<u>Disclaimer</u>: This document is compiled based on information available in the peerreviewed literature. No claim is made by VitalStim Therapy on the value and merits of the tools described. Some tools are in development and not yet available in print at the time of publishing of this review and are therefore not included. July 2009.

## Background

Outcome tracking tools are commonly used in dysphagia research as a means of objectively measuring change in swallow function and various other variables relevant to swallowing and dysphagia. While outcome tracking tools are less commonly used in the clinical setting, there are many potential benefits to clinicians. Using tracking tools to objectively measure outcomes before and after dysphagia treatment allows clinicians to critically assess the effectiveness of their treatment techniques and make modifications as necessary. Outcome measurement tools can also serve as a quick, objective means of communicating treatment results to referring physicians, hospital administrators, or insurance companies on a case by case basis.

When determining which outcome tracking tool to use, several factors should be considered. The different indications for use of each tool will make some more appropriate for individual clinic settings than others. Some of the tools require a modified barium swallow study for scoring while others do not. A few of the tracking tools require that a patient be able to communicate in order to score. In addition to these characteristics, the user should also consider a tool's reliability and validity.

Reliability refers to a measurement tool's ability to yield the same results repeatedly and not vary over time, both between different clinicians and within a single clinician's repeated administrations. Validity refers to the relationship of the tool's results to what it is designed to measure. Measurements of both reliability and validity are important in determining the accuracy and effectiveness of an outcome tracking tool.

A commonly agreed upon weakness in several dysphagia research studies is the use of custom developed scales for measuring swallowing function. When using such custom scales that have not been tested for validity, there is no certainty that the scale is accurately measuring the outcome that it is intending to measure.

Another weakness in custom scales is that they may not be tested for reliability. Reliability measures assure that if the tool was given repeatedly by one clinician or to the same patient by different clinicians that the results would be consistent. Using a reliable scale ensures that the results measured by the scale can reliably be compared from session to session.

Other measures that can be monitored during dysphagia treatment include issues related to how well the patient is meeting his/her nutritional needs such as daily weight, non-healing wounds, and issues with hydration. These can be monitored and tracked informally for additional information about how dysphagia may impact the patient medically.

# **Outcome Tracking Tools in Dysphagia Management**

Several commonly used outcome tracking tools are listed below. In addition to a list of the characteristics for each tool, details about how to obtain each scale are listed as well. Some of the tools require purchasing the materials or registering with the author in order to use them. Other tools are available merely by obtaining the publication in which they are introduced.

### **Dysphagia Outcome Severity Scale- (DOSS)**

<u>Authors, reference</u>: Karen H. O'Neil, MA, Mary Purdy, PhD, Janice Falk, MA, and Lanelle Gallo, MS. The Dysphagia Outcome and Severity Scale. *Dysphagia* 14:139-145 (1999). <u>http://www.springerlink.com/content/g35e5pha7pc03cqg/</u>

<u>Indications</u>: Assigns an objective level of function for swallowing based on multiple factors (MBS findings and functional oral intake). Designed to improve consistency of documentation.

Descriptions/characteristics:

- The tool lists objective criteria for a 7-point scale to systematically rate the functional swallowing severity (mild, mod, severe) based on symptoms observed during a MBS, the diet level, independence level, and type of nutrition
- Scoring is based on MBS (oral stage transfer, pharyngeal stage retention, penetration-aspiration) and factors critical to appropriate recommendations (premorbid nutrition, current medical status, environment, cognition, acuity of dysphagia).

Considerations:

- *Training*: SLPs involved in the research for the DOSS reportedly underwent training with regards to how to use the tool. This training is not specifically provided in publications about the DOSS; using the DOSS without this training would likely impact the reliability
- *Time to complete*: Authors report it can be used within 5 minutes by trained clinicians
- The authors state that the process of using a tool such as this may improve clinical attention to subtleties of interpreting an MBS
- Proven to have excellent inter-rater (90%) and intra-rater (93%) reliabilities.
- No comments about validity were noted for this tool
- Scale does not thoroughly define each parameter and therefore requires subjective clinical determination based on experience.
- Patient's cognitive and language skills are not a factor specific to the use of this tool
- An MBS must be completed for scoring purposes.

