Evidence Report

Hearing, Vestibular Function, and Commercial Motor Vehicle Driver Safety (Expedited Review)

Presented to

The Federal Motor Carrier Safety Administration

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Prepared for

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Policy Statement

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Executive Summary

Purpose of Evidence Report

Of all occupations in the United States, workers in the trucking industry experience the third highest fatality rate, accounting for 12 percent of all worker deaths. About two-thirds of fatally injured truck workers were involved in highway crashes. According to statistics from the United States Department of Transportation (DOT), there were 4,932 fatal crashes involving a large truck in 2005 for a total of 5,212 fatalities. In addition, there were 137,144 nonfatal crashes; 59,405 of these resulted in an injury to at least one individual (for a total of 89,681 injuries).

The purpose of this evidence report is to address several key questions posed by the Federal Motor Carrier Safety Administration (FMCSA). Each of these key questions was developed by the FMCSA to provide useful information in updating the organization's current medical standards and fitness-to-drive examination guidelines. The five key questions addressed in this evidence report are as follows:

Key Question 1: Are individuals with hearing thresholds of 40 dB or greater at 500 to 3,000 Hz at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have a hearing impairment?

Key Question 2: Is the forced-whisper test a valid measure of hearing ability?

Key Question 3: Are individuals with a vestibular dysfunction (any condition that causes dizziness and/or vertigo, including Ménière's disease and benign paroxysmal positional vertigo [BPPV]) at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have a vestibular dysfunction?

Key Question 4: How long after the most recent episode of vertigo until it is safe to drive?

Key Question 5: Which treatments have been shown to effectively treat individuals with Ménière's disease?

Identification of Evidence Bases

Separate evidence bases for each of the key questions addressed by this evidence report were identified using a process consisting of a comprehensive search of the literature, examination of abstracts of identified studies in order to determine which articles would be retrieved, and the selection of the actual articles that would be included in each evidence base.

Several electronic databases including Medline, PubMed (pre Medline), EMBASE, PsycINFO, CINAHL, TRIS, and the Cochrane Library were searched (through August 26th, 2007). In addition, we examined the reference lists of all obtained articles to identify relevant articles not identified by our electronic searches. Hand searches of "gray literature" were also performed. Admission of an article into an evidence base was determined by formal retrieval and inclusion criteria that were determined *a priori.*

Grading the Strength of Evidence

Our assessment of the quality of available evidence that addressed each key question was not restricted to an assessment of the quality of individual studies; we also considered the interplay between the quality, quantity, robustness, and consistency of the overall body of evidence.

Presentation of Findings

In presenting our findings, we make a clear distinction between qualitative and quantitative conclusions and we assigned a separate "strength of evidence" rating to each conclusion format. The strength of conclusion ratings assigned to these different types of conclusion is defined in Table 1.

Table 1. Strength-of-Evidence Ratings for Qualitative and Quantitative Conclusions

Strength of Conclusion	Interpretation
Qualitative Conclusion	
Strong	Evidence supporting the qualitative conclusion is convincing. It is highly unlikely that new evidence will lead to a change in this conclusion.
Moderate	Evidence supporting the qualitative conclusion is somewhat convincing. There is a small chance that new evidence will overturn or strengthen our conclusion. ECRI Institute recommends regular monitoring of the relevant literature for moderate-strength conclusions.
Minimally acceptable	Although some evidence exists to support the qualitative conclusion, this evidence is tentative and perishable. There is a reasonable chance that new evidence will either overturn or strengthen our conclusions. ECRI Institute recommends frequent monitoring of the relevant literature.
Insufficient	Although some evidence exists, the evidence is insufficient to warrant drawing an evidence-based conclusion. ECRI Institute recommends frequent monitoring of the relevant literature.
Quantitative Conclusion (Stability of Effect Size Estimate)	
High	The estimate of treatment effect in the conclusion is stable. It is highly unlikely that the magnitude of this estimate will change substantially as a result of the publication of new evidence.
Moderate	The estimate of treatment effect in the conclusion is somewhat stable. There is a small chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI Institute recommends regular monitoring of the relevant literature.
Low	The estimate of treatment effect included in the conclusion is likely to be unstable. There is a reasonable chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI Institute recommends frequent monitoring of the relevant literature.
Unstable	Estimates of the treatment effect are too unstable to allow a quantitative conclusion to be drawn at this time. ECRI Institute recommends frequent monitoring of the relevant literature.

Evidence-Based Conclusions

Key Question 1: Are individuals with hearing thresholds of 40 dB or greater at 500 to 3,000 Hz at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have a hearing impairment?

Three articles describing three unique studies met the inclusion criteria for Key Question 1. One of the three studies was graded as low quality. The remaining two studies were graded as moderate quality. None of these studies enrolled distinct populations of commercial motor vehicle (CMV) drivers. Instead, the three studies included private motor vehicle license holders, an unknown number of whom may have held commercial driver licenses. Conclusions from the findings of our analysis of the data extracted from the three studies are presented below:

- **Whether hearing loss (defined as a hearing threshold of 40 dB or greater at 500 to 3,000 Hz) is a risk factor for crash among CMV drivers cannot be determined at the present time.**

  No studies that examined the relationship between hearing loss and crash risk among CMV drivers were identified by our searches.

- **Evidence from the private driver license holder population does not support the contention that individuals with hearing impairment are at an increased risk for a crash (Strength of Conclusion: Minimally Acceptable).**

  One retrospective cohort study (Quality Rating: Low) reported on the incidence of crashes occurring among populations of individuals with hearing impairment and prevalence of crashes occurring among individuals without hearing impairment. This study did not provide evidence to support the contention that individuals with hearing deficits are at an increased risk for a motor vehicle crash.

  Two further studies, both of which were case-control studies (Quality Rating: Moderate), reported on the difference in the prevalence of hearing impairment among cohorts of individuals who have experienced a motor vehicle crash and comparable cohorts of individuals who have not experienced a crash. Consistent with the findings of the retrospective cohort study, neither study found evidence to support the contention that individuals with hearing impairment are at an increased risk for a crash.

Key Question 2: Is the forced-whisper test a valid measure of hearing ability?

- **The forced-whisper test is a viable tool for screening for hearing loss; however, it suffers from a number of shortcomings that limit its value as a diagnostic tool. (Strength of Conclusion: Moderate).**

  Four studies compared the performance of the forced-whisper test to pure-tone audiometry. Three of the included studies (all of low quality) found that the forced-whisper test had high sensitivity and specificity for accurately identifying individuals who have a hearing impairment. All three of these studies failed to control for a number of important attributes associated with the forced-whisper test. The fourth included study was a high-quality study in which the forced-whisper test was compared to pure-tone audiometry under tightly controlled conditions (i.e., controlling for many of the potential weaknesses associated with the forced-whisper test). Consistent with the findings of the other three studies, this study found that the forced-whisper test had a high sensitivity; however, unlike the other studies, the specificity of the forced-whisper test was found to be low.

  The finding that the forced-whisper test has a high sensitivity but a low specificity is important because it means that, while the test can pick up most individuals with hearing loss, it will also label many individuals with normal hearing as being hearing impaired. Thus, while the forced-whisper test may be considered as a good screening test for hearing impairment, it should not be considered as being diagnostic for the disorder.

Key Question 3: Are individuals with a vestibular dysfunction (any condition that causes dizziness and/or vertigo, including Ménière's disease and benign paroxysmal positional vertigo [BPPV]) at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have a vestibular dysfunction?

- **Whether vestibular dysfunction (defined as any condition that causes dizziness and/or vertigo, including Ménière's disease and benign paroxysmal positional vertigo [BPPV]) is a risk factor for crash among CMV drivers cannot be determined at the present time.**

  No studies that examined the relationship between vestibular dysfunction and crash risk among CMV drivers were identified by our searches.

- **No evidence-based conclusion pertaining to crash risk in drivers with vestibular dysfunctions can be drawn at the present time.**

  A single, low-quality, retrospective cohort study examined driving performance among individuals with vestibular dysfunctions and a comparable group of individuals who did not have vestibular dysfunctions. The study investigators stated that individuals with vestibular dysfunctions reported crashes at a rate that did not differ from normal subjects. However, they did not report the actual crash data, which prevented us from drawing an evidence-based conclusion pertaining to crash risk in individuals with vestibular dysfunctions.

  The investigators found that individuals with vestibular dysfunctions did have more difficulty performing several driving challenges when compared to individuals who do not have vestibular dysfunctions. This indirect evidence suggests that it is at least plausible that individuals with vestibular function may be at increased risk for a crash. This being said, we require that an evidence base consist of at least two studies before we are willing to consider drawing an evidence-based conclusion. Consequently, we refrain from drawing a conclusion at this time.

Key Question 4: How long after the most recent episode of vertigo until it is safe to drive?

- **No evidence-based conclusion pertaining to the length of time needed, following an episode of vertigo, for an individual to be considered safe to drive can be drawn at the present time.**

  No studies that were designed to assess the time course of changes in measures of crash risk or difficulties in driving among individuals following an episode of vertigo were identified that met our inclusion criteria.

Key Question 5: Which treatments have been shown to effectively treat individuals with Ménière's disease?

Acute episodes of Ménière's disease tend to occur in clusters (between 6 and 11 clusters per year), and remission may last several months. During the first few years after presentation, episodes have been seen to occur with increasing frequency followed by a decrease in association with a sustained deterioration in hearing. In many cases, attacks of vertigo stop completely. In addition, there is evidence of a significant placebo effect in Ménière's treatment. Because of the fluctuating, progressive, and unpredictable natural history of Ménière's disease, placebo-controlled trials addressing this question are

needed. Therefore, we looked for double-blind, placebo controlled, randomized controlled trials (RCTs) to address this question.

- **Current evidence does not provide support for the contention that diuretics are effective in the treatment of vertigo and hearing loss in individuals with Ménière's disease (Strength of Conclusion: Minimally Acceptable).**

  Our searches identified one systematic review that evaluated the impact of diuretics on vertigo and hearing loss in individuals with Ménière's disease. This review concluded that there is insufficient evidence to support the contention that diuretics represent an effective treatment for individuals with Ménière's disease. No further studies were identified by our searches that would change this conclusion at this time.

- **Betahistine appears to be effective in reducing vertigo (but not hearing loss) among individuals with Ménière's disease (Strength of Conclusion: Moderate).**

  Data from a high-quality systematic review and a single, high-quality RCT published after the search period covered by the systematic review were used to determine whether betahistine represents an effective treatment for individuals with Ménière's disease. Six RCTs were included in the systematic review. No trial met the highest quality standard set by the review because of inadequate diagnostic criteria or methods, and none assessed the effect of betahistine on vertigo adequately. Most trials suggested a reduction of vertigo with betahistine; however, the authors of the systematic review noted that this effect may have been caused by bias in the methods. None of the trials showed any effects of betahistine on hearing loss. The findings of the one RCT not included in the systematic review mirror the findings of the RCTs included in the systematic review in that the study reported a reduction in vertigo with betahistine, but like the RCTs included in the systematic review, this effect may have been caused by bias in the methods (such as allocation bias, attrition bias, compliance to treatment, and outcome assessment).

- **No evidence-based conclusion pertaining to the impact of diphenidol on vertigo and hearing loss in individuals with Ménière's disease can be drawn at the present time.**

  The evidence base for this treatment consisted of a small (n = 24), double-blind, placebo-controlled RCT. The results of this study showed a higher incidence of improvement in equilibrium functioning and symptoms during diphenidol administration than during placebo, with no change in hearing among individuals with Ménière's disease. However, this single small study was insufficient to allow an evidence-based conclusion.

- **No evidence-based conclusion pertaining to the effect of intratympanic gentamicin on vertigo and hearing loss in individuals with Ménière's disease can be drawn at the present time.**

  Data from a systematic review, a meta-analysis, and a small (N = 22), moderate-quality RCT not covered by the systematic review or meta-analysis were used to determine whether intratympanic gentamicin represents an effective treatment for individuals with Ménière's disease.

Thirty-five articles were included in the systematic review, and 15 articles were included in the meta-analysis. Both the systematic review and meta-analysis consisted of non-RCTs, which by the authors' own admission increases the likelihood of significant bias. The systematic review reported that the application of intratympanic gentamicin resulted in complete or substantial vertigo control in 89% of individuals with Ménière's disease; however, hearing was worsened in 26% of individuals. Similarly, the meta-analysis reported that the application of intratympanic gentamicin resulted in complete vertigo control in 74.7% of individuals with Ménière's disease, and complete or substantial control in 92.7% of individuals, while hearing level and word recognition were not adversely affected. Because of the progressive and unpredictable natural history of Ménière's disease, double-blind, placebo-controlled RCTs are necessary for addressing this question. As stated above, neither review consisted of these types of trials, thus increasing the likelihood that the effects reported in these reviews may have been caused by biases in the methods. Consequently, we refrain from drawing any conclusion at this time regarding the effect of intratympanic gentamicin on vertigo and hearing loss in individuals with Ménière's disease.

The single double-blind, placebo-controlled RCT examined the therapeutic value of intratympanic gentamicin in individuals with Ménière's disease. The findings of this small (n = 22), moderate-quality study suggest that intratympanic gentamicin is effective in reducing the number of vertiginous attacks among individuals with Ménière's disease. However, there was also a large reduction in vertiginous attacks in the placebo arm of this trial, which only emphasizes the importance of the need for placebo-controlled trials when evaluating the impact of treatments of the symptoms associated with Ménière's disease. Additionally, we require that an evidence base consists of at least two studies before we are willing to consider drawing an evidence-based conclusion. Consequently, we refrain from drawing any conclusion at this time regarding the effect of intratympanic gentamicin on vertigo and hearing loss in individuals with Ménière's disease.

- **No evidence-based conclusion pertaining to the effect of endolymphatic sac shunt surgery on vertigo and hearing loss in individuals with Ménière's disease can be drawn at the present time.**

  The evidence base for this treatment consisted of a single double-blind, placebo-controlled RCT with different follow-up times (1 year, 3 years, and 6 to 8 years). While the results of this study do not support the contention that endolymphatic sac shunt surgery is no more effective in the treatment of vertigo and hearing loss among individuals with Ménière's disease than placebo, we note that we require that an evidence base consists of at least two studies before we are willing to consider drawing an evidence-based conclusion. Consequently, we refrain from drawing a conclusion at this time.

Preface

Organization of Report

This evidence report contains three major sections: 1) *Background*, 2) *Methods*, and 3) *Evidence Synthesis*. These major sections are supplemented by extensive use of appendices.

In the *Background* section, we provide background information about hearing loss, vestibular function, and driving. Also included in the background section is information pertaining to current regulatory and guidelines from the FMCSA and three other government transportation safety agencies: the Federal Aviation Administration (FAA), the Federal Railroads Administration (FRA), and the Maritime Administration. In addition, we summarize equivalent information from several other countries that are generally considered to have well-developed medical fitness programs. In the *Methods* section, we detail how we identified and analyzed information for this report. The section covers the key questions addressed, details of literature searching, criteria for including studies in our analyses, evaluation of study quality, assessment of the strength of the evidence base for each question, and methods for abstracting and synthesis of clinical study results. The *Evidence Synthesis* section of this report is organized by Key Question. For each question, we report on the quality and quantity of the studies that provided relevant evidence. We then summarize available data extracted from included studies either qualitatively or, when the data permit, qualitatively and quantitatively (using meta-analysis). Each section in the *Evidence Synthesis* section closes with our conclusions based on our assessment of the available evidence.

Scope of Report

Commercial driving is a hazardous occupation. The trucking industry has the third-highest fatality rate (12% of all occupation-related deaths) in the United States. About two-thirds of fatally injured truck workers were involved in highway crashes. According to the U.S. Department of Transportation (DOT), there were 137,144 nonfatal crashes involving a large truck in 2005. 59,405 of those crashes resulted in an injury to at least one individual, for a total of 89,681 injuries. 4,932 of all crashes caused 5,215 fatalities.

The purpose of this evidence report is to address several key questions posed by the FMCSA. Each of these key questions was carefully formulated by FMCSA such that its answer will provide information to the FMCSA necessary for the process of updating its current medical examination guidelines. The key questions addressed in this evidence report are as follows:

Key Question 1: Are individuals with hearing thresholds of 40 dB or greater at 500 to 3,000 Hz at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have a hearing impairment?

Key Question 2: Is the forced-whisper test a valid measure of hearing ability?

Key Question 3: Are individuals with a vestibular dysfunction (any condition that causes dizziness and/or vertigo, including Ménière's disease and benign paroxysmal positional vertigo [BPPV]) at an

increased risk for a motor vehicle crash when compared to comparable individuals who do not have a vestibular dysfunction?

Key Question 4: How long after the most recent episode of vertigo until it is safe to drive?

Key Question 5: Which treatments have been shown to effectively treat individuals with Ménière's disease?

Background

Commercial driving is a hazardous occupation. The trucking industry has the third-highest fatality rate (12% of all occupation-related deaths) in the United States (http://www.bls.gov/iif/oshcfoiarchive.htm#2004charts). About two-thirds of fatally injured truck workers were involved in highway crashes. According to the U.S. DOT, there were 137,144 non-fatal crashes involving a large truck in 2005. 59,405 of those crashes resulted in an injury to at least one individual, for a total of 89,681 injuries. 4,932 of all crashes caused 5,215 fatalities (http://ai.volpe.dot.gov/CrashProfile/CrashProfileMainNew.asp?dy=2005).

Hearing loss may contribute to the potential for crash, injury, and death. The purpose of this evidence report is to assess and summarize the available data pertaining to the relationship between hearing loss and motor vehicle crash risk.

Hearing

Hearing consists of the system by which sound energy (or 'waves') is processed by the ear via air conduction and bone conduction into electrical signals that are transmitted through the auditory nerve to the brain and translated into what we understand as speaking, music, or other "noise," along with their volume (measured in decibels, or dB) and pitch.

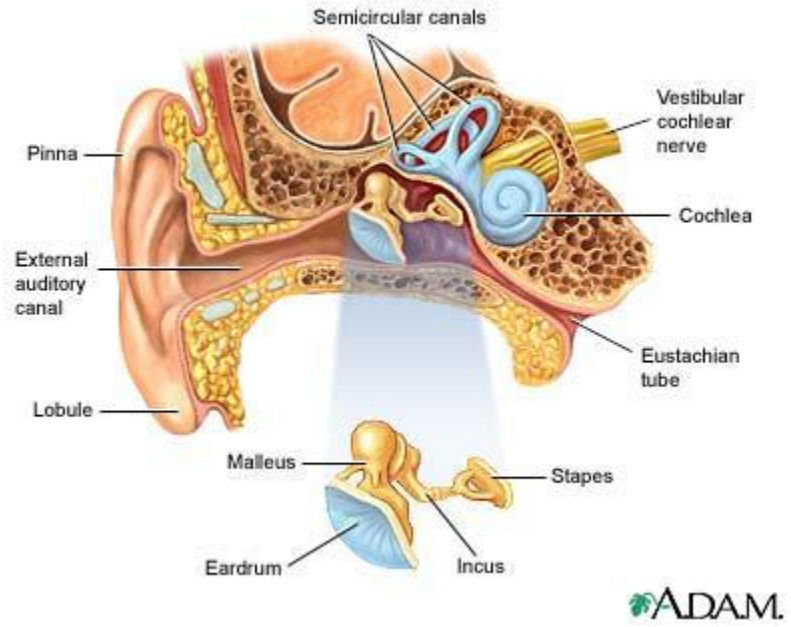
Air Conduction

The ear consists of three parts: the outer ear, the middle ear, and the inner ear (See Figure 1). The outer ear (the visible part of the ear, which includes the external auditory canals) functions to collect sound waves and funnel them to the tympanic membrane separating the outer ear from the middle ear. When the tympanic membrane encounters a sound wave, it vibrates and passes on this movement to the ossicles (the malleus, incus, and stapes) of the middle ear. The vibrations are then amplified and conducted to the inner ear, along with pressure waves produced by the stapes. Hair cells in the cochlea of the inner ear move with the introduction of the pressure waves, creating an electrical signal which travels to the brain via mechanoelectrical transduction. Volume is differentiated by the number of hair cells recruited to conduct the sound energy: the more hair cells recruited, the louder the volume. Pitch, which is dependent on the speed of the vibrations, is differentiated as the hair cells respond in unique ways to unique pressure waves.(1)

Bone Conduction

Bone conduction occurs when sound energy causes the bones of the skull to vibrate and conduct this vibration to the inner ear, where electrical signals are generated as part of the hearing process. There are three distinct types of bone conduction: compressional bone conduction, inertial bone conduction, and osteotympanic bone conduction.(2,3)

Figure 1. Illustration showing a cross section of the ear



http://www.nlm.nih.gov/medlineplus/ency/imagepages/1092.htm

Hearing Loss

Hearing loss is thought to result from the combined effects of heredity, aging, disease, and environment. The following section addresses the topic of hearing loss.

Types of Hearing Loss

Hearing loss is divided into four categories: conductive hearing loss, sensorineural hearing loss, mixed hearing loss, and central hearing loss. The two most prevalent are conductive and sensorineural hearing loss.(4)

Conductive Hearing Loss

When the conduction of sound energy through the ear is impeded by a physical dysfunction, the resulting deficit is defined as conductive hearing loss. Possible sources of dysfunction include obstructed ear canal (e.g., hematoma, foreign body in the ear canal), perforated tympanic membrane, dislocated ossicle, otitis media (infection of the middle ear), otitis externa (infection of the ear canal with tissue swelling), otosclerosis (hardening of the ossicles, which affects their ability to transmit vibrations), and the collection of fluid in the middle ear. Conductive hearing loss may not be permanent.(5-7)

Sensorineural Hearing Loss

When sound energy impulses cannot be conducted due to dysfunction in the pathway from the inner ear to the auditory nerve to the brain, the resulting deficit is defined as sensorineural hearing loss. Possible sources of dysfunction include presbyacusis (age-related hearing loss), acoustic trauma (prolonged exposure to harmful levels of noise), barotrauma (pressure trauma), head trauma, ototoxic

drugs (pharmacotherapeutics, which can damage the nerves involved in hearing, such as gentamicin, furosemide, salicylates, nonsteroidal anti-inflammatories, and antineoplastics), vascular diseases such as sickle cell disease or diabetes, kidney disease, Ménière's disease, acoustic neuroma, and infections such as mumps, measles, or influenza. Sensorineural hearing loss may be permanent.(5-7)

Mixed Hearing Loss

Mixed hearing loss results from a combination of dysfunctions in the outer, middle, and inner ear. When both conductive and sensorineural hearing loss occur in the same individual, it is known as mixed hearing loss.(5-7)

Central Hearing Loss

Hearing loss associated with damage to the central nervous system or brain is known as central hearing loss.(5-7)

Prevalence and Incidence of Hearing Loss

After hypertension and arthritis, hearing loss is the third-most common chronic condition affecting individuals in the United States.(4) A survey by Kochkin et al. in 2005 estimated that 31.5 million people in the United States are deaf or have hearing loss; this figure is expected to double by 2030.(8,9) Older people are the most affected: an estimated one-third of Americans older than age 60 and one-half of those older than age 85 have some degree of hearing loss.(7) Approximately 1.4 million children (individuals aged 18 or younger) have a hearing disability, with an estimated 14.9 million children having some level of low- or high-decibel hearing loss in one or both ears.(10) Hearing loss typically affects more males than females, possibly due to increased exposure to higher levels of occupation-associated noise. Approximately 10 million individuals in the United States have noise-induced hearing loss, with an additional 30 million at risk for the disorder each day.(11)

The incidence of hearing loss in the United States is estimated to be 314 per 1000 individuals over the age of 65; between 2 and 3 children per 1,000 born every year in the United States are born deaf or with substantial hearing loss. Every year, about 1 of 5,000 individuals in the United States develops sudden deafness (severe hearing loss, usually in only one ear, that develops over a period of a few hours or less); between 10% and 15% of these individuals can identify the cause of the disorder.(10-12)

Risk Factors for Hearing Loss

Hearing loss is a complex phenomenon that is related to a number of risk factors, including:

- Aging
- Noise
- Heredity
- Medication use
- Disease (e.g., meningitis, diabetes)(7,13)

Diagnosing Hearing Loss

Diagnosis of hearing loss must take into account the four types of dysfunction, including conductive hearing loss, sensorineural hearing loss, mixed hearing loss, and central hearing loss, in order to arrive at an appropriate diagnosis and course of treatment or therapeutic action. An understanding of the natural history of the disease will help to differentiate between these four types of dysfunction; this is achieved by a record of symptoms, physical examination, and auditory testing. Symptoms reported by individuals with hearing loss may include:(5)

- Inability to hear speech clearly and fully
- Deteriorated ability to distinguish speech (sound is muffled or otherwise diminished)
- Difficulty understanding words, especially against background noise or in a crowd of people (This may eventually culminate in avoidance of social situations and conversation withdrawal.)
- Frequent requests for repetition or clarification of speech
- Fatigue due to strain resulting from the additional effort required to understand sounds
- Need for volume of the television or radio to be increased
- “Bluffing” in conversation to mask inability to hear

The physical examination conducted may include:

- Otoscopic inspection of the ear canal and tympanic membrane
- Examination of the nose, nasopharynx , and upper respiratory tract
- Neurologic exam, including tests of the nerves that control movement, sensation, and reflexes
- Blood tests to determine whether infection, vascular dysfunction, or drug interaction is involved in the hearing loss

Hearing loss may be gradual or sudden and may range from mild or moderate loss which is successfully managed with only a few adaptations to severe loss associated with complete deafness. The severity, presence or absence of pain, speed of hearing loss, and direction of the loss (unilateral or bilateral) may help indicate the cause of the deficit. For example, sudden hearing loss with pain may be associated with otitis media or externa; a gradual loss of hearing without pain may be associated with otosclerosis. Hearing loss with neurological manifestations such as tinnitus or vertigo may be related to nerve dysfunction. Hearing loss which is rapid, fluctuating, and bilateral may be related to an autoimmune disorder.(5)

Hearing Tests

Hearing tests are conducted in order to determine the type of dysfunction and severity of hearing loss in order to arrive at a proper mode of therapy. These tests include:(5,14)

- Whispered-voice test: the examiner stands behind the individual and whispers a sequence of letters and number that the individual is expected to accurately repeat. If an incorrect response

is given, a different sequence is used. A passing score requires the individual to repeat a minimum of three out of six possible letters and/or numbers.

- Rinne tuning fork test helps distinguish between conductive and sensorineural hearing loss. Reduced air conduction and normal bone conduction indicates conductive hearing loss. Reduced air and bone conduction may be sensorineural or mixed hearing loss.
- Air Conduction, Conventional or Standard Audiometry examines frequencies required to hear and understand speech and sounds in the environment by determining the softest signals the individual can distinguish as well as frequency regions where sound acquisition is impaired.
- Bone Conduction is used to determine the type of hearing loss (i.e., conductive, sensorineural, mixed, central).
- Word Recognition is used to evaluate the ability to discriminate speech sounds and clarity of spoken words.
- Acoustic Immittance assesses the flexibility of movement for the tympanic membrane and other structures of the middle ear.
- Otoacoustic Emissions (OAEs) assesses cochlea function.
- Auditory Brainstem Response (ABR) is used to measure sensitivity of hearing; it can also determine whether neural pathways in the brain are properly transmitting sound.
- Electrocochleography (EcoG) measures the activity of the cochlea and the auditory nerve by means of an electrode placed on, or through, the eardrum.
- Magnetic resonance imaging scan or computed tomography (CT) may be used to determine if the hearing loss may be due to an abnormality in the brain.

Hearing loss is measured in decibels hearing level (dBHL). A person who can hear sounds across a range of frequencies at 0 to 20 dB is considered to have normal hearing. The thresholds for the different types of hearing loss are as follows:(5,14)

- Mild: 25 to 39 dBHL
- Moderate: 40 to 69 dBHL
- Severe: 70 to 94 dBHL
- Profound: >95 dBHL

Treatments for Hearing Loss

The treatment of hearing loss depends on the cause. Below are several examples.(6)

1. Clearing of physical blockages such as cerumen or a foreign object in the ear canal
2. Pharmacotherapy to address infection, tinnitus, vertigo, or Ménière's disease; or discontinued if it is the suspected source of the hearing loss

3. Surgical repair (i.e., treatment for a perforated eardrum, removal of acoustic neuroma, replacement of ossicles with artificial bones)

The likelihood that hearing will return depends on the cause of the hearing loss.

