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MBSS PROCEDURAL GOVERNANCE

American College of Radiology:

- 2017 ACR-SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF THE MODIFIED BARIUM SWALLOW – Section D.1.a (https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Modified-Ba-Swallow.pdf. Accessed April 20, 2018):
    - *Assessment includes all phases of swallowing from the preparatory oral phase through the oral transfer phase and pharyngeal phase. The esophageal phase may be assessed on other swallows*.

American Speech-Language Hearing Association:

- SLP must possess the ability to recognize characteristic patient complaints and obtain a clinical history, which assists in identifying primary or related esophageal phase problems
- The role of the SLP includes identifying disorders of the upper aerodigestive tract relative to swallowing, which includes oral, pharyngeal, and cervical esophageal anatomic regions
- Clinicians should be aware that oropharyngeal swallowing function is often altered in patients with esophageal motility disorders and dysphagia
- Knowledge and Skills Needed by Speech-Language Pathologists Performing Videofluoroscopic Swallowing Studies (https://www.asha.org/policy/KS2004-00076/)
    - *The implementation of the videofluoroscopic swallowing study requires advanced and specific skills in order to determine an appropriate test protocol, make online decisions regarding management options during the examination, assess oral, pharyngeal, and esophageal swallowing physiology, make specific functional diagnoses and dietary recommendations, and understand issues relative to radiation equipment and safety.*
    - *The videofluoroscopic swallowing study is a dynamic radiographic study. The examination images oral, pharyngeal, and cervical-esophageal bolus flow during swallowing*
    - Knowledge is required in: *The interrelationships of the oral, pharyngeal, and esophageal phases of swallowing; The range of symptoms that may be reported by individuals, caretakers, or parents that reflect possible oral, pharyngeal, and/or esophageal dysphagia; If esophageal screening is completed, describe any suspected anatomic and/or physiologic abnormalities of the esophagus which might impact the pharyngeal swallow, deferring to radiology for diagnostic statements.*
- ASHA Practice Portal, Adult Dysphagia (https://www.asha.org/Practice-Portal/Clinical-Topics/Adult-Dysphagia/. Accessed April 20, 2018):
    - SLPs with appropriate training and competence are involved in the diagnosis and management of oral and pharyngeal dysphagia. *SLPs also recognize causes and signs/symptoms of esophageal dysphagia and make appropriate referrals for its diagnosis and management.*
    - At minimum, a VFSS includes…Obtaining ***lateral and anterior–posterior*** views of oral cavity, pharynx, *and upper esophagus*, as needed, for each of the bolus types
- ASHA Practice Portal, Videofluoroscpic Swallow Study (https://www.asha.org/practice-portal/clinical-topics/pediatric-feeding-and-swallowing/videofluoroscopic-swallow-study/)
    - *Lateral and anterior–posterior views of the oral cavity, pharynx, and upper esophagus provide different valuable information on swallowing anatomy and physiology.*

- *Clinicians select bolus type (e.g., consistency, volume) for each trial carefully, as some consistencies and/or volumes may influence the clinician's overall impression of the swallow function more than others (Martin-Harris et al., 2008; Sandidge 2009; Hazelwood et al., 2017).*
- SLPs should make observations of the 17 physiologic components included in the MBSImP: *lip closure, tongue control during bolus hold, bolus preparation, bolus transport, oral residue, initiation of the pharyngeal swallow response, soft palate elevation, laryngeal elevation, anterior hyoid motion, epiglottic movement, laryngeal closure, pharyngeal stripping wave, pharyngeal contraction, PES opening, tongue base retraction, pharyngeal residue, esophageal clearance in the upright position*.

References

Martin-Harris, B., & Jones, B. (2008). The videofluorographic swallowing study. *Physical medicine and rehabilitation clinics of North America*, *19*(4), 769-785.

Sandidge, J. (2009). The Modified Barium Swallow Impairment Profile (MBSImP): a new standard physiologic approach to swallowing assessment and targeted treatment. *Perspectives on Swallowing and Swallowing Disorders (Dysphagia)*, *18*(4), 117-122.

Hazelwood, R., Armeson, K. E., Hill, E. G., Bonilha, H. S., & Martin-Harris, B. (2017). Identification of swallowing tasks from a modified barium swallow study that optimize the detection of physiological impairment. *Journal of Speech, Language, and Hearing Research*, *60*(7), 1855-1863.

EXPERT CONSENSUS ON USE OF MBSIMP

Consensus Articles

Martin-Harris, B., Bonilha, H., Brodsky, M., Francis, D., Fynes, M., Martino, R., O'Rourke, A., Rogus-Pulia, N., Spinazzi, N., Zarzour, J. (2021, online ahead of print). The Modified Barium Swallow Study for Oropharyngeal Dysphagia: Recommendations from an Interdisciplinary Expert Panel. *Perspectives of the ASHA Special Interest Groups,* 1-10. [DOI: 10.1044/2021_PERSP-20-00303]

