Executive Summary

Parkinson's Disease, Multiple Sclerosis, and Commercial Motor Vehicle Driver Safety

Presented to

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Prepared for

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Evidence reports are sent to the Federal Motor Carrier Safety Administration's (FMCSA) Medical Review Board (MRB) and Medical Expert Panels (MEP). The MRB and MEP make recommendations on medical topics of concern to the FMCSA.

The FMCSA will consider all MRB and MEP recommendations; however, all proposed changes to current standards and guidance (guidelines) will be subject to public-notice-and-comment and relevant rulemaking processes.

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Policy Statement

This report was prepared by ECRI Institute under subcontract to MANILA Consulting Group, Inc., which holds prime GS-10F-0177N/DTMC75-06-F-00039 with the Department of Transportation's Federal Motor Carrier Safety Administration. ECRI Institute is an independent, nonprofit health services research agency and a Collaborating Center for Health Technology Assessment of the World Health Organization. ECRI Institute has been designated an Evidence-based Practice Center (EPC) by the U.S. Agency for Healthcare Research and Quality. ECRI institute's mission is to provide information and technical assistance to the healthcare community worldwide to support safe and cost-effective patient care. The results of ECRI Institute's research and experience are available through its publications, information systems, databases, technical assistance programs, laboratory services, seminars, and fellowships. The purpose of this evidence report is to provide information regarding the current state of knowledge on this topic. It is not intended as instruction for medical practice or for making decisions regarding individual patients.

Purpose of Report

Of all occupations in the United States, workers in the trucking industry experience the third highest fatality rate, accounting for 12% of all worker deaths. About two-thirds of fatally injured truck workers were involved in highway crashes. According to statistics from the U.S. Department of Transportation (DOT), there were 4,932 fatal crashes involving a large truck in 2005 for a total of 5,212 fatalities. In addition, there were 137,144 nonfatal crashes; 59,405 of these were crashes that resulted in an injury to at least one individual (for a total of 89,681 injuries).

The purpose of this evidence report is to address several key questions posed by the Federal Motor Carrier Safety Administration (FMCSA). Each of these key questions was developed by the FMCSA such that the answers to these questions provided information that would be useful in updating its current medical examination guidelines. The six key questions addressed in this evidence report are as follows:

Key Question 1: What are the criteria that define when an individual with Parkinson's disease (PD) should stop driving a CMV?

Key Question 2: What is the impact of pharmacotherapy for PD on driver safety?

Key Question 3: Are individuals with multiple sclerosis (MS) at an increased risk for a motor vehicle crash?

Key Question 4: What factors associated with MS are predictive of an increased crash risk?

Key Question 5: How frequently should individuals with MS be assessed in order to monitor whether they remain safe to drive?

Key Question 6: What is the impact of pharmacotherapy for MS on 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 (preMEDLINE), EMBASE, PSYCH Info, CINAHL, TRIS, the Cochrane library) were searched through April 23, 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 compose 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

The set of analytic techniques used in this evidence report was extensive. 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

In presenting our findings, we made a clear distinction between qualitative and quantitative conclusions and we assigned a separate "strength of evidence" rating to each conclusion format. 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. ECRI Institute 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 Institute recommends frequent monitoring of the relevant literature.
Insufficient	Although some evidence exists, the evidence is insufficient to warrant drawing an evidence-based conclusion. ECRI Institute recommends 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. ECRI Institute 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 Institute 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 Institute recommends frequent monitoring of the relevant literature.

Evidence-Based Conclusions

Key Question 1: What criteria define when an individual with Parkinson's Disease (PD) should stop driving a CMV?

The evidence is insufficient to determine with precision what risk factors or combination of risk factors truly defines when an individual with PD should stop driving. However, potential risk factors include movement restriction/decreased motor function, stage of PD, duration of PD, decreased cognitive function, and sudden onset of sleepiness (Strength of Evidence: Minimally Acceptable).

