



Vision and Commercial Motor Vehicle Driver Safety

Volume 1: Evidence Report

Presented to

The Federal Motor Carrier Safety Administration

June 6, 2008

Prepared for



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

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Executive Summary

Purpose of Evidence Report

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

The purpose of this evidence report is to address several key questions posed by the Federal Motor Carrier Safety Administration (FMCSA) that pertain to vision and commercial motor vehicle (CMV) driver safety. Each of these key questions was developed by the FMCSA in such a way that the answers will be useful in updating its current medical examination guidelines. The five key questions addressed in this evidence report are as follows:

Key Question 1: Is monocular vision associated with an increased crash risk?

Key Question 2: Do red-green color deficiencies (either protan or deutan) increase crash risk?

Key Question 3: Is visual field (VF) loss associated with an increase in crash risk? And, if affirmative, what is the acceptable VF range in the horizontal and vertical meridians?

Key Question 4: Do cataracts increase crash risk? And, if affirmative, does cataract surgery reduce this risk?

Key Question 5: Is diplopia associated with increased crash risk?

Identification of Evidence Bases

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

A total of seven electronic databases (MEDLINE, PubMed (pre MEDLINE), EMBASE, PsycINFO, CINAHL, TRIS, the Cochrane Library) were searched (through December 3, 2007). In addition, we examined the reference lists of all obtained articles with the aim of identifying relevant articles not identified by our electronic searches. Hand searches of the “gray literature” were also performed. Admission of an article into an evidence base was determined by formal retrieval and inclusion criteria that were determined *a priori*.

Grading the Strength of Evidence

Our assessment of the quality of the evidence took into account not only the quality of the individual studies that compose the evidence base for each key question; we also considered the interplay between the quality, quantity, robustness, and consistency of the overall body of evidence.

Analytic Methods

Quantitative analysis based on pooling of results from different studies (i.e., meta-analysis) was found to be inappropriate for the evidence bases in this report. Consequently, we performed qualitative analyses of the available evidence. In certain instances, we independently calculated effect sizes based on data reported in individual studies.

Presentation of Findings

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

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

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

Evidence-Based Conclusions

Key Question 1: Is monocular vision associated with an increased crash risk?

Due to methodological limitations and inconsistency among the findings of different studies, the available evidence is insufficient to determine whether individuals with monocular vision are at

increased risk of a crash at this time. The possibility that individuals with monocular vision have an increased crash risk cannot be ruled out.

Direct Evidence – Crash Studies: Our searches identified one study that examined whether monocular CMV drivers are at an increased risk for a crash. This was a large study of all drivers with a CMV license in California. Due to methodological flaws, the quality of this study is low. The authors performed analysis of covariance with adjustment for age to compare the mean crashes/driver among three comparison groups based on visual acuity (normal, moderately impaired, and severely impaired) over a two-year period. Severely impaired meant that the drivers had monocular vision. The Dunn-Bonferroni procedure for pairwise comparisons found that monocular drivers had a significantly greater ($p < 0.05$) mean crash rate than unimpaired drivers for both Class 1 and Class 2 licenses (analyzed separately). However, when only drivers with commercial license plates were analyzed, monocular drivers did not have a significantly greater mean crash rate than unimpaired drivers. A major limitation of this analysis is the restriction of monocular drivers to intrastate driving, while unimpaired drivers were allowed to drive out of state. While there is some evidence that this restriction was not well enforced, it nevertheless creates a potential bias because out-of-state crashes are not recorded by the state of California. Thus, the mean crash rate for unimpaired CMV drivers may be underestimated in this study.

Three studies provided crash data for monocular drivers in general driver populations. Because of a number of methodological flaws, our confidence in the findings of all three of these studies is low. While two included studies found no evidence to support the contention that individuals with monocular vision are at an increased risk for a motor vehicle crash, the third study did find an association between monocular vision and increased crash risk.

Given the low quality of the included studies and the fact that the findings of these studies are inconsistent, we do not draw an evidence-based conclusion at this time.

Indirect Evidence – Driving Simulator Studies: Our searches identified a single study that indirectly assessed crash risk among individuals with monocular vision by evaluating safe driving performance among CMV cohorts of drivers with monocular vision and binocular vision. This low-quality cohort study concluded that individuals with monocular vision experienced a number of visual deficits, including decreased contrast sensitivity, problems with binocular depth perception, and decreased visual acuity in low light and glare situations. They also experienced deficits in driving functions related to these visual problems, most specifically in those functions related to binocular vision such as daytime and nighttime sign reading at a distance. There were no significant differences between monocular and binocular vision drivers in visual tests assessing static acuity, dynamic acuity, or glare recovery; or in driving performance tests such as information recognition, mirror checks, lane keeping, clearance judgment, or gap judgment.

Key Question 2: Do red-green color deficiencies (either protan or deutan) increase crash risk?

The evidence is insufficient to determine whether red-green color deficiencies increase crash risk.

Direct Evidence – Crash Studies: A single included study reported on the association between color vision deficiency and crash (self-reported). This study did not provide any evidence in support of the contention that individuals with red-green color deficiencies are at an increased risk for a crash. However, a single low-quality study is insufficient evidence to allow any conclusion concerning crash risk; more data is required.

Indirect Evidence – Driving Simulator Studies: Two studies of low methodological quality used either self-reporting of driving performance or simulated driving performance tests to evaluate traffic signal recognition among non-CMV drivers with color-deficient vision and normal vision. Individuals with color deficiency were less proficient in signal recognition and demonstrated longer response times than individuals with normal color vision. Whether these observed deficits are factors that may contribute to an increased crash risk is unclear.

Key Question 3: Is visual field (VF) loss associated with an increase in crash risk? And, if affirmative, what is the acceptable VF range in the horizontal and vertical meridians?

Drivers with VF loss measured by standard perimetry are at an increased risk of crash (Strength of Evidence: Minimally Acceptable).

- A precise estimate of the magnitude of increase in risk cannot be determined at the present time.
- Due to differences in reported measures and cutoffs, no conclusion is possible at this time regarding the degree and pattern of VF loss that is most strongly associated with the increased crash risk.

Drivers with reduced useful field of view (UFOV) measured by the UFOV test are at an increased risk of crash (Strength of Evidence: Moderate).

- A precise estimate of the magnitude of increase in risk cannot be determined at the present time.
- A $\geq 40\%$ reduction in UFOV is associated with an increased risk of crash (Strength of Evidence: Moderate).

Direct Evidence – Crash Studies: The evidence base for this key question included a total of 14 studies (in 16 publications). Two separate analyses were performed: an analysis of the findings of studies that examined the association between VF loss and crash risk using standard perimetry testing (any method), and an analysis of studies that examined the association between UFOV and crash risk.

Twelve of these studies assessed the relationship between crash risk and VF loss as measured by standard perimetry (automated or manual). Due to differences in patient characteristics, perimetry tests, cutoffs for judging VF loss, type of crash data, summary statistics, and adjustments of summary statistics, a precise quantitative estimate of effect could not be obtained. However, eight of the twelve

studies showed a statistically significant increase in crash risk associated with VF loss. Because the median quality of the evidence base was low, the strength of evidence is considered minimally acceptable. Populations most likely to contain drivers with VF loss associated with increased crash risk include drivers with glaucoma, retinitis pigmentosa, and to a lesser extent, older drivers (>54 years of age). Although slightly more evidence supports peripheral VF loss as having a greater impact on crash risk than central VF loss, only four studies separately evaluated both types of VF loss, and there were differences among studies that only examined one type of VF loss. Therefore, the relative impact of peripheral VF loss versus central VF loss on crash risk could not be determined with certainty.

Differences among the measures and cutoffs used in studies of VF range meant that a conclusion regarding what constituted an acceptable VF range could not be reached based on standard perimetry.

Six studies (in seven publications) assessed the relationship between crash risk and reduced UFOV as measured by the UFOV test. All six studies showed a statistically significant increase in crash risk associated with VF loss. Due to differences in the implementation of UFOV (full test or subtests), summary statistics, adjustments for potential confounding factors, and types of crash reported among different studies, a quantitative estimate of effect could not be obtained. However, since the direction of effect was consistent and significant in all studies, the findings were robust. When considered with the moderate quality (median measurement) of the evidence base, this means that the strength of evidence for this comparison is moderate.

Three studies found a statistically significant increase in crash risk associated with a $\geq 40\%$ reduction in UFOV. Although these were the only studies to report using this cutoff, the findings were consistent. Combined with the moderate quality (median measurement) of these studies, this means that the strength of evidence for this finding is moderate.

The generalizability of these findings to CMV drivers is unclear, as none of the studies reported whether any commercial drivers composed part of the study population.

Key Question 4: Do cataracts increase crash risk? And, if affirmative, does cataract surgery reduce this risk?

Due to inconsistency among the findings of different studies, the evidence is insufficient to determine whether cataracts increase crash risk. The possibility that cataracts increase crash risk cannot be ruled out.

Direct Evidence – Crash Risk: Four studies that met our inclusion criteria for this key question examined the direct impact of cataracts on crash risk. One of these studies found that individuals with cataracts are at an increased risk for a motor vehicle crash; the remaining three studies did not. The latter three studies did not report on the severity of cataracts; two did not report on whether enrollees had been treated with cataract surgery.

The study that found an increased risk of crash for individuals with cataracts when compared to controls without cataracts reported that drivers who did not have surgery for their cataract(s) crashed more than drivers who had surgery. Another study did not find a difference in crash risk between drivers with cataracts and drivers with cataract surgery; this study had not found an increased crash risk for drivers with cataracts compared to drivers without cataracts.

Indirect Evidence – Studies of Driving Simulation and Self-Reported Difficulty Driving: One of the crash studies, along with three additional studies in the evidence base, investigated indirect evidence to support the contention that drivers with cataracts may have an elevated crash risk. One such study suggests that driving ability is significantly decreased and self-reported driving difficulty is increased among drivers with cataracts, and that the driving ability of cataract patients improves after surgery to treat the disorder. Evidence from the additional studies consistently suggests that individuals with cataract(s) have greater difficulty driving than individuals without cataracts and that driving ability improves following surgery.

Overall Summary: Although one crash study and supporting indirect evidence suggest that cataracts are associated with increased crash risk, three other crash studies did not find an association between cataract and crash. The small size of this evidence base prohibits exploration of potential factors that might explain the different findings. Therefore, the available evidence does not permit a conclusion regarding the relationship between cataract and crash. Furthermore, the generalizability of these findings to CMV drivers is unclear; it does not appear that any commercial drivers were represented in the studies.

Key Question 5: Is diplopia associated with increased crash risk?

There is insufficient evidence to determine whether diplopia increases crash risk.

Direct Evidence – Crash Studies: A single low-quality study reported on the association between diplopia and crash risk among non-CMV drivers. This study did not provide any evidence in support of the contention that individuals with diplopia are at an increased risk for a crash. However, a single low-quality study is insufficient evidence to allow any conclusion concerning crash risk; more data is required.

Indirect Evidence – Driving Simulator Studies: A single small study of moderate quality provided self-reported driving performance through response and reaction time recognition in simulated driving performance tasks among non-CMV drivers with diplopia and nondiplopic vision. Although the included study did not provide evidence of increased risk among diplopic drivers of any type (and is therefore consistent with the findings of the crash study) two studies of low-to-moderate quality are insufficient to rule out an increase in risk. Moreover, we were not able to assess crash risk among CMV drivers with diplopia. The lack of data from studies enrolling CMV drivers with diplopia precludes one from determining whether CMV drivers with this type of vision impairment are at an increased risk for a motor vehicle crash. Thus, one cannot determine from the existing evidence base whether diplopic CMV drivers are at an increased risk for a motor vehicle crash.

Preface

Organization of Report

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

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

Scope

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

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

Key Question 1: Is monocular vision associated with an increased crash risk?

Key Question 2: Do red-green color deficiencies (either protan or deutan) increase crash risk?

Key Question 3: Is visual field (VF) loss associated with an increase in crash risk? And, if affirmative, what is the acceptable VF range in the horizontal and vertical meridians?

Key Question 4: Do cataracts increase crash risk? And, if affirmative, does cataract surgery reduce this risk?

Key Question 5: Is diplopia associated with increased crash risk?

Background

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

Vision and the Driving Task

The safe operation of a motor vehicle requires adequate visual acuity (VA), VF, and color vision. The precise definition of the level of vision necessary for safe driving has been a contentious issue due to a lack of definitive empirical evidence on which to base a clearly defensible visual performance standard.(1) It is generally accepted, however, that a driver with uncorrected visual defects may fail to detect other vehicles, pedestrians, or roadside barriers; may take appreciably longer to read road signs at a distance or at night; and may be slow to perceive and react to hazardous situations.

Many conditions impair visual function and contribute to diminished driving ability, including cataract, color vision defects, and nystagmus (see Table 2). It is important to note that many of these impairments do not simply result in a loss for one visual dimension, such as VA or VF. Visual impairments typically result in losses along many different visual dimensions: for example; glaucoma affects functional VA as well as effective VF and contrast sensitivity. This combination of impairments complicates the assessment of which factors are specifically relevant to driving ability.

Table 2. Visual Disorders and Their Associated Functional Visual Deficits

| Condition | Definition/Description | Literature Base and Associated Visual Deficits |
|----------------------------------|--|--|
| Age-related macular degeneration | A condition in which the photoreceptors in the macula degenerate | Moderate literature base Loss in central VA |
| Cataract | Condition in which the normally clear lens of the eye becomes clouded and opaque | Relatively significant literature base on this topic with respect to driving Loss in VA and contrast sensitivity; contributes to significant glare, particularly at night |

Vision and CMV Driver Safety

| Condition | Definition/Description | Literature Base and Associated Visual Deficits |
|----------------------|--|---|
| Color vision defects | Primarily inherited traits that almost exclusively affect males and usually manifest in a difficulty distinguishing red from green, with blue deficiencies occurring very rarely | Moderate literature base Difficulty distinguishing colors of traffic lights and vehicle lights and in using color to distinguish between various stimuli in the road environment |
| Corneal pathology | Results from injury or damage to the cornea | Small to no literature base Loss in VA and contrast sensitivity; contributes to significant glare, particularly at night |
| Diabetic retinopathy | Caused by specific vascular complications from diabetes mellitus, in which the blood vessels that supply the retina are damaged | Small literature base Loss in central VA |
| Glaucoma | A group of eye diseases, in which the optic nerve becomes damaged. | Relatively significant literature base on this topic with respect to driving Loss in VA and VF and contrast sensitivity |
| Hemianopia | Results in VF loss caused by damage to the optic pathways in the brain, possibly resulting from acquired brain injuries due to stroke, tumor, or trauma | Small literature base Loss in VF |
| Monocular vision | Blindness in one eye | Small to moderate literature base Loss in VF and VA, deficits in depth perception |
| Nystagmus | Involuntary and rapid movement of the eyes, usually in a horizontal manner | Little relevant data |
| Refractive errors | Myopia, hyperopia, and others | Large body of literature examined the effects of VA on driving |
| Retinitis Pigmentosa | Congenital degeneration of the pigmented layer of the retina that can lead to severe VF loss; due to loss of rods in this condition, one of the early problems is night blindness. | Moderate literature base; large literature base with respect to VF |

Measures of Visual Function

In this section, we provide details of measures of the various aspects of visual function currently available. Given the multidimensional impact of eye disease on visual function, it is generally believed that simple tests of vision such as those typically used by driver licensing agencies (e.g., static visual acuities) do not effectively identify high-risk drivers and that multifactorial assessments that will identify a broad range of vision impairments are necessary to assess and identify high-risk drivers.

Visual Acuity

Visual acuity (VA) is a term used to describe the acuteness or clearness of vision, especially from vision. VA depends upon how accurately light is focused on the macular region of the eye, the integrity of the eye's neural elements, and the interpretative faculty of the brain.

Measuring VA

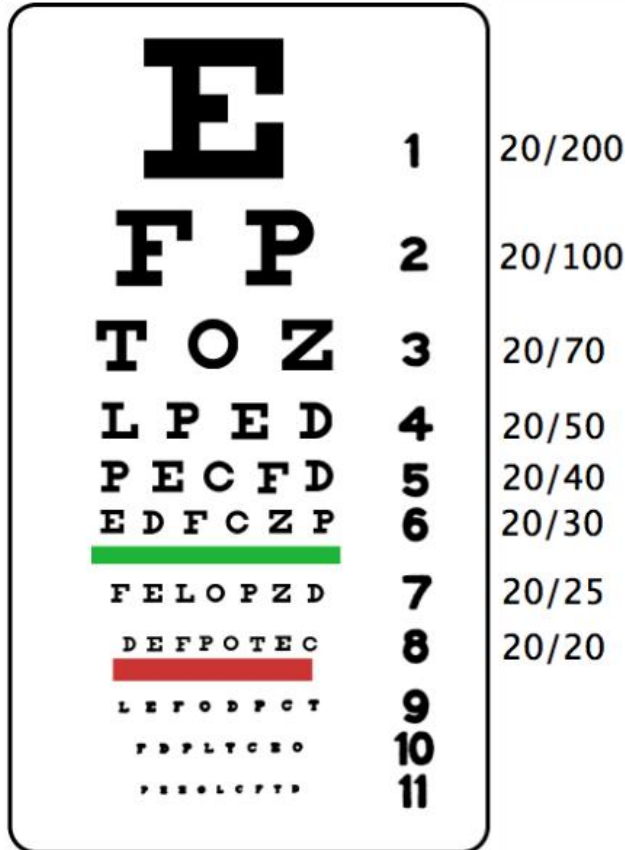
VA is a quantitative measure of the ability to identify black symbols on a white background at a standardized distance, with the size of the symbols being systematically varied. VA represents the smallest size that can be reliably identified by the individual being examined. VA is the most common clinical measurement of visual function: the phrase "20/20 vision" refers to the distance in feet that objects (separated by an angle of 1 arc minute) can be distinguished as separate objects.

“Normal” VA is frequently considered to be what was defined by Snellen as the ability to recognize an optotype when it subtended 5 minutes of arc (i.e., Snellen’s chart 20/20 feet, 6/6 meter, 1.00 decimal, or 0.0 logMAR). The maximum acuity of healthy emmetropic eyes or ametropic eyes with correctors is approximately 20/16 to 20/12, so it is inaccurate to refer to 20/20 VA as “perfect” vision. The VA needed to discriminate two points separated by 1 minute of arc is 20/20. The significance of the 20/20 standard can best be thought of as the lower limit of normal or as a screening cutoff; when used as a screening test, subjects that reach this level need no further investigation.

Snellen Eye Charts

The traditional Snellen chart is printed with 11 lines of block letters (Figure 1). The first line consists of one very large letter. Subsequent rows have increasing numbers of letters that decrease in size. A patient taking the test covers one eye and reads aloud the letters of each row, beginning at the top. The smallest row that can be read accurately indicates the patient’s VA in that eye.

Figure 1. The Snellen Eye Chart



Wall-mounted Snellen charts are inexpensive and are sometimes used for rough assessment of vision (e.g., in a primary-care physician’s office). Whenever acuity requires more precise assessment, equipment is used that can present the letters in a variety of randomized patterns.

Snellen charts have been criticized for a number of reasons, including the introduction of inherent biases through the crowding of letters (which are more difficult to read) and the large and uneven jumps in acuity levels between the rows. Additionally, a Snellen chart may simply be memorized by an individual who wishes to give the impression that his or her vision is adequate. To address these concerns, more modern charts have been designed that have the same number of letters on each row and use a geometric progression to determine the size of each row of letters.

Bailey-Lovie Eye Charts

There have been many attempts to improve the design of the Snellen chart: the Bailey-Lovie chart has emerged as the test of choice in vision research, and its use is beginning to be adopted in clinical practice because it overcomes many of the shortcomings of the Snellen chart.

This design uses 10 letters of approximately equal legibility, 5 to a line, spaced such that the separation between lines and between letters gives similar “crowding” effects at all levels. As the letter size varies on a logarithmic scale, VA can be scored according to a logMAR system in which each letter correctly identified scores -0.02 logMAR units and each correct line of 5 letters scores -0.1 logMAR units. The patient must read until no correct responses are made on a line. A Snellen fraction of 6/6 equals 0 logMAR, 6/60 (10 lines larger) scores 1.0 logMAR, and 6/3 (three lines smaller than 6/6) scores -0.3 logMAR.

Visual Field

VF is a term used to describe the space or range within which objects are visible to the immobile eyes at a given time. It is commonly referred to as field of view or field vision.

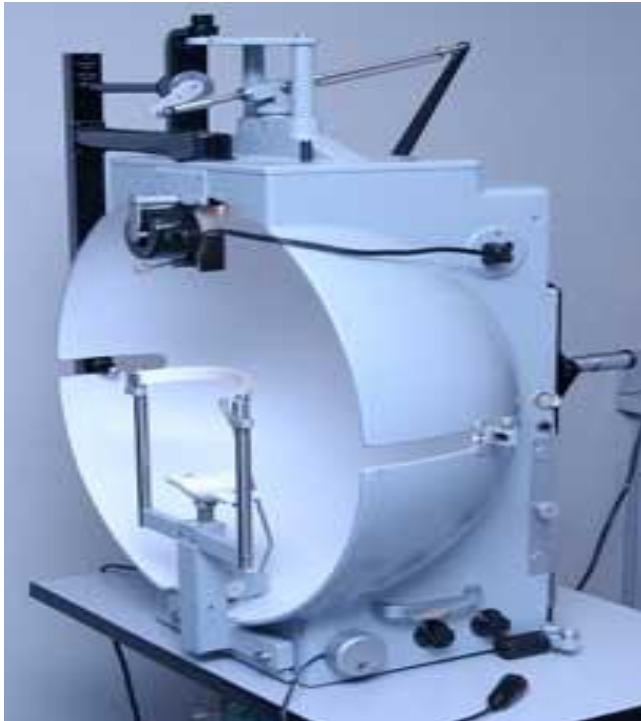
Measuring VFs

VF is measured by perimetry, which is defined as the systematic measurement of differential light sensitivity in the VF by the detection of the presence of test targets on a defined background. The VF test is used to detect defects and the site of the defect. Central and peripheral vision are measured using perimetric methods. This measurement technique is also commonly used with glaucoma patients.

Manual testing

Manual perimetry describes a kinetic method in measuring field of view, which involves a mobile stimulus moved by a perimetrist.(2) The procedures and instruments utilized in manual perimetry provide distinct measurement of the peripheral retina. In contrast to automated methods, manual testing is considered an economical method of providing basic, rapid, and effective VF information.(3) Figure 2 illustrates an example of the Goldmann perimeter used in manual testing:

Figure 2. Goldmann Manual Perimeter(4)



Automated testing

Automated technology permits more complex visual stimuli and test procedures to be performed when compared to traditional increment perimetry. Automated perimetry test types include the following:

- Frequency-doubling technology perimetry
- Short wavelength automated perimetry
- Flicker perimetry
- High-pass resolution perimetry
- Rarebit perimetry

Test algorithms applied to perimetry include the following:

- Zippy estimation of sequential thresholds (ZEST)
- Swedish interactive thresholding algorithm (SITA)
- Tendency-oriented perimetry (TOP)
- Multisampling supra-threshold perimetry(5)

Testing of peripheral field of vision involves a light point presented in a predetermined fashion (location sequence) in a lighted bowl. The individual being tested is asked to press a button when he or she sees the light point. The responses are analyzed statistically and compared with a database of normal responses. The Humphrey (Figure 3) or the Octopus perimeters are examples of measurement devices used to conduct field of vision tests.

A principle benefit of the automated perimeter is that it detects VF loss earlier (principally in the central region) than manual perimetry and is more standardized, without requiring the presence of a skilled perimetrists.

Figure 3. Humphrey Perimeter(6)



An important limitation of field testing to consider is the possibility of an individual losing up to 50% of his or her optic nerve fibers without any field defects showing up on VF testing. Several newer strategies have been introduced that allow for earlier detection of field defects (blue yellow perimetry/short wavelength automated perimetry).(7)

Useful Field of View

The useful field of view (UFOV) is a measure of the functional or useful range of peripheral vision under cognitive load conditions.(8) Cognitive load refers to the total amount of mental activity imposed on working memory at an instance in time. The major factor that contributes to cognitive load is the number of elements that need to be attended to. As cognitive load is increased by elevating task complexity, the functional range of peripheral vision (i.e., the degree of peripheral vision from which information is processed) becomes restricted. Thus, the functional extent of peripheral vision under complex, real-world conditions, such as detecting stimuli in cluttered backgrounds, is not always

equivalent to the maximum extent of peripheral vision that can be measured with clinical perimetry techniques. Reduction in UFOV has also been associated with age and neurological damage.

Measuring UFOV

UFOV[®] (9) is a computer-administered and computer-scored test of visual attention that determines the extent of a driver's UFOV. The UFOV task is divided into three parts, as follows:

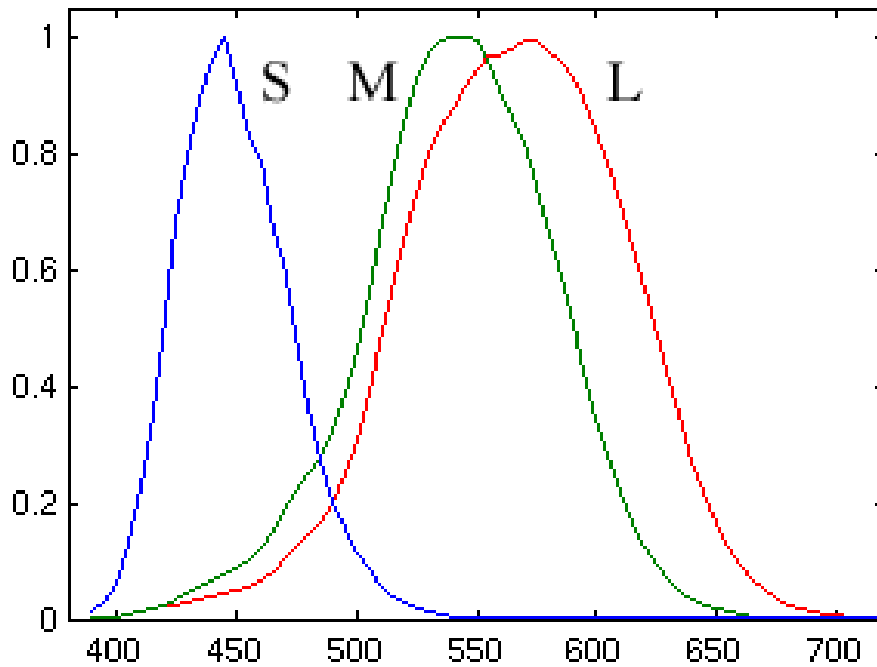
- Part 1 measures central vision and processing speed, requiring the examinee to identify a target object presented for varying lengths of time in the center of the computer's screen.
- Part 2 measures divided attention, requiring the examinee to identify a central target object as before and to localize a simultaneously presented target object displayed in the periphery of the screen.
- Part 3 measures selective attention, similar to part 2, except that the target object displayed in the periphery is embedded in distracters, making the examinee's task more difficult.

Rapidly presented target objects are viewed on a computer monitor, with the information displayed progressing from simple to complex. Reports provide scores for each part of UFOV and assign a risk level and risk statement; the results from the three subtests are used in combination to determine the UFOV Risk Level, which ranges from level 1 (Very Low Risk) to level 5 (Very High Risk).

Color Vision

Color vision is the capacity to distinguish objects based on the wavelengths (or frequencies) of the light they reflect or emit. The human nervous system perceives color by comparing the responses to light from three different photoreceptors in the retina of the eye, called "cones." Cones are sensitive to different portions of the visible spectrum (Figure 4). The brain combines the information from each type of receptor to give rise to different perceptions of different wavelengths of light.

Figure 4. Normalized Response Spectra of Human Cone Photoreceptors



Color vision deficiencies (CVDs) can be congenital or acquired. CVDs are classified into three groups: monochromasy, dichromasy, and anomalous trichromasy. Individuals with monochromasy are typically completely colorblind and may have one cone pathway in addition to the rod pathway. Individuals with dichromasy have a cone photopigment missing, therefore, they only have two cone channels. Anomalous trichromats have all three cone photopigments; however, one cone photopigment has a shifted peak sensitivity. The types and prevalence of CVDs are listed in Table 3.

Table 3. Prevalence of Congenital Color Deficiencies

| Types of CVD | Prevalence in Males | Prevalence in Females |
|------------------------------|---------------------|-----------------------|
| Overall | ~8% | ~0.5% |
| Anomalous trichromasy | | |
| • protanomaly | 1% | 0.01% |
| • deuteranomaly | 5% | 0.4% |
| • tritanomaly | rare | rare |
| Dichromasy | | |
| • protanopia | 1% | 0.01% |
| • deuteranopia | 1.5% | 0.01% |
| • tritanopia | 0.008% | 0.008% |
| Monochromasy | | |
| • rod monochromasy | rare | rare |
| • cone monochromasy | rare | rare |
| • atypical monochromasy | very rare | very rare |

CVD – Color vision deficiencies.

Dichromasy and anomalous trichromasy are classified according to the affected cone photopigment. Three terms that are also used to describe CVDs are “protan,” “deutan,” and “tritan.” A protan deficiency occurs in individuals in whom the longer wavelength cone photopigment is missing or anomalous; a deutan deficiency occurs in individuals in whom the middle wavelength cone photopigment is missing or anomalous; and a tritan CVD occurs in individuals in whom the shorter wavelength cone photopigment is missing or anomalous.

Measuring Color Vision

There are many methods for measuring color vision. In this section, we focus on tests of color vision that are commonly used in the clinical setting.

Anomaloscope

Anomaloscopes are used in testing for color blindness, including the diagnosis of red-green color vision defects. The Nagel, Neitz (Figure 5), and Pickford-Nicolson instruments are presently recognized anomaloscopes that are commercially available for use in the United States.

Figure 5. Neitz Anomaloscope(10)



Pseudo-Isochromatic Test Plates

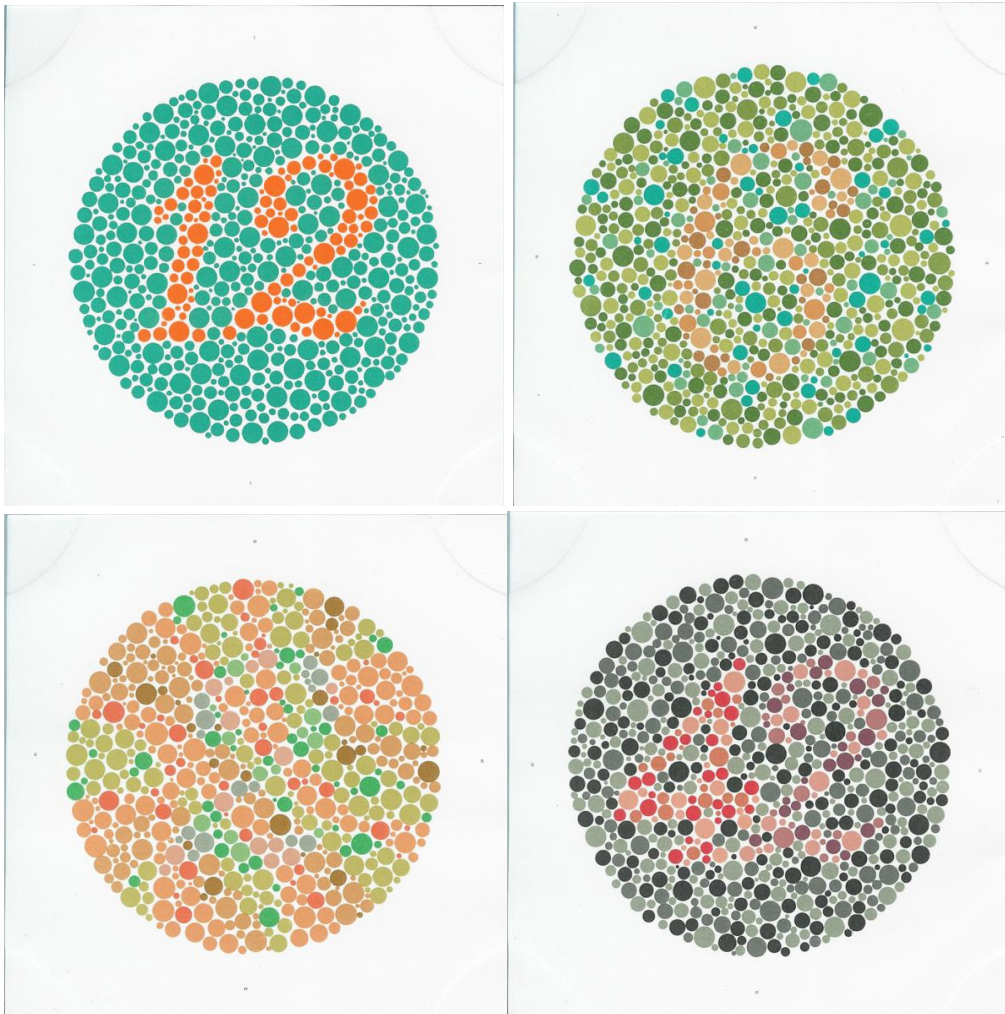
Pseudo-isochromatic test plates provide another mechanism for color vision measurement through the identification of colored symbols embedded in a multicolored background (differing to the color symbols). The best known pseudo-isochromatic test plates available are the Ishihara Plates.

Ishihara Plates

Ishihara Plates come in two formats: a 24-plate series and a 38-plate series (Figure 6). From a colorimetric perspective, four different types of test plate are employed in both the 38- and 24-plate series. The four test designs in the 38 plate series are as follows:

- Transformation plates. Anomalous color observers give different responses than normal color observers. The plates are numbered 2 to 9 inclusive.
- Disappearing digit (vanishing) plates. Only the normal observer is meant to recognize the color pattern. The plates are numbered 10 to 17, inclusive, in the 38-plate series.
- Hidden digit plates. Only the anomalous observer should see the pattern. The plates are numbered 18 to 21 inclusive. The subsets in the 24-plate series are numbered 14 and 15 or number 19 only.
- Qualitative plates. Intended to classify protan from deutan and mild from severe anomalous color perception, the plates are numbered 22 to 25.

Figure 6. Examples of Pseudo-Isochromatic Plates from Ishihara Plates Test(11)



Lantern Tests

Lantern tests were originally designed to measure the ability of seamen, railway workers, and airline pilots to identify and discriminate between navigational aids and signals. Well-known lantern tests include the Beyne lantern, the Giles-Archer lantern, the Edridge-Green lantern, the Martins lantern, the Holmes-Wright lantern, the Sloan Color Threshold Tester, and the Farnsworth lantern.

Lantern tests present colored lights (matched with the colors of signal lights) to a subject, who is asked to identify the color. Despite their simplicity and practicality, lantern tests are rarely used today.

Lanterns that are still in use today include the Optec 900, the Holmes Wright Type A and B lantern, and the Beyne lantern (Figure 7).

Figure 7. Currently Available Lantern Tests(12)



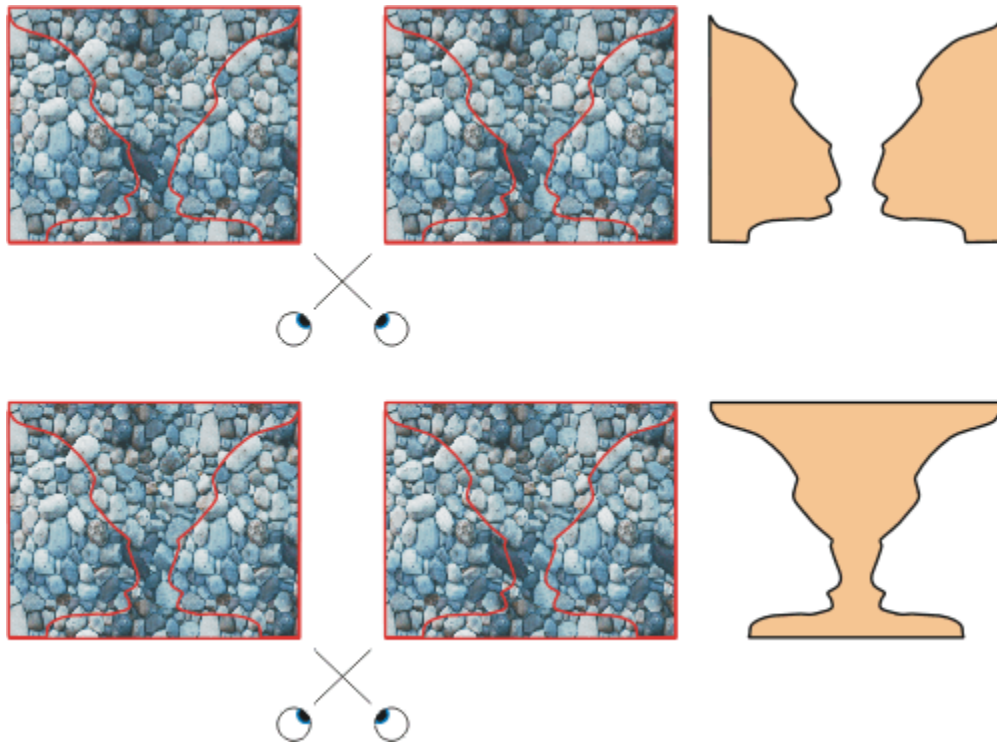
Several agencies that regulate fitness for duty still include lantern tests in their vision standards; for example, the United Kingdom Civil Aviation Authority's fitness for duty standards for commercial airline

pilots state that in order to be certified an individual must, “. . . have normal perception of colors (defined as no mistakes on Ishihara plates [24-plate version] tested in daylight or in artificial light of the same color temperature such as that provided by illuminant “C” or “D”) or be color safe. Applicants who fail Ishihara shall be assessed as color safe if they pass extensive testing with methods acceptable to the Aero Medical Section (Holmes-Wright lantern or anomaloscopy).”(13)

Stereopsis (Depth Perception)

Stereopsis is the process in visual perception of stereoscopic depth (i.e., stereo vision, three-dimensional or binocular vision). Stereoscopic depth results from the fusion of the two slightly different projections of the world on the separate retinas of the eyes, which is a result of the eyes’ horizontal separation. This separation is usually referred to as binocular disparity or retinal disparity. As indicated in Figure 8, an individual’s vision in the stereoscopic view always perceives the red contours indicated as part of the nearer surface.(14)

Figure 8. Binocular Disparity(14)

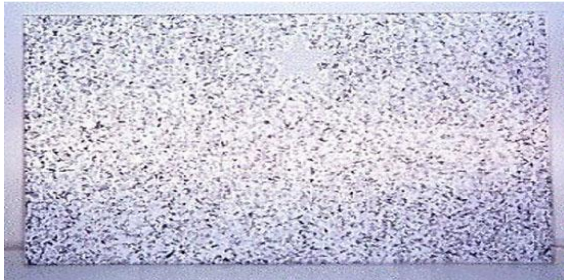


Measuring Stereopsis

Stereopsis (or depth perception) is measured by the illumination of objects placed on different planes, usually by a stereoscope.(15) The stereoscope uses cards (stereograms) that contain separate images printed side-by-side to measure binocular vision. This section focuses on those tests and stereoscopic techniques of stereopsis that are commonly used in the clinical setting.

Random-dot stereograms (RDSs), also referred to as autostereograms, are clinical tools used to test stereopsis. The RDS uses real depth (level of disparity) in the measurement of this visual impairment. Several types of stereotests are available, including the Frisby Stereotest, the Randot Stereotest, the Random-dot E Stereotest, and the Lang Stereotest (Figure 9). In these tests, individuals are requested to identify a particular geometric shape or picture (the correct target) with stereoscopic depth (target with disparity) to assess stereoacuity.

Figure 9. Lang Stereotest(12)



Monocular Vision

Individuals with monocular vision have a reduced VF, and limited depth perception and lack stereopsis; they experience a narrower view of horizontal field (10% to 20%) in the blind eye and depth perception physiological cues (visual indicators), which exist in the binocular state are lost.

Monocular Cues

Monocular cues are visual indicators available from the input from one eye. As indicated in Table 4, strong monocular cues permit the determination of relative distance and depth.(12)

Table 4. Strong Monocular Cues

| Type | Description |
|-----------------------------|---|
| Relative size | Judging distance based on past visual experiences and familiarity with objects |
| Interposition | Overlapping of objects |
| Linear perspective | Parallel lines converge as images become farther in distance |
| Aerial perspective | Color of an object gives clue to distance |
| Light and shade | Highlights and shadows give indication of objects' depth |
| Monocular movement parallax | When an individual's head moves from side to side, the object(s) move at a different relative velocity based upon the distances |

Monocular Adaptation

Individuals experiencing acquired monocular vision must adapt to and accommodate this reduction in VF. It has been recommended, particularly in guidelines for transportation workers, to have a waiting period of six months in order to learn new techniques for interpreting monocular cues before returning to work.(16) The loss of vision in a single eye requires accommodation in estimating actual distance of objects while driving but not the ability to determine the size of objects or final grip movement, allowing for quick adaptation in monocular individuals.(17)

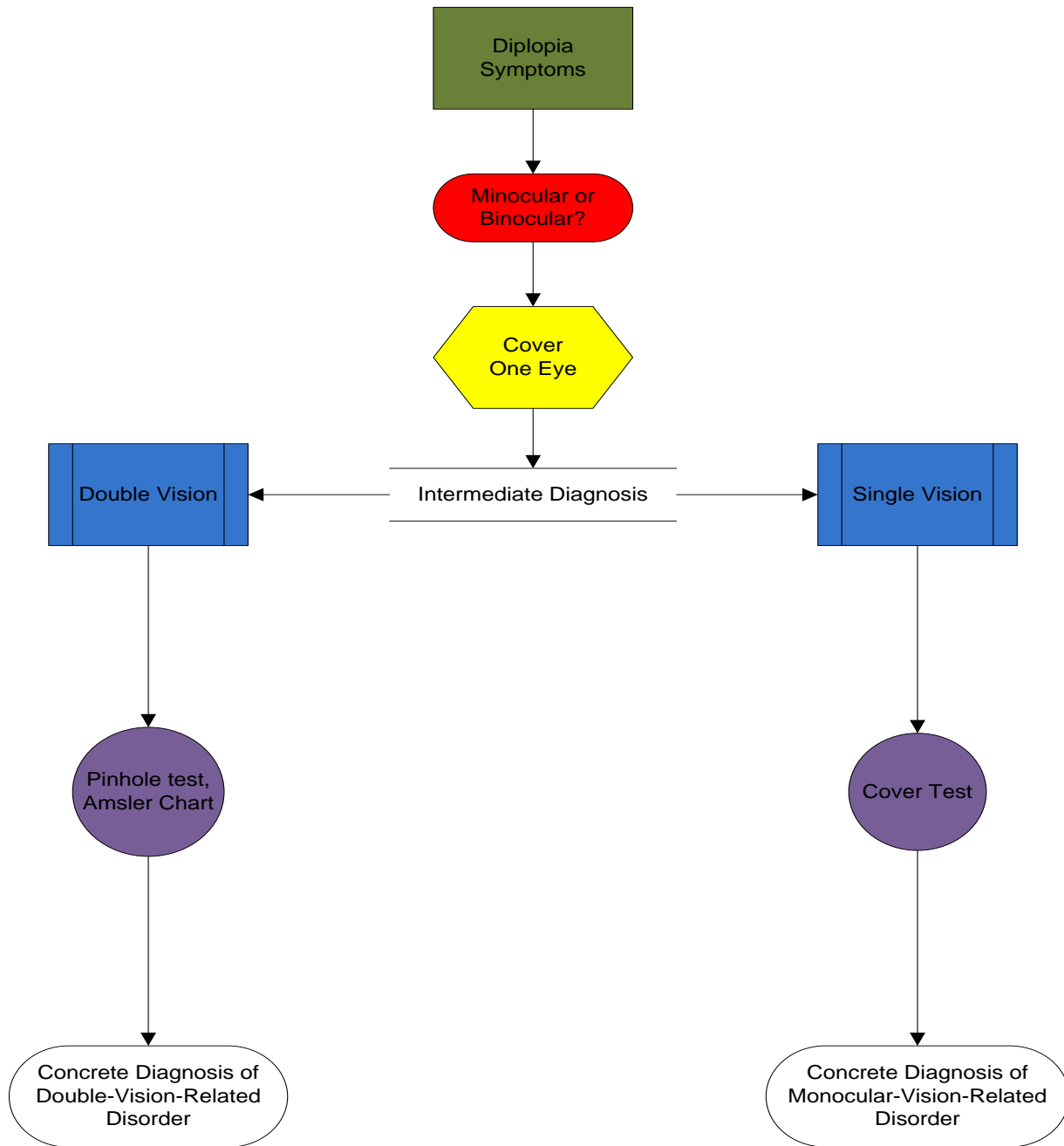
Diplopia

Diplopia is double vision caused by a defective function of the extraocular muscles or a disorder of the nerves that innervate (stimulate) the muscles. Double vision is usually a symptom of strabismus (deviation or misalignment of the two eyes); although not all strabismus produces double vision. In this condition, movement of the eye in a particular direction is impaired due to paralysis of one or more muscles. Tilting or turning the head can sometimes overcome the double vision. Rarely, double vision arises because of an abnormality within a single eye—so-called monocular diplopia. For example, a dislocation of the lens in the eye may result in some light rays passing through the lens while others pass around it so that separate images fall on the retina of one eye.