- This article provides MBSS consensus recommendations from an expert panel of SLPs, radiologists, and physicians.
- *The Modified Barium Swallow Impairment Profile (MBSImP) is a well-validated tool for assessment of 17 components of swallowing physiology and bolus clearance for each consistency of barium sulfate contrast (Hazelwood et al., 2017; Martin-Harris et al., 2008; MBSImP, 2020). The MBSImP is the only available assessment tool that has been rigorously tested and validated for the specific purpose of scoring oropharyngeal swallow physiology (Martin-Harris et al., 2017) and has been implemented widely in both research and clinical settings (MBSImP, 2020). Importantly, validation of the MBSImP has been conducted with the use of Varibar, allowing for consistent information to be obtained in the same manner both within and between patients, clinicians, and settings.*
- ***Consensus recommendation no. 4****: Minimum technical requirements for an optimal MBSS should include administration of standardized barium sulfate contrast agent volumes and consistencies, utilization of standardized protocols that specify continuous fluoroscopy settings and adequate digital video capture rates to obtain high-resolution images, implementation of As Low As Reasonably Achievable, use of standardized scoring interpretation metrics, and the ability to store and retrieve the resulting high-definition MBSS images.*

Martin-Harris, B., Canon, C. L., Bonilha, H. S., Murray, J., Davidson, K., & Lefton-Greif, M. A. (2020). Best practices in modified barium swallow studies. *American Journal of Speech-Language Pathology, 29*(2S), 1078–1093. [PMID: 32650657] [DOI: 10.1044/2020_AJSLP-19-00189]

- *The MBSS should employ a protocol characterized by validated core elements or standards that allow transparency, interoperator reproducibility, accurate and reliable measurements, and clear consumer (patients, physicians, clinicians) expectations regarding the procedure and outcomes of the examination.*
- *Valid and reproducible surrogate, visuoperceptual measures should be considered when quantifying swallowing impairment.*
- Specific measures should be chosen that capture the critical physiological elements comprising the oral, pharyngeal, and esophageal domains of the swallowing mechanism.
- *Ideal performance of the MBSS includes an agreed upon protocol by the interdisciplinary team. This provides the most standardized and therefore reproducible evaluation, particularly important in assessment of patients overtime. The Modified Barium Swallow Impairment Profile is a tool that provides this standardization and continuity between the team members and across multiple studies and facilities.*
- *The use of a standardized protocol helps the radiologist know how to optimally conduct the exam. Structured reporting also provides reproducibility over time and reduces reporting variability. Collaborative teams provide the foundation for advancement of clinical knowledge and optimization of protocols.*

SUPPORT FOR MBSIMP STANDARDIZATION

Speaking points for standardization

It is strongly recommend to review the standardization presentation that is part of MBSImP training: https://youtu.be/zYl1g7ujZ4E. This is a great resource for standardization as part of practice and gives a thorough background of how and why the MBSImP was standardized. You'll also find the 2017 Perspectives article by Martin-Harris et al. helpful. It is a summary of the MBSImP in practice. Some main talking points:

- Standardization involves implementing and developing technical standards based on the consensus of different parties. It should maximize compatibility, interoperability, safety, reproducibility, transparency and quality of the exam across clinics and laboratories. In addition to standardization of fluoroscopy settings, analysis of the exam and reporting, the protocol approach and method should also be standardized.
- The modified barium swallow study is not a feeding test. It provides information about swallowing physiology and response to interventions.Penetration/aspiration are outcomes of impaired swallowing physiology. They are neither necessary nor sufficient measures of impairment.
- *TRANSLATING RESEARCH INTO PRACTICE (TRIP)-II. FACT SHEET, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, PUBLICATION No. 01-P017:*
    - Lack of standardization impedes understanding of true functional results, produces ambiguous reporting of outcomes, and hinders our understanding of restorative surgical & rehabilitation targets.
    - The following should be standardized: the instrument (contents and format), the data collection protocol (approach and method), the analyses (to minimize variation in scoring and interpretation) and reporting (well-tested approaches to presenting results)
    - Standardized reporting improves financial performance, improves quality of care, reduces malpractice risk, complies with HIPAA and other government regulations, and improves job satisfaction for providers and staff.
- Martin-Harris, B., Brodsky, M. B., Michel, Y., Castell, D. O., Schleicher, M., Sandidge, J., ... & Blair, J. (2008). MBS measurement tool for swallow impairment-MBSImp: establishing a standard. *Dysphagia*, *23*(4), 392-405.
    - Aim of the study was to test the reliability, content, construct and external validity of a MBSS tool (MBSImP) used to quantify oropharyngeal *and esophagea l*swallowing impairment. Delphi method was used to reach consensus among a panel of experts regarding the literature-based physiologic components of oropharygneal and esophageal swallowing that should be included in the tool. The multidisciplinary panel included SLPs, otolaryngologists, *radiologists, gastroenterologists*, and physiatrists. Content validation was achieved for 17 physiologic components of oropharyngeal and pharyngoesophageal swallowing and their operational definitions representing unique observation of bolus flow. Following standardized training and reliability testing, inter- and intrarater concordance were 80% or greater for blinded scoring of MBSS. The standardized MBSImP tool *and protocol* demonstrated clinical practicality, favorable inter- and inatrarater reliability following standardized training, and content and external validity.
    - The MBSImP standardizes the method of training, administration protocol, assessment tool, vernacular, analysis and reporting methods. It also enhances reproducibility across clinics and laboratories.
    - The MBSImP is a standardized tool with proven content, construct and external validity. It is physiologic vs. symptoms based, clinically practical and linked to clinical action.
- Muckler, F. A., & Seven, S. A. (1992). Selecting performance measures:" Objective" versus" subjective" measurement. *Human factors*, *34*(4), 441-455. [DOI: 10.1177/001872089203400406]
    - There are several factors that optimize objectivity, reproducibility and validity of measurements made from VFS images. The distinction between "objective" and "subjective" measurement is neither

meaningful nor useful in human performance studies. All measurement in science and technology is necessarily filled with subjective elements, whether in selecting measures or in collecting, analyzing, or interpreting data. The following criteria should be considered when selecting measurement tools:

