



**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 sleep apnea and seizure disorders on January 28, 2008, at the Hilton Salt Lake City Center in Salt Lake City, Utah. 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:

Alan Pack, MD
Gregory Krauss, MD

FMCSA Staff:

Mary D. Gunnels, Ph.D, Director, Office of Medical Programs
Kaye Kirby, Team Leader, Medical Review Board

FMCSA Field Staff:

Robert Kelleher, FMCSA Utah Division

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
Lonnie Weiss, Weiss Consulting

Members of the Public:

Rich Adamich, Sleep Apnea Solutions
Patrick Bradley, ResMed
John Chester, Owner-Operator Independent Drivers Association
Ty Cline, Sleep Pointe
Debbie Darger, Utah Department of Public Safety
Hugh Ekengren, Sleep Pointe
Benjamin Gerson, University Services
Terry Gill, United Parcel Service
Natalie Hartenbaum, OccuMedix
Jeff Hayes, DriveSafety
Micah Henderson, Union Pacific Railroad
Jim Herdegen, University of Illinois at Chicago
Barry Kimberley, NeoSom Clinics
Grey Loyd, Union Pacific Railroad
Charles Maffei, Respiroics
Michael Megehee
Gary Moffitt, Road Ready, Inc.
Darwin Moore, ResMed
Duke Naiphon, Sleep Pointe
Bob Perry, Roadside Medical Clinics
Kevin Potts, Union Pacific Health Systems
Connie Simper, Utah Department of Public Safety
Wendy Sullivan, Precision Pulmonary Diagnostics
Melissa Theriault, Owner-Operator Independent Drivers Association
Richard Thiel, University Services
Randy Thinnis, ResMed
Dan Vancil, Road Ready, Inc.

Joel Whiteman, Road Ready Inc.
Richard Zimet, Cephalon
Jeff Zuhl, REM Medical

Teleconference Participants:
Gary Gross, Epilepsy Foundation
Jay Whitehead, New York Department of
Transportation

Call to Order

Mary D. Gunnels, Director, Office of Medical Programs, FMCSA, called the sixth public meeting of the MRB to order, noting that she was the Designated Federal Official for the meeting. She introduced Kurt Hegmann, MD, as the Chairperson of the MRB. Dr. Gunnels announced that there would be two periods of public comment during the meeting and requested that comments be limited to the topics discussed during the meeting. Dr. Gunnels stated that following the public comment period the MRB would deliberate and present their recommendations on sleep apnea as well as the deferred topic of seizure disorders for which discussions began at the July 2007 meeting.

Dr. Gunnels requested that attendees complete an evaluation form before leaving the meeting. She announced that the meeting would be recorded and minutes would be prepared. The recording will be made available upon request and the detailed summary of the meeting will be posted on the MRB Web site at www.mrb.fmcsa.dot.gov.

Agenda Overview, Approval of July 2007 Meeting Summary and Discussion of Other Matters

Dr. Hegmann opened the meeting. He noted a slight adjustment to the agenda—public comments and MRB deliberation on sleep apnea will precede the discussion on seizure disorders. Dr. Hegmann called for approval of the minutes of the fifth meeting of the MRB, held on July 26, 2007. The minutes were unanimously approved.

Dr. Hegmann invited discussion of other MRB matters. Barbara Phillips, MD, suggested that a procedure for reviewing medical topics be institutionalized in an effort to ensure the data are current and relevant for commercial drivers. She moved that the MRB recommend to FMCSA that there be annual review of the medical topics by means of a systematic literature search to ensure that guidelines stay current. The MRB unanimously approved this motion.

Dr. Phillips proposed that the MRB pass a resolution to support increased funding on research of risk factors for and prevalence of commercial vehicle crashes. The MRB unanimously approved this motion.

Sleep Apnea and Driving—Evidence-Based Research Stephen Tregear, DPhil

Stephen Tregear, DPhil, presented the highlights of the evidence report findings on “Obstructive Sleep Apnea (OSA) and Commercial Motor Vehicle Driving.” His literature search was aimed at studies that would help develop answers to the following key questions:

Key Question #1: Are individuals with OSA at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have the disorder?

Key Question #2: What disease-related factors are associated with an increased motor vehicle crash risk among individuals with OSA?

Key Question #3: Given the findings of Key Question #2, are individuals with OSA unaware of the presence of the factors that appear to be associated with an increased motor vehicle crash risk?

Key Question #4: Are there screening/diagnostic tests available that will enable examiners to identify those individuals with OSA who are at an increased risk for a motor vehicle crash?

Key Question #5: Which treatments have been shown to effectively reduce crash risk among individuals with OSA (as determined by crash rates or through indirect measures of crash risk)?

Key Question #6: What is the length of time required following initiation of an effective treatment for patients with OSA (determined by Key Question #5) to reach a degree of improvement that would permit safe driving (as determined by crash rates or through indirect measures of crash risk)?

