J Am Acad Audiol 18:151–183 (2007)

A Systematic Review of Health-Related Quality of Life and Hearing Aids: Final Report of the American Academy of Audiology Task Force on the Health-Related Quality of Life Benefits of Amplification in Adults

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Abstract

This is the final report of the American Academy of Audiology Task Force on the Health-Related Quality of Life (HRQoL) Benefits of Amplification in Adults. A systematic review with meta-analysis examined evidence pertaining to the use of hearing aids for improving HRQoL for adults with sensorineural hearing loss (SNHL). Relevant search strings applied to the CENTRAL, CINAHL, Cochrane Reviews, ComDisDome, EBMR, and PubMed databases identified randomized controlled trial, quasi-experimental, and nonexperimental pre-post test designed studies. Sixteen studies met a priori criteria for inclusion in this review. A random-effects meta-analysis showed differential results for generic versus disease-specific HRQoL measures for within- and between-subject designs. Although generic measures used for within-subject designs did not demonstrate HRQoL benefits from hearing aids, mean effect sizes and confidence intervals for within-subject designs and disease-specific instruments suggested that hearing aids have a small-to-medium impact on HRQoL. Further, the between-subject studies supported at least a small effect for generic measures, and when measured by disease-specific instruments, hearing aids had medium-to-large effects on adults' HRQoL. This review concludes that hearing aids improve adults' HRQoL by reducing psychological, social, and emotional effects of SNHL. Future studies should include control groups using randomized controlled trials.

Key Words: American Academy of Audiology Task Force on the Health-Related Quality of Life Benefits of Amplification in Adults, health-related quality of life, hearing aids, hearing loss, meta-analysis, nonacoustic benefits, systematic review

Abbreviations: AAA = American Academy of Audiology; ADPI-VAS = *Auditory Disability Preference Index—Visual Analog Scale;* AHRQ = Agency for Healthcare Research and Quality; CENTRAL = Cochrane Central Register of Controlled Trials; CI = confidence internal; CINAHL = Cumulative Index to Nursing and Allied-Health Literature; ComDisDome = Communication Sciences and Disorders DOME; EBM = evidence-based medicine; EBMR = Evidence-

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Based Medicine Review; EBP = evidence-based practice; EQ-5D = *EuroQoL-5 dimensions;* EQ-VAS = *EuroQoL-Visual Analog Scale;* ES = effect size; EuroQoL = *EuroQoL Group;* GDS = *Geriatric Depression Scale;* HHIA = *Hearing Handicap Inventory for Adults;* HHIE = *Hearing Handicap Inventory for the Elderly;* HRQoL = health-related quality of life; ICF = International Classification of Functioning, Disability, and Health; MOS SF-36 = *Medical Outcome Study 36-item Short-Form Health Survey;* NIH = National Institutes of Health; NSF = National Science Foundation; PTA = pure-tone average; QDS = *Quantified Denver Scale of Communicative Function;* RCT = randomized controlled trial; SELF= *Self-Evaluation of Life Function;* SIGN = Scottish Intercollegiate Guideline Network; SNHL = sensorineural hearing loss; SPMSQ = *Short Portable Mental Status Questionnaire;* WHO = World Health Organization; WHO-DAS II = *World Health Organization-Disability Assessment Schedule*

Sumario

Este es el reporte final del Grupo de Trabajo de la Academia Americana de Audiología en cuanto a los Beneficios en la Calidad de Vida Relacionados con la Salud (HRQoL) en la Amplificación en Adultos. Una revisión sistemática con meta-análisis examinó la evidencia relacionado con el uso de auxiliares auditivos (AA) para mejorar la HRQoL de adultos con hipoacusia sensorineural (SNHL). Pistas relevantes de búsqueda aplicadas a la base de datos de CENTRAL, del CINAHL, Revisiones Cochrane, el ComDisDome, la EBMR y PubMed identificaron estudios aleatorizados controlados, cuasi-experimentales, y estudios con diseño no experimental pre y post prueba. Dieciséis estudios cumplieron los criterios a priori para inclusión en esta revisión. Un meta-análisis de efectos aleatorios mostró resultados diferenciales para medidas de HRQoL genéricas vs. específicas para enfermedad, en diseños inter-sujetos y intra-sujeto. Aunque las medidas genéricas usadas para los diseños intra-sujeto no demostraron beneficios de los AA en HRQoL, los tamaños medios del efecto y los intervalos de confianza para los diseños intra-sujeto y los instrumentos específicos para enfermedad, sugieren que los AA tienen un impacto pequeño a mediano en la HRQoL. Más aún, los estudios entre sujetos apoyaron al menos un pequeño efecto para las medidas genéricas, y cuando se midió para instrumentos específicos de enfermedad, los AA tuvieron un efecto mediano a grande en la HRQoL de los adultos. Esta revisión concluye que los AA mejoran la HRQoL de los adultos, reduciendo los efectos psicológicos, sociales y emocionales de la SNHL. Los estudios futuros deberán incluir grupos de control utilizando estudios aleatorizados controlados.

Palabras Clave: Grupo de Trabajo de la Academia Americana de Audiología en cuanto a los Beneficios de Calidad de Vida Relacionados con la Salud en la Amplificación en Adultos, calidad de vida relacionada con la salud, auxiliares auditivos, hipoacusia, meta análisis, beneficios no acústicos, revisión sistemática

Abreviaturas: AAA = Academia Americana de Audiología; ADPI-VAS = *Índice de Preferencia en Discapacidad Auditiva – Escala Visual Analógica;* AHRQ = Agencia para Investigación en Salud y Calidad; CENTRAL = Registro Central Cochrane de Estudios Controlados; CI = intervalo de confianza; CINAHL = Índice Acumulativo en Literatura en Enfermería y Salud; ComDisDome = Ciencias y Trastornos de la Comunicación DOME; EBM = medicina basada en evidencia; EBMR = Revisión de Medicina Basada en Evidencia; EBP = práctica basada en evidencia; EQ-5D = *5 dimensiones EuroQoL;* EQ-VAS = *EuroQoL – Escala visual Analógica;* ES = tamaño del efecto; EuroQoL = *Grupo EuroQoL;* GDS = *Escala de Depresión Geriátrica;* HHIA = *Inventario sobre Impedimento Auditivo para Adultos;* HHIE = *Inventario sobre Impedimento Auditivo en el Viejo;* HRQoL = calidad de vida relacionada con la salud; ICF = Clasificación Internacional de Función, Discapacidad y Salud; MOS SF-36 = *Forma Corta de la Encuesta de Salud de 36 ítems sobre Resultados Médicos;* NIH = Institutos Nacionales de Salud; NSF = Fundación Nacional de Ciencias; PTA = promedio tonal puro; QDS = *Escala Cuantificada de Denver sobre Función Comunicativa;* RCT = estudio aleatorizado controlado; SELF = *Auto-Evaluación de Función de Vida;* SIGN = Red de Guía Intercolegial Escocesa; SNHL = hipoacusia sensorineural; SPMSQ = *Cuestionario Corto Portátil sobre Estado Mental;* WHO = Organización Mundial de la Salud; WHO-DAS II = *Esquema*

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This is the final report of the American Academy of Audiology (AAA) Task Force on the Health-Related Quality of Life Benefits of Amplification in Adults, which was created by AAA Past President Angela Loavenbruck in 2003. The task force was charged with conducting a systematic review of the evidence available pertaining to the nonacoustic benefits of amplification for adults with sensorineural hearing loss (SNHL).

Hearing loss is a significant public health problem in the United States. It is the third most common chronic health condition, exceeded only by arthritis and hypertension, in persons 65 years of age and older (Healthy People 2010, 2004). Although nearly 20 million Americans over 45 years of age have a hearing loss, less than one-third of them use hearing aids (National Council on the Aging, 1999). The low proportion of adults with hearing loss who use hearing aids is surprising and may indicate that both patients with hearing loss and related health-care professionals are unaware of the potential positive benefits that are available from today's hearing aids. It is especially important to document the benefits of hearing aids, because as the population continues to age and live longer, the number of people with hearing loss will rise and cause an associated increase in the demand for hearing health-care services.

Measuring the success of amplification can be accomplished by considering the World Health Organization's (WHO) International Classification of Functioning, Disability, and Health (ICF; World Health Organization, 2004). Within the ICF framework, the effects of SNHL and treatment outcomes can be examined at the levels of body functions and structures, activity, and participation. Body functions are the physiological and psychological tasks performed by the body systems (e.g., sensing the presence or discriminating the location, pitch, loudness, and quality of sounds), while body structures are the anatomic parts of the body (e.g., organs, limbs, and their components). The most common type of hearing disorder in adults is SNHL, which primarily affects the structures of the inner ear with the most obvious consequences being a loss of hearing sensitivity or auditory impairment.

The negative consequences of adult-onset hearing loss are not limited to an auditory impairment; they can also involve activity limitations and participation restrictions. According to the WHO-ICF, an activity is the execution of a task or action by an individual, and participation refers to involvement in life situations. Activity limitations are changes at the level of the person (e.g., inability to understand conversations), and participation restrictions are the effects of these limitations on broader aspects of life (e.g., withdrawing from social situations). Consequently, reductions in participation can negatively impact an individual's health-related quality of life (HRQoL).

SNHL is one of the few chronic conditions for which, in most cases, there are no effective medical or surgical treatments. However, audiologic intervention is available. The cornerstone of the process of audiologic intervention is the use of amplification through hearing aids, which is aimed at reducing the auditory impairment and optimizing the individual's auditory activities and minimizing participation restrictions (Kiessling et al, 2003).

Using the ICF framework, the benefits of amplification can be assessed by examining reductions in impairments, activity limitations, and/or participation restrictions (Abrams and Hnath-Chisolm, 2000). Both impairment level and acoustic outcomes can be quantified by documenting hearing aid users' aided over unaided improvements in audibility and speech recognition using objective audiologic tests. Acoustic outcomes may translate into reductions in activity limitations that can be documented through the use of subjective self-report measures that assess auditory performance in a variety of listening situations.

At the level of participation, the benefits of amplification are related to reductions in any of the many psychosocial problems associated with untreated SNHL. Documented problems include social isolation, depression, anxiety, and loneliness; lessened self-efficacy and mastery; and stress in relationships when family, friends, and coworkers experience frustration, impatience, anger, pity, and/or guilt while interacting with a person who has a hearing loss (Weinstein and Ventry, 1982; Bess et al,

1989; Uhlmann et al, 1989; Andersson and Green, 1995; Campbell et al, 1999; Keller et al, 1999; National Council on the Aging, 1999; Wayner and Abrahamson, 2001; Kramer et al, 2002). It is well known that mental, emotional, and social consequences of untreated hearing loss in adults can have negative impacts on individuals' overall HRQoL (Bess et al, 1989; Bess et al, 1990; Mulrow et al, 1990; Keller et al, 1999; National Council on the Aging, 1999; Strawbridge et al, 2000; Dalton et al, 2003; Pugh, 2004). Thus, assessing the effects of amplification in terms of changes in HRQoL involves examination of myriad nonacoustic benefits.

