Executive Summary

Traumatic Brain Injury and Commercial Motor Vehicle Driver Safety

Presented to

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Policy Statement

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% of all worker deaths. About two-thirds of fatally injured truck workers were involved in highway crashes. According to statistics from the U.S. Department of Transportation (DOT), there were 4,584 fatal crashes involving a large truck in 2007 for a total of 4,808 fatalities. In addition, there were 139,587 nonfatal crashes; 56,487 of these were crashes that resulted in an injury to at least one individual (for a total of 83,908 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 provide information that would be useful in updating its current medical examination guidelines. The four key questions addressed in this evidence report are as follows:

Key Question 1: What is the impact of traumatic brain injury on crash risk/driving performance?

Key Question 2: What factors associated with traumatic brain injury are predictive of increased crash risk or poor driving performance?

Key Question 3: What is the impact of rehabilitation programs on crash risk/driving performance among individuals with a traumatic brain injury?

Key Question 4: What is the likelihood of a future seizure among individuals with a traumatic brain injury who did not experience a seizure at the time of the injury?

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; an 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 six electronic databases (MEDLINE, PubMed [PreMEDLINE], EMBASE, TRIS, the Cochrane Library, and the National Guideline Clearinghouse™) were searched (through March, 2009). 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.

Analytic Methods

The set of analytic techniques used in this evidence report was extensive. If appropriate, random-effects meta-analyses were used to pool data from different studies. Differences in the findings of studies (heterogeneity) were identified using I^2. Sensitivity analyses, aimed at testing the robustness of our findings, included the use of cumulative random-effects meta-analysis. The presence of publication bias was tested for using the "trim and fill" method when appropriate.

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 conclusions 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 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 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 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: What is the impact of traumatic brain injury on crash risk/driving performance?

The available evidence is insufficient to determine whether crash risk is elevated for drivers with TBI compared to uninjured controls. However, driving performance as measured by on-road driving tests and driving simulators was significantly impaired among individuals with TBI compared to uninjured controls. (Strength of Evidence: Moderate)

Direct Evidence – Crash Studies: Five studies attempted to directly determine crash risk among drivers with TBI through evaluation of self-reported crashes or crashes recorded in a state licensing database. The median quality of the evidence base was moderate. Data from four of these studies was combined to determine an overall estimate of crash risk. The summary rate ratio was 1.32 (95% CI 0.77-2.25), a difference that trended toward slightly higher risk in the TBI group but did not reach statistical significance. The remaining study reported a statistically significant increase in the mean number of crashes/person among drivers with TBI compared to healthy controls. Given that the findings do not rule out either the possibility of an elevated risk for drivers with TBI or no difference in risk, the current evidence concerning crash risk among drivers with TBI remains inconclusive.

Indirect Evidence – Studies of Driving Performance: Four studies (median quality: moderate) assessed driving performance (on-road or simulated) of patients with TBI compared to healthy controls. Because none of these studies used the same measures of driving performance, we did not attempt to combine the findings in a meta-analysis. Two studies that evaluated simulated driving outcomes found statistically significant differences indicating decreased performance in at least one performance outcome for individuals with TBI compared to healthy controls. Similarly, two studies that evaluated on-road driving performance found statistically significant differences in overall test scores or scores on specific driving tasks that indicated decreased performance for individuals with TBI compared to healthy controls. Since neither study conducted actual driver licensing tests, the percentage of patients with TBI that would have been certified as fit to drive is unknown. Inclusion of individuals who may never recover enough ability to pass a driving test would lead to an underestimate of the average driving performance of individuals with TBI who are certified as fit to drive. Furthermore, the extent to which reduced performance on road tests or driving simulators impacts crash risk remains unclear.

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 2: What factors associated with traumatic brain injury are predictive of increased crash risk or poor driving performance?

The available evidence is insufficient to determine whether any factors related to TBI can predict actual crash risk. However, current evidence suggests that cognitive function measured by certain neuropsychological tests may predict the outcome of driving performance measured by a road test for patients with TBI. (Strength of Evidence: Moderate)

Direct Evidence – Crash Studies: Five studies (median quality: moderate) attempted to determine whether certain variables were associated with risk of crash/driving offenses among patients with TBI. Two of these studies had possible overlap in their enrolled study populations, so these studies were generally analyzed as a single study. Evidence for an association between any TBI-related factor and risk of crash/driving offenses was mixed. One study provided evidence of a significant association between neuropsychological functioning and crash/driving incidents while two other studies did not. However, none of the studies used the same set of neuropsychological function tests, and the severity of TBI

among individuals in one of the negative studies differed substantially from the other study populations (mild versus moderate to severe). The conflicting evidence and low number of studies means that the evidence is currently insufficient to determine whether an association exists between any TBI-related factors and crash risk.