Eating Assessment Tool (EAT-10)

# **Outcome Tracking Tools in Dysphagia Management**

<u>Authors, reference</u>: Peter C. Belafsky, MD, PhD; Debbie A. Mouadeb, MD, Catherine J. Rees, MD; Jan C. Pryor, MA; Gregory N. Postma, MD; Jacqueline Allen, MBChB, FRACS; Rebecca J. Leonard, PhD. Validity and Reliability of the Eating Assessment Tool (EAT-10). *Annals of Otology, Rhinology & Laryngology* 117 (12): 919-924 (2008). http://www.ncbi.nlm.nih.gov/pubmed/19140539

<u>Indications</u>: The EAT-10 is a self-administered, symptom-specific outcome instrument for the subjective assessment of dysphagia

Descriptions/characteristics:

• The EAT-10 consists of 10 scenarios in which the patient rates his/her perceived level of difficulty on a scale of 0-4 (0= no problem, 4=severe problem).

Considerations:

- *Training*: No training necessary
- *Time to complete*: 2 minutes
- Described by the authors as a rapidly administered and easily scored dysphagia instrument that can be administered on each patient visit in order to assess symptom severity, quality of life, and treatment efficacy.
- Normative data suggests that an EAT-10 score of 3 or greater is abnormal.
- May be utilized as a clinical instrument to document the initial dysphagia severity and monitor the treatment response
- The instrument has displayed excellent internal consistency, test-retest reproducibility, and criterion-based validity.
- No MBS is required

### **Functional Independence Measure/ Functional Assessment Measure** (FIM+FAM)

<u>Authors, reference</u>: Although used together, information about the FIM and FAM are available from different sources.

FIM: Developed by the Uniform Data System for Medical Rehabilitation, State University of New York at Buffalo. Information can be obtained at <u>www.udsmr.com/</u> FAM: Developed at Santa Clara Valley Medical Center. Information can be obtained at the Center for Outcome Measurement in Brain Injury (COMBI) <u>http://tbims.org/combi/FAM/</u>

<u>Indications:</u> Measures the severity of disability and tracks progress over time. The swallowing component is one part of this tool.

### Descriptions/characteristics:

- The FIM is an 18 item scale which includes motor and cognitive functioning and is designed to assess areas of dysfunction in activities which commonly occur in individuals with any progressive, reversible, or fixed neurological, musculoskeletal, and other disorders.
- The FAM, which includes a "swallowing" component, is an addition of 12 items to the FIM which were added specifically for patients with brain injuries (TBI, CVA, and other diagnoses that impact cognition).
- The FIM and the FAM use a 7 level ordinal rating scale. The scores for each of the 30 components are added together to form a composite score.
- Swallowing is rated based on level of assistance needed to eat safely or use compensatory strategies, diet modification, and time required to eat.

### Considerations:

- *Training*: The FIM and FAM each have different requirements for training:
  - **FIM**: In order to use the FIM, facilities must be subscribers with Uniform Data System (UDS) and undergo a credentialing process which enables UDS to maintain the integrity of the national databases. There is a membership fee for subscription.
  - **FAM**: Training for the FAM is available at <u>www.tbims.org/combi/FAM</u>. There is no charge for testing and no official certification.
- *Time to complete*: The FIM+FAM is designed to be used in its entirety. It is estimated that it takes 35 minutes to complete.
- The FAM was tested for validity looking at overall disability. It correlated significantly with indices of injury severity. The swallowing component was not validated as an isolated unit.
- The swallowing component has excellent inter-rater reliability. While many of the components of the FIM+FAM used by SLPs (communication, cognitive functioning) have only good inter-rater reliability and a possible ceiling affect for measuring change, "swallowing" is classified as a motor item on this test and has a much greater reliability and less of a ceiling affect.
- Patient's cognitive and language skills are not a factor specific to using this tool
- No MBS is required to use this tool.

### Additional articles about the FIM + FAM:

Donaghy S, Wass P. Interrater reliability of the Functional Assessment Measure in a Brain Injury Rehabilitation Program. *Arch Phys Med Rehabil* 79: 1231-1236 (1998).

