Speech-Language Pathologists' Ratings of Airway Protection Behaviors and Treatment

Recommendations for Dysphagia

By

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ABSTRACT

This study investigated speech-language pathologists' (SLPs) ability to utilize a novel 5-point airway protection scale (APS) when reviewing FEES videos, the frequency of airway protection behaviors visualized during FEES, and SLP practice patterns regarding the recommendation of modified texture diets (MTDs) for the improvement of airway protection. Five SLPs—trained in the use of the APS—were recruited to determine if they could reliably analyze FEES videos with the APS. For both scoring sessions, inter-rater reliability was "almost perfect" ($\kappa = .91$; 95% CI, .881 to .939, p < .0005) and intra-rater reliability was "substantial" ($\kappa = .80$) for one rater and was "almost perfect" ($\kappa = .95 - 1.0$) for the remaining four raters.

After determining that these five SLPs could reliably utilize the APS, a medical records review of their FEES reports was completed. Four hundred seventy-seven FEES reports, totaling 25% of all reports created from January 1, 2023 to January 1, 2024, were randomly sampled. There was a significant association between sex and APS scores (p < .001). Despite accounting for only 43.4% of the sample, females accounted for 53.8% (n = 769) of all scores of APS "2," which indicates a functionally normal airway protection score. APS scores of "5" denote the most severe complication for airway protection behaviors, and males accounted for 62.8% (n = 201) of all APS "5" scores.

SLPs who treat dysphagia recommend MTDs to prevent airway protection issues like laryngeal penetration and aspiration that can lead to severe pulmonary complications. A survey of clinical practice patterns indicated that over 90% of respondents recommend MTDs when needed. However, the use of the MTDs is not without risk. Indisputably, the use of MTDs can cause significant and systemic health risks. Hence, informed consent for the use of MTDs in healthcare settings is required. However, when surveyed about the negative health outcomes associated with consuming MTD, SLPs demonstrated poor understanding of hazards associated with MTDs—calling into question the ability of SLPs to fully inform their patients regarding the standard practice of recommending MTDs to prevent pulmonary complications.

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LIST OF ABBREVIATIONS

Abbreviation	Definition
OD	Oropharyngeal Dysphagia
SLP	Speech-Language Pathologist
QOL	Quality of Life
MTD	Modified Texture Diet
ANOVA	Analysis of Variance
APS	Airway Protection Scale
PAS	Penetration Aspiration Scale
FEES	Flexible Endoscopic Evaluation of Swallowing
VFSS	Videofluoroscopic Swallow Study
IDDSI	International Dysphagia Diet Standardization Initiative
IRB	Institutional Review Board

CHAPTER I INTRODUCTION

There are many life-sustaining processes that humans take for granted. Chief among the seemingly mundane bodily functions that garner little, if any, attention is swallowing. Swallowing begins in utero, occurs roughly 600 times per day, and remains intact until death (Doty, 1951; Matsuo & Palmer, 2009). Similar to other vital homeostatic functions like breathing and heartrate, swallowing is an automatic process that operates largely without conscious control (King et al., 2020; Oku, 2020).

Normal swallowing comprises the rhythmic, complex, and coordinated movement of over 25 pairs of muscles that are innervated by five cranial nerves and the first three spinal nerves (Vose & Humbert, 2018). Sensorimotor input from multiple cortical, subcortical, and brainstem structures further modulates and refines the reflexive swallow based on characteristics of solids or liquids that are swallowed—allowing the upper respiratory tract briefly to transform into an alimentary tract (Steele & Miller, 2010). While swallowing is a pivotal process—because it allows the dissemination of nutrients and water to cells throughout the body—eating and drinking also provide psychological, social, and cultural benefits (Gibson et al., 2020; Patterson et al., 2021; Sadeghi et al., 2021).

Dysphagia is the medical term that applies to any kind of difficulty with swallowing throughout the upper digestive tract (Spieker, 2000). More specifically, oropharyngeal dysphagia (OD) refers to any difficulty with the efficiency of swallowing—which can result in malnutrition and dehydration—or problems protecting the airway during swallowing (Clave et al., 2004). Difficulty with airway protection is a primary cause for medical intervention, because it can cause aspiration—which can lead to severe pulmonary complications such as chest infections (Mandell & Niederman, 2019).

Two terms are routinely utilized to describe problems with airway protection: laryngeal penetration and aspiration. Laryngeal penetration is operationally defined as entry of any material into the laryngeal vestibule that does not fall below the vocal folds (Robbins et al., 1992). Aspiration occurs when material moves below the plane of the vocal folds and enters the trachea (Rosenbek et al., 1996). Both laryngeal penetration and aspiration, when occurring intermittently and with appropriate reflexive responses, can be considered parts of normal swallowing function and can occur without the development of chest infections. However, certain diseases and disease processes increase the likelihood of developing pulmonary complications from OD (Ashford, 2005; Dickson & Huffnagle, 2015; Feinberg et al., 1996; Langmore et al., 1998; Prass et al., 2003).

Prevalence and Costs of Oropharyngeal Dysphagia

The prevalence of OD in healthy community dwelling individuals is underreported and difficult to estimate. Data is available for hospitals and post-acute care facilities—where 0.35% of all hospitalizations are associated with dysphagia (Altman et al., 2010) and rates of dysphagia in post-acute care facilities range from 55% (Cichero & Altman, 2012) to 68% (Steele et al., 1997). Furthermore, aspiration occurs in roughly 23% of patients admitted to acute hospitals (Leder & Suiter, 2014), while aspiration in post-acute care facilities is reported to be 55% (Ward et al., 2020). The frequency of dysphagia also increases with age (Altman et al., 2010; Cabré et al., 2009), presenting a significant public health problem for aging populations in industrialized countries. Even though OD is not a primary disease process, the development of OD in any medical setting places a significant burden on the healthcare system, causes negative psychosocial outcomes, and increases morbidity and mortality (Feng et al., 2019; Hong & Yoo, 2017; Jones et al., 2018; Rönnefarth et al., 2020; Tan et al., 2021).

Conservative estimates reveal that dysphagia adds an average of 1.64 days to length of stay during hospitalization, which results in 223,027 additional hospital days attributed to dysphagia alone—having an estimated economic impact of \$547,307,964 annually (Altman et al., 2010). Few studies have quantified an exact dollar amount associated with OD in hospitalized patients on a per patient basis, but Westmark et al. (2018) found that the average cost during a hospitalization for patients with dysphagia over age 60—was \$4,284 dollars higher than hospitalizations for patients who did not have dysphagia. Further, Medicare reimbursement data indicate that individuals with post-stroke OD had an increased average cost of \$4,510 more than individuals who did not have post-stroke OD, and this increase in cost was attributable to OD alone (Bonilha et al., 2014).

Quality of life (QOL), typically determined by patient surveys, consistently diminishes for individuals with OD—regardless of the underlying etiology of the swallowing problems (Chen et al., 2018; Hong & Yoo, 2017; Kim et al., 2020; Tan et al., 2021). In patients with cerebellar ataxia and dysphagia, unintentional weight loss and reduced health QOL were reported (Wu et al., 2020). When consuming MTDs due to dysphagia, patients report significantly decreased quality of life (Beck et al., 2018; Robbins et al., 2008). MTDs can refer to the alteration of solid diet textures or liquid viscosities, and these alterations to food and liquid are part of the standard treatment regimen for individuals with OD. Studies, spanning more than two decades, demonstrate that patients dislike MTDs, which often results in decreased oral intake (Garon et al., 1997; Logemann et al., 2008; Murray et al., 2014).

Etiology of Dysphagia

In health, swallowing is a highly coordinated motor pattern that results in the safe and efficient movement of food and liquid through the pharynx, past a temporarily closed airway, and into the esophagus—in order to maintain nutrition and hydration (Vose & Humbert, 2018). There are very few medical conditions that cannot cause or aggravate dysphagia (Carucci & Turner, 2015). As such, there is no exhaustive list of etiologies that precede dysphagia. Dysphagia can occur when there is impairment of the central or peripheral nervous system (De Cock et al., 2020; Warnecke et al., 2021), muscle weakness (Liaw et al., 2020), disorders of muscle coordination (Rönnefarth et al., 2020), discoordination between breathing and swallowing (Darwich et al., 2019), or structural alterations to normal anatomy (Manikantan et al., 2009). Further, swallowing is a neuromuscular process, and any systemic inflammation or increased body temperature can negatively impact nerve conduction and muscle function (Zeng & Schmidt, 2020). Ultimately, dysphagia can occur as the result of a multitude of diseases, disease processes, or medical conditions.

Dysphagia Risk Assessment

OD is evaluated and treated chiefly by speech-language pathologists (SLPs). OD risk assessments can be broken down into two categories: non-instrumental and instrumental. Non-instrumental evaluations consist of standardized or non-standardized protocols that use behavioral information (e.g., bedside cranial nerve exam, wet vocal quality, dysphonia, coughing after drinking, etc.) to determine the probability that a patient has OD. Although the literature is clear that non-instrumental assessments have poor sensitivity and specificity (Coyle, 2015; Leder, 2015; Leder & Espinosa, 2002; McCullough et al., 2005; O'horo et al., 2015; Rosenbek et al., 2004; Steele et al., 2011), many SLPs utilize these tests to diagnose OD and recommend treatment options (O'horo et al., 2015).

Instrumental assessments of swallowing allow for direct visualization of oropharyngeal anatomy and physiology. Of these diagnostic assessments, videofluoroscopic swallow studies (VFSS) and flexible endoscopic evaluations of swallowing (FEES) represent two "gold standard" tests for OD (Brady & Donzelli, 2013). In 1983, Logemann was the first to describe the process of assessing swallowing using VFSS (Logemann, 1983), and Langmore et al. published the first article on FEES in 1988 (Langmore et al., 1988). However, no standardized protocol was initially developed for either VFSS or FEES. It was not until 2008, 25 years after initial publication, that standardized administration and scoring protocols were created for VFSS (Martin-Harris et al., 2008), but a uniform and validated administration protocol for FEES has yet to be developed (Miller et al., 2020). This lack of control results in inaccuracies in diagnosis and reporting, misdiagnosis, poor treatment outcomes, increased economic cost, and decreased QOL (Vose et al., 2018).

Outcome Measures for Oropharyngeal Dysphagia

OD causes significant medical complications and can result in malnutrition, dehydration, asphyxiation, aspiration, pneumonia, and death (Cabré et al., 2013; Cabré et al., 2009; Cichero & Altman, 2012; Ferguson et al., 2018; Heckert et al., 2009; Kumar et al., 2010; Son et al., 2017). Pneumonia typically receives the greatest amount of attention from SLPs, doctors, nurses, and other medical professionals, because it increases morbidity and mortality. However, OD places all patients at risk for malnutrition and dehydration—both of which have systemic, deleterious effects. Malnutrition alone can increases mortality (Cederholm et al., 1995; Kawakami et al., 1999). Moreover, dehydration from OD is often insidious in the elderly (Feinsod et al., 2004) and causes significant issues such as pneumonia, urinary tract infections, and renal failure (Lavizzo-Mourey, 1987).

Reliable and Valid Measurement Scales for Airway Protection

While VFSS and FEES are both diagnostic tests that enable direct visualization of the pharynx during swallowing, these two diagnostic tests view the pharynx in significantly different ways. VFSS utilizes radiation and barium contrast primarily in the lateral and anterior-posterior plane of view, while FEES employs endoscopic technology to garner uninterrupted video images of a superior-inferior view of the pharynx (Langmore et al., 1988; Logemann, 1983). As VFSS was developed five years prior to FEES, tools for the analysis of airway protection were first developed for VFSS. Due to the different fields of view in these two diagnostic tests, rating scales for airway protection—which are utilized by SLPs who interpret VFSS and FEES—are not necessarily interchangeable.

Originally, an 8-point rating scale for laryngeal penetration and aspiration was developed for VFSS (Rosenbek et al., 1996). This scale can be reliably utilized for FEES (Butler et al., 2015). However, it has not been validated for use with FEES outside of the head and neck cancer population (Starmer et al., 2021). Also, statistical analysis revealed the 8-point scale is not ordinal in nature—as was originally thought—but is in fact descriptive. Further, scores of 4 and 6 are rarely utilized and demonstrate poor statistical reliability (Steele & Grace-Martin, 2017). Thus, the use of the 8-point scale with FEES is suboptimal, and the 5-point APS was developed for internal use when analyzing FEES videos.

