

United States Department of Transportation FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION MEDICAL REVIEW BOARD

Meeting Summary

The Medical Review Board (MRB) of the U.S. Department of Transportation (DOT) Federal Motor Carrier Safety Administration (FMCSA) convened to discuss medical standards and guidelines related to renal disease, vision, and musculoskeletal disorders on April 7, 2008, at the Westin Arlington Gateway in Arlington, Virginia. The meeting was open to the public.

Board Members Present:

Kurt Hegmann, MD, Chairperson Michael Greenberg, MD, Co-Chairperson Gunnar Andersson, MD Barbara Phillips, MD Matthew Rizzo, MD

Medical Expert Panel Representatives:

Frank Berson, MD – Vision Panel Stephen Fadem, MD – Renal Panel Nortin Hadler, MD – Musculoskeletal Panel

FMCSA Staff:

*Mary D. Gunnels, Ph.D., Director, Office of Medical Programs Chuck Horan, Director, Office of Bus and Truck Standards and Operations Christina Brooks Shashunga Clayton Teresa Doggett Christine Hydock Kaye Kirby Linda Phillips Pearlie Robinson

*Designated Federal Official (DFO)

FMCSA Contractors:

Ellison Wittels, MD, FMCSA Senior Medical Consultant Glenna Tinney, Axiom Resource Management, Inc. Purvi Shah, Axiom Resource Management, Inc. Margo Weeks, Axiom Resource Management, Inc. Jennifer Musick, Axiom Resource Management, Inc. Stephen Tregear, DPhil, Manila Consulting Group, Inc. Lonnie Weiss, Weiss Consulting

Members of the Public:

Catherine Church, United Parcel Service Christine Cullinan, American Trucking Association Gerald Donaldson, Advocates for Highway and Auto Safety Gary Gross, Epilepsy Foundation Natalie Hartenbaum, OccuMedix Roger Mackbach. Werner Enterprises Charles Maffei, Respironics Tom Manuel, American Association of Motor Vehicle Administrators Rafael Marshall, National Transportation Safety Board Amy McMahon, Transport Topics Karen Morton, American Association of Motor Vehicle Administrators Carl Soderstrom, Maryland Motor Vehicle Administration Medical Advisory Board Melissa Theriault, Owner-Operator Independent Drivers Association Dan Vancil, Road Ready, Inc. Joel Whiteman, Road Ready, Inc.

Call to Order

Mary D. Gunnels, Ph.D., Director, Office of Medical Programs, FMCSA, called the seventh public meeting of the Medical Review Board (MRB) to order, noting that she was the DFO for the meeting and introduced Kurt Hegmann, MD, as the Chairperson of the MRB. She explained that FMCSA utilizes a wide range of sources to determine specific actions, changes, or additions to medical standards and guidance. These sources include (but are not limited to) public comments, MRB recommendations, and Medical Expert Panel (MEP) recommendations, as well as evidence report findings from systematic reviews.

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

Dr. Gunnels announced that the current members of the MRB were reappointed by the Secretary of Transportation on February 8, 2008. She expressed appreciation for the Board's contributions and willingness to continue their service. She also expressed appreciation to the researchers, medical experts, and support staff for their efforts.

Dr. Gunnels explained that any proposed regulatory change must go through a public notice and rulemaking process. FMCSA is seriously considering changes to regulations on some of the medical topics that the MRB has already discussed, and the public could expect to see a notice of intent or notice of proposed rulemaking on these topics. Currently, a final rule to propose a merger of the medical certificate into the Commercial Driver's License Information System is in departmental review. FMCSA also expects to publish a notice of proposed rulemaking soon for the National Registry of Certified Medical Examiners (NRCME).

Agenda Overview, Approval of January 2008 Meeting Summary and Discussion of Other Business

Dr. Hegmann opened the meeting. He noted there would be a public comment period following each medical topic and requested that comments be limited to the topic being discussed. Dr. Hegmann stated there would also be a general public comment period at the end of the meeting for any comments not related to the medical topics being discussed.

As the first order of business, Dr. Hegmann called for approval of the minutes of the sixth public meeting of the MRB held on January 28, 2008. Barbara Phillips, MD, noted one correction on page 16 in the section regarding seizure disorders. The sentence in recommendation 3, which reads, "This applies only to individuals who are *on* medications and seizure free," should be changed to, "This applies only to individuals *off* medications and seizure free."

Dr. Hegmann stated that the minutes, as amended, were unanimously approved and invited discussion of other MRB business. Dr. Phillips moved that the MRB recommend FMCSA seek and receive appropriate resources to develop, implement, and maintain a nationwide database on all commercial motor vehicle (CMV) drivers involved in fatal crashes. This would result in quality data that could be used to develop evidence-based guidance to help reduce the unacceptably high number of fatalities among CMV drivers. She added that the data could include: the most recent and previous commercial driver medical examiner forms; driving

records, including citations and prior crashes; injuries (whether occupational or not); postmortem data, including cause of death and evidence of other conditions; toxicology studies from post-mortem exams and personal medical records, including evidence of diagnosis or treatment for prior disorders or conditions. Dr. Hegmann noted that this motion elaborates on a motion that was approved during the January meeting stating that funding was needed for research in this area. The MRB unanimously approved this motion.

Gunnar Andersson, MD, proposed the MRB recommend FMCSA seek and receive appropriate resources to develop, implement, and maintain a prospective nationwide database of CMV drivers. This national resource would collect medical and safety information on commercial drivers to assess the relationship between the driver's physical, medical, and mental health and driver safety. The MRB unanimously approved this motion.

