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Patient-Reported Outcome Measures in Medical Speech-Language Pathology

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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)
  - Functional (ability to use the phone)
  - Administrative (productivity)
  - Financial (average length of stay)
  - Social (community re-entry)
  - Client-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
  - "Do you report outcome measures (e.g. ASHA NOMS, FIM, WEE-FIM) in your documentation?"
  - "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 – Organization-specific software or customized outcome measures (e.g. Rehabilitation Outcomes Measures)

ASHA (2013)

- Most frequently used instruments were:
  - FIM
  - 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
  - "Base 10"
  - Performance over a number of trials
  - Test scores (re-assessment)
    - WAB, BDAE, CVLT, etc.
- Pre- and post-treatment (and longer)
- Used for....
  - Reimbursement
  - Demonstrating treatment effectiveness
  - Expanding services
  - 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……
  - Easy to understand
  - Addresses concerns (has face validity)
  - Can be administered in several ways
- For the clinician……
  - Is standardized
  - Has clear levels of severity
  - 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
  - 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
  - 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
  - BDAE
- Functional
  - CADL-2
  - ASHA FACS

Options

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

Options

- CETI (Lomas, et al., 1989)
  - 16 items
  - VAS
  - 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.....")
  - Physical (17)
  - Psychosocial (11)
  - Communication (7)
  - Energy (4)

SAQOL-39

- 5 point scale
  - Couldn't do at all
  - 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)
  - Perceptual ratings
  - Acoustic measures (F_0, 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)
  - Laryngectomy
  - MTD
  - 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
  - Associating VHI score with patient reports of severity

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

- F: My voice makes it difficult for people to hear me.
- 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 evidence-based 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
  - Voice handicap

PROMs in Dysphagia

- Most research in dysphagia has focused on outcomes related to:
  - Aspiration
  - Pneumonia
  - Diet type
  - Non-oral vs oral intake
  - Death
- 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

- Completed by patient, by interviewer, or by proxy
- Comprehensive – corresponds to WHO ICF domains

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) – α version)
  - 100 normal subjects (administered twice)
  - 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
  - Esophageal dysphagia
- Administered to 235 patients
  - 28% - reflux disease
  - 22% - voice disorder
  - 21% - oropharyngeal dysphagia (primarily neurogenic)
  - 18% - head & neck cancer
  - 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)
  - 0 = no problem
  - 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
  - Requires further validation with age, race, socioeconomic groups
  - No critical difference score – how much difference in scores indicate clinically significant difference
  - 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
  - Behavioral treatment
  - Surgery
  - Change in medical status (after seizure, pneumonia, exacerbation of medical condition)
- At the time of an instrumental assessment by SLP
  - MBS
  - 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
  - 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)
  - 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:
  - Psychometric properties (validity, reliability)
  - The populations that were used to develop the particular PROM
  - Your particular setting
  - Your intended use
- PROMs may be the most meaningful measure of how effective we are in improving communication and swallowing

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Questions?