continued

If you are viewing this course as a recorded course after the live webinar, you can use the scroll bar at the bottom of the player window to pause and navigate the course.

continued

This handout is for reference only. It may not include content identical to the powerpoint. Any links included in the handout are current at the time of the live webinar, but are subject to change and may not be current at a later date.



Patient-Reported Outcome Measures in Medical Speech-Language Pathology

BARBARA JACOBSON, PHD CCC-SLP DEPARTMENT OF HEARING & SPEECH SCIENCES VANDERBILT UNIVERSITY

Outline



- Introduction
- Overview of outcomes
- Definitions
- Patient-reported outcome measures (PROMs) in:

Aphasia

Voice

Dysphagia

• Application to clinical practice



Introduction



- Outcomes have been a 'buzzword'
- According to Frattali (2013), outcomes in SLP can be:
 - Clinically derived (phonation time)
 - o Functional (ability to use the phone)
 - Administrative (productivity)
 - Financial (average length of stay)
 - Social (community re-entry)
 - Oclient-defined (pt. satisfaction, quality of life)

ASHA Outcome Measures Report (2013)



- As part of the 2013 SLP Health Care Survey, ASHA asked over 2,000 SLPs how they used outcome measures in clinical documentation
 - o "Do you report outcome measures (e.g. ASHA NOMS, FIM, WEE-FIM) in your documentation?"
 - o "Which outcome measures do you report?"
- Facilities general medical and long-term acute care hospitals, rehab hospitals, pediatric hospitals, SNFs, home health care, outpatient clinics (also 'other' – e.g. independent living facilities)



Outcome Measures (ASHA)

- Functional Outcome Measures instruments that measure functioning, activities, participation (WHO - ICF) (e.g. G-codes)
- Clinically Derived Outcome Measures standardized tools that have been validated for a target population (e.g. Penetration/Aspiration Scale)
- Proprietary Outcome Measures Organizationspecific software or customized outcome measures (e.g. Rehabilitation Outcomes Measures)

ASHA (2013)

- Most frequently used instruments were:
 - o FIM
 - o ASHA NOMS
- We'll discuss several of the instruments that were on that list, including:

EAT-10, VHI, SAQOL-39 (categorized as Functional Outcome Measures)



How often were outcome measures used?

40.22% used outcomes in documentation

Outcomes - Background

- Data collection
 - o "Base 10"
 - o Performance over a number of trials
 - o Test scores (re-assessment)
 - × WAB, BDAE, CVLT, etc.
- Pre- and post-treatment (and longer)
- Used for....
 - o Reimbursement
 - o Demonstrating treatment effectiveness
 - Expanding services
 - o Patient education



What is a patient-reported outcome measure?

- A measurement based on patient report about the status of his/her health condition without interpretation from anyone else (abridged from FDA, 2010).
- Clinician biases or variability among clinicians are eliminated in PROMs
- Captures the issues that are important to the patient

What Makes a Good PROM?



- For the patient.....
 - $\circ \ Easy \ to \ understand$
 - o Addresses concerns (has face validity)
 - \circ Can be administered in several ways
- For the clinician.....
 - o Is standardized
 - o Has clear levels of severity
 - $\circ \ Demonstrates \ change$



What Makes a Good PROM?



- Standardized on a reasonable number of subjects
- Standardized on your target population
- Has a clearly stated critical difference score
- Eadie, et al. (2006) looked at a number of self-report measures in SLP and noted that none of them exclusively measured **communication participation**, although some had items that referred to that domain.
- They argued that this was critical to determining quality of life as it relates to communication

How should you use PROMs?



- With appropriate population
- Administered as a particular instrument was standardized
 - Pencil/paper/computer
 - o Face to face/interview
 - On the phone



Why not use health-related PROMs?

- SF-36
- Sickness Impact Profile
- CDC HRQOL-14 "Healthy Days Measure"
- They don't specifically address communication
- Diminished face validity for patients
- They don't give you information about issues that patients may be experiencing

PROMs in Aphasia

- We probably find the least number of PROMs for patients with aphasia
- The most obvious barrier is language impairment (language production/comprehension) in spoken and/or written modalities
- In Brady, et al. (2012), they used 'functional communication' as a primary outcome
 - o CADL, CETI as examples
 - Secondary outcomes were language measures, patient satisfaction, economic outcomes, psychosocial outcomes



Where We've Been....