Key Question #7: How soon following cessation of an effective treatment (e.g., as a consequence of noncompliance), will individuals with OSA demonstrate reduced driver safety (as determined by crash rates or through indirect measures of crash risk)?

Key Question Responses

Key Question #1

Seventeen studies were identified that addressed Key Question #1. Two of these studies were directly relevant to commercial motor vehicle (CMV) drivers and the remaining 15 applied to the general driver population. These studies were of low to moderate quality.

One of the two CMV driver studies included participant responses to a questionnaire using two sleep tests: the Multivariable Apnea Prediction Index and the Epworth Sleepiness Scale. These tests were used to make a diagnosis of whether the participants had OSA. This was not considered a high-quality study because the data were not based on a true diagnosis. Findings showed that when a threshold was set for these two tests and a diagnosis made, individuals with OSA were at increased risk for crashing.

Dr. Tregear noted that the other CMV driver study was of moderate quality. In this study, drivers were tested using a portable polysomnography (PSG) test called MESAM 4 to determine whether the drivers had OSA. The drivers were then asked to respond to a questionnaire asking about crash history in the previous 5 years. The significant findings from this study showed that individuals with a diagnosis of OSA were twice as likely to crash as those without OSA; however, the researchers found no correlation between severity of OSA and crash rate. This was most likely due to the size of the study sample, which was only 90 individuals. Dr. Tregear noted that the study also looked at the relationship between obesity and OSA and that it is common to see an association between body mass index (BMI), OSA, and crash risk.

The review of the remaining research involving the general driver population helped determine the extent to which OSA is a problem. The median quality of the 15 studies involving crash risk of people with and without OSA was low. Therefore, data from nine of the 15 studies were combined to estimate the size of the problem. Dr. Tregear indicated that the findings from this analysis showed that individuals with OSA are between 30 percent and 472 percent more likely to have a crash. The mean crash risk ratio is 2.72, which indicates a 172 percent increased chance of a crash. He concluded that, based on the data, individuals with OSA are at an increased risk for a motor vehicle crash.

Key Question #2

Ten studies were found that addressed Key Question #2, which looked at several parameters used to measure severity of OSA. Dr. Tregear highlighted the four parameters that repeatedly indicated high risk: severity of disordered respiration, presence and degree of daytime sleepiness, blood oxygen saturation levels, and BMI. He noted that these four parameters are associated with increased crash risk in individuals with a diagnosis of OSA.

Key Question #3

There was only one study that included data for CMV drivers; this was insufficient to draw a conclusion. Therefore, the research group focused on daytime sleepiness for analysis related to Key Question #3. The evidence suggests that individuals with OSA are not very good at judging how sleepy they are. Three studies used the Epworth Sleepiness Scale to measure an individual's sleepiness before and after treatment. The findings revealed that individuals discovered how much better they felt after continuous positive airway pressure (CPAP) treatment and how much sleepier they were at the beginning of the test.

Key Question #4

In response to Key Question #4, the research group reviewed 43 studies which looked at various portable treatment systems to determine if these systems are as good as a PSG test in a sleep lab. The analysis of the comparison of a variety of portable systems revealed that, although none of the instruments are as good as a PSG test in a sleep lab, they are potentially a good alternative and a less expensive option. Dr. Tregear added that a portable system may not be accurate enough to be considered acceptable. He said a formal decision analysis or cost-effectiveness analysis would need to be carried out to determine the consequences of making a mistake, as there will be mistakes using a portable system for treatment.

Key Question #5

Several studies were reviewed to determine which treatments are most effective in reducing crash risk. The studies looked at various treatment options, including behavior modification, weight-loss programs, CPAP machines, dental appliances, various medications, and surgery. Dr. Tregear stated that the inclusion criterion for these studies was that the study must be a randomized control trial. Strong data indicate that of all the treatment options available, CPAP treatment is most effective in reducing crash risk. The data indicate that there is a 72 percent reduction in crash risk for drivers on CPAP treatment.

Key Question #6

Dr. Tregear noted that only three studies addressed Key Question #6. One of the studies found that effective CPAP treatment reduced crash risk, but did not reduce it to a normal risk level. The findings of the other two studies indicated a reduction to normal risk level. He noted that because of lack of agreement and the fact that there were only three studies that addressed this question, more data would be required to make a conclusion.

Key Question #7

CPAP treatment has been identified as the only treatment demonstrated to reduce crash risk. Dr. Tregear noted that optimal effectiveness can be achieved after only one night of treatment. He stated that it is difficult to show impact on crash risk in one night, but that after one night of treatment, there is measurable improvement in the surrogate markers of crash risk (e.g., severity of disordered breathing, blood oxygen saturation). He added that the evidence is clear that after 2 weeks of treatment, CPAP reaches its maximum effectiveness.

Regarding the consequences of non-compliance, Dr. Tregear noted that missing one night of treatment can have an impact on function. Whether that increases crash risk is unknown, but it does impact the surrogate markers of crash risk. Changes to function occur within 24 hours.

