

# Association of Demographic and Hearing-Related Factors With Cochlear Implant–Related Quality of Life

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**IMPORTANCE** Only limited evidence is available describing the contribution of patient-related factors to quality of life in adults with cochlear implants.

**OBJECTIVE** Assess the association between demographic, hearing-related, and cochlear implant–related factors and quality of life by using a new Cochlear Implant Quality of Life (CIQOL) item bank, which was developed to meet rigorous psychometric standards.

**DESIGN, SETTING, AND PARTICIPANTS** Multicenter cross-sectional study of adults 18 to 89 years of age who had at least 1 year of cochlear implant use and who were recruited through a consortium of 20 cochlear implant centers in the United States. Using an online format, questionnaires were sent to the first 500 participants who contacted the research team. Of these participants, 371 (74.2%) completed the questionnaire. Demographic, hearing-related, and cochlear implant–related data were obtained along with responses to each of the 81 items in the CIQOL item bank. Multivariable linear regression was used to examine demographic, hearing-related, and cochlear implant–related factors associated with scores in each of the 6 CIQOL domains (communication, emotional, entertainment, environment, listening effort, and social).

**MAIN OUTCOMES AND MEASURES** Association among demographic, hearing-related, and cochlear implant–related factors and CIQOL scores for each of 6 domains.

**RESULTS** Of the 371 participants who completed the questionnaire, 222 (59.8%) were women, and the mean (SD) age was 59.5 (14.9) years. The CIQOL scores were normally distributed across the 6 domains. Being employed, having higher household income, longer duration of hearing loss prior to cochlear implantation, and having bilateral rather than unilateral cochlear implantation were associated with higher CIQOL scores in 1 or more domains, but the effect size varied widely ( $\beta$ , 0.1-6.9). Better sentence recognition ability (using AzBio to measure speech recognition) was associated with only a small positive effect size for the communication ( $\beta$ , 0.0 [95% CI, 0.0-0.1]), entertainment ( $\beta$ , 0.0 [95% CI, 0.0-0.1]), and environmental ( $\beta$ , 0.0 [95% CI, 0.0-0.0]) domains. Increased age was associated with lower CIQOL in the entertainment domain ( $\beta$ , -0.3 [95% CI, -1.5 to -0.4]). The demographic, hearing-related, and cochlear implant–related factors included in the multivariable regression models accounted for only a small percentage of the variance in CIQOL domain scores ( $R^2$ , 0.08-0.17).

**CONCLUSIONS AND RELEVANCE** Several factors were found to predict higher or lower CIQOL scores in specific domains, with speech-recognition ability having only a minimal association. Despite evaluating a large number of demographic, hearing-related, and cochlear implant–related factors, the multivariable models accounted for only a small amount of CIQOL variance. This suggests that patient or other characteristics that contribute to cochlear implant–related quality of life remain largely unknown.

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Despite advances in technology and performance, the manner in which cochlear implantation outcomes are measured has remained essentially unchanged. Speech recognition ability measured by individual words or sentences in quiet and in noise is the primary, and most often sole, metric used to assess cochlear implantation outcomes.<sup>1,2</sup> This focus on measuring speech recognition ability is consistent with improved detection and speech recognition serving as the main treatment targets of cochlear implantation. However, speech recognition ability, as currently measured, is poorly correlated with patients' self-report of their communication abilities.<sup>3-5</sup> Moreover, the improved communication provided by cochlear implantation results in indirect improvements in other aspects of an individual's life, including social and emotional benefits,<sup>6-9</sup> which are largely disregarded by focusing only on speech recognition abilities.

Patient-reported outcome measures (PROMs) are instruments devised to capture a patient's perspective about their overall health or treatment. For interventions in which survival is not the primary outcome, such as cochlear implantation, PROMs that assess quality of life (QOL) have become increasingly important and an accepted means to understand the full influence of a procedure on a patient's life. Assessing QOL allows direct input from patients about how disease processes and interventions affect their lives.

Adding to the importance of assessing QOL in cochlear implantation, negligible to low positive associations have been reported between speech recognition scores in quiet and in noise and QOL.<sup>3-5</sup> This suggests that how well people communicate with others and are affected by sounds in their environment is far more complex than revealed by commonly used speech recognition tasks. In contrast to speech recognition outcomes, assessing QOL allows patients with cochlear implants to report not only how well they communicate, but also how they function in real-world environments.

