Draft Evidence Report

Musculoskeletal Disorders II, Spinal Cord Injury and Commercial Motor Vehicle Driver Safety (Comprehensive Review)

Presented to

The Federal Motor Carrier Safety Administration

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

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

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 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.

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Executive Summary

Purpose of Evidence 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 4,584 fatal crashes involving a large truck in 2007 for a total of 4,808 fatalities. In addition, there were 139,587 nonfatal crashes; 56,487 of these were crashes that resulted in an injury to at least one individual (for a total of 83,908 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 so that the answers to these questions provide information that would be useful in updating its current medical examination guidelines. The three key questions addressed in this evidence report are as follows:

Key Question 1: Do musculoskeletal disorders of the hand, wrist, elbow, or shoulder (specifically carpal tunnel syndrome, cubital tunnel syndrome, radial tunnel syndrome, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

Key Question 2: Do musculoskeletal disorders of the foot, ankle, or knee (specifically plantar fasciitis, tarsal tunnel syndrome, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

Key Question 3: Does reduced limb mobility and/or control resulting from spinal cord injury increase crash risk and/or affect driving ability?

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; an 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, TRIS, the Cochrane Library, Healthcare Standards and the National Guideline Clearinghouse) were searched (through March, 2009). In addition, we examined the reference lists of all obtained articles with the aim of identifying relevant articles not identified by our electronic searches. Hand searches of the "gray literature" were also performed. Admission of an article into an evidence base was determined by formal retrieval and inclusion criteria that were determined *a priori.*

Grading the Strength of Evidence

Our assessment of the quality of the evidence took into account not only the quality of the individual studies that comprise the evidence base for each key question; we also considered the interplay between the quality, quantity, robustness, and consistency of the overall body of evidence.

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 I^2. Sensitivity analyses, aimed at testing the robustness of our findings, included the use of cumulative random-effects meta-analysis. The presence of publication bias was tested for using the "trim and fill" method when appropriate.

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 conclusions 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 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 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: Do musculoskeletal disorders of the hand, wrist, elbow, or shoulder (specifically carpal tunnel syndrome, cubital tunnel syndrome, radial tunnel syndrome, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

There is insufficient evidence to determine whether any musculoskeletal disorders of the upper extremities assessed in this report increase crash risk and/or decrease driving performance.

Our searches did not identify any studies providing crash or driving performance data addressing Key Question 1. One excluded study reported that rates of hospital treatment for carpal tunnel syndrome and elbow bursitis among long-haul truck drivers were significantly higher than the expected rates in the general population. However, hospital treatment is insufficient to infer that these disorders affected the ability to drive safely. Another excluded study reported the percentage of urban bus drivers whose work performance was affected by discomfort in the shoulder area. However, the data presented did not specify how work performance was affected or the type of disorder and thus did not meet the inclusion criteria for this question.

Key Question 2: Do musculoskeletal disorders of the foot, ankle, or knee (specifically plantar fasciitis, tarsal tunnel syndrome, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

There is insufficient evidence to determine whether any musculoskeletal disorders of the lower extremities assessed in this report increase crash risk and/or decrease driving performance.

Our searches identified no potentially relevant articles that addressed this question. One excluded study reported that the rate of hospital treatment for kneecap bursitis among long-haul truck drivers was significantly higher than the expected rate in the general population. However, hospital treatment is insufficient to infer that these disorders affected the ability to drive safely. Another excluded study reported the percentage of urban bus drivers whose work performance was affected by discomfort in the thigh/knee area. The data presented did not specify how work performance was affected or the type of disorder and thus did not meet the inclusion criteria for this question.

Key Question 3: Does reduced limb mobility and/or control resulting from spinal cord injury increase crash risk and/or affect driving ability?

Certain individuals with spinal cord injury (SCI) appear to have adequate driving ability in specially-modified cars. Individuals with paraplegia are less likely to have limitations that decrease driving ability than individuals with tetraplegia. However, certain requirements that commercial motor vehicle (CMV) drivers must meet (e.g. inspecting and adjusting loads during a long trip) would exceed the capabilities of a lone individual with SCI (the possible exception might be a sealed vehicle that did not require inspection during a trip). Driving a specially-modified CMV with a partner might be a possible option for certain individuals with enough functional ability to perform driving tasks.

Indirect Evidence-Studies of Driving Performance

Three studies evaluated driving performance (simulated or on- road) among non-CMV driver populations with SCI. Two moderate quality studies evaluated outcomes associated with simulated driving performance. One of these studies assessed driving performance outcomes for road sections on a driving simulator. This study found that patients with thoracic or lumbar cord injuries (paraplegia) drove at significantly slower speeds than uninjured drivers in several sections of the simulated course. However, slower speed does not necessarily indicate a reduced ability to drive safely. In addition, no statistically significant between-group difference was observed for steering stability, centerline violations, traffic signal violations, and driving time. The other simulation study showed significantly slower brake reaction times and workload factors (time pressure, effort) among tetraplegic individuals compared to able-bodied individuals. Whether these statistically significant differences in simulated driving outcomes have any relationship to the ability to safely drive a motor vehicle remains uncertain. The remaining study found no statistically significant difference in driving performance measures during closed-course or open-road driving with a specially-modified car between individuals with SCI (type not reported) and able-bodied individuals. However, driving a large truck would require greater functional abilities than driving smaller vehicles. Whether the magnitude of difficulty of large truck driving would make the task impractical for individuals with SCI has not been addressed or discussed in the existing literature. The requirement to check and adjust loads during a long trip would be beyond the ability of a lone driver with SCI (the exception would be a sealed vehicle that did not require inspection during a trip). Driving a modified CMV with a partner might be a possible option to overcome this problem.

Preface

Organization of Report

This evidence report contains three major sections: (1) *Background*; (2) *Methods*; and (3) *Evidence Synthesis*. These major sections are supplemented by extensive use of appendices.

In the *Background* section, we provide general information about musculoskeletal disorders and driving. Also included in the *Background* section is information pertaining to current regulatory standards and guidelines from the FMCSA and three other government transportation safety agencies: the Federal Aviation Administration (FAA); the Federal Railroad Administration; and the Maritime Administration. In addition, we summarize equivalent information from other countries that are generally considered to have well developed medical fitness programs.

In the *Methods* section, we detail how we identified and analyzed information for this report. The section covers the key questions addressed, details of literature searching, criteria for including studies in our analyses, evaluation of study quality, assessment of the strength of the evidence base for each question, and methods for abstracting and synthesis of clinical study results.

The *Evidence Synthesis* section of this report is organized by key question. For each question, we report on the quality and quantity of the studies that provided relevant evidence. We then summarize available data extracted from included studies either qualitatively or, when the data permit, qualitatively and quantitatively (using meta-analysis). Each section in the *Evidence Synthesis* section closes with our evidence-based conclusions that are based on our assessment of the available evidence.

Scope

Commercial driving is a hazardous occupation. The trucking industry has the third highest fatality rate of all occupations (12%) in the United States (http://www.bls.gov/iif/oshcfoiarchive.htm#2004charts). About two-thirds of fatally injured truck workers were involved in highway crashes. According to the U.S. DOT, there were 139,587 nonfatal crashes involving a large truck in 2007. Of those, 56,487 crashes resulted in an injury to at least one individual, for a total of 83,908 injuries, and 4,584 of all crashes caused 4,808 fatalities (http://ai.volpe.dot.gov/CrashProfile/n_overview.asp). In 2007, the U.S. DOT *Brief Statistical Summary* reported a total of 802 motorists killed in large truck crashes, which amounted to a decrease of 0.4% compared to the statistics for 2006 (n = 805). The total number of motorists injured in large truck crashes was 23,000, which was identical to the 2006 statistics (http://www-nrd.nhtsa.dot.gov/Pubs/811017.PDF).

The purpose of this evidence report is to address several key questions posed by the FMCSA. Each of these key questions was carefully formulated by the FMCSA so that each answer will provide it with the information necessary for the process of updating its current medical examination guidelines. The key questions addressed in this evidence report are as follows:

Key Question 1: Do musculoskeletal disorders of the hand, wrist, elbow, or shoulder (specifically carpal tunnel syndrome, cubital tunnel syndrome, radial tunnel syndrome, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

Key Question 2: Do musculoskeletal disorders of the foot, ankle, or knee (specifically plantar fasciitis, tarsal tunnel syndrome, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

