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Validity and reliability of the Cochlear Implant Quality of Life (CIQOL)-35 Profile and CIQOL-10 Global instruments in comparison to legacy instruments

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Abstract

Objective: Validated and reliable patient-reported outcome measures (PROMs) may provide a comprehensive and accurate assessment of the real-world experiences of cochlear implant (CI) users and complement information obtained from speech recognition outcomes. To address this unmet clinical need, the Cochlear Implant Quality of Life (CIQOL)-35 Profile instrument and CIQOL-10 Global measure were developed according to the Patient-Reported Outcomes Information System (PROMIS) and COnsensus-based Standards for the Selection of health status Measurement INstruments (COSMIN) guidelines. The CIQOL-35 Profile consists of 35 items in 6 domain constructs (communication, emotional, entertainment, environment, listening effort, and social) and the CIQOL-10 Global contains 10 items that provide an overall CIQOL score. The current study compares psychometric properties of the newly developed CIQOL instruments to two legacy PROMs commonly used in adult CI users.

Design: Using a prospective cohort design, a sample of 334 adult CI users recruited from across the United States provided responses to: (1) the CIQOL instruments; (2) a CI-specific PROM (Nijmegen Cochlear Implant Questionnaire, NCIQ); and (3) a general-health PROM (Health Utilities Index-3, HUI-3). Responses were obtained again after 1 month. The reliability and validity of the CIQOL-35 Profile and CIQOL-10 Global instruments were compared to the legacy PROMs (NCIQ and HUI-3). Psychometric properties and construct validity of each instrument were analyzed using confirmatory factor analysis (CFA), item response theory (IRT), and test-retest reliability (using Pearson’s correlations), where appropriate.

Results: All six CIQOL-35 Profile domains and the CIQOL-10 Global instrument demonstrated adequate to strong construct validity. The majority of the NCIQ subdomains and NCIQ total score had substantial CFA model misfit, representing poor construct validity. Therefore, IRT analysis could only be applied to the basic sound performance and activity limitation subdomains of the NCIQ. IRT results showed strong psychometric properties for all CIQOL-35 Profile domains, the CIQOL-10 Global instrument, and the basic sound performance and activity limitation subdomains of the NCIQ. Test-retest reliability was strong for the CIQOL-35 Profile, CIQOL-10

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Global, and NCIQ, but moderate to weak for the HUI-3; the hearing score of the HUI-3 demonstrated the weakest reliability.

Conclusion: The CIQOL-35 Profile and CIQOL-10 Global are more psychometrically sound and comprehensive than the NCIQ and the HUI-3 for assessing QOL in adult CI users. Due to poor reliability, we do not recommend using the HUI-3 to measure QOL in this population. With validation and psychometric analyses complete, the CIQOL-35 Profile measure and CIQOL-10 Global instrument are now ready for use in clinical and research settings to measure QOL and real-world functional abilities of adult CI users.

Introduction

Despite advances in cochlear implant (CI) technology and broadening of indications, assessment of clinical outcomes related to cochlear implantation has not significantly changed since CIs were first approved by the FDA in 1985. Speech recognition ability, as assessed using word and sentence recognition scores (either in quiet or noise), remains the primary clinical outcome used to evaluate treatment success (Adunka et al., 2018). Recently, patient-reported outcome measures (PROMs) that evaluate quality-of-life (QOL) have been developed and recommended to supplement the standard clinical outcomes to provide a more comprehensive assessment of the benefits of cochlear implantation to an individual’s life(Capretta & Moberly, 2016; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Nguyen, et al., 2018; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Velozo, et al., 2018). At the same time, the Centers for Medicare and Medicaid Services have identified PROMs and QOL as “Meaningful Measures,” which designate these instruments as those that “reflect core issues that are most vital to high quality care and better patient outcomes(Services).” PROMs are also now required as one of the primary outcome measures in any trial where an intervention is seeking FDA approval (Patrick et al., 2007). Therefore, measuring QOL in adult CI users is not only appropriate for research and clinical use, but is increasingly important from a regulatory perspective.

The use of PROMs to assess outcomes in adult CI users also provides a more comprehensive understanding of patients’ view of their real-world functional abilities. Despite the ubiquitous use of speech recognition outcome measures in clinical and research protocols, these outcomes are poor predictors of self-reported QOL (Capretta & Moberly, 2016; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Nguyen, et al., 2018; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Velozo, et al., 2018) and self-reported communication ability (McRackan, Hand, Velozo, & Dubno, 2019) following cochlear implantation. These poor relationships suggest that commonly used speech recognition tasks may not capture the complexities of how CI users listen, communicate and interact with their environments. For example, most CI users rely on auditory and visual cues for communication (Stevenson et al., 2017), but visual cues are typically not included in current measures of speech recognition. Moreover, the real-world listening environments in which most CI users communicate are likely poorly replicated by speech recognition in noise tasks (McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Nguyen, et al., 2018; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Velozo, et al., 2018). The use of PROMs circumvents some of the shortcoming of simulated receptive

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communication testing and allows individuals to provide direct feedback regarding their everyday functional communication experiences in their personal listening environments. In addition, by focusing solely on speech recognition outcomes, we limit our ability to understand the established social, emotional, other impacts of cochlear implantation(Hughes et al., 2018; McRackan et al., 2017). Measuring outcomes beyond communication can be time consuming and require multiple instruments. However, the use of a validated PROM that assesses QOL can incorporate multiple domains and measure the wide-ranging effects of cochlear implantation in a single instrument. As such, PROMs that assess QOL, together with other outcomes, have the potential to provide a comprehensive understanding of the benefits of cochlear implantation appropriate for research studies, clinical trials, and within a clinical test battery.

Guidelines for development of patient-reported outcome measures:

As PROM utilization has increased in importance, so too has the need to follow stringent guidelines to develop these instruments. The Patient-Reported Outcomes Measurement Information System (PROMIS) and COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) have established standards that aim to improve the quality of PROMs used to measure clinical and research outcomes(Mokkink et al., 2010; PROMIS). In general, these standards support a mixed methods research design that include: development of a construct to be measured, systematic review of prior work done on the topic, inclusion of a sample of affected patients (key-informant interviews or focus groups), cognitive interviews with the sample patients, use of modern psychometric techniques for analyses, and reliability and validity testing to evaluate the final instruments. Both standards have the ultimate aim of developing instruments that accurately portray the values of a population and stratify patients along the ability continuum of the construct of interest.

These methodologies have rarely been applied to adults with hearing loss and never to CI users prior to the current work (McRackan, Hand, et al., 2018; McRackan, Hand, Velozo, Dubno, et al., 2019). The importance of doing so is three-fold. First, incorporating stakeholder engagement in PROM development provides face and content validity by ensuring topics that affect QOL of the population of interest are included in hearing-related and CI-specific PROMs (McRackan et al., 2017). Second, cognitive interviewing ensures the items included in the final instruments are relevant to the lives of CI users and the interpretation of the item responses aligns with the intention of the research team. Third, as discussed later, the use of modern psychometric analyses has the potential to improve the measurement properties of PROMs.

Item response theory (IRT) is the core of these modern psychometric analyses used to develop PROMs and has several advantages over classical test theory (the previous standard for PROM development). First, classical test theory is grounded on observed and true scores as opposed to IRT, which focuses on the measurement of an underlying trait—referred to as person ability or person measure. As such, instruments developed with classical test theory are sample-dependent as subjects will have higher true scores on easier tests and lower true scores on more difficulty tests. In contrast, instruments developed using IRT remain sample and test independent (Prieto et al., 2003).

