FINAL REPORT 10.16.98

VISUAL REQUIREMENTS

and

COMMERCIAL DRIVERS

Frank G Berson, MD
Mark C Kuperwaser, MD
Lloyd Paul Aiello, MD, PhD
James W Rosenberg, MD

Beth Israel Deaconess Medical Center
Harvard Medical School
Boston, Massachusetts

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The objective of this project is to develop medically-based recommendations for amending the current vision requirements pursuant to the **Federal Motor Carrier Safety Regulations Section 391.41 (b) (10)** which promote (1) highway safety by ensuring that only persons who are physically qualified operate commercial motor vehicles and (2) national policy objectives as expressed in the **Rehabilitation Act of 1973** and the **Americans with Disabilities Act of 1990.**

Visual function is considered an important factor in the safe operation of commercial motor vehicles. This intuitive concept has been substantiated by a number of investigations. The question as to what aspects of visual function are most relevant to the task of motor vehicle operation is still not fully determined, but a number of studies suggest that parameters other than those which are conventionally tested (Snellen acuity, static multi-point horizontal field testing) may have a greater predictive relevance to ultimate performance safety.

The task is to determine a set of visual criteria which most closely reflect the visual performance necessary for safe vehicular operation. In a practical sense, this must reduce to a standardized set of visual performance tests which can be administered using currently available and easily accessible technology at reasonable cost. In light of the particular interest in the safety performance of drivers with some degree of visual disability, this result may have to take the form of a generalized screening standard with obligatory follow-up testing for those individuals identified to have some degree of partial visual impairment. In effect, this was achieved with the FHWA waiver program. This program provided a set of increased surveillance and monitoring tests for those individuals identified with a degree of visual disability and still wishing to obtain a CMV license.

Current federal vision standards reflect a relatively longstanding, widely accepted and easily administered set of tests of central static visual acuity and limited assessment of static peripheral horizontal visual field.

Current CMV Vision Standard

The vision requirements specified in Section 391.41 (b) (10) are as follows:

(1) Distant visual acuity of at least 20/40 (Snellen) in each eye, with or without corrective lenses.

(2) Distant binocular visual acuity of at least 20/40 (Snellen) in both eyes, with or without corrective lenses.

(3) Field of vision of at least 70 degrees in the horizontal meridian in each eye.

(4) Ability to recognize the colors of traffic signals and devices showing the standard red, green and amber.

The Rehabilitation Act of 1973, Section 504, prohibits discrimination on the basis of handicap. The Americans with Disabilities Act of 1990 prohibits discrimination against a "qualified individual with a disability" who, with or without reasonable accomodation, could perform the essential functions of a particular job.

With regard to the vision standards for operating a commercial motor vehicle, it is clear that the "essential function" of driving includes the safe operation of the vehicle. It is both intuitively obvious and proven, on the basis of retrospective review of accident and mortality statistics, that commercial vehicles accidents pose a greater risk in terms of bodily injury, mortality and property damage. It is for this reason that a higher standard is exercised in the licensing and evaluation of drivers of commercial vehicles. Similarly, the visual demands placed upon commercial vehicle drivers for safe operation are greater in that the activities associated with safe vehicle operation -- stopping time, acceleration, lane changing, response to signage, judgement of clearance -- coupled with the decreased maneuverability of a large sized vehicle and the greater potential for damage and injury would suggest that a stricter standard be in place for safe visual performance.

To the extent that the language of both the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990 is general, FHWA must determine what accomodation, if any, can be made for an operator who has a degree of visual disability without compromising the public safety. Obviously, this would require an investigation into the performance of individuals with visual disability operating commercial vehicles under a waiver of existing standards. The results of such a study, in terms of relating documented levels of reduced visual function parameters to accident rate, would provide a guide to the implementation of a set of modified visual requirements for individuals with disability. This guide, coupled with a rigorous monitoring protocol, would allow such individuals to operate commercial motor vehicles without compromising overall safety.

The Motor Carrier Safety Act of 1984, Section 206 (b) authorizes the Federal Highway Administration to "waive in whole or in part application of any regulation issued under Section 206" assuming such action "is consistent with the safe operation of commercial motor vehicles".

As part of a thorough review of the existing regulations the Federal Highway Administration contracted with the Ketron Division of the Bionetics Corporation, Malvern, Pennsylvania, to reasses the adequacy of the current vision standards. **Visual Disorders and Commercial Drivers**, authored by Decina, Breton, and Staplin of Ketron and reported in November, 1991, is an exhaustive review of the literature and critical evaluation of the current federal vision standards for operators of commercial motor vehicles. Interestingly, the authors found no compelling data to change the vision standard. However, they did address the visual field requirement and recommended a change in the wording.

In 1970 the vision standard was revised to include a requirement of visual fields of "at least 70 degrees in the horizontal meridian in each eye". Decina et al concluded that the intent of the revision was to restate the binocular requirement in terms of monocular testing and the monocular field should have been 140 degrees. To eliminate this ambiguity they recommended that the standard be restated as "a field of vision of at least 120 degrees in each eye measured separately in the horizontal meridian". This change was not adopted by the Federal Highway Administration.

A number of studies have substantiated the importance of peripheral visual field in the operation of motor vehicles. In fact, it is frequently argued that peripheral vision is a more important correlate of safe operation than is central acuity. Johnson and Keltner reported on the incidence of visual field loss in 10,000 volunteer subjects showing that the rate of undiagnosed field loss reached as high as 13% in older drivers. Half of the volunteers were not aware of any visual field problem and it was shown that those with binocular field loss had a driving accident rate which was twice as high as those with normal visual fields.