The National Institutes of Health established the Patient-Reported Outcomes Measurement Information System in 2004 to develop an extensive set of PROMs to evaluate and monitor physical, mental, and social health in adults. The organization has set forth rigorous guidelines for PROM development and validation, which has become widely adopted.<sup>10</sup> However, these rigorous methods have only rarely been applied in the hearing sciences or to assess patients with cochlear implants. Following the Patient-Reported Outcomes Measurement Information System guidelines, we completed a systematic literature search, as well as patient focus groups and cognitive interviews, to create an item pool, which included 101 items.<sup>3,4,11</sup> Using confirmatory factor analysis and item response theory, we psychometrically analyzed the item pool to create the 81-item Cochlear Implant Quality of Life (CIQOL) item bank.<sup>12</sup> The final item bank serves as the source for items that will be used to create a suite of new CIQOL instruments, including short-form, long-form (often referred to as profile), and computerized adaptive testing instruments.

Although substantial evidence is available concerning the relationship between patient-related and cochlear implant-related factors and cochlear implantation postoperative speech recognition abilities, far less attention has been directed to-

## Key Points

**Question** What is the association between demographic, hearing-related, and cochlear implant-related factors and cochlear implant-related quality of life?

**Findings** In this multicenter cross-sectional study using the 81-item Cochlear Implant Quality of Life (CIQOL) item bank, bilateral vs unilateral cochlear implantation, higher household income, being employed, and longer duration of hearing loss prior to implantation were associated with better CIQOL scores in 1 or more domains. However, traditional factors included in the multivariable linear regression models accounted for only a small percentage of the variance in CIQOL domain scores.

**Meaning** Factors accounting for much of the variance within the 6 domains of the CIQOL item bank remain largely unknown.

ward the association of these factors with QOL outcomes. The aim of this study is to assess the independent relationship of key patient-related and cochlear implant-related variables with QOL outcomes, as measured by the full CIQOL item bank.

## Methods

### Participants

This study is a secondary analysis of data collected for the purposes of item bank development and was approved by the institutional review board at the Medical University of South Carolina. Thus, sample size for the study was based on the psychometric analysis of the item pool to create the item bank.<sup>12</sup> Individuals included were cochlear implant recipients 18 to 89 years of age who had at least 1 year of cochlear implant use. Individuals who received cochlear implants for single-sided deafness were excluded. All included participants provided written informed consent.

To enroll a large and diverse sample of adults with cochlear implants with respect to age, sex, cochlear implant listening modalities, and communication abilities, the Cochlear Implant Quality of Life Development Consortium was established and consists of 20 cochlear implant centers that represent all regions of the United States. Centers distributed recruitment flyers electronically and by hard copy to adults with cochlear implants who met inclusion/exclusion criteria. Questionnaires were sent via REDCap (Research Electronic Data Capture), a secure web-based application designed to support data capture for research studies, to the first 500 participants who contacted our research team. In total, 371 (74.2%) participants completed the questionnaire.

### Data Collection

Details regarding data collection and development of the CIQOL item bank are available in eMethods of the [Supplement](#). The final CIQOL item bank consists of 81 items in 6 psychometrically sound domains (communication, emotional, entertainment, environment, listening effort, and social). Participants provided a response to each item using a 5-point Likert scale. Item-level responses were used in an item response

theory analysis to generate domain-level, interval-scale scores ranging from 0 to 100, in which higher scores indicated better cochlear implant-related QOL. Item response theory analysis evaluates the relationship between an individual's ability and item difficulty with regard to the latent trait being measured.

### Data Analyses

Full description of statistical methods is available in eMethods of the Supplement. Multivariable linear regression was used to examine demographic characteristics associated with scores in each domain. Demographic characteristics were considered for inclusion in the multivariable linear regression models on the basis of bivariate analyses that assessed associations with each of the 6 CIQOL domains; the association between categorical variables and CIQOL domain scores were analyzed with one-way analysis of variance, whereas continuous variables were examined with correlation coefficients. The final multivariable models were identified using backward stepwise regression.

## Results

### Participant Demographics

The study sample's demographics are detailed in **Table 1**. Individuals from a home institution represented 2.9% (n = 11) of those who completed the questionnaire. Participants' hearing-related and cochlear implant-related characteristics are summarized in **Table 2**. As expected, owing to the requirement that participants obtain and enter the data themselves, some speech recognition scores were missing. At least 1 of these scores was available for 236 of 371 participants (63.6%). Scores provided by participants for word and sentence recognition in quiet and in noise were similar to published values for adults with cochlear implants.<sup>13</sup>

### Overall Domain Scores

The **Figure** shows the distribution of scores for each of the 6 CIQOL domains. All domains were scored on a 0- to 100-point scale, with 0 indicating low CIQOL score and 100 indicating high CIQOL score. Shapiro-Wilk tests confirmed that the scores for each domain were normally distributed with means ranging from 46.3 (listening effort) to 62.0 (social).

