Expert Panel Recommendations
Cardiovascular Disease and Commercial Motor Vehicle Driver Safety

Panel Members

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Presented to

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Prepared for

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This report is comprised of research conducted to analyze the impact of Cardiovascular Disease on Commercial Motor Vehicle Driver Safety. Federal Motor Carrier Safety Administration considers evidence, expert recommendations, and other data, however, all proposed changes to current standards and guidance (guidelines) will be subject to public-notice-and-comment and regulatory processes.

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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 (CMVs), including large trucks and buses. One mechanism used to facilitate this effort is updating current and developing new medical fitness standards for drivers of CMVs and guidelines for medical examiners. FMCSA is committed to review and begin updating all its current standards and guidelines by 2009.

This report summarizes the considerations and recommendations of a panel of experts in the field of cardiology (termed the Medical Expert Panel (MEP)) who examined FMCSA's current cardiovascular disease (CVD)-related guidelines with the aim of determining whether they require updating.

Guideline Development Personnel

Members of the MEP charged with making recommendations pertaining to whether the current guidelines for CVD need to be updated are listed in Table 1.

Table 1. Members of the MEP

Name	Current Position
Roger S. Blumenthal, MD	Associate Professor of Medicine Director, Ciccarone Preventive Cardiology Center The Johns Hopkins University School of Medicine
Andrew E. Epstein, MD	Professor of Medicine University of Alabama at Birmingham
Richard E. Kerber, MD	Professor of Medicine University of Iowa

Methodology

Brief Overview of Evidence Report Methodology

The recommendations contained in this report are based in part on the interpretation and assimilation of information presented in a comprehensive systematic review of available literature, prepared by ECRI and Manila, and presented to the MEP on February 23, 2007. The evidence report was developed following a systematic literature search for evidence accessible from seven electronic databases — Medline, PubMed (pre Medline), EMBASE, PsycINFO, CINAHL, TRIS, and the Cochrane Library (through

November 28, 2006). 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. Included data were pooled and synthesized, where applicable, using meta-analytic techniques described in detail in the Evidence Report, "Cardiovascular Disease and Commercial Motor Vehicle Driver Safety." (See also Appendix B of this report.)

Pre-Meeting Preparation

Thirty days before the MEP meeting, each panel member received a draft copy of the Evidence Report. Panel members also received a guideline workbook. The guideline workbook consisted of 10 worksheets (see Exhibit 1) highlighting FMCSA's existing guideline recommendations for medical examiners on the assessment of CVD. (Refer to Appendix A for existing guidelines). The topics covered included:

- CMV drivers without known coronary heart disease (CHD)
- CMV drivers with known CHD
- Hypertension
- Supraventricular tachycardia
- Pacemakers
- Implantable Cardioverter Defibrillators (ICDs)
- Aortic and thoracic aneurysms
- Peripheral vascular disease
- Venous disease
- Cardiomyopathies and heart failure

Members of the panel were asked to review the existing guideline recommendations, in conjunction with their review of current information presented in the companion evidence report, to determine whether existing recommendations required updating. More specifically, panel members were instructed to determine:

1. Whether each of the existing guidelines is acceptable;
2. If not acceptable, to provide an explanation why;
3. If not acceptable, to provide suggested changes to the existing guideline;
4. If proposing a suggested change, to state whether this change is supported with evidence; and
5. If evidence exists, to provide citations for this evidence.

Exhibit 1. Snapshot of a Section of a Worksheet Provided to the MEP

SECTION 1: Worksheet for Updating Guidelines to Medical Examiners (CMV Drivers without Known CHD)

Current Guidelines				Column A	Column B	Column C	Column D	Column E
Diagnosis	Physiologic/Functional	Certification	Recertification	Are current guidelines acceptable?	If no, please list why?	What change(s) do you suggest?	Are changes supported by evidence?	If no, please provide cites Notes: If FMCSA evidence report is evidence source, write: "Evidence Report" If based on expert opinion, write "Expert Opinion"
Asymptomatic, healthy	Low CHD event risk. Assess for clinically apparent risk factors. Use, when possible, Framingham risk score model to predict 10- year CHD event risk; Increasing age is a surrogate marker for increasing atherosclerotic plaque burden	Yes, if asymptomatic. Rarely disqualifying alone.	Biennial					
Asymptomatic, high risk person (as designated by CHD risk-equivalent condition)* Asymptomatic, high risk person >45 years with multiple risk factors for CHD	Sub-clinical coronary atherosclerosis is a concern; High-risk status requires close physician follow-up and aggressive comprehensive risk factor management.	Yes, if asymptomatic. No if: • Abnormal ETT† • Ischemic changes on ECG‡ • Functional incapacitation by one of conditions.	Annual					

*CHD risk-equivalent is defined as presence of diabetes mellitus, peripheral vascular disease or Framingham risk score predicting a 20% CHD event risk over the next 10 years.

†Abnormal ETT is defined by: an inability to exceed 6 METS through Stage II or six minutes on standard Bruce Protocol; presence of ischemic symptoms and/or signs (e.g. characteristic angina pain or 1 mm or greater ST depression or elevation in 2 or more leads); inappropriate SBP and/or heart rate response (e.g. inability of heart rate to meet or exceed 85% of age-predicted maximal heart rate unless on beta blocker); a rise in SBP ≥10 mmHg; or ventricular dysrhythmia.

‡Ischemic changes on ECG –are defined by the presence of new 1 mm or more ST-segment elevation or depression and/or marked T wave abnormality

The Medical Expert Panel Meeting and Recommendation Formulation

On February 23, 2007, Manila, ECRI and members of the Expert Panel for FMCSA convened to review the existing recommendations, and to discuss changes deemed necessary following the critical assessment of the evidence in the Evidence Report and the expert opinion of the MEP members. This group reviewed each of the recommendations in the guideline worksheets and discussed the supporting evidence. In developing and revising the guidelines, panel members were guided by the following principles: that changes to the existing recommendations be 1) based on scientific evidence whenever possible, 2) concise and explicit, and 3) actionable. Recommendations for which no supporting evidence could be found are identified as such below.

This document summarizes the recommendations derived from this consensus process.

Recommended Changes to Original Guidelines

The MEP recommended that FMCSA make several changes to the current CVD guidelines. These recommendations were based on a combination of evidence provided by the Evidence Report, "Cardiovascular Disease and Commercial Motor Vehicle Driver Safety" and other sources. Below are the recommended changes and, when necessary, justification for these changes.

Section 1: CMV drivers without known heart disease

The MEP made a single recommendation regarding changes to the guideline statements found in Section 1.

1. The MEP recommends that the currently used definition for abnormal exercise tolerance testing (ETT) should be revised so that it is defined as an inability to exceed 6 METS (metabolic equivalents) on ETT.

   Justification for change: FMCSA's current guidelines define abnormal ETT as "…an inability to exceed 6 METS or through Stage II or six minutes on standard Bruce protocol." METS are standardized units (1 MET = 3.5 mL/kg/min) that allow determination and direct comparison of workload capacity data obtained across different ETTs. Consequently, to be certified to drive a CMV, an individual must be capable of exceeding 6 METS, regardless of the ETT protocol used.

Section 2: CMV drivers with known chronic heart disease

The MEP made several recommended changes to the guideline statements in Section 2.

1. The MEP recommends that it be made clear that for all guidelines in this section, there is an expectation that individuals with known CHD will have had all of their medications titrated to the optimal dose.

2. The current FMCSA guideline states that individuals with angina pectoris may be qualified for certification if they are rendered asymptomatic. The MEP recommended that CMV drivers with angina pectoris may be qualified for certification to drive a CMV if the pattern of angina is stable.

   Justification for change: By definition, a person with angina pectoris is not asymptomatic.

3. Current FMCSA guidelines state that an individual with angina pectoris who has undergone a percutaneous coronary intervention (PCI) may be qualified to drive if he or she meets all the following conditions:
   - At least one week has passed since the procedure
   - The treating cardiologist provides approval
   - The individual has demonstrated tolerance to medications
   - The individual has a normal ETT 3 to 6 months following PCI

   The MEP recommended removing the last of these conditions (normal ETT 3 to 6 months following PCI).

