



# **Opinions of Expert Panel**

## **Traumatic Brain Injury and Commercial Motor Vehicle Driver Safety**

### **Medical Expert Panel Members**

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## Introduction

The primary mission of the U.S. Department of Transportation's (DOT's) Federal Motor Carrier Safety Administration (FMCSA) is to reduce crashes, injuries and fatalities involving commercial motor vehicles (CMV), including large trucks and buses. One mechanism used to facilitate this effort is the updating of current, and the development of new, medical fitness standards and guidelines for medical examiners who are responsible for certifying drivers as fit for duty. FMCSA is committed to review and begin updating all of their current standards and guidelines by 2009.

This report serves the purpose of summarizing the considerations and opinions of a panel of four experts in the fields of neurology and occupational medicine (henceforth termed the Medical Expert Panel) who examined FMCSA's current standards and guidelines for medical examiners pertaining to traumatic brain injury (TBI) and CMV driver safety.

## Members of the Medical Expert Panel

Members of the Medical Expert Panel (MEP) charged with providing expert opinion pertaining to whether the current standards and guidelines for TBI need to be updated are listed in Table 1.

**Table 1. Members of the Medical Expert Panel**

Name	Current Position
Natalie Hartenbaum, MD, MPH, FACOEM	President and Chief Medical Officer OccuMedix, Inc. Dresher, PA
John Hastings, MD	Certified Medical Examiner - Federal Aviation Administration Tulsa, OK
Margit Bleecker, MD, PhD	Director Center for Occupational and Environmental Neurology Baltimore, MD
Steven Mandel, MD, FAADEP	Clinical Professor of Neurology Thomas Jefferson University Philadelphia, PA

## Methodology

### Brief Overview of Evidence Report Methodology

The opinions contained in this report are based in part upon the interpretation and assimilation of information presented in a comprehensive systematic review of available literature, prepared by ECRI Institute and MANILA Consulting Group, and presented to the MEP on September 1, 2009. This evidence report titled, "Traumatic Brain Injury and Commercial Motor Vehicle Driver Safety," was developed following a systematic literature search for evidence accessible from several electronic databases. These databases included (but were not limited to) Medline, PubMed (pre Medline), EMBASE, PSYCHInfo, CINAHL, TRIS, and the Cochrane Library. Additional hand searches of the published literature (i.e., bibliographies of identified relevant articles), and "gray literature" resources (e.g., Web searches) were also performed. Data obtained from these searches were screened against a set of *a priori* inclusion

criteria. The findings of this evidence report are summarized in the report's executive summary, which can be found in Appendix A.

## The MEP Meeting and Opinion Formulation

On September 1<sup>st</sup>, 2009, FMCSA, MANILA Consulting, the ECRI Institute, and the four members of the traumatic brain injury MEP convened a one-day meeting. The purpose of this meeting was several-fold:

- To review existing standards and guidelines for medical examiners pertaining to the certification and recertification of individuals with traumatic brain injury as physically qualified to drive a CMV for the purposes of interstate commerce.
- To discuss the available evidence contained in the Evidence Report and other sources pertaining to the consequences to public safety associated with allowing individuals with traumatic brain injury to drive a CMV.
- To provide expert opinion regarding changes to the existing FMCSA guidelines which are deemed necessary following the critical assessment of the available evidence.

This document reflects a summary of the one day meeting.

## Opinions of the Traumatic Brain Injury MEP

It was the opinion of the MEP that current standards and guidance to those who certify drivers as physically qualified to drive a CMV for the purposes of interstate commerce are inadequate.

Consequently, the MEP made several suggestions for improvement. Each suggestion was based on their current understanding of available information. Below we present the MEP opinions and provide justification for each.

