



**United States Department of Transportation
FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION**

Meeting Summary

The Medical Review Board (MRB) of the U.S. Department of Transportation's Federal Motor Carrier Safety Administration (FMCSA) was convened on January 6, 2010, in Washington, D.C. The meeting was open to the public.

Board Members Present:

Kurt Hegmann, M.D., Chairperson
Gunnar Andersson, M.D.
Benjamin Hoffman, M.D.
Barbara Phillips, M.D. (via teleconference)
Carl Soderstrom, M.D.

Medical Expert Panel Representatives:

Natalie Hartenbaum, M.D. – Traumatic Brain Injury Panel
Mathew Rizzo, M.D. – Parkinson's Disease and Multiple Sclerosis Panel

FMCSA Staff:

Anne S. Ferro, Administrator
Larry W. Minor, Associate Administrator for Policy and Program Development
*Mary D. Gunnels, Ph.D., Director, Office of Medical Programs
Benisse Lester, M.D., Chief Medical Officer
Angela Ward, R.N., Nurse Consultant
Linda Phillips
Madeline Boyd
Pearlie Robinson

*Designated Federal Official (DFO)

FMCSA Contractors:

Purvi Shah, Axiom Resource Management, Inc.
Mary Johnson, Axiom Resource Management, Inc.
Jennifer Musick, Axiom Resource Management, Inc.

Members of the Public:

Paula J. Caltrider, Maryland Motor Vehicle Administration (MVA)
Christie Cullinan, American Trucking Associations (ATA)
Gerald Donaldson, Advocates for Highway and Auto Safety
Commander Christopher Lucas, M.D., U.S. Navy
Bob Perry, Roadside Medical Clinics and Labs
Melissa Rohen, Owner-Operator Independent Driver Association (OOIDA)
Mary Anne Scottino, M.D., Maryland MVA

Call to Order

Mary D. Gunnels, Ph.D., Director, Office of Medical Programs, FMCSA, called the 12th public meeting of the MRB to order, noting that she is the DFO for the meeting. She announced that the MRB would discuss several topics, including Parkinson's disease (PD), multiple sclerosis (MS), narcolepsy, traumatic brain injury (TBI), psychiatric disorders, and commercial motor vehicle (CMV) driver safety. She explained that there would be presentations on the evidence report findings for each topic and a presentation of the Medical Expert Panel (MEP) opinions on PD, MS, narcolepsy and TBI. The MRB will also continue its discussion on psychiatric disorders. Each presentation would be followed by a designated public comment period and MRB deliberation.

Dr. Gunnels requested that attendees complete an evaluation form before leaving the meeting. She also announced that a detailed summary of the meeting would be prepared and posted on the MRB Web site at www.mrb.fmcsa.dot.gov.

Dr. Gunnels introduced and welcomed Benisse Lester, M.D., the newly appointed Chief Medical Officer for FMCSA.

MRB Approval of July 1, 2009 Meeting Summary

Kurt Hegmann, M.D., called for official approval of the minutes of the 11th public meeting of the MRB held on July 1, 2009. The minutes were unanimously approved.

**Presentation of Evidence Report Findings: Parkinson's Disease, Multiple Sclerosis, and CMV Driver Safety
Benisse Lester, M.D.**

Dr. Lester presented an overview of the findings of the evidence report on PD, MS, and CMV driver safety developed by James Reston, Ph.D., from the ECRI Institute/Manila Consulting. Dr. Lester stated that the evidence report investigated the potential risk of a motor vehicle crash among individuals with PD or MS. Dr. Lester stated that both PD and MS are progressive neurological disorders that may impair driving ability. Statements by Dr. Lester were based upon the evidence report information. The following questions were addressed in this report:

Key Question #1: What are the criteria that define when an individual with PD should stop driving a CMV?

Key Question #2: What is the impact of pharmacotherapy for PD on driver safety?

Key Question #3: Are individuals with MS at an increased risk for a motor vehicle crash?

Key Question #4: What factors associated with MS are predictive of an increased crash risk?

Key Question #5: How frequently should an individual with MS be assessed in order to monitor whether they remain safe to drive?

Key Question #6: What is the impact of pharmacotherapy for MS on driver safety?

Key Question Responses**Key Question #1: What are the criteria that define when an individual with PD should stop driving a CMV?**

Fifteen studies were found that addressed Key Question #1; none of which included CMV drivers. There were 13 cohort studies, one survey, and one case control study. This included three crash studies, 11 driving performance studies, and one daytime sleepiness study. The generalizability of these studies to CMV drivers may be limited because CMV drivers have greater risk exposure than non-CMV drivers. Women were over-represented relative to the CMV driver population. The average age of study participants was somewhat older (ages 62 to 73) than the average age of the CMV driver population.

In summary, the evidence was insufficient to determine with precision what risk factors or combinations of risk factors truly define when an individual with PD should stop driving. However, potential risk factors include movement restriction, decreased motor function, stage of PD, duration of PD, decreased cognitive function, and sudden onset of sleepiness. The strength of this evidence was considered minimally acceptable.

Dr. Lester asked the MRB if there were any comments regarding the evidence presented for Key Question #1. Dr. Andersson said this is an example of an evidence report that does not provide much evidence. He encouraged FMCSA to stimulate research in this area because it is important to have good research. So many lives are lost annually, and it is essential to know what factors influence this trend.

Dr. Hegmann agreed with Dr. Andersson's comment, and pointed out that one of the studies indicated that stage 1 PD does not have an elevated crash risk, but stage 2 and stage 3 PD have a three-fold elevated crash risk, which is a significant finding.

Key Question # 2: What is the impact of pharmacotherapy for PD on driver safety?

Dr. Lester stated that pharmacotherapy may affect cognitive and psychomotor abilities that could contribute to crash risk. These can include dopamine agonists, dopamine prodrugs, catechol-O-methyl transferase (COMT) inhibitors, monoamine oxidase B (MAO-B) inhibitors, amantadine, or anticholinergics.

Four studies were included in the evidence base for Key Question #2. No CMV drivers were included. The studies included three randomized control trials (RCTs), and one cohort study. The quality of the studies ranged from high to moderate. The generalizability of the evidence to CMV drivers may be limited as CMV drivers have greater risk exposure than non-CMV drivers. Women were over-represented relative to CMV population. CMV drivers are under more pressure to drive even if they are experiencing side effects of medications. Dopamine agonists were the only drug class evaluated in these studies. No studies directly evaluated crash risk (i.e., no crash data). All studies evaluated the effects of dopamine agonists on sleepiness in patients with PD. One RCT (plus an extension study) found significant elevated risk of somnolence (sleepiness) associated with ropinirole. Data from two RCTs (both evaluating pramipexole) were combined in a meta-analysis.

The evidence suggested that use of dopamine agonists may lead to somnolence in individuals with PD. The evidence was insufficient to determine whether other types of pharmacotherapy may affect driver safety. Whether measures of somnolence among individuals with PD on

pharmacotherapy can predict actual crash risk could not be determined from currently available evidence.

Key Question # 3: Are individuals with MS at an increased risk for a motor vehicle crash?

Two cohort studies were found that met the inclusion criteria for Key Question #3. Both were of moderate quality. The generalizability of these studies to CMV drivers may be limited as CMV drivers have greater risk exposure than non-CMV drivers. Women were highly over-represented relative to the CMV driver population. The average age of enrollees was within the age range of the CMV driver population. The currently available evidence was insufficient to determine whether crash risk is increased among individuals with MS. However, the possibility that crash risk is increased among a subgroup of individuals with MS and an additional impairment could not be ruled out.