   Justification for change: the American College of Cardiology (ACC), American Heart Association (AHA), and Society for Cardiovascular and Angiography Interventions (SCAI) guidelines no longer recommend exercise testing be performed six to nine months following PCI unless an individual has specific indications.

Supporting cites:

- *Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). Available at: http://www.americanheart.org.*
- *Gibbons RJ, Balady GJ, Bricker JT, et al. ACC/AHA 2002 guideline update for exercise testing—summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Update the 1997 Exercise Testing Guidelines). Circulation 2002;106:1883-92.*

4. Current FMCSA guidelines state that individuals who have undergone coronary artery bypass surgery that meet the requirements for certification should be recertified on an annual basis for five years. After this time, such individuals should undergo an exercise tolerance test annually. The MEP recommended extending the time between exercise tolerance tests to two years.

   Justification for change: After 5 years, there is a significantly increased rate of graft closure and exercise testing is recommended. The MEP recommended that the testing be the same for all individuals with CHD for the sake of consistency across all guidelines.

Section 3: CMV drivers with hypertension

The MEP recommended several changes to the guideline statements in Section 3.

1. The MEP recommends that a series of statements explaining the general principles of certification of individuals with hypertension be added to the current CVD guidelines. These general principles are as follows:

   a) Certification and recertification of individuals with hypertension should be based on a combination of factors: blood pressure, the presence of target organ damage, and co-morbidities.

   b) To provide consistency in certification, blood pressure recorded at the certification (or recertification) examination should be used to determine blood pressure stage. The certifying examiner may decide on the length of certification for drivers with elevated blood pressure despite treatment.

   c) All CMV drivers should be referred to their personal physician for therapy, education, and long-term management.

2. The MEP recommends that text be added to the current FMCSA guidelines in this section noting that there is an expectation throughout this section that blood pressure has been measured appropriately. A Scientific Statement from the AHA on what is deemed the appropriate measurement of blood pressure is available in the following citations:

   - Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, Hill MN, Jones DW, Kurtz T, Sheps SG, Roccella EJ. Recommendations for blood pressure measurement in humans and experimental animals: Part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the AHA Council on HBP. Hypertension 2005 Jan;45(1):142-61.
   - Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, Hill MN, Jones DW, Kurtz T, Sheps SG, Roccella EJ. Recommendations for blood pressure measurement in humans and experimental animals: Part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the AHA Council on HBP. Circulation 2005 Feb 8;111(5):697-716.

3. The MEP recommends that text be added to the current FMCSA guidelines in this section noting that there is an expectation throughout this section that blood pressure medication has been titrated appropriately. The target blood pressure for titration should be <140/<90.

4. The MEP recommends that text be added to the current FMCSA guidelines included in this section noting that medical examiners should ensure that individuals with hypertension are properly educated about the importance of making appropriate changes in lifestyle and proper compliance with medication.

5. The MEP recommends the current guidelines be clarified so that current ambiguity about thresholds that define hypertension stage in the existing guidelines be eliminated. The panel recommends that updated guidelines note that the hypertension stages used in updated guidelines are consistent with those recommended by the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (Table 2).

   The definition for Stage 1 hypertension proposed in the seventh report of the Joint National Committee (JNC-7) on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (see: http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.pdf) is consistent with existing FMCSA guidelines. However, JNC-7 has combined JNC-6 Stage 2 and

Stage 3 hypertension into a single stage. This reflects the fact that clinical management of Stage 2 and Stage 3 hypertensive individuals is considered similar. Despite this, the panel recommends that FMCSA continue to maintain JNC-6 Stage 3 hypertension as a distinct category of hypertension because this defines the blood pressure that requires immediate disqualification from driving a CMV.

Table 2. JNC-6 and JNC-7 Definitions of Hypertension

JNC 6 Category	SBP/DBP	JNC 7 Category
Optimal	<120/80	→ Normal
Normal	120–129/80–84	→ Prehypertension
Borderline	130–139/85–89	
Hypertension	≥140/90	→ Hypertension
Stage 1	140–159/90–99	→ Stage 1
Stage 2	160–179/100–109	→ Stage 2
Stage 3	≥180/110	

DBP, diastolic blood pressure; JNC, Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; SBP, systolic blood pressure

Section 4: CMV drivers with supraventricular tachycardias

The MEP recommends several changes to the guideline statements in Section 4.

1. The MEP recommends that the current ambiguity associated with "lone atrial fibrillation" be resolved by making it clear that the diagnosis refers to individuals with atrial fibrillation with no identifiable underlying disease. This is usually diagnosed in younger persons.

2. The MEP recommends that FMCSA provide details of how risk for stroke from embolization among individuals with atrial fibrillation should be determined. The panel recommends that the most appropriate risk stratification model currently available is $CHADS_2$ (Cardiac Failure, Hypertension, Age, Diabetes, Stroke and transient ischemic attack (TIA). The $CHADS_2$ risk index is based on a point system in which two points are assigned for a history of stroke or TIA and 1 point each is assigned for age over 75 years, a history of hypertension, diabetes, or recent heart failure (HF) (Table 3).

Table 3. Stroke risk in patients with non-valvular atrial fibrillation (AF) not treated with anticoagulation according to the CHADS2 Index

$CHADS_2$ Risk Criteria	Score
Prior stroke or TIA	2
Age >75 y	1
Hypertension	1
Diabetes mellitus	1
Heart failure	1

Patients (N=1733)	Adjusted Stroke Rate (%/y)* (95% CI)	$CHADS_2$ Score
120	1.9 (1.2 to 3.0)	0
463	2.8 (2.0 to 3.8)	1
523	4.0 (3.1 to 5.1)	2
337	5.9 (4.6 to 7.3)	3
220	8.5 (6.3 to 11.1)	4
65	12.5 (8.2 to 17.5)	5
5	18.2 (10.5 to 27.4)	6

* The adjusted stroke rate was derived from multivariate analysis assuming no aspirin usage.
AF=atrial fibrillation; CHADS2= Cardiac Failure, Hypertension, Age, Diabetes, and Stroke (Doubled); CI=confidence interval; TIA= transient ischemic attack.

Supporting citations:

- *van Walraven WC, Hart RG, Wells GA, et al. A clinical prediction rule to identify patients with atrial fibrillation and a low risk for stroke while taking aspirin. Arch Intern Med 2003;163:936–43*
- *Gage BF, Waterman AD, Shannon W, et al. Validation of clinical classification schemes for predicting stroke: results from the National Registry of Atrial Fibrillation. JAMA 2001;285:2864–70 (426).*
- *ACC/AHA/ESC. 2006 Guidelines for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines. See http://www.acc.org/qualityandscience/clinical/guidelines/atrial_fib/pdfs/AF_Full_Text.pdf.*

3. FMCSA requested clarification of the relative role of aspirin and vitamin K inhibitors in reducing stroke risk in individuals with atrial fibrillation. The MEP referred FMCSA to the current ACC/AHA/European Society of Cardiology (ESC) guidelines for appropriate antithrombotic treatment of individuals with atrial fibrillation (Table 4). The MEP noted that the current FMCSA guideline for the certification of individuals with atrial fibrillation is applicable to individuals undergoing antithrombotic therapy who have at least one moderate-risk factor for stroke, any high-risk factor for stroke, or more than one moderate-risk factor for stroke.