Hal, KM. The Functional Assessment Measure (FAM). *J Rehabil Outcomes* 1(3):63-65 (1997).

Hawley C, Taylor R, Hellawell D, Pentland B. Use of the functional assessment measure (FIM+FAM) in head injury rehabilitation: a psychometric analysis. *Journal of Neurology, Neurosurgery and Psychiatry* 67: 749-754 (1999).

## **Functional Oral Intake Scale (FOIS)**

<u>Authors, reference</u>: Michael A. Crary, PhD; Giselle D. Carnaby Mann, PhD, MPH; Michael E. Groher, PhD. Initial Psychometric Assessment of a Functional Oral Intake Scale for Dysphagia in Stroke Patients. *Arch Phys Med Rehabil* 86:1516-1520 (2005). <u>http://srl.phhp.ufl.edu/publications/FOIS.pdf</u>

<u>Indications</u>: Used to document and assign an objective numeric score to the functional level of oral intake of food and liquid in stroke patients.

<u>Descriptions/characteristics</u>: A 7-point ordinal scale that describes the amount and type of oral intake a patient consumes on a daily basis.

Considerations:

- *Training*: No training required. Tool can easily be used from the descriptions in the 7 point scale.
- *Time to complete*: Less than 5 minutes
- High inter-rater reliability and consensual validity (agreement of experts that a measure is valid) for dysphagia in stroke patients
- FOIS was found to be sensitive to change in oral intake
- FOIS ratings are associated with dysphagia severity but not aspiration severity.
- Patient's cognitive and language skills are not a factor specific to using this tool
- No MBS required to use this tool

## The Mann Assessment of Swallowing Ability (MASA)

<u>Authors, reference</u>: developed by Giselle Carnaby-Mann PhD, MPH, University of Florida. The Mann Assessment of Swallowing Ability. Clifton Park: Singular Thompson Learning; 2001. <u>www.singpub.com</u>

<u>Indications</u>: An objective means by which to assess/monitor swallowing skills and recovery over time.

Descriptions/characteristics:

- A one-page standardized tool consisting of 24 clinical items for the quick bedside evaluation of oropharyngeal dysphagia following a stroke
- The MASA is sensitive to change in the acute care setting and can provide predictive information on the severity of dysphagia and subsequent aspiration risk.
- Each clinical item is scored on a weighted 10 point scare. The rating scales were generated from information in the literature regarding potentially important clinical predictors of dysphagia following a stroke.

• Two scores are obtained: a total score out of 200, and an ordinal risk rating for both aspiration and dysphagia (definite, probable, possible, unlikely).

#### Considerations:

- *Training*: Clinicians need to familiarize themselves with the scoring scales in the manual before administering the MASA.
- *Time to complete*: Reportedly can be administered in about 15-20 minutes for a moderately impaired patient
- The manual which contains the scoring guide must be purchased from the publisher. Unlimited use of the scale after purchase.
- Tested for validity and reliability with neurogenic dysphagia.
- It has not yet been validated on other populations, such as head & neck cancer.
- Patient's cognitive and language skills are not a factor in the use of this tool, but theses skills are considered in the scoring.
- No MBS is required to use this tool.

## M.D. Anderson Dysphagia Inventory (MDADI)

<u>Authors/Reference</u>: Amy Y. Chen, MD; Ralph Frankowski, PhD; Julie Bishop-Leone, MA, CCC-SLP; Tiffany Hebert, MCD, CCC-SLP; Stacy Leyk, MA, CCC-SLP; Jan Lewin, PhD; Helmuth Goepfert, MD. The Development and Validation of a Dysphagia-Specific Quality-of-Life Questionnaire for Patients With Head and Neck Cancer. *Archives of Otolaryngology Head and Neck Surgery* 127: 870-876 (2001). http://archotol.ama-assn.org/cgi/content/abstract/127/7/870

<u>Indications</u>: Assess effects of dysphagia on the quality of life of patients with head and neck cancer

<u>Description/Characteristics</u>: Self-administered questionnaire of 20 questions to assess effects of dysphagia on the quality of life (QOL) of patients with head and neck cancer.

