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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<th>95% CI</th>
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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?

• Patient-Reported Outcomes Measurement Information System (PROMIS)
How do you create a QOL instrument?

- Patient-Reported Outcomes Measurement Information System (PROMIS)
  - 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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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

Ralph NB, et. al Int. J. Qual. Methods 2015
Cochlear implant focus groups

- Focus group transcripts coded
Cochlear implant focus groups

- Focus group transcripts coded

- Based on focus groups, established 101 question item pool

![Diagram](diagram.png)

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

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- University of Texas Southwestern
- Vanderbilt University
- Virginia Mason Seattle
- University of Miami
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- MED-EL
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 α=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
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- ciqualityoflife@musc.edu