Normal Swallowing, Disordered Swallowing, and Overall Dysphagia Severity

The larynx performs two key functions: making sounds for speech and protecting the airway during swallowing (Berke & Long, 2010). SLPs began treating swallowing disorders in 1972, but those early interventions were focused on individuals who already had symptoms of dysphagia (Larsen, 1972). Prior to 1972, SLPs were not involved in the medical treatment of dysphagia in any meaningful way. However, since SLPs were expertly trained in the workings of the larynx, it was hypothesized that they could assist individuals with OD who had difficulty protecting their airway—due to impaired laryngeal function—during swallowing. A major problem with beginning by treating individuals who already had dysphagia is that SLPs and other medical professionals did not have an understanding of normal swallowing physiology. Hence, it was assumed that many of the behaviors witnessed by very sick individuals were symptoms of OD—despite not having catalogues of normal swallowing behaviors. It was not until the early 2000s that researchers began to develop large-scale databases of normal swallowing behaviors in healthy individuals (Susan G Butler et al., 2009; Martin-Harris et al., 2008).

Research into normative swallowing data for healthy individuals continues to this day for both VFSS and FEES (Curtis et al., 2023; Humbert et al., 2009; Humbert et al., 2018; Jardine et al., 2020). The development of operational definitions for normal swallowing in healthy adults allows SLPs to distinguish between normal and aberrant swallowing behaviors (Humbert & Robbins, 2007; Kendall et al., 2000). Currently, a robust amount of information regarding normal swallowing behaviors exists in the research literature, and SLPs have access to normative data based on age and sex. Hence, the line between normal swallowing and OD appears fairly well-established (Bahia & Lowell, 2020).

Regardless of the underlying medical cause, the severity of any disease typically determines the extent of interventions suggested to the unwell individual (Kang et al., 2023; Krekeler et al., 2020; Minneci et al., 2009). Determining the severity of OD is complex, because there is great variability in swallowing across the lifespan (Humbert et al., 2018; Jones et al., 2021), which can confound SLPs attempting to discern the severity of OD. For VFSS, the Dysphagia Outcome Severity Scale was developed to assist SLPs

in defining the severity of an individual's dysphagia (O'Neil et al., 1999). For FEES, the Dynamic Imaging Grade of Swallowing Toxicity for Flexible Endoscopic Evaluation of Swallowing (DIGEST-FEES) was created, but it is valid only for use with the head and neck cancer population (Hutcheson et al., 2017; Starmer et al., 2021). This limitation of the DIGEST-FEES significantly constrains its clinical utility for SLPs who treat OD, because OD is secondary to a wide variety of virtually limitless etiologies. Hence, there is limited information for SLPs about the frequency of airway protection behaviors for individuals with OD, making it difficult to determine the severity of OD. In turn, this dearth of information impairs an SLP's ability to differentiate the risks of non-treatment versus the risks of treatment of OD with the standard practice of prescribing MTDs.

Negative Health Outcomes Associated with MTDs

The most frequently prescribed treatment for airway protection issues caused by OD is the modification of solid textures and liquid viscosities (Campbell-Taylor, 2008; O'Keeffe, 2018). The use of MTDs in a medical setting, which can include modification of liquid viscosity alone, requires informed consent from patients (O'Keeffe et al., 2023). Yet, SLPs are not required to receive training in the outcomes associated with the use of MTDs (Bice et al., 2022).

The consumption of MTDs is associated with multiple negative health outcomes. These can be significant, and they include: malnutrition (Maeda et al., 2019; Martín et al., 2018; Miles et al., 2019; Okabe et al., 2016), dehydration (Wu et al., 2021), poor recovery from illness (Ahmed & Haboubi, 2010; Mukand et al., 2003), and decreased QOL (Leow et al., 2010; Swan et al., 2015). Side effects specific to the use of thickened liquids include: dehydration (Cichero, 2013; Reber et al., 2019), respiratory infection (Wotton et al., 2008), poor recovery from illness (Ahmed & Haboubi, 2010; Mukand et al., 2003), constipation, urinary tract infection, slow digestion, ability to interfere with medication absorption, constant feeling of thirst (Cichero, 2013), and decreased QOL (Leow et al., 2010; Swan et al., 2015).

SLP Training Regarding the Utilization of MTDs

Despite their ubiquitous use, SLP undergraduate and graduate programs are not required to include training specific to the use of MTDs (Bice et al., 2022; Bice et al., 2024). Hence, a significant percentage of SLPs are likely to graduate and enter the workforce without rigorous preparation regarding the whole-body and systemic impacts of eating and drinking MTDs. Professional surveys of clinical practice patterns of SLPs who treat OD reflect this lack of training—wherein the majority of SLPs report no more than informal training about the use of MTDs (Garcia et al., 2018). This informal training for professionals, including SLPs, consist mainly of having someone at their job explain MTDs to them. Despite lacking evidence to support their use and despite the many negative health outcomes associated with eating and drinking MTDs, SLPs appear to have little formal training regarding their use.

Purpose

There is a gap in the OD literature related to two overlapping themes. First, the analysis of FEES videos requires reliable and valid rating scales that are designed specifically for FEES and can be utilized with any individual suspected of having OD. Second, SLPs routinely prescribe MTDs for individuals with OD who demonstrate issues with airway protection. While there is ample evidence in the literature regarding normal swallowing behaviors of healthy individuals, minimal data exists on the rate of airway protection issues in individuals suspected of having OD or already confirmed of having OD.

Consequently, this research project explored three facets of SLP interventions with individuals who have OD: the reliability of the APS for FEES, the frequency of airway protection behaviors captured with the APS during FEES for individuals already screened for OD, and SLPs use of MTDs for treatment of airway protection issues related to disordered swallowing. The findings are presented in three articles.

Article 1

SLPs developed a novel 5-point airway protection scale (APS) that was designed specifically for FEES and can be utilized with any patient population or subgroup. This scale is utilized clinically by SLPs who analyze FEES studies, but the reliability and validity of the scale have yet to be established. A pilot reliability study was completed to determine if the scale could be consistently and effectively utilized by SLPs already trained in its use. The study investigated inter-rater and intra-rater reliability for the use of the APS for FEES video files among five different SLPs.

Article 2

After the reliability of the APS was established, the frequency of airway protection behaviors witnessed during FEES was investigated. Stores of normal swallowing behaviors viewed during FEES in healthy adults exists throughout the research literature, and this provides a clear delineation of the binary distinction between normal and disordered swallowing (Curtis et al., 2023; Jardine et al., 2020). However, to date, little information has been published regarding the frequency of airway protection behaviors witnessed during FEES for patients who were previously screened for dysphagia.

In order to differentiate between OD and normal swallowing behaviors, SLPs rely on data collected from healthy adults who do not have OD. However, SLPs who treat individuals with OD, also require an understanding of the frequency of airway protection behaviors—such as laryngeal penetration and tracheal aspiration—in order to determine the severity of OD. Without data regarding the behaviors typically seen in individuals with OD, clinicians are unable to test the efficacy of their swallowing interventions. To this end, 477 patients who received FEES as part of their standard dysphagia evaluation and care were randomly sampled, and their airway protection behaviors were recorded by five SLPs who routinely utilize the APS.

Article 3

When there is an observed or suspected impairment in airway protection due to OD, the most common recommendation from an SLP is for individuals with dysphagia to consume MTDs (which can include alterations to both solids and liquids). Over 90% of SLPs surveyed indicate that they recommend MTDs for treatment of OD (see tables in chapter IV for exact figures). However, there is little evidence to suggest that these changes in solid textures or liquid viscosities caused by the prescription of MTDs reduces the risk of pulmonary infection (Abdelhamid et al., 2016; Alagiakrishnan et al., 2013;

Andersen et al., 2013; Bassis et al., 2015; Beck et al., 2018; Bilney et al., 2003; Campbell-Taylor, 2008; Feinberg et al., 1996; Foley et al., 2008; Hansen et al., 2022; Hanson et al., 2011; Hines et al., 2010; Loeb et al., 2003; Painter et al., 2017; Sakashita et al., 2014; Speyer et al., 2010; Thomas, 2008; Vogel et al., 2015); yet, preventing pneumonia is the primary reason that MTDs are typically prescribed. Despite the limited evidence to support their efficacy, the alteration of solid textures and liquid viscosity remains the most common intervention prescribed for OD treatment by SLPs (Chen et al., 2021; Chiang & Hwu, 2018; Hines et al., 2010; Levenson & Walker, 2019; Luk & Chan, 2014; Mesioye et al., 2018; Morley, 2015; Painter et al., 2017; Park et al., 2015; Yamada et al., 2017).

As with any medical intervention, these changes to an individual's diet are not without risk (O'Keeffe, 2018), and informed consent is required for the use of MTDs in medical settings (O'Keeffe et al., 2023). While SLPs have extensive training in diagnosing and rehabilitating OD at the graduate level, there is no requirement that SLPs receive training on the impact that MTDs have on body systems and whole-body homeostasis (Affoo et al., 2020; Bice et al., 2022). Over the past twenty-five years, multiple well-designed and replicated studies have illuminated multiple negative health outcomes associated with MTDs (Andersen et al., 2013; Cichero, 2013; Feinberg et al., 1996; Feinsod et al., 2004; Hines et al., 2010; Murray et al., 2014; Robbins et al., 2008; Wu et al., 2020). Due to the known issues with MTDs and the lack of any requirement for SLP training regarding the hazards associated with MTDs, a central question remains: do SLPs possess the knowledge required to fully inform individuals of the risks associated with MTDs versus the risks associated with non-treatment of OD?

CHAPTER II THE RELIABILITY OF A NOVEL 5-POINT AIRWAY PROTECTION SCALE FOR FEES

Introduction

Swallowing is a dynamic sensorimotor process that begins in utero and is one of the final physiological events preceding death (Doty, 1951). During swallowing, the pharynx transforms by converting the shared aerodigestive tract to an alimentary pathway, which is achieved by the coordinated movement of more than 25 pairs of muscles, which are innervated by five cranial nerves and the cervical plexus (Vose & Humbert, 2018). This highly automated, precise, and coordinated cascade of movements allows saliva, food, and liquid to rapidly pass by a closed airway—eliminating the risk of choking or aspirating. Healthy swallowing occurs over 600 times daily and is necessary for the delivery of nutrients and water to the digestive system to maintain homeostasis (Matsuo & Palmer, 2009). Disordered airway protection during swallowing can result in choking, aspiration, malnutrition, dehydration, pneumonia, and other respiratory complications (Cabib et al., 2016; Hilker et al., 2003; Martino et al., 2005). Yet, quantifying airway protection during such a rapid and dynamic process has proven historically to be a difficult task.

Instrumental assessment of swallowing—via a video fluoroscopic swallow study (VFSS) or flexible endoscopic evaluation of swallowing (FEES)—remain the two "gold standard" evaluations for disorders of swallowing and airway protection (Brady & Donzelli, 2013). In 1996, an 8-point penetration-aspiration scale (PAS) was developed to describe airway protection behaviors observed during VFSS (Rosenbek et al., 1996).

Further investigations into the PAS revealed that scores of 4 and 6 were rarely utilized and had poor statistical reliability (Steele & Grace-Martin, 2017). Despite studies indicating adequate reliability for clinicians utilizing the PAS with FEES (Susan G Butler et al., 2009; Colodny, 2002; Kelly et al., 2007), the PAS was not validated for use when analyzing FEES videos.

Several studies tailored FEES scoring protocols for specific patient populations such as stroke or head and neck cancer (Langmore, 2017; Starmer et al., 2021; Warnecke et al., 2014; Warnecke et al., 2010; Warnecke et al., 2009; Warnecke et al., 2008). However, OD is secondary to a wide array of underlying etiologies, with no single cause accounting for more than 11% of the total cases (Bhattacharyya, 2014). Hence, to be clinically viable, any scoring system must be validated for use with a heterogenous population. To this end, a novel 5-point airway protection scale (APS) was developed by SA Swallowing Services for the scoring and analysis of FEES videos. The APS has been used clinically and for educational purposes since 2018 on patients with OD from virtually all diagnostic categories—including general medical, pulmonary, head and neck cancer, stroke, Parkinson's disease, and dementia—but the reliability of the scale among various raters has not been investigated. The aim of the current pilot study is to determine if the APS can be reliably used to describe airway protection behaviors during FEES.

Methods

Participants

Five SLPs trained in the use of the APS were recruited. All participants were trained in the administration and scoring of FEES video files. Training consisted of an initial 2 hours of a basic tutorial and an additional 6 hours of interpretation and scoring FEES videos. Further, all participants utilized the APS when independently completing FEES studies. The number of independent FEES studies completed by each rater—prior to participation in this study—ranged from 100 to 4,000, and the years of experience for all clinicians ranged from 8 to greater than 21. See Table 1 for demographic information for each rater.

Table 1

	SLP-1	SLP-2	SLP-3	SLP-4	SLP-5
Education	Masters	Masters	Doctorate (Ph.D.)	Masters	Masters
Experience as SLP (in years)	6-10	11-15	>21	>21	6-10
Experience Interpreting VFSS/FEES (in years)	6-10	3-5	>21	16-20	6-10
Number of FEES Completed Independently	>1000	>1000	251-500	>1000	101-250
Number of FEES Scored Utilizing 5- Point APS	>1000	>1000	251-500	>1000	101-250
Percent of Time Utilizing Frame-by- Frame Analysis	81-100%	81-100%	81-100%	81-100%	81-100%

Demographic Information for Individual Raters

Instruments

Video files were recorded/captured using an ATMOS digital nasoendoscope (ATMOS Medical, Inc.) and were viewed on an apple iMac Professional (Apple, Inc.). As frame-by-frame analysis is the only variable shown to improve detection of biomechanical impairments (Vose et al., 2018), all studies were recorded and reviewed at 30 frames per second utilizing frame-by-frame analysis.