Szlyk et al (1991) studied the visual fields of patients with retinitis pigmentosa and the influence of visual field defects on safe driving performance, using both actual data and a computer-controlled driving simulator. Among their findings were further substantiation of the importance of an intact binocular visual field for safe driving performance. Moreover their data suggest that the form of abbreviated field assessment presently employed in licensing (i.e. limited testing of a few horizontal points to determine compliance with the stated horizontal field criterion) may seriously underestimate the defect in visual driving safety performance resulting from visual field defects due to specific eye diseases. Examples of this include a type of dense "ring scotoma", such as may be found in patients with retinitis pigmentosa or more commonly "arcuate scotomas", such as may be frequently seen in patients with glaucoma which would preserve both central acuity and far-peripheral vision (thus fulfilling the present form of visual screening) while still posing a significant visual and potential safety problem.

At the very least, these considerations should prompt a careful reassessment of the visual field criterion as it appears in Section 391.41 (b) (10). The method employed for visual field screening may need to be modified in order to assess visual field defects more accurately. In the instance of individuals with either suspected or known visual disabilities, separate and more detailed criteria for visual field screening may need to be considered.

FHWA instituted a vision waiver program in 1992 in an effort to provide necessary data for a possible change in the vision standards. This program enrolled 2656 drivers, but the number was reduced to 2275 by August 1995 through attrition, due to the revocation of waivers for program non-compliance, degradation in vision, self-termination or death. The criteria for participation in the waiver program included a detailed protocol for inclusion and monitoring of performance parameters including previous accident record, a formal examination by an ophthalmologist or optometrist who certified that the applicant could, despite the vision deficiency, perform the driving tasks required to operate a commercial motor vehicle. As part of the ongoing waiver program, the participant was required to report citations, accidents and changes in medical status. In addition a yearly vision examination by an ophthalmologist or optometrist was required.

The United States Court of Appeals for the District of Columbia Circuit issued a decision in August, 1994 concluding that "the adoption of the waiver program was contrary to law". This was in response to a challenge of the waiver program brought by the Advocates for Highway and Auto Safety. The basis for this retroactive decision was that at the time of the institution of the waiver there was not adequate data to satisfy the requirements of the Safety Act requiring the FHWA to "determine that such a waiver is consistent with the safe operation of commercial motor vehicles". The FHWA ended the vision waiver program on March 31, 1996 but the waived drivers were allowed to continue driving in interstate commerce as long as they continued to fulfill stringent requirements including an annual vision re-evaluation by an ophthalmologist or optometrist.

Although the Court's decision resulted in the termination of the Waiver Program, the data which has been accumulated from the program is extremely compelling. The waiver group accident rate was consistently **below** the national accident rate (cumulative comparison) and for drivers still in the program in August 1995, the waiver group accident rate consistently decreased to well below the national accident rate, exceeding the latter only during the first 6 months of the program.

The data obtained while the Vision Waiver Program was in effect does provide sufficient rationale for a follow-up study which might modify the current vision requirements for commercial drivers. Such a study would undoubtedly require significant effort and funding and might still risk court challenges. Alternatively, individual determinations for waivers could continue as the means for certification for some commercial drivers who do not qualify at present under Section 391.41 (b) (10). Although the original waiver program apparently cannot be re-instated, it has resulted in a useful database which clearly supports a new ongoing waiver program for the study of commercial vehicle drivers with visual impairment.

Our panel agreed that there were two major "problem areas" in vision testing:

First, it is clear that the present abbreviated protocol using the confrontation field could miss significant field defects, and field defects probably have as much, if not more, impact on visual function in driving than visual acuity. However, it may not be reasonable or practical to require formal perimetry for all applicants and for those renewing a commercial driver's license. It would seem reasonable that for screening purposes a modification in protocol to better reflect the functional requirements for driving would be appropriate. In instances where there is reason to believe that a visual field defect may exist, either by identification of underlying ocular/systemic disease which could result in a field defect or by virtue of having failed the screening protocol, then that particular individual should be required to proceed to a formal visual evaluation by an ophthalmologist or optometrist to include formal perimetry. For screening purposes, we would propose a modification of the present protocol to require the presence of a total horizontal visual field of 120 degrees and a total vertical visual field of 40 degrees (20 above the horizontal meridian and 20 below the horizontal meridian) in each eye. In practical terms this screening protocol could be implemented by changing the protocol to require that the examiner present the test stimuli (i.e. a moving finger) at selected points 20 degrees above and below the horizontal meridian. Each eye is to be tested individually with the partner eye occluded (see Appendix E). In instances where either eye fails to meet the screening standard further detailed evaluation would be required.

Second, visuocognitive/motor skill variables are much more relevant than static vision tests but evaluation of these skills with some version of a driving simulator is probably impractical except as part of a research study. The mandate to the panel that functional areas of vision to be evaluated "should be easily tested under currently available testing techniques" essentially precludes use of newer technologies. This, however, remains a promising method of evaluating the totality of visual performance as it applies to motor vehicle operation. As the computer technology needed to implement this type of evaluation becomes more accessible we would hope that further investigations of the type reported by Szlyk et al would result in a screening protocol which better evaluates and predicts driving safety.

Recommendations

With regard to the current CMV vision standard as specified in Section 391.41 (b) (10) we recommend the following:

(1) Distant visual acuity of at least 20/40 (Snellen) in each eye with or without corrective lenses. **Recommend that this standard remain unchanged.**

(2) Distant binocular visual acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses. **Recommend that this standard remain unchanged.**

(3) Ability to recognize the colors of traffic signals and devices showing the standard red, green, and amber. **Recommend that this standard remain unchanged.**

(4) Field of vision of at least 70 degrees in the horizontal meridian in each eye. **Recommend change of this standard as follows:**

With regard to the current field requirements the panel strongly supports the recommendation in the Ketron Study to restate the original language of the standard. There should be **at least 120 degrees of horizontal field in each eye.** In addition the panel feels that for adequate safe operation of commercial motor vehicles there should be a requirement of **at least 20 degrees of visual field above the horizontal axis and 20 degrees of visual field below the horizontal axis in each eye.** These standards can be confirmed by a modified protocol using confrontation visual field testing of each eye separately. **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.**

The panel would recommend a study similar to the original waiver study to provide necessary data on the extent to which visual impairment with careful evaluation and monitoring can be compatible with operation of a commercial motor vehicle to an acceptable safety standard. The data in the original vision waiver study offers evidence that, with appropriate design, such a study would not compromise overall public safety.

