



**Opinions of Expert Panel**  
**Psychiatric Disorders and Commercial Motor**  
**Vehicle Driver Safety**

**Medical Expert Panel Members**

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Presented to

**Federal Motor Carrier Safety Administration**

**August 13, 2009**



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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 who are responsible for certifying drivers as fit for duty. FMCSA is committed to review and begin updating all of their current standards and guidelines by 2009.

This report serves the purpose of summarizing the considerations and opinions of a panel of three experts in the fields of psychiatry and occupational medicine (henceforth termed the Medical Expert Panel) who examined FMCSA's current standards and guidelines for medical examiners pertaining to psychiatric disorders and CMV driver safety.

## Guideline Development Medical Expert Panel

Members of the Medical Expert Panel charged with offering their expert opinions pertaining to whether the current standards and guidelines for psychiatric disorders need to be updated are listed in Table 1.

**Table 1. Members of the Medical Expert Panel**

| Name                   | Current Position  |
|------------------------|---|
| Steven Dubovsky, MD    | Professor and Chair of the Department of Psychiatry<br>State University of New York at Buffalo<br>Professor of Psychiatry and Medicine<br>University of Colorado Health Sciences Center |
| Jeffrey Metzner, MD    | Clinical Professor of Psychiatry<br>University of Colorado School of Medicine   |
| Garson Caruso, MD, MPH | Occupational Medicine Physician<br>Private Practice<br>Sebring, FL  |

## Methodology

### Brief Overview of Evidence Report Methodology

The opinions contained in this report are based in part upon the interpretation and assimilation of information presented in a comprehensive systematic review of available literature, prepared by ECRI Institute and Manila, and presented to the Medical Expert Panel on March 18<sup>th</sup>, 2009. This evidence report titled, "Psychiatric Disorders and Commercial Motor Vehicle Driver Safety," was developed following a systematic literature search for evidence accessible from several electronic databases. These databases included (but were not limited to) Medline, PubMed (pre Medline), EMBASE, PSYCHInfo,

CINAHL, TRIS, and the Cochrane Library. Additional hand searches of the published literature (i.e., bibliographies of identified relevant articles), and “gray literature” resources (e.g., Web searches) were also performed. Data obtained from these searches were screened against a set of a priori inclusion criteria. The findings of this evidence report are summarized in the report’s executive summary that can be found in Appendix B.

## The Medical Expert Panel Meeting

On March 18<sup>th</sup>, 2009, FMCSA, Manila Consulting, the ECRI Institute, and the three members of the Psychiatric Disorders Medical Expert Panel convened a one-day meeting. The purpose of this meeting was several-fold:

- To review existing standards and guidelines for medical examiners pertaining to the certification and recertification of individuals with a known psychiatric disorder as physically qualified to drive a CMV for the purposes of interstate commerce.
- To discuss the available evidence contained in the Evidence Report and other sources pertaining to the consequences to public safety associated with allowing individuals with a known psychiatric disorder to drive a CMV.
- To obtain the expert opinion of the panel on changes to the existing FMCSA guidelines which are deemed necessary following the critical assessment of the available evidence.

This document reflects a summary of the one day meeting.

## Opinions of Psychiatric Medical Expert Panel

It was the opinion of the MEP that current standards and guidance to those who certify drivers as physically qualified to drive a CMV for the purposes of interstate commerce are inadequate. Consequently, the MEP made several suggestions for improvement. Each suggestion was based on their current understanding of available information. Below we present the MEP opinions and provide justification for each.

### 1. Psychiatric Disorders and CMV Driver Certification

**It is the opinion of the MEP that all individuals with a history of the following psychiatric disorders should undergo additional medical and psychiatric evaluation to further assess functional ability before being considered qualified to drive a CMV:**

- **Psychotic Disorders**
- **Bipolar Disorders**
- **Major Depressive Disorder with a history of psychosis, suicidal ideation, homicidal ideation or a suicide attempt**
- **Obsessive Compulsive Disorder**
- **Antisocial Personality Disorder**

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

**It is the opinion of the MEP that the FMCSA should add the two question version of the Patient Health Questionnaire (PHQ) be added to the medical examination questionnaire to screen for depression.**

- **If the PHQ-2 is positive for a possible significant depressive disorder, the medical examiner should then refer the patient to a psychiatrist to conduct an interview for major depression, including suicidal ideation and/or attempt.**

***Justification:***

**Psychotic Disorders:** The disorders included in this category of psychiatric disorders are schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, brief psychotic disorder, shared psychotic disorder, psychotic disorder due to a general medical condition, substance-induced psychotic disorder, and psychotic disorder not otherwise specified. All of these disorders potentially impact driver safety because they are associated with cognitive impairment, slowed reaction times and a variable degree of distraction and distorted thinking.

**Mood Disorders:** A mood disorder is characterized by disruption of emotional regulation. The two major types of mood disorders are **major depressive disorder** (or unipolar depression) and **bipolar disorder**. All mood disorders have the potential to deleteriously impact driver safety. Depression is known to impair cognitive function and may be associated with suicidal ideation or suicide attempts and at times with homicidal thoughts. Bipolar disorder is associated with impulsivity and poor judgment. Some individuals with mood disorders, even when treated to full remission, demonstrate residual disturbances of short-term memory, concentration and mental processing speed.