Procedures

Using a novel 5-point airway protection scale (see Table 2 below), each SLP independently scored 25 video files of individual swallows. Each video file was sampled from a database of completed FEES studies. The order of video file review was randomized for each clinician. Two weeks after the initial scoring session, each SLP scored the same 25 video files, for which the order of videos was again randomized. All raters were blinded to the results of the other raters, and each rater was also blinded to their own results from the first session of scoring. Scores for each video file were compiled and inter-rater and intra-rater reliability were established. When assessing airway protection during swallowing, each clinician could select from only one of the five descriptive categories: scored 1-5. Table 2 details a full description of each categorical score.

Table 2

Definitions of 5-Point Airway Protection Scores

Score	Description
1	Airway protected by primary larynx reflex closure, seal, and squeeze.
2	Material enters the laryngeal vestibule but is cleared out by a reflexive response in ≤ 2 seconds.
3	Material enters the laryngeal vestibule but is NOT cleared out by a reflexive response in ≤ 2 seconds
4	Material passes below the plane of the true vocal folds into the trachea stimulating a reflexive response successfully clearing the aspirated material from the tracheal airway in ≤ 2 seconds.
5	Material passes below the plane of the true vocal folds into the trachea stimulating a reflexive response that does NOT clear the aspirated material from the tracheal airway in ≤ 2 seconds or does NOT stimulate a protective reflexive response ≤ 2 seconds.

Note. The Airway Protection Scale (APS) was developed by SA Swallowing Services, PLLC, and its use, without express and written consent, is not authorized.

Statistical Analysis

Fleiss' kappa was used to determine if there was agreement between SLPs' judgement of the level of airway incursion of solids or liquids, based on a FEES video clip showing contrast material moving through the pharynx. Intra-rater reliability was also determined using Fleiss' kappa, comparing clinician scores collected from the initial scoring session and the final scoring session two weeks later. Interpretation of Fleiss' kappa scores are described as: "poor," "slight," "fair," "moderate," "substantial," "almost perfect" (Landis & Koch, 1977). See Table 3 for Fleiss kappa value interpretation.

Table 3

Value (κ)	Interpretation
< .000	Poor Agreement
.00020	Slight
.2140	Fair
.4160	Moderate
.6180	Substantial
.81 - 1.00	Almost Perfect
M . T C	(I 1: 0 V 1 1077)

Fleiss Kappa Score Interpretation

Note. Interpretation from (Landis & Koch, 1977)

Results

Demographic data was collected from all raters (see Table 1). The demographic data collected and analyzed was: education, years of experience as an SLP, experience interpreting VFSS/FEES, number of FEES completed independently, number of FEES scored using the APS, and percent of time utilizing frame-by-frame analysis. However, no relationship was found between agreement and any demographic variable. SLP scores for each video scored during both sessions were used to determine reliability. Fleiss' kappa—which determines the rate of agreement among two or more judges or raters when using a descriptive scale—calculated inter-rater and intra-rater reliability. Interrater reliability, established "almost perfect" agreement among the five raters' judgements, $\kappa = .91$ (95% CI, .881 to .939), p < .0005. Intra-rater reliability, comparing scores from scoring session one to scoring session two, ranged from "substantial" to "almost perfect" agreement among all five raters. Table 4 contains kappa values for intra-rater reliability for each rater.

Table 4

Rater	Overall Agreement (κ)	95% CI Lower Bound (κ)	Range 95% CI Upper Bound (κ)
SLP-1	.95	.75	1.14
SLP-2	.80	.60	1.00
SLP-3	.95	.75	1.15
SLP-4	.95	.75	1.15
SLP-5	1.00	.80	1.20

Intra-rater Agreement from Paired Scores for SLP Raters

Discussion

The goal of this study was to determine if SLPs could reliably score airway protection behaviors using the APS. The findings of this study demonstrate that SLPs, with adequate training, can reliably use the APS when reviewing FEES videos. There was consistent agreement among the five SLPs when judging all twenty-five video files. Furthermore, the second scoring of the same randomly presented 25 videos two weeks later, established strong intra-rater reliability. Taken together, these data indicate strong and statistically significant inter-rater and intra-rater reliability.

The foundation of any interpretive classification system rests on an ability to consistently produce the same results each time it is employed. There does not exist a table that delineates the minimum level of agreement that is required for a test to be clinically reliable. From a statistical point of view, Fleiss' kappa is not only a measure of agreement, but it is a de facto assessment of disagreement. For example, a value of $\kappa =$.80, typically interpreted as "substantial agreement," would indicate that the raters

disagreed on 20% of the data (McHugh, 2012). The data originally published for the 8point PAS, which has been a valuable clinical tool for 25 years, found that agreement among judges ranged from 60-75% (Rosenbek et al., 1996). Comparatively, our data indicate "almost perfect agreement" among multiple judges for the novel 5-point APS with judges disagreeing on fewer than 10% of the items scored—which indicates each clinician produced consistent results when interpreting FEES videos with the 5-point APS. These results make a strong case for further investigation of the exact amount of training that would be required to produce similar results for clinicians not previously familiar with the APS.

Agreement among multiple raters remains important, but agreement within the same judge is no less valuable. In fact, the data published regarding the 8-point PAS in 1996 found that the same raters disagreed with themselves on 77 of 300 videos—with 75% of the differing scores increasing in number from the first viewing to the second (Rosenbek et al., 1996). Even though the PAS is a descriptive scale and higher scores do not represent increasing severity, the increase from the first rating to the second rating was interpreted by the original authors as an increase in scoring severity on the second rating. Notably, intra-rater reliability in the current study of the 5-point APS ranged from $\kappa = .80$ to $\kappa = 1.0$ (see Table 4). Furthermore, agreement for four of the five judges was $\kappa = .95$ or higher—demonstrating reliable use of the scale when scoring the same video files in a randomized order two weeks later. As with the values for inter-rater reliability, the values for intra-rater reliability indicate that the APS can be reliably used by clinicians familiar with the scale. Prior to recommending widespread implementation of

the APS, future studies are warranted to determine the training requirements necessary for optimal use of the APS.

Limitations

One limitation of the current study was the small sample size (5 raters). Future research with a larger sample is recommended to better understand the reliability of this scale, as well as allowing researchers to look if years of experience, work setting, education, level, and other demographic data affects reliability of the APS. The consistent 8 hours of training on the APS before data collection and the routine use of the APS among the five clinicians provided a high degree of control in the study. However, this same fluency with the APS also limits the generalizability of the results in the current study. Future investigations regarding inter-rater and intra-rater reliability for the APS with raters of varied training is warranted, which will help identify the minimum training required for optimal reliability. Upon determining the necessary training duration, professionals should consider the tenability of meeting those requirements for practicing SLPs in the field. In addition, reliability alone is insufficient to propose the adoption of the scale, and future inquiries into the validity of the scale would also be required.

Conclusion

The results of the current study demonstrate strong inter-rater and intra-rater reliability among SLPs who were extensively trained (8 hours) and experienced using the APS. The APS was designed to be utilized for individuals with OD—regardless of the underlying etiology—and was created specifically for analyzing FEES videos. Currently, the vast majority of other validated airway protection scales for FEES were validated only for specific patient populations, which impedes generalizability to OD from other

causes. Consequently, clinicians analyzing FEES video files would be required to be trained to utilize multiple scales based on the underlying cause of OD. As virtually any disease can cause OD, it seems implausible for practicing SLPs to be trained in the use of multiple scales that were developed only for specific patient populations. Conversely, the APS allows a parsimonious model of training that requires the use of a single measurement tool. Replication of these results in a more diverse sample of clinicians and validation of the APS are necessary prior to widespread adoption of the APS.

APPENDIX FOR CHAPTER II IRB APPROVAL LETTER

IRB

INSTITUTIONAL REVIEW BOARD

Office of Research Compliance, 010A Sam Ingram Building, 2269 Middle Tennessee Blvd Murfreesboro, TN 37129



IRBF016 - Participant Informed Consent

A. INFORMATION AND DISCLOSURE SEGMENT

	(Pa	rticipant Copy)		
Study Title	Reliability and Validation of a 5-Point Airway Protection Scale for Flexible			
	Endoscopic Evalua	ation of Swallowing (FEES)		
Primary Investigator(s)	Matthew Ward Faculty Advisor: Dr. Samantha Johnson			
Contact information	mgw2m@mtmail.n	ntsu.edu		
Department & Institution	Health & Human P	erformance		
Protocol ID	22-2001 7i5	Approval: 07/23/2021	Expiration: 07/31/2022	

The following information is provided to inform you about the research project in which you have been invited to participate. Please read this disclosure and feel free to ask any questions. The investigators must answer all of your questions and you must be given a signed copy of this disclosure.

- Your participation in this research study is voluntary.
- You are also free to withdraw from this study at any time without loss of any benefits.
- In the event new information becomes available that may affect the risks or benefits associated with this
 research study, you will be notified so that you can make an informed decision at that time.

For additional information on your rights as a participant in this study, please contact the Middle Tennessee State University (MTSU) Office of Compliance (Tel 615-494-8918 or send your emails to <u>irb information@mtsu.edu</u>. (URL: http://www.mtsu.edu/irb).

Please read this section and sign Section B if you wish to enroll in this study. The researcher will provide you with a copy of this disclosure form for you to keep for your future reference.

1. What are the prime types of physical contact the participant will have?

The participant will have the following type(s) of contact(s) with the investigators or/and other participants at least sometimes during this research:

- 1.1 Virtual Interactions
 - Qualtrics Zoom Telephone Other
- 1.2 In person interactions

With PPE Without PPE With Social Distancing Without Social Distancing The participants will be asked to provide their contact details to be used by MTSU COVID-19 task force for contact tracing if needed

2. What is the main category of this research?

2.1 Educational Tests
 2.3 Psychological interview

2.3 Psychological intervention or procedures
 2.5 Medical Evaluation

2.2 Social/Behavioral Evaluation
 2.4 Physical Evaluation or Procedures
 2.6 Clinical Research

3. What is the purpose of this study?

To determine the reliability and validity of a novel rating scale for airway protection for flexible endoscopic evaluations of swallowing

4. What type of data will be collected from you?

A 1-5 score (rating) of each video file reviewed

IRBF016

Version 2.2

03/25/2021

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- 5. What are procedures we intend on doing to collect the above described data? You will be asked to:
 - 1. Rate 25 video files using a novel 5-point airway protection scale
 - Two weeks later, the same 25 video files will be presented in randomized order to the same 5 raters, and the scoring process will be repeated
 - 3. Each session will likely take about 30 minutes to complete

- What will you be asked to do in this study? Complete a score sheet for 25 FEES videos
- 7. What are we planning to do with the data collected using your participation? Determine the validity and reliability of a the 5-point airway protection scale utilized during this study
- 8. What are the expected results of this study and how will they be disseminated? The validity and reliability of the scale will be determined, and the information will be disseminated in a peer-reviewed journal article
- What is the approximate time commitment not including your preparation time for participating in this study? not greater than 1 hour
- 10. What are your expected costs to you, your effort, and etc.? No financial costs are expected and only the mental effort required to review video files and score them is expected.
- 11. What are the potential discomforts, inconveniences, and/or possible risks that can be reasonably expected as a result of participation in this study?

12. What are the risks and bodily harm due to COVID-19 exposure?

Although the MTSU IRB considers this research as "no more than minimal risk." the participants will be in physical contact with the PI and other participants during this study. Therefore, the participants will be exposed to the risk of contracting COVID-19.

- The participants must adhere by the following to reduce the risk for infection. All
 participants will be fully vaccinated (>2 weeks post second administration of mRNA
 vaccine), will wear a mask, and practice social distancing.
- The investigator will follow these precautions: The PI is fully vaccinated (>2 weeks post second dose of mRNA vaccine), will wear a mask, and will practice social distancing.
- COVID-19 Contact Tracing: The participants will be asked to provide their contact details will be given to the MTSU COVID-19 task force if someone you came in contact with tested positive for COVID-19. Your contact details provided in this form will be destroyed after a few days if no positivity of COVID-19 is detected.

13. What are the anticipated benefits from this study?

a. The benefits to science and humankind that may result from this research: There is currently no validated and reliable scale for airway protection when scoring FEES videos. It is hoped that the current scale may provide a valid and reliable option for clinicians performing FEES.

