Targeted Evidence Report

Cochlear Implants and Commercial Motor Vehicle Driver Safety

Presented to

The Federal Motor Carrier Safety Administration

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MANILA Consulting Group, Inc.
1420 Beverly Road, Suite 220
McLean, VA 22101

Authorship

Michelle Bieber-Tregear, PhD	MANILA Consulting Group
Dana Connor, BA	MANILA Consulting Group
Stephen Tregear, DPhil	MANILA Consulting Group

Policy Statement

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Executive Summary

Objectives

The objective of this Targeted Evidence Report is to examine issues pertaining to the potential impact of cochlear implantation (for severe to profound hearing loss) on commercial motor vehicle (CMV) driver safety. The key issues addressed in this report include:

Background Questions

- What are the different types of cochlear implants, and what types of hearing loss are they used to treat?
- What are the criteria and/or indications for a cochlear implant?
- What are the epidemiological factors associated with cochlear implantation (e.g., who is receiving the devices, how widespread is their use, what is the prevalence of conditions for which cochlear implants are used, and does this population overlap with the CMV driver population)? Additionally, what are the current trends of cochlear implant devices?

Key Research Questions

1. How effective are cochlear implants, and is auditory function following cochlear implantation restored to a level that would permit safe driving as established by existing Federal standards for hearing?
2. What is the nature of hearing capability following implantation (e.g., sound localization), and are there associated factors that may not be conducive with safe driving?
3. Are there any other factors associated with cochlear implantation that may increase crash risk, such as disrupted vestibular function?

Methods

We used electronic searches of PubMed and the Transportation Research Information Services (TRIS) databases (through September 2010) to identify relevant literature. Searches were conducted using MeSH terms related to cochlear implants (e.g., Cochlear Implants; Auditory Prosthesis; Cochlear Prosthesis; Implants, Cochlear; Cochlear Implantation) and related text words. These terms were also combined with other terms related to, effectiveness, auditory localization, sound localization, adverse effects, vestibular dysfunction, vertigo, and dizziness.

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.

Evidence Summary

Summary of Evidence for the Effectiveness of Cochlear Implants

None of the included studies (or any other studies available in the literature) examine how individuals with cochlear implants perform using the forced whispered voice test (the most common hearing test employed

with prospective CMV drivers during medical examination). The primary outcome assessed in studies that look at hearing perception following cochlear implantation is speech perception. Although not a specific requirement of FMCSA for CMV drivers, adequate speech perception is reported in some safety sensitive occupations, such as by the FAA, to be a physical fitness requirement for job safety.

Summary of Evidence for Speech Perception

When cochlear implants are compared with non-technological support, the evidence indicates that cochlear implants lead to improvements in the ability to understand speech and quality of life. This is moderately associated with age at implantation and more strongly associated with duration of deafness before implantation. These gains appear to be greater in noisy conditions, especially amongst people who are postlingually deaf. This review also found that functional hearing and quality of life appear to be improved.

In addition, these studies show that bilateral cochlear implantation increases the ability to hear more clearly in noisy conditions and understand speech, and may improve quality of life when compared with unilateral cochlear implantation. This binaural benefit is a term that is used to describe the benefit seen in both normal hearing individuals and individuals with hearing aids who have access to information from both ears. Utilizing both ears can also provide separation of the acoustic signal inputs from a noise source within the environment.

There was wide variation between patients in the degree of improvement. This is likely related to the variation between studies with factors such as type of speech tests employed, use of or absence of noise, and varying signal-to-noise ratios. However, speech perception generally improved following implantation of one or two cochlear implants. In almost all cases, patients prior to implantation were unable to hear and/or recognize verbal speech. Following implantation, most subjects could understand both words and sentences presented in formal testing conditions, and were much better at holding conversations in social, real-world conditions (e.g., with background noise present).

Another relevant auditory outcome of interest to commercial driver safety is sound localization which is addressed b y the next key question.

Summary of Evidence for Sound Localization

Monaural cochlear implant recipients have poor sound localization ability. Performance is close to chance. Studies assessing bilateral cochlear implants and/or bimodal stimulation demonstrated, to varying degrees, that localization ability was significantly improved compared to unilateral cochlear implant recipients or those using a hearing aid in the contralateral ear. However, sound localization ability in the best instances, were not returned to normal levels. Bilateral implants were observed to confer up to a 30 degrees improvement in localization acuity over unilateral use, with the best performing bilateral implant participant achieving an accuracy of 4.4 degrees in sound-source discrimination, which approximates normal hearing performance (1.7 degrees).

While sound localization ability approximates normal sound localization under the best circumstances, there is no data available to address the question of whether or not sound localization capability following bilateral implantation is restored to a level sufficient for driver safety.

Summary of Evidence for Vestibular Dysfunction

Vestibular impairment is a common condition among those who have hearing loss (range 26% to 58%; prior to cochlear implantation) and for those who receive cochlear implants (range 29% to 76%; post implant). However, the number of individuals who receive cochlear implantation and suffer from severe vestibular symptoms long-term is relatively low. Only one study (Krause, 2009) reported that a patient suffered from severe, continuous dizziness, causing long term disability following cochlear implantation. Other studies reported severe dizziness or vertigo in subjects, but found that most patients – some with the aid of vestibular rehabilitation – recovered to preoperative levels.

The studies conflicted on whether preoperative patient characteristics could predict postoperative vestibular dysfunction. Factors cited as predictors of postoperative vestibular symptoms included:

- Meniere's disease;
- Older age at implantation (e.g., >59 to >70 yrs of age);
- Age at onset of hearing loss greater than 26 years old.

Despite the conflicting conclusions, all studies reported the need for patients to be informed of the possibility and likelihood of postoperative vertigo symptoms.

Conclusions

No literature was identified that looked at outcomes in commercial drivers or in individuals in other safety sensitive occupations.

The primary outcomes considered in the studies evaluated included speech perception, sound localization, and adverse consequences, such as vestibular disruption following cochlear implantation.

Cochlear implantation improves hearing performance and speech perception, although not to the degree of people with normal hearing; the degree of improvement varies for each recipient, depending on factors such as the duration of deafness, whether or not the individual was pre- or post-lingually deaf, and age at implantation.

Bilateral cochlear implantation is an advantage to unilateral cochlear implantation for the purpose of speech perception in noise, and with sound localization tasks.

Although most individuals have a unilateral cochlear implant, there is a trend to outfit more patients with two cochlear implants or with one cochlear implant and a hearing aid in the contralateral ear to improve outcomes.

Although a large number of hearing-impaired individuals were found to suffer from vestibular symptoms preoperatively, between 20% and 76% of cochlear implant recipients exhibited vestibular impairment following cochlear implantation. Those who suffer prolonged symptoms are usually assisted with vestibular rehabilitation.

Preface

Purpose of Report

FMCSA is interested in examining issues pertaining to the potential impact of cochlear implantation (for profound hearing loss) on commercial motor vehicle (CMV) driver safety. A preliminary review of the literature in developing the scope of this report revealed that no scientific literature exists that explicitly evaluates driver safety in individuals who have undergone cochlear implantation. As a result, we identified a series of additional questions that are intended to address this issue indirectly.

The key issues addressed in this report include:

Background Questions

- What are the different types of cochlear implants, and what types of hearing loss are they used to treat?
- What are the criteria and/or indications for a cochlear implant (and does this vary by condition)?
- What are the epidemiological factors associated with cochlear implantation (e.g., who is receiving the devices, how widespread is their use, what is the prevalence of conditions for which cochlear implants are used, and does this population overlap with the CMV driver population)? Additionally, what are the current trends of cochlear implant devices?

Key Research Questions

1. How effective are cochlear implants, and is auditory function following cochlear implantation restored to a level that would permit safe driving as established by existing Federal standards for hearing?
2. What is the nature of hearing capability following implantation (e.g., sound localization), and are there associated factors that may not be conducive with safe driving?
3. Are there any other factors associated with cochlear implantation that may increase crash risk, such as disrupted vestibular function?

Organization of Report

This targeted evidence report contains four major sections: 1) Introduction, 2) Background on Cochlear Implant, 3) Comparison of Relevant Regulations, and 4) Evidence Summary.

The *Introduction* section briefly summarizes basic information on hearing loss and current epidemiological information. In the *Background on Cochlear Implants* section, we provide information on how cochlear implants function to restore hearing, the different types of cochlear implants that have received U.S. Federal Drug Administration (FDA) approval, the current indications for cochlear implants, and current trends in the use and programming of cochlear implants. The section covers the background questions described in the *Purpose of the Report*. In the *Comparison of Relevant Regulations* section, we provide information pertaining to current regulatory standards and guidelines for hearing and vestibular function

from the FMCSA and other countries, which are generally considered to have well-developed medical fitness programs. In addition, we summarize equivalent information from three other government transportation agencies; the Federal Aviation Administration (FAA), the Federal Railroads Administration (FRA), and the Maritime Administration (MARAD). The *Evidence Summary* section is organized by Key Research Questions, and summarizes available data relevant to each question.

Identification of Evidence Bases

Electronic searches of PubMed and the Transportation Research Information Services (TRIS) databases were conducted (through September 2010). Searches were conducted using MeSH terms related to cochlear implants (e.g., Cochlear Implants; Auditory Prosthesis; Cochlear Prosthesis; Implants, Cochlear; Cochlear Implantation) and related text words. These terms were also combined with other terms related to, effectiveness, auditory localization, sound localization, adverse effects, vestibular dysfunction, vertigo, and dizziness.

In addition, we examined the reference lists of all obtained articles with the aim of identifying relevant articles not identified by our electronic searches. Searches of the "grey literature" (source material not available through electronic bibliographic databases, such as PubMed and TRIS) were also performed.

1. Introduction

Hearing loss is the sixth-leading chronic disability in the United States, following arthritis, spinal problems, heart disease, psychological and respiratory diseases, and diabetes.[1] The primary cause of hearing loss is age-related (i.e., presbycusis), with more than half of all hearing loss occurring in individuals over the age of 65 years.[2] The National Institute on Deafness and Other Communication Disorders (NIDCD) estimates that about 36 million American adults suffer from hearing loss (e.g., ranging from minor hearing loss to profound deafness), a significant increase from the 31.5 million adults who had trouble hearing in 2000.[3-5] The estimate is similar to the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS) estimation of 37 million adults suffering hearing loss in 2006.[6] Based on estimates from the National Health Information Survey (NHIS) conducted during 2000-2006,[6] men were more likely than women to be deaf or have trouble hearing (4.3% and 2.4%, respectively).

Hearing loss can have a profound impact on an individual's emotional, physical, and social well-being. The prevalence of poor health status, difficulties with physical functioning, and serious psychological distress, increases with the degree of hearing loss.[6] Even moderate hearing loss can make routine communication difficult, resulting in depression, anxiety, the inability to maintain employment, reduced social interaction and recreation, poor memory and attention, and other physical disorders.[7, 8]

Additionally, because the auditory system is in close proximity to the vestibular system – which is responsible for balance and sense of spatial orientation – those with hearing loss can suffer from dizziness and, in severe cases, the inability to stand upright. Adults who are deaf or hearing impaired are about three times as likely as adults with good hearing to be in fair or poor health and to have difficulty with physical functioning, such as walking, bending, reaching, etc.[6]

For Commercial Motor Vehicle (CMV) drivers, hearing (including sound level and sound localization) and balance play an important role in safe driving. The ability to hear and localize warning sounds, such as horns, train signals and sirens, allows a driver to react to potential hazards before they are visible. Hearing is also a crucial for communication between the driver and company dispatchers, loading dock personnel, law enforcement officers and passengers. Similarly, the ability to maintain balance is essential for safe driving and task performance (e.g., vehicle inspections, securing loads) and when getting into, and out of, trucks and buses.

To ensure that CMV and bus drivers are capable of safely carrying out the activities of their job, the Federal Motor Carrier Safety Administration (FMCSA) has defined and codified hearing standards in its medical fitness requirements, 49 CFR Part 391 (Table 1).

Table 1: FMCSA's Current Hearing Regulations

49 CFR 391.41(b)(11) A person is physically qualified to drive a commercial motor vehicle if that person:
(11) 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) Z24.5–195.

The use of hearing aids has made it possible for many individuals to pass FMCSA's hearing standards, and thus qualify to operate a CMV. The increasing use of cochlear implants – an electronic device implanted in the inner ear for those with severe or profound hearing loss—may also enable individuals to pass FMCSA's hearing standards. However, questions remain about the ability of these individuals to localize sound. Therefore, FMCSA is interested in examining issues pertaining to the impact of cochlear implantation on CMV driver safety.

Although recent prevalence data of cochlear implants are lacking and inconsistent, the NIDCD estimates that 188,000 people worldwide had received cochlear implants as of April 2009. Included in that estimate are roughly 41,500 adults and 25,500 children from the United States. Earlier estimates of the prevalence of cochlear implants were much lower, with only 60,000 estimated to have received them worldwide at the beginning of this century .[9] The increasing number of cochlear implant recipients is likely due to improvements in device function and the expanding indications for their use.[10, 11] At present, there are no statistics available on the number of drivers (commercial or otherwise) who have cochlear implants. In addition, no State-level data are available on the number of intrastate commercial drivers with cochlear implants. The number, however, are expected to be low given the current physical fitness requirements with regard to hearing. Additionally, no information is available in other western countries with commercial driver license qualifications.

Since 1984, when the FDA approved the first cochlear implants for adults with profound hearing loss, cochlear implant technology has improved, progressing from single-electrode, single channel devices to multi-electrode, multichannel devices. As a result, the criteria for cochlear implantation have been expanded to include individuals with lesser degrees of hearing loss. Now that Medicare and most insurance plans cover the cost of cochlear implantation, the procedure is a viable option for the American public.

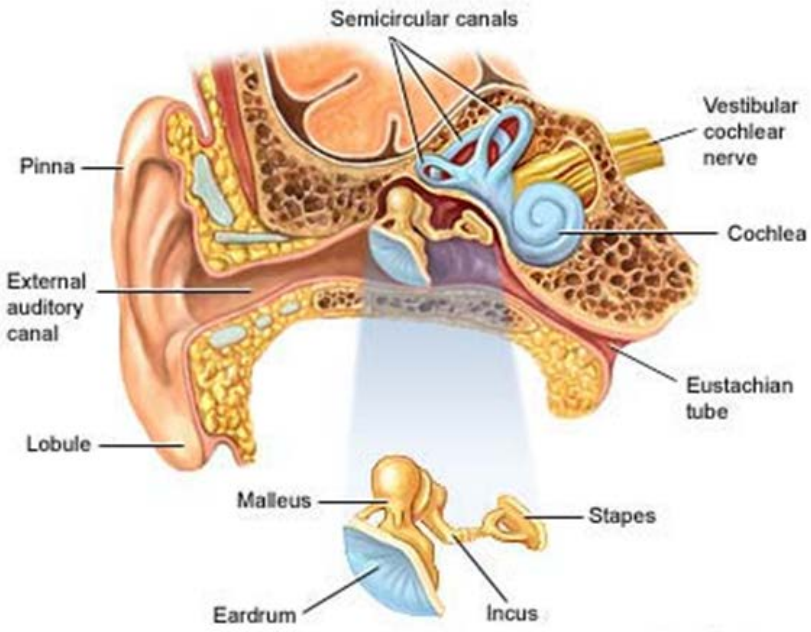
The purpose of this report is to provide a detailed summary of existing knowledge related to the use of cochlear implants and their potential impact on CMV driver safety.

2. Background on Hearing and Cochlear Implants

2.1. Normal Hearing

The human auditory system is composed of three distinct areas: the outer ear, the middle ear, and the inner ear (refer to Figure 1)

Figure 1: Anatomy of the Ear



Source: University of Maryland Medical Center

In normal hearing, sound waves traveling through air reach the ear drum (i.e., tympanic membrane) via the ear canal, causing vibrations that move the three small bones of the middle ear (i.e., the ossicles). This action produces a piston-like movement of the stapes, the third bone in the chain. As shown in Figure 2a, the "footplate" of the stapes is attached to a flexible membrane in the bony shell of the cochlea, called the oval window. Inward and outward movements of this membrane induce pressure oscillations in the cochlear fluids, which in turn initiate a traveling wave of displacement along the basilar membrane (BM), a highly specialized structure that divides the cochlea along its length. This membrane has graded mechanical properties, responding in variable patterns along its length, depending on the nature of the auditory stimulus (the frequency and amplitude). Motion of the BM is sensed by the sensory hair cells in the cochlea, causing them to move in variable ways, where transduction occurs (sound waves converted into variable electrical signals within the auditory nerve).

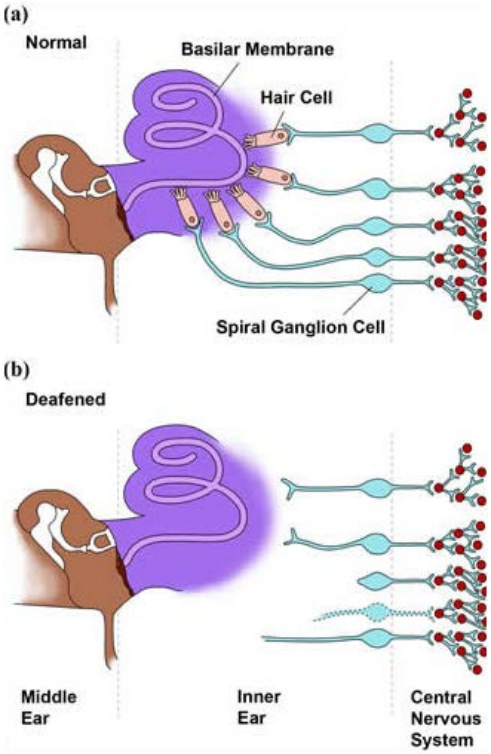
In terms of the frequency range of normal hearing, under optical conditions, humans can hear frequencies within the range of 20 to 20,000 Hertz. The size and energy of these waves determine the loudness of the sound, which is measured in decibels (dB). Examples of sound levels (in decibels) for common noises are presented in Table 2.

Table 2: Sound Levels of Common noises

Decibels	Noise source
Safe range	
10 dB	Normal Breathing
30 dB	Whisper (very quite)
50-65 dB	Normal conversation
70 dB	Vacuum Cleaner, Hair Dryer
Risk range	
85-90 dB	Heavy city traffic, power lawn mower, hair dryer
95 dB	Motorcycle
100 dB	Snowmobile, hand drill
110 dB	Chain saw, rock concert
Injury range	
120 dB	Ambulance siren
110-140 dB	Threshold of pain begins around 125 dB
140 dB	Jet engine at takeoff
165 dB	Shot gun shot
185 dB	Rocket launch

As people age, the frequency range of the hearing is reduced. The highest frequency that a normal middle-aged adult can hear is 12 to 14 kHz. The average range for elderly is 50 Hz to 8 kHz.[12]

Figure 2: Anatomy of Inner Ear



Source: Wilson et a., 2008[13]

2.2. Hearing Loss

There are five types of hearing loss, each classified according to which part of the auditory system is affected. These are listed in Table 3. Sensorineural hearing loss is the type of hearing loss most relevant to the current discussion regarding cochlear implants, and is discussed in greater depth in the subsection that follows.

Table 3: Types of Hearing loss

Most common types of hearing loss	
Sensorineural Hearing Loss	Results when there is a problem with the inner ear. It most often occurs when the sensory hair cells of the inner ear (responsible for transduction of sound waves into electrical signals) are injured, diseased, do not function properly, or have prematurely died.
Conductive Hearing Loss	Occurs because of a mechanical problem in the outer or middle ear. The three tiny bones of the ear (ossicles) may not conduct sound properly, or the eardrum may not vibrate in response to sound. Fluid in the middle ear can cause this type of hearing loss.
Mixed Hearing Loss	Frequently, a person experiences two or more types of hearing impairment, and this is called mixed hearing loss. This term is used only when both conductive and sensorineural hearing losses are present in the same ear.
Least common types of hearing loss	
Central Hearing Loss	The problem lies in the central nervous system, at some point within the brain, which causes a person to have difficulty interpreting speech.
Functional Hearing Loss	A loss of hearing without a physical basis.