1. Hearing will usually return to normal with:
    - removal of foreign bodies or cerumen in the canal,
    - treatment of otitis externa,
    - treatment of otitis media,
    - healing of tympanic membrane injuries, although this may require surgery.
2. Hearing loss due to drugs may or may not return with drug withdrawal.
3. Hearing loss due to infections may not return: steroids may be used to reduce the severity of hearing loss.
4. Hearing loss due to Meniere's disease, acoustic neuroma, and age is usually permanent.

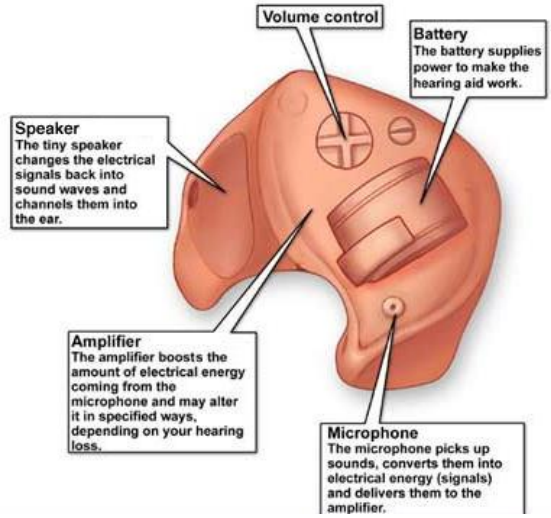
Hearing Aids

If there is no cure for the hearing loss, a hearing aid for one or both ears can assist with the dysfunction associated with conductive or sensorineural problems. Hearing aid components include (see Figure 2):

- Microphone (sound collector)
- Amplifier
- Transmission device (earpiece)
- Battery

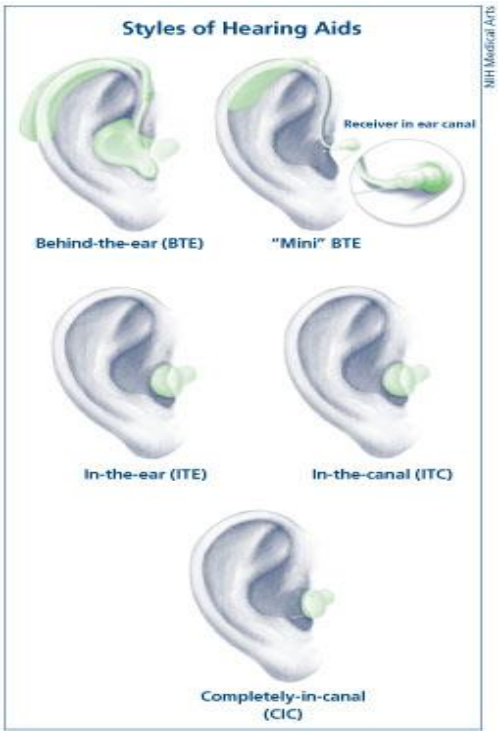
Hearing aids come in a variety of types (see Figure 3). The type of hearing aid used reflects the specific type of hearing loss being addressed: for example, higher frequency hearing loss, which affects speech recognition, benefits more from selective amplification of higher frequencies than simple amplification devices. Digital sound processing allows for more precise adaptations to individual needs.(11)

Figure 2. Hearing Aid Parts



http://www.mayoclinic.com/health/hearing-aids/HQ00812

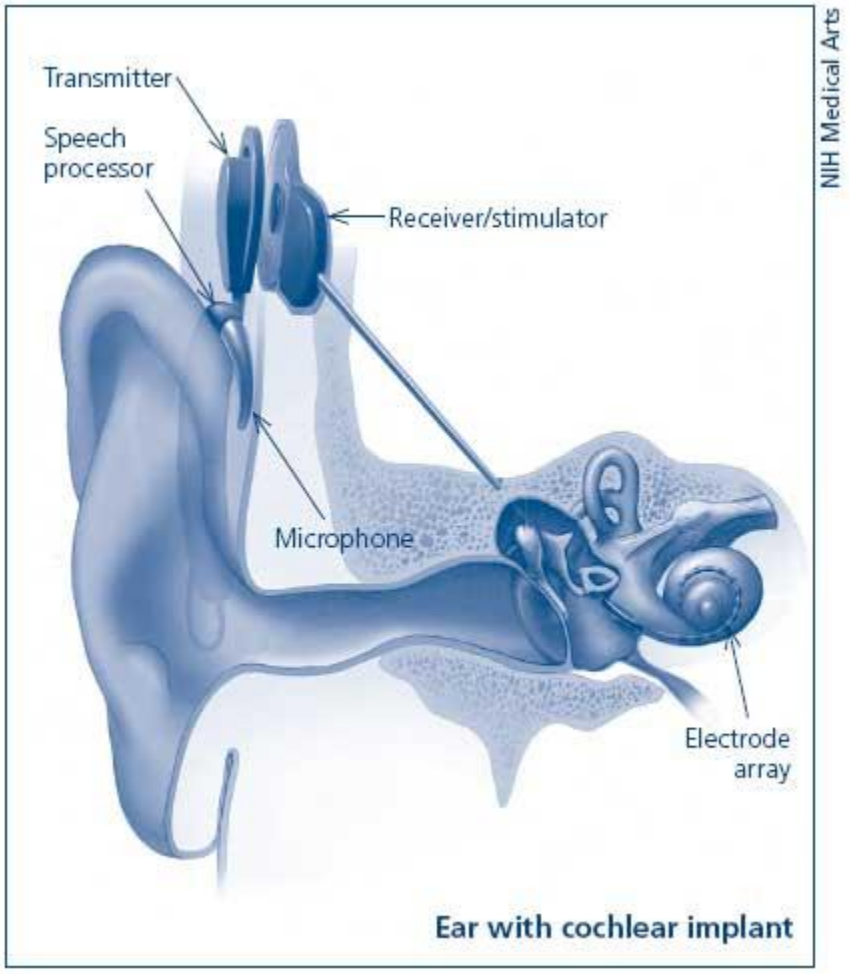
Figure 3. Hearing Aid Styles



http://www.nidcd.nih.gov/health/hearing/hearingaid.asp

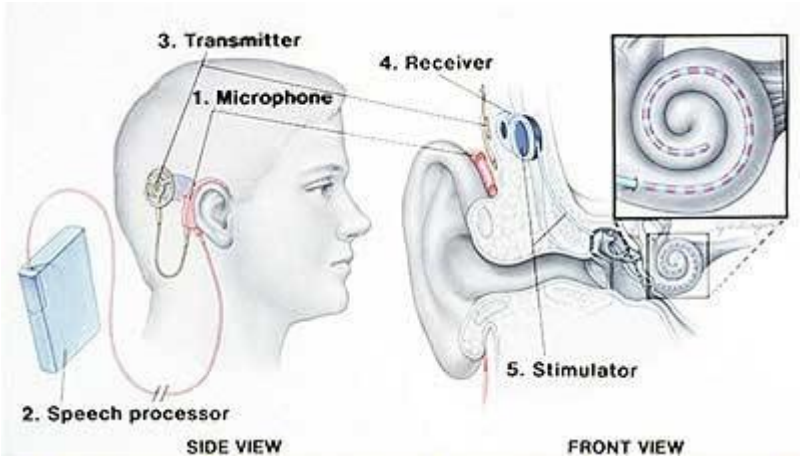
A cochlear implant may be used to provide amplification when a standard hearing aid proves ineffective. The cochlear implant transmits sound directly into the auditory nerve via electrodes which are surgically implanted into the cochlea (see Figure 4 and Figure 5).(15,16) While the utility of the implant from person to person is not uniform, and the sounds heard are electronic in nature, cochlear implants can be helpful when coupled with lip reading for understanding and producing speech. Cochlear implants may be particularly valuable for deaf children if they are implanted before the age of two, as the implant may have an impact on the formation of language skills.(17)

Figure 4. Cochlear Implant



http://www.nidcd.nih.gov/health/hearing/ear_coch_img.htm

Figure 5. How a Cochlear Implant Works



http://www.mayoclinic.com/health/hearing-loss/DS00172/DSECTION=7

A microphone (1) picks up sounds. The sounds travel through a thin cable to a speech processor (2). The processor can be worn on a belt or in a pocket. Newer models are worn behind the ear. The processor converts the signal into an electrical code and sends the code back up the cable to the transmitter (3) fastened to the head. The transmitter sends the code through the skin to a receiver-stimulator (4 and 5) implanted in bone directly beneath the transmitter. The stimulator sends the code down a tiny bundle of wires threaded directly into the cochlea, the snail-shaped primary hearing organ. Nerve fibers are activated by electrode bands on this bundle of wires. The auditory nerve carries the signal to the brain, which interprets the signal as a form of hearing.

Vestibular Disorders

Vestibular (inner ear) disorders are associated with symptoms such as dizziness, vertigo, problems with balance, changes in hearing, nausea, fatigue, anxiety, difficulty concentrating, any or all of which may affect the ability of an individual to perform tasks of daily living and work and to engage in social interaction.(18)

Causes of Dizziness, Vertigo, and Imbalance

Dizziness and/or vertigo can be associated with cardiovascular, neurological, psychological, or vestibular disorders. This section of the report will address vestibular disorders.

Dizziness Caused by Vestibular Disorders

Information about changes in head movement is provided to the brain by the vestibular organs of the inner ear: dizziness, vertigo, imbalance, spatial disorientation, and other symptoms can result from vestibular dysfunction.

Vestibular dysfunction can be caused by a variety of factors, including viral infections such as labyrinthitis or vestibular neuronitis, or bacterial infections such as otitis media or meningitis. Other factors associated with vestibular disorders include:(19)

- Allergies (associated with changes in the inner ear fluids or middle ear pressure because of swelling of the Eustachian tube and production of fluid in the middle ear)
- Head trauma (e.g., perilymph fistula, BPPV

- Ototoxins
- Age-related degenerative changes to the inner ear
- Acoustic neuroma
- Migraine
- Mal de Debarquement
- Autoimmune inner ear disease

In many cases of vestibular disorders, including Ménière's disease and other forms of endolymphatic hydrops, the underlying or original cause cannot be determined.

Specific Vestibular Disorders

Benign Paroxysmal Positional Vertigo (BPPV)

Approximately 20% of all dizziness reported to a physician is related to BPPV. BPPV is generally associated with the collection of crystals of calcium carbonate known as otoconia in the inner ear, causing vertigo, dizziness, problems with balance, and nausea. BPPV is also associated with head trauma and migraine; however, 50% of all cases of BPPV are idiopathic.

Symptoms of BPPV usually occur with a change in head position: getting out of bed and rolling over in bed are two common "problem" motions. "Top shelf vertigo" – the sensation of dizziness or vertigo associated with tipping the head back to look up – is also associated with BPPV. BPPV symptoms usually occur intermittently, with symptoms presenting for a period of a few days, with weeks in between episodes. In the presence of these symptoms, tests to confirm a BPPV diagnosis include the Dix-Hallpike test (for BPPV characteristic nystagmus) and electronystagmography (ENG).

Maneuvers to move the otoconia out of the semicircular canals, including the Epley maneuver and the Semont-liberatory maneuver, are very effective in treating BPPV. Treatment may also include individualized vestibular physical therapy exercises designed to help "retrain the brain," Brandt-Daroff habituation exercises, or surgery to block off the canal.(20)

Ménière's Disease

Ménière's disease (idiopathicendolymphatic hydrops) is a vestibular disorder that produces a relapsing and remitting set of four symptoms: rotational vertigo, aural fullness (a sensation of having air pressure in ear), tinnitus, and hearing loss.

It was previously thought that Ménière's disease was caused by the accumulation of large amounts of endolymphatic fluid in the inner ear: this theory has been largely discounted, although an alternate potential cause of Ménière's disease has not been established.(18,20,21) Potential causes for Ménière's disease including circulatory system problems, viral infection, allergies, an autoimmune reaction, and migraine have all been suggested. Head trauma has been associated with the development of secondary endolymphatic hydrops (SHE) in some individuals.(21) Research by Frykholm et al. (2006) suggests that familial Ménière's disease has an autosomal dominant pattern of inheritance associated with chromosome 12p12.3.(22,23)

While the cause of Ménière's disease is not yet understood, some of the triggers for an acute attack are known. These triggers include stress, anxiety, and abnormalities in the immune system. In most individuals, however, the specific event(s) associated with the onset of a Ménière's attack are not known.(21) Ménière's events can last from 20 minutes to 24 hours, several times a week, or they can be separated by weeks, months, and even years. The unpredictable nature of the disease means that symptoms may relapse and never return or become so severe that they are disabling.

In the early stages of Ménière's disease, the main symptoms are spontaneous vertigo, hearing loss, aural fullness, and tinnitus, sometimes followed by a period of fatigue or exhaustion. The periods between attacks are symptom-free for some people and symptomatic for others. Late-stage Ménière's disease is defined more by a distinct group of symptoms rather than as a point in time. Hearing loss is more significant and is less likely to fluctuate. Tinnitus and aural fullness may be stronger and more constant. Discrete vertigo may be replaced by continuous struggles with vision and balance, and drop attacks of vestibular origin (Tumarkin's otolithic crisis) may occur.(19,21)

Treatment

There are a number of treatments available for Ménière's disease. None of these therapies provides a cure from the disorder.

Conservative Therapy

Current conservative long-term treatment for Ménière's disease involves the use of a reduced-sodium diet and diuretics to lower inner ear fluid pressure and reduce the severity and number of attacks.(21) Other behavioral/lifestyle changes used to reduce the risk of a Ménière's attack include abstaining from caffeine, alcohol, and nicotine, and reducing stress levels.(19)

Devices

Another conservative treatment approach employs the Meniett device to deliver a series of low-pressure air pulses designed to displace inner ear fluids and interrupt the process which produces the symptoms of Ménière's disease. The use of this device is approved for general use by the U.S. Food and Drug Administration and is currently undergoing clinical trials in the United States.

Ménière's-associated tinnitus can be treated using a number of methods employing different devices. Tinnitus retraining therapy attempts to train the individual through the use of a masking device that resembles a hearing aid to adjust to the presence of tinnitus. Other devices used to deal with tinnitus include deep brain stimulation(24) and electrical stimulation to the outside of the ear.(25,26)

Pharmacotherapy

There are a wide variety of medications used in the treatment of Ménière's disease. These involve vestibular sedatives such as diazepam, promethazine, and dimenhydrinate, which function to prevent or reduce vertigo, nausea, and vomiting; diuretics such as triamterene/HCTZ and acetazolamide; and antiviral drugs such as acyclovir or valacyclovir, which are posited via anecdotal evidence to treat the herpes simplex virus which some believe to be related to the development of Ménière's disease. Antinausea drugs include scopolamine and promethazine.(19)

Ototoxins such as streptomycin and gentamicin are used to destroy all or part of the inner ear; the type of treatment selected depends in large part on the hearing currently remaining for the patient, as some ototoxins may destroy the functions of the labyrinth and the tiny hairs present in the cochlea that help process sound energy into electrical impulses necessary for hearing. Ototoxins are administered either by injection or Gelfoam.(19)

Rehabilitation

Vestibular rehabilitation therapy is sometimes used to improve the balance function of individuals with Ménière's disease by retraining the body and brain to process balance information.(27)

Surgical Treatment

For individuals who do not respond to the more conservative treatments, surgery may be able to address the vertigo and balance issues associated with Ménière's. The gold standard of surgical treatment is vestibular nerve section (VNS), in which the vestibular nerve is severed, thus disabling the ability to send balance signals to the brain. The auditory nerve remains intact, thus preserving whatever amount of hearing the individual currently possesses.(21) Other surgical treatments include:

- Endolymphatic sac decompression
- Endolymphatic sac shunt surgery
- Surgical labyrinthectomy
- Vestibular neuroectomy (VN)
- Microvascular decompression

Other Vestibular Disorders

Other vestibular disorders include:

1. Labyrinthitis and VN
2. Perilymph fistula
3. Acoustic neuroma
4. Ototoxicity
5. Vestibular migraine
6. Mal de Debarquement
7. Pediatric vestibular disorders
8. Cervicogenic dizziness
9. Otosclerosis
10. Cholesteatoma
11. Enlarged vestibular aqueduct
12. Vestibular hyperacusis
13. Autoimmune inner ear disease

14. Superior canal dehiscence.

Diagnostic Tests for Vestibular Disorders

Balance is a complex behavior involving the simultaneous coordination of systems involving gaze and postural stabilization, the voluntary motor system, and the involuntary motor system; if there is a dysfunction in any one of these systems, an individual may experience acute or chronic dizziness or imbalance.(28) Diagnostic tests for assessing vestibular system function and to rule out other plausible causes for dysfunction may be the result of the individual's medical history and physical examination. The diagnostic tests evaluate the function and structure of the inner ear and/or brain and hearing because of the close relationship these systems share. Tests of vestibular function include:(29)

- ENG is used to determine whether dizziness originates in the inner ear, brain, or is due to some other disorder.
- Rotation tests are used to determine how accurate eye movements are during head rotations.
- ABR is used to test hearing pathways from the inner ear to the brain.
- EcoG is used to examine the output ratios of the inner ear and auditory nerve: an elevated ratio may indicate Ménière's disease.
- Computerized dynamic posturography (CDP, or test of balance) is used to assess the sensory, motor, and central adaptive mechanisms of the central nervous system which are involved in posture and balance.

Tests of auditory function include:(20)

- Pure-tone audiometry is used to measure hearing through varying pitches.
- Speech audiometry is used to determine central hearing deficits and gather information about central processing.
- Acoustic-reflex testing is used to determine whether the stapedius muscle tightens the stapes appropriately given the level of the testing noise.
- OAE is used to determine whether the hair cells of the cochlea respond to sound by generating their own sound; if there is no sound from the hair cells, hearing loss is suspected.
- ABR (see above section)
- EcoG (see above section)

Previous Evidence Reports from the FMCSA

In response to the Americans with Disabilities Act of 1990, the FMCSA commissioned a series of reports to reevaluate restrictions which then existed regarding the physical standards for CMV drivers. Songer et al. (1993) produced a literature review entitled *Hearing Disorders and Commercial Motor Vehicle Drivers* that addressed, among other issues, crashes among hearing-impaired drivers. This subsection of the report presents the results of Songer et al.(30)

Songer et al. concluded that the studies reviewed yielded inconclusive results as to whether hearing loss increased the risk of crashes among private or CMV operators. The authors noted that several factors may have introduced bias into these studies, including failure to consider number of miles driven, age of the driver, and area of residence and a lack of identified CMV drivers. These biases would call the conclusions of any of the affected studies into doubt. The only study that controlled for mileage driven was then 30 years old; given the number of changes that occurred between 1962 and 1992 in automobile and truck models, driving habits, and the training that deaf individuals receive in order to drive, the applicability of this study was called into question by the authors. In addition, while the study matched the participants for age, gender, miles driven, and area of residence, selection bias may have been introduced through the use of surveys to recruit the deaf participants: the individuals were all members of an organization for the deaf, meaning that they may not have been representative of the deaf population as a whole. In addition, deaf individuals who had experienced a crash may have been less likely to return the survey and take part in the study because of concerns regarding license loss as a consequence of a crash, introducing further bias into the study results.

Studies Featured in the Songer et al. Report

Cook (1974)(31) reported on 99 hearing impaired drivers using data obtained from the Wisconsin Department of Motor vehicles. Information such as how individuals were identified for the study, period of time for which data was gathered, and the definition of hearing impairment were not reported. The original sample included 162 hearing-impaired individuals with driver's licenses, but the inability to match school and motor vehicle records eliminated approximately 50% of the population from the study. The motor vehicle records for 99 individuals with normal hearing who were "similar" in age to the hearing-impaired population were used as the comparator group; however, there was no adjustment for factors such as gender, miles driven, or geographic area. The study found an increased risk of crash associated with hearing impairment.

Coppin and Peck (1964)(32) identified potential volunteers from the files of the California Organization for the Deaf in order to investigate whether the driving behavior of the deaf was different from that of individuals who were not deaf. In this study, deafness was defined, and data on driving exposure and type of driving was obtained from deaf volunteers; however, data regarding participation rate and type of driving performed was not obtained for the control population. Crash information for both groups was obtained from the California DOT. The authors found, after matching for age, miles driven, occupation, and geographic area, that deaf men were 80% more likely to experience a crash compared

to males who were not deaf. This trend did not continue, however, when the crash rates of females in both populations were compared.

Finesilver (1962b)(33) selected 3 groups at random: 100 individuals who were deaf constituted one group, and 2 groups were composed of 100 hearing individuals. The deaf individuals were obtained from a list of people participating in a driver improvement program; the hearing controls were selected at random from Colorado Department of Motor Vehicles records. There was no control for driving exposure or gender, and the period of time for which data was obtained was not reported; the age of the deaf cohort, when compared to the hearing cohorts, was significantly older. The authors found that the deaf population experienced fewer crashes than the hearing cohorts (18% fewer than hearing group A and 31% fewer than hearing group B). The difference in crash rates may, however, have been due to the older drivers in the deaf cohort being more experienced drivers.

Schein (1968)(34) obtained data on the deaf driving population for all of Washington, DC, in an effort to understand how deafness affected quality of life. Crash and traffic violation records for deaf and non-deaf individuals were obtained from the Department of Motor Vehicles of the District of Columbia. On examination, it was found that the two populations differed significantly in ethnicity, age, and socioeconomic standards, and no adjustment was made to compensate for driving exposure (e.g., miles driven): all of these factors may have introduced bias into the study. The authors found that the deaf individuals had fewer crashes than their hearing counterparts.

Roydhouse (1967)(35) utilized driving experience data obtained from surveys administered to the New Zealand League for the Hard of Hearing and several other groups for deaf individuals. As only 10% of all individuals solicited took part, selection bias is likely to have introduced a fatal flaw into this study. Additionally, the data obtained from the control group was not presented in the report. Roydhouse reported that the number of accidents for hearing impaired drivers was 50% less than that of their "normal hearing" counterparts; given the lack of control group data, however, this finding could not be confirmed. It was also reported that severity of hearing impairment was not significantly correlated with crash.

Wagner (1962)(36) described the results of the report regarding "deaf-mutes" and driving published by the state of Pennsylvania in 1940. The report addressed the crashes of 600 deaf individuals and a cohort of normal hearing drivers over a two-year period; however, it did not adjust for driving exposure, age, gender, or geographic area. The report found that deaf drivers had a lower crash rate than normal hearing drivers (1.7 crashes/1,000 drivers, and 39 crashes /1,000 drivers, respectively).

Wolf (1991)(37) gave a preliminary report on data on motor vehicle injuries among individuals aged 65 and over who participated in a health maintenance organization in the Puget Sound counties of Washington state. Cases included individuals who had experienced a crash and required medical attention; individuals of approximately the same age who belonged to the same HMO who had not experienced a crash requiring medical attention made up the control group. The author found that there was no proof that hearing loss was associated in a causal sense with crash.

Ysander (1966)(38) reported on crash and violation history in individuals with chronic illness, including hearing impairment. He defined a crash as an event in which there was damage and a police report was

created. Over a period of 4.5 years, approximately 5% of individuals in the hearing impaired group reported a crash; this could be compared to the control group (matched by age, gender, driving exposure, and driving experience), which had a crash rate of 7.7%.

Songer et al.(30) stated that the results of the eight studies in the report evidence base were mixed. Two studies found an increased risk of crash associated with hearing loss when compared to individuals without hearing loss.(31,32) Five studies found a decreased risk of crash for individuals with hearing loss.(33-36,38) The last study found that the risk of crash for individuals with hearing loss and normal hearing were similar.(37) A similar study by Coppin and Peck (1964)(32) found that the crash rate for males with hearing loss was 80% higher than for males without hearing loss, with no difference in crash rates for females with hearing loss when compared to females with normal hearing; it is this study, however, that may have been influenced by the selection biases discussed previously. Other study level factors that made finding a definitive conclusion to the question of the impact of hearing loss on crash include differing definitions of hearing impairment between studies, lack of a standard definition of crash, differences in how hearing impaired individuals were identified and how they were contacted, and differences in study design methodology used by investigators. Altogether, these differences in studies and their contradictory results as reported by Songer et al.(30) fail to point to a definite conclusion as to the impact of hearing impairment on crash risk.

Hearing Disorders and Driving Regulations

"Loss of hearing may increase the risk for traumatic injury because oncoming cars, fire alarms, or other potential hazards are inaudible, although assistive technologies increasingly address such concerns."(39) For the purpose of public safety and CMV drivers, federal and state laws were created to enforce standards associated with CMV driving. Qualifications contained in 49 CFR Part 398.3: Qualifications of drivers or operators under the FMCSA federal regulations include the following:

> (a) Compliance required. Every motor carrier, and its officers, agents, representatives and employees who drive motor vehicles or are responsible for the hiring, supervision, training, assignment or dispatching of drivers shall comply and be conversant with the requirements of this part.
>
> (b)(5)Hearing shall not be less than 10/20 in the better ear, for conversational tones, without a hearing aid. More extensive information on this topic is available at the *Conference on Hearing Disorders and Commercial Drivers* at: http://www.fmcsa.dot.gov/.
>
> (b)(7)Initial and periodic physical examination of drivers: No person shall drive nor shall any motor carrier require or permit any person to drive any motor vehicle unless within the immediately preceding 36 month period such person shall have been physically examined and shall have been certified in accordance with the provisions of paragraph (b)(8) of this section by a licensed doctor of medicine or osteopathy as meeting the requirements of this subsection.
>
> (b)(8) Certificate of physical examination: Every motor carrier shall have in its files at its principal place of business for every driver employed or used by it a legible certificate of a licensed doctor of medicine or osteopathy based on a physical examination as required by paragraph (b)(7) of

this section or a legible photographically reproduced copy thereof, and every driver shall have in his/her possession while driving, such a certificate or a photographically reproduced copy thereof covering himself/herself.

Under the **§383.111 Required Knowledge** section of the FMCSA federal regulations, all CMV drivers must have knowledge of the following area:

(a) Safe operations regulations**.** Driver related elements of the regulations contained in 49 CFR Parts 382, 391, 392, 393, 395, 396, and 397, such as: Motor vehicle inspection, repair, and maintenance requirements; procedures for safe vehicle operations; the effects of fatigue, poor vision, hearing, and general health upon safe commercial motor vehicle operation; the types of motor vehicles and cargoes subject to the requirements; and the effects of alcohol and drug use upon safe commercial motor vehicle operations.

Current United States Federal Regulatory and Medical Advisory Criteria for CMV Operators

The FMCSA Regulations, found in 49 Code of Federal Regulations (CFRs) 301 through 399, cover businesses that operate CMVs in interstate commerce. The FMCSA regulations that pertain to fitness to drive a commercial vehicle are found in 49 CFR 391 Subpart E. Only motor carriers engaged purely in intrastate commerce are not directly subject to these regulations. However, intrastate motor carriers are subject to state regulations, which must be identical to, or compatible with, the federal regulations in order for states to receive motor carrier safety grants from the FMCSA. States have the option of exempting CMVs with a gross vehicle weight rating of less than 26,001 lbs.

Current Medical Fitness Standards and Guidelines for CMV drivers in the United States

Current Medical Fitness Standards

The current medical qualification standard for fitness to drive a CMV (49 CFR 391.41(b) subpart 5) states the following (see: http://www.fmcsa.dot.gov/rules-regulations/administration/fmcsr/fmcsrruletext.asp?section=391.41):

A person is physically qualified to drive a CMV if that person —

- First perceives a forced-whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American national Standard (formerly ASA Standard) Z24.5-1951

Current Medical Qualification Guidelines

In 1992, the FMCSA published the outcome of a conference to review the current medical standards covering hearing disorders (see: http://www.fmcsa.dot.gov/facts-research/research-technology/publications/medreports.htm), which included guidelines for patients with hearing

disorders. Unlike standards, which are regulations that a medical examiner must follow, these guidelines are recommendations that the medical examiner should follow. While not law, the guidelines are intended as standards of practice for medical examiners.

Under the current Federal guidelines:

"…persons who are deaf or who suffer from moderate to extreme hearing loss cannot be licensed to operate commercial motor vehicles in interstate commerce…The Federal Highway Administration concluded that hearing is important when a driver must act on emergency sounds or improper mechanical sounds and when a driver needs to communicate; noise levels are not high in all driving situations; and the literature suggests that accidents are higher among deaf drivers than non-deaf drivers (FHWA 1976)."

