

Safety of Audiology Direct Access for Medicare Patients Complaining of Impaired Hearing

DOI: 10.3766/jaaa.21.6.2

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Abstract

Background: Allowing Medicare beneficiaries to self-refer to audiologists for evaluation of hearing loss has been advocated as a cost-effective service delivery model. Resistance to audiology direct access is based, in part, on the concern that audiologists might miss significant otologic conditions.

Purpose: To evaluate the relative safety of audiology direct access by comparing the treatment plans of audiologists and otolaryngologists in a large group of Medicare-eligible patients seeking hearing evaluation.

Research Design: Retrospective chart review study comparing assessment and treatment plans developed by audiologists and otolaryngologists.

Study Sample: 1550 records comprising all Medicare eligible patients referred to the Audiology Section of the Mayo Clinic Florida in 2007 with a primary complaint of hearing impairment.

Data Collection and Analysis: Assessment and treatment plans were compiled from the electronic medical record and placed in a secured database. Records of patients seen jointly by audiology and otolaryngology practitioners (Group 1: 352 cases) were reviewed by four blinded reviewers, two otolaryngologists and two audiologists, who judged whether the audiologist treatment plan, if followed, would have missed conditions identified and addressed in the otolaryngologist's treatment plan. Records of patients seen by audiology but not otolaryngology (Group 2: 1198 cases) were evaluated by a neurotologist who judged whether the patient should have seen an otolaryngologist based on the audiologist's documentation and test results. Additionally, the audiologist and reviewing neurotologist judgments about hearing asymmetry were compared to two mathematical measures of hearing asymmetry (Charing Cross and AAO-HNS [American Academy of Otolaryngology—Head and Neck Surgery] calculations).

Results: In the analysis of Group 1 records, the jury of four judges found no audiology discrepant treatment plans in over 95% of cases. In no case where a judge identified a discrepancy in treatment plans did the audiologist plan risk missing conditions associated with significant mortality or morbidity that were subsequently identified by the otolaryngologist.

In the analysis of Group 2 records, the neurotologist judged that audiology services alone were all that was required in 78% of cases. An additional 9% of cases were referred for subsequent medical evaluation. The majority of remaining patients had hearing asymmetries. Some were evaluated by otolaryngology for hearing asymmetry in the past with no interval changes, and others were consistent with noise exposure history. In 0.33% of cases, unexplained hearing asymmetry was potentially missed by the audiologist. Audiologists and the neurotologist demonstrated comparable accuracy in identifying Charing Cross and AAO-HNS pure-tone asymmetries.

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Portions of this article were presented as a student research poster at AudiologyNOW! 2009, Dallas, TX.

Conclusions: Of study patients evaluated for hearing problems in the one-year period of this study, the majority (95%) ultimately required audiological services, and in most of these cases, audiological services were the only hearing health-care services that were needed. Audiologist treatment plans did not differ substantially from otolaryngologist plans for the same condition; there was no convincing evidence that audiologists missed significant symptoms of otologic disease; and there was strong evidence that audiologists referred to otolaryngology when appropriate. These findings are consistent with the premise that audiology direct access would not pose a safety risk to Medicare beneficiaries complaining of hearing impairment.

Key Words: Age-related hearing loss, audiology, delivery of health care, health-care policy, hearing loss, Medicare, presbycusis

Abbreviations: AAO-HNS = American Academy of Otolaryngology—Head and Neck Surgery; Academy = American Academy of Audiology; ASHA = American Speech-Language-Hearing Association; COM = chronic otitis media; EMR = electronic medical report; FDA = U.S. Food and Drug Administration; MRI = magnetic resonance imaging; NIDCD = National Institute on Deafness and Other Communication Disorders; SSNHL = sudden sensorineural hearing loss

The Medicare program covers 95% of our nation's aged population. Medicare expenditures have increased faster than gross domestic product (GDP) for the past several decades and are projected to rise substantially in the coming decade. By 2011, the baby boomer generation will officially qualify for Medicare benefits, swelling beneficiary ranks. Expanding Medicare benefits such as the Part D prescription drug coverage, and costs associated with health-care innovations, will also contribute to increasing expenditures. These trends may not be sustainable. For example, recent Medicare reports (Van de Water, 2008; Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2009) projected that the hospital insurance trust fund will be depleted by 2019. *The Long-Term Budget Outlook*, a U.S. Congressional Budget Office report (2009), notes that under any plausible scenario, rising costs for health care and the aging of the U.S. population will cause federal spending to increase rapidly in an unsustainable trend. Calls for more efficient health-care delivery and cost containment initiatives have become common for federal and privately funded health-care programs (Straube, 2008; Cortese and Korsmo, 2009; McLaughlin, 2009; Mitka, 2009).

Hearing loss is thought to be the third most prevalent chronic condition in the Medicare eligible population (Cruikshanks et al, 1998). The National Institute on Deafness and Other Communication Disorders (NIDCD, 2010) estimates that 30% of adults between the age of 65 and 74 yr have significant hearing loss. The percent increases to 47% in adults aged 75 yr and older. The societal impact of presbycusis hearing loss (referring to the combination of age-related and noise-related hearing loss) is likely to rise as baby boomers age, creating an increased demand for hearing-care services. These services are projected to exceed the capabilities of the current hearing health-care delivery system (Margolis, 2009). As such, the problem of caring for patients with hearing loss is a microcosm of the dilem-

mas facing the health-care system in the treatment of age-related declines in function.

As with other age-related functional declines or disabilities, the management of hearing impairment involves both physician and nonphysician providers. Primary care physicians, otolaryngologists, and audiologists are the most common providers. The primary care physician is responsible for the overall care of the patient within the context of the medical home. Otolaryngologists are physicians trained in the diagnosis and treatment of diseases of the ear, nose, throat, head, and neck. Audiologists are nonmedical practitioners who specialize in the assessment and nonmedical management of hearing and balance disorders. The efficient use of both medical and nonmedical provider resources would seem to be a basic goal of health-care cost containment.