The prevalence of hearing loss may be growing because of an aging population and increasing noise exposure. However, accurate national estimates of hearing loss prevalence based on recent objective criteria are lacking. In one study conducted from 2003-2004,[14] 16.1% of US adults (29 million Americans) had speech frequency hearing loss. In the youngest age group (20-29 years), 8.5% exhibited hearing loss, and the prevalence seems to be growing among this age group. Odds of hearing loss were 5.5-fold higher in men vs. women and 70% lower in black subjects vs. white subjects. Increases in hearing loss prevalence occurred earlier among participants with smoking, noise exposure, and cardiovascular risks.

According to the Beaver Dam Eye Study,[15] the overall prevalence of hearing loss was 45.9%. Of those with a hearing loss, 58.1% had a mild hearing loss, 30.6% had a moderate loss, and 11.3% had a marked loss. Hearing loss was usually symmetrical (94.8% experienced bilateral hearing loss). Few people had evidence of conductive losses (8.1%), a hearing loss with an onset before age 20 years (1.9%), or a history of ear surgery (1.7%). The prevalence of abnormal middle-ear function was low (12.9%). Thirty-six percent (36%) of all participants had never had a hearing test.

According to this study, the prevalence of hearing loss increased greatly with age, and men were more likely to be affected than were women. A logistic regression model indicated that, for every 5 years of age, the risk of hearing loss increased by almost 90%, and men were more than four times as likely to have a hearing loss than were women (odds ratio (OR) = 1.88, 95% confidence interval (CI) 1.80-1.97, and OR =4.42, 95% CI 3.73-5.24, respectively).

In another study, the prevalence of current hearing aid use among those with a hearing loss (pure-tone average >25 decibels hearing level over 500, 1000, 2000, and 4000 Hertz, worse ear) was only 14.6%.[16]

2.2.1. Sensorineural Hearing Loss

The principal cause of sensorineural hearing loss is damage to or complete destruction of the sensory hair cells (refer to Figure 2b, above). Damaged hair cells can subsequently lead to degeneration of adjacent auditory neurons, and if a large number of hair cells or auditory neurons throughout the cochlea are damaged, then the person with such a loss is diagnosed as profoundly deaf.

The hair cells of the inner ear are fragile structures and are subject to a wide variety of insults, including but not limited to genetic defects, infectious diseases (e.g., rubella and meningitis), overexposure to loud sounds, certain drugs (e.g., kanamycin, streptomycin, and cisplatin), and aging.[17] Disorders of and/or loss of the inner hair cell function severs the connection between the peripheral and central auditory systems. The function of a cochlear implant is to bypass the (missing or damaged) hair cells by directly stimulating the surviving neurons in the auditory nerve.

2.2.2. Treatment of Sensorineural Hearing Loss

There are two primary modes of treatment for sensorineural hearing loss, hearing aids and/or cochlear implants. The primary difference between the two devices is that hearing aids amplify sounds of the environment and present those sounds to the damaged ear, while cochlear implant systems capture sounds from the environment and convert those sounds to electrical signals that directly stimulate the auditory nerve. Unlike hearing aids, the cochlear implant is considered to be an auditory prosthesis. A summary of the key differences between these devices is provided in Table 4. Cochlear implants, including how they function, the current indications, and devices available are described in the next section. Further discussion of hearing aids is beyond the scope of this report.

Table 4: Differences between Hearing Aids and Cochlear Implants

Hearing Aids	Cochlear Implants
• Indicated for individuals with all degrees of hearing loss (from mild to profound) who can benefit from sound amplification	• Indicated only for individuals with severe to profound hearing loss who do not benefit from the amplification of sound
• Sound is amplified and conveyed through both the outer and middle ear and finally to the sensory receptor cells (hair cells) in the inner ear. The hair cells convert the sound energy into neural signals that are picked up by the auditory nerve.	• Cochlear implants bypass the outer and middle ears, and the damaged hair cells and replace their functions by converting sound energy into electrical energy that directly stimulates the auditory nerve.

2.3. Cochlear Implants

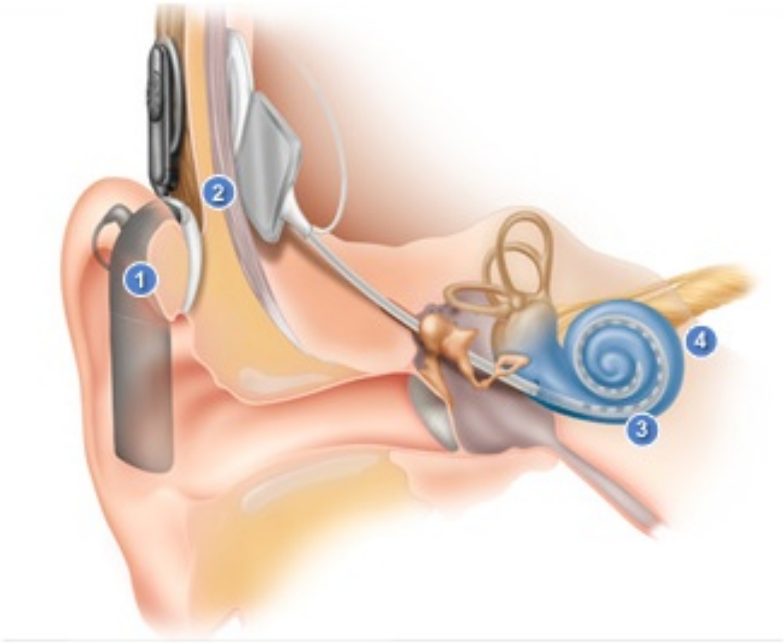
A cochlear implant is a device for individuals with severe to profound hearing loss, who only receive limited benefit from sound amplification with hearing aids. A cochlear implant provides direct electrical stimulation to the auditory nerve, bypassing the usual transducer cells that are absent or nonfunctional in deaf cochlea.

The essential components in a cochlear implant system are illustrated in Figure 3, and include both external and surgically implanted, internal components. The external component (1) captures sound through a microphone and then filters and processes sound in the environment into a set of digital codes, which are

transmitted through a transcutaneous link to an internal receiver/stimulator (2). The implanted receiver/stimulator converts the digital information into electrical signals, and sends them via a tiny cable to the delicate curl of electrodes that sits inside the cochlea (3). The electrical signals from the electrodes stimulate the hearing nerve (4), bypassing the damaged or absent sensory hair cells that cause sensorineural hearing loss, allowing the brain to perceive sound.

Traditional cochlear implants consisted of a single electrode (single channel). Modern cochlear implants consist of multiple electrodes (creating multiple channels), which are situated along the length of the electrode array. The multichannel electrode array is inserted such that electrodes are arranged along the length of the cochlea. Different electrodes along the array are stimulated depending on the frequency composition of the signal. Electrodes near the base of the cochlea are stimulated with high frequency signals (similar to natural hearing), while electrodes near the apex (the most distal end of the array) are stimulated with low frequency signals. The signal processor is responsible for deconstructing the input signal into different frequency bands or channels and delivering the filtered signals to the appropriate electrodes along the array. The main function of the signal processor is to decompose the input signal into its frequency components, much like a healthy cochlea analyzes the input signal into its frequency components. The designers of cochlear prosthesis are faced with the challenge of developing signal-processing techniques that mimic the function of a healthy cochlea.

Figure 3: Cochlear Implant System



Although the cochlear implant is able to stimulate the auditory nerve, the result is not the same as normal hearing. It is rather a useful representation of sound in the environment to help individuals understand speech and recognize warning signals and other sounds.[18] A normal ear can resolve patterns of sound energy in about 60 distinct bands of frequency in the range from 100 Hz to 20,000 Hz. The best that users of implants achieve is 6 to 8 bands, regardless of whether they have 24, 16 or 12 electrodes.

2.4. Types of Cochlear Implants

Several cochlear implants are commercially available in the United States (refer to Table 5), the Nucleus family of devices, manufactured by Cochlear Corporation; the Clarion family of devices, manufactured by Advanced Bionics; and the Med El Combi 40+ family of devices, manufactured by Med El. Over the years, subsequent generations of the various components of cochlear devices have been approved by the U.S. Food and Drug Administration (FDA), focusing on improved electrode design and speech-processing capabilities. Many of the original implants approved by the FDA are no longer implanted in patients, because their technologies have been improved. Most modern cochlear implants are versatile in that they are capable of being adjusted to respond to environmental sound in various ways. Table 5 identifies available devices, their indications for use, and the current contraindications for the use of all cochlear implant devices.

Table 5: FDA-approved Cochlear Implant Devices

Device name	Company/ Location	Date Approved	Indications for Use
Nucleus 24 Cochlear Implant System This device has undergone 57 revisions (most recently in June 2010) since its original release related to design improvements and labeling changes http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?start_search=1&pmanumber=P970051	Cochlear Americas, *Colorado*	06-25-98	• Children: ≥18 to 24 months old o Profound hearing loss • Older children: 2 through 17 years old o Severe to profound sensorineural hearing loss • Adults o Severe to profound loss pre- and postlingually
Nucleus 24 Contour			• Children: ≥12 to 18 months o Profound hearing loss • Older children: 2 through 17 years old o Severe to profound hearing loss • Adults o Severe to profound loss pre- and postlingually
Clarion Multi-Strategy Cochlear Implant This device has undergone 62 revisions (most recently in August 2010) since its original release related to design improvements and labeling changes http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?start_search=61&pmanumber=P9600	Advanced Bionics Corp., *California*	06-26-97	• Children, 2 through 17 years old • If x-rays demonstrate evidence of ossification, children as young as 18 months may be implanted • Profound bilateral sensorineural deafness • Undergone or be willing to undergo a hearing aid trial with appropriately fitted hearing aids o Lack of benefit from appropriately fitting hearing aids. In younger children, lack of benefit with hearing aids is defined as failure to attain basic auditory milestones, such as a child's inconsistent response to his/her name in quiet or to environmental sounds (meaningful auditory integration scale)

Device name	Company/ Location	Date Approved	Indications for Use
58			o In older children, lack of aided benefit is defined as scoring 0% on open-set word recognition (phonetically balanced kindergarten test - word list) administered with monitored live-voice (70 dB). Both younger and older children should demonstrate only minimal ability on age appropriate open-set sentence measures and a plateau in auditory development
Combi 40+ Cochlear Implant System This device has undergone 44 revisions (most recently in September 2010) since its original release related to design improvements and labeling changes http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?pmanumber=P000025	Med-El Corp., *Austria*	8-20-01	• Adults ≥18 years old who have bilateral sensorineural hearing impairment and obtain limited benefit from appropriately fitted binaural hearing aids o These individuals typically demonstrate severe to profound bilateral sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500Hz, 1000 Hz, and 2000 Hz. o Limited benefit from amplification is defined by test scores of 40% correct or less in best-aided listening condition on cd recorded tests of open-set sentence recognition hearing in noise test (hint) sentences. • Children age 18 months through 17 years old must demonstrate profound bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz. o In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a 3- to 6-month period. o In older children, lack of aided benefit is defined as < 20% correct on the multi-syllabic lexical neighborhood test (mlnt) or lexical neighborhood test (lnt), depending upon the child's cognitive ability and linguistic skills. o A three (3) to six (6) month hearing aid trial is required for children without previous experience with hearing aids. Radiological evidence of cochlear ossification may justify a shorter trial with amplification.
Contraindications			
• Deafness due to lesions of the eighth cranial nerve or brain stem; • Chronic infections of the middle ear and mastoid cavity or tympanic membrane perforation. • Absence of cochlear development as demonstrated on CT scans is an absolute contraindication. • Upgrades of an existing, functioning external system to achieve aesthetic improvement, such as smaller profile components or a switch from a body-worn, external sound processor to a behind-the-ear model, are considered not medically necessary.			

Source: FDA[19]

2.4.1. Indications for Cochlear Implants

Candidacy for cochlear implantation has evolved substantially during the last two decades.[20, 21] Early criteria included only postlingually deafened adults with no benefit from hearing aids or other amplification systems. In this case, 'no benefit' was defined as a 0% score on a standardized monosyllabic word tests used to evaluate candidates in the best aided condition. Currently, the FDA guidelines have broadened to include adults with a larger range of hearing loss (i.e., severe to profound hearing loss) and limited benefit

from hearing aids, now defined as 50% or less on standardized sentence tests routinely used to evaluate potential implant candidates. The inclusion criteria include prelingual hearing impaired adults, as well as infants and children who meet all the other criteria.

- Standard pure-tone and speech audiometry tests are also used to screen likely candidates for cochlear implantation.
- For children age 12 to 23 months, the pure-tone average (PTA) for both ears should equal or exceed 90 dB.
- For individuals older than 24 months, the PTA for both ears should equal or exceed 70 dB.

If the patient can detect speech with best-fit hearing aids in place, a speech-recognition test in a sound field of 55-dB HL sound pressure level (SPL) is performed. A number of speech recognition tests are currently in use.

Current FDA guidelines permit implantation in patients whose open-set sentence recognition (e.g., the Hearing In Noise Test [HINT]) is 60% or less in the best-aided condition. For patients receiving Medicare benefits, the current cutoff for cochlear implant candidacy is a HINT score of 40% or less. For Medicare patients enrolled in an acceptable clinical trial or study, the cutoff is 60% or less. Guidelines for other third-party payers vary.

2.4.2. Current Guidelines for the use of Cochlear Implants

Only two evidence-based clinical practice guidelines are identified that address the use of cochlear implants. They are:

- Cochlear implants for children and adults with severe to profound deafness. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Jan. 41 p. (Technology appraisal guidance; no. 166). (http://www.nice.org.uk/nicemedia/live/12122/42854/42854.pdf)[22]
- Cochlear implants in adults and children. NIH Consensus Statement. 1995 May 15-17;13(2):1-30[23]

In both guidelines, cochlear implants are recommended for adults and children with severe to profound deafness. In the more recent guideline released in 2009, unilateral cochlear implantation is recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids. Simultaneous bilateral cochlear implantation is also recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids, but is currently limited to children, and adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness. For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 90 dB at frequencies of 2 and 4 kHz without acoustic hearing aids. Adequate benefit from acoustic hearing aids is defined for this guidance as:

- For adults, a score of 50% or greater on Bamford–Kowal–Bench (BKB) sentence testing at a sound intensity of 70 decibels sound pressure level (dB SPL)
- For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability

In addition, people who received unilateral implants before 2009, and who fall into one of the categories described above, should have the option of an additional contralateral implant only if this is considered to provide sufficient benefit. Cochlear implantation should be considered for children and adults only after an assessment by a multidisciplinary team. As part of the assessment children and adults should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate).

2.5. Current Trends in Cochlear Implantation

Bilateral Implantation

While cochlear implants have typically been used unilaterally, in recent years, there has been an interest in bilateral implantation (implants in both ears) and bimodal stimulation (implant in one ear and hearing aid in contralateral ear).[13, 24-26]

The proposed benefits of both bilateral and bimodal implants are to improve binaural hearing, which is enjoyed by people with normal hearing function. Binaural summation hearing enables optimal performance of the auditory system, resulting in improved speech understanding in quiet and noise and sound localization ability. By improving binaural hearing, bilateral and bimodal recipients have the potential to increase their level of hearing by using several natural sub-phenomena: the head shadow effect, binaural redundancy, and binaural squelch effects.

The “head shadow effect” results with the head acting as an acoustic barrier to sounds and noise coming from different locations in space. The ear furthest from the noise source will have a more advantageous signal-to-noise ratio (SNR) than the ear closest to the noise source. This effect results in an average of 6.4 dB of noise attenuation but can be as high as 20 dB for high frequency speech sounds, improving speech intelligibility by as much as 50%. In patients with unilateral hearing loss, the head shadow effect still occurs but in this case, it can be a detriment if speech originates on the opposite side of the head from their only hearing ear. Binaural redundancy and squelch are two central auditory processes which, when combined, improve on the distinct acoustic signals arriving at each ear.

The process of receiving a bilateral cochlear implant may be performed independently with separate implants and speech processors in each ear or with a single processor. However, no single processor for bilateral cochlear implantation has been approved by the FDA for use in the United States.[19]

Cochlear Implant Processors

The primary difference between devices worn today and those from 20 years ago is that they are more flexible regarding their programming. Earlier models were not capable of using two different coding schemes simultaneously. At present, a group of electrodes can be stimulated using one strategy, and the remainder of the array can be stimulated using another strategy. Several groups of researchers are exploring the possibility of creating additional (virtual) channels of information transfer by steering a current in between electrodes.

In additional to the evolution of speech-processing strategies, electrode design has evolved from straight electrodes to curved models.[27-29] The straight electrode insertions were frequently situated near the outer ear wall, causing penetration of the basilar membrane and various degrees of damage to the osseous

spiral lamina and stria vascularis. Recent models, however, are designed to reduce trauma and sit closer to the site of cochlea structures. Other electrode design modifications include a "soft tip" to further reduce the possibility of trauma. Research on electrode design continues to be focused on the preservation of existing inner ear structures while transmitting coded stimuli efficiently and effectively.[30, 31]

Retaining Residual Hearing

Another configuration that researchers are exploring is shortening and thinning the electrode array for implantation into an ear with residual hearing and/or using hearing aids in the implanted ear. This is intended to help preserve any existing residual hearing and amplify this acoustical information that is presented to the function components of the inner ear. The configuration is showing promise in trial subjects, but there are still issues that need to be solved, such as quality of sound and the inability of the device to fuse electrical and acoustic stimuli.

Artificial Cochlea

Researchers also are looking at fully implantable devices, but there are some inherent drawbacks for such devices. The performance of these devices would have to be equal to or better than that of a traditional implant; surgery and usage would carry additional risks; replacing the battery would be a major challenge; and microphone placement would need to cause no erosion of the skin over the placement site. Despite these challenges, implant manufacturers are in the process of designing and testing the first versions, although it is not known when these devices will be ready and available for clinical trials.

2.6. Incidence and Indications for Cochlear Implantation Failure and Revision

Revision surgery for cochlear implantation is an unusual but not uncommon occurrence following cochlear implantation. A review[32] of studies examining the need for revision following initial cochlear implantation finds a rate of about 3-8% of initial surgeries require reimplantation. According to this review, the vast majority of revision procedures are the result of device failure (40-80%).The incidence of revision is greater in children undergoing initial implantation than in adults.

A number of reasons exist for device failure including hard device failure[1], soft device failure[2], cochlear implant exposure or infection, electrode migration, and receiver/stimulator migration. A number of studies have examined the incidence and indications for cochlear implantation failure and revision surgeries. A summary of the findings of these studies is provided in the table below.

According to the reports, regardless of indication, revision cochlear implant surgery is well tolerated, and most patients have successful outcomes.

[1] **Hard device failure** is defined as a complete interruption of auditory input and a malfunction of communication between the internal and external components. Hard failure is diagnosed with an inability to link the device and is often detectable on invivo integrity testing.

[2] **Soft device failure** is defined as a device failure that is not associated with a detectable defect on in-vivo integrity testing

Table 6: Need for Revision Surgery following Initial Cochlear Implant Surgery

Reference	Year	Study Type	Total N (Revision N)	Incidence/Reason for Revision Cochlear Implantation

Brown et al.[33]	2009	Retrospective Case Series	804 children and adults (28 children) (16 adults)	7.3% for children
				3.8% for adults
				• Device failure (78%)
				  o *Hard failure (55%)*
				  o *Soft failure (23%)*
				• Electrode migration (8.5%)
				• Receiver/stimulator migration (8.5%)
				• Infection/exposure (5%)

Lassig et al.[34]	2005	Retrospective Case Series	900 children and adults (58 children and adults)	5.1% overall • Internal device failure (46%) • Scalp flap complications (17%) • Optimization of electrode placement (13%) • Unexplained deterioration of performance (12%) • Technology upgrade (10%) • Intratemporal pathology (3%)
Migirov et al. [35]	2007	Retrospective Case Series	(45 children and adults)	12.5% for children 6.9% for adults • Device failure (51%) Device failure (DF) was the main cause for revision surgery (23/45) followed by wound/flap problems, magnet/receiver-stimulator displacement, foreign body/allergic reaction, subperiosteal abscess, misplaced electrode, intractable vertigo, cholesteatoma and extrusion of the positioner
Rivas et al.[36]	2008	Retrospective Case Series	825 adults (40 devices in adults)	4.8% adults • Suspected device failure (42%) • Hard failure (23%) • Electrode extrusion (15%) • Infection (12%) • Isolated facial nerve stimulation (8%)

3. Comparison of Relevant Regulations

3.1. Regulatory Medical Fitness Standards and Guidelines in Other Countries

This section highlights the auditory and vestibular standards and guidelines established by the United States and other countries regarding CMV drivers' medical fitness to drive. Regulations and guidelines from the following nations are included:

- **United States** (Part 391.41:Physical qualifications for drivers, FMCSA)
- **Australia** (Assessing Fitness to Drive; Medical Standards for Licensing and Clinical Management Guidelines; 2006)**;**
- **Canada** (Canadian Council of Motor Transport Administrators [CCMTA] Medical Standards for Drivers; 2008)**;**
- **New Zealand** (Medical Aspects of Fitness to Drive. A Guide for Medical Practitioners; Land Transport Safety Authority; 2009)**;**
- **Sweden** (Swedish National Road Administration provisions on the medical requirements for possession of a driving license, etc.; 1998);
- **United Kingdom** (For Medical Practitioners: At A Glance Guide to the Current Medical Standards of Fitness to Drive, Issued by Drivers Medical Group, Driver and Vehicle Licensing Agency of the Department for Transport (DVLA), Swansea; 2010).
- **Mexico** (Physical and Medical Qualifications Standards for Mexico-domiciled Federal-licensed Vehicle Drivers; 2009).

