Insurance Payer Status Predicts Postoperative Speech Outcomes in Adult Cochlear Implant Recipients

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Abstract

Background Cochlear implant qualifying criteria for adult patients with public insurance policies are stricter than the labeled manufacturer criteria. It remains unclear whether insurance payer status affects expedient access to implants for adult patients who could derive benefit from the devices.

Purpose This study examined whether insurance payer status affected access to cochlear implant services and longitudinal speech-perception outcomes in adult cochlear implant recipients.

Research Design Retrospective cross-sectional study.

Study Sample Sixty-eight data points were queried from the Health Insurance Portability and Accountability Act–Secure, Encrypted, Research Management and Evaluation Solution database which consists of 12,388 de-identified data points from adult and pediatric cochlear implant recipients.

Data Analysis Linear mixed-effects models were used to determine whether insurance payer status affected expedient access to cochlear implants and whether payer status predicted longitudinal postoperative speech-perception scores in quiet and noise.

Results Results from linear mixed-effects regression models indicated that insurance payer status was a significant predictor of behavioral speech-perception scores in quiet and in background noise, with patients with public insurance experiencing poorer outcomes. In addition, extended wait time to receive a cochlear implant was predicted to significantly decrease speech-perception outcomes for patients with public insurance.

Conclusion This study documented patients covered by public health insurance wait longer to receive cochlear implants and experience poorer postoperative speech-perception outcomes. These results have important clinical implications regarding the cochlear implant candidacy criteria and intervention protocols.

Keywords
► cochlear implants
► speech perception

A cochlear implant (CI) is a neural prosthetic that bypasses a malfunctioning cochlea and electrically stimulates the auditory nerve, providing access to sound for listeners who do not

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benefit from acoustic amplification. The CI is considered the most successful neural prosthetic available, with many implanted adults obtaining open-set word recognition in quiet.[1] Despite the proven safety and efficacy of the devices, best estimates suggest only 1 to 8% of persons who meet qualifying CI criteria and could benefit from the devices get implanted.[2–5] Increasing access to CIs for qualifying adult patients is imperative because untreated hearing loss is associated with significant health problems, such as social isolation, cognitive decline, limited participation, and generally decreased quality of life, resulting in long-term increased health-related costs.[6] Because the health benefits of CIs far outweigh the expensive treatment costs, both commercial and public insurance policies typically cover the costs associated with implantation.[7] Labeled CI adult candidacy criteria differ based on insurance payer status, though, which could potentially affect expedient access to and outcomes with the devices.

Adult Implant Candidacy and Insurance Payer Status

To qualify for a traditional CI, adults covered by Centers for Medicare and Medicaid Services (CMS) must score 40% or less on an open-set sentence test in the best-aided condition and have bilateral moderate-to-profound sensorineural hearing loss (SNHL).[8] Medicaid coverage for adult implants varies by state, and in some cases, the devices are not covered. Conversely, private insurance companies typically adhere to the labeled Food and Drug Administration (FDA) qualifying criteria for the specific manufacturers. Qualifying criteria for current Cochlear Americas devices include a moderate-to-profound low frequency SNHL, profound SNHL in the mid to high frequencies, and speech-perception scores up to 60% in the best-aided condition.[9] For current MED-EL devices, labeled criteria indicate a bilateral severe-to-profound SNHL and 40% or poorer on a speech recognition test in the best-aided condition.[10,11] Labeled criteria for Advanced Bionics devices indicate a bilateral severe-to-profound SNHL and 50% or poorer on a speech recognition test.[10,11]

Because CI qualifying criteria for Medicare and Medicaid patients are stricter than the labeled manufacturer criteria, insurance payer status could affect expedient access to CIs in patients who could derive benefit from an implant.[2,3] For example, an adult CI patient with qualifying audiometric thresholds but speech scores marginally outside the qualifying criterion may have to wait to receive an implant until word recognition sufficiently deteriorates to meet CMS candidacy requirements. Thus, the CMS CI candidacy criteria ensure there can be up to a 20% built-in difference in preoperative speech-perception scores compared with the patients with private insurance. This difference is important to consider because there is evidence preoperative sentence recognition scores can be predictive of postoperative speech-perception outcomes.[12,13] The relationship between pre- and postoperative speech scores appears to be linear,[12] suggesting better preoperative speech scores may serve a protective function, potentially resulting in better postoper-

ative outcomes. Given this potential relationship, it is important to examine whether differences in adult postoperative speech-perception scores exist based on insurance payer status.