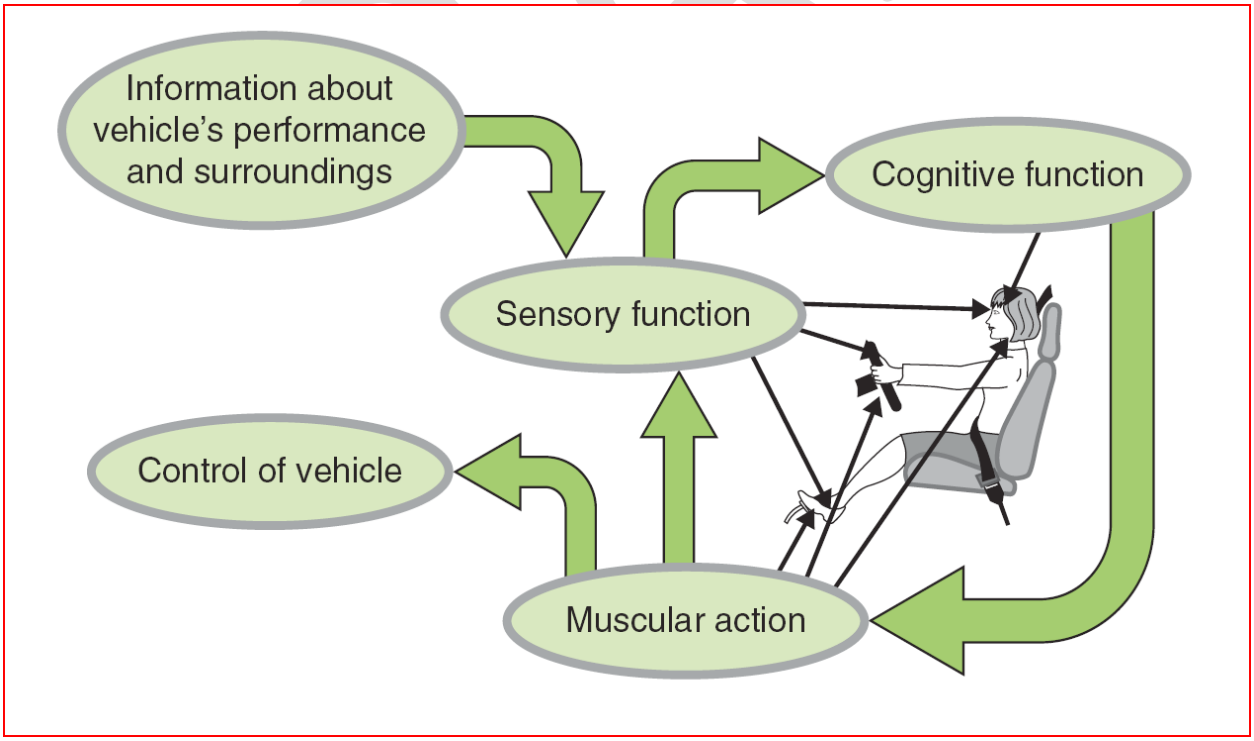
Key Question 3: Does reduced limb mobility and/or control resulting from spinal cord injury increase crash risk and/or affect driving ability?

Background

Safe driving requires the driver to be able to maintain effective and reliable control of his or her vehicle; respond to the road, traffic, and other external clues; and follow the "rules of the road." Commercial drivers consciously learn all these skills and demonstrate them as part of obtaining their commercial drivers license (CDL); the vast majority of people are able to achieve a satisfactory standard. Driving performance generally improves with experience, and driving ultimately becomes an "over-learned" skill that is subconsciously retained and can readily be used as required. Impairments caused by health problems can interfere with driving performance.

The purpose of this evidence report is to summarize the available data on the relationship between specific musculoskeletal disorders or spinal cord injury (SCI) and CMV driver performance/crash risk. Driving is a complicated psychomotor performance that depends on fine coordination between the sensory and motor systems. It is influenced by factors such as arousal, perception, learning, memory, attention, concentration, emotion, reflex speed, time estimation, auditory and visual functions, decision making, and personality. Complex feedback systems interact to produce the appropriate coordinated behavioral response (Figure 1). Anything that interferes with any of these factors to a significant degree may impair driving ability.(1) Certain musculoskeletal disorders have the potential to cause pain or limited range of motion in the limbs that might affect driving performance. Similarly, SCI may limit range of motion to a degree that impacts the ability to drive safely.

Figure 1. The Driving Task



Source: Carter, 2006 (see: http://www.dft.gov.uk/pgr/roadsafety/drs/fitnesstodrive/fitnesstodrive)

Musculoskeletal Disorders

The musculoskeletal system functions to facilitate support and motion. The system also provides the primary mechanism by which the multidirectional demands of loading—which occur as a consequence of everyday activity—can be managed. For example, the spinal column acts to support the weight of the body; the intervertebral discs of the spine act as "shock absorbers," protecting the vertebrae from the jarring motions of walking. The musculoskeletal system provides this function via a collection of tissues uniquely adapted to the requirements of these different but interrelated tasks. When these tissues are injured, the mechanical function of the system is affected, and the ability to perform a variety of activities, such as turning, bending, and lifting, may be compromised.(2)

Musculoskeletal disorders may culminate in problems in mechanical function, which can increase the potential for a reduction in driving ability and motor vehicle crash. Typical driving-related mechanical function problems associated with musculoskeletal disorders include problems in maintaining an adequate grip on the steering wheel, and difficulties with seating, reversing, and using the foot pedals. It is also important to remember that musculoskeletal conditions may not only affect the CMV operator's ability to drive; these disorders may also affect his/her ability to secure loads, or to load or unload the vehicle. Taking this into consideration, the ability to drive safely is not the only factor that needs to be considered when examining the impact of musculoskeletal disorders on CMV drivers.

Musculoskeletal disorders encompass a broad category of disorders that affect the muscles, nerves, tendons, ligaments, joints, cartilage and vertebrae, and soft tissues that surround these structures. The musculoskeletal disorders considered in the present evidence report include the following:

- Nerve compression syndromes (carpal tunnel, cubital tunnel, radial tunnel syndrome, tarsal tunnel syndrome)
- Tendonitis/tenosynovitis
- Bursitis
- Plantar fasciitis

The reader should note that the impact on driving performance of other musculoskeletal disorders (including limb amputations, arthritis, systemic lupus erythematosus, scoliosis, degenerative disc disease, and ankylosing spondylitis) was evaluated in a previous FMCSA report titled *Musculoskeletal Disorders and Commercial Motor Vehicle Driver Safety (Comprehensive Review)*.

Regardless of underlying etiology, musculoskeletal disorders generally share the same characteristic symptomology (chronic pain) and reductions in functional ability. Reductions in functional ability include limited mobility in the joints, reduced range of motion (ROM), and reduced muscular strength in the limbs. The extent of functional impairment depends on a variety of factors, including the type of musculoskeletal disorder, area(s) affected, and the severity of tissue damage.

Nerve Compression Syndromes

Nerve compression occurs when bone or connective tissue presses on a nerve; this is often the result of repetitive motion that places a strain on the affected area. Compression of nerves leads to pain and paresthesia (numbness, tingling) in the affected areas. Common nerve compression syndromes include carpal tunnel syndrome, cubital tunnel syndrome, and radial tunnel syndrome. These are sometimes referred to as nerve entrapment syndromes.(3,4)

Carpal Tunnel Syndrome

Carpal tunnel syndrome refers to compression of the medial nerve in the wrist. Acute carpal tunnel syndrome can develop following a crush injury, an upper extremity fracture, or a carpal dislocation. The more common form is chronic or idiopathic carpal tunnel syndrome, which is categorized by more gradual symptom onset and exacerbated by daily activities (driving, holding a book or phone, etc.). Such activities become more difficult due to loss of manual dexterity. In addition to pain and paresthesia in the hand, up to one third of patients experience pain and paresthesia in the forearm, elbow, shoulder, and neck.(5,6) Permanent nerve damage occurs in about 1% of cases, resulting in impaired use of the hands.(7)

Cubital Tunnel Syndrome

Cubital tunnel syndrome refers to compression of the ulnar nerve in the elbow. Symptoms usually include weakness of grip and numbness and tingling along the little finger and the ulnar half of the ring finger.(8) This results in hand clumsiness, lack of coordination, and a tendency to drop objects. Severe cases may present with atrophy of the intrinsic muscles and clawing of the fourth and fifth fingers.(9)

Radial Tunnel Syndrome

Radial tunnel syndrome refers to compression of the radial nerve in the proximal forearm. Symptoms may include weakening of extension of the thumb, fingers, or wrist; pain in the upper extensor forearm; and dysesthesia in a superficial radial nerve distribution.(4)

Tarsal Tunnel Syndrome

Tarsal tunnel syndrome refers to entrapment of the posterior tibial nerve or one of its branches. Symptoms include pain or sensory disturbance that may extend from the heel to the toes. The pain is worse during standing and walking, but may occur at rest as the disorder progresses.(10)

Tendonitis/Tenosynovitis

Tendonitis refers to inflammation of a tendon, usually characterized by pain at the site of insertions into bone.(11) Tenosynovitis is tendonitis with inflammation of the tendon sheath lining. Symptoms include pain with motion and tenderness with palpation. Chronic deterioration or inflammation can cause scars that restrict motion. Tenosynovitis can have a noninfectious (e.g., de Quervain's tenosynovitis) or infectious (e.g., gonococcal tenosynovitis) etiology. Most forms affect the hand or wrist; gonoccocal can also affect the ankle.(12,13)

Bursitis

Bursitis refers to acute or chronic inflammation of a bursa (fluid-filled cavities that occur where tendons or muscles pass over bony prominences). It can occur due to trauma, repetitive use, infection, or systemic inflammatory disease. Symptoms include pain, swelling, and tenderness. Areas commonly affected include the shoulder, elbow, knee, and foot. If inflammation persists near a joint, the joint's range of motion may be limited, possibly leading to muscle atrophy. Chronic bursitis can last for several months and recurs frequently.(14)

Plantar Fasciitis

Plantar fasciitis refers to pain at the site of attachment of the plantar fascia and the calcaneus, resulting in pain at the bottom of the heel on weight bearing. Pain tends to increase during the day with increasing activity.(15)

Risk Factors for Musculoskeletal Disorders

When considering musculoskeletal disorders, risk factors are of key importance, since interventions that may prevent or ameliorate the development and/or progression of some disorders need to take these factors into account. Risk factors include the following:

- Body mass index (BMI)
- Height
- Weight
- Obesity(16,17)
- Genetic predisposition
- Age
- Socioeconomic status (poverty)(18)
- Other medical conditions
- Lifestyle factors (i.e., diet, physical activity, smoking, excessive alcohol consumption)(19)
- Work-related factors, including posture, vibration, repetition, and force(16)

The Epidemiology of Musculoskeletal Disorders

Precise estimates of the prevalence and incidence of the musculoskeletal disorders are difficult to ascertain. This is in part because of the lack of standardization in the way that these disorders are categorized.(20) However, some estimates, while not precise, are available.

