Seizures and CMV Driver Safety

Recommendations of the Seizure Disorders Medical Expert Panel

Presenter
Gregory Krauss, MD

Purpose of Presentation

- To present the final recommendations of the "Seizure Disorders MEP" as they pertain to CMV driver fitness-for-duty
- MEP recommendations developed using a consensus decision-making process
- All of the recommendations presented today were agreed on unanimously

Members of the MEP

• Panel members:

Jerome Engel, MD, PhD (UCLA)

Robert S. Fisher, MD, PhD (Stanford)

- Gregory L. Krauss, MD (Johns Hopkins)

Allan Krumholz, MD (Univeristy of Maryland)

Mark S. Quigg, MD (University of Virginia)

• MEP met for two days (May 14–15, 2007)

Purpose of MEP Meeting

- To review existing FMCSA guidelines for medical examiners pertaining to the certification and recertification of individuals who have experienced at least one seizure
- To discuss the evidence as presented in an evidence report (and other sources as necessary) related to the consequences of allowing individuals who have experienced at least one seizure to drive a CMV for the purposes of interstate commerce
- To recommend changes to existing FMCSA guidelines if the currently available evidence supports such changes

Central Principles

- In developing our recommendations, members of the MEP were guided by three central principles:
 - Any recommended changes to existing FMCSA guidelines must be supported by evidence
 - Any recommended changes to the existing FMCSA guidelines should be actionable
 - The wording of recommended changes to existing FMCSA guidelines should be concise and unambiguous

Context - Epidemiology

While disease specific rates of fatal crashes may be moderate,
 relatively low prevalence of disease reduces impact

Year	Disease specific rates of fatal crashes (cases per 100,000 pop)	Prevalence rate (cases per 1,000)
Seizures	8.6	5.1
Diabetes	1.88	39.1
Cardiovascular and hypertensive disorders	3.74	245.2
Alcohol related	72.4	94.6
Young drivers	28.08	
Totals	22.44	

Sheth et al (2004). Mortality in epilepsy: Driving fatalities vs other causes of death in patients with epilepsy. Neurology 63; 1002-1007

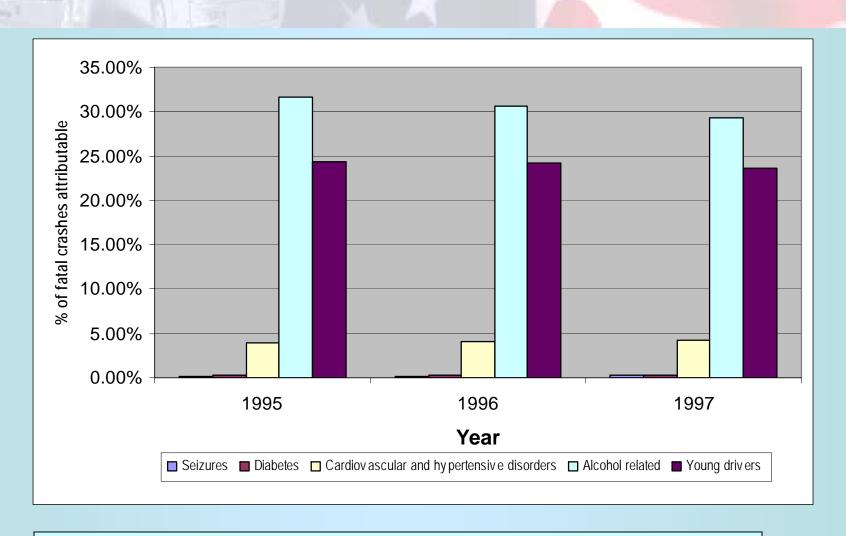
Context - Scope of Problem

• Annual number of fatal motor vehicle crashes attributable to seizure disorders per year in United States is relatively low (approx. 0.19% of total)

Year	1995	1996	1997
Seizures	82	80	97
Diabetes	127	148	156
Cardiovascular and hypertensive disorders	1,746	1,822	1,831
Alcohol related	13,881	13,557	12,870
Young drivers	10,694	10,665	10,379
Totals	43,884	44,186	44,012

Sheth et al (2004). Mortality in epilepsy: Driving fatalities vs other causes of death in patients with epilepsy. Neurology 63; 1002-1007

Context - Scope of Problem



From: Sheth et al (2004). Mortality in epilepsy: Driving fatalities vs other causes of death in patients with epilepsy. Neurology 63; 1002-1007