Insurance Payer and Access to CIs

In addition to differences in candidacy criteria, insurance payer status has also been linked to disparities in time to implantation.[14,15] Previous studies from pediatric CI centers suggests after an initial CI candidacy evaluation, children covered by private insurance receive their implants at significantly faster rates than those with public insurance policies.[14,15] Armstrong et al[14] documented pediatric patients with public insurance waited on average 39.0 months after the initial CI candidacy evaluation and diagnosis to be implanted, while patients with private insurance waited only an average of 14 months. Reasons for extensive delays in implantation after a candidacy evaluation included insurance status; delays in receiving insurance approval for appointments and hearing aids; comorbid conditions; and parental misunderstanding, noncompliance, and lack of follow-up.[14] Whether insurance payer status affects expedient access to CIs for adults after the initial CI candidacy evaluation is unknown and merits investigation.

Study Rationale

To date, few studies have examined how insurance payer status affects access to and outcomes with CIs in adult patients. The present study uses the HIPAA (Health Insurance Portability and Accountability Act)-Secure, Encrypted, Research Management and Evaluation Solution (HERMES) database to answer questions related to CI outcomes and insurance payer status in adult CI recipients. The HERMES database was created by a multidisciplinary team of CI providers, computer scientists, and software designers.[16] As a part of a nonprofit Auditory Implant Initiative, HERMES consists of a de-identified collection of data points intended for research, outreach, and collaboration to improve CI outcomes. The data are compiled using specific elements related to the implantation process, including pure-tone audiometry, speech-perception tests, surgical factors, and standardized testing at various time points.[16] Using the HERMES database, this retrospective study aims to examine the effect of insurance payer status on CI speech-perception outcomes in adult CI recipients. Specifically, we examine (1) whether payer status predicts postoperative speech-perception scores in adult CI recipients; and (2) whether insurance payer status predicts the speed at which a CI candidate receives an implant after the initial qualifying examination. Answers to these questions have implications for adult CI candidacy protocols.

Methods

Study Cohort
Data were mined using the HERMES database which consists of 12,388 individual de-identified data points from 7,275 CI

patients across the United States (each visit and test result from a patient is recorded as one data point). Twelve clinical sites from Colorado, Iowa, Maryland, New York, Ohio, Oklahoma, Tennessee, Texas, and Wisconsin contributed to the HERMES database. To be selected for inclusion in the primary analysis, the database was first queried for all adult recipients 18 years of age and older, those who had data regarding the number of days from initial CI candidacy evaluation to date of CI surgery, and individuals with a known insurance payer status differentiating between public (e.g., CMS) and private (e.g., commercial) insurance plans. This initial query returned 234 patients who did not have significantly different days (i.e., delay) to implant based on payer status [$F_{(1,234)} = 1.6$, $p = 0.21$]. These patients were then further refined to include only those who (1) had known age at onset of hearing loss and (2) had known age at implantation which produced 195 patients. The study cohort was then further refined to include only patients with 12 months postoperative speech outcome data on either the consonant-nucleus-consonant (CNC) word test[17] in quiet or the AzBio sentence-in-noise test.[18] The 12-month postoperative interval was selected because adaptation to CI processing can take up to 6 months after implantation.[19] After applying these inclusion criteria, a total of 68 patients were selected (►Fig. 1). In the database, 47 patients met the outlined inclusion criteria and had CNC outcome measures at 12 months postimplantation, and 21 patients met all inclusion criteria and had AzBio in noise scores at 12 months postoperatively.