HRQoL assessments examine the degree to which people's health status affects their self-perception of daily functioning and well-being. Quantitative measurements of HRQoL can be made using generic and/or disease-specific instruments (National Institutes of Health [NIH], 1993). Generic instruments are broad in scope and applicability, while disease-specific instruments focus on one condition, attempting to define its effects on daily functioning and well-being. Evaluating the benefits of hearing aid use with disease-specific HRQoL instruments is appealing from a clinical perspective, because they are highly responsive to interventions designed to manage a particular disease or disorder (Deyo and Patrick, 1989). Meanwhile, evaluating the benefits of hearing aids with generic HRQoL instruments is a timely endeavor, because there is increased emphasis on their use across a broad range of health-related disciplines. Interest in HRQoL measurement arises from several factors including (1) a shift in the focus from life prolongation to maintenance of an adequate HRQoL as one ages (i.e., living well; not merely living longer), (2) a general agreement about the importance of patients' self-perceptions of health, and (3) the use of HRQoL measures to conduct health status comparisons across different conditions and/or target populations (Ware and Sherbourne, 1992; Ware et al, 1993; McCallum, 1995; Bruley, 1999). Moreover, in this era of evidence-based practice (EBP), increased accountability, and shrinking health-care resources, it is reasonable for administrators, third-party payers, and adults with hearing impairment and their families to ask how different aspects of audiologic treatment impact HRQoL (Abrams and Hnath-Chisolm, 2000).

Within the EBP framework, the systematic and explicit evaluation and synthesis of a body of research evidence about specific diagnostic procedures, medical treatments, and/or rehabilitative interventions is referred to as a "systematic review." According to the Cochrane Collaboration (Higgins and Green, 2005)—which is an international nonprofit and independent organization, dedicated to producing and disseminating up-to-date and accurate systematic reviews of evidence from clinical trials and other studies about the effects of health-care interventions, and to making their findings readily available worldwide—the systematic review process involves:

- assessing amassed evidence about targeted interventions from a foundation of clearly formulated questions;
- systematically using explicit methods to identify, select, critically appraise, and narrow down a vast body of literature to focus in on only the most relevant research pertaining to the topic; and
- collecting, analyzing, aggregating, and interpreting data from pertinent studies to answer the question.

Thus, systematic reviews differ from traditional literature reviews by strictly adhering to scientific design principles, which should result in reviews that are more comprehensive, less likely to be biased, and more apt to be reliable. All systematic reviews allow for a qualitative summary of the results of individual studies to be completed. However, the Cochrane Collaboration (www.cochrane.org) and other organizations that promote the use of EBP, including the Agency for Healthcare Quality and Research (AHRQ; www.ahrq.gov) and the Scottish Intercollegiate Guideline Network (SIGN; www.sign.ac.uk), also encourage the development of quantitative systematic reviews. In a quantitative systematic review, a statistical procedure known as a "meta-analysis" is completed, which allows for the integration of the results of several independent studies. Both qualitative and quantitative systematic reviews can provide more objective appraisals of the evidence on a given topic than traditional reviews. The inclusion of a meta-analysis in a systematic review allows for more precise estimates of treatment effects. Although the importance

of EBP and the systematic review process to audiology received attention in a 2005 special issue of the *Journal of the American Academy of Audiology*, only a few quantitative systematic reviews have been completed, particularly regarding the assessment of the effectiveness of amplification.

The charge of the present AAA task force was to examine HRQoL benefits of hearing aids. To accomplish this goal, the task force members chose to conduct a quantitative systematic review of the evidence assessing the effects of the use of amplification by individuals with SNHL on their HRQoL compared to their unaided condition. The specific objective of this investigation was to determine if the use of hearing aids as compared to not using hearing aids resulted in improvements in HRQoL for individuals with SNHL as measured through both disease-specific and generic instruments.

METHODS

When conducting systematic reviews, it is important for the reviewers to establish at the outset the criteria by which studies will be included or excluded from consideration. The reviewers should pursue their search for relevant articles in the same fashion that a well-controlled research study would be conducted (i.e., the reviewers themselves become the investigators). Customarily, a team of investigators agrees on a number of a priori criteria that must be satisfied by the studies in order for them to be included in a systematic review. For example, the investigators must agree on the types of research designs, participants' age and severity of hearing loss, intervention strategies, and outcome measures. The study selection criteria for the present systematic review are described below.

Study Selection Criteria

Types of Studies

The highest priority was given to studies using a randomized controlled trial (RCT) design. Double-blinded RCTs are the design of choice for examining the efficacy of treatments, because nonrandomized, nonblinded studies may exaggerate the effects of health-care interventions by up to 40% (Schulz et al, 1995). However, if only RCTs are included in a systematic review, then important and relevant information may be lost when comparing participants' data from unaided to aided conditions for at least two reasons. First, participants cannot be blinded to the treatment arm, because there is no practical way of providing a "placebo" when comparing hearing aids as an intervention to no intervention. Second, using random assignment to a delayed treatment condition as a method of control may prolong participants from receiving hearing aid intervention, which could negatively impact their HRQoL. Therefore, to limit the investigation to only RCTs, to the exclusion of other experimental designs, could preclude the recovery of important evidence demonstrating enhanced HRQoL from hearing aids.

A convenient way of summarizing studies' designs is to assign them a level of evidence. Level of evidence refers to the ability of a particular study design to minimize or eliminate bias in the effect being measured. Several different categorization schemes are available for classifying a body of literature in terms of a hierarchy of study design (AHRQ, 2002), and reviewers must determine the most relevant level of evidence hierarchy for the type of health-care procedure under review (Robey, 2004). The hierarchy of evidence used in this study was adapted from the Scottish Intercollegiate Guideline Network (SIGN) system. The SIGN rating system is more detailed than the adapted version used here in that it also assigns pluses and minuses to designate further subcategories within the first two levels of evidence, a stratification that was not deemed to be necessary for this review. Studies accepted for inclusion in this review involved: Level 1—RCTs; Level 2—quasi-experimental controlled trials that used nonrandomized, parallel group, or crossover designs; and Level 3—well-designed nonexperimental studies, particularly those using pre-post test designs with adequate descriptions. Although studies involving less stringent levels of evidence including patient testimonials or expert opinions (Level 4) were used for valuable insight about the HRQoL benefits of hearing aids, they were not considered to be of sufficient rigor for establishing EBP. Table 1 shows the hierarchy of evidence used in this systematic review.

Table 1. Levels of Evidence Used for Rating Studies in This Review as Adapted from the Scottish Intercollegiate Guideline Network (SIGN) System

1	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2	High-quality systematic reviews of case-control or cohort studies High-quality case-control or cohort studies with a very low risk of confounding, bias, or chance, and a high probability that the relationship is causal
2	Well-conducted case-control or cohort studies with a low risk of confounding, bias, or chance, and a moderate probability that the relationship is causal
2	Case-control or cohort studies with a high risk of confounding, bias, or chance, and a significant risk that the relationship is not causal
3	Nonanalytic studies (e.g., case reports, case series)
4	Expert opinion

Types of Participants

In order for studies to meet the inclusion criteria for this review, their participants had to be new or previous hearing aid users of at least 18 years of age with normal cognitive function, independent or assisted living conditions, and SNHL with unaided severity ranging from mild to profound.

Types of Interventions

This review examined the HRQoL benefits of hearing aids; however, it was not designed to compare various technical aspects of the evaluation, selection, and fitting of amplification. Thus, all studies meeting the inclusion criteria were considered regardless of the type of hearing aid style (e.g., behind-the-ear, in-the-ear, completely-in-the-ear, etc.), signal processing circuitry (e.g., analog or digital), microphone technology (e.g., omnidirectional or directional), or fitting strategy (e.g., monaural vs. binaural) they employed.

Types of Outcome Measures

Another criterion for studies to be included in this systematic review was that they employed only previously validated generic and/or disease-specific HRQoL instruments as outcome measures. Recall that HRQoL instruments measure the degree to which participants' health status affects their self-perception of daily functioning and well-being. Generic instruments are applicable across diseases and disorders, while disease-specific instruments are designed for use with a specific patient population. Studies accepted for inclusion in this review employed widely used generic outcome measures, such as the *Medical Outcome Study 36-item Short-Form Health Survey* (MOS SF-36; Ware and Sherbourne, 1992) and the *EuroQoL-5 dimensions* (EQ-5D; EuroQoL Group, 1990). In addition, the systematic review included studies employing disease-specific self-report instruments, such as the *Hearing Handicap Inventory for the Elderly* (HHIE; Ventry and Weinstein, 1982), which measure the effects of hearing loss in the psychological, social, and emotional domains.

Search and Retrieval Process for the Identification of Studies

A full search strategy was developed to identify studies to include in the systematic review. Six of the eight authors were divided into three two-person teams with one of the remaining authors (T.C.) serving as a mediator for differences of opinion in the search and retrieval process, and the other (L.P.) serving as the compiler of search results. One team (H.A. and P.M.) searched non-peer-reviewed journals (e.g., *The Hearing Journal* and *The Hearing Review)* and recent professional conference proceedings to obtain potentially relevant studies. The other two teams (C.J. and J.D., Team 1; and C.N. and S.L., Team 2) conducted database searches of peer-reviewed journals. The reviewers created search strings using terms that were most likely to result in the greatest number of applicable hits from the database searches. Search strings that were used are shown in Table 2.