IRBF026 -Informed Consent

☑ Original □ Amended Expiration: 07/31/2022

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Office of Compliance Middle Tennessee State University

- b. The direct benefits to you which you may not receive outside the context of this research: There are no direct benefits to the partipants
- 14. How will you be compensated for your participation? There is no compensation
- 15. What happens if you choose to withdraw your participation? The data will not be used and the participant will suffer no consequences.
- 16. Can you stop the participation any time after initially agreeing to give consent/assent? yes
- 17. Contact Information. If you should have any questions about this research study or possibly injury, please feel free to contact Matthew Ward by telephone 615-878-0944 or by email mgw2m@mtmail.mtsu.edu OR my faculty advisor, Dr. Samantha Johnson, at samantha.johnson@mtsu.edu. For additional information about giving consent of your rights as a participant in this study, to discuss problems, concerns and questions, or to offer input, please feel free to contact the MTSU IRB by email: <u>compliance@mtsu.edu</u> or by telephone (615) 494 8918.
- 18. Confidentiality. All efforts, within reason, will be made to keep your personal information private but total privacy cannot be promised. Your information may be shared with MTSU or the government, such as the Middle Tennessee State University Institutional Review Board, Federal Government Office for Human Research Protections, *if* you or someone else is in danger or if we are required to do so by law.
- 19. Confidentiality and COVID-19: Your information will be provided to the University COVID-19 task force or other public health officials in the event you or one of the research participants or investigators should test positive for COVID-19. Complete the COVID-19 Contract Tracking Page after you agree to consent.

You do not have to do anything if you decide not to participate. If you wish to enroll however, please enter your name and age in the attached Segment B document and sign in the space provided.

Consent obtained by:

Researcher's Signature

Name and Title

Date

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Institutional Review Board	Office of 0	Compliance	Middle Tennessee State	University	
IRBF016 – Participant Informed Consent					
B. Consent Segment 1 - IN PERSON INTERACTION					
	(Re	searchers' Copy	y)		
Study Title	Reliability and Validation of a 5-Point Airway Protection Scale for Flexible Endoscopic Evaluation of Swallowing (FEES)				
Primary Investigator(s) Contact information	Matthew Ward Faculty Advisor: Dr. Samantha Johnson mgw2m@mtmail.mtsu.edu				
Department & Institution	Health & Human Performance				
Protocol ID	22-2001 715	Approval: 07/2	3/2021 Ex	piration: 07/31/2022	

PARTICIPANT SECTION

(To be filled by the participant and returned to the researcher)

	Participants	
I have read this informed consent document	No Yes	
The research procedures to be conducted have been explained to me verbally	□No □Yes	
I understand all of the interventions and all my questions have been answered	□No □Yes	
I am aware of the potential risks of the study	No Yes	

By entering my name and signing below, I affirm that I freely and voluntarily choose to participate in this study. I understand I can withdraw from this study at any time without facing any consequences.

 Name and Signature of the Participant
 Date
 Participant's Age

 RESEARCHER SECTION (To be filled by an investigator and the FA if applicable)
 Informed Consent obtained by:
 Faculty Verification (if administered by a student)

Name	Signature	Date	Name	Signature	Date
	Y				

IRBF026 -Informed Consent	
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Middle Tennessee State University

COVID-19 Contact Tracing

PARTICIPANT SECTION

(To be filled by the consenting participant and returned to the researcher)

Confidentiality and COVID-19:

Your information will be provided to the University COVID-19 task force or other public health officials in the event you or one of the research participants or investigators should test positive for COVID-19.

Name: Contact Address: Telephone: Email Address:

Office Use: Information Date: Expiration Date:

(Today's Date) (Date on which this sheet will be destroyed if no COVID-19 is detected)

Instruction to PI:

- Destroy this page if no COVID-19 is detected by the expiration date above
- If positivity for COVID-19 is known, then provide the participant contact information to MTSU's COVID-19 task force

Ensure to cut the box out when providing the participant's contact details and hide any protocol details from being transmitted.

IRBF026 -Informed Consent

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CHAPTER III

THE FREQUENCY OF AIRWAY PROTECTION BEHAVIORS OF POST-ACUTE CARE PATIENTS REFERRED FOR FEES

Introduction

To fully appreciate OD, SLPs require a detailed understanding of normal swallowing behaviors viewed during FEES (Butler et al., 2009). Over the last fourteen years, significant amounts of data have been collected regarding airway protection behaviors of healthy adults who do not have dysphagia. These efforts resulted in a general consensus of the differentiation between healthy swallowing (Butler et al., 2010; Curtis et al., 2023; Jardine et al., 2020; Pisegna, 2022) and OD (Braun et al., 2018; Braun et al., 2019; Morris et al., 2024; Starmer et al., 2021). Further, swallowing kinematics (i.e., the movement and coordination of various pharyngeal and laryngeal structures that result in healthy swallowing) are also known to change with normal aging. With increased age, swallow reaction time, duration of laryngeal vestibule closure, and duration of upper esophageal sphincter opening were all impacted by age; indeed, virtually all swallowing kinematics demonstrate, at a minimum, subtle changes directly associated with aging, but it is unclear if these changes alter swallowing significantly enough to account for increased rates of laryngeal penetration and aspiration that may be seen in older individuals (Humbert et al., 2018; Jardine et al., 2020). In order to determine the effectiveness of interventions and treatment strategies, SLPs who treat individuals with OD must also develop a nuanced understanding of swallowing that includes the severity of OD. Without identifying the frequency of airway protection

behaviors in individuals with OD, SLPs are unable to determine the efficacy of their interventions that are designed to ameliorate swallowing difficulties.

To date, little information regarding the frequency of airway protection behaviors visualized during FEES has been published—with most studies including relatively small numbers of participants (Gandhi & Steele, 2022; Smith et al., 2010). To this end, 477 patients who received FEES as part of their standard dysphagia evaluation were randomly sampled, and their airway protection behaviors were recorded by the five SLPs who participated in the APS reliability study. These SLPs also routinely utilize the APS in daily practice of scoring FEES videos.

Methods

Four hundred seventy-seven FEES reports from five SLPs trained in use of the APS were randomly selected for this study. From these reports, a database of patient airway protection behaviors was created, and all data was deidentified. Age, sex, and airway protection behaviors were quantified and analyzed. The five SLP raters were trained in the administration and scoring of FEES video files. Training consisted of an initial 2 hours of a basic tutorial and an additional 6 hours of interpretation and scoring FEES videos. Further, all reports were completed by SLPs who utilize the APS when independently completing FEES studies. The number of independent FEES studies completed by each rater—prior to participation in this study—ranged from 500 to 4,200. As previously reported in Chapter III, these raters showed "almost perfect agreement" among the five raters' judgements of airway protection behaviors using the APS ($\kappa =$

.91, p < .0005). Intra-rater reliability among this group of clinicians was also "substantial" or "almost perfect."

Instruments

Video files were recorded/captured using an ATMOS digital nasoendoscope (ATMOS Medical, Inc.) and were viewed on an apple iMac Professional (Apple, Inc.) or on a Microsoft Surface Pro (Microsoft Corporation). All studies were recorded and reviewed at 30 frames per second.

Procedures

Four hundred seventy-seven FEES reports—equaling 25% of the total FEES reports generated from January 1, 2023 to January 1, 2024—were randomly selected. From these reports, a database of patient age, sex, and swallowing behaviors was created. Patients were assigned a randomly generated numeric identifier, and their airway protection scores for the 5-point APS were coded. As this was a retrospective medical records review, an exemption for informed consent was approved by the Institutional Review Board at Middle Tennessee State University.

All airway protection behavior data from FEES reports were gathered from a standard test administration protocol. The administration protocol (see Table 1 for a full description of the study protocol) consists of 22 trials of varying bolus sizes and consistencies. Volumes were regulated by using standard spoons and cups that allow for measurements to be made in milliliters. For spoons, 2.5 milliliter and 5 milliliter boluses were administered; heaping and habitual bite sizes were also tested via spoon for which volume was not measured. Cup and straw sips—with the exception of the 3-ounce (or 90 milliliter) challenge—were not measured. For these trials, individuals were directed to

"take a sip/bite size that you would normally take." The SLPs administering the protocol for the FEES have the latitude to change the protocol to meet the needs of each individual being evaluated if needed. Thus, due to safety concerns, or other factors, not every study included all 22 trials. Furthermore, compensatory strategies can also be added to and utilized at the evaluating SLP's discretion. However, the goal of this study was to collect information regarding the frequency of airway protection behaviors observed in individuals referred for FEES absent SLP intervention. Therefore, any trial in which a compensatory strategy was employed was omitted from data collection and was not used for data analysis.

Table 1

Amount	Consistency	# of
(ml)	(IDDSI)	Trials
2.5	IDDSI 0	1
5	IDDSI 0	2
2.5	IDDSI 2	1
5	IDDSI 2	2
2.5	IDDSI 4	1
5	IDDSI 4	2
Habitual size bite	IDDSI 4	1
5	Dual consistency (IDDSI 6 & IDDSI 0)	1
5	Dual consistency (IDDSI 6 & IDDSI 0)	1
Habitual size bite	Dual consistency (IDDSI 6 & IDDSI 0)	1
5	IDDSI 7	1
10	IDDSI 7	1
Habitual size drink (cup)	IDDSI 0	3
Habitual size drink (straw)	IDDSI 0	3
90ml stress test (cup or straw)	IDDSI 0	1
Total Trials		22

Standard FEES Administration Protocol

Note. This administration protocol was developed by SA Swallowing Services, PLLC, and its use, without express and written consent, is not authorized.

The administration protocol utilized the International Dysphagia Diet

Standardization Initiative (IDDSI) framework to standardize the food textures and liquid viscosities that were administered. The IDDSI framework uses consistent terminology, and it allows SLPs to assess the viscosity of liquids and the texture of solid foods in a standardized way. The standard administration protocol utilized for this study included IDDSI 0 (thin liquid), IDDSI 2 (mildly thick liquid), IDDSI 4 (puree), IDDSI 6 (soft and bite size), and IDDSI 7 (regular texture solids). Other textures, which were not part of the typical protocol, were not included for analysis in this study.

Statistical Analysis

Descriptive statistics for age, sex, and airway protection behaviors were reported. As pharyngeal residue is known to increase with age in healthy individuals, Pearson's correlation was completed to determine if there was a similar relationship between age and episodes of laryngeal penetration or aspiration. To determine if there were a connection between the categorical variable of sex and the ordinal variable of the 5-point APS, a Fisher's exact test analysis was conducted.

Results

Of the 477 reports sampled, 56.6% (n = 270) of the individuals were male and 43.4% (n = 207) were female. Generally, dysphagia is known to occur more frequently in males (Adkins et al., 2020), and the current sample was compiled from individuals who were screened for OD risk prior to FEES assessment—which likely accounts for the larger representation of males sampled in this cohort. The ages of individuals in this database ranged from 21 years to 99 years. As swallowing problems are known to increase with age (Jardine et al., 2020), it is not shocking that 82.2% (n = 387) of this

referred sample were over the age of 60, and 39.8% (n = 287) of the sample were over the age of 70. The mean age for this sample was 72.2 years with a median age of 74 years.

A total of 9,227 individual swallows were coded and cleaned for analysis, which resulted in an average of 19.3 trials per FEES report reviewed. Of these recorded trials, 70.2% (n = 6,479) were rated "1," indicating no episode of laryngeal penetration or aspiration. An APS score of "2," which denotes laryngeal penetration that spontaneously and immediately cleared, was the next most frequent score at 15.5% (n = 1,429). The frequency of the remaining scores was "3" (6.6%; n = 607), "4" (4.2%; n = 392), and "5" (3.5%; n = 320). See Table 2 for definitions of APS scores and see Table 3 for the total frequency of APS scores.

Score	Description
1	Airway protected by primary larynx reflex closure, seal, and squeeze.
2	Material enters the laryngeal vestibule but is cleared out by a reflexive response in ≤ 2 seconds.
3	Material enters the laryngeal vestibule but is NOT cleared out by a reflexive response in ≤ 2 seconds
4	Material passes below the plane of the true vocal folds into the trachea stimulating a reflexive response successfully clearing the aspirated material from the tracheal airway in ≤ 2 seconds.
5	Material passes below the plane of the true vocal folds into the trachea stimulating a reflexive response that does NOT clear the aspirated material from the tracheal airway in ≤ 2 seconds or does NOT stimulate a protective reflexive response ≤ 2 seconds.

Definitions of 5-Point Airway Protection Scale (APS) Scores

Note. The Airway Protection Scale (APS) was developed by SA Swallowing Services, PLLC, and its use, without express and written consent, is not authorized.

