Quality of Life Instrument Development in Adults
Ted McRackan MD, MSCR
American Cochlear Implant Alliance 2018
3/8/18
Participating with Poll Everywhere at CI2018
(Regency Ballroom)

SMS Text Message:
• Text regency to 22333
• You will receive a response back once you have joined the poll
• When the poll is live, text your answer choice to participate
• Standard messaging rates apply; US numbers only

Mobile App or Web Browser:
• Download the CI2018 Mobile App
  • Open this session
  • Click the Poll Everywhere link
• You can also access a web version at www.pollev.com/regency
• When the poll is live, click your answer choice to participate
Disclosures

- K12 CTSA award (UL1TR001450)
- Doris Duke Foundation PERK award
- American Cochlear Implant Alliance
  - Advanced Bionics, Cochlear Corporation, MED-EL, Oticon
How do we currently evaluate CI outcomes?

• Speech recognition testing
  • Phoneme/word/sentence
  • Quiet/Noise
Why measuring QOL is important in CI patients?

- Low positive correlation between speech recognition and QOL
- Overall, speech recognition accounts for 4.0-11.6% of variance in QOL

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McRackan TR, et. al. Laryngoscope 2017
McRackan TR, et. al. Otol Neurotol 2018
Why is measuring QOL important?

- Primary outcome measure for CMS
- Required for all FDA clinical trials seeking FDA approval
How do you create a QOL instrument?
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• Patient-Reported Outcomes Measurement Information System (PROMIS)
How do you create a QOL instrument?

• Patient-Reported Outcomes Measurement Information System (PROMIS)
  o 5 step process:
    • Systematic evaluation of literature
    • Focus groups
    • Cognitive interviewing
    • Psychometric testing
    • Validity testing
  • Discuss our progress
1) Systematic Review of the Literature

- Identifies previously used questions (items)
- Help conceptualize a framework on the topic
Systematic Review of the Literature

- Our review resulted in two meta-analyses
- Identified 273 items (questions) that have been used
- Used to:
  - Develop the focus group protocol
  - Start to organize CI-QOL domains

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McRackan TR, et al. Otol Neurotol 2018

MUSC Health
Medical University of South Carolina
Changing What’s Possible | MUSCHealth.org
2) Focus Group

- Population of interest is engaged in the development process
  - Identify important topics that affect their lives
  - Confirm/deny importance of prior areas of focus
  - Identify new areas of importance that have not been previously recognized
- Has not been traditionally used
Cochlear implant focus groups

- 3 focus groups
- Developed, executed, and analyzed based on grounded theory
- The consolidated criteria for reporting qualitative research (COREQ-32) was followed
- Participants represented adult CI population based on demographics, communication ability, listening modality

Cochlear implant focus groups

- Focus group transcripts coded

![Diagram showing Adult CI QOL with subcategories: Communication, Emotion, Social, Environmental Sounds, Sound Clarity, Functional Independence, Listening Effort]

Cochlear implant focus groups

- Focus group transcripts coded

- Based on focus groups, established 101 question item pool

**Diagram:**
- Adult CI QOL
- Communication
- Emotion
- Sound Clarity
- Social
- Environmental Sounds
- Functional Independence
- Listening Effort

3) Cognitive Interviews

• Items should have 6th grade reading level or less
• Each item is reviewed for clarity
  • Population of interest
  • Diverse Sample
  • Feedback on language
• Afterward have final item pool
Cognitive Interviews

• Performed cognitive interviews with 20 CI patients to ensure item clarity
4) Psychometric testing

- Transition to quantitative methodologies
- Item Response Theory (IRT) is the modern standard
  - Hypothesis-driven
  - Requires large population
  - Several advantages over classical test theory (CTT):
    - IRT focuses on item-level psychometrics
    - IRT is sample (subject) and test independent
4) Psychometric testing

- Item Response Theory (IRT) is the modern standard
  - IRT core assumptions:
    - Unidimensionality
    - Local Independence
    - Monotonicity

Confirmatory factor analysis
CI-QOL psychometric testing

- Required n=300
- Wanted diverse population
- Established the CI-QOL Development Consortium

- Columbia University
- Duke University
- Johns Hopkins University
- House Ear Clinic
- Kaiser Health Los Angeles
- Kaiser Health San Diego
- Loyola University
- Mayo Clinic Rochester
- MUSC
- New York Eye and Ear Infirmary
- Ohio State University
- Oregon Health Sciences University
- Stanford University
- Summit Medical Group
- University of Cincinnati
- University of Colorado
- University of Maryland
- University of Pennsylvania
- University of Utah
- University of South Carolina
- University of Texas Southwestern
- Vanderbilt University
- Virginia Mason Seattle
- University of Miami
- Washington University
- Advanced Bionics
- Cochlear Corporation
- MED-EL
CI-QOL psychometric testing

