice in Communication Disorders and the Department of Veterans Affairs (VA) that examined seven behavioral swallowing treatments for disordered and nondisordered populations. The methodology used in a series of reviews conducted by ASHA and the VA will be discussed, including the development of clinical questions, search parameters, inclusion/exclusion criteria, and literature search results. Findings from the series of reviews as well as the practical applications of EBSRs will be reported in subsequent articles in this series.

Key words: critical appraisal, dysphagia, evidence-based practice, evidence-based systematic reviews, levels of evidence, methods, rehabilitation, speech-language pathology, swallowing maneuvers, swallowing postures, treatment.

INTRODUCTION

The American Speech-Language-Hearing Association's (ASHA's) National Center for Evidence-Based Practice in Communication Disorders (N-CEP) was established in 2005 to coordinate all activities related to evidence-based practice (EBP) for ASHA and its membership. The primary role of N-CEP is to provide ongoing support to ASHA members who engage in evidence-based clinical practice. Results from a Knowledge-Attitudes-Practices Survey reported insufficient time and a lack of evidence as the main barriers clinicians face in providing EBP [1]. Survey respondents remarked that they had little or no time to search and analyze the peer-reviewed literature. Further, the majority of clinicians reported that the evidence for effective clinical practice was nonexistent, conflicting, or irrelevant and ultimately identified a number of clinical areas in need of further examination [1].

ASHA initiated evidence-based systematic reviews (EBSRs) on clinically relevant topics in communication

Abbreviations: ASHA = American Speech-Language-Hearing Association, EBP = evidence-based practice, EBSR = evidence-based systematic review, N-CEP = National Center for Evidence-Based Practice in Communication Disorders, VA = Department of Veterans Affairs.

***Address all correspondence to Tobi Frymark, MA; National Center for Evidence-Based Practice in Communication Disorders, American Speech-Language-Hearing Association, 2200 Research Blvd, 245, Rockville, MD 20850; 301-296-8736; fax: 301-296-8588. Email: tfrymark@asha.org**

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sciences and disorders research to address these barriers and provide clinicians with valuable EBP tools. These reviews employ comprehensive and explicit methods to identify and assess the scientific literature, and the results reflect the current best available evidence on the target intervention or diagnostic procedure under investigation. EBSRs provide clinicians with invaluable and time-saving resources when seeking evidence.

ASHA's first EBSR was completed in 2007 and examined the effects of treatment intensity and constraint-induced language therapy for individuals with stroke-induced aphasia [2]. Since this time, a number of speech-language pathology and audiology systematic reviews have been launched, including a collaborative effort between ASHA and the Department of Veterans Affairs (VA) targeting behavioral swallowing interventions. In the fall of 2007, N-CEP and the VA initiated a series of EBSRs examining the current state of behavioral treatments for oropharyngeal dysphagia. The first review examined the effects of dysphagia behavioral interventions in healthy, nondisordered subjects, while subsequent reviews examined the effects of treatments on disordered populations. This article provides an overview of the procedures used by ASHA to conduct EBSRs and highlights the methodology set forth by N-CEP and the VA to complete their collaborative project. Specific EBSR findings and their practical applications to clinicians and researchers are presented in this *JRRD* issue's single-topic section on dysphagia (p. 175–222).

Systematic Review Process

Figure 1 highlights the steps in the EBSR process. An evidence panel, consisting of five to six experts, participates in two face-to-face meetings. The first meeting focuses on defining the clinical questions for review and establishes the search criteria and parameters for the inclusion/exclusion of the scientific evidence. Additionally, the panel completes a training session on the critical appraisal procedures for evaluating the quality of the scientific evidence. The second face-to-face meeting focuses on the analysis and synthesis of the scientific evidence.

Once the search parameters have been defined, N-CEP staff conduct a systematic search of the literature by using a number of electronic bibliographic databases (e.g., CINAHL, MEDLINE). With approximately one-third of the scientific literature reportedly identified through sources other than electronic databases [3], a hand search of all relevant references and authors is also completed. Two independent reviewers from N-CEP, blinded to each other's results, determine preliminary inclusion based on study abstracts. Full text citations are obtained for those studies meeting preliminary inclusion and are again reviewed independently by two N-CEP reviewers to determine inclusion/exclusion. Upon completion of the literature search, the full list of accepted and rejected studies detailing reason for inclusion/exclusion is reviewed by the evidence panel for final inclusion. Any discrepancies are resolved by panel consensus.