Table 2. Search Strings Used in the Databases

- Abbreviated Profile of Hearing Aid Benefit (APHAB)
- Amplification and Quality of Life in Adults
- Amplification, Hearing Aids, and Depression
- Amplification, Hearing Aids, and Functional Health Status
- Amplification, Hearing Aids, and Health Status
- Amplification, Hearing Aids, and Interpersonal Relationships
- Amplification, Hearing Aids, and Isolation
- Amplification, Hearing Aids, and Mental Status
- Amplification, Hearing Aids, and Paranoia
- Amplification, Hearing Aids, and Participation
- Amplification, Hearing Aids, and Psychosocial Function
- Amplification, Hearing Aids, and Sadness
- Amplification, Hearing Aids, and Self-Concept
- Amplification, Hearing Aids, and Social Activity
- Amplification, Hearing Aids, and Well-Being
- Amplification, Hearing Aids, and Withdrawal
- Benefit of Amplification in Adults
- Client Oriented Scale of Improvement
- Communication Profile for the Hearing Impaired
- Denver Scale of Communication Function
- Effects of Hearing Aid Use in Adults
- Glasgow Hearing Aid Benefit Profile
- Hearing Aid Benefit in Adults
- Hearing Aid Performance Inventory
- Hearing Aids and Quality of Life in Adults
- Hearing Handicap Inventory for Adults
- Hearing Handicap Inventory for the Elderly
- Hearing Handicap Scale
- Hearing Measurement Scale
- Hearing Performance Inventory
- International Outcome Inventory
- Medical Outcomes Study Short-Form 36 and Amplification
- Medical Outcomes Study Short-Form 36 and Hearing
- Medical Outcomes Study Short-Form 36 and Hearing Aids
- Nonacoustic Benefits of Amplification in Adults
- Nonacoustic Benefits of Hearing Aids in Adults
- Performance Inventory for Profound and Severe Loss
- Profile of Hearing Aid Benefit
- Self-Assessment of Communication
- Shortened Hearing Aid Performance Inventory
- Sickness Impact Profile and Hearing
- Sickness Impact Profile and Hearing Aids
- Sickness Impact Profile and Amplification
- Significant Other Assessment of Communication
- Subjective Measures and Amplification
- Subjective Measures and Hearing Aids
- Weighted Index of Social Hearing Handicap

The databases included the Communication Sciences and Disorders DOME (ComDisDome) searched by Team 1, as well as the Cumulative Index to Nursing and Allied-Health Literature (CINAHL), Evidence-Based Medicine Reviews (EBMR), the Cochrane Central Register of Controlled Trials (CENTRAL), and the Cochrane Database of Systematic Reviews (Cochrane Reviews) searched by Team 2. The ComDisDome taps into PubMed, select journals from the Linguistics and Language Behavior Abstracts for non-PubMed journals, *Seminars in Hearing*, select awarded grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF), dissertations from ProQuest, books from custom-selected multiple publisher sources, author profiles drawn from its own proprietary Scholar Universe database, and custom Web sites. Team 1's search included articles published in peer-reviewed journals since 1980; Team 2's search included those published since 1996. The search was limited to articles published in English, and the database search occurred during July 2004.

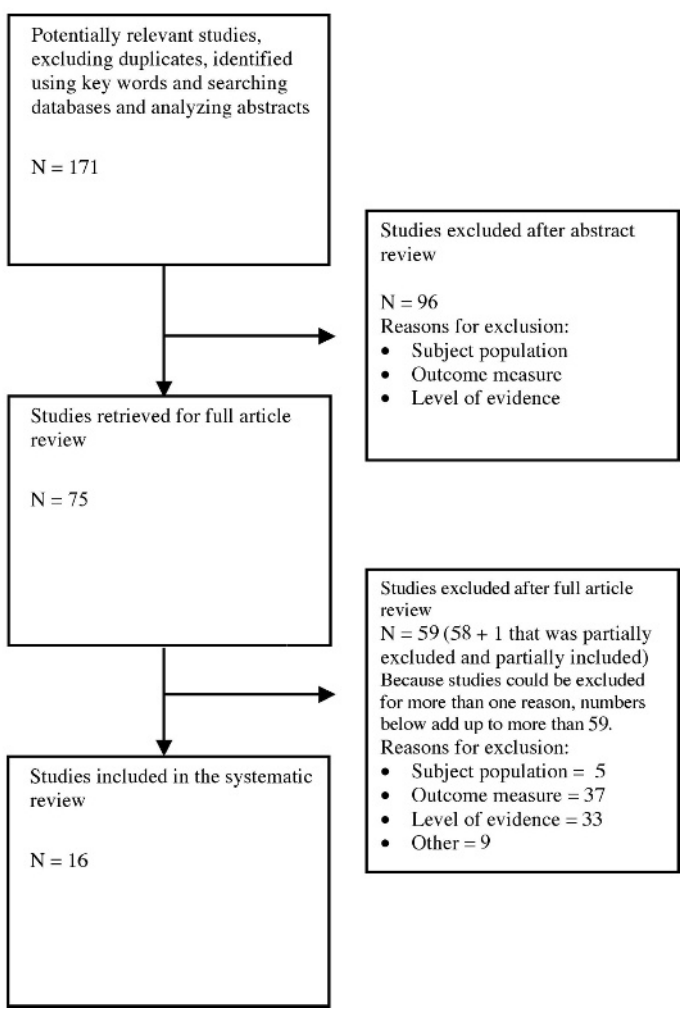

Figure 1. Flow chart for the search and retrieval process for articles to include in the systematic review.

RESULTS

Study Flow

Figure 1 summarizes the search and retrieval process used in this systematic review. Using the key words and databases described above, the search and retrieval process identified 171 relevant abstracts, excluding duplicates. Reviewing the abstracts of all 171 studies revealed that 96 did not meet inclusion criteria, and thus, they were not considered for further review. Recall that articles for inclusion in this systematic review had to involve adult participants with SNHL and use outcome measures assessing HRQoL, and had to be at an appropriate level of evidence. Because a review of the abstracts did not fully reveal whether the remaining 75 studies met inclusion criteria, a full article review was conducted on all 75 of them. These studies were randomly distributed to the three teams for consideration and categorization into included and excluded studies for the systematic review. Team members independently judged the articles with 90% or better interjudge agreement. A third judge (T.C.) settled any disagreements through mediation resulting in a group consensus.

This process yielded 16 articles for inclusion; 58 were excluded from further consideration in this investigation. Note, however, that one (Yueh et al, 2001) of the 16 articles that were categorized as included was excluded from the quantitative analysis because the methods used for reporting the results precluded extraction of the data for use in the meta-analysis conducted as part of this systematic review. However, data from the study were suitable for inclusion in the qualitative analyses, and thus, the Yueh et al (2001) study was listed as one of the 16 included studies. The journal citings for the excluded articles are provided in Appendix A, and Appendix B indicates the reason(s) why each of these studies was excluded from this review.

Study Characteristics

Appendix C provides information about the design methodologies, participant characteristics, and outcome measures used by the 16 studies that were included in this systematic review.

Design Methodology

Only two (Mulrow et al, 1990; Yueh et al, 2001) of the 16 studies used RCTs, a design of the highest level of evidence. The overall designs used in five (Abrams et al, 1992; Newman et al, 1993; Chmiel and Jerger, 1996; Jerger et al, 1996; Primeau, 1997) of the studies were quasi-experimental. Of those, only Abrams and colleagues (1992) used a control group. However, their participants were not randomly assigned to the control and the hearing aid intervention groups. Although the other four of these studies were quasi-experimental, they addressed questions that were not relevant to the present review and, thus, were grouped with the studies that used the pre-post test design. For example, Jerger and colleagues (1996) used a crossover design, in which all participants received each of three treatments, to compare outcomes with conventional hearing aids, assistive listening devices, and both interventions combined. Newman et al (1993), Chmiel and Jerger (1996), and Primeau (1997) used a between-groups comparison in which both groups were fitted with hearing aids and the effects of intervention were examined as a function of group membership. The most common methodology was the nonexperimental pre-post test design, which was used in 13 (the remaining nine plus the four just mentioned) of the 16 studies. For example, Dillon et al (1997) used this design to examine relationships among a variety of outcome measures.

Participant Characteristics

Participant characteristics of age, gender, hearing aid experience, and degree of hearing loss were examined. The hearing aid delivery system used with the participants in each study was also noted.

Age. All but one of the 16 studies used participants whose mean age was 60 years or older. The only exception (Primeau, 1997) compared outcomes for groups of younger and older individuals. The ranges and standard deviations of ages in most of the studies were large and suggested the inclusion of young and middle-aged adults in the samples. For example, Joore et al (2002) and Joore et al (2003) cited a lower age limit of 28 years, while Jerger et al (1996) and

Primeau (1997) reported age limits exceeding 95 years of age. Thus, there was considerable heterogeneity among the participants' ages across the studies.

Gender. Only one study (Dillon et al, 1997) failed to report the gender distribution of its participants. Of the remaining 15 studies, 11 used both male and female participants, while three (Newman and Weinstein, 1988; Abrams et al, 1992; Yueh et al, 2001) used only male participants from Veterans Affairs Medical Centers.

Degree of Hearing Loss. The participants' hearing levels revealed considerable diversity in how these data were collected and presented. For example, most of the studies reported pure-tone averages (PTAs), but the frequencies used in their calculation varied. In addition, some studies reported PTAs for each ear while others only presented them for the ear fitted with a hearing aid, or for the better ear in the case of binaural hearing aid fittings. A few trends emerged despite this variability. For example, although all of the studies reported mean PTAs in the mild-to-moderate range, their standard deviations and ranges revealed that they also included at least some participants whose hearing losses were severe for at least some frequencies. Also, none of the studies appeared to have included participants with PTAs in the profound range.

Hearing Aid Experience. Of the 16 studies, 15 involved new hearing aid users as participants. Of these 15 studies, three included experienced as well as new hearing aid users (i.e., Jerger et al, 1996; Primeau, 1997; Humes et al, 2001). Newman and Weinstein (1988) only included experienced hearing aid users.

Hearing Aid Delivery System. The participants in six of the studies (Newman and Weinstein, 1988; Mulrow et al, 1990, 1992a; Abrams et al, 1992; Primeau, 1997; Yueh et al, 2001) received hearing aids through the Veterans Affairs National Hearing Aid Program. Four of the studies (Dillon et al, 1997; Joore et al, 2002, 2003; Stark and Hickson, 2004) were conducted in countries where hearing aids were provided through national health programs. In the studies by Chmiel and Jerger (1996) and Jerger et al (1996), data were obtained as part of a trial period of hearing aid use. In one study (Newman et al, 1993), half of the participants received hearing aids as part of their medical insurance benefits, and the other half were private pay. In two of the remaining studies (Taylor, 1993; Humes et al, 2001), participants paid out-of-pocket for their hearing aids. Only Malinoff and Weinstein (1989a) did not report how their participants' hearing aids were funded.

Outcome Measures

Nine different outcome measures were used across the 16 studies. Eleven of the studies used a single outcome measure. Several of the studies used self-report measures, which were not considered to assess HRQoL in this review. The remaining five studies used multiple HRQoL instruments. Five generic and four disease-specific instruments were used in these studies. The five generic tools were the EQ-5D (EuroQoL Group, 1990), the *Geriatric Depression Scale* (GDS; Yesavage et al, 1982–83), the MOS SF-36 (Ware and Sherbourne, 1992), the *Self-Evaluation of Life Function* (SELF; Linn and Linn, 1984), and the *Short Portable Mental Status Questionnaire* (SPMSQ; Pfeiffer, 1975). The four disease-specific outcome measures included the *Auditory Disability Preference Index—Visual Analog Scale* (ADPI-VAS; Joore et al, 2002), the *Hearing Handicap Inventory for Adults* (HHIA; Newman et al, 1990), the *Hearing Handicap Inventory for the Elderly* (HHIE; Ventry and Weinstein, 1982), and the *Quantified Denver Scale of Communication Function* (QDS; Tuley et al, 1990).

The EQ-5D, used in two studies (Joore et al, 2002, 2003), is a two-part, self-report questionnaire. The first part assesses five dimensions of HRQoL (i.e., mobility, self-care, usual activities, pain or discomfort, and anxiety or depression) on a three-point ordinal scale. The second part is a 20 cm visual analog scale (EQ-VAS) ranging from 0 (worst imaginable health state) to 100 (best imaginable health state) on which patients estimate their current state of health.