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A second advantage of IRT is the focus on item-level, rather than test-level, psychometrics (as in classical test theory). The data provided by IRT analysis on each individual item determines its measurement characteristics and utility for inclusion in subsequent instruments. For example, IRT analysis evaluates each item for ceiling and floor effects, identifies fit to the hierarchical model, matches individual item difficulty level to person ability level, and ensures that the items cover the ability range of the population of interest. These results create an item bank that measures and differentiates individuals across the range of ability levels and serves as the source for items to be used for subsequent PROMs including short form, profile, and computerized adaptive testing (CAT) instruments. Given that the psychometric properties of each item are established, researchers can then select items for each instrument based on their highest discrimination across the ability range and best match between item difficulty and subject ability. This process results in optimized instruments with maximized capacity to differentiate individuals across a greater range of the latent trait—termed precision(Rose et al., 2008).

The third advantage relative to classical test theory is based on the more strict assumptions that must be met before IRT analysis is performed, including (Reeve et al., 2007): (1) items only contribute to one domain of QOL (unidimensionality), (2) responses to each item are unrelated to responses to other items (local independence), and (3) items fit the IRT measurement model (item fit). Confirmatory factor analysis (CFA) is used to confirm unidimensionality and local independence. Items are eliminated if they do not significantly contribute to the unidimensional construct captured by the other items in a domain, or if responses to the item are dependent upon responses to other items in the pool. In addition, item fit to the IRT model, such as infit and outfit, are examined to ensure that the included items sufficiently measure the construct of interest for individuals at ability levels close to and far from the item difficulty.

Legacy instruments

The use of hearing-related and CI-specific PROMs is important in for assessments of CI users as data suggest that patients report two times greater improvement when using these instruments rather than generic health-related QOL instruments (McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Nguyen, et al., 2018; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Velozo, et al., 2018; McRackan, Fabie, et al., 2019). However, the legacy hearing-related and CI-specific PROMs most often used to assess CI users were not developed using the stringent PROMIS and COSMIN guidelines to establish face and construct validity. In fact, commonly used instruments, such as the Hearing Handicap Inventory for Adults/Elderly (HHIA/E) (Newman et al., 1990; Ventry & Weinstein, 1982), Speech, Spatial and Quality of Hearing Scale (SSQ) (Gatehouse & Noble, 2004), and the Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox & Alexander, 1995), were developed and validated in individuals with mild to moderate hearing loss and hearing aid users. Given that CI users and those with more severe hearing loss were excluded from the development process, researchers and clinicians using these PROMs cannot be confident that the results accurately and reliably reflect the themes and constructs for adult CI users (Capretta & Moberly, 2016; Park et al., 2011; Vermeire et al., 2006; Vermeire et al., 2005).

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The Nijmegen Cochlear Implant Questionnaire (NCIQ) is by far the most commonly used CI-specific PROM (Hinderink et al., 2000; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Nguyen, et al., 2018). As summarized in a recent meta-analysis (McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Nguyen, et al., 2018), NCIQ total score and all subdomain scores improve after cochlear implantation. The NCIQ consists of 60 items with 3 domains (physical, psychological, and social). The domains are further divided into 3 subdomains: physical includes basic sound perception, advanced sound perception, and speech production; psychological includes self-esteem; social includes activity limitations and social interactions. The NCIQ includes items and domains selected by expert opinion, rather than from information provided by CI users. As such, the NCIQ does not contain certain domains and themes that have been shown to be of value to CI users in subsequent qualitative work (Hughes et al., 2018; McRackan et al., 2017). Again, this demonstrates the value of directly soliciting input from CI users to ensure that a QOL instrument adequately captures concepts that are important to members of the target population. Such stakeholder engagement is now considered standard procedure for PROM development (Mokkink et al., 2010; PROMIS). In addition, the NCIQ was only validated and tested in Dutch on 91 participants (including 46 controls) from a single clinical site in the Netherlands without cross-cultural adaptation(Hall et al., 2018) in other populations. Finally, as detailed earlier, more rigorous psychometric testing for PROM development has become standard since the NCIQ was developed.

The establishment of PROMIS and COSMIN guidelines for best-practices in PROM development provides a new opportunity for the field of hearing science to critically re-examine existing instruments and develop novel PROMs following these rigorous guidelines.

Development of the CIQOL instruments

The stages of CIQOL instrument development have been previously described in detail but are outlined here (McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Nguyen, et al., 2018; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Velozo, et al., 2018; McRackan, Hand, et al., 2018; McRackan et al., 2017). In general, this process included three main stages: (1) creation of the new Cochlear Implant Quality of Life (CIQOL) item pools; (2) psychometric analysis of the CIQOL pools to create the final CIQOL item banks; (3) selection of items for the CIQOL instruments based on the results of IRT analysis of the item bank.

Development of the CIQOL item pool—The first step in this process was to perform a systematic literature search to identify previously recognized themes thought to be important to adult CI users (McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Nguyen, et al., 2018; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Velozo, et al., 2018). These results were then used to develop the protocol for three patient focus groups. Focus group participants were representative of the adult CI population based on demographics, communication abilities, and listening modalities and were stratified based on speech recognition ability (McRackan et al., 2017). The development, execution, and analysis of the focus group protocol was based on grounded theory (Ralph et al., 2015) and the

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consolidated criteria for reporting qualitative research (COREQ-32) was followed (Tong et al., 2007). A 101-item pool was developed based on the central and minor themes identified during coding of the focus group transcripts. The item pool was finalized after item clarity was confirmed in the population of interest through cognitive interviews with 20 additional adults with CIs (McRackan et al., 2017).

Creation of the CIQOL item banks and CIQOL instrument development—The CIQOL item bank was developed based on the psychometric analyses of the item pool and serves as the collection of items available for use in subsequent instruments. To test the psychometric properties of the initial item pools, responses from 371 CI users, recruited from all regions of the United States through the 30-institution CIQOL Development Consortium (more details later), were analyzed with CFA and IRT. This resulted in 3 items being removed based on local dependence and 6 items removed due to misfit to the IRT model. One domain was removed (independence; 11 items) due to poor psychometric properties and misfit to the IRT model (McRackan, Hand, et al., 2018). Based on the above psychometric analyses, the measurement properties of each item in the CIQOL item banks are known. The CFA and IRT parameters were used to select items for the final instruments that best matched item difficulty level with the ability level of the population (item difficulty), greatest capacity to differentiate individuals according to ability (item discrimination), and best item fit to the measurement model (item fit) (McRackan, Hand, Velozo, Dubno, et al., 2019).

CIQOL-35 Profile Instrument and CIQOL-10 Global Measure—The CIQOL-35 Profile and the CIQOL-10 Global are the first two instruments developed from the CIQOL item bank using the analyses described earlier. The CIQOL-35 Profile measures domain-specific CIQOL and includes 35 items in 6 domains (communication, emotional, entertainment, environmental, listening effort, and social). The CIQOL-10 Global contains 10 items from the CIQOL-35 and provides a global assessment of a CI user's QOL without domain-specific data. Therefore, domain-specific and global QOL can be measured from the CIQOL-35 Profile. The CIQOL-35 Profile instrument and the CIQOL-10 Global measure were previously shown to demonstrate optimized precision in differentiating individuals across the range of the latent trait (McRackan, Hand, Velozo, Dubno, et al., 2019).

Current study

The current validation study compared the psychometric properties of the newly developed CIQOL instruments with legacy PROMs commonly used in adult CI users – the NCIQ (Hinderink et al., 2000) and Health Utility Index 3 (HUI-3) (Horsman et al., 2003). The purpose of these comparisons was to determine the extent to which the theoretical advantages of including stakeholder engagement and applying rigorous psychometric analysis resulted in QOL instruments with enhanced measurement properties as compared to legacy measures. The NCIQ was chosen because it is the most commonly cited CI-specific PROM(McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Nguyen, et al., 2018) and the HUI-3 was selected because it is routinely used in adult CI users and is one of the few generic health instruments that specifically addresses communication ability (McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Nguyen, et al., 2018; McRackan, Bauschard,

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Hatch, Franko-Tobin, Droghini, Velozo, et al., 2018). In addition, the HUI-3 is used in nearly all health economic evaluations for adult cochlear implantation("Criteria of candidacy for unilateral cochlear implantation in postlingually deafened adults II: cost-effectiveness analysis," 2004; Palmer et al., 1999; Smulders et al., 2016).