Risk Factors for Crash

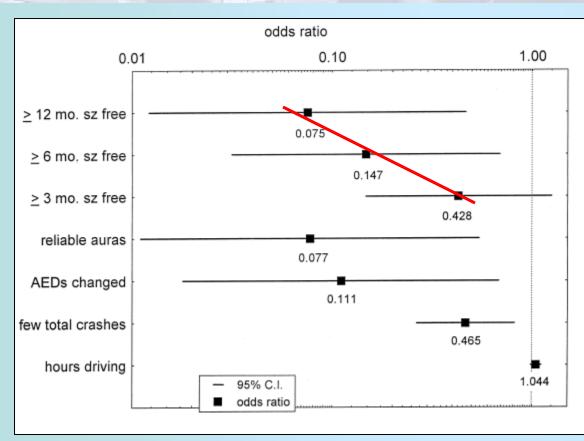
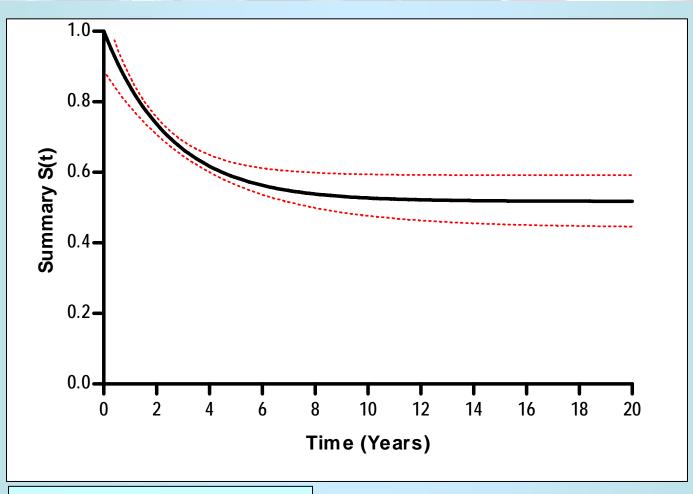


Figure. Factors associated with decreased odds of motor vehicle crashes in patients with epilepsy. The odds ratios shown for reliable auras, antiepileptic drugs (AEDs) changed (reduced or stopped), few total (nonseizure-related) motor vehicle accidents, and hours driving are from a multivariate analysis using ≥ 12 -month seizure-free intervals ($\mathbf{r}^2 = 0.49$, $\mathbf{p} = 0.0001$). Odds ratios for the other two seizure-free intervals shown (≥ 6 -month and ≥ 3 -month seizure-free intervals) are for separate models using the same other factors.

 Time since last seizure appears a good measure by which to make judgments about crash risk

Seizure Freedom and Time Since Last Seizure

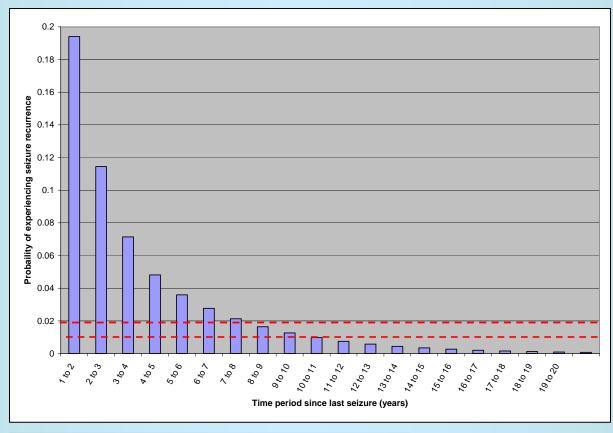


S(t) = Proportion remaining seizure free at time t

From: Tregear et al. Seizure disorders and CMV driver safety. FMCSA - 2007

Probability of Experiencing Seizure Recurrence

 Probability of experiencing seizure recurrence in next year reduces as seizure free period increases



From: Tregear et al. Seizure disorders and CMV driver safety. FMCSA - 2007

Acceptable Risk

- The number of crashes per year that can be attributed to a specific cause that society is willing to accept is not known
- Several models for determining acceptable risk have been developed
- Many organizations have adopted a 2% rule
 - The risk for experiencing a seizure in the following year must be less than 2% in order to be licensed to drive a CMV
 - Thus, the risk for experiencing a seizure while driving is <0.30% per year (assumes a 50 hour work week)
 - Annual risk for seizure-related crash is <0.17% (assumes that 56% of seizures that occur while driving lead to crash)
- This is the threshold that was chosen by the MEP as the basis for its recommendations

Current Guidelines

- Current FMCSA Standards preclude an individual with a history of seizure from driving a CMV
- However, some individuals with a history of seizures are considered for a CMV license
- Current guidance on the characteristics of individuals who may be considered for medical certification come from a 1988 conference report titled, "Conference on Neurological Disorders and Commercial Drivers"