The panel also recommends consideration of a study using a computerized driving task simulator as a possible improved future mode of testing of commercial vehicle driving performance. Such a simulator would serve a dual purpose in that it could be programmed either as a screening device or as a more detailed testing device for those individuals who have a documented visual disability. If, indeed, a pilot trial utilizing such a device were to hold promise for future testing then consideration of distributable software might allow such devices to be used at reasonable cost in future testing.

Disclaimer

The members of this advisory panel have no financial interest in any of the devices referred to in this paper.

Frank G. Berson, MD,

Chairman

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APPENDIX A: Summary of Committee Process for Developing Recommendations

09.23.97 The final budget was approved by Federal Highway Administration

10.29.97 Ms Sandra Zywokarte, the Contracting Officer's Technical Representative, travelled to Boston to meet with the panel chairman, Frank G Berson, MD and the panel consultant Donald Dawson, MD, to provide necessary background information and to discuss the project.

11.11.97 Panel meeting. Dr Berson updated the members with regard to the project's objectives, scope of work and delineation of contractual tasks. Prior to the next panel meeting each member was to review the document **Visual Disorders and Commercial Drivers (OMC November 1991).**

11.25.97 Panel meeting. The discussion centered around potential literature searches for relevant articles and studies as well as the report, **Visual Disorders and Commercial Drivers.**

12.09.97 Panel meeting. Reprints were distributed as a result of searches on the Internet and National Library of Medicine.

01.08.98 Panel meeting. The discussion centered around the FHWA Waiver Program and the final rule published by D.O.T. in 1996.

01.09.98 through 03.31.98 Dr Berson prepared the initial draft of the report. The document was expanded and revised in meetings with Dr Kuperwaser on 03.01.98 and 03.08.98. The revised draft was circulated to the other members of the panel on 03.23.98. Drs Aiello, Dawson and Rosenberg provided comments and suggested changes by 03.23.98. Drs Berson and Kuperwaser met on 03.29.98 to incorporate suggestions into another revision of the draft. This revision, dated 03.31.98, was sent to COTR in anticipation of the Washington meeting.

04.07.98 Panel meeting. An agenda for the Washington meeting was created and questions posed by D.O.T. reviewed and concensus reached.

04.24.98 Meeting with the FHWA, Department of Transportation,Washington, DC (see Appendix B: Meeting Summary).

06.09.98 Panel meeting. Questions generated by the Washington meeting and submitted by FHWA officials were discussed for possible inclusion in the final draft report.

06.10.98 through 08.21.98 Panel members worked individually and together to prepare the final draft report.

08.22.98 through 10.16.98 Review of final draft report by COTR/FHWA and preparation of final report by Drs Berson and Kuperwaser.

Appendix B: Meeting Summary
Visual Requirements and Commercial Drivers
Friday, April 24, 1998
Department of Transportation
Washington, D.C.

The entire panel (Drs Aiello, Berson, Dawson, Kuperwaser and Rosenberg) met with FHWA officials at the Department of Transportation on April 24, 1998. The proceedings were transcribed by Audio Associates of Seabrook, Maryland.

I. Introduction of Panel Members, FHWA Officials, Guests

Frank G Berson, MD, Panel Chairman
Donald Dawson, MD, Panel Consultant
Lloyd Paul Aiello, MD, PhD, Panel Member
Mark C Kuperwaser, MD, Panel Member
James W Rosenberg, MD, Panel Member
Paul Brennan, Director, Office of Motor Carrier Research and Standards
Sandra Zywokarte, Team Leader, Driver and Medical Qualifications Standards, OMC Research and Standards
Albert Alvarez, OMC Research and Standards
Joe Solomey, Attorney, OMC Law Division
Judy Rutledge, Attorney, OMC Law Division
Mike Thomas, OMC Research and Standards
Sam Rea, OMC Research and Standards
Anna Chang, Legal Counsel, FHWA
Debbie Freund, OMC Research and Standards
Kathy Gowan, OMC Research and Standards

II. Summary of Panel Activities and Proposed Draft Recommendations

Dr Berson summarized the work done by the panel since the contract was approved by FHWA in late September, 1997. The panel had met as a group five times and prepared a draft document which was completed on March 31, 1998 and sent to Ms Zywokarte in anticipation of the Washington meeting. The draft recommended that the current CMV Vision Standard remain unchanged with the exception of the field of vision requirement, which needed to be restated in a manner more consistent with what was apparently intended in FMC Safety Regulations Section 391.41 (b)(10). There were additional suggestions for testing the field as part of a screening exam, acknowledging the importance of vertical field. The FHWA vision waiver program was discussed as was the potential value of driving simulators.

III. Eye Diseases and Visual Fields

Presented by Mark C Kuperwaser, MD (see Appendix C).

IV. Review of Accident Report

Dr Rosenberg summarized an accident report which involved a one-eyed driver from the Vision Waiver Program. The accident occurred in Missouri and resulted in three fatalities. Although it was not possible to arrive at a definitive cause for the accident, there was a consensus that it may well have not been related to the driver's one-eyed status but, rather, to other factors.