### Opinion 1: Severe Traumatic Brain Injury and CMV Driver Certification

**It is the opinion of the MEP that individuals who have sustained a penetrating injury to the brain or severe TBI (i.e., loss of consciousness  $\geq$  24 hours)<sup>1</sup> should be permanently precluded from obtaining certification to drive a CMV for the purposes of interstate commerce.**

#### **Justification:**

*TBIs often result in permanent or temporary impairments in cognitive, psychosocial, sensory, and motor functioning, particularly in cases of severe TBI. These impairments may contribute to an increased likelihood of a motor vehicle crash. Particularly worrisome with regards to road safety is the increased likelihood that an individual will experience a seizure following a TBI.*

*Numerous studies have documented that at some time following a TBI, a subset of patients will experience a seizure or repeated seizures that are related to the trauma. The percentage of patients with TBI who develop seizures may be influenced by the type of TBI. Evidence from studies of TBI during various wars, including World Wars I and II, Korea, and Vietnam, suggest that patients who sustain a dural tear/penetration are at higher risk for seizure than patients with closed head injuries. The frequency of seizure development in patients with dural penetration ranged from 36% to 50%, while for patients without dural penetration the rates of seizure ranged from 6% to 23% (Hughes, 1986).*

*Since TBIs sustained by civilians are mostly closed head injuries, the rates of seizure development tend to be lower than those observed in military conflicts. Posttraumatic epilepsy rates have ranged from about 2% to 14% in larger studies (with 500 or more subjects) of civilian populations (Annegers et al., 1998; Englander et al., 2003; Pagni, 1990). Studies have also shown that differences in rates of posttraumatic epilepsy are associated with the severity of TBI, with risk of posttraumatic epilepsy increasing as severity of TBI increases (Annegers et al., 1980; Annegers et al., 1998).*

*Findings from the Evidence Report also indicate that seizure risk differs depending on the type of injury (open vs. closed) and severity. These results found that the highest rates of posttraumatic epilepsy (25%) were associated with penetrating missile TBIs and among patients with closed TBIs, a diagnosis of severe TBI was associated with higher frequencies of posttraumatic seizures than diagnoses of mild or moderate TBI.*

*These findings are also supported by a recent population-based cohort study which examined the long-term risk of epilepsy after traumatic brain injury among 1,605,216 people through data obtained from the Danish Civil Registration System (Christensen et al., 2009). These findings showed that, relative to no brain injury, the risk of epilepsy was seven times higher after severe brain injury (RR = 7.40, 95% CI = 6.16, 8.89).*

*Due to the high risk of neurological deficits and occurrence of seizures, even many years out from the incident, those with penetrating injuries to the brain or severe TBI as described as loss of consciousness  $\geq$  24 hours should be permanently precluded from being certified as physically qualified to drive a commercial motor vehicle for the purposes of interstate commerce.*

*The MEP would like to point out that there are some individuals with severe or penetrating TBI based on the criteria stated above who escape the usual consequences of severe TBI which would otherwise adversely affect driving ability. Thus, the MEP acknowledges that there may be a few exceptional cases of severe or penetrating TBI in which consideration might be possible. However, the specific characteristics of these individuals remain unclear and, therefore, the MEP refrains from providing guidance on this at this time.*

*The issue of seizure risk following surgical penetration of the dura (i.e., craniotomy) was also discussed by the MEP at great length. It was acknowledged that assigning risk to seizures after craniotomy is often very difficult given that the risk is dependent on several factors such as the type and location of the surgery and the underlying reason for the surgery. Fully assessing the risk of seizure (and other factors which may impair driving ability) post-craniotomy was outside the scope of the Evidence Report and given the inherent difficulties in determining the level of seizure risk associated with different types of craniotomies, the MEP decided to abstain from providing opinions on this topic. The panel suggests that FMCSA further investigate this issue and evaluate the risk of seizures associated with specific types of craniotomy and update this accordingly.*

## **Opinion 2: Moderate Traumatic Brain Injury and CMV Driver Certification**

It is the opinion of the MEP that individuals who have sustained a moderate TBI (i.e., loss or alteration of consciousness  $\geq$  1 hour but  $<$  than 24 hours)<sup>1</sup> should be precluded from obtaining certification to drive a CMV for the purposes of interstate commerce for 3 years.

Once the three year period has passed, the individual must then be cleared by their treating provider (who should have minimum qualifications of MD/DO). The treating provider should assess for the following symptoms of concern:

- Headaches;
- Irritability;
- Dizziness;
- Imbalance;
- Fatigue;
- Sleep disorders;
- Inattention;
- Decreased concentration and memory;
- Noise and light sensitivity;
- Thinking slowed;
- Difficulty recalling new material;
- Personality change;
- Difficulty starting or initiating activities;
- Difficulty sequencing information;
- Impaired attention to details;
- Impaired ability to benefit from experience;
- Deficits in planning and carrying out activities.