Measuring Diplopia

The measurement of diplopia includes initial testing of the symptoms to detect which of the two types (monocular diplopia or binocular diplopia) is present.(18) When conducting the vision test, patients' vision assessment must be completed with one eye closed (monocular) unless the patient has been diagnosed as having a gross strabismus, a condition related to the lack of coordination in the intraocular muscles.(19) The evaluation determines whether the symptoms are monocular diplopia (symptoms persist in one eye despite covering the other eye) or binocular diplopia (vision can be corrected by covering either eye).(18) It is essential in evaluating patients for diplopia to examine the basic visual sensory and ocular motor functions. Figure 10 illustrates the examination process for measuring diplopia:

Figure 10. Diplopia Examination Process

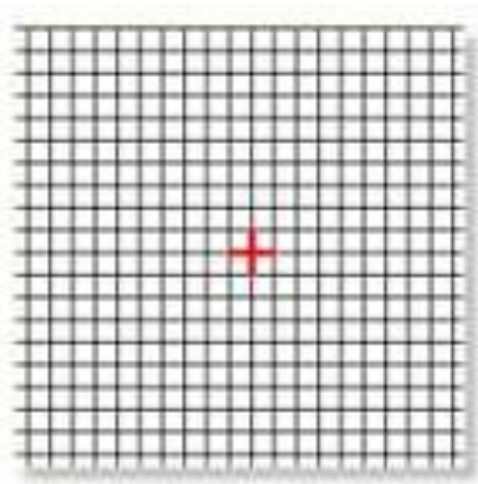


According to Pelak(19), examination techniques related to all visual and ocular motor functions are necessary to evaluate diplopia. Practical examination methods in the determination of ocular cause by diplopia type (monocular, binocular) are illustrated below in Table 5. The Amsler Grid Chart (Figure 11) is one example of an examination to measure VA and eliminate monocular diplopia found to be caused by types of refractive error.

Table 5. Methods in the Examination for Diplopia by Type

| Diplopia Type | Recommended Measurement |
|-------------------------|---|
| Monocular Diplopia (MD) | <ul style="list-style-type: none"> • Slit lamp examination—A component of a “complete ophthalmologic examination” • Pinhole test—Measurement of VA using a handheld pinhole device to give patients a monocular view (through the tool’s small holes) of an eye chart (If MD is from ocular causes, monocular diplopia will disappear when the patient looks through the pinhole. Otherwise [and uncommon] the patient will develop polyopia, seeing multiple images of an object) • Amsler chart (See Figure 11)—Used to identify macular disease because pinhole testing does not improve macular retinal disorders. |
| Binocular Diplopia | <ul style="list-style-type: none"> • Measurement of “ocular alignment, preorbital swelling, orbital normalities, injection of the ocular conjunctiva or sclera, eyelid position, and fatigable weakness of extraocular muscles or levator palpebrae muscles of the eyelids” • General neurologic examination required |

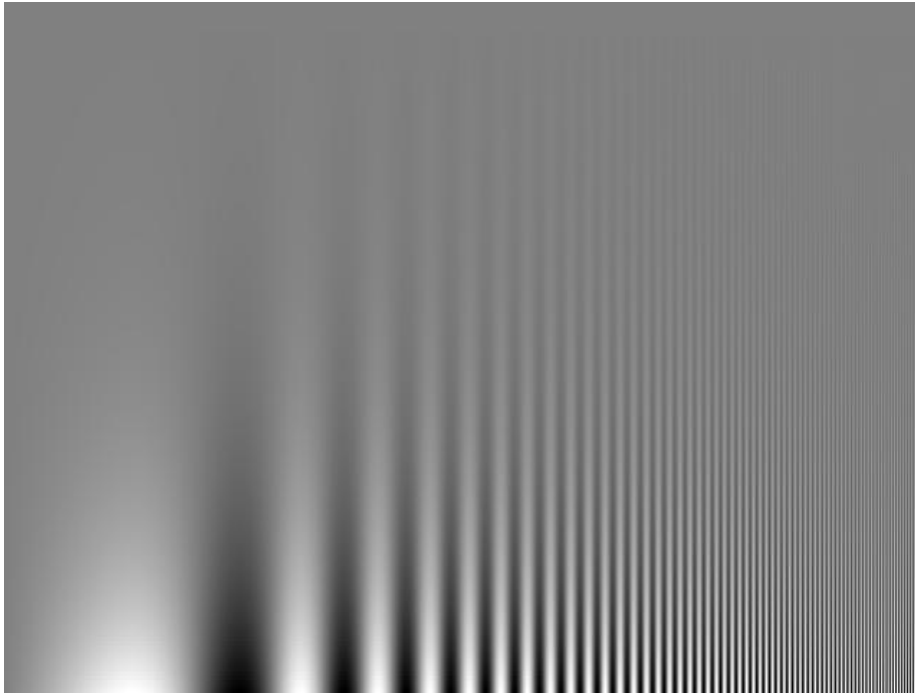
Figure 11. Amsler Grid Chart(20)



Contrast Sensitivity

Contrast sensitivity is a measure of the limit of visibility for low contrast patterns (i.e., how faded or washed out can images be before they become indistinguishable from a uniform field?). Figure 12 illustrates the form of the contrast sensitivity function. In this image, the luminance of pixels is modulated sinusoidally along the horizontal dimension. The frequency of modulation (spatial frequency) increases logarithmically (i.e., with exponential increase) in frequency from left to right. The contrast also varies logarithmically from 100% to about 0.5% (bottom to top). The luminance of peaks and troughs remains constant along a given horizontal path through the image. Therefore, if the detection of contrast is dictated solely by image contrast, the alternating bright and dark bars should appear to have equal height everywhere in the image. However, the bars appear taller in the middle of the image than at the sides. This inverted U-shaped envelope of visibility identifies an individual’s contrast sensitivity function. The exact location of the peak depends on the viewing distance.

Figure 12. The Contrast Sensitivity Function



Measuring Contrast Sensitivity

The contrast sensitivity function is determined by measuring the minimum contrast allowing the detection of gratings of various spatial frequencies. Several systems are available for measuring contrast sensitivity. In this section we focus only on those tests of contrast sensitivity that have been commonly used in the clinical setting.

Arden Plates

The Arden grating test represents the first attempt to develop a simple and inexpensive contrast sensitivity technique. Photographic plates of seven spatial frequencies (0.2 to 6.4 cycles per degree at 57 cm) are presented to the patient. Each plate contains a single spatial frequency with a sine wave grating oriented vertically. The contrast of the grating varies from high at the bottom to low at the top. One plate at a time is placed in a neutral gray holder and then slowly drawn upwards, out of the holder, until the patient reports that the grating is visible. The score on all seven plates is calculated and contrast sensitivity identified.

Vistech Vision Contrast Test System

The Vistech Vision Contrast Test System presents a series of sine-wave gratings at different levels of contrast. Each row or circular grouping of patches tests at a specific spatial frequency (cycles per degree) to measure the observer's sensitivity to a particular object size. The low frequencies test sensitivity to very large objects, while high frequencies measure sensitivity to very small objects. Each test frequency begins with a high level of contrast that diminishes with each succeeding patch. The sine waves, which appear as fuzzy gray bars, vary in their orientation within the patch and may be vertical or tilted left or

right. The observer simply reports the lowest contrast patch visible in each grouping and describes the orientation. The tester records the results to produce a contrast sensitivity function, or curve. The curve is then compared to a population norm and can be converted to a standard VA value that relates to everyday functional vision.

Poor contrast sensitivity adversely affects a variety of functions, including the ability to read text, regulate walking speed, identify the faces of individuals at a distance, or perform manual tasks that require the ability to differentiate between crucial parts of the task materials.

A variety of contrast sensitivity tests are available, including the following:

- Cambridge contrast charts, which measure a single median spatial frequency via a true forced choice procedure
- Melbourne Edge Test (MET), which measures the ability to detect an edge of varying contrast (This function is correlated with mobility in low vision individuals.)
- Peli-Robson contrast sensitivity chart, which measures contrast sensitivity using a single large letter size (20/60 optotype) with contrast varying across groups of letters (Figure 13)

Figure 13. The Peli-Robson Contrast Sensitivity Test



Glare Disability

Many people with optical irregularities in the eye, such as a cataract, are visually disabled in bright light conditions due to scattering of light within the eye, or glare. Glare may also originate external to the eye due to scatter from airborne particles or irregularities on transparent surfaces, such as windows and spectacle lenses. People with conditions that increase light scatter within the eye experience exaggerated impairments under conditions of glare.

Measurement of visual function in the clinic or the laboratory is usually performed under ideal conditions of daytime (“photopic”) lighting and in the absence of extraneous light sources. In the real world, however, levels encountered in bright sunlight can be up to 400 times greater than this and, in night driving, typically 500 times dimmer. Strong extraneous light sources such as oncoming headlights or a bright sky often surround a visual target, creating glare problems for individuals with optical irregularities, which may compromise safe driving.

The impact of glare depends on the demands of the visual task. For example, when looking at a person silhouetted against a window or a very bright sky, contrast reduction can make it difficult to discern features in the face. In driving, detecting pedestrians or the edge of the roadway or reading signs against a bright sky, sun, or headlights is likely to be difficult if the ability to see in the presence of glare is impaired. Glare disability has been associated with the occurrence of motor vehicle collisions.

Measuring Glare Disability

Glare disability is measured by determining an individual’s sensitivity to glaring bright lights. Presently, techniques available for measuring glare disability are limited. Further, measuring techniques are deficient because glare disability has been determined as highly condition dependent, with adequate cutoff values in measurement not clearly established.(21) In this section, we focus only on testing of glare disability that has been commonly used.

The Brightness Acuity Tester

The Brightness Acuity Tester (BAT) is used to test glare disability. The BAT can simulate three bright light conditions: 1) Direct overhead sunlight; 2) Partly cloudy day; 3) Bright overhead commercial lighting. If vision decreases with increasing light then the patient is deemed to have glare disability.

Visual Disorders and Driving Regulations

An important element to the safe operation of commercial motor vehicles (CMVs) is visual function. For the purpose of public safety and CMV drivers, federal and state laws were created to enforce standards for CMV drivers with visual impairments. Eligibility criteria contained in Section VII of the FMCSA Medical Reports on Visual Disorders and Commercial Drivers comprises the following:

The principle questions regarding adequate visual function revolve primarily around VA, VF, monocular status, and color vision. Thus, any investigative initiative must include individuals who have varying degrees of deficit in each of these parameters. Furthermore, the deficit in each of these parameters must be rigorously defined and evaluated by standardized

procedures. The eligibility of an individual, and determining the particular group in which they will be evaluated, must be predefined in a detailed manner. All tests, which are used to evaluate these visual functions must also be rigorously defined and performed in a standardized manner. This requires detailed protocols for ophthalmic evaluation and rigorous timing of study visits. Usually, this would also require standardized certification of the individuals who are performing the measurements.

In addition, the reporting of each applicant's physical state must be performed in a standardized manner and compiled in a central database. Rigorous and standardized reporting and follow-up of all accidents must be made on a predetermined and routine basis. Full details of all incidents must be reported on standardized forms to assure that all information is acquired. These forms should be prospectively designed to capture all necessary information upon which future analysis would be performed. As part of appropriate study design, the number of participants, the study duration, and the magnitude of the effect to which one is looking must be prospectively determined.

It is strongly suggested that an independent data and safety monitoring board be convened to assure the integrity and independent evaluation of the safety aspects of the study and to monitor safety as the trial progresses. The board will be charged with the mandate to report any unjustifiable increase in risk such that the ongoing study may be modified to improve public safety or be promptly terminated if indicated.”

More extensive information on this topic is available at the *Conference on Visual Disorders and Commercial Drivers* at: <http://www.fmcsa.dot.gov/>.

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

Current Medical Fitness Standards

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

The current medical qualification standard for fitness to drive a CMV (49 CFR 391.41[b] subpart 10) states the following (see: <http://www.fmcsa.dot.gov/rules-regulations/administration/fmcsr/fmcsrruletext.asp?section=391.41>):

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

- has distant VA of at least 20/40 (Snellen) in each eye without corrective lenses or VA separately corrected to 20/40 (Snellen) or better with corrective lenses; distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and; the ability to recognize the colors of traffic signals and devices showing standard red, green, and amber.

The term “ability to recognize the colors of” is interpreted to mean if a person can recognize and distinguish among traffic control signals and devices showing standard red, green, and amber, he or she meets the minimum standard, even though he or she may have some type of color perception deficiency. If certain color perception tests are administered (e.g., Ishihara, pseudoisochromatic, Yarn), and doubtful findings are discovered, a controlled test using signal red, green, and amber may be employed to determine the driver’s ability to recognize these colors.

The use of contact lenses are permissible if there is sufficient evidence to indicate that the driver has good tolerance and is well adapted to their use. Use of a contact lens in one eye for distant VA and another lens in the other eye for near vision is not acceptable, nor are telescopic lenses acceptable for driving CMVs.

If an individual meets the criteria with the use of glasses or contact lenses, the following statement shall appear on the medical examiner’s certificate: “Qualified only if wearing corrective lenses.” CMV drivers who do not meet the federal vision standards may call (202) 366-1790.

Additional information on Visual Disorders and Commercial Drivers is supported at <http://www.fmcsa.dot.gov/rulesregs/medreports.htm>

Medical Fitness Standards and Guidelines for Other Forms of Transportation in the United States

Current medical fitness standards and guidelines for other comparable forms of transportation in the United States are summarized in Table 6. Included in the table are pertinent rules and guidance for pilots, railroad workers, and merchant mariners.

Table 6. Standards and Guidelines for Vision from U.S. Government Transportation Safety Agencies

| Condition | FAA ¹ (all classes of airmen) | Railroad ² | Merchant Marine ³ |
|-----------|---|---|--|
| Vision | <p>AME Assisted - All Classes Glaucoma</p> <p>AME Assisted Special Issuance (AASI) is a process that provides Examiners the ability to re-issue an airman medical certificate under the provisions of an Authorization for Special Issuance of a Medical Certificate (Authorization) to an applicant who has a medical condition that is disqualifying under Title 14 of the Code of Federal Regulations (14 CFR) part 67.</p> <p>Examiners may re-issue an airman medical certificate under the provisions of an Authorization, if the applicant provides the following:</p> <ul style="list-style-type: none"> • An Authorization granted by the FAA; • Certification only granted for open-angle-glaucoma and ocular hypertension; • The FAA Form 8500-14, Glaucoma Eye Evaluation Form is filled out by the treating eye specialist; and • A set of VF measurements is provided. <p>The Examiner must defer to the AMCD or Region if:</p> <ul style="list-style-type: none"> • The FAA Form 8500-14 Glaucoma Eye Evaluation Form demonstrates VA incompatible with the medical standards; or • There is a change in VF or adverse change in ocular pressure. <p>Aerospace Medical Dispositions Item 52. Color Vision</p> <p>An applicant does not meet the color vision standard if testing reveals:</p> <p>All Classes</p> <ul style="list-style-type: none"> • Seven or more errors on plates 1-15 of the AOC (1965 edition) pseudoisochromatic plates. • AOC-HRR (second edition): Any error in test plates 7-11. Because the first 4 plates in the test book are for demonstration only, test plate 7 is actually the eleventh plate in the book. (See instruction booklet.) • Seven or more errors on plates 1-15 of Dvorine pseudoisochromatic plates (second edition, 15 plates.) • Six or more errors on plates 1-11 of the concise 14-plate edition of the Ishihara pseudoisochromatic plates. Seven or more errors on plates 1-15 of the 24-plate edition of Ishihara pseudoisochromatic plates. Nine or more errors on plates 1-21 of the 38-plate edition of Ishihara pseudoisochromatic plates. | <p>With few exceptions, most railroads have no specific medical standards</p> | <p>Potentially disqualifying conditions listed in the Physical Evaluation Guidelines for Merchant Mariner's Documents and Licenses included any disease or constitutional defect which would result in gradual deterioration of performance of duties, sudden incapacitation or otherwise compromise shipboard safety, including required response in an emergency situation. Vision guidelines and standards include the following:</p> <p>VA:</p> <p>Deck Officer—the applicant must have vision correctable to 20/40 in each eye</p> <p>Engineer Officer—the applicant must have vision correctable to 20/50 in each eye</p> <p>In all cases, the uncorrected vision should be at least 20/800. A vision waiver may be granted if the applicant's corrected vision in the better eye is at least 20/40. Waivers will not be granted where any disease or condition exists that would cause a progressive or degenerative VA beyond the standards for a waiver. The applicant must have 100 degrees horizontal field of vision. All applicants with diabetes must submit documentation from their doctor that the diabetes is not affecting their eyesight.</p> <p><i>Color Vision:</i></p> <p>Deck Officer—the applicant must have the ability to recognize basic colors in order to recognize color-coded indicator lights, diagrams, piping systems, valve and wiring. Deck officers must also be able to recognize colored lights that are used on aids to navigation, such as navigation lights on vessels</p> <p>Engineer Officer—the applicant must have the ability to distinguish the colors red, green, blue and yellow</p> <p>Satisfactory completing of any of the following methods is acceptable proof of color sense:</p> <p>Pseudoisochromatic Plates (Dvorine, 2nd Edition: AOC: revised edition or AOC-HRR; Ishihara 16-, 24-, or 38 plate editions)</p> <p>Eldrige Green Color Perception Lantern</p> <p>Farnsworth Lantern</p> <p>Keystone Orthoscope</p> |

Vision and CMV Driver Safety

| Condition | FAA* (all classes of airmen) | Railroad† | Merchant Marine‡ |
|-----------|---|-----------|--|
| | <ul style="list-style-type: none"> Seven or more errors on plates 1-15 of the Richmond (1983 edition) pseudoisochromatic plates. Farnsworth Lantern test: An average of more than one error per series of nine color pairs in series 2 and 3. (See instruction booklet.) Any errors in the six plates of the Titmus Vision Tester, the Titmus II Vision Tester, the Titmus 2 Vision Tester, the OPTEC 2000 Vision Tester, the OPTEC 900 Vision Tester the Keystone Orthoscope, or Keystone Telebinocular. LKC Technologies, Inc., APT-5 Color Vision Tester. The letter must be correctly identified in at least two of the three presentations of each test condition. (See APT-5 screening chart for FAA-related testing in instruction booklet.) Certificate Limitation. If an applicant fails to meet the color vision standard as interpreted above but is otherwise qualified, the Examiner may issue a medical certificate bearing the limitation: NOT VALID FOR NIGHT FLYING OR BY COLOR SIGNAL CONTROL Special Issuance of Medical Certificates. An applicant who holds a medical certificate bearing a color vision limitation may request a signal light test. This request should be in writing and should be directed to the AMCD or RFS. If the applicant passes the signal light test, the FAA will issue a medical certificate without the color vision limitation and provide the applicant with a "letter of evidence." The signal light test may be given at any time during flight training. Color Vision Correcting Lens (e.g., X-Chrom). Such lens are unacceptable to the FAA as a means for correcting a pilot's color vision deficiencies. Yarn Test. Yarn tests are not acceptable methods of testing for the FAA medical certificate. <p>Aerospace Medical Dispositions Item 50. Distant Vision</p> <p>When corrective lenses are required to meet the standards, an appropriate limitation will be placed on the medical certificate. For example, when lenses are needed for distant vision only:</p> <p>HOLDER SHALL WEAR CORRECTIVE LENSES For multiple vision defects involving distant and/or intermediate and/or near vision when one set of monofocal lenses corrects for all, the limitation is:</p> <p>HOLDER SHALL WEAR CORRECTIVE LENSES For combined defective distant and near VA where multifocal lenses are required, the appropriate limitation is:</p> <p>HOLDER SHALL WEAR LENSES THAT CORRECT FOR DISTANT VISION AND POSSESS GLASSES THAT CORRECT FOR NEAR VISION For multiple vision defects involving distant, near, and intermediate VA when more than</p> | | <p>Keystone Telebinocular</p> <p>SAMCTT (School of Aviation Medicine Color Threshold Tester)</p> <p>Titmus Optical Vision Tester</p> <p>Williams Lantern</p> <p>Monocular vision: In the case of an applicant with loss of sight in one eye, medical information indicates that depth perception may be affected. The degree of loss or lack of depth perception varies among individuals. The degree of variability is affected by the length of time that the applicant has been sightless in the eye and by the applicant's ability to compensate. Applicants must be evaluated individually to determine that they adequately compensate for their lack of vision and that they can safely work in the maritime environment. Such applicants shall provide letters of recommendation from former employers or co-workers attesting to their ability to perform duties similar to the duties required by the license or document sought. In cases where an applicant is unable to provide such documentation, for example, where loss of sight has recently occurred, a waiver may be based on a thorough medical report from an ophthalmologist.</p> <p>This report must substantiate that the applicant has compensated for the loss of depth perception and peripheral vision. All cases involving monocular vision must be forwarded to the National Maritime Center (NMC-4C) for resolution.</p> <p>Persons requiring the use of glasses or contact lens to perform duties will be required to have a spare pair conveniently available on board the ship. Any need to wear visual aids to meet the required standards will be recorded on each license or documented issued.</p> <p style="text-align: center;">GENERAL INFORMATION FOR MERCHANT MARINER'S DOCUMENTS, LICENSES, AND STCW CERTIFICATES</p> <p>REQUIRED MEDICAL INFORMATION</p> <p>A medical waiver from the Officer In Charge, Marine Inspection (OCMI) is required whenever a Merchant Mariner Physical Examination Report (CG-719K) reveals a medical condition that may affect your ability to perform the duties of the license or MMD applied for. Please provide a signed medical history statement from your doctor under his letterhead that includes the information below.</p> <p>STANDARD INFORMATION REQUIRED</p> |

Vision and CMV Driver Safety

| Condition | FAA* (all classes of airmen) | Railroad† | Merchant Marine‡ |
|-----------|---|-----------|--|
| | <p>one set of lenses is required to correct for all vision defects, the appropriate limitation is: HOLDER SHALL WEAR LENSES THAT CORRECT FOR DISTANT VISION AND POSSESS GLASSES THAT CORRECT FOR NEAR AND INTERMEDIATE VISION</p> <p>An applicant who fails to meet vision standards and has no SODA that covers the extent of the VA defect found on examination may obtain further FAA consideration for grant of an Authorization under the special issuance section of part 67 (14 CFR 67.401) for medical certification by submitting a report of an eye evaluation. The Examiner can help to expedite the review procedure by forwarding a copy of FAA Form 8500-7, Report of Eye Evaluation that has been completed by an eye specialist (optometrist or ophthalmologist).</p> <p>Applicants who do not meet the visual standards should be referred to a specialist for evaluation. Applicants with VA or ocular muscle balance problems may be referred to an eye specialist of the applicant's choice. The FAA Form 8500-7, Report of Eye Evaluation, should be provided to the specialist by the Examiner.</p> <p>Amblyopia. In amblyopia ex anopsia, the VA of one eye is decreased without presence of organic eye disease, usually because of strabismus or anisometropia in childhood. In amblyopia ex anopsia, the VA loss is simply recorded in Item 50 of FAA Form 8500-8, and visual standards are applied as usual. If the standards are not met, a report of eye evaluation, FAA Form 8500-7, should be submitted for consideration.</p> <p>²⁴ In obtaining special eye evaluations in respect to the airman medical certification program or the air traffic controller health program, reports from an eye specialist are acceptable when the condition being evaluated relates to a determination of VA, refractive error, or mechanical function of the eye. The FAA Form 8500-7, Report of Eye Evaluation, is a form that is designed for use by either optometrists or ophthalmologists.</p> <p>Any applicant eligible for a medical certificate through special issuance under these guidelines shall pass a MFT, which may be arranged through the appropriate agency medical authority. While waiting to complete a MFT, an applicant who is otherwise qualified for certification may be issued a medical certificate, which must contain the limitation:</p> <p>Guide for Aviation Medical Examiners Decision Considerations</p> <p>Disease Protocols Binocular Multifocal and Accommodating Devices</p> <p>This Protocol establishes the authority for the Examiner to issue an airman medical certificate to binocular applicants using multifocal or accommodating ophthalmic devices.</p> <p>Devices acceptable for aviation-related duties must be FDA approved and include:</p> <p style="padding-left: 40px;">Intraocular Lenses (multifocal or accommodating intraocular lens implants) Bifocal/Multifocal contact lenses</p> | | <ol style="list-style-type: none"> 1. The date on which the diagnosis was made. 2. A complete list of medications (current and past), including dosage and possible side effects. 3. Any limitations in the performance of your professional duties. 4. A prognosis of the potential deterioration or correction of your condition. <p>Medical conditions include:</p> <p>Vision problem:</p> <p>Results of a recent (within one year) vision exam is required that includes both uncorrected and corrected vision, field of vision, and color vision.</p> |

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| Condition | FAA* (all classes of airmen) | Railroad† | Merchant Marine‡ |
|-----------|--|-----------|------------------|
| | <p>Examiners may issue as outlined below:</p> <p>Adaptation period before certification: Postoperative period is 3 months for cataract surgery</p> <p>Multifocal (including bifocal) contact lenses requires at least 1 month</p> <p>Must provide a report to include the FAA Form 8500-Z, Report of Eye Evaluation, from the operating surgeon or the treating eye specialist. This report must attest to stable VA and refractive error, absence of significant side effects/complications, need of medications, and freedom from any glare, flares or other visual phenomena that could affect visual performance and impact aviation safety</p> <p>The following visual standards, as required for each class, must be met for each eye:</p> <p>Distant: First- and Second-Class 20/20 or better in each eye separately, with or without correction Third-Class 20/40 or better in each eye separately, with or without correction</p> <p>Near: All Classes 20/40 or better in each eye separately (Snellen equivalent), with or without correction, as measured at 16 inches</p> <p>Intermediate: First- and Second-Class 20/40 or better in each eye separately (Snellen equivalent), with or without correction at age 50 and over, as measured at 32 inches Third-Class No requirement</p> <p>Note: The above does not change the current certification policy on the use of monofocal non-accommodating intraocular lenses.</p> | | |

* http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/special_iss/all_classes/glaucoma/;
http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/exam_tech/item52/amd/;
http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/exam_tech/item50/amd/;
http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/dec_cons/disease_prot/binocular/.

† <http://www.fra.dot.gov/downloads/safety/hazmatch4.pdf>.

‡ http://www.uscg.mil/hq/g-m/nvic/2_98/n2-98.pdf.

AMCD – Aerospace Medical Certification Division.

AME – Aviation medical examiner.

AOC-HRR – American Optical Company–Hardy, Rand and Rittler (color vision test).

FDA – Food and Drug Administration.

MFT – Medical flight test.

RFS – Regional flight surgeon.

SODA – Statement of demonstrated ability.

Vision Guidelines and Medical Standards from Other Countries

Regulatory standards and guidance pertaining to vision and CMV driving in the European Union, Canada, Israel, Australia, United Kingdom, New Zealand, India, South Africa, Ireland, and Sweden are presented in Table 7.

Distinct worldwide policies by category include the following:

- **Color Vision**: A person is unfit to drive with color blindness in *India*.
- **Diplopia**: Individuals may drive if diplopia can be completely corrected with a patch or prisms in *Canada*.
- **Glare**: CMV drivers may be limited to daytime driving in *New Zealand* and *Canada*.
- **Night Driving**: CMV drivers are unfit to drive in *Sweden* and *India*.
- **Stereo Vision**: *Canadian* officials trust that individuals, even those who have lost sight in one eye, can learn to judge distance.
- **VA**: In *Israel*, drivers must have a minimum combined acuity of 6/12.
- **VF**: *European Union* member states dictate *normal* VFs should be present in both eyes.

Table 7. Vision Disorders (Guidelines and Medical Standards from Other Countries)

| Country | Reference | Color Vision | Diplopia | Glare | Night Driving | Stereovision and Depth Perception | VA | VF | General |
|----------------|---|---------------------------|---|---------------------------|--|-----------------------------------|---|--|--|
| European Union | <p>European Commission on Transport and Road Safety, Annex III to Directive 91/439/EEC; Council Directive 96/47/EC July 1996 amending Directive 91/439/EEC; IP/06/381 Member States Agree on the European Driving License 27 March 2006</p> <ul style="list-style-type: none"> ▪ Countries involved include: Austria*, Finland*, Sweden*, Belgium, Ireland, Denmark, Italy, Germany, Luxembourg, Greece, The Netherlands, Spain, Portugal, France and The United Kingdom (29 July 1991). ▪ Member states had to apply directive 91/439/EEC by 1 July 1996. ▪ European member states have to stay within a Council directive: they can be more restrictive, but not more liberal. | No requirements included. | Driving licenses shall not be issued to or renewed for applications or drivers suffering from diplopia. | No requirements included. | No requirements included. Please see recommended new standards by the Eyesight Working Group. | | <p>Must have VA, with corrective lenses if necessary, of at least 0,8 in the better eye and at least 0,5 in the worse eye. If corrective lenses are used to attain the values of 0,8 and 0,5 the uncorrected acuity in each eye must reach 0,05, or else the minimum acuity (0,8 and 0,5) must be achieved either by means of glasses with power not exceeding plus or minus four dioptres or with the aid of contact lenses (uncorrected vision = 0,05). The correction must be well tolerated.</p> <p>Please see recommended new standards by the Eyesight Working Group.</p> | <p>Driving licenses shall not be issued to or renewed for applications or drivers without a normal binocular field of vision.</p> <p>Please see recommended new standards by the Eyesight Working Group.</p> | <p>All applicants for a driving license shall undergo an appropriate investigation to ensure that they have adequate VA for driving power-driven vehicles. Where there is reason to doubt that the applicant's vision is inadequate, he shall be examined by a competent medical authority. At this examination, attention shall be paid to the following in particular: VA, field of vision, twilight vision and progressive eye diseases.</p> <p>Under the current directive, it is possible to offer a restricted license to drivers. Codes 05.01 to 05.04 restrict driving respectively to day-time, a certain radius, without passengers or with a speed limit. Additionally, the validity of the license may be time-limited. There is no guidance as to how these codes or limitations should be applied.</p> |

Vision and CMV Driver Safety

| Country | Reference | Color Vision | Diplopia | Glare | Night Driving | Stereovision and Depth Perception | VA | VF | General |
|--------------|--|---|--|--|--|--|--|---|---------|
| Canada** | Determining medical fitness to Operate Motor Vehicles. CMA (Canadian Medical Association) Driver's Guide 7 th edition. (2006) | No standards exist however all drivers should be able to discriminate among traffic lights. | Within the central 40° (i.e., 20° to the left, right, above and below fixation) of primary gaze is incompatible with safe driving for all classes of license. Individuals with uncorrected diplopia within the central 40° of primary gaze should be referred for additional assessment. An individual may be eligible to drive if the diplopia can be completely corrected with a patch or prisms. An adjustment period of 3 months is recommended prior to resuming driving. | No standards exist however partial loss of the ability to recover rapidly from exposure to glaring headlights may at times justify limiting driving to daylight hours. | No standards exist however partial loss of the ability to adapt to decreased illumination may at times justify limiting driving to daylight hours. | Most individuals can learn to judge distance even those who have lost sight in one eye. | Not less than 20/30(6/9) with both eyes open and examined together. Worse eye not less than 20/400 (6/120). Several jurisdictions require an acuity higher than 20/400 (6/120) in the worse eye. Quebec has a standard of 20/70 (6/21) and Ontario's is 20/100 (6/30). | 150° continuous along the horizontal meridian and 20° continuous above and below fixation with both eyes open and examined together. | |
| Israel | Ministry of Transportation Information Department Spokesman's Office Everything You Wanted To Know About Driver's and Vehicle Licenses www.mot.gov.il | | | | | | Minimum combined acuity of 6/12. | | |
| Australia*** | Assessing Fitness to Drive (For Commercial and Private Vehicle Drivers) Medical Standards for Licensing and Clinical Management Guidelines. Austroads and NTC (National Transport Commission) Australia (2006) | | | | | No specific standards. (see 23.2.6) 23.2.6. Dark Adaptation Health professionals may wish to recommend restrictions on the driver licenses of individuals who appear to meet the visual criteria in the clinical setting | The criteria for an unconditional license are not met: <ul style="list-style-type: none"> If the person's VA is worse than 6/9 in the better eye; OR If the person's VA is worse than 6/18 in either eye. A conditional license may be granted by the Driver Licensing Authority, taking into account the opinion of | The criteria for an unconditional license are not met: <ul style="list-style-type: none"> If the person has any VF defect. A conditional license may be granted by the Driver Licensing Authority, taking into account the opinion of an ophthalmologist or optometrist, and the nature of the driving task, and subject to | |

Vision and CMV Driver Safety

| Country | Reference | Color Vision | Diplopia | Glare | Night Driving | Stereovision and Depth Perception | VA | VF | General |
|---------|-----------|--------------|----------|-------|---------------|---|--|--|---------|
| | | | | | | <p>but may, in certain environments, have extreme difficulty. Examples of such restrictions might be 'daylight driving only'.</p> | <p>an ophthalmologist or optometrist or GP, and the nature of the driving task, and subject to periodic review:</p> <ul style="list-style-type: none"> • If the standard is met with corrective lenses; and • After consideration of the nature of any underlying disorder. (see 23.2.5) <p>A conditional license may be granted by the Driver Licensing Authority, taking into account the opinion of an ophthalmologist or optometrist, and the nature of the driving task, and subject to periodic review:</p> <ul style="list-style-type: none"> • If the person's vision is worse than 6/18 in the worse eye, provided that the VA in the better eye is 6/9 or better, and • After consideration of the nature of any underlying disorder. <p>23.3.5 Special consideration. There may be a degree of flexibility allowed at the optometrist's or ophthalmologist's discretion for individuals who barely meet visual standards but who are otherwise alert, have normal reaction times and good muscular</p> | <p>periodic review:</p> <ul style="list-style-type: none"> • If the binocular VF has an extent of at least 140 degrees within 10 degrees above and below the horizontal midline; and • If the person has no significant VF loss (scotoma, hemianopia, quadrantanopia) that is likely to impede driving performance; and • After consideration of the nature of any underlying disorder. | |

Vision and CMV Driver Safety

| Country | Reference | Color Vision | Diplopia | Glare | Night Driving | Stereovision and Depth Perception | VA | VF | General |
|-----------------|--|---|--|---|--|-----------------------------------|---|--|---------|
| | | | | | | | coordination. In such cases the Driver Licensing Authority may consider a conditional license. | | |
| United Kingdom† | At a glance Guide to the current Medical Standards of Fitness to Drive (for Medical Practitioners) Issued by Drivers Medical Group. DVLA, Swansea (February 2007) | If color blind, you need not notify DVLA. Driving may continue with no restriction on license. | Permanent refusal or revocation if insuperable diplopia. Patching is not acceptable. | | Night blindness: Group 2 acuity and field standards must be met. Cases will be considered on an individual basis. | | New applicants are barred in law if the VA, using corrective lenses if necessary, is worse than 6/9 in the better eye or 6/12 in the other eye. Also, the uncorrected acuity in the eye must be at least 3/60. Note: If obtained first Group 2 license between 02.03.1992 and 31.12.1996 uncorrected VA may be worse than 3/60 in one eye. | Normal binocular field of vision is required, i.e., any area of defect in a single eye is totally compensated for by the field of the other eye. | |
| New Zealand†† | Medical aspects of fitness to drive: A Guide for Medical Practitioners. Land Transport Safety Authority. (May 2002) | Color Blindness: Generally, no driving restrictions. However, individuals with color vision problems should be warned of the potential hazards. | Generally, considered unfit to drive. In exceptional circumstances, the Director or the Director's delegate may consider granting a license if application is supported by an optometrist or ophthalmologist report. | Practitioners should note that glare may be disabling in some instances, e.g., where a cataract is present, following some refractive surgical procedures, and for some contact lens wearers. In such cases, practitioners should take appropriate action which may include recommending the condition of daytime driving only. | Night blindness: A license is unlikely to be granted. In exceptional circumstances, the Director or the Director's delegate may consider granting a license if application is supported by an optometrist or ophthalmologist report. | | Minimum combined VA of 6/9, with or without correcting lenses. If the worse eye is less than 6/18 but better than 6/60 the applicant is to be classified as having sub-standard vision in one eye. If an individual does not meet this VA standard, they may apply to the Director of Land Transport Safety Authority for an exemption from the standards but a supporting medical or optometric assessment would be needed. | For all license classes, the minimum standard is a binocular horizontal field of 140 degrees. There should be no significant pathological field defect encroaching within 20 degrees of the point of fixation. | |

Vision and CMV Driver Safety

| Country | Reference | Color Vision | Diplopia | Glare | Night Driving | Stereovision and Depth Perception | VA | VF | General |
|---------------------|--|---|--|-------|---|-----------------------------------|---|---|---|
| India | Delhi Traffic Police New Delhi, India Driver's Check www.delhitrafficpolice.nic.in | A person is unfit to drive if he has color blindness. | | | A person is unfit to drive if he has night blindness. | | A person is unfit to drive if he has a visual impairment. | | Pre-existing vision disturbances can be the grounds to reject a license to the commercial vehicles. |
| South Africa | Regulation 102 (replacing Regulation 241) www.saoa.co.za/projects/driver.php | | | | | | Minimum VA, with or without refractive correction, of 6/9 (20/30) for each eye. | Minimum VF of 70 degrees temporal in respect of each eye, with or without refractive correction. | |
| Ireland | Irish Statute Book S.I. No. 340/1986 – Road Traffic (Licensing of Drivers) (Amendment) (No.2) Regulations, 1986 Eighth Schedule | | Fitness to drive shall not be certified if, on examination, it is found that the applicant has diplopia. | | | | Binocular vision with a VA (with corrective lenses, where necessary) of at least 0.75 (6/8) in the better eye and of at least 0.5 (6/12) in the worse eye; if corrective lenses are used, the uncorrected vision must be not less than 0.1 (6.60) and the correction must be tolerated. | Fitness to drive shall not be certified if, on examination, it is found that the applicant has a restricted field of vision. | |
| Sweden [†] | Swedish National Road Administration Statute Book Effective 1/1/99 | | There must be no double vision when looking in any direction. | | Total night blindness or any other serious limitation in vision where lighting is reduced constitutes grounds for denial of possession. | | With or without correction, be at least 0.8 in the better eye and at least 0.5 in the weaker eye. In the case of nystagmus, the level of VA shall be attained when moving the eyes 30° to the left and right while continuing to face straight ahead. If the acuity specified cannot be attained without corrective glass, neither of the lenses is to have a strength exceeding eight dioptres in the meridian with the | Normal in both eyes. A visual defect in one eye does not constitute grounds for denial of possession if the defect is limited in extent and depth and if the reduction is totally compensated by the other eye. | |

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| Country | Reference | Color Vision | Diplopia | Glare | Night Driving | Stereovision and Depth Perception | VA | VF | General |
|---------|-----------|--------------|----------|-------|---------------|-----------------------------------|--|----|---------|
| | | | | | | | highest refraction. This does not apply if vision is corrected with contact lenses that can be used without inconvenience. | | |

* added in Council Directive 96/47/EC July 1996

** Source of information for Canada: http://www.cma.ca/index.cfm/ci_id/18223/la_id/1.htm

*** Source of information for Australia: <http://www.austroads.com.au/aftd/index.html>

† Source of information for the United Kingdom: <http://www.dvla.gov.uk/medical.aspx?keywords=medical>

†† Source of information for New Zealand: <http://www.landtransport.govt.nz/licensing/docs/ltsa-medical-aspects.pdf>

‡ Source of information for Sweden: <http://www.vv.se/filer/4796/9889eng000915.pdf>

Recommended Revisions to European Union Hearing Standards

Fitness guidelines for CMV drivers in the European Union are set forth in Annex III of Council Directive 91/439/EEC. The Eyesight Working Group was established in March 2004 by the European License Driving Committee with the intention of providing updated recommendations to the visual guidelines proposed in the Annex. In 2005, a report titled “New standards for the visual functions of drivers” provided the recommendations listed in Table 8.

Table 8. Recommendations for New Standards for the Visual Functions of Drivers

| Topic | Current EU Standard | Problem | Recommendation |
|--------------|---|--|--|
| VA | At least 0.8 in the best eye, 0.5 in the fellow eye | 1) The VA requirement for the fellow eye is insufficiently justified. 2) The cut-off value of 0.8 in the better eye is arbitrary, although we consider it reasonable in Group 2 drivers to expect that the VA is normal or near normal. | 1) Change the VA in the fellow eye from 0.5 to 0.1. 2) Recommend no change to the standard of 0.8 in the better eye. |
| VFs | Normal VFs should be present in both eyes | The extent of the VF is dependent upon the shape of one’s face, thus a ‘normal’ VF for one person would not be similar to another. | Formulate the VF requirements in terms of numbers (e.g., horizontal VF should be 160 degrees). The extension should be less than 70 degrees left and right and 30 degrees up and down. No defects should be present within central 30 degrees (not even the Physiologic Blind Spot). |
| Night Vision | No standards are included | Night vision may provide useful information about driving capacity. | Future introduction of requirements for twilight vision should be made possible and anticipated, after proper research has been performed. It is reasonable to expect unimpaired contrast sensitivity in a Group 2 driver. |

Regulatory Vision Standards for the United States

Individuals operating a CMV for the purpose of intrastate commerce are subject to federal vision regulatory guidelines set forth in CFR Part 391.41 (b)(10). Intrastate vision guidelines (Table 9) are established for those individuals driving within state borders and whose cargo remains within state lines.

Distinct policies set forth by individual states include the following:

- **Wisconsin:** If a person has uncorrected or corrected VA of less than 20/60 in each eye but 20/100 or better in one eye and can demonstrate adequate compensation, a *restricted license* may be issued.
- **Kentucky:** If a commercial driver has a distance VA of 20/60 (Snellen) or better with corrective lenses in one eye or both eyes, he/she may be considered for a *medical waiver*.
- **Maryland, Texas, and Utah:** Of only five states three incorporate *color vision* in intrastate guidelines.
- **Minnesota:** To obtain a waiver, an applicant must have a VF of 105 degrees or greater in the horizontal diameter.

- **Massachusetts:** If an individual has a combined horizontal peripheral *field of vision of not less than 120 degrees*, provided they also have a distance VA of 20/40 (Snellen) in either eye, with or without corrective lenses, and the ability to distinguish colors, they may be issued a vision waiver.
- **Utah:** Intrastate drivers are profiled by their functional ability to drive. An individual profiled at level 2 or 3 qualifies for intrastate travel.