The MBSImP meets the criteria described by Muckler & Seven (1992)

- RELATIVE SIMPLICITY:
  - Measurements must be limited to most critical dimensions and events.
  - Measures should have immediacy, under-standability, and directness to reduce the need for interpretation and to aid in the preciseness of measure definition.
- ADEQUATE VALIDITY:
  - Does the tool measure what it says it measures?
  - The validity of human observer judgments can be improved by training.
  - Training of the human observer might be considered a kind of calibration of the measuring instrument.
- SUFFICIENT RELIABILITY
  - For a measure to mean anything, it must be consistent and repeatable.
  - Consistency within observers as well as across the sample of observers is necessary.
- APPRPRIATE PRECISION:
  - The fineness or grain of the unit of measurement.
  - The accuracy or correctness of the measurement.
  - Unnecessary precision while collecting or analyzing data wastes resources
- NONREACTIVITY
  - The act of measurement can interfere with the process being measured.
  - Unobtrusive measures minimize measurement reactivity.
- GENERALIZABILITY
  - The measure can be used across many research and test settings, leading to measurement standardization.
  - Standard measurement assists in evaluating and comparing results across very different situations.
- DATA-PROCESSING REQUIREMENTS
  - The entire process from sensing of data, to signal processing, to storage, to computation, to readout and display should be considered.
  - The process should be rapid and effective.
- RESOURCE REQUIREMENTS
  - The entire support and resource requirements must be considered in choosing one measure and instrument over another.
  - The human observer is said to be simple and inexpensive, but this is true only if the observer is not extensively trained and sustained.

Standardization of barium volumes & consistencies

The literature provides evidence that swallowing physiology varies based on bolus textures and volumes and the use of multiple bolus types is certainly warranted[1]. That said, presenting excessive amounts of non-inert materials to a dysphagic patient during MBS is dangerous and unnecessarily increases the risk for aspiration pneumonia. Furthermore, the absence of a succinct protocol in the radiology suite increases radiation exposure time for our patients, violating the ALARA principle which states that clinicians should make every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits as practical[2]. The MBS is not a *feeding test*! The MBS should be used for identification and assessment of *physiologic* swallowing impairment. If the presence and nature of swallowing impairment can be identified with a small but varied, standardized sample of bolus volumes and consistencies (the primary goal of MBS), the use of excessive trials of multiple, non-sterile food items during MBS is unnecessary[3]. The MBSImP uses standardized, commercial preparation of barium (Varibar E-Z-EM, Inc.) including thin liquid, nectar thick liquid, honey thick liquid, puree consistency and solid (short bread cookie) in graduated volumes[4]. When presented, these standardized consistencies allow clinicians to capture physiologic impairment in an efficient and timely manner

(even when using compensatory strategies and maneuvers), predict how patients will perform with multiple consistencies at the bedside, and allows for comparison between and within patients across multiple facilities. Keep in mind; the clinician should still observe the patient's performance with MBS recommendations at the bedside. We as a professional organization should be working towards standardization in all aspects of our field. If we ever want to be taken seriously as expert clinicians/researchers in the diagnosis and management of swallowing and swallowing disorders, we must move away from unsafe, non-standardized and unvalidated practices in the radiology suite

1. Logemann JA. Behavioral management for oropharyngeal dysphagia. Folia Phoniatr Logop. 1999;51(4-5):199-212. doi: 10.1159/000021497.
2. Bonilha, H. S., Humphries, K., Blair, J., Hill, E. G., McGrattan, K., Carnes, B., ... & Martin-Harris, B. (2013). Radiation exposure time during MBSS: influence of swallowing impairment severity, medical diagnosis, clinician experience, and standardized protocol use. Dysphagia, 28(1), 77-85.
3. Martin-Harris B, Logemann JA, McMahon S, Schleicher M, Sandidge J. Clinical utility of the modified barium swallow. Dysphagia. 2000;15(3):136-41.
4. Martin-Harris, B., Brodsky, M. B., Michel, Y., Castell, D. O., Schleicher, M., Sandidge, J., ... & Blair, J. (2008). MBS measurement tool for swallow impairment—MBSImp: establishing a standard. *Dysphagia*, *23*(4), 392-405.

There is good evidence to support that no one consistency is sufficient enough to capture all types of physiologic impairment and that the nectar or honey consistency may illicit the worst score (overall impression score) where thin, pudding or solid may not (Hazelwood, 2017). The MBSImP tool was validated using standardized barium consistencies and tasks. Deviations from the protocol poses infection control and aspiration risks and interferes with the validity and reproducibility of the exam results. Further, this practice deviates from the primary purposes of the MBS which are to diagnose the nature and severity of the swallowing impairment and cause(s) of aspiration when present, assess the appropriateness of oral intake and effects of compensatory strategies, and identify physiologic targets for swallowing treatment.

1. Hazelwood, R. J., Armeson, K. E., Hill, E. G., Bonilha, H. S., & Martin-Harris, B. (2017). Identification of Swallowing Tasks From a Modified Barium Swallow Study That Optimize the Detection of Physiological Impairment. Journal of Speech, Language, and Hearing Research, 60(7), 1855-1863.