Medical Fitness Standards and Guidelines for Individuals Performing Transportation Safety in the United States

Current medical fitness standards and guidelines for individuals performing transportation safety in the United States are summarized in Table 2. Included in the table are pertinent rules and guidance for pilots, railroad workers, and merchant mariners.

Table 2. Standards and Guidelines for Hearing Disorders from U.S. Government Transportation Safety Agencies

Condition	FAA* (all classes of airmen)	Railroad†	Merchant Mariner‡
Hearing disorders	Special Issuance of Medical Certificates. Applicants who do not meet the auditory standards may be found eligible for a SODA. An applicant seeking a SODA must make the request in writing to the Aerospace Medicine Certification Division, AAM-300. A determination of qualifications will be made on the basis of a special medical examination by an ENT consultant, a MFT, or operational experience. Bilateral Deafness. If otherwise qualified, the AMCD may issue a combination medical/student pilot certificate with the limitation. **VALID FOR STUDENT PILOT PURPOSES ONLY** as well as the limitation **NOT VALID FOR CONTROL ZONES OR AREAS WHERE RADIO COMMUNICATION IS REQUIRED**. This will enable the applicant to proceed with training to the point of a private pilot checkride. See Items 25-30. When the student pilot's instructor confirms the student's eligibility for a private pilot checkride, the applicant should submit a written request to the AMCD, for an authorization for a MFT. This test will be given by an FAA inspector in conjunction with the checkride. If the applicant successfully completes the test, the FAA will issue a third-class medical certificate and SODA. Pilot activities will be restricted to areas in which radio communication is not required. Hearing Aids. If the applicant meets the standard with the use of hearing aids, the certificate may be issued with the following restriction: **VALID ONLY WITH USE OF HEARING AMPLIFICATION** Some pilots who normally wear hearing aids to assist in communicating while on the ground report that they elect not to wear them while flying. They prefer to use the volume amplification of the radio headphone. Some use the headphone on one ear for radio communication and the hearing aid in the other for cockpit communications. **Examination Techniques**	With few exceptions, most railroads have no specific medical standards	Potentially disqualifying conditions listed in the Physical Evaluation Guidelines for Merchant Mariner's Documents and Licenses included any disease or constitutional defect which would result in gradual deterioration of performance of duties, sudden incapacitation or otherwise compromise shipboard safety, including required response in an emergency situation. Hearing thresholds are checked at 500 Hertz, 1000 Hz, 2000 Hz and 3000 Hz. The frequency responses for each ear are averaged to give a measure of hearing ability. ORIGINAL DECK AND ENGINEER OFFICER LICENSES: An average, unaided hearing threshold of 70 dB or less for each ear and functional speech discrimination of at least 90% is acceptable. RENEWAL OR RAISE OF GRADE: An average unaided hearing threshold of 70 dB or less for each ear and/or functional speech discrimination of at least 80% at 55 dB for each ear is acceptable. DECK OFFICER: Hearing aids may be used by applicants to meet the auditory requirements for all renewal or raise of grade transactions. The aided threshold should be 40 dB or less in each ear and functional speech discrimination should be at least 90% at 55 dB in both ears. The unaided threshold should be 70 dB or less in each ear and functional speech discrimination of at least 80% at 55 dB, binaural. ENGINEER OFFICER: Hearing aids may not be used to meet the auditory requirements for all renewal or raise of grade transactions. Engineer officers may not be granted a waiver because the use of a hearing aid in an engineering space may further damage the individual's hearing. Other conditions outside of the ones discussed may be considered for a waiver when recommended by the Officer in Charge Marine Inspection.

<table>
<tr><th>Condition</th><th>FAA*
(all classes of airmen)</th><th>Railroad†</th><th>Merchant Mariner‡</th></tr>
<tr><td></td><td>
Item 49. Hearing
Order of Examinations
1. The applicant must demonstrate an ability to hear an average conversational voice in a quiet room, using both ears, at a distance of 6 feet from the Examiner, with the back turned to the Examiner.
2. If an applicant fails the conversational voice test, the Examiner may administer pure tone audiometric testing of unaided hearing acuity according to the following table of worst acceptable thresholds, using the calibration standards of the American National Standards Institute, 1969:
<table>
<tr><td>Frequency (Hz)</td><td>500 Hz</td><td>1000 Hz</td><td>2000 Hz</td><td>3000 Hz</td></tr>
<tr><td>Better Ear (dB)</td><td>35</td><td>30</td><td>30</td><td>40</td></tr>
<tr><td>Poorer Ear (dB)</td><td>35</td><td>50</td><td>50</td><td>60</td></tr>
</table>
3. If the applicant fails an audiometric test and the conversational voice test had not been administered, the conversational voice test should be performed to determine if the standard applicable to that test can be met.
4. If an applicant is unable to pass either the conversational voice test or the pure tone audiometric test, then an audiometric speech discrimination test should be administered. A passing score is at least 70 percent obtained in one ear at an intensity of no greater than 65 dB.
Discussion
• Conversational voice test. For all classes of certification, the applicant must demonstrate hearing of an average conversational voice in a quiet room, using both ears, at 6 feet, with the back turned to the Examiner.
• The Examiner should not use only sibilants (S-sounding test materials). If the applicant is able to repeat correctly the test numbers or words, “pass” should be noted and recorded on FAA Form 8500-8, Item 49.
</td><td></td><td></td></tr>
</table>

Condition	FAA[*] (all classes of airmen)	Railroad[†]	Merchant Mariner[‡]
	If the applicant is unable to hear a normal conversational voice then "fail" should be marked and one of the following tests may be administered: • Standard. For all classes of certification, the applicant may be examined by pure tone audiometry as an alternative to conversational voice testing or upon failing the conversational voice test. If the applicant fails the pure tone audiometric test and has not been tested by conversational voice, that test may be administered. The requirements expressed as audiometric standards according to a table of acceptable thresholds (American National Standards Institute [ANSI], 1969, calibration) are as follows: Ear (All classes of medical certification) Frequency (Hz): 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz Better Ear (dB): 35, 30, 30, 40 Poorer Ear (dB): 35, 50, 50, 60 • Audiometric Speech Discrimination. Upon failing both conversational voice and pure tone audiometric test, an audiometric speech discrimination test should be administered (usually by an otologist or audiologist). The applicant must score at least 70 percent at intensity no greater than 65 dB in either ear. **Equipment** **Approval**. The FAA does not approve or designate specific		

Ear (All classes of medical certification)

Frequency (Hz)	500 Hz	1000 Hz	2000 Hz	3000 Hz
Better Ear (dB)	35	30	30	40
Poorer Ear (dB)	35	50	50	60

Condition	FAA* (all classes of airmen)	Railroad†	Merchant Mariner‡
	audiometric equipment for use in medical certification. Equipment used for FAA testing must accurately and reliably cover the required frequencies and have adequate threshold step features. Because every audiometer manufactured in the United States for screening and diagnostic purposes is built to meet appropriate standards, most audiometers should be acceptable if they are maintained in proper calibration and are used in an adequately quiet place. • **Calibration**. It is critical that any audiometer be periodically calibrated to ensure its continued accuracy. Annual calibration is recommended. Also recommended is the further safeguard of obtaining an occasional audiogram on a "known" subject or staff member between calibrations, especially at any time that a test result unexpectedly varies significantly from the hearing levels clinically expected. This testing provides an approximate "at threshold" calibration. The Examiner should ensure that the audiometer is calibrated to ANSI standards or if calibrated to the older ASA/USASI standards, the appropriate correction is applied (see paragraph 3 below). • **ASA/ANSI.** Older audiometers were often calibrated to meet the standards specified by the USA Standards Institute (USASI), formerly the American Standards Association (ASA). These standards were based upon a U.S. Public Health Service survey. Newer audiometers are calibrated so that the zero hearing threshold level is now based on laboratory measurements rather than on the survey. In 1969, the American National Standards Institute (ANSI) incorporated these new measurements. Audiometers built to this standard have instruments or dials that read in ANSI values. For these reasons, it is very important that every audiogram submitted (for values reported in Item 49 on FAA Form 8500 8) include a note indicating whether it is ASA or ANSI. Only then can the FAA standards be appropriately applied. ASA or USASI values can be converted to ANSI by adding corrections as follows:		

Condition	FAA* (all classes of airmen)	Railroad†	Merchant Mariner‡
	Frequency (Hz) 500 Hz 1000 Hz 2000 Hz 3000 Hz Decibels Added * 14 10 8.5 8.5 * The decibels added figure is the amount added to ASA or USASI at each specific frequency to convert to ANSI or older equivalent ISO values.		

* Source of information for FAA Regulations and Guidelines:
http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/exam_tech/item49/amd/
http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/exam_tech/item49/et/

† Source of information for Federal Railroad Administration Guidelines: http://www.fra.dot.gov/downloads/safety/hazmatch4.pdf

‡ Source of information for Merchant Mariner Guidelines: http://www.uscg.mil/hq/g-m/nvic/2_98/n2-98.pdf

Regulatory Medical Fitness Standards in Australia, Canada, the United Kingdom, New Zealand, and Sweden

The importance of establishing guidelines and medical standards for the Commercial driver's license (CDL) population can be seen in the policies established by influential countries abroad. While the topic of hearing disorders is incorporated into these worldwide guidelines, the restrictions vary from country to country. Policies pertaining to hearing disorders and CMV driving in the European Union, Canada, Australia, United Kingdom, New Zealand, Malta, Ireland, and Sweden are presented in Table 3.

Distinct worldwide policies include:

Australia

- A hearing threshold of ≥40 decibels in the better ear should be met.

Canada

- A hearing threshold of ≥40 decibels in the better ear should be met.
- Corrected word recognition of at least 50% to 60% should be met.

New Zealand

- A hearing threshold of ≥40 decibels in the better ear should be met; however, a Director of the Land Transport Safety Authority may still grant a license.

United Kingdom

- License will be refused or revoked if a condition of profound deafness is diagnosed.

Sweden

- A hearing impairment or deafness would not constitute grounds for denial of a CDL.

Malta

- A hearing impairment that may affect driving ability should be reported.

Table 3. Regulations Pertaining to Hearing and CMV driving from Selected Countries

Country	Reference	Hearing Guidelines
European Union	European Commission on Transport and Road Safety, Annex III to Directive 91/439/EEC; Council Directive 96/47/EC July 1996 amending Directive 91/439/EEC; IP/06/381 Member States Agree on the European Driving License 27 March 2006 ▪ Countries involved include: Austria*,Finland*, Sweden*, Belgium, Ireland, Denmark, Italy, Germany, Luxembourg, Greece, The Netherlands, Spain, Portugal, France and The United Kingdom (29 July 1991) ▪ Member states had to apply directive 91/439/EEC by 1 July 1996. ▪ European member states have to stay within a Council directive: they can be more restrictive, but not more liberal. *added in Council Directive 96/47/EC July 1996	Driving licenses may be issued to or renewed for applicants or drivers in Group 2 subject to the opinion of the competent medical authorities; particular account will be taken in medical examinations of the scope for compensation.
Canada	Determining Medical Fitness to Operate Motor Vehicles. CMA (Canadian Medical Association) Driver's Guide 7th edition. (2006)	The following standards are recommended as applied to the person's better ear. Drivers of Classes 1 and 3 vehicles who wish to drive in the United States must meet the same standards as outlined below for drivers of class 2 and 4. Although no hearing standards apply for holders of Class 1 (CDL) and Class 3 (CDL) in Canada, drivers transporting dangerous goods, regardless of the class of vehicle, should meet the standards for Class 2 and 4 licenses as noted in the paragraph below. If a hearing impaired person drives a Class 2 or 4 vehicle, he or she should first undergo an audiogram performed by an audiologist or otolaryngologist. Drivers with Class 2 or 4 licenses should have a corrected hearing loss of no more than 40 dB averaged at 500, 1000 and 2000 Hz and a corrected word recognition score of at least 50%-60%.

Country	Reference	Hearing Guidelines
Australia	Assessing Fitness to Drive (For Commercial and Private Vehicle Drivers) Medical Standards for Licensing and Clinical Management Guidelines. Austroads and NTC (National Transport Commission) Australia (2006)	The criteria for an unconditional license are NOT met: • If the person has an unaided average hearing threshold level or equal to or greater than 40dB in the better ear. (Average hearing threshold is the simple average of pure tone air conduction thresholds at 500, 1000, 2000 and 3000 Hz). A conditional license may be granted by the Driver Licensing Authority, taking into account the opinion of an ENT specialist, and the nature of the driving task, and subject to periodic review: • If the standard is met with a hearing aid. Further assessment of the person may be arranged with the Driver Licensing Authority and advice may be sought regarding modifications to the vehicle to provide a visual display of safety critical operations.
United Kingdom	At a glance Guide to the current Medical Standards of Fitness to Drive (for Medical Practitioners) Issued by Drivers Medical Group. DVLA, Swansea (February 2007)	If the condition of profound deafness is diagnosed, a license is likely to be refused or revoked.
New Zealand	Medical aspects of fitness to drive: A Guide for Medical Practitioners. Land Transport Safety Authority. (May 2002)	Generally no driving restrictions for classes 2, 3, 4, 05 5 license holders. Holders of P, V, I, or O endorsements should have a hearing standard of no less than 40dB in the better ear. However, the Director may grant licenses to individuals that do not meet this standard in some circumstances.
Malta	Malta Transport Driving License	If, after you obtain a license, you develop a medical condition or any medical condition you may have worsens, it is your responsibility to inform the Licensing and Testing Directorate. These include but are not restricted to reporting any hearing impairment or medical condition which may affect your driving ability.

Country	Reference	Hearing Guidelines
Ireland	Irish Statute Book S.I. No. 340/1986 – Road Traffic (Licensing of Drivers) (Amendment) (No.2) Regulations, 1986 Eighth Schedule	Only relevant to commercial with passenger vehicle 2. Hearing In the case of an applicant for a license to drive a vehicle of classes D, E, or H, fitness to drive shall not be certified if his hearing is so deficient that it interferes with the proper discharge of his duties as a driver.
Sweden	Swedish National Road Administration Statute Book Effective 1/1/99 Chapter 3/Hearing and Sense of Balance	Chapter 3/Hearing and Sense of Balance 1. Unexpected attacks of balance disorder or vertigo that could jeopardize traffic safety constitute grounds for denial of possession. 2. Morbus Meniere's (Ménière's disease) constitutes grounds for denial of possession in Group II if the disease is clinically active. 3. A hearing impairment or deafness does not constitute grounds for denial of possession in Group II. *Medical Certification* A medical certificate shall be attached to the application for a learner's permit for Group II. The certificate shall include a medical statement on whether or not the applicant suffers from a disease that implies a danger to traffic safety. In the case of hearing disorders, including vertigo with impaired hearing Morbus Meniere's or other serious vertigo disease, a certificate must be issued by an otorhinolaryngologist. The specialist shall assess the risk of sudden, unexpected attacks of balance disorders or vertigo that can constitute a traffic hazard.

Methods

The *Methods* section provides a synopsis of how we identified and analyzed information for this report. The section briefly covers the key questions addressed, literature searches performed, the criteria used including studies, evaluation of study quality, assessment of the strength of the evidence base for each key question, and the methods used for abstracting and analyzing available data. Specific details of literature searches, study quality assessment, statistical approaches used, etc. are documented in appendices.

Key Questions

This evidence report addresses five key questions. Each of these key questions was developed by the FMCSA such that the answers to these questions provided information that would be useful in updating their current medical examination guidelines. The five key questions addressed in this evidence report are as follows:

Key Question 1: Are individuals with hearing thresholds of 40 dB or greater at 500 to 3,000 Hz at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have a hearing impairment?

Key Question 2: Is the forced-whisper test a valid measure of hearing ability?

Key Question 3: Are individuals with a vestibular dysfunction (any condition that causes dizziness and/or vertigo, including Ménière's disease and benign paroxysmal positional vertigo ([BPPV]) at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have a vestibular dysfunction?

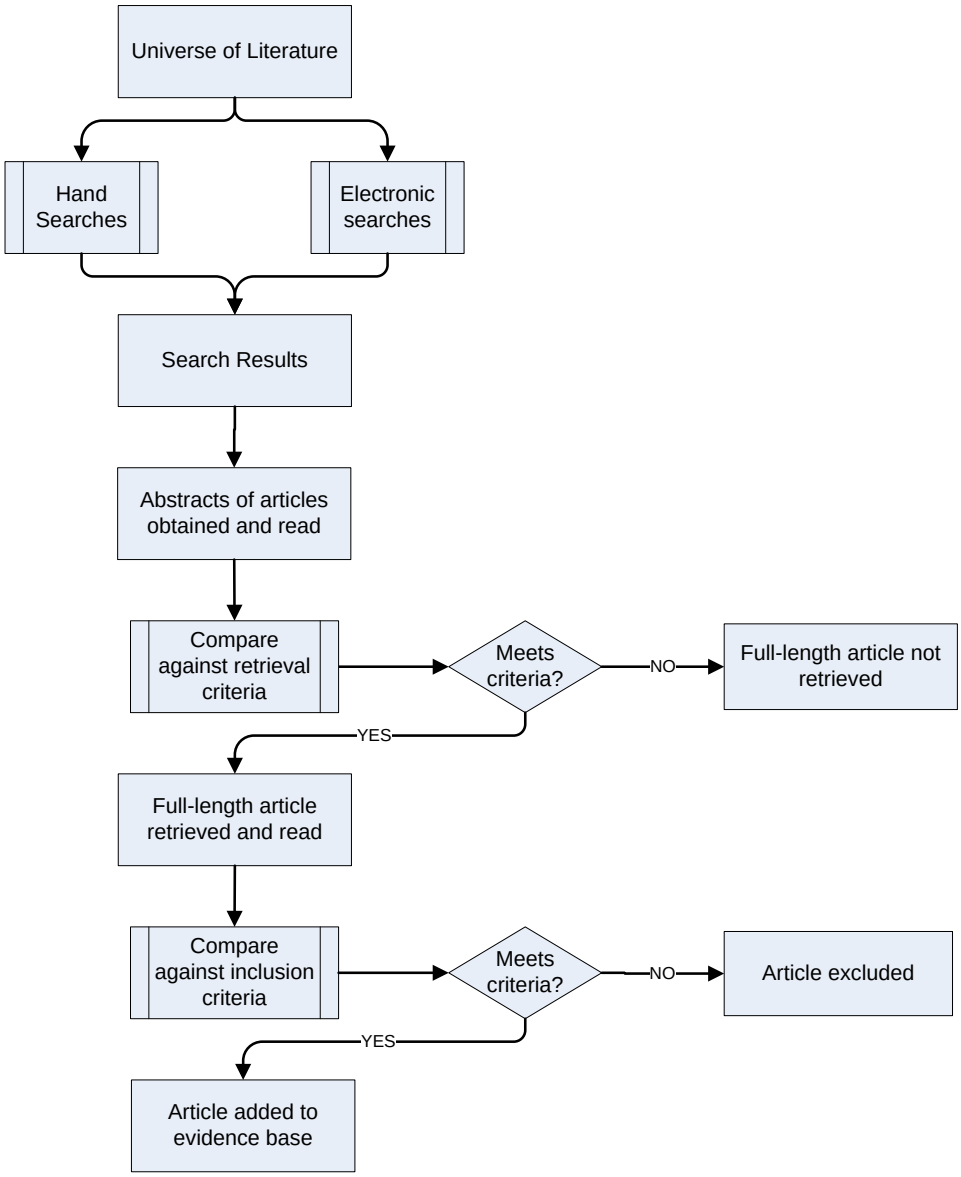
Key Question 4: How long after the most recent episode of vertigo until it is safe to drive?

Key Question 5: Which treatments have been shown to effectively treat individuals with Ménière's disease?

Identification of Evidence Bases

The individual evidence bases for each of the five key questions addressed in this evidence report were identified using the multistaged process captured by the algorithm presented in Figure 6. The first stage of this process consists of a comprehensive search of the literature. The second stage of the process consists of the examination of abstracts of identified studies in order to determine which articles will be retrieved. The final stage of the process consists of the selection of the actual articles that will be included in the evidence base.

Figure 6. Evidence Base Identification Algorithm



Searches

One characteristic of a good evidence report is a systematic and comprehensive search for information. Such searches distinguish systematic reviews from traditional literature reviews which use a less rigorous approach to identifying and obtaining literature thereby allowing a reviewer to include only articles that agree with a particular perspective and to ignore articles that do not. Our approach precludes this potential reviewer bias because we obtain and include articles according to explicitly determined *a priori* criteria. Full details of the search strategies used in this report are presented in Appendix A.

Electronic Searches

We performed comprehensive searches of the electronic databases listed in Table 4.

Table 4. Electronic Databases Searched

Name of database	Date limits	Platform/provider
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	1982 through August 27, 2007	OVID
The Cochrane Central Register of Controlled Trials (CENTRAL)	2003 through 2007, Issue 2	www.thecochranelibrary.com
The Cochrane Database of Methodology Reviews (Methodology Reviews)	2003 through 2007, Issue 2	www.thecochranelibrary.com
The Cochrane Database of Systematic Reviews (Cochrane Reviews)	2003 through 2007, Issue 2	www.thecochranelibrary.com
Database of Abstracts of Reviews of Effects (DARE)	2003 through 2007, Issue 2	www.thecochranelibrary.com
ECRI Institute Library Catalog	2003 through 2007	ECRI Institute
EMBASE (Excerpta Medica)	1980 through August 27, 2007	OVID
Health Technology Assessment Database (HTA)	2003 through 2007, Issue 2	www.thecochranelibrary.com
MEDLINE	1950 through August 27, 2007	OVID
MEDLINE in Process and other non-indexed citations	1950 through August 27, 2007	www.pubmed.gov
PsycINFO	1967 through August 27, 2007	OVID
TRIS Online (Transportation Research Information Service Database)	Searched August 27, 2007	http://ntlsearch.bts.gov/tris/index.do
U.K. National Health Service Economic Evaluation Database (NHS EED)	2003 through 2007, Issue 2	www.thecochranelibrary.com
U.S. National Guideline Clearinghouse™ (NGC™)	2003 through August 27, 2007	www.ngc.gov

Manual Searches

We reviewed journals and supplements maintained in ECRI Institute's collection of more than 1,000 periodicals. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. In addition, we examined the reference lists of all obtained articles with the aim of identifying relevant reports not identified by our electronic searches. In order to retrieve additional relevant information, we also performed hand searches of the "gray literature." Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. The latter documents do not appear in the peer-reviewed journal literature.

Retrieval Criteria

Retrieval criteria were used to determine whether a full-length version of an article identified by our searches should be ordered. Decisions pertaining to whether a full-length article should be retrieved are usually based on a review of available abstracts. For this project, retrieval criteria were determined *a priori* in conjunction with the FMCSA. The retrieval criteria are presented in Appendix B.

If an article did not meet the retrieval criteria for this evidence report, the full-length version of the article was not obtained. If it was unclear whether a potentially relevant article met our retrieval criteria (e.g., no abstract was available for evaluation), the full-length version of that article was obtained.

Inclusion and Exclusion Criteria

Each retrieved article was read in full by an ECRI Institute analyst who determined whether the article met a set of predetermined, question specific, inclusion criteria. As was the case for the retrieval criteria, the inclusion criteria for this evidence report were determined *a priori* in conjunction with the FMCSA. These inclusion and exclusion criteria are presented in Appendix C.

If an article did not meet the question-specific inclusion criteria listed in Appendix C, the article was excluded from the analysis. Each excluded article, along with the reason(s) for its exclusion, are presented in Appendix D.

Evaluation of Quality and Strength of Evidence

Rather than focus on the quality of the individual studies that comprise an evidence base, our approach to assessing the quality of evidence focused on the overall *body* of the available evidence that was used to draw an evidence-based conclusion.(40) Using this approach, which is described briefly in Appendix E, we took into account not only the quality of the individual studies that comprise the evidence base for each key question, we also considered the interplay between the quality, quantity, robustness, and consistency of the overall body of evidence.

Our approach to assessing the strength of the body of evidence makes a clear distinction between a qualitative conclusion (e.g., “Individuals with Ménière’s disease are at increased risk for a motor vehicle crash”) and a quantitative conclusion (e.g., “When compared to individuals who do not have Ménière’s disease, the risk ratio for a motor vehicle crash among individuals with the disorder is 1.37; 95% CI: 1.03–1.74; P <0.005.”). As shown in Table 5, we assigned a separate strength of evidence rating to each of type of conclusion. Evidence underpinning a qualitative conclusion was rated according to its strength, and evidence underpinning quantitative conclusions was rated according to the stability of the effect size estimate that was calculated.

Table 5. Strength of Evidence Ratings for Qualitative and Quantitative Conclusions

Strength of Evidence	Interpretation
Qualitative Conclusion	
Strong	Evidence supporting the qualitative conclusion is convincing. It is highly unlikely that new evidence will lead to a change in this conclusion.
Moderate	Evidence supporting the qualitative conclusion is somewhat convincing. There is a small chance that new evidence will overturn or strengthen our conclusion. ECRI Institute recommends regular monitoring of the relevant literature for moderate-strength conclusions.
Minimally acceptable	Although some evidence exists to support the qualitative conclusion, this evidence is tentative and perishable. There is a reasonable chance that new evidence will either overturn or strengthen our conclusions. ECRI Institute recommends frequent monitoring of the relevant literature.
Insufficient	Although some evidence exists, the evidence is insufficient to warrant drawing an evidence-based conclusion. ECRI Institute recommends frequent monitoring of the relevant literature.
Quantitative Conclusion (Stability of Effect Size Estimate)	
High	The estimate of treatment effect in the conclusion is stable. It is highly unlikely that the magnitude of this estimate will change substantially as a result of the publication of new evidence.
Moderate	The estimate of treatment effect the conclusion is somewhat stable. There is a small chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI Institute recommends regular monitoring of the relevant literature.
Low	The estimate of treatment effect included in the conclusion is likely to be unstable. There is a reasonable chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI Institute recommends frequent monitoring of the relevant literature.
Unstable	Estimates of the treatment effect are too unstable to allow a quantitative conclusion to be drawn at this time. ECRI Institute recommends frequent monitoring of the relevant literature.

The definitions presented in the table above are intuitive. Qualitative conclusions that are supported by strong evidence are less likely to be overturned by the publication of new data than conclusions supported by weak evidence. Likewise, quantitative effect size estimates that are deemed to be stable are more unlikely to change significantly with the publication of new data than are unstable effect size estimates.

Statistical Methods

The set of analytic techniques used in this report was extensive. In summary, random- and fixed-effects meta-analyses were used to pool appropriate data from different studies.(41-50) Important differences in the findings of different studies (heterogeneity) were identified using the Q-statistic and I^2.(46,51-56) Whenever appropriate, heterogeneity was explored using meta-regression techniques.(57-59) Sensitivity analyses was used to test the robustness of all findings.(60-66) The presence of publication bias was tested for using the "trim and fill" method.(67) All meta-analyses in this Evidence Report were performed using comprehensive meta-analysis software.(68-70)

We calculated several different estimates of effect. The choice of effect size estimate depended on the purpose of the studies we assessed, their design, and whether reported outcome data were continuous or dichotomous. Between-group differences in outcome measured using continuous data were analyzed in their original metric (if all included studies reported on the same outcome using the same metric) or the data were standardized into a common metric known as the standardized mean difference (SMD). Dichotomous data were analyzed using the rate ratio (RR) or the odds ratio (OR). Time-to-event data

were analyzed using the hazard ratio (RH). The formulae for these effect sizes and their variance are presented in Table 6. If means and standard deviations were not available for continuous data, every effort was made to determine an estimate of treatment effect from reported statistics (e.g., t-values, f-values) or from p-values using methods described in detail elsewhere.(71)

Table 6. Effect Size Estimates Used in Evidence Report and their Variance

Effect size	Formula (Effect size)	Formula (Variance)
WMD	$\mu_{TG} - \mu_{CG}$	$\left(\sqrt{\frac{(n_{TG}-1)(s_{TG})^2 + (n_{CG}-1)(s_{CG})^2}{n_{TG}+n_{CG}-2}}\right)\left(\frac{1}{n_{TG}} + \frac{1}{n_{cg}}\right)$
SMD	$\frac{\mu_{TG} - \mu_{CG}}{\left(\sqrt{\frac{(n_{TG}-1)(s_{TG})^2 + (n_{CG}-1)(s_{CG})^2}{n_{TG}+n_{CG}-2}}\right)}$	$\frac{n_{TG}+n_{CG}}{n_{TG}n_{CG}} + \frac{SMD^2}{2(n_{TG}+n_{CG})}$
Where: μ_{TG} = mean (treatment group); μ_{CG} = mean (control group); S_{TG} = standard deviation (treatment group); S_{CG} = standard deviation (control group); n_{TG} = enrollees (treatment group); n_{CG} = enrollees (control group)		
Event Rate	$a/a+b$	$\ln\left[\frac{1}{a} + \frac{1}{a+b}\right]$
Where: a = number of individuals in cohort experiencing an event; b = number of individuals in cohort who did not experience an event		
RR (incidence)	$\left(\frac{a_{HD}}{pt_{HD}}\right) \Big/ \left(\frac{b_{control}}{pt_{control}}\right)$	$\ln\left[\frac{1}{a_{HD}} + \frac{1}{b_{control}}\right]$
Where: a = number of individuals with a hearing disorder (HD) who crashed; pt_{HD} = rate denominator (HD grp); b = number of individuals without a HD who crashed; $pt_{control}$ = rate denominator (control grp)		
OR	$\left(\frac{a}{b}\right) \Big/ \left(\frac{c}{d}\right) = \left(\frac{ad}{bc}\right)$	$\frac{1}{a} + \frac{1}{b} + \frac{1}{c} + \frac{1}{d}$
RR	$\left(\frac{a}{a+c}\right) \Big/ \left(\frac{b}{b+d}\right)$	$\frac{1}{a} + \frac{1}{a+c} + \frac{1}{b} + \frac{1}{b+d}$
Where: a = number of individuals with a hearing disorder (HD) who crashed; b = number of individuals without a HD who crashed; c = number of individuals with a HD who did not crash; d = number of individuals without a HD who did not crash.		