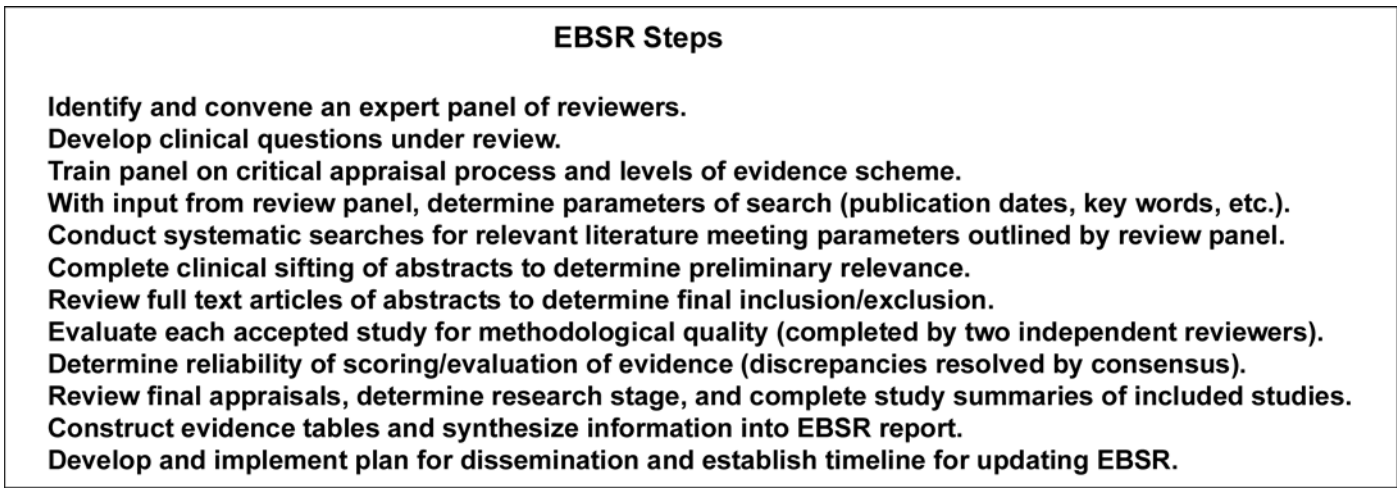

Figure 1.
Evidence-based systematic review (EBSR) steps.

Levels-of-Evidence Scheme

Accepted studies are evaluated with use of ASHA's levels-of-evidence scheme. Developed in 2005 by N-CEP and its Advisory Committee on Evidence-Based Practice, this scheme incorporates a three-pronged approach to evaluating and synthesizing the state of the evidence [4] that includes critical appraisal of study quality (**Table 1**), identification of studies by phase/stage of clinical research (**Figure 2**), and finally, synthesis of the body of evidence by quality and stage of research.

Before the development and adoption of ASHA's levels-of-evidence scheme, N-CEP and its Advisory Committee reviewed a number of existing schemes in use today [5–6]. Results of this investigation indicated that many of the schemes focused primarily on study designs such as randomized controlled trials to categorize study quality and relevance and were not well suited to evaluation of the scientific literature predominately found in the field of communication sciences and disorders. For example, single-subject designs were typically not included in levels-of-evidence schemes. Beeson and Robey [7], among others, have reported that a large body of aphasia research involved single-subject experimental studies. Therefore, criteria relevant to appraising treatment designs other than well-controlled group studies were considered in ASHA's protocol and incorporated into a single level-of-evidence scheme. These criteria included study design, blinding, sampling/allocation, group/participant comparability, outcomes, significance, precision, and intention to treat (when applicable). **Table 1** depicts the quality indicators and corresponding quality markers, ordered from highest to lowest level of quality. The highest possible quality rating is 8, 1 point per indicator when the indicator meets criteria for the highest quality level (indicated in **Table 1**). Only studies incorporating controlled trials can obtain this maximum quality score, while all other study designs in which intention to treat is not applicable can obtain a maximum quality score of 7.

Table 1.
Quality indicators used by panel to evaluate studies.