A standardized set of barium sulfate preparations or consistencies have been developed currently for distribution in the United States, are FDA approved, and are specifically labeled for MBSS (VARIBAR barium sulfate 40% weight/volume, Bracco Diagnostics, Inc.). While this set of consistencies does not represent the full and nearly endless complement of consistencies that may appear in real-life foods and liquids, they are mapped to Levels 0 and 2–4 on the International Dysphagia Diet Standardization Initiative and used in the development of standardized, validated measures of swallowing physiology (Hazelwood et al., 2017; Hind et al., 2012; Lam et al., 2017; Martin-Harris et al., 2008, 2017). There are five primary reasons to avoid off-label mixing of barium powders or suspensions with foods and liquids and instead implement a standardized protocol during the MBSS: (a) Aspiration of food and liquid materials may be a threat to pulmonary health in contrast to aspiration of inert barium; (b) alteration of contrast materials may not be compliant with food safety regulations, pharmaceutical regulations, and infection control policies at the examining institution; (c) mixing of standardized (factory produced, formulated, and premeasured with strict quality control monitoring) barium contrast agents with foods and liquids may alter their viability and visibility; (d) there is no guarantee that clinician-made mixtures in radiology will be replicated at the bedside; and (e) implementation of a standardized protocol that introduces barium contrast agents in graduated bolus volumes and consistencies minimizes risk associated with aspiration of large amounts of barium.

1. Martin-Harris, B., Canon, C. L., Bonilha, H. S., Murray, J., Davidson, K., & Lefton-Greif, M. A. (2020). Best practices in modified barium swallow studies. *American Journal of Speech-Language Pathology, 29*(2S), 1078–1093. [PMID: 32650657] [DOI: 10.1044/2020_AJSLP-19-00189]
2. Martin-Harris, B, Steele, C., & Peterson, J. (2020). Stand up for standardization: Collaborative clarification for clinicians performing Modified Barium Swallowing Studies (MBSS). *Dysphagia Café.*
3. Steele, C., Martin-Harris, B., Gosa, M., Allen, S. Applications in Contrast Imaging: Diagnosis and Management of Swallowing Physiology: Standardized Contrast, the MBSImP™, & the IDDSI Framework Continuing

Education Monograph*,* Applied Radiology, Anderson Publishing, Ltd. (0.10 ASHA CEUS, Intermediate Level; Professional Area), www.appliedradiology.org, May 1, 2021.

Varibar is the only FDA-approved barium sulfate contrast product line for evaluation of swallowing using the MBSS. Varibar products are multi-use and vary in consistency from thin to thick, with each consistency defined by a viscosity range: Thin Liquid (<15 centipoise [cps]), Nectar (<150-450 cps), Thin Honey (800-1800 cps), Honey (2500-3500 cps), and Pudding (puree). Varibar was scientifically formulated to evaluate oropharyngeal swallowing physiology under fluoroscopy, and these formulations represent consistencies known to affect swallowing physiology. Unlike other barium sulfate contrast agents formulated to maximize the mucosal coating required for standard gastrointestinal (GI) imaging studies, Varibar products are formulated to possess minimal coating properties, to facilitate clear visualization of the dynamic swallowing process. Moreover, the 40% weight/volume (w/v) concentration provides uniform opacification across all consistencies, ensuring optimal image quality.

1. Steele, C., Martin-Harris, B., Gosa, M., Allen, S. Applications in Contrast Imaging: Diagnosis and Management of Swallowing Physiology: Standardized Contrast, the MBSImP™, & the IDDSI Framework Continuing Education Monograph, Applied Radiology, Anderson Publishing, Ltd. (0.10 ASHA CEUS, Intermediate Level; Professional Area), www.appliedradiology.org, May 1, 2021.

Standardization facilitates severity classification assignment

Beall J, Hill EG, Armeson K, Garand (Focht) KL, Davidson (Humphries) K, Martin-Harris B. (2020) Classification of swallowing impairment severity: A latent class analysis of Modified Barium Swallow Impairment Profile scores. *Am J Speech Lang Pathol.* 29(2S), 1001–1011. [PMID: 32650665] [PMCID: PMC7844335] [DOI: 10.1044/2020_AJSLP-19-00080]

- MBSImP, as it is designed, ***accurately*** represents increasingly severe gradation of oral and pharyngeal physiologic swallowing impairment.
- MBSImP task-level data revealed significant underlying oral and pharyngeal ordinal class structures representing increasingly severe gradations of physiologic swallow impairment. Clinically meaningful OT and PT score ranges were derived facilitating latent class assignment.
- Diagnostic category, oral intake, feeding tube status, and maximum PAS were all found to be significantly associated with latent class.
- These findings support an evidence-based three-class structure system of severity using quantitative measures of swallow physiology in patients with dysphagia.

Value of Standardization: structural validity, internal consistency, and reliability of the MBSImP

Clain, A., Alkhuwaiter, M., Davidson, K., Martin-Harris, B. (2022). Structural Validity, Internal Consistency, and Rater Reliability of the Modified Barium Swallow Impairment Profile (MBSImP): Breaking Ground on a 52,726-Patient, Clinical Dataset. Journal of Speech, Language, and Hearing Research [Preprint]

Purpose: The purpose of the present study was to extend the testing of the validity and reliability of the Modified Barium Swallow Impairment Profile (MBSImP). In particular, we re-examined structural validity using a new and large data set, and formally examined internal consistency and rater reliability for the first time.