- We have used impairment-based and functional measures as the basis for assessing outcome of aphasia therapy
- Impairment-based
 - WAB-R
 - o BDAE
- Functional
 - o CADL-2
 - o ASHA FACS

Options



- SAQOL-39 (Hilari, et al., 2003)
- BOSS (Doyle, et al., 2004)
 - o 64 items
 - o 5 point scale
 - o Overall QOL, 3 composite scales
- QCL (Paul, et al., 2005)
 - o 18 items
 - o 5 point VAS scale
 - o Overall QOL, 3 domains



Options



- CETI (Lomas, et al., 1989)
 - 16 items
 - \circ VAS
 - o Proxy measure
- In reviewing these instruments, there is little research that demonstrates their application in clinical practice

SAQOL-39 (2003)



- Modified the Stroke Specific Quality of Life (Williams, et al., 1999)
- For patient with auditory comprehension deficits, those with mild/moderate receptive impairment are able to report reliably
- 39 items ("In the past week.....")
 - o Physical (17)
 - o Psychosocial (11)
 - o Communication (7)
 - o Energy (4)



SAQOL-39



- 5 point scale
 - o Couldn't do at all
 - o No trouble at all
- Standardized on 83 subjects
- At least 1 year post-stroke
- Gesture allowed
- Extensive directions for eliciting responses and/or clarifying responses

Advantages



- Comprehensive
- Addresses communication
- Good psychometric properties



Limitations



- Length of instrument
- Not applicable to patients with severe aphasia

Increasing Use of PROMs in Persons with Aphasia

- For patients with more severe aphasia -
- Pictograms
- Bolded font for key concepts
- Graphics
- What about proxy measures?



PROMs in Voice



- Evidence for 'objective' measures used in voice assessment (Roy, et al., 2013)
 - o Perceptual ratings
 - Acoustic measures (F₀, jitter, shimmer, SNR)
 - Laryngoscopic measures
- Branski, et al. (2010) reviewed PROMs for voice disorders and determined that many instruments had some flaws in the development process
 - He emphasized the importance of understanding how an instrument was derived and the need to adhere to international standards in creating valid measures



- Various Cochrane Reviews in voice disorders use patient report measures as **primary outcomes** in determining whether a particular treatment is effective in a given voice disorder
- Examples





- Pediatric and adult instruments available
- Pediatric scales are 'proxy' = parent report

Voice Handicap Index (VHI) (1997)



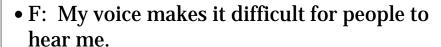
- 85 items initially generated
- Administered to 65 patients
- Diagnoses included
 - Mass lesions
 - Neurogenic (e.g. UVFP, SD)
 - o Laryngectomy
 - o MTD
 - o Inflammatory (e.g. laryngitis)
 - Atypical



- Reduced items to 30
 - Eliminated items with: gender bias, redundancy, poor correlation to other items
- Administered to 63 other patients
 - Test/retest reliability
 - o Associating VHI score with patient reports of severity

- 10 items in 3 domains
 - o Physical
 - o Functional
 - o Emotional
- 5 point scale
 - '0' = never
 - \circ '4' = always
 - Higher score = more self-perceived handicap
- Maximum score of 120
- Critical difference score = 18
 - 8 points for subscales





- P: I run out of air when I talk.
- E: I'm tense when talking with others because of my voice.

Advantages

- Addresses scope of experiences of patients with voice disorders
- Validated on patients with diverse voice disorders
- Over 1,000 citations
- Translated into many languages
- Cited as outcome measure in studies of evidencebased practice



Limitations



- ?sensitivity and ?specificity
- Lengthy
- Not derived from direct patient interviews
- Needs large scale normative study
- ?sensitive for particular patient groups/diagnoses

Other studies



- Rosen, et al (2004) developed the VHI-10
- In this process, they administered the VHI to a group of normal patients
- They determined that a score of 9 or above indicated an 'abnormal' result on the VHI
- Factor analysis indicates that while there are 3 subscales, there is probably only one factor

 O Voice handican
 - Voice handicap



PROMs in Dysphagia

- Most research in dysphagia has focused on outcomes related to:
 - Aspiration
 - o Pneumonia
 - Diet type
 - o Non-oral vs oral intake
 - Doath
- Latest Cochrane Review in Dysphagia (2012) listed 'quality of life' measures as secondary outcomes in their examination of research on the effectiveness of various interventions (behavioral treatment, acupuncture, NMES, etc.)

