



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

Meeting Summary

The U.S. Department of Transportation's (DOT) Federal Motor Carrier Safety Administration (FMCSA or the Agency) Medical Review Board (MRB) convened on October 19, 2012, in Alexandria, Virginia. The meeting was open to the public.

Board Members Present:

Gina C. Pervall, M.D., Chairperson
Christine Cisneros, M.D.
Benjamin H. Hoffman, M.D.
Brian T. Morris, M.D.
Albert J. Osbahr III, M.D.

FMCSA Staff:

*Larry W. Minor, Associate Administrator for Policy
Benisse Lester, M.D., Chief Medical Officer
Shannon Watson, Senior Policy Advisor
Valerie Height
Charles Horan, Director, Office of Bus and Truck Standards and Operations
Linda Phillips
Angela Ward, R.N., Nurse Consultant
Elaine M. Papp, R.N., Chief, Office of Medical Programs
Jack Van Steenburg, Chief Safety Officer and Assistant Administrator

*Designated Federal Officer (DFO)

FMCSA Contractors:

Michelle Tregear, Ph.D., Manila Consulting
Stephen Tregear, D.Phil., Manila Consulting

Members of the Public:

Megan Benfatti, National School Transportation Association (NSTA)
Carol Blachly, New Editions Consulting
Dr. Lisa Cooper-Lucas, LPC, CEAP, SAP, Washington Metropolitan Area Transit Authority (WMATA)
Bob Perry, Rolling Strong
Jane Rath, New Editions Consulting

Call to Order, Official Remarks and Agenda Review

Gina C. Pervall, M.D., FMCSA MRB Committee Chairperson,¹ explained the meeting's purpose (i.e., to discuss field of vision [also known as field of view or FOV] requirements for commercial motor vehicle [CMV] drivers), and invited Board members and others to introduce themselves.² Meeting attendees received an agenda, and Dr. Pervall introduced Dr. Michelle Tregear.

Field of Vision Updated Evidence Report

Background

Dr. Michelle Tregear made a presentation about FOV, and provided an updated Evidence Report (Visual Field Loss and Commercial Motor Vehicle Driver Safety). Her presentation included an overview of research findings and information relating to visual impairment statistics in the United States, federal statutes regarding vision, international guidance regarding driving and visual loss, the regulatory history of FMCSA's FOV requirements, and an update of FMCSA's exemption program. She began by characterizing visual impairment as one of the 10 most prevalent disabilities in the United States, providing a "conservative" estimate of 3.5 – 5.0 million individuals in the United States with visual impairment (i.e., vision 20/40 or worse) and asserting that approximately 1.0 million of these individuals are legally blind (i.e., vision 20/200 or worse).

Dr. Michelle Tregear said that in the United States, visual impairment is largely age-related with cataracts, a correctable condition, as the most prevalent cause of visual impairment. She addressed other leading causes including diabetic retinopathy, glaucoma (sometimes called tunnel vision in advanced stages), and age-related macular degeneration. Observing that the incidence of visual impairment increases as people age, she provided evidence from the Bureau of Labor Statistics showing the increasing median age of truck drivers, and noted the importance of understanding how visual impairment may affect CMV driver safety.

Dr. Michelle Tregear then compared FMCSA's FOV physical qualification requirement³ for CMV drivers (i.e., "FOV of at least 70 degrees in the horizontal meridian in each eye") to normal human FOV values and FOV values for other U.S. transportation agencies and those of other countries. Stating that the normal monocular human visual field is approximately 160 degrees, and the binocular FOV is about 180 degrees, she presented the following information.

¹ Dr. Pervall, Medical Director for Johns Hopkins University's Applied Physics Lab in Laurel, Maryland, also provides services for the Washington Metropolitan Area Transit Authority [WMATA] in Washington D.C., and serves on the Medical Advisory Board for the Maryland Motor Vehicle Administration [MVA].)

² Other MRB members included Brian T. Morris, M.D., a physician and attorney for One Health and Albert J. Osbahr III, M.D., an occupational physician from Hickory, North Carolina (both second time Board members); Benjamin H. Hoffman, M.D., Medical Director at General Electric and professor at the University of Texas, School of Public Health (a third time Board member); and Christine Cisneros, M.D., with U.S. Health Works in Indiana, and Jack Van Steenburg, Chief Safety Officer at FMCSA (a both first time Board members). FMCSA staff present included Larry Minor, Associate Administrator for Policy, and the Designated Federal Officer; Elaine M. Papp, R.N., Division Chief of the Medical Programs Office; Benisse Lester, M.D., Chief Medical Officer; Angela Ward, R.N., MRB liaison; and Shannon Watson, Senior Policy Advisor to the Associate Administrator for Policy. Michelle Tregear, Ph.D. is a Senior Research Analyst at Manila Consulting and FMCSA contractor.

³ 49 CFR 391.41(b)(10). This provision also sets the CMV driver visual acuity qualification standard.