Regulatory standards and guidelines pertaining to auditory and vestibular disorders are presented in Table 7 and Table 8.

Table 7 provides a quick-view assessment of the similarities between the regulations and guidance of other countries compared to the United States. Table 8 outlines the regulations from all countries.

Table 7: Quick-view Assessment of the Attributes of Standards by Different Countries

		US	AUS	CAN	NZ	SWE	UK	MEX
COCHLEAR IMPLANTS								
Addresses cochlear function or cochlear implants in the fitness-to-drive standards								
Addresses cochlear implants in "Additional Guidance"								
AUDITORY SYSTEM								
Requires auditory standards for ALL CMV drivers		•	•				•	•
Requires auditory standards for specific types of CMV drivers, i.e., transporters of dangerous goods or passengers				•	•	•		
Standards	An individual to have UNAIDED average hearing threshold level of equal to		•	•				

		US	AUS	CAN	NZ	SWE	UK	MEX
require:	or greater than 40dB in the better ear.							
	An individual to understand a tone-of-voice conversation from a distance of 3 meters in one ear WITH or WITHOUT hearing aid.				●			
	An individual's hearing in one ear must be no less than 40 decibels in audiometric assessment, WITH or WITHOUT hearing aid	●			●			
	Perceives a forced whispered voice in the better ear at not less than 5 feet, WITH or WITHOUT the use of hearing aid	●				●		
	An individual to understand a tone-of-voice conversation from a distance of 4 meters in one ear WITH or WITHOUT hearing aid.					●		
	Proven ability to communicate using a device, e.g., a MINICOM in the event of an emergency.						●	
	Standard does not specify requirements							●
A conditional license may be granted if the standard is met with a hearing aid			●	●	●			
A conditional license may be granted if the standard is met with a way to use two-way communication that would not impair ability to drive, e.g., the use of rear-view mirror upside down and inward facing on the dashboard					●			
Offers "Additional Guidance"		●	●	●	●	●		
VESTIBULAR SYSTEM								
Addresses the vestibular conditions in standards			●	●	●	●		●
Standard specifically mentions the following:	Meniere's Disease		●			●		
	Vertigo		●	●	●	●		●
	Giddiness				●			
	Balance disorder					●		●
	Ringing in ears							●
Allows for conditional license if:	Symptom-free, or condition controlled			●		●		
	Sufficiently treated				●			
	Symptom-free of Meniere's disease or recurring, unheralded attacks of vertigo for at least 12 months		●					
	Symptom-free of vertigo for at least 6 months		●					
	Approved by a specialist		●			●		
Offers "Additional Guidance"			●	●	●	●		

Auditory and vestibular fitness-to-drive standards vary greatly for CMV drivers in the United States, Australia, Canada, New Zealand, Sweden, the United Kingdom and Mexico.

All countries have auditory standards, but in some countries, such as Canada, New Zealand and Sweden, the auditory standards do not apply to all CMV drivers, but rather to only certain classes of CMV drivers, such as those who haul dangerous goods, other vehicles and passengers.

Despite this, the most common factor among the countries is the requirement that CMV drivers' hearing threshold level be equal to or greater than 40 dB (decibels) in the better ear (with pure tone air conduction tests of 500, 1,000, 2,000 and 3,000 Hz). Although this is the general standard among most countries, the United States, New Zealand and Sweden allow CMV drivers to take a less formal test first, such as the "forced-whisper" or "tone of voice" tests. Only those who fail such tests are required to take audiometric tests. The only two countries that do not require a hearing test are the United Kingdom and Mexico. The United Kingdom's standards require drivers to be able to communicate by speech or device, but it does not mention the requirement of a hearing assessment. Similarly, Mexico, which doesn't provide a specific standard for hearing threshold, states that no CMV drivers are allowed to drive if they have chronic conditions that affect auditory acuity or cause ringing in the ears, vertigo, balance, auditory tube obstruction, and/or ear infection or inflammation.

The United States and the United Kingdom are the only two countries that do not address vestibular conditions in their regulatory standards. However, the United States does offer guidance for individuals with vertigo and dizziness. This recommendation can be found in the 1988 Conference on Neurological Disorders and Commercial Drivers (http://www.fmcsa.dot.gov/documents/neuro.pdf). The other countries – Australia, Canada, New Zealand, Sweden and Mexico – address at least one or more of the following vestibular conditions: Meniere's disease, vertigo, giddiness, balance disorders and ringing in the ears (tinnitus). Aside from Mexico banning individuals with such disorders from driving, the other countries allow drivers to resume their duties once their symptoms have gone away, they've been treated sufficiently, or they have been given a specialist's approval. Australia is the strictest of these countries by not allowing sufferers of Meniere's disease to return to driving until after 12 months of being symptom-free. It also requires sufferers of vertigo, including a single incident, to not return to driving until after 6 months of being symptom-free.

None of the standards addresses cochlear function or implants, with the exception of Australia, which only briefly mentions partial cochlear function in its "additional guidance."

Table 8: Auditory and Vestibular Disorders and Driving – Guidelines and Standards from Other Countries

Country	United States (2009)
Source	http://www.fmcsa.dot.gov/rules-regulations/administration/fmcsr/fmcsrruletext.aspx?chunkKey=09016334800238b9
STANDARD (Auditory)	§391.41 Physical qualifications for drivers (b)(11) 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;
Additional Guidance (Auditory)	Medical Advisory Criteria: 391.41(b)(11) A person is physically qualified to drive a commercial vehicle if that person: First perceives a forced whispered voice in the better ear at not less than five 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 the American National Standard, [formerly American Standard Association (ASA)] Z24.5-1951. Since the prescribed standard under the FMCSRs is the American National Standards Institute (ANSI), it may be necessary to convert the audiometric results from the International Standards Organization (ISO) standard to the ANSI standard. Instructions are included on the Medical Examination Report form. If an individual meets the criteria by using a hearing aid, the driver must wear that hearing aid and have it in operation at all times while driving. Also, the driver must be in possession of a spare power source for the hearing aid. For the whispered voice test, the individual should be stationed at least 5 feet from the examiner with the ear being tested turned toward the examiner. The other ear is covered. Using the breath which remains after a normal expiration, the examiner whispers words or random numbers such as 66, 18, 23, etc. The examiner should not use only sibilants (s-sounding test materials). If the individual fails the whispered voice test, the audiometric test should be administered. If an individual meets the criteria by the use of a hearing aid, the following statement must appear on the Medical Examiner's Certificate "Qualified only when wearing a hearing aid."
Additional Guidance (Vestibular)	1988 Conference on Neurological Disorders and Commercial Drivers (http://www.fmcsa.dot.gov/documents/neuro.pdf) Vertigo and Dizziness Multiple conditions may affect equilibrium or balance resulting in acute incapacitation or varying degrees of chronic spatial disorientation in a commercial driver. Common vertigo syndromes and their relationship to certification: • Benign Positional Vertigo--This condition is disqualifying for driving a commercial vehicle. A driver can then be considered for recertification after being symptom-free for two months. • Acute and Chronic Peripheral Vestibulopathy--These conditions are disqualifying for driving a commercial vehicle. A driver can then be considered for recertification after being symptom-free for two months. • Meniere's Disease--The condition is of sufficient severity and unpredictability such that the diagnosis would render the individual unqualified for driving a commercial vehicle. • Labvrinthine Fistula--The presence of an untreated fistula would render the individual unqualified for driving a commercial vehicle. • Nonfunctioning Labyrinths--would produce a degree of potential disorientation Sufficient to render the individual unqualified for driving a commercial vehicle.
Country	Australia, *Accessing Fitness to Drive; Austroads Inc. 2003 (reprinted 2006)*
Source	http://austroads.com.au/aftd/downloads/AFTD_text_08-2006.pdf
STANDARD (Auditory)	Medical Standards for Licensing – Hearing The criteria for an unconditional license are NOT met:

	• If the person has an unaided average hearing threshold level of 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.
Additional Guidance	20.1 RELEVANCE TO DRIVING TASK 10.1.1 Mild to moderate hearing loss does not appear to affect a person's ability to drive safely. It may be that a loss of hearing is well compensated for since most people who are hard of hearing are aware of their disability and therefore tend to be more cautious and to rely more on visual cues. 10.1.2 While driving ability per se might not be affected by a hearing deficiency, responsiveness to critical events is an important safety consideration for drivers of commercial vehicles. These drivers therefore require a reasonable level of hearing in order to ensure their awareness of changes in engine or road noises which may signal developing problems, and their awareness of horns, rail crossings, emergency signals and sirens. 10.1.3 Hearing sufficient to converse with passengers is not a matter that affects safe driving and hence is not covered by these criteria. However, standards may be set for Occupational Health and Safety purposes. 10.2 MEDICAL STANDARDS FOR LICENSING 10.2.1 Medical criteria for unconditional and conditional licenses are outlined in the table opposite. 10.2.2 Note that only drivers of commercial vehicles are required to meet a hearing standard for the reasons outlined above. Compliance with the standard should be clinically assessed initially and if there is doubt about the person's hearing then audiometry should be arranged. 10.2.3 Conditional Licenses for Commercial Drivers: In addition to appropriately fitted hearing aids, various engineering solutions are available to help compensate for the risk to safety that may arise from a hearing disability. These include: • Mirrors appropriate to the vehicle to enhance rear view; • Alerting devices that provide a warning signal (visual display) when sirens, horns, and other loud noises are detected; • Technologies providing (visual) warning signals to guide safe truck operation, e.g. air pressure in braking systems, tire pressure monitoring, etc. These may be considered in recommending a conditional license for a commercial vehicle driver. They are also valuable considerations for any hearing-impaired driver (as noted below). 10.2.4 While hearing loss is not considered to preclude driving a private car, persons with severe hearing losses should be advised regarding their loss and their limited ability to hear warning signals, etc. Persons with hearing aids should be encouraged to wear them when driving. Engineering solutions such as additional mirrors (as mentioned above) might also be recommended upon consideration of the needs of the individual driver.

STANDARD (Vestibular)	Medical Standards for Licensing – Vestibular Function The criteria for an unconditional license are NOT met: • If the person has, or has had in the previous 12 months, any condition of recurrent vertigo. This includes confirmed Meniere's disease, recurrent unheralded vertigo and/or benign paroxysmal positional vertigo, with or without treatment, or any other type of vertigo. 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: • For persons who have had vertigo caused by Meniere's disease, or recurring unheralded attacks of vertigo, after at least 12 months free of vertigo; • For persons who have had one episode of vertigo caused by acute labyrinthitis (deafness and vertigo), acute neurolabyrinthitis (vestibular neuronitis), or any other type of vertigo, after at least 6 months free of vertigo; • For persons who have had BPPV only, after at least 2 months free of symptoms and signs of BPPV. The ENT Specialist is to have regard to: • The nature of the condition and response to treatment; and • The functional ability to operate the vehicle safely.
Additional Guidance	22.1 RELEVANCE TO DRIVING TASK 22.1.1 Driving ability is dependent on the normal functioning of the vestibular mechanism to sense movement and position and may be impaired by defects in balance. Vestibular malfunction can occur suddenly and with sufficient severity to make safe driving of any type of vehicle impossible. It is often accompanied by nystagmus, which compounds the disability in regard to driving. 22.2 GENERAL MANAGEMENT GUIDELINES (including temporary conditions) 22.2.1 Driving ability may be affected by unheralded attacks of vertigo which are associated with many vestibular disorders. Vestibular disorders may vary between symptomatic and asymptomatic with little warning. 22.2.2 Subsequent to an initial attack of vertigo due to acute labyrinthitis (deafness and vertigo), there may be further recurrence of vertigo for up to 12 months. Given that there are no peremptory symptoms, a sudden inability to drive may eventuate. The person should be advised not to drive while symptoms persist. 22.2.3 In cases of acute neurolabyrinthitis (syn. vestibular neuronitis, viral infection of the vestibular nerve) which causes nystagmus and vertigo, recurrence of symptoms can present for many years despite treatment. This makes it quite difficult to isolate a given phase of the condition where symptoms deleterious to an individual's fitness to drive may be present. 22.2.4 In confirmed Meniere's disease vestibular malfunction and nystagmus can occur despite treatment. The natural history is of progression in the affected ear associated with increasing hearing loss until, in the extreme, total loss of vestibular function and partial loss of cochlear function in the affected ear. While sufferers of this condition should not drive commercial vehicles as per the commercial drivers' standards, they may be able to hold a conditional private vehicle driver license. 22.2.5 Benign paroxysmal positional vertigo (BPPV). Generally patients with BPPV will not have symptoms in the upright position such as when driving. In this case they meet the criteria for private vehicle licensing. Patients with BPPV and symptoms in the upright position should not drive while symptoms persist in the upright position. 22.3 MEDICAL STANDARDS FOR LICENSING 22.3.1 Generally, those who suffer from unheralded attacks of vertigo should not drive. Vestibular function should be assessed by using a simple Romberg test, which is also required for neurological function. (A pass requires the ability to maintain balance while standing with shoes off, feet together side by side, eyes closed and arms by sides, for thirty seconds). 22.3.2 The opinion of an otorhinolaryngologist may be sought.

License Classification	The medical guidelines outline two sets of medical standards – private vehicle driver standards and commercial vehicle driver standards Private standards • Drivers applying for or holding a license class C (Car), R (Motorcycle) or LR (Light Rigid) UNLESS the driver is also applying for an authority or is already authorized to use the vehicle for carrying public passengers for hire or reward or for the carriage of bulk dangerous goods or in some jurisdictions for a driver instructor's license. Commercial standards • Drivers of 'heavy vehicles', i.e. those holding or applying for a license of class MR (Medium Rigid), HR (Heavy Rigid), HC (Heavy Combination) or MC (Multiple Combination, refer Table 1). • Drivers applying for an authority/already authorized to carry public passengers for hire or reward (bus drivers, taxi drivers, chauffeurs, drivers of hire cars and small buses etc). • Drivers applying for an authority/already authorized to carry bulk dangerous goods.
Country	Canada, *CCMTA MEDICAL STANDARDS FOR DRIVERS (June 2008)*
Source	http://www.ccmta.ca/english/pdf/medical_standards_june08.pdf
STANDARD (Auditory)	2.0 Hearing No hearing standard for Classes 1, 3, 5 and 6 with the exception of transporters of dangerous goods. Hearing loss no greater than 40 decibels averaged at 500, 1000 and 2000 Hz applies to Class 2 and 4 licenses, operators of emergency vehicles and transporters of dangerous goods.
Additional Guidance	2.1 Recommended Hearing Standards The effect of impaired hearing on driving is difficult to define. However, most hearing-impaired drivers are conscious of their impairment and compensate by being more cautious and alert and by making more use of their mirrors than drivers with normal hearing. (CMA 14) In Classes 5 and 6, hearing loss should not constitute a barrier to driving ability. While the ability to hear or communicate is of paramount importance for the operator of a passenger bus, ambulance or other emergency vehicles (Classes 2 and 4), there are a number of factors which suggest it is inappropriate to apply that same requirement to the operator of a Class 1 or 3 motor vehicle. For example, high inside noise levels in truck cabs militate against hearing standards and may induce further hearing loss should an individual be compelled to use a hearing aid to meet the standard. In addition, in recognition of the prevalence of hearing loss among holders of Class 1 and 3 licenses, manufacturers are now producing virtually soundproof cabs which eliminate outside noise thereby rendering hearing standards irrelevant. Consequently, it is suggested that the holder of a Class 2 or 4 driver license and the operators of emergency vehicles be required to have a hearing loss no more than 40 decibels in the better ear averaged at 500, 1000 and 2000 Hertz. Should the individual require the use of a hearing aid to attain the standard, the license issued should bear a notation such as "valid for Class # only when wearing a hearing aid." While it is agreed that a degree of hearing would be beneficial for all motor vehicle operators, in the absence of empirical data the totally deaf individual who is able to successfully complete the driving tests should be permitted to obtain or hold a Class 1, 3, 5 or 6 driver license. It is recommended that the applicant or holder of a Class 2 or 4 license whose degree of hearing loss is at question be requested to file a report of an audiometric assessment. It is also recommended that individuals who hold a Class 1, 3 or 5 license and are engaged in the transportation of dangerous goods meet the medical requirements corresponding to Classes 2 and 4 as stated above. Operators of emergency vehicles should also meet the hearing standards established for Classes 2 and 4. A special endorsement could be established in order to deal with emergency vehicle operators and transporters of dangerous goods.
STANDARD (Vestibular)	6.5 Vestibular Disorders Individuals with true vertigo should not drive any type of vehicle until the disorder is controlled or has subsided.

