Expert Panel Recommendations
Stroke and Commercial Motor Vehicle Driver Safety

Medical Expert Panel Members

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Introduction

The primary mission of the U.S. Department of Transportation's (DOT's) Federal Motor Carrier Safety Administration (FMCSA) is to reduce crashes, injuries and fatalities involving commercial motor vehicles (including large trucks and buses). One mechanism used to facilitate this effort is the updating of current, and the development of new, medical fitness standards and guidelines for medical examiners that are responsible for certifying drivers as fit for duty.

This report summarizes the considerations and recommendations of a panel of three experts in the field of stroke medicine (henceforth termed the Medical Expert Panel) who examined FMCSA's current physical qualification standards and guidelines for medical examiners as they pertain to stroke.

The current FMCSA's standards and guidelines pertaining to individuals who have experienced a TIA or a stroke (49 CFR 391.41(b)) can be found at the following web site: http://www.fmcsa.dot.gov/rules-regulations/administration/fmcsr/fmcsrruletext.asp?section=391.41. While none of the current physical qualification standards speak directly to individuals who have experienced a TIA or a stroke, several current standards (specifically 391.41(b) (7 through 10)) may be relevant to such individuals. These are presented below.

A person is physically qualified to drive a commercial motor vehicle if that person —

- 391.41(b)(7) Has no established medical history or clinical diagnosis of rheumatic, arthritic, orthopedic, muscular, neuromuscular, or vascular disease which interferes with his/her ability to control and operate a commercial motor vehicle safely;

- 391.41(b)(8) Has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a commercial motor vehicle;

- 391.41(b)(9) Has no mental, nervous, organic, or functional disease or psychiatric disorder likely to interfere with his/her ability to drive a commercial motor vehicle safely;

- 391.41(b)(10) Has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing standard red, green, and amber.

Unlike standards which are regulations that a medical examiner *must* follow, these guidelines are recommendations that the medical examiner *should* follow. While not law, the guidelines are intended as standards of practice for medical examiners. Current guidelines from FMCSA on the certification of individuals who have experienced a TIA or a stroke comes from a 1988 conference report (http://www.fmcsa.dot.gov/factsresearch/research-technology/publications/medreports.htm), which suggests information for patients with neurological disorders.

"Because the recurrence rate of ischemic neurological symptoms is highest during the first year after TIA or minor stroke, no commercial driver should be permitted to return to driving until he/she has had a careful evaluation of the event and a treatment plan has been outlined by a physician. The drivers should not return to commercial driving within one year of a stroke. A decision for clearance after one year will depend on the interval history, general health, neurological examination, and compliance with the treatment regimen. This clearance should be done by a neurologist. Any driver with a deficit that requires special evaluation and screening should be recertified annually. In the event that the driver is receiving drugs that have potentially high rates of complications, such as bleeding tendencies with oral anticoagulants, he/she should not return to driving. In the event the driver is taking medications that have a potentially depressing effect on the nervous system, he/she should not be qualified to drive."

"Drivers with a recent cerebral infarction warrant an evaluation to determine the source of the stroke and to establish the appropriate medical, surgical, and rehabilitation regimen. As in patients with a TIA or minor stroke, these persons are at increased risk of recurrent attacks. Restrictions on commercial driving should, at a minimum, be the same as those for patients with a TIA.

Patients with embolic or thrombotic cerebral infarction also will have residual intellectual or physical impairments severe enough to prevent a return to commercial driving. Fatigue, prolonged work, and stress may exaggerate the neurological residuals from a stroke. Most recovery from a stroke will occur within one year of the event. Commercial drivers who wish to return to full work status should undergo a careful neurological examination at one year after the stroke that includes assessment of their cognitive abilities, judgment, attention, concentration, vision, physical strength, agility, and reaction time. If the neurological residuals from the cerebral infarction are sufficiently severe to interfere with any of the above, then the driver should not be allowed to return to commercial driving. Any driver with a deficit that requires special evaluation and screening should be recertified annually.

A number of patients with an embolic or thrombotic cerebral infarction will have complicating seizures. The likelihood of seizure recurrence is associated with the location of the associated lesions. The risk is increased primarily in individuals with lesions associated with cortical or subcortical deficits."

"Individuals with strokes resulting in vascular lesions involving the cerebellum and brain stem are not at increased risk for seizures. Individuals with occlusive cerebral vascular disease with fixed deficits involving areas other than the cerebellum and brain stem should not be considered qualified to obtain a license to operate a commercial vehicle for a five-year period following the episode. Evaluation by an appropriate specialist to confirm the area of involvement may be required for waiver of this restriction."

Methods

The FMCSA asked three key questions that relate to the impact of TIA and stroke on driver safety. These three key questions were addressed in an evidence report titled, "Stroke and CMV

Driver Safety." The FMCSA asked the MEP to utilize the answers to these three questions, together with their experience and expertise, to draft a set of recommendations that pertain to the certification of individuals who have experienced a TIA or stroke as being physically qualified to drive a CMV.