Effect size	Formula (Effect size)	Formula (Variance)
HR	$\frac{O_{pi}/E_{pi}}{O_{ci}/E_{ci}}$	$\exp\left(\ln\left[\frac{1}{E_{pi}}+\frac{1}{E_{ci}}\right]\right)$
Where O_{pi} = observed number of events in treatment group; O_{ci} = observed number of events in control group; E_{pi} = logrank expected number of events in treatment group; E_{ci} = logrank expected number of events in control group		

HD = Hearing disorder
HR = Hazard ratio
OR = Odds ratio
RR = Rate ratio
SMD = Standardized mean difference
WMD = Weighted mean difference

Evidence Synthesis

This section summarizes the findings of our systematic review of the evidence pertaining to each of the key questions asked by the FMCSA.

Key Question 1: Are individuals with hearing thresholds of 40 dB or greater at 500 to 3,000 Hz at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have a hearing impairment?

Identification of Evidence Base

To meet the aims of this section of the evidence report, we searched for trials that compared the incidence of crash among individuals with a hearing impairment and otherwise comparable individuals who do not have a hearing impairment. In addition, we looked for studies that compared the prevalence of hearing impairment among cohorts of individuals who have or have not experienced a crash.

The evidence-base identification pathway for Key Question 1 is summarized in Figure 7. Our searches[1] identified a total of 44 articles that appeared relevant to this key question. Following application of the retrieval criteria for this question, 29 full-length articles were retrieved and read in full. Three of these 29 retrieved articles were found to meet the inclusion criteria[2] for Key Question 1 (Table 7). Table D-1 of Appendix D lists the 26 articles that were retrieved, read in full, and then excluded. The table also provides justification for their exclusion.

[1] See Appendix A for search strategies.

[2] See Appendix C for inclusion criteria.

[2] See Appendix C for inclusion criteria.

[3] The prevalence of hearing impairment among individuals experiencing a crash divided by the prevalence of hearing impairment among comparable individuals who do not experience a crash

[4] The odds of an individual who crashed having a hearing impairment divided by the odds of an individual who did not crash having a hearing impairment

[5] See Appendix A for search strategies.

[6] See Appendix C for inclusion criteria.

[7] See Appendix A for search strategies.

Figure 7. Development of Evidence Base for Key Question 1

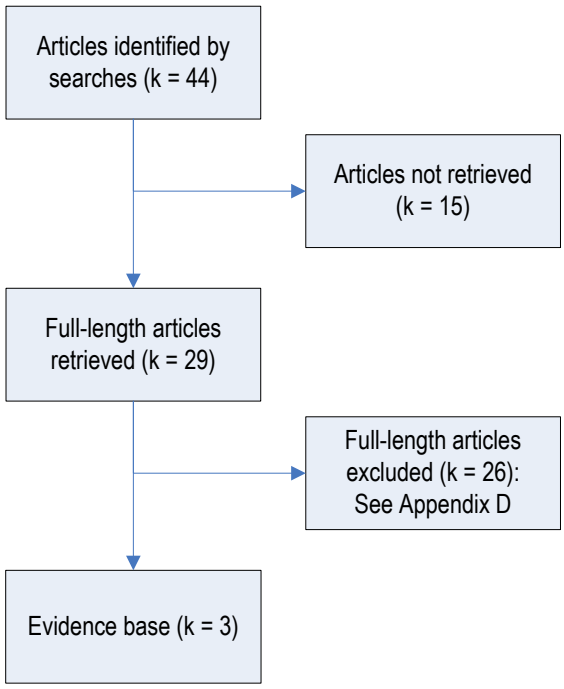


Table 7. Evidence Base for Key Question 1

Reference	Year	Study Location	Country
Ivers et al.(72)	1999	Sydney	Australia
Gresset et al.(73)	1994	Quebec	Canada
McCloskey et al.(74)	1994	Washington	USA

Evidence Base

This subsection provides a brief description of the key attributes of the three studies that comprise the evidence base for Key Question 1. As discussed in the inclusion criteria for KQ1 (see Appendix C), the studies used in this evidence base must have been published after 1992 in order to take into account the information presented in the Songer et al. report (see Background section *Previous Evidence Reports from the FMCSA*). Here we discuss applicable information pertaining to the quality of the included studies and the generalizability of each study's findings to drivers of CMVs. The key attributes of each included study are presented in Table 8.

Table 8. Key Study Design Characteristics of Studies that Address Key Question 1

Reference	Year	Study Design	Comparison	Diagnosis of hearing impairment	Factors controlled for (if compared to non-hearing impaired controls)?	Driving exposure controlled for?	Primary outcome	Definition of crash	Outcome self-reported?
Ivers et al.(72)	1999	Case-Control Study†	834 individuals with some degree of hearing loss compared with 1,444 individuals with no hearing loss	Self-report	Age Gender Past and current use of benzodiazepines, phenothiazines, and antidepressants Self-reported history of stroke, arthritis, angina, heart attack, hypertension, and diabetes health status	No	Crash risk	Not Reported	Yes (interview)
Gresset et al.(73)	1994	Case-control study*	1,400 drivers who had a crash during their 70th year compared with 2,636 drivers who did not have a crash during their 70th year	Medical examination	Not reported	Yes	Difference in proportion of individuals with hearing impairment crash risk	Driver in a crash that resulted in either property damage or in mild bodily injury	No (crash files of the Societe de l'Assurance Automobile du Quebec [SAAQ])
McCloskey et al.(74)	1994	Case-control study*	235 drivers who had sought medical care, within 7 days, for injuries sustained in a motor vehicle crash compared with 448 drivers who had not been injured in a motor vehicle crash	Medical records	Gender, age, county of residence	Yes	Difference in proportion of individuals with hearing impairment Crash risk	In Washington State, the legal criteria for reporting a motor vehicle crash to the police were physical damage of $300 or more to any single vehicle or any injury to any person in any of the involved vehicles	No (police report and medical records)

* A case-control study in which cases are defined according to whether individuals have experienced a crash and controls consist of a cohort of individuals who have not.

† A case-control study in which cases are defined according to the presence of hearing loss and controls consist of a cohort of individuals who do not

.

The three included studies (in Table 8) used one of two different study design methodologies. The most commonly used approach (*k = 2*) was to select cohorts on the basis of crash involvement (case-control design) and compare the prevalence of hearing impairment among individuals who experienced a crash (cases) and those who did not (controls). The less commonly used methodology (*k = 1*) selected drivers with hearing impairment and compared the incidence of crash over a defined time period with the incidence of crash occurring over a similar time period among comparable individuals without hearing impairment (retrospective cohort design).

Quality of Evidence Base

The findings of our assessment of the quality of the studies that comprise the evidence base for Key Question 1 are summarized in Table 9. Complete details of our quality assessment can be found in the study summary tables presented in Appendix G. Our assessment found that the quality of the included studies was not high. Two of the three included studies were graded as being moderate quality. The remaining study was graded as being low quality.

Table 9. Quality of the Studies that Assess Key Question 1

Reference	Year	Quality Scale Used	Quality
Ivers et al.(72)	1999	Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies	Low
Gresset et al.(73)	1994	Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies	Moderate
McCloskey et al.(74)	1994	Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies	Moderate

A design problem common to many risk assessment studies is the failure to control adequately for exposure. In this instance, the exposure variables of critical importance are the number of miles driven per unit time and the time frame over which data were collected. If cases and controls are not well matched for exposure to risk, then any observed differences in the risk may simply be the consequence of differences in exposure. A majority of the included studies attempted to control for both of these exposure variables.

Crash rates were determined from data obtained from two primary sources: databases and questionnaires. In order for data from databases to be informative, the relevant information contained within the database must be precise. Since we have no way of determining the precision of the information contained within any of the databases used to inform the studies included in this report, the degree of confidence that one may have in data extracted from these databases is not clear. The degree of confidence that one can have in crash rates derived from questionnaires is also unclear, primarily because questionnaires depend upon reliable reporting by the individual being questioned.

Generalizability of Evidence to Target Population

Important characteristics of the individuals represented in the three studies that comprise the evidence base for Key Question 1 are presented in Table 10. The information presented in this table demonstrates that currently available data that is directly generalizable to CMV drivers is limited. None of the included studies enrolled populations of CMV drivers. Instead, the studies included private motor vehicle license holders, an unknown number of whom may have held commercial driver licenses. The generalizability of the findings of these studies to CMV drivers is therefore unclear.

Table 10. Individuals with Hearing Impairment Enrolled in Studies that Address Key Question 1

Reference	Year	Number of individuals included (n =)	Severity of hearing impairment and how was assessed (n =)	Age distribution			% Male		% CMV drivers	Driving exposure			Ethnicity *		Generalizability to target population
Ivers et al.(72)	1999	1,444 controls 834 cases	Hearing impairment was self-reported and severity was divided into 3 categories: Mild n = 559 Moderate n = 187 Severe n = 88	NR			NR		NR	NR			NR		Unclear
Gresset et al.(73)	1994	1,400 drivers who had a crash, 2,636 drivers who did not have a crash	Hearing impairment was determined through medical evaluation. Severity was not reported.	70 years			100		NR	NR			NR		Unclear
McCloskey et al.(74)	1994	235 drivers who had a crash, 448 drivers who had not been injured in a crash	Hearing impairment was determined through medical evaluation. Severity was not reported.	**Age** **65 - 69** **70 - 74** **75 - 79** **≥80**	**Cases** 38.3% 28.1% 21.3% 12.3%	**Controls** 38.6% 28.8% 19.6% 12.7%	**Cases** 49.8%	**Controls** 50.0%	NR	**Miles driven/yr** <1,000 1,000 – 4,999 5,000 – 9,999 10,000 – 14,999 ≥15,000	**Cases** 14.5% 29.1% 25.2% 19.7% 11.5%	**Controls** 12.1% 31.8% 28.0% 18.8% 9.4%	**Cases** 91.9%	**Controls** 96.9%	Unclear

NR = Not reported

* Data expressed as percent Caucasian.

Findings

The evidence base for Key Question 1 is comprised of two distinct types of study design. One retrospective cohort study(72) compared the incidence of crash occurring among individuals with hearing impairment and a comparable group of individuals who did not have hearing impairment. The remaining two studies(73,74) were case-control studies that compared the prevalence of hearing impairment among individuals who had been involved in a crash (cases) and a comparable group of individuals who had not (controls). Although both types of study may be considered to address the same question from a qualitative perspective (Does hearing impairment represent an increased crash risk?), they differ significantly from a quantitative perspective. Outcome data from the retrospective cohort study are presented as an incidence rate ratio RR[3]. Outcome data from the case-control studies were presented as Odds Ratio (OR)[4].

Hearing Impairment and Crash Risk: Findings of the Prevalence Ratio (PR) Study

Ivers et al.(72) (Quality Rating: Low) reported on the prevalence of crashes occurring among populations of individuals with hearing impairment and prevalence of crashes occurring among individuals without hearing impairment.(72) The results of this study are summarized in Table 11. This study, although large (n = 2,326 drivers), contained the following flaws that may have compromised the reliability of the data reported: self-reported crash data; self-reported hearing impairment; no measure or control of driving experience, kilometers driven, and type or severity of crash; and no assessment of the cognitive function of the drivers.

Table 11. Association between Self-Reported Hearing Impairment and Self-Reported Car Accidents

Variable	N (%)	Age / Sex Adjusted		*P* [b]	Adjusted [a]		*P* [b]
		PR	95% CI		PR	95% CI	
Hearing loss							
Yes versus no	866 (37.5)	1.4	1.0 – 2.0		1.5	1.0 – 2.1	
None	1,444 (63.4)	1.0	Reference		1.0	Reference	
Mild	559 (24.5)	1.2	0.8 – 2.5		1.1	0.7 – 1.7	
Moderate	187 (8.2)	1.9	1.1 – 3.2		1.9	1.1 – 3.3	
Severe	88 (3.9)	1.6	0.7 – 3.6	0.03	1.5	0.7 – 3.4	0.02
Moderate/severe versus mild	275 (33.0)	1.5	0.9 – 2.5		1.7	1.0 – 2.9	
Use of hearing aid [c]	103 (6.7)	1.6	0.7 – 3.7		1.6	0.7 – 3.6	

CI = Confidence interval
PR = Prevalence ratio

[a] Adjusted for age; gender; past and current use of benzodiazepines, phenothiazines, and antidepressants; self-reported history of stroke, arthritis, angina, heart attack, hypertension, and diabetes; and health status

[b] *P* for trend

[c] versus no hearing loss

[3] The prevalence of hearing impairment among individuals experiencing a crash divided by the prevalence of hearing impairment among comparable individuals who do not experience a crash

[4] The odds of an individual who crashed having a hearing impairment divided by the odds of an individual who did not crash having a hearing impairment

Findings of studies that compared the prevalence of hearing impairment among drivers who did and did not crash

Two of the three studies (Quality Rating: Moderate) presented data on the odds of an individual who experienced a crash having impaired hearing relative to the odds of a comparable individual who did not crash having impaired hearing.(73,74) The findings of these studies are summarized in Table 12.

Table 12. Findings of Odds Ratio Studies

Reference	Year	Condition	Crash Rate Data				Evidence of increased Crash Risk?
			% with condition (crashers)	% with condition (non-crashers)	Effect Size (95% CI)	*P* =	
Gresset et al.(73)	1994	Hearing impairments	Not Reported	Not Reported	OR = 0.90 (0.65–1.24)	Not Reported	No
McCloskey et al.(74)	1994	Hearing impairment ever diagnosed	27.3	22.4	OR = 1.3 (0.9–1.8)	Not Reported	No
		Hearing aid:					
		• Prescribed	14.2	12.1	OR = 1.2 (0.8–2.0)	Not Reported	No
		• Owned	19.7	13.8	OR = 1.6 (1.1–2.6)	Not Reported	Yes
		• Used ≥12 hours / day*	9.2	7.2	OR = 1.6 (0.9–3.0)	Not Reported	No
		• Used <12 hours / day*	11.4	6.1	OR = 1.8 (0.9–3.4)	Not Reported	No
		• Owned and worn for driving*	13.0	8.7	OR = 1.9 (1.1–3.3)	Not Reported	Yes
		• Owned but not worn for driving*	8.3	5.6	OR = 1.7 (0.8–3.6)	Not Reported	No

OR = Odds ratio

* Versus non-owners

The data from these two included studies are consistent: both studies suggest that hearing impairment does not increase crash risk, and one study found that owning a hearing aid and wearing one for driving increases an individual's crash risk compared to non-owners.(74) A possible explanation for the increased risk of crash among individuals who wear a hearing aid while driving is "that a hearing aid worn while driving might produce feedback or other sounds that could distract the driver."(74) Regardless, the findings of this study do not provide compelling evidence in support of the contention that individuals with hearing loss are at an increased risk for a crash.

Summary of Findings

Three articles describing three unique studies met the inclusion criteria for Key Question 1. One of the three studies was graded as low quality. The remaining two studies were graded as being moderate quality. None of these studies enrolled distinct populations of commercial motor vehicle (CMV) drivers. Instead the three studies included private motor vehicle license holders, an unknown number of whom may have held commercial driver licenses. Conclusions from the findings of our analysis of the data extracted from the three studies are presented below:

- **Whether hearing loss (defined as a hearing threshold of 40 dB or greater at 500 to 3,000 Hz) is a risk factor for crash among CMV drivers cannot be determined at the present time.**

  No studies that examined the relationship between hearing loss and crash risk among CMV drivers were identified by our searches.

- **Evidence from the private driver license holder population does not support the contention that individuals with hearing impairment are at an increased risk for a crash (Strength of Conclusion: Minimally Acceptable).**

  One retrospective cohort study (Quality Rating: Low) reported on the incidence of crashes occurring among populations of individuals with hearing impairment and prevalence of crashes occurring among individuals without hearing impairment. This study did not provide evidence to support the contention that individuals with hearing deficits are at an increased risk for a motor vehicle crash.

  Two further studies, both of which were case-control studies (Quality Rating: Moderate), reported on the difference in the prevalence of hearing impairment among cohorts of individuals who have experienced a motor vehicle crash and comparable cohorts of individuals who have not experienced a crash. Consistent with the findings of the retrospective cohort study, neither study found evidence to support the contention that individuals with hearing impairment are at an increased risk for a crash.

Key Question 2: Is the forced-whisper test a valid measure of hearing ability?

Identification of Evidence Base

To meet the aims of this section of the evidence report, we searched for studies that were designed to test the validity of the forced-whisper test as a measure of hearing ability.

The evidence-base identification pathway for Key Question 2 is summarized in Figure 8. Our searches (Appendix A) identified a total of 108 articles that appeared relevant to this key question. Following application of a set of retrieval criteria (Appendix B), 14 full-length articles were retrieved and read in full. Of these 14 retrieved articles, 4 were found to meet the inclusion criteria for Key Question 2 (Appendix C).

Table 13 lists the four included studies. Table D-2 of Appendix D lists the 10 articles that were retrieved but then excluded from inclusion in the evidence base for Key Question 2 and provides the reason for their exclusion.

Figure 8. Development of Evidence Base for Key Question 2

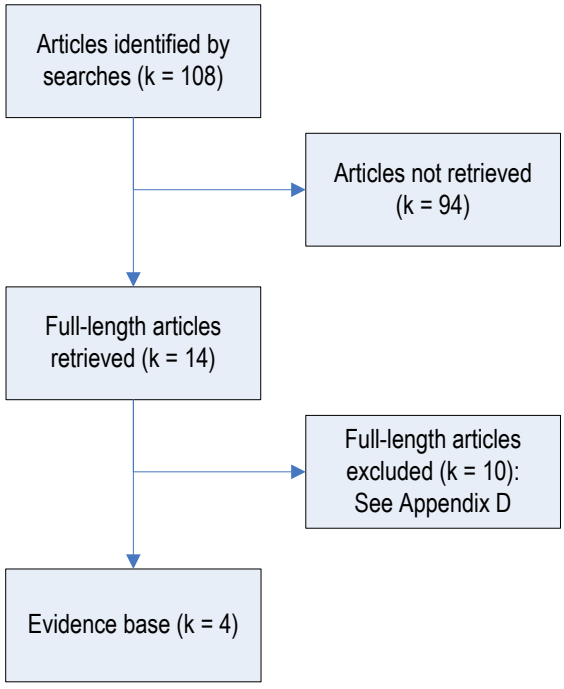


Table 13. Evidence Base for Key Question 2

Reference	Year	Study Location	Country
Lee (75)	1998	Blacksburg, VA	USA
Browning et al.(76)	1989	Glasgow	Scotland
Macphee et al.(77)	1988	Glasgow	Scotland
Swan and Browning(78)	1985	Glasgow	Scotland

Evidence Base

Key characteristics of the four included studies that address Key Question 2 are presented in Table 14. More detailed information pertinent to this section is presented in the *Study Summary Tables* that can be found in Appendix G.

Table 14. Key Study Design Characteristics of Studies that Address Key Question 2

Reference	Year	Study Design	N (% male)	Setting	Procedure for Forced-Whisper Test	Reference Standard	Participants	Consecutive Patients?
Lee (75)	1998	Diagnostic Cohort	21 (38%)	Lab	After classifying subjects based on 3 hearing categories (see next column), the subjects received a forced-whisper test presented by loudspeaker from a shelf-top stereo system. Subjects received instruction on the 3 types of words to be listened for, and a soft foam earplug was used to mask the non-test ear. The subject began the test at 5 feet from the loudspeaker, and listened to a set of 3 forced-whisper words from that distance. The listener then wrote down the words heard, if any. If 2 of 3 words were heard correctly, the test ended for that ear. If the subject was unable to pass the test at 5 feet, the test was repeated at 1-foot increments (at 4, 3, and 2 feet), ending when the listener passed the test (or failed to pass the test at the 2-foot minimum distance).	Pure-tone audiometry Subjects were placed into 3 hearing level categories: 1) -10 to 5 dBHL 2) >5 to 15 dBHL and 3) >15 dBHL	101 (202 ears) consecutive individuals referred with otological symptoms before history taking, clinical examination, or audiometric evaluation	Yes
Browning et al.(76)	1989	Diagnostic Cohort	101 (Not Reported)	Outpatient Clinic	Subjects were asked to repeat test-words spoken in a forced-whisper at a distance of 6 inches and 2 feet from the test ear while masking the non-test ear by tragal rubbing. Test-words consisted of any combination of 3 digits and letters (e.g., 6, B, 4). The hearing threshold was taken as the voice level and distance at which the patient correctly repeated at least 2 of the 3 test-words on a minimum of 2 occasions.	Pure-tone audiometry	101 (202 ears) consecutive individuals referred with otological symptoms before history taking, clinical examination, or audiometric evaluation	Yes

Reference	Year	Study Design	N (% male)	Setting	Procedure for Forced-Whisper Test	Reference Standard	Participants	Consecutive Patients?
Macphee et al.(77)	1988	Diagnostic Cohort	62 (31%)	Victoria Geriatric Unit	Standing behind the individual's field of vision, removing the ability to lip-read, and masking the hearing in the nontested ear by gently occluding and rubbing the external auditory canal. The individual was then requested to repeat a set of three random numbers (e.g., 6, 1, 9) presented to a single ear using a whispered voice following complete expiration at 6 inches and 2 feet from the ear. A pass was achieved if the individual repeated all 3 numbers correctly or achieved greater than 50% success over 3 triplet sets of numbers.	Pure-tone audiometry	62 (124 ears) consecutive individuals with a mean age of 80.8 (range: 66 to 96) years	Yes
Swan and Browning(78)	1985	Diagnostic Cohort	101 (Not Reported)	Outpatient Clinic	Standing behind the patient and masking the non-test ear, a combination of 3 numerals and letters (e.g., 5, B, 6) was whispered at arm's length (2 feet) from the test ear. Whispering was done after full expiration to ensure as quiet a voice as possible. If the individual repeated all 3 numerals or letters correctly, they were considered to have passed the screening test. If they responded incorrectly or not at all, the test was repeated once more using a different 3 numeral/letter combination. Overall an individual was considered to have passed the screening test if they repeated at least 3 out of a possible total of 6 letters or numerals correctly.	Pure-tone audiometry	101 (202 ears) consecutive individuals with aural symptoms who were seen at an audiology clinic by the authors and who had no previous audiometric assessment available Mean age of 57 (range: 17 to 89) years	Yes

dBHL = Decibels hearing level

Quality of Evidence Base

The results of our assessment of the overall quality of the evidence base for Key Question 2 are presented in Table 15. Complete details of our quality assessment can be found in the study summary tables presented in Appendix G. Our assessment found the quality of the included studies to be in the low-to-moderate range.

Table 15. Quality of Studies for Key Question 2

Reference	Year	Quality Scale Used	Quality
Lee (75)	1998	ECRI Institute Assessment Tool for Diagnostic Studies	Moderate
Browning et al.(76)	1989	ECRI Institute Assessment Tool for Diagnostic Studies	Low
Macphee et al.(77)	1988	ECRI Institute Assessment Tool for Diagnostic Studies	Low
Swan and Browning(78)	1985	ECRI Institute Assessment Tool for Diagnostic Studies	Low

Generalizability of Evidence to Target Population

Important characteristics of the individuals represented in the four studies that comprise the evidence base for Key Question 2 are presented in Table 16. The generalizability of the individuals enrolled in the included studies to CMV drivers is unclear. None of the studies provided information about the occupation or driving experience of the participants, making it difficult to generalize on the basis of employment or driving exposure. CMV drivers in the United States tend to be older (over 40 years) males. In the studies that did report age and gender, the mean age was more than 40 years but less than 40% of the subjects were male.

Table 16. Individuals Enrolled in Studies that Address Key Question 2

Reference	Year	N	Participants	Mean Age (years)	% Male	% CMV drivers	Generalizability to CMV Population
Lee(75)	1998	21	Recruited for laboratory experiment	33 (range: 20 to 65)	38	Not Reported	Unknown
Browning et al.(76)	1989	101	Referrals to outpatient clinic with otological symptoms	Not Reported	Not Reported	Not Reported	Unknown
Macphee et al.(77)	1988	62	Admitted to acute rehabilitation geriatric wards	80.8 (range: 66 to 96)	31	Not Reported	Unknown
Swan and Browning(78)	1985	101	Referrals to audiology clinic with aural symptoms	57 (range: 17 to 89)	Not Reported	Not Reported	Unknown

Findings

As noted above, four studies presented diagnostic data on the forced-whisper test compared to pure-tone audiometry. The findings of these studies are presented in Table 17.

Table 17. Sensitivity and Specificity of the Forced-Whisper Test Compared to Pure-Tone Audiometry

Reference	Year	N =	Setting	Assessment of hearing	Threshold	SEN (%)	SPE (%)	PPV (%)	NPV (%)
Lee (75)	1998	21	Lab	Whispered voice at 2 and 5 feet (dBHL)	**Whispered voice at 5 feet**			Not Reported	Not Reported
					≤40 dB HL	100	32.5		
					≤20 dB HL	100	38.2		
					≤10 dB HL	100	46.4		
					Whispered voice at 2 feet				
					≤40 dB HL	100	62.5		
					≤20 dB HL	100	73.5		
					≤10 dB HL	85.7	82.1		
Browning et al.(76)	1989	101	Outpatient Clinic	Whispered voice at 2 feet (dBHL)	**PTA average, 0.5, 1, 2 kHz**			Not Reported	Not Reported
					≤25 dB HL	86	94		
					≤30 dB HL	95	90		
					≤35 dB HL	100	84		
					PTA average, 0.5, 1, 2, 4 kHz				
					≤25 dB HL	91	96		
					≤30 dB HL	96	91		
					≤35 dB HL	98	86		
Macphee et al.(77)	1988	62	Geriatric Unit	Whispered voice at 6 inches and 2 feet (dB)	**Whispered voice at 6 inches**				NR
					≤30 dB	73	100	100	
					Whispered voice at 2 feet				
					≤30 dB	100	84	92	
Swan and Browning(78)	1985	101	Outpatient Clinic	Whispered voice at 2 feet (dB)	≤30 dB	100*	87*	85*	100*

dBHL = Decibels hearing level

* Calculated by ECRI Institute.