Additional Guidance	6.5 Vestibular Disorders Driving ability is affected by any defect of balance and is therefore dependent on the normal functioning of the vestibular mechanism. Individuals with acute vertigo should be advised not to drive any type of vehicle until the condition has subsided or responded to treatment. Persons who are subject to recurrent attacks of vertigo that occur without warning cannot safely operate any type of motor vehicle until it is certain that the attacks of vertigo have been controlled.
License Classification	• Class 1: Permits the operation of a motor vehicle of any type or size, with or without passengers, and a trailer of any size. • Class 2: Permits the operation of a motor vehicle of any type or size, with or without passengers. A Class 2 license does not permit the holder to pull a semi-trailer. • Class 3: Permits the operation of a motor vehicle of any size. A Class 3 license does not permit the holder to carry passengers or to pull a semi-trailer. • Class 4: Permits the operation of a taxicab, a bus carrying no more than 24 passengers and emergency response vehicles, such as ambulances, fire trucks and police cars. • Class 5: Permits the operation of any motor vehicle or small truck (a towed vehicle cannot exceed 4600 kg). A Class 5 license does not permit the holder to drive an ambulance, a taxicab or a bus or to pull a semi-trailer. • Class 6: Permits the operation of a motorcycle, motor scooter or mini-bike only. All other classes must be endorsed to include Class 6 before the holder may operate a motorcycle, motor scooter or mini-bike.
Country	New Zealand, *Medical aspects of fitness to drive. A guide for Medical Practitioners, Land Transport Safety Authority (2009)*
Source	http://www.nzta.govt.nz/resources/medical-aspects/
Standard (Auditory)	7.1 Hearing Impairment *Medical standards for individuals applying for or renewing a class 2, 3, 4 or 5 license:* There is no hearing standard. *Medical standards for individuals applying for or renewing a P, V, I or O endorsement (See license classes below)* Holders of passenger endorsements, vehicle recovery endorsements, testing officer endorsements and driving instructor endorsements sometimes need to be able to have two-way communication with another person without turning their head away from the driving environment. Therefore, these endorsement holders should do one of the following: • Meet the hearing standard of no less than 40dBA in the better ear (for details of testing, see below). • Apply to the Agency, which may allow an endorsement to be issued or renewed if evidence is provided that the endorsement holder will use a method of two-way communication that would not impair their ability to drive safely, e.g. the use of the rear-view mirror upside down and inward facing on the dashboard so that the individual can keep their eyes on the road or the use of a suitable hearing aid. The Agency may impose a license condition to use a method of two-way communication when driving under these endorsements. Testing for 40dBA in better ear P, V, I or O endorsement holders should pass a 'three meter' hearing test or have a threshold greater than 40dBA. This test requires that a person can hear each word spoken in a normal conversational voice at a distance of three meters. Failure of this simple screening test requires formal audiometric hearing tests to be carried out with pure tone air conduction audiometry. Such an assessment should follow the procedures laid down by the Australian National Acoustic Laboratory, where the standard is an average hearing threshold of no less than 40dBA in the better ear, measured across the lower frequencies of 500, 1000, 2000 and 3000 Hz.
Additional Guidance	7. Hearing Impairment Introduction There is very little evidence that even profound hearing loss is associated with an increased risk of road crashes (Booher 1978). Visual information is more important in making judgments and avoiding crashes. General advice

	While there are few standards in this area, medical practitioners may wish to raise the following matters with their patients. Use of hearing aids For new users of hearing aids, the medical practitioner may wish to suggest to their patients that they discuss with an audiologist or hearing therapist the possible weaknesses of using a hearing aid while driving. Use of two side mirrors In New Zealand, it is not compulsory for all vehicles to have two side mirrors. However, for individuals with a hearing impairment, medical practitioners should suggest that they use vehicles with two side mirrors as this would further help them be aware of factors in the road environment, such as emergency vehicles. Two-way communication while driving There is a potential road safety risk where a hearing-impaired individual is distracted from concentrating on the driving environment because they must turn to a passenger in order to hold a two-way conversation. In the United Kingdom, it is common practice for hearing-impaired individuals to put a rear-view mirror upside down and inward facing on the dashboard. This allows an individual to keep their eyes on the road and simultaneously communicate with a passenger without turning their heads.
STANDARD (Vestibular)	2.1 Severe disabling giddiness, vertigo or Meniére's disease *Medical standards for all license classes and/or endorsement types* Where the attacks of giddiness or vertigo are sufficiently disabling that they may impair an individual's ability to drive safely, the individual should be advised not to drive until it has been sufficiently treated.
Additional Guidance	2.0 Neurological and Related Disorders Introduction Neurological conditions or suspected neurological conditions are a major cause of medical-related crashes in New Zealand. From police crash reports, between 2003 and 2007, 533 crashes involved a driver who either had an epileptic seizure (116 crashes) or blacked out (417 crashes). Another 10 crashes were suspected of being caused by a driver who had or was suspected of having a neurological condition. These figures do not estimate the likely numbers of drivers with neurological conditions such as dementia, as these are often reported as an age-related factor. There are likely to be drivers who had a neurological condition that the Police were not aware of. Driving a motor vehicle requires the ability to perform precise, complex actions in response to an environment that is continually changing. Any disease process or substance (such as a medicine or recreational drug) that affects perception, judgment, alertness and responsiveness or the ability to carry out the necessary actions required to control a vehicle will impair an individual's fitness to drive. Individuals with progressive conditions are likely to pose a greater risk unless the condition is closely monitored in relation to the ability to drive a vehicle safely. Static conditions and those that are reversible generally pose less of a problem, and mobility may often be an important consideration for such individuals. The issue in these cases is simply one of an individual's ability to drive safely. In these circumstances, the testing officer may well be a better arbiter of fitness to drive. 2.1 Severe disabling giddiness, vertigo or Meniére's disease Meniere's disease, labyrinthine disorders and brain stem conditions may induce significant distracting giddiness. Where the attacks of giddiness are sufficiently disabling that they may impair an individual's ability to drive safely, the individual should be advised not to drive until their condition has been sufficiently treated. Vertigo occurs for many reasons, most of which are due to inner ear disturbances. The most common form of paroxysmal relatively disabling vertigo is benign paroxysmal positional vertigo, which can occur in relation to head movement. Some individuals may feel sufficiently disabled by their vertigo that they should not drive, while others who have attacks are able to pull over to the side of the road. There is no general prohibition on driving with vertigo except where the attacks of vertigo are sudden, or unpredictable, and are sufficiently disabling that they may impair an individual's ability to drive safely, e.g. where an individual is unable to concentrate on driving because of disabling giddiness. General advice to medical practitioners Where an individual is subject to attacks of disabling giddiness, medical practitioners should discuss with their patients the potential seriousness of their attacks on their driving. For example, individuals who suffer attacks where there are some warning signs should be advised to pull over to the side of the road if this is safe to do so, rather than try to continue driving during the attack.

License Classification

License Class	Motor vehicles covered by the license class	Normal requirement for medical examinations
Class 1	• A vehicle that has a GLW or GCW of 4500kg or less (this includes tractors or combinations of vehicles, but does not include motorcycles) • A moped or all-terrain vehicle • Any campervan or tradeperson's vehicle with a GLW of 6000kg or less and an on-road weight not exceeding 4500kg. • A tractor with a GLW of more than 4500kg but less than 18,001kg if driven at a speed not exceeding 30km/h A tractor/trailer combination of more than 4500kg but not more than 25,000kg if being used in agricultural or land management operations and driven at a speed not exceeding 30km/h.	None
Class 2	• Any rigid vehicle with a GLW of more than 4500kg but less than 18,001kg • Any combination vehicle (that is not a tractor/trailer combination) with a GCW of 12,000kg or less • Any combination vehicle consisting of a rigid vehicle (that is not a tractor) with a GLW of 18,000kg or less towing a light trailer (GLW of 3500kg or less) • Any rigid vehicle with a GLW of more than 18,000kg that has no more than two axles • A tractor with a GLW of more than 4500kg but less than 18,001kg if driven at a speed exceeding 30km/h • Any vehicle covered in class 1.	10-yearly
Class 3	• A combination vehicle with a GCW of more than 12,000kg but less than 25,001kg • Vehicles covered in classes 1 and 2.	10-yearly
Class 4	• A rigid vehicle (including any tractor) with a GLW of more than 18,000kg • A combination vehicle consisting of a rigid vehicle with a GLW of more than 18,000kg towing a light trailer (GLW of 3500kg or less) • Vehicles covered in classes 1 and 2, but not class 3	10-yearly
Class 5	• A combination vehicle with a GCW of more than 25,000kg • Vehicles covered in classes 1, 2, 3 and 4.	10-yearly
Class 6	• Any motorcycle, moped or all-terrain vehicle	None

Differences in examination requirements between private and commercial drivers

Commercial drivers are expected to meet higher safety standards than other motorists. The Land Transport (Driver Licensing) Rule 1999 defines classes of driver license and types of license endorsement (see appendix 3). This Rule also provides the requirements for obtaining and renewing licenses for the various categories of commercial driver, including the requirement to produce a medical certificate applicable to the class of license or type of endorsement.

	Given the potential severity of a crash involving a commercial vehicle, the following commercial type drivers applying for or renewing their license or endorsement must be examined thoroughly: • Classes 2, 3, 4 or 5 • Passenger endorsement (P) • Vehicle recovery endorsement (V) • Driving instructor endorsement (I) • Testing officer endorsement (O). The medical examination requirements for lower (private) license classes or endorsement types are generally less than for commercial drivers. Lower license classes or endorsement types include: • Classes 1 or 6 • The following endorsement types: o Dangerous goods endorsement (D) o Forklift endorsement (F) o Roller endorsement (R) o Tracks endorsement (T) o Wheels endorsement (W)
Country	Sweden *(1998)*
Source	http://www.vv.se/PageFiles/12660/9889eng000915%5b1%5d.pdf?epslanguage=sv
STANDARD (Hearing and Vestibular)	Chapter 3 Hearing and Sense of Balance *Possession* 1. Unexpected attacks of balance disorder or vertigo that could jeopardize traffic safety constitute grounds for denial of possession. 2. Morbus Ménière (Ménière's disease) constitutes grounds for denial of possession in Groups II and III if the disease is clinically active. 3. A hearing impairment or deafness does not constitute grounds for denial of possession in Groups I or II. For possession in Group III, the hearing ability must be such that the holder of the driving license has the faculty of being able to communicate with passengers and other road-users. This requirement is considered to be fulfilled if a normal tone of voice can be understood from a distance of four meters in one ear with or without a hearing aid. Reappraisal 4. In the case of Morbus Ménière or any other progressive disease, a reappraisal shall occur at intervals considered suitable in each individual case.
Additional Guidance	Chapter 15 Physical Examination • The auditory test shall be done in a normal conversational tone of voice or by using a tone audiometer. • The applicant shall be specifically questioned on any history of vertigo with a hearing impairment, Morbus Ménière or other vertiginous disease. Chapter 18 Medical Certificate -*Vertigo with impaired hearing, Morbus Ménière or other serious vertigo disease* • A certificate 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.
License Classification	Group I: Driving license category A, A1, B or BE as well as a tractor license Group II: Driving license category C or CE

	Group III: Driving license category D or DE as well as taxi driver license Possession: Holding a driving license, tractor license or taxi driver license Reappraisal: Reappraisal of possession through the requirement on a medical certificate or other medical statement A: Heavy motorcycle A1: Light motorcycle B: Private car, light lorry and any light trailer, cross-country vehicle or class I power-driven equipment in tow C: Heavy lorry and any light trailer in tow D: Bus E: Trailer, irrespective of number and weight
Country	United Kingdom *(2009)*
Source	http://www.dft.gov.uk/dvla/medical/ataglance.aspx
STANDARD (Auditory)	Chapter 8: Miscellaneous Conditions *Deafness (Profound)* GROUP 2 ENTITLEMENT VOC – LGV/PCV Of paramount importance is the proven ability to be able to communicate in the event of an emergency by speech or by using a device, e.g., a MINICOM. If unable to do so, the license is likely to be refused or revoked.
License Classification	Group 1 includes motor cars and motor cycles. Group 2 includes large lorries (category C) and buses (category D). The medical standards for Group 2 drivers are very much higher than those for Group 1 because of the size and weight of the vehicle. This also reflects the higher risk caused by the length of time the driver may spend at the wheel in the course of his/her occupation. • All drivers who obtained entitlement to Group 1, category B (motor car) before 1 January 1997 have additional entitlement to category C1 and D1. C1 is a medium size lorry of weight between 3.5 and 7.5 tonne. D1 is a minibus of between 9 and 16 seats, not for hire or reward. • Holders of C1 and D1 entitlement retain the entitlement until their license expires or it is medically revoked. On subsequent renewal the higher medical standards applicable to Group 2 will apply. • Under certain circumstances volunteer drivers can drive a minibus of up to 16 seats without having to obtain category D1 entitlement. Individuals should consult DVLA for a detailed fact sheet.
Country	Mexico (2009)
Source	
STANDARD (Auditory)	Pulmonary Standards Reglamento de Tránsito en Carreteras Federales: *Article 59: A person or company shall not permit a driver with the following conditions to operate a federal public service vehicle.* 2: Chronic conditions III. Respiration and Hearing – Nasopharyngeal apparatus: complete or incomplete nasopharynx obstruction. Laryngeal and tracheal apparatuses: chronic diseases; shortness of breath (dyspnea) controlled by breathing tubes (tracheal cannulas); vocal cord paralysis. Hearing: auditory acuity; ringing in the ears; vertigo; balance; involuntary eye movement (nystagmus); auditory tube obstruction; ear infection or inflammation. *Medical-Scientific Profile (Perfil Médico Cientifico)* 5. Respiratory System 5.1 The licensee must demonstrate anatomical and functional integrity of the respiratory passages and the lungs that allow for the safe and efficient performance of the activities

	that the license allows. There must be no evidence of the condition in 5.2. 5.2 Change in licensee's functional ability caused by the respiratory system that is incompatible with the safe and efficient performance of the activities that the license allows.

3.2. Medical Fitness Standards and Guidelines for Individuals Performing Additional Transportation-Related Occupations in the United States

Current relevant medical fitness standards and guidelines for individuals performing transportation related occupations in the United States are summarized in Table 9. Included in the table are pertinent rules and guidance for pilots, railroad workers, and merchant mariners, of which none addresses cochlear implants, although they do allow the use of hearing aids, with qualifications.

Medical fitness-for-duty programs in the transportation industry vary greatly. A pilot's medical fitness is determined by the FAA, which has specific standards (14 CFR 67) and detailed guidance for first-, second-, and third-class airmen. Class 1 medical certificates are required for commercial pilots or airline transport pilots. This class of individuals has the most stringent medical requirements.

Class 2 medical certificates are for commercial, non-airline duties such as crop dusters, charter pilots, and corporate pilots. Class 3 medical certificates are for private pilot activities only. The latter class of individuals has the least restrictive medical requirements. According to FAA regulations only a limited number of trained and designated aviation medical examiners (AMEs) are able to perform these examinations. As shown in Table 9, all three classes are subject to meet auditory medical standards.

All FAA classes' medical guidelines require that there be no disease or condition of the middle or internal ear, nose, oral cavity, pharynx, or larynx that (1) interferes with, or is aggravated by, flying or may reasonably be expected to do so; or (2) Interferes with, or may reasonably be expected to interfere with, clear and effective speech communication; and (c) be manifested by, or that may reasonably be expected to be manifested by, vertigo or a disturbance of equilibrium. Although there is no mention of cochlear implants, under some circumstances, the use of hearing aids may be for individuals who cannot pass the required hearing tests without them. The examination technique guidelines also do not allow the denial of licenses to those with unilateral or bilateral deafness if individuals can pass any of the hearing acuity tests. In addition, FAA references speech perception criteria. Individuals must be able to understand speech as determined by audiometric speech discrimination testing to a score of at least 70 percent in one ear or in a sound field environment.

Railroad fitness for duty regulations are covered by the FRA medical standards. In contrast to other modes of transportation, FRA medical standards are limited in scope (covering only vision and hearing, 49 CFR 240.121). Like the FAA, the hearing standards do not address the use of cochlear implants, however, they do allow the use of hearing aids during hearing tests.

The U.S. Coast Guard (USCG) and MARAD also provide fitness for duty standards and guidance. There are three categories of mariner rating: licensed, qualified, and unqualified or entry level ratings. Licensed includes officers, masters, and mates. This category has the strictest set of licensing requirements. Sailors are in the qualified category and have requirements that are similar to those for a licensed position. The entry level rating is for an individual with no mariner skills. These regulations address vision and hearing requirements (46 CFR 10, 12, and 13). Unlike the FAA and the FRA, Merchant Mariner hearing guidelines require individuals to demonstrate an unaided threshold of 20 decibels or

less in each ear. Although cochlear implants are not mentioned, the guideline makes it difficult for users of cochlear implants and hearing aids to pass the exam.

Table 9: Standards and Guidelines for Sleep Disorders from other U.S. Government Transportation Safety Agencies

Condition	FAA* (all classes of airmen)	Railroad†	Merchant Mariner‡
Hearing	**1. Code of Federal Regulations** **All classes: 14 CFR 67.105(a)(b)(c), 67.205(a)(b)(c), and 67.305(a)(b)(c)** (a) The person shall demonstrate acceptable hearing by at least one of the following tests: (1) 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) Demonstrate an acceptable understanding of speech as determined by audiometric speech discrimination testing to a score of at least 70 percent obtained in one ear or in a sound field environment. (3) Provide acceptable results of 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 (11 West 42nd Street, New York, NY 10036): (b) No disease or condition of the middle or internal ear, nose, oral cavity, pharynx, or larynx that – (1) Interferes with, or is aggravated by, flying or may reasonably be expected to do so; or (2) Interferes with, or may reasonably be expected to interfere with, clear and effective speech communication. (c) No disease or condition manifested by, or that may reasonably be expected to be manifested by, vertigo or a	**§ 240.121 Criteria for vision and hearing acuity data.** (d) Except as provided in paragraph (e) of this section, each person shall have hearing acuity that meets or exceeds the following thresholds when tested by use of an audiometric device (calibrated to American National Standard Specification for Audiometers, S3.6–1969): the person does not have an average hearing loss in the better ear greater than 40 decibels at 500Hz, 1,000 Hz, and 2,000 Hz with or without use of a hearing aid. (e) A person not meeting the thresholds in paragraphs (c) and (d) of this section shall, upon request, be subject to further medical evaluation by a railroad's medical examiner to determine that person's ability to safely operate a locomotive. In accordance with the guidance prescribed in appendix F to this part, a person is entitled to one retest without making any showing and to another retest if the person provides evidence substantiating that circumstances have changed since the last test to the extent that the person could now arguably operate a locomotive or train safely. The railroad shall provide its medical examiner with a copy of this part, including all appendices. If, after consultation with one of the railroad's designated supervisors of locomotive engineers, the medical	46: Shipping MERCHANT MARINER CREDENTIAL § 10.215 Medical and physical requirements. (C) *Hearing test.* If the medical practitioner conducting the general medical exam has concerns that an applicant's ability to hear may impact maritime safety, the examining medical practitioner, if not qualified to conduct the appropriate examinations, must refer the applicant to an audiologist or other hearing specialist to conduct an audiometer test and/or a speech discrimination test, as appropriate. (1) The audiometer test should include testing at the following thresholds: 500 Hz; 1,000 Hz; 2,000 Hz; and 3,000 Hz. The frequency responses for each ear should be averaged to determine the measure of an applicant's hearing ability. Applicants must demonstrate an unaided threshold of 20 decibels or less in each ear. (2) The functional speech discrimination test should be carried out at a level of 55 decibels. For issuance of an original MMC or endorsement the applicant must demonstrate functional speech discrimination of at least 90%. For renewal or raise of grade, the applicant must demonstrate functional speech discrimination of at least 80%. An applicant who is unable to meet the standards of the audiometer test, but who can pass the functional speech discrimination test, may be eligible for a medical waiver in accordance with paragraph (g) of this section. G) *Medical waivers.* Where an

Condition	FAA* (all classes of airmen)	Railroad†	Merchant Mariner‡
	disturbance of equilibrium. **II. Examination Techniques** 2. The ***external ear*** is seldom a major problem in the medical certification of applicants. Otitis externa or a furuncle may call for temporary disqualification. Obstruction of the canal by impacted cerumen or cellular debris may indicate a need for referral to an ENT specialist for examination. The tympanic membranes should be examined for scars or perforations. Discharge or granulation tissue may be the only observable indication of perforation. Middle ear disease may be revealed by retraction, fluid levels, or discoloration. The normal tympanic membrane is movable and pearly gray in color. Mobility should be demonstrated by watching the drum through the otoscope during a valsalva maneuver. 3. Pathology of the ***middle ear*** may be demonstrated by changes in the appearance and mobility of the tympanic membrane. The applicant may only complain of stuffiness of the ears and/or loss of hearing. An upper respiratory infection greatly increases the risk of aerotitis media with pain, deafness, tinnitus, and vertigo due to lessened aeration of the middle ear from Eustachian tube dysfunction. When the applicant is taking medication for an ENT condition, it is important that the Examiner become fully aware of the underlying pathology, present status, and the length of time the medication has been used. If the condition is not a threat to aviation safety, the treatment consists solely of antibiotics, and the antibiotics have been taken over a sufficient period to rule out the likelihood of adverse side effects, the Examiner may make	examiner concludes that, despite not meeting the threshold(s) in paragraphs (c) and (d) of this section, the person has the ability to safely operate a locomotive, the person may be certified as a locomotive engineer and such certification conditioned on any special restrictions the medical examiner determines in writing to be necessary. (f) As a condition of maintaining certification, each certified locomotive engineer shall notify his or her employing railroad's medical department or, if no such department exists, an appropriate railroad official if the person's best correctable vision or hearing has deteriorated to the extent that the person no longer meets one or more of the prescribed vision or hearing standards or requirements of this section. This notification is required prior to any subsequent operation of a locomotive or train which would require a certified locomotive engineer.	applicant does not possess the vision, hearing, or general physical condition necessary, the Coast Guard, after consultation with the examining licensed physician, licensed physician assistant, or licensed nurse practitioner may grant a waiver if extenuating circumstances warrant special consideration. An applicant may submit to the Coast Guard additional correspondence, records, and reports in support of a waiver. In this regard, recommendations from agencies of the Federal Government operating government vessels, as well as owners and operators of private vessels, made on behalf of their employees, will be given full consideration.