Table 4. Recommendations for antithrombotic therapy from 2006 ACC/AHA/ESC guidelines

Risk Category		Recommended Therapy
No risk factors		Aspirin, 81 to 325 mg daily
One moderate-risk factor		Aspirin, 81 to 325 mg daily, or warfarin (INR 2.0 to 3.0, target 2.5)
Any high-risk factor or more than 1 moderate-risk factor		Warfarin (INR 2.0 to 3.0, target 2.5)*
Less Validated or Weaker Risk Factors	Moderate-Risk Factors	High-Risk Factors
Female gender	Age greater than or equal to 75 y	Previous stroke, TIA or embolism
Age 65 to 74 y	Hypertension	Mitral stenosis
Coronary artery disease	Heart failure	Prosthetic heart valve*
Thyrotoxicosis	LV ejection fraction 35% or less	
	Diabetes mellitus	

4. The MEP recommends that individuals with atrial fibrillation at moderate to high risk for a stroke be recertified annually. Furthermore, the members recommend that the guidelines make it clear that in order to be recertified the individual must have his or her anticoagulation monitored by at least monthly International Normalized Ratio (INR) and demonstrate adequate rate/rhythm control.

Section 5: CMV drivers with pacemakers

The MEP recommends several changes to the guideline statements in Section 5. These recommendations, which focus on the current guideline pertaining to neurocardiogenic syncope are:

1. That the current guideline pertaining to the use of pacemakers in individuals with neurocardiogenic syncope be revised. Current guidelines state that individuals with recurrent neurocardiogenic syncope who have received a pacemaker as a treatment for the condition may be certified three months following implantation. The MEP no longer accepts a pacemaker as definitive treatment for neurocardiogenic syncope.

Justification for change: The original guideline was based on data from non-blinded randomized controlled trials that suggested that pacemakers were protective against neurocardiogenic syncope. More recent blinded studies, however, published after 2002, did not confirm that pacemakers provide protection against this form of syncope.

Supporting cites:

- *FMCSA Evidence Report— Cardiovascular Disease and Commercial Motor Vehicle Driver Safety.*

2. The MEP recommends that text be added to documentation accompanying the cardiovascular disease (CVD) guideline update that describes the appropriate evaluation of an individual who presents with syncope. The purpose of this new text will be to ensure that efforts are made to distinguish individuals with cardiogenic syncope from those with syncope from other causes.

   Supporting cites:

   - *AHA/American College of Cardiology Foundation (ACCF) Scientific Statement on the Evaluation of Syncope From the American Heart Association Councils on Clinical Cardiology, Cardiovascular Nursing, Cardiovascular Disease in the Young, and Stroke, and the Quality of Care and Outcomes Research Interdisciplinary Working Group; and the American College of Cardiology Foundation In Collaboration With the Heart Rhythm Society (J Am Coll Cardiol 2006;47:473-84).*

Section 6: CMV drivers and implantable cardioverter defibrillators

The MEP made a single recommendation on the guideline statements in Section 6.

1. The MEP recommends that the current FMCSA CVD guidelines, which preclude any individual with an implanted cardioverter defibrillator (ICD) from being certified to drive a CMV, be upheld.

   Justification: The panel acknowledged the findings of the Evidence Report, which showed that individuals with ICDs remain prone to syncope and sudden death and that some individuals will experience an ICD discharge that, if it occurs while driving, may increase the risk of a crash. However, members noted that the most compelling reason for maintaining the current guideline is that individuals who receive an ICD are considered to be at high-risk for sudden death. This is evidenced by the inclusion criteria of the many studies included in the Evidence Report and the eligibility criteria for implantation in current clinical practice guidelines. Given the safety sensitive nature of driving a CMV, such

high-risk individuals should not be considered fit to drive a CMV. Thus, recommendation that individuals with ICDs be disqualified from driving a CMV is primarily the consequence of the high risk for sudden incapacitation associated with the underlying condition for which the ICD was implanted. It may also be noted that patients receiving an ICD for primary prevention according to current guidelines are already excluded from certification regardless of the presence of an ICD since their left ventricular ejection fractions are ≤40%, a level which is exclusionary itself.

Supporting cites:

- *FMCSA Evidence Report—Cardiovascular Disease and Commercial Motor Vehicle Driver Safety.*
- *Gregoratos G, Abrams J, Epstein AE, Freedman RA, Hayes DL, Hlatky MA, Kerber RE, Naccarelli GV, Schoenfeld MH, Silka MJ, Winters SL. ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee on Pacemaker Implantation). Circulation 2002:106:2145-2161.*
- *Simpson C, Dorian P, Gupta A, Hamilton R, Hart S, Hoffmaster B, Klein G, Krahn A, Kryworuk P, Mitchell LB, Poirier P, Ross H, Sami M, Sheldon R, Stone J, Surkes J, Brennan FJ, Canadian Cardiovascular Society Consensus Conference. Assessment of the cardiac patient for fitness to drive: drive subgroup executive summary. Can J Cardiol 2004 Nov;20(13):1314-20.*
- *European Society of Cardiology, Petch MC. Driving and heart disease. Eur Heart J 1998 Aug;19(8):1165-77.*
- *European Heart Rhythm Association, Heart Rhythm Society, Zipes DP, Camm AJ, Borggrefe M, Buxton AE, Chaitman B, Fromer M, Gregoratos G, Klein G, Moss AJ, Myerburg RJ, Priori SG, Quinones MA, Roden DM, Silka MJ, Tracy C, Smith SC Jr, Jacobs AK, Adams CD, Antman EM, Anderson JL, Hunt SA, Halperin JL. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). J Am Coll Cardiol 2006 Sep 5;48(5):e247-346.*

- *National Institute for Clinical Excellence. Guidance on the use of implantable cardioverter defibrillators for arrhythmias. London: National Institute for Clinical Excellence; 2000 Sep 1. 15 p. (Technology Appraisal Guidance; no. 11). Also available: http://www.nice.org.uk.*

- *National Institute for Health and Clinical Excellence (NICE). Implantable cardioverter defibrillators for arrhythmias. Review of Technology Appraisal 11. London: National Institute for Health and Clinical Excellence (NICE); 2006 Jan 1. 33 p. (Technology Appraisal; no. 95). Also available: http://www.nice.org.uk/TA095.*

- *Hunt SA, Abraham WT, Chin MH, Feldman AM, Francis GS, Ganiats TG, Jessup M, Konstam MA, Mancini DM, Michl K, Oates JA, Rahko PS, Silver MA, Stevensen LW, Yancy CW. ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to update the 2001 guidelines for the evaluation and management of heart failure). Bethesda (MD): American College of Cardiology Foundation (ACCF); 2005 Aug. 82 p.*

Section 7: CMV drivers with abdominal or thoracic aortic aneurysms

The MEP made several recommendations for changes to the guideline statements in Section 7.

1. The MEP recommends that the upper limit for the abdominal aortic aneurysm (AAA) diameter below which an asymptomatic individual may be certified to drive a CMV be increased to 5.5 cm for men and that an upper limit of 5.0 cm be set for women.

   Justification: The MEP based its recommendation on data from several sources that demonstrate that the risk for AAA rupture is low until the diameter of the aneurysm exceeds 5.5 cm (5.0 cm in women). The current indication for surgery is 5.5 cm. FMCSA does not wish to have a driver have surgery before medically indicated. The panel recommends that the size of the aneurysm that is disqualifying is the size at which surgery is recommended. The panel also pointed out that evidence suggests that rapid expansion of an aneurysm (>1 cm per year) is also considered a significant risk factor for rupture and is often used as an indication for surgery.