Indicator	Quality Marker
Study Design	Controlled trial.*
	Retrospective case control or single participant study.
	Case series.
	Case study.
Blinding	Assessors blinded.*
	Assessors not blinded or not stated.
Sampling/Allocation	Random sample adequately described.*
	Random sample inadequately described.
	Convenience sample adequately described.
	Convenience sample inadequately described or hand-picked sample or not stated.
Group/Participant Comparability	Groups/participants comparable at baseline on important factors (between-subject design) or participant(s) adequately described (within-subject design).*
	Groups/participants not comparable at baseline, comparability not reported, or participant(s) not adequately described.
Outcomes	At least one primary outcome measure is valid and reliable.*
	Validity unknown but appears reasonable; measure is reliable.
	Invalid and/or unreliable.
Significance	*p*-Value reported or calculable.*
	p-Value neither reported nor calculable.
Precision	Effect size and confidence interval reported or calculable.*
	Effect size or confidence interval, but not both, reported or calculable.
	Neither effect size nor confidence interval reported or calculable.
Intention to Treat (controlled trials only)	Analyzed by intention to treat.*
	Not analyzed by intention to treat.

*Indicates highest level of quality.

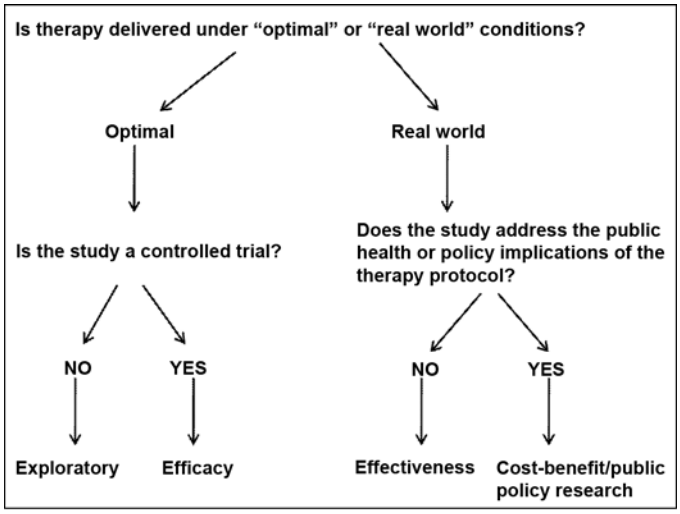

Figure 2.
Decision tree for determining stage of research for each study reviewed.

Two N-CEP reviewers, blinded to one another's results, independently appraise each included study and determine a final quality-marker score. All studies are included in the final analysis regardless of quality-marker score. Final appraisals are reviewed by one member of the evidence panel and any discrepancies in ratings between N-CEP reviewers and the evidence panel are resolved via consensus. A consensus approach is used based on its acceptance by many evidence-based review organizations (e.g., The Cochrane Collaboration). Reliability between reviewers and consensus resolutions are documented.

In addition to assessing methodological quality, a member of the evidence panel completes data extraction for each study. Data extraction points include population, participant characteristics (e.g., number of subjects, age, sex, diagnosis), intervention characteristics (e.g., type, frequency, intensity, duration), outcomes and major findings (e.g., *p*-values, effect sizes, and confidence intervals), and study limitations. Finally, the evidence panel uses the decision tree depicted in **Figure 2** to place each study into one of four stages of research.

The continuum of research stages includes (1) exploratory research, where treatment approaches are developed and assessed in the context of whether they show promise of being efficacious; (2) efficacy research, where interventions are rigorously tested under ideal, highly controlled conditions to assess predetermined outcomes measures; (3) effectiveness research, where interventions are tested in a "real world" clinical setting, typically conducted when the intervention demonstrates positive outcomes in the highly controlled setting of a clinical trial; and (4) cost-benefit/public policy research, where studies are conducted on interventions previously shown to be both efficacious and effective in the political and economic environment in which the intervention is best delivered.

The evidence panel summarizes the included studies and synthesizes the information into a final evidence report. The final synthesis of the literature reflects the extent of the current body of evidence for a given clinical intervention and is reported based on study quality and corresponding stage of research. Effect sizes with use of Cohen's *d* [8] are reported or calculated for outcome measures when possible.

