Evidence Report

Stroke and Commercial Motor Vehicle Driver Safety

Executive Summary

Presented to
The Federal Motor Carrier Safety Administration
September 2008

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.

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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 (EPC) by the U.S. 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 on the current state of knowledge on this topic. It is not intended as instruction for medical practice, nor for making decisions on 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 are involved in highway crashes. According to statistics from the U.S. Department of Transportation (DOT), there were 4,932 fatal crashes involving a large truck in 2005 for a total of 5,212 fatalities. In addition, there were 137,144 non-fatal crashes; 59,405 of these were crashes that resulted in an injury to at least one individual (for a total of 89,681 injuries).

The purpose of this evidence report is to address several key questions posed by the Federal Motor Carrier Safety Administration (FMCSA). Each of these key questions was developed by the FMCSA so that the answers to these questions would provide information that would be useful in updating its current medical examination guidelines. The three key questions addressed in this evidence report are:

Key Question 1: Are individuals who have experienced a stroke at an increased risk for a motor vehicle crash (crash risk or driving performance)?

Key Question 2: If so, can neuropsychological testing of individuals who have experienced a stroke predict crash risk?

Key Question 3: Among individuals who have experienced a TIA (transient ischemic event), what is the risk of experiencing a future stroke?

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 (PreMEDLINE), EMBASE, PsycINFO, CINAHL, TRIS, the Cochrane library) were searched (through January 10, 2008). 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 comprise the evidence base for each key question; we also considered the interplay between the quality, quantity, robustness, and consistency of the overall body of evidence.

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Analytic Methods

The set of analytic techniques used in this evidence report was extensive. Random-effects meta-analyses were used to pool data from different studies. Differences in the findings of studies (heterogeneity) were identified using the Q-statistic and I^2. Sensitivity analyses, aimed at testing the robustness of our findings, included the use of cumulative random-effects meta-analysis.

Presentation of Findings

In presenting our findings we made a clear distinction between qualitative and quantitative conclusions and we assigned a separate strength-of-evidence rating to each conclusion format. The strength-of-evidence ratings assigned to these different types of conclusion are 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 recommends regular monitoring of the relevant literature for moderate-strength conclusions.
Minimally acceptable	Although some evidence exists to support the qualitative conclusion, this evidence is tentative and perishable. There is a reasonable chance that new evidence will either overturn or strengthen our conclusions. ECRI recommends frequent monitoring of the relevant literature.
Insufficient	Although some evidence exists, the evidence is insufficient to warrant drawing an evidence-based conclusion. ECRI recommends frequent monitoring of the relevant literature.
Quantitative Conclusion (Stability of Effect Size Estimate)	
High	The estimate of treatment effect in the conclusion is stable. It is highly unlikely that the magnitude of this estimate will change substantially as a result of the publication of new evidence.
Moderate	The estimate of treatment effect in the conclusion is somewhat stable. There is a small chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI recommends regular monitoring of the relevant literature.
Low	The estimate of treatment effect included in the conclusion is likely to be unstable. There is a reasonable chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI recommends frequent monitoring of the relevant literature.
Unstable	Estimates of the treatment effect are too unstable to allow a quantitative conclusion to be drawn at this time. ECRI recommends frequent monitoring of the relevant literature.

Evidence-Based Conclusions

Key Question 1: Are individuals who have experienced a stroke at an increased risk for a motor vehicle crash (crash risk or driving performance)?

Evidence suggests that drivers who have suffered a stroke are at an increased risk of crash. (Strength of Conclusion: Minimally Acceptable) The size of this risk could not be determined.

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Direct Evidence – Crash Studies*: Current direct evidence from two of three crash studies found that individuals who have had a stroke are at an increased risk for a crash. The two studies that detected an increased risk of crash adjusted for miles driven; the study that did not find an increased risk of crash did not perform this adjustment. As risk exposure is the most important factor in determining risk, the findings of the two studies that adjusted for risk exposure should be given stronger consideration than the study that did not. The increased risk could not be quantified owing to differences in reporting. Limitations of the evidence supporting this conclusion are the small size of the evidence base (three studies) and overall low- to moderate-quality.*

Indirect Evidence – Studies of Driving Tests and Driving Simulation*: Two studies of on-road driving tests provide consistent but weak evidence suggesting that individuals who have suffered a stroke may be at increased risk for a motor vehicle crash because of their poor driving skills. The findings from two simulator studies conflict. Limitations of the evidence base include weakness of type of evidence (since it is indirect), small size of the evidence base, and overall low quality. In particular, controls may not have been well suited to drivers who had a stroke.*

The findings of the direct crash and on-road driving tests should be considered to supersede the simulator test findings because they provide more relevant information on crash risk than simulator studies.

Key Question 2: If so, can neuropsychological testing of individuals who have experienced a stroke predict crash risk?

Certain neuropsychological tests may predict the outcome of driving performance measured by a road test or in-clinic driving evaluation. (Strength of Conclusion: Moderate) Whether neuropsychological tests can predict actual crash risk cannot be determined from currently available evidence.