Methods:

Study Design:

The present study consists of a self-report questionnaire administered through REDCap (Research Electronic Data Capture), a secure web-based data collection platform. Subjects completed the questionnaire twice, separated by a 4-week interval. Subjects were remunerated with a $10 gift card after completing the second questionnaire. This study was approved by our Institutional Review Board.

Subjects and Recruitment

Subjects were recruited through the CIQOL Development Consortium, which consists of 30 institutions and was established to recruit a large sample of adult CI users representative of the broader adult CI population. Recruitment flyers were distributed electronically and on paper to CI users through these CI centers. Potential subjects emailed our research team in order to be enrolled. Subjects were required to: (1) be between 18–89 years of age (as individuals >89 years of age are considered a special population), (2) have used a CI for over one year, and (3) not have received a CI for single sided deafness. The subjects recruited for the current study were an independent cohort from those recruited previously to develop the CIQOL item bank.

Measures

The questionnaire consisted of three major sections: (1) subject demographics (completed only at Time 1), (2) the CIQOL-35 Profile (which includes all items in the CIQOL-10 Global), and (3) legacy instruments - the NCIQ, and HUI-3. Subject demographics included: age, sex, marital status, whether subjects had children (<18 years old) in the household, household income, education level, geographic region, residential area description, and hearing/CI history. Geographic regions were determined by the US Census Bureau definitions (Bureau, 2010) and subjects self-identified the developed area where they lived as urban, suburban, or rural. Regarding hearing and CI history, duration of CI use was calculated based on the date subjects had their first (or only) CI activated. Subject's listening modality was defined as the hearing device configuration they used on a routine basis (bilateral CIs, unilateral CI with or without contralateral hearing aid). Subjects also obtained their most recent best aided speech recognition scores from their audiologist and entered them into the questionnaire. These scores could include word scores (Consonant-Nucleus-Consonant [CNC]), sentence scores in quiet (Hearing in Noise Test [HINT]; AzBio quiet), or sentence scores in noise (AzBio +10 dB signal-to-noise ratio [SNR]), as these are components of the minimum reporting standards (Adunka et al., 2018). Subjects were not excluded if they could not obtain speech recognition scores.

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For the CIQOL-35 Profile, subjects respond to each item using a 5-point scale, where higher scores indicate better QOL. Scores are derived by calculating a sum of subject responses and using score conversion tables that were produced using IRT (Cochlear Implant Quality of Life Research Program, 2019). Subjects also completed the two legacy instruments - the NCIQ and HUI-3. Each item in the NCIQ is rated on a 5-point scale and item-level responses are averaged to yield scores for each NCIQ subdomain, domain, and total score. Scores were calculated based on the corrected table published after the initial NCIQ ("Corrigendum," 2017). The HUI-3 consists of 8 items, each corresponding to an attribute of health (vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain). Respondents select their health level for each attribute using a scale ranging from 1–5 (for speech, emotion, and pain) or 1–6 (for all other attributes), where higher scores indicate poorer health related QOL. Scores for each individual attribute are derived using a weighting system for the subject's item-level response (single-attribute utility function) and a HUI-3 total score is derived from the multi-attribute utility function (Horsman et al., 2003). Subjects were randomized regarding the order in which they completed the CIQOL, NCIQ, and HUI-3 instruments.

Data analysis

We examined subject demographic characteristics using descriptive statistics. Additionally, due to previously documented weak correlations between speech recognition scores and PROMs in adult CI users, we examined the extent to which CIQOL-35 Profile, CIQOL-10 Global, NCIQ, and HUI-3 scores were associated with speech recognition scores in our sample using Pearson's correlations.

Construct validity—We evaluated the construct validity of the CIQOL instruments in comparison to the NCIQ with CFA and IRT, conducted on subject responses at Time 1. We did not perform CFA or IRT on the HUI-3 as it would be inappropriate given the structure of the instrument (i.e., only one item is used to measure each construct/health attribute). As unidimensionality is a prerequisite for IRT, we first performed CFA on the CIQOL-10 Global, each domain of the CIQOL-35 Profile, and each domain and subdomain of the NCIQ. CFA results were interpreted with a-priori established indicators of fit including: (1) Standardized Root Mean Square Residual (SRMR) ≤ 0.08; (2) Root Mean Square Error of Approximation (RMSEA) $\leq .05$ for good fit, 0.06–0.09 for adequate fit, and $\geq .10$ for poor model fit (Kenny et al., 2015); (3) Comparative Fit Index (CFI) and Tucker-Lewis Index (TLI) ≥ 0.95; and (4) a minimum standardized factor loading of $\geq |0.32|$ (Tabachnick & Fidell, 2013) to indicate a significant relationship between an item and the latent construct.

Once a unidimensional set of items for each instrument was identified, we performed a one-parameter logistic IRT analysis using a rating scale model and joint maximum likelihood estimation. Rating scale appropriateness was evaluated using the following criteria (Linacre, 2002): (1) at least 10 observations per category, collapsed across all items; (2) monotonicity of rating scale categories; and (3) outfit mean square <2.0. Item and person fit to the IRT model was evaluated by examining infit and outfit mean squares and standardized z values(Kelley et al., 2002). Mean square values >1.70, as well as standardized z values greater than 2.0, were considered indicative of misfit to the IRT model (Wright & Linacre,

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1994). We also examined: (1) ceiling or floor effects, where subjects had either minimum or maximum extreme scores and >15% was indicative of a substantial effect; (2) person reliability, which is the reproducibility of person ordering and was interpreted such that values ≥0.80 were considered good and ≥0.90 were high (Linacre, 2016); (3) ability strata, which is the number of distinct person measures with centers three calibration errors apart (Wright & GN, 2002), with values > 3.0 considered minimally acceptable; (3) test targeting using a mean person measure < |1.0| to indicate that the items were well-matched to the sample; and (4) Cronbach's alpha, which was interpreted such that values ≥0.80 were considered good evidence of internal consistency.

Convergent validity—Pearson's correlations were used to examine how scores on the CIQOL-35 Profile and CIQOL-10 Global were associated with scores on conceptually similar sub-domains/domains of the NCIQ and HUI3 using subjects' responses at Time 1. Table I identifies the conceptually similar components of the CIQOL instruments and the legacy PROMs. Pearson's correlations ≥0.70 were considered strong, 0.50–0.69 were considered moderate, and <0.50 were considered weak (Rodgers & Nicewander, 1988). All assumptions for Pearson's correlations, including bivariate normality, were evaluated. Results did not reveal violations of any assumptions that would substantially affect correlation results.

Test-retest reliability—We used Pearson's correlations to examine associations between scores on each measure at Time 1 and Time 2. The same criteria as described above were used to evaluate Pearson's correlations for test-retest reliability.

Power analysis—CFA was used to determine the sample size as it is the most sample size dependent portion of the analysis. Under a variety of sample conditions based on Monte Carlo simulations, sample sizes of 300 are considered conservative (MacCallum et al., 1999). Due to the test-retest nature of the study, we estimated a 60% response rate. Therefore, questionnaires were sent to the first 500 subjects who contacted the research team.

Results

Of the 500 subjects contacted, 334 (66.8%) responded and completed the study. Tables II and III provides the demographic and clinical characteristics of the study sample. Overall, subjects were representative of the adult CI population (McRackan, Hand, et al., 2018). Most were married without children in the household and obtained at least some college education. Household income was evenly distributed among the categories except the lowest (≤20k). Subjects were recruited from all regions of the US with only 5.1% of individuals from our institution. Age, duration of CI use, listening modalities, and speech recognition ability were representative of the broader CI population (Fabie et al., 2018; Gifford et al., 2008; Holden et al., 2013). In addition, patients using all three CI device manufacturers were recruited.