Regulatory History

In 1952, the Agency set the FOV at 140 degrees in the horizontal meridian via binocular testing, and in 1970, at 70 degrees in the horizontal meridian for each eye tested individually. Dr. Michelle Tregear said that in 1993, the Federal Highway Administration commissioned the Ketron Division of Bionetics Corporation to reassess vision standards adequacy. Ketron performed a literature review and found no compelling data to change the vision standard, but did recommend that the visual field requirement instituted in 1970 be stated as “a field of vision of at least 120 degrees in each eye measured separately in the horizontal meridian.”

Authority	FOV	Other Requirements, Comments
United States		
Federal Aviation Administration	Normal ^a for all classes of pilots	None recorded
Federal Railway Administration	70° in the horizontal meridian in each eye	None recorded
U.S. Coast Guard	Not less than 100° in each eye	None recorded
International for CMV Drivers		
Australia	Binocular of 140° in the horizontal meridian and 20° above or below fixation	Visual field loss must be static and unlikely to progress rapidly
Canada	Binocular of 150° in the horizontal meridian and 20° above or below fixation	None recorded
New Zealand	Binocular of 140° in the horizontal meridian and no significant pathological field defect encroaching within 20° of the point of fixation	Addresses macular degeneration and diabetic retinopathy
International for Passenger Drivers		
Mexico	Normal ^a	None recorded
United Kingdom	140°	Visual field defect in one eye must be completely compensated for in the other eye

^a normal undefined

Dr. Michelle Tregear explained that in 1998 an expert panel reviewed the available literature and strongly supported the Ketron study recommendation to reinstate the original standard of at least 120 degrees of horizontal field in each eye. The 1998 expert panel suggested requiring at least 20 degrees of visual field above and below the horizontal axis in each eye. The 1998 expert panel concluded, “Individuals who either fail to meet this standard on screening testing or who have been identified as having a disease which may compromise the visual field, such as glaucoma, retinitis pigmentosa, stroke, or brain tumor, be required to have a full visual evaluation by an ophthalmologist or optometrist to include formal visual field testing followed by an opinion as to whether the documented formal visual field satisfies the standard.”

In 2008, the Medical Expert Panel (MEP) recommended that the standard “may need to be restated.” It concluded that the evidence available did not provide enough information to determine if the 70-degree

standard was sufficient. The MEP supported clarifying the method of visual field testing. The MEP suggested an additional test to determine visual field loss if the examinee has a history of visual disorder. However, the MEP did not suggest which test to use when evaluating these individuals.

The 2008 MRB supported clarifying the methods of visual field testing. The 2008 MRB stated the current standard of 70 degrees “may be adequate.”

Vision Exemption Program Summary

Dr. Michelle Tregear gave the following summary of the vision-exemption program offered by FMCSA to individuals not meeting the 20/40 visual acuity requirement in one eye.⁴ Among other things, eligibility for this exemption requires an applicant to have 3 years of CMV driving experience with no suspensions or accidents and an examination by an ophthalmologist or an optometrist. The optometrist must identify and define the visual deficiency. The optometrist also must certify that the driver’s visual deficiency has been stable during the 3-year driving period under review, that the driver’s visual acuity is at least 20/40 (corrected or uncorrected, in the better eye), and that the driver can perform the driving tasks required to operate a CMV. Dr. Michelle Tregear said that as of June 30, 2012, there were 1,929 active CMV drivers permitted under the program.

Dr. Michelle Tregear continued her report, asserting that in 2006, Cambridge Systematics, Inc. collected medical data about individuals in the program to complete the Vision Exemption Program Study, and stating that she reviewed the data to determine the composition of the program drivers. She reported findings that 44 percent of program drivers had amblyopia (i.e., a stable condition that occurs because of a corrective problem), that 31.5 percent of program drivers experienced an accident or traumatic injury, and that the “vast majority” of program drivers had non-progressive conditions outside normal aging.

Dr. Michelle Tregear provided the following overview of vision-exemption program drivers’ FOV. More than 53 percent had a visual field in the better eye greater than or equal to 120 degrees. Approximately 46 percent had an FOV of less than 120 degrees. She stated a finding that the majority of drivers had an FOV less of than 120, but greater than 110 degrees, that approximately 96 percent had a visual field of at least 100 degrees or greater in the better eye, and that most individuals had some level of vision in the poorer eye.

Evidence Report

Key Question #1: Are individuals with visual field loss (either CMV or passenger drivers) at an increased risk for a motor vehicle crash? If so, what is the acceptable visual field range in the horizontal and vertical meridians?

Dr. Michelle Tregear explained that the MEP⁵ identified 575 articles as potentially relevant for the evidence report. It used 17 articles, 4 of which were new to the evidence base. The majority of articles presented case-control studies, with the exception of three cross-sectional studies. She characterized the studies as “poor to moderate quality” under a strength-of-evidence rating.

Dr. Michelle Tregear provided an overview of the three FOV testing methods: Goldmann perimetry, Humphrey perimetry, and confrontation. She described Goldmann perimetry as a test method where a

⁴ A driver also may apply for the vision exemption program if the driver fails to meet the FOV requirements in 49 CFR 391.41(b)(10). FMCSA issues exemptions from driver qualification requirements in 49 CFR part 391 under 49 CFR 381.300.