Table 3

APS Score	Percent of Total Trials (%)	Total Trials (<i>n</i>)
1	70.2	6,479
2	15.5	1,429
3	6.6	607
4	4.2	392
5	3.5	320
Total	100.0	9,227

Total APS Scores for All Trials

Discussion

Age has an established relationship with the increasing likelihood of laryngeal penetration or aspiration (Ahn et al., 2020) and with increasing rates of residue in healthy individuals (Garand et al., 2023). However, there is little evidence of the role that age plays—if any—in increasing the frequency of laryngeal penetration or aspiration events in individuals referred for FEES due to concerns for OD. Given the known correlations

between age and developing dysphagia—whether through increasing residue or higher rates of laryngeal penetration and aspiration-it has been hypothesized that OD severity, specifically problems with airway protection, may also increase with age. Correlations between age and airway protection scores for each specific trial volume and consistency were investigated. None of the 50 correlations computed generated an r value that was greater than .095, indicating that there does not appear to be a relationship of any kind between age and airway protection scores for this sample. It is important to note that APS scores are ordinal, and the scale includes both normal and aberrant swallowing behaviors alike. In this sample of over 9,000 swallows of individuals previously screened and deemed to be at risk for OD, there does not appear to be a link between age and normal airway protection behaviors or age and irregular airway protection behaviors. This appears to be a departure from the well-established normative data for healthy individuals who routinely demonstrate increased residue and increased frequency of laryngeal penetration and aspiration associated with aging. From this current dataset, it does not appear that age alone predicts normal or impaired airway protection for patients evaluated for OD with FEES.

This randomly selected sample included more males (56.6%; n = 270) than females (43.4%; n = 207), which may be due to the known relationship between males and increased overall severity of dysphagia. A Fisher exact test was completed to determine if there was an association between the categorical variable of sex and the ordinal variable of APS scores. In this dataset there was a significant association between sex and APS scores (p < .001). Despite accounting for only 43.4% of the sample, females accounted for 53.8% (n = 769) of all APS "2" scores, which indicates a functionally normal airway protection score. APS scores of "5" denote the most severe complication for airway protection behaviors (i.e., material is aspirated, but the individual is unable to eject material from the trachea reflexively), and males accounted for 62.8% (n = 201) of all APS "5" scores. These data seem to support the established view that males with OD are likely to have more severe issues with airway protection than females.

APPENDIX FOR CHAPTER III IRB EXEMPTION LETTER

Angie S. Bowman

From:	do-not-reply@cayuse.com
Sent:	Friday, March 29, 2024 3:09 PM
To:	Angie S. Bowman; Kathryn M. Blankenship; Matthew Ward
Subject:	[EXTERNAL] IRB-FY2023-177 - Initial: Initial Exempt Protocol Approval Letter



Office of Research Compliance 2269 Middle Tennessee Blvd. Sam H. Ingram Bldg (ING) Room 010A Box 124 Murfreesboro, TN 37132 www.mtsu.edu/irb

Date: March 29, 2024 PI: Matthew Ward Department: Middle Tennessee State University, Health and Human Performance Re: Initial - IRB-FY2023-177 Health Outcomes for Individuals with Dysphagia in a Long-Term Acute Care Hospital

The Middle Tennessee State University Institutional Review Board has rendered the decision below for the above referenced study.

Decision: Exempt

Category: Category 4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using governmentgenerated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

1

Findings: This study meets criteria ii under Category 4, so there is no need to obtain informed consent. Research Notes:

Please note that even though your proposed study is deemed exempt from further IRB review, the following apply to your approved study:

- 1. In accordance with 45 CFR 46.110, expiration dates do not apply to research eligible for Exempt Review under the Common Rule, and continuing review is not required by the IRB.
- 2. Any unanticipated harm to participants or adverse events must be reported to the Office of Compliance.
- 3. All modifications to the approved study must be submitted for review through Cayuse IRB for approval before their implementation. Adding new researchers constitutes a modification to the protocol. Per MTSU Policy, a researcher is defined as anyone who handles the data or interacts with participants. Everyone meeting this definition for this project must have completed the required CITI training and received IRB approval prior to becoming actively involved in the project.
- 4. Closure of the study must be submitted within Cayuse when the study ends or when personal identifiers are removed from the data and all codes and keys are destroyed.
- 5. All research materials must be retained by the PI for at least three (3) years after study completion and then destroyed in a manner that maintains confidentiality and anonymity.

2

Sincerely,

The Middle Tennessee State University Institutional Review Board

CHAPTER IV

A SURVEY OF SPEECH LANGUAGE PATHOLOGISTS' KNOWLEDGE OF OUTCOMES ASSOCIATED WITH MODIFIED TEXTURE DIETS

Introduction

The use of MTDs—by any combination of altering food consistency, increasing liquid viscosity, or restricting the manner of oral eating and drinking—represents a central pillar of OD management and treatment by SLPs (Cichero, 2013, 2018; Wirth et al., 2016). For over 50 years, clinicians attempted to prevent pneumonia by the modification of eating and drinking (Larsen, 1972). However, over the past 25 years, the scientific literature from multiple disciplines clearly demonstrates that aspiration alone is insufficient for the development of pneumonia, and there is no strong evidence to support the use of MTDs to prevent pneumonia (Bock et al., 2017; Campbell-Taylor, 2008; Dickson et al., 2014; Feinberg et al., 1996; Hansen et al., 2022; Langmore et al., 1998; Logemann et al., 2008; Prass et al., 2006). Further, the literature is clear that MTDs are associated with significant negative impacts on health and QOL (Abdelhamid et al., 2016; Beck et al., 2018; Cichero, 2013; Maeda et al., 2019; Martín et al., 2018; Miles et al., 2019; O'Keeffe, 2018; Okabe et al., 2016; Wu et al., 2020). Despite an inability to prevent pneumonia and the consensus that MTDs carry their own systemic health risks, MTDs currently represent the standard of clinical care provided by SLPs (Cichero, 2018; Cichero et al., 2013; O'Keeffe, 2018a; Wirth et al., 2016).

O'Keeffe et al. (2023), raise the principle of informed consent as it relates to MTDs—noting that the prescription of altered solid textures and thickened liquids

unequivocally require informed consent. As MTDs represent a significant portion of OD management and treatment, it is the burden of the SLP to inform an individual with OD the risk of eating and drinking regular textures and the risks associated with MTDs (O'Keeffe et al., 2023). Furthermore, the consent for healthcare interventions must be informed and voluntary (Hall et al., 2012). Setting aside the voluntary portion of informed consent, the current inquiry seeks to determine if SLPs possess the knowledge to fully inform individuals with OD of the risks associated with eating and drinking MTDs.

To be informed, an individual "must be given sufficient information in a way that they can understand about what the treatment involves, including the potential benefits and harms, whether there are reasonable alternative treatments, and what will happen if treatment does not go ahead... This requires consideration of the quality of evidence that an intervention will be successful in achieving meaningful endpoints that are important to a patient (O'Keeffe et al., 2023)." Investigators have also questioned whether SLPs recognize the necessity of informed consent when it comes to MTDs, which may lead to suboptimal levels of informed consent (Askren & Leslie, 2019). However, informed consent also carries an unstated assumption that, in this case, the SLP can detail the potential benefits and harms of MTDs to an individual diagnosed with OD. The current survey sought to determine the extent to which SLPs could identify known risks associated with the consumption of MTDs.

Methods

Using Qualtrics, a pilot study was completed and disseminated to a small group of experienced SLPs who routinely evaluate and treat individuals with OD. The feedback provided allowed for hypothesis development and refinement of the questions that were ultimately utilized for the final distributed study. The results from the pilot study were used to finalize the questions and overall format of the final survey. Information obtained in this survey could not be linked to the participants, and the survey was approved by the Institutional Review Board at Middle Tennessee State University.

Distribution and Recruitment

Survey enrollment was voluntary, and no compensation or incentives were offered to participants. The following message was displayed with the anonymous survey link: "We are conducting evidence-based research on clinical decision making in dysphagia practice. Your participation will help us to better understand clinical practice patterns for those who diagnose and treat individuals with dysphagia. You will be answering questions about your typical practice when evaluating dysphagia. You will be asked to answer a series demographic and clinical questions. Answers are completely anonymous, and the survey should take between 10-20 minutes to complete. Thank you!"

The survey was active from March 16, 2022 to April 30, 2022. Respondents were not required to complete the entire survey in one session, and they were also able to return to previously answered questions and change answers. The survey could be completed on a computer or mobile device (e.g., smart phone or tablet). Respondents were allowed only to submit a single survey. To discourage participants from filling out multiple surveys, the first demographic question was, "Have you taken this survey before?" A "yes" response prevented further participation in the study.

Participants

A total of 327 respondents opened and initiated the survey. A single participant answered that they were not above 18 years old, and their responses were not utilized for analysis. The final sample included responses from 326 participants. Tables 1, 2, and 3 provide race and ethnicity for SLPs and corresponding demographics for survey participants. Thus, the demographic representation of the sample was consistent with the overall population of healthcare-based SLPs. After dispensing with demographic questions, respondents were asked nineteen survey questions about OD evaluation and treatment.

Race	ASHA Members (%)	Participants (%)
	(n = 168,359)	(n = 323)
American Indian or Alaska	0.3	0.3
Native		
Asian	3.0	3.4
Black or African American	3.7	1.8
Native Hawaiian or other	0.2	0
Pacific Islander		
White	91.4	89.5
Multiracial	1.5	1.32
Prefer not to answer	n/a	16
Elinnicity	ASHA Members (%)	Participants (%)
	(n = 168,359)	(n = 310)
Hispanic or Latino	6.3	4.2
Not Hignoria or Lating	02.7	02.0
not hispanic of Latino	73.1	73.7
Prefer not to answer	n/a	19

Demographics: Race & Ethnicity

American Speech-Language-Hearing Association. (2022). 2021 Member and affiliate profile. www.asha.org

Demographics: Age

Age	ASHA Members (%) (<i>n</i> = 177,061)	Participants (%) (n = 308)
34 and younger	28.1	36.0
35-44	28.7	33.7
45-54	22.4	19.5
55-64	12.8	8.1
64 and older	8.0	2.6

American Speech-Language-Hearing Association. (2022). 2021 Member and affiliate profile. www.asha.org

Table 3

Demographics: Primary Employment Setting

Primary Employment Setting	ASHA Members (%)	Participants (%)
(Health care)	(n = 66,743)	(n = 313)
Hospital	31.0	41.2
Skilled Nursing Facility	18.3	22.7
Other Residential HCF	3.6	6.4
All other settings	47.2	29.8

ASHA - American Speech, Language, Hearing Association. Data from 2021 Member and Affiliate Profile

Data Analysis

Descriptive statistics (i.e., frequencies, percentages, and means) were used to report demographic data and to establish patterns of practice. Participants were asked two objective questions about known risks of MTDs. Respondents were free to choose any, and all, risks they knew to be associated with altered texture solids and thickened liquids,

and they were also free to choose "none of the items apply" or "I don't know." Of the 12 responses listed as possible side effects of modifying solid textures, four are wellsupported in the research literature: malnutrition (Maeda et al., 2019; Martín et al., 2018; Miles et al., 2019; Okabe et al., 2016), dehydration (Wu et al., 2021), poor recovery from illness (Ahmed & Haboubi, 2010; Mukand et al., 2003), decreased quality of life (Leow et al., 2010; Swan et al., 2015). For side effects of thickened liquids, 9 of the 12 possible responses qualify as known side effects that are supported by research literature: dehydration (Cichero, 2013a; Reber et al., 2019), respiratory infection (Wotton et al., 2008), poor recovery from illness (Ahmed & Haboubi, 2010; Mukand et al., 2003), constipation, urinary tract infection, slow digestion, interference with medication absorption, constant feeling of thirst (Cichero, 2013), decreased quality of life (Leow et al., 2010; Swan et al., 2015). Together, these 13 items were added together to create a summed scale score. That score was employed as an analogue to determine clinician knowledge of the possible risks associated with MTDs. An ANOVA was completed to determine if descriptive statistics impacted respondent scores, and an independent samples t-test was completed to determine whether SLPs with training performed differently than those who indicated they had no training in the relationship between OD and malnutrition and dehydration.

Survey Items

The survey began with 15 demographic questions to determine professional work setting, years of experience, education, race, ethnicity, age. The American Speech, Language, and Hearing Association (ASHA) reports that 96.4% of SLPs are female and 3.6% are male. Sex assigned at birth for participants in the current survey were 94.1% female and 5.6% male, with 0.4% preferring not to answer. The full survey is available in Appendix A at the end of this chapter.

Results

Demographics

Table 4 illustrates the demographic characteristics of the study participants. The data in Table 4 show that there were 223 (88.1%) female participants, 11 (4.7%) male participants, and 1 (0.4%) participant who chose not to provide a response. The age categories for the survey were: 24 or younger, 25-34, 35-44, 45-54, and 65 years & up, with the majority of participants (69.4%) selecting 44 years or younger as shown in Table 5. A total of 250 participants reported their race; the majority of the participants (n = 225; 90.0%) reported their best described race as white and no other group represented more than 4%. Professional experience as a SLP, calculated in years, and years spent treating individuals with OD are delineated in Tables 5 and 6. The majority of clinicians reported working in acute hospitals (41.2%) and Table 7 details the breakdown of primary work settings.