King defined a whisper as “speech produced on expiration without the vibration of the vocal cords.”(79) He further defined a forced-whisper as being “produced by whispering with the residual air after expiration”; this is the method generally used when performing the forced-whisper test. There are, however, several weaknesses of the forced-whisper test.(79) These weaknesses include:

- Lack of standardization – standardization parameters include standardizing the definition of a forced whisper, the distance from the examiner to the patient, the masking technique used for the nontest ear, and the words/letters to be used.
- The inability to control the pitch and intensity of a whisper – associated with differences in timbre and quality due to overtones and to accent and inflection. The inability to control a whisper’s pitch and intensity may be influenced by ambient noise.(80)
- The lack of control of ambient noise – King(79) reported that in some rooms ambient noise levels ranged from 24 to 65 dB, with peak ambient noise over 70 dB
- The different acoustic properties of test rooms – factors contributing to this problem depend on the structure and contents of the room. In addition, the sound intensity at any given distance from a speaker’s voice may not be the same for rooms that have different contents and different dimensions.(79)

With these weaknesses in mind, we now summarize the findings of the four included studies for this key question.

Findings of Browning, Swan and Chew

Browning et al.(76) (Quality: Low) compared the results of a forced-whisper test with audiometric testing. One of two clinicians tested 101 individuals using the forced-whisper test before performing any other examinations. Individuals were asked to repeat test words spoken at distances of six inches and two feet from the test ear. Test words were a random combination of three digits and letters, and the threshold was defined as the voice level and distance for which individuals repeated two of three test words correctly for at least two tests. No differences were found between the clinicians in terms of the comparison of the forced-whisper test to the audiometric test, although the vocal intensity levels of the clinicians were not measured. The forced-whisper test at 2 feet had a sensitivity of 100% (no false negatives) and a specificity of 84% (16% false positives) for detecting hearing thresholds greater than 35 dBHL, where hearing level was measured as an arithmetic average of the hearing thresholds at 0.5, 1, and 2 kHz (see Table 17). Based on these results, the authors recommend this method for use by nonspecialists to screen for hearing impairment. However, this study has a serious flaw in that the two clinicians who performed the forced-whisper test were the first two authors of the paper and were reporting on themselves as subjects to a certain degree. Both had prior experience and were familiar with the definition of and procedure for performing forced-whisper tests. It is unclear whether the findings of this study would be the same as another study performed using inexperienced testers who have minimal training in the procedure.

Findings of Macphee, Crowther, and McAlpine

Macphee et al.(77) (Quality: Low) studied the use of a forced-whisper test to screen for hearing impairments in elderly individuals being admitted to a geriatric unit. Sixty-two individuals were tested at their bedside by a geriatrician and an otolaryngologist (each individual received two independent tests). Tragal masking was used, and the tester stood behind the individual to occlude vision. A forced-whisper test at six inches and two feet was performed for each ear. The individual was asked to repeat a set of three random numbers presented at each of these conditions. Pure-tone audiometry was then performed blindly with regards to the forced-whisper test results. Hearing impairment for the purposes of this study was defined as a mean threshold at 0.5, 1, and 2 kHz greater than 30 dBHL. The voice testing between the two testers was concordant in 88% of all ears and in 100% of all ears able to hear the forced-whisper at 2 feet. Of the 38 ears that could hear a forced-whisper at two feet, none had a hearing threshold greater than 30 dBHL. Of the 86 remaining ears that could not detect the forced-whisper at 2 feet, only 7 had hearing thresholds less than 30 dBHL. All of the ears unable to detect the forced-whisper at six inches were classified as hearing-impaired. Sensitivity, specificity, and positive predictive value of this test are shown in Table 17.

The conclusion drawn from this study was that the forced-whisper test is a reliable screening test for elderly individuals who may benefit from the use of a hearing aid. The authors cited the excellent concordance of the geriatrician and otolaryngologist as evidence that nonspecialist examiners can produce reliable results using this methodology. But several aspects of this study limit its generalizability. For example, the training of the geriatrician was not specified with regard to the forced-whisper test (either medical school training or training for the purposes of this study). The vocal intensity levels of the two testers was not measured or reported, nor were the ambient noise levels of the bedside environments reported. Since only two testers were used, intertester variability was minimized.

Findings of Swan and Browning

Swan and Browning(78) (Quality: Low) reported on an experiment comparing the results of forced-whisper tests to audiometric tests. The authors evaluated 202 ears using the forced-whisper test; the experimenter (one of the authors) stood 2 feet behind the individual and whispered a combination of 3 letters and digits while masking the untested ear with tragal rubbing. When individuals failed to repeat all three correctly, another three letter/digit combination was used. Individuals were considered to have passed the test if they were able to repeat three of the possible six letters or digits correctly. The individual's hearing was then tested by audiometry at 0.5, 1, and 2 kHz. For individuals with a hearing threshold level of 30 dBHL or less, the screening test produced a 13% false-positive rate (13% of individuals with a hearing level in this range had failed the forced-whisper test). For individuals with a hearing level greater than 30 dBHL, the forced-whisper test was 100% accurate (all individuals with hearing loss in this range had failed the forced-whisper test). Sensitivity and specificity of this test are shown in Table 17.

The authors concluded that the forced-whisper test was a simple and effective screening methodology. But the study contained several flaws. The authors were the whisperers and were familiar with the forced-whisper technique. They did not specify how the audiometry was performed (i.e., manually or

automatically), or if the audiometric test was performed blindly with regards to the results of the forced-whisper test, thus creating a potential for bias. If the forced-whisper technique is to be demonstrated as an effective screening technique to be used by a wide variety of people, it needs to be validated using as the whisperers the same people who will be expected to use the test in the field. Factors such as gender, age, and even the accent of the whisperer might affect the reliability of this test as a screening technique. The possibility of interwhisperer variability was not addressed by the authors.

Findings of Lee

In 1998, a report commissioned by the Federal Highway Administration (FHWA) was published titled "Role of Driver Hearing in Commercial Motor Vehicle Operation: An Evaluation of the FHWA Hearing Requirement."(81) In this report, the authors state the following:

"Based on this extensive review of literature, researchers also concluded that the forced-whisper test is not as reliable or valid as a hearing test based on pure-tone audiometry. A truly unbiased, comprehensive study of the validity and reliability of the forced-whisper test has not been attempted for over 50 years, during which the field of audiology has made great strides. Audiometers have become more widely available, and there are many people trained in their use. While the forced-whisper test is still a viable tool, pure-tone audiometry tests are a more precise and objective way to evaluate hearing."

This statements was based on the findings of Lee that were reported in her doctoral dissertation of the same title as the FHWA report.(76) The results of her work are summarized below.

Lee(76) (Quality: High) compared the results of a forced-whisper test with pure-tone audiometry at three frequencies. To keep the conditions as consistent as possible across subjects, a recorded forced-whisper voice was used. Twenty-one subjects, with varying degrees of hearing loss, were recruited for this study. Before beginning the experiment, subjects underwent an audiometric screening test at nine frequencies (0.125 to 8 kHz). Following audiometric testing, subjects were placed into three categories (-10 to 5 dBHL PTA, >5 to 15 dBHL PTA, and >15 dBHL PTA) based on hearing in the worse ear. There were 8 subjects in the -10 to 5 dBHL PTA group, 7 subjects in the >5 to 15 dBHL PTA group, and 6 subjects in the >15 dBHL PTA group. Nine forced-whisper words (three sets of three words each) were recorded by a subject from a previous experiment who was determined to be the most consistent whisperer (in terms of low standard deviation and proximity to the grand mean). Nine words with the least variability for this whisperer were selected as the test words. A windscreen was used when making the recordings, which were made in an anechoic chamber (to provide the quietest possible acoustic environment). Subjects received the forced-whisper test via a loudspeaker from a shelf-top stereo system. A soft foam earplug was used to mask the nontest ear. The room in which the forced-whisper test was conducted was set up so that it had similar acoustic characteristics to those of a physician's office. The listener began the test at five feet from the loudspeaker, and listened to a set of three forced-whisper words from that distance. The listener then wrote down the words heard, if any. If two of three words were heard correctly, the test terminated for that ear. If the listener was unable to pass the test at five feet, the test was repeated at one-foot increments (at four, three, and two feet), terminating when the listener passed the test (or failed to pass the test at the 2 foot minimum distance). The second ear was then tested in the same manner using a different set of three words.

The results of this study found that the forced-whisper test, performed at 5 feet from the listener, had a 100% sensitivity at the 40, 20, and 10 dBHL thresholds, however, the specificities ranged from 32.5% to 46.4% (see Table 17). The author states that these specificities are not enough to make the forced-whisper test a valid screening test, even at the 10 dBHL hearing level.(76) When the test is performed two feet from the listener, the test had a sensitivity of 100% at the 40 and 20 dBHL thresholds and 85.7% at the 10 dBHL threshold. Specificity of the test improved at two feet, ranging from 62.5% to 82.1% (see Table 17). The author states that a forced-whisper test performed under these highly standardized conditions at two feet is a good predictor of a 10 dBHL.(76)

Summary of Findings

- **The forced-whisper test is a viable tool for screening for hearing loss; however, it suffers from a number of shortcomings that limit its value as a diagnostic tool. (Strength of Conclusion: Moderate).**

  Four studies compared the performance of the forced-whisper test to pure-tone audiometry. Three of the four studies (all of low quality) found that the forced-whisper test had high sensitivity and specificity for accurately flagging individuals for hearing impairment.(76-78) All three of these studies failed to control for a number of important attributes associated with the forced-whisper test. The fourth included study was a high-quality study in which the forced-whisper test was compared to pure-tone audiometry under tightly controlled conditions (i.e., controlling for many of the potential weaknesses associated with the forced-whisper test). Consistent with the findings of the other three studies, this study found that the forced-whisper test had a high sensitivity; however, unlike the other studies, the specificity of the forced whisper test was found to be low.

  The finding that the forced-whisper test has a high sensitivity but a low specificity is important because it means that while the test can pick up most individuals with hearing loss, it will also flag many individuals with normal hearing as being hearing impaired. Thus, while the forced-whisper test may be considered as being a good screening test for hearing impairment, it should not be considered as being diagnostic for the disorder.

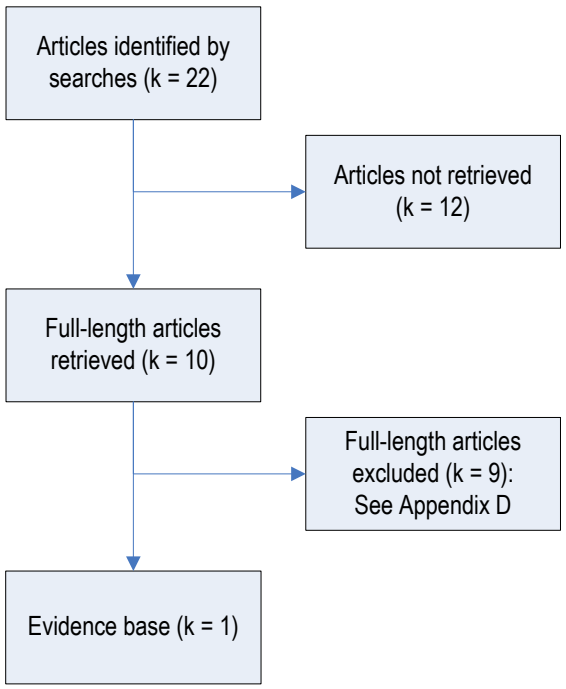
Key Question 3: Are individuals with a vestibular dysfunction (any condition that causes dizziness and/or vertigo, including Ménière's disease and benign paroxysmal positional vertigo [BPPV]) at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have a vestibular dysfunction?

Identification of Evidence Base

To meet the aims of this section of the evidence report, we searched for comparative trials that compared crash risk among individuals with a vestibular dysfunction and otherwise comparable individuals who do not have a vestibular dysfunction. In addition, we looked for studies that compared the prevalence of vestibular dysfunction among cohorts of individuals who have or have not experienced a crash.

The evidence base identification pathway for Key Question 3 is summarized in Figure 9. Our searches[5] identified a total of 22 articles that appeared relevant to this key question. Following application of the retrieval criteria for this question, 10 full-length articles were retrieved and read in full. Only 1 of these 10 retrieved articles, Cohen et al.,(82) was found to meet the inclusion criteria[6] for Key Question 3. Table D-1 of Appendix D lists the nine articles that were retrieved, read in full, and then excluded. The table also provides justification for their exclusion.

Figure 9. Development of Evidence Base for Key Question 3



[5] See Appendix A for search strategies.
[6] See Appendix C for inclusion criteria.

Evidence Base

This subsection provides a brief description of the key attributes of the single study that met the inclusion criteria for Key Question 1. Here we discuss applicable information pertaining to the quality of the study and the generalizability of the study's findings to drivers of CMVs. The key attributes of the study of Cohen et al. are presented in Table 18.

Table 18. Key Study Design Characteristics of Cohen et al. (2003)

Reference	Year	Study Design	Comparison	Diagnosis of vestibular dysfunction	Factors controlled for (if compared to non-hearing impaired controls)?	Driving exposure controlled for?	Primary outcome	Definition of crash	Outcome self-reported?
Cohen et al.(82)	2003	Retrospective cohort study	51 individuals with no vestibular dysfunctions compared to 34 individuals with benign paroxysmal positional vertigo (BPPV), 27 individuals with chronic vestibulopathy (CV), and 48 individuals with Ménière's disease	Medical Exam	Not Reported	No	Difficulty driving	Not Reported	Yes (interview and questionnaire)

Cohen and colleagues used a retrospective cohort study methodology in which several measures of driving performance obtained via a questionnaire were assessed among drivers with vestibular dysfunction compared to those obtained from comparable individuals who did not have a vestibular dysfunction.

Quality of Evidence Base

Our assessment found that the quality of the study by Cohen et al. (2003) was low. Data in this study was obtained using the Driving Habits Questionnaire (DHQ) given during a structured interview. The questionnaire contained several parts: current driving safety habits such as use of a seatbelt, driving exposure or the amount of driving the individual does per week, driving space or where the individual drives, and questions about the difficulty of driving in various challenging situations. In addition, the authors added six extra questions about problems specific to individuals with vestibular disorders. These additional questions are: "Since you developed vertigo, have you (1) pulled into or out of a parking space; (2) changed lanes while driving; (3) stayed within the lane where you are driving; (4) had to check for traffic before entering an intersection; (5) driven up or down a ramped parking garage?" and (6) "How many times in the past year (or since the vertigo started if you have had vertigo for less than one year) have you had to pull off the road because of vertigo?" The degree of confidence that one can have in data derived from questionnaires is unclear, primarily because questionnaires depend upon reliable reporting by the individual being questioned.

Complete details of our quality assessment can be found in the study summary tables presented in Appendix G.

Generalizability of Evidence to Target Population

Important characteristics of the individuals represented in Cohen et al. (2003) are presented in Table 19. Cohen and colleagues did not enroll distinct populations of CMV drivers. Instead they included private motor vehicle license holders, an unknown number of whom may have held commercial driver licenses. The generalizability of the findings from this study to CMV drivers is therefore unclear.

Table 19. Individuals with Vestibular Dysfunctions Enrolled in Cohen et al. (2003)

Reference	Year	Number of individuals included (n =)	History of vertigo in years (SD)	Age (SD)	% Male	% CMV drivers	Driving exposure (SD)	Ethnicity	Generalizability to target population
Cohen et al.(82)	2003	51 controls	None	51.9 (15.3)	47.1	NR	Controls: 6.5 (1.3) days per week Cases: 5.9 (1.8) days per week* Ménière's individuals: 5.5 (1.9) days per week Other case groups: 5.8 to 6.4 days per week†	NR	Unclear
		34 individuals with BPPV	0.92 (2.2)	54.8 (12.21)	32.4				
		27 individuals with CV	4.0 (7.1)	53.4 (13.0)	29.6				
		18 individuals with Ménière's disease from Houston, TX	6.7 (10.0)	50.9 (12.2)	27.8				
		30 individuals with Ménière's disease from Birmingham, AL	7.3 (10.3)	54.4 (13.0)	30.0				

AL = Alabama
BPPV = Benign paroxysmal positional vertigo
CV = Chronic vestibulopathy
NR = Not reported
SD = Standard deviation
TX = Texas

* p <0.006 compared to controls
† p = 0.033 compared to Ménière's individuals

Findings

As stated previously, the evidence base for Key Question 3 comprises one retrospective cohort study. This one study, conducted by Cohen and colleagues,(83) compared driving performance among individuals with vestibular dysfunctions and a comparable group of individuals who did not have vestibular dysfunctions.

Though the authors did not present actual crash data, they stated that individuals with vestibular dysfunctions "reported slightly fewer incidents of being pulled over by police, and few actual crashes, at a rate that did not differ from normal subjects." Because Cohen and colleagues did not provide any data regarding crashes, we are unable to determine a quantitative conclusion regarding crash risk in individuals with vestibular dysfunctions.

Other findings from this study pertaining to violation rates are contrary to those that one would expect to see if driving with a disorder that affects vestibular function is detrimental to safe driving. The authors reported that 10% of individuals with vestibular dysfunctions were pulled over by police for moving violations compared to 26% of normal individuals ($p = 0.017$). Similarly, 6% of individuals with vestibular dysfunctions received tickets for moving violations in the past year compared to 16% of normal individuals ($p = 0.072$). The authors explained that their finding as likely a reflection of the caution with which most individuals with vestibular dysfunctions drive.

While measures of crash and violation rates do not support the contention that individuals with vestibular dysfunction represent a safety hazard, Cohen et al. did provide some evidence that individuals with vestibular dysfunctions have more difficulty driving than comparable individuals who do not have vestibular dysfunctions. This evidence is summarized in Table 20. As indicated in the table, compared to individuals who do not have vestibular dysfunctions, individuals with vestibular dysfunctions reported having considerably more difficulty driving in the rain, driving alone, making left turns across traffic, during freeway driving, on high traffic roads, during rush hour, and at night. Furthermore, individuals with vestibular dysfunctions reported significantly more difficulty than individuals who do not have vestibular dysfunctions when pulling into or out of parking spaces, changing lanes in traffic, staying in lane while driving, checking for traffic before pulling into an intersection, and driving around a ramped parking garage. Finally, significantly more individuals with vestibular dysfunctions reported having to pull off the road due to vertigo than individuals who do not have vestibular dysfunctions.

Table 20. Findings of Cohen and Colleagues (2003) – Driving Difficulties

Reference	Year	Driving Challenge	Percent of individuals having difficulty				Cases vs. Controls (*p* value)	Evidence of increased driving difficulty
			Controls (n = 51)	BPPV (n = 34)	CV (n = 27)	Ménière's (n = 48)		
Cohen et al.(82)	2003	Rain	35	36	67	40	0.024	YES
		Alone	0	26	67	29	<0.001	YES
		Parallel parking	33	41	62	45	0.101	NO
		Left turns across traffic	4	15	46	30	0.001	YES
		Freeway driving	12	15	67	26	0.011	YES
		High-traffic local roads	13	13	58	33	0.022	YES
		Rush-hour driving	21	19	59	31	0.004	YES
		Night	22	37	73	57	0.002	YES
		Parking spaces	10	15	44	21	0.037	YES
		Changing lanes	12	18	59	30	0.007	YES
		Staying in lane	2	12	44	17	<0.001	YES
		Traffic checks	4	26	52	33	<0.001	YES
		Ramped garages	10	29	61	35	0.003	YES
		Pulled off the road due to vertigo*	0	14	36	35	<0.001	YES

BPPV = Benign paroxysmal positional vertigo
CV = Chronic vestibulopathy

*Data from Cohen et al.(82), Figure 2

Summary of Findings

- **Whether vestibular dysfunction (defined as any condition that causes dizziness and/or vertigo, including Ménière's disease and benign paroxysmal positional vertigo [BPPV]) is a risk factor for crash among CMV drivers cannot be determined at the present time.**

  No studies that examined the relationship between hearing loss and crash risk among CMV drivers were identified by our searches.

- **No evidence-based conclusion pertaining to crash risk in drivers with vestibular dysfunctions can be drawn from direct evidence at the present time.**

  A single, low-quality, retrospective cohort study examined driving performance among individuals with vestibular dysfunctions and a comparable group of individuals who did not have vestibular dysfunctions. The study investigators stated that individuals with vestibular dysfunctions reported crashes at a rate that did not differ from normal subjects. However, they did not report the actual crash data, which prevented us from drawing an evidence-based conclusion pertaining to crash risk in individuals with vestibular dysfunctions.

  The study investigators did provide indirect evidence suggesting that it is certainly plausible that individuals with vestibular dysfunction may represent a safety hazard. The investigators found that individuals with vestibular dysfunctions did have more difficulty performing several driving challenges when compared to individuals who do not have vestibular dysfunctions. Thus, it is at least plausible that individuals with vestibular dysfunction may be at increased risk for a crash. We require that an evidence base consist of at least two studies before we are willing to consider drawing an evidence-based conclusion. Consequently, we refrain from drawing a conclusion at this time.

Key Question 4: How long after the most recent episode of vertigo until it is safe to drive?

In this section of the evidence report, we attempt to identify the length of time needed, following an episode of vertigo, for an individual to be considered safe to drive.

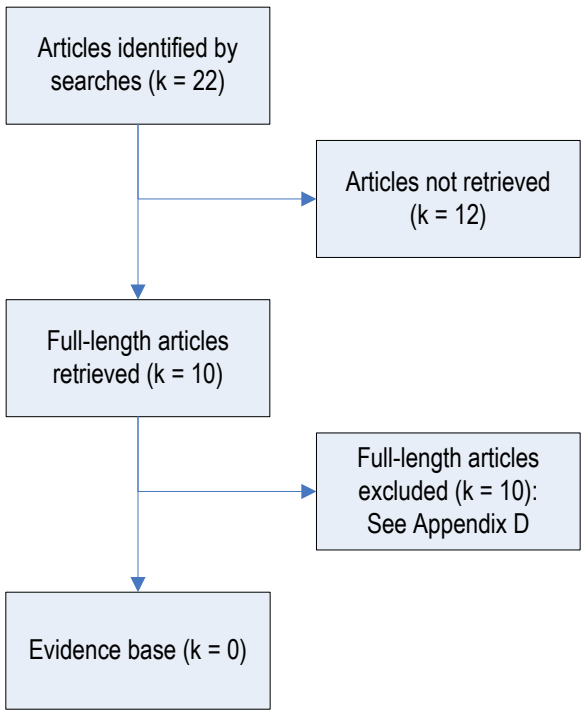
Identification of Evidence Base

To meet the aims of this section of the evidence report, we searched for trials that were designed to assess the time course of changes in measures of crash risk or driving performance among individuals who have experienced an episode of vertigo.

The identification of the evidence base for Key Question 4 is summarized in Figure 10. Our searches[7] identified a total of 22 articles that appeared relevant to this key question. Following application of the retrieval criteria for this question, 10 full-length articles were retrieved and read in full. None of these 10 retrieved articles was found to meet the inclusion criteria[8] for Key Question 4.

Table D-4 of Appendix D lists the 10 articles that were retrieved, read in full, and then excluded. The table also provides justification for their exclusion.

Figure 10. Development of Evidence Base for Key Question 4



[7] See Appendix A for search strategies.

[8] See Appendix C for inclusion criteria.

Summary of Findings

- **No evidence-based conclusion pertaining to the length of time needed, following an episode of vertigo, for an individual to be considered safe to drive can be drawn at the present time.**

  No studies that were designed to assess the time course of changes in measures of crash risk or difficulties in driving among individuals with a recent episode of vertigo were identified that met our inclusion criteria.

Key Question 5: Which treatments have been shown to effectively treat individuals with Ménière's disease?

Introduction

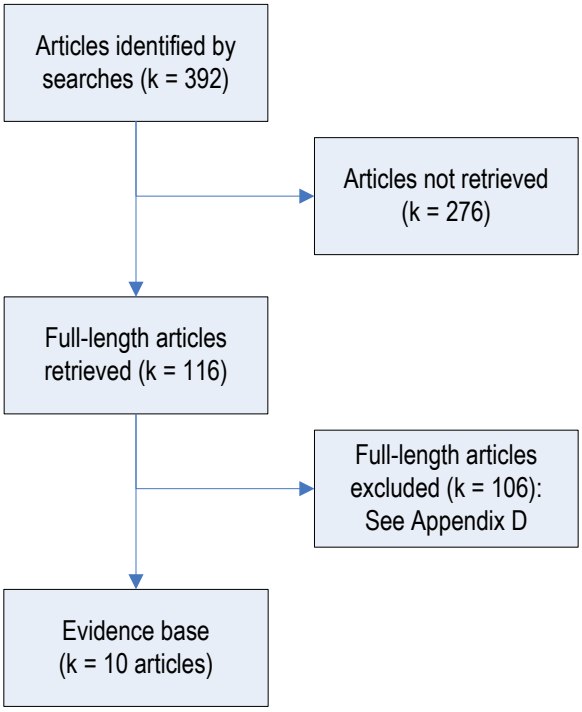
Ménière's disease is a disorder characterized by hearing loss, disabling vertigo, and tinnitus. As discussed in the section above that addressed Key Question 3, individuals with vestibular dysfunction do appear to experience more difficulty performing on several driving challenges when compared to individuals who do not have vestibular dysfunctions. The purpose of this section of the Evidence Report is to assess the evidence pertaining to the effectiveness of currently utilized treatments for Ménière's disease on vertigo and hearing loss. Treatments that we assessed for this report fell into five categories: 1) dietary manipulations, 2) diuretics (i.e., water pills), 3) anti-emetic, anti-nausea and anti-vertigo drugs, 4) ototoxic antibiotics, and 5) surgical procedures.

Identification of Evidence Base

The pathway by which the evidence base for Key Question 5 was identified is summarized in Figure 11. Our searches (Appendix A) identified a total of 392 articles that appeared to be relevant to this key question. Following application of the retrieval criteria (Appendix B) for this question, 116 full-length articles were retrieved and read in full. Of these 116 retrieved articles, 10 articles describing 8 studies were found to meet the inclusion criteria (Appendix C) for Key Question 5.

Table D-5 of Appendix D lists the 106 articles that were retrieved but not included in the evidence base for this question. We included only those articles that were systematic reviews or double-blind, placebo controlled, randomized controlled trials (RCTs). Double-blind, placebo controlled, RCTs were necessary due to the fluctuating, progressive and unpredictable natural history of Ménière's disease(84), as well as a significant placebo effect in Ménière's treatment.(85,86)

Figure 11. Development of Evidence Base for Key Question 5



Evidence Base

The treatments for Ménière's disease that were assessed by the studies that comprise the evidence base for Key Question 5 are presented in Table 21. The following articles were included:

- One article that described a systematic review(85) assessing the safety and efficacy of diuretics for the treatment of individuals with Ménière's disease.
- Three studies that assessed the impact of anti-emetics, anti-nausea, or anti-vertigo drugs on individuals with Ménière's disease. Of these three articles, two examined the safety and efficacy of betahistine,(84,87) of which one was a systematic review.(84) The third article(88) described a study that assessed the efficacy and safety of diphenidol, an anti-emetic drug.
- Three articles that described studies of the impact of intratympanic gentamicin (an ototoxic antibiotic) on Ménière's disease. Of these three articles, one was a meta-analysis(89) and one was a systematic review.(90) The final article described an RCT published after the search dates utilized by the systematic review or meta-analysis.
- Three articles describing a single study that assessed the impact of endolymphatic sac shunt surgery on Ménière's disease. These three articles reported on the impact of surgery at one year of follow-up(86), three years of follow-up(91), and after six to eight years of follow-up.(92)
- No included study assessed the impact of dietary manipulations on vertigo and/or hearing loss in individuals with Ménière's disease.

Table 21. Evidence Base: Studies of Impact of Available Treatments for Ménière's Disease on Vertigo and Hearing Loss

Reference	Year	Dietary Manipulations	Diuretics	Anti-emetic, Anti-nausea, Anti-vertigo Drugs	Ototoxic Antibiotics	Surgery
Thirlwall et al.(85)	2006		✓			
Cohen-Kerem et al.(89)	2004				✓	
Stokroos et al.(93)	2004				✓	
Diamond et al.(90)	2003				✓	
Mira et al.(87)	2003			✓		
James et al.(84)	2001			✓		
Thomsen et al.(92)	1986					✓
Thomsen et al.(91)	1983					✓
Bretlau et al.(86)	1982					✓
Futaki et al.(88)	1975			✓		
Totals =		**0**	**1**	**3**	**3**	**1***

* All three articles describe the same study (see text).

Attributes of Studies that have Assessed the Effects of Ménière's Treatments on Vertigo and Hearing Loss

Systematic Reviews and Meta-Analyses

Important characteristics of the three included systematic reviews and one meta-analysis that address Key Question 5 are presented in Table 22. A more comprehensive description of each of these studies can be found in the relevant Study Summary tables found in Appendix G.