⁵ Members of the current MEP are Drs. Alex Bowers, Cynthia Owsley, and Matt Rizzo.

trained technician maps out an individual's visual field; Humphrey perimetry as a method that tests FOV with light-spots projected on an automated screen; and the confrontation method as a screening test for measuring FOV loss.

Dr. Michelle Tregear also presented an overview of three, new cross-sectional studies examining CMV drivers from other countries, noting the studies were "not high quality" according to strength-of-evidence ratings. She said two studies (Ovenseri-Ogomo et al. 2011, Adekoya et al. 2009) reflected the use of confrontation testing to determine whether a group of CMV drivers had an FOV loss, and described the findings of an investigation about whether a driver was involved in a crash in the previous 3 – 5 years. She noted that the Adeoti et al. 2007 study investigated Humphrey-perimetry testing to identify individuals having a visual field of 120 degrees and individuals with a visual field encroaching on 20 degrees of fixation.

Dr. Michelle Tregear reported the MEP's conclusion in the evidence report that individuals with abnormal confrontation-test results were no more likely to have an automobile crash than those with normal test results. She also characterized the Adeoti et al. 2007 report as finding that individuals having an FOV of 120 degrees in the horizontal meridian had no greater crash risk than did individuals with a normal FOV, but that a small group of individuals with visual fields encroaching on the center 20 degrees of fixation had an increased crash risk compared to individuals with less severe, or no visual field losses as measured using an automated perimeter test. Responding to Dr. Osbahr's request for clarification of the phrase, "encroaching on the center 20 degrees of fixation," Dr. Michelle Tregear explained that the phrase meant, "the reduction of the individuals' visual fields was to the central 20 degrees of vision."

Dr. Michelle Tregear provided an overview of passenger-driver studies, noting a number of these studies examined older drivers "(because visual field loss increases with age)," or drivers with glaucoma. She said these studies examined whether "individuals as they get older and have reduced visual fields [also] have a higher crash rate," and all used some form of Humphrey-perimetry testing to assess driver FOV. According to Dr. Michelle Tregear, the Humphrey 30-2 test examines the central 30 degrees of vision, the Humphrey 24-2 test examines the central 24 degrees of vision, and the Humphrey Full Field 81 Point test examines 120 degrees of vision. She said the MEP's interest was whether these passenger drivers were involved in crashes, noting, "[I]n some cases these crashes were self-reported and in other cases they were based on crash files and state records."

Describing the Tanabe et al. 2011 and Haymes et al. 2007 studies, Dr. Michelle Tregear said the data involved "relatively limited field tests," and that these tests confirmed an increased crash risk for individuals with severe and moderate visual field defects in the central 20-30 degree range. Regarding the Rubin et al. 2007 study, she reported a finding that individuals missing more than 20 points on the perimetry test had an increased crash risk compared to individuals who missed less than 20 points on the perimetry test. She noted that in these studies, there was no specification of the visual field loss location. Regarding an Owsley et al. 1998 study, she reported a finding that in this study, which examined the central 120 degrees of vision, FOV loss within the central 30 and 30-60 degrees was a "univariate" predictor of crash. However, she noted that in this same study, only glaucoma and "useful FOV" were found to be reliable predictors of crash risk in multivariate analyses. In another study that looked at crash risk in a group of individuals with retinitis pigmentosa, Dr. Michelle Tregear noted there is data showing a relationship between visual field loss associated with this condition and increased crash risk.

Dr. Michelle Tregear reported on the Johnson and Keltner, 1983 study evaluating visual field extending out 100 degrees (40 degrees nasal and 60 degrees temporal), and the finding of an increased crash risk for individuals having binocular FOV loss within 100 degrees. She described two studies using California and Maryland Departments of Motor Vehicles full-field testing, and resulting in a finding of no evidence

that visual field loss affected crash rates. She continued, describing a Council and Allen, 1974 study that assessed visual field loss out to 120 degrees or 140 degrees, and finding no difference in effects between visual fields of 140 degrees or less and 120 degrees or less. She said the Council and Allen, 1974 study did not find a relationship between individuals with visual fields of 140 degrees or less (generally considered the range required in other countries for safe driving) and crash risk. The study, she said, indicated that individuals having reduced visual fields showed no increased risk for crash, relative to individuals having normal visual fields, but presented no findings for anything below 120 degrees. Describing the Hills and Burg, 1977 study, Dr. Michelle Tregear reported that there was no evidence to support a finding of increased crash risk for “most age groups,” although the study did find a weak association of increased crash risk for drivers older than 54.

Dr. Morris asked Dr. Michelle Tregear to comment on the studies discarded by the MEP from the new evidence report, and the effects of removing these studies. In response, she first identified a McGwin study where study subjects received a questionnaire, rather than perimetry testing, to assess FOV loss. The MEP removed the other studies because they reported about “useful FOV” testing, which is not a visual field test. Dr. Tregear explained “useful FOV” testing is a higher-level, cognitive test testing only a small range of the visual field. Dr. Michelle Tregear explained that because the studies removed did not address the FOV function directly, omitting them had no effect on the evidence report. Dr. Cisneros commented that “useful FOV” testing might provide an appropriate metric because “useful FOV” testing measures the “status of the retina in terms of gathering stimuli needed to operate that vehicle,” and addresses a driver’s ability to act on information. Dr. Michelle Tregear agreed that the “useful FOV” testing measure warrants additional review.