   Supporting cites:

   - *FMCSA Evidence Report— Cardiovascular Disease and Commercial Motor Vehicle Driver Safety.*

- *Mark A. Creager, Daniel W. Jones, J. Donald Easton, Jonathan L. Halperin, Alan T. Hirsch, Alan H. Matsumoto, Patrick T. O'Gara, Robert D. Safian, Gary L. Schwartz, and John A. Spittell Atherosclerotic Vascular Disease Conference: Writing Group V: Medical Decision Making and Therapy. Circulation 2004; 109: 2634-2642.*
- *Brewster DC, Cronenwett JL, Hallett JW Jr, Johnston KW, Krupski WC, Matsumura JS. Guidelines for the treatment of abdominal aortic aneurysms. Report of a subcommittee of the Joint Council of the American Association for Vascular Surgery and Society for Vascular Surgery. J Vasc Surg 2003 May;37(5):1106-17.*
- *Johnston KW. Multicenter prospective study of nonruptured abdominal aortic aneurysm. Part II. Variables predicting morbidity and mortality. J Vasc Surg 1989 Mar;9(3):437-47.*
- *Lederle FA, Wilson SE, Johnson GR, Reinke DB, Littooy FN, Acher CW, Ballard DJ, Messina LM, Gordon IL, Chute EP, Krupski WC, Busuttil SJ, Barone GW, Sparks S, Graham LM, Rapp JH, Makaroun MS, Moneta GL. Immediate repair compared with surveillance of small abdominal aortic aneurysms. N Engl J Med 2002 May 9;346(19):1437-44.*
- *Long-term outcomes of immediate repair compared with surveillance of small abdominal aortic aneurysms. N Engl J Med 2002 May 9;346(19):1445-52.*
- *UK Small Aneurysm Trial Participants. Mortality results for randomized controlled trial of early elective surgery or ultrasonographic surveillance for small abdominal aortic aneurysms. Lancet 1998 Nov 21;352(9141):1649-55.*
- *Brown LC, Powell JT. Risk factors for aneurysm rupture in patients kept under ultrasound surveillance. UK Small Aneurysm Trial Participants. Ann Surg 1999 Sep;230(3):289-96; discussion 296-7.*

2. The MEP recommends that FMCSA make changes to some of the wording of the current guidelines on certification of individuals with AAAs. The recommended changes are presented below.

    a. Individuals with an AAA 4.0 to 5.4 cm in diameter can be certified if they are asymptomatic AND they are cleared by a vascular specialist. (The word *AND* is not included in the current guidelines.)

    b. Individuals with an AAA 4.0 to 5.4 cm in diameter cannot be certified if they are either symptomatic OR a vascular specialist has recommended

that they undergo surgery. (The word *OR* is not included in the current guidelines.)

3. The MEP recommends that FMCSA add guidance to the current guideline on certification of individuals who have undergone endovascular AAA repair (EVAR). It recommends that text be added to the current guideline that ensures that recertification of individuals who have undergone EVAR comply with the follow-up protocol required following such an intervention. Compliance with the follow-up protocol is necessary following EVAR because the implanted stent may become dislodged. This in turn may result in endovascular leak that, in some cases, can result in aneurysm rupture.

   Supporting cites:

   - *ECRI. Endovascular grafts for prophylactic abdominal aortic aneurysm repair [technology assessment report]. Plymouth Meeting (PA): ECRI Health Technology Assessment Information Service; 2004 Mar. 278 p.*
   - *Endovascular repair compared with open surgical repair of AAA: Canadian practice and systematic review. Ottawa (ON): Canadian Coordinating Office for Health Technology Assessment; 2002 Dec. 63 p. (Technology report; no. 33).*

4. The MEP recommends that the upper limit for the thoracic aortic aneurysm (TAA) diameter below which an asymptomatic individual may be certified to drive a CMV be increased from 3.0 cm to 5.0 cm.

   Justification: The MEP based its recommendation on data from several sources that demonstrate that the risk for TAA rupture is low until the diameter of the aneurysm exceeds 5.0 cm, at which time elective surgery is recommended. The panel also points out that evidence suggests that rapid expansion of an aneurysm (>0.5 cm per year) is also considered a significant risk factor for rupture and is often used as an indication for surgery.

   Supporting cites:

   - *FMCSA Evidence Report—Cardiovascular Disease and Commercial Motor Vehicle Driver Safety.*
   - *Mark A. Creager, Daniel W. Jones, J. Donald Easton, Jonathan L. Halperin, Alan T. Hirsch, Alan H. Matsumoto, Patrick T. O'Gara, Robert D. Safian, Gary L. Schwartz, and John A. Spittell Atherosclerotic Vascular Disease Conference: Writing Group V: Medical Decision Making and Therapy. Circulation 2004; 109: 2634-2642.*

Section 8: CMV drivers with peripheral vascular disease

The MEP has a single recommendation for the guidelines in Section 8.

1. The current guidelines for certification of individuals with intermittent claudication state that an individual who is symptomatic should not be certified to drive a CMV. The MEP recommends that this be changed to disqualification from driving a CMV when pain occurs at rest.

   Justification: By definition, claudication is pain that comes with walking beyond what the diminished blood flow from a (partially) blocked artery can provide. Thus, the mere presence of claudication does not in of itself mean that an individual should be considered unfit to drive a CMV. Individuals who experience claudication at rest, however, will have severely limited mobility and thus they should not be considered medically fit to drive a CMV.

Section 9: CMV drivers with venous disease

The MEP recommends that the existing CVD guideline for certification of individuals with deep vein thrombosis (DVT) be updated to include the following:

1. Active DVT should disqualify an individual from driving a CMV.
2. Individuals who have experienced DVT that has resolved should be maintained on anticoagulation with a Vitamin k antagonist for a minimum of three months (preferably 6 months) following resolution.
3. If on a Vitamin K antagonist such as warfarin (Coumadin), drivers need to be regulated for at least 1 month prior to certification (or recertification) and have their INR monitored at least monthly thereafter.
4. INR should be maintained within the target range: 2.0–3.0.
5. Individuals treated with subcutaneous heparin or low molecular weight heparin may be certified (or recertified) to drive a CMV as soon as the DVT has resolved.

Supporting cites:

- *Vincenza Snow, MD; Amir Qaseem, MD, PhD, MHA; Patricia Barry, MD, MPH; E. Rodney Hornbake, MD; Jonathan E. Rodnick, MD; Timothy Tobolic, MD; Belinda Ireland, MD, MS; Jodi B. Segal, MD; Eric B. Bass, MD, MPH; Kevin B. Weiss, MD, MPH; Lee Green, MD, MPH; Douglas K. Owens, MD, MS; and the Joint American College of Physicians/American Academy of Family Physicians Panel on Deep Venous Thrombosis/Pulmonary Embolism. Management of thromboembolism: A*

clinical practice guideline from the American College of Physicians and the American Academy of Family Physicians. Ann Intern Medicine 2007;146:204-210.

- *Jodi B. Segal, MD, MPH; Michael B. Streiff, MD; Lawrence V. Hofmann, MD; Katherine Thornton, MD; and Eric B. Bass, MD, MPH Management of Venous Thromboembolism: A Systematic Review for a Practice Guideline. Ann Intern Med. 2007;146:211-222.*
- *Hirsh J, Hoak J. Management of deep vein thrombosis and pulmonary embolism: a statement for healthcare professionals. Circulation 1996; 93:2212–2245.*
- *Goldhaber SJ Medical Progress. Pulmonary Embolism. N Engl J Med 1998;339:93-104.*

Section 10: CMV drivers with cardiomyopathy

The MEP recommends several changes to the guideline statements in Section 10.

1. Since the development of the CVD guidelines published in 2002, changes have occurred in the classification of the cardiomyopathies (see Maron et al.). Consequently, the MEP recommends that the current guidelines for cardiomyopathies be updated to reflect this.

   Supporting cites:

   - *Maron BJ, Towbin JA, Thiene G, Antzelevitch C, Corrado D, Arnet D, Moss AJ, Seidman CE, Young JB. Contemporary definitions and classification of the cardiomyopathies: an American Heart Association scientific statement from the Council on Clinical Cardiology, Heart Failure and Transplantation Committee; Quality of Care and Outcomes Research and Functional Genomics and Translational Biology Interdisciplinary Working Groups; and Council on Epidemiology and Prevention. Circulation. 2006;113:1807–1816.*

2. The current guidelines state that an individual with hypertrophic cardiomyopathy should not be certified to drive a CMV. The MEP recommends that the guideline be changed to reflect the fact that not all individuals with hypertrophic cardiomyopathy are at risk for sudden incapacitation or death. Specifically the panel recommends that individuals who meet all the following criteria are at low risk and may be certified to drive:

   - No history of cardiac arrest
   - No spontaneous sustained VT
   - Normal exercise BP (e.g., no decrease at maximal exercise)

- No non-sustained VT
- No family history of premature sudden death
- No syncope
- Left ventricular (LV) septum thickness <30mm

The MEP noted that low-risk individuals must be followed closely for changes in risk status.