The treating provider should also determine if the individual has experienced a seizure at any time within the three years following the TBI. If there is a history of seizures within this period, then the FMCSA seizure guidelines should be followed for certification<sup>2</sup>.

If the treating provider reports that the individual is free of the above stated symptoms of concern and has not experienced a seizure, the individual should then be referred to a neurologist, who is aware of the functional and cognitive requirements of operating a CMV (see justification for specifics), for additional evaluation. Additional evaluation should include a complete neurological assessment and should specifically assess motor speed and dexterity, cognitive function, and symptoms of depression through objective testing (by additional referral to a neuropsychologist, psychologist or other specialist as deemed appropriate by the neurologist based on the specific symptoms of the patient).

Specifically, the following cognitive domains should be assessed by the neurologist or appropriate referral specialist (suggested assessment tools listed):

- Verbal memory and verbal learning (Hopkins Verbal Learning Test);

- Visual scanning, visual motor speed (Trail Making Test A);
- Cognitive flexibility, executive function (Trail Making Test B);
- Word fluency (COWAT – Controlled Oral Word Association Test);
- Attention (Digit Span forward);
- Working memory (Digit Span backward);
- Visual scanning, visual motor speed, visual memory (Symbol Digit Modalities);
- Motor speed and dexterity (Grooved Pegboard Test);
- Delayed recall (Hopkins Verbal Learning Test).

Both the neurologist and the commercial driver medical examiner should also assess the effects of treatment, including medications, on functional and cognitive abilities and the performance of CMV operator related tasks.

Drivers with no or minimal abnormalities on the neurological assessment and are cleared by the neurologist to perform the duties of a CMV operator should be re-certified every six months (by a provider with minimum qualifications of MD/DO) while under active treatment. Once an individual is no longer under active treatment, the driver should then be examined by a commercial driver medical examiner annually for 3 years and then as determined by the medical examiner based on other medical conditions.

**Justification:**

*The MEP believes that individuals, who have experienced a moderate TBI, should not drive a CMV for three years following the incident, primarily due to the increased risk for seizures during this period. Findings from the Evidence Report indicate that first-time late seizures occur most frequently in the first year following a TBI. Findings showed that at least 50% of patients with moderate or severe TBI who developed late seizures experience the first seizure within the first year and the percentage drops substantially within the next two years. Christensen and colleagues (2009), through their examination of data from the Danish Civil Registration System, found similar results with the risk of epilepsy being highest the first 2-3 years following the injury<sup>3</sup>.*

*Once the three year period has passed, the individual must then be cleared by their treating provider. The treating provider should be an MD/DO given the complexities associated with the care and treatment of individuals with TBIs. The treating provider should assess for the above listed symptoms of concern. These symptoms are indicative of post-concussive syndrome (PCS). PCS refers to a set of symptoms that may occur (either alone or in combination) following a concussion. PCS can also occur following moderate and severe TBIs. Symptoms may last for weeks, months, or even years; however, resolution in most patients is seen within 3-6 months following the injury. PCS can result in significant impairment which may adversely affect one's ability to safely operate a CMV, therefore, it should be ascertained that individuals are free of these symptoms before being deemed medically qualified to operate a CMV.*

*Also included in this list are symptoms which may indicate impairments in executive functioning. Recent research indicates that individuals with concussions are showing axonal disruption on diffusion tensor*

studies which may lead to problems in executive functioning (Kraus et al., 2007; Lipton et al., 2009). Kraus and colleagues (2007) found that individuals with mild TBI performed significantly worse than controls on the number of errors of commission on the continuous performance task that reflects prefrontal function (executive function) and reduced white matter integrity in the superior longitudinal fasciculus, sagittal striatum, and corticospinal tract. Given these recent findings, the MEP opines that symptoms indicative of problems with executive functioning be assessed in addition to symptoms indicative of PCS.

Once the three year period has passed and the individual has received clearance documentation from their treating provider, they should be referred to a neurologist for additional evaluation. The referral neurologist should be aware of the functional and cognitive requirements of operating a CMV. Functional abilities, divided into primary and secondary areas of importance, are featured in Table 2.

