Patient Responses To Swallowing Safety Cues:

A Comparison Of Traditional Face-To-Face And Tele-Dysphagia Instructional Methods

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ABSTRACT

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An estimated 15 million individuals in the United States have been formally diagnosed with dysphagia, defined as swallowing dysfunction — the fifth leading cause of death in Americans over the age of 65. Statistical findings indicate that at least 50% of these individuals have limited access to treatment. However, despite the rapid expansion of telepractice (defined as the use of telecommunications technology to provide services at a distance) as a statistically valid online method for the provision of medical and clinical intervention to those without access, telepractice has yet to consistently incorporate online dysphagia service delivery (referred to as tele-dysphagia) into its clinical scope. This investigation compared the outcomes of traditional face-to-face intervention to online tele-dysphagia intervention by measuring the correct and incorrect responses to visual and auditory cues presented by a clinician during dysphagia intervention sessions. Data analysis conducted via t-test indicated that there was no significant difference in the mean scores from tele-dysphagia method (M = 9.67, SD = 3.74) as compared to face-to-face method (M = 9.00, SD = 2.70), t (28) = - 0.56, p = 0.580. Additionally, inter-rater reliability scores were obtained by determining a Cohen's kappa coefficient in order to measure the degree of agreement between the two raters.

Findings indicated a kappa statistic of k=1 for all items, given a 100% agreement for all trials.

Additionally, results of a mixed-design analysis of variance suggested a significant within-subject effect with the use of cues, but there were no significant main effects of between-subject factors (gender, delivery type, etiology, or age) on the patients' responses. Given that there was no significant statistical difference between the two delivery methods and inter-rater reliability scores demonstrated perfect agreement, we can suggest that the online tele-dysphagia method can potentially yield clinical outcomes similar to a traditional face-to-face method. Results from a mixed-design analysis of variance additionally suggested that there is a significant within-subject effect given the use of cues ($F(1, 29)=14.99$, $p = .001$) on patients' responses. However, there were no significant main effects of between-subject factors (gender, delivery type, etiology, or age) on the patients' responses. It is hoped that the results of this study will lend validity and direction to future attempts to provide much-needed dysphagia intervention via online service methods. Such attempts, in turn, would have the potential to promote increased longevity and quality of life in those populations currently unable to access such services.

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It is to my children, my Emerson Rose and my William Lawrence — that I dedicate the past ten years of my doctoral journey. You are the two halves of my heart, giving purpose and meaning to absolutely. EVERYTHING.

CHAPTER I

INTRODUCTION

The act of swallowing (also known as deglutition), "is the continuous process of deglutition by placement of the food in the mouth, its manipulation in the oral cavity, and its passage through the oral cavity, pharynx, and esophagus until it enters the stomach" (Mankekar & Chavan, 2015). When defined anatomically, the act of swallowing involves both cortical and brain stem control and involves the following three phase model (Logemann, 1998; Mankekar & Chavan, 2015):

ORAL – involves the sequential action of using dentition to incise food, masticate (chew) the food into smaller pieces, form a a single cohesive *bolus* (a small, rounded mass of a substance; www.merriam-webster.com), and direct this bolus via a rolling, anterior-posterior tongue movement posteriorly toward the pharynx. There are two sub-phases in the oral phase:

> Oral Preparatory — involves the anticipation of food or liquid as demonstrated by the activation of the salivary glands; the bolus is placed into the oral cavity and prevented from leaking out by closure of the mandible (jaw) and labia (lips). With lateral movement of the tongue and rotary movements of the mandible, the bolus is repetitively moved throughout the oral cavity, where liquids are formed into a cohesive bolus by a cupping of the tongue and more solid consistencies of food are masticated (chewed) in preparation for propulsion into the pharynx.

Oral Propulsive — The resultant bolus is moved posteriorly out of the oral cavity to the larynx by an anterior-posterior rolling tongue motion that compresses the tongue superiorly to the palate, as the bolus is pushed toward the soft palate (which raises to seal off the nasal cavity). The tongue base retracts toward the posterior pharyngeal wall while the bolus is propelled out of the oral cavity into the pharynx.

PHARYNGEAL – begins with the initiation of the swallow reflex (as triggered by the glossopharyngeal nerve) as the bolus enters and travels inferiorly through the pharynx via a wave-like muscular contraction, which is triggered by the presence of the bolus. The subsequent pharyngeal sequence of events involves: 1) the anterior structures of the larynx simultaneously moving superiorly and anteriorly; 2) subsequent inversion of the epiglottis[1], which seals off the trachea (airway) to prevent the bolus from entering the respiratory system; 3) adduction (coming together) of the vocal folds to additionally protect the airway. This results in the cessation of breathing for approximately 1-1.5 seconds as the bolus is propelled out the pharynx and enters the esophagus.

ESOPHAGEAL – involves the movement of the bolus (distally) into the esophagus as the upper esophageal sphincter (UES)[2] relaxes and opens responsively; this results in the initiation of involuntary wavelike constriction of the esophageal walls, which distally push the bolus toward the lower esophageal sphincter (LES). The LES

[1] EPIGLOTTIS — flap of cartilage at the root of the tongue, which is depressed during swallowing to cover the opening of the windpipe. (www.medical-dictionary.thefreedictionary.com, 2013).

[2] UPPER/LOWER ESOPHAGEAL SPHINCTER — The upper and lower esophageal sphincters (UES/ LES) are the areas of the upper digestive tract that form a barrier between the proximal esophagus and the pharynx (UES) and the distal esophagus and stomach (LES); they intermittently open and close to allow passage of contents through the digestive tract. (www.medical-dictionary.thefreedictionary.com, 2013).

(like the UES), which is closed at rest, similarly relaxes and opens due to the sensory input of the bolus, allowing for its entry into the stomach. The approximate time of this stage is 7-8 seconds per bolus.

Dysfunction or difficulty that occurs at any of these stages of the act of swallowing is defined as dysphagia. Dysphagia is estimated to affect 1 in 25 adults in the United States (Bhattacharyya, 2014). Studies suggest that oropharyngeal dysphagia is a "highly prevalent condition, occurring in up to 50% of elderly people and 50% of patients with neurological conditions" (Clave' and Shaker, 2015). From 2010 to 2030, the elderly population is expected to increase from 39 million to 69 million Americans (Kahn, Carmona, & Traube, 2014), thus likely increasing the need for dysphagia services.

In geriatric populations, dysphagia is more than an inconvenience; it can result in malnutrition and death (Limper, 2007). Dysphagia is the primary cause of aspiration pneumonia, defined as " an inflammation of the lungs and bronchial tubes — the result when food, saliva, liquids, or vomit is breathed into the lungs or airways leading to the lungs, instead of being swallowed into the esophagus and stomach." (Dock and Boskey, 2012). Aspiration pneumonia is the fifth leading cause of death in Americans over the age of 65, and the third leading cause of death in those over 85 (http://www.ncbi.nlm.nih.gov, 2012).

Therapeutic intervention for dysphagia, primarily provided by speech-language pathologists, is an essential part of maintaining both nutrition and respiratory safety (via the prevention of aspiration pneumonia) while allowing for the quality of life and socialization associated with oral intake. In order to investigate the relative efficacy of

dysphagia intervention, a meta-analysis of both direct and indirect dysphagia therapy[3] was conducted (Drulia & Ludlow, 2013). The meta-analysis examined 27 studies conducted between 2012 - 2013. Although findings suggested small to moderate effect sizes (0.3 - 0.7) initially, moderate to high effect sizes (0.7 - 1.2) were noted in one and three-month follow-up studies. The authors concluded that this upward shift in effect may be secondary to an additional consideration — namely, the spontaneous recovery of the patient over time. It should be noted that since there are no studies directly examining the relationship between dysphagia therapy and spontaneous recovery (it was merely hypothesized by the authors), one cannot rule out that the combination of the two resulted in a high effect size, thereby validating the use of dysphagia intervention. Additionally, many of the 27 studies provide data suggesting the validity, reliability, and effectiveness of dysphagia intervention (PLEASE REFER — Chapter II, Section C — Historical Perspectives and Relevant Research — Face-to-Face Dysphagia Intervention).

Nonetheless, speech-language pathologists specializing in dysphagia anticipate an ever-increasing role in diagnosis and intervention (Coyle, 2012) given the growing geriatric population, the subsequent increase in the incidence of dysphagia, and an increasing demand for qualified dysphagia therapists.

In rural and socioeconomically challenged areas, however, access to such intervention remains even more limited due to distance, mobility challenges, and by the unavailability of speech-language pathologists to provide dysphagia services (Coyle, 2012). Data from a more recent National Health Survey revealed that an estimated 80%

[3] DIRECT dysphagia therapy refers to techniques targeting the structure and function of the swallowing mechanism exclusively, unlike INDIRECT dysphagia therapy, which targets areas influencing swallowing function — e.g., cognitive or respiratory therapy).

of the geriatric population have no access to coordination of healthcare services, possibly secondary to distance, staffing, and mobility constraints (American Geriatrics Society, 2015). As noted by James Coyle, Ph.D, in the *International Journal of Telerehabilitation* (2012), the number of individuals with dysphagia is quickly exceeding the number of qualified dysphagia therapists.

Given this need, telepractice may present a solution. The American Speech-Language-Hearing Association (ASHA) asserts that by allowing clinicians to deliver professional services from a distance through the use of telecommunications technology, telepractice has "the potential to extend clinical services to remote, rural, and underserved populations, and to culturally and linguistically diverse populations" (ASHA, 2015). There is considerable research demonstrating the validity, reliability, and effectiveness of telepractice (Baharav & Reiser, 2010; Burns et al, 2012; Brennan, Georgeadis, Baron & Barker, 2004; Grogan-Johnson et al, 2013; Hill & Theodoros, 2006; Mashima & Holtel, 2005; Hall, Boisvert & Steele, 2013; Parmanto, et al 2013; Ward & Burns, 2014) and term "tele-dysphagia" has emerged as a result of recent efforts to employ and research the merging of telepractice and dysphagia (Coyle, 2012). To date, however, *minimal* research exists to validate the use of tele-dysphagia for intervention (Ward & Burns, 2014). Therefore, given the potential benefit of tele-dysphagia to those in need of services, as well as ASHA's ongoing commitment to evidence-based practice and formal quantitative research (ASHA, 2004), the purpose of this investigation was to determine the validity, reliability, effectiveness, and feasibility of tele-dysphagia as a delivery mode for intervention. To accomplish this, participants were provided with visual and auditory cues during a task-oriented mealtime activity which targeted the independent use of a

"swallowing safety strategy". Swallowing safety strategies are defined as, "modifications in food/liquid bolus size, bolus texture, patient positioning, compensatory maneuvers, and sensory enhancement techniques" with the goal of promoting optimal safety and efficiency during oral intake (ASHA, 2002). Thirty participants were randomly assigned into two groups — – those receiving face-to-face intervention versus those receiving intervention via tele-dysphagia. The positive and negative responses of participants were compared (**positive** meaning the participant was able to successfully employ the strategy and **negative** meaning the participant was NOT able to employ the strategy), in order to determine if there was a significant difference between service delivery modes. Additionally, this study examined whether the presence or absence of cues influenced participant responses (REFER – Chapter III – METHODS).

If quantifiable research outcomes indicate no significant difference between delivery modes, numerous far-reaching consequences are anticipated, such as:

- Successful provision of dysphagia services to geriatric individuals otherwise unable to receive services secondary to distance or mobility constraints;
- The potential for increased longevity (via the prevention of aspiration pneumonia) and quality of life in such geriatric individuals; and,
- Expansion of an underestablished research base, which can ultimately contribute to increased use of evidence-based practice, thus improving the quality of patient care.

Objectives And Research Questions

The objectives of this investigation are as follows:

- Comparing the correct and incorrect responses of cognitively-compromised participants to visual and auditory cues provided during motor learning tasks via face-to-face and tele-dysphagia delivery modes;
- To determine if the use of visual and auditory cues during intervention sessions produces statistical differences in participant outcomes;
- To determine if the additional factors of age, gender, etiology and delivery type have a main effect on participant responses and/or interaction effect(s) among them;
- To determine (by the achievement of therapeutic goals) whether tele-dysphagia is a valid, reliable, effective, and reproducible method for delivery of dysphagia intervention.

The research questions addressed by this investigation are as follows:

- Can the traditional face-to-face methods of service delivery be conducted via tele-dysphagia and not demonstrate a significant difference in outcomes?
- Do participants respond to cues conveyed via a tele-dysphagia method of service delivery without a significant difference when compared to traditional face-to-face intervention?
- Do the factors of age, gender, and etiology affect outcome measures?
- Is tele-dysphagia valid, reliable, effective and reproducible? Can clinical goals be achieved via tele-dysphagia?

CHAPTER II

REVIEW OF THE LITERATURE

In order to provide clarification of and rationale for this investigation, the literature review will address the following areas:

A. Relevant Definitions and Terms

B. Historical Perspectives and Relevant Research — Telepractice in Speech-Language Pathology

C. Historical Perspectives and Relevant Research — Tele-Dysphagia

- Videofluoroscopic Swallowing Assessment
- Clinical Tele-Dysphagia Assessment
- Tele-Dysphagia Intervention

D. Historical Perspectives and Relevant Research — Face-to-Face Dysphagia Intervention

A. Relevant Definitions and Terms

1) **Aspiration Pneumonia** – Lung inflammation or infection caused by breathing foreign materials (usually food, liquids, vomit, or fluids from the mouth) into the lungs (https://www.nlm.nih.gov/medlineplus/ency/article/000121.htm).

2) **Bolus Size Regulation / Alteration** – Decreasing or limiting the bolus (a small rounded mass of a substance, especially of chewed food or liquid at the moment of swallowing) size while eating; controlling the size of the bolus

(solid or liquid) before swallowing; slowing the feeding rate and amount during a meal (Logemann, 1998).

3) **Cerebrovascular Accident (CVA)** – An abnormal condition of the brain characterized by occlusion by an embolus, thrombus, or cerebrovascular hemorrhage or vasospasm, resulting in ischemia of the brain tissues normally perfused by the damaged vessels. Paralysis, weakness, sensory change, speech defect, aphasia, or death may occur (www.medical-dictionary.thefreedictionary.com, 2013).

4) **Chin Down / Tuck Posture** – Involves touching the chin to the neck during the swallow. This pushes the anterior pharyngeal wall posteriorly. The tongue base and epiglottis are pushed closer to the posterior pharyngeal wall. The airway entrance is narrowed. The chin down / tuck posture potentially reduces the likelihood of premature spillage and widens the valleculae, reducing the speed of the bolus transfer; this subsequently gives more time for the vocal folds to close and reduces the risk of aspiration (Logemann, 1998).

5) **Cueing System** – A form of associative learning in human perception. A cue in perception is a signal (e.g., auditory, visual, gustatory, tactile) that can be measured by an observer's perceptual system and is informative about the state of some property of existence. Examples of the two types of cues utilized for this study are as follows (Haijaing et al, 2006):

   a. Auditory cue – Involves the use of sound, as in a spoken word or phrase, received by the auditory system (e.g., the listener is

verbally instructed to "slow down" and subsequently demonstrates this motor action in response to the cue).

b. Visual cue – Involves the eye receiving information in the form of light, with subsequent visual perception and interpretation of the environment.

6) **Cyclic Ingestion Compensation –** Alternating solids and liquids during ingestion to clear oral cavity of residue unable to be managed with lingual sweeping (using the tongue to move the bolus out of the oral cavity) (Logemann, 1998).

7) **Dysphagia** – A difficulty or discomfort in swallowing, as a symptom of disease (Bhattacharyya, 2014).