Dr. Hegmann expressed thanks to Dr. Tregear for his presentation and asked the MRB members if they had any questions. Dr. Phillips stated that although there is no question that OSA increases crash risk, clearly most people with OSA do not crash. The predictors of crash are sleepiness (which is not a particularly reliable measure), BMI, oxygen saturation, and apnea-hypopnea index (AHI). Dr. Tregear concurred with this clarification. Dr. Phillips referred to the study which used AHI to predict crash, and asked whether the AHI was derived from a portable device. Dr. Tregear answered yes—a portable MESAM device was used to measure oxygen desaturation.

Dr. Hegmann asked for clarification of the blanks in the Risk Factor Table included in Dr. Tregear's presentation. Dr. Tregear noted the blanks indicated they did not look at that particular measure.

Matthew Rizzo, MD, asked if any clear cut points of the four measures of prediction of crash were found. Dr. Tregear replied that the prediction models indicated a continuum rather than obvious cut points—as BMI increases the risk for crash increases. Dr. Phillips noted that the research showed a difference in crash risk between obese and non-obese individuals; obese was defined as a BMI of 30 or greater. Dr. Tregear concurred.

Sleep Apnea Medical Expert Panel Recommendations

Allan Pack, MD

Dr. Pack stated he was a member of the Sleep Apnea Medical Expert Panel (MEP) and was responsible for presenting the panel's recommendations. He noted that in middle age, the major risk factor for OSA is obesity and that overall the issue for drivers is the relationship between BMI (obesity) and OSA. He noted that the data from a study conducted in 2004 of BMI in CMV drivers showed that 30 percent of drivers had a BMI of 30-35 and 13 percent had a BMI of 35-40. Therefore, the data indicate this problem impacts a large number of drivers.

Dr. Pack explained that OSA is measured on a continuum with the AHI, which is defined as the measure of the number of breathing disturbance episodes, either cessations or declines per hour of sleep. These episodes are counted and categorized as follows to determine the AHI: mild (5-15 episodes), moderate (15-30 episodes), and severe (more than 30 episodes). Based on the data, the higher the AHI, the more likely the individual is to have excessive sleepiness.

Dr. Pack noted that a study of CMV drivers found that if BMI is used to determine who is more likely to have OSA, the recommended cut point is a BMI of 33.

The MEP recommended that FMCSA's current guidelines for individuals who have OSA be replaced with the following:

Recommendation #1: General Guidance

- A diagnosis of OSA precludes an individual from obtaining an unconditional certification to drive a CMV for the purposes of interstate commerce.
- A diagnosis of OSA, 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 OSA may be certified to drive a CMV if that individual meets the following criteria:
 - Has untreated OSA with an AHI < 20, and
 - Has no daytime sleepiness, or
 - Has OSA that is being effectively treated.
- An individual with OSA who meets the requirements for certification described above should be recertified annually, based on demonstrating satisfactory compliance with therapy.

Recommendation #2: Drivers who should be disqualified immediately or denied certification

- Individuals who report that they have experienced excessive sleepiness while driving, or
- Individuals who have experienced a crash associated with falling asleep, or
- Individuals with an AHI > 20, until such an individual has been adherent to CPAP. They can be conditionally certified based on the criteria for CPAP compliance as outlined in Guideline 3, or
- Individuals who have undergone surgery and who are pending the findings of a 3-month post-operative evaluation, or
- Individuals who have been found to be non-compliant with their CPAP treatment *at any point*, or
- Individuals who have a BMI > 33 (pending evaluation by a sleep study). (This is the position of 80 percent of panel members.)

Recommendation #3: Conditional Certification

The MEP recommends the following groups of individuals with OSA be conditionally allowed to drive a CMV:

- Individuals with a BMI greater than or equal to 33 may be conditionally certified for 1 month pending sleep study evaluation. The panel noted that this period should be less than 1 week; however, given the current infrastructure for sleep studies in the U.S., obtaining a sleep study within 1 week is unlikely to be feasible in many cases. Consequently, the panel recommends a transition period of 2 years, during which time efforts be made to improve the infrastructure so that the period between requesting a sleep study and obtaining that study can be reduced to 1 week for certification.
- If diagnosed with OSA, 1-month certification.
- If compliant with CPAP at 1 month, 3-month certification.
- If compliant with CPAP at 3 months, 1-year certification.
 - Warn drivers about the danger of stopping therapy.
 - Warn drivers they could be liable if they stop using therapy and are involved in a crash.
- Recheck compliance in 1 year (all data).
- Minimal CPAP compliance greater than 4 hours per day for 70 percent of days.

Recommendation #4: Referral for Confirmation of Diagnosis or Stratification of Severity

- Individuals who meet the following criteria should be required to undergo an evaluation to confirm the diagnosis of, and, if necessary, to stratify the severity of OSA:
 - Those categorized as high risk for OSA according to the Berlin Questionnaire, or
 - Those with a BMI ≥ 33 kg/m², or
 - Those judged to be at risk for OSA based on a clinical evaluation.