Current Guidance

History of Epilepsy

 Individuals with a history of epilepsy who have been off medication and seizure free for 10 years may be considered as fit-for-duty

Single Unprovoked Seizure

 Individuals with a history of a single unprovoked seizure who have been off medication and seizure free for 5 years may be considered as fit-for-duty

Acute Symptomatic Seizure

 Individuals with a history of a single acute symptomatic seizure who have been off medication and seizure free for 2 years may be considered as fit-for-duty

Recommendation 1: Epilepsy

- The MEP recommends that current guidelines pertaining to individuals with a diagnosis of epilepsy be replaced with the following:
 - A history of epilepsy precludes an individual from obtaining unconditional certification to drive a CMV for the purposes of interstate commerce
 - A history of epilepsy, however, should not unconditionally exclude all individuals from driving a CMV; conditional certification may be possible in some instances

Recommendation 1: Epilepsy (cont...)

- An individual with a history of epilepsy may obtain conditional certification (or maintain certification under conditional status) to drive a CMV if that individual meets the following criteria:
 - Individual must have been seizure free for minimum 8 years on or off anti-seizure medication; **AND**
 - If all anti-seizure medications have been stopped, individual must have been seizure free for a minimum of 8 years from time of medication cessation; <u>OR</u>
 - If still using anti-seizure medication, the individual must have been on a stable medication regimen for a minimum of 2 years
- An individual with a history of epilepsy who has been granted conditional certification to drive a CMV must be recertified on an annual basis

Recommendation 2: Single Unprovoked Seizure

- The MEP recommends the current guideline for individuals who have experienced a single, unprovoked seizure be replaced with the following:
 - A history of experiencing a single unprovoked seizure precludes an individual from obtaining unconditional certification to drive a CMV for the purposes of interstate commerce
 - A history of experiencing a single unprovoked seizure, however, should not unconditionally exclude all individuals from driving a CMV; conditional certification may be possible in some instances

Recommendation 2: Single Unprovoked Seizure

- An individual with a history of a single, unprovoked seizure may obtain conditional certification (or maintaining certification under conditional status) to drive a CMV if that individual meets the following criteria:
 - Individual must have been seizure free for a minimum of 4 years on or off anti-seizure medication; **AND**
 - If all anti-seizure medications have been stopped, individual must have been seizure free for minimum of 4 years from time of medication cessation; <u>OR</u>
 - If still using anti-seizure medication, the individual must have been on a stable medication regimen for a minimum of 2 years
 - An individual with a history of a single, unprovoked seizure who has been granted conditional certification to drive a CMV must be recertified on a biennial basis.

Recommendation 3: Provoked Seizure

- The MEP recommends that the current guideline for individuals who have experienced a provoked seizure be replaced with the following:
 - A history of experiencing a provoked seizure should not automatically preclude an individual from obtaining unconditional certification to drive a CMV for the purposes of interstate commerce
 - Whether an individual with such a history can be unconditionally certified requires individual evaluation to ascertain the individual is at low recurrence risk for again encountering the factor that precipitated the seizure

Recommendation 3: Provoked Seizure

- Examples of low risk for recurrence include:
 - A lidocaine-induced seizure during a dental procedure
 - A concussive seizure, loss of consciousness ≤30 minutes, no penetrating injury
 - A seizure due to syncope not likely to recur while driving
 - A seizure from an acute metabolic derangement not likely to recur
 - Drug withdrawal

Recommendation 3: Provoked Seizure

- Conditional certification may be considered for individuals with moderate-to-high risk factors for recurrence provided that the following conditions are met:
 - Individual must have been seizure free for a minimum of 8 years on or off anti-seizure medication; AND
 - If all antiseizure medications have been stopped, the individual must have been seizure free for a minimum of 8 years from the time of medication cessation; OR
 - If still using anti-seizure medication, the individual must have been on a stable medication regimen for a minimum of 2 years
- An individual with a history of a provoked seizure who has been granted a conditional certification to drive a CMV must be recertified on an annual basis

Recommendation 3: Provoked Seizure

- Examples of seizure-provoking conditions that are at moderate-to-high risk for further seizures, and therefore would weigh against certification, include the following:
 - Head injury with loss of consciousness or amnesia ≥ 30 minutes or penetrating head injury
 - Intracerebral hemorrhage of any etiology, including stroke and trauma
 - Brain infection: encephalitis, meningitis, abscess, cysticercosis
 - Stroke
 - Intracranial hemorrhage
 - Post-operative brain surgery with significant brain hemorrhage
 - Brain tumor

Recommendation 3: Provoked Seizure

 Individuals who experienced further seizures following the initial seizure that occurred in the presence of a provocative event are should be considered as having epilepsy for the purposes of certification review