- Required n=300
- Wanted diverse population
- Established the CI-QOL Development Consortium
  - 771 subjects contact research team
  - REDCap surveys sent to first 500
  - ~75% (n=371) completion rate

- Columbia University
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- Johns Hopkins University
- House Ear Clinic
- Kaiser Health Los Angeles
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CI-QOL psychometric testing

- Started with 101 items in 7 hypothesized domains
CI-QOL psychometric testing

- Started with 101 items in 7 hypothesized domains
  - Independence domain
    - Cronbach’s $\alpha$=1.0
CI-QOL psychometric testing

- Started with 101 items in 7 hypothesized domains
  - Independence domain
    - Cronbach’s $\alpha=1.0$
    - Items contributed to multiple domains (not unidimensional)
    - Subject’s rating of individual items not consistent with overall score (low monotonicity)
  - Poorly stratified subjects with regard to ability
  - 36.1% showed ceiling effect
    - Emotion domain 1.6% showed ceiling
CI-QOL psychometric testing

- All other domains were psychometrically sound
- 9 other items removed from item pool
  - 3 for local dependence
  - 6 misfit IRT model
CI-QOL psychometric testing

- Final item bank:
  - 81 items in 6 domains
    - Communication
    - Emotion
    - Entertainment
    - Environmental sounds
    - Listening effort
    - Social
CI-QOL psychometric testing

- Final item bank:
  - 81 items in 6 domains
- IRT output:
  - Establish psychometric properties for each item
Develop instrument suite from item bank

- Establish psychometric properties for each item
  - Profile measure
  - Short form (global)
  - Computerized adaptive testing (CAT)
Develop instrument suite from item bank

- Profile measure
- Short form (global)
- Computerized adaptive testing (CAT)
CI QOL Profile Measure

- 35 items, 6 domains
- Established face, content, and construct validity
- Takes approximately 4.5 minutes to complete
5) Validity Testing

- Overlap with psychometric analysis:
  - Prior steps have already established the face, content and construct validity
- Compare to legacy or functional measures (criterion validity)
- Determine the responsiveness to change
CI-QOL Validity Testing

• Our next step
• Needs to be performed with each instrument
Conclusion

- QOL instrument development is a maturing science
  - Attempting to standardize methodologies
- Our group is committed to producing instruments following strict guidelines to better understanding of the communication, health, emotional, and social benefits of cochlear implantation in adults
Acknowledgements

- Judy R. Dubno
- Craig Velozo
- Josh Fabie
- Cameron Thomas

- Paul Lambert
- Ted Meyer
- Habib Rizk
- Meredith Holcomb
- Liz Camposeo

- ACIA
- Cochlear Implant Quality of Life Development Consortium
Interested in participating?

• Minimal effort
• mcrcakan@musc.edu
• ciqualityoflife@musc.edu
Does your cochlear implant program currently collect quality of life data?

- Yes
- No
- I don't know
What is the biggest barrier in collecting quality of life data?

- Logistics
- Time
- Don't know what instrument/survey to use
- Do not have interest
Bear analogy

• Which is more dangerous?
  • 8 bears
  • 1 bear
Bear analogy

VS.
Bear analogy vs.
Conclusion

• Results from our aims will broaden our understanding of the communication, health, emotional, and social benefits of cochlear implantation in adults

• Enhance how CI outcomes are evaluated in both the clinical and research settings leading to more comprehensive assessment of functional abilities and ultimately improved patient care.
Why measuring QOL is important in CI patients

- Low positive correlation between speech recognition and QOL
- Overall, speech recognition accounts for 4.0-11.6% of variance in QOL

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Moberly AC, et al. Laryngoscope 2017
Why measuring QOL is important in CI patients

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McRackan TR, et. al. Laryngoscope 2017
Moberly AC, et al. Laryngoscope 2017
Need for a new CI-QOL instrument

• No hearing or CI-specific instrument meets current standards
Need for a new CI-QOL instrument

• Why PROMIS guidelines important?
Need for a new CI-QOL instrument

• Why PROMIS guidelines important?
  o Focus groups: establish a clear hierarchical QOL construct to conceptualize the values of the affected population
Need for a new CI-QOL instrument

• Why PROMIS guidelines important?
  o Focus groups: establish a clear hierarchical QOL construct to conceptualize the values of the affected population
  o Psychometric testing: measure capacity of each item/question in instrument to differentiate individuals based on performance/ability level
Need for a new CI-QOL instrument

• Why PROMIS guidelines important?
  o Focus groups: establish a clear hierarchical QOL construct to conceptualize the values of the affected population
  o Psychometric testing: measure capacity of each item/question in instrument to differentiate individuals based on performance/ability level
  o Validity testing: comparing instrument to legacy measure/s
Development of new CI-QOL instrument