Mulrow et al (1990, 1992a) used the GDS, SELF, and SPMSQ. The GDS is a 15-item

scale scored from 0 to 15 and is commonly used as a screening tool for assessing depression in older individuals. The SPMSQ is a 10-item scale with scores ranging from 1 to 10 for assessing cognitive function. The SELF is a 54-item global scale assessing six domains (i.e., physical disability, social satisfaction, symptoms of aging, depression, self-esteem, and personal control) and provides scores ranging from 54 to 216. Higher scores indicate greater dysfunction on the SELF, GDS, and SPMSQ.

The MOS SF-36, used in two studies (Joore et al, 2003; Stark and Hickson, 2004), is a 36-item questionnaire providing scores in eight domains (i.e., physical function, role-function physical, bodily pain, general health, vitality, social function, role-function emotional, and mental health) with higher scores indicating better functioning. Note that Joore et al (2003) reported on only the MOS SF-36 social function subscale. Raw scores or standardized T-scores can be reported for each of the MOS SF-36 subscales, with lower scores indicating greater dysfunction. Although the subscales of the MOS SF-36 also combine to provide physical and mental component summary scores, they were not reported in the studies reviewed.

The HHIE was the most commonly used disease-specific instrument. The HHIE is a 25-item questionnaire that assesses the impact of hearing loss. It provides scores ranging from 0 to 48 and 0 to 52 for social and emotional subscales, respectively, and combined scores ranging from 0 to 100. The HHIA, used in one study (Primeau, 1997), is nearly identical to the HHIE but has a few items that were modified for patients under 65 years of age. Higher scores on both the HHIE and HHIA scales indicate greater perceived hearing handicap. One study (Dillon et al, 1997) modified the HHIE by reversing the scale so that "0" indicated greater handicap and "4" indicated lesser handicap. Thus, rather than resulting in a score from 0 to 100, their group data were presented on a scale of 0 to 4. In addition, the QDS is a 25-item questionnaire, which yields scores ranging from 0 to 100, with higher scores indicating greater difficulty. The QDS was used in two studies (Mulrow et al, 1990, 1992a), and it assesses both communication and emotional difficulties resulting from hearing loss. Finally, the ADPI-VAS was used in two studies (Joore et al, 2002, 2003). It also results in scores ranging from 0 to 100, with higher scores indicating better functioning.

Study Quality

The quality of the evidence provided by each of the 16 studies was examined by assessing the methods that they used to minimize bias and to control for potentially confounding variables. The level of evidence assigned to each of the 16 studies is shown in column 2 of Table 3.

Other study quality indicators assessed were use of experimental and control groups, equivalence of experimental and control groups at baseline, a power analysis to ensure appropriate sample size, adequate detail of participant inclusion and exclusion criteria, well-described hearing aid fitting and verification protocols, application and reporting of statistical analyses, and accounting for any dropouts of participants from the studies.

Table 3 also shows the evidence levels assigned to each study. Most of the studies provided evidence at Level 3, with only one at Level 2 (Abrams et al, 1992) and two at Level 1 (Mulrow et al, 1990; Yueh et al, 2001). Thus, the quality indicator equivalence at baseline was only applicable in the Abrams et al (1992), Mulrow et al (1990), and Yueh et al (2001) studies. All three of those studies reported that their control and treatment groups were equivalent at baseline for age and hearing loss. Although additional studies used two or more participant groups (e.g., Stark and Hickson, 2004), they did not differ on factors that were relevant for the present review. Only one of the studies (i.e., Stark and Hickson, 2004) reported use of a power analysis.

Table 3 shows that all but four of the 16 studies provided sufficiently detailed participant inclusion and exclusion criteria to permit replication and generalization of their results to a specific population. Only nine of the studies provided sufficient detail about the hearing aid fittings, and all but one of those studies provided information about the verification of the fittings. Recall that this systematic review examined the HRQoL benefits of hearing aids without consideration of the type of fitting or verification procedures. Thus, the studies that did not provide detailed information were still included in the review. In addition, all 16 of the studies were judged to have used appropriate statistical analyses. However, only 10 of the studies mentioned the

Table 3. Quality Assessment of the 16 Studies Included in the Qualitative Analysis for This Systematic Review

Study	Level of Evidence	Control Group	Baseline Equivalence	Power Analysis	Inclusion Exclusion	HA Fit	Verification of HA Fit	Appropriate Statistics	Drop-outs Discussed
Abrams et al (1992)	2	Y	Y	N	Y	N	N	Y	N/A
Chmiel and Jerger (1996)	(2) 3	N	N/A	N	Y	Y	Y	Y	N/A
Dillon et al (1997)	(2) 3	N/A	N/A	N	N	Y	Y	Y	N/A
Humes et al (2001)	3	N	N/A	N	Y	Y	Y	Y	N/A
Jerger et al (1996)	(2) 3	N	N/A	N	Y	Y	Y	Y	N/A
Joore et al (2002)	3	N	N/A	N	Y	N	Y	Y	Y
Joore et al (2003)	3	N	N/A	N	Y	Y	Y	Y	Y
Malinoff and Weinstein (1989a)	3	N	N/A	N	N	N	N	Y	N/A
Mulrow et al (1990)	1	Y	Y	N	Y	N	N	Y	Y
Mulrow et al (1992a)	3	N	N/A	N	Y	N	N	Y	Y
Newman et al (1993)	3	N	N/A	N	N	Y	Y	Y	N
Newman and Weinstein (1988)	3	N	N/A	N	Y	N	N	Y	Y
Primeau (1997)	3	N	N/A	N	N	N	N	Y	N
Stark and Hickson (2004)	3	N	Y	Y	Y	Y	Y	Y	N
Taylor (1993)	3	N	N/A	N	Y	Y	N	Y	N
Yueh et al (2001) This study was used in the qualitative analysis, but not the quantitative analysis.	1	Y	Y	N	Y	Y	Y	Y	N

Note: Level 1 = randomized controlled trials; Level 2 = quasi-experimental; Level 3 = nonexperimental. When two study levels are shown, the one outside of the parenthesis was used for the analyses completed in this review. Y = yes; N = no; N/A = not applicable; HA = hearing aid.

number of participants who did not complete the study (i.e., "dropouts"), and only five of those provided sufficient description of reasons for their participants' failure to complete the protocols.

Qualitative Assessment of Study Results

Effects of Hearing Aid Use on HRQoL as Measured through Generic Instruments

Comparing pre-post test results for dimensions or scales on some of the generic HRQoL measures showed significantly improved health states of participants following hearing aid intervention. For example, Joore et al (2002, 2003) demonstrated reduced anxiety and depression as measured by the EQ-5D for new hearing aid wearers. This finding is consistent with those of Mulrow and colleagues (1990), who found significantly reduced states of depression as measured by the GDS in a group of adults with SNHL who were immediately treated with hearing aids as compared to a control group of peers. Mulrow and colleagues (1990, 1992a) also found positive improvements in mental functioning on the SPMSQ in the same treatment group after hearing aid use as compared to the control group. Additionally, Joore et al (2003) demonstrated greater social functioning post–hearing aid fitting as compared to patients' pretreatment states on the MOS SF-36. However, Stark and Hickson (2004) showed a reduction in social functioning and vitality after their participants were fit with hearing aids compared to their pretreatment

states. Also, Joore et al (2002, 2003) found no significant differences on any of the EQ-5D scales of mobility, self-care, daily activities, or pain/complaints for their participants' pre- and post-hearing-aid scores. In addition, Stark and Hickson (2004) found no significant pre- and post-hearing-aid differences in a group of participants with SNHL as measured by the physical function, role-function physical, bodily pain, general health, role-function emotional, or mental health scales of the MOS SF-36.

Effects of Hearing Aid Use on HRQoL as Measured through Disease-Specific Instruments

Contrary to the findings for the generic instruments, most of the results for the disease-specific HRQoL outcome measures showed strong reductions in the emotional and social impacts of hearing loss for participants as a result of hearing aid use when measured by the HHIE (Newman and Weinstein, 1988; Malinoff and Weinstein, 1989a; Mulrow et al, 1990, 1992a; Abrams et al, 1992; Newman et al, 1993; Taylor, 1993; Chmiel and Jerger, 1996; Jerger et al, 1996; Dillon et al, 1997; Primeau, 1997; Humes et al, 2001; Yueh et al, 2001; Stark and Hickson, 2004) and the HHIA (Primeau, 1997). Additionally, similar significant reductions in participation restriction were obtained on the QDS (Mulrow et al, 1990, 1992a).

Quantitative Assessment (Meta-analysis) of Study Results

Thoughtful, systematic qualitative reviews of research results provide important information. However, conclusions based on qualitative analysis alone cannot substitute for scientific evidence that is gathered through the application of hypotheses-testing logic using meta-analysis. Meta-analysis is the mathematical synthesis of the independent research findings from studies published throughout the literature (Robey and Schultz, 1993). The inclusion of studies for the purposes of meta-analysis is dependent on their reporting of information that is needed to compute an effect size (ES), which is a metric that expresses the overall magnitude of a result. In the present context, all of the studies included in the qualitative analysis, except Yueh et al (2001), provided sufficient information for the calculation of an ES.

A commonly used ES for describing the magnitude of the difference between two means is the difference between means divided by the pooled standard deviation, a ratio that is referred to as "Cohen's *d*" (Cohen, 1988). This ES is calculated by

$$d = \frac{Mean_{g1} - Mean_{g2}}{\sqrt{(SD_{g1}^2 + SD_{g2}^2)/2}} \quad (1)$$

where g = Group.

Although Equation 1 is often used in the calculation of ES, any of several different algebraically equivalent equations can also be used (e.g., Cooper and Hedges, 1994). For the meta-analysis in this review, ES for individual studies was calculated using the mathematical approach recommended by Hunter and Schmidt (1990). Robey and Dalebout (1998) described this approach for application to hearing, speech, and language research and noted that certain quantities must be able to be extracted clearly from the original studies in order to calculate ES. In addition to raw scores or gain scores (means as well as standard deviations or standard errors), pre-post test correlation coefficients, and reliability estimates for the outcome measures are often needed to perform meta-analyses. When these latter values were not available from a study, they were derived from the mean value of those studies that reported such statistics. When studies reported outcomes for any one instrument at more than one measurement interval (e.g., 3, 6, or 12 mo post-hearing-aid intervention), a mean ES was computed for the study as a whole. This was done to minimize a threat to the validity of a meta-analysis, which can arise from the inclusion of ESs that are not independent from each other (Robey and Dalebout, 1998). However, when different outcome measures were used within the same study, they were treated as independent measures. In addition, the meta-analysis was conducted using a random-effects approach because of the heterogeneous nature of the primary studies. Details on differences between fixed-effects and random-effects models of meta-analysis are beyond the scope of this report, but further explanation is provided in Cooper and Hedges (1994).