Methods: To assess structural validity and internal consistency, we used a large dataset (**N = 52,726**) drawn from the MBSImP Swallowing Data Registry (SDR) consisting of MBSImP scores from standard-of-care patient visits submitted by MBSImP registered SLPs. Structural validity was assessed via exploratory factor analysis. Internal consistency was measured using Cronbach's Alpha for each of the multi-component MBSImP domains, i.e. the Oral and Pharyngeal Domains (and not the single-component Esophageal Domain). Inter-rater and intra-reliability estimates were measured based on a subset of studies (N = 50) rated by four MBSImP trained and registered SLPs.

Results: The exploratory factor analysis showed a two-factor solution with factors precisely corresponding to the MBSImP Oral and Pharyngeal domains, respectively. Component 17, i.e. the Esophageal Domain, did not load onto either factor, consistent with findings from the initial study (Martin-Harris et al., 2008). Internal consistency was good for both the Oral and Pharyngeal domains (α_{oral} = 0.81; $\alpha_{pharyngeal}$= 0.87). Inter-rater reliability was found to be good with ICC_{inter} = 0.78. Intra-rater reliability was good for each rater, ICC_{rater1} =0.82, ICC_{rater2}= 0.83, ICC_{rater3} = 0.87, ICC_{rater4} = 0.87.

Conclusions: The present study provides strong evidence that ***the MBSImP assessment method has excellent structural validity and internal consistency***. In addition, the present results show that ***MBSImP-trained SLPs can demonstrate good inter-rater and intra-rater reliability***. More broadly, this study shows the value of standardization. We leveraged the standardized MBSImP to create a large, standard-of-care dataset. And in turn, we used this large dataset to further test MBSImP and produce results that are highly generalizable across clinical practice and research.

SUPPORT FOR ESOPHAGEAL FOLLOW THROUGH

Localization of esophageal problems

There are several studies demonstrating how poorly patients are at accurately identifying where their problem is occurring:

- Roeder, B. E., Murray, J. A., & Dierkhising, R. A. (2004). Patient localization of esophageal dysphagia. *Digestive diseases and sciences*, *49*(4), 697-701.
    - EGD and manometry in 100 patients, with 55% localizing problem to proximal esophagus but 42% had distal structural lesions and 56% had diffuse dysfunction (e.g., dysmotility)
- Smith, D.F., Ott, D. J., Gelfand, D. W., & Chen, M. Y. (1998). Lower esophageal mucosal ring: correlation of referred symptoms with radiographic findings using a marshmallow bolus. American *Journal of Roentgenology, 147,*261-265.
    - ½ patients with known distal obstructive lesions localized to suprasternal notch and above.
- Wilcox, C. M., Alexander, L. N., & Clark, W. S. (1995). Localization of an obstructing esophageal lesion. *Digestive diseases and sciences*, *40*(10), 2192-2196.
    - Proximal referral of symptoms was common in patients with lower esophageal mucosal rings, including neck, sternal angle, mid and lower chest

Esophageal follow-through and its association with esophageal dysfunction

- Gullung, J. L., Hill, E. G., Castell, D. O., & Martin-Harris, B. (2012) Oropharyngeal and Esophageal Swallowing Impairments: Their Association and the Predictive Value of the Modified Barium Swallow Impairment Profile and Combined Multichannel Intraluminal Impedance-Esophageal Manometry. *Annals of Otology, Rhinology & Laryngology*, *121*(11), 738-745.
    - Significant association between MBSImP Component 17 scores and abnormal findings on esophageal manometry; delay in initiation of the pharyngeal swallow was significantly associated with abnormal esophageal function (thus, importance to assess pharynx through esophagus because of the interrelationship)
- Allen, J. E., White, C., Leonard, R., & Belafsky, P. C. (2012). Comparison of esophageal screen findings on videofluoroscopy with full esophagram results. *Head & neck*, *34*(2), 264-269.
    - Compared results of esophageal screening during MBSS with findings from esophagram. Sensitivity: 63%; Specificity: 100%; Positive predictive value: 100%; Negative predictive value: 13%. The take home point is that esophageal screening can help lead to appropriate referral for GI evaluation for accurate diagnosis of esophageal dysfunction.
- Miles, A., McMillan, J., Ward, K., & Allen, J. (2015). Esophageal Visualization as an Adjunct to the Videofluoroscopic Study of Swallowing. *Otolaryngology–Head and Neck Surgery*, *152*(3), 488-493.
    - 111 consecutive mixed etiology patients underwent VFSS including esophageal follow-through. 68% of patients had abnormal esophageal transit, 1/3 had both oropharyngeal and esophageal abnormalities. Oral abnormalities, reduced PES maximum opening, and increasing age were significantly associated with esophageal abnormalities. Concluded that fluoroscopic evaluation of the pharynx alone, without esophageal view, risks incomplete diagnosis of patients with esophageal disorders.
- Also, recognition of a potential esophageal dysfunction may lead to appropriate diagnosis of a systemic disease that may have further implications for oropharyngeal dysfunction.

Effect of oropharyngeal swallow strategies on esophageal function

The modified barium swallow study not only assesses swallowing physiology but also can be used to assess the effectiveness of strategies and maneuvers to improve swallowing function. The literature shows that the strategies and maneuvers can have an impact on esophageal physiology. The use of an esophageal follow-through can provide additional insight on how oropharygngeal swallowing maneuvers are impacting the entire mechanism and direct targeted intervention planning.

- O'Rourke, A., Morgan, L. B., Coss-Adame, E., Morrison, M., Weinberger, P., & Postma, G. (2014). The effect of voluntary pharyngeal swallowing maneuvers on esophageal swallowing physiology. *Dysphagia*, *29*(2), 262-268.
    - Healthy volunteers underwent high-resolution pharyngeal manometry while performing 3 randomized swallow maneuvers. Overall number of nonperistaltic swallows was 53% during normal swallows, 66% during Mendelsohn maneuver and 33% during effortful swallow. Mendelsohn maneuver may result in decreased esophageal peristalsis while effortful swallow may improve esophageal peristalsis.