Consistent with existing literature, we found that all PROM domains, sub-domains, and total scores were weakly correlated with CNC word, HINT, AzBio in quiet, and AzBio

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+10 dB SNR scores (Table IV) (Capretta & Moberly, 2016; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Nguyen, et al., 2018; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Velozo, et al., 2018; Olze et al., 2012; Park et al., 2011; Vermeire et al., 2005). This result supports our decision to compare the psychometric properties of the CIQOL-35 Profile and CIQOL-10 Global with legacy PROMS rather than to utilize speech recognition scores as the gold standard criterion. Of note, the HUI-3 hearing score showed the weakest correlation with speech recognition ability of any analysis performed (r=0.02–0.15). Given that we anticipated CIQOL-Communication would show the strongest correlation with speech recognition ability, Table IV and Figure 1 show that the CIQOL-Communication domain still demonstrates a weak correlation (0.37–0.40) with the legacy communication scales.

Construct validity

Confirmatory Factor Analysis—The CFA results are shown in Table V. Most CIQOL-35 Profile domains and CIQOL-10 Global demonstrated good model fit. RMSEA indicated poor model fit for all CIQOl-35 domains except communication. However, this may be because RMSEA is a less reliable indicator of fit (Kenny et al., 2015) in models with few degrees of freedom. The other fit indicators included accommodate fewer degrees of freedom. In addition, the entertainment domain did not meet our threshold for acceptable SRMR. However, we proceeded with Rasch analysis given that the SRMR (0.09) was very close to our cut-off threshold of 0.08, previous work demonstrated adequate fit (McRackan, Hand, Velozo, Dubno, et al., 2019), and the two other fit indices examined were adequate. All CIQOL-35 Profile domains and CIQOL-10 Global met *a-priori* CFI and TLI model fit criteria. In addition, all items had standardized factor loading of ≥ $\left|0.32\right|$ on their respective domains.

Apart from the basic sound perception and activity limitation subdomains, all NCIQ domains and subdomains had multiple indicators of poor model fit (bolded in Table V). Given that unidimensional structure is required for IRT analysis, further psychometric analysis with IRT could only be performed on the basic sound perception and activity limitation subdomains.

Item Response Theory—All CIQOL-35 Profile domains, the CIQOL-10 Global, and NCIQ subdomains that were analyzed with IRT met our three criteria for rating scale appropriateness (i.e., monotonicity, > 10 observations per rating scale category, and outfit mean square < 2.0). Additionally, all analyses revealed: an absence of substantial ceiling or floor effect (<15% of subjects), good to high person reliability (i.e., ≥0.80), acceptable numbers (>3) of statistically distinct person strata that can be reliably differentiated, and a relatively high Cronbach's alpha ≥0.80. Table VI provides a summary of the IRT analysis results.

The CIQOL-35 Profile communication, entertainment, and social domains, as well as the NCIQ basic sound perception and activity limitation subdomains, each had one item that demonstrated model misfit. Four CIQOL-35 Profile domains and both NCIQ sub-domains had mean person measures > |1.0|, indicating a slight mismatch between subject ability and

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item difficulties. However, these values are acceptable given low ceiling and floor effects for these domains. For example, the mean person measure for the CIQOL-35 Profile social domain revealed that the average subject ability was 2.4 logits higher than the mean item difficulty. However, given that only 8.1% of subjects showed a ceiling effect for this domain, it appears that the full range of ability is being measured in the adult CI population.

While IRT analysis could not be completed on the additional NCIQ domains and subdomains, ceiling and floor effects were calculated (Table VI). No substantial ceiling or floor effects were observed except for the NCIQ speech production subdomain where 15.3% of subjects reported the highest possible score.

Convergent validity

Pearson correlations between the CIQOL-35 Profile domains and CIQOL-10 Global scores with conceptually similar components of the NCIQ and HUI-3 are shown in Table VII and Figure 2. Specifically, Table VII displays correlations between the NCIQ/HUI-3 composite scores and all CIQOL domains and conceptually similar NCIQ and CIQOL domains. Figure 2 compares conceptually similar NCIQ subdomains and CIQOL domains. Scores on the CIQOL-35 communication domain were strongly correlated with the NCIQ basic sound perception, advanced sound perception, physical function, and total score (r=0.70–0.83) and weakly correlated with speech production (r=0.42; Figure 2). The CIQOL-35 emotional domain and social domain scores were strongly correlated with scores on the NCIQ psychological domain (r=0.80) and social function domain (r=0.72), respectively. The CIQOL-10 Global score was strongly correlated with the NCIQ total score (r=0.85).

Overall, HUI-3 scores were weakly correlated with the CIQOL-35 Profile scores and CIQOL-10 Global scores. Specifically, the CIQOL-35 Profile communication domain demonstrated low correlation with the HUI-3 speech and hearing scores (r=0.17–0.32; Figure 2). All CIQOL-35 Profile domains and the CIQOL-10 Global were weakly correlated with HUI-3 total scores (r=0.20–0.31; Table VII).

Test-retest reliability

All CIQOL-35 Profile domains and the CIQOL-10 Global showed strong to very strong test-retest reliability (Table VIII), with correlation coefficients ranging from 0.83 to 0.91. NCIQ total score and all domains/subdomains were also found to have strong to very strong test-retest reliability with correlation coefficients ranging from 0.77 to 0.92.

Test-retest reliability for the HUI-3 was weaker than that of the CIQOL-35 Profile, CIQOL-10 Global, and NCIQ. The HUI-3 total score (r=0.61) and speech score (r=0.52) had moderate reliability. However, the hearing score demonstrated weak reliability (0.43).

Discussion

Comparison of psychometric properties CIQOL instruments and the NCIQ

All CIQOL-35 Profile domains and the CIQOL-10 Global were found to represent unidimensional constructs, meaning all items in each domain were found to measure a single latent trait. Therefore, users of the CIQOL instruments can be confident that domain-specific

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outcomes represent the ability level for the purported latent trait. In comparison, only the basic sound perception and activity limitations sub-domains for the NCIQ were found to be unidimensional. However, future work using exploratory factor analysis and IRT may provide information to alter the instrument (reorganize the items by domain, eliminate items) to improve its dimensionality and psychometric properties.

The measurement properties of the majority of sub-domains and domains of the NCIQ could not be compared to the CIQOL instruments because construct unidimensionality is required for IRT analysis. Therefore, only basic sound perception and activity limitations could be analyzed along with the CIQOL-35 Profile domains and CIQOL-10 Global instrument. The results showed strong psychometric properties for all sub-domains and domains analyzed. Direct comparison of the NCIQ basic sound perception sub-domain and CIQOL communication domain revealed that, although each had 10 items, the CIQOL communication domain showed greater precision than the NCIQ sub-domain, as measured by the number of distinct ability strata each instrument can reliably differentiate (4.56 vs. 3.61). Interestingly, despite the NCIQ activity limitation sub-domain having 5 more items than the CIQOL social domain, each showed similar precision (3.42 and 3.28, respectively). These examples highlight the potential benefits of using item-based psychometric analysis to optimize the measurement properties of PROMs.

Although the NCIQ was selected for the current study because it is the most commonly cited CI-specific PROM, it was not developed using modern instrument development methodologies, which may explain the reason it did not meet some of the assumptions (i.e., unidimensionality) required for IRT analysis. In contrast, comparable analyses have been performed on other, similarly developed, legacy hearing instruments, which demonstrated strong psychometric properties (Akeroyd et al., 2014; Cassarly et al., 2019; Jessen et al., 2018). While many additional legacy hearing-specific PROMs are available and have been applied to CI users, few have been developed specifically for patients with more severe hearing loss and those who use CIs. This has led to important differences in what is being measured by the legacy hearing-specific PROMs in comparison to the CIQOL instruments. Certain domains, such as communication, social, and emotional function are included in legacy instruments (Cox & Alexander, 1995; Gatehouse & Noble, 2004; Newman et al., 1990; Stika & Hays, 2015; Ventry & Weinstein, 1982; Yueh et al., 2005), but constructs that were noted to be important in CI focus groups (McRackan et al., 2017), such as enjoyment of entertainment, ability to distinguish and localize environmental sounds, and degree of effort and resulting fatigue associated with listening, have not previously been measured. There has been post-hoc attempt to develop an “effort and concentration” domain for the SSQ, but a factor analysis produced inconsistent results(Akeroyd et al., 2014). Further work is required to determine the psychometric properties of other hearing-specific PROMs in adult CI users using modern analytic practices.

