



## **Executive Summary**

### **Hearing, Vestibular Function and Commercial Motor Vehicle Driver Safety**

Presented to

## **Federal Motor Carrier Safety Administration**

**August 26, 2008**

*Prepared for*



**MANILA Consulting Group, Inc.**

1420 Beverly Road, Suite 220

McLean, VA 22101

*Prepared by*



**The ECRI Institute**

5200 Butler Pike

Plymouth Meeting, PA 19462

*Evidence reports are sent to the Federal Motor Carrier Safety Administration's (FMCSA) Medical Review Board (MRB) and Medical Expert Panels (MEP). The MRB and MEP make recommendations on medical topics of concern to FMCSA.*

*FMCSA will consider all MRB and MEP recommendations, however, all proposed changes to current standards and guidance (guidelines) will be subject to public-notice-and-comment and relevant rulemaking processes.*

## Policy Statement

This report was prepared by ECRI under subcontract to MANILA Consulting Group, Inc., which holds prime contract GS-10F-0177N/DTMC75-06-F-00039 with the Department of Transportation's Federal Motor Carrier Safety Administration. ECRI is an independent, nonprofit health services research agency and a Collaborating Center for Health Technology Assessment of the World Health Organization. ECRI has been designated an Evidence-based Practice Center (EPC) by the U.S. Agency for Healthcare Research and Quality. ECRI's mission is to provide information and technical assistance to the healthcare community worldwide to support safe and cost-effective patient care. The results of ECRI's research and experience are available through its publications, information systems, databases, technical assistance programs, laboratory services, seminars, and fellowships. The purpose of this evidence report is to provide information regarding the current state of knowledge on this topic. It is not intended as instruction for medical practice, or for making decisions regarding individual patients.

## Authorship

Nicholas Price (The ECRI Institute)

Marie Tiller, PhD (The ECRI Institute)

James Reston, PhD (The ECRI Institute)

Stephen Tregear, DPhil (Manila Consulting Group)

## Executive Summary

### Purpose of Evidence Report

Of all occupations in the United States (U.S.), 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 U.S. 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 non-fatal crashes; 59,405 of these were crashes that 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 FMCSA such that their will provide information that will be useful in updating its 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 40dB or greater at 500 – 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 (that included Medline, PubMed (pre Medline), EMBASE, PSYCH Info, CINAHL, TRIS, and the Cochrane library) were searched (through August 26th, 2007). In addition, we examined the reference lists of all obtained articles with the aim of identifying relevant articles not identified by our electronic searches. Hand searches of the “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 conclusions is defined in Table 1.

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

Strength of Conclusion	Interpretation
<b>Qualitative Conclusion</b>	
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 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 recommends frequent monitoring of the relevant literature.
Unacceptable	Although some evidence exists, the evidence is insufficient to warrant drawing an evidence-based conclusion. ECRI recommends frequent monitoring of the relevant literature.
<b>Quantitative Conclusion (Stability of Effect Size Estimate)</b>	
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 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 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 recommends frequent monitoring of the relevant literature.

### Evidence-Based Conclusions

#### Key Question 1: Are individuals with hearing thresholds of 40dB or greater at 500 – 3,000Hz 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 (CDLs). 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 40dB or greater at 500 – 3,000Hz) 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 a hearing impairment are at an increased risk for a crash (Strength of Conclusion: Acceptable).**

*One retrospective cohort study (Quality Rating: Low) reported on the incidence of crashes occurring among populations of individuals with a hearing impairment and prevalence of crashes occurring among individuals without a 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 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 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 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.*

### **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.(1) 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.(1) In many cases, attacks of vertigo stop completely.(1) In addition, there is evidence of a significant placebo effect in Ménière's disease treatment.(1,2) 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: 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 result in a change in 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, 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 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. In this case, that requirement has not been met. 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 – 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. In this case, that requirement has not been met. Consequently, we refrain from drawing a conclusion at this time.*