Having known preoperative and postoperative CNC or AzBio in noise scores was originally included as an additional selection criterion, but the query resulted in a limited number of remaining subjects, so the preoperative speech criterion was removed from the search. However, for descriptive purposes, preoperative CNC and AzBio in noise scores for all subjects in the database with a known insurance payer are provided in ►Table 1, along with the available preoperative speech data for the study cohort participants. The overall wait time to implantation after initial CI consult by payer status is also provided in ►Table 1 for the entire database and study cohort. Age of implantation and severe-to-profound hearing loss for the study cohort are displayed in ►Table 2.

Given the de-identified nature of the patient data within the database, the University of North Texas Institutional Review Board (IRB) determined research with HERMES data qualifies for an exemption from IRB approval.

Speech Recognition Testing
Speech recognition testing is an important component of the minimum standard test battery recommended for CI candidacy evaluations[20] as well as an important outcome measure after implantation. CMS and manufacturer guidelines indicate a candidacy evaluation must include a sentence
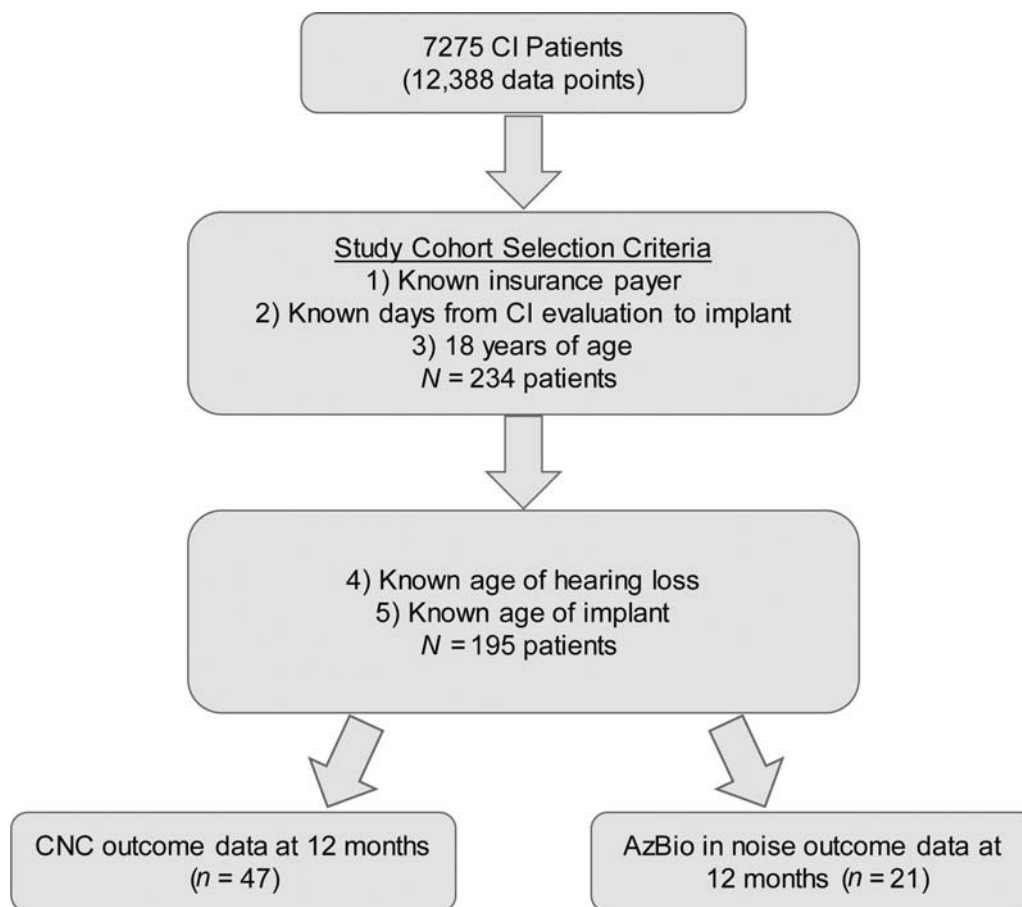

Fig. 1 Flow diagram outlining the selection criteria applied to the database for inclusion in the study cohort.