Condition	FAA* (all classes of airmen)	Railroad†	Merchant Mariner‡
	the certification decision. The same approach should be taken when considering the significance of prior surgery such as myringotomy, mastoidectomy, or tympanoplasty. Simple perforation without associated symptoms or pathology is not disqualifying. When in doubt, the Examiner should not hesitate to defer issuance and refer the matter to the AMCD. The services of consultant ENT specialists are available to the FAA to help in determining the safety implications of complicated conditions. 4. **Unilateral Deafness**. An applicant with unilateral congenital or acquired deafness should not be denied medical certification if able to pass any of the tests of hearing acuity. 5. **Bilateral Deafness**. It is possible for a totally deaf person to qualify for a private pilot certificate. When such an applicant initially applies for medical certification, if otherwise qualified, the AMCD may issue a combination medical/student pilot certificate with the limitation "Valid for Student Pilot Purposes Only." This will allow the student to practice with an instructor before undergoing a pilot check ride for the private pilot's license. When the applicant is ready to take the check ride, he/she must contact AMCD or the RFS for authorization to take a medical flight test (MFT). Upon successful completion of the MFT, the applicant will be issued a SODA, and an operational restriction will be placed on his/her pilot's license that restricts the pilot from flying into airspace requiring radio communication. 6. **Hearing Aids**. Under some circumstances, the use of hearing aids may be acceptable. If the applicant is unable to pass		

Condition	FAA* (all classes of airmen)	Railroad†	Merchant Mariner‡
	any of the above tests without the use of hearing aids, he or she may be tested using hearing aids. **Item 29.** Some conditions may have several possible causes or exhibit multiple symptomatology. Episodic disorders of dizziness or disequilibrium require careful evaluation and consideration by the FAA. Transient processes, such as those associated with acute labyrinthitis or benign positional vertigo may not disqualify an applicant when fully recovered. (Also see **Item 46**, page 103 for a discussion of syncope and vertigo).		

*Source of information for FAA Regulations and Guidelines:
http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/media/guide.pdf
† Source of information for Federal Railroad Administration Guidelines:
http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title49/49cfr240_main_02.tpl‡
‡ Source of information for Merchant Mariner Guidelines:
http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=98052981cf71e9e8e2b1416486073f1d&rgn=div5&view=text&node=46:1.0.1.2.10&idno=46#46:1.0.1.2.10.2.7.9
http://www.uscg.mil/hq/cg5/NVIC/pdf/2008/NVIC_4-08.pdf

4. Evidence Summary

The primary question of interest to FMCSA is whether or not individuals who receive cochlear implants can safely drive. As described at the outset of this report, a search of the literature revealed that **no scientific literature exists that evaluates driver safety in individuals who have undergone cochlear implantation**. In addition, there is no literature available on the safety of individuals in other safety-sensitive positions following cochlear implantation. Following our search of the literature, a single study (Kos et al., 2008) was identified which addressed professional occupation status following cochlear implantation.[37] In this study, a group of 67 adults were evaluated regarding changes in their professional occupations following cochlear implantation. The results of this study demonstrated that implanted patients had kept their jobs and many of them had developed their professional skills, although patients who were professionally inactive prior to the implantation remained inactive following the surgery. None of the patients included in this study reported being in safety-sensitive occupations.

Because of the lack of data regarding driver safety, or other occupational safety factors following cochlear implantation, we identified a series of additional questions to address this issue indirectly. They are:

1. How effective are cochlear implants, and is auditory function following cochlear implantation restored to a level that would permit safe driving as established by existing Federal standards for hearing?
2. What is the nature of hearing capability following implantation (e.g., sound localization), and are there associated factors that may not be conducive with safe driving?
3. Are there any other factors associated with cochlear implantation that may increase crash risk, such as disrupted vestibular function?

Each of these questions is addressed in turn, in the subsections that follow.

4.1. Key Research Question 1: How effective are cochlear implants, and is auditory function following cochlear implantation restored to a level that would permit safe driving as established by existing Federal standards for hearing?

For this question, we are interested in determining whether hearing following cochlear implantation may permit safe driving as established by FMCSA's current standards for hearing. As discussed earlier in this report, current FMCSA standards for hearing require that a person perceive a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid. Alternatively, if tested by use of an audiometric device, an individual must 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.

It is important to note that "normal hearing" is not restored following the implantation of a cochlear implant. Because of the way in which the cochlear implant system functions (i.e., it detects complex

sounds from the environment and process these sounds into a set of electrical signals that directly stimulate the auditory nerve), most individuals can be expected to hear sounds from the environment following implantation. Rather than simply being able to detect or hear sound, what is generally of most interest following cochlear implantation, is whether or not individuals can understand and decipher those sounds into intelligible information or speech.

Other than anecdotal reports, there is no literature available that directly looks at how individuals with cochlear implants perform using the forced whispered voice test. Most often, the outcomes considered in studies that look at hearing perception following cochlear implantation include measures of sound localization, speech perception, speech production, psychological outcomes, educational outcomes, adverse events, and quality of life. Although not a specific requirement of FMCSA, speech perception is reported in some safety sensitive occupations, such as by the FAA, to be a physical fitness requirement for the job.

4.1.1. Summary of Relevant Literature

Because of the wealth of information on the effectiveness of cochlear implantation available in the literature, we limited our search to systematic reviews. The most recent systematic evidence review examining the effectiveness of cochlear implants was that of Bond and colleagues, 2009[38, 39]. In this review, the effectiveness of cochlear implants for children and adults was considered in three different scenarios:

1. Unilateral cochlear implantation compared to no assistive hearing device;
2. Unilateral cochlear implantation compared to hearing aid; and
3. Bilateral cochlear implants compared with unilateral cochlear implants

This review included only studies assessing individuals implanted with multichannel cochlear implants, employing current strategies for speech processing (i.e., devices that are currently available and FDA-approved). The review included both randomized and non-randomized controlled trials. The authors note that meta-analysis of the data was not possible because of heterogeneity between the included studies. Implant systems from all three manufacturers of cochlear implants were represented in studies included in the systematic review. All studies included were appraised for study quality. Only one of the studies included in the assessment for adults measured sensitivity to sound. Other outcome measures of the included studies were speech perception, speech production, and quality of life. Sound localization was also reported in some of the studies; these results are discussed under Key Research Question 2.

We describe the findings of this review that are pertinent to adults for each of the scenarios they considered.

Unilateral Cochlear Implants versus No Assistive Hearing Device

In the Bond review, four studies[40-43], representing 984 patients, were included in the assessment of unilateral cochlear implantation vs. no technological support (i.e., no hearing aid or other assistive device). Refer to Table 10 for a summary of these studies. The primary outcome considered in these studies was speech perception, which was measured using a variety of outcome measures.

Measurements were taken before implantation and post implantation at various time intervals with participants acting as their own controls.

All studies reported improvements in speech perception measures following cochlear implantation. For instance, in the Parkinson et al., 2002[42] study, 53 of the 56 subjects demonstrated significant improvements for the CUNY sentence test in quiet (p-values all <0.05). Mean scores were 11.0% (SD = 17.8%) correct preoperatively, and 78.0% (SD = 28.6%) correct at the three-month evaluation, representing a 67.0% (SD = 31.5%) difference relative to the group's preoperative mean (t = 15.94, p <0.001). The mean scores for the HINT sentence test were 5.5% (SD = 10.3%) correct preoperatively, and 62.5% (SD = 29.3%) correct at the three-month postoperative evaluation (t = 14.77, p <0.001). CUNY-in-noise (SNR) test significantly increased from 4.2% (SD = 12.6%) to 59.4% (SD = 33.3%) at 3 months (t = 12.9, p <0.001). Thus, when patients were presented with prerecorded CUNY and HINT sentences in both quiet and noisy conditions, at 70 dB, they were able to reliably recite most of the words in the sentences presented to them. There was marked variability in the percent of correct responses between patients, both pre- and postoperatively. However, in all cases, there was significant improvement.

In the 2004 study conducted by Mawman et al.[41], patients were tested pre- and postoperatively with the BKB sentence test and the AB monosyllabic word test. The mean scores for the BKB sentences at the pre-implant stage were 1.3% (range = 0–35%; sd = 4.83), and at the postoperative intervals of 1 week, 32.6% (range = 0–92%; sd = 29.39); 3 months, 59.3% (range = 0–100%; sd = 34.01); 9 months, 59.26% (range = 0–97%; sd = 34.52); and >18 months 65.27% (range = 0–100%; sd = 34.32). The mean scores for the AB monosyllabic words at the pre-implant stage were 4.3% (range = 0–57.8%; sd = 9.36), and at the postoperative intervals of 1 week, 28.56% (range = 0–66%; sd = 18.24); 3 months, 43.99% (range = 0–84%; sd = 23.4); 9 months 46.85% (range = 0–89%; sd = 26.34); and >18 months 54.21% (range = 0–88%; sd = 24.69). Again, a large range in pre-implant function, and post-implant outcomes (0-100%) was observed. On average, however, there was significant improvement in sentence and word recognition following cochlear implantation. The 2004 UK Cochlear Implant Study Group (UKCISG)[40, 44], which also measured BKB sentence recognition, attempted to model what accounts for the post-implant variability, and it found that the duration of pre-implant deafness can explain much of the variability.

The 1997 study by Kessler et al.[43], measured performance both pre- and post-implant for MAC vowels, MAC consonants, CUNY lip-reading, CUNY implant, NU-6 mono words, and telephone sentences. Improvements were observed for all measures in the post-implant period. In particular, recognition of everyday sentences delivered over the telephone showed improvements from 1% pre-implant scores to 63% correct at 12 months post-implant. In this study, Kessler reported that overall speech perception results show two patterns: the best performers attain a plateau at very high levels of performance in a three- to six-month period following cochlear implantation, while the poorer performers either steadily increase in performance, or very gradually improve after six months of device use. All speech perception outcome measures show significant improvement with every user demonstrating some degree of post-operative improvement.

Table 10: Key Characteristics of Studies (Unilateral CI vs. No Assistive Hearing Device)

Reference	Year	Design	Comparison	N (% Male)	Age	Primary Outcome(s) Examined	Evidence of Improvement
Unilateral Cochlear Implantation vs. No Assistive Hearing Device							
UK Cochlear Implant Study Group (UKCISG) [40, 44]	2004	Prospective cohort	Unilateral cochlear implants vs. non-technological support (9 months post CI)	N = 311: TC = 227; MHU = 84	Age (range): 50.6 (16-82) years	Speech perception: BKB sentences, AVGN, CUNY sentences Testing Protocol: Test sentences were presented in sound-field through a single loudspeaker placed in front of the subject in a quiet testing room in the subject's hospital. The average A-weighted RMS level of the sentences at the position occupied by the subject's implant microphone was calibrated to 70 dB (A). Quality of Life: HUI-3, GHSI, GBI	Yes for all outcomes
Mawman et al. [41]	2004	Retrospective pre/post analysis	Unilateral cochlear implants vs. non-technological support (18 months post CI)	N = 214	At implantation, mean (SD): 50.4 (12.8) years	Speech perception: BKB sentences, AB monosyllables Testing protocol not described.	Yes for all outcomes
Parkinson et al. [42]	2002	Pre/post repeated prospective	Unilateral cochlear implants vs. non-technological support (3 months post CI)	N = 216	At implantation, mean (SD): 50.4 (12.8) years	Speech perception: HINT sentences, CUNY, CNC (in quiet and in noise) Testing Protocol: The CD-recorded speech perception tests were administered in a calibrated sound field at 70 dB SPL, with participants seated within the sound field at a constant azimuth (0 degrees) and distance from the transducer. Patients adjusted the hearing aid or speech processor's volume and/or sensitivity control to achieve a comfortable listening level. In the noise conditions, the SNR was 10 dB.	Yes for all outcomes
Kessler et al. [43]	1997	Pre/post repeated measures prospective	Unilateral cochlear implants vs. non-technological support (12 & 24 months post CI)	N = 238	At implantation, mean (range): 51 (18-81) years	Speech perception: MAC vowels, MAC consonants, CUNY lip-reading, CUNY implant, NU-6 mono words, telephone sentences Testing protocol not described.	Yes for all outcomes

Abbreviations:
AB=Arthur Boothroyd monosyllabic word test
AVGN=normalized index of CUNY scores;
BKB=Bamford-Kowal-Bench sentences;
CNC=Consonant Nucleus Consonant monosyllabic word test;
CUNY=City University of Ney York;
GBI=Glasgow Benefit Inventory;
GHSI=Glasgow Health Status Inventory;
HINT=Hearing in noise test;
HUI-3=Health Utilities Index 3;
MAC=Minimal Auditory Capabilities;
MUH=marginal hearing aid users;
NU-6=Northwestern University Auditory Test #6;
TC=traditional candidates

Unilateral Cochlear Implants versus Acoustic Hearing Aids

Four studies, representing 248 patients, were included in the assessment of unilateral cochlear implantation vs. hearing aid use. Refer to Table 11 for a summary of these studies. The primary outcomes considered in these studies included sound localization, speech perception and production, functional performance in real-world environments, quality of life, and adverse events of surgical implantation. Our assessment here focuses on the speech perception and production outcomes. Sound localization is addressed under Key Research Question 2.

All of the studies measured speech perception.[40, 45]-[46] Speech perception was measured using a variety of methods, all showing benefits from cochlear implants. The clearest benefit was indicated by Ching et al.[45]. The results revealed an advantage of 37 points for cochlear implants over acoustic hearing aids in noise with BKB sentences ($p < 0.001$), showing that implanted adults were able to correctly repeat back significantly more sentences than when they used hearing aids alone. This benefit however is reduced in individuals who are deaf prior to learning language.

Benefits in speech perception and production following cochlear implantation were found to be related to the duration of deafness and whether or not individuals were pre- or postlingually implanted, with shorter durations of deafness before implantation and postlingually deafened individuals demonstrating better outcomes. These studies indicate that there may be additional benefits from having cochlear implants over acoustic hearing aids. These benefits become clearer in noisy conditions with greater gain being experienced by adults who are postlingually rather than prelingually deaf.

The benefits of hearing in noise were clearest in the study by Hamzavi et al., 2001.[46] In this study, patients were presented with the Hochmaier, Schultz and Moser (HSM) sentence test. HSM sentences were presented with five different levels of noise: either without noise, or with signal to noise ratios (SNRs) of 15 dB, 10 dB, 5 dB, or 0 dB. Each patient was seated in an audiometric chamber in front of a loudspeaker placed one meter away. The speech level was presented steady at 80 dB hearing level and the noise level was varied between 80 and 65 dB HL (or no noise at all). In their results, HSM test scores of cochlear implant patients ranged between 14 and 100% (mean, 68.35%) without noise, 1 to 99% (mean, 45.6%) for SNR=15 dB, 0 to 71% (mean, 25.6%) for SNR=10 dB, 0 to 18% (mean, 3.8%) for SNR=5 dB, and 0 to 4% (mean, 0.8%) for SNR=0 dB one year after cochlear implantation. Three years following implantation, these scores improved to 84.6% (mean) without noise, 60% (mean) at SNR=15 dB, 45.1% (mean) at SNR=10 dB, 16.7% (mean) at SNR=5 dB, and 4.3% (mean) at SNR=0 dB.

It is also worth noting that the patterns of the results across studies did not change appreciably by the manufacturer of the implant, type of speech processor, or type of electrode array. These results suggest that there were no major differences in outcomes based on the type of implant system that subjects used.[40]

Table 11: Key Characteristics of Studies (Unilateral CI vs. Hearing Aid)

Reference	Year	Design	Comparison	N	Age	Primary Outcome(s) Examined	Evidence of Improvement
Unilateral Cochlear Implantation vs. Hearing Aid							
UKCISG [40]	2004	Prospective cohort	Unilateral implants vs. acoustic hearing aids (9 months post CI)	N = 84	Age, mean (range): 50.6 (16-82) years	Speech perception: BKB sentences, AVGN Testing Protocol: Test sentences were presented in sound-field through a single loudspeaker placed in front of the subject in a quiet testing room in the subject's hospital. The average A-weighted RMS level of the sentences at the position occupied by the subject's implant microphone was calibrated to 70 dB (A). Quality of Life: HUI-3, GHSI, GBI	Yes for all outcomes
Ching et al. [45]	2004	Cross-sectional	Unilateral implants vs. acoustic hearing aids	N = 21	Age, mean (range): 62 (25-84) years	Speech perception: BKB sentences in noise, functional performances in real life questionnaire Testing Protocol: Speech stimuli were presented at 70 dB SPL, measured at the subject position with the subject absent. Eight-talker babble noise was presented at 10 to 15 dB Auditory Questionnaire: To evaluate binaural advantages in real life, the subjects were asked to use each aided condition for a week, and to report on their experience in a structured interview based on a questionnaire at the end of the period.	Yes for all outcomes except sound localization
MED-EL	2001	Pre/post prospective repeated measures	Unilateral implants vs. acoustic hearing aids (6 months post CI)	N = 106 (fitted); efficacy N = 63, safety N = 50	At implantation, mean: 53 years	Speech perception: In quiet and noise HINT sentences, CUNY, CNC words (both pre and postlingually deaf) Speech production: telephone sentences, CID sentences (both pre and postlingually deaf) Quality of Life: questionnaire (both pre and postlingually deaf) Adverse events: device- and medically-related	Yes for all outcomes
Hamzavi et al. [46]	2001	Prospective cohort	Unilateral implants vs. acoustic hearing aids (12 months Post CI)	N = 37	Age, mean (range): 53 (31-76) years	Speech perception: in quiet and noise: HSM sentences, open set Testing Protocol: Speech level was steady at 80 dB HL and the noise level (SNR) was varied between 80 and 65 dB HL, or with no noise at all.	Yes for all outcomes

Abbreviations:
AVGN=normalized index of CUNY scores;
BKB=Bamford-Kowal-Bench sentences;
CID=Central Institute for the Deaf sentences;
CNC=Consonant Nucleus Consonant monosyllabic word test;
CUNY=City University of Ney York;
GBI=Glasgow Benefit Inventory;
GHSI=Glasgow Health Status Inventory;
HINT=Hearing in noise test;
HSM=Hochmaier, Schultz and Moser sentence test
HUI-3=Health Utilities Index 3
SNR=signal to noise ratio
SPL-sound pressure level

Bilateral Cochlear Implants versus Unilateral Cochlear Implants

Four studies, representing 127 patients, were included in the assessment of bilateral versus unilateral cochlear implantation[31, 47-50]. Refer to Table 12 for a summary of these studies. According to Bond et al.,[38] these studies were of good to moderate quality. The primary outcomes considered in these studies included sensitivity to sound and sound localization, speech perception, and quality of life. Sound localization outcomes are addressed in Key Research Question 2.

Speech Perception: Three studies measured speech perception in a total of 103 participants using seven outcome measures. Binaural benefits for speech perception were found to be significant in noisy conditions on all measures. In particular, advantages were shown for the head shadow effect. In particular, bilaterally implanted participants were able to use the head shadow effect when in noise.

The study by Litovsky et al., 2006[48], examined speech understanding in quiet using the CNC and HINT sentence testing. By 6-months postactivation of the cochlear implant, a significant advantage for speech understanding in quiet was found in the bilateral listening mode compared with either unilateral listening modes for both the CNC and HINT tests. Significant binaural gains on all instruments were found (CNC: left ear 40%, right ear 36%, bilaterally 54%, $p < 0.0001$; HINT: left ear 66%, right ear 67%, bilaterally 76%, $p < 0.0001$). For speech understanding in noise using the BKB sentence test, the largest and most robust bilateral benefit was when the subject was able to take advantage of the head shadow effect; i.e., results were significantly better for bilateral listening compared with the unilateral condition when the ear opposite to the side of the noise was added to create the bilateral condition. The mean (SD) head shadow effects were 4.95 dB (3.6) for noise right and 6.34 dB (3.8) for noise left, i.e., a slightly greater effect for noise left. When speech reception thresholds were compared for bilateral implants and either ear unilaterally, there was a significant gain for bilateral versus unilateral implants ($p < 0.0001$). This bilateral benefit was seen on at least one of the two unilateral ear comparisons for nearly all (32/34) subjects tested. Bilateral benefit was also found for a few subjects in spatial configurations that evaluated binaural redundancy and binaural squelch effects. In addition, using data collected from a questionnaire, bilateral users reported their own performance to be better with bilateral cochlear implants than when using a single device.

Ramsden et al., 2005[51], measured speech perception with the CNC and CUNY in quiet and noise in sequentially implanted adults. They found a significant binaural benefit over the first ear alone for speech and noise when presented from the front ($12.6 \pm 5.4\%$, $p < 0.001$) and when noise was ipsilateral to the first ear ($21 \pm 6\%$, $p < 0.001$). No bilateral advantage over the first ear was found in quiet.

