TechBrief

Programs of the Federal Motor Carrier Safety Administration (FMCSA) encompass a range of issues and disciplines, all related to motor carrier safety and security.

The mission of the FMCSA's Office of Medical Programs is to promote the safety of America's roadways through the promulgation and implementation of medical regulations, guidelines and policies that ensure commercial motor vehicle drivers engaged in interstate commerce are physically qualified to do so.

A "large truck" is any truck with a Gross Vehicle Weight rating or Gross Combination Weight rating of 10,001 pounds or greater.

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FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION

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Overview of Methodologies to Develop Medical Standards and Guidelines for Commercial Motor Vehicle Drivers

Background

This technical brief explains the methodologies FMCSA uses to make evidence-based decisions in the review and development of medical standards and guidelines for large truck and bus drivers who operate in interstate commerce. The process is based on the "best available" evidence. This is the first application of these methodologies in the Department's regulated driver populations. This technical brief summarizes the processes underpinning the program, from research to analysis and dissemination.

Overview of the Methodology

FMCSA uses systematic review and meta-analysis to examine medical conditions and crash risk for this regulated driver population. There are five distinct phases:

- Research and Development of Questions
- Identification of Evidence Base
- Systematic Review and Evidence Synthesis
- Meta-Analysis
- Dissemination

Research and Development of Questions

The first task is determining the right questions to ask. FMCSA performs this task with input from the Medical Review Board (MRB), the research team, and in some cases, medical and scientific experts in the diseases under review.

The team performs preliminary research to determine whether the Agency's requirements are met by the available evidence that addresses these questions. Preliminary research may lead to refinement of the original questions and, in some instances, development of new key questions. Next, the research team develops *a priori* question-specific retrieval and inclusion criteria that define the types of studies that will form the evidence base for each question.

Identification of Evidence Base

How do we determine the "best available" evidence? First, separate evidence bases for each question are identified by a systematic and comprehensive search of the literature. Next, the team develops a list of medical subject heading (MeSH) terms, publication types, text word combinations from MeSH tools and output from preliminary searches, review articles, and other sources that examine crucial concepts (e.g., epidemiology, screening, cost-effectiveness). Finally, a sample of the electronic databases searched are listed in Table 1. In addition, the research team reviews more than 1,000 periodicals, searches the references of all retrieved articles to make sure that no information is omitted, and reviews reports, studies, articles and monographs from government agencies, organizations, and other groups ("gray literature") that do not appear in peer-reviewed journals.

Table 1. Data Sources		
Name of database	**Date limits**	**Platform/provider**
Cochrane Library	Through 2006 Issue 3	www.thecochranelibrary.com
Embase (Excerpta Medica)	1980 – August 31, 2006	OVID
Medline	1966 – August 31, 2006	OVID
PubMed (Pre Medline)	Premedline Searched August 31, 2006	www.pubmed.gov
PSYCH Info	1968 – August 31, 2006	www.apa.org/psycinfo
TRIS Online (Transportation Research Information Service Database)	Through August 31, 2006	http://trisonline.bts.gov/search.cfm

The full-length version of potentially relevant articles are retrieved and read in full by research team analysts who determine whether they meet the inclusion criteria. If an article does not meet the criteria, it is excluded and listed, with the reason(s) for exclusion, in the evidence report appendix.

Systematic review and meta-analysis represent the highest class of evidence. In this type of review, the type of evidence is ranked by quality. Table 2 describes the classification of evidence. A systematic review is a study of secondary findings that uses the scientific method. This review is designed in the same way as any scientific study. Specific elements are: research, hypothesis generation, inclusion criteria development, data collection, and data analysis (meta-analysis).

Systematic Review and Evidence Synthesis

Evidence-based conclusions are drawn according to the synthesis findings, and a "strength-of-evidence rating" is assigned to each conclusion. The strength-of-evidence rating assigned to an evidence-based conclusion is determined by several factors including, quality of the evidence base, size of the evidence base, consistency and robustness of the findings of the studies in the evidence base, and the magnitude of any effect observed (Treadwell et al., 2006). Table 3 describes the strength-of-evidence rating system.