Justification: Major risk factors for sudden death in individuals with hypertrophic cardiomyopathy have been identified that predict the likelihood of sudden death (Table 5).

Table 5. Risk Factors for Sudden Cardiac Death in Hypertrophic Cardiomyopathy

Major Risk Factors	Possible in Individual Patients
Cardiac arrest (VF)	AF
Spontaneous sustained VT	Myocardial ischemia
Family history of premature sudden death	LV outflow obstruction
Unexplained syncope	High-risk mutation
LV thickness greater than or equal to 30 mm	Intense (competitive)
Abnormal exercise BP	physical exertion
Non-sustained spontaneous VT	

From: ACC/AHA/ESC 2006 Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death

AF=atrial fibrillation; BP=blood pressure; LV=left ventricular; VF=ventricular fibrillation; VT=ventricular tachycardia.

Supporting cites:

- *FMCSA Evidence Report—Cardiovascular Disease and Commercial Motor Vehicle Driver Safety.*
- *European Heart Rhythm Association, Heart Rhythm Society, Zipes DP, Camm AJ, Borggrefe M, Buxton AE, Chaitman B, Fromer M, Gregoratos G, Klein G, Moss AJ, Myerburg RJ, Priori SG, Quinones MA, Roden DM, Silka MJ, Tracy C, Smith SC Jr, Jacobs AK, Adams CD, Antman EM, Anderson JL, Hunt SA, Halperin JL. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). J Am Coll Cardiol 2006 Sep 5;48(5):e247-346.*

- *McKenna WJ, Behr ER. Hypertrophic cardiomyopathy: management, risk stratification, and prevention of sudden death. Heart 2002;87: 169–76.*

3. The MEP recommends changes to the text explaining the criteria that defines who should not be certified to drive a CMV, relative to those individuals with idiopathic dilated cardiomyopathy who do not have symptomatic HF. The current guidelines state that individuals with ventricular arrhythmia who present an LVEF<50% be precluded from certification. The MEP recommends that these criteria be changed to the following:

   - Sustained ventricular arrhythmia for 30 seconds or more OR requiring intervention
   - LVEF ≤40%

   Justification: This change is consistent with the latest definition of high-risk dilated cardiomyopathy from American College of Cardiology and American Heart Association.

   Supporting cites:

   - *Zipes DP, Camm AJ, Borggrefe M, Buxton AE, Chaitman B, Fromer M, Gregoratos G, Klein G, Moss AJ, Myerburg RJ, Priori SG, Quinones MA, Roden DM, Silka MJ, Tracy C. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death—executive summary: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). Circulation. 2006;114:*
   - *Owan T. E., Hodge D. O., Herges R. M., Jacobsen S. J., Roger V. L., Redfield M. M. Trends in prevalence and outcome of heart failure with preserved ejection fraction. N Engl J Medicine 2006;355:251-259.*

APPENDIX A: 2002 CV Guidelines for Medical Examiners

Section 1: Drivers without Known Cardiovascular Disease

Diagnosis	Physiologic/functional	Certification	Recertification
Asymptomatic, healthy	Low CHD event risk. Assess for clinically apparent risk factors. Use, when possible, Framingham risk score model to predict 10- year CHD event risk; increasing age is a surrogate marker for increasing atherosclerotic plaque burden.	Yes, if asymptomatic. Rarely disqualifying alone.	Biennial
Asymptomatic, high-risk person (as designated by CHD risk-equivalent condition)* Asymptomatic, high-risk person >45 years with multiple risk factors for CHD	Sub-clinical coronary atherosclerosis is a concern; High-risk status requires close physician follow-up and aggressive comprehensive risk factor management.	Yes, if asymptomatic. No if: • Abnormal ETT.† • Ischemic changes on ECG.‡ • Functional incapacitation by one of conditions.	Annual

*CHD risk-equivalent is defined as presence of diabetes mellitus, peripheral vascular disease or Framingham risk score predicting a 20% CHD event risk over the next 10 years.

†Abnormal ETT is defined by: an inability to exceed 6 METS through Stage II or six minutes on standard Bruce Protocol; presence of ischemic symptoms and/or signs (e.g. characteristic angina pain or 1 mm or greater ST depression or elevation in 2 or more leads); inappropriate systolic blood pressure (SBP) and/or heart rate response (e.g. inability of heart rate to meet or exceed 85% of age-predicted maximal heart rate unless on beta blocker); a rise in SBP ≥20 mmHg; or ventricular dysrhythmia.

‡Ischemic changes on ECG are defined by the presence of new 1 mm or more ST-segment elevation or depression and/or marked T-wave abnormality

SECTION 2: CMV Drivers with Known CHD

Diagnosis	Physiologic/functional	Certification	Recertification
Post myocardial infarction (MI)	Risk of recurrent major cardiac event highest within the first months post-MI; Drivers in a rehabilitation program can receive comprehensive secondary prevention therapy.	No if: Recurrent angina symptoms: • Post-MI ejection fraction <40% (by echocardiogram or ventriculogram),† • Abnormal ETT demonstrated prior to planned work return, • Ischemic changes on rest ECG, • Poor tolerance to current cardiovascular medications.	Not applicable
		Yes if: • At least 2 months post-MI, • Cleared by cardiologist, • No angina, • Post-MI ejection fraction >40% (by echocardiogram or ventriculogram),† • Tolerance to current cardiovascular medications.	Annual Biennial ETT at minimum (If test positive or inconclusive, imaging stress test may be indicated). Cardiologist examination recommended.

Diagnosis	Physiologic/functional	Certification	Recertification
Angina Pectoris	Lower end of spectrum among CHD patients for risk of adverse clinical outcomes. Condition usually implies at least one coronary artery has hemodynamically significant narrowing.	Yes, if asymptomatic	Annual Biennial ETT at minimum. (If test positive or inconclusive, imaging stress test may be indicated). Cardiologist examination recommended.
		No if: • Rest angina or change in angina pattern within 3 months of examination; • Abnormal ETT; • Ischemic changes on rest ECG; • Intolerance to cardiovascular therapy.	Not applicable
Post PCI	Rapid recovery for elective PCIs for stable angina; delayed re-stenosis is the major PCI limitation and requires intensive secondary prevention.	Yes if: • At least 1 week after procedure: • Cardiologist approves, • Patient tolerates medications, • ETT 3 to 6 months after PCI.	Annual Recommend cardiologist examination. Biennial ETT at minimum. (If test positive or inconclusive, imaging stress test may be indicated.)
		No if: • Incomplete healing or complication at vascular access site, • Rest angina, • Ischemic ECG changes.	Not applicable
Post Coronary Artery Bypass Surgery (CABG)	Delay in return to work to allow sternal incision healing. Because of increasing risk of graft closure over time, ETT is obtained.	Yes if: • At least 3 months after CABG, • LVEF >40% post CABG, • Approval by cardiologist, • Asymptomatic and tolerant to medications.	Annual After 5 years: annual ETT. Imaging stress test may be indicated.

*Some aspects of guidelines in this section are addressed by a Key Question in FMCSA's Evidence Report, "Cardiovascular Disease and CMV Driver Safety."

†Addressed by Key Question 5 and 6 of Evidence Report: What is the risk for sudden death or incapacitation in individuals with low LVEF? Is the relationship between LVEF and sudden death or incapacitation (if established) dependent on the underlying etiology of heart failure?