Table 1 Mean best-aided preoperative percent correct scores on the CNC test in quiet and AzBio in noise for the entire database with a known insurance payer and for the study cohort participants who also had preoperative speech data available

	Database		Study cohort	
	Commercial insurance	Public insurance	Commercial insurance	Public insurance
Preoperative CNC % correct	29.6 (25) $n = 87$	27.7 (17) $n = 187$	19.9 (8.8) $n = 8$	13.9 (7.4) $n = 26$
Preoperative AzBio in noise % correct	35.5 (30.4) $n = 14$	19.5 (17) $n = 54$	34.5 (7.8) $n = 2$	18 (15.2) $n = 6$
Days from CI consult to surgery	87.47 (69.3) $n = 70$	108 (132.9) $n = 164$	64.2(49.5) $n = 22$	78.19 (52.2) $n = 46$

Abbreviations: CI, cochlear implant; CNC, consonant-nucleus-consonant.
Note: Days from consult to surgery reflects the mean number of days from initial CI consult to implantation for the entire database and the total study cohort. n indicates the number of subjects for each analysis. Standard deviation in parentheses.

Table 2 Mean age of severe-to-profound hearing loss and age of implantation for 26 patients with commercial insurance and 42 patients with public insurance who met the inclusion criteria

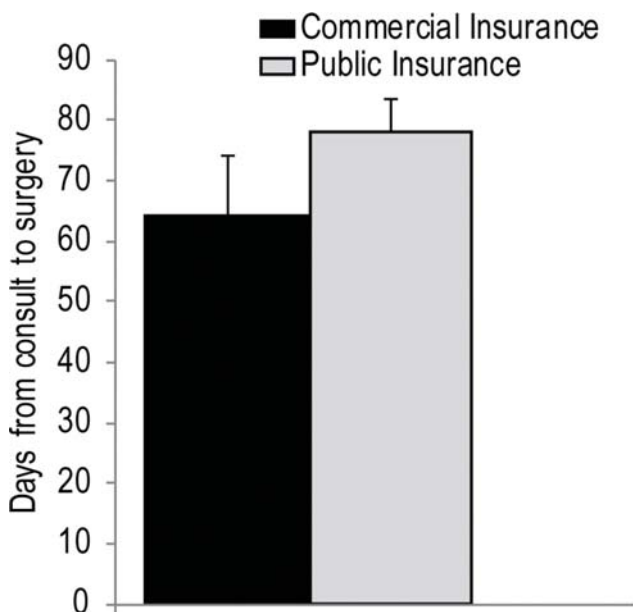|	Commercial insurance ($n = 26$)	Public insurance ($n = 42$)
Age of severe-to-profound hearing loss	30.1 y (22.4)	42.9 y (19.8)
Age of implantation	41.9 y (24.7)	68.75 y (14.5)

Note: Standard deviation in parentheses.

recognition test in the best-aided condition, but a standard assessment tool is not specified. In line with CI industry recommendations, we used the AzBio[18] sentence test to assess outcomes at 12 months after implantation. The AzBio test consists of 20 prerecorded sentences and can be performed in quiet or multitalker babble. Each sentence is scored for words correct and expressed as an overall percentage across the 20 sentences. The highest AzBio score from the implanted ear in the best-aided condition in noise

Fig. 2 Mean number of days from initial cochlear implant candidacy assessment to surgical implantation for patients with public and commercial insurance in the study cohort. Bars reflect standard errors of the means.

was selected from the database and included in the statistical analysis.

In addition to sentence materials, recent evidence suggests open-set monosyllabic CNC word testing,[17] which relies less on top-down cognitive processing than sentence testing, is useful in the pre- and postoperative test battery for assessing CI outcomes.[21] Thus, the present study also included the CNC test in quiet as an outcome measure. Scores on the prerecorded CNC test are computed as percent correct out of 50 words in the test. The best CNC score in quiet in the best-aided condition from the implanted ear was queried from the database and included in the analyses.