8) **Fiberoptic Endoscopic Evaluation of Swallowing (FEES)** – A swallowing instrumental assessment performed with a fiberoptic rhinopharyngoscope for studying the physiology and physiopathology the swallowing mechanism, particularly the pharyngeal stage. The FEES assessment examination offers detailed information of swallowing and of the relative functions of the upper airways and upper digestive tract (Nacci, et al, 2008).

9) **Head Turn Compensation** – In the case of pharyngeal hemiparesis (weakness of one side of the pharynx), head rotation (laterally to the left or right) rotates the pharynx so that the bolus flows to the stronger side of the pharynx for safer transfer. It additionally pushes the opposing side toward the midline, therefore improving adduction of the vocal folds. Lastly, The head

turn compensation opens the cricopharyngeal muscle to reduce pharyngeal residuals in the pharynx (Logemann, 1998).

10) **Tele-dysphagia** – The delivery of dysphagia assessment and intervention services via telecommunications technology (Coyle, 2012).

11) **Telemedicine –** The sharing of medical knowledge over a distance using telecommunication systems. Also referred to as "telehealth" or "e-health" (ASHA, 2015).

12) **Telepractice** – The application of telecommunications technology to deliver professional services at a distance (ASHA, 2015).

13) **Traumatic Brain Injury (TBI)** – An alteration in brain function, or other evidence of brain pathology, caused by an external force (Menon, et al, 2010).

14) **Videofluoroscopic Swallowing Study (VFSS) / Modified Barium Swallow (MBS)** – A radiologic examination performed while the person swallows barium-coated substances in order to assess quality of the swallowing mechanisms of the mouth, pharynx, and esophagus (www.medical-dictionary.thefreedictionary.com, 2013).

B. Historical Perspectives and Relevant Research – Telepractice in Speech-Language Pathology

Telepractice, defined by the American Speech, Language, and Hearing Association (ASHA) as "the application of telecommunications technology to deliver professional services at a distance" (ASHA, 2005), evolved from the earlier mode of service delivery known as telemedicine. As early as 1910, when telemedicine efforts transmitted the sound of a patient's heartbeat via radio frequency, there were intermittent

attempts to deliver "health care and [the] sharing of medical knowledge over a distance using telecommunication systems." (Boland, 2008). Initial telemedicine efforts from 1910 to 1960, exclusively limited to physicians with a medical degree, involved trials such as telephone-mediated telestethoscopy (listening to an amplified heartbeat over the telephone), radiology image transfer via video (currently referred to as teleradiology), and team videoconferencing based on interactive television (Thrall, 2007). Progress was limited until the 1990's, when low cost, high performance computers enabled communication and information transfer on a global scale (Boland, 2008), resulting in greater acceptance of technology by medical professionals and subsequent applications in virtually every medical specialty, such as teleradiology, cardiology, psychiatry, and emergency medicine. As for allied health professionals, the Comprehensive Telehealth Act of 1997 advocated the expansion of telemedicine to ancillary healthcare services such as speech-language pathology, audiology, social work and nursing, referring to the online provision of services as "telehealth". (Thrall, 2007).

Prior to 2001, however, the role of the speech-language pathologist in the field of telehealth was notable. A brief article published by ASHA in 1976 entitled "Telecommunicology" discussed the potential of the profession to provide online services – however, it was not until 1999 that a trial speech teletherapy program was initiated in the rural Oklahoma schools (ASHA, 2002). ASHA's formal involvement in telehealth, formally renamed within the profession as telepractice, began in 2001 with a published initiative and the organization of a telepractice team committed to determining the current and potential role of clinicians in the provision of telepractice services (ASHA, 2002).

To date, the speech-language pathologist has utilized online telepractice for provision of services in schools, child care centers, rehabilitation and acute care hospitals, outpatient clinics, universities, corporate settings, and in the home care environment (ASHA, 2015), both nationally and internationally. According to the Department of Health and Human Services (Edwards & Stredler-Brown, 2012), the two modes of telepractice primarily employed by health care providers include *synchronous* (real-time interaction between clinician and client/patient that simulate a face-to-face encounter) and *asynchronous* (the capturing, storing and forwarding of information for professional assessment) methods. A 2014 survey conducted by the ASHA Special Interest Group in Telepractice, 483 speech-language pathologists reported using the above telepractice methods for the following types of intervention (ASHA, 2014):

- **Articulation disorders**
- **Autism**
- **Dysarthria**
- **Fluency disorders**
- **Language and cognitive disorders**
- **Voice disorders**
- **Dysphagia**

According to ASHA (2015), "Telepractice is an appropriate model of service delivery for audiologists and speech-language pathologists", demonstrating similar outcomes to face-to-face intervention. Upon examination of the existing research to determine validity, reliability, and effectiveness, it would seem that telepractice as a service delivery model for **speech and language disorders** has been well-established in both educational and healthcare settings, both qualitatively and quantitatively (Baharav & Reiser, 2010; Brennan, Georgeadis, Baron, & Barker, 2004; Carey et al., 2012; Grogan-Johnson, Schmidt, Schenker, Alvares, Rowan & Taylor, 2013; Hall, Boisvert, & Steele,

2013; Gabel, Grogan-Johnson, Alvares, Bechstein, & Taylor, 2013; Grogan-Johnson, Alvares, Rowan, & Creaghead, 2010; Scheideman-Miller et al., 2002; Lewis et al., 2008; Waite et al., 2006). In addition, parents, clients, and clinicians involved in these settings report satisfaction with telepractice as a mode of service delivery (McCullough, 2001; Scheideman-Miller et al., 2002; Crutchley and Campbell, 2010).

C. Historical Perspectives and Relevant Research — Tele-Dysphagia

In case of tele-dysphagia, also addressed by speech-language pathologists, formal research is in its preliminary stages, although the focus has been on assessment rather than intervention (Malandraki, et al., 2011, 2013; Ward, Burns, Theodoros, & Russell, 2014) and adults rather than pediatrics (Malandraki, Roth, & Sheppard, 2014). Research in tele-dysphagia can ideally be categorized according to the areas that are predominately seen in tele-dysphagia research to date: 1) clinical tele-dysphagia assessment; 2) videofluoroscopic swallowing study and, 3) tele-dysphagia intervention.

Clinical Tele-Dysphagia Assessment

The Bedside Dysphagia Evaluation (BDE), also referred to as Clinical Swallow Examination (CSE), is historically the first step in the dysphagia evaluation process (Ward & Burns, 2014), and involves the assessment of the four stages of swallowing without instrumental interpretation. The fundamental limitation of the BDE is its inability to directly view numerous structures and functions related to the act of swallowing, as these structures are located internally and can only be visualized by either x-ray (as in the videofluoroscopic swallowing study) or endoscopy (as in the fiberoptic endoscopic evaluation of swallowing – REFER to section A — Relevant Definitions and

Terms). Therefore, assessment findings are based upon observing various clinical symptoms that are suggestive of dysphagia (Sato, et al, 2014; Leonard & Kendall, 2014, Groher & Crary, 2009; Swigert, 2007). Such clinical symptoms of swallowing difficulty, as observed by the speech-language pathologist during eating, include changes in respiration patterns, laryngeal elevation sufficient enough to adequately protect the airway, and the presence / absence of coughing or choking (Logemann, 1998).

In 2000, Lalor, Brown, and Cranfield published the outcomes of a BDE conducted via tele-dysphagia with an individual stroke patient. The researchers reported that it was difficult to assess laryngeal function during swallowing due to the inability to obtain a close-up view or maintain a sufficient audio signal with the videoconferencing equipment used for the study. Validity was not established; however, these findings did lead to two later studies (Ward, et al, 2009) that attempted to resolve visualization issues by utilizing a purpose-built videoconferencing device to assess the communication and swallowing function of ten laryngectomy patients. During these simultaneous face-to-face and telehealth assessments, communication and swallowing variables were rated by a yes/no response or according to a 3, 5, 6, or 7-point scale. Results determined that although the communication portion of the assessment did not demonstrate an overall clinically acceptable level of agreement (below 80% PEA or PCA[4]), the majority of elements examined by the swallowing assessment had an overall clinically acceptable level of agreement (80% PEA or PCA) as noted below:

[4] PEA = Percentage exact agreement; PCA = Percentage clinical agreement

Table 1. Level of agreement between FTF and remote clinicians on swallowing assessment (Ward, et al, 2006).

ASSESSMENT	VARIABLE	Percentage Exact Agreement	Percentage Clinical Agreement
OROMOTOR FUNCTION	Dentition	90	N/A
	Saliva	90	N/A
	Oral Candida	60	N/A
	Lips	100	100
	Tongue	80	100
	Jaw	100	100
SWALLOWING FUNCTION	Diet level	80	90
	Use of swallowing strategy	90	100
	Type of strategy	100	100
	Effectiveness of strategy	100	100
	Duration of meals	90	100
	Modification to meals	90	N/A
SWALLOWING TRIAL	Oral control of bolus	90	100
	Oral residue	100	N/A
	Pain on swallowing	90	N/A
	Obstruction during swallow	80	N/A
	Oral / Nasal backflow	80	100
	Swallowing limitation	100	N/A
	Swallowing well-being / distress	100	N/A
	Severity rating	60	100

N/A – variable ratings with 3-point scales or yes/no responses were not applicable to the PCA

By 2011, tele-dysphagia research was able to benefit from more advanced videoconferencing systems that allowed for the transmission of improved audio and visual signals (Sharma, et al, 2011). Subsequently, this led to a clinical trial comparing face-to-face assessment to tele-dysphagia assessment featuring 40 patients with varying etiologies contributing to dysphagia (Ward, et al, 2012). In this study, entitled "Validity of conducting clinical dysphagia assessments with patients with normal to mild cognitive impairments via Telerehabilitation", levels of agreement between the face-to-face clinician and the remote clinician were considered to be clinically acceptable, as demonstrated below:

Table 2. Levels of agreement between face-to-face clinician and remote clinician (Ward, et al, 2012).

VARIABLE	**Percentage of Exact Agreement**	**Kappa Range**
Oral, oromotor, and pharyngeal function	75-100%	0.36 – 1.0
Food and fluid trials	79-100%	0.61 – 1.0
Aspiration symptoms and clinical recommendations	79-100%	0.49-1.0

The researchers, given these findings, concluded "that a CSE conducted via telerehabilitation can provide valid and reliable outcomes comparable to clinical decisions made in the FTF [face-to-face] environment" (Ward, et al, 2012).

In conjunction with this study, the same system was used to examine if the severity of dysphagia in any way impacted assessment outcomes (Ward, Burns, Theodoros, & Russell, 2013). One hundred patients (25 with normal swallowing function, 25 with mild dysphagia, 25 with moderate dysphagia, and 25 with severe dysphagia) were again assessed by both a face-to-face and a remote clinician; results

again revealed a high degree of clinical agreement between the clinicians regarding decisions related to oral and non-oral intake, as well as determining a safe diet level. It was observed, however, that for a significant ($p<0.5$) proportion of patients with severe dysphagia, clinicians disagreed that they "were able to satisfactorily and competently assess to the best of their abilities using the telerehabilitation system" (Ward, Burns, Theodoros, & Russell, 2013).

It should be noted that the most relevant studies validating the use of tele-dysphagia for a clinical swallowing assessment involved the use of the same equipment and the same research team – therefore, future validation studies should involve a variety of equipment as well as different research teams (Ward & Burns, 2014).

Videofluoroscopic Swallowing Study

The Videofluoroscopic Swallowing Study (VFSS) (also referred to as a Modified Barium Swallow [MBS]) is a dynamic radiologic examination performed while an individual swallows barium-coated substances in order to assess both the structure and function of the swallowing mechanism. It is considered to be an essential part of dysphagia assessment, enabling the clinician to determine the goals for rehabilitation (Ward & Burns, 2014).

In 2002, Perlman and Witthawaskul reported the first pilot attempts to transmit VFSS assessments across two sites via the Teledynamic Evaluation Software System (TESS), which enabled a clinician to direct and evaluate the VFSS remotely alongside an on-site clinician. Although it did not feature clinical trials, it was the first indication that off-site technology could be utilized to assess swallowing function.

Clinical trials were finally initiated in a study entitled "Teledynamic Evaluation of Oropharyngeal Swallowing", in which Malandraki and colleagues (2011) evaluated 32 patients (with a primary diagnosis of stroke or head / neck cancer) each participating in two videofluoroscopic swallowing studies — one onsite in the face-to-face (FTF) mode, and another utilizing the TESS system from a remote location, with both studies being no more than 30 minutes apart. The study objective was to determine the feasibility of a real-time online protocol for remote assessment of oropharyngeal swallowing. Three clinicians participated in the study –two conducting the FTF study, and the third conducting the subsequent study via the remote TESS system. Agreement between sites was determined for three parameters: 1) the overall severity of swallowing difficulty; 2) the presence and severity of laryngeal penetration and aspiration via an 8-point scale; and 3) treatment recommendations. Results showed good agreement between the onsite and offsite clinicians ($k = .636$; mean absolute difference = 1.1) in both subjective severity ratings and the 8-point scale, and agreement in treatment recommendations was moderate to high, ranging from 69.3 to 100%. Although the researchers noted the study limitations (changes in patient condition between studies, inconsistent quality of images), the investigators subsequently concluded that the use of an online telepractice system was feasible for evaluating dysphagia severity, the degree of penetration / aspiration, and for determining clinical recommendations via tele-videofluoroscopy.

Malandraki and her colleagues (2013) then examined the reliability of the inter-reliability of asynchronous teleconsultation (as opposed to teleassessment) for dysphagia. Three certified speech-language pathologists were instructed to analyze the results of 17 stored and forwarded videofluoroscopic swallowing assessments. Findings revealed

good inter-rater agreement (range – 78% to 90%; kappa = 0.52-0.71) for the eight following diagnostic indicators that targeted swallowing impairment:

- Oral residue
- Vallecular residue
- Pyriform sinus residue
- Aspiration
- Silent aspiration
- Penetration
- Silent penetration
- Delayed pharyngeal response

Using a 4-point scale, overall severity ratings were agreed upon for more than half of the patients and within one-point for all other patients with the exception of one. Given this, the investigators concluded that "the use of asynchronous teleconsultation can produce better quality of care" in settings "where a dysphagia expert is not available" (Malandraki, 2013).

To date, these are the only two studies utilizing clinical trials to investigate the validity, reliability, and effectiveness of instrumental assessment conducted via tele-dysphagia.

Tele-Dysphagia Intervention

Although the above studies lend credibility to the use of telepractice for dysphagia **assessment,** minimal quantifiable studies currently exist validating dysphagia **intervention** (that is, therapy versus assessment) via telepractice. To date, two studies

exist — one examining the use of tele-dysphagia for the treatment of head and neck cancer, and the other determining the feasibility of a pediatric tele-dysphagia program. The first study, "A pilot trial of a speech pathology telehealth service for head and neck cancer patients" (Burns, et al., 2012) reported the use of videoteleconferencing to support the rehabilitation of head and neck cancer patients. Over a five-month period, 50 tele-dysphagia sessions were initiated for 18 patients, featuring patient consultations, multi-disciplinary meetings, and clinical training sessions. This qualitative study utilized patient and clinician satisfaction measures in order to conclude that "all cases were successfully managed", with all participants confirming they would be comfortable using a telepractice system to conduct intervention sessions in the future.