Table 4

Sex Assigned at Birth

Sex	Frequency (<i>n</i>)	Percent (%)
Male	12	4.7
Female	223	94.9
Prefer not to answer	1	0.4

Age Groups

Age	Frequency (<i>n</i>)	Percent (%)
24 or younger	5	2.1
25-34	81	34.5
35-44	82	34.9
45-54	44	18.7
55-64	20	8.5
65 or older	3	1.3
Missing	18	7.1
Total	253	100.0

Table 6

Race

Race	Frequency (<i>n</i>)	Percent (%)	
Native American or	1	0.4	
Alaska Native			
Asian	10	4.0	
Black or	3	1.2	
African-American			
White	225	90.0	
Multiracial	4	1.6	
Prefer Not to Answer	7	2.8	
Missing	3	1.2	
Total	253	100.0	

Table 7

Experience as SLP

Years	Frequency (<i>n</i>)	Percent (%)	
<1	12	4.9	
1-5	49	20.2	
6-10	55	22.6	
11-20	66	27.2	
21+	61	25.1	
Total	243	100.0	

Training

In the United States, the majority of SLPs who work in the medical setting have a master's degree, and 230 participants (95.0%) indicated that the highest degree they earned was at the master's level. Only 4.9% of respondents indicated that they had attained a clinical or research doctorate. While specific training in the relationship between malnutrition and dehydration secondary to OD is not a required part of educational curriculum for SLPs, 177 individuals (75.0%) indicated that they had received formal training regarding the relationship between OD and malnutrition and dehydration—with only 59 participants (25.0%) indicating that they received no formal training.

Malnutrition & Dehydration

While malnutrition and dehydration are known complications of OD, they can also result from consuming MTDs that are designed to decrease the risk of aspiration and pulmonary complications. Indeed, 96% of respondents answered that they recommended altered texture solids when needed, and 93.5% of clinicians endorsed the recommendation of thickened liquids when needed. When asked if there was a known relationship between the consumption of altered texture solids and malnutrition, 93.5% of clinicians indicated that there was a known relationship, and 98.5% of clinicians answered that there is a relationship between dehydration and eating MTDs. Furthermore, 190 participants (75.1%) selected dehydration as a known risk of consuming thickened liquids, and 183 respondents (72.3%) indicated that malnutrition was a known risk of consuming modified texture solids. SLPs were asked how often they weighed the risk of aspiration against the risks of consuming MTDs. Over 90% of clinicians specified that they "very frequently" or "almost always" weighed the known risks of consuming thickened liquids prior to recommending them for an individual with dysphagia, and 86% of clinicians indicated that they weighed the risks associated with modified texture solids prior to recommending them (see Tables 8 & 9). The majority of participants also noted that they inform the patient (see Tables 10 & 11) and the medical team (see Tables 12 & 13) of the risks associated with eating modified texture solids and drinking thickened liquids.

Table 8

"Before recommending thickened liquids, I weigh the known risks of aspiration against the known risks of consuming thickened liquids."

Response	Frequency (<i>n</i>)	Percent (%)
Almost Always	140	70.0
(90% or more)		
Very Frequently	46	23.0
(60 - 89%)		
Occasionally	10	5.0
(40 - 59%)		
Rarely	4	2.0
(10 - 39%)		
Total	200	100.0

"Before recommending altered diet textures, I weigh the known risks of aspiration against the known risks of consuming altered diet textures."

Response	Frequency (<i>n</i>)	Percent (%)
Almost Always	108	54.0
(90% or more)		_
Very Frequently	64	32.0
(60 - 89%)		
Occasionally	19	9.5
(40 - 59%)		_
Rarely	7	3.5
(10 - 39%)		
Almost Never	2	1.0
(less than 10%)		
Total	200	100.0

Table 10

"Before recommending thickened liquids, I inform the patient of the possible risks associated with thickened liquids."

Response	Frequency (<i>n</i>)	Percent (%)
Almost Always	99	49.7
(90% or more)		
Very Frequently	48	24.1
(60 - 89%)		
Occasionally	33	16.6
(40 - 59%)		_
Rarely	13	6.5
(10 - 39%)		_
Almost Never	6	3.0
(less than 10%)		_
Total	199	100.0

"Before recommending altered diet textures, I inform the patient of the possible risks associated with altered diet textures."

Response	Frequency (<i>n</i>)	Percent (%)
Almost Always	79	39.9
(90% or more)		<u> </u>
Very Frequently	50	25.3
(60 - 89%)		_
Occasionally	44	22.2
(40 - 59%)		_
Rarely	16	8.1
(10 - 39%)		<u> </u>
Almost Never	9	4.5
(less than 10%)		<u> </u>
Total	198	100.0

Table 12

"Before recommending thickened liquids, I inform the medical team (doctors, nurses, dietitians, etc.) of the risks associated with thickened liquids."

Response	Frequency (<i>n</i>)	Percent (%)	
Almost Always	86	43.2	
(90% or more)			_
Very Frequently	46	23.1	
(60 - 89%)			_
Occasionally	39	19.6	
(40 - 59%)			_
Rarely	18	9.0	
(10 - 39%)			_
Almost Never	10	5.0	
(less than 10%)			_
Total	199	100.0	

"Before recommending altered diet textures, I inform the medical team (doctors, nurses, dietitians, etc.) of the risks associated with altered diet textures."

Response	Frequency (<i>n</i>)	Percent (%)
Almost Always	63	31.8
(90% or more)		_
Very Frequently	49	24.7
(60 - 89%)		
Occasionally	48	24.2
(40 - 59%)		
Rarely	24	12.1
(10 - 39%)		<u> </u>
Almost Never	14	7.1
(less than 10%)		
Total	198	100.0

Statistical Analysis

Of the 13 risks associated with MTDs, only three were identified by more than 70% of clinicians: "decreased quality of life" when eating altered texture solids (n = 194; 76.7%), "dehydration" when drinking thickened liquids (n = 190; 75.1%), and "malnutrition" when eating altered texture solids (n = 183; 72.3%). Table 14 details the frequency that each item on the scale score was selected by study participants.

Risks Associated with Altered Texture Solids and Thickened Liquids Selected by Participating SLPs

Altered Texture Solids	Frequency (<i>n</i>)	Percent (%)
Decreased Quality of Life	194	76.7
Malnutrition	183	72.3
Poor recovery from Illness	110	43.5
Dehydration	83	32.8
Thickened Liquids	Frequency (<i>n</i>)	Percent (%)
Dehydration	190	75.1
Urinary Tract Infection	151	59.7
Decreased Quality of Life	118	46.6
Constipation	113	44.7
Poor recovery from Illness	99	39.1
Slowed Digestion	2	0.8
Constant Feeling of Thirst	2	0.8
Respiratory Infection	2	0.8
Interfere with Medication	2	0.8
Absorption		

Two hundred-fifty-three respondents answered both questions and qualified for the combined scale score (n = 253, M = 6.72, SD = 4.41). Ideally, when fully informing an individual of the risks associated with treatment of OD with MTDs versus the risks associated non-treatment of OD, SLPs would identify all known risks associated with MTDs, but respondents demonstrated poor overall fluency regarding these possible outcomes. Greater than one in five clinicians (n = 55; 21.7%) were unable to select even a single known consequence associated with MTDs, and only 16 respondents (6.3%) were able to correctly identify all 13 risks listed in this survey. Almost exactly one-half of participants (n = 126; 49.8%) listed 7 or fewer known complications. Despite being described as "vile" and "awful" by patients (McCurtin et al., 2018; Swan et al., 2015), decreased QOL—which is associated with the use of thickened liquids—was selected by fewer than half of clinicians surveyed (n = 118; 46.6%).

Insufficient training and education have been reported as barriers to evidencebased practice—related to OD—in previous studies (Carnaby & Harenberg, 2013; Vose et al., 2018). Thus, an independent samples t-test was completed to determine if there was a significant difference between the group of clinicians with formal training and the group without formal training. There was no statistically significant difference between scale scores t(234) = -.38, p = .71, of SLPs who had received formal training (n = 177, M= 7.21, SD = 4.20) and those who had not received formal training (n = 59, M = 6.97, SD= 4.30). Furthermore, an ANOVA was completed, and none of the demographic categories significantly impacted clinician scores F(13, 312) = 4.38, p = .234.

Discussion

This survey highlights an Achilles' heel for informed consent: the inability of a clinician recommending MTDs to identify known health risks associated with MTDs. SLPs, who treat OD with MTDs, must inform individuals of the potential risks and potential benefits of untreated OD versus the risks and benefits associated with of the consumption of MTDs. Yet, only 6.3% of respondents in this survey were able to identify all of the listed hazards associated with MTDs. While the overwhelming majority of clinicians who responded to the survey indicated that they recommend modifying solid textures (96%) and thickening liquids (93.5%), respondents failed to consistently identify more than half of the risks listed in this survey.

The disparity represented in these results appear shocking, but the results are in line with past seminal surveys of SLPs' practice patterns; not unlike physicians and nurses (Ubbink et al., 2011), SLPs consistently demonstrate suboptimal adherence to the use of evidence-based practice related to OD (Bice et al., 2022; Carnaby & Harenberg, 2013; Martino et al., 2004; Rumbach et al., 2018; Vose et al., 2018). However commonplace these results may be, the inability to identify possible complications of MTDs—which include dire systemic consequences like poor recovery from illness and respiratory infections—results in a body of clinicians who may not possess the knowledge to adequately inform patients about the outcomes associated with untreated OD versus treating OD with MTDs.

Limitations

This study highlights significant issues related to SLP practice patterns as they relate to the prescription of MTDs. As training in the risks associated with MTDs is not a required part of SLP training programs, it was thought that there would be a relatively small percentage of SLPs who stated that they had received training in the specific effects of MTDs on malnutrition and dehydration. Our results indicated that clinicians who had undergone training were not able to identify more risks associated with MTDs than clinicians who indicated that they had not undergone training. However, 75% of respondents indicated that they received formal training in the risks associated with the consumption of MTDs—resulting in an underpowered sample of clinicians who stated that they had not received formal training.

With such a disparity in the numbers of participants in the training versus nontraining groups, it is difficult to determine if these results would be replicated in groups of equal size. Furthermore, with the current results, formal training programs appear to be either ineffective or respondents were unclear on the specific guidelines that are required to have taken part in rigorous and efficacious training. Hence, future studies in this area would benefit from a deep dive into the exact parameters of training in which SLPs participate. Investigations should include questions about the exact nature of training regarding the prescription and use of MTDs including: the teaching methodology, time in hours or days spent in training, and of specific learning outcomes found in these training programs. These data could assist in illuminating the nuances of various training problems that could impact the ability of clinicians to identify the risks associated with the use of MTDs.

Lastly, it is not clear if SLPs—on the whole—understand that informed consent is required for the prescription of MTDs in a medical setting. Future inquiries would likely benefit from investigating whether respondents understand that informed consent is required for the use of MTDs.

APPENDIX A FOR CHAPTER IV

SURVEY QUESTIONS

1. Country

- o United States
- o Other

2. Age

- o 24 or younger
- o 25-34
- o 35-44
- o 45-54
- o 55-64
- \circ 65 or older

3. Ethnicity

- Hispanic or Latino
- Not Hispanic or Latino
- Prefer not to answer

4. Race

- o American Indian or Alaska Native
- o Asian
- o Black or African American
- Native Hawaiian or Other Pacific Islander
- o White
- o Multiracial
- Prefer not to answer

5. What is the highest degree or level of school you have completed? (If currently enrolled, select the highest degree you have received.)

- o master's (Master of Arts/Master of Education/Master of Science)
- clinical doctorate (SLPD)
- research doctorate (Doctor of Philosophy/Doctor of Education)

6. How many years have you been an SLP?

- \circ <1 \circ 1-5 \circ 6-10 \circ 11-20 \circ 21+
- 7. How many years have you treated individuals with dysphagia?
 - \circ <1 \circ 1-5 \circ 6-10 \circ 11-20 \circ 21+

8. Professional Certifications (Check ALL that apply.)

- Certificate of Clinical Competence (CCC)
- o Modified Barium Swallow Impairment Protocol (MBSImP)
- McNeill Dysphagia Therapy Program (MDTP)
- Board Certification Specialist Swallowing and Swallowing Disorders (BCS-S)
- FEES Competency Training

9. Select your current work setting. (If multiple settings apply, choose the setting you would consider your *primary* work environment.)

- Medical hospital
- Rehabilitation hospital
- Pediatric hospital
- Skilled nursing facility
- Home health
- o Outpatient
- Private practice
- Research lab
- Long-term care
- o Other

10. Including graduate school, continuing education courses, or any other structured training program, have you received formal instruction regarding the relationship between *dysphagia* and *pneumonia*?