METHODS

A panel of experts in the field of dysphagia was selected by the VA Audiology and Speech Pathology Field Advisory Council Task Force on Dysphagia Treatment to serve as the evidence panel for the review of oropharyngeal dysphagia treatment. The volunteer panel, composed of John Ashford, Daniel McCabe, Nan Musson, Carol Smith Hammond, and Karen Wheeler-Hegland, convened in October 2007 to identify the key issues related to evidence-based clinical decision making for treatment of individuals with swallowing disorders.

Clinical Questions

In constructing clinical questions for review, the panel identified specific interventions, outcomes, and populations of interest to speech-language pathologists involved in the treatment of dysphagia. A number of behavioral interventions (e.g., tactile and electrical stimulation, oral and facial exercises) currently being addressed in other ASHA-initiated systematic reviews were excluded. Therefore, the panel identified compensatory postures and maneuvers as the focus of their review.

Postures were operationally defined as a repositioning of the body, head, and/or neck before the onset of the pharyngeal swallow, with maintenance of that position until the swallow event was completed. Postures included side lying, chin tuck (neck flexion), and head rotation. Maneuvers were defined as movement of the oral, pharyngeal, or laryngeal structures before or during the pharyngeal phase of the swallow that are intended to increase swallow force or alter airway protection mechanisms. Maneuvers studied

included the effortful swallow, the Mendelsohn maneuver, the supraglottic swallow, and the super-supraglottic swallow. The evidence panel sought to identify the impact of these seven postural and maneuver-based interventions on various outcomes, including physiological, functional, and pulmonary health parameters. Physiological outcomes were defined as alterations in the pressures, timings, displacements, or muscle activation achieved during a posture or maneuver, while functional outcomes referred to changes in oral feeding, weight gain, and quality of life. Pulmonary health outcomes focused primarily on aspiration pneumonia. The panel identified three broad groups of research subjects as the populations of interest: nondisordered, healthy adults; subjects with neurological disorders; and subjects with structural disorders. **Table 2** highlights the clinical questions identified for three EBSRs. The first review addressed the impact of behavioral swallowing interventions on nondisordered healthy adults (clinical question 1). The second addressed neurologically disordered populations (clinical questions 2–4), and the third addressed structurally disordered populations (clinical questions 5–7).

Literature Search

A systematic search of the dysphagia literature was conducted from March 2007 to April 2008 to identify studies that examined postural- and maneuver-based behavioral swallow interventions. The search was initially completed from March 2007 to December 2008; however, as the panel's work progressed, the search was updated to include studies published through April 2008. Studies were initially considered for review if they were published in a peer-reviewed journal from 1985 to 2008, were written in English, and contained original data pertaining to one of the seven interventions within the two behavioral categories included. The search date was determined based on the emergence of dysphagia literature on behavioral interventions in the mid-1980s. Additionally, limiting study inclusion to peer-reviewed journals, albeit imperfect, ensured some vetting of the literature through a peer-review process. Study inclusion criteria consisted of adults

Table 2.
Clinical questions identified for evidence-based systematic review.

Population	Question
Nondisordered Healthy	1. What is effectiveness of dysphagia behavioral interventions (i.e., side-lying, chin-tuck, or head-rotation postures; effortful swallow, Mendelsohn, supraglottic swallow, or super-supraglottic swallow maneuvers) on swallowing physiology for nondisordered healthy adults?
Neurologically Disordered	2. What is effectiveness of dysphagia behavioral interventions (i.e., side-lying, chin-tuck, or head-rotation postures; effortful swallow, Mendelsohn, supraglottic swallow, or super-supraglottic swallow maneuvers) on swallowing physiology for neurologically disordered populations (i.e., head injury, stroke)?
	3. What is effectiveness of dysphagia behavioral interventions (i.e., side-lying, chin-tuck, or head-rotation postures; effortful swallow, Mendelsohn, supraglottic swallow, or super-supraglottic swallow maneuvers) on functional swallowing outcomes for neurologically disordered populations (i.e., head injury, stroke)?
	4. What is effectiveness of dysphagia behavioral interventions (i.e., side-lying, chin-tuck, or head-rotation postures; effortful swallow, Mendelsohn, supraglottic swallow, or super-supraglottic swallow maneuvers) on pulmonary health outcomes for neurologically disordered populations (i.e., head injury, stroke)?
Structurally Disordered	5. What is effectiveness of dysphagia behavioral interventions (i.e., side-lying, chin-tuck, or head-rotation postures; effortful swallow, Mendelsohn, supraglottic swallow, or super-supraglottic swallow maneuvers) on swallowing physiology for structurally disordered populations (i.e., head and neck cancer)?
	6. What is effectiveness of dysphagia behavioral interventions (i.e., side-lying, chin-tuck, or head-rotation postures; effortful swallow, Mendelsohn, supraglottic swallow, or super-supraglottic swallow maneuvers) on functional swallowing outcomes for structurally disordered populations (i.e., head and neck cancer)?
	7. What is effectiveness of dysphagia behavioral interventions (i.e., side-lying, chin-tuck, or head-rotation postures; effortful swallow, Mendelsohn, supraglottic swallow, or super-supraglottic swallow maneuvers) on pulmonary health outcomes for structurally disordered populations (i.e., head and neck cancer)?