Both qualitative and quantitative data were presented in the study "Telepractice for Pediatric Dysphagia: A Case Study" (Malandraki, Roth, & Sheppard, 2014), in which a pediatric tele-dysphagia program was developed and piloted for a 6-year, 6-month old male diagnosed with dysphagia secondary to Opitz BBB/G Syndrome and Asperger's Syndrome[5]. According to the case history, the patient received extensive surgery in the first five years of life secondary to numerous anatomical anomalies. His nutrition was exclusively via gastrostomy tube (with no oral intake) up until two weeks prior to the initiation of the telepractice program, when he was observed to accept limited amounts of liquid via straw secondary to significant delays in feeding skill acquisition. With the overall essential goal of acquiring age-appropriate feeding skills, an eight-session

[5] Opitz BBB/G Syndrome is a multiple congenital anomaly disorder characterized by facial anomalies (ocular hypertelorism, prominent forehead, widow's peak, broad nasal bridge, anteverted nares), laryngotracheoesophageal defects, and genitourinary abnormalities. Asperger's Syndrome is an autism spectrum disorder (ASD) that is characterized by significant difficulties in social interaction and nonverbal communication, alongside restricted and repetitive patterns of behavior and interests (www.medicinenet.com)

intervention program (conducted over four weeks) was developed, targeting the following outcomes: quality of life, swallowing function, and behavioral considerations. The specific variables targeting the above outcomes were as follows (Malandraki, Roth & Sheppard, 2014):

- Oral acceptance / tolerance of eating-related objects (e.g — spoon, cup) and a variety of foods (behavioral variables)
- Voluntary saliva swallows, rate of intake, and aerophagia[6] level (swallowing variables)
- Quality of life relating specifically to eating and swallowing (quality of life variable)

By the conclusion of the online intervention period, improvements were seen in each of the variables (using pre-and post-evaluative measures) as demonstrated by increased acceptance of novel foods, increased acceptance of eating-related objects intra-orally, increased salivary management, and improved ratings on a Likert scale measuring patient quality-of-life.

It should be noted that the above study is the ONLY one to date that presents **quantitative** data regarding the validity and effectiveness of dysphagia **intervention** – additionally, the data applies to a single pediatric participant, limiting the applicability of the study findings to other populations. These observations perhaps warrant the need for the investigation proposed in this dissertation.

[6] AEROPHAGIA — Swallowing too much air, a common cause of gas in the stomach and belching (www.medicinenet.com)

D. Historical Perspectives and Relevant Research – Face-to-Face Dysphagia Intervention

Swallowing safety strategies, as defined by ASHA, incorporate "modifications in food/liquid bolus size, bolus texture, patient positioning, compensatory maneuvers, and sensory enhancement techniques" with the goal of promoting optimal safety and efficiency during oral intake as well as minimizing aspiration risk (ASHA, 2002). Such strategies are employed by speech-language pathologists to maximize patient safety during oral intake following a clinical dysphagia assessment or instrumental assessment[7]. During this initial assessment, the clinician typically determines which diet modifications or safety strategies are appropriate for the patient; these are subsequently featured in the intervention plan as goals taught to the patient, with independent use being the ultimate objective. During the initial stages of treatment where the patient is NOT independent with strategy use, such intervention goals characteristically involve the use of multi-modal cueing systems (visual / auditory – REFER to Relevant Terms and Definitions, page 8), which are gradually faded as the patient becomes independent with the strategy. Such cueing systems, postural compensations, and diet modifications are a few of the face-to-face methods that have been used successfully to establish ongoing patient safety with oral intake (Logemann, 1998; Daniels, et al, 2007; Groher & Crary, 2009; McCullough & Kim, 2013).

The use of cueing systems has been well-established in the field of speech-language pathology in both the educational and medical settings. A cue, as defined by Haijiang et al (2006), is a form of associative learning in human perception. A cue in perception is a signal (e.g., auditory, visual, gustatory, tactile) that can be measured by an

[7] Likely to involve one of the following: Videofluoroscopic Swallowing Evaluation (VFSS), Fiberoptic Endoscopic Evaluation of Swallowing (FEES). Please refer to relevant definitions and terms, Chapter III.

observer's perceptual system and is informative about the state of some property of existence. Numerous studies illustrating the effects of verbal (auditory) and visual cues on bolus flow have been conducted (Daniels, et al., 2007; Martin, et al., 2004; Toogood, et al., 2005); findings suggest that swallowing is altered by the use of verbal cues to initiate swallowing in healthy adults. In the 2008 Treatment Efficacy Summaries, ASHA lends objective support to its contention that the use of cueing systems is a crucial component of dysphagia intervention success, as determined by a decrease in the occurrence of aspiration in dysphagia populations (Robbins & Hind, 2008).

Therefore, employing the use of cueing systems (via face-to-face AND telepractice modes) is seemingly beneficial in its effort to maximize the respiratory safety of individuals with dysphagia while maintaining nutrition and quality of life.

However, in order to more explicitly investigate the relative efficacy of dysphagia intervention, a meta-analysis of both direct and indirect dysphagia therapy[8] was conducted (Drulia & Ludlow, 2013). The meta-analysis examined 27 studies conducted between 2012 - 2013, categorizing them into 1) randomly controlled trials, 2) controlled clinical trials, and 3) uncontrolled case series. Although findings suggested small to moderate effect sizes (0.3 - 0.7) initially, moderate to high effect sizes (0.7 - 1.2) were noted in one and three-month follow-up studies. The authors concluded that this upward shift in effect may be secondary to an additional consideration — namely, the spontaneous recovery of the patient over time. It should be noted that since there are no studies directly examining the relationship between dysphagia therapy and spontaneous

[8] DIRECT dysphagia therapy refers to techniques targeting the swallowing mechanism; INDIRECT dysphagia therapy refers to methods that may target other systems of the body not directly related to the swallowing mechanism but that may be thought to improve swallowing function (e.g., the respiratory system).

recovery (it was merely hypothesized by the authors), one cannot rule out that the **combination** of the two resulted in a high effect size, thereby validating the use of dysphagia intervention. Additionally, results of many of the 27 studies offer varying levels of evidence suggesting the validity, reliability, and effectiveness of dysphagia intervention. Of the 27 studies analyzed, the investigations outlined below feature among those that Drulia and Ludlow rated as "of importance or major importance" (Drulia & Ludlow, 2013). It should be noted that of the 27 investigations analyzed, the ones not mentioned below either featured subjective rating scales (e.g., participant satisfaction ratings), or were not considered to be as valid according to the investigators.

Lending merit to the effectiveness of dysphagia intervention is a 2010 case series study investigating the functional and physiological outcomes of an exercise-based dysphagia therapy program. In the investigation, Crary, et al (2010) recruited nine participants with a diagnosis of dysphagia for a three-week exercise-based program. Findings revealed physiological changes after therapy — as evidenced by improved neuromuscular functioning of the swallowing mechanism. More importantly, four of the nine participants that were initially tube-feeding dependent were successfully advanced to an oral diet. In 2012, this same exercise-based program, known as the McNeill Dysphagia Therapy Program, was shown to facilitate improved timing of the swallow response in eight participants with a diagnosis of dysphagia (Lan, et al, 2012). When a independent-samples t-test analyzed group effects in participants before and after the program in addition to healthy volunteers, statistical significance was demonstrated by a α level of less than 0.05 (Lan, et al, 2012). Functional improvement was noted in all

participants, as indicated by the Mann Assessment of Swallowing Ability (Mann, 2002), which demonstrated an average increase of 17 points ($p<0.05$).

In a randomly controlled trial featuring six intervention sessions, Manor et al (2013) divided 42 participants with a diagnosis of Parkinson's disease into two groups — one receiving exercise / strategy-based traditional dysphagia therapy, and the other additionally receiving video-assisted dysphagia therapy.[9] Findings revealed a large effect size for the video-assisted / traditional therapy combination (1.6) and a moderate effect size (0.55) for traditional therapy alone, as evidenced by decreased residue in the pharynx when compared to baseline. Thus, the authors concluded that both traditional therapy alone, in addition to the visual information provided by the video-assisted intervention, both resulted in improved swallowing function outcomes (Manor, et al, 2013).

In a 2013 study by Shigematsu, Fujishima, and Onoh, a total of 20 participants with a diagnosis of dysphagia for at least one month post-CVA were randomly assigned to receive 10 therapy sessions (20 minutes in duration). These sessions featured either: 1) transcranial direct current stimulation (tDCS)[10] combined with traditional dysphagia therapy, or 2) traditional therapy alone with falsified tDCS. According to the Dysphagia Outcome Severity Scale (DOSS)[11], tDCS resulted in an improvement of 1.4 points (P = .006) directly after the last session and 2.8 points (P = .004) one month-post the last session. The falsified tDCS group improved 0.5 points (P = .059) after the last session

[9] VIDEO-ASSISTED DYSPHAGIA THERAPY involves showing videos of a normal swallow as compared to the participants' own swallow during traditional dysphagia therapy (Manor, et al, 2013).

[10] tDCS — is a non-invasive, painless brain stimulation treatment that uses direct electrical currents to stimulate specific parts of the brain (www.hopkinsmedicine.org, 2015).

[11] DOSS — a simple, easy-to-use, 7-point scale developed to systematically rate the functional severity of dysphagia based on objective assessment (O'Neil, et al, 1999).

and 1.2 points (P = .026) 1 month after the final session. The improvements in the tDCS group were significantly greater than those in the falsified tDCS group (P = .029 directly post, and P = .007 one month-post). The authors thus concluded that tDCS methods of intervention "significantly improved swallowing function" (Shigematsu, Fujishima, & Onoh, 2013).

The above study is of particular interest because the findings seem to validate a body of evidence that suggests that learning new motor skills (e.g., an exercise-based swallowing program) results in positive changes in corticomotor control, particularly if the neuroanatomical pathways involved in the control of the tongue musculature are identified (Miller, 2002; Sawczuk and Mosier, 2001) and stimulated, as proposed by this investigation (Shigematsu, Fujishima, and Onoh, 2013).

This investigation has proposed that there is a growing need for dysphagia intervention services (Coyle, 2012), one that can be potentially met through tele-dysphagia. The studies outlined in this literature search indicate successful efforts to validate the use of face-to-face dysphagia intervention, and some preliminary efforts to validate tele-dysphagia *assessment*. Tele-dysphagia *intervention* research efforts, however, have been limited, consisting of a single case study and a study targeting online team collaboration. The investigation described below serves to expand this knowledge base.

CHAPTER III

STUDY DESIGN / METHODS

This investigation is an experimental study examining three sets of outcome measures:

1) A comparison of correct versus incorrect responses of participants (the dependent variable) to visual and auditory cues (the independent variable) presented by the clinician during a participant-regulated feeding session targeting the independent use of swallowing safety strategies;
2) A comparison of the correct versus incorrect responses (the dependent variable) to the above-mentioned visual and auditory cues presented by the clinician featuring two different modes of service delivery – traditional face-to-face interaction versus tele-dysphagia (the independent variable).
3) A comparison of participant ability to achieve the goal of swallowing strategy acquisition in a clinical session given two different modes of service delivery — traditional face-to-face intervention and tele-dysphagia.

The participant group consisted of 30 individuals randomly assigned into two groups of 15. Each group received visual and auditory cues to promote the correct use of the targeted swallowing safety strategy (REFER – Relevant Terms and Definitions, page 8)—the control group via traditional face-to-face methods, and the study group via tele-dysphagia (featuring an online real-time, two-way encrypted visual/auditory signal – vsee.com, 2015).

Additionally, a mixed-design analysis of variance was calculated in order to determine: a) if there was a significant within-subject effect given the presence or absence of cues; and, b) the effects of between-subject factors (gender, delivery type, etiology, usage of cues) on the responses of participants.

A. Participant Criteria and Selection

The 30 participants selected for the study met the following criteria:

- Adults (age 18 years or above) with a confirmed medical diagnosis of cerebrovascular accident (CVA)[12] with positive findings according to CT or MRI of the brain;
- Adults (age 18 years or above) with a confirmed medical diagnosis of traumatic brain injury (TBI)[13], with positive findings according to CT or MRI of the brain;
- Confirmed competency for decision-making, according to the participant's primary physician;
- Confirmed medical diagnosis of dysphagia, defined as swallowing dysfunction (REFER – Relevant Terms and Definitions, page 8);

[12] Cerebrovascular accident (CVA) is defined as "an abnormal condition of the brain characterized by occlusion by an embolus, thrombus, or cerebrovascular hemorrhage or vasospasm, resulting in ischemia of the brain tissues normally perfused by the damaged vessels. Paralysis, weakness, sensory change, speech defect, aphasia, or death may occur."(www.medical-dictionary.thefreedictionary.com , 2013).

[13] Traumatic brain injury is a nondegenerative, noncongenital insult to the brain from an external mechanical force, possibly leading to permanent or temporary impairment of cognitive, physical, and psychosocial functions, with an associated diminished or altered state of consciousness (www.emedicine.medscape.com, 2013).

- The following scores according to the NATIONAL OUTCOMES MEASUREMENT SYSTEM (NOMS)/ FUNCTIONAL COMMUNICATION MEASURE (FCM) (ASHA, 2013):
    - Level 5 — Attention
    - Level 4-6 — Memory
    - Level 5-6 — Language Comprehension
    - Level 4-5 — Swallowing

  Participants were required to achieve the above scores on the NOMS in the areas of attention, memory, language comprehension, and swallowing to ensure the sufficient ability to participate in the study; for example, the participant had to maintain functional task attention, comprehend basic level verbal language, recall and repeat directions, and demonstrate a level of swallowing function that could benefit from intervention.

  (Please refer to attached NOMS / FCM forms in APPENDICES – the above scores ensured that **the participant was fully competent to consent and aware of all benefits and risks**).
- Need for visual and/or auditory cues to facilitate consistent use of determined safety strategy;
- Full motoric independence with feeding at 90 degrees trunk flexion, seated at a table.

Each session targeted one of the following swallowing safety strategies, as determined to be clinically effective via initial clinical dysphagia assessment (REFER – Relevant Terms and Definitions, page 8):

- CHIN DOWN / CHIN TUCK position – requires the patient to direct the chin toward the chest prior to swallowing the bolus to facilitate clearing of food residuals in the vallecular space (at risk for aspiration) and to more adequately protect the airway from bolus entry. In the most recent (2008) and largest clinical trial for dysphagia treatment efficacy, the chin down position was demonstrated to reduce the occurrence of aspiration of the bolus and subsequent onset of aspiration pneumonia (Robbins and Hind, 2008).
- HEAD TURN position – requires the patient to turn the head/neck to either the left or right side prior to swallowing the bolus. In the case of a hemiparesis (weak or paralyzed side) secondary to a CVA, turning the head toward the weaker side has been shown to direct the bolus through the pharynx via the stronger side of the swallowing mechanism, hence minimizing the risk of entrance into the airway (Logemann, 1998). Additionally, this position has been shown to increase the opening of the cricopharyngeal muscle (Logemann, 1998), thus promoting more efficient bolus propulsion through an impaired pharynx.
- CYCLIC INGESTION – requires the patient to alternate the intake of solids and liquids at prescribed intervals with the intention of a) clearing pharyngeal residuals at risk of entering the airway, and b) facilitating improved bolus transit through the esophagus (Logemann, 1998).
- BOLUS SIZE ALTERATION / REGULATION – requires the patient to independently regulate the size of the bolus (food or liquid) to a specific

amount, or to self-feed at a slower rate during feeding in order to maximize swallowing safety (as determined via clinical assessment) (Logemann, 1998).

The specific swallowing strategy (as above) that was determined for each participant was included in the following clinical goal consistent with the practice of dysphagia intervention (ASHA, 2016);

Following clinical instruction, the participant will demonstrate the targeted swallowing strategy given gradually fading visual and auditory cues with greater than or equal to 80% accuracy (12 of 15 trials).

It is this goal that became the focus of each intervention session, with the subsequent collection of data in order to determine whether the goal was achieved.