Statistical Analysis

Separate linear mixed-effects (LME) models were used to examine whether insurance payer status was predictive of 12-month postoperative word recognition scores in the best-aided condition on the CNC test in quiet and the AzBio sentence test in noise. In the full models, *CI recipient* was treated as a random effect using a random intercept to control for baseline differences across patients in the database. The factors of *age of implantation* and *age of severe-to-profound hearing loss* were included as variables to account for age differences across the insurance cohorts due to CMS qualifying age criteria. *Consult-to-surgery time* (the number of days from initial CI candidacy evaluation to surgery), and *insurance payer* (commercial or public) were included in the models as fixed effects. Significance of fixed effects in predicting word recognition outcomes on the CNC and AzBio in noise tests was assessed using $\alpha = 0.05$. The best-fitting reduced models were created by removing the least significant predictors of speech-perception outcome in a stepwise fashion to minimize the Akaike information criterion value.
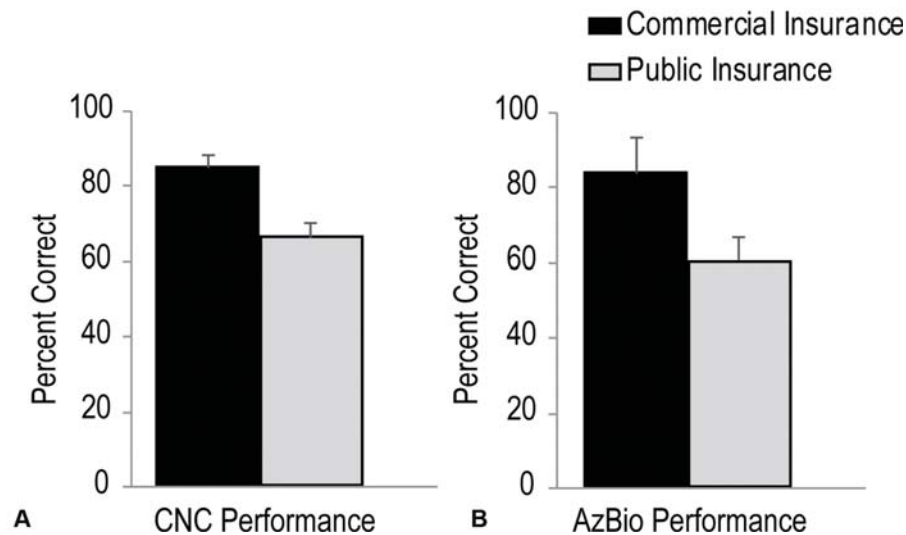
Fig. 3 Mean 12-month postoperative percent correct on the (A) CNC and (B) AzBio sentence in noise test for patients with public and commercial insurance. Bars reflect standard errors of the means. CNC, consonant-nucleus-consonant.

Results

►**Fig. 2** displays the average number of days from initial CI consult to surgery, and ►**Fig. 3** plots the average 12-month post-operative score on the CNC and AzBio by insurance group.

CNC Outcome Data

A series of LME regression analyses were performed to examine the relationship between postoperative performance on the CNC test and insurance payer status. ►**Table 3** shows the regression weights and the associated significance values for the full model and the final, reduced model. In the full model, *insurance payer* [$F(1,41) = 3.84$, $p < 0.05$] was a significant predictor of CNC speech score. *Age of implantation*, *consult-to-surgery time*, and *age of severe-to-profound hearing loss* and the interaction between fixed effects were not significant predictors of CNC score ($p > 0.05$). The full model accounted for 20.7% of the

variance in postoperative CNC performance. In the best model, *insurance payer* [$F(1,44) = 7.3$, $p < 0.05$] was a significant predictor of CNC score in quiet. While it was not a significant predictor, *age of implantation* explained additional variance and was included in the final, reduced model to control for age differences across commercial versus public insurance groups. When compared with commercial insurance, having public insurance was estimated to decrease postoperative scores on the CNC test by 15.3% points. The reduced model accounted for 16.1% of the variance in postoperative CNC performance. When comparing the full and reduced models for goodness-of-fit, likelihood ratio tests suggested there were no significant differences across the models ($p > 0.05$).