Overall Musculoskeletal Disorders

General Population

The U.S. Department of Health and Human Services statistics for the years 2003 through 2005 reported that 46.4 million adults (or 1 in 5) in the United States had a physician-diagnosed arthritic condition, with numbers projected to rise with the aging population to 67 million in 2030.(21) They also reported that musculoskeletal disorders of any cause affect approximately 7% of the total U.S. population, and account for 14% of all physician visits and 19% of all hospital stays.

In contrast to the figures presented above from the United States, a Canadian health survey found that approximately 16% of the population (or double that of the United States) reported having a musculoskeletal disorder, with 85% of the cases being present for more than 1 year. Arthritis was the most commonly reported disorder (27.2/1,000), with prevalence rates in individuals over 20 years of age estimated at 14.2%.(22,23) Similar arthritis rates were reported for Australia (15%). European estimates for musculoskeletal disease found that approximately 25% of all adults were affected by chronic musculoskeletal disease.(24) Statistics regarding musculoskeletal disorders in developing nations are more difficult to obtain. However, a study from Rwanda found population musculoskeletal disorder prevalence rates of 8.1% (95% confidence interval [CI] 5.6 to 10.6), with the highest rates among individuals aged 50 years and older (18.0% ; 95% CI: 7.0 to 290.0).(25)

CMV Drivers

A large study from Denmark reported data that allowed calculation of hospitalization rates (including inpatient, outpatient, and emergency care) due to “diseases of the musculoskeletal system and connective tissue” among 2,175 long-haul truck drivers and 15,060 other truck drivers who were followed up over a 10-year period. During the follow-up period, 20.9% of long-haul drivers and 19.6% of other truck drivers were treated in a hospital for diseases within this overall group. However, these percentages were not significantly higher than the expected rates in the general population.(26)

Estimates of incidence, prevalence, and other epidemiological information for each specific musculoskeletal disorder evaluated in this report are presented below.

Nerve Compression Syndromes

General Population

Studies of the general population reported epidemiological data separately for specific nerve compression syndromes. These studies are discussed under the headings for specific nerve compression syndromes below.

CMV Drivers

The Denmark study noted above reported data concerning hospitalization rates for "mononeuropathies of the upper limb" (which would include carpal tunnel syndrome, cubital tunnel syndrome, and other nerve compression syndromes) among long-haul and other truck drivers over a 10-year period. The hospitalization rate was 1.29% among long-haul truck drivers and 1.14% among other truck drivers. Both rates were significantly higher than the expected rates in the general population.(26)

Carpal Tunnel Syndrome

General Population

Carpal tunnel syndrome has a reported incidence of 1-3 cases per 1000 subjects per year, and a prevalence of about 50 cases per 1000 subjects in the general population.(6) The incidence is about two-fold higher in women than in men. A large population-based study in the U.K. reported that the annual age-standardized rates were 87.8 per 100,000 new presentations in men and 192.8 per 100,000 in women.(27) Another large population-based study in the U.S. reported an age-standardized incidence rate of 258 per 100,000 person-years in men and 491 per 100,000 person-years in women. This latter study also reported that the overall incidence of carpal tunnel syndrome increased over time, from 258 per 100,000 person-years during 1981-1985 to 424 per 100,000 during 2001-2005.(28) In certain high-risk groups, incidence has been reported up to 150 cases per 1000 subjects per year, and prevalence greater than 500 cases per 1000 subjects.(6) The overall prevalence of carpal tunnel syndrome in the U.S. may be as high as 1.9 million people.(29) The U.S. Bureau of Labor Statistics reported that in 2007 the incidence rate for carpal tunnel syndrome that led to lost work days among all occupations was 1.3 per 10,000 full-time workers.(30) Carpal tunnel syndrome appears most frequently in the 40 to 60 year age group.(28,31)

CMV Drivers

The study from Denmark mentioned above also provided data that allowed calculation of hospitalization rates due to carpal tunnel syndrome for long-haul truck drivers and other truck drivers. During a 10-year period, 0.97% of long-haul drivers and 0.76% of other truck drivers were treated in a hospital for carpal tunnel syndrome. In both groups this rate was significantly higher than the expected rate in the general population.(26) The U.S. Bureau of Labor Statistics reported that in 2007 the incidence rate for carpal tunnel syndrome that led to lost work days among truck drivers (heavy and tractor-trailer) was 1 per 10,000 full-time truck drivers.(30)

Cubital Tunnel Syndrome

General Population

Cubital tunnel syndrome is the second most common nerve compression syndrome (after carpal tunnel syndrome). A population-based study from the U.K. reported that the annual age-standardized rates for occurrence of ulnar neuropathy (cubital tunnel syndrome) were 25.2 per 100,000 for men and 18.9 per 100,000 for women.(27) The state of Connecticut reported that 3% of claims for occupational disorders of the upper extremity were for cubital tunnel syndrome.(32)

CMV Drivers

Data from the Denmark study on long-haul and other truck drivers allowed calculation of hospitalization rates related to ulnar nerve lesions (cubital tunnel syndrome). During a 10-year period, 0.23% of long-haul drivers and 0.21% of other truck drivers were treated in a hospital for cubital tunnel syndrome. Although these rates were somewhat elevated compared to the expected rates in the general population, the difference did not reach statistical significance.(26)

Radial Tunnel Syndrome

General Population

A large population-based study from the U.K. reported that the annual age-standardized rates for occurrence of radial tunnel syndrome were 2.97 per 100,000 for men and 1.42 per 100,000 for women.(27) These rates are much lower than the reported rates for carpal tunnel syndrome and cubital tunnel syndrome in the same population.

CMV Drivers

Our searches did not identify any relevant epidemiological data concerning radial tunnel syndrome in the CMV driver population.

Tarsal Tunnel Syndrome

Our searches did not identify specific studies of the incidence and prevalence of this disorder in either the general population or the CMV driver population. However, two U.K. foot and ankle specialists reported that they had observed 10 new cases of tarsal tunnel syndrome out of 15,000 new patients during a 13 year period. This led them to estimate an incidence of about 2 new cases per million per year,(33) but this is a rough estimate. Thus, although tarsal tunnel syndrome has been reported to be the most common nerve compression syndrome in the foot and ankle area,(34) it appears to be relatively rare compared to upper extremity nerve compression syndromes.

Tendonitis/Tenosynovitis

General Population

A survey of more than 30,000 “recent” workers in 1988 found that 0.31% had experienced an upper extremity form of tendonitis/tenosynovitis.(35) Extrapolated to the larger population of 127 million “recent” workers in the U.S. mentioned in the same reference, this percentage would translate to 393,700 cases of tendonitis/tenosynovitis. The U.S. Bureau of Labor Statistics reported that in 2007 the incidence rate for tendonitis that led to lost work days among all occupations was 0.5 per 10,000 full-time workers.(30) Middle-aged adults are more likely than any other age group to develop tendonitis.(11) Achilles tendonitis has a reported incidence of 6.5-18% in runners;(36) the incidence and prevalence of this condition in the general population is unclear. De Quervain’s tenosynovitis (which affects the wrist) has a higher incidence in women, with some studies reporting a female-to-male ratio of 8:1. It is much more common in adults than children, appearing most frequently in the 30 to 50 year age group.(12)

CMV Drivers

The U.S. Bureau of Labor Statistics reported that in 2007 the incidence rate for tendonitis that led to lost work days among truck drivers (heavy and tractor-trailer) was 1 per 10,000 full-time truck drivers.(30)

Bursitis

General Population

According to the 1995 National Health Interview survey, bursitis has a prevalence rate of 3.2% in the U.S.(37) Our searches did not locate any estimates of the incidence rate of bursitis.

CMV Drivers

The Denmark study of long-haul and other truck drivers reported hospitalization rates related to olecranon (elbow) bursitis and prepatellar (knee) bursitis over a 10-year period. The rates for olecranon bursitis were 0.83% among long-haul truck drivers and 0.52% among other truck drivers. The rates for prepatellar bursitis were 0.55% among long-haul truck drivers and 0.22% among other truck drivers. The rates for olecranon bursitis and prepatellar bursitis among long-haul drivers were significantly elevated compared to the expected rate in the general population, while the rates among other truck drivers did not differ significantly from the general population expected rates.(26)

Plantar Fasciitis

General Population

Plantar fasciitis is believed to occur in about 10% of adults in the general population, and accounts for about 10% of runner-related injuries. It has been reported to account for about 11-15% of all foot symptoms requiring professional care among adults.(15,38) The condition may occur at any age, but some studies have found a peak incidence may occur in women aged 40-60 years. Among younger people the condition occurs equally in both genders. Race and ethnicity are unrelated to the incidence of plantar fasciitis.(38)

CMV Drivers

Our searches did not identify any relevant epidemiological data concerning plantar fasciitis in the CMV driver population.

Summary of Epidemiological Data on Musculoskeletal Disorders among Truck Drivers

Table 2 summarizes the findings of the study by Jensen et al. of hospitalization rates for various musculoskeletal disorders among long-haul and other truck drivers in Denmark.(26) This study suggests that long-haul truck drivers are at higher risk than the general population for developing severe cases of carpal tunnel syndrome and bursitis that require treatment.