Once a potential participant was identified, the informed consent process began with an orientation session with the participant designed to: 1) determine interest by providing a step-by-step description of the intervention session (as outlined above), conducted via tele-dysphagia versus face-to-face methods; and, if interest is verbally expressed, 2) review the informed consent form (Please refer to APPENDIX G) for signature.

During the face-to-face orientation session (conducted via verbal conversation, featuring a written consent form) as outlined above, the following points were addressed:

- Review of the issues associated with the subject's formally diagnosed dysphagia, which subsequently inhibit safety with oral intake and place the said subject at risk for respiratory compromise;
- Review of the benefits of dysphagia intervention, specifically cueing systems, in the prevention of respiratory compromise secondary to dysphagia;

- The description of the study: To provide environmental cues to promote safety with oral intake via either face-to-face or tele-dysphagia methods;
- The intention of the study: To obtain information regarding the benefits of intervention of tele-dysphagia methods via face-to-face methods.

Following the orientation session and PRIOR to signing the informed consent and HIPAA forms, the participant was asked the following questions, which were constructed to meet the specific linguistic and cognitive level of the intended recipient and to ensure participant understanding of the study (refer – APPENDIX L):

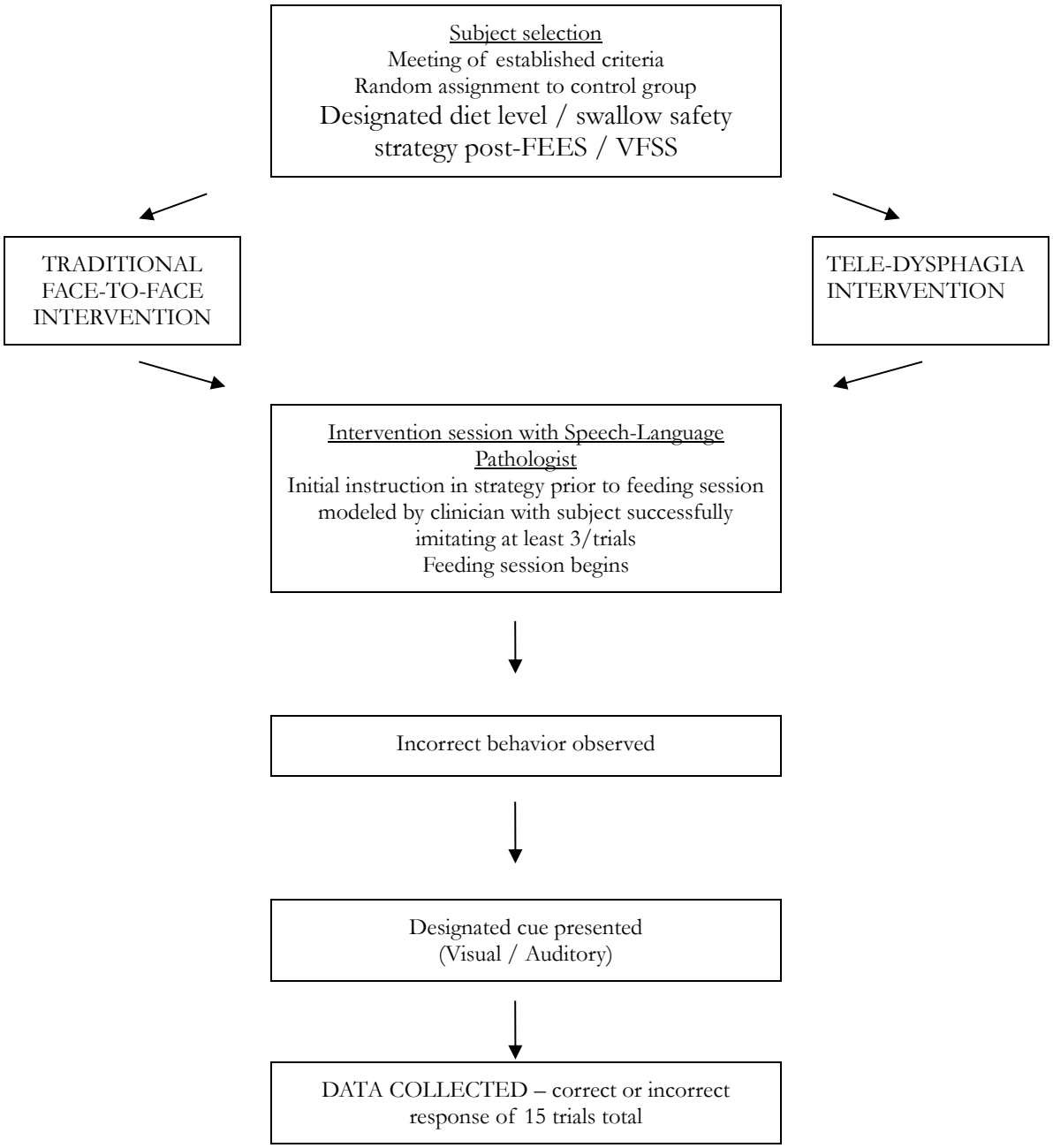
- Can you explain what this study will be examining?
- Can you explain how your swallowing affects your safety when you eat?
- What can happen if food or liquid enter your airway and/or lungs?
- Can you explain how therapy can potentially help you eat more safely?
- What specific technique was recommended to you in therapy to promote safety when you swallow food and/or liquid?
- What will the information you provide be used for?
- Are you interested in being a participant in this study?
- What questions do you have regarding this study?

If these questions were answered with 100% accuracy following instruction, and the potential participant expressed interested in participating, the Informed Consent form was provided for signature (with a copy given to the participant).

B. Session Protocol

The following is a diagrammatic overview of the study design /procedures:

Figure 1. Study protocol flowchart.



Following the format outlined above, each participant engaged in a dysphagia therapy session targeting the first 15 oral intake trials in either the face-to-face or tele-dysphagia format following their random assignment into each group. Fifteen oral intake

trials were assessed because this was the minimum number of trials achieved by each participant.

Each trial tele-dysphagia session was conducted between the clinician and the participant (targeting the strategies outlined above) using the Macintosh FaceTime videoconferencing system to allow for a real-time interaction, as well as VSee, a HIPPA-compliant, encrypted telehealth application that ensured participant confidentiality (VSee, 2015). The participants were given a brief orientation to the equipment and needed to demonstrate sufficient ability (as determined by sufficient participant scores on the NOMS and clinical judgment) to see and hear the video / audio signal and respond to commands.

The investigation was conducted in a designated therapy area of the sub-acute / long-term medical center, featuring the clinician in either the face-to-face or tele-dysphagia format. Sessions were conducted by two certified speech-language pathologists – the principal investigator and an attending speech-language pathologist. All sessions were recorded and viewed by a third certified speech-language pathologist for inter-rater reliability.

In the face-to-face setting, the clinician was present in the therapy room, seated approximately three feet directly across from the participant in the therapy room during the participant's snack or mealtime (the food tray from which the participant self-fed was at a distance necessary for independent oral intake, approximately 3 to 6 inches from the seated edge of the table).

In the tele-dysphagia setting, the clinician was located in a remote site, interacting with the participant via the FaceTime / VSee videoconferencing applications. The

participant was seated (with the same food set-up as outlined above) three feet directly across from a 21-inch computer screen that allowed for two-way video / audio communication. Sony MDR-7506 stereo headphones were employed for all tele-dysphagia sessions to maximize audio integrity.

In BOTH settings, the primary medical personnel (e.g., nursing, physician, physician's assistant) were present throughout the session to ensure the safety of the participant, with immediate intervention should any concerns arise (e.g., positive signs of aspiration).

C. Participant Confidentiality

Following participant selection and consent, all participants were assigned a referential number and were referred to exclusively by that number during medical chart review, data collection, analysis, and report of findings. A master list (linking participant to number), together with the informed consent and HIPAA forms containing personal information, is kept in the principal investigator's home in a locked cabinet, preventing access to such information by anyone with the exception of the principal investigator.

The data collection site, which is a sub-acute / long-term medical facility, employs a licensed interpreting service, which must be used for provision of all medical and therapeutic services requiring translation services. Interpreters are required to sign legally binding agreements to ensure patient/participant confidentiality.

Most imperative to ensuring confidentiality was protecting the privacy of the participant during online tele-dysphagia sessions. Currently, there is significant evidence in indicating that risks associated with telecommunication includes impersonation, interception, harassment, and unwanted surveillance (www.privacyinternational.org,

2015). Participant confidentiality was ensured via the use of the VSee user interface during tele-dysphagia sessions (www.vsee.com, 2015). VSee uses a novel network-sensing algorithm to adapt to network conditions. Unlike Skype, the most commonly used system for online videocommunication (www.skype.com, 2015), which reportedly lacks sufficient encryption to ensure confidentiality (www.privacyinternational.org, 2015), the VSee real-time videoconferencing capabilities offer "FIPS 140-2 certified 256 bit AES encryption and a full suite of administrator management and control capabilities to ensure patient confidentiality" (www.vsee.com, 2015).

D. Technology Risk Factors

In addition to confidentiality risks as outlined above, the use of technology to facilitate an assessment or intervention session is not without its challenges and limitations. As noted by Malandraki, et al (2011), the following challenges exist, but with potential solutions:

Table 3. Telepractice challenges and proposed solutions Malandraki, et al (2011).

TELEPRACTICE CHALLENGE	PROPOSED SOLUTION
Equipment (software/hardware) failure	• Adequate equipment testing time • Collaboration with technology assistant • Knowledge of basic technology interventions
Image transfer delays	• Establish faster Internet connections • Train remote personnel
Reduced image quality during real-time transmission	• Establish faster Internet connections • Use equipment during low traffic volumes • Re-analyze data post-assessment
Licensure obligations	• Obtain appropriate licensure (multi-state/international)
Limited access to medical records	• Obtain legal remote access to medical records

E. Participant Risk Factors

The participant ***risks*** associated with this study – namely, the risk of aspiration during eating, a risk associated with most dysphagia intervention (with subsequent respiratory compromise), are projected to be REDUCED during the proposed therapy sessions, since dysphagia intervention and the use of safety strategies have been determined to SIGNIFICANTLY decrease the likelihood of aspiration while facilitating improved swallowing safety (Robbins and Hind, 2008). These strategies (to be taught and monitored in face-to-face or tele-dysphagia formats) have been pre-determined to be beneficial to the patient via clinical assessment, which is the long-standing method for strategy selection (ASHA, 2002). Should any concerns about subject safety arise, they would be immediately be addressed by the attending medical staff, as is standard site protocol for all therapy sessions.

The following protocol was utilized to maximize participant safety in both the face-to-face and tele-dysphagia setting:

1) A signed order by the subject's primary physician approving the aforementioned intervention;
2) The presence of the primary medical staff (e.g., physician, registered nurse, physician's assistant) on site throughout the therapy session;
3) Respiratory monitoring (mandated protocol for all admissions) throughout the therapy session and the subject's medical stay in the sub-acute / long-term care setting;
4) Immediate discontinuation of the therapy session (with medical intervention) should there be any concerns regarding the participant's respiratory status.

5) Ongoing care by the primary medical staff following the therapy session until the participant discharged from the acute care environment upon stable medical status.

In the course of the investigation, NO participants were observed to have respiratory distress in the course of the session (as determined by medical staff); additionally, all participants were reported by the primary medical staff to have unchanged, stable respiratory status.

CHAPTER IV

RESULTS

A. Mixed-design Analysis of Variance

A mixed-design analysis of variance was conducted to examine if there are main effects of cue, gender, delivery type, etiology, or age on participant responses and/or interaction effect(s) among them. The cue is treated as a within-subject (repeated) factor with two categories (with cues and without cues) as each participant's outcome was repeatedly measured both with cues and without cues. On the other hand, the remaining variables (gender, delivery type, etiology, and age) are treated as between-subject factors with two categories each; specifically, (a) gender (female vs. male), (b) delivery type (tele-dysphagia versus face-to-face), (c) etiology (CVA vs. TBI), and (d) age ($<$ 70 versus $\geq$ 70 years old).

Table 4. Result of mixed-design analysis of variance.

Source	*df*	*F*	*p*
Cues	29	14.99	.001
(a) Gender	25	.07	.800
(b) Delivery	25	1.36	.260
(c) Etiology	25	.38	.540
(d) Age	25	.49	.490

Note. *df* = denominator degrees of freedom

As shown in Table 4, the results indicated that there was a significant within-subject effect of cues (F (1, 29)=14.99, p = .001) on participant responses. However, there were no significant main effects of between-subject factors (gender, delivery type,

etiology, or age) on participant responses. To ensure that the effect of cues interact with the between-subject factors, two-way interaction effects were additionally tested. There were no interaction effects between cues and any of the four factors with respect to participant responses.

B. Independent sample t-tests: Effects of Between-subject Factors

In order to determine if tele-dysphagia as a service delivery method demonstrated a significant difference when compared to a traditional face-to-face method (with respect to services given with cues or without cues, two independent t-tests were conducted. For the tests, total scores of a set of question responses to the services with cues and without cues were calculated.

First, a t-test was conducted by treating a total score to the services *with* cues as a dependent variable and a service delivery method as an independent variable with two categories: tele-dysphagia (n=15; study group) or face-to-face (n=15; control group). The result suggested that there was no significant difference in the mean scores from tele-dysphagia method ($M = 9.67$, $SD = 3.74$) as compared to face-to-face method ($M = 9.00$, $SD = 2.70$), $t(28) = - 0.56$, $p = 0.580$.

Second, another t-test was conducted by treating a total score to the services *without* cues as a dependent variable and a service delivery method as an independent variable with the two categories (tele-dysphagia or face-to-face). Similar to above, it was found that there was no significant difference in the mean scores from tele-dysphagia method ($M = 3.93$, $SD = 4.65$) as compared to face-to-face method ($M = 4.20$, $SD = 4.13$), $t(28) = 0.17$, $p = 0.870$.

Table 5. Independent t-tests comparing treatment and control groups (n = 30).

	Face-to-face (n=15)		Tele-Dysphagia (n=15)			
Score	*M*	*SD*	*M*	*SD*	*t*	*p*
With Cues	9.00	2.70	9.67	3.74	-0.56	0.580
Without Cues	4.20	4.13	3.93	4.65	0.17	0.870

Note. *df* = 28 for both tests

Table 6. Independent t-tests comparing gender difference (n = 30).

	Female (n=18)		Male (n=12)			
Score	*M*	*SD*	*M*	*SD*	*t*	*p*
With Cues	9.78	3.47	8.67	2.80	0.92	0.364
Without Cues	3.39	4.51	5.08	3.98	-1.05	0.301

Table 7. Independent t-tests comparing gender difference within FTF group (n = 15).

	Female (n=9)		Male (n=6)			
Score	*M*	*SD*	*M*	*SD*	*t*	*p*
With Cues	9.22	3.23	8.67	1.86	.38	.711
Without Cues	3.56	4.67	5.17	3.31	-.73	.479

Table 8. Independent t-tests comparing gender difference within tele-dysphagia group (n = 15).

	Female (n=9)		Male (n=6)			
Score	*M*	*SD*	*M*	*SD*	*t*	*p*
With Cues	10.33	3.81	8.67	3.72	.84	.417
Without Cues	3.22	4.63	5.00	4.90	-.71	.489

Similarly, there were no differences due to injury types or gender in the participant responses (regardless of the use of cues or not). Table 4.A and 4.B indicate that there was no effect of injury type either within the FTF group or within the tele-dysphagia group.

Table 9. Independent t-tests comparing injury types (n = 30).