Direct Evidence – Crash Studies: Three studies in non-CMV driver populations provided direct evidence to address this question. One low-quality case-control study found that subgroups of patients with Hoehn and Yahr (H&Y) stages 2 and 3 showed a significantly increased crash risk compared to control individuals without PD (p = 0.001, p = 0.008). No evidence of increased crash risk was found among patients in H&Y Stage 1. A low-quality cohort study evaluating outcomes in driving patterns among individuals with PD found that individuals with movement restriction had a significantly increased crash risk compared to individuals without movement restriction (p = 0.034). One low-quality survey study evaluating outcomes of sudden onset of sleepiness and driving behavior found that disease severity, sleepiness, and driving exposure showed a significant association with crash prediction. However, these findings need to be replicated before a definitive conclusion can be reached. Limitations of the evidence supporting this conclusion are the small size of the evidence base (three studies) and overall low quality.

Indirect Evidence – Studies of Driving Tests and Driving Simulation: Six cohort studies (four moderate-quality, two low-quality) evaluated outcomes indirectly associated with crash risk among non-CMV drivers with PD. One study showed a significant association of Epworth Sleepiness Scale scores and Inappropriate Sleep Composite Scores with risk of falling asleep while driving (p <0.001). Two studies' multivariate assessment of driving fitness showed a significant difference in factors (disease duration, contrast sensitivity, cognitive function, and motor function) associated with PD individuals who failed a driving assessment compared to individuals passing a driving assessment. However, predicting which individuals will pass or fail a driving assessment is not the same as predicting which individuals who pass a driving assessment will have an increased crash risk. Whether the variables identified in these two studies can predict which patients with PD who pass a driving assessment are at increased risk of crash remains to be determined. Another study identified disease stage, car test score, and reaction time to brake as predictors of driving suitability using stepwise discriminant analysis. Of the remaining two studies, one assessed stage of PD related to driving simulator crash and showed a significant increase in simulator crash correlated with increasing H& Y stage (p = 0.006). The other study identified various neuropsychological measures as variables correlating with performance measures on a driving simulator. However, the possibility exists that some of these variables might not have remained significantly correlated with driving performance had a multivariate analysis been performed. The findings of the four studies that used multivariate assessment or discriminant function analysis for predicting driving performance should be given greater consideration than the studies that did not, as these studies attempt to isolate the true predictability of the associated risk factors evaluated within the studies.

We were not able to assess the crash risk for PD among CMV drivers. The lack of studies enrolling CMV drivers with PD precludes one from determining whether CMV drivers with this condition are at an increased risk for a motor vehicle crash.

Key Question 2: What is the impact of pharmacotherapy for PD on driver safety?

Evidence suggests that somnolence (sleepiness) associated with pharmacotherapy in individuals with PD may affect driver safety. (Strength of Evidence: Minimally Acceptable) Whether measures of somnolence among individuals with PD taking pharmacotherapy can predict actual crash risk cannot be determined from currently available evidence.

Direct Evidence – Crash Studies: No included studies provided direct evidence of crash risk with noncommercial drivers.

Indirect Evidence – Studies of Driving Performance: The three included studies (ranging from low to high quality) evaluated an indirect outcome (sleepiness) which may be associated with driver safety. The combined data from two randomized controlled trials found that individuals with PD given treatment tend to be at an increased risk of somnolence compared to those given placebo ($p = 0.002$).

We were not able to assess the impact of pharmacotherapy for PD on driver safety among CMV drivers. The paucity of data from studies enrolling CMV drivers treated with PD pharmacotherapy precludes one from determining whether CMV drivers with this type of condition are at an increased risk for a motor vehicle crash.

Key Question 3: Are individuals with Multiple Sclerosis (MS) at an increased risk of motor vehicle crash?

Currently available evidence is insufficient to determine whether crash risk is increased among individuals with MS. However, the possibility that crash risk is increased among a subgroup of individuals with MS and an additional impairment cannot be ruled out.