Dr. Lester asked if the MRB had any comments related to the evidence presented on Key Question #3. Dr. Andersson said that the lack of decision about the severity of the disease for PD and MS is common. This is a significant weakness of all the studies: that the individual disease severity cannot be determined. He added that there is a huge range of functional abilities depending on the severity of disease.

Key Question # 4: What factors associated with MS are predictive of an increased crash risk?

Three cohort studies were found that met the inclusion criteria for Key Question #4. The overall quality of these studies was moderate. The generalizability of these studies to CMV drivers may be limited as CMV drivers have greater risk exposure than non-CMV drivers. Women were highly over-represented relative to the CMV driver population. Average age of enrollees was within the age range of the CMV driver population. The currently available evidence is insufficient to determine whether factors associated with MS are predictive of increased crash risk among individuals with MS. However, the possibility that crash risk is increased among a subgroup of individuals with MS and cognitive impairment cannot be ruled out.

Dr. Lester asked if the MRB had any comments regarding the evidence presented on Key Question #4. Dr. Soderstrom pointed out that one study mentioned the Useful Field of View (UFOV) test, which has a great deal of science behind it. Some studies suggest that if a person does poorly on the UFOV test, it indicates that he/she might not be able to pass a driving test, and if a person does well, he/she will pass. The implication is that they are taking the results and applying them as if they had taken a driving test. It is important to remember that they are just UFOV test results, which are not the same as a person being tested for actual driving ability.

Key Question #5: How frequently should an individual with MS be assessed in order to monitor whether they remain safe to drive?

No evidence was identified that addressed this question. Therefore, no evidence-based conclusion is possible at the present time.

Key Question #6: What is the impact of pharmacotherapy for MS on driver safety?

No evidence was identified that addressed this question. Therefore, no evidence-based conclusion is possible at the present time.

Presentation of the MEP Opinions: PD, MS, and CMV Driver Safety
Matthew Rizzo, M.D.

Dr. Rizzo presented the opinions of the MEP on PD, MS, and CMV driver safety.

- **MEP Opinion #1: PD and CMV Driver Certification**
 - A diagnosis of PD precludes an individual from obtaining unconditional certification to drive a CMV for interstate commerce.
 - A diagnosis of PD should not exclude all individuals; CMV certification may be possible in some instances.
 - A person with PD may be considered for CMV certification if he/she meets a set of criteria based upon an evaluation by appropriate, qualified specialists. This qualified specialist (e.g., neurologist, movement disorders specialist, neuropsychologist, as appropriate) should assess for symptoms that may adversely affect driving ability.
 - Shows mild symptoms only, as indicated by a Hoehn Yahr (HY) scale stage 1 or less, and a high score (90 percent or higher*) on the Schwab and England Activities of Daily Living Scale**.
 - *HY1 – Signs and symptoms on one side only, symptoms mild, symptoms inconvenient but not disabling, usually present with tremor of one limb.
 - **90 percent – Completely independent. Able to do all chores with some degree of slowness, difficulty, and impairment. Might take twice as long. Beginning to be aware of difficulty.
 - Tolerates medications well, without cognitive, motor, or other side effects that might affect driving.
 - Shows no significant fluctuations in motor response or “on-off” effects (i.e., sudden fluctuations in disability involving rapid and abrupt alterations between periods of good mobility and periods of hypokinesia, tremor, and dyskinesia).
 - Demonstrates satisfactory functioning on a battery of tests assessing key cognitive functions important for safely driving a motor vehicle (e.g., processing speed, attention, perception, memory, executive functions, and emotion).
 - Satisfactory functioning should be defined as performing within or above the normal range using test norms that adjust for relevant factors, such as age and education.
 - Shows no evidence of a mood disorder or satisfactory control of an existing mood disorder (see psychiatric disorders MEP report).
 - Provides written documentation of the specialist’s report at the time of the CMV medical evaluation.
 - The medical examiner form should be updated by adding a place to indicate that the applicant has been referred to a specialist who has documented the individual’s condition relevant to safely operating a CMV.
 - An individual with PD who meets the criteria for certification should be re-evaluated on a semi-annual basis by a neurologist or other qualified specialist, and obtain an annual neuropsychological evaluation.
 - The choice of a qualified specialist should be based on the judgment of the medical examiner in the context of the complexity of the examinee’s case.
 - This choice depends on factors of illness severity, symptoms, duration, stability over time, and such interventions as medications required for management.

- It also depends on the available resources, with general preference given to more highly trained and experienced consultants.

Dr. Rizzo asked the MRB if there were any comments or questions. Dr. Soderstrom asked if most patients with stage 1 PD are treated with medication. Dr. Rizzo said that patients with stage 1 PD may be treated with medication. Dr. Rizzo added that it is likely that more than half would be treated with medication.

Dr. Rizzo continued his presentation by explaining the different typical patterns of progression of MS. There are various kinds of patterns that occur. The most common form is the relapsing and remitting MS.

Dr. Rizzo presented the following MEP opinions:

- **MEP Opinion #2: MS and CMV Driver Certification**
 - A diagnosis of MS precludes an individual from obtaining unconditional certification to drive a CMV for interstate commerce.
 - A diagnosis of MS, however, should not exclude all individuals with the disorder from driving a CMV; certification may be possible in some instances.
 - An individual with a diagnosis of MS may be considered for certification to drive a CMV if that individual meets a set of criteria (to follow).
 - Based upon an evaluation by a qualified specialist (e.g., neurologist, MS specialist, neuropsychologist, ophthalmologist, occupational therapist, as appropriate, depending upon the signs and symptoms of the individual being evaluated).
 - Shows no signs of recent relapse or chronic progression.
 - Tolerates medications well, without cognitive, motor, or other side effects that might affect driving.
 - Has satisfactory vision, including acuity, fields, and ocular alignment (see vision MEP report).
 - Demonstrates satisfactory cognitive functioning based upon a standardized neuropsychological test battery assessing key domains important for safely driving a motor vehicle (e.g., processing speed, executive functioning, attention, perception, memory, and emotion). Satisfactory functioning should be defined as performing within or above the normal range using test norms that adjust for relevant factors, such as age and education.
 - Shows no evidence of a mood disorder or satisfactory control of an existing mood disorder (see psychiatric disorders MEP report).
 - Shows satisfactory motor function and mobility (see musculoskeletal MEP report).
 - Has no history of excessive fatigability or periodic fluctuations of motor performance, as in relation to heat, physical and emotional stress, and infections.
 - Provides written documentation of the specialist's report at the time of his or her medical examination.
 - The medical examiner form should be updated by adding a place to indicate that the applicant has been referred to a specialist who has assessed the individual's condition relevant to safely operating a motor vehicle.
- An individual with MS who meets the criteria for certification above should be re-evaluated on a semi-annual basis by a neurologist or other qualified specialist and obtain an annual neuropsychological evaluation.

- The choice of a qualified specialist should be based on the judgment of the medical examiner in the context of the complexity of the examinee's case. This choice depends on factors of illness severity, symptoms, duration, stability over time, and interventions, such as medications required for management. It also depends on the available resources, with general preference given to more highly trained and experienced consultants.