Treatment for hearing loss focuses on two goals. The first goal is to identify and manage any otologic conditions that may affect hearing or overall health. The second goal is to reestablish useful hearing abilities, typically through audiological services (accurate hearing assessments; hearing aid fittings; aural rehabilitation; assessment of cochlear implant candidacy; and fitting, programming, and follow-up services for cochlear implant recipients). Although important to detect, the prevalence of otologic conditions in the Medicare beneficiary population is small. Table 1 presents the most common otologic conditions encountered in patients over the age of 65, with the prevalence rates for active otologic disease reflecting the highest levels found in the literature. From Table 1, chronic otitis media (COM) has a prevalence of 4.5% in the general population and an unknown prevalence in patients over the age of 65. Beyond COM, less than 0.3% of the Medicare beneficiary population would be expected to have active otologic disease or medically treatable conditions. Therefore, under the most conservative assumptions, greater than 89% of Medicare beneficiaries complaining of hearing loss would not be expected to have active

Table 1. Estimated Prevalence of Hearing Loss by Etiology

Condition	Prevalence	Cases/1,000,000	References
Presbycusis	25%	250,000	Kochkin; Ries, 1994; Arts, 2005; Bagai et al, 2006; Agrawal et al, 2008
Age range: 65–74	30–35%*		
Age range: 75+	40–50%*		
Noise induced hearing loss	15%	150,000	National Institute on Deafness and Other Communication Disorders (NIDCD), 2008
Chronic otitis media	4.5%	44,989	Kemppainen et al, 1999; Lin et al, 2009
Ménière's disease	0.15%	1500	Ruckenstein, 2000; Deafness Research Foundation, 2001
Otosclerosis	0.06%	560	House and Cunningham, 2005; AAO-HNS
Sudden idiopathic sensorineural hearing loss	0.02%	200	Byl, 1984; National Institute on Deafness and Other Communication Disorders (NIDCD), 2003; Rauch, 2008
Cholesteatoma	0.01%	92	Kemppainen et al, 1999
Hearing loss in multiple sclerosis	0.01%	86	National Multiple Sclerosis Society; Wrong Diagnosis
Labyrinthitis	0.004%	35	Ergul et al, 2006
Vestibular schwannoma or other retrocochlear mass	0.002%	15	Dawes and Jeannon, 1988; National Institutes of Health, 1991

Note: Presbycusis prevalence (25%) was based on the most conservative estimate found for the age group 65 years and older. Prevalence values with asterisks are from the NIDCD Web site and are higher than the 25% rate used in this paper. Other prevalence estimates apply to the general adult population.

otologic disease or medically treatable conditions affecting hearing. They have presbycusis related hearing loss, for which audiological evaluation and management services best address the presenting complaints.

These numbers suggest that it may be more cost-effective to address hearing impairment in the Medicare population by allowing direct access to audiological services. The rationale would be that audiologists can effectively screen for otologic disease and audiological evaluation and management services will be needed in the majority of cases regardless. However, there are strong historical biases against audiologists, as non-medical practitioners, providing evaluation and management services in the health-care setting. For example, since its inception, FDA (U.S. Food and Drug Administration) hearing aid regulations stipulate a medical evaluation (preferably by a specialist in diseases of the ear) prior to obtaining hearing aids, even when audiological assessment does not indicate active or treatable otologic disease. The stated rationale for medical evaluation in the current position statement is that “all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased” (FDA, 2009). Similar warnings can be found in the online advice from the U.S. Federal Trade Commission (FTC, 2009a, 2009b). Audiologists, by implication, are deemed unable to detect medical conditions affecting hearing.

Is there any evidence to support this belief? In a 2001 study commissioned by the Agency for Healthcare Research and Quality (AHRQ) and the U.S. Centers for Medicare and Medicaid Services (CMS), Levine et al (2001) performed a literature review for papers published between 1996 and 2001 pertaining to evaluation of patients with hearing loss. The purpose was to deter-

mine whether there was any peer-reviewed evidence regarding health outcomes of patients with hearing loss who were evaluated by an audiologist as an entry point in the health-care system. They found no direct evidence or clinical trial data addressing clinical outcomes when audiologists were entry points. Moreover, they could not find evidence in audiology curricula to support audiologist competence in the areas of case history taking or physical examination, which may be vital in detecting life-threatening diseases. According to the AHRQ Web site, a similar review is planned in the near future.

With rising health-care costs, audiology direct access for Medicare beneficiaries would seem to be a cost-effective option for managing patients whose primary complaint is hearing loss. But is it less safe than requiring physician evaluation prior referral? This study addresses the safety issue. We specifically wanted to know if audiologist decision making when assessing patients with the primary complaint of hearing loss would result in missing medical conditions associated with mortality or morbidity that could have been detected by physician specialist (otolaryngologist) providers.

METHODS

Setting

Mayo Clinic Florida is a multidisciplinary facility with an integrated electronic medical record (EMR). Audiological evaluations may be delivered as a complement to otolaryngology, neurology, or primary care evaluation, or independently when patients seek hearing aid-related services. Regardless of whether medical management will be required, all audiological evaluations

include a brief case history and physical examination of the ears, as well as development of clinical impression (evaluation) statements and treatment or management plan(s).

Subjects and Materials

All methods were completed under institutional review board oversight (IRB Protocol #:96-06). The electronic medical records of all patients aged 62 and older presenting with a primary complaint of hearing loss seen in the audiology department at Mayo Clinic Florida in the year 2007 were queried. All presenting complaints, test results, impressions, and management plans from the audiological evaluation were selected and stored in a secured database. Additionally, any subsequent otolaryngology evaluation results relating to the same chief complaint were selected and included in the same database. Specific items selected from the otolaryngology record included chief complaint, assessment, impressions, and treatment or management plans. Finally, demographic data consisting of patient age and gender were included in the database. These data became the study material for all analyses.

Subject records were segregated into two groups: those evaluated jointly by both audiology and otolaryngology, and those evaluated solely by audiology. In the group evaluated jointly by both audiology and otolaryngology, the audiological evaluation always preceded the otolaryngology evaluation. Different review processes were completed for each subgroup and are described below.

Group 1: Patients Seen Jointly by Audiology and Otolaryngology

Records from patients seen jointly by audiology and otolaryngology were reviewed by four independent reviewers blinded to each other's judgments. Two reviewers were audiologists, and two were otolaryngologists. The reviewers examined the study material (audiological and otolaryngologic evaluations) from each patient and judged if the treatment plans developed by the audiologist were "congruent" or "incongruent" with the plans developed by the otolaryngologist. "Incongruent," in this context, means that if the audiologist's treatment or management plan had been followed, a medical condition or problem would have been missed if not for subsequent otolaryngology evaluation. If the treatment plan was found to be incongruent, a brief description as to why the plan was incongruent was noted (e.g., risk of retrocochlear pathology, otosclerosis, autoimmune ear disease).

The judgments of each reviewer were tallied to determine levels of overall agreement and to determine if there were any discipline-specific trends in the reviewer's

judgments. Additionally, incongruent records were reviewed, and the reasons for the observed incongruence were tabulated.

Group 2: Patients Seen Solely by Audiology without Subsequent Otolaryngology Evaluation

Records from patients seen by audiology without subsequent otolaryngology evaluation were reviewed by a board certified neurotologist. The neurotologist reviewed each record and assessed if the patient could have potentially benefited from additional neurotologic assessment or if no additional evaluation was necessary. The neurotologist's professional clinical judgment was based solely on the information available in the database material. Outside information, such as primary care notes, prior neurologic evaluations, or imaging studies not mentioned in the audiologist's report were unavailable.

Two additional calculations proposed for detecting retrocochlear pathology based on pure-tone asymmetries were also determined for each subject in this group. These were the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) and the Charing Cross asymmetry calculations (both calculations are described in Obholzer et al, 2004).¹ The reviewing neurotologist was blinded to these calculations during data review.