### Development of the Regression Model Analyses

Because we established the unidimensionality of the instrument's 6 domain constructs,<sup>12</sup> independent regression models were built for each domain. To accomplish this, bivariate analyses were first performed between participant variables (listed in Tables 1 and 2) and CIQOL domain scores. The following variables were not significantly associated with any CIQOL domains in bivariate analyses and/or multivariable models and, as such, were not included in any of the final multivariable models: sex, marital status, children younger than 18 years in the home, education level, residential setting, duration of cochlear implant use, and hybrid/electro-acoustic stimulation use. All other variables met criteria for inclusion in at

**Table 1. Demographic Characteristics of the Study Sample**

Characteristic	No. (%)
Sex	
Male	149 (40.2)
Female	222 (59.8)
Marital status	
Married/domestic partnership	251 (67.7)
Not married/no domestic partnership	120 (32.3)
Children <18 y in the home	
Yes	56 (15.1)
No	315 (84.9)
Combined household income, \$	
0-20 000	26 (7.0)
20 001-50 000	63 (16.9)
50 001-80 000	87 (23.4)
80 001-110 000	66 (17.7)
>110 000	93 (25.0)
Unknown/not reported	36 (9.7)
Highest level of education	
Did not complete high school	3 (0.8)
High school graduate or equivalent	27 (7.3)
Some college/trade, technical, or vocational training	109 (29.4)
Bachelor's degree	112 (30.2)
Master's degree or higher	120 (32.3)
Employment status	
Employed	160 (43.1)
Not employed	45 (12.1)
Retired	166 (44.7)
Residential setting	
Urban	81 (21.8)
Suburban	214 (57.7)
Rural	76 (20.5)
Region of United States	
Midwest	
East North Central	57 (15.5)
West North Central	33 (8.9)
Northeast	
Mid-Atlantic	30 (8.2)
New England	17 (4.6)
South	
South Atlantic	94 (25.5)
East South Central	18 (4.9)
West South Central	30 (8.2)
West	
Mountain	37 (10.1)
Pacific	52 (14.1)

least 1 of the CIQOL domain multivariable models. **Table 3** summarizes the results of the best-fitting multivariable regression models.

### Associations of Participant Demographics With CIQOL

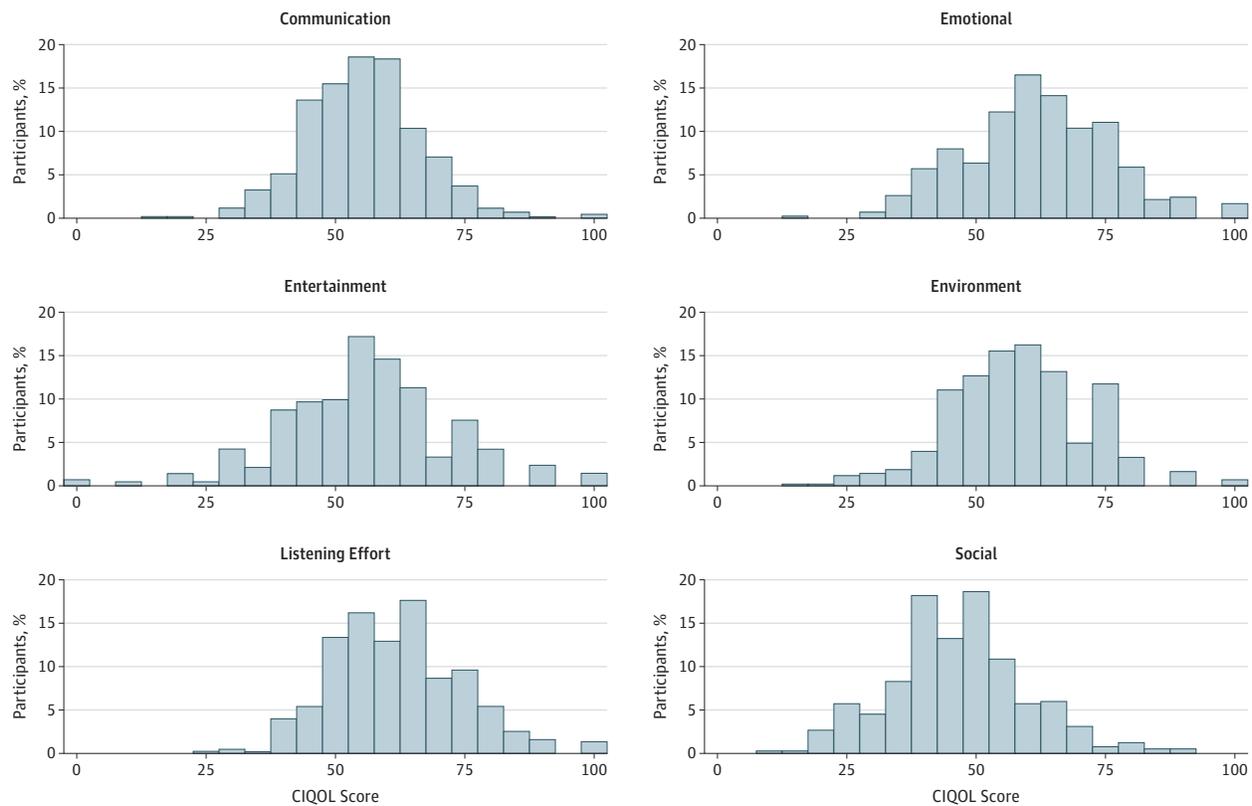
Some demographic factors were associated with CIQOL score when controlling for all other variables (**Table 3**). Age was associated with a small, negative outcome on entertainment CIQOL scores ( $\beta$ , -0.3; 95% CI, -1.5 to 0.4), meaning that for