- Incorporates 3 domains (emotional, functional, and physical) as well as 1 global question.
- Each subscale with five possible responses scored on a scale of 1 to 5 (strongly agree, agree, no opinion, disagree and strongly disagree).
- Scores range from 0 (extremely low functioning) to 100 (higher functioning). Thus, a higher MDADI score represents better day-to-day functioning and better QOL.

#### Considerations:

- *Training*: No training required.
- *Time to complete*: Not stated, variable by patient

- First validated and reliable self-administered questionnaire designed specifically for evaluating the impact of dysphagia on the QOL of patients with head and neck cancer.
- Can be used to assess how patients view the outcome of their swallowing ability as a result of treatment.
- Patients with primary tumors of the oral cavity and oropharynx may have an adverse QOL and significantly greater swallowing disability compared with patients with primary tumors of the larynx and hypopharynx.
- Patients with a malignant lesion may have significantly greater disability than patients with a benign lesion.
- No MBS required.

## National Outcome Measurement System- (NOMS)

Authors, reference: ASHA; http://www.asha.org/members/research/NOMS/health.htm

<u>Indications</u>: Used at admission and again at discharge to assess the amount of functional change and, thus, the benefits of treatment.

Descriptions/characteristics:

- 7 point scale, ranging from least functional level 1 to most functional level 7.
- The rating scale is not dependent upon administration of any particular formal or informal measures but on clinical observations.
- The scale is based on the degree to which the patient requires diet restrictions, the use of compensatory strategies for swallowing, verbal cues for safe PO intake, and non-oral methods of feeding.

#### Considerations:

- *Training*: Each SLP must complete NOMS training and become a registered NOMS user before submitting data. The training includes a self-study on-line training which takes approximately 2 hours. It also includes a test which clinicians must pass with a score of 80% or above to become registered NOMS users. A facility can also become a registered NOMS facility.
- *Time to complete*: After training, the measure should take less than 5 minutes to complete
- Designed to indicate the benefits of treatment/SLP services and is not specific to the improvement of swallow function.
- Not a standardized or validated scale
- To use the NOMS, a facility or clinician must register with ASHA (all SLPs must be ASHA members) and sign a letter of agreement for commitment to submit their data to ASHA. The scale is available to registered NOMS users only.
- Patient's cognitive and language skills are not a factor specific to the use of this tool
- No MBS is required to use this tool.

## Penetration Aspiration Scale (Pen/Asp Scale)

<u>Authors, reference</u>: John C. Rosenbek, PhD, Jo Anne Robbins, PhD, Ellen B. Roecker, PhD, Jame L. Coyle, MA, and Jennifer L. Wood, MS. A Penetration-Aspiration Scale. *Dysphagia* 11: 93-98 (1996). http://www.springerlink.com/content/k166h165348110u6/

<u>Indications</u>: Provides quantification of selected penetration and aspiration events during MBS. It is one tool to be included as a part of a total swallowing assessment battery.

Descriptions/characteristics:

- An 8-point interval scale to describe penetration and aspiration events
- Scores are determined primarily by the depth to which material passes in the airway (does not enter airway, enters larynx and stays above vocal folds, enters larynx to level of vocal folds, passes below vocal folds) and the swallower's response to the bolus (expelled, partially expelled, not expelled).

#### Considerations:

- *Training*: No specific training is indicated for this tool. Clinicians should be comfortable and familiar with MBS analysis.
- *Time to complete*: Time needed to complete analysis of MBS
- Examines only penetration and aspiration and not other factors that could indicate improved swallowing function. Therefore it may have a ceiling affect of not measuring changes in swallowing function after the patient is no longer penetrating or aspirating.
- Inter-rater reliability was fair (57-75%) between judge pairs, and overall intrajudge reliability was 74%.
- The validity of the Pen-Asp is based upon the user's ability to attribute a score based on observations during the MBS.
- Patient's cognitive and language skills are not a factor specific to the use of this tool
- An MBS must be completed for scoring purposes.