Development and Findings of Evidence Report

The three key questions asked in the evidence report were as follows:

> Key Question 1: Among individuals who have experienced a TIA (transient ischemic event), what is the risk of experiencing a future stroke?

> Key Question 2: Are individuals who have experienced a stroke at an increased risk for a motor vehicle crash (crash risk or driving performance)?

> Key Question 3: If so, can neuropsychological testing of individuals who have experienced a stroke predict crash risk?

Identification of Evidence Bases Used in Evidence Report

In developing the evidence report titled, Stroke and Commercial Motor Vehicle Driver Safety, a comprehensive systematic literature search was undertaken accessing several electronic databases: MEDLINE, PubMed (PreMEDLINE), EMBASE, PsycINFO, CINAHL, TRIS, the Cochrane library (through January 10, 2008). Abstracts of identified studies were examined to determine which articles would be retrieved, before they could be included in each evidence base. Hand searches of the "gray literature" were also performed.

Inclusion Criteria for All Key Questions

Articles obtained from the searches described above were screened against a set of general and key question specific inclusion criteria that were determined *a priori.*

General Inclusion Criteria

The general inclusion criteria used in this systematic review are presented below:

- Article must have been published in the English language.

- Article must be a full-length article. Abstracts and letters to the editor will not meet this inclusion criterion.

- Article must have enrolled 10 or more subjects per group

- Article must have enrolled subjects aged ≥18.

- If the same study is reported in multiple publications, the most complete publication will be the primary reference. Data will be extracted to avoid double-counting individuals.

Additional Key Question Specific Inclusion Criteria (Key Question 1)

Additional inclusion criteria specific to Key Question 1 are presented below:

- Studies limited to individuals with TIA only (no reversible ischemic attacks or reversible ischemic neurologic deficits).

- Studies that evaluated both TIA and other neurologic deficits were included as long as data for TIA subjects could be analyzed separately from that of other subject populations.

- Studies that attempted to determine the risk of stroke associated with TIA or attempted to determine the prevalence of TIA in subjects who had a stroke.

- Studies that included a comparison group comprised of comparable subjects who do not have TIA or includes a comparison group comprised of comparable subjects who did not have a stroke.

Additional Key Question Specific Inclusion Criteria (Key Question 2)

Additional inclusion criteria specific to Key Question 2 are presented below:

Studies that attempted to evaluate the relationship between people who have had a stroke and the following direct and indirect measures of driver safety:

- o Direct evidence of crash risk

- o Measures of driving-related performance (laboratory and experimental)

Additional Key Question Specific Inclusion Criteria (Key Question 3)

Additional inclusion criteria specific to Key Question 3 are presented below:

Studies that attempted to evaluate the relationship between neuropsychological testing scores and crash incidence or driving performance in drivers who have had a stroke.

Grading the Strength of Evidence

Our assessment of the evidence took into account not only the quality of the individual studies that comprise the evidence base for each key question; we also considered the interplay between the quality, quantity, robustness, and consistency of the overall body of evidence.

Analytic Methods

Random-effects meta-analyses were used to pool data from different studies. Differences in the findings of studies (heterogeneity) were identified using the Q-statistic and I^2. Sensitivity analyses, aimed at testing the robustness of our findings, included the use of cumulative random-effects meta-analysis.

Presentation of Findings

The strength of evidence ratings assigned to these different types of conclusion are defined in Table 1

Table 1.   Strength of Evidence Ratings for Qualitative and Quantitative Conclusions

Strength of Evidence	Interpretation
Qualitative Conclusion	
Strong	Evidence supporting the qualitative conclusion is convincing. It is highly unlikely that new evidence will lead to a change in this conclusion.
Moderate	Evidence supporting the qualitative conclusion is somewhat convincing. There is a small chance that new evidence will overturn or strengthen our conclusion. We recommend regular monitoring of the relevant literature for moderate-strength conclusions.
Minimally acceptable	Although some evidence exists to support the qualitative conclusion, this evidence is tentative and perishable. There is a reasonable chance that new evidence will either overturn or strengthen our conclusions. We recommend frequent monitoring of the relevant literature.
Insufficient	Although some evidence exists, the evidence is insufficient to warrant drawing an evidence-based conclusion. We recommend frequent monitoring of the relevant literature.
Quantitative Conclusion (Stability of Effect Size Estimate)	
High	The estimate of treatment effect in the conclusion is stable. It is highly unlikely that the magnitude of this estimate will change substantially as a result of the publication of new evidence.
Moderate	The estimate of treatment effect the conclusion is somewhat stable. There is a small chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. We recommend regular monitoring of the relevant literature.
Low	The estimate of treatment effect included in the conclusion is likely to be unstable. There is a reasonable chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. We recommend frequent monitoring of the relevant literature.
Unstable	Estimates of the treatment effect are too unstable to allow a quantitative conclusion to be drawn at this time. We recommend frequent monitoring of the relevant literature.

Findings of Evidence Report

Key Question 1: Among individuals who have experienced a TIA, what is the risk of experiencing a future stroke?