SECTION 3: CMV Drivers with Hypertension

Diagnosis	Physiologic/functional	Certification	Recertification
Essential Hypertension	Evaluate for other clinical CVD including target organ damage (TOD) Presence of TOD, CVD, or diabetes may affect therapy selected.		
Stage 1 (140-159/90-99 mmHg)	Usually asymptomatic. Low risk for near-term incapacitating event.	Yes Rarely disqualifying alone.	Annual BP ≤140/90 at annual exam; If not, but <160/100, certification extended 1 time for 3 months.
Stage 2 (160-179/100-109 mmHg)	Low risk for incapacitating event; risk increased in presence of TOD. Indication for pharmacologic therapy.	Yes, one-time certification for 3 months.	
		Yes, at recheck if: BP ≤140/90mmHg. Certify for 1 year from date of initial exam.	Annual BP ≤140/90.

Diagnosis	Physiologic/functional	Certification	Recertification
Stage 3 (>180/110 mmHg)	High risk for acute hypertension-related event.	No, immediately disqualifying	
		Yes, at recheck if: • BP ≤140/90 mm/Hg and treatment is well tolerated. • Certify for 6 months from date of initial exam.	Every 6 months BP ≤140/90
Secondary Hypertension	Evaluation warranted if persistently hypertensive on maximal or near-maximal doses of 2-3 pharmacologic agents. May be amenable to surgical/specific therapy.	Based on above stages. Yes if: • Stage 1 or non-hypertensive. • At least 3 months after surgical correction.	Annual BP ≤140/90

SECTION 4: CMV Drivers with Supraventricular Tachycardias

Diagnosis	Physiology/ Functional	Certification	Recertification
Lone Atrial Fibrillation	Good prognosis and low risk for stroke.	Yes	Annual
Atrial Fibrillation as cause of or a risk for stroke	Risk for stroke decreased by anticoagulation.	Yes if: • Anticoagulated adequately for at least 1 month, • Anticoagulation monitored by at least monthly INR, • Rate/rhythm control deemed adequate (recommend assessment by cardiologist).	Annual
Atrial fibrillation following thoracic surgery	Good prognosis and duration usually limited.	In atrial fibrillation at return to work; • Yes if: • Anticoagulated adequately for at least 1 month, • Anticoagulation monitored by at least monthly INR, • Rate/rhythm control deemed adequate (recommend assessment by cardiologist).	Annual
Atrial flutter	Same as for atrial fibrillation.	Same as for atrial fibrillation. Yes if: • Isthmus ablation performed and • At least 1 month after procedure, • Arrhythmia successfully treated, • Cleared by electrophysiologist.	Same as for atrial fibrillation. Annual
Multifocal Atrial Tachycardia	Often associated with comorbidities, such as lung disease, that may impair prognosis.	Yes, if asymptomatic (unless associated condition is disqualifying)	Annual
		No, if symptomatic.	Not applicable
		Yes, if symptoms controlled and secondary cause is not exclusionary.	Annual
Atrioventricular Nodal Reentrant Tachycardia (AVNRT) Atrioventricular Reentrant Tachycardia (AVRT) and Wolff-Parkinson-White (WPW) Syndrome Atrial Tachycardia Junctional Tachycardia	Prognosis generally excellent, but may rarely have syncope or symptoms of cerebral hypoperfusion. For those with WPW, preexcitation presents risk for death or syncope if atrial fibrillation develops.	No if symptomatic, or WPW with atrial fibrillation.	Not applicable
		Yes if: • Asymptomatic, • Treated and asymptomatic for at least 1 month and assessed and cleared by expert in cardiac arrhythmias.	Annual Recommend consultation with cardiologist.

*SECTION 5: CMV Drivers with Pacemakers**

Diagnosis	Physiology/ Functional	Certification	Recertification
Sinus node dysfunction	Variable long-term prognosis depending on underlying disease, but cerebral hypoperfusion corrected by support of heart rate by pacemaker.	No	Not applicable
		Yes if: • 1 month after pacemaker implantation; documented correct function by pacemaker center. • Underlying disease is not disqualifying.	Annual Documented pacemaker checks.
Atrioventricular (AV) block	Variable long-term prognosis depending on underlying disease, but cerebral hypoperfusion corrected by support of heart rate by pacemaker.	No	Not applicable
		Yes if: • 1 month after pacemaker implantation and documented correct function by pacemaker center. • Underlying disease is not disqualifying.	Annual Documented pacemaker checks.
Neurocardiogenic syncope†	Excellent long-term survival prognosis but risk for syncope may be caused by cardioinhibitory (slowing heart rate) or vasodepressor (drop in blood pressure) components, or both. Pacemaker will affect only cardioinhibitory component, but will lessen effect of vasodepressor component.	No, with symptoms.	Not applicable
		Yes if: • 3 months after pacemaker implantation. • Documented correct function by pacemaker center. • Absence of symptom recurrence.	Annual Documented pacemaker checks. Absence of symptom recurrence.
Hypersensitive carotid sinus with syncope	Excellent long-term survival prognosis but risk for syncope may be caused by cardioinhibitory (slowing heart rate) or vasodepressor (drop in blood pressure) components, or both. Pacemaker will affect only cardioinhibitory component, but will lessen effect of vasodepressor component.	No, with symptoms.	Not applicable
		Yes if: • 3 months* after pacemaker implantation; documented correct function by pacemaker center; • Absence of symptom recurrence.	Annual Documented regular pacemaker checks. Absence of symptom recurrence.

*Some aspects of guidelines in this section are addressed by a Key Question in FMCSA's Evidence Report, "Cardiovascular Disease and CMV Driver Safety."

†Addressed by Key Question 3 of Evidence Report: Is implantation of a pacemaker effective in preventing vasovagal syncope recurrence?

*SECTION 6: Implantable Cardioverter Defibrillators**

Diagnosis	Physiology/ Functional	Certification	Recertification
Implantable Defibrillators (primary prevention)†	Patient has high risk for death and sudden incapacitation.	No	Not applicable
Implantable Defibrillators (secondary prevention)†	Patient demonstrated to have high risk for death and sudden incapacitation.	No	Not applicable

*Some aspects of guidelines in this section are addressed by a Key Question in FMCSA's Evidence Report Titled, "Cardiovascular Disease and CMV Driver Safety."

†Addressed by Key Question 4 of Evidence Report: What is the risk of sudden incapacitation or sudden death following implantation of an implantable cardioverter defibrillator (ICD)?

*SECTION 7: CMV Drivers with Abdominal or Thoracic Aortic Aneurysms**

Diagnosis	Physiology/ Functional	Certification	Re-certification
Abdominal Aortic Aneurysm†	Evaluate for associated cardiovascular diseases		
	Aneurysm <4.0 cm	Yes, if asymptomatic	Annual
	Aneurysm 4.0 to <5.0 cm	Yes if: • Asymptomatic • Cleared by vascular specialist	Annual Ultrasound to identify change in size
		No, if: • Symptomatic • Surgery recommended by vascular specialist	Not applicable
		Yes, if at least 3 months after surgical repair cleared by cardiovascular specialist	Annual
	Aneurysm ≥5.0 cm	No	Not applicable
		Yes if at least 3 months after surgical repair cleared by cardiovascular specialist	Annual
Thoracic Aneurysm†	Evaluate for associated cardiovascular diseases	No, if >3.5cm	Not applicable
		Yes, if at least 3 months after surgical repair cleared by cardiovascular specialist	Annual

*Some aspects of guidelines in this section are addressed by a Key Question in FMCSA's Evidence Report, "Cardiovascular Disease and CMV Driver Safety."

†Addressed by Key Question 2 of Evidence Report: What are the risk factors for rupture of an aortic (abdominal or thoracic) aneurysm?