Given that depression often goes undiagnosed, the MEP also suggests the addition of a short, two question, screening tool to the medical examination questionnaire to screen for possible depression. The PHQ is a diagnostic tool for mental health disorders used by health care professionals. The PHQ-9 is a tool specific to depression and the first two questions of the PHQ-9, also known as the PHQ-2, can be used as an easy screen for possible depression. These questions ask the following:

Over the last two weeks, how often have you been bothered by any of the following problems?

- 1) Little interest or pleasure in doing things
  - a) not at all; b) several days; c) more than half the days; d) nearly every day
- 2) Feeling down, depressed, or hopeless
  - a) not at all; b) several days; c) more than half the days; d) nearly every day

If an individual responds with c) or d) to either of these questions, the medical examiner should then refer the individual to a psychiatrist to conduct an interview for major depression, including suicidal

ideation and/or attempt. It should be noted that the PHQ-2 is still in its early stages of validation (Gilbody, Richards, Brealey, & Hewitt, 2007) and this suggestion is an attempt to improve the current process but is not a 'definitive' solution to the problem of identification of depression.

**Obsessive-Compulsive Disorder (OCD):** OCD is a type of anxiety disorder characterized by obsessions and/or compulsions. Obsessions are distressing, repetitive, intrusive thoughts or images that the individual often realizes are senseless. Compulsions are repetitive behaviors that the person feels forced or compelled to do to relieve anxiety or in response to an obsession. OCD may increase the risk of a motor vehicle crash if the symptoms are severe enough to interfere with concentration or motor/functional skills needed for safe driving.

**Antisocial Personality Disorder:** Diagnostic criteria for antisocial personality disorder include a pervasive pattern of disregard for and violation of the rights of others. It is associated with behaviors such as aggression, egocentricity, impulsiveness, resentment of authority, disregard of rules, intolerance of frustration, substance misuse, and irresponsibility. All of these behaviors may increase the risk for a motor vehicle crash.

Findings from the evidence report also suggest that individuals with traits associated with some personality disorders are at an increased risk for a motor vehicle crash when compared with comparable drivers who do not have a trait associated with a personality disorder. These traits include aggression, hostility, impulsivity, disregard for law (i.e. attitude toward traffic law violations), and various psychological symptoms. Because the studies included in this evidence used a number of different scales and methodologies to measure the traits and behaviors, and the outcome measures could not be assumed to be uniform, we were precluded from combining them for quantitative analysis. Instead, we have provided a qualitative summary of the findings.

Overall, the studies suggest that traits such as aggression, hostility, impulsivity, disregard for laws (i.e., attitude toward traffic law violations), and various psychological symptoms are associated with an increase in crash risk. The same can be said of behaviors such as risky driving and violation of traffic laws. In turn, behaviors such as risky driving are associated with aggression, impulsivity, and psychological symptoms such as anxiety, depression, and psychosis. Violation of traffic laws is associated with risky driving and aggression. Table 5 provides a quick summary of the associations between factors and outcomes.

**Table 2. Associations between Factors and Outcomes for Key Question 3**

|                            | Aggression | Hostility | Impulsivity | Attitude toward traffic law violations | Psychological symptoms* | Behaviors     |                            |
|----------------------------|------------|-----------|-------------|--|-------------------------|---------------|----------------------------|
|                            |            |           |             |  |                         | Risky Driving | Violations of traffic laws |
| Crash                      |            |           |             |  |                         |               |                            |
| Risky Driving              |            | NA        |             |  |                         | —             |                            |
| Violations of traffic laws |            | NA        | NA          | NA                                     | NA                      |               | —                          |
| Aggression                 | —          | NA        | NA          | NA                                     |                         |               |                            |

Factor has a negative impact on this outcome such that crash risk is increased.

\* Psychological symptoms include anxiety, paranoid ideation, depression, psychosis, personality disorder, irritability, negativism, antisocial tendencies  
 NA - Not applicable. This factor was not examined in relationship to the outcome of interest.

## 2. Medications for Psychiatric Disorders and CMV Driver Certification

The MEP believes that all individuals currently taking benzodiazepines or similar drugs which act on benzodiazepine receptors should be immediately prohibited from driving a CMV.

- Individuals who take benzodiazepines for any length of time should not be allowed to drive until the drug has been cleared from their system (i.e., within seven half-lives of the drug and any active metabolites). Chronic users of benzodiazepines (i.e., regular use for more than a month) should also wait an additional week after the drug has cleared from their system before resuming driving to ensure that the drug has been completely eliminated. It is also suggested that FMCSA provide information regarding the half-life and seven half-lives of benzodiazepines and active metabolites to medical examiners for use at the time of examination.

### **Justification:**

Benzodiazepines are one of the most commonly prescribed classes of psychotherapeutic drugs with varying properties including anxiolytic, sedative, hypnotic, anticonvulsant, muscle relaxant, and amnesic. These properties can have significant effects on the central nervous system with the potential to impair driving ability.