AzBio in Noise Outcome Data

A series of LME regression analyses were performed to examine the relationship between 12-month postoperative performance on the AzBio in noise test and insurance payer

Table 3 F-statistics and regression coefficients (β) for the fixed effects and interactions between fixed effects in the full and best reduced linear mixed-effects regression models for prediction of CNC word score

Full model, $R^2 = 0.207$			Best model, $R^2 = 0.16$		
Variable	CNC		Variable	CNC	
	F	β		F	β
Intercept	555.9[a]	–	Intercept	564.5[a]	–
Age of implant	2.52	−0.19	Age of implant	1.02	−0.22
Age hearing loss	2.08	−0.08	Insurance (CMS)	7.3[a]	−15.3
Insurance (CMS)	3.84[a]	−24.14			
Time to surgery	1.41	−0.03			
Insurance:Surgery	0.66	0.12			

Abbreviations: CMS, Centers for Medicare and Medicaid Services; CNC, consonant-nucleus-consonant.
[a]$p < 0.05$.

Table 4 F-statistics and regression coefficients (β) for the fixed effects and interactions between fixed effects in the full and best reduced linear mixed-effects regression models for prediction of AzBio in noise sentence score

Full model, $R^2 = 0.47$			Best model, $R^2 = 0.46$		
Variable	AzBio noise		Variable	AzBio noise	
	F	β		F	β
Intercept	182.14[a]	–	Intercept	201.9[a]	–
Age of implant	1.16	−0.35	Age of implant	1.28	−0.26
Age hearing loss	0.38	0.14	Insurance (CMS)	4.7[a]	−10.9
Insurance (CMS)	4.3[a]	−15.8	Time to surgery	7.6[a]	−0.25
Time to surgery	6.6[a]	−0.34			
Insurance:Surgery	0.22	0.12			

Abbreviation: CMS, Centers for Medicare and Medicaid Services.
[a]$p < 0.05$.

status (►**Table 4**). The full model accounted for 47% of the variance in postoperative AzBio in noise scores. The reduced model accounted for 46% of the variance in postoperative AzBio scores and indicated, controlling for *age of implantation*, *insurance* [$F(1,17) = 4.7$, $p < 0.05$], and *consult-to-surgery time* [$F(1,17) = 7.62$, $p < 0.05$] were significant predictors of AzBio in noise scores. When compared with commercial insurance, having public insurance is estimated to decrease scores on the AzBio in noise test by 11% points. Likewise, for every additional day between initial consult and CI surgery, the AzBio in noise score is predicted to decrease by 0.25%. When comparing the full and reduced model for goodness-of-fit, likelihood ratio tests suggested there were no significant differences across the models ($p > 0.05$).

Discussion

The majority of postlingually deafened adults who receive CIs experience significantly improved speech-perception abilities and improved quality of life ratings.[2,22] However, estimates suggest, at most, only 5 to 7% of adults who are CI candidates go on to receive an implant.[4,5] The goal of the present study was to investigate whether insurance payer status is a barrier to success with CIs. The regression analyses in this study confirmed both insurance payer and CI consult-to-surgery time are significant predictors of postoperative adult CI speech-perception scores in quiet and in noise. These results have significant clinical implications for the CI evaluation process.

CMS Speech-Perception Candidacy Criteria
The stricter CMS CI candidacy criteria ensure patients covered by CMS could have preoperative speech-perception scores that are up to a 20% poorer compared with the patients with private insurance. For the present study cohort, patients with commercial insurance had preoperative AzBio in noise scores that were 17% higher and CNC scores that were 6% higher than those with public insurance. These trends are fairly consistent with the overall trends observed in the HERMES database where CI recipients with private insurance had better preoperative speech recognition scores

(►**Table 1**). The results of the present study indicate it is likely preoperative disparities significantly affect post-operative speech-perception outcomes in both quiet and noise for adult CI recipients. Our data indicate publically insured patients are predicted to have longitudinal CNC scores in quiet that are 15% poorer than those with private insurance and sentence in noise scores that are 11% poorer, even when controlling for differences in age of implantation across the insurance cohorts. Thus, even at 12 months postimplant, for patients covered by CMS, their speech-perception outcomes do not catch up to those with private insurance.