In the current study, the new CIQOL instruments demonstrated strong convergent validity. However, close examination of the results reveals two important considerations. First, despite the strong correlation between the shared CIQOL and NCIQ domains, substantial variance exists. For example, although the CIQOL and NCIQ social domains showed strong correlation, the coefficient of determination, which describes the proportion of variance

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explained, was r^2=0.52. This means that only 52% of the variance in CIQOL social scores was accounted for by the NCIQ social domain score, meaning that a large degree of variation in CIQOL and NCIQ social domain scores remains independent. This variation may be partially related to differences in how the NCIQ and CIQOL items are written. For example, nearly all the NCIQ social domain item begin with "Does your hearing impairment present a serious problem/obstacle/hinderance when..." In contrast, the CIQOL social domain items allow the answer choices (never, rarely, sometimes, often, or always) to define the severity of the social impact and avoid terms such as "serious" in the item stem.

Second, we were unable to assess the convergent validity of several CIQOL domains because there was no comparable NCIQ domain/subdomain. This highlights the importance of using focus groups and subsequent thematic analysis to develop items and group them into domains, which establishes face and content validity. In fact, several constructs of the CIQOL —entertainment, environment, and listening effort—that were identified as important to CI users were not included in the NCIQ. This supports the conclusion that the CIQOL instruments provide a more comprehensive evaluation of CI users' QOL. The implementation of these instruments represents a patient-centered approach as it measures outcomes that have the greatest impact on adult CI users' daily lives. This provides an opportunity to critically reevaluate the pre/post change patients receive from cochlear implantation and a chance to redefine success after implantation from a patient's perspective.

Although there was convergent validity for nearly all comparable domains, there was weak correlation between the CIQOL-35 Profile communication domain and NCIQ speech production subdomain. Examination of the items in this NCIQ subdomain and patients' responses to those items provide a potential interpretation of these results. First, the NCIQ separates communication into three subdomains (basic sound perception, advanced sound perception, and speech). In contrast, the CIQOL-35 combines expressive and receptive communication into a single domain, which was found to represent a unidimensional construct, and includes a range of item difficulty that matches the adult CI users' ability(McRackan, Hand, et al., 2018; McRackan, Hand, Velozo, Dubno, et al., 2019). Therefore, the CIQOL communication domain likely measures a different construct than the 3 NCIQ communication subdomains, which would explain some of the variance described above. Second, the NCIQ speech production subdomain had a large ceiling effect, which represents a barrier to demonstrating linear correlation.

Use of HUI-3 in adult CI users

Generic health-related QOL instruments, such as the HUI-3, SF-36 and EQ-5D are routinely used to determine the health utility and health economic benefit from a medical intervention. The HUI-3 was selected as a comparator legacy measure for the current study based on the frequency of use (Arnoldner et al., 2014; Damen et al., 2007; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Velozo, et al., 2018; Palmer et al., 1999; Smulders et al., 2016; van Zon et al., 2017) and data suggesting that it may be valid for adult CI users (Yang et al., 2013). Based on responsiveness data and differentiation of subjects with and without hearing loss, Yang et al.(Yang et al., 2013) reported that the HUI-3 was the best available measure

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to evaluate generic health-related QOL in individuals with hearing loss, but noted the lack of reliability data for the HUI-3 in the hearing loss population. This may be a reasonable assumption as the HUI-3 is the only such instrument that includes a hearing dimension. However, the wording of the hearing dimension may help explain the poor reliability of the HUI-3 in CI users who participated in our study.

The HUI-3 hearing dimension asks users to identify their health level on a 1–6 scale. Interestingly, levels 1–5 all specifically mention the use of hearing aids and level 6 is simply "Unable to hear at all." There is no mention of CIs or other assistive listening devices, which may lead to confusion and different interpretations in CI users. For example, some users may consider their CI a hearing aid while others do not. In addition, many CI users communicate with bimodal hearing, that is, a CI in one ear and hearing aid in the other (31.4% in the current study), causing further confusion on these items. The wording of the HUI-3 hearing dimension is logical when measuring QOL in a large sample of individuals with hearing loss, where hearing aid use far outnumbers CI use, but is problematic when applied specifically to CI users. At times, the HUI-3 hearing dimension has been altered to read "hearing aid or cochlear implant," (Palmer et al., 1999) but it is unclear to what extent this changes the instrument's measurement properties and alters the health utility index calculation. We opted to maintain the original, validated language for the current study so our results could be more readily compared with others in the literature. Nevertheless, this wording may be responsible for a substantial portion of the low correlation between the HUI-3 hearing dimension and the CIQOL-communication domain.

The wording of the HUI-3 hearing dimension is also likely responsible for the relatively low observed test-retest reliability of this domain in the current study. For example, patients may interpret the item stem differently, as described earlier, on repeated administrations. As the CIQOL-35 Profile, CIQOL-10 Global, and NCIQ demonstrated high test-retest reliability, it is unlikely that changes in functional ability account for the low test-retest reliability of the HUI-3 hearing dimension. Although all instruments/domains demonstrated relatively low correlations with speech recognition scores, the HUI-3 hearing dimension values were even lower, which is consistent with published data (Damen et al., 2007; Kumar et al., 2016). Thus, we do not recommend using the HUI-3 to evaluate health utility benefit in adult CI users and recommend caution in interpreting results from previous studies that have done so.

Given this, researchers are currently limited in the availability of generic health-related QOL measures for use in health economic assessments in adult CI users. Most generic health-related QOL measures include domains such as mobility and bodily pain that are unrelated to cochlear implantation. Thus, these instruments may underestimate the benefits of cochlear implantation, as has been previously reported (McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Nguyen, et al., 2018; McRackan, Bauschard, Hatch, Franko-Tobin, Droghini, Velozo, et al., 2018; McRackan, Fabie, et al., 2019). Future research is needed to determine which instruments can be used to more accurately estimate benefits of cochlear implantation within the health economic framework.

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Implementation of the CIQOL instruments

The current project represents the culmination of a multi-year and multi-institutional study that demonstrates the value of following stringent guidelines and using qualitative to quantitative approaches to develop CI-specific PROMs. From the initial CI focus groups to this validation study, 748 unique adult CI users from around the United States participated in the development of the CIQOL instruments. These results were used to develop instruments that represented the important themes for adult CI users and had superior measurement properties to the currently available PROMs. The results of this study revealed that the CIQOL-35 Profile and CIQOL-10 Global demonstrate strong convergent validity with conceptually similar domains on the NCIQ, yet the CIQOL instruments have stronger evidence of content validity. Additionally, the CIQOL-35 Profile and CIQOL-10 Global demonstrated test-retest reliability in adult CI users similar to the NCIQ and superior to the HUI-3.

Given these results, the CIQOL-35 Profile and CIQOL-10 Global are ready for clinical and research use in adults with CIs. These direct measures complement data obtained from speech recognition outcomes and provide a broader understanding of the benefits of cochlear implantation to an individual’s life. The comprehensive nature of the CIQOL-35 Profile provides assessment of outcomes in domains unrelated to speech recognition ability as measured using traditional tasks. Further, the weak correlation between speech recognition scores and the CIQOL-communication domain suggest that this domain measures a seemingly distinct construct of real-world functional communication abilities. Therefore, the CIQOL instruments can serve as valuable supplements to the traditional speech recognition test battery to evaluate post-CI progress and also the extent to which new CI device technologies, listening modalities, and processing strategies may improve outcomes.