Prior research has shown potential associations between benzodiazepines and impaired driving ability. In short-term studies of patients with anxiety, benzodiazepine use was associated with impairment of cognitive function and driving ability for up to three weeks (de Gier et al., 1981; O’Hanlon et al., 1995; van Laar & Volkerts, 1998; van Laar, Volkerts, & van Willigenburg, 1992).

The evidence report also included analyses of nine studies that presented data on the ratio of crashes experienced by a group of individuals using benzodiazepines compared with a group of individuals who did not use benzodiazepines (Barbone et al., 1998; Hemmelgarn et al., 1997; Honkanen et al., 1980; Leveille et al., 1994; McGwin et al., 2000; Movig et al., 2003; Neutel, 1995; Ray, 1992; Wadsworth, 2005). Pooling of the data from the included studies using a random effects analysis found that the crash odds ratio associated with benzodiazepines is between 1.28-2.20,  $p < 0.0001$ , suggesting that the crash risk associated with benzodiazepine use is between 1.3 and 2.2 times greater than the crash risk for comparable individuals who do not use benzodiazepines. The results of the meta-analysis were found to be robust. A subgroup analysis of five studies that presented separate crash data for users of anxiolytics also found an increased crash risk among users of benzodiazepine anxiolytics. Further analyses to identify factors that may lead to increased risk for benzodiazepine users identified timing of exposure (i.e., highest crash risk during the first week of the index prescription) and patient age (highest crash risk for benzodiazepine users  $\leq 40$  years of age) as potential risk factors.

Given the functional impairments and increased crash risk associated with benzodiazepine use, the MEP believes that:

- 1) individuals currently taking benzodiazepines not be allowed to drive a CMV;
- 2) individuals who are taking benzodiazepines should stop taking them long enough ahead of driving for them to be cleared from their systems before being allowed to drive a CMV (it takes seven half lives for a drug to be completely eliminated from the body);
- 3) chronic users of benzodiazepines should wait an additional week after the drug has been cleared from the body (i.e., seven half lives plus one week) before driving a CMV to ensure that it has been completely eliminated.

Table 3 presents the half-life and seven half-life values for benzodiazepines and other drugs with effects similar to benzodiazepines.

**Table 3. Half-life (hrs) and Seven Half-lives (hrs) of Benzodiazepines**

| Drug  | Half-life (hrs)<br>[active metabolite] | 7 half lives (hrs) |
|---|--|--------------------|
| <b>Benzodiazepine</b>                                   |  |                    |
| • Alprazolam (Xanax, Xanor)                             | 6-12                                   | 42-84              |
| • Bromazepam (Lexotan, Lexomil)                         | 10-20                                  | 70-140             |
| • Chlordiazepoxide (Librium, Tropium)                   | 5-30 [36-200]                          | 35-210 [252-1400]  |
| • Clobazam (Frisium)                                    | 12-60                                  | 84-420             |
| • Clonazepam (Klonopin, Klonapin, Rivotril, Liktorivil) | 18-50                                  | 126-350            |
| • Clorazepate (Tranxene)                                | [36-200]                               | [252-1400]         |
| • Diazepam (Valium, Apzepam, Stesolid)                  | 20-100 [36-200]                        | 140-700 [252-1400] |
| • Estazolam (ProSom)                                    | 10-24                                  | 70-168             |
| • Flunitrazepam (Rohypnol, Fluscand)                    | 18-36 [36-200]                         | 126-252 [252-1400] |

| Drug   | Half-life (hrs)<br>[active metabolite] | 7 half lives (hrs) |
|--|--|--------------------|
| • Flurazepam (Dalmane)                                 | [40-250]                               | [280-1750]         |
| • Halazepam (Paxipam)                                  | [30-100]                               | [210-700]          |
| • Ketazolam (Anxon)                                    | 30-100 [36-200]                        | 210-700 [252-1400] |
| • Loprazolam (Dormonox)                                | 6-12                                   | 42-84              |
| • Lorazepam (Ativan, Temesta)                          | 10-20                                  | 70-140             |
| • Lormetazepam (Noctamid)                              | 10-12                                  | 70-84              |
| • Medazepam (Nobrium)                                  | 36-200                                 | 252-1400           |
| • Nitrazepam (Mogadon, Apodorm)                        | 15-38                                  | 105-266            |
| • Oxazepam (Serax, Serenid, Serepax, Sobril, Oxascand) | 4-15                                   | 28-105             |
| • Prazepam (Centrax)                                   | [36-200]                               | [252-1400]         |
| • Quazepam (Doral)                                     | 25-100                                 | 175-700            |
| • Temazepam (Restoril, Normison, Euhypnos)             | 8-22                                   | 56-154             |
| • Triazolam (Halcion)                                  | 2                                      | 14                 |
| <b>Non-benzodiazepines with similar effects</b>        |  |                    |
| • Zaleplon (Sonata)                                    | 2                                      | 14                 |
| • Zolpidem (Ambien, Stilnox)                           | 2                                      | 14                 |
| • Zopiclone (Zimovane, Imovane, Zopiklon)              | 5-6                                    | 35-42              |
| • Eszopiclone (Lunesta)                                | 6-9                                    | 42-63              |

**The MEP is of the opinion that all individuals currently taking lithium be excluded from driving a CMV at night.**

***Justification:***

Lithium can impair night vision and cognition, which obviously can negatively impact a driver's ability to drive safely.