Summary: **The overall findings indicate that individuals are at an increased risk for stroke following a TIA (transient ischemic attack) when compared to their counterparts who did not experience a TIA (Strength of Evidence: Strong).**

The increase in stroke risk is highest immediately following TIA and decreases as a function of time since the event (Strength of Evidence: Moderate).

An evidence base of 13 case-controls or controlled cohort studies (representing approximately 30,000 individuals) consistently reported an elevated risk of stroke in individuals who experienced a TIA compared with controls who did not experience a TIA. Separate analyses based on four moderate-quality cohort studies with data at multiple follow-up periods suggests that the increased risk is very high within the first month following TIA (at least 65 times higher than the risk for individuals who have not had a TIA) and drops rapidly during the first year. A small cumulative elevated risk continues to decrease steadily out to five years following TIA.

In addition to the above findings of the evidence report (based mostly on pooled analyses of controlled studies), the MEP thought that the following specific evidence should also be considered in addressing this question.

One cohort study found that the initial stroke risk from the time of first assessment by a neurologist (following a TIA) was 1.9% [95% confidence interval (CI), 0.1 to 3.8] at 7 days and 4.4% (95% CI, 1.6 to 7.2) at 30 days. However, the 7- and 30-day stroke risks from referral were 2.4% (95% CI, 0.3 to 4.5) and 4.9% (95% CI, 1.9 to 7.8), respectively, and from onset of first-ever TIA were 8.6% (95% CI, 4.8 to 12.4) and 12.0% (95% CI, 7.6 to 16.4), respectively (3).

Another cohort study reported that the estimated risk of recurrent stroke was 8.0% (95% confidence interval 2.3% to 13.7%) at seven days, 11.5% (4.8% to 18.2%) at one month, and 17.3% (9.3% to 25.3%) at three months after a TIA. The risks at these three time periods after a minor stroke were 11.5% (4.8% to 11.2%), 15.0% (7.5% to 22.5%), and 18.5% (10.3% to 26.7%) (4).

Patients with a TIA or minor stroke have an unstable clinical course. A cohort study found that during the 90 days after index TIA, 180 patients (10.5%) returned to the ED with a stroke, 91 of which occurred in the first 2 days. Other adverse events occurred in 428 patients (25.1%) in the 90 days after the TIA and included 44 hospitalizations for cardiovascular events (2.6%), 45 deaths (2.6%), and 216 recurrent TIA's (12.7%) (5).

The risk of stroke after TIA in a population based study was 9.5% (95% CI 8.3 to 10.7) at 90 days and 14.5% (95% CI 12.8 to 16.2) at 1 year. The risk of combined stroke, myocardial infarction, or death was 21.8% (95% CI 20.0 to 23.6) at 1 year. Hypertension, diabetes mellitus, and older age predicted stroke at 1 year (6).

Of the 1,273 patients with ischemic cerebral infarction who were entered into the Stroke Data Bank, a prospective, observational study, the risk of recurrence within 30 days was greater for atherothrombotic infarction (7.9%) and least for lacunar infarction (2.2%); both cardio embolic infarction (4.3%) and infarction of undetermined cause (3.0%) had intermediate risks or early recurrence. A history of hypertension and diabetes mellitus, as well as diastolic hypertension and elevated blood sugar concentration at admission, were associated with early recurrence (7).

During 10 years follow up in a community-based study of stroke patients, 108 (26%) experienced recurrent stroke. The cumulative recurrence rates were 35.3% at five years and 51.3% at 10 years. The 10 year recurrence rates of subarachnoid hemorrhage (SAH), brain hemorrhage, and brain infarction were 70.0%, 55.6%, and 49.7%, respectively; the difference between SAH and brain infarction was significant (p = 0.004). Most recurrent episodes after SAH or brain hemorrhage happened within a year after the index stroke, whereas recurrence of brain infarction increased consistently throughout the observation period. Cardioembolic stroke

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had a higher recurrence rate (75.2%) than lacunar infarction (46.8%) (p = 0.049). The 10 year risk of stroke recurrence increased with age after lacunar or atherothrombotic brain infarction, but not after the other types or subtypes (8).

Key Question 2: Are individuals who have experienced a stroke at an increased risk for a motor vehicle crash (crash risk or driving performance)?

Summary: **Evidence suggests that drivers who have suffered a stroke are at an increased risk of crash (Strength of Conclusion: Minimally Acceptable). The size of this risk could not be determined.**

Direct Evidence – Crash Studies: Current direct evidence from two of three crash studies (9, 10, 11) found that individuals who have had a stroke are at an increased risk for a crash. The two studies that detected an increased risk of crash adjusted for miles driven; the study that did not find an increased risk of crash did not perform this adjustment. As risk exposure is the most important factor in determining risk, the findings of the two studies that adjusted for risk exposure should be given stronger consideration than the study that did not. The increased risk could not be quantified due to differences in reporting. Limitations of the evidence supporting this conclusion are the small size of the evidence base (three studies) and overall low-to-moderate quality.