**Table 2. Age, Hearing, and Cochlear Implant Characteristics of the Study Sample**

Characteristic	Mean (SD)	Range	No. (%)
Age, y	59.5 (14.9)	19-88	371 (100)
Duration of hearing loss prior to cochlear implantation, y	27.1 (18.4)	0-80	371 (100)
Duration of cochlear implant use, y	7.6 (6.5)	1-33	371 (100)
Listening modality			
Unilateral cochlear implant with no contralateral hearing aid	NA	NA	87 (23.4)
Bilateral cochlear implant	NA	NA	96 (25.8)
Unilateral cochlear implant with contralateral hearing aid	NA	NA	188 (50.6)
Hybrid/electro-acoustic stimulation			
Yes	NA	NA	12 (3.2)
No	NA	NA	358 (96.4)
AzBio quiet score, %	81.2 (23.0)	0-100	185 (49.9)
AzBio +10 dB SNR score, %	64.3 (27.5)	0-100	121 (32.6)
CNC Word score, %	69.6 (24.4)	0-100	173 (46.6)
HINT score, %	76.1 (30.2)	0-100	78 (21.0)

Abbreviations: CNC, consonant-nucleus-consonant; HINT, Hearing in Noise Test; SNR, signal-to-noise ratio.

**Figure. Frequency Distribution of Participant Scores for Each of the Cochlear Implant Quality of Life (CIQOL) Domains**



All domains were scored on a 0- to 100-point scale, with 0 indicating low CIQOL score and 100 indicating high CIQOL score.

each 10-year increase in age, CIQOL score in the entertainment domain decreased by 1 unit while controlling for all other variables. This association was not significant in other CIQOL domains. The association between US Census Bureau region and CIQOL scores varied substantially by domain. Perhaps most notably, individuals residing in the Northeast Mid-Atlantic region had significantly higher CIQOL scores than those residing in the West Pacific region in all CIQOL domains except com-

munication and listening effort (emotional  $\beta$ , 6.3; 95% CI, 0.2-12.5; entertainment  $\beta$ , 10.0; 95% CI, 3.2-16.9; environment  $\beta$ , 6.1; 95% CI, 0.6-11.6; and social  $\beta$ , 5.4; 95% CI, 0.0-10.7).

Being employed had a significant positive association with the communication, listening effort, and social CIQOL domains compared with not being employed or being retired. Household income was associated with several CIQOL

**Table 3. Association of Demographic, Hearing-Related, and Cochlear Implant-Specific Factors With the 6 Cochlear Implant Quality of Life Domains**