Table 22. Design Characteristics of Included Systematic Reviews and Meta-Analyses

Reference	Year	Study Design	Objectives	Search Strategy	Selection Criteria	Data Collection and Analysis	Outcomes
Thirlwall et al.(85)	2006	Systematic review	To assess the effect of diuretic treatment in individuals with Ménière's disease.	The authors searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library,* Issue 1 2005), MEDLINE (1966 to 2005), EMBASE (1974 to 2005), CINAHL and the *meta*Register of Controlled Trials (*m*RCT) (up to 2005).	Randomized controlled trials of diuretic versus placebo in Ménière's patients.	One author identified studies that loosely met the inclusion criteria and full texts were retrieved. Two authors independently applied the inclusion criteria.	Number and severity of acute attacks of vertigo Changes in hearing
Cohen-Kerem et al.(89)	2004	Meta-analysis	To systematically review the world literature on intratympanic gentamicin treatment for Ménière's disease and aggregate their outcomes data in a quantitative synthesis.	A medical literature search was performed using MEDLINE and EMBASE databases for studies that were published from 1985 to 2003.	All clinical trials dealing with intratympanic gentamicin treatment for Ménière's disease and reporting on 10 or more individuals were considered.	Two reviewers independently assessed trial quality and extracted data.	Frequency of vertigo Hearing Word recognition
Diamond et al.(90)	2003	Systematic review	To assess and summarize the best available evidence for the use of intratympanic gentamicin in individuals with Ménière's disease.	Comprehensive electronic searches were conducted on the databases of MEDLINE (1966 to the third week of February 2003), EMBASE (1988 to week 8 2003), and the Cochrane Central Register of Controlled Trials (fourth quarter of 2002).	All clinical trials dealing with intratympanic gentamicin treatment for Ménière's disease were considered.	All generated titles were independently reviewed by two reviewers. Full articles were obtained for all titles identified by either reviewer as being potentially relevant to the study. Each full article was independently reviewed by two reviewers for assessment of inclusion into the final review.	Vertigo control Hearing change
James et al.(84)	2001	Systematic review	To assess the effects of betahistine in people with Ménière's disease.	The authors searched the Cochrane Controlled Trials Register (The Cochrane Library, Issue 4, 1999), MEDLINE (January 1966 to December 1999), EMBASE (January 1985 to December 1999), and Index Medicus (1962 to 1966).	Randomized controlled trials of betahistine versus placebo in Ménière's patients.	Two reviewers independently assessed trial quality and extracted data.	Number and severity of acute attacks of vertigo Changes in hearing

Randomized Controlled Trials

Important characteristics of the six included RCTs that address Key Question 5 are presented in Table 23. A more comprehensive description of each of these studies can be found in the relevant Study Summary tables found in Appendix G.

Table 23. Design Characteristics of Included Randomized Controlled Trials

Reference	Year	Study Design	Prospective?	Comparison	Period data collected?	Number treated?	Number in control group	Outcomes
Stokroos et al.(93)	2004	Double-blind, placebo-controlled RCT	Prospective	Intratympanic gentamicin versus placebo	Between 6 and 28 months	12	10	Number of vertiginous attacks per year Changes in hearing
Mira et al.(87)	2003	Double-blind, placebo-controlled RCT	Prospective	Betahistine versus placebo	1, 2, and 3 months	41	40	Number of monthly vertigo attacks Intensity score of vertigo Duration of attacks
Thomsen et al.(92)	1986	Double-blind, placebo-controlled RCT	Prospective	Endolymphatic sac shunt surgery versus a placebo operation (regular mastoidectomy)	6 – 8 years after surgery	12	13	Frequency, duration, and severity of vertigo attacks Hearing
Thomsen et al.(91)	1983	Double-blind, placebo-controlled RCT	Prospective	Endolymphatic sac shunt surgery versus a placebo operation (regular mastoidectomy)	3 years after surgery	13	13	Frequency, duration, and severity of vertigo attacks Hearing
Bretlau et al.(86)	1982	Double-blind, placebo-controlled RCT	Prospective	Endolymphatic sac shunt surgery versus a placebo operation (regular mastoidectomy)	1 year after surgery	15	15	Frequency, duration, and severity of vertigo attacks Hearing
Futaki et al.(88)	1975	Double-blind, placebo-controlled cross-over trial	Prospective	Diphenidol versus placebo	3 and 6 weeks	24	24	Hearing

Quality of the Randomized Controlled Trials that have Assessed the Effects of Ménière's Treatments on Vertigo and Hearing Loss

The findings of our assessment of the quality of the six RCTs that comprise the evidence base for Key Question 5 are presented in Table 24. Overall, our analysis found the quality of these six studies to be from moderate to high.

Table 24. Quality of Included Studies

Reference	Year	Quality assessment Instrument Used	Quality Rating
Stokroos et al.(93)	2004	ECRI Institute's Assessment Tool for Controlled Interventional Studies That Have Independent Groups	Moderate
Mira et al.(87)	2003	ECRI Institute's Assessment Tool for Controlled Interventional Studies That Have Independent Groups	High
Thomsen et al.(92)*	1986	ECRI Institute's Assessment Tool for Controlled Interventional Studies That Have Independent Groups	High
Thomsen et al.(91)†	1983	ECRI Institute's Assessment Tool for Controlled Interventional Studies That Have Independent Groups	High
Bretlau et al.(86)	1982	ECRI Institute's Assessment Tool for Controlled Interventional Studies That Have Independent Groups	High
Futaki et al.(88)	1975	ECRI Institute's Assessment Tool for Controlled Interventional Studies That Have Independent Groups with crossover questions	High

* same study as Bretlau et al.(86) but follow-up period is six to eight years

† same study as Bretlau et al.(86) but follow-up period is three years

Characteristics of the Individuals Enrolled in the Randomized Controlled Trials on the Effects of Ménière's Treatments on Vertigo and Hearing Loss

Important characteristics of the individuals enrolled in the six RCTs that address Key Question 5 are presented in Table 25. A more comprehensive description of each of these studies can be found in the relevant Study Summary tables found in Appendix G.

Table 25. Characteristics of Individuals Enrolled in the Randomized Controlled Trials

Reference	Year	Duration of disease	Age distribution (yrs)	% Male	Ethnicity
Stokroos et al.(93)	2004	Not Reported	Gentamicin: 59 (range: 34 – 74) Control: 58 (range: 45 – 70)	Overall: 59%	Not Reported
Mira et al.(87)	2003	Not Reported	Not Reported	Not Reported	Not Reported
Thomsen et al.(92)	1986	Not Reported	Shunt surgery: 54 (range: 36 – 67) Control: 56 (range: 32 – 73)	Shunt surgery: 58% Control: 54%	Not Reported
Thomsen et al.(91)	1983	Not Reported	Not Reported	Not Reported	Not Reported
Bretlau et al.(86)	1982	Range of symptom duration: 6 – 60 months	Shunt surgery: 49.9 (range: 25 – 63) Control: 53.9 (range: 28 – 69)	Shunt surgery: 60% Control: 60%	Not Reported
Futaki et al.(88)	1975	Not Reported	43 (range: 21 – 68)	42%	Not Reported

Findings of the Studies that Assessed the Impact of Available Treatments for Ménière's Disease on Vertigo and Hearing Loss

The purpose of this subsection is to provide details of the impact that the treatments for Ménière's disease have on vertigo and hearing loss. Of the eight included studies, one assessed the effectiveness

of diuretics; three assessed the effectiveness of anti-emetic, anti-nausea, and/or anti-vertigo drugs; three assessed the effectiveness of ototoxic antibiotics; and one assessed the effectiveness of surgery on vertigo and hearing among individuals with Ménière's disease. None of the studies assessed the effectiveness of dietary manipulations on vertigo and hearing.

Diuretics

The evidence base for this treatment consisted of one systematic review by Thirlwall and Kundu.(85) Thirlwall and Kundu attempted to assess the effects of diuretics in individuals with Ménière's disease. Specifically, the authors assessed the effect of diuretic treatment on the frequency and severity of vertigo attacks, as well as hearing loss. They included only RCTs of diuretic versus placebo in individuals with Ménière's disease. Although their searches identified a total of seven trials, none met the inclusion criteria for the systematic review. As a result, the authors concluded that there is insufficient good evidence of the effect of diuretics on vertigo and hearing loss in clearly defined Ménière's disease.

Anti-emetic, Anti-nausea, and Anti-vertigo Drugs

Betahistine

The evidence base for this treatment consists of one systematic review by James and Burton(84) and one double-blind, placebo-controlled RCT by Mira et al.(87) that was published after the final search date utilized by the systematic review.

The systematic review of James and Burton attempted to assess the effects of betahistine in individuals with Ménière's disease. Specifically, the authors assessed the effect of betahistine treatment on the frequency and severity of vertigo attacks, as well as on hearing loss. They included only RCTs of betahistine versus placebo in individuals with Ménière's disease. Their searches identified 65 clinical trials of betahistine, but only 19 were placebo controlled and only 6 complied with the inclusion criteria of the review. The 6 included trials recruited a total of 162 individuals. The smallest included trial studied 10 individuals and the largest studied 36. No trial met the highest quality standard set by the review because of inadequate diagnostic criteria or methods, and none assessed the effect of betahistine on vertigo adequately. Most trials suggested a reduction of vertigo with betahistine, but this effect may have been caused by bias in the methods. None of the trials showed any effects of betahistine on hearing loss. No adverse effects were found with betahistine. As a result, the authors concluded that there is no evidence that betahistine is effective or ineffective in individuals with Ménière's disease.

Mira et al. (Quality Score: High) examined the effectiveness of betahistine in comparison to a placebo in recurrent vertigo related to Ménière's disease in a double-blind, RCT. Compared to the baseline rate, the number of monthly vertigo attacks in individuals with Ménière's disease was reduced with betahistine (from 6.70 ±9.56 at baseline to 2.06 ±2.78 after three months of treatment). It was concluded that compared to placebo, betahistine had a significant effect on the frequency, intensity, and duration of vertigo attacks. The findings of Mira et al. mirror the findings of the studies included in the systematic review of James and Burton(84) in that Mira et al. reported a reduction in vertigo with betahistine, but like the studies included in the above systematic review this effect may have been

caused by bias in the methods (such as allocation bias, attrition bias, compliance to treatment, and outcome assessment).

Diphenidol

The evidence base for this treatment consists of one double-blind, placebo-controlled cross-over trial by Futaki et al.(88)(Quality Score: High). This study examined the effectiveness of diphenidol, an antiemetic medication, in improving vertigo and hearing for individuals with Ménière's disease. Both the symptoms and the results of equilibrium function tests showed a higher incidence of improvement during the period of diphenidol administration than during that of placebo. The difference was statistically significant with respect to vertigo and dizziness or unsteadiness. The audiometric results showed no change in pure-tone audiometry.

Ototoxic Antibiotics

Intratympanic Gentamicin

The evidence base for this treatment consists of one systematic review by Diamond et al.(90), one meta-analysis by Cohen-Kerem et al.,(89) and one double-blind, placebo-controlled RCT by Stokroos and Kingma(93) that was not included in the previous two articles.

Diamond et al. attempted to assess and summarize the best available evidence for the use of intratympanic gentamicin in individuals with Ménière's disease with respect to improvement of vertigo and change in hearing. For inclusion in the review, studies must have included individuals with Ménière's disease who were treated with intratympanic installations of gentamicin. A comparison of pretreatment with posttreatment symptom control was essential. There were no minimum follow-up requirements, and all methods of drug delivery, drug concentrations, and dosing frequencies were included. Individual case reports and non-English articles were excluded from the review. Their searches identified 423 article titles. Reviewers identified 118 potentially relevant articles for full review, 35 of which were included in the final review. The authors noted that none of the studies used a proper control group for comparison. Extractible results on vertigo control were available in 34 studies and on hearing change in 30 studies. Overall pooled results on vertigo control revealed complete or substantial control in 89% of individuals (range: 73% to 100%). Hearing was worsened in 26% (range: 0% to 90%). Different treatment protocols all resulted in similar rates of vertigo control. The authors concluded that "intratympanic gentamicin appears effective in controlling the symptoms of Ménière's disease, regardless of the protocol used. Although the literature on this treatment is extensive, there is a likelihood of significant bias in many currently published reports. There is a clear need for a prospective, randomized, blinded, placebo-controlled trial to assess the true effectiveness of this treatment."

Cohen-Kerem et al. attempted to systematically review the world literature on intratympanic gentamicin treatment in individuals with Ménière's disease and aggregate their outcomes data in a quantitative synthesis. Acceptable study designs were those designed as RCTs, case-control studies, and prospective cohorts or retrospective cohorts reporting on 10 or more individuals. Non-English articles were also considered for analysis. Administration of gentamicin into the middle ear, either by transtympanic injection or by using a specially designed catheter as the only intervention, was considered. Studies reporting on concomitant administration of other drugs were excluded. There was no age limitation for

inclusion of studies. Studies reporting on animal trials, comments, letters, editorials, and reviews were also excluded. Their searches identified 226 publications. Reviewers identified 61 potentially relevant articles for full review, 15 of which (627 individuals) were included in the final analysis. Eight studies were designed as prospective, and seven were designed as retrospective cohorts. No double-blind or blinded prospective control trials were identified.

The reviewers reported that complete (class A) vertigo control was achieved in 74.7% (95% CI: 67.8% to 81.5%) of individuals, and complete or substantial (class B) control was achieved in 92.7% (95% CI: 89.5% to 96.0%). The success rate was not affected by gentamicin treatment regimen (fixed versus titration). Hearing level and word recognition were not adversely affected. The authors concluded that "intratympanic gentamicin treatment appears to be effective in the relief of vertigo. However, the level of evidence reflected from the eligible articles is insufficient, especially because of relatively poor study design. Further investigation with this treatment modality with control subjects is warranted."

Stokroos and Kingma (Quality Score: Moderate) examined the therapeutic value of intratympanic gentamicin in individuals with Ménière's disease in a double-blind, placebo-controlled, RCT. Compared to the pretreatment rate, the number of vertiginous attacks per year in individuals with Ménière's disease was reduced with gentamicin (from 74 ±114 before treatment to 0 after treatment, p = 0.002). However, the number of vertiginous attacks per year in individuals with Ménière's disease was also reduced with placebo (from 25 ±31 before treatment to 11 ±10 after treatment, p = 0.028). The findings of this study suggest that intratympanic gentamicin is effective in reducing the number of vertiginous attacks among individuals with Ménière's disease. The fact that a large reduction in vertiginous attacks was seen in the placebo arm of this trial emphasizes the importance of the need for placebo-controlled trials when evaluating the impact of treatments of the symptoms associated with Ménière's disease.

Surgical Procedures

Endolymphatic Sac Shunt Surgery

The evidence base for this treatment consists of three articles(86,91,92) (Quality Score: High) reporting on the same study at different follow-up times (1 year, 3 years, and 6 to 8 years). The study was a double-blind, placebo-controlled RCT assessing the effect of an endolymphatic sac shunt operation versus the effect of a placebo operation (regular mastoidectomy) on 30 individuals with Ménière's disease. Regular mastoidectomy was considered a placebo surgery as long as "very much care was taken not to remove the bone over the endolymphatic sac in order to avoid a decompression in this way".(86) Outcomes assessed in this study included vertigo control and hearing stabilization using the American Academy of Ophthalmology and Otolaryngology (AAOO) classification system, which is as follows:

- Class A – vertigo controlled, hearing improvement
- Class B – vertigo controlled, hearing unchanged
- Class C – vertigo controlled, hearing worse
- Class D – uncontrolled vertigo

The AAOO classification for the individuals at the three follow-up periods is shown in Table 26. The table below separates the individuals included in the study by follow-up time, whether they received active or

placebo surgery, and the level of vertigo control and hearing stabilization they experienced at follow-up using the AAOO classification system described above (Class A, B, C or D).

Table 26. American Academy of Otolaryngology Classification 12, 36, and 84 Months after Surgical Treatment

	12 months					36 months					84 Months			
	Active		Placebo			Active		Placebo			Active		Placebo	
AAOO class	No.	%	No.	%		No.	%	No.	%		No.	%	No.	%
Class A	1	7	1	7		3	23	2	15		2	17	5	39
Class B	12	80	6	40		6	46	8	62		3	25	6	46
Class C	0		3	20		0		2	15		4	33	2	15
Class D	2	13	5	33		4	31	1	8		3	25	0	
Total	**15**		**15**			**13**		**13**			**12**		**13**	

12-month follow-up

In Table 26, the postoperative overall AAOO results are shown for all 30 individuals at 12 months postsurgery. There is a tendency toward greater improvement in the actively treated group in which a greater number of individuals showed hearing stabilization (Class A and B) than in the placebo group. However, if the control of vertigo is considered the major factor in evaluating the success or failure of treatment, then classes A, B, and C are regarded as success and only class D as failure. With this classification of success and failure, there is no significant difference between the effect of the active (shunt) operation and the placebo (mastoidectomy) operation. When audiometric threshold was tested at 250, 500 and 1,000 Hz, only at 250 Hz could a statistical difference ($p < 0.05$) be found.

36-month follow-up

In Table 26, the postoperative overall AAOO results are shown for all 26 individuals followed-up at 36 months post-surgery. At 36 months there is no difference between the distribution in the classes when active is compared to placebo. If success (classes A, B and C) is considered the absence of vertigo, then four individuals in the active group still had periodic attacks, while only one individual in the placebo group still had vertigo. If only classes A and B are included in the success group, no difference can be detected between the groups. When audiometric threshold was tested at 250, 500, 1,000, 2,000, and 4,000 Hz, no statistical differences could be shown at the 5% level.

84-month follow-up

In Table 26, the postoperative overall AAOO results are shown for all 25 individuals followed up at 84 months postsurgery. At 84 months, there is no difference in the distribution of the classes when the active group is compared with the placebo group. If success (classes A, B and C) is considered the absence of vertigo, then three individuals in the active group still had periodic attacks, while none of the individuals in the placebo group still had vertigo. When audiometric threshold was tested at 250, 500, and 1,000 Hz, no statistical differences could be shown at the 5% level.

The authors of these papers concluded that endolymphatic sac shunt surgery is a nonspecific treatment modality, there is no need for this surgery, and the vast majority of individuals with Ménière's disease can be successfully treated by nonsurgical means.

Summary of Findings

The overall findings of all our analyses for Key Question 5 are summarized in Table 27.

Table 27. Summary of Findings – Key Question 5

	Diuretics	Anti-emetic, Anti-nausea, Anti-vertigo Drugs		Ototoxic Antibiotics	Surgery
		Betahistine	Diphenidol	Intratympanic Gentamicin	Endolymphatic Sac Shunt Surgery
Vertigo Control	?	?	?	?	?
Hearing	?	?	?	?	?

? Results equivocal – strength of evidence too weak at present time to draw an evidence–based conclusion (see text for details)

Taking all the findings summarized in the table above into account, we draw the following evidence-based conclusions:

- **No evidence-based conclusion pertaining to the effect of diuretics on vertigo and hearing loss in individuals with Ménière's disease can be drawn at the present time.**

  Double-blind, placebo-controlled RCTs are necessary due to the fluctuating, progressive, and unpredictable natural history of Ménière's disease(84), as well as a significant placebo effect in Ménière's treatment.(85,86) The evidence base for this treatment consisted of one systematic review in which no double-blind, placebo-controlled RCTs were identified. As a result, the authors of the review concluded that there is insufficient good evidence of the effect of diuretics on vertigo and hearing loss.

- **No evidence-based conclusion pertaining to the effect of betahistine on vertigo and hearing loss in individuals with Ménière's disease can be drawn at the present time.**

  Data from a high-quality systematic review and a single, high-quality RCT published after the search period examined by the systematic review were used to determine whether betahistine represents an effective treatment for individuals with Ménière's disease. Six RCTs were included in the systematic review. No trial met the highest quality standard set by the review because of inadequate diagnostic criteria or methods, and none assessed the effect of betahistine on vertigo adequately. Most trials suggested a reduction of vertigo with betahistine; however, this effect may have been caused by bias in the methods. None of the trials showed any effects of betahistine on hearing loss. The findings of the one RCT mirror the findings of the RCTs included in the systematic review in that the study reported a reduction in vertigo with betahistine, but like the RCTs included in the systematic review, this effect may have been caused by bias in the methods (such as allocation bias, attrition bias, compliance to treatment, and outcome assessment). As a result, no evidence-based conclusion pertaining to the effectiveness or ineffectiveness of betahistine on vertigo and hearing loss in individuals with Ménière's disease can be drawn at the present time.

- **No evidence-based conclusion pertaining to the effect of diphenidol on vertigo and hearing loss in individuals with Ménière's disease can be drawn at the present time.**

  The evidence base for this treatment consisted of a small (n = 24), double-blind, placebo-controlled RCT. The results of this study showed a higher incidence of improvement in equilibrium functioning and symptoms during diphenidol administration than during placebo, with no change in hearing among individuals with Ménière's disease. However, we require that

an evidence base consists of at least two studies before we are willing to consider drawing an evidence-based conclusion. In this case, that requirement has not been met. Consequently, we refrain from drawing a conclusion at this time.

- **No evidence-based conclusion pertaining to the effect of intratympanic gentamicin on vertigo and hearing loss in individuals with Ménière's disease can be drawn at the present time.**
- *Data from a systematic review, a meta-analysis, and a small (n = 22), moderate-quality RCT not covered by the systematic review or meta-analysis were used to determine whether intratympanic gentamicin represents an effective treatment for individuals with Ménière's disease.*
- *Thirty-five articles were included in the systematic review, and 15 articles were included in the meta-analysis. Both the systematic review and meta-analysis consisted of non-RCTs, which by the authors' own admission increases the likelihood of significant bias. The systematic review reported that the application of intratympanic gentamicin resulted in complete or substantial vertigo control in 89% of individuals with Ménière's disease; however, hearing was worsened in 26% of individuals. Similarly, the meta-analysis reported that the application of intratympanic gentamicin resulted in complete vertigo control in 74.7% of individuals with Ménière's disease and complete or substantial control in 92.7% of individuals, while hearing level and word recognition were not adversely affected. Because of the progressive and unpredictable natural history of Ménière's disease, double-blind, placebo-controlled RCTs are necessary for addressing this question. As stated above, neither review consisted of these types of trials, thus increasing the likelihood that the effects reported in these reviews may have been caused by biases in the methods. Consequently, we refrain from drawing any conclusion at this time regarding the effect of intratympanic gentamicin on vertigo and hearing loss in individuals with Ménière's disease.*
- *The only double-blind, placebo-controlled RCT examined the therapeutic value of intratympanic gentamicin in individuals with Ménière's disease. The findings of this small (n = 22), moderate-quality study suggest that intratympanic gentamicin is effective in reducing the number of vertiginous attacks among individuals with Ménière's disease. However, there was also a large reduction in vertiginous attacks in the placebo arm of this trial, which only emphasizes the importance of the need for placebo-controlled trials when evaluating the impact of treatments of the symptoms associated with Ménière's disease. Additionally, we require that an evidence base consists of at least two studies before we are willing to consider drawing an evidence-based conclusion. Consequently, we refrain from drawing any conclusion at this time regarding the effect of intratympanic gentamicin on vertigo and hearing loss in individuals with Ménière's disease.*
- **No evidence-based conclusion pertaining to the effect of endolymphatic sac shunt surgery on vertigo and hearing loss in individuals with Ménière's disease can be drawn at the present time.**

  The evidence base for this treatment consisted of three papers reporting results from the same double-blind, placebo-controlled RCT at different follow-up times (one year, three years, and six to eight years). The results of the study indicate that there was no significant difference between active and placebo treatment and that there is actually a significant placebo effect, which may render endolymphatic sac shunt surgery unnecessary. However, this single study is insufficient to allow an evidence-based conclusion at this time.

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Appendix A: Search Summaries

Search Summary for Key Question 1

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), Emtree, PsycINFO, and Keywords

Conventions:

OVID

$	=	truncation character (wildcard)
exp	=	"explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)
.de.	=	limit controlled vocabulary heading
.fs.	=	floating subheading
.hw.	=	limit to heading word
.md.	=	type of methodology (PsycINFO)
.mp.	=	combined search fields (default if no fields are specified)
.pt.	=	publication type
.ti.	=	limit to title
.tw.	=	limit to title and abstract fields

PubMed

[mh]	=	MeSH heading
[majr]	=	MeSH heading designated as major topic
[pt]	=	publication type
[sb]	=	subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
[sh]	=	MeSH subheading (qualifiers used in conjunction with MeSH headings)
[tiab]	=	keyword in title or abstract
[tw]	=	text word

Topic-specific Search Terms

Hearing Threshold

exp auditory threshold

hearing threshold

Accidents

Controlled vocabulary	**Text words**
exp Accidents, traffic/	Accident$
exp Highway safety/	Collision$
exp Motor traffic accidents/	Crash$
exp Traffic accident/	Wreck$
exp Traffic safety/	

Driving

Controlled Vocabulary	**Text Words**
exp Car driving	Auto$
exp Driving behavior	Automobile driving
exp Motor vehicle	Automobiles
exp Motor vehicles	Car
	Commercial
	Driving
	Haul$
	Long distance
	Professional
	Truck

CINAHL/EMBASE/MEDLINE/PsycINFO

English language, human

Set Number	Concept	Search Statement	
1	Hearing threshold	exp auditory threshold or hearing threshold.mp.	
2	Crash	1 and (Accidents, traffic/ or highway safety or motor traffic accidents or traffic accident or traffic safety).de. or crash$.ti. or wreck$.ti. or collision$.ti. or accident$.ti.	
3	Combine sets	1 AND 2	
4	Limit by language	3, English, English language	
5	Limit by population	4, human, humans	
6	Remove overlap	5, remove duplicates	
Total Identified	**Total Downloaded**	**Total articles received (requested)**	**Total cited**
44	**2**		

Search Summary for Key Question 2

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), Emtree, PsycINFO, and Keywords

Conventions:

OVID

$	=	truncation character (wildcard)
exp	=	"explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)
.de.	=	limit controlled vocabulary heading
.fs.	=	floating subheading
.hw.	=	limit to heading word
.md.	=	type of methodology (PsycINFO)
.mp.	=	combined search fields (default if no fields are specified)
.pt.	=	publication type
.ti.	=	limit to title
.tw.	=	limit to title and abstract fields

PubMed

[mh]	=	MeSH heading
[majr]	=	MeSH heading designated as major topic
[pt]	=	publication type
[sb]	=	subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
[sh]	=	MeSH subheading (qualifiers used in conjunction with MeSH headings)
[tiab]	=	keyword in title or abstract
[tw]	=	text word

Topic-Specific Search Terms

Hearing Test

exp hearing test

forced-whisper$

forced whisper$

hearing test$

CINAHL/EMBASE/MEDLINE/PsycINFO

English language, human

Set Number	Concept	Search Statement	
1	Forced whisper hearing test	(exp hearing test/ or hearing test$) and (forced whisper$ or forced-whisper)	
2	Valid measure	1 and ((intraobserver or intra-observer or interobserver or inter-observer or interpret$ or kaap or observer bias or observer variability or reader$ or reader concordance or reliab$ or repeatab$ or replicat$).tw. or observer variation.de. or (exp prediction/ and forecasting/) and (((predictive value of tests or receiver operating characteristic or ROC curve or sensitivity) and specificity) or accuracy or diagnostic accuracy or precision or likelihood).de. or ((false or true) adj (positive or negative)).mp.)	
3	Combine sets	1 AND 2	
4	Limit by language	3, English, English language	
5	Limit by population	4, human, humans	
6	Remove overlap	5, remove duplicates	
Total Identified	**Total Downloaded**	**Total Articles Received (Requested)**	**Total Cited**
108	**1**		

Search Summary for Key Questions 3 and 4

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), Emtree, PsycINFO, and Keywords

Conventions:

OVID

$	=	truncation character (wildcard)
exp	=	"explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)
.de.	=	limit controlled vocabulary heading
.fs.	=	floating subheading
.hw.	=	limit to heading word
.md.	=	type of methodology (PsycINFO)
.mp.	=	combined search fields (default if no fields are specified)
.pt.	=	publication type
.ti.	=	limit to title
.tw.	=	limit to title and abstract fields