	CVA (n=21)		TBI (n=9)			
Score	*M*	*SD*	*M*	*SD*	*t*	*p*
With Cues	9.48	3.28	9.00	3.24	0.37	0.717
Without Cues	3.90	4.36	4.44	4.48	-0.31	0.760

Note. CVA= cerebrovascular accident; TBI= traumatic brain injury

Table 10. Independent t-tests comparing injury types within FTF group (n = 15).

	CVA (n=12)		TBI (n=3)			
Score	*M*	*SD*	*M*	*SD*	*t*	*p*
With Cues	9.33	2.81	7.67	2.08	.95	.358
Without Cues	3.58	4.20	6.67	3.21	-1.17	.262

Note. CVA= cerebrovascular accident; TBI= traumatic brain injury

Table 11. Independent t-tests comparing injury types within tele-dysphagia group (n = 15).

	CVA (n=9)		TBI (n=6)			
Score	*M*	*SD*	*M*	*SD*	*t*	*p*
With Cues	9.67	4.00	9.67	3.67	.00	1.00
Without Cues	4.33	4.77	3.33	4.84	.40	.70

Note. CVA= cerebrovascular accident; TBI= traumatic brain injury

C. Dependent sample t-test: Effect of using Cues

Next, we examined if there is any difference between services provided with cues and without cues with respect to participant responses. For this, we conducted a dependent sample t-test; we treated a total score of participant responses (n=30) as a dependent variable and the use or absence of cues as an independent variable with the two categories 'with cues' and 'without cues'. Findings indicated that the mean scores to services provided with cues ($M = 9.33$, $SD = 3.22$) lead to significantly greater outcomes than the services without cues ($M = 4.07$, $SD = 4.32$), $t(29) = 3.87$, $p = 0.001$.

Table 12. Paired t-test comparing service delivery types (n = 30).

With Cues		Without Cues			
M	*SD*	*M*	*SD*	*t*	*p*
9.33	3.22	4.07	4.32	3.87***	0.001

Note. $df = 29$; ***= $p \leq .001$

D. Measures of Inter-rater Reliability

Inter-rater reliability was determined for each individual item (given a 0/1 score to indicate a positive or negative response, with or without cues) via a Cohen's kappa coefficient (Cohen, 1960) in order to measure the degree of agreement between the two raters. Findings indicated a kappa statistic of k=1 for all items, given a 100% agreement for all trials.

E. Measures of Effectiveness

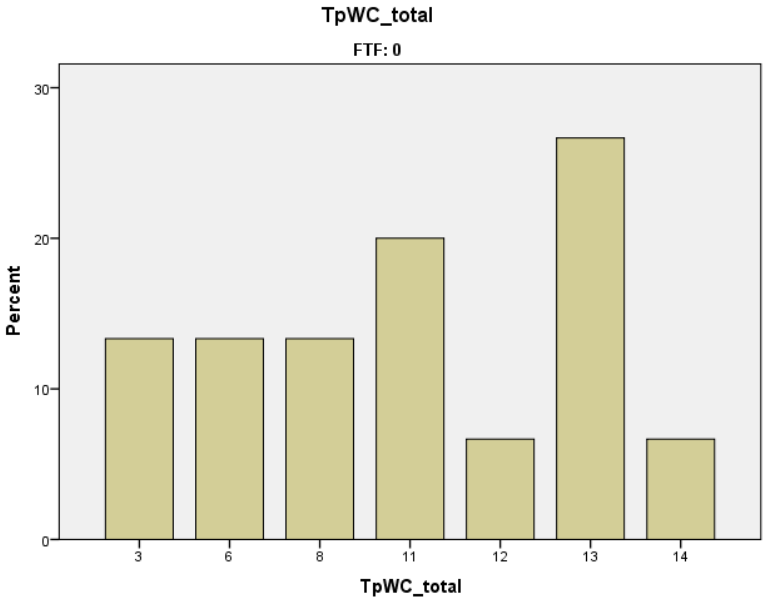
In order to determine the effectiveness of each mode of intervention, the following percentage and corresponding bar charts demonstrate distributions of the positive responses of participants with percentages and corresponding bar charts. Results are presented by delivery methods (Tele/FTF).

A. Tele-Dysphagia

A-1. With Cues (n=15 participants)

When using cues, among the 15 trials in total, all participants demonstrated positive responses with cues at least 3 times. Four participants (26.7%) showed the positive responses 13 out of 15 times most often.

Table 13. Measures of effectiveness: tele-dysphagia with cues.



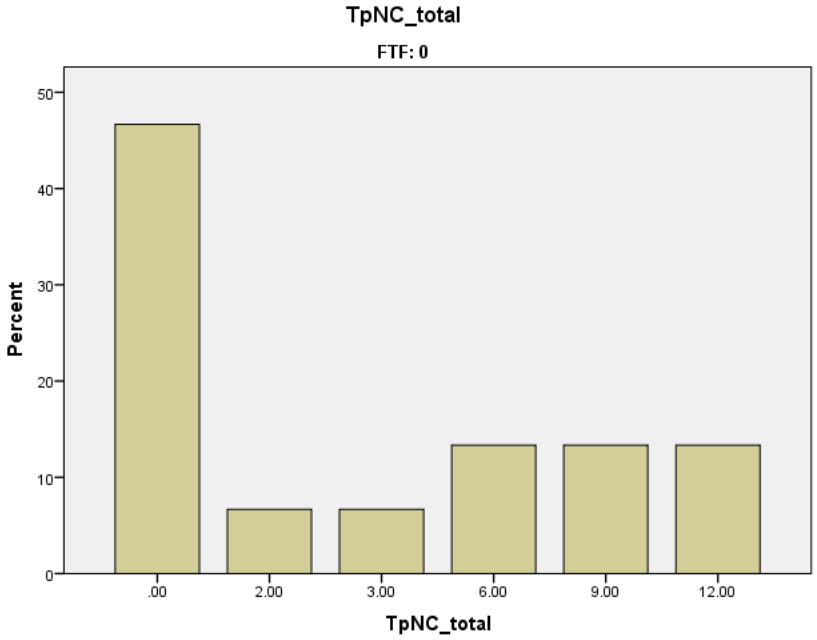
Participant Responses with Cues

Positive responses		Number of participants	Percent	Valid Percent	Cumulative Percent
Valid	3	2	13.3	13.3	13.3
	6	2	13.3	13.3	26.7
	8	2	13.3	13.3	40.0
	11	3	20.0	20.0	60.0
	12	1	6.7	6.7	66.7
	13	4	26.7	26.7	93.3
	14	1	6.7	6.7	100.0
	Total	15	100.0	100.0	

A-2. Without Cues (n=15 participants)

When cues were not used, seven participants (46.7%) showed no (or negative) responses most often.

Table 14. Measures of effectiveness: tele-dysphagia without cues.



Participant Responses without Cues

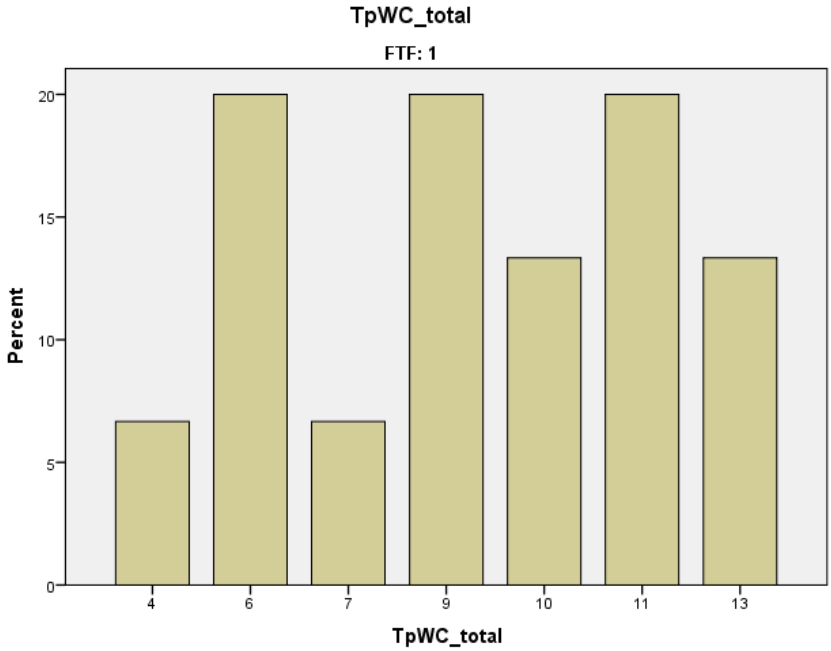
Positive responses		Number of participants	Percent	Valid Percent	Cumulative Percent
Valid	0	7	46.7	46.7	46.7
	2	1	6.7	6.7	53.3
	3	1	6.7	6.7	60.0
	6	2	13.3	13.3	73.3
	9	2	13.3	13.3	86.7
	12	2	13.3	13.3	100.0
	Total	15	100.0	100.0	

B. Face to Face

B-1. With Cues (n=15 participants)

When using cues, among the 15 trials in total, all participants showed their positive responses at least 4 times. Participants showed the positive responses 6 (20%), 9 (20%), and 11 (20%) out of 15 times most often.

Table 15. Measures of effectiveness: face-to-face with cues.



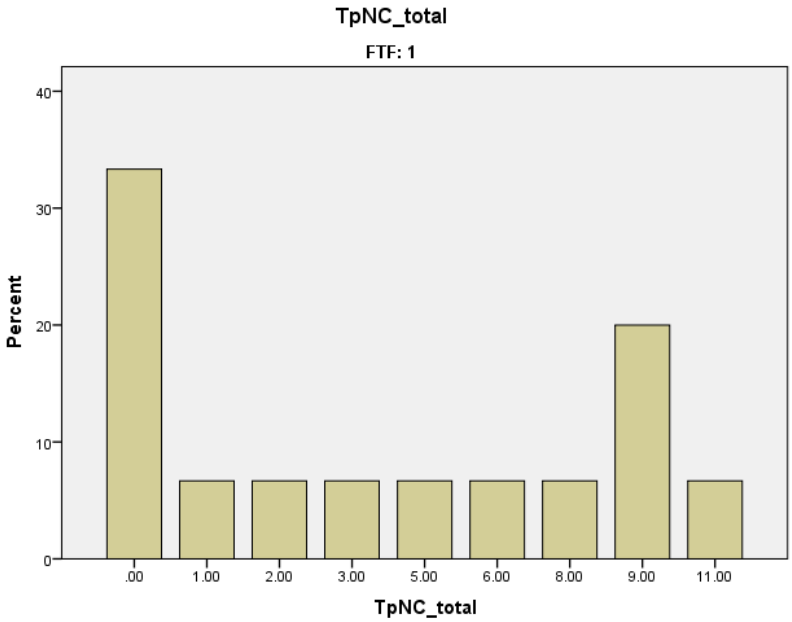
Participant Responses with Cues

Positive responses		Number of participants	Percent	Valid Percent	Cumulative Percent
Valid	4	1	6.7	6.7	6.7
	6	3	20.0	20.0	26.7
	7	1	6.7	6.7	33.3
	9	3	20.0	20.0	53.3
	10	2	13.3	13.3	66.7
	11	3	20.0	20.0	86.7
	13	2	13.3	13.3	100.0
	Total	15	100.0	100.0	

B-2. Without Cues

When cues were not used, seven participants (33.3%) showed no (or negative) responses most often. Also, there was no one who showed positive responses more than 11 out of 15 times.

Table 16. Measures of effectiveness: face-to-face without cues.



Participant Responses without Cues

Positive responses		Number of participants	Percent	Valid Percent	Cumulative Percent
Valid	0	5	33.3	33.3	33.3
	1	1	6.7	6.7	40.0
	2	1	6.7	6.7	46.7
	3	1	6.7	6.7	53.3
	5	1	6.7	6.7	60.0
	6	1	6.7	6.7	66.7
	8	1	6.7	6.7	73.3
	9	3	20.0	20.0	93.3
	11	1	6.7	6.7	100.0
	Total	15	100.0	100.0	

C. Clinical goal achievement as a determination of effectiveness

Following clinical instruction, the participant will demonstrate the targeted swallowing strategy given gradually fading visual and auditory cues with greater than or equal to 80% accuracy (12 of 15 trials).

Given the 30 participants (15 randomly assigned to receive tele-dysphagia intervention, 15 to receive face-to-face intervention), 87% of the tele-dysphagia participants achieved their clinical goal (>=80%), while 80% of the face-to-face participants achieved this goal. This indicates that both modes of service delivery facilitated effective and successful outcomes, with tele-dysphagia demonstrating slightly increased effectiveness (7%).

Table 17. Achievement of clinical goal, tele-dysphagia participants (87% achieved goal).

PARTICIPANT #	*GOAL ACHIEVED (>=12 of 15 trials)*	*GOAL NOT ACHIEVED (<12 TRIALS)*
2	*15 of 15*	
4	*13 of 15*	
6	*13 of 15*	
8	*15 of 15*	
10		*11 of 15*
12	*15 of 15*	
14	*14 of 15*	
16	*14 of 15*	
18	*14 of 15*	
20	*14 of 15*	
22	*14 of 15*	
24		*11 of 15*
26	*13 of 15*	
28	*13 of 15*	
30	*15 of 15*	

Table 18. Achievement of clinical goal, face-to-face participants (80% achieved goal).

PARTICIPANT #	*GOAL ACHIEVED (>=12 of 15 trials)*	*GOAL NOT ACHIEVED (<12 TRIALS)*
1	*15 of 15*	
3	*13 of 15*	
5	*13 of 15*	
7	*15 of 15*	
9		*11 of 15*
11		*9 of 15*
13	*12 of 15*	
15	*12 of 15*	
17	*15 of 15*	
19	*15 of 15*	
21	*15 of 15*	
23	*13 of 15*	
25	*14 of 15*	
27	*15 of 15*	
29		*11 of 15*

CHAPTER V

DISCUSSION

This chapter discusses the relationship of findings to the proposed research questions, and to past research findings; in addition to clinical implications, and study limitations.

A. Relationship of Findings to the Proposed Research Questions

- Can the traditional face-to-face methods of service delivery be conducted via tele-dysphagia and not demonstrate a significant difference in outcomes?
- Do participants respond to cues conveyed via a tele-dysphagia method of service delivery without a significant difference when compared to traditional face-to-face intervention?
- Do the factors of age, gender, and etiology affect outcome measures?
- Is tele-dysphagia valid, reliable, effective and reproducible?

The results of independent t-tests comparing face-to-face and tele-dysphagia delivery modes (both with and without cues – each analyzed as the dependent variable), did not demonstrate a significant statistical difference. These results provide validation for the use of tele-dysphagia services in cases where face-to-face dysphagia intervention is not an option due to factors such as mobility or distance – though it should be noted

that these results are limited to the specific safety strategies investigated[14] (REFER below – Limitations).

The results of the mixed-design analysis of variance indicate that there were no significant main effects of *between-subject* factors (gender, delivery type, etiology, or age) on participant responses regardless of delivery mode. In an examination of the data, one can conclude that both tele-dysphagia and face-to-face modes of service delivery can provide comparable clinical results (again, only for the swallowing strategies investigated) regardless of participant gender, age (>or equal to 18 years), or etiology (CVA or TBI, as these were the only diagnoses included in the study).

Conversely, the mixed-design analysis of variance demonstrated a high within-subject effect when a comparison was made between services provided with and without cues, in both face-to-face and tele-dysphagia delivery modes. The cue is treated as a within-subject (repeated) factor with two categories (with cues and without cues) as each participant's outcome was repeatedly measured both with cues and without cues. In the within-subject design, studying multiple outcomes (15 trials) for each participant allows each participant to be an individual control (e.g., the investigator can remove subject-to-subject variation). Findings determined that the use of cues resulted in a significant increase in the positive responses in both the face-to-face and tele-dysphagia groups, validating not only the use cues to improve positive outcomes, but to validate tele-dysphagia as an alternate service mode.