Dr. Rizzo asked if there were any questions from the MRB. Dr. Andersson noted that it is important to acknowledge that there are different levels of disease. There are some people with very mild disease who should be able to drive. He asked how difficult is it for the physician community to identify those people who fall in the mild category where they could potentially be a CMV driver. Dr. Rizzo said he did not think it would be difficult for an expert neurologist to make that determination. The family doctor would often recognize a neurological problem that needs a specialty evaluation.

Dr. Hegmann asked whether a person could be certified to drive by seeing a specialist other than a neurologist. Dr. Rizzo said no; the MEP's general view is that the person should be evaluated by a specialist based on how complicated the presentation (i.e., number of symptoms and severity of disease). In general, the MS patient should see a specialist.

Dr. Andersson noted that the first bullet of the MEP opinion indicates interstate commerce. He asked if that means they could drive intrastate. Dr. Hoffman pointed out that FMCSA does not have jurisdiction over intrastate drivers.

Dr. Andersson said it is not just a jurisdictional issue; it is an issue of safety. Dr. Andersson asked whether it was the MEP's intention to allow a person to drive inside the state unconditionally with this diagnosis. Dr. Rizzo said his intention here is to talk about what applies to FMCSA jurisdiction, which is interstate commerce. Dr. Rizzo added that these same criteria could potentially apply to intrastate commerce.

Dr. Hegmann asked whether a person with optic neuritis needs to see a neurologist, as well as have a visual field test. Dr. Rizzo said that someone who has optic neuritis probably needs to visit a neurologist to determine if there are other problems in the nervous system. The presenting problem may be optic neuritis, but maybe something else is going on. Dr. Rizzo added that the person probably should visit a vision specialist to document acuity and visual fields.

Dr. Soderstrom asked how fast these diseases progress. Dr. Rizzo said that there is really no way to know that for sure.

Dr. Hoffman asked if MEP felt a 6-month window for re-evaluation was the appropriate time. Dr. Rizzo concurred.

Dr. Rizzo presented the final MEP opinion on PD, MS, and CMV driver safety.

- **MEP Opinion 3: Fitness to Drive Framework**
 - The MEP believes that FMCSA should adopt a general framework for determining fitness to drive a CMV that relies upon a "functional" evaluation of multiple domains (cognitive, motor, perceptual, and psychiatric), which are important for safe driving.
 - Such a framework could be applied across many diseases/conditions, including ones that have rarely been studied with respect to CMV driving.
 - Of note, this framework is compatible with MRB considerations regarding approach to drivers with multiple conditions.

- The framework would serve as a functional “screen” comprising elements of cognitive, psychomotor, and psychiatric function. It would screen for primary effects of illness (e.g., cognitive dysfunction), effects of medications (e.g., sedation), and illness-medication interactions. Examples include:
 - Cognitive: processing speed, attention, perception, memory, executive functions, and emotion.
 - Psychomotor: heel-to-toe walking, rapid alternating movement, and measures of perseveration for psychomotor function.
 - Psychiatric: Patient Health Questionnaire (PHQ) or PHQ-2 for depression, among others.
- The screen would be administered by the medical examiner, based on the obtained medical and psychological history, and used as an additional guide for referral.
- Two key elements of this approach are validity of each element of screening and practicality.
 - The screen would need to comprise validated testing measures and not be easily defeatable by examinees.
 - The evaluation would need to be easily teachable to medical examiners (e.g., through the National Registry Program process) and relatively quickly and effectively administered during the certification examination.
- We suggest revisiting evidence reports on other conditions (e.g., stroke, diabetes, TBI, etc.) and pooling these data to examine the predictive value of various factors (e.g., cognitive, motor, medication, etc.) in determining ability to drive safely and crash risk.

MRB Questions and Discussion on PD and MS

Dr. Hoffman asked how these suggested items should be added to the examination. Dr. Rizzo said that screening tests would need to be added; however, some thought would need to be given to exactly which tests and what the thresholds should be.

Dr. Soderstrom said that it is very appropriate to present this framework for PD and MS, particularly for MS as it is a cognitive, psychological, musculoskeletal, and a visual disease. Dr. Rizzo said that this framework will work for other kinds of conditions as well.

Ad Hoc Committee Report on PD, MS, and CMV Driver Safety Gunnar Andersson, M.D.

Dr. Andersson said that the ad hoc committee was underwhelmed with the evidence report on PD, MS, and CMV driver safety. Unfortunately, this has been the case with many of the diseases the MRB has studied. Dr. Andersson suggested that more research should be done in this area. However, the committee was very impressed with the MEP opinions.

Public Comment on PD, MS, and CMV Driver Safety

Gerald Donaldson, Advocates for Highway and Auto Safety, noted that Dr. Andersson’s remarks about the safety implications between interstate and intrastate drivers were very important. It sheds light on what will eventually evolve as potential disparities between an interstate and intrastate set of criteria for driver qualifications. Eventually, when there are much more stringent criteria for evaluating drivers with multiple conditions, many states will object that the criteria are

too restrictive. As a result, some states will have more disparities between State and Federal regulations.

Natalie Hartenbaum, M.D., pointed out that the MEP recommended semi-annual evaluations by the specialist for both PD and MS patients. Dr. Hartenbaum asked if that included semi-annual certifications by the medical examiner. If the certification does not happen, there is no assurance that the semi-annual examination by the specialist actually took place. Dr. Rizzo agreed with Dr. Hartenbaum's comments.

Dr. Hartenbaum said that many medications used to treat PD cause sleep attacks. Dr. Rizzo responded that this raises a bigger question about prescribing medications that can have psychoactive effects. The MRB and FMCSA have addressed this issue before with medications. Dr. Rizzo said there is an absence of evidence that these medications used for PD make a person an unsafe driver, but it is clear that there has been association with adverse outcomes like sleepiness. However, there is not enough evidence to recommend changing existing regulations.

Dr. Hartenbaum expressed a concern that FMCSA has made cautionary statements about some medications but not others. An examiner is going to assume that if a medication is not prohibited, it must be permitted. For those PD medications where there is high warning of sleep attacks, it would be helpful to have official guidance.

Dr. Rizzo said these are potential areas for research. This lack of evidence is a wake-up call and motivation to do the research that needs to be done. This question is important, but there is little evidence to make a recommendation at this time.

Bob Perry, President, Roadside Medical Clinics, said he looks forward to the implementation of the National Registry Program and seeing more consistency with medical examinations. Mr. Perry added that more research is needed to help address the health issues these drivers face.

MRB Discussion and Deliberation on PD, MS, and CMV Driver Safety

Dr. Hoffman said that it is his opinion that people diagnosed with PD or MS should be evaluated by a neurologist. It would be the responsibility of the neurologist to make a referral to another type of practitioner, based on the patient's condition. Dr. Hegmann agreed with Dr. Hoffman's opinion.

Dr. Phillips noted that the issue of sleepiness is something that the MRB has been dealing with for a long time. There is no perfect measure for determining sleepiness. Any measurement is just a snapshot of how sleepy the person is at that time, but it does not really predict sleepiness. This is a huge issue for the MRB in trying to assess sleepiness. The approach that Dr. Rizzo and the MEP have taken is the best that can be done at this time.

Dr. Andersson presented the following motions on PD and MS:

- **MRB Recommendation #1: PD**
 - The MRB accepts the opinions of the MEP on PD. In summary, the MEP had three opinions:
 - Not allowing people with PD an unconditional certification.
 - Allowing people with early or mild PD to drive provided they fulfill certain qualifications.

- Individuals with PD should be re-evaluated on a semi-annual basis. Not only should they be re-evaluated by a neurologist, they should also be recertified.