Results

A total of 1550 patient records were found that met study criteria. Of these, 18.5% (287/1550) were from patients prescheduled for evaluation by both audiology and otolaryngology. An additional 4.2% (65/1550) were initially seen by audiology and subsequently referred by the audiologist for otolaryngology evaluation. These two groups formed the data set for patients seen jointly by otolaryngology and audiology (Group 1). The remaining 77.3% (1198/1550) of identified patients were seen by audiology without subsequent otolaryngology evaluation (Group 2). These patients were referred by their primary care provider or specialty physician or were self-referred for audiological assessment. Figure 1 presents an overview of how patient records were stratified into outcome groups.

Analysis of Group 1: Patients Seen Jointly by Otolaryngology and Audiology

A total of 352 patients were evaluated jointly by audiology and otolaryngology. Of these, the patients prescheduled to see both audiology and otolaryngology comprised 81.5% (287/352) of Group 1. The remaining 18.4% (65/352) of Group 1 patients were initially scheduled for audiological evaluation only but were subsequently referred for otolaryngology evaluation based on audiological evaluation results. Figure 2 summarizes

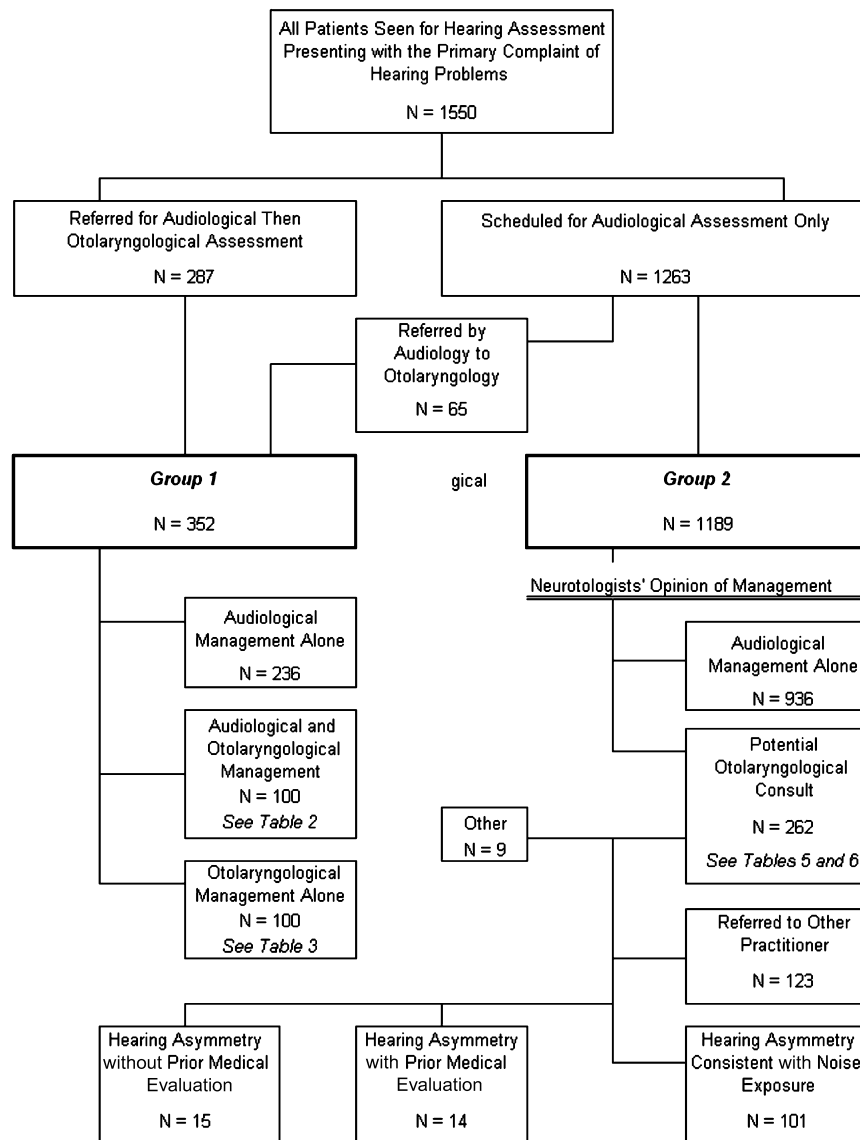


Figure 1. Summary of stratification of 1550 consecutive cases evaluated in this study.

how these patients were ultimately managed. Following both audiology and otolaryngology assessments, the vast majority of patients (95.2% or 335/352) were found to have problems requiring audiological management. Audiological management strategies included the selection, fitting, and training in use of hearing aids, assistive listening devices, patient counseling or training in communication strategies, tinnitus management, and hearing conservation services. These would be services consistent with presbycusis hearing loss. In 67% (236/352) of Group 1 patients, audiological management was all that was needed.

Of the remaining 32.95% (116/352) of Group 1 patients, some form of otologic management was utilized. Otologic management strategies included medical and surgical treatment of disease, further evaluative procedures such as magnetic resonance imaging (MRI), vestibular or bal-

ance testing, and assessment of surgical candidacy for cochlear implantation. In 28.41% (100/352) of patients, a combination of audiological and otologic management strategies was utilized. Otologic management strategies alone were utilized in 4.55% (16/352) of Group 1 patients.

Tables 2 and 3 describe the nature of otologic services employed in Group 1 patients. For patients having hearing loss that an audiologist could manage (Table 2), the most common co-occurring otologic management issue was the risk of retrocochlear tumor. Consequently, high-resolution MRI scans with contrast were recommended in 9.09% (32/352) of cases to assess the internal auditory canals. Of these patients, 15 were initially scheduled in audiology and referred by the audiologist for further otologic evaluation as a result of a suspicious history, physical examination, or test findings. Correspondingly, 17 patients were prescheduled

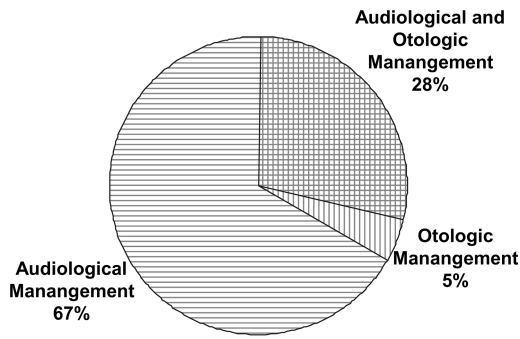


Figure 2. Utilization of audiology and otology management in patients with primary complaint of hearing loss seen by both audiology and otology.

by other health-care providers for otologic evaluation, which included an audiological assessment. An additional six cases were referred for MRI who did not ultimately need or receive audiological management. Indications for MRI assessment in these cases included sudden sensorineural hearing loss, unilateral tinnitus, and hearing asymmetry. Only one retrocochlear labyrinthine tumor was identified in this group of 38 scans. This patient was initially seen in audiology and referred for further otologic evaluation based on the audiologist’s assessment. Other otologic management and treatment services employed are shown in Tables 2 and 3.