Table 2. Hospitalization Rates for Various Musculoskeletal Disorders among Long-haul and Other Truck Drivers in Denmark, 1994-2004 (Jensen et al. 2008)(26)

Disorder	Hospitalization rates for long-haul truck drivers (number of cases)	Significantly higher than expected rates (based on general population norms)?	Hospitalization rates for other truck drivers (number of cases)	Significantly higher than expected rates (based on general population norms)?
All Mononeuropathies of Upper Limb	1.29% (28/2,175)	Yes	1.14% (172/15,060)	Yes
Carpal Tunnel Syndrome	0.97% (21/2,175)	Yes	0.76% (115/15,060)	Yes
Cubital Tunnel Syndrome	0.23% (5/2,175)	No	0.21% (31/15,060)	No
Radial Tunnel Syndrome	NR	NR	NR	NR
Tarsal Tunnel Syndrome	NR	NR	NR	NR
Tendonitis/Tenosynovitis	NR	NR	NR	NR
Olecranon Bursitis (elbow)	0.83% (18/2,175)	Yes	0.52% (78/15,060)	No
Prepatellar Bursitis (kneecap)	0.55% (12/2,175)	Yes	0.22% (33/15,060)	No
Plantar Fasciitis	NR	NR	NR	NR

NR: Not reported

The Burden of Musculoskeletal Disorders

Worldwide, musculoskeletal disorders are considered the most common cause of chronic disability, making up an estimated 2% of the global burden of disease.(39) Information on musculoskeletal disease as calculated by the World Health Organization (WHO) is featured in Table 3.(24,40)

Table 3. Estimated Burden of Musculoskeletal Conditions[1], by Gender and Region, 2001 (Disability Adjusted Life Years in Thousands)

Condition	Total	Males	Females	Developing Countries	Industrialized Countries
Osteoarthritis	16,372	6,621	9,750	11,049	5,323
Rheumatoid Arthritis	4,757	1,353	3,404	3,238	1,520
Other Musculoskeletal Conditions	8,699	5,033	3,638	6,679	1,880
All Musculoskeletal Conditions	29,798	13,007	16,792	21,076	8,723

A survey by Yee of drivers aged 55 or older in the United States found that 35% stated they had arthritis. A total of 83% of all individuals surveyed stated that stiff or painful joints “never” interfered with driving; 11% stated that joint problems “seldom” interfered with driving; and 3% claimed that joint dysfunction “sometimes” interfered with driving. Weak, stiff, or painful joints required approximately 7% of the individuals surveyed to use an automobile with automatic transmission; 9% required a vehicle with power steering for the same reason.(41)

The National Institute of Occupational Safety and Health (NIOSH) has reported that carpal tunnel syndrome required the longest recuperation period of all conditions that result in lost work days, with a median of 30 work days lost.(42) A Washington state study of time lost for individuals making workers’

[1] Primary musculoskeletal dysfunctions according to the WHO include osteoarthritis, osteoporosis and other metabolic bone disease, inflammatory arthritis, back pain, musculoskeletal injuries (e.g., sports injuries) and crystal arthritis (gout).

compensation claims for carpal tunnel syndrome reported even higher median days of time lost per claim: 138 days for all claimants, 188 days for workers in construction and transportation.(43) Each year in the U.S. there are 300,000 to 500,000 surgeries for the condition, at a total cost of more than $2 billion.(29) This represents roughly 25% to 30% of diagnosed cases in the U.S. A large population study in the U.K. also reported that in the year 2000, 31% of newly-diagnosed patients with carpal tunnel syndrome and 30% of newly-diagnosed patients with cubital tunnel syndrome underwent surgery.

Treatments for Musculoskeletal Disorders

The treatments available for musculoskeletal disorders vary according to the disorder, its etiology, and its severity. While some of the treatments can alter the progression of the disease or illness, others function solely to relieve symptoms.(44) Treatments are shown in Table 4 and include the following:

- Conservative treatment (physical therapy, exercise, and behavioral modification)
- Pharmacotherapy
- Surgery
- Combination approaches

Conservative Treatment

Typical conservative treatments associated with musculoskeletal disorders include exercises that incorporate stretching, strengthening, and ROM movements designed to improve overall strength, muscle mass, balance, and flexibility, and reduce pain and stiffness. Other conservative treatments may include the following:

- Heat or cold applied to the affected area(s)
- Weight loss to decrease stress on load-bearing joints
- Rest
- Assistive devices (crutches, braces, canes, etc.)
- Diet modification

Pharmacotherapy

Pharmacotherapy is used to address musculoskeletal disorder symptoms, prevent damage or systemic illness, produce remission of the disorder, and assist in the retention of functional ability. Drug therapies for musculoskeletal disorders include the following:

- Analgesics (oral and topical)
- Opiates (codeine, oxycodone)
- Nonsteroidal anti-inflammatory drugs (NSAIDs)

- Local corticosteroid injections
- Tricyclic antidepressants
- Anticonvulsants
- Muscle relaxants
- Disease-modifying antirheumatic drugs (DMARDs) (biologic response modifiers (BRMs))
- Viscosupplementation (hyaluronic acid injections to the joint)

Surgery

When conservative and pharmacotherapeutic treatments have failed to provide relief from symptoms and quality of life has diminished, surgery for musculoskeletal disorders is a treatment option. The decision to treat a musculoskeletal disorder with surgery requires considering many factors, including the risks associated with surgery and the progression of the disease in the absence of surgery. Complications of surgery include blood clots and infection, and the recovery period can be long and physically demanding. Delaying surgery, however, may result in additional pain and loss of function, which may exacerbate the need for surgical intervention and prolong recovery while reducing the efficacy of the procedure. Surgical options for the musculoskeletal disorders covered in this report include the following:

- Arthroscopy – insertion of a small tube viewing instrument, arthroscope, for joint examination via through surgical skin incisions for the diagnosis, visualization and treatment of problems within the joint(45)
- Bursectomy – removal of a bursa due to chronic inflammation (bursitis) or infection(14)
- Endoscopic or open release surgery – transection of the transverse carpal ligament(42)
- Neurolysis – release of a nerve sheath by cutting it longitudinally; also removal of adhesions from connective tissue surrounding a nerve(42)
- Decompression – cutting tissues from the roof of the cubital tunnel, radial tunnel, or tarsal tunnel to relieve nerve compression(42)
- Epicondylectomy – removal of the medial epicondyle and reattachment of the flexor-pronator muscle groups to the site of removal. Usually performed at the same time as decompression for cubital tunnel syndrome(42)
- Ulnar nerve transposition – repositioning the ulnar nerve outside of the cubital tunnel, anterior to the medial epicondyle(42)
- Plantar fascia release – cutting part of the plantar fascia ligament to relieve tension(46)
- Release of tendon sheaths – to relieve nerve entrapment(42)

- Tendon and ligament reconstruction – arthroscopic reconstruction surgery technique using segments of the tendon or ligament to replace the damaged segment (e.g., commonly used in replacement of a torn anterior cruciate ligament [ACL])(47)

Combination Treatment

Combination treatment brings together a variety of elements—exercise, pharmacotherapy, behavioral modification, surgery, and psychological services to provide optimal care through an approach that encompasses the etiology of the disorder and the psychological and social issues that interact within the individual's experience of illness.

A list of treatment options for each specific musculoskeletal disorder covered in this report appears in Table 4.

Table 4. Musculoskeletal Disorder Treatments

Disorder	Treatment
Carpal Tunnel Syndrome(42,48)	Job/activity modifications, night wrist splints, oral or injected anti-inflammatory drugs, cortisone injections, surgery (arthroscopy, endoscopic or open release, neurolysis)
Cubital Tunnel Syndrome(42,49)	Splinting, surgery (decompression, epicondylectomy, ulnar nerve transposition)
Radial Tunnel Syndrome(49)	Splinting, surgical decompression
Tarsal Tunnel Syndrome(3,50)	Foot inversion(foot is strapped in neutral/slightly inverted position or orthotic used for inverting foot) for nerve tension reduction, injection (corticosteroid/anesthetic if due to inflammation or fibrosis) or a combined treatment of the preceding; NSAIDS; underlying cystic lesion aspiration; control of edema and varicosity, surgical decompression
Tendonitis(11)	NSAIDs, reduce activity level/rest, ice, splinting, exercises, low-intensity pulsed ultrasound, arthroscopic/open surgical treatment (tendon reconstruction, though seldom required)
Tenosynovitis(13,42)	NSAIDs, peritendinous lidocaine/corticosteroid injection, activity modification, IV/intramuscular antibiotics (gonococcal tenosynovitis), surgery (tendon sheath release)
Bursitis(14,51)	Rest, NSAIDs (high dose), antibiotic for cystal-induced disease or infection, aspiration, depot corticosteroids intrabursal injection, surgery (drainage or bursectomy)
Plantar Fasciitis(15,38,46)	Orthotics (heel pads and cups for arch support and/or heel elevation and cushioning, splinting and stretching. NSAIDs, intermittent use of corticosteroid injections, weight loss (obese patients), physical therapy (cold/ice, massage therapy), extracorporeal shock-wave therapy and surgery (plantar fascia release, for a minute subgroup of patients with severe constant symptoms notwithstanding nonsurgical intervention in previous 6-12 months)

Spinal Cord Injury

The spinal cord, as a component of the central nervous system, functions to transport nerve impulses to and from the brain to the rest of the body. Therefore, an injury to the spinal cord may culminate in problems that modify motor, sensory or autonomic function.(52) Injury to connected nerves near and below the site affect sensation and muscle control resulting in temporary or permanent damage.(52) For example, if the spinal cord is severed or pathways are destroyed, a permanent loss may result. In contrast, a "blunt injury" (fall, collision) jarring the cord may result in temporary loss resolving over time (days, weeks, months).(53)

Typical driving-related mechanical -function problems associated with SCI include maintaining an adequate grip on the steering wheel, one hand operation of brake and difficulties with seating, reversing, and using

the foot pedals as a result of loss range of motion and/or strength. Thus driving cannot be completed in a normal way and must occur coupled with driving control technology (such as reduced effort steering systems, joystick driving servo brake and accelerator control) including wheelchair access.(54) It is also important to remember that SCI may not only affect the CMV operator's ability to drive; this injury affects his/her ability to secure loads, or to load or unload the vehicle. Taking this into consideration, the ability to drive safely is not the only factor that needs to be considered when examining the impact of SCI on CMV drivers.

SCIs are classified into two distinct types of paralysis considered in this evidence report: tetraplegia (also referred to as quadriplegia), which affects both upper and lower limb function, and paraplegia, which affects lower limb function. The extent of decreased function depends on the location of level of the injury.(55) Specifically, injury level determination is based upon the intact neurologic functioning above the injury and absence or diminishing of function below the injury site.