Dr. Hegmann clarified that the MRB was moving to reaffirm the MEP opinion potentially allowing people in HY stage 1 PD to drive, but people in HY stage 2 and stage 3 PD would be precluded.

The MRB unanimously approved this motion.

Dr. Andersson made the following recommendation on MS.

- **MRB Recommendation #2: MS**
 - The MRB accepts the opinions of the MEP on MS with the addition that not only are they semi-annually evaluated by a neurologist or other qualified specialist, but also recertified.

Dr. Hegmann asked for clarification as to whether the person is to be evaluated by a neurologist and, possibly, by another qualified specialist as specified. Dr. Andersson said that in this particular case the MEP mentioned neurologist *or* other qualified specialist, so they did not specifically mention the various specialists as indicated in the PD opinion. He reiterated that the MEP opinion states that the person should be evaluated by a neurologist *or* other qualified physician specialist.

Dr. Soderstrom asked if the reference to “other qualified specialist” includes an occupational therapist. Dr. Andersson said that in all cases the specialist should be able to use whatever subspecialists they need to make their decisions.

The MRB unanimously approved this motion.

Dr. Andersson made the following motion.

- **MRB Recommendation # 3: Functional Evaluation**
 - The MRB accepts the MEP opinion to develop a driver evaluation based on function.

The MRB unanimously approved this motion.

Presentation of Evidence Report Findings: Narcolepsy and CMV Driver Safety Benisse Lester, M.D.

Dr. Lester presented an overview of the evidence report findings on narcolepsy and CMV driver safety. This evidence report addressed the following Key Questions:

Key Question #1: Are individuals with narcolepsy (with or without cataplexy) at an increased risk for a motor vehicle crash when compared to comparable individuals without the disorder?

Key Question #2: Do currently recommended treatments for narcolepsy reduce the risk for a motor vehicle crash?

Key Question Responses**Key Question #1: Are individuals with narcolepsy (with or without cataplexy) at an increased risk for a motor vehicle crash when compared to comparable individuals without the disorder?**

The currently available evidence supported the contention that drivers with narcolepsy are at significantly increased risk for a motor vehicle crash when compared to otherwise similar individuals who do not have the disorder. The strength of this evidence is strong and stability of the evidence was considered to be moderate.

Key Question #2: Do currently recommended treatments for narcolepsy reduce the risk for a motor vehicle crash?

The currently available evidence suggested that amphetamines and/or methylphenidate or other pharmaceuticals may be effective in improving symptoms of excessive daytime sleepiness (EDS) in individuals with narcolepsy. The vast majority of individuals on such treatments, however, do not return to normal levels of daytime sleepiness. The strength of this evidence was considered low to moderate.

In summary, the available evidence supported the position that narcolepsy is associated with a significantly increased risk of occurrence of crashes in CMV and non-CMV drivers, with or without treatment. Existing pharmacotherapy does not return the vast majority of individuals with narcolepsy to normal levels of daytime sleepiness.

Dr. Hegmann noted that there was no MEP on narcolepsy that had been formed and then turned the meeting over to Dr. Phillips for the ad hoc committee report on narcolepsy.

**Ad Hoc Committee Report on Narcolepsy and CMV Driver Safety
Barbara Phillips, M.D.**

Dr. Phillips said that of all the topics currently under review, the evidence for narcolepsy is the most clear and compelling. There have been some changes in the treatment of narcolepsy in the last decade. The data that were collected demonstrate that people with narcolepsy are not safe to drive on the basis of sleepiness alone, which does not even consider the issue of cataplexy. The evidence report was straightforward, and there is no reason to change the current guidance that CMV drivers with narcolepsy are not eligible for a commercial driver's license.

Dr. Soderstrom pointed out that the medications evaluated in the evidence report were limited to amphetamines. But the entire report suggested that with all classes of drugs, the patient does not return to normal or safe sleep levels. Dr. Phillips concurred with Dr. Soderstrom's comment and added that amphetamines are not approved by the U.S. Food and Drug Administration (FDA) for the treatment of narcolepsy, even though they are frequently used.

Public Comment on Narcolepsy and CMV Driver Safety

The public offered no comments on this topic.

MRB Discussion and Deliberation on Narcolepsy and CMV Driver Safety

Dr. Hegmann invited MRB discussion and deliberation on narcolepsy and CMV driver safety.

Dr. Phillips made the following motion:

- **MRB Recommendation #1: Narcolepsy**
 - The MRB recommends that FMCSA retain the current regulation on narcolepsy, which indicates that people with narcolepsy are ineligible for a commercial driver's license, even if treated.

The MRB unanimously approved this motion.

**Presentation of Evidence Report Findings: Traumatic Brain Injury and CMV Driver Safety
Benisse Lester, M.D.**

Dr. Lester presented an overview of the findings of the evidence report on TBI and CMV driver safety. The focus of this report evaluated the potential risk of a motor vehicle crash among individuals with TBI. The severity ranged from mild to moderate to severe. This evidence report addressed the following Key Questions:

Key Question #1: What is the impact of TBI on crash risk/driving performance?

Key Question #2: What factors associated with TBI 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 TBI?

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

Key Question Responses

Key Question #1: What is the impact of TBI on crash risk/driving performance?

Nine cohort studies were included in the evidence base for Key Question #1; none of which included CMV drivers. The quality of the studies was low to moderate. The generalizability of these studies to the CMV driver population may be limited since CMV drivers have greater risk exposure than non-CMV drivers. Women were over-represented relative to the CMV driver population. CMV drivers are under more pressure to drive even if they are experiencing symptoms of TBI.

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. The strength of this evidence was considered to be moderate.

Dr. Lester asked the MRB if there were any comments on the evidence presented for Key Question #1. Dr. Andersson pointed out that the simulator tests were done on patients with either moderate or severe TBI. Only one study actually indicated the TBI level as severe. How appropriate is it to combine these data with other studies that did not indicate the TBI level?

Dr. Hegmann added that this is a very good question; if the data are that heterogeneous, then the central point estimate is potentially invalid.

Key Question #2: What factors associated with TBI are predictive of increased crash risk or poor driving performance?

Twelve cohort studies were included in the evidence base for Key Question #2. None of these studies included CMV drivers. The quality of these studies ranged from low to moderate. The available evidence was insufficient to determine whether any factors related to TBI can predict actual crash risk. However, evidence suggested that cognitive function measured by certain neuropsychological tests may predict the outcome of driving performance measured by a road test for patients with TBI. The strength of this evidence was considered to be moderate. Dr. Hegmann said that the same issue for Key Question #1 regarding variability of the populations could apply to this group of studies. Dr. Soderstrom noted that another major weakness is that most of these studies involved self-reported data.

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

One low-quality cohort study was found that addressed Key Question #3. This study did not include CMV drivers. It compared on-road driving performance of individuals with a TBI who had full motorized vehicle training to individuals with TBI who did not have full training. The study enrollees had a severe TBI. The study did not control for potential confounding factors, such as, driving exposure, age, etc.

The results of this study found statistically significant differences among groups favoring full vehicle training on the post-training scores for percent tracking; percent correct signs, composite score, and the driver educator's score. The available evidence was insufficient to determine the impact of rehabilitation programs on crash risk or driving performance among individuals with a TBI.

Dr. Lester asked the MRB if there were any comments regarding the evidence presented for Key Question #3. Dr. Hegmann noted that the sample size of this one, low-quality study of only 24 individuals provides such a low impact that it is virtually useless for evidence-base purposes.