Protocol/standardization of the esophageal follow-through

Standardization involves implementing and developing technical standards based on the consensus of different parties. It should maximize compatibility, interoperability, safety, reproducibility, transparency and quality of the exam across clinics and laboratories. In addition to standardization of fluoroscopy settings, analysis of the exam and reporting, the protocol approach and method should also be standardized. Recent work has established a standardized protocol for evaluation of bolus flow through the esophagus in the upright position during videofluroscopy. Additionally, normative values for esophageal transit times in the upright position during videoflurocsopy have been published.

- Martin-Harris, B., Brodsky, M. B., Michel, Y., Castell, D. O., Schleicher, M., Sandidge, J., ... & Blair, J. (2008). MBS measurement tool for swallow impairment-MBSImp: establishing a standard. *Dysphagia*, *23*(4), 392-405.
    - Aim of the study was to test the reliability, content, construct and external validity of a MBSS tool (MBSImP) used to quantify oropharyngeal*and esophageal*swallowing impairment. Delphi method was used to reach consensus among a panel of experts regarding the literature-based physiologic components of oropharygneal and esophageal swallowing that should be included in the tool. The multidisciplinary panel included SLPs, otolaryngologists, *radiologists, gastroenterologists*, and physiatrists. In addition to 16 physiologic components of oropharyngeal swallowing, content validation was achieved for *esophageal clearance*and its operational definitions representing unique observation of bolus flow. Following standardized training and reliability testing, inter- and intrarater concordance were 80% or greater for blinded scoring of MBSS. The standardized MBSImP tool *and protocol*demonstrated clinical practicality, favorable inter- and inatrarater reliability following standardized training, and content and external validity.
- Modified Barium Swallow Impairment Profile (MBSImP™©) Guide, v.092517, p.11 (mbsimp.com. Accessed April 20th, 2017.
    - Esophageal clearance… represents bolus clearance through the esophagus in the upright position assisted by gravity. That is, the position in which the patient eats and drinks.
    - The bolus should be followed through the oral cavity and the lower esophageal segment (LES) when possible in order to adequately score esophageal clearance.
    - It must be made clear to the attending radiologist that the speech language pathologist is not attempting to diagnose motility or structural anomalies. Rather, esophageal clearance in the upright position affects the process of eating and drinking and other treatment strategies, and empirical studies have shown to influence oropharyngeal-swallowing function.
- Miles, A., Clark, S., Jardine, M., & Allen, J. (2016). Esophageal swallowing timing measures in healthy adults during videofluoroscopy. *Annals of Otology, Rhinology & Laryngology*, *125*(9), 764-769.

- Study aim was to measure esophageal transit times (ETT) of liquid, pill and paste during upright videofluoroscopy to establish normative values. 118 health adults underwent MBS with esophageal follow-through. Mean ETT were: 20mL fluid, 10.7 seconds; pill, 25.3 seconds; paste 28.6 seconds. Age was significantly associated with increasing 20mL fluid ETT ($p<.001$) but not pill ($p=.58$) or paste ETT ($p=.12$). Fluid ETT over 10 seconds occurred in 10% of participants between 20 and 59 years compared to 35% over 60 years old ($p<.001$). These normative values provide a standardized protocol and guidance in interpretation when completing esophageal follow-through as part of videofluroscopy.

Reporting the esophageal follow-through

Include the following statement at the beginning of all MBSS reports.

"NOTE: this study was performed for interpretation only of the oropharyngeal and pharyngoesophageal domains of swallowing. It is not intended to diagnose any other radiologic abnormalities or substitute for a formal esophagram study."

Only use terminology that describes bolus flow/clearance through the esophagus and be careful not to make statements that attempt to diagnose motility or structural abnormalities. If the radiologists provides a diagnosis during the exam, feel free to note: _____ *observed and consistent with a diagnosis of* _____ *per the consulting radiologist. Please reference radiologist's report for formal diagnostic information.*

The MBSImP includes a protocol for assessing esophageal clearance in the AP view (and lateral if necessary) a Likert rating scale and associated operational definitions. The following nomenclature should be used in your reports:

0 = Complete clearance; esophageal coating
1 = Esophageal retention
2 = Esophageal retention with retrograde flow below pharyngoesophageal segment (PES)
3 = Esophageal retention with retrograde flow through PES
4 = Minimal to no esophageal clearance

Again, the goal of the esophageal follow-through is to assess bolus clearance through the esophagus in the upright position assisted by gravity. It must be made clear in your report that the speech language pathologist is not attempting to diagnose motility or structural anomalies.