Indirect Evidence – Studies of Driving Tests and Driving Simulation: Two studies of on-road driving tests provide consistent but weak evidence suggesting that individuals who have suffered stroke are at increased risk for a motor vehicle crash due to their poor driving skills (12, 13). The findings from two simulator studies are conflicting. Limitations of the evidence base include weakness of type of evidence (since it is indirect), small size of the evidence base, and overall low quality. In particular, controls in these studies were not matched to drivers who had a stroke.

The direct crash and on-road driving tests findings should supersede the simulator test findings because they provide more relevant information on crash risk than simulator studies (14).

Key Question 3: If so, can neuropsychological testing of individuals who have experienced a stroke predict crash risk?

Summary: **Certain neuropsychological tests can predict the outcome of driving performance measured by a road test or in-clinic driving evaluation (Strength of Conclusion: Moderate). Whether neuropsychological tests can predict actual crash risk cannot be determined as no such currently available evidence exists.**

No studies are available to provide direct evidence of an association between neuropsychological test results and crash risk. The only available evidence at this time is indirect and it evaluates neuropsychological tests as potential outcome predictors for road tests or in-clinic driving assessments. However, prediction of driving test outcomes is not the same as prediction of crash

risk. Patients who fail road tests or in-clinic driving assessments would either not be allowed to drive or at least advised not to drive, depending on the laws of the particular state or country of residence. Thus, they would not be expected to be at risk for motor vehicle crash (unless they disregard laws or advice). Whether neuropsychological testing can identify stroke patients at increased risk of crash who passed a road test has not been evaluated in the currently available literature.

<u>Indirect Evidence</u> - Twelve studies (median quality: moderate) with 879 patients who had a stroke and were evaluated by various neuropsychological tests as potential outcome predictors for road tests or in-clinic driving assessments (15-25). Eleven of the 12 studies found that one or more neuropsychological tests were significant predictors of the outcome of road tests or driving evaluations in this patient population. These findings cannot be combined in a quantitative analysis because no two studies used the same array of tests or evaluated the same combination of variables when attempting to identify predictors of outcome. However, certain tests were found to be significant outcome predictors in multiple studies. They were: Figure of Rey (15, 16, 20, 24); the dot cancellation test, the Road Sign Recognition test and What Else is in the Square test which are part of Stroke Driver Screening Assessment (SDSA) (16, 19, 23, 25); and the Motor-Free Visual Perception Test (MVPT) (14, 15, 17, 21, 23). Given the moderate quality of these studies and their consistency of the findings for neuropsychological tests overall, the strength of evidence supporting the ability of these tests to predict crash risk is limited. The majority of these studies did not report the presence of commercial motor vehicle (CMV) drivers (if any) in their study population, the generalizability of these findings to CMV drivers is unknown.

Recommendations of the Medical Expert Panel

The Medical Expert Panel made the following recommendations based on the current level of available information.

Recommendation 1: Single TIA and CMV Driver Certification

The MEP recommends that all individuals who have experienced a single TIA be immediately excluded from driving a CMV.

Individuals who have remained free from recurrent TIA or stroke for a period of at least one year and who are otherwise physically qualified may be considered qualified to drive a CMV.

- o **Such individuals must demonstrate that they are likely to be able to perform their normal duties by undergoing a thorough evaluation of their physical and mental function by a qualified neurologist.**

> o **The certification process should include an on road driving evaluation, just as it is required in 49 CFR §391.31 for new truck drivers. Considering the length, width, weight and other difficulties including seeing objects in the blind angle and the special spatial requirements of driving a CMV, on-road test after one year cessation due to a TIA or Stroke should be mandatory.**

Justification - In 70% of cases, the symptoms associated with a TIA may resolve in less than 10 minutes, and in 90% they may resolve in less than 4 hours. Although TIA usually lasts for < 30 minutes, traffic accidents only take seconds to occur. TIA symptoms, their descriptions, and potential impacts on driving ability are presented in Table 2. One health outcome of TIAs not indicated in Table 2 below, is death. Within a year, up to 25% of people who have had a transient ischemic attack die. This percentage is higher among people 65 and older (26).

Table 2.   TIA Health Consequences and Potential Impacts on Driving[a,b,c]