PubMed

[mh]	=	MeSH heading
[majr]	=	MeSH heading designated as major topic
[pt]	=	publication type
[sb]	=	subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
[sh]	=	MeSH subheading (qualifiers used in conjunction with MeSH headings)
[tiab]	=	keyword in title or abstract
[tw]	=	text word

Topic-specific Search Terms

Dizziness

exp Dizziness

Balance

Dizzi$

Imbalance

Vertig$

Meniere Disease

exp Meniere Disease

exp Ménière's Disease

exp Endolymphatic Hydrops

Meniere$

Endolymphatic Hydrops.ti,ab

Vestibular dysfunction

exp Vestibular Neuronitis/

exp Vestibular Function/

exp Vestibular Disorder/

exp Vestibular System/

exp Meniere Disease/

exp Ménière's Disease/

exp Acoustic Neurinoma/

exp Vestibular Schwannoma/

exp Endolymphatic Hydrops/

exp Labyrinthitis/

exp Vestibular Diseases/

exp Neuroma, Acoustic/

Labyrinthitis

Vest Neuritis

Perilymph Fistula

Acoustic Neuroma

Ototoxicity

Vestibular Migraine

Mal de Debarquement

Otosclerosis

Cholesteatoma

Enlarged Vestibular Aqueduct Vestibular Hyperacusis

Canal Dehiscence

Benign Paroxysmal Positional Vertigo BPPV

Accidents

Controlled Vocabulary

exp Accidents, traffic/

exp Highway safety/

exp Motor traffic accidents/

exp Traffic safety/

Text Words

Accident$

Collision$

Crash$

Traffic accident

Wreck

Driving

Controlled Vocabulary	Text Words
exp Car driving	Auto$
exp Driving behavior	Automobile driving
exp Motor vehicle	Automobiles
exp Motor vehicles	Car
	Commercial
	Driving
	Haul$
	Long distance
	Professional
	Truck

Recovery

Controlled Vocabulary	Text Words
Recovery of function/	Recover$
	Episod$

CINAHL/EMBASE/MEDLINE/PsycINFO

English language, human

Set Number	Concept	Search Statement	
1	Vestibular dysfunction	exp VESTIBULAR NEURONITIS/ or exp VESTIBULAR FUNCTION/ or exp VESTIBULAR DISORDER/ or exp VESTIBULAR SYSTEM/ or exp MENIERE DISEASE/ or exp Ménière's Disease/ or exp Acoustic Neurinoma/ or exp vestibular schwannoma/ or exp endolymphatic hydrops/ or exp labyrinthitis/ or exp vestibular diseases/ or exp Neuroma, Acoustic/ or exp DIZZINESS/ or exp VERTIGO/ or (Meniere s Disease or Endolymphatic Hydrops or Labyrinthitis or Vest Neuritis or Perilymph Fistula or Acoustic Neuroma or Ototoxicity OR vestibular Migraine or Mal de Debarquement or Otosclerosis or Cholesteatoma or Enlarged Vestibular Aqueduct or Vestibular Hyperacusis or Canal Dehiscence or benign paroxysmal positional vertigo or bppv).mp or (dizz$ or vertig$ or balance or imbalance).ti,ab.	
2	Recovery	Recovery of function/ or ((recover$ or episod$) and function$).mp.	
3	Driving	Automobile driving.de. or exp motor vehicles/ or automobiles.de. or exp driving behavior/ or exp car driving/ or exp motor vehicle/ or (driving or commercial or professional or truck or car or automobile$ or long distance or haul$).ti.	
4	Accident	Accidents, traffic/ or highway safety or motor traffic accidents or traffic accident or traffic safety).de. or crash$.ti. or wreck$.ti. or collision.ti. or accident$.ti.	
5	Combine sets	1 AND 2	
6	Combine sets	5 AND (3 OR 4)	
7	Limit by publication type	6 not ((letter or editorial or news or comment or case reports or review or note or conference paper).de. or (letter or editorial or news or comment or case reports or review).pt.)	
8	Limit to English language	7, English, English language	
9	Limit to human population	8., human, humans	
10	Remove overlap	9, remove duplicates	
Total Identified	**Total Downloaded**	**Total Articles Received (Requested)**	**Total Cited**
6	**0**		

Search Summary for Key Question 5

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), Emtree, PsycINFO, and Keywords

Conventions:

OVID

$	=	truncation character (wildcard)
exp	=	"explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)
.de.	=	limit controlled vocabulary heading
.fs.	=	floating subheading
.hw.	=	limit to heading word
.md.	=	type of methodology (PsycINFO)
.mp.	=	combined search fields (default if no fields are specified)
.pt.	=	publication type
.ti.	=	limit to title
.tw.	=	limit to title and abstract fields

PubMed

[mh]	=	MeSH heading
[majr]	=	MeSH heading designated as major topic
[pt]	=	publication type
[sb]	=	subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)
[sh]	=	MeSH subheading (qualifiers used in conjunction with MeSH headings)
[tiab]	=	keyword in title or abstract
[tw]	=	text word

Topic-Specific Search Terms

Meniere Disease

exp Meniere Disease

exp Ménière's Disease

exp Endolymphatic Hydrops

Meniere$

Endolymphatic Hydrops.ti,ab

CINAHL/EMBASE/MEDLINE/PsycINFO

English language, human

Set Number	Concept	Search Statement	
1	Meniere Disease	Exp MENIERE DISEASE or exp Ménière's Disease or exp Endolymphatic Hydrops or Meniere$ or endolymphatic hydrops	
2	Limit by study type	1 and ((Randomized controlled trials or random allocation or double-blind method or single-blind method or placebos or cross-over studies or crossover procedure or double blind procedure or single blind procedure or placebo or latin square design or crossover design or double-blind studies or single-blind studies or triple-blind studies or random assignment or exp controlled study/ or exp clinical trial/ or exp comparative study/ or cohort analysis or follow-up studies.de. or intermethod comparison or parallel design or control group or prospective study or retrospective study or case control study or major clinical study or evaluation studies or follow-up studies).de. or random$.hw. or random$.ti. or placebo$ or ((singl$ or doubl$ or tripl$ or trebl$) and (dummy or blind or sham)) or latin square or ISRTCN)	
3	Limit by publication type	2 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.)	
4	Limit by language	3, English, English language	
5	Limit by population	4, human, humans	
6	Eliminate overlap	5, remove duplicates	
Total Identified	**Total Downloaded**	**Total Articles Received (Requested)**	**Total Cited**
1,548	**392**		

Appendix B: Retrieval Criteria

Appendix B lists the retrieval criteria for each of the five key questions addressed in this evidence report.

Retrieval Criteria for Key Question 1

- Article must have been published in the English language.
- Article must have enrolled ≥ 10 subjects.
- Article must have enrolled subjects aged ≥18.
- Article must describe a study that attempted to determine the risk for a motor vehicle crash directly (risk for a fatal or nonfatal crash) associated with hearing impairment.
- Article must describe a study that includes a comparison group comprising comparable subjects who do not have a hearing impairment.

Retrieval Criteria for Key Question 2

- Article must have been published in the English language.
- Article must have enrolled 10 or more subjects.
- Article must have enrolled subjects aged ≥18.
- Article must describe a study that attempted to determine whether the forced-whisper test is a valid measure of hearing ability by comparing the forced-whisper test to some other valid measure of hearing ability (e.g., pure tone audiometry).

Retrieval Criteria for Key Question 3

- Article must have been published in the English language.
- Article must have enrolled 10 or more subjects.
- Article must have enrolled subjects aged ≥18.
- Article must describe a study that attempted to determine the risk for a motor vehicle crash directly (risk for a fatal or nonfatal crash) associated with any condition that causes dizziness and/or vertigo, including Ménière's disease and benign paroxysmal positional vertigo (BPPV).
- Article must describe a study that includes a comparison group comprised of comparable subjects who do not have a condition that causes dizziness and/or vertigo, including Ménière's disease and BPPV.

Retrieval Criteria for Key Question 4

- Article must have been published in the English language.
- Article must have enrolled 10 or more subjects.

- Article must have enrolled subjects aged ≥18.
- Article must describe a study that attempted to determine the length of time required following a recent episode of vertigo for an individual to be considered safe to drive.

Retrieval Criteria for Key Question 5

- Article must have been published in the English language.
- Article must have enrolled 10 or more subjects.
- Article must have enrolled subjects aged ≥18.
- Article must describe a study that attempted to determine the effectiveness of a treatment for Ménière's disease.

Appendix C: Inclusion Criteria

Appendix C lists the inclusion criteria for each of the five key questions addressed in this evidence report.

Inclusion Criteria for Key Question 1

- Article must have been published in the English language. Mohr et al.(94) have demonstrated that exclusion of non-English language studies from meta-analyses has little impact on the conclusions drawn. Juni et al.(95) found that non-English studies typically were of lower methodological quality and that excluding them had little effect on effect size estimates in the majority of meta-analyses they examined. Although we recognize that in some situations exclusion of non-English studies could lead to bias, we believe that the few instances in which this may occur do not justify the time and cost typically necessary for translation of studies to identify those of acceptable quality for inclusion in our reviews.(94,95)
- Article must be full length. Abstracts and letters to the editor will not meet this inclusion criterion.
- Article must have enrolled 10 or more subjects.
- Article must have enrolled subjects aged ≥18.
- Studies were limited to individuals with hearing thresholds of 40 dB or greater at 500 to 3,000 Hz.
- Article must describe a study that attempted to directly determine the risk for a motor vehicle crash (risk for a fatal or nonfatal crash) associated with having a hearing impairment using direct measure of crash (no indirect measures, [e.g., driving simulator data]).[9]
- Article must describe a study that includes a comparison group comprising comparable subjects who do not have a hearing impairment.
- Article must present motor vehicle crash risk data in a manner that will allow ECRI Institute to calculate (directly or through imputation) effect size estimates and confidence intervals.
- If the same study is reported in multiple publications, the most complete publication will be the primary reference. Data will be extracted so as to avoid double-counting individuals.

[9] No studies published before 1992 were included in this report. For a review of studies published before this date, please see Songer et al.(30)

Inclusion Criteria for Key Question 2

- Article must have been published in the English language. Mohr et al.(94) have demonstrated that exclusion of non-English language studies from meta-analyses has little impact on the conclusions drawn. Juni et al.(95) found that non-English studies typically were of lower methodological quality and that excluding them had little effect on effect size estimates in the majority of meta-analyses they examined. Although we recognize that in some situations exclusion of non-English studies could lead to bias, we believe that the few instances in which this may occur do not justify the time and cost typically necessary for translation of studies to identify those of acceptable quality for inclusion in our reviews.(94,95)
- Article must be full length. Abstracts and letters to the editor will not meet this inclusion criterion.
- Article must have enrolled 10 or more subjects.
- Article must have enrolled subjects aged ≥18.
- Article must describe a study that attempted to determine whether the forced-whisper test is a valid measure of hearing ability by comparing the forced-whisper test to some other valid measure of hearing ability (e.g., pure tone audiometry) in the same individuals.
- Article must report outcome in terms of sensitivity and specificity of the forced-whisper test relative to some other valid measure of hearing ability (e.g., pure tone audiometry) or present data in a manner that will allow ECRI Institute to calculate sensitivity and specificity of the forced-whisper test.

Inclusion Criteria for Key Question 3

- Article must have been published in the English language. Mohr et al.(94) have demonstrated that exclusion of non-English language studies from meta-analyses has little impact on the conclusions drawn. Juni et al.(95) found that non-English studies typically were of lower methodological quality and that excluding them had little effect on effect size estimates in the majority of meta-analyses they examined. Although we recognize that in some situations exclusion of non-English studies could lead to bias, we believe that the few instances in which this may occur do not justify the time and cost typically necessary for translation of studies to identify those of acceptable quality for inclusion in our reviews.(94,95)
- Article must be full-length. Abstracts and letters to the editor will not meet this inclusion criterion.
- Article must have enrolled 10 or more subjects.
- Article must have enrolled subjects aged ≥18.
- Studies were limited to individuals with a vestibular dysfunction (any condition that causes dizziness and/or vertigo, including Ménière's disease and benign paroxysmal positional vertigo (BPPV)).
- Article must describe a study that attempted to directly determine the risk for a motor vehicle crash (risk for a fatal or non-fatal crash) associated with having a vestibular dysfunction using direct measure of crash (no indirect measures, e.g., driving simulator data).

- Article must describe a study that includes a comparison group comprised of comparable subjects who do not have a vestibular dysfunction.
- Article must present motor vehicle crash risk data in a manner that will allow ECRI to calculate (directly or through imputation) effect size estimates and confidence intervals.
- If the same study is reported in multiple publications, the most complete publication will be the primary reference. Data will be extracted so as to avoid double-counting individuals.

Inclusion Criteria for Key Question 4

- Article must have been published in the English language. Mohr et al.(94) have demonstrated that exclusion of non-English language studies from meta-analyses has little impact on the conclusions drawn. Juni et al.(95) found that non-English studies typically were of lower methodological quality and that excluding them had little effect on effect size estimates in the majority of meta-analyses they examined. Although we recognize that in some situations exclusion of non-English studies could lead to bias, we believe that the few instances in which this may occur do not justify the time and cost typically necessary for translation of studies to identify those of acceptable quality for inclusion in our reviews.(94,95)
- Article must be a full-length article. Abstracts and letters to the editor will not meet this inclusion criterion.
- Article must have enrolled 10 or more subjects.
- Article must have enrolled subjects aged ≥18.
- Studies were limited to individuals with a recent episode of vertigo.
- Article must describe a study that attempted to determine the length of time required following a recent episode of vertigo for an individual to be deemed safe to drive.
- If the same study is reported in multiple publications, the most complete publication will be the primary reference. Data will be extracted so as to avoid double-counting individuals.

Inclusion Criteria for Key Question 5

- Article must have been published in the English language. Mohr et al.(94) have demonstrated that exclusion of non-English language studies from meta-analyses has little impact on the conclusions drawn. Juni et al.(95) found that non-English studies typically were of lower methodological quality and that excluding them had little effect on effect size estimates in the majority of meta-analyses they examined. Although we recognize that in some situations exclusion of non-English studies could lead to bias, we believe that the few instances in which this may occur do not justify the time and cost typically necessary for translation of studies to identify those of acceptable quality for inclusion in our reviews.(94,95)
- Article must be a full-length article. Abstracts and letters to the editor will not meet this inclusion criterion.

- Article must have enrolled 10 or more subjects.
- Article must have enrolled subjects aged ≥18.
- Studies were limited to individuals with Ménière's disease (no other vestibular dysfunctions).
- Studies that evaluated both Ménière's disease and other vestibular dysfunctions in individuals were included as long as data for Ménière's disease subjects could be analyzed separately from that of other subject populations.
- Article must describe a double-blind, placebo-controlled, randomized study that attempted to determine the effectiveness of treatments for Ménière's disease on vertigo and/or hearing loss.
- If the same study is reported in multiple publications, the most complete publication will be the primary reference. Data will be extracted so as to avoid double-counting individuals.

Appendix D: Excluded Articles

Table D-1. Excluded Studies (Key Question 1)

Reference	Year	Reason for Exclusion
Chaparro et al.(96)	2005	Appropriate outcome data not presented
Rice CE(97)	2004	Review
Costanzo A(98)	2002	Review
Hager LD(99)	2002	Review of noise and hearing in industrial accidents
Ames et al.(100)	2001	Review
Blanchfield et al.(101)	2001	Review
Mohr et al.(39)	2000	Review
Seshagiri B(102)	1998	Assessed occupational noise exposure of operators of heavy trucks
Forrest et al.(103)	1997	Appropriate outcome data not presented
Van den Heever et al.(104)	1996	Assessed noise exposure of truck drivers
Poser CP(105)	1993	Review
Wolf et al.(37)	1991	Published before 1992
Dufresne et al.(106)	1988	Published before 1992
Stone HE(107)	1987	Published before 1992
Leopold J(108)	1980	Published before 1992
Kehajov et al.(109)	1979	Published before 1992
Booher HR(110)	1978	Published before 1992
Nickerson RS(111)	1978	Published before 1992
Taylor JF(112)	1977	Published before 1992
Nerbonne et al.(113)	1975	Published before 1992
Cook JJ(31)	1974	Published before 1992
Ewertsen HW(114)	1973	Published before 1992
Rodstein M(115)	1972	Published before 1992
Wagner T(36)	1972	Published before 1992
Brody AG(116)	1971	Published before 1992
Burg et al.(117)	1970	Published before 1992
Ysander L(118)	1970	Published before 1992
Grattan et al.(119)	1968	Published before 1992
Schein JD(34)	1968	Published before 1992
Roydhouse N.(35)	1967	Published before 1992
Ysander L(38)	1966	Published before 1992
Coppin and Peck(32)	1964	Published before 1992
Finesilver SG(33)	1962b	Published before 1992

Table D-2. Excluded Studies (Key Question 2)

Reference	Year	Reason for Exclusion
Sidhaye DG.(120)	2001	Does not assess the forced-whisper test
King PF.(79)	1953	Review
Hinchcliffe R.(121)	1981	Review
Browning GG.(122)	1986	Review
Uhlmann et al.(123)	1980	Used demented and nondemented older adults
Demster et al.(124)	1992	Assessed hearing children
Carabellese et al.(125)	1993	Does not assess the forced-whisper test
Hood JD.(126)	1981	Review
Penrod JP.(127)	1994	Review
Casali et al.(81)	1998	Report from the Federal Highway Administration

Table D-3. Excluded Studies (Key Question 3)

Reference	Year	Reason for exclusion
Evans et al.(128)	2006	Purpose of the study was to assess Scottish ENT surgeons' knowledge of the current Driver and Vehicle Licensing Agency guidelines on fitness to drive relating to otolaryngological conditions.
Lewis RF.(129)	2004	Case Report
Brookler KH.(130)	2002	Case Report
Sindwani et al.(131)	1999	Appropriate outcome data not presented
Parnes et al.(132)	1997	Appropriate outcome data not presented
Sindwani et al.(133)	1997	Purpose of the study was to learn about the concerns and current practices of Canadian otolaryngologists with regard to the reporting of vestibular patients.
Frank et al.(134)	1988	Subjects did not have vestibular dysfunctions
Clack et al.(135)	1985	Appropriate outcome data not presented
Page et al.(136)	1985	Case Reports

Table D-4. Excluded Studies (Key Question 4)

Reference	Year	Reason for exclusion
Evans et al.(128)	2006	Purpose of the study was to assess Scottish ENT surgeons' knowledge of the current Driver and Vehicle Licensing Agency guidelines on fitness to drive relating to otolaryngological conditions.
Lewis RF.(129)	2004	Case Report
Cohen et al.(82)	2003	Appropriate outcome data not presented
Brookler KH.(130)	2002	Case Report
Sindwani et al.(131)	1999	Appropriate outcome data not presented
Parnes et al.(132)	1997	Appropriate outcome data not presented
Sindwani et al.(133)	1997	Purpose of the study was to learn about the concerns and current practices of Canadian otolaryngologists with regard to the reporting of vestibular patients.
Frank et al.(134)	1988	Subjects did not have vestibular dysfunctions
Clack et al.(135)	1985	Appropriate outcome data not presented
Page et al.(136)	1985	Case Reports

Table D-5. Excluded Studies (Key Question 5)

Reference	Year	Reason for Exclusion
Helms et al.(137)	1981	Not an RCT
Rask-Anderson et al.(138)	2005	Less than 10 individuals per group
Pyykko et al.(139)	1988	Review
Rahko et al.(140)	1985	Less than 10 individuals per group
Babin et al.(141)	1984	Data for individuals with Ménière's disease not reported separately
Brookes et al.(142)	1982	Control group had hearing loss and vertigo
Kilpatrick et al.(143)	2000	Not an RCT
Mizukoshi et al.(144)	1988	No placebo group
Moser et al.(145)	1984	Not a treatment for Ménière's disease that we assessed
Mizukoshi et al.(146)	1983	No placebo group
Weintraub et al.(147)	1975	No placebo group
Bertrand RA.(148)	1971	No placebo group
Konishi et al.(149)	1991	It is unknown if any of the individuals included in this study had Ménière's disease
Perez et al.(150)	2002	Not an RCT
Casani et al.(151)	2005	Not an RCT
Gouveris et al.(152)	2005	Not an RCT
Perez et al.(153)	2005	Not an RCT
Suryanarayanan et al.(154)	2004	Not an RCT
Lange et al.(155)	2004	Not an RCT
Atlas et al.(156)	2003	Not an RCT
Sala T.(157)	2003	Not an RCT
Bottrill et al.(158)	2003	Not an RCT
Perez et al.(159)	2003	Not an RCT
Bauer et al.(160)	2001	Not an RCT
Yetiser et al.(161)	2002	Not an RCT
Hoffer et al.(162)	2001	Not an RCT
Harner et al.(163)	2001	Not an RCT
Schoendorf et al.(164)	2001	Not an RCT
Charabi et al.(165)	2000	Not an RCT
Eklund et al.(166)	1999	Not an RCT
Quaranta et al.(167)	1999	Not an RCT
McFeely et al.(168)	1998	Not an RCT
Corsten et al.(169)	1997	Not an RCT
Sala T.(170)	1997	Not an RCT
Nedzelski et al.(171)	1992	Not an RCT
Yamazaki et al.(172)	1991	Not an RCT
Lange G.(173)	1989	Not an RCT
Youssef et al.(174)	1998	Not an RCT
Kaasinen et al.(175)	1998	Not an RCT
Hirsch et al.(176)	1997	Not an RCT

Reference	Year	Reason for Exclusion
Rauch et al.(177)	1997	Not an RCT
Toth et al.(178)	1995	Compared two different treatment protocols
Odkvist LM.(179)	1988	Not an RCT
Yamazaki et al.(180)	1988	Not an RCT
Beck C.(181)	1986	Not an RCT
Gates GA.(182)	1999	Not an RCT
Pensak et al.(183)	1998	Not an RCT
Quaranta et al.(184)	1998	Not an RCT
Moffat DA.(185)	1994	Not an RCT
Huang et al.(186)	1991	Not an RCT
Goldenberg et al.(187)	1990	Not an RCT
Huang et al.(188)	1989	Compares shunt surgery to other surgeries
Matsuoka et al.(189)	1989	Not an RCT
Huang et al.(190)	1985	Not an RCT
Cody et al.(191)	1983	Not an RCT
Goldenberg et al.(192)	1983	Not an RCT
Gardner G.(193)	1975	Not an RCT
Durland et al.(194)	2005	Not an RCT
Smith et al.(195)	1997	Not an RCT
Arenberg et al.(196)	1977	Not an RCT
Gibson WPR.(197)	1996	Not an RCT
Goksu et al.(198)	1999	Not an RCT
Pappas et al.(199)	1997	Not an RCT
Rosenberg et al.(200)	1996	Not an RCT
Wazen et al.(201)	1990	Not an RCT
Jones et al.(202)	1989	Not an RCT
McElveen et al.(203)	1988	Not an RCT
Boyce et al.(204)	1988	Not an RCT
Claassen et al.(205)	1987	Not an RCT
Primrose et al.(206)	1986	Not an RCT
Smyth et al.(207)	1986	Not an RCT
Silverstein et al.(208)	1985	Not an RCT
Palva et al.(209)	1979	Not an RCT
Palva et al.(210)	1988	Not an RCT
Adams et al.(211)	1982	Not an RCT
Benecke et al.(212)	1986	Not an RCT
Graham et al.(213)	1984	Not an RCT
Pedersen et al.(214)	1971	Not an RCT
Pedersen et al.(215)	1970	Not an RCT
Sugawara et al.(216)	2003	Not an RCT
Welling et al.(217)	2000	Review

Reference	Year	Reason for Exclusion
Huang TS.(218)	1999	Not an RCT
Colletti et al.(219)	1989	Not an RCT
Ried E.(220)	1988	Not an RCT
Futaki et al.(221)	1988	Not an RCT
Dionne J.(222)	1985	Not an RCT
Brown JS.(223)	1983	Not an RCT
Ford CN.(224)	1982	Not an RCT
Maddox HE.(225)	1977	Not an RCT
Rivas et al.(226)	1994	Not an RCT
Arenberg IK.(227)	1987	Not an RCT
Silverstein et al.(228)	1984	Not an RCT
Arenberg IK.(229)	1979	Review
Welling et al.(230)	1996	Compares two different surgical procedures
Hughes et al.(231)	1988	Compares multiple treatments on same individuals
Kinney et al.(232)	1997	Not an RCT
Hommes OR.(233)	1970	Individuals included in the study were not randomized to treatment
Bertrand RA.(234)	1970	Case reports and healthy individuals
Quaranta et al.(235)	2001	Data included in the meta-analysis performed by Cohen-Kerem et al.(89)
Derebery et al.(236)	2004	Not a treatment for Ménière's disease that we assessed
Thomsen et al.(237)	1983	Included same individuals as Thomsen et al.(91)
Bretlau et al.(238)	1984	Included same individuals as Thomsen et al.(91)
Goin et al.(239)	1992	Individuals not randomized
Filipo et al.(240)	1994	Individuals not randomized
Asawavichianginda et al.(241)	2000	It is unknown if any of the individuals included in this study had Ménière's disease
Silverstein et al.(242)	1989	Individuals not randomized

Appendix E: Determining the Stability and Strength of a Body of Evidence

As stated in the main text, ECRI Institute evidence reports differ substantially from other systematic reviews in that we provide two types of conclusion: qualitative conclusions and quantitative conclusions. In order to reach these conclusions, we use an algorithm developed by ECRI Institute to guide the conduct and interpretation of the analyses performed during the development of this evidence report.(40) The algorithm, which is presented in Figure E-3 through Figure E-6, formalizes the process of systematic review by breaking the process down into several discrete steps. At each step, rules are applied that determine the next step in the systematic review process and ultimately to the stability and strength of evidence ratings that are allocated to our conclusions. Because the application of the rules governing each step in the algorithm (henceforth called a decision point) guide the conduct of the systematic review process and how its findings are interpreted, much time and effort was spent in ensuring that the rules and underlying assumptions for each decision point were reasonable.

The algorithm comprises three distinct sections: a *General* section, a *Quantitative* section, and a *Qualitative* section. Each of these sections, the decision points that fall within them, and the decision rules that were applied at each step in the present evidence report are described below.

Decision Point 1: Acceptable Quality?

Decision Point 1 serves two purposes: 1) to assess the quality of each included study; and 2) to provide a means of excluding studies that are so prone to bias that their reported results cannot be considered useful. To aid in assessing the quality of each of the studies included in this evidence report, we used two study quality assessment instruments. The choice of which instrument to use was based on the design of the study used to address the key questions of interest. In this evidence report, we used the ECRI Institute Quality Scale I (for randomized and nonrandomized comparative studies), the ECRI Institute Quality Scale III (for pre/post studies) and a revised version of the Newcastle-Ottawa Quality Assessment Scale (for case-control studies).(243) These instruments are presented in Appendix F.

Decision Point 2: Determine Quality of Evidence Base

We classified the overall quality of each key question specific evidence base into one of three distinct categories: high, moderate, or low quality. Decisions about the quality of each evidence base were based on data obtained using the quality assessment instruments described above using the criteria presented in Table E-1.

Table E-1. Criteria Used to Categorize Quality of Evidence Base

Category	Median EQS I Score	Median EQS III Score	Median NOQAS Score	Median EQS VI Score
High Quality	≥7.5			
Moderate Quality	6.0 to 7.4	≥9.0	≥8.0	≥8.0
Low Quality	≤6.0	<9.0	<8.0	<9.0

Decision Point 3: Quantitative Analysis Performed?