FMCSA/Road Ready Driver Medical Examination Data Project Presentation Joel Whiteman

Joel Whiteman, Vice President of Operations, Road Ready, Inc., presented an overview of the FMCSA/Road Ready Driver Medical Examination Data Project. He explained that his company provides the DOT Medical Examination Report Form in an electronic, Web-based format for use in a clinic environment. Examination information is collected in a database along with an image of the examination form and medical examiner's certificate, which allows for statistical reporting on all aspects of the examination.

The statistical data collected include driver demographics, patient information (e.g., height, weight, age, and body mass index), lab and physical exam results, and certification information. Mr. Whiteman noted that in some areas of the exam, the self-reported data were compared with medical examiner findings, which revealed inconsistencies.

The primary purpose of the partnership with FMCSA is to combine FMCSA crash data with driver medical examination data in order to analyze the relationship between certain medical conditions and crashes within the commercial driver population. This reliable data source could be used to statistically evaluate the health status of the CMV driver population and allow FMCSA to monitor the effect of changes to the medical standards. It will also provide the opportunity for FMCSA to evaluate the quality of medical examinations as the Agency moves forward with the NRCME.

Dr. Hegmann expressed appreciation to Mr. Whiteman for his presentation and asked MRB members if they had any questions.

Questions & Answers

Matthew Rizzo, MD: What caused the discrepancy between self-reported and examiner findings?

Mr. Whiteman: Drivers have a tendency to not report health situations that will impact their ability to pass the medical examination.

Dr. Phillips: Are data being collected on driver mileage?

Mr. Whiteman: It varies by carrier and their willingness to provide the information.

Dr. Phillips: Are any data on kidney disease being collected?

Mr. Whiteman: The only information being collected is what is recorded on the Medical Examination Report Form.

Dr. Hegmann: How many carriers are involved in this project?

Mr. Whiteman: Data from three carriers are currently included in the database.

Dr. Hegmann: Some carriers have higher screening standards. Does that impact inclusion in the database?

Mr. Whitehead: Different carriers use a variety of screening methods, and an increasing number of carriers are taking a closer look at the medical examination process. The goal is to get more medical clinics involved, which would cover a variety of carriers.

Dr. Rizzo: Are any data on drugs, such as Schedule II drugs included?

Mr. Whiteman: The data available are what has been inserted in the "Comments" section of the examination form.

Dr. Rizzo: Are the data on vision and hearing tests standard, or does variation exist among sites?

Mr. Whiteman: The data on vision and hearing tests are standard.

Dr. Phillips: Do any of the carriers offer or require blood work as a part of the medical examination?

Mr. Whiteman: There is not a consistent standard that all carriers and/or medical examiners follow.

Dr. Phillips: Are blood work data being collected if the blood work is done?

Mr. Whiteman: If a hemoglobin A1c test is conducted, the results are collected in the database.

Chronic Kidney Disease and CMV Driver Safety—Evidence Report Stephen Tregear, DPhil

Stephen Tregear, DPhil, Manila Consulting Group, Inc. presented the highlights of the evidence report on chronic kidney disease and CMV driver safety. He explained that currently, there are no regulations that address CMV drivers with chronic kidney disease (CKD); however, there are regulations and guidelines pertaining to some of the comorbidities associated with CKD, such as cardiovascular disease.

The focus of this evidence report was to look at the complications related to CKD, other than cardiovascular disease, and the impact on CMV driver safety. There are several potential threats to driver safety in individuals with CKD related to the following factors: fatigue, lack of sleep, daytime sleepiness, neurocognitive symptoms, cardiovascular events, and hypoglycemia.

The literature search identified two studies that looked at whether individuals with CKD were at greater risk for a crash; one was a case-controlled study and the other was a cohort study. The total sample size was 94. Neither study found evidence that individuals with CKD were at an increased risk for a crash. The studies were low quality and retrospective in nature. One study

relied on self-reported crash data, which are not considered reliable. The data were inconclusive and therefore not useful.

The research team also looked for studies of individuals with Stages 1 to 4 CKD to help determine the problems related to these individuals and whether the problems are likely to lead to reduced driver safety. No studies were found that looked at these individuals and their ability to drive safely, or that contained indirect evidence that they might be at an increased risk for a crash.

They looked at the research on dialysis patients but found no crash data or simulator data specific to these individuals. They did find data on individuals undergoing dialysis who had been assessed with various neurocognitive tests and sleep studies. These studies looked at a specific set of neurocognitive deficits considered by experts to be related to driver safety. The findings suggest that dialysis has a positive impact on neurocognitive function. However, sleep disordered breathing was found to be four times more prevalent in individuals undergoing hemodialysis than in the general population. This is an important finding as previous evidence reports have shown that sleep disordered breathing is highly predictive of reduced driver safety.

The evidence also indicates that individuals with CKD have an increased risk of having cardiovascular disease. About 80 percent of individuals on dialysis have left ventricular hypertrophy (LVH). Data from the 2007 United States Renal Data System Atlas show that individuals on dialysis (hemodialysis or peritoneal) have a high probability of having cardiac arrest over time. Transplant patients and individuals with Stage 1 to 4 CKD have a high probability of cardiac arrest, but the probability in the first 36 months is reduced. Individuals on dialysis are clearly at high risk for cardiac arrest.

Little direct crash-risk data are available, but the data that are available do not suggest that individuals with CKD, who are on dialysis, are at increased risk for a crash. However, the indirect data suggest that drivers with CKD, treated with dialysis and medications, are at increased risk for a crash. Further research is needed in this area to determine direct crash risk. Dr. Tregear noted that it is unclear whether the type of dialysis (hemodialysis or peritoneal) has any impact on crash risk.