Figure 3 shows the overall agreement rate between audiology and otology treatment plans as evaluated by the four reviewers (two audiologists and two otolaryngologists). The overall agreement rate was very high (average agreement rate of 98.5%) and demonstrated excellent interrater agreement (percentage of overall agreement = 97.5%, free marginal Kappa = 0.95). A total of 16 cases (16/352 or 4.6% of Group 1 cases) were found to be incongruent by at least one reviewer.

The reasons for incongruity are detailed in Figure 4. Tinnitus management strategies (masking, effects of caffeine and stress, etc.) were recommended by the otolaryngologist in six cases and not discussed in the audiological report. These patients were referred back to audiology for symptomatic tinnitus treatment (directive counseling, tinnitus masking strategies, tinnitus retraining therapy, etc.), which is customary in our clinic. Consequently, it was not surprising that specific management strategies were not addressed on the initial audiological evaluation. Topical cream for dermatitis or itching in the ear canal was prescribed by the otolaryngologist in three cases. Hearing aids and/or assistive listening devices were recommended by the otolaryngologist and not mentioned by the audiologist in three cases.

Additional incongruities were noted in patients with sudden sensorineural hearing loss (SSNHL). Six patients were treated with steroids for SSNHL. Two cases came from the group of patients prescheduled to see audiology only. They were subsequently referred to otology because a sudden onset hearing loss was identified. However, in reviewing the documentation, two judgments of incongruity were noted when the audiologist did not mention the need for follow-up hearing assessment following otology referral.

Ototoxic monitoring for planned chemotherapy treatment was recommended by the otolaryngologist in one case. This was not mentioned by the audiologist on the hearing test prior to otology consult, resulting in another incongruity judgment. One patient was given a topical nasal steroid and was eventually referred for an allergy evaluation. The sinus condition was not mentioned by the audiologist.

In nonemergent cases, the time interval between the audiological assessment and otology assessment

Table 2. Patients Receiving Audiological and Otologic Management

	Referred by Audiology to Otolaryngology	Scheduled for Joint Audiology and Otolaryngology Evaluation	Total	% of 352
Otologic Management				
MRI for possible retrocochlear pathology	15	17	32	9.1%
Management of ear canal itch (dermatitis, eczema, etc.)	4	13	17	4.8%
Cochlear implant evaluation	9	5	14	4.0%
Otologic surgery	1	9	10	2.8%
Sinus congestion	2	5	7	2.0%
SSNHL treatment	2	5	7	2.0%
Eustachian tube dysfunction, considering surgical management	1	2	3	0.9%
Diet control for Ménière’s/hydrops	0	3	3	0.9%
Vestibular testing	0	2	2	0.6%
Dysphasia evaluation	1	1	2	0.6%
Mastoid cavity maintenance	0	2	2	0.6%
Management of autoimmune hearing loss	0	1	1	0.3%
Total			100	28.4%

Table 3. Patients Receiving Otologic Management Alone

Otologic Management	Referred by Audiology to Otolaryngology	Scheduled for Joint Audiology and Otolaryngology Evaluation	Total	% of 352
MRI for possible retrocochlear pathology	1	5	6	1.7%
Sinus congestion	0	4	4	1.1%
Management of ear canal itch (dermatitis, eczema, etc.)	0	2	2	0.6%
Otologic surgery	0	1	1	0.3%
SSNHL treatment	0	1	1	0.3%
Carotid ultrasound for pulsatile tinnitus	0	1	1	0.3%
Management of genetic hearing loss	0	1	1	0.3%
Total			16	4.6%

varied from between one hour and several weeks. We wondered if the time interval between the audiology assessment and otolaryngology could account for incongruities. Only three cases were identified in which there could have been a time interval effect. These cases included three cases of external ear canal eczema and one case of eustachian tube dysfunction and allergy referral. In the latter case, there was a potential time interval effect. The diagnosis of eustachian tube dysfunction was made about one week after the audiological evaluation. Referral for allergy testing occurred five weeks after eustachian tube dysfunction was noted by the otolaryngologist.

Overall, most patients referred for otolaryngology evaluation for hearing loss experienced presbycusis hearing loss that was recognized and ultimately managed by an audiologist. Audiologists appeared able to accurately detect and refer patients with potential otologic conditions, including the detection of one vestibular schwannoma. Out of all 16 cases where the audiologist's management plan was incongruent with that of the otolaryngologist, no conditions associated with significant mortality or morbidity (such as unde-

tected infection, retrocochlear disease or malignancy) were missed. Rather, incongruent records seemed to be related to the audiologist deferring to the otolaryngologist for treatment planning and documentation.

Audiologist performance in detecting and referring cases with signs and symptoms of co-occurring otologic disease is shown in Table 4. Here the otologic diagnoses of the 65 cases initially scheduled for audiological evaluation and subsequently referred for neurotologic evaluation are summarized. Audiologists referred in cases of unexplained hearing loss or hearing asymmetry, otosclerosis, and infectious states such as otitis media or otitis externa, and for cochlear implant surgery candidacy. Cases of dizziness, otalgia, and sinus disease were also referred.

Analysis of Group 2: Patients Seen by Audiology without Subsequent Otolaryngology Evaluation

A total of 1198 patients, 77% of the 1550 study patients seen in the audiology section in 2007, were evaluated and managed by audiology alone for their hearing complaints. An additional 65 patients were scheduled for

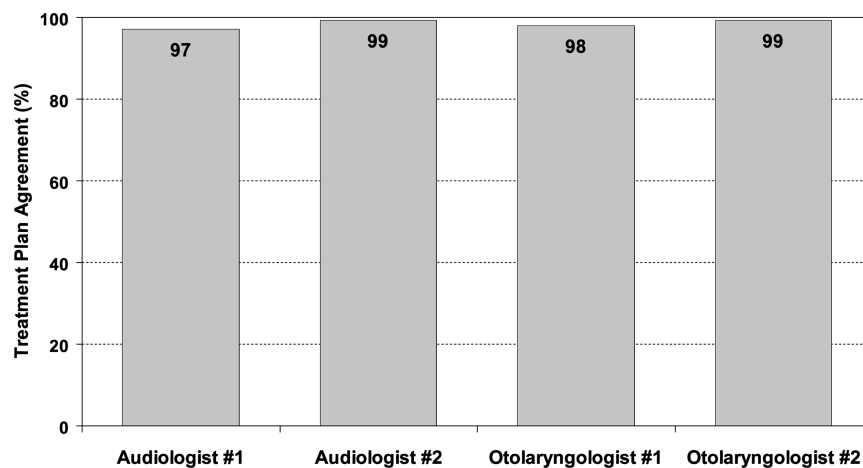


Figure 3. Agreement between audiology and otolaryngology treatment plans in patients with primary complaint of hearing loss seen by both audiology and otolaryngology (Group 1), stratified by judge (congruent treatment plans).