Measurement	$\beta^a$ (95% CI)					
	Communication	Emotional	Entertainment	Environment	Listening Effort	Social
$R^2$	0.17	0.12	0.19	0.17	0.14	0.19
Variable						
Intercept	49.9 (45.1 to 54.8)	54.8 (49.7 to 59.8)	55.7 (45.7 to 65.7)	46.3 (40.0 to 52.6)	41.9 (37.0 to 46.8)	54.0 (47.3 to 60.6)
Age	NA <sup>b</sup>	NA <sup>b</sup>	-0.3 (-1.5 to -0.4)	NA <sup>b</sup>	NA <sup>b</sup>	NA <sup>b</sup>
Duration of hearing loss	NA <sup>b</sup>	0.1 (0.0 to 0.19)		0.1 (0.0 to 0.2)	0.1 (0.0 to 0.1)	0.1 (0.0 to 0.2)
Household income, \$						
0-20,000	1 [Reference]	NA <sup>b</sup>	1 [Reference]	1 [Reference]	NA <sup>b</sup>	1 [Reference]
20 001-50 000	0.28 (-4.6 to 5.2)	NA <sup>b</sup>	-0.1 (-7.8 to 6.2)	-1.1 (-6.7 to 4.6)	NA <sup>b</sup>	-0.6 (-6.2 to 5.0)
50 001-80 000	3.5 (-1.2 to 8.3)	NA <sup>b</sup>	4.6 (-2.1 to 11.3)	3.6 (-1.8 to 9.0)	NA <sup>b</sup>	3.3 (-2.1 to 8.7)
80 001-110 000	2.7 (-2.1 to 7.6)	NA <sup>b</sup>	2.0 (-5.0 to 9.1)	2.9 (-2.8 to 8.6)	NA <sup>b</sup>	3.2 (-2.4 to 8.8)
>110 000	5.9 (1.2 to 10.5)	NA <sup>b</sup>	6.5 (-0.2 to 13.2)	6.0 (0.6 to 11.4)	NA <sup>b</sup>	5.8 (0.5 to 11.1)
Unknown	4.7 (-0.7 to 10.1)	NA <sup>b</sup>	6.2 (-1.6 to 14.0)	3.9 (-2.4 to 10.2)	NA <sup>b</sup>	3.8 (-2.3 to 10.0)
Employment status						
Employed	1 [Reference]	NA <sup>b</sup>	NA <sup>b</sup>	NA <sup>b</sup>	1 [Reference]	1 [Reference]
Not employed	-4.2 (-7.7 to -0.6)	NA <sup>b</sup>	NA <sup>b</sup>	NA <sup>b</sup>	-3.9 (-8.1 to 0.4)	-4.5 (-8.6 to -0.3)
Retired	-2.0 (-4.4 to 0.3)	NA <sup>b</sup>	NA <sup>b</sup>	NA <sup>b</sup>	-3.3 (-6.1 to -0.5)	-3.1 (-5.8 to -0.4)
US Census Bureau region						
West						
Pacific	NA <sup>b</sup>	1 [Reference]				
Mountain	NA <sup>b</sup>	1.0 (-4.8 to 6.7)	3.3 (-3.1 to 9.9)	2.7 (-3.3 to 7.2)	-0.5 (-5.7 to 4.7)	1.6 (-3.5 to 6.7)
Midwest						
East North Central	NA <sup>b</sup>	2.7 (-2.4 to 7.8)	5.8 (0.0 to 11.5)	5.1 (0.5 to 9.8)	3.6 (-1.1 to 8.3)	3.5 (-1.0 to 8.0)
West North Central	NA <sup>b</sup>	7.4 (1.4 to 13.4)	9.8 (3.1 to 16.6)	2.6 (-2.9 to 8.0)	7.4 (2.0 to 12.9)	8.2 (3.0 to 13.5)
Northeast						
Mid-Atlantic	NA <sup>b</sup>	6.3 (0.2 to 12.5)	10.0 (3.2 to 16.9)	6.1 (0.6 to 11.6)	4.0 (-1.6 to 9.6)	5.4 (0.0 to 10.7)
New England	NA <sup>b</sup>	1.3 (-6.2 to 8.8)	5.2 (-3.3 to 13.6)	3.2 (-3.6 to 10.0)	1.1 (-5.8 to 7.9)	1.0 (-5.6 to 7.7)
South						
South Atlantic	NA <sup>b</sup>	1.7 (-2.9 to 6.3)	3.6 (-1.6 to 8.8)	2.7 (-1.5 to 6.9)	2.7 (-1.5 to 6.9)	2.2 (-1.9 to 6.2)
East South Central	NA <sup>b</sup>	-6.1 (-13.4 to 1.2)	-5.5 (-13.8 to 2.8)	-1.9 (-8.6 to 4.8)	-4.8 (-11.5 to 1.9)	-5.9 (-12.4 to 0.6)
West South Central	NA <sup>b</sup>	6.9 (0.7 to 13.1)	7.1 (0.1 to 14.1)	5.1 (-0.6 to 10.7)	3.5 (-2.2 to 9.1)	6.1 (0.7 to 11.6)
Listening modality						
Unilateral cochlear implant without contralateral hearing aid	1 [Reference]					
Unilateral cochlear implant with contralateral hearing aid	-1.6 (-4.8 to 1.5)	-2.5 (-6.5 to 1.5)	-1.4 (-6.0 to 3.2)	-1.9 (-5.6 to 1.8)	-2.3 (-6.0 to 1.4)	-2.4 (-6.0 to 1.1)
Bilateral cochlear implant	5.7 (3.0 to 8.4)	4.8 (1.2 to 8.3)	3.3 (-0.7 to 7.4)	6.5 (3.3 to 9.8)	5.1 (1.9 to 8.4)	4.5 (1.4 to 7.6)
AzBio quiet score	0.0 (0.0 to 0.1)	NA <sup>b</sup>	0.0 (0.0 to 0.1)	0.0 (0.0 to 0.0)	NA <sup>b</sup>	NA <sup>b</sup>

<sup>a</sup> The degree of change in Cochlear Implant Quality of Life score for each 1-unit change in the predictor variable.