- o No
- o Yes

(For individuals who answered yes, the following text was displayed.) You indicated that you received formal training regarding the relationship between *dysphagia* and *pneumonia*. Please indicate the setting in which you received your training.

- Master's program
- Doctoral program
- Continuing education course
- Other (please specify):

11. Including graduate school, continuing education courses, or any other structured training program, have you received formal instruction regarding the relationship between *dysphagia* and *malnutrition/dehydration*?

- o No
- o Yes

(For individuals who answered yes, the following text was displayed.) You indicated that you received formal training regarding the relationship

between *dysphagia* and *malnutrition/dehydration*. Please indicate the setting in which you received your training.

- Master's program
- Doctoral program
- Continuing education course
- Other (please specify):

12. In a typical week, how many dysphagia evaluations do you perform?

- o <1
- o 1**-**2
- o **3-5**
- o 6-10
- o 11+
13. Give your best estimate of the percentage of individuals who you evaluated for dysphagia that were referred for flexible endoscopic evaluation of swallowing *(FEES)* or modified barium swallow study *(MBS/VFSS)*?

o 0

- o 1**-**20%
- o 21-40%
- o 41-60%
- 61-80%
 81-100%

14. What percentage of your caseload would you estimate involves dysphagia treatment?

- o 1**-**20%
- o 21-40%
- o 41-60%
- o 61**-**80%
- o 81-100%

Survey Questions:

1. From the list provided, select the *primary goal* of a *swallowing evaluation* completed by a SLP.

- To optimize nutrition and hydration
- To improve quality of life for individuals with dysphagia
- To determine the least restrictive diet
- To develop a treatment plan for rehabilitation or maintenance of swallowing function
- To prevent aspiration
- To prevent pneumonia from aspiration
- \circ $\,$ To determine the biomechanical deficits associated with dysphagia
- Other:

2. When making recommendations from a swallowing evaluation, the *primary goal of dysphagia intervention* should be:

- To prevent aspiration
- To prevent laryngeal penetration
- To prevent pneumonia
- To optimize nutrition and hydration
- To improve quality of life
- Other:

3. Is the aspiration of food or liquid all that is required for the development of pneumonia?

- o No
- o Yes

4. What presents a greater risk to the overall health of an individual with dysphagia?

- Aspiration
- Malnutrition and dehydration
- o I don't know

5. Expressed as a percentage, how often does visualized aspiration result in pneumonia in the patients with *acute stroke*?

- o 1**-**10%
- o 11-25%
- o 26-40%
- o >40%
- I don't know

6. Expressed as a percentage, how often does visualized aspiration result in pneumonia in patients who have *NOT had an acute stroke*?

- o 1**-**10%
- o 11-25%
- o 26-40%
- o >40%
- o I don't know

7. As part of dysphagia management, I recommend modified diet textures when needed.

- o No
- o Yes

8. As part of dysphagia management, I recommend thickened liquids when needed.

- o No
- o Yes

9. Is there a relationship between *malnutrition* and the consumption of modified diet textures?

- o No
- o Yes
- o I don't know

10. Is there a relationship between *dehydration* and the consumption of modified diet textures or thickened liquids?

- o No
- o Yes
- o I don't know

11. From the list below, select *any risk you know to be associated* with the consumption of *modified diet textures*. (Select <u>ALL</u> that apply.)

- Malnutrition
- Dehydration
- Respiratory infection
- Poor recovery from illness
- Constipation
- Urinary tract infection
- Slow digestion
- Interfere with medication absorption
- Decreased quality of life
- Constant feeling of thirst
- None of the items apply
- I don't know

12. From the list below, select *any risk you know to be associated* with the consumption of *thickened liquids*. (Select <u>ALL</u> that apply.)

- o Malnutrition
- o Dehydration
- Respiratory infection
- Poor recovery from illness
- Constipation
- Urinary tract infection
- Slow digestion
- Interfere with medication absorption
- Decreased quality of life
- Constant feeling of thirst
- None of the items apply
- o I don't know
- 13. For a typical individual with dysphagia, I feel it is *MOST important* to:
 - Eliminate or reduce aspiration
 - Improve quality of life
 - Improve nutrition and hydration
 - Reduce pneumonia risk
- 14. Before recommending thickened liquids,

I weigh the known risks of aspiration against the known risks of consuming thickened liquids.

- Almost never (less than 10%)
- Rarely (10-39%)
- Occasionally (40-59%)
- Very frequently (60-89%)
- Almost always (90% or more)

I inform the patient of the possible risks associated with thickened liquids.

- Almost never (less than 10%)
- Rarely (10-39%)
- Occasionally (40-59%)
- Very frequently (60-89%)
- Almost always (90% or more)

I inform the medical team (doctors, nurses, dietitians, etc.) of the risks associated with thickened liquids.

- Almost never (less than 10%)
- Rarely (10-39%)
- Occasionally (40-59%)
- Very frequently (60-89%)
- Almost always (90% or more)

15. Before recommending altered diet textures,

I weigh the known risks of aspiration against the known risks of consuming altered diet textures.

- Almost never (less than 10%)
- Rarely (10-39%)
- Occasionally (40-59%)
- Very frequently (60-89%)
- Almost always (90% or more)

I inform the patient of the possible risks associated with altered diet textures.

- Almost never (less than 10%)
- o Rarely (10-39%)
- Occasionally (40-59%)
- Very frequently (60-89%)
- Almost always (90% or more)

I inform the medical team (doctors, nurses, dietitians, etc.) of the risks associated with altered diet textures.

- Almost never (less than 10%)
- Rarely (10-39%)
- Occasionally (40-59%)
- Very frequently (60-89%)
- Almost always (90% or more)

16. Indicate the *primary reason* that you would recommend an individual consume an altered texture diet.

- Reduced signs/symptoms of aspiration at bedside
- Improvement in overall medical condition
- Improvement in mastication
- Clinical signs of malnutrition or dehydration
- Reduced quality of life
- Improvement in cognition
- o Improvement in airway protection on FEES/MBS

17. Indicate the *primary reason* that you would recommend upgrading an individual's diet from an altered texture to a regular texture diet.

- Reduced signs/symptoms of aspiration at bedside
- Improvement in overall medical condition
- Improvement in mastication
- Clinical signs of malnutrition or dehydration
- Reduced quality of life
- Improvement in cognition
- o Improvement in airway protection on FEES/MBS

18. Indicate the *primary reason* that you would recommend an individual consume thickened liquids.

- Signs/symptoms of aspiration at bedside
- Aspiration observed on FEES/MBS
- Patient request
- Reduced oral intake of thin liquids
- Concern for dehydration
- Risk of aspiration
- o Risk of pneumonia

19. Indicate the *primary reason* that you would recommend upgrading an individual's liquid viscosity from thickened to thin liquids.

- Reduced signs/symptoms of aspiration at bedside
- Improvement in overall medical condition
- Improvement in mastication
- Clinical signs of malnutrition or dehydration
- Reduced quality of life
- Improvement in cognition
- o Improvement in airway protection on FEES/MBS

APPENDIX B FOR CHAPTER IV

IRB APPROVAL LETTER

IRB

INSTITUTIONAL REVIEW BOARD

Office of Research Compliance, 010A Sam Ingram Building, 2269 Middle Tennessee Blvd Murfreesboro, TN 37129 FWA: 00005331/IRB Regn. 0003571



IRBN007b - CLASS PROJECTS EXEMPTION NOTICE

Friday, February 26, 2021

Protocol Title	HLTH 6750 Survey Methods Class Project	
Protocol ID	21-4122 2q	
Principal Investigator	Angela Bowman (Faculty)	
Co-Investigators	Registered Class Students	
Investigator Email(s)	angie.bowman@mtsu.edu	

NONE

Health and Human Performance

Investigator Email(s) Department/Affiliation Funding

Dear Investigator(s),

The above identified research proposal has been reviewed by the MTSU Institutional Review Board (IRB) through the **EXEMPT** review mechanism under 45 CFR 46.101(b)(2) within the research category (2) *Educational Tests, surveys, interviews or observations of public behavior (Qualtrics Surveys).* A summary of the IRB action and other particulars of this protocol are shown below:

IRB Action	EXEMPT fro Exempt from fur	m further IRB Review ther continuing review but other ov	ersight requirements apply		
Date of Expiration	2/28/2023	Date of Approval: 2/26/21	Recent Amendment: NONE		
Sample Size	TEN THOUSA	ND (10,000)			
Participant Pool	Healthy adult	s (18 or older)			
Exceptions	Online consen	t followed by internet-based sur	vey using Qualtrics is permitted		
Type of Interaction	 Non-interventional or Data Analysis Virtual/Remote/Online Interview/survey In person or physical- Mandatory COVID-19 Management (refer next page) 				
Mandatory Restrictions	1. All restricti 2. Data Collee compliance p 3. Recruitme ID, title, stude 4. Training: The procedures a 5. Informed C templates pri	ons for exemption apply. tion: The PI will review all of rior to their use. This include nt: All non-verbal recruitmen ont name and PI name. All of the student workers mu PI must train the students on pproved (documentation is re onsent: The PI must review a or their use, including online	the research instruments for s any Qualtrics links. t scripts must contain the protocol st complete the necessary CITI the approved methods & commended). nd approve all informed consent consent.		
Approved IRB Templates	IRB Template Non-MTSU Te	s: Scripts will be validated by the mplates: NONE	PI		
Research Inducement	NONE				
Comments	Class Project	Protocol			

IRBN007b (Ve1.0 - 02.23.2021)

FWA: 00005331

IRB Registration. 0003571

FWA: 00005331

IRB Registration. 0003571

Summary of the Post-approval Requirements: The PI must read and abide by the post-approval conditions (Refer "Quick Links" in the bottom):

- Final Report: The PI must close-out this protocol by submitting a final report before 2/28/2023; if more time
 is needed to complete the data collection, the PI must request an extension by email. <u>REMINDERS WILLNOT
 BE SENT</u>. Failure to close-out (or request extension) may result in penalties including cancellation of
 the data collected using this protocol or withholding student diploma.
- Protocol Amendments: IRB approval must be obtained for all types of amendments, such as:
 - Addition/removal of subject population and sample size
 - Change in investigators
 - o Changes to the research sites appropriate permission letter(s) from may be needed
 - Alternation to funding
 - Amendments must be clearly described in an addendum request form
 - The proposed change must be consistent with the approved protocol and they must comply with exemption requirements
- Reporting Adverse Events: Research-related injuries to the participants and other events, such as, deviations & misconduct, must be reported within 48 hours of such events to compliance@mtsu.edu
- Research Participant Compensation: Compensation for research participation must be awarded as
 proposed in Chapter 6 of the Exempt protocol. The documentation of the monetary compensation must
 Appendix J and MUST NOT include protocol details when reporting to the MTSU Business Office.
- COVID-19: Regardless whether this study poses a threat to the participants or not, refer to the COVID-19 Management section for important information for the FA.

Class Project Restrictions

- <u>Data Collection</u>: The PI will review all of the research instruments for compliance prior to their use. This includes any Qualtrics links.
- <u>Recruitment</u>: All non-verbal recruitment scripts must contain the protocol ID, title, student name and PI name.
- <u>Training</u>: All of the student workers must complete the necessary CITI training. The PI must train the students on the approved methods & procedures approved (documentation is recommended).
- Informed Consent: The PI must review and approve all informed consent templates prior their use, including online consent.
- Project Reports: The PI must ensure all of the student workers submit a final report outlining the endpoints of their, including any deviations.

COVID-19 Management:

The PI must follow social distancing guidelines and other practices to avoid viral exposure to the participants and other workers when physical contact with the subjects is made during the study.

- The study must be stopped if a participant or an investigator should test positive for COVID-19 within 14 days
 of the research interaction. This must be reported to the IRB as an "adverse event."
- The MTSU's "Return-to-work" questionnaire found in Pipeline must be filled by the investigators on the day
 of the research interaction prior to physical contact.
- PPE must be worn if the participant would be within 6 feet from the each other or with an investigator.
- Physical surfaces that will come in contact with the participants must be sanitized between use
- PI's Responsibility: The PI is given the administrative authority to make emergency changes to protect the wellbeing of the participants and student researchers during the COVID-19 pandemic. However, the PI must notify the IRB after such changes have been made. The IRB will audit the changes at a later date and the PI will be instructed to carryout remedial measures if needed.

Post-approval Protocol Amendments:

The current MTSU IRB policies allow the investigators to implement minor and significant amendments that would not result in the cancellation of the protocol's eligibility for exemption. **Only THREE procedural amendments will be entertained per year** (changes like addition/removal of research personnel are not restricted by this rule).

Date	Amendment(s)	IRB Comments
NONE	NONE.	NONE

Institutional Review Board, MTSU

FWA: 00005331

IRB Registration. 0003571

Post-approval IRB Actions:

The following actions are done subsequent to the approval of this protocol on request by the PI or on recommendation by the IRB or by both.