Individuals with kidney transplants were also considered, but no crash studies, driver simulator studies, or direct evidence were found, so the impact of renal transplantation on driver safety is unclear. However, two small studies totaling 43 individuals were found that looked at neurocognitive function. Both studies found improvement in neurocognitive function following transplant. Another study looked at sleep-related outcomes in 841 renal transplant patients. The findings of this study indicated that one-fourth of the patients still had sleep apnea following transplant.

Dr. Hegmann thanked Dr. Tregear for his presentation and asked the MRB members if they had any questions.

Questions & Answers

Dr. Phillips: Was a difference in risk identified between hemodialysis and peritoneal dialysis patients in the data on neurocognitive fluctuation? Did any of the studies include peritoneal dialysis patients or were only hemodialysis patients involved?

Dr. Tregear: Some of the studies only looked at hemodialysis, some only looked at peritoneal dialysis, and others looked at a combination of both types. A meta-analysis of this data set would

be required to look at the differences directly. However, since there are so many neurocognitive tests, it is difficult to conduct a meta-analysis on data from different instruments.

Dr. Rizzo: What is the relationship between LVH and crash risk and did any of the studies find that LVH is measured in a standard way?

Dr. Tregear: The data were from an epidemiological study that considered the prevalence of LVH and measured it using an echocardiogram.

Dr. Rizzo: Does LVH put a driver at risk for an arrhythmia.

Dr. Tregear: A previous evidence report on cardiovascular disease included data on the impact of left ventricular ejection fraction (LVEF) on incidents of sudden death. The evidence revealed a strong correlation between LVEF and sudden death. While this evidence does not indicate a direct relationship—there does appear to be a relationship between LVH and sudden death. The prevalence of arrhythmia for individuals on dialysis in those studies was about 28 percent.

Dr. Rizzo: Was there evidence of a direct link between LVH and crash risk, and if so how much?

Dr. Tregear: No direct link was indicated.

Dr. Rizzo: Was there evidence to show that individuals with CKD and LVH are at a greater crash risk than those with LVH of the same degree and no CKD?

Dr. Tregear: I am not aware of any such evidence.

Chronic Kidney Failure and CMV Driver Safety—MEP Recommendations Stephen Fadem, MD

Dr. Fadem presented the MEP recommendations on CKD and CMV driver safety. He reviewed the significant data related to individuals with CKD, noting that 26 million Americans have CKD and 340,057 individuals are currently on dialysis therapy (hemodialysis and peritoneal). Statistics show that 106,912 new patients begin dialysis every year. However, the rate is slowing due to better disease management and new medications. Dialysis patients are healthier than ever and more able to continue normal daily activities, including driving a CMV.

Dr. Fadem presented the statistics related to morbidity in the dialysis patient population. Fiftytwo percent have diabetes, 83 percent have high blood pressure, and 34 percent have congestive heart failure in addition to other problems that could impair the ability to function as a CMV driver. He defined CKD as a glomerular filtration rate (GFR) < 60 mL/min/1.73 m² for \ge 3 months with or without kidney damage, or structural or functional abnormalities of the kidney with or without decreased GFR.

Dr. Fadem noted that the MEP recommendations are based on scientific evidence whenever possible. He stressed that FMCSA does not have physical qualification standards regarding CKD and that no guidance exists for medical examiners related to certifying an individual with CKD. Although evidence is limited, individuals with CKD do appear to constitute a risk to road safety, especially considering the underlying diseases they may have.

Recommendation #1: Identification of Individuals with CKD

The MEP recommends that FMCSA instruct its medical examiners to determine the kidney function status of all potential CMV drivers. Specifically, the MEP made the following recommendation:

- All individuals applying for medical certification to drive a commercial motor vehicle should have a serum creatinine test with calculation of the Modification of Diet in Renal Disease (MDRD) GFR in order to determine whether chronic kidney disease is present and, if present, to determine the stage of the disorder. The MDRD GFR, or eGFR is readily available from standard labs.
- All individuals with risk factors for chronic kidney disease should have a serum creatinine test with calculation of the GFR in order to determine whether CKD is present. Specific risk factors identified by the MEP included the following:
 - o Individuals with a known history of kidney disease.
 - o Individuals with a family history of kidney disease.
 - Individuals over 65 years of age.
 - o Individuals with diabetes.
 - Individuals with high blood pressure.
 - Individuals with proteinuria.

Recommendation #2: Certification of Individuals with Stages 1, 2, or 3 CKD

It is the opinion of the MEP that the mere presence of CKD does not necessarily provide grounds for restricting the driving privileges of individuals with the disease. Some individuals with early CKD may be certified as physically qualified to drive a CMV. Specifically, the MEP made the following recommendations:

- Provided that an individual is not precluded from being certified as physically qualified to drive a CMV for other reasons (e.g., because of issues related to cardiovascular disease or diabetes), individuals with Stage 1, 2, or 3 CKD may be considered as physically qualified to drive a CMV.
- Individuals with Stage 1 or 2 CKD should be re-evaluated every 2 years as part of the normal recertification process.
- Individuals with Stage 3 CKD should be recertified on an annual basis.

Recommendation #3: Certification of Individuals with Stage 4 CKD

The MEP unanimously agreed that some individuals with stage 4 CKD may be considered as qualified to drive a CMV.

- An individual with stage 4 CKD who has a normal electrocardiogram (EKG) and blood pressure less than 140 mm Hg (systolic) and 90 mm Hg (diastolic) may be certified as being physically qualified to drive a CMV for a period not to exceed 6 months. Whereupon, the individual must present for recertification.
- An individual with stage 4 CKD who has a normal EKG, but whose blood pressure falls within the range of 140/180 mm Hg (systolic) or 90/110 mm Hg (diastolic), may be certified as medically qualified to drive a CMV for a period not to exceed 3 months. Whereupon, the individual must present for recertification.
- An individual with stage 4 CKD who has an abnormal EKG, an echocardiogram that reveals LVH, blood pressure that is greater than or equal to 180 mm Hg (systolic) or 110 mm Hg (diastolic) cannot be considered as being physically qualified to drive a CMV.