The individual ES estimates calculated for each of the outcome measures used in the studies are shown in Table 4. The ES estimates are organized hierarchically based on whether the data were obtained from generic or disease-specific outcome measures, then by whether the study design provided between-subjects data (i.e., experimental vs. control group data from Level 1 RCT or Level 2 quasi-experimental designs) or within-subjects data (i.e., pre-post test data from Level 3 nonexperimental designs), and then by study. For each study, two estimates of ES are shown: (1) the unadjusted ES *(d_0)* and (2) the adjusted ES for the reliability of the outcome measure *(d)*.

An important step in conducting a meta-analysis is to examine the ES estimates that are obtained for the potential of publication bias. It is possible that when studies fail to provide data reaching statistical significance, they do not get published. If this occurs, then the studies that are available in the literature for research synthesis might yield ES estimates that are positively biased, because the studies having negative findings are not

Table 4. Unadjusted Effect Sizes *(d_o)* and Effect Sizes Adjusted for the Test-Retest Reliabilities of the Outcome Measure *(d)* as a Function of HRQoL Domain, Design, (and Levels of Evidence in Parentheses), and Outcome Measure for the 15 Studies Used in the Meta-analysis; Yueh et al (2001) Did Not Meet the Criteria for Inclusion

Domain	Design	Outcome Measure	Study	d_o	d
Generic	Between (1–2)	SELF	Mulrow et al (1990)	0.11	0.12
		GDS		0.25	0.27
		SPMSQ		0.42	0.47
	Within (3)	**EQ-5D**: Anxiety/depression	Joore et al (2002)	-0.28	-0.33
		EQ-5D: Mobility		-0.07	-0.07
		EQ-5D: Self-Care		-0.05	-0.06
		EQ-5D: Pain and Complaints		-0.02	-0.03
		EQ-5D: Daily Activities		0.05	0.06
		EQ-5D: Visual Analog Scale		0.09	0.10
		EQ-5D: Daily Activities	Joore et al (2003)	-0.26	-0.31
		EQ-5D: Self-Care		0.02	0.03
		EQ-5D: Pain and Complaints		0.04	0.04
		EQ-5D: Visual Analog Scale		0.06	0.06
		EQ-5D: Mobility		0.06	0.07
		EQ-5D: Anxiety/depression		0.18	0.21
		MOS SF-36: Social Function		0.23	0.28
		SPMSQ	Mulrow et al (1992a)	0.10	0.11
		GDS		0.15	0.16
		MOS SF-36: General Health	Stark and Hickson (2004)	-0.13	-0.15
		MOS SF-36: Vitality		-0.11	-0.12
		MOS SF-36: Physical Function		-0.06	-0.06
		MOS SF-36: Bodily Pain		-0.05	-0.05
		MOS SF-36: Mental Health		-0.02	-0.02
		MOS SF-36: Role-Function Physical		0.03	0.03
		MOS SF-36: Role-Function Emotional		0.09	0.10
		MOS SF-36: Social Function		0.09	0.11
Disease-Specific	Between (1–2)	HHIE	Abrams et al (1992)	0.93	0.95
		QDS	Mulrow et al (1990)	1.90	2.22
	Within (3)	HHIE	Chmiel and Jerger (1996)	0.45	0.46
		HHIE	Dillon et al (1997)	1.35	1.38
		HHIE	Humes et al (2001)	0.76	0.77
		HHIE	Jerger et al (1996)	0.25	0.26
		ADP-VAS	Joore et al (2002)	1.38	1.52
		ADP-VAS	Joore et al (2003)	1.35	1.49
		HHIE	Malinoff and Weinstein (1989a)	1.68	1.72
		QDS	Mulrow et al (1992a)	0.44	0.52
		HHIE	Mulrow et al (1992a)	0.85	0.87
		HHIE	Newman and Weinstein (1988)	1.65	1.68
		HHIE	Newman et al (1993)	1.06	1.09
		HHIE	Primeau (1997)	1.29	1.32
		HHIE	Stark and Hickson (2004)	1.17	1.20
		HHIE	Taylor (1993)	1.06	1.08

available for inclusion in the analysis. Thus, funnel plots are constructed to check for the possibility of negative bias in any group of studies (Greenhouse and Iyengar, 1994). In a funnel plot, the sample size is plotted against the ES. The funnel or triangular shape formed by the data points indicates that, as expected from sampling theory, the magnitude of the ESs obtained from studies having small numbers of participants vary much more than those obtained from studies having larger numbers of participants, but that the ESs for all sample sizes are centering on a single point on the abscissa (Robey and Dalebout, 1998). The funnel plot is examined to determine if the left angle is missing or sparsely populated. If this occurs, then bias is indicated. Examination of funnel plots for studies providing ES estimates in the present meta-analyses revealed that publication bias did not influence the results.

The adjusted ES estimates shown in Table 4 are plotted in Figure 2 along with their 95% confidence intervals (CIs). The effect sizes for each type of data, between and within subjects, were ordered by their magnitude for clarity of presentation in Figure 2. Examination of Table 4 and Figure 2 reveals that ES estimates varied considerably among the studies with the greatest differences being for type of HRQoL outcome measure used. Larger ES estimates were found for disease-specific than for generic outcome measures. For each type of HRQoL measure, ES estimates were larger for between-subject than for within-subject analyses. For many of the generic outcome measures, particularly those obtained from within-subject analyses, the CIs for the individual ES estimates encompassed zero, suggesting that there was no statistically significant effect of hearing aid intervention on HRQoL (i.e., zero is a plausible value for the population ES). In contrast, only two of the ES estimates obtained for disease-specific outcome measures yielded CIs encompassing zero.

One of the advantages of conducting a meta-analysis is that the individual ESs, which are weighted for sample size, can be averaged, thus increasing the accuracy and efficiency with which the population parameter is estimated. That is, effects obtained from small samples do not unduly influence the calculated value of the average (Robey and Dalebout, 1998). Mean ESs and CIs, as a function of HRQoL and data types, were calculated here using the approach recommended by Hedges and Olkin (1985). The results are shown in Figure 3. As would be expected from the individual ES estimates, larger mean ESs were obtained when HRQoL was assessed using disease-specific rather than generic outcome instruments.

The benchmarks proposed by Cohen (1988) were used to interpret ES estimates for studies using between-subjects analyses

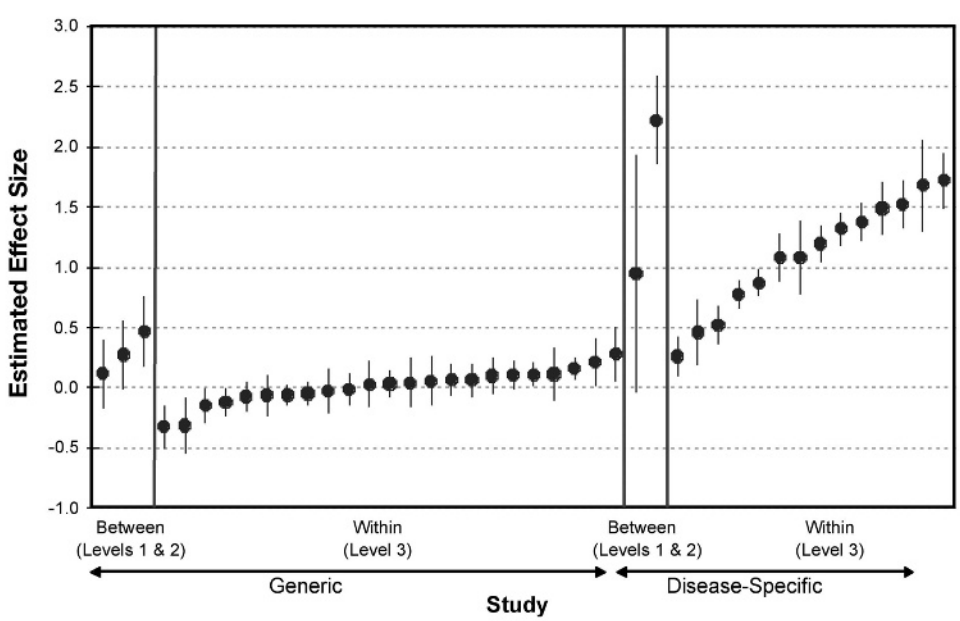

Figure 2. Estimated effect size and confidence intervals (vertical bars) for individual studies by design, level of evidence, and type of outcome measure.

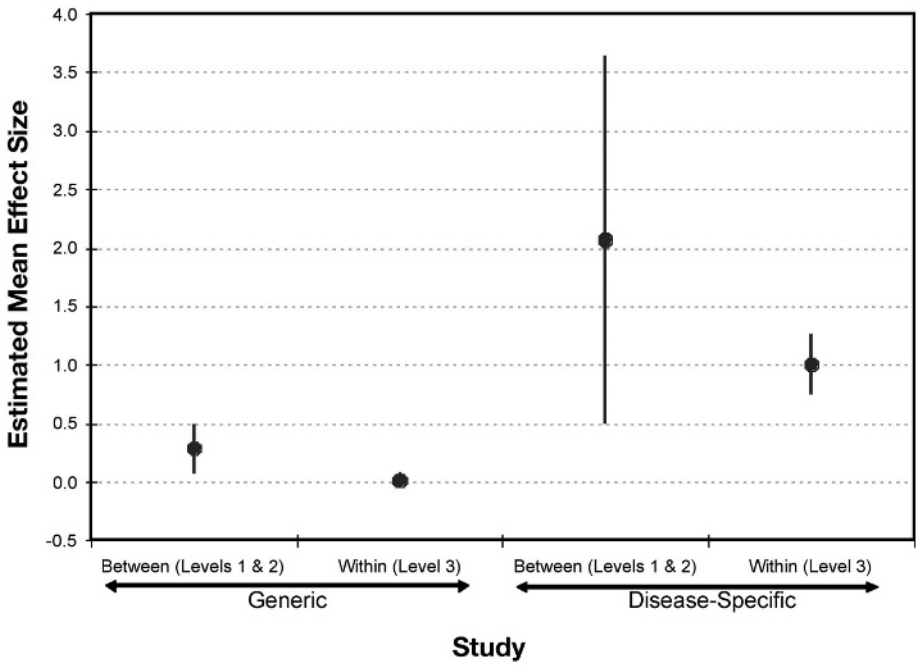

Figure 3. Estimated mean effect sizes and confidence intervals by research design, level of evidence, and type of outcome measure.

for both the generic and the disease-specific outcome measures. These benchmarks are d = 0.20, 0.50, and 0.80 for small, medium, and large effects, respectively. Benchmarks for effects from within-subjects analyses were calculated using a transformation suggested by Barcikowski and Robey (1985):

$$d_{within} = \frac{d_{between}}{\sqrt{1 - r_{pre\text{-}post\ test}}} \qquad (2)$$

The average correlation coefficient calculated for the pre-post test data reported in the studies was r = 0.83, resulting in within-subjects benchmarks of d = 0.48, 1.21, and 1.95 for small, medium, and large effects, respectively. It is important to note that both the benchmarks recommended by Cohen (1988) and the ones calculated for examining ESs from within-subjects analysis provide only a starting point for examination of the effects of hearing aid use on HRQoL. In stating benchmarks, Cohen (1988) made it clear that the values proposed were selected to reflect the typical ESs encountered in the behavioral sciences, and thus they might be misleading when applied to any one specific area. In the absence of discipline-specific benchmarks, however, comparison of a specific effect, such as that of hearing aid intervention on HRQoL, against the broad criterion proposed by Cohen (1988), is considered a reasonable starting point.