**The MEP is of the opinion that all individuals currently taking antipsychotic medications undergo additional evaluation before being allowed to operate a CMV.**

- **The medical examiner should obtain from a referral specialist a neuropsychological battery for individuals currently taking antipsychotic medications to screen for psychomotor impairments.**
- **If the neuropsychological screening tests suggest impairment, then a road test must be administered.**
- **Individuals starting a new antipsychotic medication must be evaluated within one month.**

***Justification:***

Antipsychotic medications are mostly used to treat symptoms of psychotic disorders, including disorganized thinking, hallucinations, delusions, hostility, and, in some cases, negative symptoms of schizophrenia. Some antipsychotics also may treat symptoms of mood disorders such as mania. Prior research has shown potential associations between various antipsychotic medications and impaired driving ability. For example, several studies have found an association between antipsychotics and impaired psychomotor function or simulated driving performance in patients with schizophrenia (Brunnauer et al., 2004; Grabe et al., 1999; Soyka, Kagerer, et al., 2005; Soyka, Winter, et al., 2005; Wylie, Thompson, & Wildgust, 1993).

In the evidence report, only one study addressed the potential association between antipsychotic drugs and crash risk (Neutel, 1995). This study found no excess risk of crash associated with antipsychotic agents within two weeks (OR 0.7, 95% CI: 0.2-2.9) or four weeks (OR 0.6, 95% CI: 0.2 – 1.9) of the index prescription. As this is a single moderate quality study with no measures of dosage or compliance and the 95% CIs do not rule out the possibility of increased risk, more evidence is needed to confirm these findings.

Given the potential for impaired driving ability as the result of antipsychotic drug use, the MEP recommends that individuals currently taking these medications undergo additional evaluations to screen for psychomotor impairments before being allowed to drive a CMV.

**The MEP is of the opinion that all individuals currently taking antidepressants should undergo additional evaluation before being allowed to operate a CMV.**

- **The medical examiner should use clinical judgment to determine if the patient is too sedated to drive. This should include consideration of: 1) acute effects of the specific antidepressant(s); 2) the additive effects of other medications the examinee is currently taking; and 3) the additive and cumulative effects of job demands such as long hours of driving, often over extended periods of many days.**
- **For individuals currently taking SSRIs additional evaluations should include assessments of psychomotor function**
  - **The medical examiner must assess balance and coordination with heel-to-toe walking, rapid alternating movement, and measures of perseveration.**
  - **If impairment is suggested by clinical examination, the medical examiner must obtain a neuropsychological battery of tests from a referral specialist to further test for psychomotor impairment.**

***Justification:***

Antidepressants are primarily used to treat depression and anxiety (including obsessive compulsive disorder and posttraumatic stress disorder). The four major classes of antidepressants include tricyclic antidepressants (TCAs), selective serotonin reuptake inhibitors (SSRIs), mixed action antidepressants,

and monoamine oxidase inhibitors (MAOIs). All of these agents have effects on the central nervous system with the potential to impair driving ability. Prior research has shown an association between certain antidepressants (usually TCAs) and impaired driving performance (Brunnauer et al., 2006; Clayton, Harvey, & Betts, 1977; Ramaekers, 2003).

Many antidepressants have sedating side effects which is of particular concern when evaluating one's ability to drive a CMV. Because of this side effect, the MEP recommends that the medical examiner assess the sedation level of all patients currently taking antidepressants to determine if they are medically fit to drive a CMV.

SSRIs also have the potential to adversely affect psychomotor function. Common side effects can include dizziness, tremors, and less frequently akathisia. Side effects may resolve after a few weeks, but their severity and duration vary greatly from person to person. Therefore, the MEP believes that additional tests should be conducted to assess the psychomotor function of individuals currently taking SSRIs. These tests include heel-to-toe walking (tandem walking), rapid alternating movements, and tests of perseveration. If an individual shows impairment with any of these tests, the MEP believes a full neuropsychological battery should be obtained from a referral specialist to further test for psychomotor impairment.

**The MEP is of the opinion that all individuals currently taking anticonvulsants undergo additional evaluation before being allowed to operate a CMV.**

- **The medical examiner should use clinical judgment to determine if the patient is too sedated to drive. This should include consideration of: 1) acute effects of the specific anticonvulsant(s); 2) the additive effects of other medications the examinee is currently taking; and 3) the additive and cumulative effects of job demands such as long hours of driving, often over extended periods of many days.**
- **The medical examiner must assess balance and coordination as noted above.**
- **If impairment is found on clinical examination, a neuropsychological battery of tests should be obtained from a referral specialist to further test for psychomotor impairment.**

***Justification:***

Anticonvulsants are a diverse group of medications, primarily used for the treatment of epileptic seizures; however, some of them are increasingly being used to treat other diseases, such as bipolar disorder, given their apparent mood stabilizing properties.

As with antidepressants, anticonvulsants have sedating effects; therefore the MEP believes that the medical examiner assess the sedation level of all patients currently taking anticonvulsants to determine if they are medically fit to drive a CMV. Additionally, anticonvulsant use may result in psychomotor impairment; therefore the MEP recommends that the medical examiner assess the psychomotor function of individuals currently taking these medications through the heel-to-toe walking test and tests

of coordination. If impairment is found a full neuropsychological battery of tests should be obtained from a referral specialist to further test for psychomotor impairment.