Health Consequences (short term): TIA and Associated Symptoms	Description of TIA and Associated Symptoms	Potential impact on driving (short term)
Numbness	Sensory loss; Paresthesias; Tingling and numbness; Loss of sensation.	Cannot steer or apply breaks as usual. Slower reaction time.
Weakness	A reduction in the strength of one or more muscles.	Cannot steer or apply breaks as usual. Slower reaction time.
Speech or language impairment	Language impairment; Impairment of speech; Inability to speak; Aphasia, a problem with expressing or understanding written or spoken language; Impairment of ability to read may occur; Dysarthria; Slurred speech	Inability to tell someone, including the police, what the problem is. In the case of aphasia, person may not understand directions or traffic signs.
Changes in vision and visual-spatial orientation	Loss of vision, decreased vision, double vision, abnormality of spatial orientation	Inability to see what is going on and where self and other cars are while driving; may get lost
Vertigo, dizziness, or lack of balance	Sensation that the person or the room is moving	Inability to properly operate vehicle may result in accident.
Lack of coordination or loss of coordination	Lack of coordination and irregularity of voluntary movements; Coordination impairment; Ataxia; Clumsiness	Inability to properly apply breaks or steer which may result in accident
Confusion	An inability to think with the usual speed or clarity. When confused, people have difficulty focusing their attention and may have disorientation. Confusion interferes with a person's ability to make decisions.	Inability to make appropriate decisions when driving. Slow reaction time.
Apathy or inappropriate behavior	Inability to attend to sensory stimuli or demonstrate appropriate behavior	May produce poor attention or erratic or illogical behavior that could interfere with driving and with making decisions related to driving.
Excessive somnolence or drowsiness	A state of near- sleep , a strong desire for sleep, or sleeping	May lose control of vehicle and not apply breaks or steer as quickly as needed. Slow response time.
Neglect syndrome	Inattention to surrounding environment, particularly to one side; if severe, patient may be unaware of deficit or own body parts.	Lack of attention to surrounding environment and poor reaction time.

a) Transient ischemic attack. [internet]. Rochester (MN): Mayo Foundation for Medical Education and Research (MFMER); 2007 Mar 9 [accessed 2008 Apr 13]. [3 p]. Available: https://health.live.com/article.aspx?id=articles%2fmc%2fpages%2f0%2fDS00220.html&qu=Transient+Ischemic+Attack.
b) Transient ischemic attack. [internet]. Bethesda (MD): MedlinePlus Medical Encyclopedia; 2007 Feb 20 [accessed 2008 Apr 11]. [4]. Available: http://www.nlm.nih.gov/medlineplus/ency/article/000730.htm.
c) Driving. [internet]. London (UK): The Stroke Association; 2008 [accessed 2008 Apr 8]. [1 p]. Available: http://www.stroke.org.uk/information/all_about_stroke/life_after_stroke/driving.html.

While the symptoms associated with TIA are clinically defined as temporary, some persons have evidence of stroke on brain imaging studies. Furthermore, TIA is an important warning sign for the occurrence of stroke. Studies show an increased risk for stroke among patients who have experienced a TIA (4, 5, 6).

The relationship between the Relative Risk (RR) for stroke as a function of time since experiencing a TIA is shown in Figure 1. This is based on pooled analyses of data from controlled cohort studies that assessed stroke risk in patients who had experienced a TIA compared to patients who had not experienced a TIA. The RR used on the curve represents the 95% CI of the effect estimate for the time points of one month, six months, 12 months, 24 months, and 36 months. This is a conservative estimate of the RR for each time point. At one month following TIA patients have at least a 65-fold increase in the risk of stroke compared to individuals without prior TIA. The cumulative risk for stroke given prior TIA decreases to a minimum RR of 16 times the control risk at six months, six times the control risk at 12 months, three times the control risk at 24 months, and 1.6 times the control risk at 36 months. The data suggest that the risk drops rapidly after the first month, although it remains fairly high during the first year. Therefore, the early period following a TIA is of the greatest concern regarding the potential for sudden incapacitating events that could lead to a motor vehicle accident.

Figure 1.   **Risk Ratio for Stroke over Time since TIA (Conservative Estimate)**
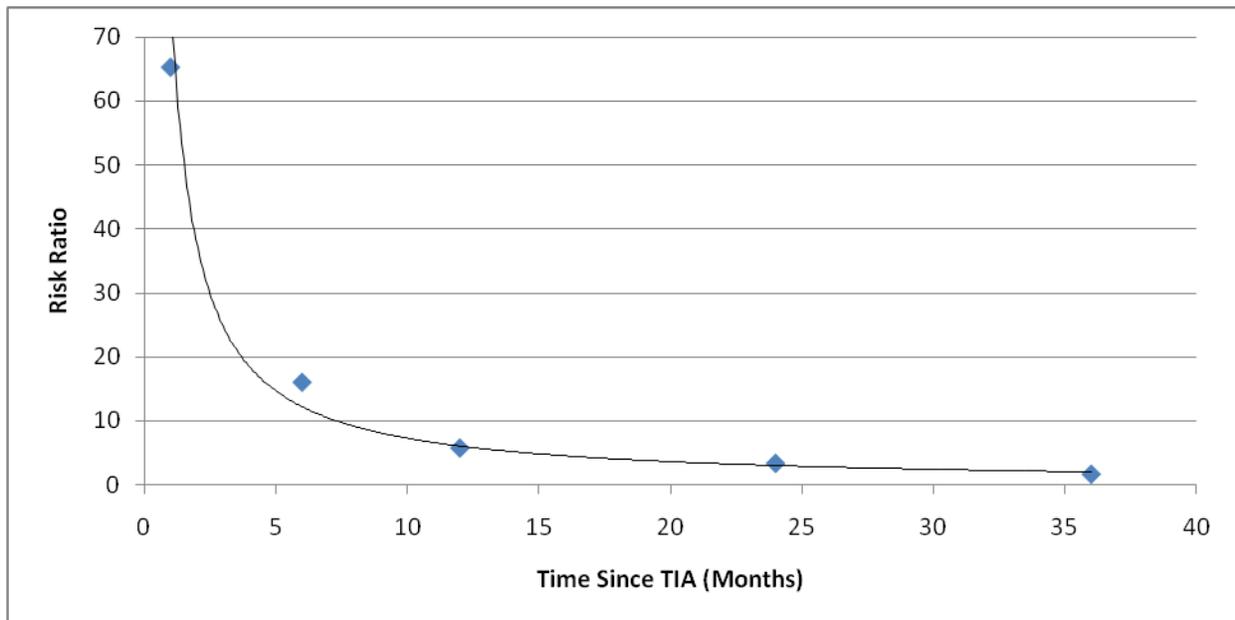
Recommendation 2: Preventative Treatment Following Single TIA or Minor Stroke Event