<sup>b</sup> The variable is not applicable (NA) because it was not included in the final regression model.

domains, whereby participants whose annual household income was greater than \$110 000 had significantly higher communication ( $\beta$ , 5.9; 95% CI, 1.2-10.5), environment ( $\beta$ , 6.0; 95% CI, 0.6-11.4), and social ( $\beta$ , 5.8; 95% CI, 0.5-11.1) CIQOL scores compared with participants whose annual household income was less than \$20 001. No other associations related to household income were found.

### Hearing and Cochlear Implant History and CIQOL

For hearing-related and cochlear implant-specific factors, only duration of hearing loss and listening modality were associated

with CIQOL scores while controlling for all other variables. For example, longer duration of hearing loss prior to cochlear implantation had a very small positive association with CIQOL scores in all domains except communication and entertainment (emotional  $\beta$ , 0.1; 95% CI, 0.04-0.19; environment  $\beta$ , 0.1; 95% CI, 0.0-0.2; listening effort  $\beta$ , 0.1; 95% CI, 0.0-0.1; social  $\beta$ , 0.1; 95% CI, 0.0-0.2). Bilateral cochlear implant use was associated with higher CIQOL domain scores in communication ( $\beta$ , 5.7; 95% CI, 3.0-8.4), emotional ( $\beta$ , 4.8; 95% CI, 1.2-8.3), environment ( $\beta$ , 6.5; 95% CI, 3.3-9.8), listening effort ( $\beta$ , 5.1; 95% CI, 1.9-8.4), and social ( $\beta$ , 4.5; 95% CI, 1.4-7.6).

Scores for AzBio, a measure of speech recognition, in quiet were selected for inclusion in the multivariable model, which was determined as follows. Because participants were recruited from multiple sites, not all participants had AzBio scores using the same set of speech recognition measures, and not all participants were successful in obtaining scores from their audiologists. For these reasons, scores for all 4 tests listed in Table 2 were available for only 43 of 371 participants (11.6%). Thus, inclusion of all tests in the multivariable model would have substantially reduced the sample size and power. Moreover, because scores are known to be highly intercorrelated (eg,  $r = 0.75$  for AzBio in quiet score/consonant-nucleus-consonant word score in the current study), use of multiple speech scores is not appropriate in a regression model. Thus, because the highest number of participants provided AzBio in quiet scores ( $n = 185$  [49.9%]), these scores were used in the regression models. Bivariate associations (Pearson correlations), which do not account for interactions with other variables, demonstrated very weak positive correlations between AzBio in quiet scores and the 6 CIQOL domain scores ( $r = 0.14$ - $0.22$ ). In the multivariable regression models, higher AzBio in quiet scores were associated with very small improvements in communication, entertainment, and environment CIQOL scores while controlling for all other variables. No associations were found between AzBio in quiet scores and emotional, listening effort, and social CIQOL scores.

### Coefficients of Determination

Despite including a large number of demographic, hearing-related, and cochlear implant-related variables in our analysis, the coefficients of multiple determination ( $R^2$ ) for the multivariable regressions were relatively low for each domain (Table 3). Overall, the proportion of variance in CIQOL scores predicted by the independent variables ranged from 12% (emotional domain) to 19% (entertainment and social domains). This suggests that a large portion of the variance in CIQOL scores is unaccounted for by factors assumed to predict cochlear implantation outcomes.

## Discussion

As the collection of QOL data reported through PROMs becomes increasingly common and important, a better understanding of the factors that influence this outcome is needed to meet the goal of improving patient care. To our knowledge, this study is the first to apply multivariable regression analyses to assess how demographic, hearing-related, and cochlear implant-related factors are independently associated with cochlear implant-related QOL. The approach taken in the interpretation of the results was to evaluate modifiable and nonmodifiable factors associated with increased or decreased cochlear implant-related QOL. For example, the region of the United States where a patient lives, and their household income and employment status, were associated with increased CIQOL scores, but these factors are beyond the control of the cochlear implant audiologist or surgeon. In contrast, one of the strongest and most consistent variables asso-

ciated with increased CIQOL scores across the domains was the use of bilateral vs unilateral cochlear implants. This modifiable factor was associated with increased communication, emotional, environmental, listening effort, and social CIQOL scores when controlling for all other variables.