- Completed:
  - Systematic evaluation of literature
  - Focus groups
  - Cognitive interviewing

- In progress:
  - Psychometric testing
Psychometric testing

- Confirmatory factor analysis
- Item Response Theory
- 300 subjects needed to evaluate item bank responses
- All data collection performed electronically through REDCap
Psychometric testing

• Established the Cochlear Implant Quality of Life Development Consortium to:
  • Assist with recruitment
  • Ensure a diverse sample
Psychometric testing

- Cochlear Implant Quality of Life Development Consortium:
  - Columbia University
  - Johns Hopkins University
  - House Ear Clinic
  - Kaiser Health Los Angeles
  - Kaiser Health San Diego
  - Mayo Clinic Rochester
  - Medical University of South Carolina
  - Ohio State University
  - Oregon Health Sciences University
  - Stanford University
  - University of Cincinnati
  - University of Colorado
  - University of Maryland
  - University of Pennsylvania
  - University of Utah
  - University of Texas Southwestern
  - Vanderbilt University
  - Virginia Mason Seattle
  - University of Miami
  - Washington University in Saint Louis

CI companies:
- Advanced Bionics
- Cochlear Corporation
- MED-EL
Psychometric testing

- Met enrollment goals
- Currently analyzing data
End product: QOL instrument suite

- Long-form (profile instrument)
- Short-form
- Computer adaptive testing (CAT)
Questions?
Psychometrics

• **Unidimensionality:**
  • Comparative fit index (>0.95)
  • Root mean square error of approximation (<0.06)
  • Tucker-Lewis Index (>0.95)
  • Standardized root mean residuals (<0.08)
  • Average absolute residual correlations (<0.10).

• **Local independence determined by:**
  • evaluating item residual correlations, with values >0.2 considered to be locally dependent.

• **Monotonicity determined by:**
  • Calculate item outfit mean squares values (<2.0 acceptable) and to ensure that calibrated rating scale averages advance with each higher rating.
• Score: 40%
  • AzBio (25-55%)
  • CNC (24-58%)
• Score: 60%
  • AzBio (45-75%)
  • CNC (42-75%)
• Score: 80%
  • AzBio (68-93%)
  • CNC (64-92%)

Thornton A and Raffin M. Hearing Res 1978
Currently available CI instruments

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Type of instrument</th>
<th>Validated in CI patients</th>
<th>Hearing specific questions</th>
<th>Includes domains other than hearing</th>
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<tr>
<td>GBI</td>
<td>General</td>
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<td>✓</td>
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<td>HUI-3</td>
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- **Gerena**
Cochlear Implantation and quality of life

• Clear impact on patient quality of life
  • SMD CI and hearing
  • General health

very large effect size (1.77[1.28-2.26]), which likely results from the inclusion of communication-related items in these instruments. In contrast, improvements in QOL from pre to post implantation showed a medium effect (SMD=0.79 [0.39-1.19]) using
Topics to be discussed

- Why important
- Own published data on SMD
  - VAS data
- What do we currently measure
  - MSTB
- Show our correlation data
- Why do we need new instrument
  - Why focus groups
  - Why IRT
- Future directions:
  - Use to correlate with pre-operative testing
  - Behind the times? NEJM ortho articles
- This is the way outcomes research is going, this is the way reimbursement is going
  - Field needs to embrace this,
  - If going to do it, need to do it right
Cochlear Implantation

- Dramatic improvement in communication
- Dramatic improvement in patient quality of life
QOL instruments currently used in CI patients

• Three categories
  o General health-related QOL (SF-36, HUI-3, GBI)
  o Hearing specific (SSQ, HHIA, HHIE)
  o CI-specific (NCIQ, HISQUI-29, CIFI)
How do we currently evaluate CI outcomes?

- Speech recognition testing
  - Communication is extremely important
  - How well do these tests mimic real world experience?
  - Are we narrowing our understanding?
How do we currently evaluate CI outcomes?

• Speech recognition testing
  • Communication is extremely important
  • How well do these tests mimic real world experience?
Why is measuring QOL important?

- Patient reported outcome measures (PROMs) are used to measure QOL
  - Capture a patient's perspective
  - Allow direct input from impacted population
  - Direct measures that avoid the need for clinical interpretation
Does speech recognition ability correlate with QOL?

- Two meta-analyses to evaluate how speech recognition ability correlated with patient self-report QOL

McRackan TR, et. al. Laryngoscope 2017
Need for a new CI-QOL instrument

- No hearing or CI-specific instrument meets current standards
- Need recognized by:
  - ACIA
  - NIDCD
  - AAO-HNS
Score vs. Measure