Recommendation #4: Certification of Individuals with Stage 5 CKD

The MEP unanimously agreed that individuals with kidney failure should not be considered as qualified to drive a CMV.

• Individuals who require renal replacement therapy (excluding renal transplant), and those with stage 5 CKD who are not receiving renal replacement (dialysis or renal replacement) therapy, cannot be considered as fit for duty and should be disqualified from operating a CMV.

Recommendation #5: Individuals with Renal Transplants

The MEP recommended that FMCSA consider adopting the following guidelines for people who have undergone renal transplants:

- Individuals who have undergone a renal transplant with successful kidney transplantation may drive a CMV 90 days postoperatively provided that they have been cleared as fit for duty by their transplant physician.
- With the exception of differences in recertification periods, individuals who have undergone successful renal transplantation should be assessed as per recommendations 1 through 4 above.
- All individuals who have undergone successful renal transplantation should be recertified at 3, 6 and 12 months postoperatively. Thereafter, individuals should be recertified on an annual basis.

Recommendation #6: Recommendations for Further Research

The MEP recognizes that there is a dearth of data pertaining to CKD and driver safety. In particular, the association between CKD and CMV crash rates (with a particular focus on the impact of the stage of CKD) needs to be examined. Given the difficulty associated with obtaining crash data from individuals with CKD, another avenue of potentially fruitful investigation would be to examine the impact of CKD (all stages) on simulated driving performance.

Questions & Answers

Dr. Hegmann: Are the mortality rates presented annual rates?

Dr. Fadem: Yes, they are annual mortality rates.

Dr. Hegmann asked if there were any other questions from the MRB for Dr. Fadem. Noting none, he turned the meeting over the Dr. Gunnels for public comments.

Public Comments on Renal Disease

Natalie Hartenbaum, MD, speaking on behalf of the American College of Occupational and Environmental Medicine (ACOEM), stated that medical examiners have been struggling with renal disease for a long time and urged FMCSA and the MRB to expedite the relevant recommendations and standards. There is a lot of pressure on medical examiners to certify drivers on dialysis (hemodialysis and peritoneal). Distribution of guidance by FMCSA would be appreciated by medical examiners.

Dr. Hartenbaum said she thought it would be helpful to have an occupational medicine physician on the MEPs; though she added that some MEP members really do seem to understand the lifestyle of a CMV driver, as well as the role and responsibilities of the medical examiner.

Dr. Phillips: Is the urgency focused primarily on dialysis patients? Should blood be drawn as a routine part of CMV driver medical exam?

Dr. Hartenbaum: The urgency is focused on those drivers that do not belong on the road, including drivers on dialysis. Resistance can be expected from examiners on having to draw blood routinely, as it is invasive and expensive. It might be more appropriate to test the drivers with the highest risk, which would require the medical examiner to obtain the driver's history from the primary provider.

Dr. Gunnels: FMCSA has initiated a process with ACOEM to provide referrals of physicians within their membership to participate in upcoming MEPs. There are currently occupational medicine physicians involved in other FMCSA projects as well.

MRB Deliberations and Recommendations on Renal Disease

Dr. Phillips stated that the lack of direct evidence regarding renal disease and CMV driver safety provides strong support for the motions the MRB made earlier regarding the need to collect information and develop a database with significant information on CMV drivers, crash risk, and other factors. One of the issues the MRB struggled with was the discrepancies in the blood pressure cut off rates for different combinations of CKD and those that were proposed and approved previously by the MRB during their cardiovascular deliberations. The opinion of the MRB is that two different sets of blood pressure parameters and guidelines could cause confusion. The MRB also struggled with the lack of direct evidence that CKD causes crashes, although they believe it to be true.

Requiring blood work for every driver or a significant portion of the driving population is a change from existing guidelines. This raises several concerns such as, cost increases, delays in obtaining certification, false positives/negatives, liability and possible unexpected findings requiring follow-up. Additionally, precluding those on dialysis (whether hemodialysis or peritoneal) from commercial driving would also be a departure from the current regulations. The MRB needs to specifically address the issue of LVH in the presence of CKD. It is difficult to measure LVH and currently the best way is by echocardiography, which is expensive and time consuming. The MRB will conduct further discussion on renal disease. The MRB recognizes that this is an important issue that affects road safety and driver health.

Dr. Phillips concluded her comments stating that the MRB agreed with the observations and the recommendations of the MEP, with modifications, to Recommendation 5 and moved that FMCSA accept Recommendation 5 from the MEP Report as follows:

Recommendation #5: Individuals with Renal Transplants

- Individuals who have undergone renal transplant with successful kidney transplantation may drive a CMV 90 days postoperatively provided that they have been cleared as fit for duty by their transplant physician.
- With the exception of differences in recertification periods, individuals who have undergone successful renal transplantation should be assessed as per recommendations 1 through 4.
- All individuals who have undergone successful renal transplantation should be recertified at 3, 6, and 12 months postoperatively. Thereafter, individuals should be recertified on an annual basis.

Dr. Hegmann noted that the MRB unanimously approved this motion and asked if there was further discussion needed on this issue. Dr. Greenberg suggested that this topic should be included on the agenda for the July 2008 MRB meeting. Dr. Hegmann responded that his suggestion would be taken under advisement.

Vision and Commercial Motor Vehicle Driver Safety—Evidence Report Stephen Tregear, DPhil

Dr. Tregear presented the evidence report on vision and CMV driver safety. The specific areas of concern in this evidence report include the impact of the following conditions on driver safety: monocular vision, red-green color deficiency, visual field (VF) loss, cataracts, and diplopia.