### **3. National Database of CMV Driver Medical History and Medication Use**

**It is the opinion of the MEP that FMCSA create a national database containing the medical histories and medication use of CMV drivers to facilitate future research on possible risk factors for CMV crashes.**

#### ***Justification:***

Given the lack of data regarding medical history, medication use, and crash risk, the MEP believes that FMCSA should create a national database containing the medical histories and medication use of CMV drivers to facilitate future research on possible risk factors for CMV crashes. Given the large number of CMV drivers in the United States, the MEP agrees that this database could consist of a random subsample of CMV drivers in order to decrease burden and facilitate implementation. The MEP also acknowledges that HIPAA regulations should be followed and special precautions should be taken to ensure the confidentiality of the data. It should also be emphasized that this database would not be used to track individual CMV drivers, but as aggregate data to examine relationships between different medical characteristics and crash risk over time.

### **4. Differentiation of Acute and Chronic Psychiatric Disorders**

**The MEP believes FMCSA should define acute psychiatric disorders as those that have occurred for less than six months and chronic as those which have lasted more than six months.**

- **Remission is defined as having no or minimal symptoms and no longer meeting the diagnostic criteria for the disorder. Determining whether or not an individual is in remission, however, is often a difficult judgment call as it involves assessment of functioning as well as symptoms.**
- **Anyone who has had a history of a psychiatric disorder of concern, as previously defined, within the past 3 years or a history of a recurrent disorder of concern should be re-evaluated intermittently by a qualified psychologist or psychiatrist upon referral from the medical examiner.**

#### ***Justification:***

Individuals with a history of a psychiatric disorder of concern within the past 3 years, such as a psychotic disorder not otherwise specified or a major depressive disorder may be asymptomatic at the time of the medical evaluation but at risk for recurrence. Obtaining a mental health assessment by a qualified psychologist or psychiatrist should assist the medical examiner in assessing the likelihood of a recurrence and/or need for treatment to decrease such a likelihood. In addition, the mental health professional should recommend whether future monitoring/assessment of the individual is necessary, from a mental health perspective.

## **Addendum: Clarification’s to opinions presented above requested by FMCSA’s Medical Review Board**

The opinions of the Psychiatric Disorders MEP were presented to the FMCSA and its MRB on June 30<sup>th</sup>, 2009. A number of questions were raised by the members of the MRB. *This section provides details of the Medical Expert Panel’s response to these questions and provides clarification to a number of issues raised.*

### **Clarification 1: Definitions**

*With regard to what the MEP means by a “psychologist or psychiatrist” in the context of mental health professional consultation and referral, and what the MEP feels is the appropriate level of training and skill required for commercial motor vehicle operator evaluation as it pertains to mental health issues.*

- The MEP opined that mental health professionals may exist on a continuum of training and credentials from board-certified psychiatrists through doctorate- and masters-level neuropsychologists and psychologists to advanced practice registered nurses
- In the context of the opinions stated above, the MEP members concur that:
  - The term “psychiatrist” refers to a physician who has completed a 4-year psychiatric residency. Psychiatrists in this context should also be ‘board eligible’ or preferably board certified by the American Board of Psychiatry and Neurology.
  - “Psychologist” is a proprietary term that refers to a PhD who has had at least two years of supervised clinical work, has passed a certifying exam, and is licensed under an appropriate state jurisdiction.
  - The term “neuropsychologist” applies to an individual who is a licensed psychologist who has completed a postdoctoral fellowship in neuropsychology.
- The MEP opined that appropriate consultant referral should be determined by the judgment of the medical examiner in the context of the complexity of the examinee’s case (with consideration of such factors as illness severity, duration, and stability over time; duration of condition; and interventions such as medications required for management) and the available resources, with general preference given to more highly trained and experienced consultants.

### **Clarification 2: Nature and Frequency of Psychiatric Evaluation**

*In response to questions about the nature and frequency of psychiatric evaluation, the Psychiatric Disorders MEP consolidated Opinion One and Four into the following:*

The MEP is of the opinion that acute psychiatric disorders be defined as those that have occurred for less than six months and chronic as those which have lasted more than six months. Remission is defined as having no or minimal symptoms and no longer meeting the diagnostic criteria for the disorder. Determining whether or not an individual is in remission, however, is often a difficult judgment call as it involves assessment of functioning as well as symptoms.

The MEP proposes that all individuals with a history within the past 3 years of the following psychiatric disorders, or a history of recurrent episodes of any of the following disorders, undergo additional medical and psychiatric evaluation to further assess functional ability before being considered qualified to drive a CMV:

- Psychotic Disorders
- Bipolar Disorders
- Major Depressive Disorder with a history of psychosis, suicidal ideation, homicidal ideation or a suicide attempt
- Obsessive Compulsive Disorder
- Antisocial Personality Disorder

Such individuals should demonstrate that they are likely to be able to perform their normal duties by undergoing a thorough evaluation of physical and mental function by a qualified psychiatrist. In this context, “physical” refers to behavioral phenomena such as tics, tremors, and other psychomotor movements or activities which have the potential to interfere with safe commercial motor vehicle operation.