No studies provided direct evidence of an association between neuropsychological test results and crash risk. The only available indirect evidence evaluates neuropsychological tests as potential outcome predictors for road tests or in-clinic driving assessments. However, prediction of driving test outcomes is not the same as prediction of crash risk; patients who failed road tests or in-clinic driving assessments would either not be allowed to drive or at least advised not to drive, depending on the laws of the particular state or country of residence. Thus, they would not be expected to be at risk for motor vehicle crash (unless they disregard laws or advice). Whether neuropsychological testing can identify stroke patients at increased risk of crash who were able to pass a road test has not been evaluated in the currently available literature.

Indirect Evidence – Studies of Driving Performance*: Twelve studies (median quality: moderate) with 879 patients who had experienced stroke evaluated various neuropsychological tests as potential outcome predictors for road tests or in-clinic driving assessments. Eleven of the studies found that one or more neuropsychological tests were significant predictors of the outcome of road tests or driving evaluations in this patient population. These findings could not*

be combined in a quantitative analysis because no two studies used the same array of tests or evaluated the same combination of variables when attempting to identify predictors of outcome. However, certain tests were found to be significant outcome predictors in multiple studies. Figure of Rey was identified as a significant outcome predictor in three out of five studies that used it. The dot cancellation test, which is part of the Stroke Driver Screening Assessment (SDSA), was found to be a significant outcome predictor in four out of four studies. Another SDSA test (the Road Sign Recognition test) was found to be a significant outcome predictor in two out of four studies. A third SDSA test (What Else is in the Square test) was a significant outcome predictor in two out of three studies. Two out of three studies that used the Motor-Free Visual Perception Test (MVPT) identified it as a significant outcome predictor. Given the moderate quality of the studies and the consistency of the findings for neuropsychological tests overall, the strength of evidence supporting the ability of these tests to predict driving test outcomes is moderate.

Since the majority of studies did not report the percentage of commercial motor vehicle (CMV) drivers (if any) in their study population, the generalizability of these findings to CMV drivers is unknown.

Key Question 3: Among individuals who have experienced a TIA, what is the risk of experiencing a future stroke?

A number of conclusions can be drawn from the findings of the analyses described above. These conclusions are presented below:

TIA and Stroke Risk: Overall Findings

Individuals are at an increased risk for stroke following a TIA when compared with their counterparts who did not experience a TIA (Strength of Evidence: Strong).

The increased stroke risk is highest immediately following TIA (within one month) and decreases steadily out to five years following TIA (Strength of Evidence: Moderate).

The entire evidence base of 13 studies (representing approximately 30,000 individuals) consistently reported an elevated risk of stroke in individuals who experienced a TIA compared with controls who did not experience a TIA. Separate analyses based on four moderate-quality cohort studies with data at multiple follow-up periods suggests that the increased risk is very high within the first month following TIA (at least 65 times higher than the risk for individuals who have not had a TIA) and drops rapidly during the first year. A small cumulative elevated risk continues to decrease steadily out to five years following TIA.

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TIA and Stroke Risk: Findings based on Time since TIA

At one month and six months following a TIA event, individuals are at an increased risk for stroke when compared with their counterparts who did not experience a TIA (Strength of Evidence: Moderate).

- **A precise estimate of the magnitude of this increased risk cannot be determined at this time.**

Two studies (Quality Rating: Moderate) at each follow-up time presented data directly relevant to these time points. The data were qualitatively consistent and the magnitude of increased risk at each time point examined was large. Although precise summary effect estimates could not be determined, individuals with TIA had at least a 65-fold increase in risk at one month and a 16-fold increase at six months compared with controls without TIA. Therefore, it is unlikely that future studies will overturn our finding.

At one year following a TIA, individuals are at an increased risk for stroke when compared with their counterparts who did not experience a TIA (Strength of Evidence: Strong).

- **The estimated magnitude of increased risk at one year is RR (risk ratio) = 12.02 (95% CI 5.66 to 25.53) (Stability of Evidence: Low).**

Three studies (Quality Rating: Moderate) presented data at one year following TIA. Pooling of these data revealed that the mean stroke risk associated with TIA is RR = 12.02 (95% CI 5.66 to 25.53) one year after experiencing a TIA, representing a 12-fold increase in risk compared with individuals who have not experienced a TIA. The finding of increased stroke risk was robust, although the stability of the summary effect size was low. The data were qualitatively consistent and the effect size was very large, making it very unlikely that future studies will overturn this finding.

At two and three years following a TIA event, individuals are at an increased risk for stroke when compared with their counterparts who did not experience a TIA (Strength of Evidence: Moderate).

- **A precise estimate of the magnitude of this increased risk cannot be determined at this time.**

Three studies (Quality Rating: Moderate) presented data on stroke risk at three years following TIA. Pooling of these data revealed that the risk of experiencing a stroke three years after a TIA event is at least 1.6 times greater than the control risk level. Two of these studies also evaluated stroke risk at two years, which was found to be elevated by at least three-fold in individuals with TIA compared with controls without TIA.

At four and five years following a TIA event, individuals are at an increased risk for stroke when compared with their counterparts who did not experience a TIA (Strength of Evidence: Minimally Acceptable).

Two studies (Quality Rating: Moderate) at each follow-up time presented data directly relevant to this question. The findings were qualitatively consistent, but the data could not be combined in a pooled analysis. Thus, the evidence is considered minimally acceptable to support the conclusion.

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