Epidemiology

Traumatic SCI has a reported incidence of approximately 30-60 cases per million population (10,000 patients/year) in the United States. SCI reportedly affects more men than women (male-to-female as 4:1 ratio; an approximate 80% of the population are males) in the United States alone. Furthermore, recent SCI estimates found that individuals 16-30 years of age represent 50% of all cases that occur.(52)

Level of Injury

According to the American Spinal Injury Association (ASIA), injuries are classified as incomplete and complete tetraplegia and incomplete and complete paraplegia. Complete is defined as "absence of sensory and motor functions in the lowest sacral segments."(52) In contrast, incomplete is defined as "preservation of sensory or motor function below the level of injury, including the lowest sacral segments."(52)

The ASIA Impairment Scale defines the injury extent by the categories shown in Table 5.(52)

Table 5. Extent of SCI by Category

Category	Definition
A-Complete	No sensory or motor function is preserved in sacral segments S4-S5*.
B-Incomplete	Sensory, but not motor, function is preserved below the neurologic level and extends through sacral segments S4-S5.
C-Incomplete	Motor function is preserved below the neurologic level, and most key muscles below the neurologic level have muscle grade less than 3.
D-Incomplete	Motor function is preserved below the neurologic level, and most key muscles below the neurologic level have muscle grade greater than or equal to 3.
E-Normal	Sensory and motor functions are normal.

*Lower spine's segments(56)

Spinal cord level of injury is defined by C level for tetraplegia with C5 neurological level reported as the most common.(52) For paraplegia, injury level is defined as thoracic (T1-T12) and lumbar with T12

(thoracolumbar junction) neurological level reported as the most common.(52,57) SCI neurological levels and definitions are shown in Table 6.

Table 6. SCI Level of Injury (57)

SCI Level	Definition
Tetraplegia	
C1-C4 (High Tetraplegia)	Minimal or no upper and lower extremity muscles movement. Movement in head or neck. Innervation of the diaphragm at C4 injury level. Dependent on others for assistance with the majority self-care and mobility needs.
C5-C6	Individuals have elbow flexion functional use and feeding and grooming independence with specialized assistive devices (e.g., wrist or hand orthotics) use. For C6 level, wrist extension is an added function permitting tenodesis ("passive thumb adduction on the index finger during active wrist extension") and tenodesis splint use (wrist-hand orthosis) can facilitate these abilities. Patients with C6 injury level are at the highest level in which an individual with a complete injury is able to function independently without attendant assistance (though uncommon).
C7-C8	Highest SCI injury level for which individuals are able to live independently. Elbow extension ability exists to improve mobility and self-care skills. C8 level of injury is characterized by individuals with added functional finger flexion for independent hand grasp and release improvement. Independent driving with an adapted car with hand controls is possible at this level.
Paraplegia	
Thoracic	All upper extremity muscles have innervations and function in T1-T12 paraplegia. Functional self-care independence is achievable. Independent driving with adapted van or adapted car with hand controls use is possible. T2-T9 injury is characterized by paraspinal and abdominal muscles trunk control (variable) and possible standing ability with bilateral knee-ankle-foot orthoses (KAFOs) coupled with crutches or walker. Wheel chair mobility can be preferred as tremendous energy is required for walking. For T10-T12 paraplegia, better trunk control is achieved than in higher injury individuals.
Lumbar	All mobility, self-care, and bladder and bowel skill functional independence is achievable at this level including unassisted ambulation with/without braces and assistive devices use at over 150 feet distances. The part or full-time use of a manual wheelchair use is required. Frequently prescribed specialized assistive devices to aid in lower extremity standing and walking at the lumbar level include orthotic devices (knee-ankle-foot orthoses and ankle-foot orthoses). Independent driving with car adaptation (hand controls) is possible.

Causes

Epidemiological data compiled for non-traumatic SCI does not currently exist though spondylosis and cancer have been cited as common causes of injury.(52) Trauma-related SCI impacts the functional, medical, financial and psychosocial well-being of the injured individual. The most common reported causes of SCI include:(52)

- Motor vehicle accidents (44.5%)
- Falls (18%; most common in individuals over 45 years)
- Violence (16.6 %; most common in urban settings)
- Sports injuries (12.7%)

Treatments for Spinal Cord Injury

Various treatments exist for SCI. Treatments include: pharmacotherapy, emergency room treatment and surgery.

Pharmacotherapy

Pharmacotherapy is used to reduce acute SCI secondary effects while providing motor function improvement and sensation in spinal cord injury patients.(58) Drug therapy for spinal cord injury include corticosteroids(or glucocorticoids), a class of high-dose steroids.(58) Specifically, methylprednisolone (Solu-Medrol) is a drug in this steroid class indicated for acute SCI secondary effects reduction. Other drug therapies include analgesics (pain relievers-acetaminophen or ibuprofen) and muscle relaxants (baclofen or tizanidine) for injury-related pain and muscle spasms respectively.(58) Recently, experimental drugs have been introduced to administer orally or injected epidurally (space around spinal cord).(58)

Surgery

The treatment of SCI with surgery is necessary for the removal of blood and bone fragments accumulating around the spinal cord region. Spine stabilization may require steel rod implants to prevent further SCI and provide spine immobility for bone and other tissue healing. This enables patients to recover more quickly when the injury has resulted solely in partial loss of function.(59)

CMV Drivers and Musculoskeletal Disorders or Spinal Cord Injury

In this section of the evidence report we examine the interaction between musculoskeletal disorders or SCI and CMV driving.

Are CMV drivers at an increased risk for developing musculoskeletal disorders?

The degree to which operating a CMV is associated with the onset of musculoskeletal disorders is unknown. However, the interaction between lifestyle factors and occupational factors associated with such individuals may predispose CMV drivers to the development of musculoskeletal disorders.(60-64) Lifestyle factors that might contribute to the development of musculoskeletal disorders include the following:

- Unhealthy eating habits
- Smoking
- Alcohol consumption
- Physical inactivity
- Overweight/obese BMI

Occupational factors that may contribute to the development of musculoskeletal disorders in CMV drivers include the following:

- Long working hours
- Irregular working hours
- Sedentary nature of the job

- Exposure to certain types of materials handling tasks
- Work-related factors, including posture and truck vibration

As discussed earlier, a recent study from Denmark found that long-haul truck drivers have a high relative risk of receiving hospital treatment (inpatient, outpatient, or emergency care) for mononeuropathies of the upper limb, carpal tunnel syndrome, olecranon bursitis, and prepatellar bursitis compared to the general population.(26) This study suggests that CMV drivers are at higher risk than the general population for developing severe cases of these disorders that require treatment. Cases with symptoms severe enough to require treatment may have a greater likelihood of interfering with normal driving ability.

What are the physical demands associated with CMV operation that potentially limit the ability of an individual with musculoskeletal disorders or spinal cord injury to operate a CMV safely?

The act of CMV driving places a number of demands on the human body: if a condition compromises the ability to perform the tasks required to safely operate a motor vehicle, the results may include crash, injury, or death. The interplay of functional abilities with the safe operation of a motor vehicle was explored by Mazer et al. (2004), who noted that shifting gears, use of the emergency brake, and the ability to use the steering wheel in both directions was largely a product of sufficient ROM.(65)

A list of functional abilities required for motor vehicle operation, the component of the driving process they involve, and the proposed solutions for individuals with disabilities was created by Jones et al. as a way of assessing driver performance.(66) It was considered necessary to have satisfactory performance in two or more of these functional abilities in order to drive. These functional abilities were divided into primary and secondary areas of importance for each of the tasks required to operate a motor vehicle, which are featured in Table 7.

Table 7. Tasks Required to Operate a Motor Vehicle

Primary Area of Function	Secondary Area of Function	Component of Driving Process	Proposed Solutions
Hand	Upper limb	Seat belt manipulation Manipulation of key Use of hand brake	Non-inertia reel. Extend stem of seat belt attachment. Modify seat belt clip. Build up key. Conversion of vertical lever for knock on/off action. Keep car in gear when parked. Use accelerator/clutch for hill start. Buy automatic transmission car.
Upper limb	Hand	Open and close door Adjustment of mirror Use of gears	Keep door hinges and handles oiled. Modify buttons. Enlarge door handles. Ask other car drivers to reposition mirror. Increase length of gear stick. Modify hand piece. Buy automatic transmission car. Modify automatic gear stock to “push down” type.
Upper limb	Upper spine	Reaching seat belt Steering/cornering	Hook belt around seat lever. Prevent full recoil of seat belt. Steering wheel cover to increase bulk of wheel. “Threading” steering technique. Increase front tire pressure. Power steering.
Upper spine	Upper limb	Reversing	Undo seat belt when reversing. Install wide rear view mirror. Install near and off side mirrors. “Reversing” with mirrors.
Lower spine	Lower limb	Seat comfort and position	Extend seat runners. Alter seat back position. Wedge cushions. Lumbar cushion.
Lower limb	Lower spine	Vehicle exit and entry Use of foot pedals	Enter buttocks rather than legs first. Extend seat runners. Pedal modification. Automatic transmission car.

Primary Area of Function	Secondary Area of Function	Component of Driving Process	Proposed Solutions
Supratentorial		Awareness of traffic and pedestrians Confidence	Practice with experienced driver in quiet streets. Limit driving to familiar streets. Take lessons with qualified driving instructor.
Pain and fatigue on long drives			Frequent stops on long trips. Judicious use of nonsteroidal anti-inflammatory drugs (NSAIDs) and analgesics. Establish a relaxed driving position.