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

Nine cohort studies were included in the evidence base for Key Question #4. None of the studies included CMV drivers. The quality of these studies ranged from low to moderate. The generalizability to CMV drivers may be less important because the question does not address crash/driving performance. The generalizability relative to age and gender might be important if these factors influence seizure risk. Women were over-represented relative to the CMV driver population, but most studies were generalizable by age. CMV drivers are on the road much longer than other drivers, which increase the chance of a seizure while driving.

In summary, individuals with TBI who have not experienced a seizure within the first post-injury week still have a significant likelihood of experiencing late seizures. Reported frequencies of late seizures in this population ranged from 1 percent to 25 percent during follow-up periods ranging from 1 to 11 years. The strength of this evidence is moderate. The highest rate of late seizures (25 percent) was associated primarily with penetrating missile TBIs. The strength of this evidence is 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. The strength of this evidence was minimally acceptable.

Among adults with moderate or severe TBIs who develop late seizures, more than 50 percent experience their first late seizure within the first year after TBI. The rates fall substantially within the next 2 years. The rates stabilize after the third year at roughly 2 to 4 percent (out of the total number of patients who develop late seizures) out to 11 years. The pattern for mild TBI is less clear, but the rate of late seizure development does not appear to be much higher in the first year compared to subsequent years. The strength of this evidence is minimally acceptable.

Dr. Lester asked the MRB if there were any comments on the evidence presented for Key Question #4. Dr. Andersson noted that these two studies were published in 1972 and 1980. Given the frequency of these types of injuries in the military, one would assume military rules exist on how to address this problem.

Dr. Soderstrom noted that the larger study in this evidence base was a military study. A typical military-issue round travels at 1,000 meters per second, which is very different from a non-military round that travels at 800 feet per second. A military round is usually associated with blowing off a head, hand, arm, leg, etc. It seems that these data are about fragments from grenades and other types of artillery. He added that it is surprising there is such a lack of evidence on this subject, particularly with regard to seizures.

Dr. Andersson speculated that based on the study's publication date, it must be referring to the Vietnam War, when weapons were different and indirect TBIs were much less frequent because many soldiers did not survive. Now we are seeing these soldiers return home alive, but with TBIs and loss of limbs. Dr. Lester added that this is partly due to the improved body armor employed in recent military exercises. Now, more soldiers survive with head trauma and severe orthopedic injuries—who might otherwise have died—due to the improved body armor.

Presentation of the MEP Opinions: TBI and CMV Driver Safety **Natalie Hartenbaum, M.D.**

Dr. Hartenbaum presented the MEP opinions on TBI. She noted that MEP tried to make sure the opinions were practical, feasible, and applicable to the population. She noted that MEP reviewed literature and guidelines from other transportation modes, both inside and outside the U.S., in addition reviewing the evidence report. She pointed out there was some inconsistency on how the report defined mild, moderate, and severe TBI. Therefore, MEP developed the following classification for TBI severity:

- **Mild:** 0-30 minutes of loss of consciousness (LOC)/alteration of consciousness (AOC)/post-traumatic amnesia (PTA).
- **Moderate:** 30 minutes to 24 hours of LOC/AOC/PTA, or skull fracture *and* 0-30 minutes of LOC/AOC/PTA.
- **Severe:** > 24 hours of LOC/AOC/PTA.

Dr. Hartenbaum presented the following MEP opinions on TBI and CMV driver safety.

- **MEP Opinion #1: TBI and CMV Driver Certification**
 - Individuals who have sustained a penetrating injury to the brain or severe TBI (i.e., loss of consciousness \geq 24 hours) should be permanently precluded from obtaining certification to drive a CMV for interstate commerce.

- **Justification for MEP Opinion #1: TBI and CMV Driver Certification**
 - TBIs often result in permanent or temporary impairments, particularly in cases of severe TBI cognitive, psychosocial, sensory, and motor functioning.
 - These impairments may contribute to an increased likelihood of a motor vehicle crash.
 - Increased likelihood that an individual will experience a seizure following TBI.

Dr. Hartenbaum noted that there may be a few exceptional cases of severe or penetrating TBI in which consideration might be possible. Specific characteristics of these individuals remain unclear; therefore, MEP refrains from providing guidance at this time. She added that one of the older neurological reports mentioned seizure risk following surgical penetration of the dura (outermost layer surrounding the brain). The MEP determined that assigning risk to seizures after a craniotomy was very difficult because it would depend on many factors, such as type and location of surgery and the underlying reason for surgery. It is MEP's opinion that FMCSA should investigate this issue, evaluate the risk of seizures associated with specific types of craniotomy, and update its guidance accordingly.

- **MEP Opinion #2: Moderate TBI and CMV Driver Certification**
 - Individuals with moderate TBI should be precluded from obtaining certification to drive a CMV for interstate commerce for 3 years. After a 3-year wait, the individual must be cleared by the treating provider (minimum qualifications of M.D. or D.O.).
 - 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 things.
 - Difficulty sequencing information.
 - Impaired attention to details.
 - Impaired ability to benefit from experience.
 - Deficits in planning and carrying out activities.
 - If seizure occurred during the waiting period, follow current FMCSA guidance for individuals with a seizure disorder.
 - If cleared by the treating provider, then the driver should be evaluated by a neurologist who is aware of the functional and cognitive requirements of operating a CMV.
 - Additional evaluation by a neurologist should:
 - Include complete neurological assessment.
 - Assess motor speed and dexterity, cognitive function, and symptoms of depression through objective testing.
 - Refer individual to a neuropsychologist, psychologist, or other specialist, as appropriate, based on specific symptoms.

- Recommend that the following cognitive domains should be assessed (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).
- Neurologist and medical examiner should assess the effects of treatment, including medications, on functional and cognitive abilities.
- Drivers with no or minimal abnormalities who are cleared should be recertified every six months while under active treatment.
- Examiner should be M.D./D.O.
- Once an individual is no longer under active treatment, annual recertification is required for 3 years and then as determined by the medical examiner.

- **MEP Opinion #3: Mild TBI and CMV Driver Certification**
 - Individuals with mild TBI can be deemed medically qualified if they are determined by their treating provider (minimum qualifications of M.D./D.O.) to be clinically symptom free.
 - No LOC – 30-day waiting period.
 - LOC – 90-day waiting period to ensure individual remains symptom free.
 - Individuals with mild TBI should be free of the following symptoms of concern before they are qualified :
 - 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 things.
 - Difficulty sequencing information.
 - Impaired attention to details.
 - Impaired ability to benefit from experience.
 - Deficits in planning and carrying out activities.
 - Seizure free.
 - No evidence of intracranial blood if imaging was done
 - Individuals who have experienced mild TBI and lost consciousness as a result and/or are found to be symptomatic at exam time should be referred to a neurologist for additional evaluation.

- Evaluation should be the same as for those who have experienced moderate TBI.
 - Waiting period following mild TBI as symptoms of concern may not be immediately apparent.
 - The more severe the injury, the greater the risk of symptoms development.
 - If loss of consciousness, the driver should have evaluation by specialist prior to returning to work.
- **MEP Opinion #4: Anti-Seizure Medication and CMV Driver Certification**
 - Individuals placed on anti-seizure medication either following a single provoked seizure or prophylactically should not be medically qualified to drive a CMV until they meet the current FMCSA criteria for individuals taking anti-seizure medication.
- **MEP Opinion #5: Extremity Impairment and CMV Driver Certification**
 - Individuals who meet earlier criteria for certification after TBI and whose only residual deficit is impairment of an extremity may be eligible for a Skill Performance Evaluation (SPE) certificate and should be referred to apply for one if otherwise medically qualified.
- **MEP Opinion #6: TBI and Medical Examiner Qualifications**
 - It is the opinion of the MEP that due to the risk of seizures and neurological and cognitive dysfunction after TBI, physicians (M.D. or D.O.) should perform the commercial driver medical examination on those who have sustained TBI.