Recommendation #5: Identification of Individuals with Undiagnosed OSA

- Medical examiners should actively screen for OSA in all individuals who request fitness for duty certification for the purpose of driving a CMV in interstate commerce.
- Symptoms suggestive of OSA include:
 - Chronic loud snoring.
 - Witnessed apneas or breathing pauses during sleep.
 - Daytime sleepiness.
- Risk factors for OSA are:
 - Advancing age.
 - BMI ≥ 28 kg/m².
 - Small jaw.
 - Large neck size [≥ 17 inches (male) ≥ 15.5 (female)].
 - Small airway (a narrow or edematous oropharynx).
 - Family history of OSA.
- Conditions known to be associated with a high risk of OSA include the following:
 - Hypertension (treated or untreated).
 - Type 2 diabetes mellitus (treated or untreated).
 - Hypothyroidism (untreated).

Recommendation #6: Method of Diagnosis and Severity

- The preferred method of diagnosis and assessment of disease severity is overnight PSG.
- Acceptable alternative methods for assessment of risk in CMV drivers include objective recording devices validated against PSG that include at least 5 hours of measurement of:
 - Oxygen saturation, and
 - Nasal pressure, and
 - Sleep/wake time.
- Regardless of the type of study performed, individuals should be tested while on their usual chronic medication regime.

Recommendation #7: Treatment of OSA—Continuous Positive Airway Pressure (CPAP)

The MEP recommends that FMCSA consider adopting the following guidelines on the appropriate treatment of individuals with moderate-to-severe OSA:

- All individuals with OSA who require treatment should be referred to a clinician with relevant expertise.
- CPAP is the preferred method of therapy.
- Adequate CPAP pressure should be established through one of the following means:
 - An in-laboratory titration study.
 - An auto-titration system without an in-laboratory titration.
- Individuals with OSA who have been treated with CPAP may be certified if they have been successfully treated for a minimum of 1 week.
 - Successful CPAP treatment is defined as follows:
 - Demonstration of good compliance with treatment (see below).
 - Resolution of excessive sleepiness when driving.
- Individuals with OSA who are treated with CPAP must demonstrate compliance with treatment and this must be documented objectively.
 - Compliance is defined as using CPAP for the duration of total sleep time.
 - Optimal treatment efficacy occurs with 7 hours or more of use during sleep; however, 4 hours of documented time at pressure per major sleep episode is minimally acceptable.

- Based on current standards of practice, an acceptable CPAP use is at least 4 hours of use per night on at least 70 percent of nights.

Recommendation #8: Treatment of OSA—Alternatives to CPAP

- Dental appliances and surgery are considered to be potential alternatives to CPAP for the treatment of OSA.
 - Currently there is no method to monitor compliance among individuals treated with dental appliances. Consequently, use of dental appliances cannot be considered an acceptable alternative to CPAP in individuals who require certification to drive a CMV in interstate commerce.
 - Compliance among individuals who have undergone surgical treatment for OSA is less of an issue. Consequently, surgical treatment (bariatric, upper airway soft tissue, facial bone, and tracheostomy) is deemed an acceptable alternative to CPAP (see later guidelines).

Recommendation #9: Treatment of OSA—Bariatric Surgery

- Individuals who have undergone bariatric surgery may be certified if they are:
 - Compliant with CPAP (see guideline for CPAP requirements), or
 - 6 months post-operative (to allow time for weight loss), and
 - Cleared by treating clinician, and
 - Sleep exam indicates that $AHI \leq 10$, and are
 - No longer excessively sleepy.
- For individuals certified based on these criteria, re-evaluation by sleep study within 2 years should be required if they are not on CPAP therapy.
- Individuals who are off CPAP therapy should be given information that they need to seek re-evaluation if they gain significant weight (more than 5 percent) or their symptoms of OSA recur.

Recommendations #10, #11 and #12: Treatment of OSA—Oropharyngeal, Tracheostomy, and Facial Bone Surgery

- Individuals with OSA who have been treated with oropharyngeal, tracheostomy, or facial bone surgery may be certified if they:
 - Are more than 1 month post-surgery, and
 - Are cleared by treating clinician, and
 - Do not experience daytime sleepiness, and
 - Have an $AHI < 10$.
- Annual recertification required:
 - Annual objective testing with $AHI < 10$, and
 - No daytime sleepiness.

Recommendation #13: Patient Education

- Individuals with OSA who meet the criteria for certification should be provided with education on the following:
 - The importance of adequate sleep.
 - Lifestyle changes:
 - Weight loss.
 - Smoking cessation.
 - Exercise.
 - Reduced alcohol intake.
 - The importance of treatment compliance (if relevant).

- The consequences of untreated OSA, including:
 - Loss of certification.
 - Crash.
 - Hypertension.
 - Cognitive dysfunction.
 - Heart disease.
 - Reduced quality of life.
 - Reflux.
 - Headaches.
 - Shorter survival.
 - Sleep disruption.
- Effects of respiratory or central nervous system depressants on OSA.