Reproducibility of this investigation (e.g., can the study can be reduplicated) was noted in both face-to-face and tele-dysphagia modes, for all 30 participants successfully

[14] Chin down posture, cyclic ingestion compensation, head turn posture, bolus size regulation.

completed 15 oral intake trials each, responding with either a negative or positive response. As this study is the first of its kind, this study could perhaps be reproduced featuring a larger sample size and / or a greater variety of populations, which would provide additional evidence regarding reproducibility.

Evidence contributing to the reliability of this investigation (e.g., do results have the same statistical significance when performed on another group), thus far, is limited solely to the results of this study — as demonstrated by results from the mixed-design analysis of variance. For example, the between-subject effect demonstrates no significant main effects with regard to gender, delivery type, etiology, or age, which offers some evidence of reliability, but this study would need to be repeated with additional groups in order to truly substantiate this claim.

Effectiveness measures, as noted above (REFER – page 45), demonstrate that in the case of tele-dysphagia delivery mode, WITH the use of cues, 4 of 15 participants had positive responses for 13 of 15 trials (26.7 percent); and when NO cues were provided, 7 of 15 participants had 0 of 15 positive responses (46.7 percent). One can therefore conclude that participants utilizing tele-dysphagia benefit *significantly* from the use of visual and auditory cues. Effectiveness was additionally demonstrated during a comparison of clinical goal achievement in both groups, with the tele-dysphagia group achieving slightly higher outcomes (87% of tele-dysphagia participants versus 80% of face-to-face participants). One could therefore conclude that the tele-dysphagia mode of intervention is as effective as the face-to-face mode given a standard dysphagia intervention goal (ASHA, 2016).

B. Relationship of Findings to Past Research

ASHA's position on telepractice – namely, that it is "an appropriate model of service delivery for the profession of speech-language pathology" (ASHA, 2005) is supported by the findings of this study; more importantly, the findings of this investigation offer an additional contribution to a limited research base of tele-dysphagia **intervention.** To date, the only studies targeting the above consist of a single case quantitative study (Malandraki, Roth, & Sheppard, 2014), and a multi-disciplinary qualitative study (Burns, et al., 2012) which did not target direct intervention (REFER – Review of the Literature). This investigation is singular in that it offers both a greater sample size (30 participants randomly assigned into two groups of 15) and is quantitative in nature. Expanding on these findings, however, by repeating the study with a larger sample size featuring a greater variety of populations will only serve to further validate the use of tele-dysphagia as a service delivery mode.

C. Clinical Implications

Statistics targeting the geriatric population have projected three trends: 1) half of all Americans will experience dysphagia after the age of 60 (ASHA, 2009); 2) this population will have limited or no access to intervention due to mobility and distance constraints (American Geriatric Society, 2009); and, 3) the number of individuals with dysphagia is quickly exceeding the number of qualified dysphagia therapists (Coyle, 2012). Given the above, the findings of this investigation potentially offer validation for the use of tele-dysphagia for intervention and rehabilitative purposes. Such efforts, if successful, could promote increased longevity and quality of life in populations currently

unable to access such services by traditional face-to-face methods, particularly geriatric populations.

Another consideration is the anticipated advance of technology, which may potentially yield improved audio and visual signals that would provide clinicians with additional information regarding swallowing function; for example, to allow for optimal auditory amplification of the swallow response. Research is currently investigating the potential of accelerometry[15] to monitor the swallow response (Dudik, et al, 2015), with the possibility of doing so remotely. In this study, 55 participants were asked to swallow their saliva five times in succession; swallow responses were measured via accelerometry (the measurement of vibrations) and auscultation (the measurement of sounds) and compared. Findings revealed that swallowing accelerometry and swallowing auscultation "provide different information about deglutition despite utilizing similar transduction methods" (Dudik, et al, 2015), therefore indicating a future need to analyze swallowing sounds and vibrations separately. Studies such as these will undoubtedly impact the future of tele-dysphagia.

D. Study Limitations

The fact that the principal investigator was one of the two clinicians involved in data acquisition may lend itself toward study bias. This was an unforeseen circumstance, due to billing requirements of the medical center / investigation site – which appropriately declined to bill for the dysphagia services provided during this study. Subsequently, the attending speech-language pathologist was periodically unavailable to

[15] An instrument for measuring acceleration or for detecting and measuring vibrations (Dudik, et al, 2015).

participate in this investigation. Having an additional certified clinician analyze all trials for inter-rater reliability served as an attempt to minimize study bias.

It is important to note that a crucial element of successful tele-dysphagia is the presence of an additional individual at the participant site to troubleshoot issues with the telepractice equipment and ensure participant safety. Although the above safety precautions were employed for this investigation, it may be difficult for dysphagia practitioners to generalize or establish the same degree of safety for their patients.

Additionally, this investigation was limited to adults (> or equal to age 18) with a primary medical diagnosis of either CVA (cerebrovascular accident) or TBI (traumatic brain injury), which limits generalization of findings to these populations.

Participants in a tele-dysphagia mode of service delivery, by general principle, can only interact in visual and auditory (not tactile) modes. Since face-to-face dysphagia assessment and intervention frequently incorporate tactile observations (e.g – palpation[16] of the larynx) (Swigert, 2000), current intervention practices via tele-dysphagia would need to be limited to visual and auditory observations and interactions, which could potentially influence outcomes negatively. For example, certain strategies, such as the DOUBLE SWALLOW strategy (where a participant is instructed to swallow twice after each bolus presentation) (Logemann, 1998), or a PREP SET strategy (where a participant is asked to hold the bolus in the oral cavity for a designated period of time) (Logemann, 1998) were not chosen for this study given that participant responses may not be accurately perceived via video / audio alone. Subsequently, this may limit current tele-dysphagia intervention sessions to those that only require visual and auditory

16 PALPATION — a method of feeling with the fingers or hands during a physical examination (http://www.medical-dictionary.thefreedictionary.com/palpation).

observations, though one cannot exclude that future advances in technology may allow for monitoring of tactile input.

CHAPTER VI

CONCLUSIONS AND FUTURE RESEARCH

This investigation was proposed and initiated because a review of the literature has established two primary considerations: 1) a clearly defined need for tele-dysphagia services given projected geriatric and dysphagic population trends; and, 2) limited research determining the reliability, validity and effectiveness of tele-dysphagia intervention. Although the results of this investigation profess to expand upon the current knowledge base by validating the use of tele-dysphagia for intervention, future studies should ideally feature a larger sample size and target a greater variety of populations in order to allow for a greater generalization of information. Additionally, investigations should continue to focus on the acquisition of longitudinal and quantifiable data.

The raw data provided by this research study (REFER – Appendices) also allows for additional studies to be conducted – particularly with a larger sample size. For example, further studies can potentially investigate the following:

- The relationship between the use of cues versus absence of cues as influenced by gender, age, diet consistency, or etiology (TBI / CVA).
- The effectiveness of swallowing strategies given differences in gender, age, diet consistency, or etiology (TBI / CVA).
- Outcomes regarding the type of swallowing strategy selected.

As outlined above, another consideration for future research would be the investigation of improved audio and visual signals during tele-dysphagia sessions, as well

as an investigation of the potential for the immediate transfer of tactile input, since palpation of the larynx features prominently in face-to-face dysphagia assessment and intervention (Swigert, 2000). This could potentially allow for a more comprehensive assessment, as well as for the instruction and monitoring of a greater number of safety strategies.

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APPENDIX A

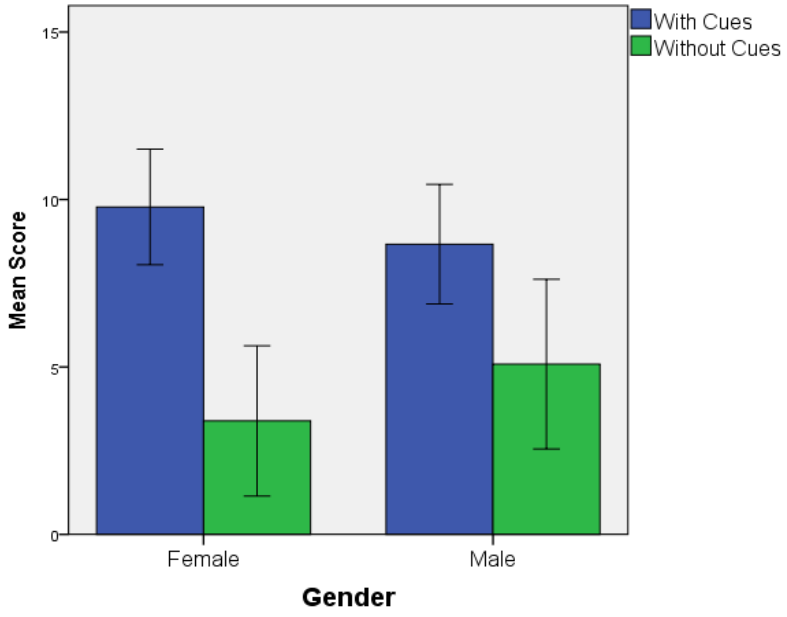

Figure 2. Bar chart comparing gender differences (with 95% Confidence Intervals)

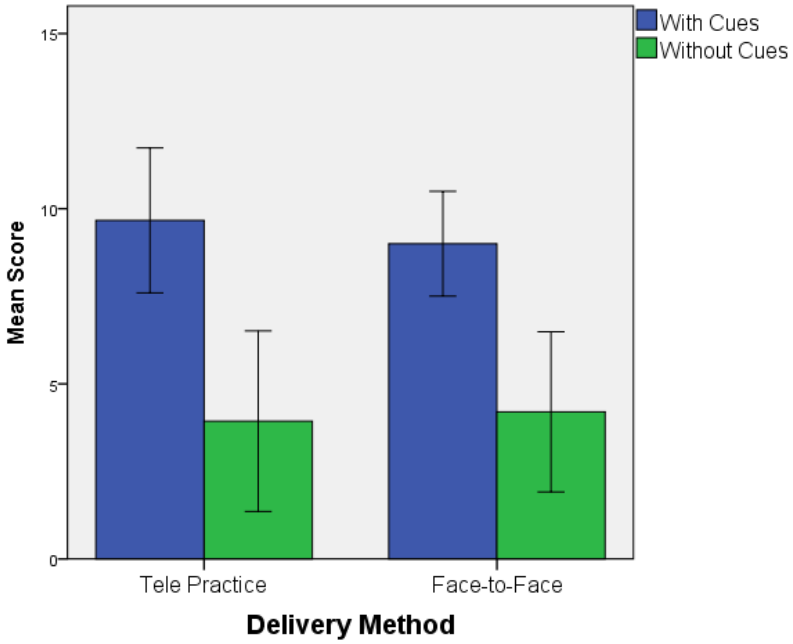

Figure 3. Bar chart comparing delivery methods (with 95% Confidence Intervals)

APPENDIX B

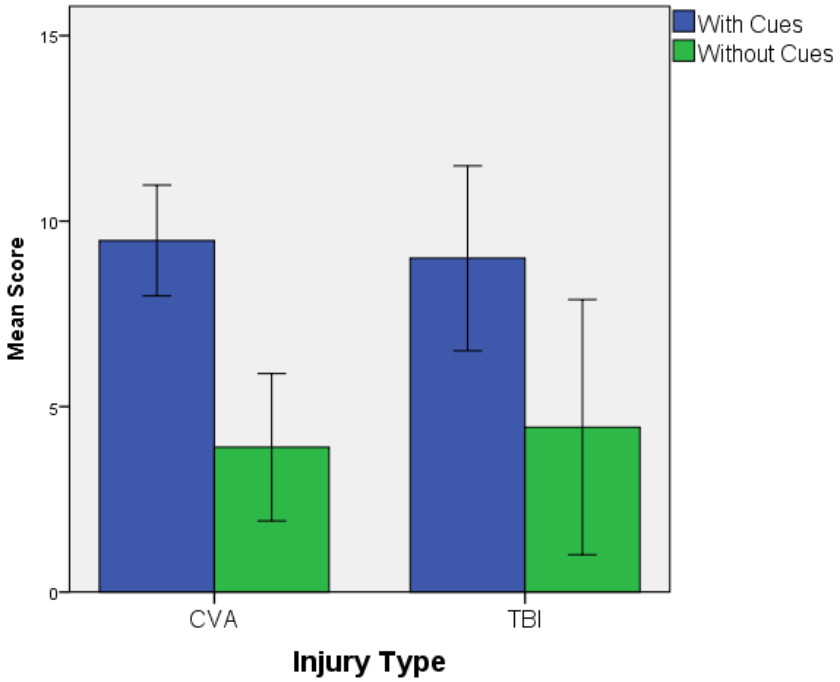

Figure 4. Bar chart comparing injury types (with 95% Confidence Intervals)

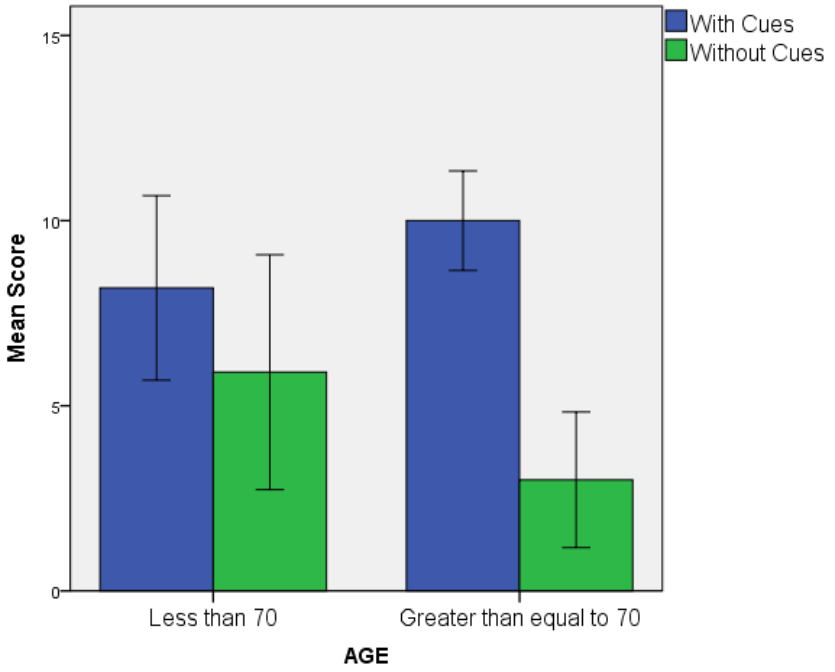

Figure 5. Bar chart comparing age groups (with 95% Confidence Intervals)

APPENDIX C

Table 19. Demographic analysis of participants.

Demographic Parameters	All participants (n=30)	Telepractice (n=15)	Face-to-face (n=15)
Gender			
Male	12	6	6
Female	18	9	9
Age range			
60-65	3	1	2
65-70	3	3	0
70-75	5	3	2
75-80	13	7	6
80-85	4	0	4
>85	2	1	1
Etiology			
CVA	21	9	12
TBI	9	6	3

APPENDIX D

Table 20. Analysis of safety strategies.