SECTION 8: CMV Drivers with Peripheral Vascular Disease

Diagnosis	Physiology/ Functional	Certification	Recertification
Peripheral Vascular Disease	Evaluate for associated cardiovascular diseases	Yes, if no other disqualifying cardiovascular condition met.	Annual
Intermittent Claudication	Most common presenting manifestation of occlusive arterial disease	Yes, if: • At least 3 months after surgery • Relief of symptoms • No other disqualifying cardiovascular disease met	Annual
	Pain at rest	No, if symptoms	Not applicable
		Yes, if: • At least 3 months after surgery • Relief of symptoms and signs • No other disqualifying cardiovascular disease met	Annual

SECTION 9: CMV Drivers with Venous Disease

Diagnosis	Physiology/ Functional	Certification	Re-certification
Acute Deep Vein Thrombosis (DVT)		No, if symptoms	Not applicable
		Yes if: • No residual acute deep venous	Annual

Diagnosis	Physiology/ Functional	Certification	Re-certification
		thrombosis • If on Coumadin, regulated for at least 1 month • INR monitored at least monthly	
Superficial phlebitis		Yes if: • DVT ruled out • No other disqualifying cardiovascular disease.	Biennial
Pulmonary Embolus		No, if symptoms	Not applicable
		Yes if: • No pulmonary embolism for at least 3 months • On appropriate long-term treatment • If on Coumadin, regulated for at least 1 month; INR monitored at least monthly • No other disqualifying cardiovascular disease	Annual
Chronic Thrombotic Venous Disease		Yes, if no symptoms	Biennial
Varicose veins		Yes, if no complications	Biennial
Coumadin	Use of INR required.	Yes if: • Stabilized for 1 month • INR monitored at least monthly	Annual

*SECTION 10: CMV Drivers with Cardiomyopathy**

Diagnosis	Physiology/ Functional	Certification	Re-certification
Hypertrophic Cardiomyopathy†		No	Not applicable
Idiopathic Dilated Cardiomyopathy and Congestive Heart Failure (CHF)†		No, if symptomatic CHF	Not applicable
		No, if: • Asymptomatic • Ventricular arrhythmias present and • LVEF ≤50%	Not applicable
		No if: • Asymptomatic • No ventricular arrhythmias but LVEF <40%	Not applicable
		Yes if: • Asymptomatic • No ventricular arrhythmias • LVEF 40% to 50%	Annual Requires annual cardiology evaluation including Echocardiography and Holter monitoring.
Restrictive cardiomyopathy		No	Not applicable

*Some aspects of guidelines in this section are addressed by a Key Question in FMCSA's Evidence Report, "Cardiovascular Disease and CMV Driver Safety."

†Addressed by Key Question 5 and 6 of Evidence Report: "What is the risk for sudden death or incapacitation in individuals with low left ventricular ejection fraction (LVEF) (<50%, <40%, <35%)?" and "Is the relationship between LVEF and sudden death or incapacitation (if established) dependent on the underlying etiology of heart failure?"

APPENDIX B: Findings of Evidence Report

Purpose of Evidence Report

The purpose of the evidence report is to address several Key Questions FMCSA posed. FMCSA developed each of these Key Questions so that the answers would provide information useful in updating its current medical examination guidelines, "Cardiovascular Advisory Panel Guidelines for the Medical Examination of Commercial Motor Vehicle Drivers."(1) The six Key Questions addressed in this evidence report are:

Key Question 1: Are individuals with cardiovascular disease at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have the disorder?

Key Question 2: What are the risk factors for rupture of an aortic (abdominal or thoracic) aneurysm?

Key Question 3: Is implantation of a pacemaker effective in preventing vasovagal syncope recurrence?

Key Question 4: What is the risk of sudden incapacitation or sudden death following implantation of an ICD?

Key Question 5: What is the risk for sudden death or incapacitation in individuals with low LVEF (<50%, <40%, <35%)?

Key Question 6: Is the relationship between LVEF and sudden death or incapacitation (if established) dependent on the underlying etiology of heart failure?

Identification of Evidence Bases

The research team identified separate evidence bases for each of the Key Questions addressed by this evidence report by a comprehensive search of the literature and examination of abstracts of identified studies to determine which articles to retrieve, and selecting 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 November 28, 2006). In addition, we examined the reference lists of all obtained articles with the aim of identifying relevant articles not found in our electronic searches. We also performed hand searches of the "gray literature." We determined whether to admit an article into an evidence base by using formal retrieval and inclusion criteria that were determined *a priori.*

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 6.

Table 6. 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 recommends regular monitoring of 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 the 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.
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 in 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

Key Question 1: Are individuals with cardiovascular disease[1] at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have the disorder?

A number of conclusions can be drawn from the findings of the analyses of the evidence pertaining to Key Question 1. These conclusions are presented below.

Drivers of CMVs

1. **A paucity of data from studies that enrolled CMV drivers with CVD precludes one from determining whether CMV drivers with the disorder are at an increased risk for a crash.**

[1] With an emphasis on crash risk associated with myocardial infarction, angina pectoris, coronary insufficiency, and thrombosis.

Two studies presented data directly relevant to the question of whether CVD has an impact on CMV driver safety.[#445360][#438769] Medgyesi et al.[#445360] (Quality Rating: Low) presented crash data for drivers with Class 1 through 4 licenses (comparable to U.S. CMV drivers) separately from Class 5 license holders (private motor vehicle drivers). However, we were precluded from calculating an estimate of the risk ratio for this study because crash data for the controls with Class 1 though Class 4 licenses were not presented; only crash data for the entire control group (Class 1 through Class 5) were presented and this group was dominated by Class 4 license holders. Thus, useful evidence on the relationship between CVD and crash risk among CMV drivers is limited to the findings of just one study.

Dionne et al.[#438769] estimated the effects of different medical conditions on truck driver crash risk using data from a nested case-control study (Quality Rating: Moderate). These investigators did not find evidence supporting the contention that CMV drivers with CVD are at an increased risk for a crash. While these results are interesting, the study is not high quality and its results have not been replicated. Consequently, an evidence-based conclusion about whether CMV drivers with CVD are at an increased risk for a motor vehicle crash is not drawn at this time.

Drivers of Non-Commercial Motor Vehicles

Because data from studies of CMV drivers with CVD are scarce, we deemed it worthwhile to examine relevant data from studies that investigated crash risk associated with CVD among more general driver populations. While the generalizability of the findings of these studies to CMV drivers may not be clear, such findings do, at the very least, allow the opportunity to draw evidence-based conclusions about the relationship between CVD and motor vehicle crash risk in general. The findings of our analyses of crash data from these studies are summarized in Table 7.

Table 7. Summary of Findings

Cardiovascular Disease	Rate Ratio (RR) studies	Strength of evidence Stability of Summary Effect Size (SES)	Odds Ratio (OR) studies	Strength of evidence Stability of SES
Any	Increased crash risk RR=1.43 (95% CI: 1.11–1.84)	Strength of Evidence: Acceptable Stability of Estimate: Low	No evidence-based conclusion	Unacceptable
Hypertension	Increased crash risk RR = NP	Strength of Evidence: Acceptable Stability of Estimate: Unstable	No evidence-based conclusion	Unacceptable
Arrhythmia	No evidence-based conclusion	Unacceptable	No evidence-based conclusion	Unacceptable
Coronary Arterial Disease (CAD)	No evidence-based conclusion	Unacceptable	No evidence-based conclusion	Unacceptable
Other	No evidence-based conclusion	Unacceptable	No evidence-based conclusion	Unacceptable

RR=rate ratio; NP=not presented; SES=summary effect size (summary estimate of RR)

The conclusions we draw from the findings summarized above are as follows:

1. **As a group, drivers with CVD are at an increased risk for a motor vehicle crash when compared with comparable drivers who do not have the disorder (Strength of Evidence: Acceptable).**
   - **The magnitude of this increased risk is small but statistically significant (RR=1.43, 95% CI: 1.11–1.84). In other words, the crash risk for an individual with cardiovascular disease is 1.43 times greater than a comparable individual who does not have the condition (Stability of Estimate: Acceptable)**

   Eight studies (Quality Rating: Low) contain data on the relative incidence of crash among individuals who have CVD (any type) and comparable individuals without the disorder. The findings of the eight studies were quantitatively consistent. Pooling the data, the crash-rate ratio associated with CVD is 1.43 (95% CI: 1.11 to 1.84). Thus, if the underlying crash risk for a CMV driver is 0.08 crashes per person-year, the average crash risk for a CMV driver with CVD will be approximately 0.11 crashes per person-year. Although a series of sensitivity analyses found this estimate to be robust, the strength of our conclusion must be tempered by the fact that the studies providing the data used to produce this estimate were of low methodological quality. In addition, the fact that the crash data used in our analyses did not pertain to CMV drivers may further limit the value of our findings, because the extent to which our findings can be generalized to this population of drivers is not known.