Recommendation #14: Areas Requiring Development of Guidance

- Other causes of excessive daytime sleepiness:
 - Insufficient sleep.
- Insufficient time in bed/sleep deprivation.
- Medical illnesses:
 - e.g., chronic pain syndromes.
 - Other primary sleep disorders:
 - Narcolepsy.
 - Idiopathic hypersomnia.
 - Restless Legs Syndrome.
 - Shift work sleep disorder.
- Development of a national registry of certified drivers with full medical histories.
- Further research is required in the following areas:
 - Effects of OSA on crash risk among CMV drivers.
 - Effects of various OSA treatments on crash risk among CMV drivers.
 - Risk factors for crash among individuals with OSA and other sleep problems.
 - Improved risk stratification and prediction in CMV drivers.
 - Evaluation of alternatives to PSG in CMV drivers.

Additional Recommendations:

- FMCSA should consider creating incentives for large trucking companies to develop fatigue management models.
- FMCSA should couple an information dissemination program with these models.

Dr. Hegmann expressed appreciation for Dr. Pack's presentation.

During discussion, Dr. Phillips asked for examples of how sleep/wake time can be assessed without electroencephalography (EEG). Dr. Pack said that actigraphy or modified actigraphy would be an acceptable alternative to EEG in assessing sleep/wake time. Dr. Pack noted that individuals need to be retested following any corrective surgery. Although the issue was not discussed by the MEP specifically, Dr. Pack indicated that portable PSG systems would be acceptable for OSA testing.

Dr. Rizzo asked for clarification regarding the percentage of drivers with a BMI of 30 or higher. Dr. Pack stated that 42 percent of drivers have a BMI of 30 or above. Dr. Rizzo noted that one expert panel member indicated that a BMI of >30 should trigger an evaluation for OSA, which

would mean that about 40 percent of all truckers currently driving would need to be evaluated. Dr. Pack concurred with his statement and added that if a BMI of 33 was used to trigger an evaluation for OSA, the number of truckers needing evaluation would drop to 24 percent.

Public Comments on Sleep Apnea

Ms. Wendy Sullivan, formerly with Schneider National, Inc., expressed appreciation to the MRB for their efforts. She stated that Schneider National has conducted extensive research on medical issues and has a considerable database that includes more than 13,000 drivers. She added that getting to the root of the problem is essential and noted that there will be a significant health care savings when proper treatment is implemented; however, the trucking and motor carrier companies will be the ones paying for the tests and treatment, which should be taken into consideration.

Ms. Sullivan agreed that compliance monitoring is essential and proposed that ways be sought to keep drivers driving while on CPAP. She emphasized that 2 or 3 hours of CPAP treatment is better than none because of the degree of immediate correction as noted by the experts. She also stated that Schneider National requires mandatory testing and compliance monitoring for OSA and that more than 1,900 drivers have been treated for OSA. Ms. Sullivan pointed out that bariatric surgery is not the best treatment option as it is not covered by insurance. Drivers cannot afford it and many drivers still need CPAP after surgery. She said compliance monitoring is critical, as is FMCSA and medical examiners holding the drivers accountable.

Natalie Hartenbaum, MD, OccuMedix, stated that finding a reliable way of monitoring effective treatment is essential. She expressed a concern that for many drivers, getting a new machine that is capable of measuring compliance is an issue because new machines are expensive and usually not covered by insurance.

In relation to Ms. Sullivan's comment, Dr. Hartenbaum expressed the concern that many smaller companies may not be able to control or monitor OSA to the same degree as the larger companies like Schneider National. Dr. Hartenbaum suggested that there could be a mechanism in place to provide ongoing compliance monitoring while allowing drivers to keep driving.

MRB Deliberations on Evidence Report and Panel Recommendations on Sleep Apnea

Dr. Phillips noted that the original MEP report made reference to the "clinician" who would be evaluating and treating CMV drivers. As a point of clarification, she moved that the MRB recommend replacing the word "clinician" in the MEP Recommendations with the phrase "a qualified physician with relevant expertise in sleep apnea." The MRB unanimously approved this motion.

Dr. Phillips stated that the data regarding BMI are compelling. She also recognized that the cut point for BMI is a contentious issue for both the MEP and the MRB. She moved that the MRB recommend a BMI cut point of >30 as the criterion which would trigger referral for testing for sleep apnea. Dr. Hegmann noted that the motion carried four to one, with one negative vote.

During discussion, Dr. Rizzo explained his objection to the motion. He noted that the data are quite clear that BMI is related to sleep apnea and that BMI alone may be a risk factor for crashes. The evidence for the cut point is unclear and needs further investigation.

Noting no further comments on the topic, Dr. Hegmann introduced Gregory Krauss, MD, to present the MEP recommendations on seizure disorders.

Seizure Disorders Medical Expert Panel Recommendations Gregory Krauss, MD

Dr. Krauss reported on the recommendations of the MEP related to seizure disorders and CMV driver standards. The MEP reviewed existing FMCSA guidelines regarding seizure disorders and the evidence report compiled by Dr. Tregear. The MEP unanimously agreed on all the recommendations.