Date	IRB Action(s)	IRB Comments
NONE	NONE.	NONE

Mandatory Data Storage Requirement:

All research-related records (signed consent forms, investigator training and etc.) must be retained by the PI or the faculty advisor (if the PI is a student) at the secure location mentioned in the protocol application. The data must be stored for at least three (3) years after the study is closed. Additionally, the Tennessee State data retention requirement may apply (*refer "Quick Links" below for policy 129*). Subsequently, the data may be destroyed in a manner that maintains confidentiality and anonymity of the research subjects. **The IRB reserves the right to modify/update the approval criteria or change/cancel the terms listed in this notice**. Be advised that IRB also reserves the right to inspect or audit your records if needed.

Sincerely,

Institutional Review Board Middle Tennessee State University

Quick Links:

- Post-approval Responsibilities: <u>http://www.mtsu.edu/irb/FAQ/PostApprovalResponsibilities.php</u>
- Exemption Procedures: <u>https://mtsu.edu/irb/ExemptPaperWork.php</u>
- MTSU Policy 129: Records retention & Disposal: <u>https://www.mtsu.edu/policies/general/129.php</u>

CHAPTER V

OVERALL CONCLUSIONS

The aim of this research project was to investigate whether SLPs—who are the medical professionals primarily tasked with treating disorders of oropharyngeal swallowing—can reliably evaluate airway protection behaviors when assessing swallowing via FEES and whether SLPs can adequately inform their patients of the risks associated with untreated OD versus the risks associated with the treatment of OD with MTDs. For this research project, FEES was utilized as the "gold standard" criterion for determining individual airway protection during swallowing tasks. As noted previously, the distinction between normal and disordered airway protection behaviors appears clear. The normative data on which this distinction between normal swallowing and disordered swallowing comes largely from groups of healthy volunteers who do not have OD. While the distinction between healthy swallowing and OD is vital to the field of deglutology, SLPs who treat individuals with OD also require knowledge of the frequency of airway protection behaviors demonstrated by individuals with OD. The majority of studies investigating airway protection behaviors in patients with OD have been completed with relatively small sample sizes or on specific subgroups like stroke or neurodegenerative diseases. As the etiology of OD is heterogenous, practicing clinicians require large sample sizes from the general medical population that is representative of the patients with OD that they treat.

Without adequate and accurate data from individuals with OD, it is difficult for SLPs to determine the severity of airway protection impairments or to determine the

efficacy of any treatment recommendation. To date, there have been few large-scale studies that have published the airway protection behaviors of persons with OD when observed during FEES. To assess whether swallowing is normal or disordered, SLPs first require a reliable airway protection scale for analyzing airway protection using FEES, and the 5-point APS was created specifically for use with FEES in a heterogenous patient population. The APS has been utilized clinically by SLPs performing FEES since 2018, but the reliability of the scale had not been investigated.

The initial piece of this research project was designed to determine if multiple SLPs, trained in the use of the APS for FEES, could reliably interpret FEES video files using the APS. Inter-rater agreement—determined via Fleiss' kappa—found "almost perfect agreement" among the five SLPs, $\kappa = .91$ (95% CI, .881 to .939), p < .0005. Intra-rater agreement for the randomized video files, when scored two weeks after the initial rating session, ranged from "substantial" ($\kappa = .80$) for one judge to "almost perfect agreement" for the remaining four SLP raters ($\kappa = .95 - 1.0$). These results present strong evidence that these five raters can reliably rate airway protection behaviors with the APS when reviewing FEES videos.

After establishing the reliability of the five SLP raters with the APS, the frequency of airway protection behaviors for individuals with OD was explored. By randomly sampling 25% of all FEES reports from the same five SLP raters from the previous reliability study, a database of APS scores was created.

In this cohort of 477 patients admitted to post-acute care facilities, the most striking finding was the number of completely "normal" or "functionally normal" swallows. Of the 9,227 swallows evaluated with the APS, 85.7% (n = 7,908) of all swallows were rated as "normal" or "functionally normal." Hence, in this sample of individuals with suspected or confirmed OD, swallow function remained relatively intact even in the setting of significant medical debility. However, factors such as age and sex are known to influence the frequency and severity of OD. Thus, the relationship between age and dysphagia as well as sex and dysphagia were investigated.

Age is associated with increased likelihood of developing OD and with higher rates of laryngeal penetration and aspiration in healthy adults. The current group of patients contained individuals who were previously screened for OD and who were referred for further evaluation with FEES—allowing for the identification of the frequency of airway protection behaviors commonly seen in a typical inpatient population comprised of individuals in post-acute care facilities. The average age of the cohort was 72.2 years old, and age—especially age 65 and older—has been shown to be a reliable predictor of developing OD (Langmore et al., 1998). While this dataset contains a significant portion of individuals over 65, the range of ages in this population was 21 years to 99 years.

All individuals in the sample were patients admitted to post-acute care facilities who had already been referred for FEES due to concerns for OD. Hence, it was unclear if age would impact the APS ratings for this population. In this group, there did not appear to be a significant relationship between age and APS scores. Correlations were computed for all 50 distinct textures and volumes given during FEES. No value reported was higher than r = .095—which does not indicate even a weak correlation between age and APS scores. Hence, while age may be a good predictor of initially developing OD, age itself does not appear to impact airway protection behaviors in patients with OD who were evaluated with FEES.

Age, in healthy adults with normal swallowing, reliably predicts increases in the frequency of aspiration and of increases in the amount of pharyngeal residue, and the likelihood of developing OD increases with age. This may be due to the known fact that swallowing physiology changes with age (Humbert et al., 2009). However, the data collected from individuals in this study indicates that age had no relationship to airway protection behaviors. Again, it should be noted that the population for this research study consists of patients who were already screened for and deemed likely of having OD. Rather than disagreeing with previous studies about the relationship between age and OD, our data likely provide a more nuanced view of the relationship between OD and age. Namely, the variability in swallowing behaviors that comes with normal aging likely accounts for increases in pharyngeal residue and for more frequent episodes of laryngeal penetration or aspiration. However, age alone appears insufficient for the development truly disordered swallowing. Furthermore, age by itself does not appear able to predict the frequency or severity of laryngeal penetration or aspiration for patients who are suspected of having or who are confirmed as having OD.

The relationship between sex and OD—especially between sex and aspiration has been previously noted in the literature (Langmore et al., 1998; Ward et al., 2020). It is likely that males made up a larger part of this sample (56.6%; n = 270), because males are more likely to have OD than females. Hence, prior to receiving FEES more males in this cohort either failed a swallow screening or were already determined to have dysphagia via FEES or VFSS. A Fisher exact test was completed on this dataset, and sex did appear to have a significant relationship with OD (p < .001). In this study, males were also significantly more likely to have more frequent and more severe issues with airway protection. An APS score of "5" denotes aspiration without the ability to clear material from the trachea, which is the most severe APS score. Males accounted for 62.8% (n =201) of all APS scores of "5." The inverse of this principle also appears true, because females—who accounted for only 43.6% (n = 207) of the reports sampled—demonstrated significantly more APS scores of "2" (53.8%; n = 769) than their male counterparts. This score describes a functionally normal airway protection behavior. Hence, in this group, males were more likely to have OD and have more severe problems with airway protection than females.

While the first two components of this project investigated the reliability of SLPs when using the APS to analyze FEES videos, the final element examined SLP practice patterns when making treatment recommendations for patients with airway protection issues related to OD. Modifying liquid viscosity or modifying solid food textures is the most common intervention recommended by SLPs for individuals with OD (O'Keeffe et al., 2023). Indeed, the standard practice for treatment of OD appears myopically focused on preventing aspiration by using MTDs, and this practice has been the primary form of intervention for at least five decades of SLP involvement in OD treatment (Carnaby & Harenberg, 2013; Larsen, 1972; O'Keeffe, 2018). Modifying patient diets originated from a desire to have individuals with OD eat and drink with a reduced risk of aspiration—in

hopes that reduced aspiration would lead to less frequent rates of pneumonia and lower overall mortality, but MTDs do not appear to reduce rates of pulmonary complications.

In a medical setting such as a hospital or post-acute care facility, diet recommendations made by SLPs require informed consent (O'Keeffe et al., 2023). However, there is ample evidence from repeated and well-designed studies that altering the viscosity of liquids and the texture of solids does not prevent pulmonary complications like pneumonia (Feinberg et al., 1996; O'Keeffe et al., 2018; O'Keeffe et al., 2021). Additionally, as with most medical interventions, there can be significant health risks associated with consuming MTDs. Hence, any improvement in airway protection—due to the consumption of MTDs—must be weighed against the health risks associated with the consumption of MTDs, which include decreased QOL, malnutrition, dehydration, poor recovery from illness, and respiratory infection (O'Keeffe, 2018).

Practicing SLPs in the United States typically complete a 4-year undergraduate program and a 2-year intensive graduate course of study. The American Speech-Language-Hearing Association (ASHA) accredits graduate programs for SLPs. As part of their graduate education, SLPs are not required to have specific training regarding the health risks to patients when consuming MTDs (ASHA, 2014; Bice et al., 2022; Bice et al., 2024). Since the implementation of their use for patients with OD, many negative health outcomes associated with the use of MTDs have been recognized. Thirteen risks of MTDs, which are well-supported by research literature, were identified and utilized for this survey of SLP practice patterns. Over 93% of SLPs surveyed indicated that they recommend MTDs—which includes altering the texture of solid foods or changing the viscosity of liquids. Typically, these recommendations for MTDs are made based on problems with airway protection when swallowing either visualized directly with instrumental studies (e.g., FEES or VFSS) or with non-instrumental evaluations. SLPs prescribe the use of MTDs for patients to protect against pulmonary complications like pneumonia, but SLPs who advise patients to consume MTDs must be able to fully inform their patients about the risks associated with this form of treatment. Yet, SLPs are not required to have specific training, in graduate school or at their job, in these risks to individuals who eat and drink MTDs. Thus, a simple research question arose: do SLPs have sufficient knowledge of the outcomes associated with MTDs to fully inform their patients of the potential hazards that come with eating and drinking MTDs?

The last phase of this research project was a survey of clinical practice patterns of SLPs. Fewer than half of all SLPs surveyed reported that they "almost always" informed patients and families of the risks associated with MTDs, and 70% of SLPs surveyed (n = 140) stated that they "almost always" weigh the risk of aspiration against the risks associated with the use of thickened liquids. However, when asked to select known risks associated with MTDs, on average SLPs were able to identify only 6.72 of the 13 known risks (n = 253, M = 6.72, SD = 4.41), and only 6.3% (n = 16) of practicing SLPs correctly selected all 13 known risks. These data indicate, at a minimum, that the overwhelming majority of SLPs surveyed do not possess the knowledge of the risks associated with MTDs that would be required to garner informed consent from their patients. Moreover, the current survey supports the findings of an already existing body of literature from seminal surveys of clinical practice patterns. Namely, SLPs, much like other medical professionals (Ubbink et al., 2011), exhibit suboptimal levels of evidence-based

practice—which has been verified in multiple studies spanning at least 20 years (Bice et al., 2022; Carnaby & Harenberg, 2013; Martino et al., 2004; Rumbach et al., 2018; Vose et al., 2018). Finally, the survey data collected from this current study calls into question the use of MTDs as a frontline defense against preventable pulmonary complications, because of their limited efficacy coupled with the fact that many practicing SLPs appear unable to fully inform their patients of the benefits versus the risks associated with consuming MTDs.

These findings have significant implications for practicing SLPs and for medical professionals who treat OD. Previously published surveys—which also found poor adherence to evidence-based practice for SLPs—hypothesized that graduate and professional training may be insufficient to prepare SLPs to treat the complex disorder that is OD (Bice et al., 2022; Vose et al., 2018). Caseload, productivity, and other workplace related demands on SLPs have also been suggested as barriers to optimal practice patterns (Vose et al., 2018). Regardless of the barriers, the literature appears quite clear that MTDs have minimal efficacy when it comes to preventing pulmonary complications like pneumonia. Yet, preventing chest infections is the primary driver for SLP intervention and for the recommendation of MTDs. Despite the consensus that MTDs do not prevent pneumonia and other pulmonary complications, greater than 93% of SLPs continue to prescribe MTDs as the primary method of preventing chest infections.

Lastly, the fact that only 6.3% of SLPs surveyed could name all of the known hazards associated with MTDs is disconcerting. Informed consent is required for medical

professionals who recommend any intervention, and MTDs carry no less risk than many other medical treatments. In fact, MTDs are associated with serious medical complications like poor recovery from illness, malnutrition, and dehydration—all of which can have dire consequences. Despite the serious and negative health outcomes that are associated with MTDs, the field of speech-language pathology appears unaware of, or unable to deal with, the perils of prescribing MTDs as the primary method of treating OD. The results of this project stand alongside previous research into the efficacy of MTDs and present in high relief the need for sea change within the field of swallowing disorders.

CHAPTER VI

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