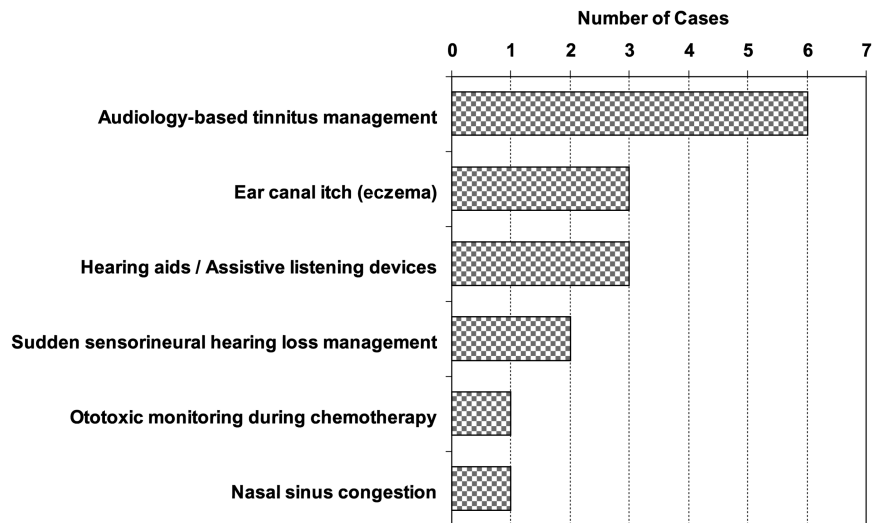


Figure 4. Conditions addressed by otolaryngologist and not addressed by the audiologist on the audiological evaluation (incongruent treatment plans).

audiology services alone but were subsequently identified as having signs or symptoms of otologic disease on case history, physical examination, or objective testing (e.g., fluctuating hearing loss, dizziness or imbalance, acoustic reflex decay, unexplained asymmetries in hearing sensitivity or word recognition). These patients were subsequently referred to otolaryngology and were reported as Group 1 patients above.

Of the remaining 1198 Group 2 patients, 72% (865/1198) were referred by primary care providers, 16% (195/1198) were referred by audiologists, and 12% (138/1198) were self-referred.

Just over 78% (936/1198) of Group 2 patients were judged on neurotologist review to be adequately evaluated and treated by audiology alone. However, 22% (262/1198) of cases were identified as potentially bene-

fitting from subsequent otology evaluation. The primary reason for potential otolaryngology referral was pure-tone asymmetry, either as noted by the audiologist in the report, or upon neurotology inspection of audiometric data. Hearing asymmetry and unexpected progression in hearing loss may be important signs of otologic disease. However, specific standards for when hearing asymmetries or hearing loss progression warrants referral are not universally agreed upon (Margolis and Saly, 2008). Moreover, different criteria may be used depending on the presentation of additional clinical signs and symptoms (Obholzer et al, 2004). To highlight the subjective variability in asymmetry identification and retrocochlear risk, audiology and neurotology impressions of asymmetry were compared with a calculation of asymmetry proposed by AAO-HNS

Table 4. Group 2 Patients Potentially Benefitting from Otolaryngology (ORL) Evaluation Based on Neurotology Review

	Cases (%)	AAO-HNS Asymmetry	Charing Cross Protocol Asymmetry
Referral Indicated (Overall)	21.9% (262/1198)	1.1% (13/1198)	2.9% (35/1198)
No Pure-Tone Asymmetry	9.2% (110/1198)		
Deferred to referring physician, referred to non-ORL physician, or referral recommendation not followed	101 (8.4%)	1 (0.1%)	2 (0.2%)
Other reasons for referring to ORL	9 (0.8%)		
Pure-Tone Asymmetry (PTAsy)	12.7% (152/1198)	1.0% (12/1198)	2.8% (33/1198)
Deferred to referring physician, referred to non-ORL physician, or referral recommendation not followed	22 (1.8%)		
Patients WITH prior internal ORL evaluation	51 (4.3%)	8 (0.7%)	15 (1.3%)
History of noise exposure and PTAsy	37 (3.1%)	7 (0.6%)	13 (1.1%)
No noise exposure history and PTAsy	14 (1.2%)	1 (0.1%)	2 (0.2%)
Patients WITHOUT prior internal ORL evaluation	79 (6.6%)	4 (0.3%)	18 (1.5%)
History of noise exposure and PTAsy	64 (5.3%)	4 (0.3%)	14 (1.2%)
No noise exposure history and PTAsy	15 (1.3%)	0 (0.0%)	4 (0.3%)

Table 5. Patients with Symmetrical Hearing Who May Have Benefited from Otolaryngology Consult

Neurologists' Reason for Otolaryngology Referral	Number of Cases	Comments
Severity of Hearing Loss (Potential cochlear implant candidate)	4	Ages: 85, 93, 94, and 96
Prior Surgery	2	History of tympanoplasty; no change in hearing compared to past results; Outside diagnosis of otosclerosis; current hearing aid user
Dizziness	1	Vague complaint of dizziness by patient
Sudden Loss	1	Hearing loss after receiving chemotherapy in past; hearing aids recommended
Tinnitus	1	Long-standing unilateral tinnitus

and a calculation proposed by Obholzer et al (2004), referred to as the "Charing Cross asymmetry." These rates are shown in Table 4 (top row).

Subsequent rows in Table 4 stratify Group 2 cases by indication for otolaryngology referral (pure-tone asymmetry versus no asymmetry), referral rate to nonotolaryngology specialists, and history (prior otolaryngology evaluation and reported noise exposure). Of this group, 9% (110/1198) of patients had indications that would merit further medical evaluation beyond pure-tone asymmetry. These would include conditions such as dizziness, tinnitus, otalgia, otorrhea, fluctuating or progressive hearing loss, tympanic membrane perforation, ear or head trauma, falls, as so on. Of these, 8% (101/1198) were referred back to other medical providers or were lost to follow-up.

A small subgroup of nine patients (0.75% of patients possibly benefitting from otolaryngology consult) was not referred for further medical evaluation. These patients are detailed in Table 5. Four patients, ranging in age between 85 and 96 yr, were identified as potentially being cochlear implant candidates by the reviewing neurotologist. Two patients had a history of prior ear surgery. One patient with a history of a tympanoplasty displayed no change in hearing thresholds compared to previous test results. The other patient reported an outside diagnosis of otosclerosis and was a long-time hearing aid user. One patient reported vague complaints of dizziness, and no further evaluation was recommended by the audiologist. Another patient reported a past history of sudden bilateral hearing loss following chemotherapy treatment. Binaural hearing aids were recommended. The final patient reported unilateral tinnitus since late adolescence.

The reviewing neurotologist identified 13% (152/1198) of Group 2 patients as having a noteworthy pure-tone asymmetry (Table 4). Only 33 of these cases (3% of 1198) met criteria for the Charing Cross asymmetry, and of these, 12 (1% of 1198) met criteria for an AAO-HNS asymmetry. In 22 cases (2% of 1198) with neurotologist-identified asymmetry, the audiologist recommended that the referring physician initiate an

otolaryngology or other specialty care provider referral. Patients who had the recommendation for otolaryngology evaluation but did not have evidence for that evaluation during the time interval of this study were placed in this group, along with patients referred to other medical providers for follow-up.

