Vision and Commercial Motor Vehicle Driver Safety

Executive Summary

Presented to

The Federal Motor Carrier Safety Administration

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Prepared for

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

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.

Policy Statement

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

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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.

<u>Direct Evidence – Crash Studies</u>: 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.

<u>Indirect Evidence – Driving Simulator Studies</u>: 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 ≥40% reduction in UFOV is associated with an increased risk of crash (Strength of Evidence: Moderate).**

<u>Direct Evidence – Crash Studies</u>: 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 ≥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.

<u>Direct Evidence – Crash Risk</u>: 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.

<u>Indirect Evidence – Studies of Driving Simulation and Self-Reported Difficulty Driving:</u> 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.

<u>Overall Summary</u>: 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.

<u>Direct Evidence – Crash Studies</u>: 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.

<u>Indirect Evidence – Driving Simulator Studies</u>: 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.