### Socioeconomic Status

Two variables that are traditionally used as proxies for socioeconomic status—household income and employment status—were each independently associated with higher CIQOL scores across several domains. Being employed (with any salary) contributed to improved cochlear implant-related QOL, with an added benefit of higher combined household income. These associations were independent of level of education—the third component of socioeconomic status—which was found to not be associated with cochlear implant-related QOL.

The influence of socioeconomic status has been thoroughly investigated in the pediatric population who use cochlear implants but only rarely investigated in adults.<sup>14</sup> Although causation cannot be determined through a cross-sectional study, these results may have potentially important public policy implications if they are replicated in future prospective studies.

### Bilateral Cochlear Implants

Increased QOL from a second cochlear implant has been previously reported in the literature,<sup>5,15,16</sup> but the effect of the second cochlear implant has varied greatly depending on the PROM used to measure QOL.<sup>17</sup> The present study, with its large sample size and ability to control for other participant variables, further supports and extends the results that suggest a significant positive association between a second cochlear implant and QOL.

Results of previous studies provide some suggestions that might explain why bilateral cochlear implantation may be associated with higher QOL as compared with unilateral implantation. The use of binaural hearing, even with cochlear implants, allows listeners to take advantage of binaural squelch<sup>18,19</sup> and summation,<sup>20</sup> and help eliminate the head shadow effect.<sup>21,22</sup> These real-world advantages of bilateral hearing may contribute to improved communication abilities for users of bilateral cochlear implants, which may in turn have resulted in higher CIQOL scores in the communication domain for users of bilateral cochlear implants in the present study.

In addition to the communication domain, as compared with users of unilateral cochlear implants, users of bilateral cochlear implants also had significantly higher QOL in the emotional, environmental, listening effort, and social domains. The association between these CIQOL domains and bilateral cochlear implantation has not been widely studied and may represent an important, but hidden, benefit of a second cochlear implant.<sup>23</sup> The environment domain contains items related to spatial hearing, and the significantly higher environmental CIQOL scores for users of bilateral cochlear implants may represent the benefit of sound localization.<sup>24</sup> Similarly, listening effort CIQOL scores may have been higher for those with bilateral cochlear implants owing to the contribution of binau-

ral squelch and spatial release from masking from bilateral cochlear implant use.<sup>18,19,25,26</sup> The results of the present study provide preliminary evidence that the modifiable factor of bilateral implantation is associated with significantly higher CIQOL for communication, emotional, environment, listening effort, and social domains as compared with unilateral implantation. Further research is needed to test specific hypotheses that further explain the benefits of a second cochlear implant to these aspects of cochlear implant-related QOL.

### Duration of Hearing Loss

The small, positive association between duration of hearing loss prior to cochlear implantation (a modifiable factor) and improved CIQOL score in the emotional, entertainment, environment, listening effort, and social domains was unexpected and contradicts the established view of factors that influence post-cochlear implantation outcomes (typically limited to speech recognition abilities).<sup>27-31</sup> The results of this study suggest that patients with longer duration of hearing loss without cochlear implantation (or well-fit hearing aids) achieved slightly more QOL benefit after implantation than patients with shorter durations, perhaps owing to a larger implication of re-entering the hearing world after a long period of time. These results showing small increases in CIQOL scores in 5 domains (all but communication) with longer duration of hearing loss provide additional evidence that support including outcomes beyond speech recognition ability because they provide a more comprehensive understanding of the effects of cochlear implantation.

Unfortunately, currently available data (and cross-sectional designs) cannot fully explain this result. Hearing histories and serial audiograms from the onset of hearing loss to cochlear implantation were not available for the participants who provided responses to the questionnaire, and therefore, the specific nature of their communication and other difficulties that may have influenced QOL over the long term remain unknown. An additional consideration is the strength of the association in addition to its statistical significance. For example, a longer duration of hearing loss was associated with higher environmental CIQOL score. However, for each 1-year increase in duration of hearing loss, QOL increased by only 0.1 units. In contrast, the bilateral cochlear implantation, relative to a unilateral cochlear implantation without a contralateral hearing aid, increased environmental QOL by 6.5 units. Thus, the duration of hearing loss would have to differ by 65 years between individuals to be equivalent to the results of bilateral cochlear implantation ( $\beta$ , 6.5). Therefore, although a statistically significant association was observed between duration of hearing loss and CIQOL score, the magnitude of the association was quite small. Nevertheless, this result has been reported in the hearing loss population<sup>32</sup> and is an area that needs further research.