Dr. Tregear summarized the findings of the report, stating that researchers looked at the evidence related to monocular vision and whether these individuals were at a higher risk for a CMV crash. Three studies met the inclusion criteria for this report. The total sample size was 74. None of the studies included in the analysis involved CMV drivers specifically, since the available data were related to general drivers. Only one of the studies found an increased risk for crash.

Another study compared simulated driving performance for 40 CMV drivers with monocular vision to CMV drivers with binocular vision. Drivers were assessed on signal recognition distance, mirror checks, lane keeping, clearance judgment, and gap errors. In general, the study found no difference between groups. There was no evidence indicating that individuals with monocular vision preformed worse than the group with binocular vision. The only exception was sign recognition among drivers with monocular vision—signs were recognized, but it took longer. It remains unclear whether individuals with monocular vision can safely drive a CMV based upon the available evidence. More evidence is needed to draw an evidence-based conclusion on this topic.

The next factor researchers examined was red-green color vision deficiency and driver safety. A cohort study was found, in which 151 individuals with color vision deficiency were compared directly to individuals with normal vision to determine crash rates between the two groups. No differences in crash rate were found. Additional studies reviewed by researchers looked at indirect measures of signal recognition and response time. Two small, low-quality studies found that individuals with color vision deficiency made more signal recognition errors than individuals with normal vision. One small, low-quality study revealed that individuals with color vision deficiency responded more slowly to color signals than individuals with normal vision. Data involving CMV drivers were not available. There is some evidence that red-green color deficiency has an impact on some tasks associated with driving, but whether it results in reduced driver safety is unknown.

The research group looked at two types of data related to VF loss—automated and manual systems. Twelve studies of low to moderate quality were reviewed. The number of individuals included in the entire evidence base was 62,500. Eight of the 12 studies found significant association between VF loss and increased crash risk. However, the data were difficult to interpret, so researchers were unable to determine if specific types of VF loss are true predictors of crash risk. Based on the data collected, optimal vision field testing parameters could not be determined.

Six studies using the Useful Field of Vision (UFOV) test were found. UFOV is not a VF test in the true sense because it measures an individual's ability to see things in a visual field under distracted circumstances. All of the studies found a strong association between loss in the UFOV and crash risk. Three of the studies set 40 percent loss in the UFOV as the threshold above which crash risk was considered significantly higher. There is strong evidence that this is a useful test; however, the data collected were not specific to CMV drivers. The conclusion is that VF loss, whether measured by standard perimetry or UFOV test, is certainly associated with crash risk.

Researchers also examined the impact of cataracts on driver safety. Only one of the four studies indicated that individuals with cataracts were at increased risk for a crash. The same study also found that crash risk is reduced following cataract surgery. A possible reason for the discrepancy between the studies is the fact that most people have cataract surgery as standard medical practice when visual acuity (VA) and visual function drop below acceptable levels. Although it is plausible for individuals with cataracts to be at increased risk for a crash because of increased glare, reduced VA, and the potential of developing diplopia, the evidence does not indicate that individuals with cataracts are at increased risk for a crash.

The final factor reviewed for the evidence report was diplopia and driver safety. Researchers found one small study that included 10 individuals. The findings of this study revealed no evidence that individuals with diplopia were at increased risk for a crash. Another study that looked at simulated driver performance was reviewed, which also provided no evidence that individuals with diplopia had reduced driving ability. Overall, the evidence is inconclusive as to whether individuals with diplopia are at increased risk for a crash.

Vision and CMV Driver Safety—MEP Recommendations Frank Berson, MD

Dr. Berson presented the recommendations of the Vision MEP. He provided a summary of the current vision standard found in CFR 391.41 and a history of the changes made to the vision standards from 1937 to 1998. The MEP agreed that some individuals with visual disorders constitute an additional risk to road safety. Regulations pertaining to minimal standards of vision are needed. Having considered the evidence reports, the MEP is prepared to make the following recommendations:

Recommendation #1: Monocular Vision

• The current standard, which precludes individuals with monocular vision from driving a CMV for the purposes of interstate commerce, cannot be changed at this time.

Recommendation #2: Red-Green Color Deficiencies

- The current standard cannot be changed at this time.
- Revisions in testing guidelines should be considered with regard to specific tests.

Recommendation #3: Visual Field Loss

- It is the opinion of the MEP that the standard should be restated and the minimal field possibly modified.
- The current standard of 70 degrees may be adequate.
 - Whether a modification is needed and what that modification should be has yet to be determined.
- The method(s) of visual field testing should be clarified.
- The confrontational test may be considered acceptable except in situations where the examinee has a history of visual disorders.
 - If the examinee has a history of visual disorders such as glaucoma, another test must be used to determine visual field loss.
 - If the examinee fails the confrontational test, another test must be used to determine visual field loss.
 - A test to determine visual field loss for individuals who fail the confrontational test or have a history of visual disorders has not been determined by the MEP.

Recommendation #4: Cataracts

• The MEP agreed that there is insufficient evidence to modify the current standard to include the possible impact of cataracts on CMV driving eligibility.

Recommendation #5: Diplopia

• The MEP did not recommend any change in the standard for diplopia.

Dr. Hegmann expressed appreciation to Dr. Berson for his presentation.

Questions & Answers

Dr. Rizzo: Are the recommendations for contrast sensitivity and glare testing potentially useful on individuals with cataracts or as general performance measures even in the absence of cataracts?

Dr. Berson: They are useful performance measures; however, the panel did not discuss them.

Dr. Rizzo: What is your clinical opinion on visual disorders or performance deficits that might create risks for nighttime driving?

Dr. Berson: The panel did not discuss this issue but certainly glare from headlights during nighttime driving would be one. For example, this could be a significant issue for an individual with posterior subcapsular cataracts that might be missed on conventional vision testing.