V. Considerations for Future Study

Presented by Lloyd Paul Aiello, MD, PhD (see Appendix D)

VI. Additional Questions for Panel

A number of questions submitted to the panel prior to the meeting were discussed.

Appendix C: Visual Field and Driving Performance

Mark Kuperwaser, MD

I. Background

The integration of information from the peripheral visual field into the total visual input is of particular importance in driving tasks. More often than not a visual motor response depends upon information coming from peripheral visual areas rather than straight-on vision. This is true both for static situations (i.e. avoidance of peripherally sensed objects such as curbs, barriers) and for dynamic situations (i.e. vehicles, objects, persons approaching from the side). Indeed in a rating of visual parameters deemed to be important for safe vehicular maneuvering (passing, lane changing, collision avoidance, height clearance) peripheral visual field was rated as the most important parameter (1).

Our increasing understanding of the organization of the human visual system suggests that our visual systems are in fact organized into two complementary functional entities. These two functional entities are subserved by somewhat different types of neuronal cells and have somewhat different representations and pathways in the human visual system (2). Their performance characteristics are somewhat different and yet they clearly are intended to combine and enhance the overall visual experience. Briefly put, these two complementary visual systems comprise:

(a) a system for processing detailed visual input from the central or straight-ahead position. This system apparently carries a high degree of detailed visual information: fine contrast gradation, color, and fine detail. Such a system is useful for a task such as reading a straight-ahead road sign or a license plate number. The trade-off in this system is processing speed, and the information from this system tends to get to the visual centers of the brain in a slower fashion. In neuro-anatomic terminology this system is referred to as the **parvocellular** visual system.

(b) a system for integrating changes in the peripheral visual field (particularly the "near peripheral" visual field) and transmitting this information to the visual centers of the brain in a fairly rapid fashion. The trade-off in this system is that of detail for speed. Thus this system does not resolve fine detail, color information, or fine gradations of contrast. In contrast to the above system this is referred to as the **magnocellular** visual system.

Taken together these two systems perform a complementary task. We utilize the parvocellular system to scrutinize fine detail wherever it is that we have directed our vision (i.e. the straight-ahead position), typically to read print or appreciate some finely detailed object. An enormous amount of information emanates from this parvocellular system which has its representation in the macula or central portion of the human retina. In order to re-direct this system we need a signal that something is occurring elsewhere. This information need not necessarily be detailed but should be particularly sensitive to change or motion, be rapidly transmitted to the brain, and result in a re-orientation of the position of gaze so that we may now study this new object, previously in the periphery of our vision. Were the entirety of our visual system to consist of a highly-detailed processing entity our brains would suffer "information overload" and not be able to distinguish between that which is visually important (that which we choose to look at) and that which is not visually important at the moment (that which is in the periphery of our vision). By limiting the detailed system to a small area of straight-ahead vision the brain is free to direct visual attention to a limited set of objects, but is also made aware of other objects through the less detailed peripheral system. If a change is sensed and for some reason it is important to re-direct visual attention, then this information is supplied by the peripheral visual system.

It is therefore obvious that both good central acuity (as measured by Snellen chart acuity) and good peripheral function (as measured by perimetry or visual field testing) are necessary in order for the visual system to provide meaningful and timely information to the brain. In the instance of driving it is important to be able to both process the information (such as a warning sign, directional sign, etc.) which is usually straight ahead while at the same time having the capacity to change the direction of gaze in order to evaluate and react appropriately to an object or objects either stationary or moving in the periphery.

A number of fairly common disease entities can adversely impact on either or both of these visual systems and it is the prevalence of these disease entities which makes it necessary to screen for visual performance in the operation of a motor vehicle. It is a fact that the person affected by these entitites may not always realize or perceive the extent of damage or deficit on their own. Typically diseases which affect central visual acuity are fairly noticeable to the individual since our visual pathways direct a large amount of central visual information to the brain (the brain is "aware" of central vision). However diseases which affect peripheral visual function may frequently not create a deficit of which the individual is aware and thus "silently" and perhaps seriously impair visual performance. An extreme example might be a person with advanced glaucoma who maintains 20/20 central vision but has lost extensive peripheral visual field and now essentially has "tunnel" vision. Thus the importance of visual screening for safe motor vehicle operation becomes apparent.

II. Common Causes of Peripheral Visual Field Defects

The generalized increase in life expectancy in the U.S.A. over the past century has resulted in an ever expanding aging population. With this we have witnessed an increase in eye diseases whose prevalence increases with age (cataract, glaucoma, macular degeneration, diabetic eye disease). A separate significant impact on visual function results from stroke and other neurologic disease which affect the integrity of the visual pathways leading from the eye to the brain. The population over age 65 is presently the fastest growing population sector in the country. Additionally more and more people over 65 continue to lead active lives and, of necessity, frequently continue to work. With more emphasis on independent and partially assisted living the need for mobility increases. This has resulted in a larger number of older individuals operating both commercial and private motor vehicles. Thus the impact of eye and neuro-visual disease on this aging population is significant.

The Framingham Eye Study (3) identified and characterized the prevalence of the four common eye diseases in the aging American population: cataract, glaucoma, macular degeneration, and diabetic eye disease. Each of these entities can affect both central and peripheral vision with consequent impact on driving safety. Moreover these diseases can occur in combination with one another as well as in combination with systemic disease which can further impact driving performance. While some of these conditions are amenable to therapy, frequently the therapy can at best only **arrest** the progressive damage caused by the disease and cannot restore visual function. As a result individuals who have achieved therapeutic control of their visual condition still operate with a fixed visual deficit. As more is understood about the subtler aspects of visual function we begin to appreciate that these diseases affect visual modalities beyond those which were originally used in characterizing the disease state.