18 years or older with or without the diagnosis of dysphagia. Studies using mixed swallowing treatment regimens or medical or pharmacological interventions in conjunction with swallowing treatment were excluded. Fourteen databases were searched with use of key words related to dysphagia or swallowing intervention. Databases searched included PubMed; CINAHL; PsycINFO; PsycArticles; Combined Health Information Database; Health Source: Nursing, Science Citation Index; ScienceDirect; NeLH; REHABDATA; Social Science Citation Index; SUMSearch; TRIP Database; and Cochrane Database of Systematic Reviews. Additional searches in all ASHA journals, National Institutes of Health Abstracts, and Google Scholar were conducted along with manual searches of all article references.

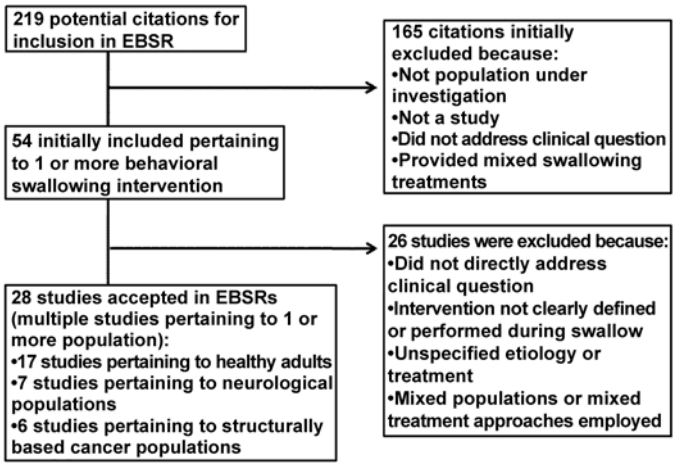

Figure 3.
Process for identification of included studies. EBSR = evidence-based systematic review.

RESULTS

The initial results, which included disordered and nondisordered populations, yielded a total of 219 citations. Each citation was reviewed independently by two of the coauthors (TF and TS) for preliminary inclusion. The full text of citations was then obtained for 54 studies and further reviewed to determine final inclusion. Half the studies that met the preliminary inclusion criteria were further rejected upon review of the full text. Reliability between reviewers for study inclusion was 90 percent. Before final inclusion/exclusion, the full set of rejected and accepted bibliographies (n = 219) was reviewed by the evidence panel. **Figure 3** schematizes the literature search results with a total of 28 studies included in the final analysis across three reviews.

Table 3 details the studies included in three separate EBSR reports. Seventeen studies were identified for nondisordered healthy adults; seven studies pertained to neurologically disordered populations and six to structurally disordered populations. Two studies provided data across multiple populations [9–10].

All the included studies were independently appraised by coauthors TF and TS using the criteria outlined in **Table 1**. The kappa statistic was used to determine interrater reliability between reviewers for methodological quality of accepted studies [11]. Interrater reliability was good for the majority of indicators (study design, blinding, allocation, subjects, significance, and precision), with κ = 0.650–1.000 [12]. Interrater reliability between coders for outcome measures was fair, with κ = 0.364. One member of the evidence panel reviewed each study's final appraisal ratings, completed the data extraction, and determined stage of research. To minimize errors and potential biases, an additional evidence panel member reviewed all final appraisal ratings, stage of research assignment, and data extraction summaries a final time. Reliability between N-CEP reviewers and the evidence panel was 92 percent.