**Table 2. Tasks Required to Operate a Motor Vehicle**

Primary Area of Function	Secondary Area of Function	Component of Driving Process	Proposed Solutions
Hand	Upper limb	Seat belt manipulation Manipulation of key Use of hand brake	Non-inertia reel. Extend stem of seat belt attachment. Modify seat belt clip. Build up key. Convert of vertical lever for knock on/off action. Keep car in gear when parked. Use accelerator/clutch for hill start. Buy automatic transmission car.
Upper limb	Hand	Open and close door Adjustment of mirror Use of gears	Keep door hinges and handles oiled. Modify buttons. Enlarge door handles. Ask other car drivers to reposition mirror. Increase length of gear stick. Modify hand piece. Buy automatic transmission car. Modify automatic gear stock to "push down" type.
Upper limb	Upper spine	Reaching seat belt Steering/cornering	Hook belt around seat lever. Prevent full recoil of seat belt. Steering wheel cover to increase bulk of wheel. "Threading" steering technique. Increase front tire pressure. Power steering.
Upper spine	Upper limb	Reversing	Undo seat belt when reversing. Install wide rear view mirror. Install near and off side mirrors. "Reversing" with mirrors.
Lower spine	Lower limb	Seat comfort and position	Extend seat runners. Alter seat back position. Wedge cushions. Lumbar cushion.
Lower limb	Lower spine	Vehicle exit and entry Use of foot pedals	Enter buttocks rather than legs first. Extend seat runners. Pedal modification. Automatic transmission car.
Supratentorial		Awareness of traffic and pedestrians Confidence	Practice with experienced driver in quiet streets. Limit driving to familiar streets. Take lessons with qualified driving instructor.
Pain and fatigue on long drives			Frequent stops on long trips. Judicious use of nonsteroidal anti-inflammatory drugs (NSAIDs) and analgesics. Establish a relaxed driving position.

Adapted from Jones et al., 1991

*Cognitive requirements of operating a CMV include:*

- *Good sensory and perceptual function for monitoring the complex driving situation;*
- *Good cognitive skills for processing sensory information;*
- *Good judgment skills for making safe decisions;*
- *Good psychomotor function to allow rapid implementation of decisions.*

*The neurologist should conduct a thorough neurologic evaluation, including assessments of motor speed, dexterity, cognitive function, and symptoms of depression. These assessments should be based on objective tests.*



*Specifically, the following cognitive domains should be assessed by the neurologist or appropriate referral specialist (suggested assessment tools listed<sup>A</sup>):*

- *Verbal memory and verbal learning (Hopkins Verbal Learning Test);*
- *Visual scanning, visual motor speed (Trail Making Test A);*
- *Cognitive flexibility, executive function (Trail Making Test B);*
- *Word fluency (COWAT – Controlled Oral Word Association Test);*
- *Attention (Digit Span forward);*
- *Working memory (Digit Span backward);*
- *Visual scanning, visual motor speed, visual memory (Symbol Digit Modalities);*
- *Motor speed and dexterity (Grooved Pegboard Test);*
- *Delayed recall (Hopkins Verbal Learning Test).*

*If the individual is currently undergoing treatment, both the neurologist and the commercial driver medical examiner should assess the effects of the treatment, including medications, on functional and cognitive abilities and the performance of CMV operator related tasks (see Opinion 4 for specifics regarding anti-epileptic medication) .*

*Drivers with no or minimal abnormalities on the neurological assessment and are cleared by the neurologist to perform the duties of a CMV operator should be re-certified every six months while under active treatment in order to assess for possible side effects of treatment and other new or previously unidentified symptoms have manifested which may impact driving ability. Once an individual is no longer under active treatment, the driver should then be examined by a commercial driver medical examiner annually for 3 years and then as determined by the medical examiner based on other medical conditions. The rationale for the increased frequency of medical examination is that both the underlying pathology and clinical expression of white matter change secondary to TBI evolves over time. More frequent examination is therefore necessary to determine if any new symptoms have developed which may impact driving performance.*

### **Opinion 3: Mild Traumatic Brain Injury and CMV Driver Certification**

**It is the opinion of the MEP that individuals who have sustained a mild TBI (i.e., loss or alteration of consciousness of < 1 hour)<sup>1</sup> can be deemed medically qualified to drive a CMV for the purposes of interstate commerce if they are determined by their treating provider (who should have minimum qualifications of MD/DO) to be clinically symptom free.**

**Drivers who did not experience loss of consciousness (LOC) as a result of their head injury could be considered eligible to return to commercial driving 30 days after the injury. Those who did experience loss of consciousness should refrain from commercial driving for 90 days to ensure that they are symptom free.**