MRB Questions and Discussion on TBI

Dr. Soderstrom asked if MEP is suggesting the use of prophylactic anti-seizure medications in planned cranial surgery. He pointed out that use of anti-seizure medications automatically disqualifies the patient for 2 years.

Dr. Hartenbaum clarified that MEP removed the issue of cranial surgery from its opinions. She added that the only reason it was addressed is because it was mentioned in a previous report. MEP thought it was important to acknowledge this is a problem, and that FMCSA should look at this issue in a separate evidence report. If an individual is on anti-seizure medication for a craniotomy, the current FMCSA guidance for anti-seizure medication would apply.

Public Comment on TBI and CMV Driver Safety

Commander Christopher Lucas, M.D., U.S. Navy, noted that TBI is being diagnosed more often these days among veterans returning from the Iraq and Afghanistan wars—especially blunt, mild TBIs. Many of these veterans are military drivers who often go on to become civilian drivers, applying for government-service jobs on a base. He expressed his support for the National Registry Program.

MRB Discussion and Deliberation on TBI and CMV Driver Safety

Dr. Hegmann reiterated that there are issues with the quality of evidence on this topic; specifically the diversity of the injuries and heterogeneous nature of the studies.

Dr. Soderstrom expressed his concern that it is highly unlikely that a person with a penetrating TBI would be able to drive. However, there will be some individuals with TBI who test out to be functionally normal. He expressed a concern that these individuals are not prevented from returning to the work force.

Dr. Hoffman said he was surprised how little literature exists on this topic. Additional military research would be very useful if we could obtain it prior to making a final recommendation, or provide that separately to FMCSA. There may be some valuable data that would help guide recommendations on this topic.

Dr. Andersson said it would be helpful to have more information, but the MRB should deal with the subject based on the information presented today. He added that MEP was very thoughtful in recommending a system for classifying the severity of these patients and the need for evaluation based on the level of severity. He expressed his support for the MEP opinions as outlined and acknowledged they may change when the MRB receives more information.

Dr. Hegmann pointed out that process of publishing peer-reviewed literature, which are the criteria used for developing evidence reports, and then ultimately an evidence review is at least a 2- to 3-year process. The MRB has the opportunity to revisit this topic in the future.

Following this discussion, Dr. Andersson made the following motion:

- **MRB Recommendation #1: TBI**
 - The MRB accepts MEP opinions on TBI.

The MRB unanimously approved this motion.

**Ad Hoc Committee Report on Psychiatric Disorders and CMV Driver Safety
Kurt Hegmann, M.D.**

Dr. Hegmann noted that the type of provider examining a patient should be based on severity of the disorder. He recalled that previous MEP opinions on psychiatric disorders indicated that psychiatrists or psychologists should evaluate the patient, and the MRB finds that requirement overly restrictive; especially for patients with mild psychiatric conditions.

Dr. Hegmann presented the following proposed recommendations:

Ad Hoc Committee’s Proposed Approaches for Certification of Commercial Drivers with Chronic Psychiatric Disorders

Proposed Recommendation #1: Matrix for Evaluating CMV Drivers with Chronic Psychiatric Conditions

- The ad hoc committee proposes that the MRB recommend to FMCSA that the following matrix be adopted for evaluating CMV drivers with chronic psychiatric conditions. Patients with acute psychiatric conditions are not able to be potentially qualified until the condition is evaluated, diagnosed, and successfully treated.

Disorder	Severity*	Examiner	Guidance
Psychotic Disorders†	Mild	Treating healthcare and/or mental health professional	May be qualified**

Disorder	Severity*	Examiner	Guidance
	Moderate	Psychiatrist or advanced-degree mental health professional	May be qualified***
	Severe	Psychiatrist	Unqualified§§
Mood Disorders‡	Mild	Treating healthcare and/or mental health professional	May be qualified**
	Moderate	Psychiatrist or advanced-degree mental health professional	May be qualified***
	Severe	Psychiatrist	Unqualified§§
Personality Disorders§	Mild	Treating healthcare and/or mental health professional	May be qualified**
	Moderate	Psychiatrist or advanced-degree mental health professional	May be qualified***
	Severe	Psychiatrist	Unqualified§§

***Severity** is inferred largely based on prior history. **Mild** is considered minimally incapacitating, readily controlled with one medication or no medication. **Moderate** is sometimes incapacitating, recurring, and/or persistent, requiring one or two medications to control, but control is generally complete or nearly complete. **Severe** is substantially incapacitating, frequent and/or prolonged, requiring multiple medications to control; control is incomplete. Those with severe disorders may be able to qualify at a later date. They generally should not have had severe conditions in the prior 5 years.

**Supportive letter from the treating healthcare professional is required.

***Supportive letter from a psychiatrist is required.

†Individuals with active psychosis are not qualified. At least 1 year without symptoms must be present prior to consideration of commercial driving. Those with a brief, reactive psychosis may be re-evaluated earlier, at 6 months, if the clinical condition has resolved.

‡This includes anxiety, depressive, and bipolar disorders. Drivers with mania, severe major depression, or suicidal behavior or ideation are not qualified. At least 1 year without symptoms must be present prior to consideration of commercial driving. Those with a non-psychotic major depressive disorder without suicidal behavior and symptom free may be re-evaluated at 6 months.

§This includes obsessive compulsive and antisocial personality disorders. Individual clinical assessment is recommended with determination of suitability for commercial driving based upon whether the disorder and behavior pose a driving risk to the public. These traits include aggression, hostility, impulsivity, disregard for the law, and other psychological symptoms.

The committee also recommends the duration of certification be a maximum of 1 year for mild conditions and 6 months for moderate conditions.

§§These individuals are believed to nearly always be unable to be qualified. There may be limited, highly select exceptions. Careful evaluation of those cases is recommended prior to consideration of potential ability to operate commercial vehicles.

The committee affirms a prior recommendation to FMCSA that these psychiatric conditions be included in the Fitness for Duty matrix on multiple conditions. Special consideration (scrutiny) should be given to the certification of drivers handling hazardous materials/waste or driving buses.

Proposed Recommendation #2: Anti-convulsants Taken for Non-epileptic Conditions

- The ad hoc committee proposes that the MRB recommend to FMCSA that CMV drivers taking anti-convulsant medications be evaluated individually by the healthcare providers prescribing the medication, and that a supportive opinion regarding driving safety be obtained prior to consideration of CMV operation. The supportive opinion should state the purpose of the medication and that the medication is not used for control of a seizure disorder. Those with mild, stable conditions and lack of adverse effects may be qualified for up to 2 years. Other individuals may be qualified for a maximum of 1 year, and some with adverse effects may not be qualified.

Recommendation # 3: Research Recommendation

- The ad hoc committee proposes that the MRB recommend to FMCSA that research be conducted into the effects of psychiatric disorders, as well as psychiatric medications, on CMV safety.