Individuals who receive immediate (secondary) prophylactic treatment following a TIA are at reduced risk for TIA or stroke recurrence compared to those who do not receive treatment or receive treatment later. The MEP recommends that:

Such individuals are immediately excluded from driving a CMV.

Individuals who have remained free from recurrent TIA or stroke for a period of at least one year and who are otherwise physically qualified may be considered qualified to drive a CMV.

- o **Such individuals must demonstrate that they are likely to be able to perform their normal duties by undergoing a thorough evaluation of their physical and mental function by a qualified neurologist.**

- o **The certification process should include an on road driving evaluation, just as it is required in 49 CFR §391.31 for new truck drivers. Considering the length, width, weight and other difficulties including seeing objects in the blind angle and the special spatial requirements of driving a CMV, on-road test after one.**

Justification – Several treatments have been shown to effectively prevent TIA recurrence or stroke in the long-term following a TIA or minor stroke event including aspirin and other antiplatelet agents, blood pressure lowering drugs, statins, and anticoagulation for atrial fibrillation (27). At this time, however, there is insufficient evidence to determine whether the observed reductions in risk are such that one can recommend that individuals who receive immediate prophylactic treatment be considered eligible to drive a CMV.

Two recent studies one being the EXPRESS study (the early use of EXisting PREventative Strategies for Stroke; EXPRESS), nested within a population-based study in Oxfordshire, England (the Oxford Vascular Study; OXVASC) compared early access to care and treatment (≤ 24 hours) of TIA and minor stroke using medical therapy (e.g., antiplatelet agents, blood pressure lowering drugs and cholesterol lowering drugs) to standard treatment in all patients with TIA or stroke presenting to medical attention in a population of 100,000 people in Oxfordshire. The study showed that initiation of treatment early on reduced the early risk of major stroke by 80% at 90 day follow-up compared to less expedient care (Figure 2) (28). However, long-term stroke risk reduction is still not known.

Figure 2.   **Risk of recurrent stroke in all patients with TIA or stroke**
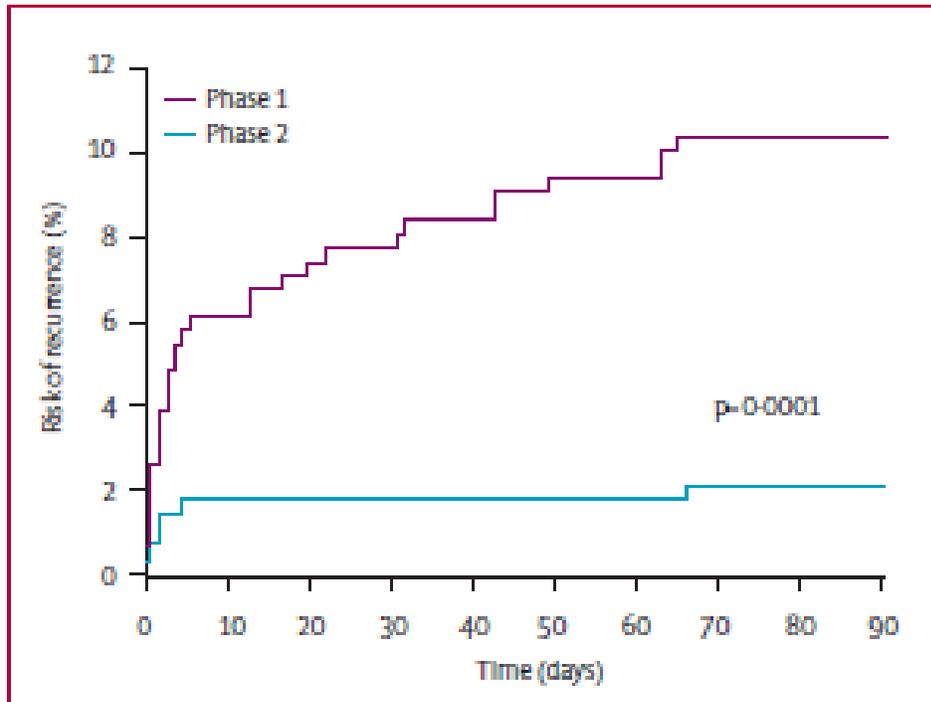
Phase 1 – Treatment of patients who had experienced a TIA or minor stroke not initiated immediately.
Phase 2 – Treatment of patients who had experienced a TIA or minor stroke was initiated immediately.