2. **Drivers with hypertension are at an increased risk for a motor vehicle crash when compared with comparable drivers who do not have the disorder (Strength of Evidence: Acceptable).**
   - **The magnitude of this increased risk cannot be determined at the present time**

   Two included studies (Quality Rating: Low) reported on the difference in the incidence of a motor vehicle crash observed among individuals with hypertension and comparable individuals without the disorder. Because data from only two studies are available, we have not pooled their data to obtain a summary estimate of the magnitude of this increased risk. However, the findings of both studies suggest that individuals with hypertension are at an increased risk for a motor vehicle crash when compared with individuals without the disorder.

3. **A paucity of consistent data precludes drawing evidence-based conclusions about whether individuals with CAD, arrhythmias, or other types of cardiovascular disease are at increased risk for a motor vehicle crash.**

Key Question 2: What are the risk factors for rupture of an aortic (abdominal or thoracic) aneurysm?

Specific findings of our assessment of the evidence addressing Key Question 2 are presented below:

1. **The most common risk factor for abdominal aortic aneurysm is aneurysm size (Strength of Evidence: Moderate).**
   - **Because there were a number of methodological problems involving heterogeneity of the populations studied, biases, statistical power issues, and lack of standardization in aneurysm measurement and reporting, no attempt was made to construct a quantitative model describing the risk for rupture for an aortic aneurysm or thoracic aortic aneurysm.**

   Fourteen (total n = 3,317) moderate-quality studies assessed the potential risk factors for rupture of an abdominal aneurysm. These 14 studies demonstrated that aneurysm size was the most important risk factor associated with aneurysm rupture (n = 10 studies). Other risk factors for abdominal aortic rupture identified included chronic obstructive pulmonary disease (COPD_ (n = 1 study), presence of hypertension (n = 2 studies), AAA expansion rate (n = 3 studies), smoking status (n = 1 study), aortic wall stress (n = 1 study), aortic tortuosity (n = 1 study), bronchiectasis (n = 1 study), aortic outpouching (n = 1 study) and female gender (n = 2 studies).

2. **The most important risk factor for thoracic aortic aneurysm rupture is aneurysm size (Strength of Evidence: Acceptable).**
   - **Because there were a number of methodological problems involving heterogeneity of the populations studied, biases, statistical power issues, and lack of standardization in aneurysm measurement and reporting, we did not attempt to determine a quantitative model describing the risk of rupture for an aortic aneurysm or thoracic aortic aneurysm.**

   Seven (total n = 3,908) low-quality studies assessed the potential risk factors for rupture of a thoracic aortic aneurysm. All seven studies demonstrated that aneurysm size was the most important risk factor associated with aneurysm rupture. Other risk factors identified for thoracic aortic rupture included age, presence of uncharacteristic chronic pain, and COPD.

Key Question 3: Is implantation of a pacemaker effective in preventing vasovagal syncope recurrence?

Our assessment of the evidence addressing Key Question 3 is presented below:

1. **The best available evidence does not support the contention that permanent implanted dual-chamber pacemakers are effective in reducing the recurrence of**

vasovagal syncope in individuals with high recurrence rates (Strength of Evidence: Moderate).

- **Because of inconsistencies in the findings of the studies that comprise the evidence base for Key Question 3, we refrain from providing a single estimate of treatment effect at this time.**

Five moderate- to high-quality randomized controlled trials addressed Key Question 3. Outcomes assessed by all five studies included the proportion of individuals experiencing recurrent syncope, the time to recurrence, and adverse events.

Analysis of these data found the results of the high quality (k=2) and moderate quality (k=3) studies differed significantly. All three moderate-quality studies found that permanent dual-chamber pacemakers significantly reduce the number of recurrences of vasovagal syncope when compared with standard treatment. However, neither of the two high-quality studies found evidence to support the contention that permanent dual-chamber pacemakers offer an effective treatment option for individuals with recurrent syncope. The difference in findings may be attributed to a lack of blinding in the three moderate- quality studies in a group of individuals who are known to respond strongly to placebo.

Key Question 4: What is the risk of sudden incapacitation or sudden death following implantation of an implantable cardioverter defibrillator (ICD)?

Specific findings of our assessment of the evidence addressing Key Question 4 are presented below:

1. **Whether individuals with an ICD implant experience crashes that can be directly attributed to CVD or the ICD implant itself cannot be determined at this time.**

   Four of the six included studies presented data on the number or frequency of crashes that occurred among individuals with an ICD. None of these studies compared crash rates occurring among individuals with an ICD to crash rates among individuals without CVD. Consequently, it is not possible to determine whether individuals with an ICD are at increased risk for a motor vehicle crash.

   Crashes reportedly occurred in only one of the four included studies. Eleven individuals enrolled in this study experienced at least one crash during follow-up. Of these, only one was purportedly the fault of the driver and none were the consequence of either CVD or an event associated with the implanted ICD. The fact that no crashes reportedly occurred in the remaining studies may be the combined consequence of the small size of these studies and their short follow-up times. To determine a reliable estimate of the crash rate associated with ICDs, studies with far larger sample sizes and longer follow-up times will need to be performed.

2. **Whether individuals with an ICD implant experience sudden death or incapacitation during driving cannot be determined at the present time.**

   Three of the six included studies reported on the occurrence of syncope and sudden death while an individual with an ICD was driving. None of the individuals enrolled in the three included studies above experienced syncope or sudden cardiac death while driving. Given the fact that syncope and sudden death while driving have to be considered a rare event, the fact that no cases were observed in the three included studies cannot be considered as evidence that such events will not occur while driving.

3. **Some individuals with an ICD will experience ICD discharge while they are driving (Strength of Evidence: Strong).**

   - **Quantitative assessment of the available data suggests that approximately 6.3% (95% CI: 4.7–8.4%) of individuals who drive with an ICD will experience an ICD discharge while driving (Stability of Estimate: Low).**

   Six included studies reported on the occurrence of ICD discharge during driving. Five of these six studies reported that ICD discharge occurred in some individuals while driving. Despite the fact that follow-up times varied across studies, ICD discharge data were remarkably consistent. Pooling of these data found that the number of individuals with an ICD who experience at least one shock during driving (appropriate or inappropriate) was in the order of 6.3 percent. A series of sensitivity analyses determined the findings of this analysis to be robust.

Key Question 5: What is the risk for sudden death or incapacitation in individuals with low left ventricular ejection fraction (LVEF) (<50%, <40%, <35%)?

1. **Decreasing LVEF increases the risk for sudden death or incapacitation among individuals with CVD (Strength of Evidence: Moderate).**

   - **Because no more than two studies used the same levels of LVEF stratification, no attempt was made to determine a quantitative estimate of the risk of sudden death or incapacitation in individuals with low LVEF.**

   Ten low- to moderate-quality studies assessed the risk of sudden death or incapacitation in individuals with low LVEF. Five studies used multiple levels of LVEF stratification. The remaining five used a single level of LVEF stratification. The 10 studies consistently demonstrated that decreasing LVEF increases the risk of sudden death or incapacitation in individuals with CVD. However, several studies have indicated that although LVEF is an important risk factor for sudden death or incapacitation, it is not the only risk factor, and in order to better predict sudden death or incapacitation other risk factors should be included with LVEF. For example, one study noted that rather than using particular risk markers, the use of a number of

accumulated risk markers was a more powerful predictor for sudden death in patients with chronic heart failure.

Key Question 6: Is the relationship between LVEF and sudden death or incapacitation (if established) dependent on the underlying etiology of heart failure?

1. **Owing to a paucity of data, no conclusion is drawn as to whether there is a relationship between sudden death or incapacitation and LVEF.**

   No studies met the inclusion criteria for this Key Question.