Development of School-Age & Parent Proxy Health-Related Quality of Life Measures for Children With Cochlear Implants

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COIs

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Background

• Severe to profound hearing loss is associated with deficits in HRQoL, including concomitant effects on:
  • Oral language, social and emotional functioning, and academic performance

• However, the majority of studies on children with cochlear implants (CIs) focus primarily on language and communication
  • These studies fail to capture the effects on daily functioning

• To date, there are no CI-specific HRQoL measures for young children and their parents

• This study developed the first HRQoL instruments for children with CIs (ages 6-12) and their parents
Health-Related Quality of Life

- HRQoL measures capture how an individual feels, functions, and survives with a chronic medical condition or disability\(^1\)\(^-\)\(^4\)

- HRQoL encompasses four domains:
  1. Disease severity and physical symptoms
  2. Functional status
  3. Emotional/cognitive functioning
  4. Social functioning

- FDA and NICHD have pushed for the development HRQoL measures for children with chronic illnesses and disabilities using the PRO Guidance (2009)
FDA Measure Development Process

Cognitive testing → Determine population

Literature review → Conceptual framework

Item and instrument development

Coding interviews → Discussion guides

Child and parent interviews → Stakeholder interviews

Iterative
Methodology

• Two sites: University of Miami and Children’s Hospital of Philadelphia

• Focus group interviews (n = 5) were conducted with stakeholders at both sites (n = 30) (e.g., physicians, audiologists, SLPs, teachers of the deaf)

• Open-ended interviews were also completed with children with CIs, ages 6-12, and their parents (n = 21 dyads)
  • We included children with comorbidities to capture the full CI population

• Cognitive testing of the measures were completed with a new set of children and their parents (n = 20 dyads)
## Child Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Open-Ended Interviews (N=21) (%)</th>
<th>Cognitive Testing (N=20) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unilateral</td>
<td>1 (4.76%)</td>
<td>3 (15.00%)</td>
</tr>
<tr>
<td>Bimodal</td>
<td>6 (28.57%)</td>
<td>4 (20.00%)</td>
</tr>
<tr>
<td>Bilateral</td>
<td>14 (66.67%)</td>
<td>13 (65.00%)</td>
</tr>
<tr>
<td><strong>Type of hearing loss</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congenital</td>
<td>13 (61.90%)</td>
<td>13 (65.00%)</td>
</tr>
<tr>
<td>Progressive</td>
<td>9 (42.86%)</td>
<td>5 (25.00%)</td>
</tr>
<tr>
<td>Sudden</td>
<td>2 (9.52%)</td>
<td>2 (10.00%)</td>
</tr>
<tr>
<td><strong>Age at implantation (mean in months (SD))</strong></td>
<td>52.05 (32.78)</td>
<td>34.00 (27.39)</td>
</tr>
<tr>
<td><strong>Additional Comorbidities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>12 (57.14%)</td>
<td>10 (50.00%)</td>
</tr>
<tr>
<td>Yes</td>
<td>9 (42.86%)</td>
<td>10 (50.00%)</td>
</tr>
<tr>
<td><strong>Mode of communication</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral language</td>
<td>15 (71.44%)</td>
<td>19 (95.00%)</td>
</tr>
<tr>
<td>Sign language</td>
<td>1 (4.76%)</td>
<td>1 (5.00%)</td>
</tr>
<tr>
<td>Total communication</td>
<td>3 (14.28%)</td>
<td>0 (0.00%)</td>
</tr>
<tr>
<td>Sign/speech mixture with speech emphasis</td>
<td>2 (9.52%)</td>
<td>0 (0.00%)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>16 (76.19%)</td>
<td>13 (65.00%)</td>
</tr>
<tr>
<td>Female</td>
<td>5 (23.81%)</td>
<td>7 (35.00%)</td>
</tr>
<tr>
<td><strong>Age (in years)</strong></td>
<td>9.11 (SD=1.66)</td>
<td>9.17 (SD=1.87)</td>
</tr>
</tbody>
</table>
Conceptual Framework

Childhood Deafness

- Oral Communication
  - Poor comprehension
  - Trouble with exp. language

- Child Acceptance
  - Acceptance of device
  - Future plans

- Academic Functioning
  - Academic performance
  - School support

- Physical Functioning
  - Magnet falls off/discomfort
  - Injuries

- Hearing in Different Environments
  - Noisy Environments
  - TV, movies, videogames/music