Adapted from Jones et al.(66)

As noted earlier, nerve compression syndromes in the wrist (carpal tunnel syndrome), forearm (radial tunnel syndrome), or elbow (cubital tunnel syndrome) can cause pain or weakness in the hand and/or upper limb. This could affect driving functions noted in the table such as use of the hand brake, mirror adjustment, use of gears, and possibly steering/cornering. Tendonitis/tenosynovitis of the hand, wrist, elbow, or forearm could also affect these functions, as could bursitis of the elbow or shoulder. Disorders affecting the foot, ankle, or knee (plantar fasciitis, tarsal tunnel syndrome, tendonitis/tenosynovitis, bursitis) could impair ability to use foot pedals, possibly reducing braking force and reaction time. However, the effect of any of these specific disorders on driving ability has not been well-evaluated in the literature to date.

SCI may affect several important driving functions, including steering/cornering, reversing, and use of foot pedals. Because the limitations associated with paraplegia and tetraplegia are usually severe, vehicles often must be modified to accommodate specialized driving control technology and wheelchair access. Modifications may include reduced effort steering and braking systems, joystick driving systems (allowing one hand operation of brake, accelerator and steering), servo brake and accelerator control, mechanical hand controls, and steering systems that positions the steering wheel within functional range of motion.(54) These modifications are typically done in a sedan or van, not large trucks. Drivers with SCI have been generally reported to find driving long distances more tiresome compared to able-bodied drivers,(67) which is another potential difficulty drivers with SCI may encounter with long-haul truck driving.

In addition, SCI will also severely restrict or eliminate an individual's ability to secure or adjust loads or to load and unload a truck. Someone else could load the truck at the beginning of the trip (and unload at the end), but certain FMCSA regulations specify that cargo must be inspected and adjusted if necessary at various points during a long trip. This is beyond the capability of a lone driver with SCI. Driving with a partner would be necessary to fulfill this regulatory requirement, unless the truck is a sealed vehicle that does not require cargo inspection and adjustment during the trip.

Musculoskeletal Disorders, Spinal Cord Injuries and Driving Regulations

As indicated by the National Highway Traffic Safety Administration, stiff and/or swollen joints limit how far an individual can bend, move his/her shoulders, grasp a steering wheel, brake immediately, or look over a shoulder to check for blind spots. Consequently, drivers with musculoskeletal disorders may be at increased risk for a motor vehicle crash. To provide for public safety, U.S. federal and state laws have been

created that set physical standards for individuals with lost or impaired limbs. Further information on this topic is available at: http://www.nhtsa.dot.gov/.

Current Medical Fitness Standards and Guidelines for CMV drivers in the United States

Current Medical Fitness Standards

FMCSA Regulations, found in 49 Code of Federal Regulations (CFRs) 301 through 399, cover businesses that operate CMVs in interstate commerce. FMCSA regulations that pertain to fitness to drive a commercial vehicle are found in 49 CFR 391 Subpart E. Only motor carriers engaged purely in intrastate commerce are not directly subject to these regulations. However, intrastate motor carriers are subject to state regulations, which must be identical to, or compatible with, the federal regulations in order for states to receive motor carrier safety grants from the FMCSA. States have the option of exempting CMVs with a gross vehicle weight rating of less than 26,001 lbs.

The current medical qualification standard for fitness to drive a CMV (49 CFR 391.41(b) states the following (see: http://www.fmcsa.dot.gov/rules-regulations/administration/fmcsr/fmcsrruletext.asp?section=391.41):

A person is physically qualified to drive a CMV if that person—

- Has no loss of a foot, a leg, a hand, or an arm, or has been granted a skill performance evaluation certificate pursuant to § 391.49.
- Has no impairment of:
    - a hand or finger that interferes with prehension or power grasping; or
    - an arm, foot, or leg that interferes with the ability to perform normal tasks associated with operating a CMV; or any other significant limb defect or limitation which interferes with the ability to perform normal tasks associated with operating a CMV; or has been granted a skill performance evaluation (SPE) certificate pursuant to § 391.49.
- Has no established medical history or clinical diagnosis of rheumatic, arthritic, orthopedic, muscular, neuromuscular, or vascular disease which interferes with his/her ability to control and operate a CMV safely.

49 CFR 349 Alternative Physical Qualification Standards for the Loss or Impairment of Limbs

49 CFR 349 states the following:

(a) A person who is not physically qualified to drive under § 391.41(b)(1) or (b)(2) and who is otherwise qualified to drive a commercial motor vehicle, may drive a commercial motor vehicle, if the Division Administrator, FMCSA, has granted a Skill Performance Evaluation (SPE) Certificate to that person.

(b) *SPE certificate.* -- (b)(1) *Application.* A letter of application for an SPE certificate may be submitted jointly by the person (driver applicant) who seeks an SPE certificate and by the motor carrier that will employ the driver applicant, if the application is accepted.

(b)(2) *Application address.* The application must be addressed to the applicable field service center, FMCSA, for the State in which the co-applicant motor carrier's principal place of business is located. The address of each, and the States serviced, are listed in § 390.27 of this chapter.

(b)(3) *Exception.* A letter of application for an SPE certificate may be submitted unilaterally by a driver applicant. The application must be addressed to the field service center, FMCSA, for the State in which the driver has legal residence. The driver applicant must comply with all the requirements of paragraph (c) of this section except those in (c)(1)(i) and (iii). The driver applicant shall respond to the requirements of paragraphs (c)(2)(i) to (v) of this section, if the information is known.

(c) A letter of application for an SPE certificate shall contain:

(c)(1) Identification of the applicant(s):

(c)(1)(i) Name and complete address of the motor carrier coapplicant;

(c)(1)(ii) Name and complete address of the driver applicant;

(c)(1)(iii) The U.S. DOT Motor Carrier Identification Number, if known; and

(c)(1)(iv) A description of the driver applicant's limb impairment for which SPE certificate is requested.

(c)(2) Description of the type of operation the driver will be employed to perform:

(c)(2)(i) State(s) in which the driver will operate for the motor carrier coapplicant (if more than 10 States, designate general geographic area only);

(c)(2)(ii) Average period of time the driver will be driving and/or on duty, per day;

(c)(2)(iii) Type of commodities or cargo to be transported;

(c)(2)(iv) Type of driver operation (*i.e.,* sleeper team, relay, owner operator, etc.); and

(c)(2)(v) Number of years experience operating the type of commercial motor vehicle(s) requested in the letter of application and total years of experience operating all types of commercial motor vehicles.

(c)(3) Description of the commercial motor vehicle(s) the driver applicant intends to drive:

(c)(3)(i) Truck, truck tractor, or bus make, model, and year (if known);

(c)(3)(ii) Drive train;

(A) Transmission type (automatic or manual -- if manual, designate number of forward speeds);

(B) Auxiliary transmission (if any) and number of forward speeds; and

(C) Rear axle (designate single speed, 2 speed, or 3 speed).

(c)(3)(iii) Type of brake system;

(c)(3)(iv) Steering, manual or power assisted;

(c)(3)(v) Description of type of trailer(s) (*i.e.,* van, flatbed, cargo tank, drop frame, lowboy, or pole);

(c)(3)(vi) Number of semitrailers or full trailers to be towed at one time;

(c)(3)(vii) For commercial motor vehicles designed to transport passengers, indicate the seating capacity of commercial motor vehicle; and

(c)(3)(viii) Description of any modification(s) made to the commercial motor vehicle for the driver applicant; attach photograph(s) where applicable.

(c)(4) Otherwise qualified:

(c)(4)(i) The coapplicant motor carrier must certify that the driver applicant is otherwise qualified under the regulations of this part;

(c)(4)(ii) In the case of a unilateral application, the driver applicant must certify that he/she is otherwise qualified under the regulations of this part.

(c)(5) Signature of applicant(s):

(c)(5)(i) Driver applicant's signature and date signed;

(c)(5)(ii) Motor carrier official's signature (if application has a coapplicant), title, and date signed. Depending upon the motor carrier's organizational structure (corporation, partnership, or proprietorship), the signer of the application shall be an officer, partner, or the proprietor.

(d) The letter of application for an SPE certificate shall be accompanied by:

(d)(1) A copy of the results of the medical examination performed pursuant to § 391.43;

(d)(2) A copy of the medical certificate completed pursuant to § 391.43(h);

(d)(3) A medical evaluation summary completed by either a board qualified or board certified physiatrist (doctor of physical medicine) or orthopedic surgeon. The coapplicant motor carrier or the driver applicant shall provide the physiatrist or orthopedic surgeon with a description of the job-related tasks the driver applicant will be required to perform;

(d)(3)(i) The medical evaluation summary for a driver applicant disqualified under § 391.41(b)(1) shall include:

(A) An assessment of the functional capabilities of the driver as they relate to the ability of the driver to perform normal tasks associated with operating a commercial motor vehicle; and

(B) A statement by the examiner that the applicant is capable of demonstrating precision prehension (*e.g.,* manipulating knobs and switches) and power grasp prehension (*e.g.,* holding and maneuvering the steering wheel) with each upper limb separately. This requirement does not apply to an individual who was granted a waiver, absent a prosthetic device, prior to the publication of this amendment.

(d)(3)(ii) The medical evaluation summary for a driver applicant disqualified under § 391.41(b)(2) shall include:

(A) An explanation as to how and why the impairment interferes with the ability of the applicant to perform normal tasks associated with operating a commercial motor vehicle;

(B) An assessment and medical opinion of whether the condition will likely remain medically stable over the lifetime of the driver applicant; and

(C) A statement by the examiner that the applicant is capable of demonstrating precision prehension (*e.g.,* manipulating knobs and switches) and power grasp prehension (*e.g.,* holding and maneuvering the steering wheel) with each upper limb separately. This requirement does not apply to an individual who was granted an SPE certificate, absent an orthotic device, prior to the publication of this amendment.