RADIATION & CANCER RISKS

Radiation Exposure

The literature supports that the use of the MBSImP standardized protocol (including an esophageal follow-through) does not increase radiation exposure times:

- Bonilha, H. S., Humphries, K., Blair, J., Hill, E. G., McGrattan, K., Carnes, B., ... & Martin-Harris, B. (2013). Radiation exposure time during MBSS: influence of swallowing impairment severity, medical diagnosis, clinician experience, and standardized protocol use. *Dysphagia*, *28*(1), 77-85.
    - When using MBSImP protocol, which includes 2 swallows in A-P view with full scanning of the esophagus to stomach, average radiation exposure was 2.9 minutes (N=739 patients), which is well below the 5 minutes limit. Further, the ~3 minutes included those patients that required further trials with use of maneuvers, compensatory strategies, etc.
- Xinou, Ekaterini, et al. "Longitudinal Evaluation of Swallowing with Videofluoroscopy in Patients with Locally Advanced Head and Neck Cancer After Chemoradiation." *Dysphagia*(2018): 1-16.
    - *In the present study, the use of the MBSImP protocol did not lead to unnecessary radiation exposure. Our mean radiation exposure time (2.2-2.5 min) is well under the reported 3.37–8.2 min encountered in previous studies and is comparable to that reported by Bonilha et al., 2014 (2.9 min) and Zammit-Maempel et al., 2007 (2.85 min). This short exposure time may be mainly due to the use of the MBSImP protocol itself, which permits capturing physiologic swallowing impairment without administration of repeated swallows of varied, non-standardized consistencies.*

In a 2019 publication, Bonilha et al. elucidated the radiation exposure and related cancer risks for adult patients undergoing VFSSs. They found that the radiation exposure was an average of 0.27mSv per exam (for perspective, this is less than the amount of radiation emitted from your body in a year, and similar to the radiation exposure associated with living 32 days on earth). This radiation exposure is less than that from a mammogram (0.4mSv) and approximately 1/8th that from a head CT (2mSv). The radiation exposure from adults undergoing VFSS have a related cancer incidence risk ranging from 0.0032% for a 20-year-old female to 0.00049% for a 60-year-old male. When paired with conservative US cancer incidence data that indicates 33% of the population will have a diagnosis of cancer in their lifetime, these values indicate an extremely low increased cancer incidence risk of 0.0097% for a 20-year old female with lower increased risks for males or older individuals. We are widely disseminating this information so that hospitals, clinicians and patients can make informed decisions regarding the benefits and risks of adults undergoing VFSSs.

These extremely low values indicate that the cancer risk from an adult undergoing a VFSS is so low that it is <u>not</u> reasonable to alter the exam in a manner that may reduce diagnostic accuracy in order to reduce radiation exposure.

- Bonilha, H. S., Huda, W., Wilmskoetter, J., Martin-Harris, B., & Tipnis, S. V. (2019). Radiation risks to adult patients undergoing modified barium swallow studies. *Dysphagia*, *34*(6), 922-929. [PMID: 30830303] [PMCID: PMC6722025] [DOI: 10.1007/s00455-019-09993-w]

Pulse Rate

The following is taken from Martin-Harris, B., Canon, C. L., Bonilha, H. S., Murray, J., Davidson, K., & Lefton-Greif, M. A. (2020). Best practices in modified barium swallow studies. *American Journal of Speech-Language Pathology, 29*(2S), 1078–1093. [PMID: 32650657] [DOI: 10.1044/2020_AJSLP-19-00189]:

The standard of care for adults has been continuous fluoroscopy or 30 unique PPS (Bonilha, Blair, et al., 2013; Logemann, 1998; Martin-Harris & Jones, 2008; Peladeau-Pigeon & Steele, 2015). In adults, lower pulse rates have been associated with compromises in diagnostic accuracy and clinical utility (Bonilha, Blair, et al., 2013; Cohen, 2009). Intuitively, a lower pulse rate would not provide imaging of very rapidly evolving physiological movements, such as thin liquid bolus

advancement, sequential pharyngeal contractions, or airway closure. Some discernments (i.e., measures of delayed swallowing) require the clinician to determine normality or disorder based on differences of very short durations, sometimes as short as one tenth of a second (Clavé et al., 2006). Loss of any frame could lead to misdiagnosis.

In a study by Bonilha, Blair, et al. (2013), clinicians viewed studies at the maximum temporal resolution of 30 PPS and at a lesser resolution of 15 PPS while employing the MBSImP and PAS. The clinicians viewing the studies were also asked to make treatment recommendations following both viewing conditions. The authors found significant differences in both physiological observations and in the detection of penetration and aspiration when comparing the two pulse rate recordings. The authors noted a difference in recommendations for treatment when pulse rates were reduced. Misdiagnosis can imperil the patient's health and quality of life. In a similar study, Mulheren et al. (2019) also found differences in certain duration and functional measures of swallowing when comparing 15 PPS to 30 PPS. These findings would suggest that the best practice for capturing and reviewing the MBSS should require image acquisition at 30 PPS as there is a demonstrable reduction in perceptual error.

One study of patients (ranging from 9 days to 21 years), with imaging restricted by equipment to 25 PPS, reported the identification of structures with radiation screening times and dose area products within the previously reported ranges for pediatric VFSS studies (Henderson et al., 2016; Weir et al., 2007). Pulse rates of less than 30 PPS for children have been advocated to reduce exposure during evaluations. However, there are concerns about missing episodes of supraglottic penetration or aspiration during VFSS examination in babies and young children with lower frame rates (e.g., 12.5–15 PPS; Cohen, 2009). With lower pulse rates, it is not known whether examinations are longer or are repeated more often because important findings may have been missed.