The final synthesis of the evidence was summarized into three separate EBSRs based on population. Each population is presented in its own systematic review and their results are provided in subsequent articles in this *JRRD* issue. Part II (Wheeler-Hegland et al., this issue, p. 185) focuses on the effect of behavioral swallowing treatments with nondisordered healthy adults, Part III (Ashford et al., this issue, p. 195) examines these same interventions in neurologically disordered populations, and Part IV (McCabe et al., this issue, p. 205) addresses structurally disordered populations.

DISCUSSION AND CONCLUSIONS

ASHA has created a levels-of-evidence scheme designed to appraise the current and future evidence that supports the treatments used by its members. This scheme assesses evidence through the appraisal of study quality and stage of research. It uses comprehensive literature searches, well-designed inclusion and exclusion criteria, and the critical appraisal of study quality with eight quality indicators. Well-designed clinical questions are created

Table 3.
Studies included in evidence-based systematic review.

Study	Nondisordered Healthy	Neurologically Disordered	Structurally Disordered
Bodén et al., 2006 [1]	X	—	—
Bülow et al., 1999 [2]	X	—	—
Castell et al., 1993 [3]	X	—	—
Crary et al., 2004 [4]	—	X	X
Ding et al., 2002 [5]	X	—	—
Drake et al., 1997 [6]	—	X	—
Hind et al., 2001 [7]	X	—	—
Hiss & Huckabee, 2005 [8]	X	—	—
Huckabee et al., 2005 [9]	X	—	—
Huckabee & Steele, 2006 [10]	X	—	—
Kahrilis et al., 1991 [11]	X	—	—
Lazarus et al., 1993 [12]	—	—	X
Lazarus et al., 2002 [13]	—	—	X
Lazarus et al., 2002 [14]	—	—	X
Lever et al., 2007 [15]	X	—	—
Lewin et al., 2001 [16]	—	—	X
Logemann et al., 1989 [17]	X	X	—
Logemann et al., 1997 [18]	—	—	X
Logemann et al., 2008 [19]	—	X	—
Nagaya et al., 2004 [20]	—	X	—
Ohmae et al., 1996 [21]	X	—	—
Ohmae et al., 1998 [22]	X	—	—
Pouderoux & Kahrilis, 1995 [23]	X	—	—
Robbins et al., 2008 [24]	—	X	—
Shanahan et al., 1993 [25]	—	X	—
Steele & Huckabee, 2007 [26]	X	—	—
Van Daele et al., 2005 [27]	X	—	—
Welch et al., 1993 [28]	X	—	—

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Table 3. (Continued)
Studies included in evidence-based systematic review.

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and applied to specific populations to increase the validity and predictive ability of the systematic reviews.

ASHA's levels-of-evidence scheme was applied to behavioral treatments for dysphagia in 2007–2008 in collaboration with the VA. Clinical questions included physiological, functional, and pulmonary health outcomes as they were applied to nondisordered healthy subjects, individuals with neurologically based dysphagia, or individuals with structurally based dysphagia. Twenty-eight studies were selected as meeting the inclusion and exclusion criteria, and these studies were judged as meeting or lacking in seven to eight quality indicators. The panel of reviewers worked through consensus to arrive at their systematic reviews of the three target populations, with their findings presented in the subsequent articles in this series.

Because the principles of EBP incorporate current best evidence in conjunction with the knowledge base of the clinician and the patient's preferences, Part V (Wheeler-Hegland et al., this issue, p. 215), the final article in the series, will address the application of the findings of these reviews for clinical decision-making. Future research needs and directions will also be suggested to address the applications of EBSRs for researchers.

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Author Contributions:

Study concept and design: T. Frymark, T. Schooling, R. Mullen, K. Wheeler-Hegland, J. Ashford, D. McCabe, N. Musson, C. Smith Hammond.

Analysis and interpretation of data: T. Frymark, T. Schooling, R. Mullen, K. Wheeler-Hegland, J. Ashford, D. McCabe, N. Musson, C. Smith Hammond.
Drafting of manuscript: T. Frymark, T. Schooling.
Critical revision of manuscript for important intellectual content: T. Frymark, T. Schooling, R. Mullen, K. Wheeler-Hegland.
Statistical analysis: R. Mullen.

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