The MEP suggest that the frequency of re-evaluation should be determined by the referral mental health professional or by the medical examiner in consultation with the referral mental health professional with training and experience appropriate to the complexity of the examinee’s case, as described above.

The MEP further suggests that the two question version of the Patient Health Questionnaire (PHQ) be added to the medical examination questionnaire to screen for depression. If the PHQ-2 is positive for a possible significant depressive disorder, the medical examiner should then refer the patient to a psychiatrist to conduct an interview for major depression, including suicidal ideation and/or attempt.

### **Clarification 3: Medication Use**

*Several requests for clarification pertaining to Opinion 2 were requested by members of the MRB. These requests for clarification are addressed below.*

- With respect to clarifications pertaining to their original statements regarding benzodiazepine use the MEP noted the following:
  - The phrase “Individuals who take benzodiazepines for any length of time” as it is used in Opinion 2 above includes those CMV operators who use a single dose of benzodiazepine at any time;
  - There is no need to attempt to differentiate CMV operators by age and possible resultant differences in metabolic clearance of drug.
- With respect to clarifications pertaining to their original statements regarding lithium use the MEP noted the following :
  - With regard to the original statement that “...all individuals currently taking lithium be excluded from driving a CMV at night”, the Panel members agreed in principle that an

alternative might be application of a test for adequate night vision once steady state dosing on the drug is achieved.

- With respect to clarifications pertaining to the original statements regarding the use of antipsychotic medications, the MEP noted the following:
  - The statement that “...all individuals currently taking antipsychotic medications undergo additional evaluation...” refers to formal evaluation by an appropriate mental health consultant with training and experience appropriate to the complexity of the examinee’s case;
  - The nature and extent of the “neuropsychological battery” to be performed by the consultant should be determined by the consultant in the context of the examinee’s individual situation;
  - With regard to the statement that “Individuals starting a new antipsychotic medication must be evaluated within one month”, the Panel members agreed that such evaluation might be accomplished within as little as two weeks, depending on drug pharmacodynamic properties such as half-life and side effect profile and the patient’s clinical presentation.
  
- With respect to clarifications pertaining to their original statements regarding the use of antidepressant medications the MEP noted the following:
  - The “additional evaluation” suggested by the MEP in Opinion 2 referred to a process comprising of the following:
    - Evaluation by the medical examiner for excessive sedation by medications (with consideration of the three aspects listed);
    - For those CMV operators using selective serotonin re-uptake inhibitors, evaluation by the medical examiner for psychomotor function (including “heel-to-toe walking, rapid alternating movement, and measures of perseveration”), with referral for further mental health professional evaluation (i.e., the “neuropsychological battery” described above) based on screening results.
  
- With respect to clarifications pertaining to their original statements regarding the use of anticonvulsant medication the MEP noted the following:
  - The same “additional evaluation” considerations as described for antidepressant medication use should be applied to anticonvulsant medication use.

## References

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## APPENDIX A: Findings of Evidence Report

This appendix summarizes the findings of the Evidence Report titled, “Psychiatric Disorders and Commercial Motor Vehicle Safety.” The purpose of this evidence report was to address several key questions posed by Federal Motor Carrier Safety Administration. Each of these key questions was developed by FMCSA such that the answers to these questions provided information that the Agency believed would be useful in updating their current medical examination guidelines. The X key questions addressed in the evidence report were:

Key Question 1: Are individuals with a psychiatric disorder at an increased risk for motor vehicle crash? If so, are there specific psychiatric disorders that present a particularly high risk?

Key Question 2: Are individuals using psychotherapeutics for a psychiatric disorder at an increased risk for crash when compared to comparable individuals who are not using psychotherapeutics?

Key Question 3: What traits associated with personality disorders are associated with reductions in motor vehicle driver safety?

### Identification of Evidence Bases

Separate evidence bases for each of the key questions addressed by this evidence report were identified using a process consisting of a comprehensive search of the literature, examination of abstracts of identified studies in order to determine which articles would be retrieved, and the selection of the actual articles that would be included in each evidence base.

A total of seven electronic databases (Medline, PubMed (pre Medline), EMBASE, PsycINFO, CINAHL, TRIS, the Cochrane library) were searched (through January 28, 2008). In addition, we examined the reference lists of all obtained articles with the aim of identifying relevant articles not identified by our electronic searches. Hand searches of the “gray literature” were also performed. Admission of an article into an evidence base was determined by formal retrieval and inclusion criteria that were determined *a priori*.

### Grading the Strength of Evidence

Our assessment of the quality 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.

### Presentation of Findings

In presenting the findings of the evidence synthesis, a clear distinction was made between qualitative and quantitative conclusions and a separate “strength of evidence” rating was assigned to each of conclusion format. The strength of evidence ratings assigned to these different types of conclusion are defined in Table 4.