**Individuals with mild TBI should be free of the following symptoms of concern before they are qualified (i.e., 30 days after injury if no LOC, 90 days after injury if LOC):**

- **Headaches;**

- Irritability;
- Dizziness;
- Imbalance;
- Fatigue;
- Sleep disorders;
- Inattention;
- Decreased concentration and memory;
- Noise and light sensitivity;
- Thinking slowed;
- Difficulty recalling new material;
- Personality change;
- Difficulty starting or initiating activities;
- Difficulty sequencing information;
- Impaired attention to details;
- Impaired ability to benefit from experience;
- Deficits in planning and carrying out activities.

Additionally, they should be free of seizures and if imaging was performed, there should be no evidence of intracranial blood.

Prior to certification, the commercial driver medical examiner should obtain documentation from the treating provider, indicating whether the individual is able to return to work without restriction and whether the individual has any of the above listed symptoms.

Individuals, who have experienced a mild TBI and lost consciousness as a result of the TBI, should be referred to a neurologist for additional evaluation. This evaluation should be the same as that for individuals who have experienced a moderate TBI (see above).

***Justification:***

*As previously mentioned, the above stated symptoms of concern are indicative of PCS or impairments in executive functioning. These symptoms can result in significant impairment which may adversely affect one's ability to safely operate a CMV. Individuals who have sustained a mild TBI but do not experience any of the above stated symptoms (or have quick resolution of these symptoms) are unlikely to develop seizures or other impairments which would be of concern with regards to road safety. Therefore, in order for an individual to be deemed eligible to drive a CMV, they must be free of any of the clinical symptoms at the time of certification which would indicate post-concussive syndrome or executive functioning impairment.*

*Given that symptoms of concern following a mild TBI may not be immediately apparent, the MEP believes that individuals with a mild TBI who did not experience loss of consciousness should wait 30 days following the injury before returning to CMV driving and those who did experience loss of consciousness should wait 90 days, in order to ensure that they are symptom free. The MEP also believes that*

individuals who lost consciousness as a result of the TBI should be referred to a neurologist for additional evaluation since this can indicate a more significant trauma to the brain.

#### **Opinion 4: Anti-Seizure Medication and CMV Driver Certification**

**It is the opinion of the MEP that individuals who are placed on anti-seizure medication following a single provoked seizure or are placed on anti-seizure medication prophylactically, should not be medically qualified to drive a CMV for the purposes of interstate commerce until they meet the current FMCSA criteria for individuals taking anti-seizure medication<sup>2</sup>.**

***Justification:***

*The MEP believes that the medical qualification of individuals who have experienced a TBI and are placed on anti-seizure medication following a single provoked seizure or prophylactically should be consistent with others (who have not experienced a TBI) taking anti-seizure medication following a single provoked seizure or prophylactically. In other words, the criteria for these individuals should not differ simply because they are post-TBI.*

*It is acknowledged that the Seizure Disorders MEP opined that there is no justification for the current FMCSA criteria regarding disallowing individuals who are currently taking anti-seizure medication from driving a CMV, provided they meet the criteria set for remaining seizure free; therefore, if the guidelines are changed based on this, they should apply to this opinion, as well.*

#### **Opinion 5: Extremity Impairment and CMV Driver Certification**

**It is the opinion of the MEP that individuals who meet the above stated criteria and whose only residual deficit as a result of the TBI is impairment of an extremity, may be eligible for a skill performance evaluation certificate and should be referred to apply for one if otherwise medically qualified.**

***Justification:***

*The MEP believes that if the only residual deficit as a result of a TBI is the impairment of an extremity, then these cases should be handled consistent with other cases where the only limitation is limb impairment.*

#### **Opinion 6: Traumatic Brain Injury and Commercial Driver Medical Examiner Qualifications**

**It is the opinion of the MEP that due to the risk of seizures, and neurological and cognitive dysfunction after TBI, only physicians (MD or DO) should perform the commercial driver medical examination on those individuals who have sustained a TBI.**

***Justification:***

*Given the complexities associated with the care and treatment of individuals with traumatic brain injuries, such as cognitive neuropsychiatric dysfunction and risk of seizures, the MEP believes that the commercial driver medical examination of these individuals should be conducted by physicians (MD or DO).*