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Table 9. Medical Standards for Vision Disorders for CMV Drivers by U.S. State

| State | Reference | Color Vision | Diplopia | VA | VF | General |
|---------|--|---|----------|--|---|---|
| Alabama | Alabama Department of Public Safety Motor Carrier Safety Unit/FAQ www.dps.state.al.us/public/highwaypatrol | | | | | Please refer to Federal Regulations 391.45 for persons who must be medically examined and certified. Please refer to Federal Regulations 391.43 for guidelines on obtaining a medical card. |
| Alaska | Title 2 Administration Chapter 90 Driver Licensing and Safety Responsibility Article 6 Standards for Licensing of Drivers 2 AAC.90.440 Medical Standards | The department will not issue A commercial driver license (CDL) to a person unable to meet the color vision standards defined by 49 CFR 391, Subpart E, revised as of October 1, 2005 | | A CDL will not be issued to a person whose best corrections in both eyes together is less than 20/40 | A CDL will not be issued to a person wearing telescopic or compound lenses whose field of vision is less than 70% | The department will not issue a CDL to a person with a progressive eye disease or condition |
| Arizona | Arizona State Legislature Chapter 8 Motor Vehicle Driver Licensing Article 5 Commercial Driver Licensing 28-3223. Original applicant; requirements; expiration; renewal examination | | | | | A. In addition to the requirements applicable to all driver license applicants, an original applicant for a class A, B or C license is subject to the following requirements: 1. The applicant shall submit evidence of compliance with medical standards and requirements that the department adopts by rule. |
| | Article 4 General Licensing Provisions 28-3159. Restricted licenses | | | | | A. With good cause, the department may issue the following restricted driver license: 2. A class A, B or C driver license that restricts the driver from operating: (b) a vehicle in interstate commerce, if the applicant is not subject to 49 Code of Regulations part 391 |
| | Arizona Driver License Manual and Customer Service Guide Motor Vehicle Division D.O.T. Medical Examination Report Commercial Driver Fitness Determination | | | At least 20/40 acuity (Snellen) in each eye with or without correction. | At least 70° peripheral in horizontal meridian measured in each eye. | |

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| State | Reference | Color Vision | Diplopia | VA | VF | General |
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| Arkansas | Arkansas Code Title 27. Transportation Chapter 16. Driver's Licenses Generally 27-16.704. Examinations of applicants | | | Minimum uncorrected 20/40 for unrestricted and minimum corrected of 20/50 for a restricted license | At least 140° for a person with two functional eyes and at least 105° for a person with one functional eye | |
| California | Department of Motor Vehicles Medical Report for Commercial Driver License (CDL) www.dmv.ca.gov/commercial/commercial.htm | | | | | A medical form completed by a U.S. licensed doctor of medicine (M.D.), osteopathy (D.O.), licensed physician assistant (P.A.), a nurse practitioner (N.P.), advance practice nurse, or chiropractor who is clinically competent to perform the medical examination, must be given to the DMV with your original application for a driver license or instruction permit. The medical form must be dated within the last 2 years and on a form approved by the Federal Highway Administration, the Federal Aviation Administration, DMV, or on the DMV Report of Medical Examination Report form DL 51 (examiners asked to refer to Federal Regulations 49 C.F.R. 391.41). |
| Colorado | Revised statutes | | | | | No mention of medical qualifications |
| | Division of Motor Vehicles Motor Carrier Services/Forms DOT Medical Form (CDL Drivers) | | | | | Medical Examination Report for Commercial Driver Fitness Determination. No additional explanation is listed. |
| Connecticut | Department of Motor Vehicles www.ct.gov Obtaining a Commercial Driver's License/Documents required when appearing for CDL Knowledge testing | | | | | Physical examination by a physician dated within the last two years, reported on an Examination to Determine Physical Condition of Driver (form R-323) or a U.S. D.O.T. Medical Examiner's Physical Examination Form CO730, which meets D.O.T. requirements in 49 C.F.R. 391.41-391.49. |
| | Connecticut Code Title 14 – Motor Vehicles Chapter 246/Section 14-44E | | | | | Sec 14-44E. Limitations on issuance of commercial driver's license. Qualification standards. Waiver of skills test. Requirements for license endorsement to operate vehicle transporting hazardous materials. Commercial driver's instruction permit. (b) The commissioner shall not issue a commercial driver's license to any person who has a physical or psychobehavioral impairment that affects such person's ability to operate a commercial motor vehicle safely. In determining whether to issue a commercial driver's license in any individual case, the commissioner shall apply the standards set forth in |

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| | | | | | | 49 C.F.R 391.41, as amended, unless it is established that the person will operate such vehicle only in this state, in which case the commissioner shall apply the standards set forth in this chapter and in regulations adopted thereunder. |
| Delaware | Delaware Code Title 21 Motor Vehicles Chapter 47. Motor Carrier Safety-Responsibility | | | | | 4702. Adoption of federal requirements – In general. (a) The State hereby adopts the following parts of the Code of Federal Regulations, Title 49, Chapter III, Subchapter B, except as modified by this chapter:.. Part 391. adopted pursuant to the Transportation Article of the United States Code (49 U.S.C. §101 et seq.). |
| | Chapter 220 Formerly Bill No. 156 As Amended by Senate Amendment No.1 | | | | | Section 1. Amend Section 4704(b) [Effective September 30,2005] of Title 21 of the Delaware Code by deleting said subsection in its entirety and substituting in lieu thereof a new subsection (b) to read as follows: (b) Intra-State Only Restricted Commercial Driver License Medical Waiver Program. Persons who are not physically qualified to drive a commercial motor vehicle per 49 C.F.R. Section 391.41 may apply for an intra-State only restricted commercial driver license waiver provided they are otherwise qualified to drive a motor vehicle, other than a motor vehicle which requires endorsements to transport passengers or hazardous materials, and meet the other provisions of this subsection, Title 21 and the Federal Motor Carrier Regulations....The Division will establish policy to administer the CDL medical waiver program. The applicant must provide recent physical examinations signed by the driver's primary physician and, if appropriate, from a medical specialist. The Division may require the applicant to successfully complete a training course and evaluation by a physical rehabilitation center. The Division may refer individual applications to the Medical Advisory Board for their advice concerning the applicant's ability to safely operate motor vehicles weighing more than 26,000 pounds...A "K" restriction will be added to the CDL driver license once a medical waiver is granted. The CDL medical waiver expires on the CDL expiration date or upon a date determined by the Division. Once an applicant is initially granted a CDL medical waiver, the Division may issue a 90-day temporary CDL medical waiver pending the results of medical or rehabilitation examinations. Section 2. Amend Section 4704 [Effective September 30, 2005] of Title 21 of the Delaware Code by adding a new subsection (c) to read as follows: "State, county and local government |

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| | | | | | | employees who hold a commercial driver license and operate commercial motor vehicles as defined by §2603(6) as part of their official duties for the State or any political subdivision therein, shall meet the Federal physical qualifications and examination requirements found in 49 C.F.R. Part 391, Subsection E unless approved by an intra-State only restricted commercial driver license in accordance with Section 4704(b). |
| | Commercial Driver's Manual Delaware – Version 2.0 | | | | | Basic CDL License Requirements: Able to obtain Medical certification under the Federal Motor Carrier Safety Regulations (Part 391.41 – Physical Qualifications for Drivers) If you do not meet part 391.41 Physical Qualifications for Drivers, you may be able to obtain a Delaware intrastate only restricted CDL medical waiver, if otherwise qualified to drive a motor vehicle (excluding transporting passengers or hazardous materials) |
| District of Columbia | District of Columbia Municipal Regulations Title 18 Vehicle and Traffic Chapter 13: Classification and Issuance of Commercial Driver's Licenses www.dmv.dc.gov | | | | | 1327.4 A licensed ophthalmologist or optometrist may perform so much of the medical examination as pertains to VA, field of vision, and the ability to recognize colors as specified in §1327.2 (as pertains to 49 CFR 391) |
| Florida | 2006 Florida Statutes Title XXIII Motor Vehicles Chapter 322 Drivers' Licenses | | | | | 322.12 Examination of applicants. (4) The examination for an applicant for a CDL shall include a test of the applicant's eyesight given by a driver's license examiner designated by the department or by a licensed ophthalmologist, optometrist, physician... |
| Georgia | Georgia Department of Driver Services Commercial Driver's License Rules Chapter 1 Commercial Driver's Licensing Requirements www.dds.ga.gov | Ability to recognize the colors of traffic signals and devices showing standard red, green, and amber | | At least 20/40 in each eye without corrective lenses or VA separately corrected to 20/40 or better with corrective lenses; distant binocular acuity of at least 20/40 in both eyes | At least 70 degrees in the horizontal meridian in each eye | 1-1-.04 Minimum Physical Requirements Required to Obtain a Commercial Driver's License. Amended. (2) Applicants for a CDL shall have a distant VA of at least 20/40 in each eye without corrective lenses or VA separately corrected to 20/40 or better with corrective lenses; distant binocular acuity of at least 20/40 in both eyes; or without corrective lenses, field of vision of at least 70 degrees in the horizontal meridian in each eye; and the ability to recognize the colors of traffic signals and devices showing standard red, green, and amber. |

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| | | | | | | <p>1-1-.05 Exemptions from Medical Requirements.</p> <p>Operators of city, county, state or federal vehicles are exempt from the medical requirements.</p> <p>Drivers who operate on an occasional basis receive no compensation and are not involved in commercial enterprise.</p> |
| | <p>Georgia Code – Motor Vehicles & Traffic</p> <p>Title 40, Section 40-5-147</p> | | | | | <p>(2) an applicant for the commercial driver's instruction permit must pass the vision test for the type of vehicle he intends to operate</p> |
| | <p>Georgia Department of Driver Services</p> <p>Application for Georgia Commercial Driver's License</p> | | | | | <p>Part 4. Medical Certification</p> <p>Medical Qualifications: Unless specifically exempted, you must possess a valid medical examiner's certificate in order to operate a commercial motor vehicle (49 CFR § 391.41). Government employees (e.g., federal, state, county, or city employees) while operating government owned vehicles are exempt from this medical requirement</p> |
| | <p>Georgia Department of Driver Services</p> <p>Forms and Manuals</p> | | | | | <p>Medical Examination Report for Commercial Driver Fitness Determination with accompanying 49 CFR 391.41 available</p> |
| Hawaii | <p>Hawaii Revised Statutes</p> <p>Title 17 Motor and other Vehicles</p> <p>Chapter 286 Highway Safety</p> <p>Part XIII Commercial Driver Licensing</p> | | | | | <p>§ 286-236 Commercial driver's license qualification standards. (a) No person shall be issued a commercial driver's license unless that person meets the qualification standards of 49 Code of Federal Regulations, Part 391, Subparts B and E..... (e) A commercial driver's instruction permit may be issued to an individual who holds a valid driver's license, meets the qualification standards of 49 Code of Federal Regulations, Part 391, Subparts B and E, and has passed the written tests required for the desired class of a commercial driver's license.</p> |
| Idaho | <p>Commercial Driver's License Manual</p> <p>Idaho 2007</p> <p>Itd.idaho.gov/dmv/driverservices/cdl_manual</p> | | | | | <p>1.4 How to Get a CDL</p> <p>You will be asked if you are subject to and in compliance with the requirements of Part 391 of the Federal Motor Carrier Safety Regulations (Qualifications of Drivers). These include the DOT medical card requirements. Information regarding who is subject to these requirements may be found in Section 13 of this manual.</p> <p>Section 13: Forms/General Qualifications of Driver Requirements</p> <p>Unless exempt, every person who operates a commercial motor vehicle in interstate, foreign or intrastate commerce is subject to</p> |

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| State | Reference | Color Vision | Diplopia | VA | VF | General |
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| | | | | | | <p>the Qualifications of Driver Requirements.</p> <p>(Refer to Federal Motor Carrier Safety Regulations, 49 CFR 391.11 for exact wording)</p> <p>B. An individual is qualified to drive a commercial vehicle if he/she:</p> <p>4. Carries a current medical examiner's certificate (DOT medical card) stating that he/she is physically qualified to drive a commercial vehicle. (391 Subpart E)</p> |
| | <p>Idaho Administrative Code IDAPA 11.13.01 Motor Carrier Rules</p> | | | | | <p>019. Carrier Safety Requirements</p> <p>01. Adoption of Federal Regulations. Adoption of Federal Regulations 49 CFR Parts...and 390 through 399 are hereby adopted by reference. Whenever any one (1) of these federal regulations (except Section 391.11(b)(1) exempts intrastate carriers from any of their requirements, this Rule at IDAPA 11.13.01, "The Motor Carrier Rules", Section 019, removes that exemption and subjects the intrastate carrier to the same requirements.</p> <p>a. All interstate and foreign carriers and intrastate carriers, except those carriers listed in Subsection 019.01.b., subject to the safety authority of the Idaho State Police while operating in Idaho that transport passengers or property, must comply with 49 CFR Parts...and 390 through 399, and the law and rules of the state of Idaho (except 391.11(b)(1) for intrastate carriers).</p> <p>b. Intrastate carriers operating commercial motor vehicles transporting property with a GVW, GVWR, GCW or GCWR greater than ten thousand (10,000) pounds and up to twenty-six thousand (26,000) pounds, subject to the authority of the Idaho State Police, must comply with 49 CFR part 390 Subpart A, Part 391.15, Parts 392, 393, and Part 396.1, 396.3(a), (a)(1), and (a)(2), and 396.5 through 396.9 and the law and rules of the state of Idaho.</p> |
| Illinois | <p>Illinois Administrative Code Title 92 Transportation Chapter 1: Department of Transportation Subchapter D: Motor Carrier Safety Regulations Part 391: Qualification of Drivers</p> | | | | | <p>Section 391.2000 Incorporation by Reference of 49 CFR 391</p> <p>(c) The following interpretations of, additions to and deletions from 49 CFR 391 shall apply for purposes of this Part.</p> <p>3) Paragraph (b)(10) (minimum VA) of 49 CFR 391.41 shall not apply to the driver of a commercial motor vehicle with a gross vehicle weight rating or gross combination weight of over 12,000 lbs., used in the intrastate transportation of property who immediately prior to July 29, 1986 was eligible and licensed to operate a motor vehicle subject to the Illinois Motor Carrier</p> |

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| State | Reference | Color Vision | Diplopia | VA | VF | General |
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| | | | | | | <p>Safety Regulations (IMCSR) and was engaged in operating such vehicles, and who was disqualified on July 29, 1986 by the adoption of 49 CFR 391 by reason of the application of paragraph (b)(10) of 49 CFR 391.41 with respect to a physical condition existing at that time unless such driver has a record of accidents which would indicate a lack of ability to operate a motor vehicle in a safe manner (Section 18b-105 of the Law)</p> <p>4) Paragraph (b)(10) of 49 CFR 391.41 shall not apply to a commercial motor vehicle which either has a gross vehicle weight rating (GVWR) or gross combination weight rating (GCWR) of between 10,000 and 12,001 pounds; or which has a GVWR or GCWR of less than 12,001 pounds and transports hazardous materials in a quantity requiring placarding under the Illinois Hazardous Materials Transportation Act. The vehicle must be used in intrastate transportation. The driver must have been eligible and licensed to operate a motor vehicle subject to the IMCSR and engaged in operating such vehicle immediately prior to January 17, 1992. The driver must have been disqualified on January 17, 1992 by the adoption of Public Act 87-829 which made the IMCSR applicable to vehicles described above. The reason for disqualification must have been the application of paragraph (b)(10) of 49 CFR 391.41 with respect to a physical condition existing at that time. This exception does not apply to any driver who has a record of accidents which would indicate a lack of ability to operate a motor vehicle in a safe manner.</p> |
| | Illinois Commercial Driver's License Study Guide cyberdriveillinois.com | | | | | Federal Motor Carrier Safety Regulations are listed in Table C, pgs 131-132 |
| Indiana | Indiana Administrative Code Title 140 Article 7 Driver's License Division | | | | | <p>Rule 3. Commercial Driver's Licensing</p> <p>140 IAC 7-3-1 Definitions</p> <p>(h) "VA screening" means an eye screening given by the bureau to applicants for a CDL which must be passed in accordance with the standards utilized by the bureau for other types of driver's licenses.</p> <p>140 IAC 7-3-5 Learner's permit</p> <p>Sec. 5 (a) Any person who is a resident of Indiana may apply for a commercial driver's license learner's permit. The applicant must</p> <p>(3) Meet all visual and physical examination requirements</p> |

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| | | | | | | <p>140 IAC 7-3-6 Physical examination requirements</p> <p>Sec. 6. Every applicant or holder of a commercial driver's license must pass a physical examination described as follows:</p> <p>(1) For interstate operation, a physical examination as described by the United States Department of Transportation, 49 C.F.R. 391.43.</p> <p>(2) For intrastate operation, a physical examination as prescribed by the bureau.</p> |
| | <p>Indiana Department of Revenue</p> <p>Motor Carrier Services Division</p> <p>Commercial Driver's License Section</p> | | | | | <p>IDOR Physical Examination</p> <p>Instructions and Information for Physical Examination Forms of CDL Holders</p> |
| Iowa | <p>Iowa Administrative Code 2000</p> <p>Chapter 607 CDL</p> | | | | | <p>761-607.26(321) Vision screening</p> <p>An applicant for a CDL must pass a vision screening test administered by the department. The vision standards are given in 761-604.11 (321). This rule is intended to implement Iowa Code sections 321.186 and 321.186A.</p> |
| | <p>Iowa Administrative Code</p> <p>IAC 1/8/92, 2/11/98</p> <p>761-604.11 (321)</p> <p>604.11(1) VA standards</p> <p>604.11(2) Field of vision standards</p> <p>This rule is intended to implement Iowa Code sections 321.186, 321.193, and 321.196</p> | | | <p><i>a. When the applicant is screened without corrective lenses. If the VA is 20/40 or better with both eyes or with the better eye, no restriction will be imposed. If the VA is less than 20/40 but at least 20/50 with both eyes or with the better eye, the applicant shall be restricted to driving when headlights are not required. If the VA is less than 20/50 but at least 20/70 with both eyes or with the better eye, the applicant shall be restricted to driving when headlights are not required and restricted to a maximum speed of 35 m.p.h.</i></p> <p><i>b. When the applicant is</i></p> | <p><i>a. if the binocular field of vision is at least 140 degrees, no restrictions will be imposed.</i></p> <p><i>b. if the binocular field of vision is less than 140 degrees but at least 115 degrees and one eye has a monocular field of vision of at least 70 degrees temporal and 45 degrees nasal, the applicant shall be restricted to driving a vehicle with both left and right outside rearview mirrors.</i></p> | |

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| State | Reference | Color Vision | Diplopia | VA | VF | General |
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| | | | | <p><i>screened with corrective lenses.</i> If the VA is 20/40 or better with both eyes or with the better eye, applicant shall be required to wear corrective lenses. If the VA is less than 20/40 but at least 20/50 with both eyes or with the better eye, the applicant shall be required to wear corrective lenses and shall be restricted to driving when headlights are not required. If the VA is less than 20/50 but at least 20/70 with both eyes or with the better eye, the applicant shall be required to wear corrective lenses, restricted to driving when headlights are not required, and restricted to a maximum speed of 35 m.p.h.</p> <p><i>c. Other standards.</i> If the VA in the left eye is less than 20/100, the applicant shall be restricted to driving a vehicle with a left outside rearview mirror. However, if the applicant has a VA of 20/40 in the right eye and less than 20/100 in the left eye without corrective lenses and has corrective lenses that improve the vision in the left eye to better than 20/100, the applicant shall have the option of being restricted to driving with corrective lenses or driving a vehicle with a left outside rearview mirror.</p> | | |

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| | Iowa Code Section 321.449 Motor Carrier Safety Rules | | | | | <p>1. A person shall not operate a commercial vehicle on the highways of this state except in compliance with rules adopted by the department under chapter 17A. The rules shall be consistent with the federal motor carrier safety regulations promulgated under United States Code, Title 49, and found in 49 C.F.R. pts. 390 – 399 and adopted under chapter 17A.</p> <p>5.a. Notwithstanding other provisions of this section, rules adopted under this section concerning physical and medical qualifications for drivers of commercial vehicles engaged in intrastate commerce shall not be construed as disqualifying any individual who was employed as a driver of commercial vehicles engaged in intrastate commerce whose physical or medical condition existed prior to July 29, 1996.</p> |
| Kansas | Motor Carrier Regulations of the Transportation Division of The State Corporation Commission of The State of Kansas June 30, 2006 | | | | | <p>82-4-6d. Waiver of physical requirements.</p> <p>(a) Any person failing to meet the requirements of 49 C.F.R. 391.41 may be permitted to drive a vehicle, other than a vehicle transporting passengers, if the director finds that the granting of a waiver is consistent with highway safety and the public interest.</p> <p>(2) The application shall be accompanied by the following:</p> <p>(ii) Letters of recommendation regarding vision impairments shall be provided by a licensed ophthalmologist or optometrist who treated the driver applicant.</p> <p>(g) All intrastate vision waiver recipients shall be subject to the following conditions:</p> <p>(1) each driver shall be physically examined every year by the following individuals</p> <p>(A) A licensed ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the standard set forth in 49 C.F.R. 391.41(b)(10); and</p> <p>(B) a licensed medical practitioner who attests that the individual is otherwise physically qualified under the standards set forth in 49 C.F.R. 391.41.</p> <p>(2) Each driver shall provide a copy of the ophthalmologists, or optometrists, report to the medical practitioner at the time of the annual medical examination.</p> |

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| Kentucky | Kentucky Legislature Kentucky Administrative Regulation Title 601 Transportation Cabinet Department of Vehicle Regulation | To be considered for a medical waiver, the commercial driver shall readily distinguish which light of traffic signals and devices showing standard red, green and amber is illuminated. | To be considered for a medical waiver, the commercial driver shall not have uncorrectable double vision. | To be considered for a medical waiver, the commercial driver shall have a distance VA of 20/60 (Snellen) or better with corrective lenses in one (1) or both eyes. | To be considered for a medical waiver, the commercial driver shall have horizontal VFs which are not narrowed to less than 110 degrees of total VF. | <p>601 KAR 11:040 Medical waivers for intrastate operators of commercial motor vehicles</p> <p>NECESSITY, FUNCTION, AND CONFORMITY: The federal requirements for the issuance of a commercial driver's license to a driver operating in interstate commerce include a certification that the driver meets the qualification requirements contained in 49 C.F.R. 391. The Federal Highway Administration does not require a person who operates entirely in intrastate commerce to be subject to 49 C.F.R. 391. He is subject, however to Kentucky driver qualification requirements in 601 KAR 1:005 the Transportation Cabinet adopted the majority of the driver qualification requirements of 49 C.F.R. Part 391 on both an interstate and intrastate commerce basis. However, medical waivers in addition to those allowed in 49 C.F.R. 391.49 are allowed by the Federal Highway Administration for drivers operating exclusively in intrastate commerce. This administrative regulation sets forth the procedure and standards for obtaining an intrastate medical waiver.</p> <p>Section 1. Application for Intrastate Medical Waiver.</p> <p>(4)(a) Except as provided in paragraph (b) of this subsection, a copy of the applicable supplemental medical report form shall be completed by a licensed doctor or medicine or osteopathy.</p> <p>(b) The "Vision Conditions" form shall be completed by a licensed doctor of optometry or ophthalmology. The</p> <p>Section 2. (2) The following medical guidelines shall be considered by the Division of Driver Licensing in evaluating the information related to the commercial driver:</p> <p>(b) Vision. To be considered for a medical waiver, the commercial driver shall:</p> <ol style="list-style-type: none"> 1. Have a distance VA of 20/60 (Snellen) or better with corrective lenses in one (1) or both eyes; 2. Have horizontal VFs which are not narrowed to less than 110 degrees of total VF; 3. Readily distinguish which light of traffic signals and devices showing standard red, green and amber is illuminated; 4. Not wear bioptic lenses; and 5. Not have uncorrectable double vision. |

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| Louisiana | Louisiana Office of Motor Vehicles Web01.dps.louisiana.gov | | | | | FMCSA medical forms available |
| | Louisiana Revised Statutes Title 32 Motor Vehicles and Traffic Regulation | | | | | <p>§403.4 Medical evaluation report required of persons driving a commercial motor vehicle</p> <p>A. A person applying for a Class "A", "B", or "C" commercial driver's license shall not have any physical or mental disability affecting the ability to exercise ordinary reasonable control in the operation of a commercial motor vehicle. Such person, unless exempted by the office of motor vehicles or by a rule or regulation, shall provide a current medical report, on a form approved by the office of motor vehicles, prepared by a duly licensed medical examiner, certifying that he is capable of exercising ordinary reasonable control in the operation of a commercial motor vehicle. Such person shall submit a valid medical report at every renewal and shall carry a current medical certificate on his person at all times when driving a commercial motor vehicle requiring either a Class "A", "B", or "C" commercial driver's license as defined herein.</p> |
| Maine | Maine Commercial Driver License Manual | | | Minimum VA is a distance rating of 20/40 with best eye. If you cannot attain the 20/40 VA reading, the examiner will refer you to an eye doctor of your choice for a visual examination. | At least 140 degrees in order to avoid being restricted to left and right outside mirrors. If you cannot attain the field of vision of less than 110 degrees, the examiner will refer you to an eye doctor of your choice for a visual examination. | No permit will be issued until you present a properly completed doctor referral form to show the visual requirements have been met. If you meet the visual requirements with glasses or contact lenses, the permit and operator's license will be restricted to corrective lenses. |
| Maryland | Maryland Motor Vehicle Administration maryland.mva.com/resource/DL-171 Maryland Motor Vehicle Administration Maryland.mva.com/resources/CDLwaive | Must be able to distinguish red, green and amber | | 20/40 each eye (corrected or uncorrected) | Peripheral – at least 70 degrees each eye (110 degrees continuous) | <p>Medical Examination Report for Commercial Driver Fitness Determination available</p> <p>CDL Medical Waiver Information Packet</p> <p>Requesting Interstate Waiver/Exemption/Requesting Intrastate Waiver</p> <p>1. General</p> <p>B. The MVA may issue an intrastate waiver, which covers the following physical/medical conditions listed below.</p> <p>Vision</p> <p>B. The MVA may issue an intrastate waiver, which covers the</p> |

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| | | | | | | <p>following combined physical/medical conditions: No other combinations will be waived.</p> <ul style="list-style-type: none"> • Vision and amputation or loss of limb • Vision and power grasping or prehension <p>3. Intrastate Waivers</p> <p>Individuals who do not meet the physical requirements of §391.41(b)(10) and cannot obtain a FMCSA waiver or exemption may apply for an intrastate waiver, which is issued by the Motor Vehicle Administration. An intrastate waiver restricts the individual to driving a commercial motor vehicle within Maryland.</p> <p>B. Examination of Individuals Applying for Vision Intrastate Waiver</p> <p>Individuals who do not meet the physical requirements in §391.41(b)(10) must submit a physical examination form performed by a licensed medical examiner.</p> <p>Minimum vision requirements for commercial licenses are:</p> <ul style="list-style-type: none"> • See standards noted under Color Vision, VA and VF |
| | Annotated Code of Maryland .06 49 CFR 391, Qualifications of Drivers – Amendments and Exemptions | | | | | <p>E.49 CFR§391.41(b).</p> <p>(1) an intrastate driver ..who does not meet the physical qualifications of 49 CFR §391.41 (b) may drive in intrastate commerce if issued a waiver for intrastate operation by the Administrator. The waiver is valid for up to 2 years from the date of issue.</p> |
| Massachusetts | Massachusetts Registry of Motor Vehicles Application for Intrastate Medical Waivers | See waiver conditions | | See waiver conditions | See waiver conditions | <p>The Registrar may issue an intrastate waiver for the following conditions only:</p> <p>a. A Vision Impairment if:</p> <p>the individual has a combined horizontal peripheral field of vision of not less than 120 degrees, provided the individual also has a distant VA of at least 20/40 (Snellen) in either eye, with or without corrective lenses, and the ability to distinguish the colors red, green, and amber</p> |
| | Massachusetts Registry of Motor Vehicles | | | | | Medical Examination Report for Commercial Driver Fitness Determination available |

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| | <p>Massachusetts Registry of Motor Vehicles</p> <p>Intrastate Medical Waiver Policy Statement for Commercial Motor Vehicle License</p> <p>Classes A, B, and C as of June 16, 1998</p> | | | | | <p>The Registry of Motor Vehicles will waive compliance with the federal requirements pertaining to commercial motor vehicles for the purposes of driving intrastate only (within the borders of Massachusetts only) and will issue intrastate medical waivers for the following conditions only, provided the Registrar determines that the condition, in an individual case, will not interfere with the safe operation of a commercial motor vehicle.</p> <p>1. Vision Impairment (see application for conditions)</p> |
| Michigan | <p>Michigan Department of State michigan.gov</p> <p>Michigan Code Chapter 480 Motor Carrier Safety</p> | | | | | <p>Medical Examination Report for Commercial Driver Fitness Determination available</p> <p>480.13; Section 3.</p> <p>(2) A person who is not physically qualified to drive under 49 CFR 391.41 and who is otherwise qualified to drive a commercial motor vehicle may drive a commercial motor vehicle if the motor carrier division of the department of state police or the appeal board has granted a waiver to that person.</p> |
| Minnesota | <p>Minnesota/Department of Transportation</p> <p>Office of Freight and Commercial Vehicle Operations</p> <p>Minnesota Trucking Regulations</p> | | | | | <p>Section 06</p> <p>Physical Qualifications for Drivers (49 CFR §391.41 and 391.43)</p> <p>A person is not allowed to drive a commercial motor vehicle unless physically qualified to do so and carries in his or her possession a current, valid copy of a medical examiner's certificate (health card) showing he or she is qualified.</p> <p>In general, a person is physically qualified if he or she:</p> <p>Has a VA of at least 20/40 in each eye, with or without corrective lenses</p> <p>Section 07</p> <p>Minnesota Intrastate Driver Waivers</p> <p>The Minnesota Department of Transportation may issue a waiver to drivers who cannot meet the minimum physical qualifications as established in the Driver Qualification Rules 49 CFR part 391 and Minn. Stat. Chapter 221</p> <p>Waiver programs available to Minnesota intrastate drivers include vision</p> |

Vision and CMV Driver Safety

| State | Reference | Color Vision | Diplopia | VA | VF | General |
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| | Minnesota/Department of Transportation Office of Freight and Commercial Vehicle Operations Minnesota Commercial Truck and Passenger Regulations Fact Sheet Vision Waiver | | | To obtain a waiver, an applicant must have a VA of at least 20/40 (Snellen), corrected or uncorrected, in the better eye of an applicant | To obtain a waiver, an applicant must have a VF of 105 degrees or greater in the horizontal diameter with either one usable eye or with both eyes | |
| Mississippi | Senate Bill 3042 2007 Regular Session This act shall take effect and be in force from and after July 1, 2007. | | | | | An act to amend sections 77-7-7 and 77-7-716, Mississippi Code of 1972, to exempt certain vehicles from regulation under the Mississippi motor carrier regulatory law of 1938; to provide that the state enacts the exemption allowed under federal regulations for intrastate commerce; and for related purposes. Section 3. Notwithstanding the provisions of this chapter to the contrary, Parts 390 through 397, Title 49, Code of Federal Regulations, shall not apply to commercial motor vehicles operated in intrastate commerce to transport property which have a gross vehicle weight rating or gross combination weight rating of twenty-six thousand (26,000) pounds or less. |
| Missouri | Missouri Motor Carrier Services Missouri Department of Transportation Medical Program | | | | | Medical Examination Report for Commercial Driver Fitness Determination available Exemptions: MoDOT can grant a medical exemption for intrastate commercial drivers by issuing a Skill Performance Evaluation certificate if the individual meets alternate standards which satisfy the department that the applicant can safely operate a commercial vehicle. MoDOT can only issue SPE Certificates to applicants, who are not physically qualified because of vision impairment. SPEC-2 Form for applicants with Impaired Vision and Medical Evaluation Summary is available online. No specific standards are noted only guidelines for examination. |
| Montana | Montana Department of Transportation Motor Carrier Services Division 2003-2005 Law Book Effective October 1, 2003 | | | | | 61-5-112. Types and classes of commercial driver's licenses – classification – rulemaking – reciprocity agreements. (1) The department shall adopt rules that it considers necessary for the safety and welfare of the traveling public governing the classification of commercial driver's licenses and related endorsements and the examination of commercial driver's |

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| State | Reference | Color Vision | Diplopia | VA | VF | General |
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| | | | | | | license applicants and renewal applicants. The rules must: (a) subject to the exceptions provided in this section, comport with the requirements of 49 CFR, part 383, and the medical qualifications of 49 CFR, part 391 (b) Allow for the issuance of a type 2 (intrastate only) commercial driver's license in accordance with medical qualification and VA standards prescribed by the department. |
| | 2005 Commercial Driver's Manual Montana Rules and Regulations | | | At least 20/40 (best corrected) in either eye | | "Exemption" to Physical Qualifications If the Interstate driver cannot meet the DOT requirements, but they can meet the Montana medical requirements, they will be issued a Montana medical card allowing them to drive in the State of Montana only. Drivers must meet the medical qualifications for a Commercial Drivers License (CDL): 12. A CDL driver must have at least 20/40 vision (best corrected) in each eye. (<i>Interstate CDL</i>) 13. However, a driver may be able to obtain an Intrastate CDL if they have at least 20/40 vision (best corrected) in either eye. (<i>Intrastate CDL</i>) |
| Nebraska | Nebraska Administrative Code Title 291 – Nebraska Public Service Commission Chapter 3 – Motor Carrier Rules and Regulations | Ability to distinguish colors of red, green, and yellow | | At least 20/40 (Snellen) in each eye either without glasses or by correction with glasses | In the horizontal meridian of not less than a total of 140 degrees | 005 Safety Regulations 005.01 Minimum Qualifications 005.01B: see guidelines listed under color vision, VA and VF |
| | Nebraska Revised Statutes | | | | | Section 60-4,146 Application; operation on intrastate commerce; certification; restrictions. (1) Upon making applications pursuant to section 60-4, 144, any applicant who operates or expects to operate a commercial motor vehicle solely in intrastate commerce and who is not subject to 49 C.F.R. part 391 adopted pursuant to section 75-363 shall certify that he or she is not subject to 49 C.F.R. part 391. Any applicant making certification pursuant to this section shall meet the physical and vision requirements established in section 60-4,118 60-4,118 Vision requirements; persons with physical impairments; physical or mental incompetence; prohibited act; penalty |

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| State | Reference | Color Vision | Diplopia | VA | VF | General |
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| | | | | | | <p>(1) No operator's license shall be granted to any applicant until such applicant satisfied such applicant satisfies the examiner that he or she possesses sufficient powers of eyesight...The Department of Motor Vehicles, with the advice of the Health Advisory Board, shall adopt and promulgate rules and regulations:</p> <p>(a) Requiring a minimum acuity level of vision. Such level may be obtained through the use of standard eyeglasses, contact lenses, or bioptic or telescopic lenses which are specially constructed vision correction devices which include a lens system attached to or used in conjunction with a carrier lens;</p> <p>(b) Requiring a minimum field of vision. Such field of vision may be obtained through standard eyeglasses, contact lenses, or the carrier lens of the bioptic or telescopic lenses.</p> |
| Nevada | Nevada Revised Statutes | | | | | <p>NRS 483.330 Examination of applicants; waiver of examination by Department.</p> <p>1. The Department may require every applicant for a driver's license, including a commercial driver's license issued pursuant to NRS 483.900 to 483.940, inclusive, to submit to an examination. The examination may include:(d) Except as otherwise provided in subsection 3, an actual demonstration of his ability to exercise ordinary and reasonable control in the operation of a motor vehicle of the type or class of vehicle for which he is to be licensed. The examination may also include such further physical and mental examination as the Department finds necessary to determine the applicant's fitness to drive a motor vehicle safely upon the highways.</p> |
| | Nevada Administrative Code | | | At least 20/40, corrected or uncorrected, in at least one eye if the applicant suffers from a visual deficiency | | <p>NAC 483.803 Waiver of certain physical requirements: Submission and contents of application. (NRS 483.908)</p> <p>A person who is not physically qualified to operate a commercial motor vehicle pursuant to 49 C.F.R. § 391.41, but who is otherwise qualified to operate a commercial motor vehicle, may apply to the Department for a waiver of the physical requirements with which he does not comply.</p> <p>NAC 483.8031 Prerequisites for waiver of certain physical requirements</p> <p>1. An applicant for a waiver of one or more of the physical requirements described in 49 C.F.R. § 391.41 must submit to the Department with his application:</p> <p>(c) A medical evaluation signed by a physician or optometrist if the applicant suffers from a visual impairment. The medical</p> |

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| State | Reference | Color Vision | Diplopia | VA | VF | General |
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| | | | | | | evaluation must: (1) Identify and describe the visual impairment of the applicant; (2) Indicate whether the applicant's condition is stable or progressive; (3) Certify that the applicant is able to operate a commercial motor vehicle; (4) Certify that the vision of applicant is at least 20/40, corrected or uncorrected, in at least one eye if the applicant suffers from a visual deficiency |
| New Hampshire | State of New Hampshire Office of Legislative Services Administrative Rules/Department of Safety Chapter Saf-C 1800 Commercial Driver Licensing Saf-C 1004.02 Pass. No Restrictions. Saf-C 1004.03 Pass. Corrective Lenses Restriction. | | | Each applicant shall pass the VA exam if the applicant: (1) accurately perceives the line of symbols designated 20/40 with both eyes; or (2) Is legally blind in one eye and accurately perceives the line of symbols designated 20/30 with the other eye. (b) For the purposes of this section, "accurately perceives" means determining the symbols presented with no more than one error. (Saf-C 1004.02) Each applicant who meets the standards set forth in Saf-C 1004.02 with the use of corrective lenses shall pass the VA examination subject to the corrective lenses restriction pursuant to RSA 263:13 and Saf-C 1008.03 (Saf-C 1004.03) | | <p>Part Saf-C 1804. Original CDL and Endorsements: Examinations Required</p> (a) Each applicant for an original CDL or endorsements, unless otherwise provided in these rules, shall satisfactorily complete the following: (1) The VA examination set forth in Saf-C 1004 Part Saf-C 909 Medical Waiver Saf-C 909.02 Waiver A person who is not physically qualified to drive due to having physical deficiency, as listed in 49 CFR 391.41(b)(1)-(13), but who is qualified to drive a commercial motor vehicle pursuant to 49 CFR 391.11 and has not been disqualified pursuant to 49 CFR 391.15, shall be authorized to drive a commercial motor vehicle if the commissioner grants a waiver pursuant to Saf-C 909.09. Saf-C 909.07 Contents of a Medical Evaluation Summary Each driver-applicant, who is not physically qualified pursuant to 49 CFR 391.41(b), shall obtain a medical evaluation summary, ... from a medical examiner, who has expertise with the driver-applicant's specific medical condition (e) Each driver applicant who is not physically qualified pursuant to 49 CFR 391.41(b)(3)-(13) shall obtain a medical evaluation summary that includes the following: (1) Whether the impairment interferes with the driver-applicants ability to perform normal tasks associated with driving a commercial motor vehicle; (2) An assessment and medical opinion of whether the condition is likely to remain medically stable for the duration of the |

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| State | Reference | Color Vision | Diplopia | VA | VF | General |
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| | | | | | | <p>medical waiver; and</p> <p>(3) A recommendation as to the period of time the medical waiver shall be valid, not to exceed 2 years.</p> |
| New Jersey | State of New Jersey Motor Vehicle Commission/Commercial | Able to recognize red, green and amber colors | | 20/40 vision in each eye (with or without glasses/corrective lenses) | | <p>39:3019.11 Definitions relative to commercial driver licenses.</p> <p>“Disqualification” means either:</p> <p>(b) A determination by the Federal Motor Carrier Safety Administration under the rules of practice for motor carrier safety contained in 49 C.F.R.s386, that a person is no longer qualified to operate a commercial motor vehicle under 49 C.F.R. 391</p> |
| New Mexico | New Mexico Statutes | | | | | <p>66-5-60. Commercial driver's license; qualifications; standards.</p> <p>The division shall not issue a commercial driver's license to a person unless that person is a resident of New Mexico and has passed a knowledge test and skills test for driving a commercial motor vehicle and for related endorsements, has passed a fitness test and has satisfied any other requirements of the New Mexico Commercial Driver's License Act [66-5-52 NMSA 1978]</p> <p>65-3-7 Qualifications of drivers</p> <p>C. The driver may adopt regulations pertaining to the qualification and disqualification of commercial motor carrier vehicle drivers including documentation thereof. The regulations shall include but not be limited to background and character, road testing and written examination, physical qualification, examination and waivers of certain physical defects.</p> |
| New York | New York State Department of Motor Vehicles Federal Requirements for Commercial Driver License (CDL) Applicants | | | | | <p>Informs first-time CDL applicants about federal medical requirements</p> |
| | Commercial Driver License (CDL) Certifications | | | | | <p>When you apply for an original NYS Commercial Driver License (Class A, B or C) or a renewal, you must certify that:</p> <p>You meet or do not meet, the requirements of the Federal regulations in 49 CFR Part 391, which include a requirement for a medical examination.</p> |

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| | | | | | | <p>49 CFR Part 391 Certification</p> <p>The federal regulations include a requirement that a commercial driver have a medical examination every 2 years and receive a Medical Examiner's Certificate.</p> |
| | New York State Commercial Driver's Manual | | | | | <p>1.3 Commercial Driver License Requirements</p> <p>1.3.4 Medical Requirement</p> <p>The federal government requires most CMV drivers to have a medical examination in order to detect physical or mental conditions that may affect your ability to operate a motor vehicle safely. The examination requirements are found in the U.S. DOT Federal Motor Carrier Safety Regulations under 49 CFR Part 391.</p> <p>You are exempt from needing a medical examiner's certificate if you: are a government employee at any level of government</p> |
| North Carolina | North Carolina Department of Transportation Division of Motor Vehicles | Demonstrated ability to distinguish colors that pertain to driving and traffic control | | At least 20/40 for each eye and both eyes together; with or without corrective lenses | At least 70 degrees in the horizontal meridian in each eye | <p>Commercial Trucking/License Eligibility/Requirements</p> <p>6. Medical and Physical Requirements</p> <p>i. Vision (see guidelines listed under color vision, VA and VF)</p> |
| North Dakota | North Dakota Century Code Article 37-08 Visual Requirements for Operators Licenses or Permits | | | | | <p>37-08-01-05. Minimum vision requirements and restrictions.</p> <p>Except as provided in ND Century Code section 39-08-21, the driver of a commercial class A,B, or C motor vehicle shall comply with the federal motor carrier regulations, pursuant to 49 CFR section 391.41(b)(10).</p> |
| | Chapter 39-08 Regulations Governing Operators | | | | | <p>39-08-21. Medical qualifications exemption for intrastate drivers. Notwithstanding the adoption by the superintendent of the state highway patrol of federal motor carrier safety regulations pursuant to subsection 3 of section 39-21-46, the provisions of 49 CFR 391.41(b)(1)-(11) do not apply to a person who is qualified through a state medical waiver program to operate a commercial motor vehicle within the boundaries of this state or a person who:</p> <ol style="list-style-type: none"> 1. Is otherwise qualified to operate a commercial motor vehicle and who possesses, on March 26, 1991, a class 1 license issued pursuant to section 39-06-14, as that section existed on June 30, 1989, or a class A license issued pursuant to chapter 39-06.2; 2. Operates a commercial motor vehicle only within the boundaries of this state; and |