(d)(4) A description of the driver applicant's prosthetic or orthotic device worn, if any;

(d)(5) Road test:

(d)(5)(i) A copy of the driver applicant's road test administered by the motor carrier coapplicant and the certificate issued pursuant to § 391.31(b) through (g); or

(d)(5)(ii) A unilateral applicant shall be responsible for having a road test administered by a motor carrier or a person who is competent to administer the test and evaluate its results.

(d)(6) Application for employment:

(d)(6)(i) A copy of the driver applicant's application for employment completed pursuant to § 391.21; or

(d)(6)(ii) A unilateral applicant shall be responsible for submitting a copy of the last commercial driving position's employment application he/she held. If not previously employed as a commercial driver, so state.

(d)(7) A copy of the driver applicant's SPE certificate of certain physical defects issued by the individual State(s), where applicable; and

(d)(8) A copy of the driver applicant's State Motor Vehicle Driving Record for the past 3 years from each State in which a motor vehicle driver's license or permit has been obtained.

(e) *Agreement.* A motor carrier that employs a driver with an SPE certificate agrees to:

(e)(1) File promptly (within 30 days of the involved incident) with the Medical Program Specialist, FMCSA service center, such documents and information as may be required about driving activities, accidents, arrests, license suspensions, revocations, or withdrawals, and convictions which involve the driver applicant. This applies whether the driver's SPE certificate is a unilateral one or has a coapplicant motor carrier;

(e)(1)(i) A motor carrier who is a coapplicant must file the required documents with the Medical Program Specialist, FMCSA for the State in which the carrier's principal place of business is located; or

(e)(1)(ii) A motor carrier who employs a driver who has been issued a unilateral SPE certificate must file the required documents with the Medical Program Specialist, FMCSA service center, for the State in which the driver has legal residence.

(e)(2) Evaluate the driver with a road test using the trailer the motor carrier intends the driver to transport or, in lieu of, accept a certificate of a trailer road test from another motor carrier if the trailer type(s) is similar, or accept the trailer road test done during the Skill Performance Evaluation if it is a similar trailer type(s) to that of the prospective motor carrier. Job tasks, as stated in paragraph (e)(3) of this section, are not evaluated in the Skill Performance Evaluation;

(e)(3) Evaluate the driver for those nondriving safety related job tasks associated with whatever type of trailer(s) will be used and any other nondriving safety related or job related tasks unique to the operations of the employing motor carrier; and

(e)(4) Use the driver to operate the type of commercial motor vehicle defined in the SPE certificate only when the driver is in compliance with the conditions and limitations of the SPE certificate.

(f) The driver shall supply each employing motor carrier with a copy of the SPE certificate.

(g) The State Director, FMCSA, may require the driver applicant to demonstrate his or her ability to safely operate the commercial motor vehicle(s) the driver intends to drive to an agent of the State Director, FMCSA. The SPE certificate form will identify the power unit (bus, truck, truck tractor) for which the SPE certificate has been granted. The SPE certificate forms will also identify the trailer type used in the Skill Performance Evaluation; however, the SPE certificate is not limited to that specific trailer type. A driver may use the SPE certificate with other trailer types if a successful trailer road test is completed in accordance with paragraph (e)(2) of this section. Job tasks, as stated in paragraph (e)(3) of this section, are not evaluated during the Skill Performance Evaluation.

(h) The State Director, FMCSA, may deny the application for SPE certificate or may grant it totally or in part and issue the SPE certificate subject to such terms, conditions, and limitations as deemed consistent with the public interest. The SPE certificate is valid for a period not to exceed 2 years from date of issue, and may be renewed 30 days prior to the expiration date.

(i) The SPE certificate renewal application shall be submitted to the Medical Program Specialist, FMCSA service center, for the State in which the driver has legal residence, if the SPE certificate was issued unilaterally. If the SPE certificate has a coapplicant, then the renewal application is submitted to the Medical Program Specialist, FMCSA field service center, for the State in which the coapplicant motor carrier's principal place of business is located. The SPE certificate renewal application shall contain the following:

(i)(1) Name and complete address of motor carrier currently employing the applicant;

(i)(2) Name and complete address of the driver;

(i)(3) Effective date of the current SPE certificate;

(i)(4) Expiration date of the current SPE certificate;

(i)(5) Total miles driven under the current SPE certificate;

(i)(6) Number of accidents incurred while driving under the current SPE certificate, including date of the accident(s), number of fatalities, number of injuries, and the estimated dollar amount of property damage;

(i)(7) A current medical examination report;

(i)(8) A medical evaluation summary pursuant to paragraph (d)(3) of this section, if an unstable medical condition exists. All handicapped conditions classified under § 391.41(b)(1) are considered unstable. Refer to paragraph (d)(3)(ii) of this section for the condition under § 391.41(b)(2) which may be considered medically stable.

(i)(9) A copy of driver's current State motor vehicle driving record for the period of time the current SPE certificate has been in effect;

(i)(10) Notification of any change in the type of tractor the driver will operate;

(i)(11) Driver's signature and date signed; and

(i)(12) Motor carrier coapplicant's signature and date signed.

(j)(1) Upon granting an SPE certificate, the State Director, FMCSA, will notify the driver applicant and co-applicant motor carrier (if applicable) by letter. The terms, conditions, and limitations of the SPE certificate will be set forth. A motor carrier shall maintain a copy of the SPE certificate in its driver qualification file. A copy of the SPE certificate shall be retained in the motor carrier's file for a period of 3 years after the driver's employment is terminated. The driver applicant shall have the SPE certificate (or a legible copy) in his/her possession whenever on duty.

(j)(2) Upon successful completion of the skill performance evaluation, the State Director, FMCSA, for the State where the driver applicant has legal residence, must notify the driver by letter and enclose an SPE

certificate substantially in the following form:Skill Performance Evaluation Certificate Name of Issuing Agency:Agency Address:Telephone Number: ( ) Issued Under 49 CFR 391.49, subchapter B of the Federal Motor Carrier Safety Regulations Driver's Name:Effective Date: SSN:DOB:Expiration Date:Address:Driver Disability:Check One:_New_Renewal Driver's License:_____ (State) (Number)

In accordance with 49 CFR 391.49, subchapter B of the Federal Motor Carrier Safety Regulations (FMCSRs), the driver application for a skill performance evaluation (SPE) certificate is hereby granted authorizing the above-named driver to operate in interstate or foreign commerce under the provisions set forth below. This certificate is granted for the period shown above, not to exceed 2 years, subject to periodic review as may be found necessary. This certificate may be renewed upon submission of a renewal application. Continuation of this certificate is dependent upon strict adherence by the above-named driver to the provisions set forth below and compliance with the FMCSRs. Any failure to comply with provisions herein may be cause for cancellation.

CONDITIONS: As a condition of this certificate, reports of all accidents, arrests, suspensions, revocations, withdrawals of driver licenses or permits, and convictions involving the above-named driver shall be reported in writing to the Issuing Agency by the EMPLOYING MOTOR CARRIER within 30 days after occurrence.

LIMITATIONS: 1. Vehicle Type (power unit):* 2. Vehicle modification(s): 3. Prosthetic or Orthotic device(s) (Required to be Worn While Driving):4. Additional Provision(s):

NOTICE: To all MOTOR CARRIERS employing a driver with an SPE certificate. This certificate is granted for the operation of the *power unit only.* It is the responsibility of the employing motor carrier to evaluate the driver with a road test using the trailer type(s) the motor carrier intends the driver to transport, or in lieu of, accept the trailer road test done during the SPE if it is a similar trailer type(s) to that of the prospective motor carrier. Also, it is the responsibility of the employing motor carrier to evaluate the driver for those non-driving safety-related job tasks associated with the type of trailer(s) utilized, as well as, any other non-driving safety-related or job-related tasks unique to the operations of the employing motor carrier.

The SPE of the above named driver was given by a Skill Performance Evaluation Program Specialist. It was successfully completed utilizing the above named power unit and _____(trailer, if applicable)

The tractor or truck had a _____ transmission.

Please read the *NOTICE* paragraph above. Name:Signature:Title:Date:

(k) The State Director, FMCSA, may revoke an SPE certificate after the person to whom it was issued is given notice of the proposed revocation and has been allowed a reasonable opportunity to appeal.

(l) Falsifying information in the letter of application, the renewal application, or falsifying information required by this section by either the applicant or motor carrier is prohibited.

[65 FR 25287, May 1, 2000, as amended at 65 FR 59380, Oct. 5, 2000; 67 FR 61824, Oct. 2, 2002]

More extensive information on this topic is available at the *Conference on Neurological Disorders and Commercial Drivers* at: http://www.fmcsa.dot.gov/

Medical Fitness Standards and Guidelines for Individuals Performing Transportation Safety in the United States

Current medical fitness standards and guidelines for individuals performing transportation safety in the United States are summarized in Table 8. Included in the table are pertinent rules and guidelines for pilots, railroad workers, and merchant mariners.