Direct Evidence – Crash Studies: Two moderate-quality cohort studies evaluated outcomes directly associated with crash risk among non-CMV drivers with MS. Although the summary effect size in both studies suggested increased crash risk among drivers with MS, the findings did not reach statistical significance in either study. However, in one of these studies a subgroup of MS patients with cognitive impairment showed significantly increased crash risk compared to control individuals without MS, whereas a subgroup of MS patients without cognitive impairment did not show significantly increased crash risk compared to controls. The individuals in this study had minimal or no physical limitations, so they were not in a severe stage of MS. This finding suggests that cognitive impairment caused by MS may be a more important predictor of crash risk than simply having MS. However, this finding needs to be replicated before a definitive conclusion can be reached. Limitation of the evidence supporting the conclusion includes small sample size (one study) and moderate quality.

Indirect Evidence: *No included studies provided indirect evidence of crash risk with non-CMV drivers.*

We were not able to assess the crash risk for MS among CMV drivers. The lack of studies enrolling CMV drivers with MS precludes one from determining whether CMV drivers with this condition are at an increased risk for a motor vehicle crash.

Key Question 4: What factors associated with MS are predictive of an increased crash risk?

The available evidence is insufficient to determine which factors may be predictive of increased crash risk among individuals with MS. However, the possibility that crash risk is increased among subgroups of individuals with MS and cognitive impairment cannot be ruled out.

Direct Evidence – Crash Study: One moderate-quality cohort study evaluated outcomes directly associated with crash risk among non-CMV drivers with MS. The individuals in this study had minimal or no physical limitations. A subgroup of MS patients with cognitive impairment showed significantly increased crash risk ($p = 0.012$) compared to control individuals without MS, whereas a subgroup of MS patients without cognitive impairment did not show significantly increased crash risk compared to control ($p = 0.887$). The results suggest that cognitive impairment caused by MS may be an important predictor of crash risk. However, this finding needs to be replicated before a definitive conclusion can be reached. Limitations of the evidence include small sample size (one study) and moderate study quality.

Indirect Evidence – Road Test and Driving Simulator Studies: *Two moderate-quality cohort studies evaluated outcomes that may be indirectly associated with crash risk among non-CMV drivers with MS. One study found that MS drivers who failed a road test scored significantly worse ($p <0.05$) on 6 out of 23 cognitive tests compared to MS drivers who passed a road test. This study included patients with a wide spectrum of disease severity, ranging from independent mobility to wheelchair dependence. In the other study, assessment of Useful Field of Vision (UFOV) performance related to driving showed that a subgroup of MS patients with cognitive impairment had a significant increase in estimated crash risk ($p <0.01$) compared to control individuals without MS, whereas a subgroup of MS patients without cognitive impairment did not show a significant increase in estimated crash risk compared to the control group. Assessment of neurocognitive driving performance within the same study showed a significant increase in latency time scores for MS patients with cognitive impairment compared to MS patients without cognitive impairment and healthy controls. The errors subcategory did not show a significant difference among these three groups. The patients in this study had minimal or no physical limitations. Whether these findings have any relationship with actual crash risk remains uncertain. Limitations of this evidence include small sample size (two studies) and moderate study quality.*

We were not able to assess the crash risk for MS among CMV drivers. The lack of studies enrolling CMV drivers with MS precludes one from determining whether CMV drivers with this condition are at an increased risk for a motor vehicle crash.

Key Question 5: How frequently should an individual with MS be assessed in order to monitor whether they remain safe to drive?

No evidence was identified regarding assessment time interval for monitoring driver safety in patients with MS. Therefore, no evidence-based conclusion is possible at the present time.

Our searches identified no potentially relevant articles that addressed this question.

Key Question 6: What is the impact of pharmacotherapy for MS on driver safety?

No evidence was identified concerning the relationship between MS pharmacotherapy and driver safety outcomes. Therefore, no evidence-based conclusion is possible at the present time.

Our searches identified no potentially relevant articles that addressed this question.