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| | | | | | | <p>3. Has a medical or physical condition that:</p> <ul style="list-style-type: none"> a. Would prevent such person from operating a commercial motor vehicle under federal motor carrier safety regulations contained in 49 CFR, chapter III, subchapter B; b. Existed on March 26, 1991, or at the time of the first required physical examination after that date; and c. An examining physician has determined has not substantially worsened since March 26, 1991, or the time of the first required physical examination after that date |
| | Commercial Drivers License Guide 2005-2007 | | | | | <p>Medical Qualifications</p> <p>North Dakota state law requires that if any licensed Class A, B, or C operator suffers permanent loss of damage of an eye, he or she must make a report of explanation to the Drivers License and Traffic Safety Division.</p> |
| Ohio | Ohio Administrative Code 4501:1-1-20 Vision Standards for driver license applicants | | | See (D) | See (G) | <p>(D) This paragraph applies to CDL applicants who are not required to meet the standards of 49 C.F.R. 391.</p> <p>(1)(a) Persons with binocular vision whose VA is 20/40 or better, without corrective lenses, shall be issued a license restricted to intrastate operation of commercial motor vehicles (CMV).</p> <p>(b) Persons with binocular vision whose combined VA is poorer than twenty/fourty but not worse than twenty/sixty shall be issued a license restricted to daytime driving only.</p> <p>(c) Persons with binocular vision unable to attain a combined VA of at least twenty/sixty shall be denied a license.</p> <p>(2)(a) Persons with monocular vision whose VA is twenty/thirty or better, without corrective lenses, shall be issued a license without visual restriction.</p> <p>(b) Persons with monocular vision whose VA is poorer than twenty/thirty but not worse than twenty/sixty shall be issued a license restricted to daytime driving.</p> <p>(c) Persons with monocular vision unable to attain acuity of at least twenty/sixty shall be denied a license.</p> <p>(G) This paragraph contains horizontal-peripheral vision standards for CDL applicants who are not required to meet the standards of 49 C.F.R. 391.</p> <p>(1) A person possessing a seventy-degree VF on both sides of the fixation point shall be issued a non-restricted license.</p> <p>(2) If the VF on one side of fixation is less than seventy degrees the applicant shall be tested and must demonstrate a VF of</p> |

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| State | Reference | Color Vision | Diplopia | VA | VF | General |
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| | | | | | | <p>at least seventy degrees on one side of fixation and forty-five degrees on the other side of fixation, and the applicant is subject to a restricted license and the use of an outside mirror on the side of the more limited VF, in addition to an inside mirror, and an applicant for a CDL shall be restricted to intrastate operation of commercial vehicles.</p> <p>(3) A person who does not demonstrate a VF of at least seventy degrees on one side of fixation and forty-five degrees on the other side of fixation shall not be issued a license.</p> <p>(4) Anyone who does not meet VF standards of seventy degrees on one side and forty-five degrees on the other side, will be referred to an ophthalmologist or a licensed optometrist for further examination.</p> |
| Oklahoma | <p>Oklahoma Commercial Driver's Manual Section 1.8 Federal and State Qualifications for Commercial Motor Vehicle Drivers www.dps.state.ok.us</p> | Ability to recognize the colors of traffic signals and devices showing standard red, green, and amber | | At least 20/40 (Snellen) in each eye without corrective lenses or VA separately corrected 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses | At least 70 degrees in the horizontal meridian of each eye | |
| | <p>Oklahoma Administration Rules Title 595/Department of Public Safety Chapter 10 Driver License and Identification Cards Subchapter 3 - Examination</p> | | | | | <p>595:10-3-6. Vision</p> <p>(d) VA and field of vision – Class A, B, or C CDL applicants who are exempt from 49 C.F.R., §391.41(b)(10), if the applicant meets the vision standards established in OAC 595:10-5-7(a)(2) and 595:10-5-7(b)(2)</p> |
| | <p>Oklahoma Administration Rules Title 595/Department of Public Safety Chapter 10 Driver License and Identification Cards Subchapter 5 – Medical Aspects</p> | | | | | <p>595:10-5-7. Vision standards and problems</p> <p>(a) Acuity</p> <p>(2) A person may be considered for a Class A, B, or C intrastate commercial driver license if the VA in one eye alone or with both eyes is twenty-fourty (20/40) or better, with or without corrective lenses.</p> <p>(b) Field of vision</p> <p>(2) A person may be considered for a Class A, B, or C intrastate CDL if the field of vision is at least seventy (70) degrees in the horizontal meridian in one eye alone.</p> |

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| Oregon | Oregon Administrative Rule | | | | | <p>735-074-0260 Medical Standards for Drivers of Commercial Motor Vehicles</p> <p>(1) The Driver and Motor Vehicle Services Division of the Department of Transportation (DMV) adopts the United States Department of Transportation regulations contained in 49 CFR 391.41 through 391.49 (2004) pertaining to physical qualifications and medical examination of drivers of commercial motor vehicles.</p> <p>(2) DMV may issue a Class A, B, or C commercial driver license to a person who does not qualify for a medical certificate under section (1) of this rule if the person is issued:</p> <p>(a) a waiver of physical disqualification by the Motor Carrier Transportation Division of the Oregon Department of Transportation (MCTD) under OAR 740-100-0104</p> |
| | Oregon ODOT/DMV | | | | | <p>Physical Qualifications</p> <p>Physical qualifications are listed in CFR 49 § 391.41. If you do not meet these physical qualifications due to vision limitations and want to operate a CMV interstate, you may be able to satisfy alternative physical qualifications or qualify for an exemption.</p> <p>If you cannot meet the medical qualifications for interstate CMV operation, you may qualify for a Waiver of Physical Disqualification available from ODOT, Motor Carrier Transportation Division. Such a waiver would permit operation of a CMV within the State of Oregon only.</p> |
| | Oregon 2006-2007 Commercial Driver License Manual | | | | | <p>Physical Examination</p> <p>A medical waiver may be issued for some otherwise disqualifying conditions, but a medical waiver issued by ODOT is good for no more than two years. It applies only to intrastate drivers.</p> |
| | Oregon Statutes | | | | | <p>740-100-0140 Oregon Waiver of Physical Disqualification</p> <p>(3) Explains waiver conditions and procedures</p> |
| Pennsylvania | PA Public Utility Commission Motor Carrier Services and Enforcement Division | | | | | <p>Safety Fitness Review Program</p> <p>Educational and Technical Assistance Package</p> <p>Part 391 – Qualifications of Drivers</p> <p>Motor Carriers must ensure that all drivers meet the Physical Qualifications and Examinations required in Part 391.41 and possess a valid medical certificate.</p> |

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| Rhode Island | Rules and Regulations Governing Applicants for Commercial Driver's Licenses, Permits, Renewals and Endorsements Adopted 2007 Department of Revenue/Division of Motor Vehicles | | | | | Rule 3. Minimum Eligibility for Commercial Driver's License, Permit or Endorsement 3.2 At the time of submitting the application, the applicant must be physically qualified to safely operate a commercial motor vehicle. In making this determination, the Division of Motor Vehicles shall follow applicable federal guidelines contained in 49 C.F.R. § 391.41 and may seek recommendations from the Medical Advisory Board pursuant to Section 31-10-44 of the Rhode Island General Laws. |
| | Rhode Island Code | | | | | § 31-10.3-19 – Examination of Applicants (a) the department shall examine every applicant for a commercial driver's license. The examination shall include (1) a test of the applicant's eyesight to be administered according to standards set by the Federal Motor Carrier Regulations |
| South Carolina | Commercial Motor Vehicle Manual | | | | | Transfer of Commercial Driver's License To transfer a CDL from another state to SC: 2) Certify you have read and understand and meet the qualifications requirements under 49 CFR, Part 39 of the FMCSRs. You must also show a valid DOT physical card or long form. |
| South Dakota | South Dakota Code 49 | | | | | 49-28A-3 Adoption of federal regulations—Violation as misdemeanor. The state hereby adopts Title 49 of the Code of Federal Regulations, subtitle B, chapter III, subchapter B, parts 390 to 397, inclusive as amended through January 1, 2006, with the following modifications: Intrastate drivers are exempt from the physical requirements of part 391.41 |
| Tennessee | Rules of TN Department of Safety Division of Driver License Issuance Chapter 1340-Classified and Commercial Drivers Licenses and Certificates for Driving | | | If 20/40 of better, right eye and left eye – No restrictions unless corrective lenses are needed to achieve VA. If 20/40 or better one eye – Corrective lenses restriction if applicable. | | Chapter 1340-1-13.10 Vision Standards (1) Applicants for CDL shall pass a vision test with the minimum qualifications as specified in 49 C.F.R. §391 unless they are exempted from meeting federal physical and mental standards by 1340-1-13.09. If exempt, they shall meet the general vision standards set forth below. (see guidelines listed under VA) |

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| | | | | <p>If 20/60 to blind other eye – Restricted to outside rear-view mirrors.</p> <p>If 20/60 or better, right eye and left eye – Outside rear-view mirrors and corrective lenses restriction if applicable.</p> | | |
| Texas | <p>Texas Administrative Code Title 37 Public Safety and Corrections Part 1 Texas Dept of Public Safety Chapter 16 Commercial Drivers License Subchapter A Licensing Requirements, Qualifications, Restrictions, and Endorsements</p> | <p>Ability to recognize the colors of traffic signals and devices showing standard red, green, and amber</p> | | <p>20/40 (Snellen) or better distant VA with corrective lenses in the better eye; OR the applicant's vision is uncorrectable in one eye and the applicant does not wear corrective lenses, then uncorrected vision must be at least 20/25 (Snellen) in the better eye</p> | | <p>Rule 16.9 Qualifications to Drive in Intrastate Commerce</p> <p>(a) Persons who do not qualify in intrastate commerce may still qualify to drive in intrastate commerce. In such cases, the commercial driver's license (CDL) will contain an "M" restriction..</p> <p>(3) An applicant may present the department's vision waiver certificate in lieu of meeting the vision requirements of Title 49, Code of Federal Regulations, Part 391.41. Waivers issued by the department may be renewed through the License Issuance Bureau of the department in Austin.</p> <p>(5) A driver who operates a CMV in intrastate commerce only may obtain a vision waiver provided the following qualifications are met: (only one waiver can be used to obtain a CDL)</p> <p>(A) Vision Waiver requirements: (see guidelines listed under Color Vision and VA)</p> <p>(9) applicants for a Texas Intrastate Vision Waiver must be able to meet all other physical requirements specified in 49 CFR, Part 391.41 without the benefit of any other waiver.</p> <p>Rule 16.8 Qualifications to Drive in Interstate Commerce</p> <p>(4) The applicant must meet the federal vision requirements set out in 49 Code of Federal Regulations, Part 391.41. or have been issued an exemption. Note: Vision waivers issued by the department are valid for intrastate operations only as stated in §16.9 of this title (see above)</p> |
| Utah | <p>Utah Department of Public Safety Driver License Division Functional Ability in Driving: Guidelines and Standards for Health Care Professionals</p> | <p>See information listed under Category I: VA/Commercial</p> | <p>See information listed under Category I: VA/Commercial</p> | <p>See information listed under Category I: VA/Commercial</p> | <p>See information listed under Category I: VA/Commercial</p> | <p>Application of Commercial Intrastate Medical Standards</p> <p>The 2006 Functional Ability in Driving: Guidelines and Standards for Health Care Professionals has outlined the medical standards as applying to ALL commercial intrastate drivers, irrespective of the type of vehicle or cargo involved, i.e., Class A, B, C, and D of Utah's Classified License System.</p> |

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| | | | | | | <p>(2) Commercial Intrastate Drivers must be profiled in the appropriate categories in order to be considered for an intrastate license.</p> <p>(3) Also, pursuant to Utah Code Annotated 53-3-303.5 an intrastate driver is no longer able, or required to carry a Federal DOT card. The intrastate only (K) restriction is sufficient to indicate the driver has met the State of Utah medical guidelines for the commercial license he/she will hold.</p> <p>Category I: VA/Commercial</p> <p>Profile Level 1</p> <p><i>Central VA:</i> 20/40 or better in each eye</p> <p><i>Peripheral VFs:</i> Monocular - 120° in each eye. Binocular - 70° to the right and to the left in the horizontal meridian.</p> <p><i>Color Vision:</i> Normal</p> <p><i>Interval for Review:</i> N/A</p> <p><i>License Class & Restrictions:</i> Commercial Unlimited</p> <p>Profile Level 2</p> <p><i>Central VA:</i> 20/40 or better in better eye</p> <p><i>Peripheral VFs:</i> Monocular - 120° in each eye. Binocular - 60° to the right and left in the horizontal meridian.</p> <p><i>Color Vision:</i> Normal</p> <p><i>Interval for Review:</i> 2 years</p> <p><i>License Class & Restrictions:</i> Commercial Intrastate</p> <p>Profile Level 3</p> <p><i>Central VA:</i> 20/40 or better in better eye</p> <p><i>Peripheral VFs:</i> Binocular -120° total, 60° to both the right and left. Or, in patients with impaired VFs in one eye, a VF in the better eye or 120° total, with 60° of field to both the right and to the left</p> <p><i>Color Vision:</i> Normal</p> <p><i>Interval for Review:</i> 2 years</p> <p><i>License Class & Restrictions:</i> Commercial Intrastate. Requires prior commercial vehicle experience documentation and MAB approval.</p> |

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| State | Reference | Color Vision | Diplopia | VA | VF | General |
|-------|-----------|--------------|----------|----|----|--|
| | | | | | | <p>Profile Level 4</p> <p><i>Central VA:</i> 20/40 or better in better eye</p> <p><i>Peripheral VFs:</i> Binocular VF – at least 90° total with at least 45° to both the right and left. Or, in patients with impaired VFs in one eye, a VF in the better eye of 90° total, with 45° of field to both the right and to the left</p> <p><i>Color Vision:</i> Not required</p> <p><i>Interval for Review:</i> N/A</p> <p><i>License Class & Restrictions:</i> No commercial driving</p> <p>Profile Level 5</p> <p><i>Central VA:</i> 20/50 to 20/70 in better eye</p> <p><i>Peripheral VFs:</i> Binocular VF – at least 90° total with at least 45° to both the right and left. Or, in patients with impaired VFs in one eye, a VF in the better eye of 90° total, with 45° of field to both the right and to the left</p> <p><i>Color Vision:</i> Not required</p> <p><i>Interval for Review:</i> N/A</p> <p><i>License Class & Restrictions:</i> No commercial driving</p> <p>Profile Level 6</p> <p><i>Central VA:</i> 20/80 to 20/100 in better eye</p> <p><i>Peripheral VFs:</i> Binocular VF – at least 60° total with at least 30° to the right and left. Or, in patients with impaired VFs in one eye, a VF in the better eye of 60° total, with 30° of field to both the right and to the left</p> <p><i>Color Vision:</i> Not required</p> <p><i>Interval for Review:</i> N/A</p> <p><i>License Class & Restrictions:</i> No commercial driving</p> <p>Profile Level 7</p> <p><i>Central VA:</i> Special circumstances not covered by any of the above</p> <p><i>Peripheral VFs:</i> Binocular VF – at least 60° total with at least 30° to the right and left. Or, in patients with impaired VFs in one eye, a VF in the better eye of 60° total, with 30° of field to both the right and to the left</p> |

Vision and CMV Driver Safety

| State | Reference | Color Vision | Diplopia | VA | VF | General |
|-------|-----------|--------------|----------|----|----|--|
| | | | | | | <p><i>Color Vision:</i> Not required <i>Interval for Review:</i> N/A <i>License Class & Restrictions:</i> No commercial driving</p> <p>Profile Level 8 <i>Central VA:</i> 20/40 or better in better eye <i>Peripheral VFs:</i> Binocular VF – at least 60° total with at least 30° to the right. (Includes left homonymous defects) <i>Color Vision:</i> Not required <i>Interval for Review:</i> N/A <i>License Class & Restrictions:</i> No commercial driving</p> <p>Profile Level 9 <i>Central VA:</i> 20/40 or better in better eye <i>Peripheral VFs:</i> Binocular VF – at least 60° total with at least 30° to the left. (Includes right homonymous defects) <i>Color Vision:</i> Not required <i>Interval for Review:</i> N/A <i>License Class & Restrictions:</i> No commercial driving</p> <p>Profile Level 10 <i>Central VA:</i> 20/200 or worse <i>Peripheral VFs:</i> Binocular VF less than 60° <i>Color Vision:</i> N/A <i>Interval for Review:</i> N/A <i>License Class & Restrictions:</i> No commercial driving</p> <p>Aspects of Licensing and Medical Certification of Commercial Intrastate Drivers</p> <p>In general, a profile of 2, 3, and 4, depending on the category, may qualify the applicant for a commercial intrastate license.</p> <p>Because of the greater responsibilities involved, this program will differ from the usual licensing procedures for private vehicle drivers:</p> <p>(3) Recognition of red, green and amber used in traffic lights may be tested with simple color cards, rather than more complex test devices.</p> |

Vision and CMV Driver Safety

| State | Reference | Color Vision | Diplopia | VA | VF | General |
|------------|--|--------------|----------|--|--|--|
| | | | | | | (4) For commercial intrastate licensing, the health care professional will be expected to mark all categories upon initial examination repeating this process every two years depending on the medical condition and profile level registered at the time of the examination. |
| Vermont | Vermont Statutes Title 23 Motor Vehicles Chapter 39: Commercial Driver License Act | | | | | 4110. Application for commercial driver license (A) for an applicant who operates or expects to operate in interstate or foreign commerce or who is otherwise subject to 49 C.F.R. part 391, the applicant meets the qualifications requirements contained in part 391; or operates or expects to operate entirely in intrastate commerce and who is not subject to part 391, that the applicant is subject to state driver qualification requirements and is not subject to part 391 |
| | Department of Motor Vehicles CDL Manual | | | | | Physical Examination Requirements If you are subject to the Federal Motor Carrier Safety Regulations, you must have a physical examination every 2 years and carry the medical card at all times. To have a hazardous materials endorsement, you must meet the Federal Motor Carrier Safety regulations except for age requirements for intrastate travel. |
| Virginia | Commonwealth of Virginia Department of Motor Vehicles Vision Screening/Commercial Driver's License www.dmv.state.va.us | | | 20/40 or better vision in each eye. Commercial drivers with only one eye must meet these requirements: 20/40 or better vision in one eye | 140 degrees or better, horizontal vision. Commercial drivers with only one eye must meet these requirements: 120 degrees, or better, horizontal vision | |
| | Virginia Code 46.2-341.9. Eligibility for CDL | | | | | No person should be eligible for a VA CDL until he has applied for such license and has passed the applicable vision test |
| Washington | WA State Licensing: Commercial Driver Fitness Determination | | | | | 1.3 Medical Waivers All commercial drivers must meet the medical standards established by federal and state laws, rules, and regulations. Reference: FMCSR parts 391.41 and 391.49 Intrastate If you don't meet the medical standards, you can apply to the Department of Licensing (DOL) for an Intrastate Medical Waiver. This waiver is : |

Vision and CMV Driver Safety

| State | Reference | Color Vision | Diplopia | VA | VF | General |
|---------------|---|--------------|----------|---|---|--|
| | | | | | | <p>Valid for operation within the state of Washington only</p> <p>Valid for no more than a two-year cycle</p> <p>Medical Waiver</p> <p>Drivers with the following conditions may be eligible to apply for an intrastate waiver: A condition of monocular vision</p> |
| West Virginia | Commercial Driver's Manual | | | | | <p>Age and Fitness Requirements</p> <p>Federal Motor Carrier Regulations (49 CFR Part 391.41) require that drivers subject to those rules meet specific physical qualification standards and carry evidence of such qualification in the form of a medical certificate.</p> <p>Note: all drivers are subject to FMSCR requirements (DOT medical) except for city, county, state or federal employees which would require an eye examination.</p> |
| Wisconsin | <p>Department of Transportation Chapter Trans 112</p> <p>Medical Standards for Driver Licensing and General Standards for School Bus Endorsements</p> | | | At least 20/60 or better in at least one eye as assessed by a vision specialist | A horizontal, temporal field of vision of 70° or more from center in at least one eye | <p>Trans 112.14 Conditions affecting sensory function.</p> <p>(3)(a) <i>Licensing standards.</i> No endorsement or license may be issued to, renewed by, or held by a person who does not meet the medical review standards for conditions affecting sensory functions of this subsection.</p> <p>(b) <i>Corrective lenses.</i> A person needing corrective lenses to meet the standards in this section shall be restricted to use of those lenses while driving. No person may use a bioptic telescopic or similar lens in order to meet the VA standards of this subsection if the lens reduces the field of vision below the standards in this subsection.</p> <p>(d) <i>Medical standards for CDL.</i> A person who applies for, renews, or holds a CDL shall meet all of the following criteria:</p> <ol style="list-style-type: none"> 1. VA of at least 20/60 or better in at least one eye as assessed by a vision specialist. 2. A horizontal, temporal field of vision of 70° or more from center in at least one eye. <p>(e) <i>Medical standards for all classes of operator licenses.</i> A person, who applies for, renews, or holds for any classification of operator's license shall meet all of the following criteria:</p> <ol style="list-style-type: none"> 1. If a person has uncorrected or corrected VA of less than 20/40 in each eye, but at least 20/60 in one eye, the department shall refer the person to a vision specialist for an examination and an advisory recommendation. The person shall complete a driving evaluation as recommended by the vision specialist. The |

Vision and CMV Driver Safety

| State | Reference | Color Vision | Diplopia | VA | VF | General |
|-------|-----------|--------------|----------|----|----|--|
| | | | | | | <p>person's license shall be assigned restrictions based upon a recommendation from the vision specialist or the results of a driving evaluation demonstrating adequate compensation for the loss of vision.</p> <p>2. If a person has uncorrected or corrected VA of less than 20/60 in each eye, but 20/100 or better in one eye, the department shall refer the person to a vision specialist for examination and an advisory recommendation. The person shall complete a driving evaluation. The person's license shall be assigned restrictions, based upon a recommendation from the vision specialist and the results of a driving evaluation demonstrating adequate compensation for the loss of vision.</p> <p>3. If a person has a horizontal, temporal field of vision of less than 70° from center in one eye and 70° or more from center in the other eye, the person's license shall be restricted to driving with an outside rear view mirror to compensate for the loss of field of vision. A person restricted to driving with a right outside rear view mirror may have this restriction waived based on a driving evaluation demonstrating adequate compensation for the loss of field of vision.</p> <p>4. If a person has horizontal, temporal field of vision of less than 70° from center in each eye, the person shall be referred to a vision specialist for an examination and an advisory recommendation. The person shall complete a driving evaluation. The person's license shall be restricted to driving with outside rear view mirrors to compensate for the loss of field of vision. The person's license may be subject to additional license restrictions, but these may be waived based on a recommendation from a vision specialist and a driving evaluation demonstrating adequate compensation for the loss of field of vision.</p> <p><i>(g) Special restricted operator's license.</i></p> <p>1. No persons with VA of 20/200 or less in the better corrected eye, as certified by a vision specialist, may be issued a special restricted operator's license.</p> <p>2. Person's applying for or holding a special restricted operator's license with VA between 20/100 and 20/200, but not including 20/200 in the better corrected eye, as certified by a vision specialist, shall be restricted to daylight hours of operation only.</p> |

Vision and CMV Driver Safety

| State | Reference | Color Vision | Diplopia | VA | VF | General |
|---------|--|--------------|----------|----|----|---|
| Wyoming | Wyoming Statutes Title 31 Motor Vehicles Article 3 Commercial Driver's License | | | | | 31-7-304. Issuance; classifications and endorsements. (f) Before issuing or renewing a commercial driver's license, the department shall require that the applicant present a current federal medical qualification certificate. |

The FHWA Vision Exemption Program

In 1992, the Federal Highway Administration (FHWA) instituted a vision waiver program. The purpose of this program was to provide necessary data for a possible change in the vision standards. This program enrolled 2,656 drivers. The criteria for participation in the waiver program included a detailed protocol for inclusion and monitoring of performance parameters, including previous accident record and a formal examination by an ophthalmologist or optometrist who certified that the applicant could, despite the vision deficiency, perform the driving tasks required to operate a CMV. As part of the ongoing waiver program, the participant was required to report citations, accidents, and changes in medical status. In addition, a yearly vision examination by an ophthalmologist or optometrist was required.

The United States Court of Appeals for the District of Columbia Circuit issued a decision in August 1994, concluding that “the adoption of the waiver program was contrary to law.” This was in response to a challenge of the waiver program brought by the Advocates for Highway and Auto Safety. The basis for this retroactive decision was that at the time of the institution of the waiver there was not adequate data to satisfy the requirements of the Safety Act requiring FHWA to “determine that such a waiver is consistent with the safe operation of CMVs.” FHWA ended the vision waiver program on March 31, 1996, but the waived drivers were allowed to continue driving in interstate commerce as long as they continued to fulfill stringent requirements, including an annual vision reevaluation by an ophthalmologist or optometrist. As of January 2007, more than 1,000 active CMV drivers continue to drive a CMV under the auspices of the Vision Exemption Program.

The FMCSA Medical Exemption Program

In 2006, a program study was conducted for the Vision Exemption Program established by the FMCSA.(22) The purpose of the Vision Exemption Program was to provide information related to the exemption program for informing policy and guidance for program improvement. To date, 1,155 drivers are enrolled in this program and characterized as primarily male (98%) with a median age of 52 years. Vision characteristics of program drivers were categorized by deficiency including amblyopia, accident/injury/trauma, congenital, disease and unknown. The program study’s findings conclude that the Vision Exemption Program does not appear to negatively affect highway safety.

Methods

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

Key Questions

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

Key Question 1: Is monocular vision associated with an increased crash risk?

Key Question 2: Do red-green color deficiencies (either protan or deutan) increase crash risk?

Key Question 3: Is VF loss associated with an increase in crash risk? And, if affirmative, what is the acceptable VF range in the horizontal and vertical meridians?

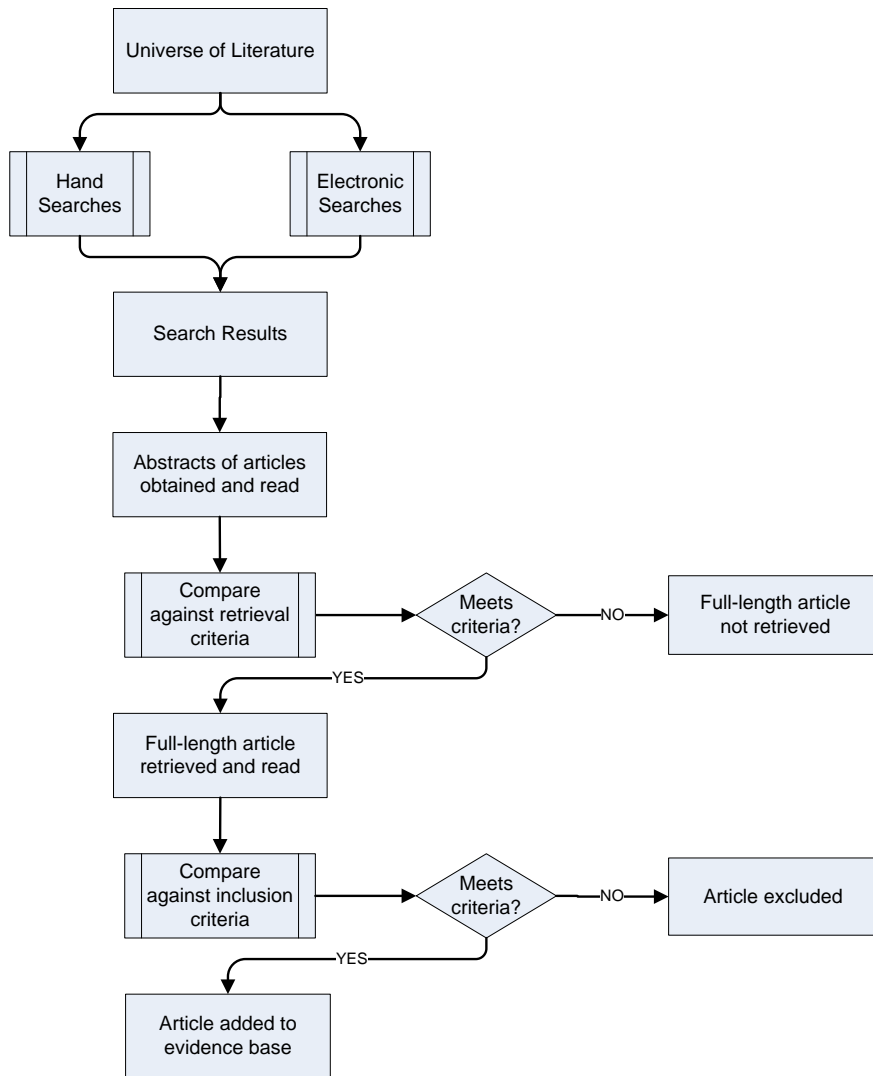
Key Question 4: Do cataracts increase crash risk? And, if affirmative, does cataract surgery reduce crash risk?

Key Question 5: Is diplopia associated with increased crash risk?

Identification of Evidence Bases

The evidence bases for each of the five key questions addressed in this evidence report were identified using the multistage process captured by the algorithm presented in Figure 14. The first stage of this process consists of a comprehensive search of the literature. The second stage of the process consists of the examination of abstracts of identified studies in order to determine which articles will be retrieved. The final stage of the process consists of the selection of the actual articles that will be included in the evidence base.

Figure 14. Evidence Base Identification Algorithm



Searches

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

Electronic Searches

We performed comprehensive searches of the electronic databases listed in Table 10.

Table 10. Electronic Databases Searched

| Name of Database | Date Limits | Platform/Provider |
|---|---|---|
| CINAHL (Cumulative Index to Nursing and Allied Health Literature) | 1982 through December 3, 2007 | OVID |
| The Cochrane Central Register of Controlled Trials (CENTRAL) | Through 2007, Issue 4 | http://thecochranelibrary.com |
| The Cochrane Database of Methodology Reviews (Methodology Reviews) | Through 2007, Issue 4 | http://thecochranelibrary.com |
| The Cochrane Database of Systematic Reviews (Cochrane Reviews) | Through 2007, Issue 4 | http://thecochranelibrary.com |
| Database of Abstracts of Reviews of Effects (DARE) | Through 2007, Issue 4 | http://thecochranelibrary.com |
| ECRI Institute Library Catalog | Through December 3, 2007 | ECRI Institute |
| EMBASE (Excerpta Medica) | 1980 through December 3, 2007 | OVID |
| Health Technology Assessment Database (HTA) | Through 2007, Issue 4 | http://thecochranelibrary.com |
| Healthcare Standards | 1975 through September 12, 2007 | ECRI Institute |
| International Health Technology Assessment (IHTA) | Through September 12, 2007 | ECRI Institute |
| MEDLINE | 1950 through December 3, 2007 | OVID |
| PsycINFO | Through December 3, 2007 | OVID |
| PubMed (PreMEDLINE) | PreMEDLINE[sb] Searched December 3, 2007 | http://www.pubmed.gov |
| TRIS | Searched November 5, 2007 | http://ntlsearch.bts.gov/tris/index.do |
| U.K. National Health Service Economic Evaluation Database (NHS EED) | Through 2007, Issue 4 | http://thecochranelibrary.com |
| U.S. National Guideline Clearinghouse™ (NGC) | Searched September 21, 2007 | http://www.ngc.gov |

Manual Searches

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

Retrieval Criteria

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

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

Inclusion and Exclusion Criteria

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

If the article did not meet the question-specific inclusion criteria listed in Appendix C: Inclusion Criteria, the article was excluded from the analysis. Each excluded article, and the reason or reasons for its exclusion are presented in Appendix D: Excluded Studies.

Evaluation of Quality and Strength of Evidence

Rather than focus on the quality of the individual studies that compose an evidence base, our approach to assessing the quality of evidence focused on the overall *body* of the available evidence that was used to draw an evidence-based conclusion.⁽²³⁾ Using this approach, which is described briefly in Appendix E: Determining the Stability and Strength of a Body of Evidence, we took into account not only the quality of the individual studies that compose the evidence base for each key question, but also the interplay between the quality, quantity, robustness, and consistency of the overall body of evidence.

Our approach to assessing the strength of the body of evidence makes a clear distinction between a qualitative conclusion (e.g., “Individuals with VF loss are at increased risk for a motor vehicle crash”) and a quantitative conclusion (e.g., “When compared to individuals who do not have VF loss, the risk ratio for a motor vehicle crash among individuals with the disorder is 1.37; 95% CI: 1.03 – 1.74; $P < 0.005$.”). As shown in Table 11, we assigned a separate strength-of-evidence rating to each of type of conclusion. Evidence underpinning a qualitative conclusion was rated according to its strength, and evidence underpinning quantitative conclusions was rated according to the stability of the effect-size estimate that was calculated.

Table 11. Strength of Evidence Ratings for Qualitative and Quantitative Conclusions

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

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

Statistical Methods

Quantitative analysis based on pooling of results from different studies (i.e., meta-analysis) was found to be inappropriate for the evidence bases in this report. Either the number of studies were too few or there were too many differences among the available studies for a meta-analysis to provide meaningful results. Consequently, we performed qualitative analyses of the available evidence.

In certain instances, we independently calculated effect sizes based on data reported in individual studies. The choice of effect-size estimate depended on the purpose of the studies we assessed, their design, and whether reported outcome data were continuous or dichotomous. Between-group differences in outcome measured using continuous data were analyzed in their original metric (if all included studies reported on the same outcome using the same metric), or the data were standardized into a common metric known as the standardized mean difference (SMD). Dichotomous data were analyzed using the rate ratio (RR) or the odds ratio (OR). Time-to-event data were analyzed using the hazard ratio (HR). The formulae for these effect sizes and their variance are presented in Table 12. If

means and standard deviations were not available for continuous data, every effort was made to determine an estimate of treatment effect from reported statistics (e.g., t-values, f-values) or from *p*-values using methods described in detail elsewhere.(24)

Table 12. Effect-Size Estimates Used in Evidence Report and their Variance

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

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

HR – Hazard ratio.
 OR – Odds ratio.
 RR – Rate ratio.
 SMD – Standardized mean difference.
 WMD – Weighted mean difference.

Evidence Synthesis

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

Key Question 1: Is Monocular Vision Associated with an Increased Crash Risk?

Introduction

Monocular vision is defined as very limited or no vision in one eye (commonly resulting from macular degeneration, glaucoma, cataracts, or trauma) while vision exists in the other eye. In the United States, monocular blindness is defined as a best corrected VA of 20/200 vision or worse in one eye combined with better than 20/200 in the other eye. In contrast, in the eye with better vision, visual impairment is defined as a best corrected VA worse than 20/40 and better than 20/200.⁽²⁵⁾ Presently, no prevalence or incidence rates have been reported on monocular vision. Treatment options are limited and etiology dependent.

Identification of Evidence Base

The evidence base identification pathway for Key Question 1 is summarized in Figure 15. Our searches¹ identified a total of 38 articles that appeared to be relevant to this key question. Following application of the retrieval criteria for this question (Appendix B: Retrieval Criteria), 32 full-length articles were retrieved and read in full. Five of these 32 retrieved articles were found to meet the inclusion criteria (Appendix C: Inclusion Criteria) for this key question (Table 13). Table D-1 of Appendix D lists the 32 articles that were retrieved, read in full, and then excluded. The table also provides justification for their exclusion.

¹ See Appendix A for search strategies.

Figure 15. Development of Evidence Base for Key Question 1

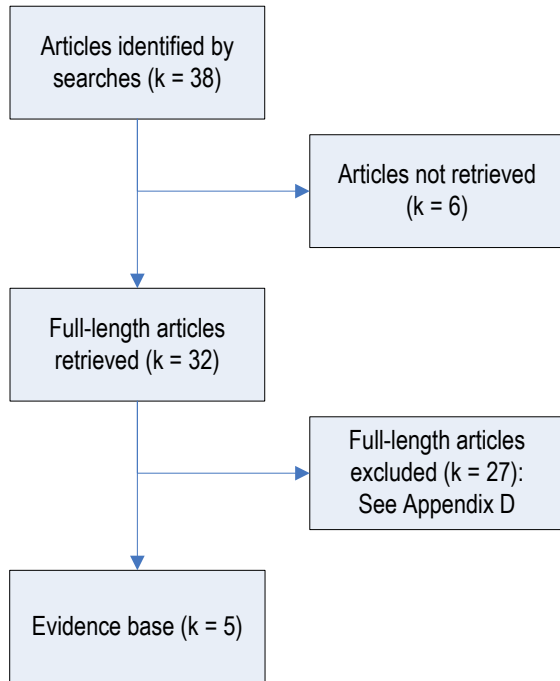


Table 13. Evidence Base for Key Question 1

| Reference | Year | Study Location | Country |
|-----------------------|------|--------------------|---------|
| McCloskey et. al.(26) | 1994 | Washington (State) | USA |
| Gresset et. al.(27) | 1994 | Quebec | Canada |
| Rogers and Janke(28) | 1992 | California | USA |
| McKnight et. al.(29) | 1991 | Maryland | USA |
| Keeney et. al.(30) | 1981 | Kentucky | USA |

Evidence Base

This subsection provides a brief description of the key attributes of the four studies that compose the evidence base for Key Question 1. Here we discuss applicable information relevant to the quality of the included studies and the generalizability of each study’s findings to CMV drivers.

Characteristics of Included Studies

Two types of study (crash and simulator) and two methodologies characterized the crash studies in the evidence base. One methodology compared the prevalence of visual impairments, including monocular vision, among individuals who had been involved in a crash (cases) and a comparable group of individuals who had not (controls). The alternative approach was to select a cohort on the basis of crash involvement and then compare the incidence among monocular individuals who experienced a crash

(cases) to those in the general population who experienced crash (controls). Cohort design methodology was used to study a group of monocular and binocular CMV drivers who were selected and observed to determine the development of safe driving performance (the primary outcome) using simulator driving techniques.

A single crash study controlled for driving exposure (i.e., miles driven and prevailing driving conditions). Failure to adequately control for exposure is a problem commonly found in risk assessment studies of this type. Driving exposure (i.e., ensuring that driving patterns were matched for cases and controls) and adjusting crash risk data for differences in driving exposure using statistical techniques such as regression were performed for only one crash study. If cases and controls are not well matched for exposure, then observed differences in risk may simply be the consequence of differences in exposure.

Four of the five included studies assessed the risk of crash associated with any motor vehicle accident. The fifth distinct study focused on simulator driving and safe driving performance. Some heterogeneity occurred in comparisons between the studies. Rogers and Janke(28) was the only study to directly assess crash risk in drivers with CMV licenses. Gresset(27) and Keeney(30) analyzed crash data for individuals who were involved as the driver in an accident; the McCloskey et al.(26) study focused its attention on the risk for an injurious motor vehicle crash for individuals who were involved as the driver in an accident. Crash data was derived primarily from two sources: medical records and accident files. In order for data from medical records and accident files to be informative, the documentation provided must be accurate; if the accuracy of the information cannot be established, the degree of confidence in the data extracted from these sources is unclear. Differences in the definition of monocularity between studies further complicated the ability to analyze the available information.

The primary characteristics of the four included studies that address Key Question 1 are presented in Table 14 below.

Table 14. Key Study Characteristics of Studies That Address Key Question 1

| Reference | Year | Study Design | Comparison | How Was Monocularity Defined? | Monocular Vision Clinically Confirmed | Factors Controlled For (Compared to Non-Monocular Controls) | Driving Exposure Controlled For? | Primary Outcome | Definition of Crash | Outcome Self-Reported? |
|--------------------------|------|----------------------|---|--|---|---|---|-------------------------------|--|------------------------|
| Crash | | | | | | | | | | |
| McCloskey et al.(26)* | 1994 | Case-control | Injurious crash vs. noninjurious crash | Unilateral blindness, unilateral visual loss, and strabismus | Yes; clinic-based medical records | Yes; age and gender | Unclear | Crash | Police reported crash of vehicle physical damage or injury | No |
| Gresset et al.(27)* | 1994 | Case-control | Crash vs. no crash | NR | NR | Yes | Yes; controlled for mileage and prevailing driving conditions | Crash | Property damage or mild bodily injury registered to SAAQ | No |
| Rogers and Janke(28) | 1992 | Retrospective cohort | Crash vs. no crash | Best corrected 20/200 vision or worse in one eye | Yes; medical records reported in driver license files | Yes; age | No | Crash | Police-reported crash within state of California | No |
| Keeney et al.(30) | 1981 | Retrospective cohort | Crash vs. no crash | Best corrected 20/200 vision or worse in one eye | Yes; medical records reported in driver license files | No | No | Crash | Police-reported crash of physical damage and injury | No |
| Driving Simulator | | | | | | | | | | |
| McKnight et al.(29)† | 1991 | Prospective cohort | Monocular vs. binocular heavy-truck drivers | NR | NR | No | No | Simulator driving performance | N/A | No |

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

† A case-control study in which cases are defined according to the presence of monocular vision, and the control group consists of a cohort of individuals who do not monocular vision.

SAAQ – Société de l'assurance automobile du Québec.

Quality of Evidence Base

The findings of our quality assessment of the included studies composing the evidence base for Key Question 1 are summarized in Table 15. Complete details of our quality assessment can be found in the study summary tables presented in Appendix G. Our analysis using the Newcastle Ottawa Scale(31) concluded that overall included study quality was low.

Table 15. Quality of the Studies That Assess Key Question 1

| Reference | Year | Quality Scale Used | Quality |
|--------------------------|------|--|---------|
| Crash Studies | | | |
| McCloskey et al.(26) | 1994 | Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies | Low |
| Gresset et al.(27) | 1994 | Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies | Low |
| Rogers and Janke(28) | 1992 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Low |
| Keeney et. al.(30) | 1981 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Low |
| Simulator Studies | | | |
| McKnight et al.(29) | 1991 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Low |

The included crash and simulator studies utilized case-control and cohort designs. Within all crash studies, crash history was ascertained through secure records, including state crash files and medical records. Particularly in the case-control studies, all selected cases (drivers experiencing crash) and controls (drivers not experiencing crash) were representative of the population over a defined period of time and location.

Generalizability of Evidence to Target Population

The purpose of this subsection is to provide details of the extent to which individuals enrolled in the studies that address Key Question 1 are similar to CMV drivers in the United States. The generalizability of the findings of the included studies to CMV drivers is unclear because only two of the included studies examined monocular vision among individuals who held a current commercial drivers license (CDL).(28,29) Exposure to risk (as represented by driving exposure) is far lower among noncommercial vehicle drivers, particularly in the elderly population, which composed half the included studies.(26) Consequently, this limited the value of the available data. Important characteristics of the individuals included in the studies that address Key Question 1 are presented in Table 16.

Table 16. Generalizability of Studies That Address Key Question 1

| Reference | Year | Number of Individuals with MV included (n =) | Diagnosis (monocular vision) | % Drivers with Functional MV | Age Distribution | % Male | % CMV Drivers | Driving Exposure (i.e., average miles driven annually) | Driving Conditions (e.g., night driving, driving alone) |
|----------------------------------|------|---|------------------------------|------------------------------|---------------------------------|--------|---------------|--|---|
| Crash Studies | | | | | | | | | |
| McCloskey et al.(26) | 1994 | 7 | Medical records | NR | 65-80+ | NR | NR | NR | NR |
| Gresset et al.(27) | 1994 | 15 | Crash files | NR | All 70 | 100 | 0 | NR | NR |
| Rogers and Janke(28) | 1992 | 660 | Medical records | 100 | Mean age 34-42 | 100 | 100 | NR | NR |
| Keeney et al.(30) | 1981 | 52 | Crash files | 100 | NR | NR | 0 | NR | NR |
| Driving Simulator Studies | | | | | | | | | |
| McKnight et al.(29) | 1991 | 40 | Driver records | NR | Mean age 46.5 (SD not reported) | 100 | 100 | 58,259 km/year | Freeway and urban/suburban/rural streets; day and night driving |

Findings

The findings of each of the four studies that address Key Question 1 are presented in detail in Appendix G. Overall, our analysis found inconsistent evidence regarding whether monocular vision leads to an increase in risk of crash. Of the studies that met the inclusion criteria for Key Question 1, two presented data that is directly relevant to CMV drivers and the impact of monocular vision on driving and crash risk. Studies differed in type (simulator and crash), and crash studies varied in sample size and crash definition.