Dr. Michelle Tregear summarized the findings for Key Question #1. She concluded that studies focusing on glaucoma and older age found an increased crash risk in severe cases of visual field loss. She stated that retinitis pigmentosa also results in an increased crash risk. Dr. Michelle Tregear explained the larger, full-field studies showed weak or inconsistent evidence regarding whether or not moderate levels of visual field loss results in an increased risk for crash.

Responding to Dr. Morris’s assertion that FMCSA has population data stratified according to vision loss, Dr. Michelle Tregear said the MEP did not use that data. Ms. Papp suggested reviewing the specified FMCSA data when completing the next evidence report. Dr. Hoffman noted FMCSA might have data suggesting whether there is crash risk associated with FOV between 20/30 degrees and 120/140 degrees.

Dr. Michelle Tregear asserted that FMCSA holds individuals admitted to the exemption program to a higher standard. She referenced the Cambridge Systematics, Inc. Medical Exemption Program study, which found that crash rates for exemption-program individuals were lower than crash rates for the general population. Mr. Minor added that FMCSA records FOV information when individuals apply for the vision-exemption program, but was unsure if that information currently is available in a readily accessible database “that tells the FOV for that population of drivers so that the crash involvement can be reviewed.” He suggested establishing a database containing the information. Mr. Van Steenburg asked if the Agency tracks crash involvement statistics for individuals admitted to the exemption program. Mr. Minor confirmed FMCSA reviews driving records regularly.

In response to a question from Dr. Cisneros concerning a study regarding FOV and performance, Dr. Michelle Tregear said, “Some studies look if individuals with more vision deficit self-regulate their own driving (especially if an individual has glaucoma). One study showed drivers in the program drive less under risky conditions (e.g., driving at night).” Dr. Michelle Tregear noted the studies do not present strong assessments of visual field, in part because the studies involve patients with glaucoma who have severe visual field loss already. Dr. Michelle Tregear said the term “drivers” refers to drivers of passenger

vehicles. All evidence-report studies involved non-commercial passenger vehicle drivers, except the top three, which looked at CMV drivers. She noted the studies with CMV drivers took place outside the United States where “driving is very different than within the United States.”

Dr. Michelle Tregear said data in the new evidence report was consistent with a finding in the 2008 report: that is, passenger drivers are at an increased crash risk when standard perimetry shows FOV loss. She said there are particular studies showing that for drivers with glaucoma or retinitis pigmentosa, the risk of crash increases as the FOV decreases. Dr. Michelle Tregear further explained that because of variability in diagnostic measures and criteria, the data do not show how much greater is the crash incidence for passenger drivers with an FOV loss.

Key Question #3: What are the most accurate methods for assessing/screening for visual field loss in the medical examiner setting?

Dr. Michelle Tregear stated that medical examiners typically use confrontation testing to screen CMV drivers for FOV. She said that the report team found five evidence-based studies comparing confrontation testing to Humphrey-perimetry testing. (Dr. Michelle Tregear said that although the team found three studies evaluating Goldmann testing, her presentation would not focus on that test measure because medical examiners generally do not use it.)⁶

Dr. Michelle Tregear described the Kerr et al. study, which evaluated six types of confrontation testing,⁷ comparing the sensitivity and specificity of different confrontation tests performed in combination against the sensitivity and specificity of the Humphrey-perimetry test. She reported a finding that confrontation testing does not detect visual field loss as well as perimetry testing does. Dr. Michelle Tregear also noted the following findings from the Kerr study: confrontation-testing sensitivity is useful for measuring severe visual field loss and that the red-comparison test is more sensitive than both finger counting and face description, which are not able to identify individuals with visual field losses.

Regarding a slide in the presentation, Dr. Hoffman asked how the scale of mild, medium, and severe correlated to degrees of visual field loss. Dr. Stephen Tregear responded that the scale on the slide represents threshold averages across the central 30 degrees, irrespective of whether the vision loss is severe but in a small area, or moderate but in a large area, but that the scale does not reflect the shape of the vision loss. When Dr. Hoffman asked if Dr. Michelle Tregear could identify the most sensitive screening test for measuring an FOV of 70 degrees, Dr. Michelle Tregear replied that current data do not permit her to do so. She explained that confrontation testing generally detects visual field losses only in the periphery. Dr. Stephen Tregear added that confrontation testing can miss even severe visual loss in the central 30 degrees, and that the sensitivity numbers for the screening tests are poor, considering the prevalence of glaucoma in the general population.

Dr. Hoffman concluded that the typical finger wiggle is not a good screening test because the test has high specificity but low sensitivity. Dr. Michelle Tregear confirmed that there is no effective screening measure for detecting visual loss in the medical examiner setting, although using multiple confrontation tests in combination can increase the sensitivity of those tests.