The mean within-subjects ES calculated for the generic HRQoL measures was equal to 0.02, with 95% CIs of -0.04 and 0.07. This result suggests that the effect of hearing aid use on HRQoL is essentially negligible. Recall that the within-subjects data were obtained from Level 3, nonexperimental studies, and thus should be interpreted with caution. Indeed, the interpretation is different when the mean between-subjects ES estimate, which was obtained from higher-level studies (i.e., Level 1 and Level 2), is considered. The mean ES of 0.28 with corresponding confidence intervals of 0.09 and 0.48 suggests that hearing aid use may result in a small effect on HRQoL when measured using disease-specific instruments.

In contrast to the results obtained with generic measures, the mean within-subjects ES estimate of 1.01 with 95% CIs of 0.76 and 1.26 obtained for disease-specific outcomes in Level 3 studies supports a conclusion that hearing aids provide a small to medium effect on HRQoL. As with the mean ES estimate obtained for generic HRQoL measures, when the between-subjects data from Level 1 and Level 2 studies are considered, the mean ES estimate is higher (i.e., 2.07 with 95% CIs of

0.51 and 3.63). This result suggests that hearing aids have a robust, medium-to-large effect on HRQoL when outcomes are measured using disease-specific instruments.

DISCUSSION

The present investigation was designed to examine the HRQoL benefits of hearing aids for adults with SNHL by conducting both a qualitative and a quantitative systematic review of the available research literature. In the current era of evidence-based practice, quantitative, meta-analytic, systematic reviews provide a high level of evidence upon which health-care decisions can be made. When the question is one about treatment efficacy, systematic reviews would ideally limit studies for inclusion to those using RCT designs. Of all the experimental designs, RCTs have the least likelihood of introducing any biases that can influence results, particularly when double blinding is used. As demonstrated in the present review, hearing aid research has typically not employed RCTs. In fact, only two of the studies included here used an RCT design, and blinding was not employed in any of the studies. Generally, the hearing aid literature reveals that quasi-experimental designs are commonly used. However, although several studies included in this review employed quasi-experimental designs, only one used that methodology to address the question of concern here. In fact, most of the included studies were judged to be nonexperimental in nature, because they lacked appropriate control groups, which increased the likelihood for bias and limited the usefulness of their findings. Although the data from these latter studies are still useful, the potential for bias can limit making strong recommendations from them, especially if they were the only study designs found. Therefore, in order to strengthen the recommendations that can be made regarding the benefits of HRQoL from the use of hearing aids, future research in this area should strive to include appropriate control groups and the RCT as the optimal strategy.

In addition to the level of evidence and experimental designs employed, quality assessment of studies is important when considering their contribution to the evidence for making clinical decisions about a particular treatment. Quality assessment revealed that the studies included in this systematic review had both weaknesses and strengths. For example, weaknesses in most of the studies involved their failure to include control groups, power analyses to determine appropriate sample sizes, and adequate discussions of dropouts. Strengths observed in the studies involved descriptions of their inclusion/exclusion criteria for participants, hearing aid fitting procedures, verifications of hearing aid fittings, use of appropriate statistical analyses, and, when control groups were used, equivalence of the groups at baseline. Again, attending to these methodological considerations would strengthen future studies.

Although some caution should be taken in interpreting the overall results of this systematic review and meta-analysis, the findings can be helpful in making recommendations about treatments for adults with SNHL. The disease-specific HRQoL measures complemented the qualitative findings of this systematic review and demonstrated a clear and robust positive benefit of hearing aid use. The ES estimates and CIs were in the medium-to-large range for studies using control groups, and the mean ES estimate was in the medium range for those lacking control groups. Thus, the positive findings from both the qualitative and quantitative synthesis of the studies measuring disease-specific HRQoL outcomes are important, because they show that hearing aid use improves the psychological, social, and emotional well-being of adults with acquired SNHL.

The outcomes for hearing aid intervention as measured by generic instruments were also important because these tools can be used to compare treatments for different diseases and disorders. However, because of their broad applicability, outcomes measured with generic instruments are often not as robust as those observed from disease-specific instruments. Indeed, in the body of literature reviewed here, fewer studies reported statistically significant changes in HRQoL as a function of hearing aid use for generic than for disease-specific measures. Further, examination of the corresponding ESs for within-subjects effects on generic measures generally revealed that they failed to provide evidence to support a strong conclusion that hearing aids improve HRQoL. Even so, it was encouraging that the few

studies that provided potentially less biased results due to their inclusion of control groups (i.e., between-subjects effects) had mean ES estimates for generic HRQoL that were at least in the small range.

Considering the known negative impacts that hearing loss has on adults' quality of life (Bess et al, 1989; Mulrow et al, 1990; Keller et al, 1999; National Council on the Aging, 1999; Strawbridge et al, 2000; Dalton et al, 2003; Pugh, 2004), it is reasonable to question why so few studies provide evidence of positive treatment effects resulting from the use of hearing aids when measured by generic instruments. In discussing this issue, Abrams and colleagues (2005) pointed out that most of the available generic health status instruments fail to include any questions that are directly related to hearing and oral communication. Earlier, Bess (2000) noted the lack of sensitivity to hearing aid intervention by many of the generic HRQoL instruments used in the studies included in this systematic review.

Future studies should consider using new outcome measures that are both sensitive to the consequences of hearing loss on HRQoL and responsive to interventions for it. For example, McArdle and colleagues (2005) examined the use of the *World Health Organization-Disability Assessment Schedule* (WHO-DAS II; World Health Organization, 1999), which is a multidimensional tool containing two domain scores (communication and participation) that are specifically related to the consequences of hearing loss and measuring the outcomes of hearing aid intervention. McArdle et al (2005) examined the effects of hearing aid intervention on the WHO-DAS II composite or total score, using a randomized-controlled research design in a study having 380 participants. They reported a statistically significant treatment effect and an ES estimate of $d = 0.20$, which is further evidence that hearing aid use does provide a measurable and consistent, albeit small, effect in terms of generic HRQoL.

Although this quantitative systematic review revealed that hearing aids provide only a small effect on generic HRQoL, it should not be concluded that this might be the case for all patients with hearing loss across all rehabilitative contexts. Recall that the studies included in this review involved participants with different ages, degrees of hearing loss, hearing aid experience, and health-care delivery systems. Moreover, considering the National Council on the Aging (1999) report of untreated hearing loss being associated with depression, anxiety, and social isolation, hearing aids may have a greater impact on generic HRQoL for *some* patients and their families than for others (Van Vliet, 2005). For example, hearing aids may reduce depression in some elderly persons or in those with severe degrees of communication impairment. Future studies should focus on assessing the effects of hearing aid treatment on generic HRQoL using homogeneous groups of participants comparing new versus experienced hearing aid users with specific personality profiles in similar rehabilitative contexts and carefully selected outcome measures (Cox, 2005). In addition, future research should build on the findings from this investigation for deriving contextually appropriate benchmarks to use in audiologic treatment (Cohen, 1988; Kline, 2004).

The findings of this quantitative systematic review are important for at least three reasons. First, conducting systematic reviews with meta-analyses and computing ESs improves upon traditional approaches to intervention research that use null-hypothesis significance testing to assess whether a particular result is statistically significant (Cox, 2005). Null-hypothesis significance testing assesses whether a particular result is statistically significant, with significance translating to possible evidence supporting the use of a given type of intervention. However, statistical significance is dependent on factors like sample size and does not always translate into clinical significance for use in EBP. The use of ESs emphasizes the magnitude of the finding independent of sample size (Cox, 2005). Therefore, audiologists can now confidently say that the use of hearing aids greatly enhances patients' disease-specific HRQoL by reducing the psychological, social, and emotional effects of SNHL and, further, that the strongest evidence supports a conclusion that hearing aids have a positive influence on generic aspects of HRQoL.

Second, in an era of increased accountability and shrinking health-care resources, the results of this quantitative systematic review provide evidence for administrators, third-party payers, and adults with hearing impairment and their families that hearing aid use impacts

positively on HRQoL. Third-party payers often require evidence about the efficacy of medical interventions prior to reimbursement. Although results from disease-specific HRQoL outcome measures preclude comparisons of hearing aids to other interventions, the findings of the meta-analysis serve as convincing evidence of the quality of life enhancement derived from the use of amplification.

Third, the results of this quantitative systematic review revealed that our profession has a relatively good arsenal of disease-specific HRQoL outcome measures that are highly responsive to interventions that are designed to manage SNHL among heterogeneous patient populations (Deyo and Patrick, 1989). Alternatively, there appear to be few generic HRQoL outcome measures available that are likely to be responsive to aspects of hearing aid intervention.

Some possible limitations of the systematic review process should be addressed before drawing conclusions from this report. These limitations include publication bias, heterogeneity of the studies included in the meta-analysis, the time-sensitive nature of the search and retrieval process, and weaknesses of the individual studies. As discussed previously, publication bias can result from the tendency for journals to publish only statistically significant findings. Recall that the search and retrieval process used in this review did include hand searching for unpublished studies in proceedings of recent conferences and studies reported in non-peer-reviewed journals. However, a decision was made to focus on studies published in peer-reviewed journals to enhance the chances of finding support at the highest levels of evidence. Although the exclusion of unpublished data could have biased the results of this systematic review, examination of the funnel plot for the extracted ES measures suggested that it did not.

A good systematic review assesses for the homogeneity of the findings of individual studies that are included in a meta-analysis. Ideally, meta-analyses are conducted with studies having similar characteristics (i.e., designs, participant samples, application of interventions, etc.) and that do not differ in clinically significant ways. Traditional fixed-effects meta-analyses test for heterogeneity using the Q-statistic, which attempts to isolate studies that have homogeneous findings and exclude outlier studies. As stated earlier, the meta-analysis completed here was conducted using a random-effects rather than a fixed-effects approach because of the heterogeneous nature of the studies. The random-effects approach accounts for the differences among all studies when determining the magnitude of an effect. Therefore, the heterogeneity of the studies was accounted for through use of this statistical procedure. Future studies should focus on more homogeneous patient populations for assessing generic HRQoL.

Another limitation of systematic reviews of the published literature is the time-sensitive nature of the search and retrieval process. For example, the search and retrieval process for this systematic review was completed in August 2004. As noted earlier, at least one additional study (i.e., McArdle et al, 2005) that would have met the inclusion criteria has been published since then. Unfortunately, the time cutoff for this systematic review precluded evidence published after August 2004 from being included here. Thus, systematic reviews should be updated regularly in order to insure inclusion of the most up-to-date information on a topic. Despite their ability to provide highly relevant and useful aggregated information on a given topic, published systematic reviews are static and can only present the state of evidence for interventions up to a particular point in time.