Public Comment on Psychiatric Disorders and CMV Driver Safety

Dr. Hartenbaum expressed her concern regarding the 2-year certification cycle for individuals who have mild psychiatric disorders, or who are on anti-epileptic medications for non-epileptic conditions. She suggested 1 year at most, and, as severity increases, the cycle should be 6 months to monitor medications.

Christie Cullinan, ATA, expressed her concerns regarding the diagnosis and treatment of psychiatric and mood disorders—the two brain-based disorders. She did not feel that it was appropriate for a healthcare generalist to diagnose and treat people with these conditions. They should be seen by a psychiatrist who specializes in the diagnosis and treatment of these disorders. She urged the MRB to take this into consideration when making its final recommendations.

Dr. Hegmann asked whether Ms. Cullinan's concern is with mild psychiatric disorders. Ms. Cullinan clarified that her concern was with mild psychiatric disorders and psychotic disorders. She added that it is better for a mental health professional or a psychiatrist to diagnose and treat people with these disorders.

Dr. Gunnels noted that FMCSA sees many situations where medications are taken for diagnoses other than what was indicated, such as anti-convulsants for non-epileptic conditions. Is the MEP/MRB suggesting off-label uses?

Dr. Hegmann said that some of these are off-label and some are on-label uses. It depends on which agent. The problem is they all do have some potential adverse central nervous system effects.

Dr. Gunnels noted that it is FMCSA's policy to work in sync with FDA, which does not sanction off-label use of medications. Perhaps there are some exceptions to this policy. Dr. Lester said her recommendation would be based on a case-by-case review. Dr. Gunnels said that this issue does not need to be addressed at this moment, but it can be revisited in the future.

Dr. Andersson said it is not the MRB's intention to encourage off-label use. Dr. Hegmann added that the MRB should not be in the position of dictating this type of practice.

MRB Discussion and Deliberation on Psychiatric Disorders and CMV Driver Safety

During discussion, Dr. Hoffmann suggested that the *Matrix for Evaluating CMV Drivers with Chronic Psychiatric Conditions* reflects an advanced-degree mental health professional for treatment of mild psychosis rather than a treating healthcare provider. He added that the reason for this is because it is very difficult to see a psychiatrist in many parts of the country.

Dr. Hegmann noted that there is general consensus from the MRB to make Dr. Hoffman's suggested change to the matrix to reflect psychiatrist or advanced-degree mental health professional for mild psychosis. He asked if there were any other changes or comments to the mood disorder section of the matrix. No additional changes were suggested.

Dr. Hegmann asked if there were any changes to the personality disorders section of the matrix. No additional changes were suggested. He reminded the MRB that the suggestion was made during the public comment period to change the evaluation timeframe for *Recommendation #2: Anti-Convulsants Taken for Non-epileptic Conditions* from 2 years and 1 year to 1 year and 6 months. This change was reflected as follows:

Those with mild, stable conditions and lack of adverse effects may be qualified for up to 1 year. Other individuals may be qualified for a maximum of 6 months, and some with adverse effects may not be qualified.

Dr. Hegmann noted that there is general agreement from the MRB to make the above change. For the record, Dr. Soderstrom said he thought this was excessive.

Dr. Hegmann asked whether someone who has moderate psychosis be qualified to drive a bus. Dr. Andersson said he had a difficult time differentiating between those who drive a bus and those who drive another heavy vehicle that could potentially kill just as many people as a bus. Dr. Phillips added that a bus driver might have more interaction with people which might trigger a psychotic episode. She agreed with Dr. Andersson's comments. Dr. Hegmann added for the record that he could never sign a certificate for someone with a moderately severe disorder who drives a bus because there is too much risk.

Dr. Hoffman suggested that a statement be added that indicates that special consideration be given for bus drivers with these types of disorders. Dr. Phillips asked if Dr. Hoffman was suggesting a psychotic individual be certified to drive an 18-wheel truck but not a bus.

Dr. Hegmann said that there is a big difference between driving buses and trucks. In a bus, the driver is transporting 10 to 30 people, so a bus crash would be a potentially catastrophic event as opposed to a single operator rig where only one or two people die. Dr. Andersson added that he is uncomfortable differentiating between the risk of killing two people and the risk of killing 20 people. Dr. Hegmann agreed with Dr. Andersson.

Dr. Gunnels said that the MRB has brought this up before, but the other approach is to identify situations where the MRB would not qualify a driver. Dr. Hegmann noted that the MRB has actually taken a position that is precautionary. Dr. Hoffman added that this is a high barrier for approval for someone who has a history of psychosis; not active psychosis. A person with active psychosis is not going to be certified.

Dr. Hegmann asked if the MRB was in agreement with these recommendations on psychiatric disorders as proposed by the ad hoc committee. The MRB voted and unanimously approved the recommendations to include the revisions discussed by the MRB.

MRB Further Business

Dr. Hegmann said he had concerns about adequate public access to the evidence reports and other public documents. He noted that FMCSA is working to make these documents available electronically.

Dr. Hegmann noted that the next item was Key Question development for pulmonary disease. He pointed out that there is not an evidence report or MEP yet, but FMCSA is planning for these because the regulations around the topic of pulmonary conditions are out of date. The MRB has been asked to help FMCSA develop questions for the pulmonary evidence report. He presented the following items for the MRB to consider:

Key Question Development for Pulmonary Evidence Report (July 2009 Meeting)

1. What is the pulmonary capacity (VO₂ Max) required to do the following: *
 - a. Driving?
 - b. Pre-trip inspection?
 - c. Tying down loads?
 - d. Placing chains?
 - e. Driving 6,000 feet? Driving 11,000 feet?
 - f. Placing chains at 6,000 feet? 11,000 feet?

*Note: These data may not be available through MedLine. Consider looking at Department of Labor, Veterans Affairs, and Social Security Administration databanks/databases. Dr. Hoffman also stated that has some contacts that can help with obtaining this data. Dr. Lois Sheldahl performed work in this area at the Milwaukee Veterans Affairs Medical Center and indicated that thousands of jobs had already been measured in the 1990s (but she is now retired).

2. What criteria should be used to screen for respiratory impairment? **
3. Is there quality evidence that pulmonary dysfunction increases crash risk?
4. What is the evidence that drivers who are on supplemental oxygen are safe to drive?

**Note: Dr. Hoffman stated that will think further about the point at which a pulmonary exercise test is needed.

Key Question Development for Pulmonary Evidence Report (April 2009)

1. What functional evaluations are appropriate for pulmonary disease? Spirometry? Full pulmonary function tests (PFT)? Oximetry? Oxygen? Arterial blood gas? Exercise? Look at other sources, such as the American Medical Association, to determine which functional evaluations would be most appropriate.
2. What are the minimum pulmonary criteria for safe trip preparation and operation and loading of a CMV? Only driving?
3. Is there quality evidence that pulmonary disorders result in a CMV crash? Does the loss of pulmonary function increase the risk for a CMV crash?
4. Does the literature specify the threshold below which your function is impaired?

Dr. Hegmann added that there are data that have been developed for most of the items mentioned. The Veterans Administration has measured oxygen demands. It is a different type of literature from what FMCSA has traditionally been using for these evidence reports because it is not an epidemiological data set. In this case, there is a high degree of specificity in measuring what someone can and cannot do. It is possible to measure oxygen capabilities and assess the job demands; therefore, it is possible to match a person very precisely to job capabilities.