Demographic Parameters	Safety Strategy				
	Chin down	Head turn	Cyclic ingestion	Cyclic ingestion + slow rate	Slow rate
Gender					
Male (n=12)	4	3	3	0	2
Female (n=18)	5	0	6	1	6
Age Range					
60-65 (n=3)	2	0	1	0	0
65-70 (n=3)	2	0	0	0	1
70-75 (n=5)	1	0	1	0	3
75-80 (n=13)	1	3	6	1	2
80-85 (n=4)	3	0	1	0	0
>85 (n=2)	0	0	0	0	2
Treatment Modality					
Telepractice (n=15)	3	2	4	1	5
Face-to-face (n=15)	6	1	5	0	3
Etiology					
CVA (n=21)	6	1	8	1	5
TBI (n=9)	3	2	1	0	3

APPENDIX E

Table 21. Analysis of liquid and solid bolus consistencies.

Demographic Parameters	Liquid Consistency			Solid Consistency		
	Thin	Nectar	Honey	Regular	Soft	Pureed
Gender						
Male (n=12)	5	6	1	5	5	2
Female (n=18)	5	9	4	1	8	9
Age Range						
60-65 (n=3)	3	0	0	3	0	0
65-70 (n=3)	2	1	0	0	3	0
70-75 (n=5)	3	2	0	2	3	0
75-80 (n=13)	1	9	3	1	6	6
80-85 (n=4)	1	2	1	0	1	3
>85 (n=2)	0	1	1	0	0	2
Treatment Modality						
Telepractice (n=15)	6	6	3	4	6	5
Face-to-face (n=15)	4	9	2	2	7	6
Etiology						
CVA (n=21)	6	11	4	5	7	9
TBI (n=9)	4	4	1	1	6	2

APPENDIX F

The following tables offer more in-depth information regarding data collection and investigation parameters.

Patient	Gender	Service Delivery Mode	Age Range	Etiology	Liquid Consistency	Solid Consistency	Swallowing Strategy
Patient_01	Female	Face-to-face	80-85	CVA	Nectar liquids	Puréed solids	Chin down
Patient_02	**Male**	**Telepractice**	**70-75**	**CVA**	**Thin liquids**	**Regular solids**	**Cyclic ingestion**
Patient_03	Female	Face-to-face	80-85	CVA	Thin liquids	Soft solids	Chin down
Patient_04	**Female**	**Telepractice**	**65-70**	**CVA**	**Nectar liquids**	**Soft solids**	**Slow rate**
Patient_05	Female	Face-to-face	75-80	CVA	Nectar liquids	Soft solids	Cyclic ingestion
Patient_06	**Male**	**Telepractice**	**70-75**	**TBI**	**Thin liquids**	**Regular solids**	**Slow rate**
Patient_07	Male	Face-to-face	70-75	CVA	Nectar liquids	Soft solids	Chin down
Patient_08	**Female**	**Telepractice**	**75-80**	**CVA**	**Nectar liquids**	**Soft solids**	**Slow rate**
Patient_09	Male	Face-to-face	60-65	CVA	Thin liquids	Regular solids	Cyclic ingestion
Patient_10	**Male**	**Telepractice**	**75-80**	**TBI**	**Nectar liquids**	**Puréed solids**	**Head turn**
Patient_11	Female	Face-to-face	>85	CVA	Honey liquids	Puréed solids	Slow rate
Patient_12	**Female**	**Telepractice**	**65-70**	**TBI**	**Thin liquids**	**Soft solids**	**Chin down**
Patient_13	Female	Face-to-face	75-80	CVA	Nectar liquids	Puréed solids	Cyclic ingestion
Patient_14	**Male**	**Telepractice**	**75-80**	**CVA**	**Nectar liquids**	**Soft solids**	**Head turn**
Patient_15	Female	Face-to-face	80-85	CVA	Nectar liquids	Puréed solids	Chin down
Patient_16	**Female**	**Telepractice**	**70-75**	**TBI**	**Nectar liquids**	**Soft solids**	**Slow rate**
Patient_17	Female	Face-to-face	70-75	TBI	Thin liquids	Soft solids	Slow rate
Patient_18	**Male**	**Telepractice**	**75-80**	**CVA**	**Honey liquids**	**Puréed solids**	**Cyclic ingestion**
Patient_19	Female	Face-to-face	75-80	CVA	Nectar liquids	Puréed solids	Cyclic ingestion
Patient_20	**Female**	**Telepractice**	**>85**	**CVA**	**Nectar liquids**	**Puréed solids**	**Slow rate**
Patient_21	Male	Face-to-face	60-65	CVA	Thin liquids	Regular solids	Chin down
Patient_22	**Female**	**Telepractice**	**65-70**	**TBI**	**Thin liquids**	**Soft solids**	**Chin down**
Patient_23	Male	Face-to-face	75-80	TBI	Nectar liquids	Soft solids	Head turn
Patient_24	**Female**	**Telepractice**	**75-80**	**TBI**	**Honey liquids**	**Puréed solids**	**Cyclic ingestion**
Patient_25	Male	Face-to-face	75-80	CVA	Nectar liquids	Soft solids	Slow rate
Patient_26	**Female**	**Telepractice**	**75-80**	**CVA**	**Honey liquids**	**Puréed solids**	**Cyclic ingestion**
Patient_27	Male	Face-to-face	75-80	TBI	Nectar liquids	Soft solids	Chin down
Patient_28	**Female**	**Telepractice**	**75-80**	**CVA**	**Thin liquids**	**Regular solids**	**Cyclic ingestion**
Patient_29	Female	Face-to-face	80-85	CVA	Honey liquids	Puréed solids	Cyclic ingestion, slow rate
Patient_30	**Male**	**Telepractice**	**60-65**	**CVA**	**Thin liquids**	**Regular solids**	**Chin down**

Patient	T01	T02	T03	T04	T05	T06	T07	T08	T09	T10	T11	T12	T13	T14	T15
Patient_01	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc
Patient_02	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc
Patient_03	- wc	+ wc	+ wc	- wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc
Patient_04	+ wc	+ wc	+ wc	+ wc	+ wc	- wc	+ wc	+ wc	+ wc	- wc	+ wc	+ wc	+ wc	+ wc	+ wc
Patient_05	- wc	- wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc
Patient_06	- wc	- wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc
Patient_07	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc
Patient_08	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc
Patient_09	- wc	- wc	+ wc	+ wc	- wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	- wc	+ wc	+ wc	+ wc
Patient_10	-wc	-wc	-wc	+ wc	+ wc	-wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc
Patient_11	- wc	- wc	+ wc	- wc	+ wc	+ wc	+ wc	- wc	+ wc	+ wc	- wc	+ wc	+ wc	- wc	+ wc
Patient_12	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc
Patient_13	+ wc	- wc	+ wc	- wc	- wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc
Patient_14	+ wc	- wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc
Patient_15	- wc	- wc	+ wc	+ wc	+ wc	- wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc
Patient_16	+ wc	- wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc
Patient_17	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc
Patient_18	- wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc
Patient_19	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc
Patient_20	-wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc
Patient_21	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc
Patient_22	-wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc	+ nc	+ nc	+ wc	+ wc	+ nc
Patient_23	-wc	-wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ wc	+ nc	+ nc
Patient_24	- wc	- wc	- wc	+ wc	+ wc	+ wc	- wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc
Patient_25	- wc	+ wc	+ wc	+ nc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ wc	+ nc	+ nc	+ nc	+ wc
Patient_26	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	- wc	- wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc
Patient_27	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc
Patient_28	+ wc	- wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	+ wc	- wc	+ wc	+ wc	+ wc	+ wc
Patient_29	- wc	+ wc	- wc	+ wc	+ wc	+ wc	+ wc	- wc	+ wc	+ wc	+ wc	- wc	+ wc	+ wc	+ wc
Patient_30	+ wc	+ wc	+ wc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc	+ nc

+ wc: positive response with cue; + nc: positive response, no cue; - wc: negative response with cue (no instances of negative response, no cue were recorded)

APPENDIX G

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INFORMED CONSENT AGREEMENT

DESCRIPTION OF THE RESEARCH: You are invited to participate in a research study on the effectiveness of computer-televised dysphagia ("swallowing") therapy.

You have been asked to take part in this study because you have a diagnosis of dysphagia (a problem with swallowing). You have been referred by a physician for dysphagia therapy, and your Speech-Language Pathologist (SLP) has determined that particular "safe swallowing" techniques will be helpful for you.

The purpose of this research is to help us understand whether swallowing therapy of this kind can be given through a computer, without the SLP being present in the room, and still be effective.

You will receive the same dysphagia therapy that you would be receiving anyway from your Speech-Language Pathologist. However, if you agree to take part in this study, you will be randomly assigned to take part either in a face-to-face session, or in a computer session (the SLP will be in the next room, but will speak with you via computer). The session will be video recorded, and we will collect data that will help us to decide how effectively you are able to respond to instructions from the SLP.

The research will be conducted by Stacy Gallese Cassel, M.S., CCC-SLP, ABD (Speech-Language Pathologist). The research will be conducted at the SEASHORE GARDENS LIVING CENTER in Galloway, New Jersey.

If necessary, a board-certified interpreter will be used in this study as approved and utilized by SEASHORE GARDENS; the use of an interpreter for any and all procedures remains standard of practice in this facility.

RISKS AND BENEFITS: The risks and possible benefits associated with this study are the same as those involved in taking part in dysphagia therapy. Because you have a swallowing problem, there is a risk of aspiration: that is, the entry of food or liquid into the airway or lungs. Aspiration is dangerous and can

lead to problems with breathing or infections if not treated.

By taking part in this study, your risk of aspiration will not be increased. To make sure that you are safe if you are assigned to a computer-based therapy session, the SLP will be right in the next room. If you show any signs of distress during the session, she will be there to help you immediately. All the therapy sessions will take place at the medical center as usual, so that you also have the support of your attending medical team (primary physician, nurse, and all additional relevant medical practitioners involved in your care).

The aim of dysphagia therapy is to make swallowing safer for you. It is anticipated that the techniques you will learn and practice in your therapy sessions will increase your safety. If your SLP sees any indication that this is not the case, she will stop the therapy immediately. Potential benefits of the study include improved swallowing, maximized respiratory safety, and increased comfort level during eating.

If you decide to take part in this study, you can change your mind at any time, and go back to having your therapy as normal.

PAYMENTS: There is no payment for study participation. However, you will not be charged for any therapy session that you have as part of the study. If you decide not to take part, you will still have the same therapy that you have been prescribed, that will be billed as normal, and there is no penalty to you whatsoever.

DATA STORAGE TO PROTECT CONFIDENTIALITY: Your name and identifying information will be kept private. If you take part in this study you will be assigned a number. All the data we collect will have only the number, not your name, attached to it. Only I, as the investigator, will have the list that allows me to match numbers to names. The video recordings of the therapy sessions, and any notes that we make about these sessions, will be stored on a password-protected computer that can be accessed only by me. The only people who will see the video are myself, and other licensed speech therapists and students that will sign a form that will make sure that your identity is protected.

We will need to find out about your medical history from your chart located here at the center. You will be asked to sign a separate document (HIPAA form) to show that you give consent for us to access this information.

When we report the findings of this research, we report averages and aggregate data. You will not be identified in any report of this research.

TIME INVOLVEMENT: Your participation will take approximately 30 minutes, which is the normal length of a standard dysphagia therapy session.

HOW WILL RESULTS BE USED: The results of the study will be used for the researcher's doctoral dissertation. Findings from the study may be presented at professional conferences or written up for publication in professional journals. No names or identifying information will be used.

APPENDIX H

Teachers College, Columbia University
525 West 120th Street
New York NY 10027
212 678 3000
www.tc.edu

A STATEMENT OF PARTICIPANT'S RIGHTS

Principal Investigator: Stacy Gallese Cassel, M.S., CCC-SLP, ABD

Research Title: PATIENT RESPONSES TO SWALLOWING SAFETY CUES: A COMPARISON OF TRADITIONAL FACE-TO-FACE AND TELEPRACTICE INSTRUCTIONAL METHODS.

- I have read and discussed the Research Description with the researcher. I have had the opportunity to ask questions about the purposes and procedures regarding this study.
- My participation in research is voluntary. I may refuse to participate or withdraw from participation at any time without jeopardy to future medical care, employment, student status or other entitlements.
- The researcher may withdraw me from the research at his/her professional discretion.
- If, during the course of the study, significant new information that has been developed becomes available which may relate to my willingness to continue to participate, the investigator will provide this information to me.
- Any information derived from the research project that personally identifies me will not be voluntarily released or disclosed without my separate consent, except as specifically required by law.
- If at any time I have any questions regarding the research or my participation, I can contact the investigator, who will answer my questions. The investigator's phone number is (610) 213-6818.
- If at any time I have comments, or concerns regarding the conduct of the research or questions about my rights as a research subject, I should contact the Teachers College, Columbia University Institutional Review Board /IRB. The phone number for the IRB is (212) 678-4105. Or, I can write to the IRB at Teachers College, Columbia University, 525 W. 120th Street, New York, NY, 10027, Box 151.
- I should receive a copy of the Research Description and this Participant's Rights document.

- Written materials ( ) may be viewed in an educational setting outside the research

  ( ) may NOT be viewed in an educational setting outside the research.

- My signature means that I agree to participate in this study.

Participant's signature:
_____

Date:____/____/____

Name:
_____

APPENDIX I

Teachers College, Columbia University
525 West 120th Street
New York NY 10027
212 678 3000
www.tc.edu

Investigator's Verification of Explanation

I certify that I have carefully explained the purpose and nature of this research to _____ (participant's name) in age-appropriate language. He/She has had the opportunity to discuss it with me in detail. I have answered all his/her questions and he/she provided the affirmative agreement (i.e. assent) to participate in this research.

Investigator's Signature:
_____

Date: _____

Name:
_____

APPENDIX J

DYSPHAGIA SESSION DATA COLLECTION FORM

PARTICIPANT NUMBER / INITIALS: _____

SESSION FORMAT (CIRCLE ONE): Face-to-Face
Telepractice

DIET LEVEL: _____

TARGETED COMPENSATION: _____

INITIAL TRAINING COMPLETED WITH THREE SUCCESSFUL IMITATIONS (Must be demonstrated by participant): _____

TRIAL NUMBER	POSITIVE RESPONSE POST-CUE	NEGATIVE RESPONSE POST-CUE	INDEPENDENT WITH NO CUE

APPENDIX K

MEDICAL INTAKE FORM

PARTICIPANT NUMBER / INITIALS: _____

FUNCTIONAL COMMUNICATION SCALE (Check if demonstrated):

Level 5 — Attention _____
Level 4-6 – Memory _____
Level 5-6 — Language Comprehension _____
Level 4-5 – Swallowing _____

MEDICAL HISTORY:

CONFIRMED DYSPHAGIA DIAGNOSIS: _____

SWALLOWING COMPENSATION TARGETED: _____

APPENDIX L

CONFIRMATION OF PATIENT COMPREHENSION OF INVESTIGATION FORM

PARTICIPANT NUMBER / INITIALS: _____

1) Can you explain what this study will be examining?

_____

_____

_____

_____

2) Can you explain how your swallowing affects your safety when you eat?

_____

_____

_____

_____

3) What can happen if food or liquid enter your airway and/or lungs?

_____

_____

_____

_____

4) Can you explain how therapy can potentially help you eat more safely?

_____

_____

_____

_____

5) What specific technique was recommended to you in therapy to promote safety when you swallow food and/or liquid?

_____

_____

_____

_____

6) What will the information you provide be used for?

_____

_____

_____

_____

7) Are you interested in being a participant in this study?

8) If so, what questions do you have regarding this study?

_____

_____

_____

_____

APPENDIX M

Adults in Health Care

Functional Communication Measures (FCMs)

Speech-Language Pathology

AMERICAN SPEECH-LANGUAGE-HEARING ASSOCIATION

Functional Communication Measures

Introduction

The Functional Communication Measures (FCMs) are a series of 15 disorder-specific seven-point rating scales, ranging from least functional (Level 1) to most functional (Level 7). They have been developed by ASHA to describe the different aspects of a patient's functional communication and swallowing abilities over the course of speech-language pathology intervention and are part of ASHA's National Outcome Measurement System (NOMS) data collection and reporting tool.