Another recent study the SOS-TIA, a hospital clinic with 24 hour access and immediate initiation of preventive treatment showed that patients immediately treated after a TIA had a decrease in length of stay and a 90-day stroke rate of 1.245% compared to predicted rate of 5.96% from ABCD scores (29).

Recommendation 3: Stroke and CMV Driver Certification

The MEP recommends that all individuals who have experienced a single stroke be excluded from driving a CMV.

Provided an individual is otherwise physically qualified, individuals who have remained free from recurrent stroke for a period of at least one year may be considered qualified to drive a CMV.

- o **Such individuals must demonstrate that they are likely to be able to perform their normal duties by undergoing a thorough evaluation of their physical and mental function by a qualified neurologist. Individuals who have experienced severe disabling stroke resulting in their needing assistance or supervision in their activities of daily living are to be disqualified from driving due to the severity of their impairments.**

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o **The certification process should include an on road driving evaluation, just as it is required in 49 CFR §391.31 for new truck drivers. Considering the length, width, weight and other difficulties including seeing objects in the blind angle and the special spatial requirements of driving a CMV, on-road test after one year cessation due to a TIA or Stroke should be mandatory.**

Justification – Approximately 14% of men and 20% of women who experience a first stroke will die within 30 days of its occurrence (30). Of those individuals that survive a stroke, between 35% and 60% will experience consequent disability severe enough to preclude independent living at six months follow-up. Longer-term disability data are presented in Table 3 (31). While these data do not identify the proportion of individuals who will be capable of driving a commercial motor vehicle following a stroke, they are instructive in that they indicate that only a small proportion of such individuals are likely to remain functionally independent and therefore able to operate a commercial motor vehicle safely will be small.

Table 3. Long-term impact of stroke on ability to function independently (Adapted from Mohr et al. (31))

Study *	Strokes (No.)	Age (Mean or Range, yr)	Duration of Follow-up	Outcome(s) Measured	Survival (%)	Independent Survivors (%)
Community-Based Studies						
Auckland Stroke Study	1761	71	6 yr	Disability (ADLs)SF-36	----	39
	680	70	6 mo	Disability (Katz)		76
Rochester, Minnesota	292	72	5 yr	Disability (ADLs) SF-36	----	39
				Disability (Katz)		76
Perth Community Stroke Study	492	73	5 yr	Disability (BI)	59	38
Newcastle, UK	229	82	3 yr	Disability (BI)	49	45
OSCI	675	72	1 yr	Handicap (Rankin)	----	71
NEMESIS	264	72	1 yr	Handicap (Rankin)	77	65
Southern England	456	65	1 yr	Disability (BI)	----	71
L'Aquila Registry	819	75	1 yr	Disability (BI)	64	76
Bristol, UK	976	75	6 mo	Disability (BI)	63	64
Tartu, Estonia	519	70	6 mo	Disability (undefined)	63	24
NOMASS	395	69	6 mo	Disability (ADLs)	59	33
Hospital-Based Studies						
Iowa Registry of Stroke in Young Adults	296	15-45	16 yr	Disability (BI)	79	49
Southeast London, UK	291	71	5 yr	Disability (BI)	42	34
				Handicap (Rankin)		36
Hong Kong	304	70	20 mo	Disability (B)	58	57
Gain Americas	1367	70	3 mo	Disability (BI)	80	38
				Handicap (Rankin)		27

ADLs, activities of daily living; BI, Barthel Index; GAIN, Glycine Antagonist in Neuroprotection (trial); Katz, Katz Index of Independence in Activities of Daily Living; NEMESIS, North East Melbourne Stroke Incidence Study; NOMASS, Northern Manhattan Stroke Study; SF-36, Medical Outcome Study's 36-item short-form health survey; OSCP, Oxfordshire Community Stroke Project. *Superscript numbers indicate chapter references.

All individuals who experience a stroke are at risk for stroke recurrence. Reported stroke recurrence rates following an initial stroke vary widely from an immediate risk of 5% in the first 2 days to 4% to 8% in the first month, 9.5% at 90 days and 15% at 1-year.[5-19]. These

variations relate to methodological differences or differences in age, gender, or coexistent morbidities among the cohorts studied and time post-TIA/minor stroke (3-8). The following risk factors have been identified for recurrent stroke: age, hypertension, atrial fibrillation and congestive heart failure, diabetes and hyperglycemia, and prior TIA or stroke (3-8).

Recommendation 4: Occurrence of Seizures Consequent to Stroke

Individuals who experience a seizure following a stroke should not be certified as physically qualified to drive a CMV.