Dr. Hoffman asked FMCSA: When an examiner is signing off a medical card is he/she saying that the driver can do all the tasks indicated in #1 including “e” and “f” (refer to: *Key Question Development for Pulmonary Evidence Report (July 2009 Meeting)*)? Dr. Gunnels responded that there is no specification regarding “e” and “f”. If the driver was in a state with high elevations, he/she would be more attuned to “e” and “f”.

Dr. Hegmann noted that Interstate 80 is the busiest interstate in the U.S., with numerous passes between 6,000 and 7,000 feet. Dr. Hoffman clarified that the requirements are tasks “a” through “d”; however, it does not specify an elevation. He added that most drivers cannot place chains at 11,000 feet, and most cannot even drive at that elevation without experiencing some clinical effects.

Dr. Hegmann reviewed the remainder of the questions and noted that no formal motion was needed.

Public Comment on Pulmonary Key Question Development

Dr. Hartenbaum expressed her concern with the assumption that the medical examiner knows where and what the drivers drive. She highlighted that the medical examiner is only assessing whether the driver is qualified to drive a CMV. The instructions to the examiner are to assess for all driving and non-driving tasks. Unless medical examiners are instructed to find out if the driver transports hazardous materials or operates a passenger carrying vehicle, they are not going to do so. She added that it would be an improvement if medical examiners had the authority to place restrictions on the driver with multiple conditions. Currently, drivers have a fully transferable medical certificate; they can work for any company, anywhere in the U.S., with no restrictions. This is a problem that needs to be considered when any new guidance or recommendations are made.

Diabetes Mellitus and Crash Risk Kurt Hegmann, M.D.

Dr. Hegmann explained that in 2006 there was an expedited evidence review on diabetes and an expedited MEP. At that time, there was fairly weak evidence. A new study was published in 2009 that warrants addressing and comment. He added that the study would certainly qualify as at least moderate if not high quality based on the criteria used.

Dr. Hegmann presented highlights from the study and indicated that the evidence base is now considerably stronger for diabetes mellitus than when the MRB previously reviewed this matter. He pointed out that based on this study, there is an overall 40 percent increased crash risk for individuals with diabetes who are insulin treated. This is statistically significant. By comparison, the results in the expedited review that the MEP and the MRB had previously relied on indicated a 35 percent increased risk. These data actually validate the previous findings, which indicate there is increased crash risk for drivers with diabetes who are insulin treated. He also pointed out that the data do not show an increased risk with increased age.

Dr. Hegmann explained that the evidence base is considerably stronger for diabetes than it was when the MRB first reviewed this matter. Diabetes treated with OHA is associated with a 20 percent increased risk of crash. Treatment with insulin is associated with a 40 percent increased risk of crash. Treatment with combined use (insulin and OHA) is associated with a 40 increased risk of crash. There is no evidence of lower risk among younger or middle-aged adults. He added that based on this evidence, prior recommendations should be revisited. This evidence supports shorter certification periods for diabetes in general.

Dr. Andersson said this study should initiate another review of the recommendations on diabetes. However, there may be some issue with generalizability to CMV drivers, as CMV drivers have greater risk exposure than non-CMV drivers.

Dr. Lester asked whether Dr. Hegmann had any comment regarding the fact that the crash risk seem to be lower for women in all age groups. Dr. Hegmann said he noticed that but did not have an explanation for it. He suggested that it could be an exposure issue.

Dr. Gunnels noted that the evidence report needs to be updated, and it is important that the MRB raised the issue.

Dr. Hegmann moved on to the topic of multiple conditions. He explained that the issue of multiple conditions has come up repeatedly in cases when the MRB had discussed interactions between different conditions. After having dealt with this for about a year and a half now, the question is whether the MRB feels that it should be forwarded to FMCSA as a formal recommendation. The MRB unanimously approved this motion.

Fitness for Duty

The MRB recommends that FMCSA adopt the following for the evaluation of fitness, for duty among drivers, with multiple physical and medical conditions:

Number of Conditions ****	Certification
0 or 1	Maximum 2 years
2+++	Maximum 1 year
3+++	Maximum 6 months
≥4+++	Not eligible until resolution of at least one condition

*****Diabetes mellitus requiring medication; cardiovascular disease; hypertension; dysrhythmias; obstructive sleep apnea (OSA); body mass index (BMI) >35 kg/m²; opioid or benzodiazepine use; renal disease; pulmonary disease with pulmonary function test (PFT) abnormality; epilepsy seizure free for >10 years; musculoskeletal disease requiring medical, surgical or prosthetic treatment; requirement for visual exemption; major psychiatric illness (as defined pending formal review by the MRB); and other conditions as identified by FMCSA.*

+++ Evaluation to be conducted by a CDME who is a licensed M.D. or D.O.

Purvi Shah, Axiom Resource Management, Inc., said that the MRB previously recommended that transient ischemic attacks (TIA) and stroke be added to the matrix and asked whether the MRB intended to separate out TIA and stroke within cardiovascular disease? Dr. Hegmann said that those conditions are included with cardiovascular disease.

Dr. Hegmann's Closing Remarks

Almost four years ago, the MRB, including Larry Minor, was incepted and began to meet. The medical standards for truck and other CMV operators were rather old—15 to 20 or more years out of date—and a process was begun to update that evidence base and provide better guidance to FMCSA and, ultimately, examiners, drivers, companies, and owner-operators. Yet, commercial drivers continue to die at an alarming, albeit gradually declining, rate. The mortality statistics continue to show approximately 4,600 deaths per year. An unknown number of those, although likely a minority, are directly related to medical conditions. In others, medical conditions contribute. For example, a driver who is drowsy may not see clues that an elderly driver is likely to pull out in front of them and the death of the elderly driver is then attributed to the other person, but the other driver played a role. Thus, the total impact of medical conditions is unclear.

To address the medical risks, the MRB has worked to provide guidance for the prevention of accidents. We also have some observations for the future we wish to share. Evidence reports require regular updating when significant studies are found. The MRB has previously recommended every 3 years, and the recent evidence on diabetes suggests that is necessary. It does not; however, require comprehensive rewriting of the report. Rather, a search needs to be performed to ascertain whether there is a need to provide a notification that it possibly remains up to date, or needs a minor edit or a major revision. Based on our experience to date, comprehensive rewriting of evidence reports is likely to be, unfortunately, infrequently required.

MEPs are susceptible to biases based on sole inclusion of individuals from tertiary research centers. Careful balancing of panel composition is necessary, particularly to include individuals familiar with truck drivers, driving requirements, and occupational issues, including the natural motivations of drivers in answering questions. The overall evidence base underlying these conditions is tremendously weak compared with the burden of injuries and illnesses. Compared with other disorders with far more research funding and information, one could be lead to the conclusion that these deaths are relatively unimportant.

The U.S. requires a concerted effort to support research efforts and to the understanding of and prevention of CMV driver deaths and injuries. We look forward to seeing the work of so many individuals involved in the evidence reports, MEPs, the MRB, and FMCSA itself come to full fruition with additional guidance to examiners. We eagerly look forward to the achieving of our collective goal to further reduce the morbidity and mortality among truckers on our roads. On behalf of the MRB, thank you.

Adjournment

Dr. Hegmann adjourned the meeting at 1:01 p.m.



CERTIFICATION

The minutes were approved by the Medical Review Board on 4/2/10.
(Date)

We hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

Kurt Hegmann, M.D.
Chairperson
Medical Review Board

Mary D. Gunnels, Ph.D.
Designated Federal Official
Medical Review Board