Impact of Monocular Vision on Driving Performance

One included study provided data pertaining to the impact of monocular vision on CMV driver safety. Using a prospective cohort study design, McKnight et al.(29) compared the driving performance of monocular and binocular truck drivers. The visual assessment evaluated monocular versus binocular commercial driving performance as measured by a simulator test battery. Surrogate markers of driver safety included the following:

- Driving performance (simulated, closed course)
- Cognitive and psychomotor function

The five types of driving exposure that were assessed based upon performance on driver visual tasks included, as follows:

- Recognition distance – responding to signs and lane markings created to call for an immediate response and corresponding to the static VA task
- Mirror checks – the length of mirror fixations during lane changes and merges and corresponding to visual search task
- Lane keeping – trailer lane excursion related to the static VA task
- Clearance judgment—performing an alley dock maneuver and corresponding to VA and depth perception tasks
- Gap errors—acceptance/rejection of gaps when crossing, entering, or making a left turn across traffic and corresponding to VA and depth perception tasks

The study found similar findings of significance in performance measure when assessing day and night driving between the two groups. Overall, no evidence was found to indicate that a performance difference existed between the groups, with the exception of the single true finding—recognition distance task. Comparing binocular and monocular drivers, there is also evidence that recognition at night occurs at closer distances. Although monocular vision is poorer for sign recognition, this does not necessarily relate to poorer driving performance. Relevant study findings are summarized in Table 17.

Table 17. Findings among CMV Drivers' Driving Performance (McKnight et al.)

| Driving Task Type | Day | | | Night | | |
|---------------------------------|-----------|-----------|------------|-----------|-----------|--------------------------------------|
| | Monocular | Binocular | Conclusion | Monocular | Binocular | Findings Significant? ($p < 0.05$) |
| Recognition Distance (m) | | | | | | |
| Signs | 41.8 | 47.4 | Yes | 25.5 | 28.5 | Yes |
| Markings | 15.8 | 15.2 | No | * | * | * |
| Mirror Check (per km) | | | | | | |
| Single lane | 18.1 | 13.5 | No | * | * | * |
| Multilane | 11.1 | 14.8 | No | * | * | * |
| Lane Keeping | | | | | | |
| (% success) | 77 | 78 | No | 79 | 84 | No |
| Clearance Judgment | | | | | | |
| Time (minutes) | 2.14 | 2.40 | No | 1.85 | 2.03 | No |
| Stops (n) | 2.05 | 1.55 | No | 1.57 | 1.34 | No |
| Contacts (n) | 0.53 | 0.50 | No | 0.78 | 0.90 | No |
| Distance (m) | 11.9 | 13.7 | No | 5 | 5 | No |
| Struck dock (%) | 14 | 6 | No | 5 | 5 | No |
| Gap Errors | | | | | | |
| Rejected safe (%) | 1.5 | 2.4 | No | 3.8 | 1.6 | No |
| Accepted unsafe (%) | NR | NR | NR | NR | NR | NR |
| Crossing/center (%) | 28 | 26 | No | 24 | 22 | No |
| Lane change (%) | 28 | 32 | No | 31 | 43 | No |

km – Kilometer.
 m – Meter.
 n – Number.
 NR – Not reported.

*Driver response data collection could not be completed at night.

Adapted from McKnight et al.(29)

Impact of Monocular Vision on Crash Risk

One included study (Rogers and Janke) provided data concerning crash risk in a population of CMV drivers.(28) The study compared the number of crashes among CMV drivers who had visual impairment to CMV drivers who did not have visual impairment in the state of California; all drivers had Class 1 or Class 2 licenses. Visual impairment was divided into two categories: moderate and severe. Drivers in the severe category had monocular vision (visual acuity 20/200 or worse best-corrected vision in one eye); 81% of drivers in this category were totally blind in one eye. The authors performed analysis of covariance (ANCOVA) with adjustment for age to compare the mean crashes/driver among the three groups (normal, moderately impaired, and severely impaired) over a two-year period. The Dunn-Bonferroni procedure for pairwise comparisons found that severely impaired (monocular) drivers had a significantly greater ($p < 0.05$) mean crash rate than unimpaired drivers for both Class 1 and Class 2 licenses (analyzed separately). However, when only drivers with commercial license plates were

analyzed, monocular drivers did not have a significantly greater mean crash rate than unimpaired drivers. The findings of this study appear in Table 18.

This study suffers from unavoidable methodological difficulties that limit any inferences that can be drawn from the findings. The most important limitation is that drivers with visual impairment were technically restricted to in-state driving, whereas unimpaired drivers were allowed to drive out of state. This creates a possible bias because only in-state crashes are recorded in the state of California, which means that the mean crash rate for unimpaired drivers may be underestimated in this study. However, the authors reviewed the medical records of 50 randomly selected monocular drivers and found that, in only 10% of cases, was it clear that the drivers received restricted medical certificates. In 68% of cases the drivers had received the inappropriate standard medical certificate, and in the remainder, the type of certificate could not be determined. An informal telephone poll also found that Department of Motor Vehicle (DMV) employees, highway patrol officers, and a large employer of interstate CMV drivers were unaware of the restriction to intrastate driving. This implies that many monocular drivers may have driven out of state due to their own (and possibly their employers’) unawareness of the restriction. This is partially suggested by a random survey of drivers that found no significant difference in statewide or nationwide mileage estimated between monocular and unimpaired drivers. If true, there would be less bias in the comparative mean crash rates; but this cannot be confirmed. The analysis of drivers with commercial license plates may remove certain types of non-heavy vehicles from the mix, but it also includes light pickup trucks that are not used for commercial purposes. Therefore, neither total crashes based on CMV licenses nor crashes based on CMV plates are completely “clean” measures of heavy-vehicle accidents, which may limit the generalizability of the findings.

Table 18. Crash Risk for CMV Drivers with Monocular Vision

| Reference | Year | Population Analyzed | Mean Crashes/Driver (unadjusted) | | Mean Crashes/Driver (adjusted for age) | | Evidence of Increased Crash Risk? |
|----------------------|------|---|------------------------------------|------------------------------------|--|------------------------------------|-----------------------------------|
| | | | Monocular Vision | Unimpaired Vision | Monocular Vision | Unimpaired Vision | |
| Rogers and Janke(28) | 1992 | All drivers with CMV licenses | Class 1: 0.2611 Class 2: 0.2222 | Class 1: 0.1968 Class 2: 0.1946 | Class 1: 0.2709 Class 2: 0.2328 | Class 1: 0.1856 Class 2: 0.1773 | Yes ($p < 0.05$) |
| | | All drivers of vehicles with CMV license plates | Class 1: 0.0810 Class 2: 0.0855 | Class 1: 0.0716 Class 2: 0.0294 | Class 1: 0.0846 Class 2: 0.0891 | Class 1: 0.0676 Class 2: 0.0233 | No ($p > 0.10$) |

Two of the three remaining crash studies that examined the effects of monocular vision on crash risk within the general driver population did not provide evidence of an increased crash risk (see Table 19).(26,27) Outcome data from this group of studies were presented as the OR—the odds of having monocular vision having experienced a motor vehicle crash divided by the odds of having monocular vision and having not experience a crash. As shown in Table 14, crash risk was assessed by comparing the prevalence of monocular vision among a group of individuals who had experienced a motor vehicle crash with the prevalence of monocular vision among a group of individuals who had not experienced a crash. Since both of these studies had a very small number of drivers with monocular vision, the findings may not be generalizable to the larger population of drivers with monocular vision.

Table 19. Crash Risk for General Drivers with Monocular Vision

| Reference | Year | Crash | | Non-Crash | | Raw OR* (95% CI) | Adjusted OR (95% CI) |
|----------------------|------|----------------------|------------------------|--------------------------|----------------------------|---------------------|-------------------------|
| | | Total Crashes (N) | Crashes with MV (N) | Total Non-Crashes (N) | Non-Crashes with MV (N) | | |
| Gresset et al.(27) | 1994 | 1,400 | 5 | 2,636 | 10 | 1.00 (0.34-2.93) | 0.95 (0.32-2.77) |
| McCloskey et al.(26) | 1994 | 204 | 2 | 410 | 5 | 0.81 (0.15-4.20) | 0.7 (0.1-4.1) |

CI – Confidence interval.
 MV – Monocular vision.
 NS – Not significant.
 OR – Odds ratio.

*Calculated by ECRI Institute from reported data.

Only one study provided evidence of increased crash risk among monocular drivers in a general driving population.(26) Crash risk was assessed by the approach of comparing the rate of crash among monocular drivers with that of the general population who had experienced crash. Outcome data from this study is presented as the RR; relevant findings are summarized in Table 20.

Table 20. Crash Rate Findings among General Drivers with Monocular Drivers

| Reference | Year | Crash Rate Data | | | |
|--------------------|------|--|--|-------------------------|---|
| | | Crashes per Person/Year (Monocular Drivers) | Crashes per Person/Year (General Driving Population) | Rate Ratio* (95% CI) | Evidence of Increased Crash Risk? ($p < 0.05$) |
| Keeney et. al.(26) | 1981 | 0.085 | 0.0452 | 1.89** (NC) | Yes |

* The rate of monocular drivers having experienced a motor vehicle crash divided by the rate of having general driving population experiencing a crash.

** Calculated by ECRI Institute from reported data.

NC – Not calculated; information necessary to calculate 95% confidence interval not reported.

Section Summary

Due to methodological limitations and inconsistency among the findings of different studies, the available evidence is insufficient to determine whether individuals with monocular vision are at increased risk of a crash at this time. The possibility that individuals with monocular vision have an increased crash risk cannot be ruled out.

Direct Evidence – Crash Studies: Our searches identified one study that examined whether monocular CMV drivers are at an increased risk for a crash. This was a large study of all drivers with a CMV license in California. Due to methodological flaws, the quality of this study is low. The authors performed ANCOVA with adjustment for age to compare the mean crashes/driver among three comparison groups based on VA (normal, moderately impaired, and severely impaired) over a two-year period. Severely impaired meant that the drivers had monocular vision. The Dunn-Bonferroni procedure for pairwise comparisons found that monocular drivers had a significantly greater ($p < 0.05$) mean crash rate than unimpaired drivers for both Class 1 and Class 2 licenses (analyzed separately). However, when only drivers with commercial license plates were analyzed, monocular drivers did not have a significantly

greater mean crash rate than unimpaired drivers. A major limitation of this analysis is the restriction of monocular drivers to intrastate driving, while unimpaired drivers were allowed to drive out of state. While there is some evidence that this restriction was not well enforced, it nevertheless creates a potential bias because out-of-state crashes are not recorded by the state of California. Thus, the mean crash rate for unimpaired CMV drivers may be underestimated in this study.

Three studies provided crash data for monocular drivers in general driver populations. Because of a number of methodological flaws, our confidence in the findings of all three studies is low. While two included studies found no evidence to support the contention that individuals with monocular vision are at an increased risk for a motor vehicle crash, the third study did find an association between monocular vision and increased crash risk.

Given the low quality of the included studies and the fact that the findings of these studies are inconsistent, we do not draw an evidence-based conclusion at this time.

Indirect Evidence – Driving Simulator Studies: Our searches identified a single study that indirectly assessed crash risk among individuals with monocular vision by evaluating safe driving performance among CMV cohorts of drivers with monocular vision and binocular vision. This low-quality cohort study concluded that individuals with monocular vision experienced a number of visual deficits, including decreased contrast sensitivity, problems with binocular depth perception, and decreased VA in low light and glare situations. They also experienced deficits in driving functions related to these visual problems, most specifically in those functions related to binocular vision, such as daytime and nighttime sign reading at a distance. There were no significant differences between monocular and binocular vision drivers in visual tests assessing static acuity, dynamic acuity, or glare recovery or in driving performance tests such as information recognition, mirror checks, lane keeping, clearance judgment, or gap judgment.

Key Question 2: Do Red-Green Color Deficiencies (Either Protan and/or Deutan) Increase Crash Risk?

Introduction

Red-green color deficiency (i.e. color blindness) is an acquired (secondary to diseases of the optic nerve or retina or to pharmacotherapy) or congenital (X chromosome linked) visual defect in which an affected individual cannot differentiate between the two colors. Overall, congenital color deficiency has been estimated to occur in 8% of males and 0.5% of females in the population.(32) Color vision deficiency (CVD) is detected by tests such as the Ishihara pseudoisochromatic plates and lantern tests. No treatment is available for CVD.(33)

Identification of Evidence Base

The evidence base identification pathway for Key Question 2 is summarized in Figure 18. Our searches² identified a total of 1,114 articles that were potentially relevant to this key question. Following application of the retrieval criteria for this question (Appendix B: Retrieval Criteria), 124 full-length articles were retrieved and read in full. Three of these retrieved articles were found to meet the inclusion criteria (Appendix C: Inclusion Criteria) for this key question (Table 21). Table D-2 of Appendix D: Excluded Studies lists the 44 articles that were retrieved, read in full, and then excluded. The table also provides justification for their exclusion.

Figure 16. Development of Evidence Base for Key Question 2

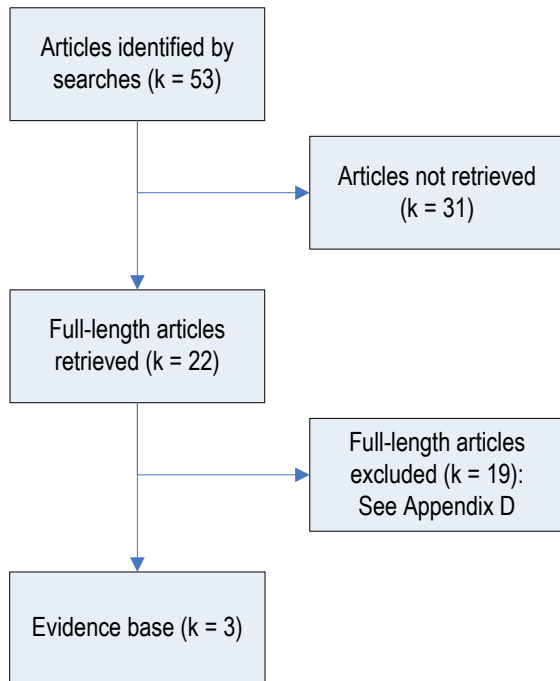


Table 21. Evidence Base for Key Question 2

| Reference | Year | Study Location | Country |
|----------------------|------|-----------------------------|-----------|
| Atchison et al.(34) | 2003 | NR | Australia |
| Shirley et al.(35) | 1968 | NR | Canada |
| Tagarelli et al.(36) | 2004 | Calabria (Cosenza province) | Italy |

NR – Not reported.

² See Appendix A for search strategies.

Evidence Base

This subsection provides a brief description of the key attributes of the three studies that compose the evidence base for Key Question 2. Here we discuss applicable information relevant to the quality of the included studies and the generalizability of each study's findings to CMV drivers.

Characteristics of Included Studies

One relevant study of task performance provided self-reported crash data that allowed independent calculation of crash risk. The remaining two included studies examined driving signal recognition using a cohort design in which the sample population group with a defined known difference are followed up to determine the development of the outcome. The cohorts of color-deficient and normal drivers were selected and observed to determine their potential driving performance (the primary outcome) using traffic signal recognition and simulated driving performance tasks. None of the studies in the present evidence base controlled for exposure by adjusting crash risk data for differences in driving exposure (i.e., miles driven and prevailing driving conditions). Recognition and task performance data were analyzed to observe whether errors in simulated tasks correlated with an increase in driving response time risk.

Clinical confirmation of color deficiency and defect levels data were primarily determined from three sources: Ishihara plate tests, Hardy-Rand-Rittler color deficiency tests, and Farnsworth lantern tests. In order for data to be informative, the documentation provided must be accurate; if the accuracy of the information cannot be established, the degree of confidence in data extracted from these sources is unclear. In this case, the degree of confidence in the data extracted is based upon the accuracy of the test measures, because the results are provided mainly through participant reports. Differences in the definition of red-green color deficiency between studies further complicated the ability to analyze the available information.(34,36) Questions regarding the ability of lantern testing to pass red-green color-deficient individuals (primarily red-protanomals) was also problematic and may lead to a Type II error, falsely rejecting the study hypothesis of an increase in driver response times risk when a true difference may exist.(37)

The primary characteristics of the three included studies that address Key Question 2 are presented in Table 22.

Table 22. Key Study Design Characteristics of Studies that Address Key Question 2

| Reference | Year | Study Design | Comparison | How Was Red-Green Color Deficiency Defined? | Red-Green Color Deficiency Clinically Confirmed | Factors Controlled for (If Compared to Non Red-Green Deficient Controls) | Driving Exposure Controlled For? | Primary Outcome | Definition of Crash | Outcome Self-Reported? |
|-----------------------------------|------|--------------|---|--|---|--|----------------------------------|---|---------------------|------------------------|
| Task Performance | | | | | | | | | | |
| Tagarelli et al.(36) | 2004 | Cohort | Defective color vision vs. normal vision | >5 mistakes on 17 Ishihara plates and confirmed in following plates #s 18-21 | Yes; Ishihara plate | Yes; age | No | Color vision tasks performance including driving | NR | Yes; questionnaire |
| Driving Signal Recognition | | | | | | | | | | |
| Shirley et al.(35) | 1968 | Cohort | Red-green color defective vs. normal vision | NR | Yes; Ishihara plate test and Hardy-Rand-Rittler Test | No | N/A | Traffic signal recognition performance | N/A | No |
| Atchison et al.(34) | 2003 | Cohort | Red-green color-deficient vs. color-normal vision | Reduced ability to see red, green and yellow green signal code within binocular VA 6/6 or better | Farnsworth Lantern and Farnsworth-Munsell Panel D-15 test; Nagel Anomaloscope and Trendelenberg Plate | No | N/A | Traffic signal recognition (response times performance) | N/A | No |

N/A – Not applicable.

NR – Not reported.

† A cohort study in which the population group is defined according to the presence of color vision, and the control group is defined according to the presence of CVDs.

Quality of Evidence Base

The findings of our quality assessment of the included studies composing the evidence base for Key Question 2 are summarized in Table 23. Complete details of our quality assessment can be found in the study summary tables presented in Appendix G. Our analysis using the Newcastle Ottawa Scale(31) concluded that the quality of the included studies was low or moderate.

Table 23. Quality of the Studies that Assess Key Question 2

| Reference | Year | Quality Scale Used | Quality |
|---|------|--|----------|
| Task Performance Studies | | | |
| Tagarelli et al.(36) | 2004 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Moderate |
| Driving Signal Recognition Studies | | | |
| Shirley et al.(35) | 1968 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Low |
| Atchison et al.(34) | 2003 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Low |

The included task performance and driving signal recognition studies utilized a cohort design. The task performance study included a crash-related question that relied on driver self-reporting.(36) Within all studies, color signal recognition performance was ascertained through self-reporting from performing simulated driving and traffic signal recognition. It was unclear whether the cohort in the included studies was truly representative of vision-deficient individuals in the general population; only one cohort study identified the color-deficient individuals as representative of the total population group of cases (color-deficient drivers experiencing color-related difficulties in daily life and car driving) and controls (normal vision drivers experiencing color-related difficulties in daily life and car driving) over the defined period of study time and location.(36)

Generalizability of Evidence to Target Population

The purpose of this subsection is to provide details of the extent to which individuals enrolled in the studies that address Key Question 2 are similar to CMV drivers in the United States. The generalizability of the findings of the included studies to CMV drivers is unclear because none of the included studies examined red-green color deficiencies among CMV drivers. Important characteristics of the individuals included in the studies that address Key Question 2 are presented in Table 24.

Table 24. Generalizability of Studies That Address Key Question 2

| Reference | Year | Number of Individuals with-RGDC Included (n =) | Diagnosis (Red-Green Defective Color Vision) | % Drivers with Functional Red-Green Defective Color Vision | Age Distribution (SD) | % Male | % CMV Drivers | Driving Exposure (i.e., Average Miles Driven Annually) | Driving Conditions (e.g., Night Driving, Driving Alone) | Generalizability to Target Population? |
|---|------|---|---|--|-------------------------------|--------|---------------|--|---|--|
| Task Performance Studies | | | | | | | | | | |
| Tagarelli et al.(36) | 2004 | 151 | Ishihara plate test record | NR | 21.4 (±1.3) | 100 | 0 | NR | NR | Unclear |
| Driving Signal Recognition Studies | | | | | | | | | | |
| Shirley et al.(35) | 1968 | 52 | Ishihara plate test record | 71* | NR | 100 | 0 | NR | NR | Unclear |
| Atchison et al.(34) | 2003 | 49 | Farnsworth Lantern and Farnsworth-Munsell Panel D-15 test; Nagel Anomaloscope and Trendelenberg Plate | NR | 16-35 years (SD not reported) | 100 | 0 | NR | NR | Unclear |

NR – Not reported.

RGDC – Red-green defective color vision.

SD – Standard deviation.

* Calculated by ECRI Institute from reported data.

Findings

The findings of each of the three studies that address Key Question 2 are presented in detail in Appendix G. None of the studies that met the inclusion criteria for Key Question 2 presented data that are directly relevant to the impact of red-green color deficiencies on CMV drivers. One of the three included studies provided no evidence of increased crash risk with noncommercial drivers. This was the only study that provided actual crash data (self-reported) from which crash risk could be determined. The remaining two studies evaluated indirect outcomes (signal recognition and response time performance), which may or may not be associated with crash risk. These studies demonstrated that color-deficient individuals had longer response times relative to color-normal individuals. All studies were of similar study design, with variances in sample size and in the definition of red-green color deficiency (as previously reported in Table 22).

Impact of Red-Green Color Deficiencies on Signal Recognition/Response Time Performance

The two recognition studies examining the effects of red-green color deficiencies on safe driving performance within the general (noncommercial) driver population did not provide evidence of an increased crash risk. However, the included studies provided data pertaining to the impact of red-green color deficiencies on general driver safety. Traffic signal/response time performance was the primary outcome measured within the findings. Specifically, performance was assessed through detection of a difference in errors (high intensity and low intensity) made in flashing directive and traffic signals testing and mean adjusted response times to simulated traffic signals.(34) Color-deficient individuals were found to have made a larger number of mistakes in signal recognition and longer response times than those with normal color vision. A significant difference was also found in one study based upon the color deficiency (protan or deutan) experienced. Relevant findings are summarized in Table 25 and Table 26.

Table 25. Signal Recognition Findings among Color-Deficient Individuals

| Reference | Year | Signal Recognition Performance Data | | |
|---------------------|------|---|---|---|
| | | % Mistakes Made by Color Normal Individuals | % Mistakes Made on Traffic Light Testing by Color Deficient Individuals | % Mistakes on Flashing Directive Signal Testing by Color Deficient Individuals |
| Shirley et al.(35) | 1968 | 0% (no mistakes on any test) | Ordinary traffic lights Deutans: Low intensity – 5.2% High intensity – 3.7% Protans: Low intensity – 10% High intensity – 0% | 11% at high intensity (A – 22% total mistakes at high intensity; W – 12.8% total mistakes at high intensity) 13% at low intensity (A – 24% low intensity, W – 21.4% low intensity) Deutans: Low intensity – 14% High intensity – 12.2% Protans: Low intensity – 14.5% High intensity – 11% |
| Atchison et al.(34) | 2003 | Red signal – 2% Yellow signal – 0% | Deuteranopes: Red signal – 30% Yellow signal – 23% ; Deuteranomals: Red signal – 10% Yellow signal – 3% Protanopes: Red signal – 7% Yellow signal – 0% Protanomals: Red signal – 1% Yellow signal – 1% | Test not performed |

A – Amber signal.
W – White signal.

Table 26. Response Findings among Color-Deficient Individuals

| Reference | Year | Response Times Performance Data | |
|----------------------|------|---------------------------------|-----------------------------|
| | | Response Times Protans (%)* | Response Times Deutans (%)* |
| Atchinson et al.(34) | 2003 | Red Lights | |
| | | 35 | 53 |
| | | Yellow Lights | |
| | | 53 | 85 |

* Increase in response times of color deficient (n = 49) relative to color normals (n = 20).

Impact of Red-Green Color Deficiencies on Crash Risk

The task performance study(36) provided evidence to determine increased crash risk among red-green color-deficient noncommercial drivers. Crash risk was assessed by comparing the rate of crash among red-green color-deficient drivers with that of the normal color-vision driver population who had experienced crash. Outcome data from this study is presented as the RR and relevant findings are summarized in Table 27.

Table 27. Crash Rate Findings among Red-Green Color-Deficient Drivers

| Reference | Year | Crash Rate Data | | | |
|----------------------|------|---|--|----------------------|---|
| | | Crashes (Red-Green Color Deficient Drivers/Total) | Crashes (Normal Color Vision Driving Population/Total) | Rate Ratio* (95% CI) | Evidence of Increased Crash Risk? (p ≤0.05) |
| Tagarelli et al.(36) | 2004 | 23**/126 | 50**/252 | 0.92** (NC) | No |

* The rate of motor vehicle crashes among red-green color-deficient drivers divided by the rate of motor vehicle crashes among the general driving population.

** Calculated by ECRI Institute from reported data.

CI – Confidence interval.

NC – Not calculated; information necessary to calculate 95% confidence interval not reported.

Section Summary

The evidence is insufficient to determine whether red-green color deficiencies increase crash risk.

Direct Evidence – Crash Studies: A single included study reported on the association between CVD and crash (self-reported). This study did not provide any evidence in support of the contention that individuals with red-green color deficiencies are at an increased risk for a crash. However, a single low-quality study is insufficient evidence to allow any conclusion concerning crash risk; more data are required.

Indirect Evidence – Driving Simulator Studies: Two studies of low methodological quality used either self-reporting of driving performance or simulated driving performance tests to evaluate traffic signal recognition among non-CMV drivers with color-deficient vision and normal vision. Individuals with CVD were less proficient in signal recognition and demonstrated longer response times than color-vision

normal individuals. Whether these observed deficits are factors that may contribute to an increased crash risk is unclear.

Key Question 3: Is visual field loss associated with an increase in crash risk? What is the acceptable visual field range in the horizontal and vertical meridians?

Introduction

Visual field (VF) is a term used to describe the visual space (expressed as a range of visual angle) within which objects are visible to the immobile eyes at a given time. It is commonly referred to as field of view or field of vision. VF is typically measured by perimetry. During perimetry, a patient is required to stare at a fixation target (typically a light) while additional target stimuli are presented in the periphery. Perimetry can be manual or automatic. Manual perimetry describes a conventional method in measuring field of view using kinetic methods, which involve a mobile stimulus moved by a perimetrist.(2) The procedures and instruments utilized in manual perimetry provide distinct measurement of the peripheral retina. The development of computerized automated perimetry has allowed the use of more complex visual stimuli and test procedures (see Background section for more detailed description of these tests). While manual testing is considered an economical method of providing basic VF information in a rapid manner, automated perimetry has the advantage of detecting VF loss earlier (principally in the central region) and is more standardized without requiring the presence of a skilled perimetrist.(3)

A more complex test than standard perimetry is the useful field of view (UFOV) test, a measure of the functional or useful range of peripheral vision under cognitive load conditions.(8) Cognitive load refers to the total amount of mental activity imposed on working memory at an instant in time. The major factor that contributes to cognitive load is the number of elements that need to be attended to. As cognitive load is increased by elevating task complexity, the functional range of peripheral vision (i.e., the degree of peripheral vision from which information is processed) becomes restricted. Thus, the functional extent of peripheral vision under complex, real-world conditions, such as detecting stimuli in cluttered backgrounds, is not always equivalent to the maximum extent of peripheral vision that can be measured with clinical perimetry techniques. The UFOV test is divided into three subtests that respectively measure central vision and processing speed, divided attention, and selective attention. The subtests determine the subject's ability to identify target objects in the center and periphery of a computer screen under increasingly complex conditions (for a more detailed description, see Background section). Reduction in UFOV scores has also been associated with age and neurological damage.

Identification of Evidence Base

Our searches³ identified a total of 255 potentially relevant publications. Following the application of our retrieval criteria (Appendix B: Retrieval Criteria), we retrieved 91 full-length articles. Sixteen of the 91 retrieved articles were found to meet the inclusion criteria (see Appendix C: Inclusion Criteria) for this key question (see Table D- 3 of Appendix D for citations and reason for exclusion). These 16 articles

³ See Appendix A for search strategies.

described a total of 14 studies (two studies were reported on by two articles). The evidence base identification pathway for Key Question 4 is summarized in (Figure 17). The included studies are listed in Table 28.

Figure 17. Development of Evidence Base for Key Question 3

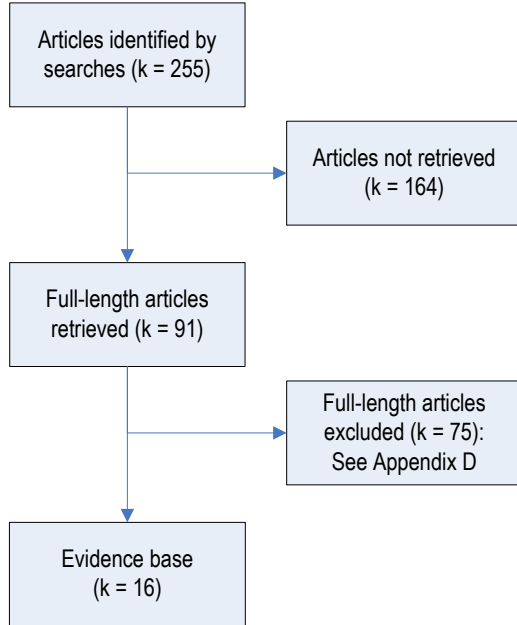


Table 28. Table Evidence Base for Key Question 3

| Reference | Year | Study Location | Country |
|--|------------|----------------|---------|
| Haymes et al.(38) | 2007 | Nova Scotia | Canada |
| Rubin et al.(39) | 2007 | Maryland | USA |
| Ball et al.(8) | 2006 | Maryland | USA |
| McGwin et al.(40) | 2005 | Alabama | USA |
| McGwin et al.(41) | 2000 | Alabama | USA |
| McGwin et al.(42) Owsley et al.(43) | 1998 | Alabama | USA |
| Owsley et al.(44) | 1998 | Alabama | USA |
| Szlyk et al.(45) | 1993 | Illinois | USA |
| Szlyk et al.(46) | 1992 | Illinois | USA |
| Owsley et al.(47) | 1991 | Alabama | USA |
| Johnson and Keltner(48) | 1983 | California | USA |
| Fishman et al.(49) | 1981 | Illinois | USA |
| Hills and Burg(50) Burg(51) | 1977, 1971 | California | USA |
| Council and Allen(52) | 1974 | North Carolina | USA |

Evidence Base

This section provides a brief description of the key attributes of the 14 studies that compose the evidence base for Key Question 3. Here we discuss applicable information relevant to the quality of the included studies and the generalizability of each study's findings to CMV drivers.

Characteristics of Included Studies

The primary characteristics of the 14 included studies that address Key Question 3 are presented in Table 29. Two different study designs (case-control and cohort) characterize the studies included in the evidence base for this key question. One study design (the case-control design) compared the prevalence of visual impairments including VF loss among individuals who had been involved in a crash (cases) and a comparable group of individuals who had not (controls). In studies that utilized the alternative study design (the cohort design), cohorts were created on the basis of whether individuals demonstrated VF loss or normal VF. The incidence of crash in these two groups was then compared. Within the cohort design, a group of visually impaired individuals (including those with VF loss) were selected and followed up during a specified time interval to determine crash occurrence. An alternative approach was to select a group of visually impaired individuals (including those with VF loss) and follow them during a specified time period to determine driving performance (the primary outcome) using a test battery; in these latter studies, crash data was included as a secondary outcome. For this key question, we assess only the crash data from these studies.

The driving exposure variable, in this case number of miles driven, was controlled for in 7 of the 14 crash studies. Failure to adequately control for exposure is a problem commonly found in risk assessment studies of this type. If cases and controls are not well matched for exposure, then observed differences in risk may simply be the consequence of differences in exposure.

All 14 included studies assessed the risk of crash associated with any motor vehicle accident; however, there was slight difference across studies in the way by which crash data was reported. The majority (12 studies) reported on any crash type. In contrast, McGwin(41) analyzed crash data only for individuals who were involved at fault as the driver in the crash. The Owsley et al.(43) study focused its attention on the risk for an injurious motor vehicle crash for individuals who were involved as the driver in a crash. Crash data from which rates were determined were obtained primarily from accident files from motor vehicle departments and (occasionally) insurance records. In order for data from crash files to be informative, pertinent documentation contained within these data sources must be accurate. Four studies also reported crash data based on individual self-reporting; this is considered the least reliable source of data. Because we cannot determine the accuracy of information from these sources, the degree of confidence in data extracted from these sources is unclear. Furthermore, these studies differed in how they defined VF loss (varying testing measures, medical records) when reported.

Table 29. Table Key Study Characteristics of Studies that Address Key Question 3

| Reference | Year | Study Design | Comparison | How was VF Loss Defined? | VF Loss Clinically Confirmed? | Factors Controlled For (If Compared to Non VF Loss Controls) | Driving Exposure Controlled For? | Primary Outcome | Definition of Crash | Outcome Self-Reported? |
|-------------------|------|---------------------|---|--|--|---|----------------------------------|-----------------|--|------------------------|
| Rubin et al.(39) | 2007 | Cohort | N/A | >20 points missed for binocular VFs | Yes; Humphrey Field Analyzer; UFOV test | Age and race | Yes; miles driven | Crash | State reported crash files from MAARS* | No |
| Haymes et al.(38) | 2007 | Cohort | Glaucoma vs. normal vision | NR | Yes; HFA Swedish Interactive Threshold Algorithm (SITA); UFOV test | Yes; age, gender, body mass index, number of systemic medications and better eye HFA mean deviation | Yes; on-road driving km/week | Crash | Self-report and police-reported crash in the previous 5 years | Sometimes |
| Ball et al.(8) | 2006 | Cohort | Crash vs. no crash | 353 ms or longer on UFOV subtest in a 75% correct detection threshold | Yes; UFOV test | N/A | Yes; annual mileage | Crash | Crash records from state crash files | No |
| McGwin et al.(40) | 2005 | Nested case-control | Crash vs. no crash | NR. Only severe visual defect scoring 12-20 based on AGIS scoring system | Yes; medical records | No | No | Crash | Crash records from state crash files during a 6-year period | No |
| McGwin et al.(41) | 2000 | Case-control | At-fault crash drivers, not at-fault crash drivers, and drivers not involved in crashes | Visual Functioning Questionnaire (VFQ) scores of ≤75 | No; Visual Functioning Questionnaire used | Age, gender, race, driving. (page 426) | Yes; annual mileage. (page 426) | Crash | Department of Public Safety reported at-fault/not at-fault driving; involved in at least 1 crash in 1996 | No |
| Owsley et al.(44) | 1998 | Cohort | N/A | Impaired vision defined as 40% reduction or greater in UFOV | Yes; UFO V test | N/A | Yes | Crash | State-reported crash | No |
| Owsley et al.(43) | 1998 | Case-control | Injurious crash vs. noninjurious crash | Loss of sensitivity of more than 1 log unit (10 dB) | Yes; Humphrey Field Analyzer | NR | No | Crash | At least one vehicle crash in a 5 year period resulting injury from state crash files | No |
| McGwin et al.(42) | 1998 | Case-control | Crash vs. no crash | Varying peripheral targets at 10, 20, 30 degree mark; central and peripheral sensitivity >10 and | Yes; eye examination, Humphrey Field Analyzer | No | No | Crash | Self report and state crash files during previous 5 years | No |

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| Reference | Year | Study Design | Comparison | How was VF Loss Defined? | VF Loss Clinically Confirmed? | Factors Controlled For (If Compared to Non VF Loss Controls) | Driving Exposure Controlled For? | Primary Outcome | Definition of Crash | Outcome Self-Reported? |
|--------------------------------|---------------|--------------|---|--|--|--|----------------------------------|-----------------|--|------------------------|
| | | | | UFOV \geq 40 | | | | | | |
| Szlyk et al.(45) | 1993 | Cohort | Central vision impairment vs. normal vision individuals | NR | Yes; Goldmann perimeter | NR | No | Crash | Individual self-report of crash within the past 5 years resulting in property damage | Yes |
| Szlyk et al.(46) | 1992 | Cohort | Retinitis pigmentosa vs. normal vision drivers | 4 major peripheral field loss profiles (partial restriction, ring scotoma, temporal islands, and severe concentric peripheral restriction) | Yes; Goldmann perimeter | NR | No | Crash | Self report and state crash files from previous 5 years that resulted in property damage | Yes |
| Owsley et al.(47) | 1991 | Cohort | Visual attention disorder drivers vs. nonattention disorder drivers | \neq 34 dB on the Humphrey test | Yes; eye health examination including Humphrey VF Analyzer | NR | No | Crash | Crash in the previous 5 years as reported from state crash files | No |
| Johnson and Keltner(48) | 1983 | Cohort | VF loss vs. normal vision | Substantial depression of all or part of the peripheral field or 2 or more adjacent target missed in testing | Yes; Fieldmaster automated perimeter | Yes; age and gender | Yes | Crash | State-reported crash 3 years prior to VF test date | No |
| Fishman et al.(49) | 1981 | Cohort | Retinitis pigmentosa vs. normal vision | Field efficiency from the central fixation point | Yes; eye examination including Goldmann perimeter | No | No | Crash | Crash records and self-reported crash during a 5-year period | Yes |
| Hills and Burg(50) Burg(51) | 1977, 1971 | Cohort | N/A | NR | Yes; perimeter | N/A. though age controlled | Yes; annual mileage | Crash | State crash files during past 3 years | No |
| Council and Allen(52) | 1974 | Cohort | Crash vs. no crash; limited vs. normal vision | VFs \leq 120 degrees | Yes, perimeter testing | No | No | Crash | State crash files | No |

AGIS – Advanced Glaucoma Intervention Study.

HFA – Humphrey Field Analyzer.

MAARS – Maryland Automated Accident Reporting System.

N/A – Not applicable.

NR – Not reported.

UFOV – Useful field of view.

Quality of Evidence Base

The findings of our assessment of the studies included in the evidence base for Key Question 3 are summarized in Table 30. Complete details of our quality assessment can be found in the study summary tables presented in Appendix G.

All included studies were rated as being either of low or moderate quality. The quality of case-control and cohort studies is limited because of the nonrandom allocation of individuals to different groups. Although observational studies often statistically adjust for known confounding factors, only random allocation can control for unknown confounding factors; however, random allocation is not possible in these study designs. Therefore, the quality rating of case control and cohort studies can never be high.

Table 30. Table Quality of Studies that Address Key Question 3

| Reference | Year | Quality Scale Used | Quality |
|--|---------------|--|----------|
| Haymes et al.(38) | 2007 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Moderate |
| Rubin et al.(39) | 2007 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Moderate |
| Ball et al.(8) | 2006 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Moderate |
| McGwin et al.(40) | 2005 | Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies | Low |
| McGwin et al.(41) | 2000 | Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies | Moderate |
| McGwin et al.(42) Owsley et al.(43) | 1998 | Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies | Low |
| Owsley et al.(44) | 1998 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Moderate |
| Szyk et al.(45) | 1993 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Low |
| Szyk et al.(46) | 1992 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Low |
| Owsley et al.(47) | 1991 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Low |
| Johnson and Keltner(48) | 1983 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Moderate |
| Fishman et al.(49) | 1981 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Low |
| Hills and Burg(50) Burg(51) | 1977, 1971 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Low |
| Council and Allen(52) | 1974 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Moderate |

Generalizability of Evidence to Target Population

The findings of our assessment of the generalizability of the findings of the studies that form the evidence base for Key Question 3 is based on the characteristics of the individuals enrolled in each of the included studies. These characteristics are presented in Table 31. The mean age of enrolled drivers (where reported) ranged widely from 36 to 73. In most studies, the proportion of males was roughly half, ranging (where reported) from 40% to 57%. Compared with a CMV driver population, these studies have a greater proportion of women. Not all studies reported the race of enrolled drivers, but among those that did, the proportion of white drivers ranged from 61% to 93%, with African-Americans composing the rest of the population. No studies reported comorbid medical diagnoses of the drivers. Two studies reported the number of comorbidities. In those studies, most patients had at least one comorbidity.

Patients were recruited from a variety of settings, including ophthalmologist or optometrist offices, DMVs, or licensed drivers in a community. None of the included studies specifically sought to recruit a specific population of CMV drivers. While it is possible that some CMV drivers were included among the enrollees in these studies, no studies report on the number of CMV drivers that they included. Consequently, the degree to which the findings of the included studies can be generalized to CMV drivers is uncertain. In an attempt to assess the comparability of drivers in the included studies to CMV drivers, we assessed the age, sex, race, and comorbidity profile of the included drivers. However, due to a general lack of complete reporting among the included studies, it is unclear how generalizable the subjects in these studies are to CMV drivers. Some studies reported characteristics for the entire studied sample, but did not report on drivers with VF deficiency separately.

Table 31. Generalizability of Studies that Address Key Question 3

| Reference | Year | Number of Relevant Patients | CMV Drivers? | Patient Selection | Characteristics of People with VF Loss | | | |
|-------------------|------|---|--------------|--|---|---|---|--|
| | | | | | Mean Age (SD) | Proportion Male | Race | Comorbidity |
| Haymes et al.(38) | 2007 | 48 | No | Glaucoma patients with related optic disk and VF damage selected from university hospital | 69 (9) | 50% | NR | Median 3 (range 0-10) medical conditions per patient, median 2 (range 0-8) systemic medical conditions per patient |
| Rubin et al.(39) | 2007 | 1,801 | No | Participants in Salisbury Eye Evaluation (SEE) longitudinal population-based study | NR; 34.2% 65-69 years, 34.4% 70-74 years, 20.7% 77-79 years, 10.7% 80-85 years | 49.8% | 80.8% white, 19.2% African American | 9.6% have none, 21.8% have 1, 68.7% have 2 or more |
| Ball et al.(8) | 2006 | 1,910 | No | Older adults renewing their license at one or three sites in Maryland, patients at community site, and patients referred to Maryland advisory board for assessment | 68.55 (7.95) | 54% | 93% white | NR |
| McGwin et al.(40) | 2005 | 120 | No | Older adults with glaucoma involved in police-reported motor vehicle collision and under care at a university-affiliated ophthalmology and optometry practice | 73.4 (NR) | 56.9% | 61.0% white, 34.2% African-American, 4.9% other | Cataract 88.6%, diabetic retinopathy 32.5%, age-related maculopathy 29.3%, hearing aid 33.3%, fall 49.6% |
| McGwin et al.(41) | 2000 | 174 | No | Mobile County (AL) residents aged 65+ years with drivers license and at least one recorded automobile crash | NR for glaucoma patients; all drivers aged 65 and older See Appendix G for age distribution by categories | NR for glaucoma patients; for all at-fault drivers 49.6%, for at-fault drivers, 51%, for no-crash drivers 49.1% | NR for glaucoma patients See Appendix G for all patients | None reported |
| McGwin et al.(42) | 1998 | 278 | No | Licensed drivers aged ≥55 years in Jefferson County (AL) | 71 (range 56-90)† | 48.9%† | NR | NR |
| Owsley et al.(43) | 1998 | 294 | No | | | | | |
| Owsley et al.(44) | 1998 | 294 drivers total, 127 with a UFOV <40% | No | Licensed drivers aged ≥55 years in Jefferson County (AL) | NR for drivers with decreased VF; See Appendix G for all drivers | NR for drivers with decreased VF; See Appendix G for all drivers | NR for drivers with decreased V; See Appendix G for all drivers | NR for drivers with increased VF; See Appendix G for all drivers |
| Szlyk et al.(45) | 1993 | 20 | No | Patients with juvenile macular dystrophies | 36.1 (10.5) | 40% | NR | NR |
| Szlyk et al.(46) | 1992 | 21 | No | Patients with retinitis pigmentosa and varying degrees of peripheral field loss | 42.3 (11.8) | 57% | NR | NR |

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| Reference | Year | Number of Relevant Patients | CMV Drivers? | Patient Selection | Characteristics of People with VF Loss | | | |
|--------------------------------|---------------|--|--------------|--|--|--|------|-------------|
| | | | | | Mean Age (SD) | Proportion Male | Race | Comorbidity |
| Owsley et al.(47) | 1991 | 53 (NR how many have VF deficiency) | No | Recruited from Primary Care Clinic of School of Optometry at University of Alabama at Birmingham | NR for VF deficiency patients; for all mean 70 years range 57-83 | NR for VF deficiency patients; for all 49% | NR | NR |
| Johnson and Keltner(48) | 1983 | 580 | No | NR | NR | NR | NR | NR |
| Fishman et al.(49) | 1981 | 42 | No | From a retinitis pigmentosa clinic population | 38 (range 21-75) | 52% | NR | NR |
| Hills and Burg(50) Burg(51) | 1977, 1971 | NR how many have field deficiency; 14,381 total | No | 1967 California driver vision study; successful drivers license applicants at any of 46 California DMVs 11/1962-4/1966 | NR; range for entire sample 16-92 | NR; for entire sample 62.8% male | NR | NR |
| Council and Allen(52) | 1974 | 44,838 tested; number with VF deficiency depends on definition | No | North Carolina drivers applying for a license during 12/1972 | NR | NR | NR | NR |

NR – Not reported.