Finally, as discussed earlier, systematic reviews only reflect the inherent strengths and weaknesses of the included studies. Only two of the studies included here used RCTs, while most of the investigations used pre-post test designs. Many of the studies that were reviewed here failed to (1) conduct power analyses specifying adequate sample sizes, (2) randomize participants to treatment and control groups, and (3) discuss drop-outs. Investigators addressing the efficacy of audiologic treatment should seek to design high-quality, randomized, double-blinded, controlled clinical trials according to recommended guidelines (CONSORT, 2006a, 2006b). In addition, researchers could facilitate future systematic reviews if they would consistently and fastidiously develop article titles that accurately reflect the true nature of their studies, provide well-constructed abstracts that reveal critical aspects about the design of the study, use

well-selected key words that lead to easy retrieval and evaluation, and report ESs and CIs for their results (CONSORT, 2006a, 2006b). Only studies that provide results at the highest levels of evidence can permit inferences about causality between audiologic treatment and improved outcomes for adults with SNHL.

One way to summarize the results of any systematic review of the literature, while keeping the cautions discussed above in mind, is to assign a grade to the health-care recommendations that result from the evidence. Grading provides an indicator of the extent to which the evidence supports a particular recommendation. Cox (2005) discussed how recommendations from systematic reviews can be used for clinical decision making by assigning them grades of "A," "B," "C," or "D." For example, a grade of "A" suggests that clinicians can be very confident in making the recommendation for a particular intervention, because it is supported by a body of high-quality relevant research. However, a grade of "D" means the recommendation must be made with great caution.

The findings of this quantitative systematic review suggest that a recommendation grade of "B" appears to be warranted for the use of hearing aids to improve adults' HRQoL considering the levels of evidence and quality of the included studies. Moreover, the average ES estimates and CIs discerned from the meta-analysis support a recommendation for the use of hearing aids to improve adults' HRQoL. Improvement is the most likely outcome, particularly when hearing-related effects are directly assessed.

As stated earlier, EBP refers to an approach by which current, high-quality research evidence is integrated with practitioner expertise and patient preferences and values into the process of making clinical decisions (American Speech-Language-Hearing Association, 2004). Systematic reviews with meta-analyses are becoming more common in the audiologic literature and can assist patients, audiologists, primary-care physicians, and other health-care professionals in selecting the most appropriate treatment options for SNHL. However, unlike other chronic health conditions with multiple treatment alternatives, the only viable option for most cases of SNHL is the use of hearing aids, which relegates the clinical decision to one of simply whether to pursue treatment. In doing so, patients and their health-care professionals must weigh the risks and benefits of pursuing amplification, a comparatively noninvasive, low-risk treatment with considerable potential benefits. Indeed, most states now require trial periods for hearing aids so that patients face little financial risk if they are not completely satisfied with the results of their purchase. Therefore, the modest evidence of benefits in HRQoL provided by this systematic review become quite powerful when considering that hearing aid use is the only viable treatment for SNHL, a condition with insidious, potentially devastating effects when left untreated (National Council on the Aging, 1999).

CONCLUSIONS

This systematic review with meta-analysis resulted in the following conclusions:

- Hearing aid use (a comparatively noninvasive, low-risk option with considerable potential benefits, which is the only viable treatment for SNHL) improves adults' HRQoL by reducing psychological, social, and emotional effects of SNHL, an insidious, potentially devastating chronic health condition if left unmanaged.
- The quantitative systematic review process provided a powerful method for assessing the HRQoL benefits of amplification; however, its conclusions are only as robust as the studies that are included in the review, and it is a time-sensitive endeavor that needs to be updated periodically in order to reveal the best and most current evidence for particular treatments.
- Although the field of audiology appears to have a sufficient battery of disease-specific tools, it should strive to use, adapt, or develop generic instruments that are sensitive to and appropriate for assessing changes in hearing aid users' and their families' HRQoL as a result of amplification.
- Researchers should exercise great care in designing, conducting, and

reporting their studies in order to maximize their contributions to EBP.

- Future research in this area should strive to use RCT designs and generic HRQoL measures that are sensitive to the effects of and treatments for hearing loss. Investigators should conduct power analyses, employ both experimental and control groups, use double blinding, adequately describe participant inclusion/exclusion criteria, provide intention-to-treat analyses, discuss dropouts, and compute ESs and CIs for statistically significant results whenever possible.
- The audiologic community, patients with hearing loss and their families, physicians and other health-care providers, and third-party entities should be encouraged that hearing aids can provide considerable HRQoL benefits for the increasing numbers of the population having SNHL.

Acknowledgments. Funding for this work was provided in part by the American Academy of Audiology. The members of the Health-Related Quality of Life Benefits of Amplification in Adults Task Force wish to thank Angela Loavenbruck, Past President of the American Academy of Audiology, for her vision in establishing this group and its mission. We would also like to thank Jeff Kromrey, Ph.D., for his assistance in the completion of the meta-analysis. Additionally, we would like to thank Lindsey Latiolais and Amber Reith for their assistance with compiling the references for this review.

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Appendix A. Excluded Studies

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Appendix B. List of Studies That Were Excluded from This Systematic Review and Reasons for Their Exclusion Based on A Priori Criteria of Participant Population, Outcome Measure, Level of Evidence, and Presence of Study Flaws

STUDY	Participant Population	Outcome Measure	Level of Evidence	Other
Baumfield and Dillon (2001)	Y	N	N	
Beamer et al (2000)	Y	N	N	
Berninger and Karlsson (1999)	Y	N	N	
Bridges and Bentler (1998)	Y	N	Y	
Brooks and Hallam (1998)	Y	N	Y	
Brooks et al (2001)	Y	N	Y	
Cacciatore et al (1999)	Y	Y	Y	Lacked specificity re: participants' characteristics
Cord et al (2000)	Y	Y	N	
Cox and Alexander (1995)	Y	N	Y	
Cox et al (2003)	Y	N	Y	
Crowley and Nabelek (1996)	Y	Y	N	
Cunningham et al (2001)	Y	Y	N	
Dillon et al (1991)	Y	Y	Y	Only figures were provided; no data tables
Dye and Peak (1983)	Y	Y	Y	Multivariate analysis of variance precluded extraction of data from relevant outcome measures
Gatehouse (1994)	Y	Y	Y	No unaided and aided values were provided for comparison
Gatehouse (1999)	Y	Y	N	
Gatehouse and Noble (2004)	Y	N	N	
Haggard et al (1981)	Y	N	Y	Outcome measures were created from existing tools; measurements not provided
Harless and McConnell (1982)	Y	Y	N	
Haskell et al (2002)	Y	N	Y	
Horwitz and Turner (1997)	Y	N	Y	
Humes (2001)	Y	Y	N	
Humes (2003)	Y	Y	N	
Humes and Wilson (2003)	Y	Y	N	
Humes et al (1997)	Y	N	Y	
Humes et al (2002a)	Y	Y	Y	Only figures were provided; no data tables
Humes et al (2002b)	Y	N	Y	
Humes et al (2003)	Y	Y	N	
Hutton and Canahl (1985)	Y	N	Y	
Jerram and Purdy (1997)	Y	N	N	

STUDY	Participant Population	Outcome Measure	Level of Evidence	Other
Jerram and Purdy (2001)	Y	Y	N	
Kochkin (1997)	Y	Y	N	
Kochkin (1998)	Y	N	N	
MacKenzie and Browning (1991)	Y	N	Y	
Mäki-Torkko et al (2001)	N	N	N	
Malinoff and Weinstein (1989b)	Y	Y	Y	Duplicate publication
Marttila and Jauhiainen (1996)	Y	N	Y	
McCarthy (1996)	N	N	N	
Mulrow et al (1992b)	Y	N	N	
Newman and Weinstein (1989)	Y	Y	N	
Newman et al (1991)	Y	Y	N	
Norman et al (1994)	Y	N	Y	
Owens and Fujikawa (1980)	Y	N	Y	
Palmer et al (1999)	Y	N	N	
Parent et al (1997)	Y	N	N	
Parving et al (2001)	Y	N	N	Purpose was to see if participants could complete the questionnaires
Ricketts et al (2003)	Y	N	Y	
Riko et al (1986)	Y	N	Y	
Ringdahl et al (1998)	N	Y	N	
Salomon et al (1988)	Y	N	Y	
Saunders et al (2004)	Y	Y	N	
Schum (1992)	Y	N	N	
Schum (1993)	Y	N	N	
Schum (1999)	Y	N	N	
Surr et al (1998)	Y	N	Y	
Surr et al (1999)	Y	N	Y	
Swan and Gatehouse (1987)	N	N	N	
Taylor and Jurma (1997)	Y	Y	N	
Wesselkamp et al (2001)	N	N	N	
Yueh et al (2001)	Y	Y	Y	Study was used in the qualitative analyses, but reporting methods precluded extraction of data for meta-analysis

Appendix C. Characteristics of Studies That Were Included in This Systematic Review

Study	Design	Participants in Studies Included in the Systematic Review with Meta-Analysis	Outcome Measure(s) and Results	Notes
Abrams et al (1992) Σ	Quasi-experimental, parallel group	N = 20 veterans who were new HA users in two groups HA alone group: 11 Males M age = 71.3 yr. R = 63–82 yr. PTA (in dB HL) for 2000, 3000, 4000, and 8000 Hz M (SD) = Rt: 63.4 (14.5) L: 53.8 (11.8) Control group: 9 Males M age = 63.9 yr. R = 55–71 yr. PTA (in dB HL) for 2000, 3000, 4000, and 8000 Hz M (SD) = Rt: 46.8 (8.0) L: 43.9 (7.4) HAs received at no cost	HHIE • HA alone group pre-post test difference[a] • Control group pre-post test difference[b]	A 3rd group, whose data were not considered, received treatment by HAs plus a 3-week group aural rehabilitation program. Random assignment was made to two treatment groups, but not to the control group. Control group was advised that an HA would be beneficial; however, they were not eligible for HAs through the VA.
Chmiel and Jerger (1996)	Overall study design was quasi-experimental Data used here were from a pre-post test component	N = 63 new HA users 42 had normal performance on the Dichotic Sentence Identification task 29 Males 13 Females M age = 72.4 yr. SD = 5.6 yr. PTA (in dB HL) for 500, 1000, and 2000 Hz M (SD) = Rt: 32.4 (11.5) L: 35.1 (10.2) PTA (in dB HL) for 1000, 2000, and 3000 Hz M (SD) = Rt: 44.8 (10.3) L: 47.3 (9.3) 21 had abnormal performance on the Dichotic Sentence Identification task 13 Males 8 Females M age = 70.3 yr.	HHIE • Within *n* = 63 Ss, pre-post test difference[a]	The Dichotic Sentence Identification (Fifer et al, 1983) task assesses central auditory processing. Study was designed to assess effect of central auditory processing disorder on self-reported HA outcomes using a between-groups design. For this review, only the within-subjects component, where pre- and post-HHIE scores were obtained for baseline and post-HA use, was considered. The HHIE was also administered to significant others.