Cataract

Cataract is the commonest cause of visual impairment in the adult population. It is estimated that there are some 5 million visually significant cataracts in the adult American population. Cataract is a slow progressive opacification of the crystalline lens of the eye which results in visual impairment by distorting the optical passage of light to the retina. Cataract formation can be accelerated by a number of conditions including injury, exposure to radiation, gout, certain medications (steroids), and the presence of diabetes. The visual disturbance of cataract and its impact on driving is variable. One of the earliest symptoms reported is that of glare particularly during night driving in the face of oncoming headlights. While this represents a difficult visual task in general (the ability to maintain visual attention and resolution on a dark road in the presence of an oncoming bright light just off-axis) the difficulty of the task is compounded by the light-scattering effect of the cataract. It has been shown that the ability to read Snellen letters in the presence of cataract can be critically dependent and significantly altered by the conditions of illumination. Thus a person with cataract may be able to resolve a 20/20 visual task under the controlled lighting of an examination room, but driving on a roadway into a low sunset may have the visual equivalent of 20/200 as a result of cataract. Not only is glare significant, but overall acuity, contrast, and color resolution are diminished with cataract. While there is not a specific impact on the peripheral field of vision, any part of the visual system can be compromised by the optic distortion introduced by cataract. Although the progression of visual symptoms is gradual there is usually a point at which the individual recognizes that vision has limited the performance of a specific task and at that point therapeutic help is usually sought. The therapy of cataract is surgical removal of the cataract and replacement of an intraocular lens. Generally the visual result is quite good and represents a rehabilitation of visual function following cataract. Of note some individuals continue to suffer visual symptoms following cataract surgery as a result of optical aberrations induced by the edge of the artificial lens implant, particularly during night driving when the pupil normally dilates and allows light to strike this optical edge. For this reason there has been a general trend to enlarge the optical zone of lens implants so as to minimize this effect.

Glaucoma

Glaucoma is defined as an abnormality in the regulation of intraocular pressure which can result in chronic, generally painless, pressure elevation which produces a gradual progressive atrophy of the nerve cells comprising the optic nerve whose job it is to transmit visual information from the retina of the eye to the brain. Some 2-4 million Americans suffer glaucoma, there is a sizeable cohort of as-yet undetected individuals with this disease and about four times as many people are regarded as "suspects" for this disease with increased risk for subsequent development of visual deficit. Some types of glaucoma can progress at normal intraocular pressures. The development of chronic, elevated intraocular pressure is generally painless and gives no clue to its presence. Thus it is much like systemic hypertension which can be present undetected for years while doing its damage. Furthermore the visual field deficits of glaucoma can progress to a relatively advanced state without being noticeable to the individual. In fact there are many instances in which an individual presents for eye evaluation only after having experienced a "near-miss" in a traffic situation and thus became aware of the peripheral vision deficit. In that the damage of glaucoma is the death of neuronal cells the visual deficit cannot be reversed. The therapeutic goal, is therefore the lowering of intraocular pressure to a level which preserves the existing neuronal cells and prevents further progression of the visual field deficit. To achieve this a combination of therapeutic modalities may be used. Commonly the first therapy is that of topically administered eyedrops which can be used individually or in combination to lower intraocular pressure. Strict and ongoing compliance with these medications is mandatory. Many of these drops may have significant impact on vision in and of themselves (i.e. pilocarpine, a traditional glaucoma medication which decreases night vision as a result of induced miosis or contraction of the pupil). The newer medical therapies have fewer visual side effects and are more easily complied with. Laser trabeculoplasty may be added to medical therapy and ultimately glaucoma filtration surgery may be necessary for pressure control. As our understanding of the functional aspects of the visual system increases, we are also finding that a number of subtler visual functions (such as re-direction of visual attention, night vision, color vision) may be affected in addition to peripheral field. An individual with glaucomatous damage might exhibit an excellent Snellen acuity but with careful peripheral field testing may show deficits in the peripheral visual field.

Macular Degeneration

Macular degeneration is a term used to describe a variety of disease processes all of which in some way impact upon the functioning of the central portion of the retina, called the macula, which is responsible for the central, detailed, straight-ahead portion of visual function. These diseases increase in frequency with age, affecting some 30% of all Americans by age 70. For the majority of these people macular degeneration is a slow, subtle process resulting in subtle visual defect. However about 10% of the people afflicted with this condition can progress to a more rapid,"malignant" form of the disease which can destroy all of the straight-ahead acute visual function. Interestingly the peripheral vision is frequently spared in macular degeneration so that this represents a sort of "inverse" of the visual deficit in glaucoma. Since so many of our daily visual tasks (reading, writing, watching TV, etc.) utilize the central visual system, people are generally aware of the effects of macular degeneration. One of the earliest symptoms is metamorphopsia, a "bending" or distortion of objects in the central visual field. Visual acuity generally drops, recovery from bright lights is generally lengthened, and the eventually the individual may develop a partial or total scotoma (blocked-out area) in the direction of attempted gaze. Thus while the periphery is in good view the straight-ahead view is blocked. The impact of macular degeneration on visual function is usually apparent from diminishing, uncorrectable Snellen type acuity, although attention should be paid to the visual field deficits, generally central, which can result from this condition. The para-central visual field defects may create a blind-spot near the straight-ahead position into which a passing vehicle in an adjacent lane may seemingly disappear. Therapeutic options are generally limited. Some forms of macular degeneration (such as epimacular membranes) may be amenable to surgical treatment, while other forms of the disease may be arrested by laser ablation (which in itself can create a larger scotoma or blind-spot). However, this is still the leading cause of untreatable legal blindness in the country. Partial visual rehabilitation may be achieved through the use of telescopes which allow the recruitment of the unaffected peripheral retina, but telescopes achieve their effect at the cost of reduction in peripheral field. Thus an individual driving with a telescope mounted in his eyeglasses may be able to read a road sign but is effectively doing so in the setting of "tunnel-vision" induced by the telescope. It is generally felt that telescopic aids do not reconstitute useful and safe driving vision.