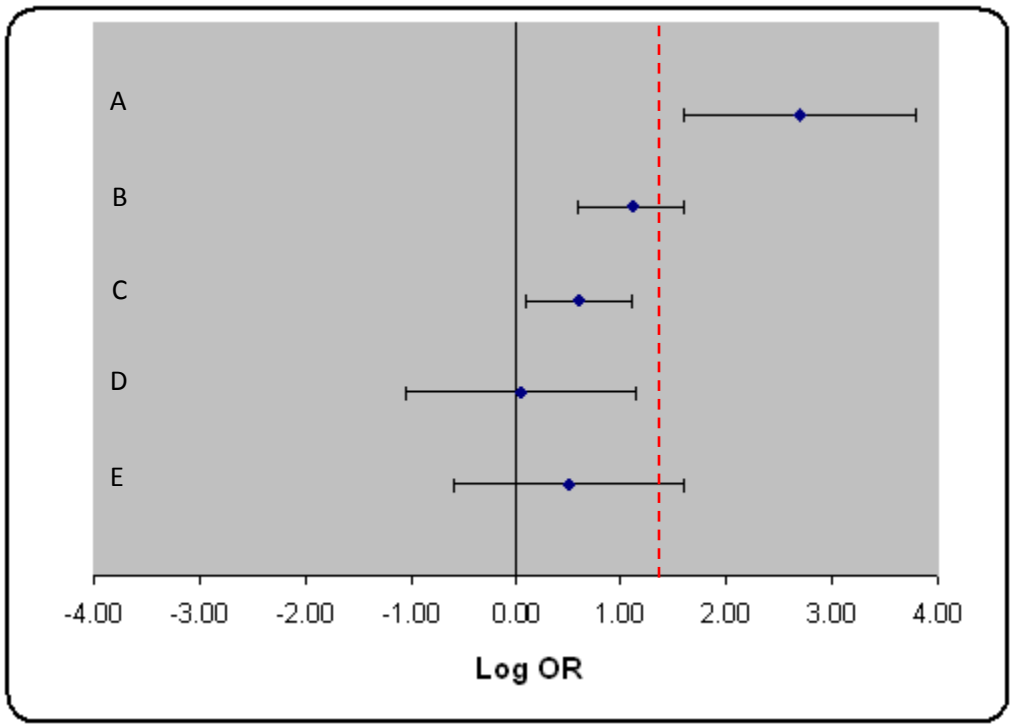
In this evidence report, the answer to Decision Point 3 depended on a number of factors: the number of available studies and the adequacy of reporting of study findings. For any given question, combinable data from at least three studies must be available before a quantitative analysis will be considered. If four or more studies were available but poor reporting precluded ECRI Institute from directly computing relevant effect size estimates for >75% of the available studies, no quantitative analysis were performed. If no quantitative analyses were performed, we moved directly to Decision Point 8, which deals with the assessment of the available evidence with the aim of drawing a purely qualitative conclusion.

Decision Point 4: Are Data Quantitatively Consistent (Homogeneous)?

This decision point was used only when the answer to Decision Point 3 was affirmative and a quantitative analysis was performed. Quantitative consistency refers to the extent to which the quantitative results of different studies are in agreement. The more consistent the evidence, the more precise a summary estimate of treatment effect derived from an evidence base will be. Quantitative consistency refers to consistency tested in a meta-analysis using a test of homogeneity. For this evidence report, we used both the Q-statistic and Higgins and Thompson's I^2 statistic.(53) By convention, we considered an evidence base as being quantitatively consistent when I^2 <50% and *P*(Q) >0.10.

If the findings of the studies included were homogeneous (I^2 <50% and *P*(Q) >0.10), we obtained a summary effect size estimate by pooling the results of these studies using fixed-effects meta-analysis (FEMA). Having obtained a summary effect size estimate, we then determined whether this estimate effect size estimate was informative. That is, we determined whether the findings of the meta-analysis allowed a conclusion to be drawn. To see what is meant by this, consider Figure E-1. Four of the findings in this figure are informative (A to D). Only finding E is noninformative.

Figure E-1. Informative Findings



Dashed Line = Threshold for a clinically significant difference

Finding A shows that the treatment effect is statistically significant and clinically important. Finding B shows that the treatment effect is statistically significant, but it is unclear whether this treatment effect is clinically important. Finding C shows that the treatment effect is statistically significant but that the treatment effect is too small to be considered clinically important. Finding D shows that it is unclear whether there is a statistically important treatment effect; regardless, this treatment effect is not clinically important. Finding E shows that it is unclear whether there is a statistically important treatment effect and it is also unclear whether the treatment effect is clinically important. This latter finding is thus noninformative.

Decision Point 5: Are Findings Stable (Quantitatively Robust)?

If the findings of the fixed-effects meta-analysis were found to be informative, we next assessed the stability of the summary effect size estimate obtained. Stability refers to the likelihood that a summary effect estimate will be substantially altered by changing the underlying assumptions of the analysis. Analyses that are used to test the stability of an effect size estimate are known as sensitivity analyses. Clearly, confidence in the validity of a treatment effect estimate will be greater if sensitivity analyses fail to significantly alter the summary estimate of treatment effect.

For this evidence report, we utilized the following four different sensitivity analyses:

1. *Random-effects meta-analysis of complete evidence base.* When the quantitative analysis is performed on a subset of available studies, a random-effects meta-analysis that includes imprecise estimates of treatment effect calculated for all available studies will be performed.

For this evidence report, the summary estimate of treatment effect determined by this analysis will be compared to the summary effect size estimate determined by the original fixed-effects meta-analysis. If the random-effects effect size estimate differs from the original fixed-effects meta-analysis by some prespecified tolerance, the original effect size estimate will not be considered stable.

The prespecified tolerance levels for each of the potential effect size estimates we could have utilized in this evidence report are presented in Table E-2.

Table E-2. Prespecified Tolerance Levels

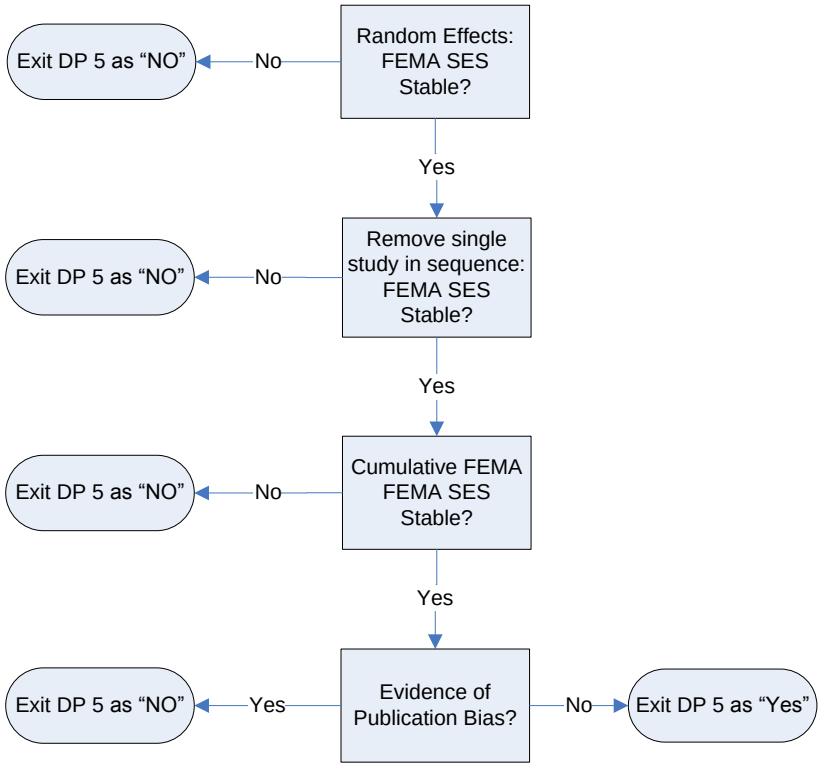
Effect Size Estimate	WMD	SMD	% of Individuals	RR	OR
Tolerance	+/-5%	+/-0.1	+/-5%	+/-0.05	+/-0.05

2. *Removal of one study and repeat meta-analysis.* The purpose of this sensitivity analysis is to determine whether a meta-analysis result is driven by a particular trial. For example, a large trial may have a very strong impact on the results of a meta-analysis because of its high weighting.
3. *Publication bias test.* The publication bias test used in this evidence report was that of Duval and Tweedie.(67-70)Based on the degree of asymmetry in a funnel plot constructed from the findings of the included studies, this test(69,70)estimates the number of unpublished studies (and their effect sizes). After addition of any "missing" data to the original meta-analysis, the overall effect size is estimated again. If evidence of publication bias was identified and the summary effect size estimate, adjusted for "missing" studies, differed from the pooled estimate of treatment effect determined by the original fixed-effects meta-analysis by >±5%, we determined that the findings of our original analysis are not robust and that the effect size estimate is not stable.
4. *Cumulative fixed-effects meta-analysis.* Cumulative meta-analysis provides a means by which one can evaluate the effect of the size of the evidence base (in terms of the number of individuals enrolled in the included studies and the number of included studies) on the stability of the calculated effect size estimate. For this evidence report, we performed the following three cumulative fixed-effects meta-analyses:
    a. Studies were added in order of weight.
    b. Studies were added cumulatively to a fixed-effects meta-analysis by date of publication—oldest study first.
    c. Studies were added cumulatively to a fixed-effects meta-analysis by date—newest study first.

In each instance, the pooled effect size estimate was considered unstable if any of the last three studies to be added resulted in a change in the cumulative summary effect size estimate effect of >±5%.

Because it is possible to reach Decision Point 6 with two different types of evidence base (100% or <100% ≥75% of total available evidence base), two slightly different sets of sensitivity analyses are needed. Figure E-2 shows the procedural algorithm that was used when dealing with these two types of evidence base.

Figure E-2. Sensitivity Analysis Algorithm 1: Used when Original Fixed-Effects Meta-Analysis Utilized Data from All Available Studies



Decision Points 6 and 7: Exploration of Heterogeneity

We will always attempt to determine the source of heterogeneity when the evidence base consists of 10 or more studies using metaregression. In preparing this evidence report, we did not encounter any situations in which we had a heterogeneous evidence base consisting of at least 10 studies. Consequently, Decision Points 6 and 7 are irrelevant to the present report and we do not discuss them further.

Decision Point 8: Are Qualitative Findings Robust?

Decision Point 8 allows one to determine whether the qualitative findings of two or more studies can be overturned by sensitivity analysis. For this evidence report, a single sensitivity analysis was performed–a cumulative random-effects meta-analysis (cREMA). We considered our qualitative findings to be overturned only when the findings of the cREMA altered our qualitative conclusion (i.e., a statistically significant finding became nonsignificant as studies were added to the evidence base). If the qualitative

findings of the last three study additions were in agreement, then we concluded that our qualitative findings were robust.

Decision Point 9: Are Data Qualitatively Consistent?

The purpose of this decision point is to determine whether the qualitative findings of an evidence base consisting of only two studies are the same. For example, one might ask, "When compared to insulin injection, do all included studies find that inhaled insulin is a significant risk factor for a motor vehicle crash?"

Decision Point 10: Is Magnitude of Treatment Effect Large?

When considering the strength of evidence supporting a qualitative conclusion based on only one or two studies, magnitude of effect becomes very important. The more positive the findings, the more confident one can be that new evidence will not overturn one's qualitative conclusion.

The algorithm divides the magnitude of effect into two categories–large and not large. Determining the threshold above which the observed magnitude of effect can be considered to be "large" cannot usually be determined *a priori*. In cases in which it is necessary to make judgments about whether an estimate of treatment effect is extremely large, the project director will present data from the two studies to a committee of three methodologists who will determine whether an effect size estimate is "extremely large" using a modified Delphi technique.

Figure E-3. General Section

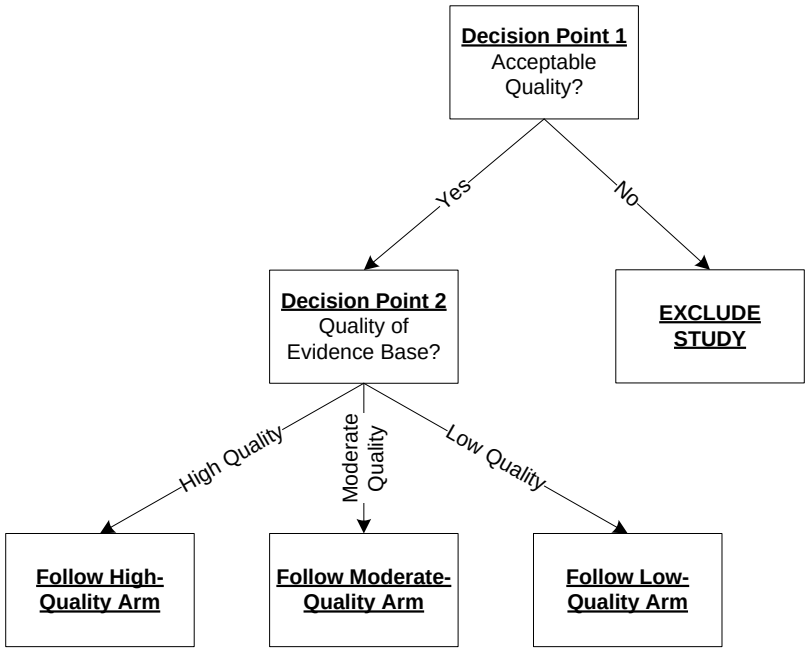


Figure E-4. High-Quality Pathway

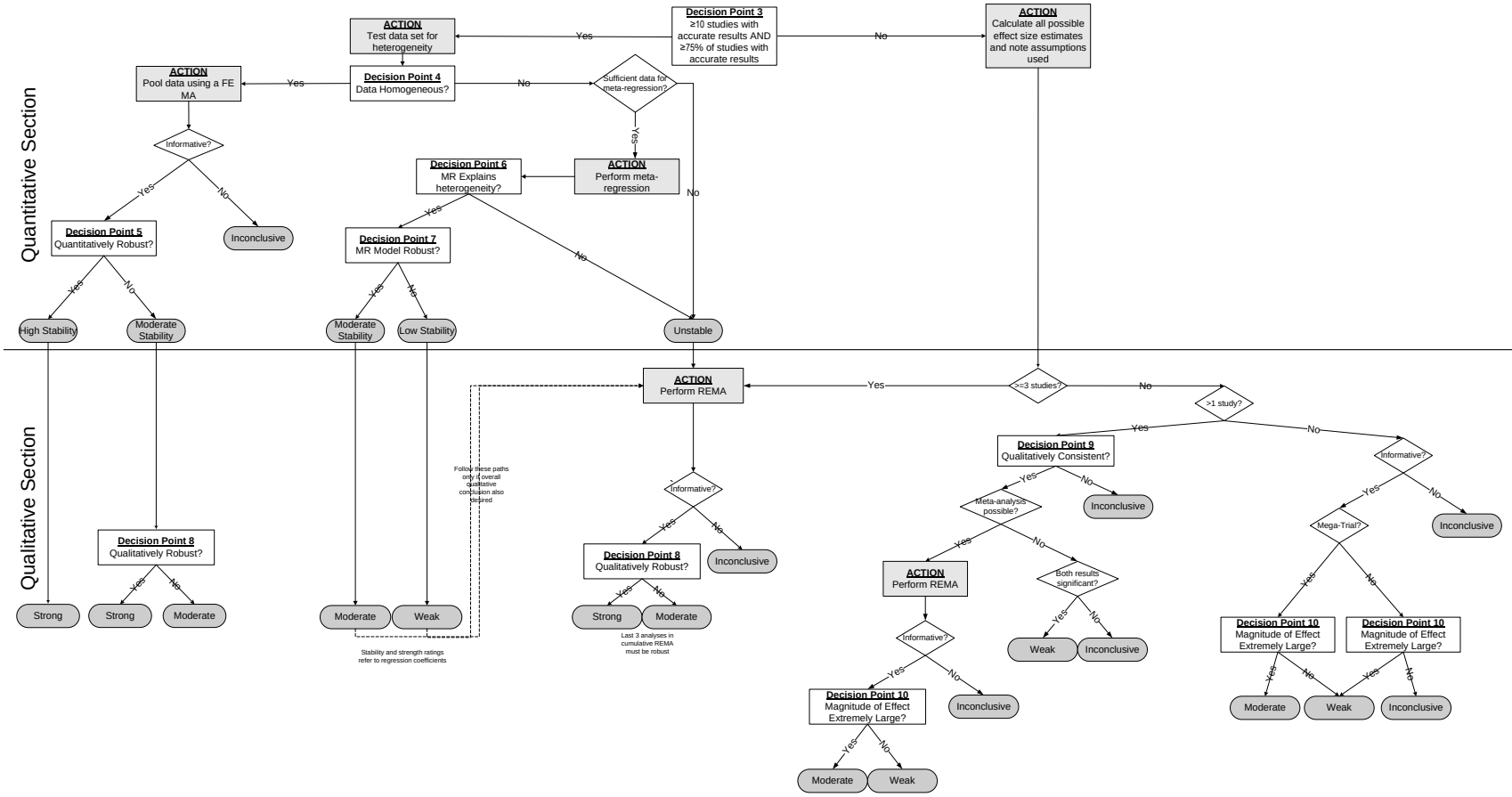


Figure E-5. Moderate-Quality Pathway

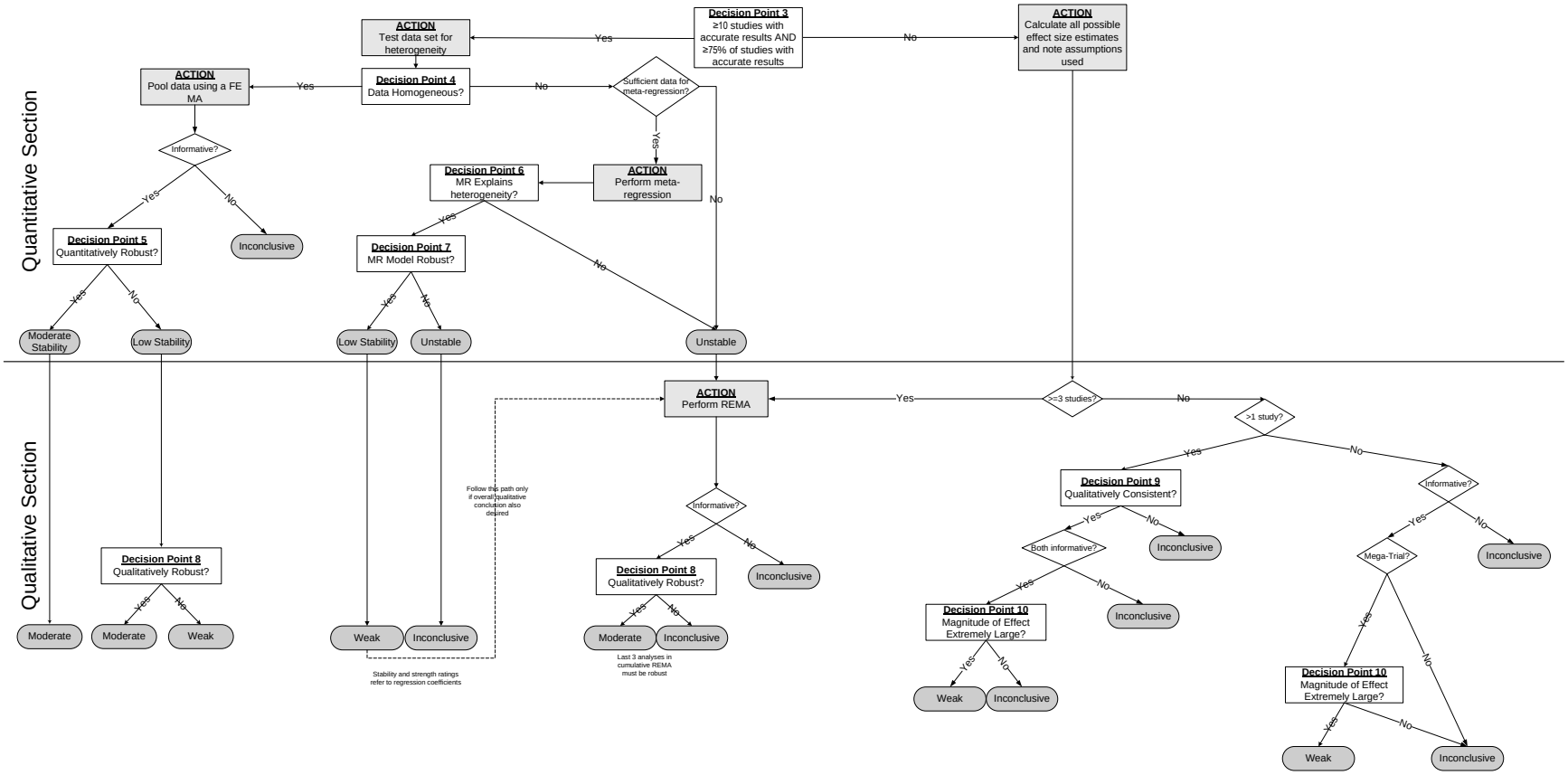
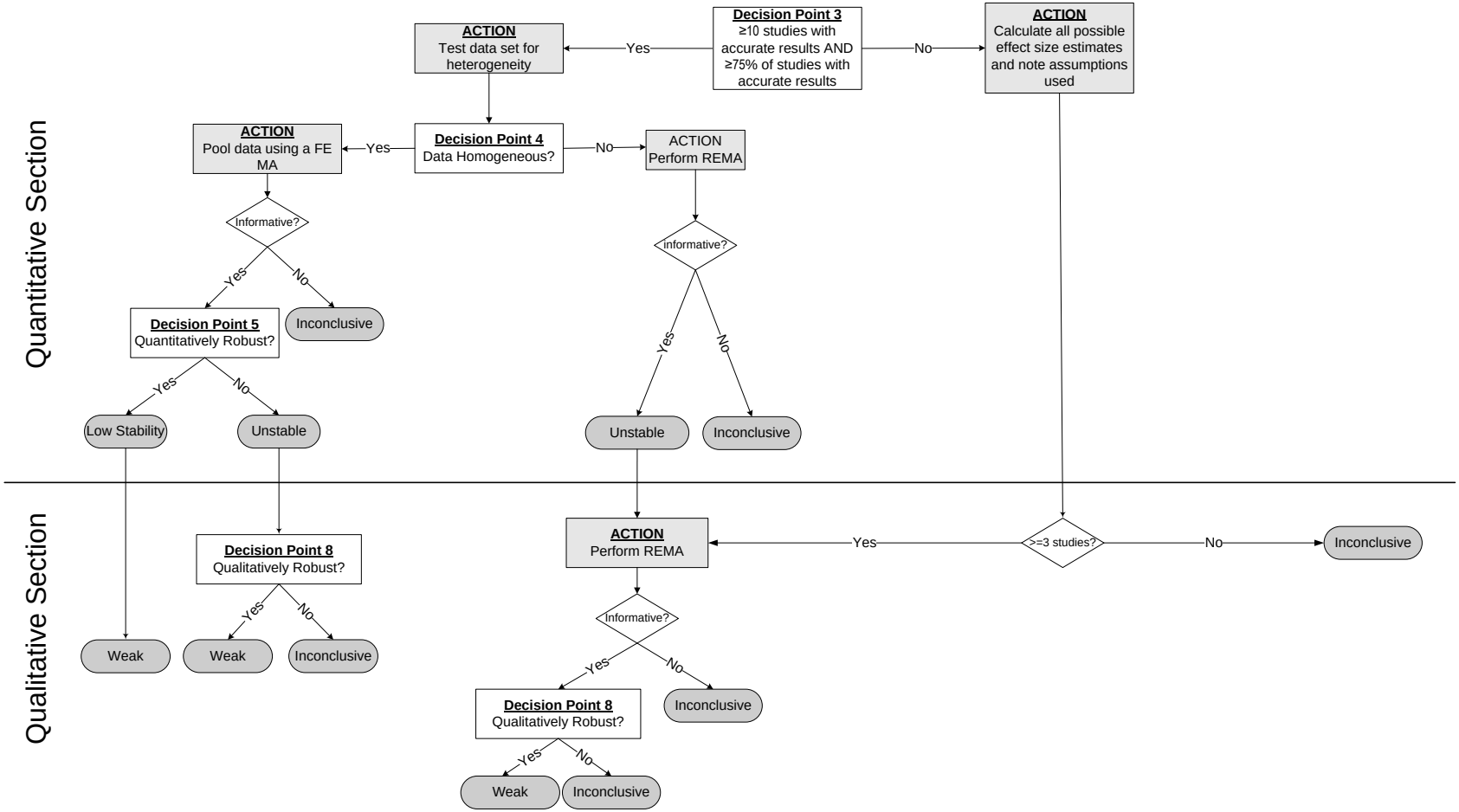


Figure E-6. Low-Quality Pathway



Appendix F: Quality Assessment Instruments Used

Three different assessment instruments were used to assess the quality of the studies included in the evidence bases for the key questions addressed in this evidence report: ECRI Institute Quality Scale I for comparative trials, ECRI Institute Quality Checklist III for before/after studies, and a revised version of the Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies.(243)

ECRI Institute Quality Scale I: Controlled Trials

Question #	Question
1	Were patients randomly assigned to the study's groups?
2	Did the study employ stochastic randomization?
3	Were any methods other than randomization used to make the patients in the study's groups comparable?
4	Were patients assigned to groups based on factors other than patient or physician preference?
5	Were the *characteristics* of patients in the different study groups comparable at the time they were assigned to groups?
6	Did patients in the different study groups have similar levels of performance on ALL of the outcome variables at the time they were assigned to groups?
7	Was the comparison of interest prospectively planned?
8	Did ≥85% of the patients complete the study?
9	Was there a ≤15% difference in completion rates in the study's groups?
10	Were all of the study's groups concurrently treated?
11	Was compliance with treatment ≥85% in both of the study's groups?
12	Were all of the study's groups treated at the same center?
13	Were subjects blinded to the treatment they received?
14	Did the authors perform any tests after completing the study to ensure that the integrity of the blinding of patients was maintained throughout the study?
15	Was the treating physician blinded to the groups to which the patients were assigned?
16	Were those who assessed the patient's outcomes blinded to the group to which the patients were assigned?
17	Was there concealment of allocation?
18	Was the outcome measure of interest objective **and** was it objectively measured?
19	Were the same laboratory tests, clinical findings, psychological instruments, etc. used to measure the outcomes in all of the study's groups?
20	Was the instrument used to measure the outcome standard?
21	Was the same treatment given to all patients enrolled in the experimental group?
22	Was the same treatment given to all patients enrolled in the control group
23	Were the follow-up times in all of the study's relevant groups approximately equal?
24	Was the funding for this study derived from a source that does not have a financial interest in its results?
25	Were the author's conclusions, as stated in the abstract **or** the article's discussion section, supported by the data presented in the article's results section?

ECRI Quality Scale III: Pre/Post Studies

Item	Question
1	Was the study prospective?
2	Did the study enroll all patients or consecutive patients?
3	Were the criteria for including and excluding patients based on objective laboratory and/or clinical findings?
4	Were the patient inclusion/ exclusion criteria established a priori?
5	Was the same initial treatment given to all patients enrolled?
6	Did all patients receive the same subsequent treatment(s)?
7	Was the outcome measure objective, and was it objectively measured?
8	Did ≥85% of patients complete the study?
9	Were the characteristics of those who did and did not complete the study compared, and were these characteristics similar?
10	Was the funding for this study derived from a source that does not have a financial interest in its results?
11	Were the author's conclusions, as stated in the abstract or the article's discussion section, supported by the data presented in the article's results section?

ECRI Quality Scale VI: Surveys

Item	Question
1	Were the questions developed from an expert group or focus group?
2	Was the pretest sample sufficiently large (>40 respondents)?
3	Were the characteristics of those who did not complete the study compared with those who completed the study, and were those characteristics similar?
4	Were the pretest sample respondents similar in characteristics to the study's respondents?
5	Were the respondents selected for the survey either consecutively or randomly?
6	Are the questions about crash (or other relevant outcome) not in the first 25% of the questions?
7	Does the questionnaire have reliability checks by asking the same question more than once but differently?
8	Were the respondents informed that their responses were confidential?
9	Were the conclusions, as stated in the abstract and discussion, consistent with the data presented in the results section?
10	Was the funding for this study derived from a source that does not have a financial interest in its results?

Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies

The original Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies consisted of ten questions. We adapted the instrument to better capture some sources of bias that were not considered in the original 10-item scale.

Question #	Question
1	Do the cases have independent validation?
2	Are the cases representative?
3	Are the controls derived from the community?
4	At the designated endpoint of the study, do the controls have the outcome of interest?
5	Does the study control for the most important confounder?
6	Does the study control for any additional confounders?
7	Was exposure/outcome ascertained through a secure record (surgical, etc.)
8	Was the investigator who assessed exposure/outcome blinded to group/patient assignment?
9	Was the same method of exposure/outcome ascertainment used for both groups?
10	Was the nonresponse rate of both groups the same?
11	Was the investigation time of the study the same for both groups?
12	Was the funding free of financial interest?
13	Were the conclusions supported by the data?

Appendix G: Study Summary Tables

Appendix G is available on request.