Dr. Rizzo: Is there any evidence that visual fields need to be continuous, and if so, what sort of interruptions or scotoma would be permissible?

Dr. Berson: The panel did not discuss this topic and further investigation would be required if changes were to be made to the standard.

Dr. Rizzo: What is the importance of the upper and lower visual fields?

Dr. Berson: If an individual has altitudinal field loss (i.e., complete loss of lower field), it would be hard to look down at the road and see what was below. The previous panel held this position as well. Alternatively, if one had complete upper field loss, it would be hard to see an overpass or a sign hanging from an overpass. The previous panel thought it made sense that there should be some vertical requirement and made the arbitrary recommendation that the vertical requirement be 20 degrees above and below fixation even though there is no evidence base to support this requirement. The current panel did not discuss this issue.

Dr. Rizzo: How would an examiner measure color vision and VF in a standard way?

Dr. Berson: The previous panel recommended an expanded description of how to do a confrontation field test. This test is carried out in a variety of ways and that more careful testing of the confrontation field is needed, particularly if there is altitudinal field loss. As for color testing, the panel suggested a standardized red, green, and amber circle be printed on a sheet of paper and the applicant be asked to identify the three colors. It would be a simple and inexpensive way to test color vision.

Dr. Rizzo: What would be the best method for detecting a potential VF loss on a detailed assessment?

Dr. Berson: The panel tried to be as generous as possible because different medical offices have different equipment and some only have central field programs. The Humphrey or Goldmann visual exams sufficiently measure the visual field if the correct program is used.

Dr. Phillips: What would be the most likely scenario in which a driver would interact with an ophthalmologist if formal visual field testing were required?

Dr. Berson: Individuals in the Federal Vision Exemption Program typically have an optometrist or ophthalmologist they are familiar with; however, a general applicant may not.

Dr. Phillips: Would a detailed evaluation for VF testing be typical for the general applicant?

Dr. Berson: The applicant would need to see an optometrist or ophthalmologist for a formal vision exam if he or she failed the confrontation field or if another problem was identified that needed further evaluation.

Dr. Phillips: The current requirement indicates that the applicant would have to see an ophthalmologist for a formal vision exam. Would it be acceptable for the exam to be done by an optometrist?

Dr. Berson: As clarification, the current requirement states that if the applicant has diabetic retinopathy, the patient is required to see an ophthalmologist to certify the condition is stable for the foreseeable future. It would be appropriate for a general applicant to see either an optometrist or ophthalmologist.

Dr. Phillips: Could a patient with diabetic retinopathy see an optometrist instead of an ophthalmologist?

Dr. Berson: The panel did not discuss this specifically, but an ophthalmologist is in a better position to manage a patient with diabetic retinopathy. Patients with this condition should see an ophthalmologist.

Dr. Rizzo: What are the options for a person with progressive ophthalmoplegia (i.e., paralysis of one or more ocular muscles)?

Dr. Berson: There are currently no restrictions against such a patient driving, but perhaps there should be.

Dr. Rizzo: What about patients with ptosis (i.e., drooping of the upper eyelid)?

Dr. Berson: The panel did not discuss ptosis, but in significant cases, ptosis would affect upper field and certainly could be a functional issue for the driver.

Dr. Hegmann: To clarify, the medical examination would be a two-step process when these more difficult subspecialty issues are involved. If the initial examiner does not feel a person is safe to drive, regardless of the issue, the examiner may preclude the applicant from driving prior to dealing with the subspecialty concerns.

Public Comments on Vision

Dr. Hartenbaum commented on Dr. Rizzo's question regarding the type of tests that medical examiners use to test visual field and color vision, noting that examiners use various VF tests from simple confrontation field to detailed vision screening machines. Color vision testing is not specific and the test used is dependent on the examiner.

Dr. Hartenbaum: Were the data presented from the Federal Vision Exemption Program or were they actually from the waiver program?

Dr. Gunnels: The data were from a recent study that included approximately 1,200 drivers from the Federal Vision Exemption Program. There were some limitations to the study. It could be made available if needed.

Dr. Hartenbaum: Are individuals who have intentional monocular vision through LASIK eligible to drive?

Dr. Berson: Examiners will not qualify them because they have only one eye for driving.

Dr. Hartenbaum: Would a driver who had LASIK for monocular vision correction be eligible for the Federal Vision Exemption Program?

Dr. Berson: These individuals are not appropriate because their best corrected vision is still 20/20, or better than 20/40. Individuals are considered for the program when they cannot correct the vision to 20/40 or better in both eyes, so these individuals would not be eligible for the program.

Dr. Hartenbaum: Why would these individuals be considered less safe than someone who has monocular vision? It seems unfair that these individuals should be forced to wear glasses when someone who can't see at all through one eye doesn't have to wear glasses and would be eligible for the program.

Dr. Berson: Agreed, it is a dilemma.

Ms. Christine Hydock, Office of Medical Programs, Federal Vision and Diabetes Exemption Programs: There currently are not any individuals who applied for exemption under this situation. There was one individual in the past who chose to wear the corrective lenses.

Dr. Berson: The waiting period after LASIK surgery also needs to be discussed.

Dr. Hartenbaum: Do the current criteria for the Federal Vision Exemption Program provide reasonable assurance that these individuals are safer than the individuals that are not in the program?

Dr. Berson: The 3-year limit seems to be arbitrary, leaning in favor of safety. Perhaps this time frame could be shorter.

Dr. Rizzo: It might be helpful to discuss the crash risk of people with monocular vision or with vision of 20/100 or worse.

Dr. Tregear: The study compared safe drivers with monocular vision to drivers with normal vision who were not safe drivers and found that when the VA in the bad eye is worse than 20/100, the crash rate is higher than any other better VA.