Meta-analysis

The data synthesis methodology used to address a question differs by the question, the size of the evidence base, and the available outcome data. The research team attempts to address each question both quantitatively and qualitatively, however, the team performs qualitative analysis when quantitative analysis is precluded.

Meta-analysis, or quantitative synthesis, is a mechanism to pool outcome data from different studies to provide a single estimate of effect. For example, data from several studies of the crash risk associated with a medical condition can be combined to calculate an estimate of crash risk. Analytic techniques used include:

- Random- and fixed-effects meta-analyses to pool data from different studies when appropriate.
- The Q-statistic and I^2 are explored using meta-regression techniques to detect heterogeneity or the differences in the findings of different studies.
- Sensitivity analyses to test the robustness of the findings and determine the presence of bias.

Table 2. Classification of Evidence		
Rank	**Type of Evidence**	**Description**
1	Systematic review and meta-analysis	Systematic review: review of a body of data that uses explicit methods to locate primary studies, and explicit criteria to assess their quality Meta-analysis: A statistical analysis that combines or integrates the results of several independent clinical trials considered by the analyst to be "combinable"
2	Randomized control trial (RCT)	Individuals are randomly allocated to a control group and a group who receive a specific intervention. Otherwise the two groups are identical for any significant variables. They are followed up for specific end points
3	Cohort study	Groups of people are selected on the basis of their exposure to a particular agent and followed up for specific outcomes
4	Case-control study	"Cases" with the condition are matched with "controls" without, and a retrospective analysis used to look for differences between the two groups
5	Cross sectional survey	Survey or interview of a sample of the population of interest at one point in time
6	Case report	A report based on a single patient or subject; sometimes collected together into a short series
7	Expert opinion	A consensus of experience from scientific, medical experts
8	Anecdote	A short account or narrative of an event or incident

Dissemination

The primary reference document is the evidence report, which can be comprehensive wehn medical topics are more complex. An executive summary of the evidence report is also available to the public. All evidence reports are catalogued in the government library. Study results undergo peer review evaluation, and all findings are made public. Recommendations derived from the evidence report are made by expert panels as well as the Agency's Medical Review Board. These findings are available in separate recommendation summary reports.

Summary of Conclusions

The FMCSA uses the evidence-based systematic review process to revise or develop medical standards and guidelines for commercial drivers. There are five distinct phases of this methodology which include: 1) Research and Development of Questions, 2) Identification of Evidence Base, 3) Systematic Review and Evidence Synthesis, 4) Meta-Analysis, and 5) Dissemination. This methodology is complex and represents FMCSA's commitment to using the best available evidence to ensure that drivers are medically fit for duty.

For more information about FMCSA's medical program, go to: www.fmcsa.dot.gov/rules-regulations/topics/medical/medical.htm.

For questions about FMCSA's medical program via email: fmcsamedical@dot.gov.

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Table 3. Strength-of-Evidence Rating	
Strength of Evidence	**Interpretation**
Qualitative Analysis	
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. The recommendation is to regularly monitor the relevant literature for moderate-strength conclusions.
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. The recommendation is for frequent monitoring of the relevant literature.
Insufficient	Although some evidence exists, the evidence is insufficient to warrant drawing an evidence-based conclusion. The recommendation is for frequent monitoring of the relevant literature.
Quantitative Analysis	
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. The recommendation is for 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. The recommendation is for regular monitoring of relevant literature.
Unstable	Estimates of the treatment effect are too unstable to allow a quantitative conclusion to be drawn at this time. The recommendation is for regular monitoring of the relevant literature.

References

Treadwell JT, Tregear SJ, Reston JT, Turkelson CM. A system for rating the stability and strength of medical evidence. BMC Med Res Methodol 2006 Oct 19;6:52.

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