Study	Design	Participants in Studies Included in the Systematic Review with Meta-Analysis	Outcome Measure(s) and Results	Notes
		SD = 7.1 yr. PTA (in dB HL) for 500, 1000, and 2000 Hz M (SD) = Rt: 33.1 (16.2) L: 37.7 (13.7) PTA (in dB HL) for 1000, 2000, and 3000 Hz M (SD) = Rt: 46.4 (13.1) L: 50.7 (13.8) HAs worn as part of a trial period		
Dillon et al (1997)	Overall study design was correlational Data used here were from a pre-post test component	N = 98 new HA users Gender distribution not given M age = 71 yr. Inter-quartile R = 67–75 yr. PTA (in dB HL) for 500, 1000, and 2000 Hz R = 10–20 dB HL and 70–80 dB HL; Mode = 30–40 dB HL HAs received at no cost	HHIE • Pre-post test difference[a]	Additional subjective measures were administered.
Humes et al (2001)	Pre-post test	N = 173 105 new and 68 experienced HA users 118 Males 55 Females M age = 73.1 yr. SD = 6.5 yr. HAs purchased	HHIE • Pre-post test difference[a]	Additional subjective measures were administered.
Jerger et al (1996)	Overall study design was quasi-experimental Data used here were from a pre-post test component	N = 80 new HA users 50 Males 30 Females M age = 74.3 yr. R = 60–96 yr. Better ear: PTA (in dB HL) for 500, 1000, and 2000 Hz M (R) = 37.4 (16–76) PTA (in dB HL) for 1000, 2000, and 3000 Hz M (R) = 36.8 (18–67) HA worn as part of a trial period	HHIE • Statistically significant difference for all aided relative to unaided conditions, including the conventional HA condition[a]	Crossover design was used to examine outcomes as a function of: conventional HAs, assistive listening devices, and a combination of the two. Only data from conventional HAs were considered. A second group of N = 100 experienced HA users was also examined, but no unaided data were available. Additional subjective measures were administered.

Study	Design	Participants in Studies Included in the Systematic Review with Meta-Analysis	Outcome Measure(s) and Results	Notes
Joore et al (2003)	Pre-post test	N = 81 new HA users 44 Males 37 Females M age = 68 yr. R = 28–95 yr. SD = 11.5 yr. Better ear: PTA (in dB HL) for 1000, 2000, and 4000 Hz M (SD) = 47.4 (9.9) R = 27–80 HAs received at no cost	EQ-5D • Pre-post test difference • Mobility[b] • Self-care[b] • Daily activities[b] • Pain/Complaints[b] • Anxiety/ Depression[a] EQ-VAS • Pre-post test difference[b] ADPI-VAS • Pre-post test difference[a] MOS SF-36 • Pre-post test difference • Social Function[a]	
Joore et al (2002)	Pre-post test	N = 98 new HA users 53 Males 45 Females M age = 67 yr. R = 28–95 yr. Better ear: PTA (in dB HL) for 1000, 2000, and 4000 Hz M (SD) = 46 (10) HAs received at no cost	EQ-5D • Pre-post test difference • Mobility[b] • Self-care[b] • Daily activities[b] • Pain/Complaints[b] • Anxiety/Depression[a] EQ-VAS • Pre-post test difference[b] ADPI-VAS • Pre-post test difference[a]	The ADPI consists of 5 additional questions that assess auditory disability, which were not included in this review. The study was designed to assess "response shift" of baseline scores. In addition to baseline and post-HA use outcomes, individuals were asked to rate their unaided performance after HA use (Then-test). Only baseline and HA data were used.
Malinoff and Weinstein (1989a)	Pre-post test	N = 45 new HA users Gender distribution was not reported. M age = 69.55 yr. R = 55–90 yr. Fitted ear: PTA (in dB HL) for 500, 1000, and 2000 Hz M (SD) = 45.13 (14.4) R = 15–88 No statement about how HAs were received	HHIE • Pre-post test difference[a]	

Study	Design	Participants in Studies Included in the Systematic Review with Meta-Analysis	Outcome Measure(s) and Results	Notes
Mulrow et al (1990)	RCT	N = 193 veterans who were new HA users in two groups Immediate treatment group (ITG) 95 Males M age = 73 yr. SD = 7 yr. Better ear: PTA (in dB HL) for 1000, 2000, and 4000 Hz M (SD) = 53(10) Delayed treatment control group (DTG) 98 Males 1 Female M age = 71 yr. SD = 5 yr. Better ear: PTA (in dB HL) for 1000, 2000, and 4000 Hz M (SD) = 51 (8) HAs received at no cost	HHIE • ITG change score > DTG change score[a] QDS • ITG change score > DTG change score[a] SPMSQ • ITG change score > DTG change score[a] GDS • ITG change score > DTG change score[a] SELF • ITG change score[b] DTG change score[b]	
Mulrow et al (1992a)	Pre-post test	N = 192 veterans who were new HA users 191 Males 1 Female M age = 72 yr. SD = 6 yr. Better ear: PTA (in dB HL) for 1000, 2000, and 4000 Hz M = 52 HAs received at no cost	HHIE • Pre vs. all post change at 4 months[a] 8 months[a] 12 months[a] QDS • Pre vs. all post change at 4 months[a] 8 months[a] 12 months[a] SPMSQ • Pre vs. all post change at 4 months[a] 8 months[b] 12 months[b] GDS • Pre vs. all post change at 4 months[a] 8 months[a] 12 months[a]	Follow-up of Mulrow et al (1990) assessing outcomes at 4, 8, and 12 mo.

Study	Design	Participants in Studies Included in the Systematic Review with Meta-Analysis	Outcome Measure(s) and Results	Notes
Newman et al (1993)	Overall study design was quasi-experimental Data used here were from a pre-post test component	N = 52 new HA users in two groups 26 uninsured 11 Males 15 Females M age = 74.1 yr. R = 65–85 yr. SD = 5.7 yr. Fitted/better ear: PTA (in dB HL) for 500, 1000, and 2000 Hz M (SD) = 34.2 (10) PTA (in dB HL) for 500, 1000, and 4000 Hz M (SD) = 44.3 (23) 26 insured 13 Males 13 Females M age = 75.2 yr. R = 65–86 yr. SD = 6.0 yr. Fitted/better ear: PTA (in dB HL) for 500, 1000, and 2000 Hz M (SD) = 35.6 (10) PTA (in dB HL) for 500, 1000, and 4000 Hz M (SD) = 47.6 (24) 1/2 received HAs via insurance 1/2 paid for HAs	HHIE • Pre-post test difference[a]	Study was designed to assess effect of insurance for HA status on outcomes. This question was addressed with a between-groups design. Only within-subject pre– and post–HA fitting data were considered for this review.
Newman and Weinstein (1988)	Pre-post test	N = 18 experienced, male HA users M age = 70.5 yr. R = 66–84 yr. Better ear: PTA (in dB HL) for 500, 1000, and 2000 Hz M (SD) = 43.1 (20.5) Poorer ear: M (SD) = 56.6 (24.2) HAs received at no cost	HHIE • Pre-post test difference[a]	The HHIE was also administered to significant others.

Study	Design	Participants in Studies Included in the Systematic Review with Meta-Analysis	Outcome Measure(s) and Results	Notes
Primeau (1997)	Overall study design was quasi-experimental Data used here were from a pre-post test component	N = 233 veterans; new and experienced HA users 227 Males 6 Females R age = 27–97 yr. 139 older 58 new HA users and 81 experienced HA users M age: 74 yr. SD = 6 yr. 94 younger 54 new HA users and 40 experienced HA users M age = 54 yr. SD = 14.5 yr. Bilateral: PTA (in dB) for 250, 500, 1000, 2000, 4000, and 8000 Hz Older M (SD) = 54 (14) Younger M (SD) = 44 (13) HAs received at no cost	HHIE • Pre-post test difference[a] HHIA • Pre-post test difference[a]	Study included conductive and sensorineural hearing losses. Only sensorineural data were included for this review. Number of older adults with sensorineural hearing loss was 81 (HHIA) and 123 (HHIE).
Stark and Hickson (2004)	Pre-post test	N = 93 new HA users 76 Males 17 Females M age = 71.7 yr. R = 47–90 yr. SD = 8.6 yr. PTA (in dB HL) for 500, 1000, and 2000 Hz R = <25–55 HAs received at no cost	HHIE • Pre-post test difference[a] MOS SF-36 • Pre-post test difference • Physical Function[b] • Role-Function Physical[b] • Bodily Pain[b] • General Health[b] • Vitality[c] • Social Function[c] • Role-Function Emotional[b] • Mental Health[b]	Significant others were administered a modified version of the QDS and the MOS SF-36.
Taylor (1993)	Pre-post test	N = 58 new HA users 39 Males 19 Females M age = 72.1 yr. R = 65–81 yr. SD = 5.2 yr. Fitted/better ear: PTA (in dB HL) for 2000, 3000, and 4000 Hz M (SD) = 34.5 (7.7) R = 25–55 HAs purchased	HHIE • Pre-post test difference[a]	

Study	Design	Participants in Studies Included in the Systematic Review with Meta-Analysis	Outcome Measure(s) and Results	Notes
Yueh et al (2001) This study was used in the qualitative analysis, but not the quantitative analysis.	RCT	N = 60 male veterans who were all new HA users in four groups Control group 15 Males M age = 67 yr. R = 52–85 yr. PTA (in dB HL) M (SD) = Rt: 32.8 (3.7) L: 33.3 (5.0) Assistive Listening Device (ALD) group 15 Males M age = 66.6 yr. R = 53–79 yr. PTA (dB HL) M (SD) = Rt: 32.6 (5.6) L: 32.4 (4.7) Standard HA group 15 Males M age = 72.1 yr. R = 53–82 yr. PTA (in dB HL) M (SD) = Rt: 34.6 (5.8) L: 33.0 (6.1) Programmable HA group 16 Males M age = 68.5 yr. R = 50–86 yr. PTA (in dB HL) M (SD) = Rt: 31.5 (7.2) L: 31.0 (6.9) HAs received at no cost	HHIE • Pre-post test difference[a]	Additional self-report measures were administered, but only the HHIE was considered an HRQoL measure for this review. Diary data were considered HRQoL qualitative data. Data from all groups except ALD were relevant for the present analysis. Frequencies for PTA were not specified.

Note: HA = hearing aid; L = left ear; M = mean; N = number; R = range; Rt = right ear; SD = standard deviation; Ss = subjects; VA = Veterans Affairs.

[a]Statistically significant increase in HRQoL.
[b]No significant change in HRQoL as a function of hearing aid use.
[c]Statistically significant decrease in HRQoL.