Study limitations

Limitations of the current study are mostly related to the methods used to enroll patients. To make results generalizable, a large sample of adult CI users was recruited from a 30-member CI center consortium. Overall, it appears that this sample may have received more education and had higher income than the general population of the United States. However, it is important to note that the demographics and potential disparities in CI care in the United States have not been thoroughly studied and remain largely unknown. In any study, there is a risk of selection bias where those with strong opinions, positive or negative, may be those most likely to enroll in research studies. We aimed to minimize this effect by enrolling a large patient sample. In addition, we can never know if participants quickly filled out the questionnaires randomly to obtain remuneration. Time to completion data was not obtainable through REDCap. However, such individuals should have been found to misfit the IRT model during analysis and, if large in number, would have affected the reliability data. Neither was detected in the study.

Conclusion: CIQOL-35 Profile instrument and CIQOL-10 Global measure

The CIQOL-35 Profile and CIQOL-10 Global demonstrated strong construct validity, convergent validity, and test-retest reliability — highlighting the importance of using of modern PROM development guidelines. Based on the results of this study, the CIQOL

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instruments are appropriate for use in clinical and research protocols in adult CI users to provide a comprehensive outcome assessment of CI-related QOL. Moreover, the consistent low correlation of CIQOL scores with traditional speech recognition scores emphasizes the unique value of including these instruments in CI test batteries. The availability and application of these CIQOL instruments should provide a broader and more nuanced understanding of CI outcomes, and benefits of novel processing strategies, listening modalities, and new CI technology.

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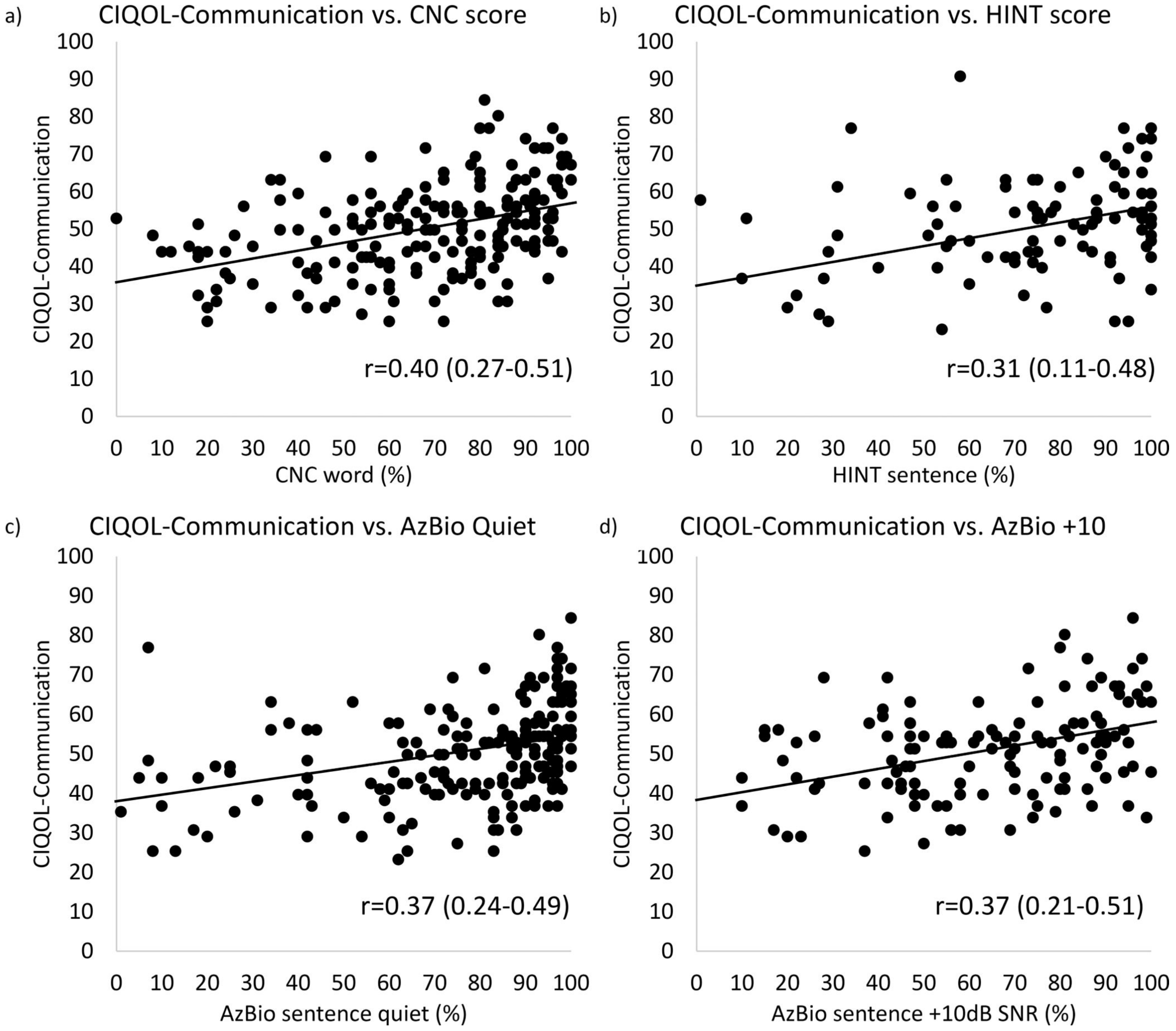

Figure 1:

Cochlear Implant Quality of Life (CIQOL)-Communication domain scores plotted against (a) Consonant-Nucleus-Consonant (CNC) word scores, (b) Hearing in Noise Test (HINT) sentence scores, (c) AzBio sentence scores in quiet, (d) AzBio sentence scores in +10 dB SNR. Correlation coefficients and 95% confidence intervals are provided. Solid line represents the line of best fit.

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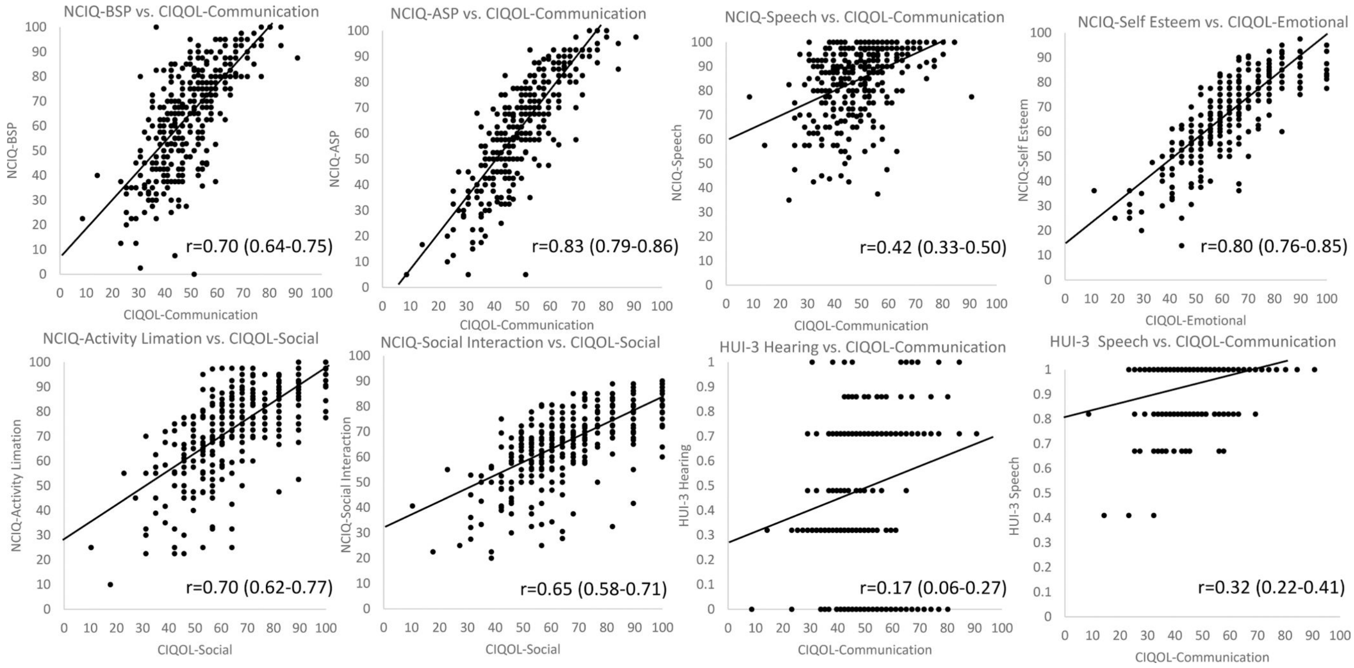