### Speech Recognition Ability

In the present study, a very small positive association was found between sentence recognition ability (as assessed by AzBio scores in quiet) and communication, entertainment, and environment CIQOL scores, suggesting that participants with

higher sentence recognition scores reported very small increases in QOL in these 3 CIQOL domains. These results are consistent with the well-known weak correlations between QOL and word and sentence recognition in quiet and in noise.<sup>3-5,8</sup> In this study, despite using the most rigorous PROM development standards, the lack of agreement between traditional measures of speech recognition and participant self-report of QOL persists—even for the communication domain ( $\beta$ , 0.03). These results provide additional evidence that the current battery of speech recognition measures do not adequately assess the broad range of experiences of users of cochlear implants, which further supports the direct assessment of QOL using instruments specifically developed and validated for patients with cochlear implants.

Additional support for the use of CIQOL instruments is found by examining the coefficient of determination for each domain's multivariable regression model. Despite including many of the traditional patient-related and hearing-related or cochlear implant-related factors, the variables included in the regression models account for relatively low percentages of the variance in QOL ( $R^2$ , 12%-19%). These results suggest that a large portion of a patient's CIQOL score within 6 domains is accounted for by variables other than those reported to contribute to cochlear implantation outcomes and remain largely unknown. These data further show the need to explore non-traditional variables, including cochlear implantation outcome expectations, cognitive function, and psychosocial characteristics, among others, which may contribute to cochlear implant-related QOL outcomes. Identification of factors that contribute significantly to cochlear implant-related QOL will help direct development of interventions that can improve cochlear implantation outcomes and patient care.

### Study Strengths

The present study reports the first outcomes using the new CIQOL item bank, which was developed in accordance with rigorous Patient-Reported Outcomes Measurement Information System standards and includes normative data and multivariable analyses on adult cochlear implant-related QOL from a large multicenter cross-sectional study. The study's large sample size also provides a unique opportunity to perform robust statistical analyses to determine patient demographic, hearing-related, and cochlear implant-related factors that are associated with the 6 CIQOL domains. Previous studies with smaller sample sizes that examined these relationships with univariate techniques have reported mixed results.<sup>5,8,33</sup> The benefits of multivariable analyses is that they can account for associations and interactions among the predictor variables and, thus, can make inferences about associations between demographic, hearing-related, and cochlear implant-related factors and QOL while controlling for all other variables.

### Limitations

The principal limitations of this study are related to its online format. First, participants were assumed to have provided accurate data, although responses may have been susceptible to recall bias or response bias. Second, although the survey was designed to be simple, the sample was limited to those who

had the technological capabilities to complete it online. A paper version of the questionnaire was available, but it was never requested. In addition, the study sample likely included patients who were motivated to participate in cochlear implant research. Through the online nature of the study and the establishment of the Cochlear Implant Quality of Life Development Consortium, we made every attempt to recruit a sample that was demographically representative of the adult US population who uses cochlear implants. Nevertheless, the online format may have made the study less representative of the community who uses cochlear implants as a whole. Finally, speech recognition scores were not available for all participants. In addition, owing to the multicenter nature of the study, the listening conditions and speech recognition task(s) likely varied across sites. However, with the known weak correlation between QOL and speech recognition ability,<sup>3-5,34</sup> enrolling a large sample representative of the adult US population who uses cochlear implants was given higher priority than obtaining speech recognition scores for all participants.

Despite these limitations, results of this study provide valuable information about the unique and shared information conveyed by patient-related, hearing-related, and cochlear implant-related factors, as well as self-reported QOL. The next steps of this research will be to continue the development of the CIQOL into 3 instruments including: (1) profile measure, (2) global measure, and (3) computerized adaptive testing. The

development of these 3 instruments will provide a complete CIQOL PROM suite for use in patients with cochlear implants in clinical settings and in research studies that include participants with cochlear implants.

## Conclusions

Increased CIQOL scores in 1 or more domains were associated with several factors, including bilateral rather than unilateral cochlear implantation, higher household income, being employed, and longer duration of hearing loss prior to implantation. Higher sentence recognition scores in quiet were associated with only very small increases in CIQOL score in certain domains. These results provide additional evidence of the unique contribution of QOL to cochlear implantation outcomes, as an entity distinct from speech-recognition abilities. However, the traditional patient-related, hearing-related, and cochlear implant-related factors included in the current study's multivariable regression models accounted for only a small percentage of the variance in CIQOL scores, which suggests that variables contributing to CIQOL scores within 6 domains remain largely unknown. Future prospective studies with a longitudinal design will assess these and other factors to determine the predictive accuracy of factors identified in this study.

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**Acquisition, analysis, or interpretation of data:** All authors.

**Drafting of the manuscript:** McRackan, Hand.  
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