Diabetic Retinopathy

There are some 20 million diabetics in the United States and the number continues to grow. Diabetes can impact many aspects of vision ranging from changes in refractive state as a result of blood sugar fluctuation to the acceleration of cataract formation. However the principal effect of diabetes on the eye is that of a metabolically induced vasculopathy which initially results in the formation of incompetent, leaking blood vessels (background retinopathy) and eventually can result in an inadequacy of blood delivery to the retinal tissue of the eye (ischemic proliferative retinopathy). In the latter instance the body attempts to effect repair by growing new blood vessels, however these new vessels are abnormal and result in hemorrhaging within the eye. The visual effects of diabetic retinopathy thus result from fluid leakage near the macula (diabetic macular edema) which can affect central visual acuity and create partial scotomas (blind spots) or from gross hemorrhage in the eye which can obscure vision and eventually lead to retinal detachment and blindness. Strict control of blood sugar as well as medical control of concurrent disease (hypertension, renal disease, cardiac disease) is felt to be of help in controlling this retinopathy; however, the presence of certain levels of retinopathy mandates the use of laser treatment either to ablate leaking vessels or to ablate zones of peripheral ischemic retina. Once again the laser treatment itself may result in significant visual field deficit. For example a complete pan-retinal photocoagulative ablation may seriously diminish the peripheral visual field for the sake of maintaining central visual acuity. As with the other common diseases we have begun to appreciate the impact on subtler visual modalities (contrast sensitivity, flicker fusion frequency, color discrimination) at a stage in which clinical damage is not evident. One should also consider that not only does the diabetic motor vehicle operator suffer from impaired visual input but also frequently suffers concurrent neuropathy which may affect other sensory input and motor coordination.

Stroke-related Visual Disease

Stroke remains a leading cause of functional impairment in the elderly as well as a significant cause of death in this country. Stroke is neuronal cell ischemia and/or cell death resulting from interruption of normal blood supply to a portion of the brain, either through the occlusion of a blood vessel by a clot or embolus or as a result of hemorrhage from an incompetent blood vessel. Recovery from stroke is variable, depending in part on the redundancy of blood supply to the affected region of the brain. There is usually some residual deficit. In that a major portion of the brain comprises not only the visual pathways from the eye to the brain itself but also regions in which visual information is processed, it is not surprising that strokes can frequently result in visual deficits of various kinds. Strokes affecting the pathways from the eye to the primary visual cortex of the brain effectively interrupt the transmission of images or parts of images to the brain and can result in various types of scotomas. Depending on the severity and location of the stroke these scotomas can, for example, obscure all of the vision to the right (or left) side of the visual field from **both** eyes so that all objects to one side are blocked (homonymous hemianopsia). Another type of defect, more typically resulting from a pituitary tumor, may block the outer half vision from either eye, leaving a person with vision only in the inner nasal portion of the visual field (bitemporal hemianopsia). While the basic field deficits resulting from stroke can be assessed in the usual clinical fashion it is important to remember that stroke may affect levels of visual information processing (visuo-cognitive processes) which are not readily measurable but which can have profound impact on overall visual performance. The evaluation and rehabilitation of an individual recovering from stroke may thus mandate careful and close follow-up, particularly in terms of assessing that individual's capability to safely operate a motor vehicle.

Retinal Degenerative Disease

A number of retinal degenerative conditions can impact visual function. These are somewhat less common in their prevalence in the general population, but again exhibit an increasing visual impact with age. Some of these conditions can manifest at a relatively early age and result in progressive visual deficit at a much earlier point than the common eye diseases of the elderly. While some of these diseases result from familial genetic tendencies and can thus be targeted for early screening, many of these diseases may occur sporadically in the population. Depending upon the nature of the disease they may manifest primarily through either deficits in peripheral vision first or through deficits in central vision first. Invariably, as they progress they eventually compromise the other modality and can result in severely limited vision or total blindness. Retinitis Pigmentosa is a group of such retinal degenerative diseases which can occur either through heriditary patterns or spontaneously, manifest early in life, and result in night-blindness, peripheral visual field deficits and eventual loss of central visual acuity. The degree and manifestation of symptoms can vary widely from individual to individual as can the rate of progression. A particular type of scotoma (the "ring scotoma") can have insidious effect on a driver's vision as an approaching vehicle can vanish from sight as it enters the ring scotoma and then re-appear. Unless detailed peripheral field testing is done, the ring scotoma may not even be detected since it only blocks a mid-peripheral zone of vision. Thus individuals identified with degenerative retinal conditions and still deemed capable of operating motor vehicles require careful and detailed evaluation and monitoring of their disease condition.

III. Conclusions

The parameters of central visual acuity, peripheral field and color detection constitute three important parameters of visual function in motor vehicle operation. They form the basis of the screening standard for commercial motor vehicle licensing. The presence of eye disease may alter any one or more of these parameters with a resultant negative impact on visual function and safety of motor vehicle operation. The degree of this adverse impact can vary widely among individuals and thus mandates more detailed and careful evaluation prior to determining that individual's fitness to operate a motor vehicle within acceptable safety standards.

Peripheral visual field is an extremely important part of visual processing in driving in that information which may be critical to decision-making frequently first appears in the periphery of the visual field. As driving is a dynamic visual task with constant change in visual input, the location of objects in the peripheral field is constantly changing and requires an intact field for appropriate evaluation and response. To lose an object approaching from the visual periphery even for a short period of time might have devastating consequences. Moreover the processes by which peripheral visual information is integrated may be critical to the overall presentation of orderly visual data to the cognitive portion of the brain.