Dr. Krauss stated that the MEP's goal was to recommend changes to existing guidelines if the currently available evidence supported such changes.

The MEP's guiding principles in developing recommendations were as follows:

- Any recommended changes to existing guidelines must be supported by evidence.
- Any recommended changes to existing guidelines should be actionable (i.e., easily carried out by medical examiners and well understood by the general public).
- The wording of the recommended changes to existing FMCSA guidelines should be concise and unambiguous.

Dr. Krauss provided background regarding the risk of seizures and driving. He noted that little data currently exist for commercial drivers with seizures, but there is significant data in the general population. The U.S. mortality rate report indicates that seizure-related fatal crashes are slightly more likely when compared to diabetes, cardiovascular disease, hypertensive disorder, alcohol, young drivers, and other risk groups. The number of fatal driver crashes related to seizures is still quite small. He noted that during a 3-year period there were 80-97 fatal crashes annually involving drivers with seizure disorders, indicating that only a small fraction of total fatal driver crashes in the U.S. are related to seizures.

In examining the various subgroups of patients who have epilepsy, it was determined that there is a high level of heterogeneity, which affected the meta-analysis. Dr. Krauss stated that about 60 percent of patients have seizures that are easy to control, and 40 percent of patients have seizures that are difficult to control. Based on this, researchers determined that the best way to stratify this group was not to evaluate each of their causes for epilepsy and specific treatment factors individually, but to rely on seizure-free periods as an index of seizure control. This has been a relatively reliable marker used throughout the United States to restrict driving for non-commercial drivers with epilepsy.

Dr. Krauss referred to a study he conducted that compared patients with epilepsy who had driven and crashed to those who had epilepsy, had driven, and not crashed. He said that the odds of crashing are markedly reduced with long seizure-free intervals. Patients with a seizure-free period greater than 12 months had .075 odds of crashing compared to persons with shorter seizure-free intervals. He noted that using this cut point reduces the odds of crashing by about 93 percent. He concluded that the duration of the seizure-free period is a good marker in terms of predicting future risk for seizure recurrence. The MEP guidelines are based on this conclusion.

Dr. Krauss indicated that the random effects meta-analysis of several studies considered by the MEP included limited data regarding individuals receiving medical treatment; however, it was consistent with those who had surgical treatment for their epilepsy. The outcome data measured patients who had surgery and risk of seizure recurrence over time.

He noted that risk of seizure recurrence after 8 years was less than 2 percent and the risk of seizure recurrence after 10 years was less than 1 percent. He said that many other countries, such as Canada, Australia, Sweden, and the United Kingdom, accept an annual risk of less than 2 percent. He concluded that an annual risk of less than 2 percent is sufficiently low to permit an individual to be certified to drive a CMV.

Dr. Krauss stated that given a 2 percent risk of seizure recurrence, the chance of a patient having a recurring seizure while driving is less than 0.3 percent annually in a 50-hour work week. He also noted that a majority of patients crash if they have a seizure while driving, but overall, the annual risk of having a seizure-related crash in this population is still less than .017 percent.

Dr. Krauss reviewed existing FMCSA guidelines regarding seizure disorders and then presented the following MEP recommendations:

Recommendation #1: Epilepsy

The MEP recommends that current guidelines pertaining to individuals with a diagnosis of epilepsy be replaced with the following:

- A history of epilepsy precludes an individual from obtaining unconditional certification to drive.
- A history of epilepsy, however, should not unconditionally exclude all individuals from driving, and conditional certification may be possible in some instances.
- An individual with a history of epilepsy may obtain conditional certification if they meet the following criteria:
 - An individual must have been seizure free for a minimum of 8 years on or off anti-seizure medication; and
 - If all anti-seizure medications have been stopped, the individual must have been seizure free for a minimum of 8 years from time of medication cessation; or
 - If still using anti-seizure medication, the individual must have been on a stable medication regimen for a minimum of 2 years.
 - An individual with a history of epilepsy who has been granted conditional certification to drive a CMV must be recertified on an annual basis.

Recommendation #2: Single Unprovoked Seizure

The MEP recommends the current guideline for individuals who have experienced a single, unprovoked seizure be replaced with the following:

- A history of experiencing a single, unprovoked seizure precludes an individual from obtaining unconditional certification; however,
- A history of experiencing a single, unprovoked seizure should not exclude all individuals from driving a CMV.
- An individual with a history of a single, unprovoked seizure may obtain conditional certification to drive a CMV if that individual meets the following criteria:
 - An individual must have been seizure free for a minimum of 4 years on or off anti-seizure medication; and
 - If all anti-seizure medications have been stopped, the individual must have been seizure free for minimum of 4 years from time of medication cessation; or
 - If still using anti-seizure medication, the individual must have been on a stable medication regimen for a minimum of 2 years.
 - An individual with a history of a single, unprovoked seizure who has been granted conditional certification to drive a CMV must be recertified on a biennial basis.