In 2008, eight of the 15 FCMs from the NOMS Adult Healthcare data collection component were submitted to the National Quality Forum (NQF) (www.qualityforum.org) for review. All eight were endorsed and subsequently became available for use as part of the Centers for Medicare and Medicaid Services Physician Quality Reporting System. It is important to note that the FCMs are only one component of NOMS. To receive access to all of the components of NOMS – national database of treatment outcomes and customized data reports – your organization must subscribe to NOMS and become a registered NOMS site. If you would like to learn more about NOMS and register your organization to participate in data collection, visit www.asha.org/NOMS.

The following are the eight FCMs that were endorsed by NQF for use in the Physician Quality Reporting System.

- Attention
- Memory
- Motor Speech
- Reading
- Spoken Language Comprehension
- Spoken Language Expression
- Swallowing
- Writing

Description of Seven-Level FCM scoring

Each level of the FCMs contains references to the intensity and frequency of the cueing method and use of compensatory strategies that are required to assist the patient in becoming functional and independent in various situations and activities. Both the amount and intensity of the cueing must be considered in scoring an FCM. Familiarize yourself with the following descriptors and refer to them when scoring the FCM scales.

Frequency of Cueing

Consistent	Required 80-100% of the time.
Usually	50-79% of the time.
Occasionally	20-49% of the time.
Rarely	Less than 20% of the time.

Intensity of Cueing

Maximal	Multiple cues that are obvious to nonclinicians. Any combination of auditory, visual, pictorial, tactile, or written cues.
Moderate	Combination of cueing types, some of which may be intrusive.
Minimal	Subtle and only one type of cueing.

You will notice that the intensity and frequency of the cueing may be modified from one FCM level to another as the complexity of the information/task or situation increases.
Outlined below are some examples of general types of activities in which the patient may engage throughout the course of recovery. These are provided merely for illustration and are not intended as must-do activities for rating a patient at a particular FCM level.

Simple routine living activities	Basic self-care activities that most adults carry out every day: following simple directions; eating a meal; and completing personal hygiene, dressing, etc.
Complex living activities	Changing a flat tire; reading a book; planning and preparing a meal; and managing one's own medical, financial, and personal affairs, etc.

We tried as much as possible to ensure consistency among similar levels of performance on the various FCM scales; however, this was not always possible given the nature of the different aspects of communication and swallowing abilities. For example, do not assume that a Level 5 on one scale is comparable to a Level 5 on a different scale.

Attention

Note: *The following are some examples of living activities as used with this FCM:*

Simple living activities	*following simple directions, reading environmental signs, eating a meal, completing personal hygiene, and dressing.*
Complex living activities	*watching a news program, reading a book, planning and preparing a meal, and managing one's own medical, financial, and personal affairs.*

LEVEL 1: Attention is nonfunctional. The individual is generally unresponsive to most stimuli.

LEVEL 2: The individual can briefly attend with consistent maximal stimulation, but not long enough to complete even simple living tasks.

LEVEL 3: The individual maintains attention over time to complete simple living tasks of short duration with consistent maximal cueing in the absence of distracting stimuli.

LEVEL 4: The individual maintains attention during simple living tasks of multiple steps and long duration within a minimally distracting environment with consistent minimal cueing.

LEVEL 5: The individual maintains attention within simple living activities with occasional minimal cues within distracting environments. The individual requires increased cueing to start, continue, and change attention during complex activities.

LEVEL 6: The individual maintains attention within complex activities and can attend simultaneously to multiple demands with rare minimal cues. The individual usually uses compensatory strategies when encountering difficulty. The individual has mild difficulty or takes more than a reasonable amount of time to attend to multiple tasks/stimuli.

LEVEL 7: The individual's ability to participate in vocational, avocational, or social activities is not limited by attentional abilities. Independent functioning may occasionally include the use of compensatory strategies.

Memory

Note: *The following terms are used with this FCM:*

External Memory Aid	*calendars*, *schedules*, *communication/ memory books*, *pictures*, *color coding*.
Memory Strategies	*silent rehearsals*, *word associations*, *chunking*, *mnemonic strategies*.

LEVEL 1: The individual is unable to recall any information, regardless of cueing.

LEVEL 2: The individual consistently requires maximal verbal cues or uses external aids to recall personal information (e.g., family members, biographical information, physical location, etc.) in structured environments.

LEVEL 3: The individual usually requires maximal cues to recall or use external aids for simple routine and personal information (e.g., schedule, names of familiar staff, location of therapy areas, etc.) in structured environments.

LEVEL 4: The individual occasionally requires minimal cues to recall or use external memory aids for simple routine and personal information in structured environments. The individual requires consistent maximal cues to recall or use memory aids for complex and novel information (e.g., carry out multiple steps activities, accommodate schedule changes, anticipate meal times, etc.), plan and follow through on simple future events (e.g., use calendar to keep appointments, use log books to complete a single assignment/task, etc.) in structured environments.

LEVEL 5: The individual consistently requires minimal cues to recall or use external memory aids for complex and novel information. The individual consistently requires minimal cues to plan and follow through on complex future events (e.g., menu planning and meal preparation, planning a party, etc.).

LEVEL 6: The individual is able to recall or use external aids/memory strategies for complex information and planning complex future events most of the time. When there is a breakdown in the use of recall/memory strategies/external memory aids, the individual occasionally requires minimal cues. These breakdowns may

occasionally interfere with the individual's functioning in vocational, avocational, and social activities.

LEVEL 7: The individual is successful and independent in recalling or using external aids/memory strategies for complex information and planning future events in all vocational, avocational, and social activities.

Motor Speech

***Note**: Individuals who exhibit deficits in speech production may exhibit underlying deficits in respiration, phonation, articulation, prosody, and resonance. In some instances it may be beneficial to utilize additional FCMs focusing on voice if disordered phonation is a large component.*

LEVEL 1: The individual attempts to speak, but speech cannot be understood by familiar or unfamiliar listeners at any time.

LEVEL 2: The individual attempts to speak. The communication partner must assume responsibility for interpreting the message, and with consistent and maximal cues, the patient can produce short consonant-vowel combinations or automatic words that are rarely intelligible in context.

LEVEL 3: The communication partner must assume primary responsibility for interpreting the communication exchange; however, the individual is able to produce short consonant–vowel combinations or automatic words intelligibly. With consistent and moderate cueing, the individual can produce simple words and phrases intelligibly, although accuracy may vary.

LEVEL 4: In simple structured conversation with familiar communication partners, the individual can produce simple words and phrases intelligibly. The individual usually requires moderate cueing in order to produce simple sentences intelligibly, although accuracy may vary.

LEVEL 5: The individual is able to speak intelligibly using simple sentences in daily routine activities with both familiar and unfamiliar communication partners. The individual occasionally requires minimal cueing to produce more complex sentences/messages in routine activities, although accuracy may vary and the individual may occasionally use compensatory strategies.

LEVEL 6: The individual is successfully able to communicate intelligibly in most activities, but some limitations in intelligibility are still apparent in vocational, avocational, and social activities. The individual rarely requires minimal cueing to produce complex sentences/messages intelligibly. The individual usually uses compensatory strategies when encountering difficulty.

LEVEL 7: The individual's ability to successfully and independently participate in vocational, avocational, or social activities is not limited by speech production. Independent functioning may occasionally include the use of compensatory techniques.

Reading

LEVEL 1: The individual attends to printed material, but doesn't recognize even single letters or common words.

LEVEL 2: The individual reads single letters and common words with consistent maximal cueing.

LEVEL 3: The individual reads single letters and common words, and with consistent moderate cueing, can read some words that are less familiar, longer, and more complex.

LEVEL 4: The individual reads words and phrases related to routine daily activities and words that are less familiar, longer, and more complex. The individual usually requires moderate cueing to read sentences of approximately 5–7 words.

LEVEL 5: The individual reads sentence-level material containing some complex words. The individual occasionally requires minimal cueing to read more complex sentences and paragraph-level material. The individual occasionally uses compensatory strategies.

LEVEL 6: The individual is successfully able to read most material but some limitations in reading are still apparent in vocational, avocational, and social activities. The individual rarely requires minimal cueing to read complex material. Although reading is successful, it may take the individual longer to read the material. The individual usually uses compensatory strategies when encountering difficulty.

LEVEL 7: The individual's ability to successfully and independently participate in vocational, avocational, and social activities is not limited by reading skills. Independent functioning may occasionally include use of compensatory strategies.

Spoken Language Comprehension

LEVEL 1: The individual is alert, but unable to follow simple directions or respond to yes/no questions, even with cues.

LEVEL 2: With consistent, maximal cues, the individual is able to follow simple directions, respond to simple yes/no questions in context, and respond to simple words or phrases related to personal needs.

LEVEL 3: The individual usually responds accurately to simple yes/no questions. The individual is able to follow simple directions out of context, although moderate cueing is consistently needed. Accurate comprehension of more complex directions/messages is infrequent.

LEVEL 4: The individual consistently responds accurately to simple yes/no questions and occasionally follows simple directions without cues. Moderate contextual support is usually needed to understand complex sentences/messages. The individual is able to understand limited conversations about routine daily activities with familiar communication partners.

LEVEL 5: The individual is able to understand communication in structured conversations with both familiar and unfamiliar communication partners. The individual occasionally requires minimal cueing to understand more complex sentences/messages. The individual occasionally initiates the use of compensatory strategies when encountering difficulty.

LEVEL 6: The individual is able to understand communication in most activities, but some limitations in comprehension are still apparent in vocational, avocational, and social activities. The individual rarely requires minimal cueing to understand complex sentences. The individual usually uses compensatory strategies when encountering difficulty.

LEVEL 7: The individual's ability to independently participate in vocational, avocational, and social activities is not limited by spoken language comprehension. When difficulty with comprehension occurs, the individual consistently uses a compensatory strategy.

Spoken Language Expression

Note: *This FCM should not be used for individuals using an augmentative/alternative communication system.*

LEVEL 1: The individual attempts to speak, but verbalizations are not meaningful to familiar or unfamiliar communication partners at any time.

LEVEL 2: The individual attempts to speak, although few attempts are accurate or appropriate. The communication partner must assume responsibility for structuring the communication exchange, and with consistent and maximal cueing, the individual can only occasionally produce automatic and/or imitative words and phrases that are rarely meaningful in context.

LEVEL 3: The communication partner must assume responsibility for structuring the communication exchange, and with consistent and moderate cueing, the individual can produce words and phrases that are appropriate and meaningful in context.

LEVEL 4: The individual is successfully able to initiate communication using spoken language in simple, structured conversations in routine daily activities with familiar communication partners. The individual usually requires moderate cueing, but is able to demonstrate use of simple sentences (i.e., semantics, syntax, and morphology) and rarely uses complex sentences/messages.

LEVEL 5: The individual is successfully able to initiate communication using spoken language in structured conversations with both familiar and unfamiliar communication partners. The individual occasionally requires minimal cueing to frame more complex sentences in messages. The individual occasionally self-cues when encountering difficulty.

LEVEL 6: The individual is successfully able to communicate in most activities, but some limitations in spoken language are still apparent in vocational, avocational, and social activities. The individual rarely requires minimal cueing to frame complex sentences. The individual usually self-cues when encountering difficulty.

LEVEL 7: The individual's ability to successfully and independently participate in vocational, avocational, and social activities is not limited by

spoken language skills. Independent functioning may occasionally include use of self-cueing.

Swallowing

Note: *In Levels 3–5, some patients may meet only one of the "and/or" criteria listed. If you have difficulty deciding on the most appropriate level for an individual, use dietary level as the most important criterion if the dietary level is the result of swallow function rather than dentition only. Dietary levels at FCM Levels 6 and 7 should be judged only on swallow function, and any influence of poor dentition should be disregarded.*

LEVEL 1: Individual is not able to swallow anything safely by mouth. All nutrition and hydration are received through non-oral means (e.g., nasogastric tube, PEG).

LEVEL 2: Individual is not able to swallow safely by mouth for nutrition and hydration, but may take some consistency with consistent maximal cues in therapy only. Alternative method of feeding is required.

LEVEL 3: Alternative method of feeding is required as individual takes less than 50% of nutrition and hydration by mouth, and/or swallowing is safe with consistent use of moderate cues to use compensatory strategies and/or requires maximum diet restriction.

LEVEL 4: Swallowing is safe, but usually requires moderate cues to use compensatory strategies, and/or the individual has moderate diet restrictions and/or still requires tube feeding and/or oral supplements.

LEVEL 5: Swallowing is safe with minimal diet restriction and/or occasionally requires minimal cueing to use compensatory strategies. The individual may occasionally self-cue. All nutrition and hydration needs are met by mouth at mealtime.

LEVEL 6: Swallowing is safe, and the individual eats and drinks independently and may rarely require minimal cueing. The individual usually self-cues when difficulty occurs. May need to avoid specific food items (e.g., popcorn and nuts) or require additional time (due to dysphagia).

LEVEL 7: The individual's ability to eat independently is not limited by swallow function. Swallowing would be safe and efficient for all consistencies. Compensatory strategies are effectively used when needed.

Diet levels/restrictions are defined on the next page. Your facility's levels may not exactly match these, but please use these levels as a guide in scoring this FCM.

Swallowing FCM continued

Swallowing: Dietary Levels/Restrictions

Maximum restrictions: Diet is two or more levels below a regular diet status in solid and liquid consistency.

Moderate restrictions: Diet is two or more levels below a regular diet status in either solid or liquid consistency (but not both), OR diet is one level below in both solid *and* liquid consistency.

Minimum restrictions: Diet is one level below a regular diet status in solid *or* liquid consistency.

Solids

Regular: No restrictions.

Reduced one level: Meats are cooked until soft, with no tough or stringy foods. Might include meats like meat loaf, baked fish, and soft chicken. Vegetables are cooked soft.

Reduced two levels: Meats are chopped or ground. Vegetables are of one consistency (e.g., soufflé, baked potato) or are mashed with a fork.

Reduced three levels: Meats and vegetables are pureed.

Liquids

Regular: Thin liquids; no restrictions.

Reduced one level: Nectar, syrup; mildly thick.

Reduced two levels: Honey; moderately thick.

Reduced three levels: Pudding; extra thick.

Writing

Note: *This FCM should not be used for individuals using an augmentative-alternative communication system. References made here to the writing of words assume that the words are spelled correctly.*

LEVEL 1: The individual attempts to write, but doesn't produce recognizable single letters or common words.

LEVEL 2: The individual writes single letters and common words with consistent maximal cueing.

LEVEL 3: The individual writes single letters and common words, and with consistent moderate cueing, can write some words that are less familiar, longer, and more complex.

LEVEL 4: The individual writes words and phrases related to routine daily activities and words that are less familiar, longer, and more complex. The individual usually requires moderate cueing to write sentences of approximately 5–7 words.

LEVEL 5: The individual writes sentence-level material containing some complex words. The individual occasionally requires minimal cueing to write more complex sentences and paragraph-level material. The individual occasionally uses compensatory strategies.

LEVEL 6: The individual is successfully able to write most material, but some limitations in writing are still apparent in vocational, avocational, and social activities. The individual rarely requires minimal cueing to write complex material. The individual usually uses compensatory strategies when encountering difficulty.

LEVEL 7: The individual's ability to successfully and independently participate in vocational, avocational, and social activities is not limited by writing skills. Independent functioning may occasionally include use of compensatory strategies.