Medical records of the remaining 130 patients in this group were reviewed for previous audiology and otolaryngology evaluations. Of these, 51 patients (4% of 1198) were identified as receiving a prior internal otolaryngology evaluation at Mayo Clinic Florida, with 37 (3% of 1198) having a documented history of noise exposure and prior pure-tone asymmetry. The remaining 14 patients (1% of 1198) did not have a noise exposure history but had been evaluated by otolaryngology for their asymmetry at an earlier visit. It is important to keep in mind that the reviewing neurotologist did not have access to these earlier medical records. However, these records were available to the audiologist at the time of evaluation and were only known to the reviewing neurotologist if they were mentioned in the audiologist's report.

In 79 patients (7% of 1198 patients in Group 2) a prior otolaryngology evaluation was not documented. The majority of these patients (64 out of 79) had a history of noise exposure and compatible pure-tone asymmetry based on the evaluating audiologists' judgment. No history of noise exposure was documented in 15 patients (1% of 1198) with pure-tone asymmetry as judged by the reviewing neurotologist. However, only four of these patients (0.3% of 1198) met criteria for a Charing Cross asymmetry, and none met criteria for an AAO-HNS asymmetry (right columns of Table 4). Of the four with a Charing Cross asymmetry, one was offered otolaryngology consult and refused.

Table 6. Asymmetries Not Recognized by the Evaluating Audiologist or the Reviewing Neurotologist

	Audiology "Miss"	Otolaryngology "Miss"
AAO-HNS Asymmetry	1.0%	1.2%
Charing Cross Protocol Asymmetry	2.8%	3.6%

Recognition of hearing asymmetry is important for detecting otologic disease. While otologic disease is rare in the Medicare population (see Table 1), retrocochlear deficits from strokes, vestibular schwannomas or metastatic tumors in the posterior fossa can be fatal. Detection of these conditions requires a high index of suspicion on the part of the clinician. While there were no disagreements in the management of patients with other obvious signs or symptoms of ear disease, patients with asymmetric pure-tone audiograms as solitary findings did result in a high number of disagreements on neurotologist review. Retrospective analysis of audiologist and neurotologist decisions about what constituted an asymmetry did not reveal clear rules. Rather, all providers were using subjective impressions that appeared to be unevenly applied.

One way to compare the performance of audiologists and medical specialists' ability to recognize potentially important hearing asymmetry is to compare each profession's performance against mathematically defined definitions of asymmetry. In this case, we compared audiologist and neurotologist decisions about hearing asymmetry against the AAO-HNS and Charing Cross asymmetry definitions. The percentages of "missed" asymmetries are shown in Table 6. A "miss" was defined as not identifying or mentioning an asymmetry in the audiological report or not noting an asymmetry on neurotology review. The overall "miss" rates between audiology and neurotology are comparable, falling in the 1% range for the relatively conservative AAO-HNS criteria and in the 3% range for the more liberal Charing Cross criteria.

In terms of "hits" for the entire year, only one vestibular schwannoma was detected in this cohort of 1550 Medicare patients. The patient was initially referred to audiology for a hearing evaluation. As a result of audiologist recommendation, this patient was referred on for otolaryngology consultation with subsequent MRI where a 4 mm intracanalicular vestibular schwannoma was diagnosed. We also note that no case of unilateral serous otitis media was identified in this cohort during the interval of this study. Further, no subsequent detection of nasopharyngeal carcinoma or metastatic disease affecting hearing or balance was noted at the time of EMR review (10–22 mo following the study period).

DISCUSSION

Hearing impairment is very common in the elderly population. Allowing Medicare beneficiaries who experience hearing problems to be evaluated by audiologists would seem to direct resources to those providers most likely to provide care for presbycusis hearing loss, while reducing expenses associated with unnecessary specialty evaluations. The argument against direct access has been that, unlike physicians, nurse practi-

tioners, podiatrists, and social workers (who can currently refer patients for audiology evaluations under current Medicare and Medicaid rules), audiologists may not be trained to accurately identify and refer patients with diseases associated with hearing loss (Rogers, 1994; Levine et al, 2001; FDA, 2009; FTC, 2009a, 2009b). Naturally, professional audiological organizations argue that audiologists are adequately trained for these activities and are within their scope of practice (American Speech-Language-Hearing Association [ASHA], 1996; American Academy of Audiology [Academy], 2004). Missing from the debate, to this point, has been evidence. Is there a safety risk to the public by allowing Medicare beneficiaries to have direct access to audiologists for audiological services? The aim of this work has been to collect evidence to answer this question.

We attempted to fairly evaluate audiologists' decision making by having four independent reviewers, two otolaryngologists and two audiologists, analyze the clinical records produced by audiologists and otolaryngologists in the same set of patients in a blinded fashion (Group 1 analysis). The overall agreement of the reviewers was very high and demonstrated inconsequential differences between audiologist- and otolaryngologist-generated treatment plans. Where treatment plans differed (in less than 5% of cases), three distinct types of discrepancies were noted. The most common situation was when audiologists deferred their recommendations to start audiological-based services until medically cleared by otolaryngology review. Second, treatments for topical ear canal skin conditions ("itching ears") were addressed by the otolaryngologist and not the audiologist. This is the custom in our clinic. However, such treatment hardly requires specialty referral unless the condition is associated with ear pain, which has a more complex set of potential causes. Finally, in a small subset of cases, medical management was indicated, as occurred in the settings of SSNHL. Audiologists accurately identified and referred SSNHL cases. However, they did not always document audiological follow-up recommendations. In effect, this was likely the same deferral to the treating physician as mentioned above. Importantly, audiologists did not miss any cases of active otologic disease, and there was strong evidence that audiologists appropriately referred to otolaryngology where there was a reasonable possibility of active ear disease or an otherwise medically treatable condition (see Table 2).

Evaluating the performance of audiologists when patients were not seen in otolaryngology is a more difficult proposition. Potential key pieces of information gleaned through an interactive case history discussion or upon physical examination observations may not be captured in a written document. Moreover, each discipline looks for specific pieces of information to make clinical decisions. Patients in Group 2 did not receive

an otolaryngology evaluation immediately following the audiological evaluation. Thus the reviewing neurotologist had to make decisions regarding the identification of patients possibly benefitting from full otologic evaluation with incomplete discipline-specific information. Additionally, as mentioned in the results section, prior history of otolaryngology evaluation was also unavailable to the reviewing neurotologist in many cases. Finally, by training and position in the health-care system, neurotologists tend to have a high index of suspicion for ear disease, particularly when practicing in a tertiary care setting such as Mayo Clinic Florida. Understandably, all of these factors likely encouraged the reviewing neurotologist to favor aggressive referral for full otolaryngology evaluation in even slightly ambiguous case presentations. Even so, in over 78% (936/1198) of Group 2 cases, audiological evaluation and management was all that was required to manage the Medicare beneficiaries with a complaint of hearing loss, in the reviewing neurotologists' opinion.