SD – Standard deviation.

† Reported in Ball et al. 1993(53)

Findings

The findings of each of the 14 included studies (in 16 publications) that address Key Question 3 are summarized below; data from each study are presented in more detail in Appendix G. As noted above, the degree to which the findings of these studies can be generalized to CMV drivers is unclear. However, it is plausible that the association between VF loss and crash risk among the general driver population will be similar among CMV drivers.

Our evidence synthesis is divided into two major categories: an analysis of the findings of studies that examined the association between VF loss and crash risk using standard perimetry testing (any method), and an analysis of studies that examined the association between UFOV and crash risk. This reflects the fact that tests of VF and UFOV are markedly different. One study reported assessment of VF loss without using standard perimetry or UFOV; this study used a visual functioning questionnaire and was analyzed separately from the rest of the evidence base.

Standard Perimetry Testing

Twelve included studies evaluated crash risk among drivers with VF loss as determined by various standard perimetry tests (Table 32). Seven studies used automated perimetry (six used the Humphrey VF Analyzer, one used the Fieldmaster), while five studies used manual perimetry (three used the Goldmann perimeter, one used the American Optical Company Screening perimeter, and one used an unnamed manual perimeter). Six of the 12 studies evaluated older populations (>54 years), and two additional studies analyzed individuals in various age categories (including older drivers) separately. Three studies focused predominantly on younger drivers (mean ages ranging from 36 to 42) with a specific VF disorder (retinitis pigmentosa in two studies, juvenile macular dystrophies (JMDs) in one study). Two of the studies that evaluated older patients also focused on a specific VF disorder (glaucoma). Thus, the majority of these studies sampled from populations with an increased likelihood of having individuals with substantial VF loss.

Due to differences in patient characteristics, perimetry tests, cutoffs for judging VF loss, type of crash data, summary statistics, and adjustments of summary statistics based on potential confounding factors, combining these studies in a meta-analysis to obtain a quantitative estimate of effect would be inappropriate. However, a qualitative assessment of the findings reveals that 8 of the 12 studies found a statistically significant increase in crash risk among individuals with VF loss. Several of these studies presented multiple comparisons (e.g., adjusted and unadjusted, total crash and at-fault crash, self-reported and state-reported crash), and not all comparisons within certain studies were statistically significant. Of the eight studies that showed at least one statistically significant comparison, six of the eight also showed at least one comparison that was not statistically significant, although the direction of effect was usually consistent (i.e., suggesting an increased crash risk with greater VF loss). Regardless of whether a comparison found a statistically significant effect, 10 of the 12 studies showed a direction of effect suggesting that VF loss increases crash risk. The findings are therefore marginally consistent, although this does not necessarily mean that all types of perimetry perform equally well. Because the

median quality of the evidence base is low, the strength of evidence supporting this finding is minimally acceptable.

We also looked at various subgroups of studies to determine whether the findings were similar across these subgroups, including studies focusing on specific eye disorders. The two studies evaluating drivers with glaucoma both found statistically significant effects suggesting that VF defects increase crash risk among glaucoma patients. In one of these studies (McGwin et al. 2005), the statistically significant comparisons all involved moderate or severe defects in the worse eye (in the better eye there were nonstatistically significant effects in the same direction). In the other study (Haymes et al. 2007), the statistically significant effects were found for self-reported crashes but not police-reported crashes, although the direction of effect was the same for all crash comparisons.

Of the two studies evaluating drivers with retinitis pigmentosa, the study by Szlyk et al. (1992) found a statistically significant increase in crash risk associated with VF loss for every comparison. The study by Fishman et al. (1981) showed a statistically significant effect when drivers with the disease were compared to normal vision drivers, but the correlation between peripheral VF deficiency and crash risk was not statistically significant in the retinitis pigmentosa group. However, the direction of effect was the same for both comparisons. This study may have been underpowered to detect a correlation because only 42 drivers had retinitis pigmentosa and the majority of drivers had only mild VF loss.

The single study that included patients with JMD (Szlyk et al. 1993) did not find a significant association between JMD and crash risk or between measures of central VF loss and crash risk, and there was no trend in that direction.

Of the seven studies that included a broader group of individuals with visual field defects, six of these studies either enrolled older drivers (age >54) exclusively or provided separate analyses of older drivers. Three of the six studies found a statistically significant association between VF loss and crash risk among older drivers. Two of the remaining three studies found the same direction of effect, although the finding was not statistically significant.

When divided by use of automated or manual perimetry, five of seven studies that used automated perimetry and three of five studies that used manual perimetry showed a statistically significant association between VF loss and crash risk in at least one comparison.

Of the five studies that adjusted for driving exposure (miles driven), four showed a statistically significant association between crash risk and VF loss. It is notable that in 3 studies that made 10 comparisons of unadjusted and adjusted ORs, adjusting the summary statistic did not alter the statistical significance of the comparison in 9 out of 10 cases (in the remaining instance, a borderline statistically significant finding became nonsignificant because the lower 95% confidence interval of the OR shifted from 1.0 to 0.9).

If VF loss does increase crash risk, another question that might be asked is whether central VF loss and peripheral VF loss have the same impact on crash risk. Four studies reported separate evaluations of

central VF loss and peripheral VF loss. The findings differed among the studies but were internally consistent in three of the four studies (all by Owsley et al.). One study found a statistically significant effect of both central and peripheral VF loss on crash risk, while two studies did not show a statistically significant effect of either central or peripheral VF loss on crash risk. One of the latter studies (Owsley et al. 1991) included only 53 drivers and may have been underpowered to find a significant association. The remaining study (Rubin et al. 2007) found a statistically significant association between lower peripheral VF loss ≥ 10 points and increased crash risk, but no association between central or upper peripheral VF loss and increased crash risk.

Five additional studies evaluated either central VF loss or peripheral VF loss, but not both. Two studies in drivers with specific disorders (glaucoma and JMD) evaluated the potential relationship between central VF loss and crash risk. The glaucoma study found a statistically significant association between central VF loss and crash risk, while the JMD study found no association between central VF loss and crash risk. Two studies of patients with retinitis pigmentosa measured peripheral VF loss; one study (Szlyk et al. 1992) found a statistically significant association between peripheral VF loss and crash risk, while the other study (Fishman et al. 1981) did not, although the crash risk was elevated for drivers with retinitis pigmentosa compared to normal vision controls in this study. One additional study of a general driving population (Johnson and Keltner 1983) found a statistically significant association between peripheral VF loss and crash risk. The remaining three studies did not perform separate measurement of peripheral and central VF loss. In summary, two out of six studies found a statistically significant association between central VF loss and crash risk, while four out of seven studies found a statistically significant association between peripheral VF loss and crash risk. Thus, the evidence slightly favors peripheral VF loss as having a greater impact on crash risk. However, only four studies separately evaluated both central and peripheral VF loss, and three of these four studies showed the same results for both types of VF loss. Studies that evaluated only one type of VF loss also differed in terms of the driver characteristics and other factors that might account for differences in the results. Thus, it is difficult to judge with certainty the relative impact of each type of VF loss on crash risk.

The question of acceptable VF range as determined by standard perimetry tests is difficult to answer with the available evidence base. The 12 studies that used standard perimetry tests described a variety of cutoffs or scoring systems that do not necessarily translate well into an estimate of VF range in the horizontal and vertical meridian (Table 32). Two studies used cutoffs of central 30° VF sensitivity >10 dB and peripheral 30°-60° VF sensitivity >10 dB, but only one of the two studies found an increased crash risk associated with this cutoff. Another study measured the correlation between crash risk and central 30° VF sensitivity or peripheral 30° VF sensitivity and found no statistically significant correlation. These were the only studies that used the same measure or the same cutoffs for VF loss. Because other measures or cutoffs appeared only in single studies, it is difficult to reach a conclusion about the appropriateness of those cutoffs without replication of findings by other studies.

UFOV Testing

Six included studies (in seven publications) examined the association between reduction in UFOV and crash risk (Table 32); four of these studies also used standard perimetry tests and were included in the previous analysis. The six studies varied with regard to whether they presented findings based on the complete UFOV test or various subtests. Three studies compared crash risk between drivers with $\geq 40\%$ reduction in UFOV scores to drivers with $< 40\%$ reduction in UFOV scores. Two publications (McGwin et al.(42); Owsley et al.(43)) included overlapping data on the same patient population, so these two publications are counted as a single study. We present data from both publications because they made different comparisons based on the type of crash (one reported state-recorded crashes and self-reported crashes, while the other reported injurious crashes and noninjurious crashes). One additional study presented a Pearson correlation between UFOV score and crash frequency. Two of these four studies also compared crash risk based on the results of the three separate subtests of UFOV (visual speed of processing impairment, divided attention impairment, and selective attention impairment). Two additional studies presented findings based only on one subtest of UFOV. Studies also differed in the reported summary statistics: four studies summarized their data as ORs, one used relative risks, one used HRs, and one used Pearson correlations. Most summary statistics are adjusted for potential confounding factors, but the studies varied in the type and number of factors used in the adjustment. Studies also differed in the type of crash data used (e.g., total crashes, at-fault crashes, state-recorded crashes, self-reported crashes).

Due to heterogeneity in the implementation of UFOV (full test or subtests), summary statistics, adjustments for potential confounding factors, and types of crashes reported among different studies, combining the data in a meta-analysis to obtain a quantitative effect estimate was inappropriate. However, the results of these studies show consistency in the direction of effect. Each study found a statistically significant relationship between UFOV reduction and increased crash risk, and four of these studies used the complete UFOV test. The two additional studies that only reported findings for one subtest of UFOV also found evidence of increased crash risk, so one can assume that the finding would have also been significant for the complete UFOV test (in two studies that reported complete test and subtest results, at least one of the subtests always showed a statistically significant association with crash risk). Thus, one can conclude that functional VF loss as determined by the complete UFOV test is associated with increased crash risk. These findings are qualitatively robust, and since the median quality of these studies was moderate, the strength of evidence supporting this conclusion is moderate.

The findings showed some inconsistency when the various subtests of UFOV were evaluated separately. Subtest 1, reported in two studies, showed a statistically significant HR (indicating increased crash risk with visual speed of processing impairment) in one study but a nonstatistically significant relative risk in another (although the effect sizes were similar in both studies). Subtest 2, reported in three studies, showed consistent findings in that all three studies found a statistically significant increased crash risk associated with divided attention impairment. Subtest 3, reported in three studies, showed a large and statistically significant increase in crash risk with selective attention impairment in one study, but the

other two studies showed no statistically significant increase in crash risk with selective attention impairment.

Three studies using the UFOV test found that a $\geq 40\%$ reduction in UFOV was associated with an increase in crash risk (Table 32). This is a consistent finding and appears to be a reasonable cutoff for determining increased crash risk. The median quality of these studies is moderate, and the strength of evidence supporting this finding is moderate. As noted earlier, this measure incorporates cognitive load as well as VF loss, so it is not always equivalent to the maximum extent of peripheral vision that can be measured with standard perimetry techniques.

Table 32. Crash Risk in Drivers with VF Loss Compared to Drivers without VF Loss

| Reference | Year | Number of Drivers | Crash Rate Data | | | | Evidence of Increased Crash Risk | |
|--|------------------------|--|--|---------------------------|--|-------|----------------------------------|--|
| | | | Outcome Measure | Effect Size | Adjusted for... | P = | | |
| Studies Reporting VF Loss Using Perimetry | | | | | | | | |
| Haymes et al.(38) | 2007 | 84 (40 with glaucoma) | OR of having a crash in past 5 years | | | | | |
| | | | Self-reported MVCs | | | | | |
| | | | All crashes (glaucoma vs. normal vision controls) | Unadjusted OR (95% CI) | NA | <0.05 | Yes | |
| | | | | 5.18 (1.33 – 20.24) | | | | |
| | | | At-fault crashes (glaucoma vs. normal vision controls) | Adjusted OR (95% CI) | Age, gender, number of systemic medications, better eye HFA MD, on-road driving exposure (km/week) | <0.05 | Yes | |
| | | | | 6.62 (1.40 – 31.23) | | | | |
| | | | At-fault crashes (glaucoma vs. normal vision controls) | Unadjusted OR (95% CI) | NA | <0.05 | Yes | |
| | | | | 10.75 (1.28 – 90.34) | | | | |
| | | | At-fault crashes worse eye HFA MD ≤-10 dB | Adjusted OR (95% CI) | Age, gender, number of systemic medications, better eye HFA MD, on-road driving exposure (km/week) | <0.05 | Yes | |
| | | | | 12.44 (1.08 – 143.99) | | | | |
| | | | At-fault crashes worse eye HFA MD ≤-10 dB | Adjusted OR (95% CI) | Age, gender, number of systemic medications, on-road driving exposure (km/week) | NS | No | |
| | | | | 4.97 (0.73 – 33.81) | | | | |
| Police-reported MVCs | | | | | | | | |
| All crashes (glaucoma vs. normal vision controls) | Unadjusted OR (95% CI) | NA | NS | No | | | | |
| | 2.67 (0.73 – 9.69) | | | | | | | |
| At-fault crashes (glaucoma vs. normal vision controls) | Adjusted OR (95% CI) | Age, gender, number of systemic medications, better eye HFA MD, on-road driving exposure (km/week) | NS | No | | | | |
| | 3.21 (0.72 – 14.27) | | | | | | | |
| At-fault crashes (glaucoma vs. normal vision controls) | Unadjusted OR (95% CI) | NA | NS | No | | | | |
| | 6.67 (0.74 – 60.08) | | | | | | | |
| At-fault crashes (glaucoma vs. normal vision controls) | Adjusted OR (95% CI) | Age, gender, number of systemic medications, better eye HFA MD, on-road driving exposure (km/week) | NS | No | | | | |
| | 7.21 (0.46 – 113.40) | | | | | | | |
| Rubin et al.(39) | 2007 | 1801 | Hazard Ratio | | | | | |
| | | | Binocular VFs <20 points missed | No mileage adjustment | Age, race, gender, MMSE score, education, comorbidities, living alone, depression | NS | No | |
| | | | | 0.60 (0.35 – 1.03) | | | | |
| | | | Binocular VFs ≥20 points missed | Adjusted for miles driven | Miles driven, age, race, gender, MMSE score, education, comorbidities, living alone, depression | NS | No | |
| 0.59 (0.34 – 1.00) | | | | | | | | |
| Binocular VFs ≥20 points missed | No mileage adjustment | Age, race, gender, MMSE score, education, comorbidities, living alone, depression | < 0.05 | Yes | | | | |
| | 1.29 (1.09 – 4.06) | | | | | | | |

Vision and CMV Driver Safety

| Reference | Year | Number of Drivers | Crash Rate Data | | | | Evidence of Increased Crash Risk | | |
|-------------------|------|------------------------|--|--|---|----------------------|----------------------------------|--|--|
| | | | Outcome Measure | Effect Size | Adjusted for... | P = | | | |
| | | | | Adjusted for Miles Driven 1.31 (1.13 – 4.27) | Miles driven, age, race, gender, MMSE score, education, comorbidities, living alone, depression | <0.05 | Yes | | |
| | | | Lower peripheral VF ≥10 points missed (Central VF and upper peripheral VF were not associated with crash risk) | 1.96 | NR | 0.01 | Yes | | |
| McGwin et al.(40) | 2005 | 240 (all had glaucoma) | OR of having a crash during the 6-year observation period | | | | | | |
| | | | All crashes (better eye) (VF defects scored by the Advanced Glaucoma Intervention Study scoring system, which measures central 24° radius field based on automated perimetry) | Unadjusted OR (95% CI) Mild defect: 1.4 (0.8 – 2.5) Moderate defect: 1.6 (0.7 – 3.3) Severe defect: 2.8 (1.0 – 8.0) | NA | NS NS 0.05 | Yes (severe defect only) | | |
| | | | | Adjusted OR (95% CI) Mild defect: 1.5 (0.7 – 2.8) Moderate defect: 1.4 (0.5 – 3.4) Severe defect: 3.2 (0.9 – 10.4) | Alcohol consumption, cataract, diabetic retinopathy, worse eye VA | NS NS NS | No | | |
| | | | All crashes (worse eye) | Unadjusted OR (95% CI) Mild defect: 1.5 (0.6 – 3.3) Moderate defect: 3.0 (1.3 – 7.1) Severe defect: 4.3 (1.8 – 10.3) | NA | NS <0.05 <0.05 | Yes (moderate and severe defect) | | |
| | | | | Adjusted OR (95% CI) Mild defect: 1.3 (0.5 – 3.4) Moderate defect: 3.6 (1.4 – 9.4) Severe defect: 4.4 (1.6 – 12.4) | Alcohol consumption, cataract, diabetic retinopathy, worse eye VA | NS <0.05 <0.05 | Yes (moderate and severe defect) | | |
| | | | At-fault crashes (better eye) | Unadjusted OR (95% CI) Mild defect: 1.5 (0.7 – 3.0) Moderate defect: 2.2 (0.9 – 5.3) Severe defect: 3.7 (0.9 – 15.3) | NA | NS NS NS | No | | |
| | | | | Adjusted OR (95% CI) Mild defect: 1.7 (0.7 – 3.7) Moderate defect: 2.0 (0.7 – 5.4) Severe defect: 4.2 (0.9 – 19.8) | Alcohol consumption, cataract, diabetic retinopathy, worse eye VA | NS NS NS | No | | |

Vision and CMV Driver Safety

| Reference | Year | Number of Drivers | Crash Rate Data | | | | Evidence of Increased Crash Risk | | | | |
|----------------------|-----------------|---|---|--|-----------------|--------------|----------------------------------|-------------------------------------|---|----------------------|-------------------------------------|
| | | | Outcome Measure | Effect Size | Adjusted for... | P = | | | | | |
| | | | At-fault crashes (worse eye) | Unadjusted OR (95% CI) Mild defect: 1.9 (0.7 – 5.1) Moderate defect: 3.3 (1.1 – 9.6) Severe defect: 6.9 (2.3 – 20.3) | | NA | NS <0.05 <0.05 | Yes (moderate and severe defect) | | | |
| | | | | Adjusted OR (95% CI) Mild defect: 1.9 (0.6 – 6.1) Moderate defect: 4.2 (1.2 – 15.0) Severe defect: 9.0 (2.4 – 33.2) | | | | | Alcohol consumption, cataract, diabetic retinopathy, worse eye VA | NS <0.05 <0.05 | Yes (moderate and severe defect) |
| Owsley et al.(43) | 1998 | 294 | OR of having a crash in past 5 years | | | | | | | | |
| | | | Central 30° VF sensitivity >10 dB | | | | | | | | |
| | | | Injurious crashes | 2.6 (1.1 – 6.3) | | NR | <0.05 | | Yes | | |
| | | | Noninjurious crashes | 1.8 (0.8 – 4.4) | | NR | NS | | No | | |
| | | | Peripheral 30-60° VF Sensitivity >10 dB | | | | | | | | |
| | | | Injurious crashes | 2.4 (1.3 – 4.5) | | NR | <0.05 | | Yes | | |
| Noninjurious crashes | 1.8 (1.0 – 3.1) | | NR | <0.05 | Yes | | | | | | |
| Owsley et al.(44) | 1998 | 294 | Crash rate per million person-miles of travel | | | | | | | | |
| | | | Central 30° VF sensitivity (cases >10 dB) | 7.0 | 7.1 | Miles driven | NS | | | No | |
| | | | Peripheral 30-60° VF sensitivity (cases >10 dB) | 5.8 | 7.6 | Miles driven | NS | | | No | |
| | | | Relative risk of having a crash during the 3-year follow-up period | | | | | | | | |
| | | | Central 30° VF sensitivity (cases >10 dB) | 0.99 (0.36 – 2.74) | | Miles driven | 0.73 | | | No | |
| | | | Peripheral 30-60° VF sensitivity (>10 dB) | 0.77 (0.42 – 1.40) | | Miles driven | 0.39 | | | No | |
| Szyk et al.(45) | 1993 | 49 (20 with JMD) (patients have central field defects) | Number (%) of subjects with: | | | | | | | | |
| | | | No self-reported crashes | 13 (65) | 18 (62) | NA | | | | NS | No |
| | | | ≥1 self-reported crash | 7 (35) | 11 (38) | | | | | | |
| | | | No state-recorded crashes | 6 (60) | 11 (61) | NA | | | | NS | No |
| | | | ≥1 state-recorded crash | 4 (40) | 7 (39) | | | | | | |
| | | | OR for self-reported crash | 0.88 (0.27 – 2.89) | | NA | | | | 0.83 | No |

Vision and CMV Driver Safety

| Reference | Year | Number of Drivers | Crash Rate Data | | | | Evidence of Increased Crash Risk | | |
|-------------------------|---|-------------------|---|---|-----------------|-------------------|----------------------------------|-----|--|
| | | | Outcome Measure | Effect Size | Adjusted for... | P = | | | |
| | | | Spearman Correlations between VF measures and crash involvement | | | | | | |
| | | | Horizontal extent of central scotoma | 0.10 | | NR | NS | No | |
| | | | Binocular area of central scotoma | -0.22 | | NR | NS | No | |
| Szlyk et al.(46) | 1992 | 52 (21 with RP) | Number (%) of subjects with: | | | | | | |
| | | | No crashes | 5 (24) | 19 (61) | NA | 0.005 | Yes | |
| | | | ≥1 crash | 16 (76) | 12 (39) | | | | |
| | | | OR for crash | 5.07 (1.47 – 17.46) | | NA | 0.01 | Yes | |
| | | | Spearman Correlations between peripheral VF measures and self-reported crashes | | | | | | |
| | | | Horizontal field extent: | | | | | | |
| | | | II-4-e | No. of crashes: -0.50 No. of peripheral crashes: -0.52 | | NR | <0.05 | Yes | |
| | | | III-4-e | No. of crashes: -0.60 No. of peripheral crashes: -0.62 | | NR | <0.01 | Yes | |
| | | | V-4-e | No. of crashes: -0.56 No. of peripheral crashes: -0.56 | | NR | <0.01 | Yes | |
| | | | Binocular area, V-4-e | No. of crashes: -0.57 No. of peripheral crashes: -0.57 | | NR | <0.01 | Yes | |
| Field profile | No. of crashes: 0.42 No. of peripheral crashes: 0.56 | | NR | <0.05 (crashes) <0.01 (peripheral crashes) | Yes | | | | |
| Owsley et al.(47) | 1991 | 53 | Pearson Correlations | | | | | | |
| | | | VF, central 30° | 0.13 | | NA | NS | No | |
| | | | VF, peripheral 30° | 0.12 | | NA | NS | No | |
| Johnson and Keltner(48) | 1983 | 10,000 | Crashes per person per 160,000 km | | | | | | |
| | | | Peripheral VF loss (one eye involved) | 0.8* | 0.67* | Kilometers driven | >0.2 | No | |
| | | | Peripheral VF loss (both eyes involved) | 1.33* | 0.61* | Kilometers driven | <0.005 | Yes | |
| | | | Rate ratio (one eye involved) | 1.19* | | Kilometers driven | NS | No | |

Vision and CMV Driver Safety

| Reference | Year | Number of Drivers | Crash Rate Data | | | | Evidence of Increased Crash Risk | | |
|--------------------------------|--------------|-------------------|--|-------------|----------------|-------------------|----------------------------------|---------------------------|--|
| | | | Outcome Measure | Effect Size | | Adjusted for... | | P = | |
| | | | Rate ratio (both eyes involved) | 2.18* | | Kilometers driven | <0.05 | Yes | |
| Fishman et al.(49) | 1981 | 129 (42 with RP) | Number of drivers with: | | | | | | |
| | | | No crashes in the previous 5 years | 21 | 62 | NA | 0.02 | Yes | |
| | | | ≥1 crash in the previous 5 years | 21 | 25 | | | | |
| | | | Correlation between peripheral VF efficiency and number of crashes | r = -0.13 | | NA | NR | No | |
| Hills and Burg(50) Burg(51) | 1977 1971 | 14,381 | Correlation between total VF and crash rate | | | | | | |
| | | | Age <25 | r = 0.010 | | Miles driven | NS | No | |
| | | | Age 25-39 | r = 0.014 | | Miles driven | NS | No | |
| | | | Age 40-54 | r = -0.009 | | Miles driven | NS | No | |
| | | | Age >54 | r = 0.044 | | Miles driven | <0.05 | Yes, but weak association | |
| Council and Allen(52) | 1974 | 44,838 | Mean accidents/driver | | Total VF ≥160° | | | | |
| | | | Age ≤25, total VF ≤120° | 0.067 | 0.222 | NR | <0.01 | No | |
| | | | total VF ≤140° | 0.234 | | NR | NS | No | |
| | | | Age 26-40, total VF ≤120° | 0.185 | 0.160 | NR | NS | No | |
| | | | total VF ≤140° | 0.188 | | NR | NS | No | |
| | | | Age 41-60, total VF ≤120° | 0.143 | 0.128 | NR | NS | No | |
| | | | total VF ≤140° | 0.122 | | NR | NS | No | |
| | | | Age 61-70, total VF ≤120° | 0.083 | 0.110 | NR | NS | No | |
| | | | total VF ≤140° | 0.120 | | NR | NS | No | |
| Age ≥71, total VF ≤120° | 0.139 | 0.105 | NR | NS | No | | | | |
| | | | total VF ≤140° | 0.169 | | NR | NS | No | |
| Studies Reporting UFOV | | | | | | | | | |
| Haymes et al.(38) | 2007 | 84 (40 with | OR of having a crash in past 5 years | | | | | | |

Vision and CMV Driver Safety

| Reference | Year | Number of Drivers | Crash Rate Data | | | | Evidence of Increased Crash Risk | |
|---|-------------|-------------------|--|---|--|--------|----------------------------------|-----|
| | | | Outcome Measure | Effect Size | Adjusted for... | P = | | |
| | | glaucoma) | UFOV substest 3 selective attention processing speeds >350 ms (self-reported MVCs) | Adjusted OR (95% CI) 10.29 (1.10 – 96.62) | Age, gender, number of systemic medications, better eye HFA MD, on-road driving exposure (km/week) | NR | Yes | |
| Rubin et al.(39) | 2007 | 1,801 | Hazard Ratio | | | | | |
| | | | UFOV (40% loss) | No mileage adjustment 2.12 (1.32 – 3.39) | Age, race, gender, MMSE score, education, comorbidities, living alone, depression | <0.01 | Yes | |
| | | | | Adjusted for miles driven 2.21 (1.32 – 3.39) | Miles driven, age, race, gender, MMSE score, education, comorbidities, living alone, depression | <0.01 | Yes | |
| | | | UFOV substest 1 (visual speed of processing impairment) | 1.27 (CI: NR) | Age, race, gender, MMSE score, education, comorbidities, living alone, depression | 0.04 | Yes | |
| | | | UFOV substest 2 (divided attention impairment) | 1.47 (CI: NR) | Age, race, gender, MMSE score, education, comorbidities, living alone, depression | 0.001 | Yes | |
| | | | UFOV substest 3 (selective attention impairment) | 1.45 (CI: NR) | Age, race, gender, MMSE score, education, comorbidities, living alone, depression | 0.22 | No | |
| Ball et al.(8) | 2006 | 1,910 | UFOV substest 2 (range 16 – 500 ms) | Crashers 213.54 ± 174.43 (mean ± SD) | Non-crashers 176.35 ± 153.62 (mean ± SD) | NR | 0.03 | Yes |
| | | | OR of having an at-fault crash during the 4- to 5-year follow-up | | | | | |
| | | | UFOV substest 2 | 1.31 (1.08 – 1.59) | Annual miles driven | 0.006 | Yes | |
| McGwin et al.(42) | 1998 | 278 | OR of having a crash in past 5 years | | | | | |
| | | | State-recorded crashes (UFOV ≥40%) | 13.7 (6.7 – 28.3) | NR | NR | Yes | |
| | | | Self-reported crashes (UFOV ≥40%) | 3.4 (1.9 – 6.0) | NR | NR | Yes | |
| | | | All crashes (UFOV ≥40%) | 10.6 (5.2 – 21.9) | NR | NR | Yes | |
| Owsley et al.(43) (same study population as McGwin et al.(42)) | 1998 | 294 | OR of having a crash in past 5 years | | | | | |
| | | | UFOV | | | | | |
| | | | Injurious crashes | | | | | |
| | | | 23 to 40% | 5.3 (1.9 – 14) | NR | <0.001 | Yes | |
| | | | 41 to 60% | 16.3 (5.8 – 46) | | | | |
| >60% | 22 (7 – 69) | | | | | | | |

Vision and CMV Driver Safety

| Reference | Year | Number of Drivers | Crash Rate Data | | | | Evidence of Increased Crash Risk | |
|--|------|-------------------|---|--|-----------------|--|----------------------------------|-----|
| | | | Outcome Measure | Effect Size | Adjusted for... | P = | | |
| | | | Noninjurious crashes | | | | | |
| | | | 23 to 40% | 2.3 (1.1 – 4.5) | NR | <0.001 | Yes | |
| | | | 41 to 60% | 4.6 (2.1 – 10.1) | | | | |
| | | | >60% | 7.1 (2.9 – 17.5) | | | | |
| Owsley et al.(44) | 1998 | 294 | Crash rate per million person-miles of travel | | | | | |
| | | | UFOV (cases ≥40% reduction in UFOV) | 9.8 | 4.7 | Miles driven | NR | Yes |
| | | | Relative Risk of having a crash during the 3-year follow-up period | | | | | |
| | | | UFOV (≥40% reduction in UFOV) | 2.08 (1.15 – 3.44) | | NR | 0.02 | Yes |
| | | | UFOV (≥40% reduction in UFOV for older drivers) | 2.21 (1.20 – 4.09) | | Age, gender, race, chronic medical conditions, mental status | 0.01 | Yes |
| | | | UFOV substest 1 (visual speed of processing impairment) | 1.49 (0.9 – 2.9) | | Age, gender, race, chronic medical conditions, mental status, days driven per week | 0.18 | No |
| | | | UFOV substest 2 (divided attention impairment) | 2.3 (1.2 – 4.4) | | Age, gender, race, chronic medical conditions, mental status, days driven per week | 0.01 | Yes |
| | | | UFOV substest 3 (selective attention impairment) | 1.10 (0.6 – 2.0) | | Age, gender, race, chronic medical conditions, mental status, days driven per week | 0.68 | No |
| Owsley et al.(47) | 1991 | 53 | Pearson Correlations | | | | | |
| | | | UFOV | 0.36 | | NA | <0.05 | Yes |
| Studies reporting VF loss using a test other than perimetry or UFOV | | | | | | | | |
| McGwin et al.(41) | 2000 | 901 | OR of having a crash in past 5 years | | | | | |
| | | | Peripheral vision score ≤75%† | | | | | |
| | | | At-fault crashes | Unadjusted OR (95% CI) 1.5 (0.8 – 2.7) | | NA | NR | No |
| | | | | Adjusted OR (95% CI) 1.4 (0.8 – 3.0) | | Age, gender, race, annual mileage | NR | No |

* Calculated by ECRI Institute.

† Assessed by using a modified version of the National Eye Institute Visual Functioning Questionnaire (VFQ), scores ≤75% were defined as impaired.

CI – Confidence interval.

HFA MD – Humphrey Field Analyzer mean deviation.

JMD – Juvenile macular dystrophies.

MMSE – Mini-mental state examination.

MVC – Motor vehicle crash.

NA – Not applicable.

NC – Not calculated.
NR – Not reported.
NS – Not Significant.
OR – Odds ratio.
RP – Retinitis pigmentosa.
UFOV – Useful field of view.

Section Summary

Drivers with VF loss measured by standard perimetry are at an increased risk of crash (Strength of Evidence: Minimally Acceptable).

- A precise estimate of the magnitude of increase in risk cannot be determined at the present time.
- Due to differences in reported measures and cutoffs, no conclusion is possible at this time regarding the degree and pattern of VF loss that is most strongly associated with the increased crash risk.

Drivers with reduced UFOV as measured by the UFOV test are at an increased risk of crash (Strength of Evidence: Moderate).

- A precise estimate of the magnitude of increase in risk cannot be determined at the present time.
- A $\geq 40\%$ reduction in UFOV is associated with an increased risk of crash (Strength of Evidence: Moderate).

Direct Evidence – Crash Studies: The evidence base for this key question included 14 studies (in 16 publications). Two separate analyses were performed: an analysis of the findings of studies that examined the association between VF loss and crash risk using standard perimetry testing (any method), and an analysis of studies that examined the association between UFOV and crash risk.

Twelve studies assessed the relationship between crash risk and VF loss as measured by standard perimetry (automated or manual). Due to differences in patient characteristics, perimetry tests, cutoffs for judging VF loss, type of crash data, summary statistics, and adjustments of summary statistics, a precise quantitative estimate of effect could not be obtained. However, eight of the twelve studies showed a statistically significant increase in crash risk associated with VF loss. Because the median quality of the evidence base was low, the strength of evidence is considered minimally acceptable. Populations most likely to contain drivers with VF loss associated with increased crash risk include drivers with glaucoma, retinitis pigmentosa, and to a lesser extent, older drivers (>54 years of age). Although slightly more evidence supports peripheral VF loss as having a greater affect on crash risk than central VF loss, only four studies separately evaluated both types of VF loss, and there were differences among studies that only examined one type of VF loss. Therefore, the relative impact of peripheral VF loss versus central VF loss on crash risk could not be determined with certainty.

Differences among the measures and cutoffs used in studies of VF range meant that a conclusion regarding what constituted an acceptable VF range could not be reached based on standard perimetry.

Six studies (in seven publications) assessed the relationship between crash risk and reduced UFOV as measured by the UFOV test. All six studies showed a statistically significant increase in crash risk

associated with VF loss. Due to differences in the implementation of UFOV (full test or subtests), summary statistics, adjustments for potential confounding factors, and types of crash reported among different studies, a quantitative estimate of effect could not be obtained. However, since the direction of effect was consistent and significant in all studies, the findings were robust. When considered with the moderate quality (median measurement) of the evidence base, this means that the strength of evidence for this comparison is moderate.

Three studies found a statistically significant increase in crash risk associated with a $\geq 40\%$ reduction in UFOV. Although these were the only studies to report using this cutoff, the findings were consistent. Combined with the moderate quality (median measurement) of these studies, this means that the strength of evidence for this finding is moderate.

The generalizability of these findings to CMV drivers is unclear, because none of the studies reported whether any commercial drivers composed part of the study population.

Key Question 4: Do cataracts increase crash risk? Is crash risk reduced after cataract surgery?

Introduction

A cataract is defined as a clouding of the natural lens of the eye that can occur with age, injury or trauma, metabolic disorders, or disease. A cataract may cause symptoms such as dimming of vision, sensitivity to light and/or glare, halos around lights, fading of colors, and double vision in a single eye. Types of cataracts include nuclear, cortical, or subcapsular. It is estimated that approximately 50% of individuals aged 65 or older have some degree of cataract development, with 70% of individuals over the age of 75 having cataracts sufficient to affect vision. The only effective treatment currently available is surgical removal of the clouded lens followed by insertion of an intraocular lens (IOL).⁽⁵⁴⁾

Identification of Evidence Base

Our searches⁴ identified a total of 98 potentially relevant publications. We identified three studies by hand searching. After evaluating the titles and abstracts for relevance and evaluating them with our retrieval criteria (Appendix B: Retrieval Criteria), we retrieved 15 of them in full length. Ten of these 15 retrieved articles were found to meet the inclusion criteria (see Appendix C: Inclusion Criteria) for this key question (see Table D- 4 of Appendix D for citations and reason for exclusion). However, these 10 articles represent only seven studies, because one study is reported on in three publications, and another study is reported on in two publications. The evidence base identification pathway for Key Question 4 is summarized in Figure 18. The included studies are listed in Table 33.

⁴ See Appendix A for search strategies.

Figure 18. Development of Evidence Base for Key Question 4

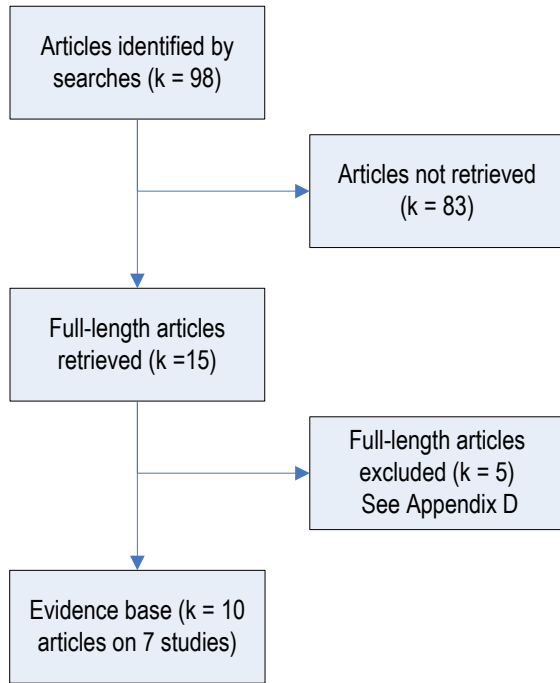


Table 33. Evidence Base for Key Question 4

| Reference | Year | Secondary reference | Year | Study Location | Country |
|---|------|----------------------------|------|--------------------|-----------|
| McCloskey et al.(26) | 1994 | – | – | Washington (State) | USA |
| McGwin et al.(41) | 2000 | – | 2000 | Alabama | USA |
| Monestam and Wachtmeister(55) | 1997 | – | – | Umea | Sweden |
| Monestam et al.(56)* | 2005 | Monestam and Lundqvist(57) | 2006 | Umea | Sweden |
| Impact of Cataracts on Mobility Study (ICOM) Owsley et al.(58) | 2002 | Owsley et al.(59) | 2001 | Alabama | USA |
| | | Owsley et al.(60) | 1999 | Alabama | USA |
| Owsley et al.(43) | 1998 | – | – | Alabama | USA |
| Wood and Carberry(61) | 2006 | – | – | Not reported | Australia |

Evidence Base

This section provides a brief description of the key attributes of the seven studies of which the evidence base for Key Question 4 is comprised. Here we discuss applicable information relevant to the quality of the included studies and the generalizability of each study’s findings to CMV drivers.

Characteristics of Included Studies

The seven studies enrolled a total of 1,990 individuals with cataract(s). Outcomes reported by the studies included crash, driving tests, and self-reported difficulty driving. None of the studies stated that CMV drivers were sought or asked to participate.

Four studies directly assessed the relationship between cataract and crash. However, each reported somewhat different comparisons. Of the four crash studies, one differentiated at-fault and not-at-fault crash in drivers with cataract (without reference to whether they had surgery) compared with controls(41), one differentiated injurious and noninjurious crash in drivers with cataract (without reference to whether they had surgery) compared with controls(43), one reported all crashes in drivers with cataract (surgically and nonsurgically treated) compared to controls,(26) and one reported all crashes in drivers who had not had cataract surgery compared with controls, and also postsurgery cataract patients compared with patients with cataracts who elected not to have surgery.(58-60) The first three studies did not report on the severity of cataracts, and two of these three did not report on whether their enrollees had been treated with cataract surgery.

One of the studies that assessed crash(58-60) and all the remaining studies in the evidence base reported noncrash outcomes that may be associated with crash risk. These outcomes were all assessed prospectively. One study assessed driving skills in a road test, and three studies collected data on self-reports of difficulty driving. The differences in study designs caused differences in the studies that make their findings difficult to compare and made their combination in meta-analysis inappropriate. The primary characteristics of the studies that address Key Question 4 are presented in Table 34 below.

Table 34. Characteristics of Studies Included for Key Question 4

| Study | Year | Study Design | Comparison | How Was Cataract Defined? | Cataract Clinically Confirmed? | Driving Exposure Controlled For? | Primary Outcomes | Definition of Crash | Outcome(s) Self-Reported? |
|-------------------------------|------|---------------------------------|---|---------------------------|--------------------------------|----------------------------------|---|--|---|
| ICOM Study(58-60) | 2001 | Retrospective cohort-controlled | Controls without cataracts | NR | Yes | Yes | Crash, subjective driving, vision study | Police-documented motor vehicle collision | No (crash, vision) Yes (subjective difficulty driving) |
| | | Controlled cohort study | People with cataract(s) who underwent surgery compared to those who did not undergo surgery | | | | | | |
| | | Pre-post | Before and after surgery | | | | | | |
| McGwin et al.(41) | 2000 | Case-Controlled | Crash vs. no crash; odds of having cataracts in both groups | NR | NR | Yes | Crash | Police-documented motor vehicle collision | No (but cataract status was) |
| McCloskey et al.(26) | 1994 | Case-controlled | Injurious crash vs. noninjurious crash | NR | Yes | Unclear | Crash | Police reported crash of vehicle, physical damage, or injury | No |
| Monestam and Wachtmeister(55) | 1997 | Pre/post | Before and after surgery | NR | Yes | N/A | Subjective driving | N/A | Yes |
| Monestam et al.(56,57) | 2005 | Pre/post | Before and after surgery | NR | Yes | N/A | Subjective driving, vision | N/A | No (vision), Yes (subjective driving) |
| Owsley et al.(43) | 1998 | Case- controlled | Crash vs. no crash; odds of having cataracts in both groups | NR | Yes | No | Crash with or without injuries | Police-documented motor vehicle collision with injury | No |
| Pfoff and Werner(62) | 1994 | Cohort-controlled | Controls without cataracts | NR | Yes | N/A | Vision | N/A | No |
| | | Pre/post | Before and after surgery | | | | | | |

N/A – Not applicable.
NR – Not reported.

Quality of Evidence Base

We assessed the quality of all included studies using a quality assessment instrument. For cohort-controlled studies, we used a revised version of the Newcastle-Ottawa Quality Assessment Scale for Cohort Studies; for case-controlled studies we used a revised version of the Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies.(31) For pre/post studies, we assessed quality using the ECRI Institute Quality Assessment Scale for Pre/Post Studies. The quality assessment instruments are shown in Appendix F: Quality Assessment Instruments Used. For studies that used both cohort-controlled and pre/post study designs, each instrument was applied to each outcome with a different design. The quality of case control and cohort studies is limited because of nonrandom allocation of individuals to different groups. Although observational studies often statistically adjust for known confounding factors, only random allocation can control for unknown confounding factors; however, random allocation is not possible in these study designs. Therefore, the quality rating of case control and cohort studies can never be high. The quality of pre/post studies is limited because no parallel control group is present to help determine the amount of improvement that can be attributed to the treatment. For this reason, the quality rating of pre/post studies is never high.