Table 12: Key Characteristics of Studies (Bilateral vs Unilateral CI)

Reference	Year	Design	Comparison	N (% Male)	Age	Primary Outcome(s) Examined	Evidence of Improvement
Bilateral Cochlear Implantation vs. Unilateral Cochlear Implantation							
Summerfield et al. [47]	2006	RCT Waiting list control subjects Sequential implants	Bilateral cochlear implants vs. unilateral cochlear implants	N = 24	Age, median (range): 56 (29-82) years Already use one implant	Quality of life, GHSI, HUI-3, VAS quality of life, EQ-5D, tinnitus questionnaire	Yes for all outcomes except the HUI-3, VAS, and EQ-5D
Litovsky et al. [48]	2006	Pre/post prospective Repeated measures Own control Simultaneous implants	Bilateral cochlear implants vs. unilateral cochlear implants	N = 37	Age, median (range): 53.6 (26.6-86.6) years	Speech perception: in quiet: CNC, HINT; in noise: BKB Testing Protocol: Speech stimuli were presented at 65 dB SPL. In the noise conditions, the level of the noise was varied in 3 dB steps at fixed SNRs, beginning at +21 dB SNR (very easy), and descending to 0 or −6 dB SNR (very difficult) Quality of life: APHAB	Yes for all outcomes
Ramsden et al. [49]	2005	RCT Waiting list control Sequential implants	Bilateral cochlear implants vs. unilateral cochlear implants	N = 29	Age, median (range): 57 (29-87) years	Speech perception: in quiet: CUNY, CNC; in noise: CUNY noise front, CUNY noise left, CUNY noise right Adverse events	Yes, but not significant
Laszig et al. [31]	2004	Pre/post prospective Repeated measures Own control Simultaneous = 22 Sequential = 15	Bilateral cochlear implants vs. unilateral cochlear implants	N =37	Age ≥ 18 years Age at bilateral implantation, mean (SD): 46 (11) years Time between sequential implants, mean (SD): 2.2 (1.4) years	Speech perception: in quiet and noise: HSM, OLSA; in quiet: FMWT Testing Protocol: Speech comprehension measures were performed in quiet at 0 degree azimuth and in the presence of background noise simultaneously presented from the same speaker and spatially separated by 90 degrees, at S+45°N45° and at S−45°N+45°. The HSM and OLSA sentences presented at 70 dB SPL. The noise level in noise conditions was set at 65 dB	Yes (borderline in some cases)

Abbreviations:
AVGN=normalized index of CUNY scores;
BKB=Bamford-Kowal-Bench sentences;
CID=Central Institute for the Deaf sentences;
CNC=Consonant Nucleus Consonant monosyllabic word test;
HUI-3=Health Utilities Index 3
CUNY=City University of Ney York;
GBI=Glasgow Benefit Inventory;
GHSI=Glasgow Health Status Inventory;
HINT=Hearing in noise test;
HSM=Hochmaier, Schultz and Moser sentence test

4.1.2. Summary of Evidence for the Effectiveness of Cochlear Implants

None of the included studies (or any other studies available in the literature) examine how individuals with cochlear implants perform using the forced whispered voice test (the most common hearing test employed with prospective CMV drivers during medical examination). The primary outcome assessed in studies that look at hearing perception following cochlear implantation is speech perception. Although not a specific requirement of FMCSA for CMV drivers, adequate speech perception is reported in some safety sensitive occupations, such as by the FAA, to be a physical fitness requirement for job safety.

Summary of Evidence for Speech Perception

When cochlear implants are compared with non-technological support, the evidence indicates that cochlear implants lead to improvements in the ability to understand speech and quality of life. This is moderately associated with age at implantation and more strongly associated with duration of deafness before implantation. These gains appear to be greater in noisy conditions, especially amongst people who are postlingually deaf. This review also found that functional hearing and quality of life appear to be improved.

In addition, these studies show that bilateral cochlear implantation increases the ability to hear more clearly in noisy conditions and understand speech, and may improve quality of life when compared with unilateral cochlear implantation. This binaural benefit is a term that is used to describe the benefit seen in both normal hearing individuals and individuals with hearing aids who have access to information from both ears. Utilizing both ears can also provide separation of the acoustic signal inputs from a noise source within the environment.

As noted above, however, there was wide variation between patients in the degree of improvement. This is likely related to the variations between studies with factors such as type of speech tests employed, use of or absence of noise and with varying signal-to-noise ratios. However, speech perception generally improved following implantation of one or two cochlear implants. In almost all cases, patients prior to implantation were unable to hear and/or recognize verbal speech. Following implantation, most subjects could understand both words and sentences presented in formal testing conditions, and were much better at holding conversations in social, real-world conditions (e.g., with background noise present).

Another relevant auditory factor of interest to commercial driver safety is sound localization which is discussed in the next section

4.2. Key Research Question 2: What is the nature of hearing capability following implantation (e.g., sound localization), and are there associated factors that may not be conducive with safe driving?

For this question, we are interested in examining key aspects of hearing capability following cochlear implantation. In particular, we examined studies that looked at sound localization outcomes. Reports in

the literature suggest that a unilateral hearing individual may experience a compromised ability to localize sound sources within the environment.

The ability to localize sounds is important as it allows individuals to hear where sounds are coming from, as well as to focus on speech in noisy situations and tune into the softer sounds of their environment. For driving purposes, the ability to localize sound means individuals can use their eyes and ears to know which direction a car is coming from. It also provides individuals the ability to tune in immediately to whoever is speaking so they do not miss the first vital seconds of communication.

Sounds are localized primarily according to which ear receives the higher-intensity signal (interaural intensity difference [IID]) or earlier stimulation (interaural time difference [ITD]). That is, if a sound is located to one side of the head, the sound reaching the further ear is delayed in time and is lower in intensity relative to the sound reaching the nearer ear.

Interaural intensity difference effects predominate at higher frequencies and are minimal at low frequencies. This is a result of low-frequency sounds having a long wavelength when compared with the size of the head, and therefore the sound diffracts well around the head. High-frequency sounds, on the other hand, have a shorter wavelength when compared with the size of the head, and therefore only slight diffraction can occur. The short wavelength of the high frequencies causes the head shadow effect, discussed previously in this report, which causes the intensity of the signal at the far ear to be less than that at the near ear. For interaural time differences, the effects of frequency are different. At high frequencies, ITD tends to give ambiguous phase cues and hence the usefulness of ITD cues is limited to low frequencies. Therefore, lower frequencies are localized on the basis of time differences, while intensity differences are responsible for localization of high frequencies due to the head shadow effect.

For recipients of unilateral cochlear implants, the localization of sound is compromised because of their inability to make use of IID and/or ITD, which requires binaural hearing. Limited research has been carried out on the localization abilities of unilateral cochlear implant recipients, although a few have been conducted comparing bilateral implants or bimodal cochlear recipients to unilateral cochlear implants.

4.2.1. Summary of Relevant Literature

We have identified five studies[31, 45, 47, 50, 52] and one systematic evidence review[53] to address the question of sound localization, with cochlear implantation. The systematic evidence review summarizes data from 29 studies (most with an N<10 patients) that highlight the findings of sound localization in bilateral cochlear implant recipients compared to unilateral cochlear implant recipients. Three studies included in this review (with $N \geq 20$ patients) examine sound localization with bilateral cochlear implants compared with unilateral cochlear implantation. Also included in this section is an additional study by Buhagiar et al., 2004, which assesses localization ability in unilateral cochlear implant recipients. We identified only one study, Ching et al., 2004, that assesses the localization ability of bimodal cochlear implants recipients compared with unilateral implantation and/or hearing aid alone.

Sound Localization with Unilateral Cochlear Implants (Alone or Bimodal)

In this subsection we discuss findings for unilateral cochlear implantation. Refer to Table 13 for a summary of the characteristics of these studies. In the first study, Buhagiar et al., 2004,[50] examined sound localization in 18 individuals with unilateral cochlear implants. All localization tests were performed in an anechoic chamber in order to have a controlled acoustic environment. The subject was seated in the center of a semicircular horizontal array of 11 loudspeakers spaced at intervals of 18 degrees. Seven sound stimuli were generated under computer control for presentation via the main loudspeakers at an SPL of 60 dB (±5 dB). The stimuli chosen for this study are representative of real life, since they contained different temporal structure, frequency content, and duration. The stimulus was presented 33 times in each run, three times from each loudspeaker. The order of the 33 presentations was randomized. During presentation of the repeated speech token, subjects were allowed to move their heads to help locate the sound source. Results for each test run comprised 33 data pairs: the azimuth (or angular position) of the loudspeaker from which the stimulus was delivered and the azimuth chosen by the subject. The absolute value of the difference between these two angles was calculated for each data pair and then the mean absolute difference was calculated across the 33 data pairs. The study concluded that unilateral cochlear implant users have poor localization ability and that they perform better from the front than from the side. However, it was determined that there is small influence of head movement, which improves performance slightly and might explain why patients report that they perform better in real life than in experimental conditions such as those used in Buhagiar study.

In the second study reviewed, Ching et al., 2004, investigated the localization ability of adults using bimodal cochlear implants compared to their use of their cochlear implant alone, or their hearing aid alone (i.e., single mode condition). This study found that under bimodal conditions, users derive binaural hearing benefits, including improved horizontal sound localization relative to the single mode condition. Ching assessed 21 adults implanted with a Nucleus 22 or Nucleus 24 cochlear implant system. Twelve of the adults were experienced hearing aid and implant users, whereas nine did not use a hearing aid immediately after implantation.

To evaluate binaural advantages in localization, a horizontal array of 11 loudspeakers spaced 18 degrees apart (180 degrees arc) was used. The array was situated in an anechoic chamber with internal dimensions of 6 meters times 3.9 meters times 4.5 meters, and all loudspeakers were closely matched using software-controlled digital filters. The subject was seated directly facing the center of the array at a distance of about 1 meter. A test run consisted of one presentation of a 0.83 seconds pulsed pink noise signal from each of the 11 loudspeakers in random order. The nominal presentation level was 70 dB SPL, with actual levels varied randomly around the nominal level by plus or minus 3 dB.

During the tests, subjects were instructed to maintain the designated position while awaiting each presentation, but were free to move their heads as soon as the sound began. The subjects were given one practice run, and six test runs for each aided condition (bimodal and the two single mode conditions). After each stimulus, the subject made a judgment about the loudspeaker (designated by a number) from which the sound originated. The subjects did not know that there was only one stimulus from each loudspeaker within each run, and all test runs were administered continuously with no breaks between runs.

Performance error was scored as the horizontal distance in terms of number of loudspeakers between the actual source and the perceived source. For each listener, an average root mean square (RMS) error for each aided condition was calculated by taking the square root of the squared deviation across runs. Mean RMS errors for each aided condition were calculated across all listeners and all runs. Eighteen adults completed testing; three could not be tested due to equipment constraints.

Analyses of variance with listening experience (experienced bimodal user vs. new bimodal user) as an independent factor and device condition (bimodal vs. cochlear implant vs. hearing aid) as a dependent variable indicated that the main effect of device was significant ($p < 0.001$). There was no significant difference in binaural benefits obtained by the experienced bimodal users compared with the new bimodal users ($p > 0.05$). On average, the errors for bimodal condition were significantly less than those for the cochlear implant condition ($p < 0.003$) or hearing aid alone condition ($p < 0.001$). Twelve of the 18 subjects made significantly less errors when listening binaurally than monaurally.

Table 13: Key Characteristics of Studies (Unilateral Cochlear Implantation)

Reference	Year	Design	Comparison	N	Age	Primary Outcome(s) Examined	Evidence of Improvement
Buhagiar et al. [52]	2004	Prospective Cohort	Unilateral cochlear implant: Localization ability for different stimuli	N = 18	Adults (age range not specified)	Localization ability: Loudspeaker tests Test Protocol: 11 loudspeakers spaced 18° apart (over a 180° arc) was used. The subject was seated directly facing the centre of the array, at a distance of about 1meter. A 0.83 sec pulsed pink noise signal from each of the 11 loudspeakers in random order. The nominal presentation level was 70 dB SPL, with actual levels varied randomly around the nominal level by plus or minus 5 dB.	No
Unilateral Cochlear Implantation vs.Bimodal Stimulation							
Ching et al. [45]	2004	Cross-sectional	Bimodal vs. unilateral implants or. acoustic hearing aid	N = 21	Age, mean (range): 62 (25-84) years	Auditory: direction of sound Test Protocol: To evaluate binaural advantages in localization, a horizontal array of 11 loudspeakers spaced 18° apart (over a 180° arc) was used. All loudspeakers were closely matched using software-controlled digital filters. The subject was seated directly facing the centre of the array, at a distance of about 1meter. A 0.83 sec pulsed pink noise signal from each of the 11 loudspeakers in random order. The nominal presentation level was 70 dB SPL, with actual levels varied randomly around the nominal level by plus or minus 3 dB.	Yes, in the bimodal condition versus unilateral CI or hearing aid.

Abbreviations:
dB= decibel
CI=cochlear implant
SPL-sound pressure level

Sound Localization with Bilateral Cochlear Implants

We identified one systematic evidence review, which summarized data from studies assessing the benefits of binaural hearing in bilateral cochlear implants recipients. Murphy et al., 2007[53] conducted a detailed search of the medical literature using the Medline, Embase, and CINAHL databases and assessed the quality of each of the included studies.

A total of 37 studies were included; 28 (76%) investigated adult participants only, seven (19 percent) investigated child participants, and two (5%) contained both groups. Most of the included studies had small patient counts of 10 or less. The studies reporting on sound localization abilities showed bilateral implants confer up to a 30 degrees improvement in localization acuity over unilateral use, with the best performing bilateral implant participant achieving an accuracy of 4.4 degrees in sound-source discrimination, which approximates normal hearing performance (1.7 degrees).

The studies presented in Table 14 reflect relevant studies from this review which looked at sound localization following bilateral implantation and included N $\geq$ 20 patients. The primary outcomes considered in these studies included sensitivity to sound and sound localization, among other measures not described further here.

Three studies examine sensitivity to sounds and/or localization in individuals with bilateral cochlear implants compared with unilateral cochlear implantation.

Summerfield et al., 2006, an RCT[47], measured self-reported spatial hearing, qualities of hearing, and hearing for speech using the Speech Hearing, Spatial Hearing, and Qualities of Hearing questionnaires (SSQ) in 24 adults who either had sequentially received a second cochlear implant or were waiting for one. They found that there was a significant benefit for spatial hearing at three and nine months post implantation compared with preimplantation in individuals receiving bilateral cochlear implants when compared with individuals who used only one cochlear implant. In addition, pooling of the group results showed significant binaural gains for quality of hearing and hearing for speech. For all three questionnaire results, improvements were seen at three months, with further improvements observed at nine months.

Verschuur et al., 2005[50], examined sound localization in 20 individuals with either unilateral or sequential bilateral implants. Sound localization was assessed in an anechoic room with an 11-loudspeaker array under four test conditions: right cochlear implant, left cochlear implant, binaural cochlear implants, and dual microphone. Two runs were undertaken for each of five stimuli (speech, tones, noise, transients, and reverberant speech). Order of conditions was counterbalanced across subjects. Mean localization error with bilateral implants was 24 degrees compared with 67 degrees for monaural implant and dual microphone conditions (chance performance is 65 degrees). Normal controls average 2 to 3 degrees in similar conditions. Binaural performance was significantly better than monaural performance for all subjects, for all stimulus types, and for different sound sources. Only small differences in performance with different stimuli were observed. The study reported that bilaterally aided participants made significantly fewer errors in sound direction detection than unilateral patients.

Laszig et al., 2004, an RCT[50], examined sound localization in 37 individuals with simultaneous or sequential bilateral cochlear implants. Repeated single measures were carried out for each subject, with each subject serving as their own control. Tests of localization were performed in the horizontal plane with 12 speaker locations 30 degrees apart using a shortened sentence stimulus from the Hochmair-Schulz-Moser sentences at two possible presentation levels of 55 and 70 dB sound pressure level for assessment of directionality. The binaural advantage provided by bilateral stimulation was calculated with respect to each ear separately, classified as either the better or poorer performing ear for each speech material in quiet and in noise test conditions. For localization of sound, the binaural advantage was compared with left and right ears separately. Paired comparisons for performance data in all conditions were carried out by considering measurements for each subject in different conditions as paired observations and applying the Student's *t* test to determine the statistical difference between the data sets. The results showed that binaural stimulation led to a significant improvement in localization ability over either monaural condition, with the RMS degrees of error reduced by 38 degrees compared with that observed for unilateral stimulation. The study concluded that bilateral electrical stimulation provides the foundation for the potential advantages of the head shadow effect, providing a binaural head shadow benefit and binaural auditory processing such as binaural redundancy and binaural squelch effects, all of which combine to lead to improved localization ability and speech comprehension over unilateral listening.

Table 14: Key Characteristics of Studies (Bilateral vs Unilateral CI)

Reference	Year	Design	Comparison	N (% Male)	Age	Primary Outcome(s) Examined	Evidence of Improvement
Bilateral Cochlear Implantation vs. Unilateral Cochlear Implantation							
Laszig et al.[31]	2004	Pre/post prospective Repeated measures Own control Simultaneous = 22 Sequential = 15	Bilateral cochlear implant vs. unilateral cochlear implants	N = 37	Age at bilateral implantation for all subjects: 46 (18-67)	Localization ability: HSM sentences	Yes
Summerfield et al. [47]	2006	RCT Waiting list control subjects Sequential implants	Bilateral cochlear implants vs. unilateral cochlear implants	N = 24	Age, median (range): 56 (29-82) years Already use one implant	Auditory: SSQ questionnaire	Yes
Verschuur et al. [50]	2005	Cross-section (from larger RCT) Own control Sequential implants	Bilateral cochlear implants vs. unilateral cochlear implants	N = 20	Age at first implant, mean (SD): 58.9 (12.67) years Time between implants, mean (SD): 37.0 (14.40) months	Auditory: detection of sound direction	Yes

Abbreviations:
HSM=Hochmaier, Schultz and Moser sentence test
SSQ=Speech Hearing, Spatial Hearing, and Qualities of Hearing questionnaire

4.2.2. Summary of Evidence for Localization

Monaural cochlear implant recipients have poor localization ability. Performance is close to chance. Studies assessing bilateral cochlear implants and/or bimodal stimulation all demonstrated, to varying degrees, that localization ability was materially improved compared to unilateral cochlear implant recipients or those using a hearing aid in the contralateral ear.

The head shadow effect appears to be the most robust and obvious advantage for the majority of bilateral cochlear implant users. In real-world situations, most individuals who receive bilateral cochlear implants will be more successful in locating, turning toward, and attending to sound more readily when binaurally stimulated, and detecting signals in noise, compared to unilateral cochlear implant users.

4.3. Key Research Question 3: Are there any other factors associated with cochlear implantation which may increase this crash risk, such as disrupted vestibular function.

As described in the previous sections, cochlear implantation is widely accepted as an effective rehabilitation option for severely to profoundly hearing-impaired individual and is effective in improving speech perception, and when combined with a hearing aid and/or used bilaterally, improving sound localization skills. However, cochlear implantation may result in other outcomes that can have a deleterious impact on driver safety. One of the most commonly studied adverse effects known to be associated with cochlear implantation is new onset vestibular dysfunction (e.g., arising as a result of the cochlear implantation procedure).

The human vestibular system is the sensory organ responsible for maintaining balance, posture, and the body's orientation in space. This system also regulates locomotion and other movements and keeps objects in visual focus as the body moves. The vestibular system works with other body systems, such as the visual system, the auditory system, and the skeletal-muscular system to check and maintain position of the body at rest or in motion. Problems with any of these associated systems can result in vestibular disorders such as vertigo or dizziness.

In addition, the vestibular system is intricately associated anatomically with the auditory system (refer back to Figure 1). The vestibular system is comprised of the vestibular apparatus (i.e., the saccule, utricle, and semicircular canals) which are closely situated next to the inner ear structures. In addition, nerves deriving from the vestibular system feed into the vestibule-cochlear nerve. The vestibular and auditory nerves join in the auditory canal and become the eighth cranial nerve of the brain. Thus, disruptions of the auditory system can also affect vestibular function.