- Device Management/Usage
  - Additional accessories
  - Needing a break

- Behavior
  - Attention/Distractibility
  - Fatigue

- Emotional Functioning
  - Frustrated/Anxious
  - Happy

- Social Functioning
  - Trouble making friends
  - Social withdrawal/isolation
Creation of Draft Instruments

• Scales and subscales were created based on the conceptual framework and open-ended interviews
  • Includes impact on HRQoL, as measured by frequency and relationship to the original conceptual framework

• Items were worded by reviewing the language used by patients/parents during the open-ended interviews

• Draft measures were tested with 20 new dyads (11 at UM and 9 at CHOP)
  • Process utilized standardized “think aloud” procedures
Cognitive Testing

• CI-QoL measures
  • Self-report questionnaire was designed using a multimodal approach, which consisted of audio recordings of the items, written choices, and pictorial response options
  • Administered using Filemaker Pro 14 on iPads
  • Scores ranged from 0-100 with higher scores indicating better HRQoL
Sample Item

Thinking about the past week:
16) How often do you take your CI off to have a break?

- Always
- Often
- Sometimes
- Never
## Final Item Generation: Self-Report Measure

<table>
<thead>
<tr>
<th>Scale</th>
<th>Number of items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic Functioning</td>
<td>5</td>
</tr>
<tr>
<td>Child Acceptance</td>
<td>3</td>
</tr>
<tr>
<td>Device Management</td>
<td>3</td>
</tr>
<tr>
<td>Emotional Functioning</td>
<td>5</td>
</tr>
<tr>
<td>Fatigue</td>
<td>4</td>
</tr>
<tr>
<td>Noisy Environments</td>
<td>5</td>
</tr>
<tr>
<td>Oral Communication</td>
<td>3</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>5</td>
</tr>
</tbody>
</table>
Sample Items

• Academic Functioning
  • How hard is it for you to hear in class? How hard is reading for you in school?

• Child Acceptance:
  • How hard is it for you to ask people to repeat what they said?

• Fatigue
  • How tired do you feel after listening for a long time?

• Social Functioning
  • How often are you teased about your CI?

• Device Management
  • How much does it annoy you when your magnet falls off?
## Final Item Generation: Parent-Proxy Measure

<table>
<thead>
<tr>
<th>Scale</th>
<th>Number of items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic Functioning</td>
<td>4</td>
</tr>
<tr>
<td>Child Acceptance</td>
<td>5</td>
</tr>
<tr>
<td>Device Management</td>
<td>5</td>
</tr>
<tr>
<td>Emotional Functioning</td>
<td>4</td>
</tr>
<tr>
<td>Fatigue</td>
<td>4</td>
</tr>
<tr>
<td>Noisy Environments</td>
<td>6</td>
</tr>
<tr>
<td>Oral Communication</td>
<td>5</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>4</td>
</tr>
<tr>
<td>Behavioral Problems</td>
<td>5</td>
</tr>
</tbody>
</table>
Sample Items

• Noisy Environments
  • How much does your child like listening to music?

• Oral Communication:
  • How often does your child rely on lip reading to understand others?

• Child Acceptance
  • How much does it annoy your child when others ask him/her about the CI?

• Social Functioning
  • How hard is it for your child to make friends?

• Device Management
  • How hard is it for your child to pay attention?
Feasibility and Clinical Utility

• The QoL-CI measures provide a CI-specific **standardized tool** to assess all aspects of daily functioning

• These instruments were designed with consideration of dissemination and implementation in clinics
  • Both measures are administered digitally via tablet using a free software
  • Can be completed in 10 minutes – potentially in waiting area
  • Scored automatically – ability to see scale and item-level responses instantly

• Self-report measure designed using a multimodal approach (text, audio, pictorial response options) which enables use of multiple context clues to understand an item
Feasibility and Clinical Utility

• Healthcare providers can use to track overall outcomes post-implantation

• Assessment of the efficacy of new therapies or processing strategies

• Identify those in need of additional resources and support

• Identify those who would benefit from mental health services

• Parenting Stress module can be used to identify parents in need of support
Future Directions

• Next steps:
  • Psychometric validation
  • Submission to FDA
  • Translation to other languages (Spanish)
  • Dissemination

• Research:
  • Compare HRQoL across different etiologies of hearing loss
  • Compare benefits of simultaneous vs sequential bilateral implantation
  • Examine relationship among key audiological predictors and HRQoL
  • Determine the effects of comorbidities
Thank You!!

• We would like to extend a very special thank you to Children’s Hospital of Philadelphia for allowing us to access their patient population.
• We would also like to thank all of the families in this study for sharing their experiences with us.
References