Our quality assessments of the studies in the evidence base for Key Question 4 are summarized in Table 35. All studies were rated as either low or moderate quality. Complete details of our quality assessment can be found in the study summary tables presented in Appendix G.

Table 35. Quality of the Studies that Assess Key Question 4

| Reference | Year | Quality Scale Used | Quality |
|-------------------------------|------|--|----------|
| ICOM Study(58-60) | 2002 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Moderate |
| | | ECRI Institute Quality Scale for Pre/Post Studies | Moderate |
| McCloskey et al.(26) | 1994 | Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies | Low |
| McGwin et al.(41) | 2000 | Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies | Moderate |
| Monestam and Lundqvist(57) | 2006 | ECRI Institute Quality Scale for Pre/Post Studies | Low |
| Monestam and Wachtmeister(55) | 1997 | ECRI Institute Quality Scale for Pre/Post Studies | Low |
| Monestam et al.(56) | 2005 | ECRI Institute Quality Scale for Pre/Post Studies | Low |
| Owsley et al.(43) | 1998 | Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies | Moderate |
| Wood and Carberry(61) | 2006 | ECRI Institute Quality Scale for Pre/Post Studies | Moderate |

Generalizability of Evidence to Target Population

The purpose of this subsection is to provide details of the extent to which individuals enrolled in the studies that address Key Question 4 are similar to CMV drivers in the United States. Most importantly, none of the included participants were CMV drivers. The mean age of study participants with cataracts at enrollment ranged from 70.8 (standard deviation [SD] 11.0) to 73.8 (SD not reported) years. This population may be generally older than a population of CMV drivers. The proportion of men, where reported, ranged from 50% to 59%. Women are overrepresented in the evidence base population compared with a CMV driver population. Race and comorbidity were not reported by most studies. For these reasons, the generalizability of the population in the evidence base to CMV drivers is unclear.

Characteristics of the individuals included in the studies that address Key Question 4 are presented in Table 36, shown below.

Table 36. Generalizability of Studies that Address Key Question 4

| Study | Year | Number of Individuals with Cataract | CMV Drivers? | Patient Selection | Characteristics of People with Cataracts | | | |
|--|------|-------------------------------------|--------------|---|--|--|--|--|
| | | | | | Mean Age (SD) | Percentage Male | Race | Comorbidity |
| ICOM Study(58-60) | 2002 | 277 | No | All licensed drivers meeting inclusion criteria recruited from 12 eye clinics from 10/1994–3/1996 | Surgery 71.2 (6.6) years; no surgery 71.5 (5.4) years; overall 71(6) years | Surgery 47.1; no surgery 65.1; overall 53 | Surgery 90.2% white; no surgery 80.6% white; overall 86% white, 14% African-American | Mean (SD) number of comorbidities, 4.4 (2.2) in surgery group; 4.1 (2.3) in no-surgery group |
| McCloskey et al.(26) | 1994 | 150 | No | Elderly licensed drivers who resided in 8 Washington counties and received medical care at 5 facilities. Cases sought medical care within 7 days for injuries sustained in a crash that was reported to the police. | Not reported separately, but all were age 65 or older | Not reported separately | Not reported separately | NR |
| McGwin et al.(41) | 2000 | 374 | No | Residents of Mobile County, AL age ≥65 years who had a driving license in 1996. Cases were involved in at least one automobile accident; controls were involved in none. | NR; Range of total sample 65–93 years | Surgery/no surgery NR; 50.4 | NR; For race distribution of total sample see Appendix G | NR |
| Monestam and Wachtmeister(55) | 1997 | 208 | No | Consecutive patients with driving licenses who had cataract surgery during a 1-year period (4/1/1992–3/31/1993) | Median age men 74; women 71 | 59 | NR | NR |
| Monestam et al.(56) and Monestam and Lundqvist(57) | 2005 | 810 | No | All patients who had cataract surgery during a 1 year period (6/1/1997–5/31/1998) | 70.8 (11.0) | 56% | NR | NR |
| Owsley et al.(43) | 1998 | 142 | No | All licensed drivers in Jefferson County, AL, age ≥55 years | NR for drivers with cataract; For all study participants, see Appendix G | NR for drivers with cataract; For all study subjects, 54 | NR for drivers with cataract; For all study subjects 80% white | NR for drivers with cataract; For all study subjects see Appendix G |
| Wood and Carberry(61) | 2006 | 29 | No | Patients scheduled for bilateral cataract surgery were recruited. Method of selection not reported. | 73 (8) years | NR | NR | NR |

CMV – Commercial motor vehicle
 NR – Not reported
 SD – Standard deviation

Findings

The seven included studies reported the following three relevant outcomes:

- Actual crash data
- Driving test results
- Self-reported difficulty driving

These outcomes were assessed in the following four ways:

- Comparison of individuals with cataracts and controls without cataracts
- Comparison of individuals with cataract surgery and controls without cataracts
- Comparison of individuals with cataract surgery to individuals with cataracts
- Comparison of scores in the same cohort of individuals before and after cataract surgery

The outcomes reported by the included evidence base are listed by study in Table 37 below, followed by the study findings.

Table 37. Outcomes Addressed by Studies Included for Key Question 4

| Study | Year | Crash | | Driving Test | | | Self-Reported Difficulty Driving | | | |
|-------------------------------|------|--|--|--|------------------|---|--|--|------------------|---|
| | | Drivers with Cataracts vs. Drivers without Cataracts | Drivers with Cataracts Divided by Whether They Had Surgery | Drivers with Cataracts Who Had Surgery vs. Those Who Did Not | Pre/Post Surgery | Drivers with Cataracts Who Had Surgery vs. Controls | Drivers with Cataracts vs. Drivers without Cataracts | Surgically-Treated Individuals with Cataracts vs. Nonsurgically Treated Individuals with Cataracts | Pre/Post Surgery | Drivers with Cataracts Who Had Surgery vs. Controls |
| ICOM Study(58-60) | 2002 | | ✓ | ✓ | | | ✓ | ✓ | | |
| McCloskey et al.(26) | 1994 | ✓ | ✓ | | | | | | | |
| McGwin et al.(41) | 2000 | ✓ | | | | | | | | |
| Monestam and Wachtmeister(55) | 1997 | | | | | | | | ✓ | |
| Monestam et al.(56,57) | 2005 | | | | | | | | ✓ | |
| Owsley et al.(43) | 1998 | ✓ | | | | | | | | |
| Wood and Carberry(61) | 2006 | | | | ✓ | ✓ | | | | |
| Total | | 3 | 2 | 1 | 1 | 1 | 1 | 1 | 2 | 0 |

* Although the study protocol states that glare disability data was collected in the ICOM study and baseline values were reported, no postsurgical outcomes were reported for glare disability.

Actual Crash Data

The most convincing and direct evidence to associate cataracts and crash is actual crash data. Four studies, the Impact of Cataract on Mobility (ICOM) study(58,59), McCloskey et al.(26), McGwin et al.(41), and Owsley et al. 1998(43), reported actual crash data of drivers with cataracts. These studies used retrospective police data review to assess crash incidence among a total of 943 older drivers with cataracts.

The ICOM study compared crash in individuals with cataracts with cataract-free controls(59) and crash in individuals who underwent cataract surgery with individuals who did not have cataract surgery over the course of four to six years.(58) This was the only study to specifically recruit individuals with cataracts and to describe the diagnostic criteria used to determine inclusion of individuals with cataracts. The requirements were visual acuity of 20/40 or worse in one eye and no previous cataract surgery in either eye. The remaining three studies did not report any information related to the severity of cataracts among their enrollees. McCloskey et al. compared the proportion of drivers with cataracts in crashes to the proportion of drivers with cataracts among individuals who did not crash.(26) McGwin et al. compared the proportion of drivers with cataracts in at-fault crashes to the proportion of individuals with cataracts among drivers who did not crash or who were involved in not-at-fault crashes, over the course of one year.(41) Owsley et al. compared injurious and noninjurious crash rate in drivers with and without cataracts.(43)

Individuals with Cataracts vs. Individuals without Cataracts

The ICOM study evaluated crash involvement over the previous five years for 276 drivers with cataracts and 103 drivers without cataracts (some additional drivers initially thought to be eligible were found to have out-of-state licenses, so no records could be retrieved for them and they were therefore excluded). The crude relative risk of individuals who crashed and were at least partially at fault to have cataracts was 2.3 (95% CI 1.00 – 5.76; $P = 0.044$). Adjusted for driving exposure (days driven per week and miles driven per week), the relative risk was 2.48 (95% CI 1.00 – 6.14; $P = 0.050$).⁽⁶⁰⁾ Both differences are statistically significant. These findings are shown in Table 38.

Three additional studies compared the crash risk of a total of 666 individuals with and 1,209 without cataracts:(26,41,43) McGwin et al. reported on at fault and not-at-fault crashes, McCloskey et al. reported on injurious crashes, and Owsley et al. reported on injurious and noninjurious crashes. McGwin reported an increased risk of not-at-fault crash among drivers with cataracts, but this risk became insignificant after results were controlled for age, gender, race, and driving mileage. None of the other comparisons provided evidence of increased crash risk. All three studies reported ORs with 95% confidence intervals. Number of crashes per group was not reported. P -values for these studies were calculated by ECRI Institute. The findings from these studies are presented in Table 38. A possible explanation for the disagreement in findings between these studies and the ICOM study is that the severity of cataracts may have been higher in the ICOM study (ICOM authors specifically selected patients with 20/40 or worse VA). However, this remains speculation since the other three studies did not report the severity of cataracts for their enrollees.

Table 38. Crash in Individuals with Cataracts vs. Individuals without Cataracts

| Reference | Year | Units | Crash Data | | | Evidence of Increased Crash Risk |
|--|------|---------------------------------------|--------------------------------|--|--------|----------------------------------|
| | | | Effect Size (95% CI) | Adjusted for... | P = | |
| Noncommercial Motor Vehicle Drivers | | | | | | |
| ICOM Study(58-60) | 1999 | Number of at-fault crash involvements | Rate Ratio: 2.3 (1.00 – 5.76) | – | 0.044* | Yes |
| | | | Rate Ratio: 2.48 (1.00 – 6.14) | Exposure: days driven per week and miles driven per week | 0.050 | Yes |
| McCloskey et al.(26) | 1994 | Injurious crash | Odds ratio: 1.0 (0.7 – 1.6) | Age, gender, county of residence | 0.832* | No |
| McGwin et al.(41) | 2000 | At-fault crash | Odds ratio: 1.1 (0.8 – 1.5) | – | 0.552* | No |
| | | | Odds ratio: 1.0 (0.7 – 1.5) | Age, gender, race, and annual mileage | NS** | No |
| | | Not-at-fault crash | Odds ratio: 1.5 (1.0 – 2.2) | – | 0.044* | Yes |
| | | | Odds ratio: 1.1 (0.7 – 1.8) | Age, gender, race, and annual mileage | 0.692* | No |
| Owsley et al.(43) | 1998 | Injurious crash | Odds ratio: 1.0 (0.6 – 1.8) | – | NS | No |
| | | Noninjurious crash | Odds ratio: 1.1 (0.6 – 1.8) | – | NS | No |

NS – Non significant

* P-values calculated by ECRI Institute.

** P-value could not be calculated by ECRI Institute due to asymmetry of reported 95% CI, but is not statistically significant.

Researchers in the ICOM study also assessed variables to determine association with crash involvement.(59) Rate was assessed by function in the better eye and worse eye. Contrast sensitivity impairment (defined as a score of 1.25 or less) in both eyes was associated with crash involvement (OR = 5.78, 95% CI: 1.87 – 17.86). Regarding the better eye, only one variable, contrast sensitivity of 1.25 or less, was associated with crash involvement (OR = 2.65, 95% CI: 1.06 – 6.61); the size of this association was greater when adjusted for demographics, cognitive function, general health, and driving exposure (OR = 4.97, 95% CI: 1.69 – 14.63). Adjusted VA in the range of 20/35 to 20/50 was also associated with increased risk of crash (OR = 3.17, 95% CI: 1.15 – 8.69). For the worse eye, contrast sensitivity of 1.25 was also associated with a crash involvement (crude OR = 3.39, 95% CI: 1.21 – 9.47; adjusted OR = 7.06, 95% CI: 1.88 – 26.52).

Individuals with Cataract Surgery vs. Individuals with Cataracts

In the ICOM study, 174 drivers who had cataract surgery had a reduced absolute crash rate and adjusted crash rate ratio compared with 103 drivers with cataracts.(58) At baseline, the unadjusted crash rate per million miles for the prior 5 years was 4.6 for surgically treated patients and 5.2 for patients with cataracts, a difference that is not statistically significant (P = 0.63) During the 4- to 6-year follow-up, the surgery group had an adjusted crash rate of 5.77 per million person miles, and the cataract group had a crash rate of 8.95 per million person miles. Therefore, the surgery group had a rate reduction of 4.74 crashes per million miles. The crude RR of crashes in individuals with surgery to those who did not have surgery was 0.64 (95% CI: 0.37-1.13; P = 0.117) and the rate adjusted for race, VA, and contrast sensitivity was 0.47 (95% CI: 0.23-0.94; P = 0.031). These data are shown in Table 39.

Although McCloskey et al. did not directly compare crash risk for drivers with cataract surgery and drivers with cataracts, the study presented enough data to allow us to independently calculate an OR for

this comparison (Table 39). The OR showed no difference in crash risk between these groups (OR = 1.03, 95% CI: 0.4–2.18), a finding that is not surprising given that this study did not find an increased crash risk for drivers with cataracts compared to drivers without cataracts. As noted earlier, one potential explanation for the differences between these studies is that the ICOM study may have selected patients with more severe cataracts (with greater VA loss).

Table 39. Crash in Individuals with Cataract Surgery vs. Individuals with Cataracts

| Reference | Year | Units | Crash Data | | | | Evidence of Reduced Crash Risk after Surgery | |
|--|------|--------------------------------------|--|---|----------------------------------|---|--|-----|
| | | | Drivers with Surgically Treated Cataracts | Drivers with Nonsurgically Treated Cataracts | Effect Size (95% CI) | Adjusted for... | | P = |
| Noncommercial Motor Vehicle Drivers | | | | | | | | |
| ICOM study(58-60) | 2002 | Number of crash involvements | 174 | 103 | Rate Ratio: 0.64 (0.37 – 1.13) | – | 0.117* | No |
| | | | | | Rate Ratio: 0.47 (0.23 – 0.94) | Race, visual acuity, contrast sensitivity | 0.031 | Yes |
| McCloskey et al.(26) | 1994 | Proportion of drivers with cataracts | Drivers with surgically-treated cataracts who crashed: 14/56 | Drivers with surgically-treated cataracts who did not crash: 25/102 | Odds Ratio: 1.03* (0.48 – 2.18)* | – | 1.00* | No |

* Calculated by ECRI Institute.

Driving Tests

Driving tests are usually administered off-road and provide a measure of driving ability. However, driving test results are not a perfect substitute for actual crash data.

One study, Wood and Carberry, administered closed-course driving tests. The study tested 29 older drivers with bilateral cataracts and 18 controls without cataracts and with normal vision. The tests were administered before drivers with cataracts underwent surgery and at least one month (mean 80 days) after surgery; to promote comparability, controls were retested as well. Driving measures tested were sign recognition, road hazard recognition, road hazard avoidance, gap perception, maneuvering time, time to complete course, and an overall score. The overall score was calculated using the z-scores for all of the individual tests except for maneuvering.

Individuals with Cataracts vs. Individuals without Cataracts

During the test administered before cataract surgery, drivers with cataracts performed statistically significantly worse than the drivers without cataracts. Impairment was shown on road sign recognition ($t_{(45)} = -3.23, P = 0.002$), road hazard recognition ($t_{(45)} = -3.04, P = 0.004$), road hazard avoidance ($t_{(45)} = 4.01, P < 0.001$), and overall performance ($t_{(45)} = -2.68, P = 0.01$).

Pre/Post Cataract Surgery

Compared with scores before cataract surgery, significant improvements were reported after cataract surgery on overall driving scores ($F_{1,28} = 14.88, P = 0.001$), road sign recognition ($F_{1,28} = 20.51, P < 0.001$),

road hazard recognition ($F_{1,28}=14.72$, $P = 0.001$), and road hazard avoidance ($F_{1,28}=17.28$, $P < 0.001$). On one measure, a divided attention test, a significant difference was also observed in controls, so repeated testing may have had an important effect on that outcome.

Individuals with Cataract Surgery vs. Individuals without Cataracts

As discussed above, drivers who underwent surgery for their cataracts had significant improvements on the driving tests. However, the normal-vision controls also improved significantly, suggesting a learning effect. The study authors reported no significant group by test interactions.

Self-reported Driving Difficulty

Self-reported driving difficulty is a subjective outcome that may be more subject to bias than other, more objective outcomes. However, a substantial proportion of drivers reporting difficulty driving may signify difficulty driving among individuals with cataracts in general. The relationship between difficulty driving and crash seems logical; however, no correlation between these outcomes has been definitively established.

The ICOM study compared self-reported driving difficulty in older individuals with cataracts not treated with surgery and individuals with cataracts; individuals with cataracts not treated with surgery and individuals with cataracts after surgery were also compared.(60) Monestam and Wachtmeister(55) and Monestam et al.(56) compared self-reported difficulty driving before and after cataract surgery. No studies compared self-reported driving difficulty in individuals with cataracts who had undergone surgery and controls who had never had cataracts.

Individuals with Cataracts vs. Individuals without Cataracts

In the ICOM study, the Driving Habits Questionnaire, which contains questions on difficulty driving in different driving situations, was administered to 279 older drivers with cataracts and 105 older drivers without cataracts.(60) A statistically significantly ($P = 0.001$ for all) greater proportion of drivers with cataracts reported difficulty with the following driving maneuvers: driving in the rain (67% of individuals with cataracts versus 44% of individuals without cataracts), driving alone (24% versus 5%), parallel parking (30% versus 26%), left turns in traffic (21% versus 3%), driving on interstate highways (26% versus 10%), driving in high traffic (36% versus 19%), driving in rush hour (45% versus 24%), and driving at night (77% versus 41%).

Individuals with Cataract Surgery vs. Individuals with Cataracts

In the ICOM study, the Driving Habits Questionnaire was administered to 277 older drivers with cataracts, of whom 174 had surgery and 103 did not at baseline, 1 year after baseline, and 2 years after baseline.(58) Driving difficulty was reported in terms of the mean driving difficulty composite score. At baseline, 174 drivers who would have surgery reported statistically significantly greater difficulty driving than 103 drivers not planning to have surgery ($P < 0.001$). One year later, the surgery group ($n = 155$) improved in mean score compared with the nonsurgery group ($n = 87$), and the difference was no longer statistically significant ($P = 0.68$). An additional year later, the surgery group ($n = 138$) showed continued improvement, while the nonsurgery group ($n = 75$) did not ($P = 0.01$). These findings suggest that drivers

who have surgery for their cataracts subjectively experience less difficulty driving than counterparts who do not have surgery at two years; however, the effect of attrition is unclear.

Pre/Post Cataract Surgery

Monestam et al.(56,57) assessed self-reported difficulty driving in 189 active drivers with cataracts before and after surgery, and Monestam and Wachtmeister assessed it in 208 active drivers.(55) In both studies, data were collected by questionnaire. Both studies administered the questionnaire before and after surgery. The duration of time that passed before the questionnaire was administered after surgery was unclear. Monestam et al. administered the questionnaire a third time five years after surgery.

Difficulty driving during the day was reported by 50% (110/222) of drivers before, 6% (17/281) of drivers after, and 5% (9/188) of drivers five years after cataract surgery in Monestam et al.

Difficulty driving at night was reported by 69% (150/217) of drivers before surgery, 24% (67/281) of drivers after surgery, and 32% (61/188) of drivers five years after surgery in Monestam et al. Of the drivers who reported specific driving difficulties (an unreported number) in Monestam and Wachtmeister, 71% reported difficulty driving at night. A significantly larger proportion of drivers with cataracts reported more difficulty driving at night than during the day after cataract surgery ($P < 0.001$). (57)

Visual problems while driving were reported by 82% of drivers preoperatively to 5% of drivers postoperatively in Monestam and Wachtmeister. An unreported number of drivers reported specific visual problems, including 37% reporting problems with distance estimation, 11% with glare, and 7% with eye fatigue.

Section Summary

Due to inconsistency among the findings of different studies, the evidence is insufficient to determine whether cataracts increase crash risk. The possibility that cataracts increase crash risk cannot be ruled out.

Direct Evidence – Crash Risk: Four studies that met our inclusion criteria for this key question examined the impact of cataracts on crash risk directly. One of these studies found that individuals with cataracts are at an increased risk for a motor vehicle crash; the remaining three studies did not. The latter three studies did not report on the severity of cataracts; two did not report on whether their enrollees had been treated with cataract surgery.

The study that found an increased risk of crash for individuals with cataracts when compared to controls without cataracts reported that drivers who did not have surgery for their cataracts crashed more than drivers who had surgery. Another study did not find a difference in crash risk between drivers with cataracts and drivers who had undergone cataract surgery; this study had not found an increased crash risk for drivers with cataracts compared to drivers without cataracts.

Indirect Evidence – Studies of Driving Simulation and Self-Reported Difficulty Driving: One of the crash studies, along with three additional studies in the evidence base, investigated indirect evidence to

support the contention that drivers with cataracts may have an elevated crash risk. One such study suggests that driving ability is significantly decreased and self-reported driving difficulty is increased among drivers with cataracts and that the driving ability of cataract patients improves after surgery to treat the disorder. Evidence from the additional studies consistently suggests that individuals with cataracts have greater difficulty driving than individuals without cataracts, and that driving ability improves following surgery.

Overall Summary: Although one crash study and supporting indirect evidence suggests that cataracts are associated with increased crash risk, three other crash studies did not find an association between cataract and crash. The small size of this evidence base prohibits exploration of potential factors that might explain the different findings. Therefore, the available evidence does not permit a conclusion regarding the relationship between cataract and crash. Furthermore, the generalizability of these findings to CMV drivers is unclear; it does not appear that any commercial drivers were represented in the studies.

Key Question 5: Is Diplopia Associated With Increased Crash Risk?

Introduction

Diplopia (i.e., double-vision, seeing double) is defined as a condition in which a single object appears as a double image.(18) The condition is primarily diagnosed by subjective reporting or discovered during medical examination. The two types of diplopia (monocular and binocular) can be the result of any number of conditions, including cataract, astigmatism, ocular aberration, and ocular misalignment.(18) Binocular diplopia can be corrected by covering one eye; monocular diplopia persists despite similar measures. Treatments for diplopia depend on the etiology of the condition and include wearing an eye patch when driving or using an ophthalmic lens with prismatic effects to correct or train the affected eye(s).(63) No figures are available regarding prevalence or incidence of diplopia among individuals in the United States. It should be noted that the literature available on the potential effects of this condition on driving performance is limited.

Identification of Evidence Base

The evidence base identification pathway for Key Question 5 is summarized in Figure 18. Our searches⁵ identified a total of 93 articles that appeared relevant to this key question. Following application of the retrieval criteria for this question (Appendix B: Retrieval Criteria), nine full-length articles were retrieved and read in full. Two of the nine retrieved articles were found to meet the inclusion criteria (Appendix C: Inclusion Criteria) for this key question. Table 40 lists these included studies. Table D- 5 of Appendix D lists the seven articles that were retrieved, read in full, and then excluded. The table also provides justification for their exclusion.

⁵ See Appendix A for search strategies

Figure 19 Development of Evidence Base for Key Question 5

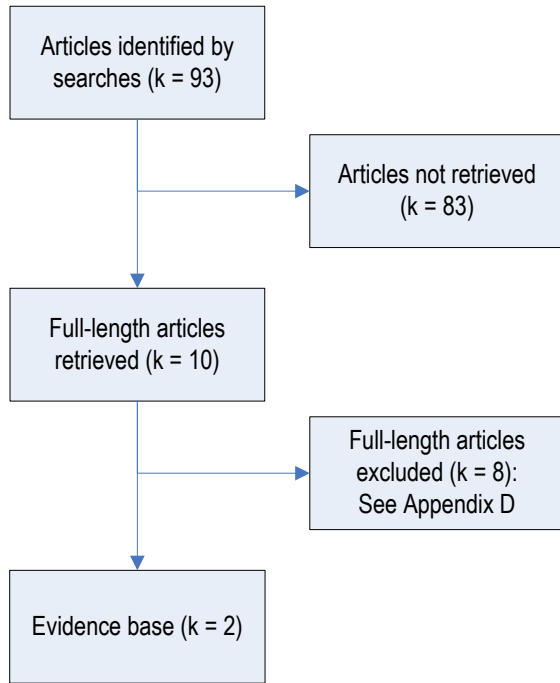


Table 40 Evidence Base for Key Question 5

| Reference | Year | Study Location | Country |
|----------------------|------|--------------------|---------|
| White et al.(64) | 2001 | Saskatchewan | Canada |
| McCloskey et al.(26) | 1994 | Washington (State) | USA |

Evidence Base

This subsection provides a brief description of the key attributes of the two studies of which the evidence base for Key Question 5 is composed. Here we discuss applicable information relevant to the quality of the included studies and the generalizability of the findings to CMV drivers.

Characteristics of Included Studies

One relevant crash study with a case-control design was found for inclusion within the evidence base. This study was not specific for drivers with diplopia; instead, the study focused on older drivers and evaluated the potential crash risk for several vision disorders. The second study utilized a cohort design to examine driving task performance. The cohort of diplopic and nondiplopic drivers was selected and followed-up to determine potential driving performance using simulated driving response and reaction recognition tasks with simulated driving machinery. Recognition task performance data were analyzed among individuals to observe whether errors in simulated tasks correlated with an increase in driving response and reaction times risk. All diplopic individuals were identified through medical record review to clinically confirm the existence of the impairment. The key attributes of the included studies that address Key Question 5 are summarized in Table 41.

Table 41. Key Study Design Characteristics of Studies That Address Key Question 5

| Reference | Year | Study Design | Comparison | How Was Diplopia Defined? | Diplopia Vision Clinically Confirmed? | Factors Controlled For (If Compared to Non Red-Green Controls)? | Driving Exposure Controlled For? | Primary Outcome | Definition of Crash | Outcome Self-Reported? |
|---------------------------------|------|--------------------|--|--|---------------------------------------|---|----------------------------------|--------------------------|--|---|
| Crash | | | | | | | | | | |
| McCloskey et al.(26) | 1994 | Case-control | Injurious crash vs. noninjurious crash | Unilateral blindness, unilateral visual loss, and strabismus | Yes; clinic-based medical records | Yes; age and gender | Unclear | Crash | Police-reported crash of vehicle physical damage or injury | No |
| Driving Task Performance | | | | | | | | | | |
| White et al.(64) | 2001 | Prospective cohort | Diplopia vs. no diplopia | Stable diplopia of ≥6 months' duration | Yes; medical records | Yes; age | No | Safe driving performance | N/A | Yes; response/reaction times reported from cue and threat recognition driving films |

N/A – Not applicable.
 NR – Not reported.

Quality of Evidence Base

The findings of our quality assessment of the included study composing the evidence base for Key Question 5 is summarized in Table 42. Complete details of our quality assessment can be found in the study summary tables presented in Appendix G. Our analysis concluded that the quality was low for the crash study and moderate for the driving performance study.

Table 42. Quality of the Studies That Assess Key Question 5

| Reference | Year | Quality Scale Used | Quality |
|----------------------------|------|--|----------|
| Crash | | | |
| McCloskey et al.(26) | 1994 | Revised Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies | Low |
| Driving Performance | | | |
| White et al.(64) | 2001 | Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies | Moderate |

Generalizability of Evidence to Target Population

The purpose of this subsection is to provide details of the extent to which individuals enrolled in the study that addressed Key Question 5 are similar to CMV drivers in the United States. The generalizability of the findings of the included studies to CMV drivers is unclear as these studies only examined diplopia among non-CMV drivers. Important characteristics of the individuals included in the study that addresses Key Question 5 are presented in Table 43.

Table 43. Generalizability of Studies That Address Key Question 5

| Reference | Year | Number of Individuals with-Diplopia Included (n =) | Diagnosis | % Drivers with Functional Diplopia Vision | Age Distribution (SD) | % Male | % CMV Drivers | Driving Exposure (i.e., Average Miles Driven Annually) | Driving Conditions (e.g., Night Driving, Driving Alone) | Generalizability to Target Population? |
|----------------------------|------|---|-----------------|---|-----------------------|--------|---------------|--|---|--|
| Crash Risk | | | | | | | | | | |
| McCloskey et al.(26) | 1994 | 10 | Medical records | NR | 65–80+ | NR | NR | NR | NR | Unclear |
| Driving Performance | | | | | | | | | | |
| White et al.(64) | 2001 | 10 | Medical record | 10 | 39.2* (±17.5) | 60 | NR | NR | N/A | Unclear |

*Mean age
 NR – Not Reported
 SD – Standard deviation

Findings

Impact of Diplopia on Crash Risk

The findings of the study by McCloskey et al. are presented in detail in Appendix G. This study did not present data that were directly relevant to CMV drivers. This study did not provide evidence of an increased crash risk (see Table 44). Crash risk was assessed by comparing the prevalence of diplopia among a group of individuals who had experienced a motor vehicle crash with that observed among a group of individuals who had not experienced crash. Outcome data

were presented as the OR (OR, or the odds of having diplopia having experienced a motor vehicle crash divided by the odds of having diplopia and having not experienced a crash). Although this study found no evidence that diplopia leads to an increase in crash risk among noncommercial drivers, this single, low-quality study is not sufficient to rule out the possibility that such a relationship may exist.

Table 44. Crash Findings in General Driving Population

| Reference | Year | Crash | | Noncrash | | Raw OR* (95% CI) | Adjusted OR (95% CI) |
|--------------------------------|------|----------------------|---------------------------------|----------------------------|------------------------------------|---------------------|-------------------------|
| | | Total Crashes (N) | Crashes with Diplopia (N) | Total Noncrashes (N) | Noncrashes with Diplopia (N) | | |
| Diplopia and Crash Risk | | | | | | | |
| McCloskey et al.(26) | 1994 | 204 | 4 | 410 | 6 | 1.3 (0.4 – 4.8) | 1.2 (0.4 – 4.2) |

CI – Confidence interval.

OR – Odds ratio.

* Calculated by ECRI Institute from reported data.

Impact of Diplopia on Simulated Driving Performance

The findings of the one study that addresses Key Question 5 are presented in detail in Appendix G. This study did not present data that were directly relevant to CMV drivers and the impact of diplopia on driving. Although this study found no evidence that diplopia leads to a decrease in safe driving performance among noncommercial drivers, this single small study is not sufficient to rule out the possibility that such a relationship may exist.

White et al.(64) compared the simulated driving performance of diplopic and nondiplopic drivers. The study examined stimulus recognition and reaction times associated with functional problems in driving skills. The performance assessment evaluated diplopic versus nondiplopic driving performance as measured by a driving simulator through the use of surrogate markers of driver safety from two driving films (Cue Recognition and Threat Recognition). Recognition and reaction tasks (including cue and threat recognition) were assessed by comparing the responses (events missed) and reaction times of diplopic drivers with that of the nondiplopic cohort. No significant differences were identified between the groups for any driving performance measure. Findings from this study are summarized in Table 45.

Table 45. Driving Simulator Findings among Diplopic Drivers

| Driving Performance Measures | Safe Driving Performance Data | | | |
|--|-------------------------------|-----------------|---------------------------------|---|
| | Events | Diplopic Group* | Control Group* (Nondiplopic) | Evidence of Increased Risk? (p value) |
| Recognition Responses (events missed) | | | | |
| Cue recognition | 24 | 1.2 | 0.6 | No. (0.53) |
| Threat recognition (part I) | 10 | 0.1 | 0 | No. (0.33) |
| Threat recognition (part II) | 10 | 3.3 | 2.3 | No. (0.39) |
| Combined missed responses | 44 | 4.6 | 2.9 | No. (0.39) |

| Driving Performance Measures | Safe Driving Performance Data | | | |
|--|-------------------------------|-----------------|------------------------------|---------------------------------------|
| | Events | Diplopic Group* | Control Group* (Nondiplopic) | Evidence of Increased Risk? (p value) |
| Recognition Responses (events missed) | | | | |
| Reaction Times | | | | |
| Cue recognition | – | 107.7 | 92.9 | No. (0.28) |
| Threat recognition (part I) | – | 136.0 | 106.7 | No. (0.31) |
| Threat recognition (part II) | – | 42.5 | 48.0 | No. (0.38) |
| Combined reaction time | – | 95.4 | 82.5 | No. (0.35) |

*n = 10 for the diplopia and control group.

Section Summary

There is insufficient evidence to determine whether diplopia increases crash risk.

Direct Evidence – Crash Studies: A single low-quality study reported on the association between diplopia and crash risk among non-CMV drivers. This study did not provide any evidence in support of the contention that individuals with diplopia are at an increased risk for a crash. However, a single low-quality study is insufficient evidence to allow any conclusion concerning crash risk; more data are required.

Indirect Evidence – Driving Simulator Studies: A single small study of moderate quality provided self-reported driving performance through response and reaction time recognition in simulated driving performance tasks among non-CMV drivers with diplopia and nondiplopic vision. Although the included study did not provide evidence of increased risk among diplopic drivers of any type and is therefore consistent with the findings of the crash study, two studies of low-to-moderate quality are insufficient to rule out an increase in risk. Moreover, we were not able to assess crash risk among CMV drivers with diplopia. The lack of data from studies enrolling CMV drivers with diplopia precludes one from determining whether CMV drivers with this type of vision impairment are at an increased risk for a motor vehicle crash. Thus, one cannot determine from the existing evidence base whether diplopic CMV drivers are at an increased risk for a motor vehicle crash.

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Appendix A: Search Summaries

Search Summary for Key Question 1

The search strategies employed combinations of free text keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases that compose the Cochrane Library.

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

Conventions:

OVID

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

PubMed

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

Topic-Specific Search Terms

Monocular Vision

Controlled vocabulary

exp Vision, monocular/

Text words

Monocular vision

Accidents

Controlled vocabulary

exp Accidents, traffic/

exp Highway safety/

exp Motor traffic accidents/

exp Traffic safety/

Text words

Accident\$

Collision\$

Crash\$

Traffic accident

Wreck

Driving

Controlled Vocabulary

exp Car driving

exp Driving behavior

exp Motor vehicle

exp Motor vehicles

Text Words

Auto\$

Automobile driving

Automobiles

Car

Commercial

Driving

Haul\$

Long distance

Professional

Truck

CINAHL/EMBASE/MEDLINE/PsycINFO

English language, human

| Set number | Concept | Search statement |
|------------|---------------------|--|
| 1 | Monocular vision | Vision, Monocular/ or monocular vision.mp. or monocular\$.tw. |
| 2 | Driving | Automobile driving.de. or exp motor vehicles/ or automobiles.de. or exp driving behavior/ or exp car driving/ or exp motor vehicle/ or (driving or commercial or professional or truck or car or automobile\$ or long distance or haul\$.ti. |
| 3 | Accident | Accidents, traffic/ or highway safety or motor traffic accidents or traffic accident or traffic safety).de. or crash\$.ti. or wreck\$.ti. or collision.ti. or accident\$.ti. |
| 4 | Combine sets | 1 AND 2 |
| 5 | Combine sets | 1 AND 3 |
| 6 | Limit by study type | 4 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.) |
| 7 | Limit by study type | 5 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.) |
| 8 | Limit by language | 6, English, English language |
| 9 | Limit by population | 8, human, humans |
| 10 | Limit by language | 7, English, English language |
| 11 | Limit by population | 10, human, humans |
| 12 | Eliminate overlap | 9, remove duplicates |
| 13 | Eliminate overlap | 11, remove duplicates |

| Total Identified | Total Downloaded | Total articles received | Total cited |
|------------------|------------------|-------------------------|-------------|
| 38 | 32 | 32 | 5 |

Search Summary for Key Question 2

The search strategies employed combinations of free text keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases that compose the Cochrane Library.

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

Conventions:

OVID

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

PubMed

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

Topic-Specific Search Terms

Color Discrimination

Controlled vocabulary

exp Color Blindness/
exp Color Discrimination/
exp Color Vision/
exp Color Vision Defect/
exp Color Vision Defects/
exp Color Vision Test/
exp Deuteranopia/
exp Protanopia/
exp Vision/

Text words

Color Blind\$
Color Vision Defect\$
Defect
Deficienc\$
Deutan
Protan
Red or green
Red-green
Vision

Accidents

Controlled vocabulary

exp Accidents, traffic/
exp Highway safety/
exp Motor traffic accidents/
exp Traffic safety/

Text words

Accident\$
Collision\$
Crash\$
Traffic accident
Wreck

Driving

Controlled vocabulary

exp Car driving
exp Driving behavior
exp Motor vehicle
exp Motor vehicles

Text Words

Auto\$
Automobile driving
Automobiles
Car
Commercial
Driving
Haul\$
Long distance
Professional
Truck

CINAHL/EMBASE/MEDLINE/PsycINFO

English language, human

| Set number | Concept | Search statement |
|------------|----------------------|---|
| 1 | Color discrimination | exp Color Discrimination/ or exp Color Blindness/ or exp Color Vision Test/ or exp Color Vision/ or exp Color Vision Defect/ or exp Color Vision Defects/ or exp deuteranopia/ or exp protanopia/ or (Color Vision Defect\$ or Color Blind\$ or ((Protan or Deutan) and (Defect or Deficienc\$))).mp. or ((red or green or red-green).mp. and (exp vision/ or vision.mp.)). |
| 2 | Driving | Automobile driving.de. or exp motor vehicles/ or automobiles.de. or exp driving behavior/ or exp car driving/ or exp motor vehicle/ or (driving or commercial or professional or truck or car or automobile\$ or long distance or haul\$.ti. |
| 3 | Accident | Accidents, traffic/ or highway safety or motor traffic accidents or traffic accident or traffic safety).de. or crash\$.ti. or wreck\$.ti. or collision.ti. or accident\$.ti. |
| 4 | Combine sets | 1 AND 2 |
| 5 | Combine sets | 1 AND 3 |
| 6 | Limit by study type | 4 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.) |
| 7 | Limit by study type | 5 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.) |
| 8 | Limit by language | 6, English, English language |
| 9 | Limit by population | 8, human, humans |
| 10 | Limit by language | 7, English, English language |
| 11 | Limit by population | 10, human, humans |
| 12 | Eliminate overlap | 9, remove duplicates |
| 13 | Eliminate overlap | 11, remove duplicates |

| Total identified | Total downloaded | Total articles received | Total cited |
|------------------|------------------|-------------------------|-------------|
| 129 | 53 | 22 | 3 |

Search Summary for Key Question 3

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

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

Conventions:

OVID

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

PubMed

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

Topic-Specific Search Terms

VF Defect

Controlled vocabulary

exp VF Defect/

exp VF/

exp VFs/

Text words

FOV

loss\$

range\$

VF\$

Accidents

Controlled vocabulary

exp Accidents, traffic/

exp Highway safety/

exp Motor traffic accidents/

exp Traffic safety/

Text words

Accident\$

Collision\$

Crash\$

Traffic accident

Wreck

Driving

Controlled vocabulary

exp Car driving

exp Driving behavior

exp Motor vehicle

exp Motor vehicles

Text words

Auto\$

Automobile driving

Automobiles

Car

Commercial

Driving

Haul\$

Long distance

Professional

Truck

CINAHL/EMBASE/MEDLINE/PsycINFO

English language, human

| Set number | Concept | Search statement |
|------------|---------------------|--|
| 1 | VF Defect | VF Defect/ or exp VF/ or exp VFs/ or (VF\$ and (loss\$ or range\$)) or FOV.mp. |
| 2 | Driving | Automobile driving.de. or exp motor vehicles/ or automobiles.de. or exp driving behavior/ or exp car driving/ or exp motor vehicle/ or (driving or commercial or professional or truck or car or automobile\$ or long distance or haul\$.ti. |
| 3 | Accident | Accidents, traffic/ or highway safety or motor traffic accidents or traffic accident or traffic safety).de. or crash\$.ti. or wreck\$.ti. or collision.ti. or accident\$.ti. |
| 4 | Combine sets | 1 AND 2 |
| 5 | Combine sets | 1 AND 3 |
| 6 | Limit by study type | 4 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.) |
| 7 | Limit by study type | 5 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.) |
| 8 | Limit by language | 6, English, English language |
| 9 | Limit by population | 8, human, humans |
| 10 | Limit by language | 7, English, English language |
| 11 | Limit by population | 10, human, humans |
| 12 | Eliminate overlap | 9, remove duplicates |
| 13 | Eliminate overlap | 11, remove duplicates |

| Total identified | Total downloaded | Total articles received | Total cited |
|------------------|------------------|-------------------------|-------------|
| 255 | 91 | 91 | 16 |

Search Summary for Key Question 4

The search strategies employed combinations of free text keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases that compose the Cochrane Library.

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

Conventions:

OVID

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

PubMed

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

Topic-Specific Search Terms

Cataract

Controlled vocabulary

exp Cataract/
exp Contrast sensitivity
exp Glare/

Text words

Cataract\$
Contrast sensitivity\$
Glare

Accidents

Controlled vocabulary

Accidents, traffic/
Highway safety
Motor traffic accidents
Traffic safety

Text words

Accident\$
Collision\$
Crash\$
Traffic accident
Wreck

Driving

Controlled vocabulary

exp Car driving
exp Driving behavior
exp Motor vehicle
exp Motor vehicles

Text words

Auto\$
Automobile driving
Automobiles
Car
Commercial
Driving
Haul\$
Long distance
Professional
Truck

CINAHL/EMBASE/MEDLINE/PsycINFO

English language, human

| Set number | Concept | Search statement |
|------------|---------------------|--|
| 1 | Cataract | exp cataract/ or exp contrast sensitivity/ or exp glare/ or cataract\$.mp. or contrast sensitivit\$.mp. or glare.mp. |
| 2 | Driving | Automobile driving.de. or exp motor vehicles/ or automobiles.de. or exp driving behavior/ or exp car driving/ or exp motor vehicle/ or (driving or commercial or professional or truck or car or automobile\$ or long distance or haul\$.ti. |
| 3 | Accident | Accidents, traffic/ or highway safety or motor traffic accidents or traffic accident or traffic safety).de. or crash\$.ti. or wreck\$.ti. or collision.ti. or accident\$.ti. |
| 4 | Combine sets | 1 AND 2 |
| 5 | Combine sets | 1 AND 3 |
| 6 | Limit by study type | 4 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.) |
| 7 | Limit by study type | 5 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.) |
| 8 | Limit by language | 6, English, English language |
| 9 | Limit by population | 8, human, humans |
| 10 | Limit by language | 7, English, English language |
| 11 | Limit by population | 10, human, humans |
| 12 | Eliminate overlap | 9, remove duplicates |
| 13 | Eliminate overlap | 11. remove duplicates |

| Total identified | Total downloaded | Total articles received | Total cited |
|------------------|------------------|-------------------------|-------------|
| 253 | 101 | 15 | 10 |

Search Summary for Key Question 5

The search strategies employed combinations of free text keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases that compose the Cochrane Library.

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

Conventions:

OVID

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

PubMed

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

Topic-Specific Search Terms

Diplopia

Controlled vocabulary

exp Diplopia/

Text words

Nerve Disease\$

Oculomotor Nerve Disease\$

Refractive Error\$

Strabismus

Trochlear Nerve Disease\$.Mp.