Recommendation #3: Provoked Seizures

The MEP recommends that individuals with a history of experiencing a provoked seizure should not automatically be precluded from obtaining an unconditional certification.

- Whether an individual with such a history can be unconditionally certified requires individual evaluation to ascertain if the individual is at low recurrence risk for encountering again the factor that precipitated the seizure.
- Examples of low risk for recurrence include:
 - A lidocaine-induced seizure during a dental procedure.
 - A concussive seizure, immediate seizure—associated with mild head injury, loss of consciousness less than 30 minutes with no penetrating injury.
 - A seizure due to syncope not likely to recur while driving.
 - A seizure from an acute metabolic derangement not likely to recur would permit a patient to be unconditionally certified.
- Conditional certification may be considered for individuals with moderate-to-high risk factors for recurrence provided that the following conditions are met:
 - An individual must have been seizure free for a minimum of 8 years on or off anti-seizure medication; and
 - If all anti-seizure medications have been stopped, the individual must have been seizure free for a minimum of 8 years from the time of medication cessation; or
 - If still using anti-seizure medication, the individual must have been on a stable medication regimen for a minimum of 2 years.
 - An individual with a history of a provoked seizure who has been granted a conditional certification to drive a CMV must be recertified on an annual basis.
- Examples of seizure-provoking conditions that are at moderate-to-high risk for further seizures, and therefore would weigh against certification, include the following:
 - Head injury with loss of consciousness or amnesia greater than 30 minutes or penetrating head injury.
 - Intracerebral hemorrhage of any etiology, including stroke and trauma.
 - Brain infection: encephalitis, meningitis, abscess, cysticercosis.
 - Stroke.
 - Post-operative brain surgery with significant brain hemorrhage.
 - Brain tumors.
- Individuals who experienced further seizures following the initial seizure that occurred in the presence of a provocative event should be considered as having epilepsy for the purposes of certification review.

Dr. Hegmann thanked Dr. Krauss for his presentation and asked if the MRB had any questions on the topic.

Dr. Phillips expressed concern that sleepiness is a common side effect with anti-seizure drugs and asked Dr. Krauss if he knew of any anti-seizure drugs in which sleepiness is not a side effect. Dr. Krauss said there have been recent studies that used EEG and cognitive performance tests to look at various anti-epilepsy drugs and their effects on brain slowing and psychomotor test performance. Some drugs, including lamotrigine and levetiracetam, do not cause EEG slowing, while other drugs, such as topiramate, are associated with an increased risk of sleepiness. He added that much of the risk is also associated with the dosage.

Dr. Rizzo asked for clarification regarding the 2 percent rule adopted by Australia and other countries. Is this a risk of 2 percent per patient per year for a seizure? Dr. Krauss said the risk is

less than 2 percent based on the meta-analysis of outcomes, which suggests that a seizure-free period longer than 8 years reflects a decrease in crash risk below 2 percent.

Dr. Rizzo asked about the annual risk of seizure in the general population. Dr. Krauss stated that there are two numbers; one is the risk of recurring epileptic seizure in individuals with prior epilepsy that has been controlled, and the other is the risk in patients who have spontaneous seizures. In the U.S. there is a 9 percent risk of having a single seizure. In patients with controlled epilepsy, the risk drops below 2 percent once they are seizure free for more than 10 years. The annual risk would be approximately .05 percent.

Dr. Rizzo clarified that the 2 percent cut point is actually a 40-fold greater risk of seizures annually than seizures in the general population. Dr. Krauss responded that at the 8-year point it is a 40-fold increase in annual risk and that it would drop considerably from year to year beyond that point.

Before beginning the public comment period on the topic of seizure disorders, Dr. Gunnels asked the MRB to clarify its overall acceptance of the MEP's general recommendations on the topic of sleep apnea or if further discussion was needed.

Dr. Phillips responded that the MRB had some recommendations on how to modify the MEP Recommendations Report to correct inconsistencies in sections indicating "equal to" or "greater than." She noted other changes that were suggested to reorganize the document. She added that the MRB accepted the MEP's recommendations as amended, both in written comments and in formal motions. The MRB unanimously approved the recommendations.

Public Comment on Seizure Disorders

Dr. Hartenbaum expressed concern that of the two expert panels that presented, none of the members is an occupational medicine physician. She indicated that it is essential to have individuals who have experience administrating the medical exam program for carriers or doing the medical exams to be involved in developing the guidelines and recommendations.

In response to the acceptable standards of risk in Australia and Canada noted by Dr. Krauss, Dr. Hartenbaum stated that there is significant difference in liability for physicians qualifying drivers in those countries compared to the United States. In the United States, drivers will often not report changes to medications or recurrence of seizures to their carrier or medical examiner. Setting a threshold of acceptable exposure is different in the U.S., because private physicians do not have or want the responsibility for commercial or vocational driver programs.