Standard static visual perimetry presently represents the best tool that we have widely available for testing peripheral visual field. Standard static perimetry, however, has a number of drawbacks and may not accurately represent the type of peripheral visual field processing which is necessary for driving. Perimetry does lend itself to modification (for example dynamic perimetry, two-point discrimination perimetry, etc); however, these specialized modalities are not widely understood or accepted. They may provide improved predictive value in the future and warrant investigation, particularly in the presence of visual system disease. A recent study has suggested that a two-object discrimination type of test of peripheral vision may be a very good predictor of motor vehicle safety in the elderly population (4).

The principal motivating factor behind this panel's recommendation for further investigation of the visual factors affecting motor vehicle safety is the absence of concrete scientific data. Certainly the parameter of peripheral visual field function suffers from the same absence of concrete predictive data and should be carefully assessed in any future investigations.

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Appendix D: Consideration for Future Studies Regarding the Visual Requirements for Drivers of Commercial Vehicles

Lloyd Paul Aiello, MD, PhD

I. Overview:

There is considerable need to ascertain the exact visual requirements for safe and efficient operation of motor vehicles by commercial drivers. The considerable impetus for determining these requirements lies with the desires to maximize both the commercial opportunity for individual employment (the drivers) as well as the safety of our roads and highways (pedestrians, other drivers and the commercial drivers themselves). To optimize the balance between these two mandates, a detailed understanding of how the various aspects of visual functioning relate to the safety and performance of commercial motor vehicle operation is essential. Unfortunately, there is a considerable lack of empirical and well-substantiated data upon which to draw such conclusions. As such, there is considerable need for the performance of rigorously controlled scientific investigations to provide the data upon which future policy modifications may be based.

II. Rationale Justifying Future Studies:

The vision waiver program demonstrated that it was feasible to closely monitor a cohort of commercial motor vehicle drivers with impaired visual function and that during the course of this program public safety was not compromised. Although the waiver program was terminated due to a court ruling citing a lack of sufficient preliminary data to justify the program's inception, data from the waiver program during its existence provides substantial support for the rationale, feasibility and initial safety of such a program. A well designed study, based on the waiver program model, could yield valuable, scientifically valid data upon which to justify future visual function requirements for the drivers of commercial motor vehicles.

III. Primary Goal:

The primary goal for these initial studies must be to determine if commercial motor vehicle drivers with well-defined and well-characterized visual impairments are at higher risk of motor vehicle accident than motor vehicle drivers without such impairments.

IV. Secondary Goals:

a. Determine which visual impairments have the least effect on the safe operation of commercial motor vehicles.

b. Determine which visual impairments have the most hazardous effect on the operation of commercial motor vehicles.

c. Determine if certain driving conditions are associated with increased accident rates in commercial motor vehicle drivers with visual impairment.

d. Determine if accident rates change over time in commercial motor vehicle drivers with visual impairment.

e. Determine when commercial motor vehicle drivers with visual impairment should be re-evaluated with regard to their commercial motor vehicle licensure.

V. Overriding Consideration:

Public safety and safety of the commercial driver must be the overriding concern. Since any relaxation of the visual function standards is associated with potential public safety risk, any trial design must incorporate detailed and timely evaluation of accident rates in order to modify the program should accident risk be shown to increase in any particular group or subgroup of commercial drivers.

VI. General Consideration:

Since it is the hope that the outcome of any such future studies of visual impairment in commercial motor vehicle drivers will be used to modify current visual requirement standards, the studies themselves must be performed in a rigorous and scientific manner. This will require full utilization of scientific trial methodology, consideration of confounding variables, maintenance of data integrity; non-biased evaluation of the data and prospective standardization of as many variables as possible. There is a vast body of knowledge concerning the appropriate performance of such trials. It is highly recommended that, should such a trial eventually be considered, multiple individuals with expertise in clinical trial design, visual functioning,commercial driving requirements, highway safety, and legal and government representatives be convened in order to begin the rigorous design of these trials. The expertise of all these individuals will be critical to prospectively define a study, which, at its conclusion, will yield robust and accurate data upon which to base future policy changes.

VII. Defining Eligibility Criteria:

The principle questions regarding adequate visual function revolve primarily around visual acuity, visual field, monocular status, and color vision. Thus, any investigative initiative must include individuals who have varying degrees of deficit in each of these parameters. Furthermore, the deficit in each of these parameters must be rigorously defined and evaluated by standardized procedures. The eligibility of an individual, and determining the particular group in which they will be evaluated, must be predefined in a detailed manner. All tests, which are used to evaluate these visual functions must also be rigorously defined and performed in a standardized manner. This requires detailed protocols for ophthalmic evaluation and rigorous timing of study visits. Usually, this would also require stndardized certification of the individuals who are performing the measurements. In addition, the reporting of each applicant's physical state must be performed in a standardized manner and compiled in a central database. Rigorous and standardized reporting and follow-up of all accidents must be made on a predetermined and routine basis. Full details of all incidents must be reported on standardized forms to assure that all information is acquired. These forms should be prospectively designed to capture all necessary information upon which future analysis would be performed. As part of appropriate study design, the number of participants, the study duration, and the magnitude of the effect to which one is looking must be prospectively determined.

It is strongly suggested that an independent data and safety monitoring board be convened to assure the integrity and independent evaluation of the safety aspects of the study and to monitor safety as the trial progresses. The board will be charged with the mandate to report any unjustifiable increase in risk such that the ongoing study may be modified to improve public safety or be promptly terminated if indicated.