⁶ The eight studies were as follows: Kerr et al. 2010; Bass et al. 2007; Lee et al. 2003; McLean et al. 2002; Agarwal et al. 2000; Manji et al. 2000; Shahinfar et al. 1995; and Johnson et al. 1991.

⁷ The six types were face description, finger counting, red comparison, static finger wiggle, kinetic finger wiggle, and kinetic 5-mm red target (a moving red target in the periphery).

Key Question #2: What specific conditions are associated with visual field loss and may warrant more rigorous field of view (FOV) testing as part of the physical qualifications examination to determine a driver's fitness for operating a CMV in interstate commerce?

Dr. Michelle Tregear said that the report team considered glaucoma, diabetic retinopathy, retinitis pigmentosa, and ocular hypertension as conditions associated with visual loss that might warrant more rigorous FOV testing during the driver physical qualification examinations. She said that the report team also identified risk factors for those conditions, including family history; ocular history; advancing age; African-American descent; smoking; hypertension; low blood pressure; diabetes; stroke; previous episode of hypotensive shock, trauma, vascular surgery, or hemorrhage; and medications (e.g., steroids, antimalarials, and anticholinergics).

Dr. Morris concluded that there is no evidence showing an increased crash risk for CMV drivers with visual field losses, that existing studies provide only minimally acceptable results to suggest increased risk for passenger drivers, and that medical examiners have no good way to screen for an abnormal FOV in any case. Dr. Michelle Tregear added that there is no practical FOV test for CMV driver screening, noting that some tests are more sensitive than others are.

Dr. Michelle Tregear noted that the current MEP and the 2008 panel agree that FMCSA's FOV 70 degrees in each eye requirement "may be adequate," but that medical examiners should conduct binocular testing.⁸

According to Dr. Michelle Tregear, the current MEP acknowledged that the 70-degree monocular requirement established in 1971 was probably an incorrect restatement of the original 140-degree binocular requirement. She added that the 1993 and 1998 workgroups recommended changing the standard to 120 degrees in each eye to correct the error, but the workgroups made their recommendations "arbitrarily without sufficient supporting evidence."

Dr. Hoffman asked how the current MEP concluded that FMCSA's current FOV standard of 70 degrees in each eye was adequate. He observed that there is a difference between having no data regarding risk and establishing that there is no risk, and that there is no data indicating whether the current standard is inadequate or adequate. Dr. Lester said the MEP's Opinion 1 statement should indicate that there is no current evidence to support an opinion on what constitutes an adequate FOV standard.

Dr. Steven Tregear said that the MEP found itself in a difficult position, having evidence of increased crash risk only for individuals with severe vision loss in the central 30 degrees because of glaucoma. He said that changing the standard from 70 to 30 degrees would be hard to justify when "everybody else" requires 120 degrees. He added that the MEP lacked evidence that 70 degrees is less safe than 120 degrees. Dr. Hoffman agreed, but added that the MEP's Opinion 1 statement did not clarify that there was no evidence to justify changing the standard.

Dr. Michelle Tregear stated that some studies tested general populations for a larger visual field range. As an example, she cited the Johnson and Keltner study testing visual field losses up to 100 degrees, and finding that crash risk increased with severe binocular, central FOV loss (e.g., visual field loss due to severely advanced glaucoma). She said that the MEP lacked sufficient evidence to recommend raising the FOV standard, nor could MEP recommend lowering the standard.

⁸ See Opinion 1 in Dr. Michelle Tregear's presentation.

Dr. Morris asked if the MEP discussed returning to a binocular standard, similar to the standards in other countries. Dr. Michelle Tregear replied that the MEP recommended conducting binocular visual field testing. The panel preferred binocular testing to monocular testing, she said, because people drive binocularly and because binocular tests can help assess how one eye compensates for loss in the other. Dr. Michelle Tregear agreed with Dr. Morris that FMCSA should change the current FOV standard of 70 degrees to fit a binocular measurement system. Mr. Minor asked why the MEP did not recommend returning to a 140-degree binocular standard to correct the “apparent mistake” of changing the original 140-degree binocular requirement to a 70-degree monocular requirement. Dr. Michelle Tregear replied that the MEP lacked evidence to support changing the requirement.

Continuing her presentation on the MEP’s Opinion 1, Dr. Michelle Tregear gave the following summary. Regarding vertical range, she said, “For practical purposes, a visual field extending at least 20 degrees above and below fixation would be appropriate,” but reiterated that the panel “lacked evidence to support making an opinion to change the standard for that purpose.” She stated the panel noted, “The requirements that would be suitable for monocular drivers needs to take into consideration the factors and conditions that led to the visual field loss (e.g., the condition or disease).” She reported the MEP’s observation that an individual with visual acuity less than 20/40 in one eye likely has enough vision in that eye to detect stimuli the peripheral FOV. Dr. Michelle Tregear reported the MEP’s finding that confrontation testing is an acceptable measure for FOV screening if the administering medical examiner is trained in performing the test. She further reported the panel’s recommendations that FMCSA require a full-vision evaluation by an ophthalmologist or an optometrist for individuals who fail a screening test, or who are diagnosed with a disease or condition⁹ that might result in an FOV loss. She said the panel determined that such an evaluation should include formal perimetry testing and the doctor’s opinion of whether the individual met FOV standard.