Dr. Hartenbaum added her concern about the issue of stable medication, asking about situations in which the driver changes or discontinues medication. In response to Dr. Phillips' earlier comments about the higher incidence of cognitive impairment while on medication, Dr. Hartenbaum suggested that those medications that have the highest risk of cognitive impairment should be prohibited and medications with lowest risk of impairment should be recommended.

Dr. Hartenbaum concluded her comments, stating that a 2 percent general risk is still 40 times greater than the general population. She noted that in the United States, a 1 percent annual risk of sudden impairment or incapacitation should be the acceptable level of risk.

A former independent owner-operator commented that he had one seizure and had to stop driving. He said he discovered that many drivers lie about their medical condition and continue to drive because of the blanket law prohibiting those individuals on anti-seizure medications from driving. He emphasized that the rules need to be individualized because every driver is different, every seizure condition is different, and everyone responds to medication differently. If too many restrictions on someone's seizure condition exist, then it increases the chances that individuals will lie about their condition and not receive the proper treatment or medication.

Mr. Gary Gross, Epilepsy Foundation, asked whether the recommendations would allow for consideration of specific characteristics of seizure-type factors rather than relying entirely on seizure-free periods. He noted the following factors: the presence of simple partial seizures that do not interfere with consciousness or motor control; seizures with consistent and prolonged auras; an established pattern of pure nocturnal seizures; and seizures related to reversible acute illnesses. These are some of the factors that are favorable in decreasing the seizure-free period.

Dr. Tregear stated that the data show there is evidence that some seizure types create lower risk than others. Dr. Krauss noted that the MEP determined that the risk standard for commercial driving should be quite conservative compared to that for non-commercial driving. He said that seizure type is not a sufficient way to define risk for crashes in these patients. He referred to a study that looked at patients with various seizure types who also had a seizure behind the wheel. The findings indicated that a high percentage of these patients crashed. Therefore, the MEP recommends being cautious about evaluating patients with auras or mild seizure types in terms of letting them drive commercially.

A mechanic with the New York Department of Transportation stated that he has a commercial drivers license (CDL) restricted to intrastate travel. He asked if the MEP looked at state CDLs and compared the drivers that checked "yes" on their application to their crash ratio. Dr. Gunnels responded, stating that FMCSA does have some information about what states are doing in terms of who has programs, but that this comparison has not been made. She further indicated that FMCSA could take a look at this issue as it varies between states. He added that he feels the 8-year limit is excessive to those individuals on seizure medications and those who have been seizure free.

MRB Discussion and Deliberations on Seizure Disorders

During discussion, Dr. Rizzo indicated that the commentary from both the audience and those participating on the phone was very helpful. Dr. Rizzo stated that the MRB understands there is a balancing act between the needs of an individual and the potential risks to the motoring public. The MRB thoroughly considers the comments made by the public and that the MRB considered all of these factors in the following recommendations:

Recommendation #1

For individuals with a history of epilepsy, retain the existing guidance on the management of seizures and commercial drivers, supporting a minimum of 10 years off anti-seizure medications and seizure free.

Recommendation #2

For individuals with a history of a single, unprovoked seizure, retain the existing guidance on the management of seizures and commercial drivers, supporting a minimum of 5 years off anti-seizure medication and seizure free.

Recommendation #3

Individuals with cases of provoked seizures that are caused by structural brain lesions (e.g., tumor, trauma, and infection) should be assessed more stringently than those with other causes (e.g., a single, unprovoked seizure caused by exposure to a medication, such as lidocaine). The MRB recommends individualization of time restrictions from driving for a minimum of 5 years, but for up to 10 years—based on consultation with a neurologist. This applies only to individuals who are off medication and seizure free.

Recommendation #4

Individuals with a probable single episode of drug toxicity may be treated less restrictively than those with structural brain lesions, depending on the outcome of the neurological consultation.

The MRB approved these recommendations. Dr. Hegmann invited further discussion on this topic.

Dr. Phillips stated that she wanted to explain her dissent on the earlier recommendation regarding persons with epilepsy. She noted that having a seizure is not the same as having a crash. Her position is that restrictions will not keep people with epilepsy from obtaining commercial drivers licenses; it will merely keep them from reporting and getting appropriate treatment.

Before adjourning the meeting, Dr. Gunnels noted that the next MRB meeting is scheduled for April 7, 2008, and will be held in Washington, D.C. She announced that FMCSA is planning to have a meeting during the summer that will focus on the National Registry of Certified Medical Examiners and issues related to medical practitioners. She expressed appreciation to MEP members for their presentations and to MRB members for their work.

Dr. Gunnels added that all the information discussed during the meeting would be made available on the Web site at www.mrb.fmcsa.dot.gov.

Adjournment

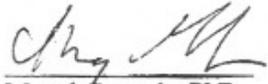
Noting there were no additional comments, Dr. Hegmann adjourned the meeting.



CERTIFICATION *(with one change)*
The minutes were approved by the Medical Review Board on April 7, 2008
(Date)

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


Kurt Hegmann, MD
Chair
Medical Review Board


Maggi Gunnels, PhD
Designated Federal Official
Medical Review Board