## Addendum: Revision of the Classification of Mild and Moderate TBI

Upon additional review of the literature and discussion, the Medical Expert Panel on TBI would like to modify our classification of the severity of TBI. As there are many different classification systems used, our initial consideration was to base our classification on what had been used in aviation. Upon additional review, we believed it would be more appropriate to base the criteria upon what is more commonly found in the recent medical literature. Therefore, we recommend the following classification of severity of TBI;

- Mild: 0-30 minutes of LOC/AOC,PTA
- Moderate: 30 minutes-24 hours LOC/AOC/PTA, or skull fracture AND 0-30 minutes of LOC/AOC,PTA
- Severe: > 24 hours of LOC/AOC, PTA

LOC – loss of consciousness

AOC – alteration of Consciousness

PTA – post-traumatic amnesia

We are not making any changes to the recommendations that accompany these classifications. The only difference between the initial classification and this is that mild TBI had initially been loss or alteration of consciousness of <60 minutes and moderate had been 60 minutes to 24 hours. The duration of loss or alteration of consciousness has been modified and post-traumatic amnesia has been added to the criteria. In addition, the presence of a skull fracture, even with the shorter (<30 minutes of loss or alteration of consciousness or post-traumatic amnesia) would place the TBI in the moderate category.

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<sup>1</sup> The stated criteria for classification of mild, moderate, and severe TBI is based on the expert opinion of the panel and current trends in the field (Becker et al., 1979). The MEP acknowledges that there is a wide range of criteria that is used for classifying the severity of TBI including the results from imaging tests, Glasgow Coma Scale, PTA, and LOC.

<sup>2</sup> Current FMCSA guidance states that drivers with a history of epilepsy/seizures who are off anti-seizure medication and who have been seizure-free for 10 years may be qualified to operate a CMV in interstate commerce. Additionally, individuals with a history of a single unprovoked seizure may be qualified to drive a CMV in interstate commerce if they have been seizure-free and off anti-seizure medication for a 5-year period or more. Individuals who have been prescribed anti-seizure medication prophylactically may be qualified if they have been off the medication and seizure-free for two years.

<sup>3</sup> One panel member dissented on this opinion stating that there was not enough evidence to warrant drivers from being precluded from obtaining certification for 3 years compared to 2 years.

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<sup>4</sup> These suggested assessment tools are based on a neuropsychological battery compiled by Lovell and Collins (1998) and shown to have good stability coefficients when used repeatedly.

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## APPENDIX A: Findings of Evidence Report

This appendix summarizes the findings of the Evidence Report titled, “Traumatic Brain Injury and Commercial Motor Vehicle Safety.” The purpose of this evidence report is to address several key questions posed by the Federal Motor Carrier Safety Administration (FMCSA). The FMCSA developed each of these key questions so that the answers would provide information useful in updating its current medical examination guidelines. The four key questions addressed in this evidence report are:

**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

We identified separate evidence bases for each of the key questions addressed by this evidence report through a comprehensive search of the literature, an examination of abstracts of identified studies to determine which articles would be retrieved, and 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. We also performed hand searches of the “gray literature.” We determined whether to admit an article into an evidence base using formal retrieval and inclusion criteria 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, but also the interplay between the quality, quantity, robustness, and consistency of the overall body of evidence.

## Analytic Methods

We used an extensive set of analytic techniques in this evidence report. 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 3.

**Table 3. Strength-of-evidence Ratings for Qualitative and Quantitative Conclusions**

Strength of Evidence	Interpretation
<b>Qualitative Conclusion</b>	
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
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.
Insufficient	Although some evidence exists, the evidence is insufficient to warrant drawing an evidence-based conclusion.
<b>Quantitative Conclusion (Stability of Effect-size Estimate)</b>	
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
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.
Unstable	Estimates of the treatment effect are too unstable to allow a quantitative conclusion to be drawn at this time.

## Evidence-based Conclusions

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

**The available evidence is insufficient to determine whether crash risk is elevated for drivers with TBI compared with uninjured controls. However, driving performance as measured by on-road driving tests and driving simulators was significantly impaired among individuals with TBI compared with 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 were 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 with 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 on 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 with 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 with 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 with 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 affects 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 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.*

*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 with 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% to 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 with 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). Owing 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 follow up, 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 owing 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% versus 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 follow up. 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 with subsequent years.*