Figure 2:

Convergent validity between comparable CIQOL domains and NCIQ subdomains and HUI-3 health attributes. Correlation coefficients for each comparison are provided with 95% confidence intervals. Solid line represents the line of best fit. BSP: basic sound perception; ASP: advanced sound perception

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Table I:

Conceptually similar components (green dots) of the CIQOL-35 Profile domains, CIQOL-10 Global, and the components of the NCIQ and HUI-3.

	CIQOL						
	Communication	**Emotional**	**Entertainment**	**Environment**	**Listening Effort**	**Social**	**Global**
NCIQ							
Physical	●						
Basic sound perception	●						
Advanced sound perception	●						
Speech production	●						
Psychological		●					
Self-esteem		●					
Social						●	
Activity limitation						●	
Social interaction						●	
Total							●
HUI-3							
Speech	●						
Hearing	●						
Total							●

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Table II.

Demographics of the 334 participants.

Variable	N (%)
Sex	
Female	198 (59.3)
Male	136 (40.7)
Race	
Asian	3 (0.9)
Black	6 (1.8)
Hawaiian or Other Pacific Islander	1 (0.3)
More than one race	5 (1.5)
White	312 (93.4)
Not reported	7 (2.1)
Ethnicity	
Hispanic or Latino	11 (3.3)
Not Hispanic or Latino	300 (89.8)
Not reported	23 (6.9)
Has Children < 18 Living in Home	
Yes	47 (14.1)
No	287 (85.9)
Marital status	
Married/domestic partnership	221 (66.2)
Separated/divorced	51 (15.3)
Single, never married	46 (13.8)
Widowed	16 (4.8)
Combined household income	
$0–$20,000	14 (4.2)
$20,001–$50,000	66 (19.8)
$50,001–$80,000	79 (23.7)
$80,001–$110,000	59 (17.7)
>$110,000	86 (25.7)
Unknown/Not reported	30 (9)
Highest level of education	
High school graduate or equivalent	19 (5.7)
Some college	42 (12.6)
Trade/tech/vocational training	11 (3.3)
Associate degree	30 (9)
Bachelor’s degree	109 (32.6)
Master’s degree	82 (24.6)
Professional degree	12 (3.6)
Doctorate degree	29 (8.7)
Employment status	

Variable	N (%)
Employed, working ≥ 40 hr per week	100 (29.9)
Employed, working < 40 hr per week	51 (15.3)
Not employed, looking for work	12 (3.6)
Not employed, not lot looking for work	14 (4.2)
Retired	138 (41.3)
Disabled, not able to work	19 (5.7)
Environment where subject lives	
Rural	54 (16.2)
Suburban	194 (58.1)
Urban	86 (25.7)
Region	
Midwest East North Central	44 (13.2)
Midwest West North Central	24 (7.2)
Northeast Mid-Atlantic	34 (10.2)
Northeast New England	15 (4.5)
South Atlantic	81 (24.3)
South East South Central	11 (3.3)
South West South Central	28 (8.4)
West Mountain	33 (9.9)
West Pacific	54 (16.2)
Not Reported	9 (2.7)
Listening Modality	
Bilateral CI	158 (47.3)
CI and Hearing Aid	105 (31.4)
CI without Hearing Aid	71 (21.3)

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Table III.

Demographic and hearing characteristics of the 334 participants.

Variable	Mean ± Standard Deviation
Age, years	59.4 ± 15.6
Duration of hearing loss, years	26.0 ± 17.7
Duration of CI use, years	7.6 ± 6.9
CNC (N=210)	67.3% ± 23.3%
HINT (N=105)	75.0% ± 24.0%
AzBio quiet (N=202)	76.7% ± 25.0%
AzBio+10 dB SNR (N=141)	64.5% ± 25.1%

At least one speech recognition score was available for 72.2% (N=241) of subjects (43 participants had one score available; 65 had two scores; 96 had three scores; and 47 had all four scores). The N in parentheses for each speech recognition tests represents the number of subjects with available scores. CNC: CNC word recognition score; HINT: HINT sentence recognition score; AzBio quiet: AzBio sentence recognition score in quiet; AzBio +10 dB SNR: AzBio sentence score in +10 dB signal to noise ratio.

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Table IV:

Correlations between PROM scores and speech recognition scores.

Instrument, Domains and Subdomains	CNC (n=210)	HINT (n=105)	AzBio Quiet (n=202)	AzBio +10 dB SNR (n=141)
	r (95% CI)	r (95% CI)	r (95% CI)	r (95% CI)
CIQOL-35 Profile				
Emotional	0.15 (0.01, 0.28)	0.25 (0.05, 0.43)	0.19 (0.05, 0.32)	0.33 (0.17, 0.47)
Entertainment	0.28 (0.15, 0.40)	0.23 (0.03, 0.41)	0.32 (0.19, 0.44)	0.33 (0.17, 0.47)
Environmental	0.30 (0.17, 0.43)	0.27 (0.08, 0.45)	0.21 (0.08, 0.35)	0.27 (0.10, 0.42)
Listening effort	0.29 (0.15, 0.41)	0.24 (0.04, 0.42)	0.28 (0.14, 0.41)	0.40 (0.24, 0.53)
Social	0.14 (0.00, 0.28)	0.23 (0.03, 0.41)	0.21 (0.07, 0.34)	0.28 (0.12, 0.43)
CIQOL-10 Global	0.34 (0.21, 0.46)	0.37 (0.18, 0.53)	0.34 (0.20, 0.46)	0.42 (0.27, 0.55)
NCIQ				
Physical	0.32 (0.19, 0.44)	0.31 (0.11, 0.48)	0.35 (0.22, 0.47)	0.30 (0.13, 0.44)
BSP	0.24 (0.11, 0.37)	0.19 (−0.01, 0.38)	0.23 (0.09, 0.36)	0.21 (0.04, 0.37)
ASP	0.20 (0.06, 0.33)	0.23 (0.03, 0.41)	0.28 (0.15, 0.41)	0.15 (−0.02, 0.31)
SP	0.36 (0.23, 0.47)	0.35 (0.17, 0.52)	0.39 (0.26, 0.50)	0.36 (0.20, 0.50)
Psychological	0.20 (0.06, 0.33)	0.23 (0.03, 0.41)	0.27 (0.14, 0.40)	0.36 (0.21, 0.50)
SE	0.20 (0.06, 0.33)	0.23 (0.03, 0.41)	0.27 (0.14, 0.40)	0.36 (0.21, 0.50)
Social	0.22 (0.09, 0.35)	0.20 (0.00, 0.39)	0.23 (0.09, 0.36)	0.33 (0.17, 0.48)
AL	0.24 (0.10, 0.36)	0.20 (0.00, 0.39)	0.24 (0.10, 0.37)	0.35 (0.19, 0.49)
SI	0.18 (0.05, 0.32)	0.18 (−0.02, 0.36)	0.20 (0.06, 0.33)	0.26 (0.10, 0.42)
Total	0.30 (0.16, 0.42)	0.29 (0.09, 0.46)	0.33 (0.20, 0.45)	0.35 (0.19, 0.49)
HUI-3				
Speech	0.26 (0.13, 0.39)	0.16 (−0.04, 0.35)	0.32 (0.19, 0.44)	0.11 (−0.06, 0.28)
Hearing	0.09 (−0.06, 0.22)	0.02 (−0.18, 0.22)	0.15 (0.01, 0.29)	0.06 (−0.11, 0.23)
Total	0.13 (−0.01, 0.27)	0.04 (−0.16, 0.24)	0.21 (0.07, 0.34)	0.15 (−0.02, 0.31)

Note that speech recognition scores were not available for all subjects. CIQOL-Communication correlations with speech recognition scores are found in Figure 1. CNC: CNC word recognition score; HINT: HINT sentence recognition score; AzBIO quiet: AzBio sentence recognition score in quiet; AzBio +10 dB SNR: AzBio sentence score performed in +10 dB signal to noise ratio; BSP: basic sound perception; ASP: advanced sound perception; SP: speech production; SE: self-esteem; AL: activity limitations; SI: social interaction.