Dr. Gunnels: FMCSA is considering changes to the vision standard and will take the MRB and MEP recommendations into consideration and also determine if the Federal Vision Exemption Program should be continued.

Ms. Hydock: Individuals in the Federal Vision Exemption Program whose physicians recommend more frequent certification than the current annual requirement or who feel there is any potential for change, are monitored more closely.

MRB Deliberations and Recommendations on Vision

Dr. Rizzo moved that FMCSA accept MEP Recommendations 1 through 5 with modifications as listed below. The MRB unanimously adopted these recommendations.

Recommendation #1: Monocular Vision

The current standard which precludes individuals with monocular vision from driving a CMV for the purposes of interstate commerce should not be changed at this time.

Recommendation #2: Red-Green Color Deficiency

The current standard regarding red-green color deficiencies should not be changed at this time, and a revision in testing guidelines should be considered with regard to specific tests.

Recommendation #3: Visual Field Loss

The current standard of 70 degrees *may be* adequate and whether this needs a modification and what that modification should be has yet to be determined. The methods of VF testing should be clarified.

Recommendation #4: Cataracts

There is insufficient evidence to modify the current standard to include the possible impact of cataracts on CMV driving ability.

Recommendation #5: Diplopia

There should be no change to the standard on diplopia.

Musculoskeletal Disorders and CMV Driver Safety—Evidence Report Stephen Tregear, DPhil

Dr. Tregear presented the findings of the evidence report on the impact of musculoskeletal disorders on CMV driver safety. Researchers examined the following issues: amputation, arthritis, reduced range of motion, modifications and prosthetics, and their impact on driver safety.

Researchers found three studies regarding the impact of amputation on driver safety, none of which addressed CMV drivers directly. Two of the studies examined the prevalence of individuals with amputations to determine impact on crash numbers. The third study did not look at a specific type of amputation. None of the available evidence suggested that individuals who have amputations are at an increased risk for a crash.

Researchers looked at the evidence for arthritis, which was restricted to osteoarthritis and rheumatoid arthritis. None of the studies looked at the CMV driver population specifically. Seven studies examined the impact of osteoarthritis, rheumatoid arthritis, or a combination of both on driver safety. Three of those studies had crash data. Two of the three studies indicated that there is no evidence that individuals with osteoarthritis or rheumatoid arthritis are at an increased risk for a crash. One study carried out a subgroup analysis looking at the effect of gender on crash risk. This study found that women with arthritis are at an increased risk for a crash. This finding may not be particularly relevant as it resulted from only one study, and the CMV driver population is predominantly male.

Another topic researched was the impact of head and neck restrictions on driving ability and crash risk. Three studies were found, none of which included CMV driver data or crash data. All of the studies evaluated the impact of range of motion on various driving tasks. The findings indicate that restricted range of motion, especially of the neck, has an impact on various driving tasks. The implications for driver safety are unclear, but some aspect of driving ability is made more difficult.

No formal studies were found that looked at the impact of prosthetic devices or vehicle modifications for individuals with musculoskeletal disorders that met the inclusion criteria for the report. While it is assumed that modifications to vehicles and the use of prostheses do have an impact on driver safety, qualified studies demonstrating this to be true do not exist.

Dr. Andersson clarified that although some of these musculoskeletal conditions cause functional loss, there is no evidence to tie that function loss to crash risk. Dr. Tregear concurred with Dr. Andersson's restatement.

Musculoskeletal Disorders and CMV Driver Safety—MEP Recommendations Nortin Hadler, MD

Dr. Hadler, the representative from the Musculoskeletal Disorder MEP, stated that the panel had nothing to add to the review of the literature presented by Dr. Tregear. The MEP's approach to suggesting changes to the standards was focused on function, rather than specific diagnoses, and included investigative recommendations. The MEP's recommendations are as follows:

Recommendation #1: Current Standards

The current FMCSA standards for musculoskeletal disorders should be altered. The current standards are too general and in their present form are not appropriate for the broad spectrum of conditions which comprise the category of musculoskeletal disorders.

Recommendation #2: Functional Tests of Capacity/Fitness for Duty

FMCSA should use trained driving testers to perform functional capacity examinations of CMV drivers under the premise that there must be a minimum level of musculoskeletal capability required to safely drive a CMV. The process for Skill Performance Evaluation (SPE) as currently constituted should not be altered. Specifically, the MEP made the following recommendations:

- A functional capacity evaluation should be required for any individual with an episodic and/or potentially progressive musculoskeletal disorder who had required evaluation and/or treatment by a physician/health care provider for a particular disorder in the prior 12 months.
- The functional examination of musculoskeletal capacity should take place every 2 years, regardless of type or severity of impairment.

- If there is a significant confounding medical problem exacerbation, progression, or new symptoms that require evaluation and/or treatment, re-examination may need to be done sooner.
- A thorough assessment, including a functional driving test and testing of ability to perform pre-trip and en route vehicular safety checks, dictated by the type of impairment, should be performed by trained driving testers to determine whether the individual in question should be allowed to drive a CMV.
 - The tests would not need to be administered by a medical examiner. Instead, they could be administered by a physician or others as approved by FMCSA.
 - The tests need to be sensitive and specific to the disorder.
 - It should be required that individuals who undergo the assessment do so in the CMV they intend to operate and use whatever adaptive equipment required to drive the CMV.
 - If the examination is comprehensive (includes 100 percent of all safety skills), and the individual passes the examination using adaptive equipment in the vehicle they intend to drive, then that individual has satisfied the requirements.
- A restriction should be instituted requiring the individual to use the adaptive equipment when operating a CMV. This restriction would operate in much the same way as the requirement for private motor vehicle drivers to wear corrective lenses while driving to address visual disorders such as myopia.