Looking even more closely at the data in Table 4, an additional 15% (174/1198) of Group 2 patients were appropriately referred for medical or otolaryngology evaluation for stable hearing asymmetries in the past. This would suggest that over 92% (1110/1198) of Medicare beneficiaries were correctly managed by audiologist-provided evaluation and management. If we further assume that audiologists can determine noise-induced hearing loss as well as otolaryngologists, an additional 64 cases who had presumed noise-induced (typically firearm noise exposure) hearing asymmetries were correctly managed, bringing the total to essentially 98% of cases (1174/1198) correctly managed by the audiologist.

We might ask what evidence is there that the audiologists correctly identified noise-induced hearing asymmetries. There is no way to directly answer this question, and in fact the identification of noise-induced hearing loss is controversial (Dobie, 2008). We can note that all patients with an AAO-HNS asymmetry and no history of noise exposure were referred for further medical evaluation. Only 0.3% of patients (4/1198) demonstrating the more liberal Charing Cross asymmetry were not referred for further evaluation (Table 4, last line). While this seems like a very small number, the error may be associated with significant morbidity or even mortality if a retrocochlear lesion were to be missed.

On the other hand, how likely is it that an otolaryngologist would "miss" an asymmetry? To answer this, we calculated the "miss" rates for AAO-HNS and Charing Cross asymmetries by audiologists and the reviewing neurotologist. The "error" rates are comparable. Both the audiologists and the neurotologist missed 1% of AAO-HNS asymmetries and 3% of Charing Cross asymmetries.

At this point, it is important to consider that there is very little consensus about what constitutes a sig-

nificant hearing asymmetry, a minimum significant change in hearing loss, or what the optimum screening methods should be to detect retrocochlear hearing disorders (Margolis and Saly, 2008). However, these problems apply equally to both otolaryngology and audiology. We believe it would be helpful to calculate these asymmetry scores as part of the standard audiological evaluation to more systematically screen for asymmetric hearing loss. Until more refined methods for determining hearing asymmetry or changes in hearing can be developed, audiologists need to remain cognizant of current red flag indications of medically significant conditions and refer appropriately.

Limits of the Current Study

The professional scope of practice for audiology (ASHA, 1996; Academy, 2004) encompasses many skills and services beyond the assessment and management of hearing problems. We limited our study to look at the relative safety of audiology direct access for patients who complain specifically of hearing impairment. It is beyond the scope of this paper to evaluate the much broader concept of audiology direct access for all aspects of the audiology scope of practice such as the evaluation and management of vestibular disorders.

We also made an assumption about patients seeking services for hearing-related problems as a primary complaint. We compared audiologist decision making against otolaryngologist decision making, which in our integrated setting focused on the detection of otologic, and to a lesser extent, head and neck disease. Because, in an integrated health-care system, primary care providers first evaluate and manage patients, detection of general medical conditions such as heart disease is accomplished prior to referral for evaluation of hearing status. In effect, this means our definition of conditions that cause mortality and morbidity was limited to otologic or related head and neck conditions identified by otolaryngologists. This is not a limitation in the sense that the implicit reason for medical evaluation advocated in statements by the FDA and FTC is that audiologists may miss diseases that affect hearing. The results of this study provide evidence to refute this argument. However, we cannot say the same thing about audiologists' ability to detect heart disease or other general medical problems. This study was not designed to answer this question. Further, we do not propose that audiologists offer this service as part of their scope of practice. Rather, we believe that patients seeking treatments for hearing problems as a primary complaint do not have the expectation that the audiologist will offer general medical services.

Further, we recognize three possible factors that may limit the generalizability of this study. First, the audiology staff at Mayo Clinic may not be representative of the

overall audiology community. In 2007, the audiology staff consisted of two PhD audiologists, three AuD audiologists, and two master's level audiologists. All had access to continuing education in the areas of audiology and medicine, and they work closely with other physicians, most notably otolaryngologists. In our setting, it is relatively easy to have a quick "hallway consult" with an otolaryngologist colleague to discuss a questionable case. These hallway consults clearly offer opportunities to learn preferential referral patterns and improve practice integration.

Second, our documentation standards may not be common among audiologists. Every hearing evaluation summary in our clinic explicitly presents the patients' primary audiological complaint, case history, physical examination, test summary, listing of evaluation impressions, and a treatment plan. This made it easy to compare audiologist and otolaryngologist records. It also facilitates communication between caregivers using the EMR and plays an important role in our departmental information management system by making it easy to conduct clinical research and quality control studies.

This documentation strategy may not be common in all audiology settings. Certainly, when audiologists work in a physician's office and do not see patients independently, such documentation is redundant with the medical examination and time-consuming. This should not be taken as evidence that audiologists do not know how to evaluate or manage patients with hearing loss. On the other hand, we could not find a peer-reviewed report validating audiologist evaluation, management, or documentation performance prior to this study. Indeed, within the current study, there was a group of patients with hearing asymmetry who were previously evaluated for otologic disease by otolaryngology and did not have that piece of evidence documented in the audiological report when the implicit decision to not rerefer to otolaryngology was made (see Table 4, patients with hearing asymmetry). When seen against the context of the entire medical record, such an omission seems trivial. However, in as much as a report may be read in isolation from the entire EMR, it would seem wise to document all evidence supporting a subsequent treatment plan. The absence of this evidence clouds the work actually performed by the audiologist and makes subsequent decision making suspect to the uninformed reviewer. Audiologists should expect that documentation omissions strongly communicate to other health-care providers that audiologists are not performing the cognitive tasks required for competent evaluation and management services beyond administration of a test.

The final factor that may limit generalizability is that, although unlikely, we cannot prove that patients in Group 2 who were not referred to otolaryngology

indeed were free of ear disease. However, we would argue that the risk of ear disease in this group would have to be small given the absence of overt ear symptoms, negative history, negative test results, the absence of subsequently detected disease 18 to 22 mo after the study interval, and the low incidence of ear disease in general. A very small number of cases (<0.3% of Group 2 cases) probably should have seen an otolaryngologist based on the current record review. At the time of this review (6 to 18 mo after the study inclusion dates), none of these four patients has been found to subsequently have ear disease based on the record review.

We also did not see discrepancies in otoscopic results between audiologists and otolaryngologists in Group 1 patients. While otolaryngologists may describe and diagnose middle ear conditions with a precision that audiologists did not duplicate, audiologists did recognize when the otoscopic examination was abnormal and referred for further evaluation (Group 1). Overall then, we feel the weight of evidence does not support the proposition that there was missed disease in Group 2.

Should Mayo Clinic Audiology be considered a special case? Like every employer, we strive to attract, train, and retain the best audiologists available, and we believe we succeed. So on one hand, one may rightly question whether the practice setting and staff are representative of the audiology community. However, this may not be as significant a challenge to generalizability as it may seem on first glance. Audiology training has always emphasized the importance of medical referral. If anything, it has been our experience that audiologists are more likely to over-refer than to under-refer to otolaryngology.