In line with previous work that concluded CMS CI criteria are likely too stringent,[2,13] the results of the present study merit a discussion as to whether CMS CI candidacy criteria should be modified and expanded to allow for implantation with better preoperative speech scores that, at a minimum, match the least restrictive FDA-labeled criteria for the different manufacturers. For example, Gifford et al[2] examined whether the stricter CI qualifying criteria for publicly insured patients reduced the number of adult CI recipients who could significantly benefit from the devices. The study documented adult CI recipients with preoperative speech-perception scores up to 68% correct, placing them outside of CMS candidacy criteria, received significant speech-perception benefit from their CI devices.[2] Advanced age was previously considered a significant reason for the more conservative CMS CI criteria,[8] but a large body of literature indicates that advanced age at implantation is not a significant predictor of postoperative speech outcomes.[23–25]

Disparities in CI Success: Service Delays
Postoperative outcomes in adult CI recipients are affected by numerous variables outside of patient or clinician control such as the age hearing loss occurs, duration and etiology of hearing loss, and the integrity of the auditory pathway. In contrast, the rate at which a person is moved through the CI evaluation process can be changed and improved. The results of the present study indicate patients with public insurance wait longer to receive their devices after their initial CI consult than those with private insurance and experience poorer speech-perception outcomes in noise. Our results

indicated patients with public insurance waited only an average of 2 weeks longer than those with commercial insurance, which may not seem clinically meaningful; however, our prediction models indicate having public insurance could lead to hearing health care disparities if and when significant service delays are experienced. Based on these results it would be beneficial for implant centers to determine what steps can be undertaken to move patients covered by CMS more expediently through the CI process.

Where the delay in receiving CI services arises for patients covered by CMS cannot be determined from the present study. Whether surgery is delayed for patients with comparable preoperative speech-perception scores on the basis of their insurance status alone also cannot be determined from the present study. It should be noted that patients in the CMS cohort were older than the patients covered by commercial insurance, and there is evidence older CI recipients experience higher rates of comorbidities than younger patients.[26] While we controlled for age of implantation in our models, the presence of potential comorbidities could have contributed to service delays if additional testing for surgical clearance was required.

Study Limitations

The present retrospective study used data points queried from a large clinical database. Thus, we could not tightly control for the variability in the study cohort. For example, the public insurance cohort consisted of patients covered by both Medicaid and Medicare policies. Medicaid coverage for CIs varies dramatically by state, and in some cases, Medicaid does not cover adult implantation. Because this was a retrospective study, it is impossible to determine whether some of the patients with Medicare were initially covered by Medicaid in states without CI coverage and waited for the CI surgery and related audiological services to be paid for by Medicare, contributing to the observed effects. Likewise, we did not have access to additional information known to contribute to CI outcomes such as etiology of hearing loss, language used in the home, type of device, or whether patients adhered to the recommended follow-up rehabilitation and programming schedules. However, the use of LME models and the inclusion of CI patient as a random effect can account for this inherent variability across recipients, controlling for baseline differences across subjects.[27]

In addition, we could not control the data and collection protocols. However, the clinics contributing to the HERMES database are large CI centers that have well-established CI evaluation procedures. Moreover, the FDA-labeled criteria for CMS, MED-EL, and Cochlear Americas require the use of recorded speech materials for CI evaluations, which would control for talker variability effects associated with live voice presentation. Finally, there are a significant number of subjects with incomplete data fields. To increase the number of subjects available for future analyses, the group managing the HERMES database may want to consider reducing the number of data input fields for centers to complete to facilitate more complete demographic and speech-perception data.

Conclusion

Using the national HERMES CI database, we found that having public insurance leads to poorer postoperative speech-perception results in quiet and noise as well as longer wait times to implantation after the initial CI candidacy evaluation. These results have important clinical implications regarding the expansion of CMS CI candidacy criteria to reduce hearing health care disparities. Future controlled studies should examine how variables related to gender, race, and geographic region interact with insurance payer status and access to CIs.

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