Indirect Evidence – Studies of Driving Performance*: Seven studies (median quality: moderate) evaluated the association between various predictor variables and road test or closed-course driving outcomes. Several studies evaluated one or more neuropsychological tests; although there was overlap in some of the specific individual tests used, none of the studies evaluated the exact same set of tests. The only individual test that showed a significant association with road test outcome in more than one study was the Trail-making Test (two studies showed an association while a third study did not). Several tests that were used in only a single study showed a significant association with road test outcomes. Therefore, while it is difficult to determine which specific tests have the best association with outcome, one can conclude that reduced cognitive function (as measured by neuropsychological tests as a group) seems to be associated with poor outcomes on a road test.*

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

Note that prediction of driving test outcomes is not the same as prediction of crash risk. Patients who failed road tests 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).

Key Question 3: What is the impact of rehabilitation programs on crash risk/driving performance among individuals with a traumatic brain injury?

The available evidence is insufficient to determine the impact of rehabilitation programs on crash risk or driving performance among individuals with TBI.

No studies provided direct evidence to address this question.

Indirect Evidence – Studies of Driving Performance*: One low-quality study compared the effectiveness of different rehabilitation strategies (structured exercises on an electric wheelchair vs. use of wheelchair with no structured exercises) for improving road test driving performance in patients with TBI. Although patients in the structured exercise group achieved significantly better mean scores on several road test measures (percent tracking, percent correct signs, composite score, and driver educator's score) compared to controls, the numerous quality deficiencies in this single small study preclude an evidence-based conclusion.*

Key Question 4: What is the likelihood of a future seizure among individuals with a traumatic brain injury who did not experience a seizure at the time of the injury?

Individuals with TBI who have not experienced a seizure within the first week post-injury still have a significant likelihood of experiencing late seizure(s). Reported frequencies of late seizures in this population ranged from 1% to 25% during follow-up periods ranging from 1 to 11 years. (Strength of Evidence: Moderate)

The highest rate of late seizures (25%) was associated primarily with penetrating missile TBIs. (Strength of Evidence: Minimally Acceptable)

Among patients with closed TBIs, a diagnosis of severe TBI was associated with higher frequencies of first-time late seizures than diagnoses of mild or moderate TBI. (Strength of Evidence: Minimally Acceptable)

Among adults with moderate or severe TBI who develop late seizures, ≥50% experience their first late seizure within the first year after TBI. The rates fall substantially within the next two years and stabilize after the third year at roughly 2-4% (of the total patients who develop late seizures) per year out to 11 years. The pattern for mild TBI is less clear, but the rate of late seizure development does not appear much higher in the first year compared to subsequent years. (Strength of Evidence: Minimally Acceptable)

Our searches identified nine studies (median quality: moderate) that reported (or allowed independent calculation of) the frequency of patients whose first seizure was a late seizure (i.e., occurring after one week post-TBI). Due to differences in several important factors among these studies, we did not attempt to combine the data from each study in a pooled analysis. Differences included severity of TBI, how severity was determined, length of followup, whether children were analyzed with adults, whether patients with alcoholism were included, and whether prophylactic anti-seizure medication was used in the study.

The percentage of patients with a first-time late seizure ranged from 1% to 25%, most likely due to one or more of the differences noted above. The study with the highest rate was the only study where most patients had penetrating missile TBIs; a comparison of missile and non-missile TBIs in this study found that the rate of late seizure development was much higher among patients with missile TBIs (32% vs. 5%). The study with a 1% rate was unusual because all patients were classified as having severe TBI (other studies with similar patients reported rates close to 10%), but it was the only study where all patients were given prophylactic phenobarbital for the entire 12-month followup. This finding is not consistent with findings from controlled studies that did not find a preventive benefit of prophylactic anti-seizure medication for late seizures. One study that analyzed seizure data separately based on severity of TBI found that first-time late seizures occurred more frequently among patients with severe TBI than among patients with mild or moderate TBI.

Two studies assessed the timing of late seizure development and found that first-time late seizures occurred most frequently in the first year following TBI. At least 50% of patients with moderate or severe TBI who developed late seizures experienced the first seizure within this time period (e.g., if the overall late seizure rate was 10%, then about 5% of the total patient group would develop late seizures within the first year after TBI). The percentage dropped substantially within the next two years and then stabilized at roughly 2-4% per year out to 11 years. The pattern for mild TBI is less clear, but the rate of late seizure development does not appear much higher in the first year compared to subsequent years.