#### Additional articles about the Pen-Asp scale:

Robbins J, Coyle J, Rosenbek J, Roecker EB, Wood J. Differentiation of normal and abnormal airway protection during swallowing using the Penetration-Aspiration Scale. *Dysphagia* 14: 228-232 (1999).

McCullough GH, Rosenbek JC, Coyle JA, Wood JL. Ordinality and intervalidity of a penetration-aspiration scale. *Journal of Medical Speech-Language Pathology* 6: 65-72 (1998).

## SWAL-QOL and SWAL-CARE

<u>Authors, reference</u>: To obtain a copy of this tool and the scoring manual, the author has given permission to contact her directly: <u>colleen\_mchorney@merck.com</u>

<u>Indications:</u> Objectively measures a patient's perspective of swallowing which can be used in addition to more traditional clinician-driven parameters. The tool can also be used to assist in ascertaining specific problems patients are experiencing.

Descriptions/characteristics:

- The SWAL-QOL is a 44 item tool that asks patients to rate several factors about 10 quality-of-life concepts related to swallowing on a 5 point scale.
- The SWAL-CARE is a 15 item tool that asks patients to rate quality of care and patient satisfaction.
- The authors state that patient-centered quality-of-life measures and cliniciandriven bolus flow measures provide distinct yet complementary information about oropharyngeal dysphagia.

#### Considerations:

- *Training*: No formal training is required. Tool can be obtained from author.
- *Time to complete*: It reportedly takes respondents an average of 14 minutes to complete the SWAL-QOL and 5 minutes to complete the SWAL-CARE.
- Scales demonstrate internal-consistency reliability and short term reproducibility.
- Validated to discriminate between patients with and without dysphagia and sensitivity to disease severity.
- Use of the SWAL-QOL or the SWAL-CARE may be more or less appropriate depending on the application and population- either one or both tools may be used
- Patients must be able to communicate to use this tool
- No MBS is required to use this tool.

#### Additional articles about the SWAL-QOL/SWAL-CARE:

McHorney CA, Martin-Harris B, Robbins J, Rosenbek J. Clinical validity of the SWAL-QOL and SWAL-CARE outcome tools with respect to bolus flow measures. *Dysphagia* 21(3) 141-8 (2006).

McHorney CA, Bricker DE, Kramer AE, Rosenbek JC, Robbins J, Chignell KA, Logemann JA, Clarke C. The SWAL-QOL outcomes tool for oropharyngeal dysphagia in adults: I. Conceptual foundation and item development. *Dysphagia* 15 (3): 115-21 (2000).

McHorney CA, Bricker DE, Robbins J, Kramer AE, Rosenbek JC, Chignell KA. The SWAL-QOL outcomes tool for oropharyngeal dysphagia in adults: II. Item reduction and preliminary scaling. *Dysphagia* 15 (3) 122-33 (2000).

# **Outcome Tracking Tools in Dysphagia Management**

McHorney CA, Robbins J, Lomax K, Rosenbek JC, Chignell K, Kramer A, Bricker DE. The SWAL-QOL outcomes Tool for Oropharyngeal Dysphagia in Adults: III. Documentation of Reliability and Validity. *Dysphagia* 17: 97-114 (2002).

	Instrumental assessment NOT required	Validated	Tested for reliability	No pt communication needed to use	Time needed to complete	Ease of use
DOSS			x	Х	5 min	Training may be necessary for reliability- details about training not readily available
EAT-10	Х	х	х		Less than 2 min	Simple
FIM/FAM	x	X *	x	Х	35 min	Test is designed to be given in its entirety which makes it less simple than swallowing only measures
FOIS	Х	Х	Х	Х	> 5 min	Simple
MASA	Х	Х	х	Х	15-20 min	Must be familiar with scoring guide
MDADI	x	х	x		Not stated, variable by patient	Simple
NOMS	x			Х	> 5 min	Must complete training and pass certification test
Pen-Asp		N/A	x	Х	Time to analyze MBS	Must be familiar with MBS studies
SWAL-QOL	Х	Х	Х		14 min	Simple

\* Validated as a measure of overall recovery during rehab. The swallowing component of this tool was not individually tested.