The problem in addressing the broader issue of generalizability is that this specific type of review may not be easily duplicated in other settings. Three specific institutional requirements were necessary to complete this study. First, all authors needed to share a certain degree of trust and honesty among each other. This was possible at the Mayo Clinic Florida because of the institutional ethics of the clinic. Teamwork and placing the needs of the patient first are two important ethics engendered in the clinic. All practitioners are also salaried, removing certain financial obstacles to teamwork.

Second, a common electronic medical record (EMR) and the documentation system were required. The importance of the EMR is not only in facilitating communication between practitioners, it is also in the opportunity it affords to measure outcomes of a medical system, rather than individual practitioners.

Finally, stemming from the systems perspective mentioned above, replicating this study requires a patient load of Medicare beneficiaries that are seen for audiology services with and without concurrent medical referral. The integrated setting in which our audiology practice

works allows for the multidisciplinary evaluation of outcomes in medical patients who may ultimately end up in our hearing aid and aural rehabilitation program, as well patients directly referred or self-referring to the same program. There are probably not many facilities or health-care systems that would have all of the three factors necessary to replicate this study. We can also look to the Veterans Administration experience, which has successfully used audiology direct access as a standard of care for several years. However, a final proof would likely require study of practitioner's performance after implementation of direct access.

Implications of the Present Study

Hearing loss is a common problem among Medicare beneficiaries, affecting 30% of adults between the ages of 65 and 74 yr and 47% of adults over the age of 74 yr. Audiologists are relatively inexpensive yet apparently effective managers of presbycusis hearing loss. In this study of 1550 consecutive cases, 95% of patients seeking services for hearing problems as a primary complaint ultimately received audiological treatment, and 83% (1287/1550) did not require medical evaluation of their ears prior to initiation of an audiological treatment plan. Further, of cases seen by audiologists who potentially could have been referred for further evaluation, between 91 and >99% were referred, depending on the criteria used to warrant referral. A 9% miss rate for patients potentially requiring referrals (worse case assuming 91% correct referral rate) equates with a 2% error rate across all patients seeking evaluation and management of hearing problems, because the base rate for these conditions is low. The error rate is likely substantially lower, as the criteria used to estimate a 9% miss rate is likely too strict (see discussion of Table 4 and asymmetry criteria discussion above). Still, assuming a 2% error rate, this is comparable with the error rates all practitioners demonstrated in detecting pure-tone asymmetries (Table 6). Given this, we submit that within the limits of this study, our data provide compelling evidence that audiologist decision-making (the cognitive skills that underpin evaluation and management services) is comparable to otolaryngologist decision-making when approaching presbycusis hearing loss. In this sense, audiologist direct access does not present a safety risk to Medicare beneficiaries.

Current Medicare regulations effectively prohibit utilization of audiology services in this manner. Audiologist-provided evaluation and management services are not recognized by current Medicare regulations. Audiological services are conceived as a technical "assessment" service under the current Social Security Act (U.S. Social Security Administration, 1995). Medicare only recognizes audiological services as an "other diagnostic test" benefit

and will pay for these services only when they are deemed necessary for physicians or other health-care practitioners. Direct access to audiologists for assessment services and all management services are specifically disallowed (CMS, 2008). This bias (that medical assessment, and specifically assessment by an otolaryngologist, is a prerequisite for management of presbycusis hearing loss) is further engendered in current FDA requirements for the purchase of hearing aids (FDA, 2009) and online advice from the FTC (2009a, 2009b). It is also promoted by AAO-HNS, whose Web site recommends, "Because some hearing problems can be medically corrected, first visit a physician who can refer you to an otolaryngologist (an ear, nose, and throat specialist)."

It is a rare patient who recognizes that they definitely do not have a medically treatable hearing loss. Rather, erring on the "safe side," our health-care system encourages Medicare-eligible patients to seek medical opinion (even specialist opinion) to avoid the risk of missing otologic diseases that are improbable, and most often easily identified on the standard audiological evaluation. Medicare pays the cost of these unnecessary health-care visits, often to specialists, for conditions that cannot be properly evaluated or managed without audiological evaluation. Medicare does not recognize or pay audiologists for the cognitive skills and effort required to detect these same conditions.

As the Medicare population swells (the leading edge of the baby boomer population is predicted to become Medicare eligible in 2011; Medicare enrollment will double in the next 20 yr), managing finite financial resources will become an increasingly important goal for the entire health-care system. Policies that bar the efficient utilization of health-care resources and practitioners, both medical and nonmedical, are not fiscally sustainable.

Based on our experience, audiology direct access would not reduce health-care quality in patients complaining of hearing impairment. In as much as audiologist evaluation and management services would be less expensive than requiring prior physician evaluation for those same services (Freeman and Lichtman, 2005), direct access to audiology services increases value.² It represents a lower cost alternative to the delivery systems engendered in Medicare statute (physician referral) and FDA rules for hearing aids (physician, preferentially specialist referral).

We strongly value the synergy that exists when the disciplines of audiology and otolaryngology work together, and we are convinced that the interaction between our two disciplines enhances quality and cost-effectiveness. Consequently, we expect that audiologists and otolaryngologists will continue to work together in shared clinical settings. However, not all hearing problems may require bidiscipline evaluation and management.

In this study, 95% of Medicare beneficiaries who complain of hearing impairment will ultimately require

audiological services. Moreover, in the majority of cases, audiological services will be all the health-care services these patients will need to address their complaint. We have also shown that, based on the actual audiologist performance, direct access for hearing problems will pose little risk to the Medicare beneficiary population. Audiologist treatment plans for patients complaining primarily of hearing impairment were not substantially different from otolaryngologist plans for the same condition. There was no definitive evidence that audiologists were likely to miss significant symptoms of otologic disease, and there was strong evidence that audiologists referred to otolaryngology when appropriate. These findings are consistent with the premise that audiology direct access for patients complaining of hearing problems would not pose a risk to Medicare beneficiaries and would likely improve value in the hearing health-care delivery system.

Acknowledgments. We would like to acknowledge the help of Larry Lundy, MD, for his opinions and judgments throughout the course of this project. We would also like to thank the three anonymous reviewers for their constructive comments and suggested improvements during the review process of this paper.

NOTES

1. Calculations of asymmetry: American Academy of Otolaryngology—Head and Neck Surgery: Significant pure-tone asymmetry if there is a ≥ 15 dB difference between the average of 0.5, 1, 2, and 3 kHz; Charing Cross: Significant pure-tone asymmetry if there is an asymmetry between two adjacent octave frequencies of greater than 15 dB when the mean thresholds are ≤ 30 dB in the better ear (unilateral hearing loss) or > 20 dB when the mean thresholds are > 30 dB in the better ear (bilateral asymmetrical hearing loss).
2. In this use of the term, “value” implies a ratio of the quality of health care (outcomes of care, service, and safety) per patient cost over time (Smoldt and Cortese, 2007).

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