Dr. Morris asked Dr. Michelle Tregear to comment further on the MEP’s deliberations regarding confrontational testing. He said that the data indicated that individual confrontation tests are inadequate and that examiners must combine two tests to improve sensitivity. She replied that the panel preferred a perimetry test for visual-field testing (i.e., Esterman), but having considered the practicality of an FOV screening test, deemed confrontation testing sufficient for that purpose. She said that the MEP did not provide a substantive rationale for that conclusion. Dr. Morris questioned why the panel found confrontation testing acceptable just because it is easy to perform, and Dr. Michelle Tregear reiterated the panel’s recommendations that only medical examiners with formal training in administering confrontation tests can screen driver candidates. Noting past criticism of the MEP for impracticality, Dr. Steven Tregear added that the panel’s report should reflect practicality considerations, and that it preferred testing all individuals with the monocular Humphrey-perimetry full-field 120-degree test, rather than with confrontation tests. (Dr. Michelle Tregear added that one member of the current MEP, Dr. Bowers, preferred the Esterman binocular perimetry test.)

Dr. Cisneros commented that if FMCSA adopts binocular FOV testing, it should be with the provision that the Agency require individuals with certain diagnoses (e.g., glaucoma) “as part of the process to get one formal visual field examination.” She suggested that taking such an approach would minimize the

⁹ The MEP determined that based on prevalence and degree of functional impairment, the following conditions warranting additional testing: glaucoma; diabetic retinopathy; lesions along the optic pathways (including the optic nerve and chiasm); brain lesions or injury (including stroke or trauma); retinitis pigmentosa; macular degeneration; and bilateral ocular trauma. Dr. Michelle Tregear reported the panel’s finding against including amblyopia as among the conditions requiring evaluation by an ophthalmologist or optometrist for an individual meets the other physical qualification standards for driving. She noted that amblyopia is not a progressive condition.

examination expense for driver candidates who must pay for more sophisticated tests than medical examiner screening.

Dr. Michelle Tregear presented the MEP's opinion on other considerations. These included that in screening drivers for vision qualification requirements, medical examiners should consider other factors that may limit FOV (e.g., inattention, neck mobility, eye movements). Additionally, she reported that the MEP found the current visual acuity and FOV standards confusing, and recommended that FMCSA restate the standards. Finally, she reported further on the MEP's recommendation to add visual performance studies (e.g., driver simulator studies, non-crash-related studies, and function studies) to the evidence base for Key Question #1 in future versions of the evidence report.

MRB Deliberation on Field of Vision

Following the Evidence Report, MRB members discussed changing the current FOV and visual acuity standards.

Dr. Morris suggested that the Board recommend temporarily suspending the FOV requirement, or, in the alternative, suggested the Agency establish a binocular standard, which other countries use. If examiners must use confrontation testing, he endorsed the MEP's recommendation for training medical examiners regarding proper confrontational testing methods. Dr. Morris had no recommendation about the appropriate degree value for peripheral FOV, although he proposed 140 degrees, based on doubling the current 70-degree monocular requirement.

Dr. Hoffman recommended that the Board endorse correcting the current standard, which is apparently in error, and he stated that he would like to learn more about the error (i.e., the original 140-degree binocular standard restated as a 70-degree monocular requirement). He mentioned that FMCSA has data that could clarify whether there is heightened crash risk for people with known peripheral field cuts. He remarked that crash risk clearly exists for drivers with tunnel vision, but he also suggested that people with this impairment make accommodations as time passes. Dr. Hoffman said that before the Board adopted the MEP's recommendations, he would like to have a better understanding of the relationship between visual field loss and driver safety. He said that although the MEP's Opinion 1 statement indicates that the panel finds the current standard is safe, there is no evidentiary basis for that opinion.

Dr. Osbahr said the data show that the "arbitrary 70"-degree value is non-specific. He said that because the standard eliminates drivers whose vision is acceptable and who can drive a CMV safely, the standard requires FMCSA first to disqualify candidates with acceptable vision, and then provide an exemption program for these disqualified individuals. He did not know which FOV degree value to use beyond the 120 degrees endorsed by the 1993 and 1998 expert panels, and expressed an opinion that an FOV standard based on this value would disqualify only those drivers with poor vision and increased crash risk.

Responding to a question from Dr. Pervall about whether the Board should recommend testing for binocular vision, Dr. Hoffman replied that medical examiners use inadequate screening tests, irrespective of whether the tests are monocular or binocular. He expressed concern that the screening tests do not identify drivers with unacceptable vision. Dr. Pervall responded that she agreed with Dr. Osbahr that a 120-degree FOV standard would screen out most drivers with unacceptable vision, but noted that FMCSA should require drivers with chronic conditions to have formal testing by an ophthalmologist or optometrist. Dr. Hoffman agreed that most experienced, professional drivers with 70- to 120-degree vision drive safely. However, regardless of this, he suggested that individuals above 70 degrees up to 140 degrees may need evaluation and approval by an eye specialist.