4.3.1. Summary of Relevant Literature

We were unable to identify any systematic reviews that addressed the issue of vestibular dysfunction following cochlear implantation. We did however, identify 11 individual studies that addressed this issue (refer to Table 15 for a list of included studies). The results of these studies are described in this section.

Table 15: Included Studies - Cochlear Implantation and Vestibular Dysfunction

Author	Year	Study Design	Country	Study Objectives
Bonucci et al. [54]	2008	Prospective cohort	Brazil	Analyze vestibular function in the pre- and postoperative periods for CI individuals.
Brey et al. [55]	1995	Prospective cohort	United States	Determine vestibular risks posed by cochlear implantation.
Buchman et al. [56]	2004	Prospective observational study	United States	To understand the risks of vestibular dysfunction as a result of CI, especially in light of bilateral CIs.
Enticott et al. [57]	2006	Prospective observational study	Australia	To document incidences of vestibular dysfunction after CI and investigate why it occurs.
Filipo et al. [58]	2006	Retrospective case review, prospective observational study	Italy	Assess vestibular impairment and symptoms in a homogenous group of patients receiving CIs.
Fina et al. [59]	2003	Case-control embedded in cohort	United States	Determine the prevalence, symptom characteristics, and potential risk factors for vestibular symptoms after CI.
Huygen et al. [60]	1995	Prospective cohort	Holland	Assess the risk of vestibular function loss after CI.
Ito et al. [61]	1998	Prospective cohort	Japan	Assess the influence of the multichannel CI on vestibular function.
Krause et al. [62][10]	2009	Prospective cohort	Germany	Assess the incidence of vestibular disturbance in patients after CI and evaluate the quality of vertigo symptoms.
Melvin et al.[63]	2009	Prospective cohort	United States	Determine the risk posed by CI to the labyrinth.
Steenerson et al. [64]	2001	Retrospective Case Review	United States	Determine the incidence of vertigo after CI and describe appropriate intervention.

Abbreviations: CI= Cochlear implant or cochlear implantation

As shown in Table 16, 11 studies measured vestibular function both pre- and postoperatively in 697 patients undergoing cochlear implantation. The measures consisted of subjective measures of vestibular dysfunction using questionnaires (e.g., Dizziness Handicap Inventory (DHI), and the Activities-specific Balance Confidence (ABC) scale) and/or quantitative measures using a variety of vestibulo-ocular tests (e.g., eye-tracking tests; optokinetic nystagmus; post-headshake nystagmus; peak slow phase eye velocity) and other vestibular tests (e.g., harmonic acceleration test; caloric electronystagmography; rotational chair test; vestibular-evoked myogenic potentials; vestibule-ocular reflex; and the vestibular velocity step test).

Table 16: Characteristics of Studies Examining Vestibular Function with Cochlear Implantation

Author	Year	N enrolled	N completed	Age Mean (range)	Unilateral or Bi- CI?	Testing intervals following implantation	Vestibular Testing / Outcome Measures
Bonucci et al. [54]	2008	38	38	30.65±16. 32 yrs (4-62)	Multichannel unilateral CI	Testing before and after surgery (CI interval not stated)	Vestibular function was evaluated using: ENG, self-reported dizziness interviews
Brey et al. [55]	1995	22	22	56.5 yrs (17-77)	Unilateral	Testing before and after surgery (post CI interval ranged from 1.5 to 59 mo)	Vestibular function was evaluated using: ENG, PSPEV, CDP, HAC
Buchman et al. [56]	2004	86	86	<18 years: 22 or 26% (2-16)	Unilateral, bilateral	Preoperative and 1 mo, 4 mo, 1 year and 2 year postoperative checkups	Vestibular function was evaluated using: VOR, ENG, SHA, CDP, DHI

Author	Year	N enrolled	N completed	Age Mean (range)	Unilateral or Bi- CI?	Testing intervals following implantation	Vestibular Testing / Outcome Measures
				≥18 years: 64 or 74% (18-87)			
Enticott et al. [57]	2006	146	146	60 (20-90)	Multichannel Unilateral (144) and (2) Bilateral	Testing before surgery; post CI assessments between 10 and 39 weeks (mean, 28 wks).	Vestibular function was evaluated using: Self-report vestibular disturbances lasting 1 wk or longer, DHI and ABC; ENG, electrode position radiographs
Filipo et al. [58]	2006	93	93	Prospective:41 (18-79) Retrospective: 51 (17-51)	Prospective: (20) Unilateral and (1) bilateral Retrospective : NA	Before and after CI surgery. Post surgery: 5 wks and 30, 60, 90 days after CI activation	Vestibular function was evaluated using: ENG
Fina et al. [59]	2003	75	75	57 (20-86)	Multichannel Unilateral (69) and Bilateral (6) CIs	Testing before and after CI surgery. Postoperative assessments: 24 hrs, 1 wk, 2 wk, 4 wk, 3 mo, 6 mo, 12 mo, yearly thereafter, and as needed by patient. 1 mo postoperative, daily visits for 3 consecutive days. Minimum duration of follow-up for this study was five months.	Vestibular function was evaluated using: ENG, passive headshake, CDA, rotational VOR, eye movement recordings.
Huygen et al. [60]	1995	60 (30 Men 30 women)	60	(5-68)	Unilateral	Testing before and after surgery. (Post CI interval not quoted)	Vestibular function was evaluated using: ENG and VVST
Ito et al. [61]	1998	55	55	No details provided but all patients were 18+	Unilateral	Testing before and after surgery (post CI 1-6 months)	Vestibular function was evaluated using Romberg or Mann test, OKN, ETT, caloric stimulation
Krause et al. [62, 65]	2008, 2009	47 (15 men 32 women)	47	54 yrs (16-83)	Multichannel Unilateral CI	Preoperative: 1 to 9 mo before surgery Postoperative: 1 week, 4 weeks, 3 months and six months after CI	Preoperative: Self-reported level of dizziness using questionnaire designed especially for this study; ENG, video-oculography (spontaneous nystagmus, RCT, HAC). Postoperative: Self-reported level of dizziness using questionnaire designed especially for this study; visual analogue scale to rate the intensity of subjective impairment.

Author	Year	N enrolled	N completed	Age Mean (range)	Unilateral or Bi- CI?	Testing intervals following implantation	Vestibular Testing / Outcome Measures
Melvin et al.[63]	2009	35 (36 ears)	28 (ears)	46 yrs (23-69)	Unilateral (30) 4 Bilateral (4)	Testing before surgery, and 4 and 8 weeks post surgery	Vestibular function was assessed using: qHIT (all 28 ears) and cHIT, HSN, ENG, VEMP, and DVA (17 ears) Self-reported level of dizziness using DHI (all 26 individuals)
Steenerson et al. [64]	2001	47 (15 men 32 women)	47	50.3 yrs (22-85)	Multichannel Unilateral CI	Testing before and after surgery	Standardized balance assessment of sensory organization using a static force plate Self-reported level of dizziness using questionnaire

Abbreviations: ABC=Activities-specific Balance Confidence scale; AD= autosomal dominant; AR=autosomal recessive; BVH=bilateral hypofunction; BPPV=benign paroxysmal positional vertigo; CI= cochlear implant or implantation; cHIT=clinical head impulse test; DHI=Dizziness Handicap Inventory; DVA=dynamic visual acuity; ETT=eye-tracking test; HAC= harmonic acceleration test; HSN=post-headshake nystagmus; ENG=caloric electronystagmography; OKN= optokinetic nystagmus; PSPEV=peak slow phase eye velocity; qHIT=quantitative 3D head; RCT=rotational chair test; SNHL=sensorineural hearing loss; SP= side preponderance; SPAV=slow phase angular velocity UVH=unilateral hypofunction; UW=unilateral weakness; VEMP=vestibular-evoked myogenic potentials; VOR= vestibule-ocular reflex; VVST: vestibular velocity step test;

Results of Vestibular Dysfunction Studies

Pre-implantation Vestibular Dysfunction. As noted at the start of this section, hearing loss is often associated with vestibular dysfunction. Therefore, studies aimed at evaluating the effect of cochlear implantation on vestibular function have to characterize the degree and nature of vestibular function in patients prior to receiving cochlear implants. Krause et al. (2008)[65] conducted a study to determine the frequency and characteristics of preoperative vertigo symptoms in patients preparing to undergo cochlear implantation. In this study, 47 cochlear implant candidates (both male and female, between the ages of 16 and 83 years) underwent a series of vestibular function tests. The causes of deafness in this group of individuals included sudden sensorineural hearing loss, hereditary factors, toxic or drug-induced loss, traumatic injury, meningitis, and unknown causes. Of these 47 patients, 25 (53%) reported vertigo or balance problems before cochlear implantation was performed that consisted of rotary or to-and-fro vertigo.

Buchman et al., 2004[56], used the standardized DHI questionnaire and found reports of serious vertigo in only 4 percent of the 78 cochlear implant patients interviewed before the operation. Thirteen (17%) other patients in this sample reported a mild vertigo with a frequency of 12 times per year or less. Enticott et al., 2006[57], also used the DHI questionnaire along with the ABC scale to assess vertigo symptoms before and after cochlear implantation in 146 patients. The authors stated that before cochlear implantation most patients had few or no balance disturbances. Filipo et al., 2006[58], reported a prevalence of vertigo of 26% in 72 patients pre-implantation, as determined by a retrospective study using a questionnaire. Fina et al., 2003[59], described a prevalence of 29% in 76 patients. More recently, Bonucci et al., 2008[54], reported 58% of patients experiencing pre-operative vestibular dysfunction.

Post-implantation Vestibular Dysfunction. The detailed results of these studies are presented in Table 17. Bonucci et al.,[54] reported that while vestibular symptoms were present at a high frequency prior

to surgery, following surgery 17% of the patients reported improvements in vestibular symptoms, and only 3% of the 31 patients reported worsening. The remaining noticed no change from pre-CI levels. Brey et al.[55] reported that individuals under 60 years of age did not seem to have persistent vestibular complaints following cochlear implantation, and, in general, did not require vestibular rehabilitation. Consistent with this finding, Buchman et al.,[56] reported that unilateral cochlear implant recipients rarely rarely reported adverse effects on the vestibular system as measured by the DHI, ENG, SHA and CDA. And in fact, for the group as a whole, patients who underwent cochlear implantation experienced significant improvements in the objective measures of postural stability.

Enticott et al.,[57] reported that overall, about one-third of implant recipients experienced significant vestibular disturbance lasting 1 week or longer after surgery. They further noted that recipients aged 70 years and older had significantly greater incidences of permanent vestibular damage after implant surgery. They argued that their results suggested that the older ear may be more prone to permanent injury as a result of cochlear implant surgery. Filipo et al.,[58] found that in the immediate postoperative period, vestibular impairment was displayed as true rotational vertigo in 21.4% and unsteadiness in 42.8% of the study group. Severe unsteadiness was present during the first 2 days after activation in 14.3% of the subjects. However, all of these returned to preoperative levels within a short period following surgery.

Fina et al.,[59] reported a postoperative prevalence of dizzy in 39% of patients. This dizziness was mild to moderate in 76%, severe in 7%, and incapacitating in 7% of the patients reporting dizziness. Fina et al found that probability of experiencing vestibular symptoms after cochlear implantation was higher in the following individuals:

- Preimplantation vestibular symptoms, especially Meniere's disease
- Age at implantation greater than 59 years
- Age at onset of hearing loss greater than 26 years old

Krause et al.,[62] observed that vertigo was a common complication after cochlear implantation. The noted that themost common cause seems to be direct damage to the peripheral vestibular organ during electrode insertion. Symptoms mostly occur only transiently and lead to only mild to moderate subjective impairment (seen in two-thirds of the study patients).

According to Ito et al.,[61] reports of subjective dizziness sensations were made by 47% of post-cochlear implant patients. Fifteen of 26 (58%) patients experienced symptoms early; nine (34%) had prolonged symptoms; and two (8%) experienced delayed symptoms.

In the study by Steenerson et al.,[64] while imbalance was found to be common preoperatively in cochlear implant patients, positional vertigo was a common sequela postoperatively. However, patients with vertigo were found to respond well to vestibular therapy. Long-term intermittent vertigo or imbalance was rare in this study after vestibular therapy intervention, and all patients returned to their preoperative activities.

Despite the conflicting conclusions, all studies reported the need for patients to be informed of the possibility and likelihood of postoperative vertigo symptoms.

Table 17: Summary of Primary Results of Reviewed Studies

Author	Year	Summary of Results	Conclusion	Evidence of Vestibular Disturbance?	Return to Normal?
Bonucci et al. [54]	2008	Preoperative Self Report: Dizziness 55%, positional vertigo 36%, non-positional vertigo 9% ENG (implanted ear): Normal 34%, altered 66%, inconclusive 0% ENG (non-implanted ear): Normal 40%, altered 55%, inconclusive 5% Postoperative Self Report: Dizziness: 61%, positional, vertigo 28%, non-positional vertigo 11% ENG (implanted ear): Normal 16%, altered 81%, inconclusive: 3% ENG (non-implanted ear): Normal 24%, altered 76%, inconclusive 0%	Vestibular symptoms were reported at a high frequency prior to surgery (58% for 31 patients). Following surgery 17% of the patients reported improvements in vestibular symptoms, and only 3% of the 31 patients reported worsening. The remaining noticed no change from pre-CI levels. There was evidence of worsening of vestibular function as measured using ENG. There was an observed mismatch between reported vestibular dysfunction and objectively measured ENG. CI surgery also resulted in dysfunction as measured using the ENG in the non-implanted ear.	Yes	Not evaluated
Brey et al. [55]	1995	Preoperative Positional testing with eyes closed: < 60 years: 1 of 10 (10%) had positional nystagmus. ≥ 60 years: 9 of 12 (75%) had positional nystagmus. Two of 22 (11%) with preoperative positional nystagmus improved postoperatively. PSPEV testing: 5 of 22 (23%) demonstrated bilateral vestibular weakness. (These subjects were not included in the caloric portion of the study) Postoperative Positional testing with eyes closed: N=22 < 60 years: 3 of 10 (30%) had positional nystagmus. ≥ 60 years: 8 of 12 (67%) had positional nystagmus. PSPEV testing: N=17 < 60 years: 3 of 7 (43%) had peripheral vestibular weakness ≥ 60 years: 4 of 10 (40%) showed peripheral weakness. Three (30%) were normal. All candidates: Seven of 17 (41%) demonstrated onset of peripheral vestibular weakness (inter-ear difference ≥ 20%) in	Preoperative evaluation to determine the candidacy of CI should include a vestibular evaluation. The benefits of pre- and postoperative tests, such as the ENG, CDP and HAC, could affect compensation ability if disruption does occur during implantation. The literature indicates that the risk of losing peripheral function is about 60%. Among patients in the present study, the risk of inducing a peripheral weakness in the implanted ear was 41% if preoperative vestibular function was normal. In the under 60 age group, patients did not seem to have persistent vestibular complaints, and, in general, did not require vestibular rehabilitation. Caloric stimulation was not significantly different when comparing pre- and postoperative responses. In the over 60 age group, there was a significant drop in the caloric response of the implanted ear. This could be related to patients continuing to have persistent balance symptoms that may require vestibular rehabilitation. CI candidates should be informed of the possibility of postoperative vestibular effects.	Yes	Not evaluated

Author	Year	Summary of Results	Conclusion	Evidence of Vestibular Disturbance?	Return to Normal?
		implant ear postoperatively. Two (12%) produced borderline (19% inter-ear difference) peripheral weakness. Eight (47%) remained normal. Pre- and post-operative mean differences PSPEV: Preoperative mean was 57° per second, and postoperative mean was 30.47° per second. The drop in mean output was significant (p = .0100) < 60 years: Five of 7 (71%) had reduction in caloric response in implant ear, and 2 (29%) had an increase. Mean values were 35° per second preoperatively and 23.71° postoperatively. Mean difference was not significant (p = .2163). ≥ 60 years: 8 of 10 (80%) had reduced caloric output in implant ear, and 2 (20%) had demonstrated an increase. The means were 72.4° per second preoperatively and 35.2° per second postoperatively. Reduction in output was significant (p = .0238) Posturography: Showed little change in overall balance for both age groups. < 60 years: Four of 9 (44%) were normal before and after CI. Three (33%) exhibited vestibular deficit before and after CI. One (11%) displayed onset of vestibular deficit after CI. One (11%) had vestibular deficit before CI improved after surgery. ≥ 60 years: Seven of 10 (70%) were normal before and after CI, 2 (20%) had vestibular deficit before and after CI, and 1 (10%) improved after surgery.			
Buchman et al. [56]	2004	Preoperative Prevalence of self-perceived dizziness (N=78): 3 (4%) had total DHI scores higher (mean ± 2 SD) than a group of patients that were continuously affected by dizziness. Physical, emotional, and functional category scores were with continuous dizziness in 3 (4%), 3 (4%), and 3 (4%), respectively. Note: Most patients preparing to undergo CI in the present study were either minimally or not significantly affected by dizziness. VOR, ENG (N=47): mean response for implanted ears was 31 ± 21°, mean response for unimplanted ears was 29 ± 25°.	Unilateral CI rarely results in significant adverse effects on the vestibular system as measured by the DHI, ENG, SHA and CDA. On the contrary, for the group as a whole, patients who underwent CI experienced significant improvements in the objective measures of postural stability as measured by CDP. Moreover, device activation in music appeared to have an additional positive effect on postural stability during CDP testing. Although VOR testing demonstrated some decreases in response, it was unable to identify those patients that would suffer disabling vestibular effects after CI.	Yes	Only 1 patient had substantial reduction in balance.