VIII. Feasibility:

The waiver program, as of 1993, included 2,656 waiver program commercial motor vehicle drivers among which there were 1.553 accidents per million vehicle miles. These drivers with visual impairment in the waiver program actually had a 35% lower risk of accident than did the non-visually impaired commercial motor vehicle drivers. Standard commerical drivers in 1993 had 2.422 accidents per million vehicle miles and were at a 56% higher risk of accident than those in the waiver program. These statistics demonstrate that significant numbers of individuals can be followed for a significant period of time resulting in large numbers of vehicle-miles for evaluation. Furthermore, it suggests that when the waivers are determined with care, there is no increased risk to the general population.

IX. Summary:

A well designed, prospective study evaluating the accident risk in commercial motor vehicle drivers with defined visual impairments could most likely be implemented with minimal public safety risk and could provide currently unavailable, scientifically valid data upon which to base future policies regarding the visual function requirements for commercial motor vehicle drivers.

X. Potential Study Design:

There is a wide range of potential study designs that could be implemented to achieve the desired evaluation. As stated above, it is strongly recommended that a diverse group of individuals with expertise in associated areas be convened in an effort to determine the optimum study design should such a study be implemented. A potential design, which could yield data with a minimum of extra effort and minimal additional expense follows:

1. Rigorously define the range of visual impairments that one wishes to study. These will include defined ranges of visual acuity, visual field, monocular status and color vision deficits.

2. Rigorously determine the method by which such visual impairments are to be quantitated. Assessment must be done using standardized ophthalmologic procedures with the specific details of performing these procedures stated prospectively.

3. Institute a program similar to the initial waiver program that will allow commercial motor vehicle drivers with the deficits defined above to participate despite their visual impairment.

4. Granting of a commercial motor vehicle waiver should be made dependent upon the driver's participation in the ongoing waiver program study. An individual who does not want to participate in the vision waiver study should not be granted a waiver for commercial vehicle operation. This policy should be justifiable since there is an unknown risk to the general population and participation is required for appropriate monitoring. Program participants should be accepting of this requirement since otherwise they would not be able to participate as a commercial motor vehicle operator.

5. Participation in the vision waiver study should be dependent upon the applicant receiving an appropriate ophthalmologic and medical evaluation prior to the granting of the waiver. Such evaluation must be completed on standardized forms, which will be prospectively defined for the study. Failure to complete this ophthalmologic or physical evaluation should result in the applicant not being eligible for a commercial motor vehicle waiver. The expense for these examinations should be borne by the participant. Again, this approach should be feasible to implement since the financial and time impact for a single individual would be far less than if the government were to assume this responsibility. In addition, the individuals will now be gaining additional employment revenues which could offset these costs.

6. Maintenance of a participant's commercial motor vehicle waiver should be dependent upon the prompt and complete reporting of all accident events. Any event, which is not appropritely reported, should result in immediate termination of the individual's commercial motor vehicle waiver. This approach is justified, since the primary concern is the safety of the general population, and failure to report such incidents would make it impossible to monitor whether particular groups are at increased risk of accident.

7. Maintenance of a commercial motor vehicle waiver should be dependent upon reevaluation at a predefined interval. This interval should be prospectively determined prior to the initiation of the waiver program and possibly modified as additional data is evaluated. Failure to be re-evaluated at the designated time should result in immediate termination of the individual's commercial motor vehicle waiver. Again, this is essential in order to obtain the data required to assess whether safety is being maintained over time.

XI. Summary:

This study design allows for the granting of commercial motor vehicle waivers in a manner that will assure:

a. Appropriate enrollment of drivers into the prospective study
b. Proper driver evaluation prior to entry into the study
c. Reduction in the governmental cost of performing this study
d. Appropriate reporting of all accidents
e. Timely re-evaluation of each participant

The data derived from this study will answer many critical questions, particularly those concerning the:

a. Level of visual acuity required for safe operation of a commercial motor vehicle
b. Extent of visual field required for safe operation of a commercial motor vehicle
c. Effect of monocular status on the safe operation of a commercial motor vehicle
d. Need for color vision
e. Effects of associated medical conditions
f. Effects of various driving conditions
g. Maintenance of motor vehicle safety over time in individuals with visual impairment

Such a study would answer the vast majority of critical questions for which essential data is currently unavailable and which is required to determine if alterations to the current visual requirements for the operation for commercial motor vehicles are justifiable.

XII. Conclusion:

It is our opinion that a prospective evaluation of the effects of visual function on the performance of commercial motor vehicle drivers is feasible and can be implemented with reasonable effort, cost, and time commitment. In fact, due to the current lack of appropriate data upon which to set visual function requirements for commercial motor vehicle drivers, it can be argued that such a study is essential before any further modifications which might loosen the current standards can be ethically entertained.

Appendix E: Protocol for Screening the Visual Field Using a Confrontation Method

1. The examiner is standing or seated approximately 2 feet in front of the examinee with eyes at about the same level.

2. The examinee covers the left eye with the palm of the left hand for testing of the right eye.

3. The examiner asks the examinee to fixate on the left eye of the examiner.

4. The examiner extends his/her arms forward, positioning the hands halfway between the examinee and the examiner. The right hand is held one foot to the right of the straight-ahead axis and six inches above the horizontal plane. The left hand is held one-and-a-half feet to the left of the straight-ahead axis and six inches above the horizontal plane.

5. The examinee is asked to confirm when a moving finger is detected. The procedure is repeated with the examiner testing six inches below the horizontal meridian.

6. The entire procedure (2. through 5.) is then repeated for the examinee's left eye which should fixate on the examiner's right eye. The hand placement is appropriately reversed.

Appendix F: Protocol for Testing Color Vision

Examiners would use three standardized testing sheets developed and distributed by the Department of Transportation. Each sheet would contain one colored circle (red, green, and amber) with chromicity determined by the National Bureau of Standards, which specifies the colors of traffic control signals in the United States.

The examinee is asked to look at each colored circle with both eyes simultaneously. Correct identification of all three circles would indicate that the examinee meets the current standard.