Dr. Hoffman noted that optometrists are readily available and an eye test by an optometrist is not expensive. He said the Board could recommend that, beyond 70 degrees up to 120 or 140 degrees in each eye, the individual see a specialist for a vision evaluation. He asked if optometrists have the necessary equipment. Dr. Lester responded that some optometrists do, and that training and knowledge vary by optometrist.

In response to Dr. Morris's suggestion that a Titmus machine would be "an expensive solution" for screening FOV, Dr. Michelle Tregear said that the Titmus machine functioned well as a screening test. Dr. Lester commented the flashing lights of a Titmus machine may distract test subjects, and Dr. Morris replied that such a concern might apply for visual acuity testing, but not for peripheral vision testing. Dr. Morris noted that only new Titmus machines are configured to test peripheral vision.

Dr. Osbahr asked how medical examiners could screen in the office "at-risk" individuals, without incurring additional economic burdens, noting that examiners already experience burdens from meeting National Registry of Certified Medical Examiners requirements. He suggested that "physicians" could do confrontational testing as an add-on to a peripheral binocular 120-degree test. He assumed that if an individual did not pass that test, FMCSA would require the individual to see an optometrist or ophthalmologist for more formal screening. Dr. Osbahr said further that eye doctors should receive guidance about which screening test is appropriate. He suggested the Humphrey-perimetry test as an option that can be conducted in the office, noting it would not involve "undue burden" on the medical examiners. He suggested that an individual cleared by an ophthalmologist or optometrist would not go through the exemption program. He concluded that having a process for a formal vision evaluation and approval from an optometrist or ophthalmologist would prevent drivers having acceptable vision from being disqualified.

Dr. Morris stated that medical examiners are responsible for using the confrontational method to identify individuals with undiagnosed FOV loss. He understands the recommendation to send people with known eye problems like retinitis pigmentosa and glaucoma to an ophthalmologist.

Dr. Lester asked if the evidence report indicates what percentage of individuals with significantly reduced visual fields have associated visual problems or diagnoses. Dr. Michelle Tregear replied that the studies generally do not include that information, but that visual field loss tends to be associated with some condition, whether it is a progressive disease, such as glaucoma or retinitis pigmentosa, or a non-progressive trauma or brain injury. She said some of the studies evaluated large, general populations, in which there was low prevalence of visual field loss. Dr. Lester suggested that that information could help the medical examiners, explaining that there is a high association between significant reduction in visual field and a diagnosable visual problem, although some individuals go undiagnosed.

Dr. Pervall asked if the Board members felt comfortable recommending binocular testing for peripheral FOV. Dr. Cisneros commented that the Board's recommendations would not have "dire consequences," and that adopting horizontal and vertical FOV standards would make the United States consistent with other countries. Dr. Morris recommended against a testing requirement for the vertical meridian. He acknowledged that testing vertically seems reasonable because 20 degrees above and below fixation corresponds to looking through a windshield. He noted that other agencies and other countries do not test vertically. He fears that people will develop a false sense of security believing the Board recognized a risk and determined the perfect method to screen for it. Regarding voting on the recommendation, Dr. Morris abstained because he was unsure about the appropriate FOV degree value, and Dr. Hoffman abstained saying he did not have sufficient data to decide. He listed reasons for changing the standard to 120 degrees: other countries use a 120-degree requirement and the change from a binocular requirement to a

monocular requirement was “an apparent error.” He also said he was unsure how the original 120-degree requirement was determined.

Dr. Hoffman asked whether FMCSA could access the vision-exemption program data on FOV and driver crash risk. If the data indicate an undue crash risk for drivers in the exemption program, he said, the finding could justify changing the FOV standard to 120 degrees. Ms. Papp said that except for FOV data, FMCSA has a database on the 1,926 individuals in the vision exemption program. She suggested FMCSA probably could conduct a study on driver crash risk, FOV, and acuity. Replying to a question from Dr. Hoffman asking what the difference was between binocular and monocular vision testing, Dr. Morris said a binocular test reflects the way people drive, and Dr. Michelle Tregear reiterated that binocular tests can measure how one eye compensates for FOV loss in the other eye.

MRB Motions and Recommendations

Requiring a Binocular 120-degree FOV Standard

Dr. Osbahr moved that the Board recommend a binocular testing requirement at 120 degrees. Dr. Cisneros seconded the motion, and the MRB recommended a binocular 120-degree peripheral FOV requirement for CMV drivers, with Drs. Morris and Hoffman abstaining.

Dr. Pervall asked whether the Board should wait until the FMCSA data become available to the Board or proceed with developing its recommendations and revisit the data later. Mr. Minor replied that he does not know whether the data would provide any valuable information, noting that crashes are rare for the population of drivers that FMCSA regulates. He recommended that the Board proceed with recommendations while FMCSA gathers the data.

Requiring ME Referral to an Ophthalmologist or Optometrist for CMV Drivers who do not meet the FOV Standard

Dr. Osbahr moved that FMCSA require medical examiners to refer commercial drivers failing to meet a 120-degree binocular FOV standard to an ophthalmologist or an optometrist for further screening and clearance. Drs. Cisneros and Hoffman agreed.