**Table 4. Strength of Evidence Ratings for Qualitative and Quantitative Conclusions**

| Strength of Evidence   | Interpretation   |
|--|--|
| <b>Qualitative Conclusion</b>                                      |  |
| 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. ECRI recommends 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. ECRI recommends frequent monitoring of the relevant literature.               |
| Unacceptable   | Although some evidence exists, the evidence is insufficient to warrant drawing an evidence-based conclusion. ECRI recommends frequent monitoring of the relevant literature.   |
| <b>Quantitative Conclusion (Stability of Effect Size Estimate)</b> |  |
| 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. ECRI recommends 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. ECRI recommends 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. ECRI recommends frequent monitoring of the relevant literature.  |

## Evidence-Based Conclusions

The findings of our analysis of the best available data addressing each of the questions asked by the FMCSA are presented below.

### Key Question 1: Are individuals with a psychiatric disorder at an increased risk for motor vehicle crash? If so, are there specific psychiatric disorders that present a particularly high risk?

- **The evidence concerning crash risk for drivers with psychiatric disorders is inconclusive. The possibility of an increased risk of crash for some drivers with psychiatric disorders cannot be ruled out (Strength of Evidence: Minimally Acceptable).**

*Our searches identified eight direct crash risk studies with a total of 1,931 individuals with psychiatric disorders. The quality assessment was low for six studies and moderate for two studies. None of the study participants were specifically identified as CMV drivers, so the generalizability of findings to the CMV driver population is unclear .*

*The findings of seven studies could be combined in a quantitative analysis. Pooling of the data from these studies found no statistically significant difference in crash risk between drivers with psychiatric disorders and drivers without psychiatric disorders. However, the possibility of an increased crash risk for some drivers with psychiatric disorders could not be ruled out. We note that the patient populations enrolled in these studies were unlikely to have included individuals with severe symptoms who would be more likely to have impaired driving ability.*

### *Subgroup Analyses: Specific Psychiatric Disorders and Crash Risk*

- **Psychotic Disorders**: Currently available evidence does not suggest an increased crash risk for individuals with psychotic disorders when compared to individuals without these disorders, but an increased crash risk cannot be ruled out (Strength of Evidence: Minimally Acceptable).
- **Mood Disorders**: Although evidence suggests the possibility that individuals with mood disorders are at an increased risk for a motor vehicle crash when compared with drivers who do not have mood disorders, more evidence is needed to reach a firm conclusion.
- **Anxiety Disorders**: A paucity of evidence prevents us from being able to draw an evidence based conclusion about the effects of anxiety disorders on the risk of motor vehicle crash.
- **Personality Disorders**: Due to inconsistencies in the available evidence, we are precluded from drawing an evidence-based conclusion pertaining to the strength of the relationship between personality disorders and crash risk at this time.

*Our searches identified four studies with a total of 332 individuals with psychotic disorders, three studies with a total of 377 individuals with mood disorders, one study with 95 individuals with anxiety disorders, and three studies with 217 individuals with personality disorders. The median quality assessment for each subgroup analysis was low. Even when pooling of data was possible, none of these analyses found a statistically significant increase in crash risk for any of the four types of disorders compared to patients without psychiatric disorders. However, the possibility of increased crash risk could not be ruled out in any of these subgroup analyses.*

### **Key Question 2: Are individuals using psychotherapeutics for a psychiatric disorder at an increased risk for crash when compared to comparable individuals who are not using psychotherapeutics?**

#### *Analysis 1: Benzodiazepine Use and Crash Risk*

- **Benzodiazepine use is associated with an increased risk for a motor vehicle crash. (Strength of Evidence: Moderate)**
  - **Benzodiazepine anxiolytic use is associated with an increased risk for a motor vehicle crash. (Strength of Evidence: Minimally Acceptable)**
  - **Crash risk may be greater during the first week of an index prescription of benzodiazepines. (Strength of Evidence: Minimally Acceptable)**
  - **Crash risk may be greater among benzodiazepine users ≤40 years of age. (Strength of Evidence: Minimally Acceptable)**

*Our searches identified nine direct crash risk studies with a total of approximately 235,000 individuals using benzodiazepines. The average quality of these studies was moderate. None of the study participants were specifically identified as CMV drivers, so the generalizability of the findings to the CMV*

driver population is unclear. The findings of the nine studies were inconsistent. However, pooling of the data from each study found elevated odds of crash associated with benzodiazepine use. This finding was statistically significant and robust.

Because benzodiazepine anxiolytics are more likely to be used than hypnotics in patients with psychiatric disorders, we performed a subgroup analysis of five studies that presented separate crash data for users of anxiolytics. The pooled data analysis found that the odds of crash were significantly increased in users of benzodiazepine anxiolytics.

Further analysis to identify factors that may lead to increased risk for benzodiazepine users identified timing of exposure and patient age as potential risk factors. Two studies found the highest risk of crash to occur during the first week of the index prescription, and two studies found that crash risk was higher in benzodiazepine users  $\leq 40$  years of age.

### **Analysis 2: Antipsychotic Use and Crash Risk**

- **The evidence concerning crash risk associated with antipsychotic use is inconclusive. The possibility of an increased crash risk associated with antipsychotic use cannot be ruled out.**

One study addressed the potential association between antipsychotic drugs and crash risk. This study found no excess risk of crash associated with antipsychotic agents within two weeks or four weeks of the index prescription. As this is a single moderate-quality study and the 95% CIs around the effect estimates do not rule out the possibility of increased risk, more evidence is needed to confirm these findings.