Author	Year	Summary of Results	Conclusion	Evidence of Vestibular Disturbance?	Return to Normal?
		11 (23%) implanted ears and 15 (32%) unimplanted ears had total caloric responses of ±15° (hypo or areflexic). 5 (11%) of 7 patients with a single vestibular reactive ear underwent CI in their only vestibular functioning ear. 15 (68%) of 22 children had preoperative total caloric responses in the implanted ear of 15° or less. The children with total caloric responses greater than 16° were all older than 5 years of age at the time of CI. SHA (N=81): In general, mean values were in line with the manufacturer's normal values. Categorical analysis suggested one-third had low frequency phase lead or low gain values. CDP (N=82): Postural control was substantially below normal for the group as a whole. Composite scores were below published normal values for 52 (61%), 46 (54%), and 48 (56%) patients, respectively. Postoperative Note: N changed at testing/assessment intervals DHI: No significant changes in physical or functional subcategories scores at any of the evaluation periods. Significant decreases (less handicap) in emotional subcategory at both 4-mo (p = .046) and 1 yr (p = .037). At 4 mo, there was only one with a large increase (worsening) in total score, and there were no major outliners for worsening at 1 yr. VOR ENG: Pair-wise changes revealed no significant mean changes in total caloric responses for implanted and unimplanted ear over study period. In most patients, caloric response in implanted ear were accompanied by similar changes in unimplanted ear. In only 1 patient did the implanted ear decrease by 21° or more, whereas the unimplanted ear increased in responsiveness. SHA: Pair-wise comparisons revealed no significant changes in phase, gain, or symmetry value at any of the testing intervals except symmetry at the 0.01 Hz was higher at 1 yr (p = 0.04), phase at 0.02 Hz was borderline higher at 1 yr (p = .055) and gain at 0.02 Hz was lower at 1 yr (p = .001). CDP: Substantial increases (improvements) in scores were observed across nearly all testing intervals with the device			

Author	Year	Summary of Results	Conclusion	Evidence of Vestibular Disturbance?	Return to Normal?
		"off" and "on." Some patients that routinely fell were able to maintain stability at 1 yr after CI. Only 1 patient had substantial reduction in balance.			
Enticott et al. [57]	2006	Preoperative Prevalence of vestibular disturbance (N=146): 47 (32%) Prevalence of bilaterally weak caloric responses (N=146): 21 (14%) Etiology (N=47): 21 (45%) unknown cause; 9 (19%) ostoclerosis; and 4 (9%) familial hearing impairment. Postoperative Prevalence of significant vestibular differences from pre-op cases (N=21): 7 (33%) Combined results DHI and ABC (N=46): Changes in scores after surgery for each individual were then examined, and 46 subjects had completed questionnaires both before and after surgery. Those subjects reporting a postoperative vestibular disturbance showed significantly poorer changes in DHI and ABC scores after surgery compared with subjects reporting no vestibular symptoms ($p = 0.05$). Caloric results (N=86): Nonsymptomatic subjects had a nonsignificant change in the UW median from 4 to 10 after surgery (nonsignificant Mann-Whitney result). However, the symptomatic subjects had their median UW values change from 3 to 26 after surgery, showing significantly poorer responsiveness on the implanted side after surgery (as confirmed by the Mann-Whitney U test). There were 63 subjects in the younger group (mean, 53 yr) and 23 subjects in the older group (mean, 78 yr) having paired caloric data. Before surgery, the UW medians were 3 and 3.5 for the younger and older groups, respectively, which were not significantly different. Total loss of caloric responses on the implanted side after surgery was observed in two (3%) younger subjects and five (22%) older subjects. W2 test showed a significantly greater proportion of older patients had total loss of caloric responses on the implanted side compared with younger subjects ($p = 0.05$).	Patient age, cause, and preoperative caloric result were unable to predict who would experience a vestibular disturbance after CI in this study. Overall, about one-third of implant recipients experienced significant vestibular disturbance lasting 1 week or longer after surgery. Recipients aged 70 years and older had significantly greater incidences of permanent vestibular damage after implant surgery as demonstrated by the caloric results, and this was not related to the position of the intracochlear electrode or operating surgeon. These results suggested that the older ear is more prone to permanent injury as a result of cochlear implant surgery, and an additional study into this is planned. Further study into the susceptibilities of other inner ear suborgans and the actual cause of trauma from implant surgery is necessary to reduce the occurrences. This topic is becoming increasingly relevant because more people with surviving sensory inner ear function, including hearing, are now considered for the cochlear implant.	Yes	Not evaluated
Filipo et al. [58]	2006	Prospective group, preoperative	In 14.3% of the prospective study group, a grade I and II	Yes	CI activation was

Author	Year	Summary of Results	Conclusion	Evidence of Vestibular Disturbance?	Return to Normal?
		Caloric testing (N=14): 3 (21%) presented with eardrum perforation; 4 (29%) showed complete areflexia; Average SPAV for entire group was equal to 16.44º SP Values (> 20% considered significant), 6 (?) showed preoperative normality, 3 showed prevalence of the side chosen for implantation and 5 of the nonimplant ear. Prospective group, postoperative Caloric testing (N=15): A mean reduction to 7.51º was observed; in 13 (86%), the SPAV on implanted side was reduced after CI; in 1 (7%), the SPAV remained unchanged; in 1 (7%), the SPAV increased. After activation, the mean SPAV values went to 7.58º, decreasing in 6 (40%), increasing in 8 (53%), and remaining unchanged in 1 (7%). After 1 mo post activation, values went back to pre-activation figures in those patients whom a post-activation excitatory effect was found, while they shifted only slightly in others (mean distribution = 6.45º). SP values > 20% considered as significant (N=8): 3 (38%) maintained preoperative normality; 1 (12%) who received bilateral implantation showed right hyporeflexia; 2 (25%), showed hyporeflexia on the implanted side. Among the five with prevalence on the side opposite to implantation, 2 (25%) remained unchanged, 2 (25%) showed increased prevalence, while 1 (12%) returned to normal. Retrospective group, preoperative Prevalence of self-report vestibular impairment (N=72): 19 (26%) Retrospective group, postoperative Prevalence of self-report vestibular impairment (N=72): 25 (35%) reported subjective episodes of vertigo [10 of the 25 (40%) continued to have symptoms until activation]; 15 (21%) had true rotational vertigo; 30 (42.8%) displayed unsteadiness; 1 (1%) reported accentuation of vertigo; 6 (8%) reported first vertigo episode.	spontaneous nystagmus was evidenced pre-operatively and remained unchanged during the whole assessment period. A grade II spontaneous nystagmus was present in 3 patients (21.4%) of the same group after surgery. In the immediate postoperative period, vestibular impairment was displayed as true rotational vertigo in 21.4% and unsteadiness in 42.8% of the study group. Severe unsteadiness was present during the first 2 days after activation in 14.3% of the subjects. In 21.4% of the patients a VPPB episode occurred. In the retrospective study group, 26.4% of the subjects referred pre-operative dizziness and 25 patients (34.7%) referred immediate post-operative vertigo episodes, which remained in a milder form after CI activation in 12% of them. The hearing threshold showed to deteriorate in both vestibular-impaired and control CI population without significant difference.		shown to significantly affect 8 patients, all of whom returned to preoperative levels.
Fina et al. [59]	2003	Preoperative Prevalence of vestibular symptoms (N=75): 22 (29%) Type of symptoms described (N=22): 10 (45%) imbalance; 9 (41%) lightheadedness; 2 (9%) vertigo; 1 (3%) not reported.	CDP seemed to have a predictive value in determining who might become dizzy postoperatively. Subjects with the following preoperative characteristics have a higher probability of experiencing vestibular symptoms after CI:	Yes	Yes A continuous sensation of imbalance after a

Author	Year	Summary of Results	Conclusion	Evidence of Vestibular Disturbance?	Return to Normal?
		All three patients with the diagnoses of Meniere's Diseasee qualified their dizziness as lightheadedness, whereas the 2 patients with perception of vertigo had diagnoses of syphilis and idiopathic sudden hearing loss. Postoperative Prevalence of dizzy subjects (N=75): 29 (39%) Characteristics of dizziness (N=29): 22 (76%) mild or moderate dizziness; 2 (7%) severe; 2 (7%) incapacitating; 3 (10%) not documented. Onset of dizziness (N=29): 4 (14%) experienced dizziness immediately (0-24 hrs after surgery); 25 (86%) delayed dizziness; Mean (SD) time of delayed onset was 74 days, and in the inquartile range (25 to 75 percentile) was 26 to 377 days; 24 (83%) experienced spontaneous dizziness; 4 (14%) experienced positional dizziness; and 1 (3%) received symptoms with CI activation. Combined results Preoperative vestibular symptoms: Detected in 13/29 (45%) postoperative dizzy patients and 9/46 (20%) of subjects not dizzy after surgery. (p = 0.0357) CDP (N=16): 4/46 not dizzy postoperatively and 12/29 dizzy after implementation. (p = 0.0027, X^2 = 14.13, df =3) Age at implantation: 63 (57-69) years was the mean age of postoperative dizziness. 53 (48-59) years was the mean age of those not becoming dizzy postoperatively. (p = 0.025, t = 2.288, df = 73) Age at onset of hearing loss: 31 (22-39) was the mean age of those becoming dizzy postoperatively. 20 years (14-26) was the mean age of those not becoming dizzy postoperatively. (p= 0.0369, t = 2.127, df = 71)	• Preimplantation vestibular symptoms, especially Meniere's disease • Age at implantation greater than 59 years • Age at onset of hearing loss greater than 26 years old • Preimplantation abnormal CDP		delayed episode of dizziness was described by 2 patients.
Huygen et al. [60]	1995	Preoperative Vestibular symptoms (N=60): 0 had gaze-evoked or spontaneous nystagmus; 2 (3%) had smooth pursuit and OKN responses; 38 (63%) had vestibular areflexia. Postoperative Vestibular dysfunction (N=13): 3 (23%) developed a vestibular deficit following surgery; 1 (8%) did not experience any appreciable symptoms; 8 (62%) had classical symptoms of	Study results indicate there is a 31% risk of damage to the basilar membrane following CI surgery, somewhat lower than the 50% to 60% mentioned in previous reports. Patients should be advised of this risk before surgery, to help avoid vestibular areflexia. The selection of candidates for this study offered an indication as to what can be expected to happen in vestibular function in relation to aetiology in similar cases.	Yes	3 patients had a vestibular deficit. 2 had unilateral vestibular deficit. 8 had complete preservation of vestibular function.

Author	Year	Summary of Results	Conclusion	Evidence of Vestibular Disturbance?	Return to Normal?
		unilateral vestibular deficits.	• Bilateral areflexia is to be found in Usher's type 1 syndrome, and it generally occurs in patients with bilateral deafness following meningitis or head trauma. • AD syndrome of progressive SNHL that starts in early childhood at high frequencies is generally associated with normal vestibular function, and presumably, this applies to AR progressive SNHL with childhood onset. • Vestibular function post-CI is unknown in those with acquired bilateral SNHL, congenital AD SNHL, congenital AR severe SNHL and ostosclerosis.		
Ito et al. [61]	1998	Preoperative OKN (N=55): 47 (85%) patients normal; 8 (15%) abnormal (ataxic or saccadic pattern). ETT (N=55): 45 (82%) normal; 10 (18%) abnormal (ataxic or saccadic pattern). Caloric stimulation (N=55): 18 (33%) bilateral normal function; 3 (5%) unilateral hypofunction; 16 (29%) bilateral hypofunction; 18 (33%) bilateral afunction. Postoperative Subjective dizziness sensations: (N=55): 26 (47%) had symptoms; 15 of 26 (58%) experienced symptoms early; 9 (34%) had prolonged symptoms; and 2 (8%) experienced delayed symptoms. Relationship between dizziness and ES from the CI device (N=11): 2 (18%) dizziness during use; 9 (82%) no symptoms. .	In this study, the change of the vestibular function judged by the caloric stimulation test before and after surgery and the relationship between the sensation of dizziness and electrical current spread from the implant device were investigated. The causes of each of the types of dizziness revealed were estimated. The preoperative OKN test and ETT revealed that more than 80% of the patients showed normal function. It was surprising that more than one-third of the patients showed normal function in the caloric stimulation test, even though most of these patients were almost deaf. As has been previously reported, the cochlear function and vestibular function are not always correlated with each other. Among the 24 patients whose vestibular functions were normal or showed a degree of hypofunction, 9 (38%) had a deterioration in function after the surgery. In other words, 15 (63%) of these 24 patients showed no deterioration in function even though the destructive procedure of making a hole in the cochlea was performed. This result indicates that such a destructive procedure to the inner ear as the CI did not greatly affect to the vestibular function, or that vestibular function was very rapidly compensated. In several previous reports of caloric stimulation test results before and after cochlear implant surgery, 20% to 50% of the patients showed deterioration in vestibular function after surgery. The criteria used to define an abnormal level of the caloric stimulation test were somewhat different between institutions; however, this study's findings showed that only 38% of the patients had functional	Yes	57.7% of patients showed vestibular dysfunction early after CI was performed. This type of dizziness was thought to be caused by surgical trauma and was easily recovered within 2 weeks. 9 (34%) patients experienced prolonged symptoms 1 mo after CI and 2 (22%) needed medication. 2 (8%) experienced delayed symptoms 1 mo after CI, and 1 (11%) needed medication. Patients with the prolonged or delayed type felt dizziness when the implanted device was in use. Their dizziness was clearly caused by the electrical current

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			decreases.		spread from the implanted device to the vestibular nerve.
Krause et al. [62]	2008, 2009	Preoperative Prevalence (N=47): 25 (57%) reported vertigo problems before CI was performed. Length of symptoms: 157 mo (range, 2 mo. to 312 mo.) 8 of 25 (32%) could not make precise statements about time of onset of symptoms. About one-third also reported symptoms as being irregular. Two-thirds could identify a trigger, e.g. rapid head movement, darkness or loud noise. Prodromal symptoms were reported by 7 (58%). Type of symptoms: Majority of patients described vertigo symptoms as rotary or to-and-fro vertigo. • Elevator sensation: Not reported • Aural symptoms (aural pressure, hearing loss, tinnitus): 5 (20%) • Nuchal pain: 1 (4%) • Presyncopal symptoms: 1 (4%) • Accompanying symptoms (tinnitus, headache, vegetative symptoms): 15 (60%) Degree of disturbance caused by vertigo: 4.8 (moderate), rated on a visual analog scale; each degree was represented at least once. Vestibular function tests (N=47): 45 patients were measured/ • ENG and video-oculography: Horizontal spontaneous nystagmus: 16 of 45 (36%) • Rotating chair test: 24 (53%) normal; 18 (45%) had directional preponderance of more than 20%; 2 (4%) horizontal canal function loss; • ENG: 27 (60%) side difference of more than 20%; 4 (9%) bilateral loss of caloric response. Postoperative Prevalence: 21 of 47 patients (45%) developed vestibular disturbances after CI. Time of onset: More than half of the 21 affected patients (n =	Preoperative A considerable number of deaf patients with an indication for CI already have vertigo symptoms. To understand why CI patients develop postoperative vertigo, the preoperative and postoperative findings should be analyzed thoroughly. Postoperative Vertigo is a common complication after CI. The most common cause seems to be direct damage to the peripheral vestibular organ during electrode insertion. Symptoms mostly occur only transiently and lead to only mild to moderate subjective impairment (seen in two-thirds of the study patients). Patients should be informed of the possibility and quality of post-operative vertigo symptoms. Exposing CI patients to the risk of possible balance disorders is justified in view of the hearing rehabilitation achieved, even with the current, broader indications for CI.	Yes	Only one patient was seriously disabled, suffering from continuous vertigo.

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		11) experienced vertigo symptoms directly after surgery. In almost one-third, the symptoms started between day one and week one after CI. Quality of vertigo: Vertigo was described as rotary by 9 (43%) patients and as to-and- fro by 12 (57%). Light-headness and unsteadiness was described by almost one-third. Elevator sensation was not described. Frequency and duration: The frequency of vertigo attacks was described by most patients (76%) as episodic, with 10 (48%) reporting sporadic and 5 (24%) reporting by day, and 1 (5%) reporting weekly. Nearly half the patients reported the attacks lasted several minutes. In 4 (19%), the attacks lasted several seconds and in 2 (10%), they lasted several hours. One patient (5%) reported a vertigo episode lasting several days. Two (10%) said their vertigo symptoms are continuous. Triggering factors and prodromal signs: A triggering factor for the vertigo was reported by 12 (57%) patients. Age, sex, cause of deafness and pre-operative horizontal semicircular canal function do not seem to have a significant influence. Concomitant symptoms: More than two-thirds of the patients (71%) reported concomitant symptoms. A common symptom was tinnitus, occurring in more than one-third (38%). Origin of Vertigo: Individual questionnaire analysis suggested a possible or probable otogenic origin in 90% of the symptomatic patients.			

Author	Year	Summary of Results	Conclusion	Evidence of Vestibular Disturbance?	Return to Normal?
Melvin et al.[63]	2009	Preoperative qHIT N=35: 9 (26%) mild-to-moderate UVH; 7 (20%) mild-to-moderate BVH; 3 (8.6%) severe-to-profound UVH; 1 (2.9%) severe-to-profound BVH. cHIT (N=14): 0 tested HSN (N=19): 1 (5.3%) tested ENG (N=20): 6 (30%) abnormal VEMP (N=19): 7 (37%) tested DVA passive (N=18): 0 tested DVA-passive (N=15): 0 declined DVA active (N=17): 3 (18%) were abnormal DHI: 26 reported variable levels of dizziness Postoperative qHIT (N=28): 1 (4%) showed a decline from pre-CI score. cHIT (N=10): 0 tested HSN (N=11): 0 tested ENG (N=16): 1 (6.3%) tested abnormal VEMP (N=15): 5 (31%) worsened DVA-active (N=15): 2 ears tested were abnormal DHI (N=26): 3 (12%) reported worsening of perceived dizziness; 4 (15%) reported improvements in dizziness	Of 28 ears that underwent qHIT both before and after implantation, only 1 ear (3.6%) suffered new onset profound loss for all vestibular function as measured at 4 and 8 weeks post-CI, but this individual gradually regained the ability to walk and resumed driving 10 days after surgery. The 1/28 observed incidence of severe injury on qHIT in this study implies an estimated risk of 3.6±6.9% (95% confidence interval assuming a binomial distribution). The data suggest with 95% confidence that the true risk of high frequency vestibular injury due to CI is <10.5%. No meaningful changes were observed for HSN, DVA or DHI. The test with the highest rate of apparent new onset postoperative vestibular hypofunction was the VEMP, which showed evidence of saccular injury in 31% of post CI ears.	Yes	One subject who had severe BHP had not returned to postoperative levels 6 yrs after CI.
Steenerson et al. [64]	2001	Preoperative Prevalence (N=45): 19 (42%) reported dizziness or demonstrated imbalance; 22 (49%) had abnormal sensory organization. Pre-operative findings were primarily imbalance sensations Postoperative Prevalence (N=45): 35 (74%) demonstrated vertigo or imbalance; 32 (71%) demonstrated abnormal sensory organization. Post-operative findings were more movement related vertigo and primarily positional vertigo. Positional Vertigo (N=35): 23 (49%) demonstrated benign positional vertigo with positive Dix-Hallpike responses	In this study, imbalance was found to be common preoperatively in CI patients in this study. Positional vertigo was a common sequela postoperatively in multichannel CI patients; its origin was in the implanted ear in every patient. Vertigo after multichannel CI responded well to vestibular therapy. Long-term intermittent vertigo or imbalance was rare in this study after vestibular therapy intervention. All patients returned to their preoperative activities.	Yes	All 47 patients returned to their pre-implant occupations and activities, although 8% experienced prolonged symptoms of vertigo. Average number of visits for symptom resolution was 3 over 37 wks.

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		measured by infrared video goggles. The origin of this vertigo was from the implanted ear in all 23; New symptoms of vertigo or imbalance appeared in 12 (34%) after CI. Follow-up survey (N=-47): 32 (68%) returned questionnaires; 12 (38%) reported no symptoms of vertigo; 10 (31%) reported occasional symptoms; 10 and (31%) reported symptoms in specific situations (dealing with uneven surfaces, when tires or acting with fast movements).			

Abbreviations: ABC=Activities-specific Balance Confidence scale; AD= autosomal dominant; AR=autosomal recessive; BVH=bilateral hypofunction; BPPV=benign paroxysmal positional vertigo; CI= cochlear implant or implantation; cHIT=clinical head impulse test; DHI=Dizziness Handicap Inventory; DVA=dynamic visual acuity; ETT=eye-tracking test; HAC= harmonic acceleration test; HSN=post-headshake nystagmus; ENG=caloric electronystagmography; OKN= optokinetic nystagmus; PSPEV=peak slow phase eye velocity; qHIT=quantitative 3D head; RCT=rotational chair test; SNHL=sensorineural hearing loss; SP= side preponderance; SPAV=slow phase angular velocity UVH=unilateral hypofunction; UW=unilateral weakness; VEMP=vestibular-evoked myogenic potentials; VOR= vestibule-ocular reflex; VVST: vestibular velocity step test;

4.3.2. Summary of Evidence for Vestibular Dysfunction

According to the studies highlighted above, vestibular impairment is a common condition among those who have hearing loss (prior to cochlear implantation; range 26% to 58%). Cochlear implantation may also result in temporary vestibular disruption (range 29% to 76% patients). However, the number of those who receive cochlear implantation and suffer from severe vestibular symptoms long-term is relatively low. Only one study (Krause, 2009) reported that a patient suffered from severe, continuous dizziness, causing disability. Other studies reported severe dizziness or vertigo in subjects following cochlear implantation, but most patients recovered with some with the vestibular rehabilitation.

The studies conflicted on whether preoperative characteristics help determine whether vestibular impairment can be predicted. For those studies that found preoperative characteristics make a difference, the following factors were cited as predictors of vestibular symptoms post implantation:

- Those with Meniere's disease,
- Age at implantation ranging from >59 to >70
- Age at onset of hearing loss greater than 26 years old

Despite the conflicting conclusions, all studies reported the need for patients to be informed of the possibility and likelihood of postoperative vertigo symptoms.

4.4. Conclusions

Cochlear implantation improves hearing performance and speech perception, although not to the degree of people with normal hearing; the degree of improvement varies for each recipient, depending on factors such as the duration of deafness, whether or not the individual was pre- or post-lingually deaf, and age at implantation.

Bilateral cochlear implantation is an advantage to unilateral cochlear implantation for the purpose of speech perception in noise, and with sound localization tasks. Although most individuals have a unilateral cochlear implant, there is a trend to outfit more patients with two cochlear implants or with one cochlear implant and a hearing aid in the contralateral ear.

Although a number of hearing-impaired individuals suffer from vestibular symptoms prior to implantation, between 20% and 76% of cochlear implant recipients will suffer from vestibular impairment following cochlear implantation. These individuals however, are usually assisted with vestibular rehabilitation.

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