Dr. Hoffman asked Dr. Osbahr for clarification about the outcome of the evaluation for an individual who has an abnormal FOV and undergoes further evaluation. He noted that, in addition to an FOV number, the evaluation should include a risk evaluation. Dr. Osbahr supported requiring an individual with an abnormal FOV screen to present a written statement from an ophthalmologist or optometrist stating that the doctor evaluated the individual. He asked whether the evaluation should include acuity, perimeter, a full eye evaluation, and a “clearance” from the eye doctor that the individual meets the standards.

Dr. Morris commented that if he measures an unacceptable FOV, he refers the individual to a specialist, and that if the ophthalmologist also measures an unacceptable FOV, the individual must apply to FMCSA under the vision exemption program to qualify for a commercial license. Dr. Osbahr agreed, adding that the medical examiner must consider the information received from the specialist, and that the specialist should certify whether the individual could drive safely. Dr. Hoffman asked whether drivers must apply to FMCSA under the vision exemption program if they fail to meet the current FOV standard, even if a doctor identifies no elevated risk based on a formal vision evaluation.

Mr. Minor responded that an individual not meeting the current vision standard must apply for a vision qualification exemption, and that FMCSA must evaluate whether the terms and conditions of any exemption would achieve a level of safety equivalent to or better than the level of safety attainable by

complying with the rule. Mr. Minor said that without data, FMCSA would have no basis to conclude that an individual not meeting the 70-degree FOV standard could drive as safely as one who did meet the requirement. He said FMCSA most likely would deny the exemption application through a required statutory process that involves publishing a notice in the *Federal Register*, accepting comments, and making a decision. Dr. Lester noted that FMCSA had no driver requests for exemption from the FOV standard, and that all applicants have requested an exemption from the visual acuity standard.

Requiring ME Referral to an Ophthalmologist or Optometrist for CMV Drivers with a Diagnosis of Certain Systemic Diseases

Dr. Osbahr moved that the Board recommend having FMCSA require individuals with a diagnosis of macular degeneration, glaucoma, or retinitis pigmentosa to receive further formal testing by an ophthalmologist or optometrist. Following discussion and the final language as described below, all Board members agreed to the recommendation. Dr. Hoffman requested the MRB add “diabetic retinopathy” and “any other medical conditions that may affect visual fields and acuity” to Dr. Osbahr’s statement. Dr. Osbahr reviewed the MRB suggestion to add “retinitis pigmentosa, macular degeneration, cataracts, glaucoma, and any other visual conditions that affect visual field” as conditions to the proposed MRB recommendation.

Dr. Michelle Tregear explained that the MEP listed cataract as a condition requiring additional testing in the evidence review, but noted that although cataract diminishes sensitivity overall, the condition does not necessarily reduce visual fields. Dr. Hoffman agreed with Dr. Michelle Tregear’s explanation, noting that factors other than aging may cause cataracts.

Dr. Pervall stated the proposed recommendation as follows: “Drivers with macular degeneration, glaucoma, retinitis pigmentosa, diabetic retinopathy, cataract or any other condition that may affect the visual field should be referred to an ophthalmologist or optometrist for visual field testing.” She suggested adding “for a thorough exam.” Dr. Hoffman asked if clinically licensed professionals other than ophthalmologists or optometrists were qualified to conduct these evaluations. Dr. Osbahr suggested including only those two specialists categories (with which the Board agreed).

Other Possible Recommendations

Dr. Morris reemphasized his recommendation for FMCSA to incorporate visual-field testing techniques into medical examiner training to improve ME skills in this area. Dr. Pervall suggested adding “the use of confrontation testing by” to the first motion. Dr. Morris was unsure whether his recommendation should be vague about visual-field testing or more specific about confrontation testing.

Dr. Morris reasserted his discomfort with relying on confrontational testing as a screening measure. Dr. Hoffman observed that using a confrontation test to screen for FOV probably yields a low number of false negatives “with normal numbers.” Dr. Hoffman stated if a doctor says vision is normal there is a very high chance of having a normal peripheral FOV.

Dr. Osbahr he said he would not instruct an examiner to use confrontational testing, and thought MRB should avoid making such a recommendation. Dr. Morris supported leaving room to add other testing methods as they develop in the future.

Dr. Pervall concluded the deliberation on FOV.

Public Comment Period

There were no public comments.

Call to Adjourn

Mr. Minor thanked the MRB, and stated the Agency's hope of initiating an FOV rulemaking in 2013. Dr. Pervall adjourned the meeting.



CERTIFICATION

The minutes were approved by the Medical Review Board on January 17, 2013
(Date)

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

A handwritten signature in black ink, appearing to read 'Gina C. Pervall', written over a horizontal line.

Gina C. Pervall, M.D.
Chairperson
Medical Review Board

A handwritten signature in black ink, appearing to read 'Larry W. Minor', written over a horizontal line.

Larry W. Minor
Designated Federal Officer
Medical Review Board