Recommendation #3: Development of a Functional Screening Protocol

As stated in Recommendation 2, a functional capacity test to determine whether an individual is physically qualified to drive a CMV should be performed. Currently no such test exists. Further research should be performed to determine the elements of the functional screening protocol and should include the following:

- A determination of the physical requirements needed to safely drive a CMV, including pretrip and en route vehicle safety checks. Possible physical requirements include:
 - Body size, reach, and range of motion (ROM), strength, and similar metrics need to be characterized in the context of tasks required to safely drive a CMV.
- Once the metrics have been characterized, a panel of experts should be convened to decide the following:
 - The tests that would best examine these metrics.
 - The parameters for passing or failing these tests.
 - Three to seven 'vital skills' to assess the ability of an individual with a musculoskeletal disorder to safely drive a CMV.
 - The panel of experts may consist of physicians, ergonomists, occupational therapists, industry, union and advocacy group representatives, and individuals with specific academic or industry expertise in motor vehicle safety and musculoskeletal function.

Recommendation #4: The Role of Musculoskeletal Disorders in CMV Crashes

There is not enough evidence on musculoskeletal disorders and crashes to make a determination as to the possible risk of motor vehicle crash associated with the disorders. Possible areas to explore include:

- Convening an expert panel to advise how to use existing databases and/or how to design future studies to answer the critical questions.
- Creating a sampling plan of a subset of at fault or partially at fault drivers to investigate some of the causal factors for crashes used in the *Large Truck Crash Causation Study* (LTCCS).
- Identifying resources for obtaining information on crashes such as trucking fleets, the United States military, the United States Postal Service, and manufacturers of trucks, etc.

Recommendation #5: Specific Disorders and CMV Driving

The MEP recommended that individuals with musculoskeletal disorders should be allowed to drive provided they pass the functional capacity testing.

- CMV drivers with episodic and/or progressive conditions and/or impairments should be responsible for identifying any exacerbation and disease residuals and to plan their driving accordingly.
- CMV drivers who are recent amputees should receive counseling on driving pedal techniques.

Dr. Andersson stated that the MRB reviewed the evidence report and MEP recommendations and agrees with the idea that the focus should be on function and not on diagnosis. The MRB agrees that functional standards should be determined and a simple screening test could be developed for the purpose of testing an individual's ability to meet the standards. There should also be a driving-specific capacity test or road test for those who fail the screening test.

Dr. Hegmann stated his understanding was that the exam is currently a two-step process—the driver is screened by the initial medical examiner and if they fail, they would go through testing similar to the current SPE examination.

Dr. Hadler clarified that the initial medical examiner decides whether an SPE is necessary based on criteria that are not established (except for amputations). There is no uniformity of data to trigger an SPE in the examination process and outcome data are not available. These issues represent criteria for research questions, and given the number of drivers, it should not be difficult to generate data. A simple screening test should be developed for task demands and used during the physical examination.

Questions & Answers

Dr. Hegmann: Who must perform the SPE exam?

Dr. Gunnels: It should be conducted by FMCSA or State level personnel.

Public Comment on Musculoskeletal Disorders

Roger Mackbach, a CMV driver, stated that he lost his right arm in a boating accident on May 29, 2006. The accident caused the amputation of his right arm above the elbow, which has severely affected his ability to drive a CMV, though the prosthetic devices have helped compensate for his lost abilities. He regained his CDL with SPE certification in February of this year and has logged approximately 200 hours since.

Mr. Mackbach stated he understands the need to screen amputee drivers, but if a driver can demonstrate at the DOT physical that they are able to perform the necessary tasks, they should not have to go through the SPE Certification Program. He emphasized that SPE is a great program that should definitely be continued and that the SPE Program he went through to regain his CDL was very well planned out.

Dr. Hartenbaum noted that this is one of the areas where the examiner is not just looking at the driver's ability to drive. The examiner is asked on the medical exam form to assess if the driver can do both driving and non-driving tasks (e.g., inspecting, loading, unloading, getting into and out of the vehicle, etc.). Many carriers use these exams for pre-placement to determine if the

driver can do the job, but the exam is not vehicle or carrier specific. While the data are being evaluated for driving and crashes, perhaps some thought could be given to how the examiner is to assess the non-driving tasks they are asked to evaluate.

MRB Deliberations on Musculoskeletal Disorders

Dr. Andersson presented the following recommendations as adopted from the MEP:

Recommendation #1

The focus of the evaluation of musculoskeletal conditions should be on function rather than diagnosis.

Recommendation #2

FMCSA should obtain information about the physical requirements needed to safely drive a CMV, to include pre-trip and en route safety inspections.

Recommendation #3

FMCSA should convene an expert panel tasked with developing a physical screening instrument for the medical examiner.

Recommendation #4

FMCSA should standardize the driving-specific work capacity evaluation (road test) to include pre-trip and en route safety inspections.

Recommendation #5

FMCSA should stimulate research on the effect of musculoskeletal injuries on driver safety.

These recommendations were unanimously approved by the MRB.

General Public Comments

Following deliberations, Dr. Hegmann turned the meeting over to Dr. Gunnels for a general public comment period. Dr. Gunnels noted that the MRB finalized recommendations on sleep apnea and seizure disorders at the last MRB meeting. She invited the public to comment on these or any other topics not discussed during the meeting. No comments were made.

Adjournment

Noting no further comments, Dr. Hegmann adjourned the meeting at 11:01 a.m.



CERTIFICATION

The minutes were approved by the Medical Review Board on

(Date)

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

Kurt Hegmann, MD

Chairperson Medical Review Board

Maggi Gunnels, PhD Designated Federal Official Medical Review Board