### **Analysis 3: Antidepressant Use and Crash Risk**

- **The evidence concerning crash risk associated with antidepressant use is inconclusive. The possibility of an increased crash risk associated with antidepressant use (particularly tricyclic antidepressant [TCA] use) cannot be ruled out. (Strength of Evidence: Minimally Acceptable)**

Our searches identified seven direct crash risk studies with an unknown number of individuals using antidepressants – the number is not reportable because the raw data needed to calculate the total study population using antidepressants was not reported in all studies. Because these are seven of the nine studies identified under benzodiazepines, the generalizability issues and quality assessments are described in the earlier summary.

The findings of six of the seven studies could be combined to obtain a summary estimate of the relative odds of crash associated with antidepressant use. Pooling of the data from these studies found that the odds of crash was not significantly different for drivers using antidepressants compared to drivers not using antidepressants. However, there was a trend toward elevated risk associated with antidepressants, and the wide confidence interval around the summary estimate means that the possibility of increased crash risk cannot be ruled out. The same finding was shown for a subgroup meta-analysis of studies that separately reported data on TCA use.

### Key Question 3: What traits associated with personality disorders are associated with reductions in motor vehicle driver safety?

- The evidence suggests that individuals with traits associated with personality disorders are at an increased risk for a motor vehicle crash when compared with comparable drivers who do not have a trait associated with a personality disorder. These traits include aggression, hostility, impulsivity, disregard for law (i.e. attitude toward traffic law violations), and various psychological symptoms. However, inconsistencies in the methodologies of the included studies preclude us from drawing an evidence-based conclusion pertaining to the strength of the relationship between traits associated with personality disorders and crash risk at this time.

*Our searches identified 21 direct crash risk studies with a total study population of 164,539 individuals, 512 of whom were CMV drivers. The quality assessment of 14 of the included studies was low; the quality assessment of the remaining 7 studies was moderate. Methodological limitations of these studies include the lack of uniformity in the definition of the traits, behaviors, and outcomes; and the use of scales which may not have been age or gender appropriate. Since most of the studies did not include CMV drivers, the generalizability of the findings to the CMV driver population is unclear.*

*Because the studies used a number of different scales and methodologies to measure the traits and behaviors, and the outcome measures could not be assumed to be uniform, we were precluded from combining them for quantitative analysis. Instead, we have provided a qualitative summary of the findings.*

*Overall, the studies suggest that traits such as aggression, hostility, impulsivity, disregard for laws (i.e. attitude toward traffic law violations), and various psychological symptoms are associated with an increase in crash risk. The same can be said of behaviors such as risky driving and violation of traffic laws. In turn, behaviors such as risky driving are associated with aggression, impulsivity, and psychological symptoms such as anxiety, depression, and psychosis. Violation of traffic laws is associated with risky driving and aggression. Table 5 provides a quick summary of the associations between factors and outcomes.*

**Table 5. Associations between Factors and Outcomes for Key Question 3**

|                            | Aggression | Hostility | Impulsivity | Attitude toward traffic law violations | Psychological symptoms* | Behaviors     |                            |
|----------------------------|------------|-----------|-------------|--|-------------------------|---------------|----------------------------|
|                            |            |           |             |  |                         | Risky Driving | Violations of traffic laws |
| Crash                      |            |           |             |  |                         |               |                            |
| Risky Driving              |            | NA        |             |  |                         | —             |                            |
| Violations of traffic laws |            | NA        | NA          | NA                                     | NA                      |               | —                          |

|            | Aggression | Hostility | Impulsivity | Attitude toward traffic law violations | Psychological symptoms*   | Behaviors   |   |
|------------|------------|-----------|-------------|--|---|---|---|
|            |            |           |             |  |   | Risky Driving   | Violations of traffic laws  |
| Aggression | —          | NA        | NA          | NA                                     |  |  |  |

 Factor has a negative impact on this outcome such that crash risk is increased.

\* Psychological symptoms include anxiety, paranoid ideation, depression, psychosis, personality disorder, irritability, negativism, antisocial tendencies  
 NA - Not applicable. This factor was not examined in relationship to the outcome of interest.

## Overall Summary

This report did not find conclusive evidence of an association between increased crash risk and any of four classes of psychiatric disorders (psychotic disorders, mood disorders, anxiety disorders, and personality disorders). However, given the limitations of the available studies and the likelihood that patients with severe symptoms would not be driving and thus would not be enrolled, the possibility of increased crash risk for some patients with psychiatric disorders cannot be ruled out. In contrast, the evidence was sufficient to show an association between use of at least one class of psychotherapeutic medications (benzodiazepines) and increased crash risk. This association held in a subgroup analysis of benzodiazepine anxiolytics which are likely to be used by patients with anxiety disorders. Further evidence suggested that the risk of crash was highest during the first week of index treatment, and that benzodiazepine users of age < 40 years were at higher risk than other age groups. The evidence was unclear as to whether any type of antipsychotic or antidepressant was associated with increased crash risk. The available evidence also suggested an association between certain traits of patients with personality disorders (including aggression, hostility, impulsivity, disregard for law, and various psychological symptoms) and increased crash risk.