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Table V:

Confirmatory factor analysis results for the CIQOL-35 Profile, CIQOL-10 Global, and NCIQ.

Instrument	SRMR	RMSEA	CFI	TLI	% of items with standardized factor loadings ≥|0.32|
CIQOL-35 Profile					
Communication	0.04	0.06	>0.99	>0.99	100
Emotional	0.05	**0.10**	>0.99	0.99	100
Entertainment	**0.09**	**0.27**	0.99	0.99	100
Environmental	0.08	**0.20**	0.99	0.98	100
Listening effort	0.05	**0.10**	0.99	0.99	100
Social	0.05	**0.11**	>0.99	0.99	100
CIQOL-10 Global	0.04	0.06	>0.99	>0.99	100
NCIQ					
Physical	0.08	**0.11**	**0.69**	**0.67**	93
Basic sound perception	0.03	0.06	0.97	0.97	100
Advanced sound perception	0.07	**0.15**	**0.82**	**0.77**	100
Speech production	**0.09**	**0.16**	**0.74**	**0.67**	100
Psychological	0.06	**0.10**	**0.87**	**0.84**	90
Self-esteem	0.06	**0.10**	**0.87**	**0.84**	90
Social	0.05	0.08	**0.89**	**0.88**	95
Activity limitation	0.03	0.06	0.97	0.96	100
Social interaction	0.04	0.08	**0.94**	**0.99**	90
Total	0.08	0.08	**0.64**	**0.63**	92

Bolded text designates values outside of our a-priori established model fit criteria as described in the methods section. SRMR: standardized root mean square residual; RMSEA: root mean square error of approximation; CFI: comparative fit index; TLI: Tucker-Lewis index

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Table VI:

Summary of item response theory (IRT) analysis results for the CIQOL-35 Profile, CIQOL-10 Global, and NCIQ subdomains that met criteria for unidimensionality.

Instrument	Item Misfit	Person Misfit (%)	Ceiling / Floor (% of Subjects)	Person Reliability	Person Strata	Mean Person Measure (logits)	Cronbach's alpha
CIQOL-35 Profile							
Communication	**1**	7.78	0.00 / 0.00	0.91	4.56	0.22	0.92
Emotional	0	7.78	2.69 / 0.00	0.82	3.16	**1.58**	0.84
Entertainment	**1**	7.49	6.89 / 2.99	0.86	3.60	0.63	0.91
Environmental	0	6.89	3.29 / 0.30	0.84	3.36	**1.83**	0.87
Listening effort	0	5.39	0.00 / 0.60	0.83	3.32	**−1.04**	0.84
Social	**1**	7.49	8.08 / 0.00	0.83	3.28	**2.39**	0.88
CIQOL-10 Global	0	6.59	0.00 / 0.00	0.87	3.78	0.55	0.88
NCIQ							
Physical							
Basic sound perception	**1**	7.49	8.08 / 0.00	0.86	3.61	0.92	0.89
Advanced sound perception	—	—	1.19 / 0.30	—	—	—	—
Speech production	—	—	**15.27** / 0.00	—	—	—	—
Psychological	—	—	0.00 / 0.00	—	—	—	—
Self-esteem	—	—	0.00 / 0.00	—	—	—	—
Social	—	—	0.00 / 0.00	—	—	—	—
Activity limitation	0	6.59	0.00 / 0.00	0.84	3.42	**1.70**	0.90
Social interaction	—	—	0.00 / 0.00	—	—	—	—
Total	—	—	0.00 / 0.00	—	—	—	—

Bolded text designates values outside of our a-priori established criteria as described in the methods section. Dashes represent the domains and subdomains where IRT was not performed due to poor model fit.

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Table VII:

Convergent validation of CIQOL instruments with legacy measures where conceptually similar domains exist (Table I).

	CIQOL-35 Profile						CIQOL-10 Global
Instrument and domain	**Communication r (95% CI)**	**Emotional r (95% CI)**	**Entertainment r (95% CI)**	**Environmental r (95% CI)**	**Listening Effort r (95% CI)**	**Social r (95% CI)**	**r (95% CI)**
NCIQ							
Physical	**0.78 (0.74, 0.82)**	—	—	—	—	—	—
Psychological	—	**0.80 (0.76, 0.84)**	—	—	—	—	—
Social	—	—	—	—	—	**0.72 (0.66, 0.76)**	—
Total	**0.81 (0.77, 0.84)**	**0.73 (0.67, 0.77)**	0.68 (0.62, 0.74)	**0.73 (0.67, 0.77)**	**0.73 (0.68, 0.78)**	**0.77 (0.72, 0.81)**	**0.85 (0.82, 0.88)**
HUI-3 Total	0.31 (0.21, 0.41)	0.23 (0.12, 0.33)	0.27 (0.17, 0.36)	0.29 (0.19, 0.39)	0.24 (0.14, 0.34)	0.2 (0.09, 0.3)	0.29 (0.19, 0.38)

Values represent Pearson correlation coefficients with strong relationships in bold. Subdomain data are displayed in Figure 2. Dashes denote correlations not performed as the respective domains/ subdomains had no hypothesized association based on the constructs they purport to measure. NCIQ physical domain includes basic sound perception, advanced sound perception, and speech production; psychological includes self-esteem; social includes activity limitations and social interactions.

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Table VIII:

Test-retest reliability results for the CIQOL-35 Profile, CIQOL-10 Global, NCIQ, and HUI-3.

Instrument	Pearson's r (95% CI)
CIQOL-35 Profile	
Communication	**0.89 (0.86, 0.91)**
Emotional	**0.83 (0.80, 0.86)**
Entertainment	**0.90 (0.88, 0.92)**
Environmental	**0.84 (0.80, 0.87)**
Listening effort	**0.85 (0.81, 0.88)**
Social	**0.83 (0.80, 0.86)**
CIQOL-10 Global	**0.90 (0.88, 0.92)**
NCIQ	
Physical	**0.90 (0.88, 0.92)**
Basic sound perception	**0.86 (0.83, 0.88)**
Advanced sound perception	**0.83 (0.79, 0.86)**
Speech production	**0.90 (0.88, 0.92)**
Psychological	**0.83 (0.79, 0.86)**
Self-esteem	**0.83 (0.79, 0.86)**
Social	**0.86 (0.83, 0.89)**
Activity limitation	**0.83 (0.80, 0.86)**
Social interaction	**0.77 (0.73, 0.81)**
Total	**0.92 (0.90, 0.93)**
HUI-3	
Speech	0.52 (0.43, 0.59)
Hearing	0.43 (0.34, 0.51)
Total	0.60 (0.53, 0.67)

Values represent Pearson correlation coefficients with strong relationships in bold. Com: Communication; Emo: emotional; Ent: entertainment; Env: environment; LE: listening effort; Soc: social; BSP: basic sound perception; ASP: advanced sound perception; SP: speech production; SE: self-esteem; AL: activity limitations; SI: social interaction.