 The challenge in collecting PROMs for patients with dysphagia is their ability to participate/understand/complete the particular instrument

- Patients with neurogenic dysphagia often have issues related to language and/or cognition
- Fluctuating neurological status can influence responses to questions/statements, particularly in the acute care setting.



What's available?



- SWAL-QOL (2000)
- DHI (2012)
- EAT-10 (2008)
- We'll review the SWAL-QOL and DHI briefly, and then concentrate on the particular characteristics of the EAT-10

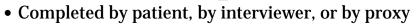
SWAL-QOL



- Assesses physical, social, emotional, and cultural responses to dysphagia
- 44 items
- 10 QOL domains
- 5 point scale
- Lower score = worse QOL
- Validated on 386 patients



Advantages





Limitations



- Long instrument (fatiguing?)
- Can be difficult to understand



Dysphagia Handicap Index (DHI)

- 25 items (reduced from 60 initial statements)
- 3 subscales
 - Physical 9 items
 - Emotional 7 items
 - Functional 9 items
- 7 point scale "never", "sometimes", "always"
- Patient severity rating (7 point scale)
- 63 patients

Advantages

- Not disease-specific
- Validated on patients with a variety of diseases and disorders
- Validated on normals
- Good for patients with lower literacy levels



Limitations



- Few patients in original study had severe symptoms
- ? Less sensitive because of only 3 response options
- Has not been assessed for a variety of treatments

EAT-10



- Belafsky PC, Mouadeb DA, Rees CJ, Pryor JC, Postma GN, Allen J, Leonard RJ. (2008). Validity and reliability of the Eating Assessment Tool (EAT-10). Ann Otol Rhinol Laryngol, 117, 919-924.
- Questions developed by clinicians (reduced to 20 from 35) $-\alpha$ version)
 - o 100 normal subjects (administered twice)
 - o 235 patients with voice & swallowing disorders
- Eliminated redundant and poorly correlated items
- Administered β version to 100 healthy subjects





- Mean score + 2 SD = upper limit of normal
- Administered to 46 patients pre-/post-treatment
 - o Esophageal dysphagia
- Administered to 235 patients
 - o 28% reflux disease
 - o 22% voice disorder
 - o 21% oropharyngeal dysphagia (primarily neurogenic)
 - o 18% head & neck cancer
 - \circ 11% esophageal dysphagia (motility, stricture, neoplasia, web, ring)

EAT-10



- My swallowing problem has caused me to lose weight.
- My swallowing problem interferes with my ability to go out for meals.
- Swallowing liquids takes extra effort.
- Swallowing solids takes extra effort.
- Swallowing is painful.
- The pleasure of eating is affected by my swallowing.
- When I swallow food sticks in my throat.
- I cough when I eat.
- Swallowing is stressful.





- Patients respond on a 5-point scale (0-4)
 - \circ 0 = no problem
 - \circ 4 = severe problem
- Maximum score is 40
- "Abnormal" score is 3 or greater

EAT-10



- Advantages (Keage, et al., 2014)
 - Quick administration (authors state < 2 minutes)
 - More easily read and understood than other comparable measures
 - No subscales (for ease of calculating score)
 - Specific to stages of swallowing
 - Good test/retest reliability indicating its usefulness in clinical practice



EAT-10



- Limitations (Keage, et al., 2014))
 - No longitudinal studies so we don't know how well it measures change in status over time
 - Primary emphasis is on the symptoms of dysphagia and doesn't go into depth about the psychological, social, or emotional impact of dysphagia
 - o Requires further validation with age, race, socioeconomic groups
 - No critical difference score how much difference in scores indicate clinically significant difference
 - o No correlation with patients' overall judgment of swallowing severity
 - No correlation with clinicians' judgment of severity (e.g. using NOMS)

How to use PROMs



- Initial assessment
- After any intervention
 - o Behavioral treatment
 - Surgery
 - Change in medical status (after seizure, pneumonia, exacerbation of medical condition)
- At the time of an instrumental assessment by SLP
 - o MBS
 - o FEES
 - Videostroboscopy
- For long-term follow-up



How to use PROMs



- For screening
 - Administer to all patients coming to Otolaryngology, GI, Pulmonary, Neurology, Neurosurgery, Cardiology, Thoracic Surgery, General Surgery, Trauma Clinics
- For education
 - Patients will often comment that they didn't realize the scope of their problem until they had completed a PROM
- For clinical research
 - We have long ignored the measurement of the impact of various communication/swallowing disorders on patients' lives in the assessment of the effectiveness of an intervention

Patient Experience vs Clinician Experience



 Correlation between patient scores on various instruments and clinician judgments of severity (Bush & Jacobson, 1998)

r = 0.33



Do I need permission to use PROMs?