Accidents

Controlled vocabulary

exp Accidents, traffic/

exp Highway safety/

exp Motor traffic accidents/

Traffic safety/

Text words

Accident\$

Collision\$

Crash\$

Traffic accident

Wreck

Driving

Controlled vocabulary

exp Car driving

exp Driving behavior

exp Motor vehicle

exp Motor vehicles

Text Words

Auto\$

Automobile driving

Automobiles

Car

Commercial

Driving

Haul\$

Long distance

Professional

Truck

CINAHL/EMBASE/MEDLINE/PsycINFO

English language, human

| Set number | Concept | Search statement |
|------------|---------------------|--|
| 1 | Diplopia | exp diplopia/ or refractive error\$.mp. or strabismus.mp. or oculomotor nerve disease\$.mp. or trochlear nerve disease\$.mp. or nerve disease\$.mp. or double vision.mp |
| 2 | Driving | Automobile driving.de. or exp motor vehicles/ or automobiles.de. or exp driving behavior/ or exp car driving/ or exp motor vehicle/ or (driving or commercial or professional or truck or car or automobile\$ or long distance or haul\$.ti. |
| 3 | Accident | Accidents, traffic/ or highway safety or motor traffic accidents or traffic accident or traffic safety).de. or crash\$.ti. or wreck\$.ti. or collision.ti. or accident\$.ti. |
| 4 | Combine sets | 1 AND 2 |
| 5 | Combine sets | 1 AND 3 |
| 6 | Limit by study type | 4 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.) |
| 7 | Limit by study type | 5 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.) |
| 8 | Limit by language | 6, English, English language |
| 9 | Limit by population | 8, human, humans |
| 10 | Limit by language | 7, English, English language |
| 11 | Limit by population | 10, human, humans |
| 12 | Eliminate overlap | 9, remove duplicates |
| 13 | Eliminate overlap | 11, remove duplicates |

| Total identified | Total downloaded | Total articles received | Total cited |
|------------------|------------------|-------------------------|-------------|
| 93 | 10 | 10 | 2 |

Appendix B: Retrieval Criteria

Appendix B will list the retrieval criteria for each key question. An example of a small set of retrieval criteria are presented below.

Retrieval Criteria for Key Question 1

- Article must have been published in the English language.
- Article must have enrolled 10 or more subjects.
- Article must describe a study that attempted to determine the risk for a motor vehicle crash directly (risk for a fatal or nonfatal crash) associated with monocular vision or a study that attempted to evaluate the relationship between monocular vision and the following direct and indirect measures of driver safety:
 - Measures of driving-related performance (laboratory and experimental)
 - Measures of driving-related cognitive function
 - Measures of driving-related psychomotor function
- Article must describe a study that includes a comparison group comprising comparable subjects who do not have monocular vision.

Retrieval Criteria for Key Question 2

- Article must have been published in the English language.
- Article must have enrolled 10 or more subjects.
- Article may describe a study that attempted to evaluate the relationship between red-green color deficiency and the following direct and indirect measures of driver safety:
 - Measures of driving-related performance (laboratory and experimental)
 - Measures of driving-related cognitive function
 - Measures of driving-related psychomotor function
- Article must describe a study that includes a comparison group comprising comparable subjects who do not have red-green color deficiency.

Retrieval Criteria for Key Question 3

- Article must have been published in the English language.
- Article must have enrolled 10 or more adults per arm.
- Article must describe a study that assessed the relationship between VF loss and crash risk using actual crash data.

Retrieval Criteria for Key Question 4

- Article must have been published in the English language.
- Article must have enrolled 10 or more adults per arm.
- Article must describe a study that assessed the relationship between cataract and the following direct and indirect measures of driver safety:
 - Actual crash data
 - Driving-related performance (laboratory and experimental [i.e., road tests, driving simulator tests])
 - Self-reported difficulty driving

Retrieval Criteria for Key Question 5

- Article must have been published in the English language.
- Article must have enrolled 10 or more subjects.
- Article may describe a study that attempted to evaluate the relationship between diplopia and the following direct and indirect measures of driver safety:
 - Measures of driving-related performance (laboratory and experimental)
 - Measures of driving-related cognitive function
 - Measures of driving-related psychomotor function
- Article must describe a study that includes a comparison group comprising comparable subjects who do not have diplopia.

Appendix C: Inclusion Criteria

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

Inclusion Criteria for Key Question 1

- Article must have been published in the English language.
- Article must be a full-length article. Abstracts and letters to the editor will not meet this inclusion criterion.
- Article must have enrolled ten or more subjects.
- Article must have enrolled subjects aged ≥ 18 .
- Article must describe a study that attempted to determine the risk for a motor vehicle crash associated with monocular vision or a study that attempted to evaluate the relationship between monocular vision and the following direct and indirect measures of driver safety:

- Measures of driving-related performance (laboratory and experimental)
- Measures of driving-related cognitive function
- Measures of driving-related psychomotor function
- Article may compare the proportion of drivers with monocular vision who crashed (cases) with the proportion of comparable individuals without the disorder who did not crash (controls).
- Article may compare proportion of individuals with monocular vision who crashed (cases) to those in the general population who experienced crash (controls).
- Studies that evaluated both monocular and other visual impairments among individuals were included as long as the monocular participants' data could be analyzed separately from that of other populations.
- If the same study is reported in multiple publications, the most complete publication will be the primary reference. Data will be extracted in order to avoid double-counting patients.

Inclusion Criteria for Key Question 2

- Article must have been published in the English language.
- Article must be a full-length article. Abstracts and letters to the editor will not meet this inclusion criterion.
- Article must have enrolled 10 or more subjects.
- Article must have enrolled subjects aged ≥ 18 .
- Article must have enrolled patients in whom red-green color-deficiency was measured through valid test instruments (Ishihara plate test, lantern test, anomaloscope).
- Article may be prospective or retrospective with consecutive enrollment.
- Article may describe a study that attempted to evaluate the relationship between red-green color deficiency and the following direct and indirect measures of driver safety:
 - Measures of driving-related performance (laboratory and experimental)
 - Measures of driving-related cognitive function
 - Measures of driving-related psychomotor function
- Article must describe a study that includes a comparison group comprising comparable subjects who do not have red-green color deficiency.

Inclusion Criteria for Key Question 3

- Article must have been published in the English language.
- Article must have enrolled 10 or more adults per arm.

- Article must have enrolled subjects aged ≥ 18 .
- If the same study is reported in multiple publications, the most complete publication will be the primary reference. Additional relevant data will be collected from the secondary publication(s). Data will be extracted in order to avoid double-counting patients.
- Article must describe a study that assessed the relationship between VF loss and crash risk using actual crash data.
- Study must have included individuals without VF defects for comparison with individuals with VF defects.
- Study must have reported the test used to assess VF loss.

Inclusion Criteria for Key Question 4

- Article must have been published in the English language.
- Article must have enrolled 10 or more adults per arm.
- Article must describe a study that assessed the relationship between cataract and the following direct and indirect measures of driver safety:
 - Actual crash data
 - Driving-related performance (laboratory and experimental [i.e., road tests, driving simulator tests])
 - Self-reported difficulty driving
- If the same study is reported in multiple publications, the most complete publication will be the primary reference. Additional relevant data will be collected from the secondary publication(s). Data will be extracted in order to avoid double-counting patients.
- For actual crash data, study may compare the following:
 - The proportion of drivers with monocular vision who crashed (cases) with the proportion of comparable individuals without the disorder who did not crash (controls).
 - The proportion of individuals with monocular vision who crashed (cases) to those in the general population who experienced crash (controls).
- For driving tests and simulation and self-reported difficulty driving, the following comparisons will be considered:
 - Individuals with cataracts and controls without cataracts
 - Individuals with cataract surgery and controls without cataracts
 - Individuals with cataract surgery and individuals with cataracts
 - Scores in the same cohort of individuals before and after cataract surgery

Inclusion Criteria for Key Question 5

- Article must have been published in the English language.
- Article must be a full-length article. Abstracts and letters to the editor will not meet this inclusion criterion.
- Article must have enrolled 10 or more subjects.
- Article must have enrolled subjects aged ≥ 18 .
- Article must have enrolled patients in whom diplopia was diagnosed through valid visual assessment and clinically confirmed.
- Article may describe a study that attempted to evaluate the relationship between diplopia and the following direct and indirect measures of driver safety:
 - Measures of driving-related performance (laboratory and experimental)
 - Measures of driving-related cognitive function (recognition)
 - Measures of driving-related psychomotor function (response timing)
- Article must describe a study that includes a comparison group comprising comparable subjects who do not have diplopia.

Appendix D: Excluded Studies

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

| Reference | Year | Reason for Exclusion |
|---------------------------|------|--|
| Backman et al.(65) | 1972 | No relevant outcome data |
| Brandeleone et al.(66) | 1972 | Research protocol |
| Cohen et al.(67) | 2007 | No relevant outcome data |
| Davison(68) | 1985 | No relevant outcome data |
| Dionne et al.(69) | 1995 | Unclear if relevant to monocular vision |
| Fatt et al.(70) | 1994 | Beyond scope |
| Freytag et al.(71) | 1968 | Case study |
| Gresset et al.(72) | 1994 | Same study as Gresset(27); less complete publication |
| Haymes et al.(38) | 2007 | No relevant outcome data |
| Humphriss(73) | 1987 | No relevant outcome data |
| Humphriss(73) | 1987 | Unclear if relevant to monocular vision |
| Keeffe et al.(74) | 2007 | No relevant outcome data |
| Laberge-Nadeau et al.(75) | 1996 | Unclear if relevant to monocular vision |
| Liesmaa(76) | 1973 | Unclear if relevant to monocular vision |
| Maag et al.(77) | 1997 | No relevant outcome data |
| Maag(77) | 1997 | Unclear if relevant to monocular vision |
| McGwin et al.(42) | 1998 | No relevant outcome data |
| Owsley et al.(43) | 1998 | No relevant outcome data |
| Owsley et al.(44) | 1998 | No relevant outcome data |
| Owsley et al.(47) | 1991 | No relevant outcome data |
| Owsley et al.(78) | 1994 | No relevant outcome data |
| Phillips et al.(79) | 1975 | No relevant outcome data |
| Reading et al.(80) | 1969 | No relevant outcome data |
| Rubin et al.(39) | 2007 | No relevant outcome data |
| Slade et al.(81) | 2002 | No relevant outcome data |
| Staplin et al.(82) | 2003 | No relevant outcome data |

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

| Reference | Year | Reason for Exclusion |
|----------------------|------|--|
| Alferdinck(83) | 2006 | No relevant outcome data |
| Allen(84) | 1965 | No relevant outcome data |
| Cole et al.(37) | 1982 | Background information article |
| Cole et al.(85) | 1997 | Review |
| Cole(86) | 1972 | Background information article |
| Cole(87) | 2002 | No complete and relevant outcome data; background information article |
| Faraldi et al.(88) | 1977 | Review |
| Logan(89) | 1982 | No relevant outcome data |
| Nathan et al.(90) | 1964 | Studied recognition tasks outcomes but does not provided relevant outcomes from recognition system that is equivalent to traffic signals standards |
| Neubauer et al.(91) | 1978 | No relevant outcome data |
| Norman et al.(92) | 2006 | No relevant outcome data |
| Steward et al.(93) | 1989 | Included children |
| Verriest et al.(94) | 1980 | No clear definition of color blindness |
| Vingrys et al.(95) | 1988 | Review |
| Vingrys et al.(96) | 1983 | No relevant outcome data |
| Vingrys et al.(97) | 1986 | No relevant outcome data |
| Vingrys(98) | 2002 | Letter to the editor |
| Voke et al.(99) | 1979 | No relevant outcome data |
| Whillans et al.(100) | 1992 | Background information article |

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

| Reference | Year | Reason for Exclusion |
|--------------------------|------|---|
| Ball et al.(101) | 1998 | Examines driving avoidance |
| Ball et al.(53) | 1993 | Multiple publications, same population |
| Barsam et al.(102) | 2006 | No crash/simulator |
| Bowers et al.(103) | 2007 | Abstract |
| Brooks et al.(104) | 2005 | None of the participants had visual problems; study simulated visual problems in participants |
| Cashell(105) | 1970 | Test instrument not reported |
| Coeckelbergh et al.(106) | 2002 | No crash data |
| Coeckelbergh et al.(107) | 2004 | No crash data |
| Crundall et al.(108) | 1999 | All participants had normal vision |
| Davison et al.(68) | 1985 | Does not report VF deficits |
| Decina et al.(1) | 1993 | Reported only on combined criteria |
| Drance et al.(109) | 1967 | No crash/simulator data |
| Fisk et al.(110) | 2002 | Did not report crash risk as a result of VF defect |
| Fisk et al.(111) | 2002 | Although crash, no relevant outcome data |
| Foley et al.(112) | 1995 | Does not measure VF defects |
| Freeman et al.(113) | 2005 | No relevant outcome data; focuses on driving cessation, not crash/driver simulation |

Vision and CMV Driver Safety

| Reference | Year | Reason for Exclusion |
|---------------------------|------|--|
| Freeman et al.(114) | 2006 | No VF-related data |
| Gresset et al.(72) | 1994 | Does not report on VF deficits |
| Gresset et al.(27) | 1994 | Does not measure VF deficits |
| Hiatt et al.(115) | 1968 | Does not report crash data |
| Hoffman et al.(116) | 2005 | No relevant outcome data |
| Hu et al.(117) | 1998 | No relevant outcome data; glaucoma focused |
| Ivers et al.(118) | 1999 | No clear data or association with VF |
| Jones(119) | 2006 | No crash reported; simulation |
| Kane et al.(120) | 1996 | Abstract |
| Lamble et al.(121) | 2002 | <10 patients/group |
| Lees et al.(122) | 2007 | Not divided into drivers with field defects compared to those without |
| Mantjarvi et al.(123) | 1998 | No crash data |
| Marottoli et al.(124) | 1994 | Does not measure VF defects |
| McCloskey et al.(26) | 1994 | Does not report VF data |
| McGwin et al.(125) | 2000 | Does not report crash data |
| Owsley et al.(59) | 2001 | Does not measure VF |
| Owsley et al.(78) | 1994 | Multiple publication, same population |
| Parisi et al.(126) | 1991 | No control group; no crash data |
| Peli et al.(127) | 2005 | Simulator design |
| Perryman et al.(128) | 1996 | "Normal" participants visual acuities of 20/40 at least; passed peripheral vision test |
| Roge et al.(129) | 2004 | <10 patients |
| Sagberg et al.(130) | 2006 | Does not separate VF defects from hyperopia or myopia |
| Schieber et al.(131) | 1998 | No crash data; driving simulator |
| Schulte et al.(132) | 1999 | <10 patients/group |
| Sims et al.(133) | 2004 | Multiple publication, same population |
| Sims et al.(134) | 2000 | Multiple publication, same population |
| Steel et al.(135) | 1996 | <10 participants |
| Szlyk et al.(136) | 2002 | Driving simulator, incomplete data |
| Szlyk et al.(137) | 1995 | Does not report data for VF |
| Szlyk et al.(138) | 1993 | <10 patients/group |
| Szlyk et al.(139) | 2005 | Incomplete data reporting |
| Szlyk et al.(140) | 1995 | Incomplete data reporting |
| Troutbeck et al.(141) | 1994 | All normal subjects and <10 participants |
| Vargas-Martin et al.(142) | 2005 | <10 participants |
| Wood et al.(143) | 1992 | <10 participants |
| Wood et al.(144) | 1994 | Simulated visual impairment |
| Wood et al.(145) | 1995 | Simulated visual impairment |
| Wood et al.(146) | 1993 | All participants were normal |

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

| Reference | Year | Reason for Exclusion |
|--------------------------------|------|---|
| Ivers et al.(118) | 1999 | Crash or relevant indirect outcomes in individuals with cataract not reported |
| Mantjarvi and Tuppurainen(147) | 1999 | Crash and relevant indirect outcomes not reported |
| Parmentier et al.(148) | 2005 | Crash and relevant indirect outcomes not reported |
| Pfaff and Werner(62) | 1994 | Crash and relevant indirect outcomes not reported |
| Superstein et al.(149) | 1997 | Crash and relevant indirect outcomes not reported |

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

| Reference | Year | Reason for Exclusion |
|-----------------------|------|--------------------------------|
| Ball et al.(53) | 1993 | No relevant outcome data |
| Bedard et al.(150) | 1997 | No relevant outcome data |
| Lovsund et al.(151) | 1991 | No relevant outcome data |
| Marottoli et al.(124) | 1994 | No relevant outcome data |
| Odenheimer(152) | 1994 | No relevant outcome data |
| Owsley et al.(44) | 1998 | No relevant outcome data |
| Taylor(63) | 1987 | Background information article |
| Trobe(153) | 1998 | Editorial |

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

As stated in the main text, ECRI Institute evidence reports differ substantially from other systematic reviews in that we provide two types of conclusion: qualitative conclusions and quantitative conclusions. In order to reach these conclusions, we use an algorithm developed by ECRI Institute to guide the conduct and interpretation of the analyses performed during the development of this evidence report.⁽²³⁾ The algorithm, which is presented in Figure E-2 through Figure E-5, formalizes the process of systematic review by breaking the process down into several discrete steps. At each step, rules are applied that determine the next step in the systematic review process and lead ultimately to the stability and strength of evidence ratings that are allocated to our conclusions. Because the application of the rules governing each step in the algorithm (henceforth called a decision point) guide the conduct of the systematic review process and how its findings are interpreted, much time and effort was spent in ensuring that the rules and underlying assumptions for each decision point were reasonable.

The algorithm comprises three distinct sections: a *General* section, a *Quantitative* section, and a *Qualitative* section. The system employs 14 decision points (Table 46). Four are listed in the General section because they apply to both quantitative conclusions as well as qualitative conclusions. The other 10 apply specifically to either quantitative conclusions (Decision Points 5 through 9) or qualitative conclusions (Decision Points 10 through 14). The rest of this appendix defines these decision points and describes how we resolved them for this report. After these descriptions, the pathways for the full system appear in Figure E-2 through Figure E-5.

Note that we applied this system separately for each outcome of interest. This is because many aspects of the evidence (e.g., quality, consistency) can vary by outcome.

Table 46. Decision Points in the ECRI Institute System

| Category | Decision Point |
|--------------|--|
| General | 1) What is the quality of individual studies? |
| | 2) What is the overall quality of evidence? |
| | 3) Is a quantitative estimate potentially appropriate? |
| | 4) Are data informative? |
| Quantitative | 5) Are data quantitatively consistent (homogeneous)? |
| | 6) Are findings stable (quantitatively robust)? |
| | 7) Are there sufficient data to perform meta-regression? |
| | 8) Does meta-regression explain heterogeneity? |
| | 9) Is the meta-regression model robust? |
| Qualitative | 10) Are data qualitatively robust? |
| | 11) Is meta-analysis possible? |
| | 12) Are data qualitatively consistent? |
| | 13) Was at least one study a multicenter study? |
| | 14) Is the magnitude of effect extremely large? |

Decision Point 1: Acceptable Quality?

Decision Point 1 serves two purposes: (1) to assess the quality of each included study; and (2) to provide a means of excluding studies that are so prone to bias that their reported results cannot be considered useful. To aid in assessing the quality of each of the studies included in this evidence report, we used two study quality assessment instruments. The choice of which instrument to use was based on the design of the study used to address the key questions of interest. In this evidence report we used the ECRI Institute Quality Scale III (for pre/post studies) and two revised versions of the Newcastle-Ottawa Quality Assessment Scale (one for case-control studies, one for cohort studies).(31) These instruments are presented in Appendix F. To assess the quality of an individual study, we computed a normalized score so that a perfect study received a score of 10, a study for which the answers to all items was “No” received a score of 0, and a study for which the answers to all questions was “NR” was 5. Quality scores were converted to categories as shown in Table 11 (see Methods section of main document). The definitions for what constitutes low-, moderate-, or high-quality evidence were determined *a priori* by a committee of four methodologists. Because the quality was determined separately for each outcome, a study that scored as high quality for one outcome might score as moderate or low quality for another outcome.

Decision Point 2: Determine Quality of Evidence Base

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

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

| Category | Median EQS III Score | Median NOQAS Score (case-control) | Median NOQAS Score (cohort) |
|------------------|----------------------|-----------------------------------|-----------------------------|
| High Quality | | | |
| Moderate Quality | ≥9.0 | ≥8.0 | ≥8.0 |
| Low Quality | <9.0 | <8.0 | <8.0 |

Decision Point 3: Is a Quantitative Analysis Potentially Appropriate?

The answer to Decision Point 3 depends upon the adequacy of reporting in available studies as well as the number of available studies. In order to permit a quantitative estimate of an effect size for a given outcome, the data for that outcome must be reported in at least three studies in a manner that allows the data to be pooled in a meta-analysis. If fewer than three studies are available, no quantitative estimate is usually appropriate, regardless of reporting. Another situation that does not permit a quantitative estimate is when at least three studies are relevant to the general topic, but fewer than 75% of them reported the outcome as well as sufficient information for determination of the effect size and its dispersion, either by direct reporting from the trial or calculations based on reported

information. If no quantitative estimate would be appropriate, then one moves directly to Decision Point 10 to determine whether the evidence supports a qualitative conclusion.

Decision Point 4: Are Data Informative?

When there are only a small number of patients in an evidence base, statistical tests generally do not perform well. Under such circumstances, statistics cannot determine whether a true difference exists between treatments. This means that no clear conclusion can be drawn. For this decision point, we determined whether the precision of an evidence base was sufficient to permit a conclusion. Statistically significant results are informative because they mean that a treatment effect may exist. Statistically insignificant results are also potentially informative, but only if they exclude the possibility that a clinically significant treatment effect exists.

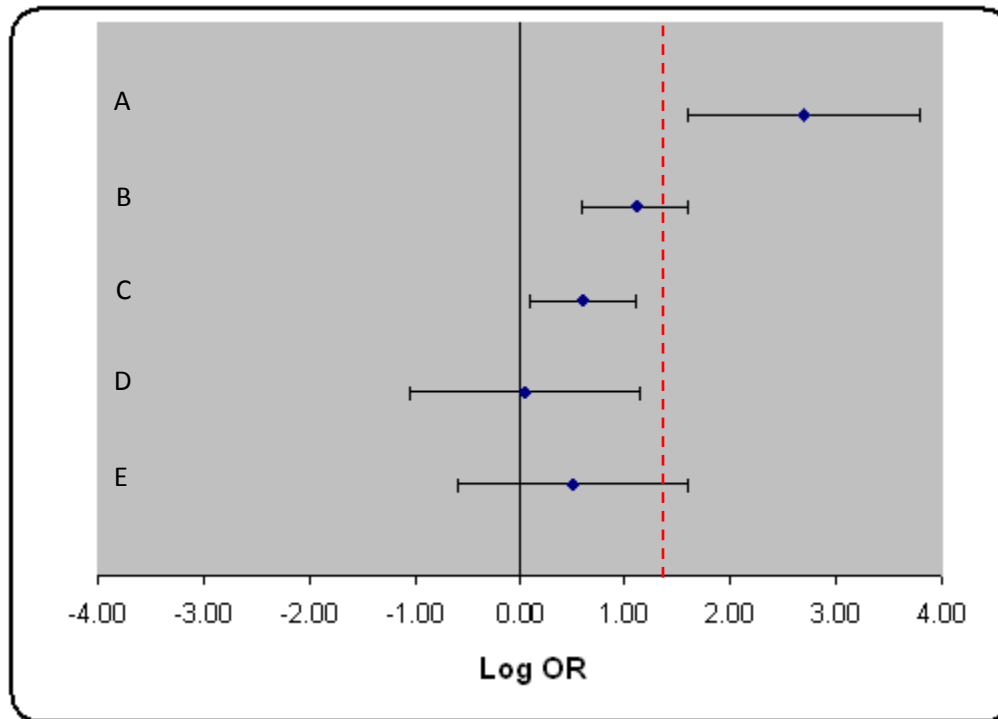
When a meta-analysis is performed, a key concern is the confidence interval around the random-effects summary statistic. If this interval is so wide that it includes a clinically significant (or substantial) effect in one direction *and also an effect in the opposite direction*, then the evidence is inconclusive and therefore uninformative.(154)

Thus, when considering the summary effect size from a meta-analysis (or the effect size from a single study), there are three ways in which the effect can be informative as follows:

- 1) The effect size is statistically significantly different from 0. This would be indicated whenever the confidence interval does not overlap 0.
- 2) The confidence interval is narrow enough to exclude the possibility that a *clinically significant difference* exists.
- 3) The confidence interval is narrow enough to exclude the possibility that a *substantial difference* exists. This possibility is included to address situations when even a very small effect can be considered clinically significant (e.g., a difference in mortality rates), but the effect may not be substantial.

Consider Figure E-1. Four of the findings in this figure are informative (A to D). Only finding E is uninformative.

Figure E-1. Informative Findings



Dashed line – Threshold for a clinically significant difference.

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

Note that when the evidence base consists of one or two studies, and the only usable data from one study consists of a p -value that was calculated using the wrong statistical test, then the data cannot generally be considered “informative.” If, however, the study reported sufficient information for one to perform the correct test, then informativeness can be determined.

Decision Point 5: Are Data Quantitatively Consistent (Homogeneous)?

This decision point was used only when the answer to Decision Point 3 was affirmative and a quantitative analysis was performed. Quantitative consistency refers to the extent to which the quantitative results of different studies are in agreement. The more consistent the evidence, the more precise a summary estimate of treatment effect derived from an evidence base will be. Quantitative consistency refers to consistency tested in a meta-analysis using a test of homogeneity. For this

evidence report we used Higgins and Thompson’s I^2 statistic.(155) By convention, we considered an evidence base as being quantitatively consistent when $I^2 < 50\%$.

If the findings of the studies included were homogeneous ($I^2 < 50\%$), we obtained a summary effect-size estimate by pooling the results of these studies using random-effects meta-analysis (REMA). If the findings were not homogeneous, we moved on to Decision Point 7 (exploration of heterogeneity, if ≥ 10 studies) or Decision Point 9 (qualitative analysis).

Decision Point 6: Are Findings Stable (Quantitatively Robust)?

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

If a meta-analysis was conducted, we utilized two different sensitivity analyses. These sensitivity analyses are:

1. Remove one study, and repeat meta-analysis. The purpose of this sensitivity analysis is to determine whether a meta-analysis result is driven by a particular trial. For example, a large trial may have a very strong impact on the results of a meta-analysis because of its high weighting.
2. Cumulative random-effects meta-analysis. Cumulative meta-analysis provides a means by which the effect of the size of the evidence base (in terms of the number of individuals enrolled in the included studies and the number of included studies) can be evaluated on the stability of the calculated effect-size estimate. For this evidence report, we performed two different cumulative random-effects meta-analyses:
 - a. Studies were added cumulatively to a random-effects meta-analysis by date, publication-oldest study first.
 - b. Studies were added cumulatively to a random-effects meta-analysis by date, newest study first.

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

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

Table E-2. Prespecified Tolerance Levels

| Effect-size estimate | WMD | SMD | % of individuals | RR | OR |
|----------------------|-------|--------|------------------|---------|---------|
| Tolerance | +/-5% | +/-0.1 | +/-5 | +/-0.05 | +/-0.05 |

Decision Point 7: Are There Sufficient Data to Perform Meta-Regression?

We required a minimum of 10 studies before attempting meta-regression.

Decision Points 8 and 9: Exploration of Heterogeneity

We will always attempt to determine the source of heterogeneity when the evidence base consists of 10 or more studies using meta-regression. In preparing this evidence report, we did not encounter any situations in which we had a heterogeneous evidence base consisting of at least 10 studies with combinable data. Consequently, Decision Points 8 and 9 are irrelevant to the present report, and we do not discuss them further.

Decision Point 10: Are Qualitative Findings Robust?

Decision Point 10 allows one to determine whether the qualitative findings of two or more studies can be overturned by sensitivity analysis. The same sensitivity analyses used to test quantitative robustness were used to test qualitative robustness. We considered our qualitative findings to be overturned only when the sensitivity analyses altered our qualitative conclusion (i.e., a statistically significant finding became insignificant as studies were added to the evidence base). Otherwise, we concluded that our qualitative findings were robust.

Decision Point 11: Is Meta-Analysis Possible?

This Decision Point is used only when the evidence base for an outcome consists of two studies.

A meta-analysis is possible if each study reports an effect size and its standard error or if each study reports sufficient information for the reader to calculate these values. Note that meta-analysis is never appropriate if two studies have statistically significant effect sizes in opposite directions.

Decision Point 12: Are Data Qualitatively Consistent?

This Decision Point is used only when the evidence base for an outcome consists of two studies.

The purpose of this decision point is to determine whether the qualitative findings of an evidence base consisting of only two studies are the same. For example one might ask, “When compared to drivers with no VF defects, do all included studies find that drivers with VF loss are at an increased risk for a motor vehicle crash?”

Decision Point 13: Is at Least One Study a Multicenter Study?

Multicenter trials may increase the strength of a one- or two-study evidence base because they demonstrate partial replication of findings; they have shown that different investigators at different centers can obtain similar results using the same protocol. We defined a multicenter trial as any trial that met the following two conditions: (1) at least three centers and (2) either ≥ 100 patients or at least three centers enrolled 20 or more patients per center.

Decision Point 14: Is Magnitude of Treatment Effect Large?

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

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

Additional Consideration: Evidence from Indirect or Surrogate Outcomes

In certain instances when an evidence base includes only one or two studies with direct evidence (e.g., crash data), the strength of evidence may be increased by additional studies of indirect outcomes (e.g., driving simulator tests, visual function tests) that show findings consistent with the direct evidence study findings.

Figure E-2. General Section

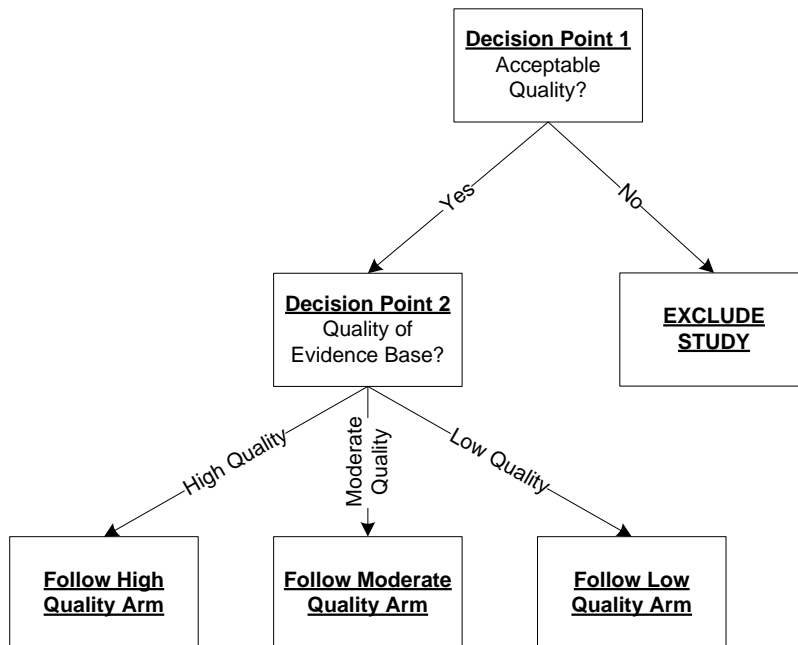


Figure E-3. High Quality Pathway

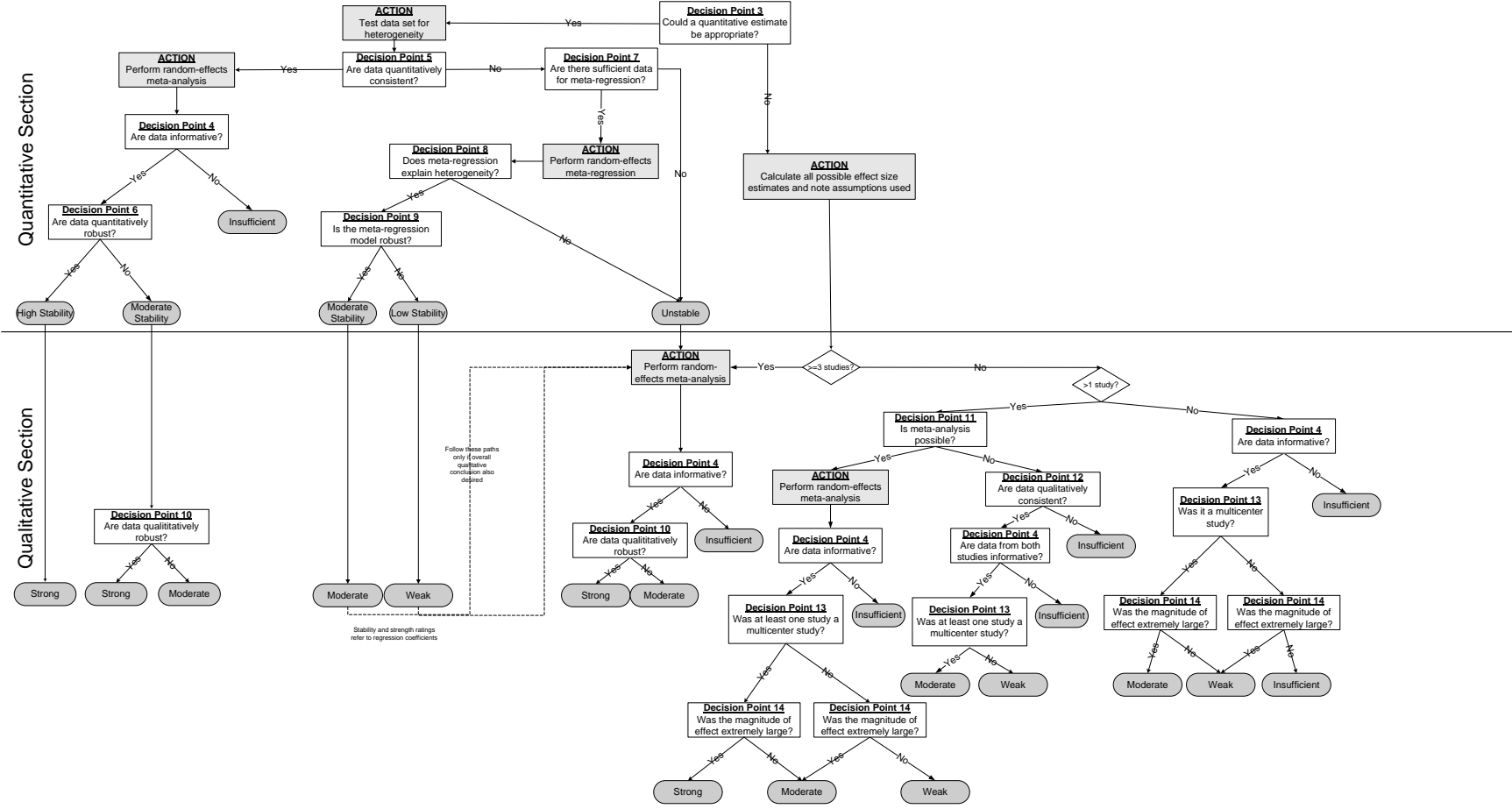


Figure E-4. Moderate Quality Pathway

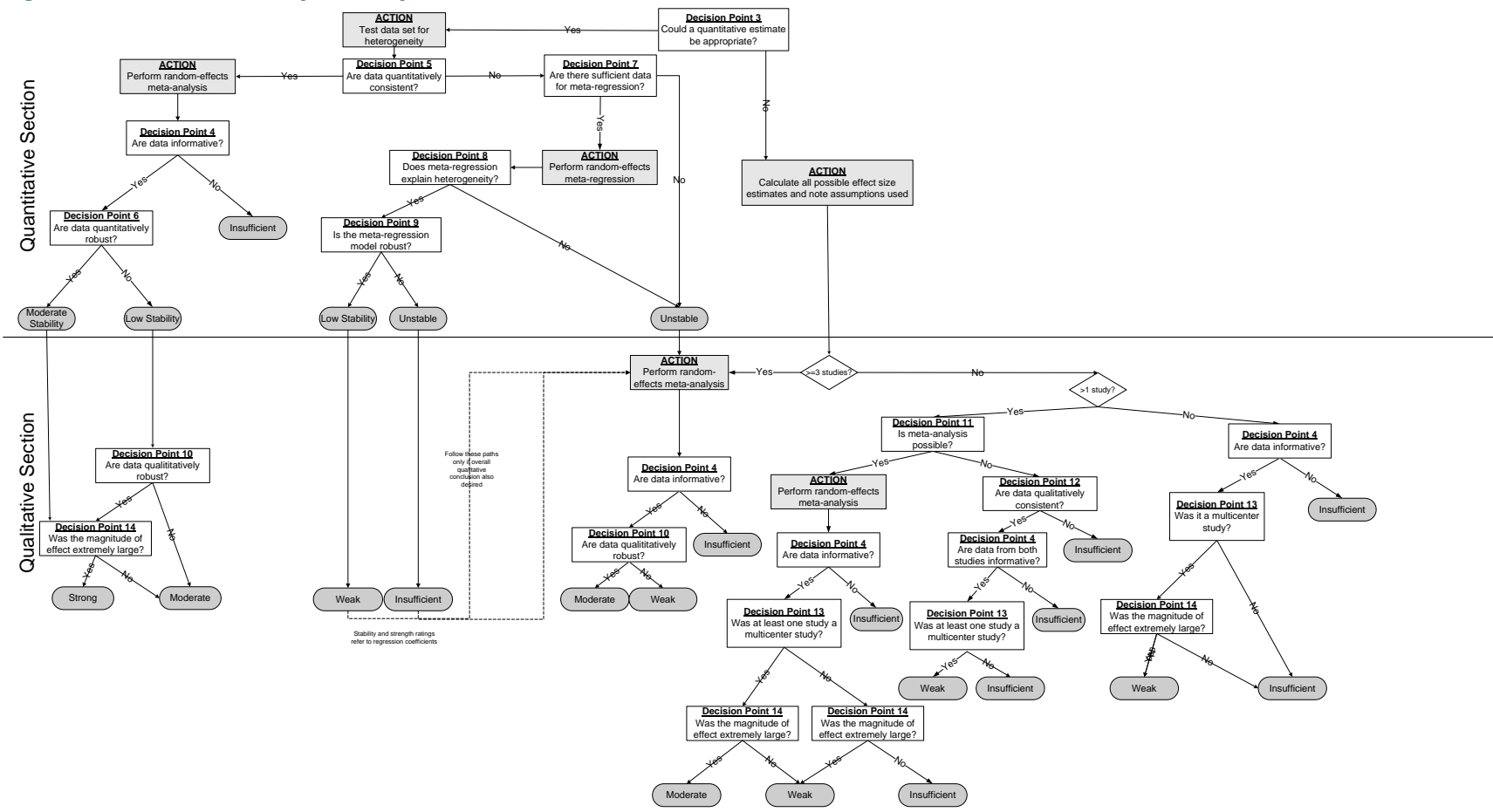
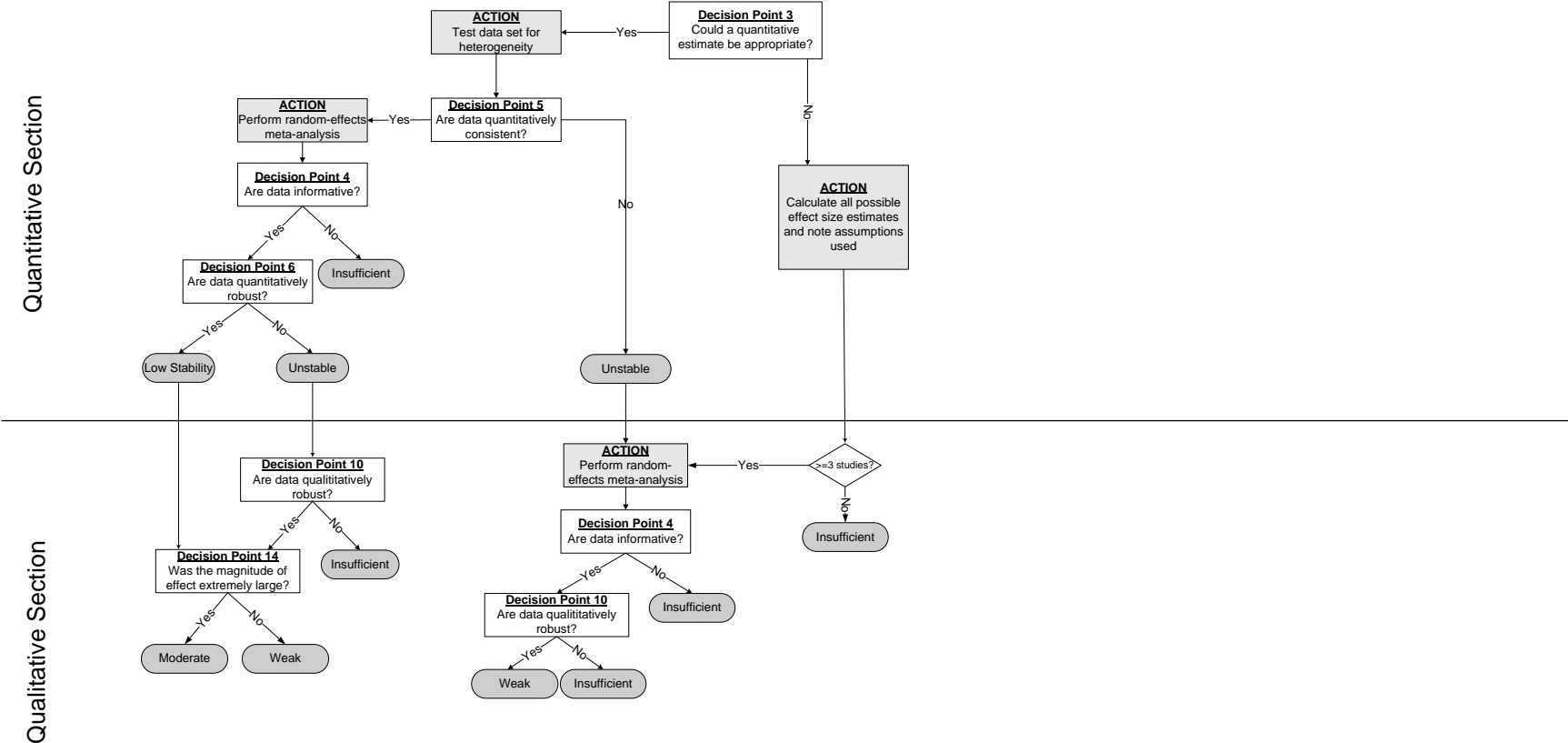


Figure E-5 Low Quality Pathway



Appendix F: Quality Assessment Instruments Used

Three different assessment instruments were used to assess the quality of the studies included in the evidence bases for the key questions addressed in this evidence report: the ECRI Institute Quality Checklist III for pre/post studies and revised versions of the Newcastle-Ottawa Quality Assessment Scale for Cohort Studies and the Newcastle-Ottawa Quality Assessment Scale for Case-Control Studies.(31)

ECRI Institute Quality Scale III: Pre/Post Studies

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

Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies

| Question # | Question |
|------------|---|
| 1 | Are the exposed cohort representative of the average motor vehicle driver in the community? |
| 2 | Are the nonexposed cohorts representative? |
| 3 | How was exposure determined – secure record? |
| 4 | At the designated start of the study, were the controls free of the outcome of interest? |
| 5 | What is the comparability of the cohorts on the basis of design or analysis? |
| 6 | How was the outcome assessed? |
| 7 | Was follow-up adequate for outcome to occur? |
| 8 | Was the follow-up adequate for both exposed and nonexposed cohorts? |
| 9 | Was the funding free of financial interest? |
| 10 | Were the conclusions supported by the data? |

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

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

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

Appendix G: Study Summary Tables

<<See Volume 2>>