Justification – about 5% to 20% of all individuals who have a stroke will have subsequent seizures, (32, 33) but epilepsy (recurrent seizures) will develop in only a small subset of this group. The largest and most rigorous methodological attempt to examine poststroke seizures was the prospective multicenter report from the Seizures After Stroke Study Group (32). The study enrolled 1897 patients and found an overall incidence of seizures of 8.9%. Recurrent seizures consistent with the development of epilepsy occurred in 2.5% of the patients, for a mean follow-up 9 months. Seizures was more common accompaniment of hemorrhagic rather than ischemic stroke. Bladin et al (32) found the incidence of seizures to be 10.6% among 265 patients with intracerebral hemorrhage vs. 8.6% among 1632 with ischemic stroke. In another prospective series, (34) seizures occurred in 4.4% of 1000 patients, including 15.4% with lobar or extensive intracerebral hemorrhage, 8.5% with subarachnoid hemorrhage, 6.5% with cortical infarction, and 3.7% with hemispheric transient ischemic attacks. Most early-onset seizures occur during the first 1 to 2 days after ischemia. Almost half (43%) of all patients in the Stroke after Seizures Study experienced a seizure within the first 24 hours after stroke (32). In a series restricted to early-onset seizures, 90% of the 30 patients had ictal activity within the first 24 hours (35). Most seizures associated with hemorrhagic stroke also occur at onset or within the first 24 hours (36).

Cortical location is the most reliable risk factors for poststroke seizures (32). Poststroke seizures were more likely to develop in patients with large lesions involving multiple lobes of the brain than in those with single lobar involvement (37). However, any stroke, including those with only subcortical involvement, may be associated with seizures (37). The only clinical predictor for seizures after ischemic stroke is the severity of the initial neurologic deficit. Greater initial stroke severity (38) or stroke disability (32) predicted seizures. By contrast, in the Oxfordshire Community Stroke Project, 3% of 225 patients who were independent 1 month after a stroke experienced a seizure between 1 month and 5 years (38). Patients presenting with greater neurologic impairment tended to have larger strokes that involved wider cortical areas.

In a study of early-onset seizures in 90 patients, simple partial seizures were the most common type (61%), followed by secondarily generalized seizures (28%) (39). In another series, early-onset seizures were more likely to be partial, whereas late-onset seizures were more likely to generalize secondarily (33, 35). Most recurrent seizures are of the same type as the presenting episode, and they tend to recur within 1 year on average. In a large series of patients with poststroke seizures, 9% had status epilepticus (40). The only associated finding was higher functional disability.

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Thus individuals who experience a stroke-related seizure usually have suffered from a severe stroke and will be severely and permanently debilitated. As a consequence, such individuals will be unable to operate a CMV.

Recommendation 5: Annual Recertification

Individuals who have experienced a TIA or Stroke and who have been certified as being physically qualified to drive a CMV (Recommendations 1 through 3) should be recertified on an annual basis.

- o **The annual recertification process should include a thorough neurologic assessment performed by a qualified neurologist.**

- o **Driving history should also be considered and should include the number of total miles driven, traffic violations and crash involvement (at fault or not at fault).**

- o **Any history TIA or Stroke recurrence, history of traffic violation including reckless driving, speeding, and running traffic light/signs, driving under the influence of alcohol or any illicit drug, or history of involvement in an "at fault" accident will result in permanent disqualification from operating a CMV.**

Recommendation 6: Neuropsychological Tests and On-road Evaluation

Off-road tests shown to predict driving ability after stroke are: the figure of Rey test; the dot cancellation test, road sign recognition and square matrix tests from the SDSA and the Motor-free Visual Perception Test. However, the MEP is of the opinion that while neuropsychological tests may provide a reasonable guide as to which person will likely pass a driver evaluation test, on-road evaluation should remain the gold standard for certification.

It is the opinion of the MEP, that one must not only confirm that the physical and mental function of individuals who have experienced a TIA or stroke are such that they are likely to be able to operate a CMV, but that such individuals demonstrate that they are able to operate a CMV by performing an on-road evaluation.

<u>**Justification**</u> – Physical and mental functions alone are not sufficient to fully determine the ability to operate, maneuver and drive on public roads especially after a TIA or stroke (14). We recommended the inclusion of an actual driving test because the on-road test remains the closest approximation to natural driving performance. It is used in many studies as the single criterion of driving ability after stroke (18, 19, 21-25) and in a recent retrospective study by Akinwuntan et. al. in 104 stroke patients, it was found that on-road test alone accounted for 42% of the variance in the decision of being fit to drive or not (20). Though standardized on-road test is a valid and

reliable test of driving ability after stroke (41, 42), it does not test the full potential for accident involvement. Other limitations of the on-road test include unpredictability of traffic during testing and subjectivity when administered by a driving assessor without experience in assessing persons with TIA or stroke.

Recommendation 7: Undertake Research as to How Stroke Affects CMV Safety

- **The MEP recommends that FMCSA consider the relative lack of high quality studies specific to Stroke and Commercial Motor Vehicle Safety and in particular the association between TIA/Stroke and CMV driver crash safety.**

- **The MEP recommends that FMCSA consider funding additional studies to investigate the US adapted version of the SDSA in predicting on-road performance of drivers, including CMV drivers, after TIA and stroke.**

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