- Typically, most PROMs are in the public domain unless you see '©' symbol
 - o So, you can use these in clinical practice
- That indicates that instrument is probably proprietary and you must request permission to use it
- If you reproduce any instrument for use in a publication (booklet, article, book) you must request permission from the publisher or holder of the copyright (and, by courtesy, the author)

The Future



- Item banks specifically for communication and swallowing
- You will be able to create your own instruments customized for your practice
- University of Washington researchers are creating item banks for communication participation
- You will also see more 'cognitive interviewing' described in articles about the development of particular measures

 essentially these are focus groups for determining critical issues for specific patient groups
- Designed to develop items for PROMs





- PROMIS Patient-Reported Outcomes Measurement System (NIH)
 - o Item banks
 - Across many diseases and disorders
- www.nihpromis.org

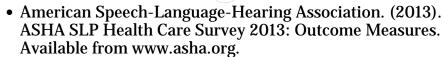
Conclusions



- Patient-reported outcome measures are available for many of the disorders we assess and treat in medical speech-language pathology
- It is important to select instruments based on:
 - o Psychometric properties (validity, reliability)
 - \circ The populations that were used to develop the particular PROM
 - o Your particular setting
 - o Your intended use
- PROMs may be the most meaningful measure of how effective we are in improving communication and swallowing



Selected References



- Belafsky PC, Mouadeb DA, Rees CJ, Pryor JC, Postma GN, Allen J, Leonard RJ. (2008). Validity and reliability of the Eating Assessment Tool (EAT-10). Ann Otol Rhinol Laryngol, 117, 919-924.
- Brady MC, Kelly H, Godwin J, Enderby P. (2012). Speech and language therapy for aphasia following stroke. Cochrane Database of Systematic Reviews, Issue 5. Art. No.: CD000425. DOI: 10.1002/14651858.CD000425.pub3.

 Doyle PJ, Matthews C, Mikolic JM, Hula W, McNeil MR. (2006). Do measures of language impairment predict patient-reported communication difficulty and distress as measured by the Burden of Stroke Scale (BOSS)? Aphasiology, 20, 349-361.

 Geeganage C, Beavan J, Ellender S, Bath PMW. (2012). Interventions for dysphagia and nutritional support in acute and subacute stroke. Cochrane Database of Systematic Reviews, Issue 10. Art. No.: CD000323. DOI: 10.1002/14651858.CD000323.pub2.

• Hilari K, Byng S, Lamping DL, Smith SC. (2003). The stroke and aphasia quality of life scale-39 (SAQOL-39): evaluation of acceptability, reliability and validity. *Stroke*, *34*, 1944-1950.





- Jacobson B, Johnson A, Grywalski C, Silbergleit A, Jacobson G, Benninger M, Newman C. (1997). The Voice Handicap Index (VHI): Development and validation. Am J of Speech-Language Pathology, 6, 66-70.
- Keage M, Delatycki M, Corben L, Vogel A. (2014). A systematic review of self-reported swallowing assessment in progressive neurological disease. Dysphagia, Oct 4. [Epub ahead of print].
- Lomas J, Pickard L, Bester S, Elbard H, Finlayson A, Zoghaib C. (1989). The Communicative Effectiveness Index: development and psychometric evaluation of a functional communication measure for adult aphasia. *Journal of Speech & Hearing Disorders*, *54*, 113-124.

0

- McHorney CA, Bricker DE, Kramer AE, Rosenbek JC, Chignell KA, Logemann JA, Clarke C. (2000). The SWAL-QOL outcomes tool for oropharyngeal dysphagia in adults: I. Conceptual foundation and item development. Dysphagia, 15, 115-121.
- Ruotsalainen JH, Sellman J, Lehto L, Jauhiainen M, Verbeek JH. (2007). Interventions for treating functional dysphonia in adults. Cochrane Database of Systematic Reviews, Issue 3. Art. No.: CD006373. DOI: 10.1002/14651858.CD006373.pub2.
- Silbergleit AK, Schultz L, Jacobson BH, Beardsley T, Johnson AF. (2012). The Dysphagia Handicap Index: Development and validation. *Dysphagia*, *27*, 46-52.



Questions?	