Current evidence on radiation exposure and cancer risks confirms that the ***MBSS is a low-dose exam****. The cancer risks for adults undergoing MBSS are very low and should not drive clinical decision making (use of pulse rates of 15 PPS or lower, deciding not to do an MBSS because of radiation exposure concerns, limiting the time of the MBSS due to radiation concerns at the cost of acquiring clinically important information). For adults or children undergoing MBSS, using pulse rates of 15 PPS has been shown to decrease diagnostic accuracy and impact treatment decision making. Best practice is to use a pulse rate of 30 PPS.*

References

Bonilha, H. S., Blair, J., Carnes, B., Huda, W., Humphries, K., McGrattan, K., Michel, Y., & Martin-Harris, B. (2013). Preliminary investigation of the effect of pulse rate on judgments of swallowing impairment and treatment recommendations. Dysphagia, 28(4), 528–538. https://doi.org/10.1007/s00455-013-9463-z

Cohen, M. D. (2009). Can we use pulsed fluoroscopy to decrease the radiation dose during video fluoroscopic feeding studies in children? Clinical Radiology, 64(1), 70–73. https://doi.org/10.1016/j.crad.2008.07.011

Clavé, P., Kraa, M. D., Arreola, V., Girvent, M., Farré, R., Palomera, E., & Serra-Prat, M. (2006). The effect of bolus viscosity on swallowing function in neurogenic dysphagia. Alimentary Pharmacology & Therapeutics, 24(9), 1385–1394. https://doi.org/10.1111/j.1365-2036.2006.03118.x

Mulheren, R. W., Azola, A., & González-Fernández, M. (2019). Do ratings of swallowing function differ by videofluoroscopic rate? An exploratory analysis in patients after acute stroke. Archives of Physical Medicine and Rehabilitation, 100(6), 1085–1090. https://doi.org/10.1016/j.apmr.2018.10.015

Henderson, M., Miles, A., Holgate, V., Peryman, S., & Allen, J. (2016). Application and verification of quantitative objective videofluoroscopic swallowing measures in a pediatric population with dysphagia. The Journal of Pediatrics, 178, 200–205.e1. https://doi.org/10.1016/j.jpeds.2016.07.050

SLP AND RADIOLOGIST COLLABORATION

The following article published by the American College of Radiology that provides discussion of MBS protocol by Dr. Canon (radiologist from UAB) and Dr. Martin-Harris. This is a great article showcasing the collaboration between the 2 fields during the MBSS (https://www.acr.org/Practice-Management-Quality-Informatics/Imaging-3/Case-Studies/Quality-and-Safety/Collaboration-Comes-Standard)

Other articles discussing the importance of SLP and radiologist collaboration are:

Martin-Harris, B., Canon, C. L., Bonilha, H. S., Murray, J., Davidson, K., & Lefton-Greif, M. A. (2020). Best practices in modified barium swallow studies. *American Journal of Speech-Language Pathology, 29*(2S), 1078–1093. [PMID: 32650657] [DOI: 10.1044/2020_AJSLP-19-00189]

- *Radiologists and SLPs implement a collaborative approach when conducting the MBSS. The radiologist consults with the SLP before the exam to review the patient's clinical history, during the exam to ensure the study is effective, and after the exam to coordinate their findings and review them with the patient.*
- *The radiologist assures the safety of not only the patient but also the SLP and others present in the fluoroscopy suite. The radiologist works in partnership with the SLP to determine appropriate patient positioning and constantly assesses risk to the patient.*
- *Engagement between the radiologist and the SLP is critical, as they are often exposed to different bodies of scientific literature, and it is the cross-fertilization of this knowledge that allows for optimal practice. Without collaboration, lack of alignment may arise between team members.*
- *Collaboration between the radiologist and the SLP assures best care for the patient as both are exposed to different bodies of scientific literature that contribute to optimal practice. Opportunities to demonstrate the importance of understanding the complexities of pharyngeal swallowing and how to run a fluoroscopy practice are aided by this type of engagement between the radiologist and the SLP.*

Martin-Harris, B., Bonilha, H., Brodsky, M., Francis, D., Fynes, M., Martino, R., O'Rourke, A., Rogus-Pulia, N., Spinazzi, N., Zarzour, J. (2021, online ahead of print). The Modified Barium Swallow Study for Oropharyngeal Dysphagia: Recommendations From an Interdisciplinary Expert Panel. *Perspectives of the ASHA Special Interest Groups,* 1-10. [DOI: 10.1044/2021_PERSP-20-00303]

***Consensus recommendation no. 5**: In an ideal setting, a radiologist, a radiologic technologist, and an SLP should be present for every MBSS to perform the following:*

- *Radiologist to operate the fluoroscopy equipment, observe anatomic and physiologic components of swallowing during fluoroscopy, confer with the SLP regarding the fluoroscopy images as they appear on the screen, prepare a radiology report (see Reporting section below)*
- *SLP to administer the series of contrast agent consistencies, observe anatomic and physiologic components of swallowing during fluoroscopy, confer with the radiologist regarding the interpretation of fluoroscopy images as they appear on the screen, attempt any compensatory strategies to assist the patient with a maximally efficient and safe swallow, review the video capture of the MBSS as appropriate, perform off-line analysis of videofluoroscopic images, prepare an SLP report*
- *Radiologic technologist to set up contrast materials in the fluoroscopy suite; assist in positioning of the patient; in the absence of a radiologist, operate the fluoroscopy equipment*

UTILIZATION AND UPTAKE

All **50** American states utilize the MBSImP in at least one medical facility.

41 countries have registered MBSImP clinicians practicing in their healthcare systems.

185 universities currently use the MBSImP standardized training within their dysphagia class curriculum.

6,800 SLPs to date have completed the MBSImP standardized training and testing. View Clinician Roster here.

77,000 MBSImP swallow studies have been added to the global swallow data registry, which have contributed much needed data to further the study of dysphagia.