Table 8. Standards and Guidelines Pertaining to Individuals with Musculoskeletal Disorders: FAA, Railroad, and Merchant Marine

Condition	FAA* (all classes of airmen)	Railroad†	Merchant Marine‡
Musculoskeletal Disorders	Examiners may reissue an airman medical certificate under the provisions of an Authorization, if the applicant provides the following: • An authorization granted by FAA • The type of arthritis • A general assessment of condition and effect on daily activities • The name and dosage of medication(s) used for treatment and/or prevention with comment regarding side effects • Comments regarding ROM of neck, upper and lower extremities, hands, etc. **Guide for Aviation Medical Examiners** **Decision Considerations** **Disease Protocols** **Musculoskeletal Evaluation** The Examiner should defer issuance. An applicant with a history of musculoskeletal conditions must submit the following if consideration for medical certification is desired: • Current status report • Functional status report • Degree of impairment as measured by strength, ROM, and pain **Note**: If the applicant is otherwise qualified, FAA may issue a limited certificate. This certificate will permit the applicant to proceed with flight training until ready for a medical flight test. At that time, and at the applicant's request, FAA (usually AMCD) will authorize the student pilot to take a medical flight test in conjunction with the regular flight test. The medical flight test and regular private pilot flight test are conducted by an FAA inspector. This affords the student an opportunity to demonstrate the ability to control the aircraft despite the handicap. The FAA inspector prepares a written report and indicates whether there is a safety problem. A medical certificate and (SODA), without the student limitation, may be provided to the inspector for issuance to the applicant, or the inspector may be required to send the report to the FAA medical officer who authorized the test. When prostheses are used or additional control devices are installed in an aircraft to assist the amputee, those found qualified by special certification procedures will have their certificates limited to require that the device(s) (and, if necessary, even the specific aircraft) must always be used when exercising the privileges of the airman certificate.	No specific standards or guidelines	Potentially disqualifying conditions listed in the Physical Evaluation Guidelines for Merchant Mariner's Documents and Licenses included any disease or constitutional defect that would result in gradual deterioration of performance of duties, and sudden incapacitation or otherwise compromise shipboard safety—including required response in an emergency situation. Orthopedic conditions, including amputation, deformity, or arthritis, resulting in impairment of motion or use of limbs or back would require the following: • Requests for waivers should include a report of a practical demonstration of mobility • Details of the test shall be determined by the OCMI using the Marine Safety Manuel as a guide • The test should be conducted under conditions appropriate for the credential, route, and tonnage the applicant is applying for • Applicant should be able to respond adequately in emergency situations

*Source of information for FAA Regulations and Guidelines:
http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/special_iss/all_classes/arthritis/
http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/dec_cons/disease_prot/musculoskeletal/

†Source of information for Federal Railroad Administration Guidelines: http://www.fra.dot.gov/us/content/1586
‡Source of information for Merchant Mariner Guidelines: http://www.uscg.mil/hq/g-m/nvic/2_98/n2-98.pdf

AMCD: Aerospace Medical Certification Division
FAA: Federal Aviation Association
OCMI: Officer in charge, marine inspection
ROM: Range of motion
SODA: Statement of demonstrated ability

Regulatory Medical Fitness Standards for the United States and Selected Countries

The United States and other countries have established regulatory medical fitness standards for the protection and safety of the public interest, including licensed drivers. The medical standards are used to assess and determine the fitness of drivers operating CMVs. Likewise, musculoskeletal disorders are defined, and the criteria for establishing these standards are constructed. Each country demonstrates its interpretation of musculoskeletal disorders through definition and by determining the relevant population(s).

Regulatory standards and guidelines pertaining to musculoskeletal disorders and CMV driving in several selected countries are presented in Table 9.

Table 9. Regulations and Guidelines Pertaining to Musculoskeletal Disorders and CMV Driving from Selected Countries

Musculoskeletal Disorder	Australia	Canada	UK	New Zealand	Sweden
Reference source	Assessing Fitness to Drive (For Commercial and Private Vehicle Drivers) Medical Standards for Licensing and Clinical Management Guidelines. Austroads and NTC (National Transport Commission) Australia (2006)	Determining medical fitness to Operate Motor Vehicles. CMA (Canadian Medical Association) Driver's Guide 7th edition. (2006)	At-a-glance Guide to the current Medical Standards of Fitness to Drive (for Medical Practitioners) Issued by Drivers Medical Group. Driver and Vehicle Licensing Agency (DVLA), Swansea (February 2007)	Medical aspects of fitness to drive: A Guide for Medical Practitioners. Land Transport Safety Authority. (May 2002)	Swedish National Road Administration (1999)
Loss of limbs, deformities and prosthetics	The criteria for an unconditional license are NOT met: • If there is an amputation or congenital absence of a limb (whole or part) required to operate a hand or foot control; or • If the thumbs are missing from both hands. A conditional license may be granted by the Driver Licensing Authority, taking into account the opinion of an appropriate specialist, and the nature of the driving task, and subject to practical assessment and periodic review: • If the person has a lower limb prosthesis for a below-knee amputation and does not have to operate a brake pedal with the prosthesis, and the clutch pedal (if present) has been modified for use by a prosthesis. Automatic transmission and/or modification to hand controls may also be required. A spinner knob will be needed if a power-boosted handbrake control has been added; or • The person has the forefoot, first metatarsophalangeal joint or large toe amputated; or • The person has less than a thumb and two fingers on each hand or only one arm, provided a spinner knob or other device is fitted to the vehicle.	Those with a loss or deformity of the upper or lower extremities may drive any vehicle provided they can demonstrate their ability to drive to the satisfaction of the driver examiner. Many people with an amputation or deformity of one arm are able to drive a private vehicle safely. Some people with an amputation below the elbow who are fitted with an adequate prosthesis may operate any class of vehicle provided they demonstrate their ability to a driver examiner. People who have an amputation below the knee of one or both legs are usually able to drive any class of motor vehicle safely provided they have full strength and movement in their back, hips, and knee joints and a properly fitted prosthesis or prostheses.	Some disabilities may be compatible with the driving of large vehicles if mild and nonprogressive. Individual assessment will be required.	Driving should cease: ▪ If there is an amputation, congenital loss, or functional loss of a limb required to operate a hand or foot control where no modification is practicable. ▪ If there is an amputation, congenital loss, functional loss of both upper or both lower limbs, or one upper and one lower limb where no modification is practicable. Driving may resume or may occur in the following condition if the individual is able to demonstrate his or her ability to meet all necessary practical driving requirements: ▪ Absence of both thumbs * A full "off-road" and "on-road" driving assessment from a suitably trained occupational therapist is often necessary. Individuals with musculoskeletal conditions, such as a below-knee prosthesis or a forefoot amputation, may be considered fit for a license with conditions, provided that suitable vehicle modifications are in place, such as automatic transmission, spinner knobs, hand controls, or other necessary adaptations, and provided they have been able to show a satisfactory level of driving competence. Such people should be fully assessed on an individual basis before any decision is made.	Licence denied if ability to drive safely is impaired. May continue to drive if prosthesis and/or vehicle modifications can compensate for disability.

Musculoskeletal Disorder	Australia	Canada	UK	New Zealand	Sweden
Arthritis	Painful joints may arise due to inflammatory or degenerative arthritis. People who have persistent pain and marked reduction in range of movement in shoulders, elbows, wrists, hands, hips, knees, ankles, or feet may not meet the criteria (listed below). They may be usefully assessed by a driver assessor. The criteria for an unconditional license are NOT met: • if rotation of the cervical spine is chronically restricted to less than 45° to the left of right; or • if chronic pain and restriction of peripheral joint movement interferes with the relevant movements or concentration such that a vehicle cannot be operated safely; or • if there is ankylosis or chronic loss of joint movement of sufficient severity that control of vehicle is not safe. A conditional license may be granted by the Driver Licensing Authority, taking into account the opinion of an appropriate specialist, and the nature of the driving task, and subject to practical assessment and periodic review: • If there is pain and stiffness in any joint or a joint replacement, having regard for the range of movement and muscle power required to operate a heavy vehicle and the task of getting in and out of vehicles. A practical driver assessment is helpful for most final decisions.	Degenerative or inflammatory arthritis can result in pain; and loss of muscle strength, range of motion, and function of the involved joint(s). People with arthritis may have difficulty turning their head to perform safety checks due to pain and stiffness of their cervical and thoracolumbar spine. Inflammatory arthritis can result in persistent pain and reduced range of movement in multiple joints, including knees, ankles, hips, shoulders, elbows, wrists, and hands. A patient should be restricted from driving if pain adversely affects their ability to drive safely or if he or she lacks range of movement or strength to execute the coordinated activities required. Most difficulties can be overcome by simple modifications to the vehicle or adjustment of driving technique. However, if there are concerns, the individual should be required to demonstrate his or her ability to a driver examiner.	Some disabilities may be compatible with the driving of large vehicles if mild and nonprogressive. Individual assessment will be required.	Not mentioned	Licence denied if ability to drive safely is impaired. May continue to drive vehicle if vehicle modifications can compensate for disability.
Ankylosing spondylitis	Not mentioned	Not mentioned	Some disabilities may be compatible with the driving of large vehicles if mild and nonprogressive. Individual assessment will be required.	Not mentioned	Not mentioned

Musculoskeletal Disorder	Australia	Canada	UK	New Zealand	Sweden
General spinal			Driving is possible in both static and progressive or relapsing disorders, but vehicle modification may be needed.		Licence denied if ability to drive safely is impaired. May continue to drive if vehicle modifications can compensate for disability.
Cervical	A person with severe neck pain and very reduced mobility, including that arising from wearing soft collars or braces, should be advised not to drive for the duration of their treatment. Some loss of neck movement is allowable if the vehicle is fitted with adequate outside mirrors. In the case of permanent disability, the criteria may not be met (see criteria listed under Arthritis).	Some degree of loss of movement of the head and neck may be permitted, but the driver should then be restricted to driving vehicles equipped with panoramic mirrors, which may alleviate the need to do shoulder checks. People wearing a neck brace or cast or those with severe pain or very restricted range of movement should be advised not to drive until pain and restrictions of movement are minimal or appropriate adaptive devices are in place.		Driving may resume or may occur in the following condition if the individual is able to demonstrate his or her ability to meet all necessary practical driving requirements: ▪ Reduction in rotation of the cervical spine to less than 45 degrees either to the right or left.	
Thoracic	People with severe pain and reduced mobility of the thoracolumbar region, including those required to wear a brace or body cast that severely limits mobility, should be advised not to drive for the duration of their treatment. In the case of permanent disability, the criteria may not be met (see criteria listed under Arthritis).	People with a marked deformity or painfully restricted motion in the thoracic vertebrae are not able to drive large commercial transport or passenger-carrying vehicles safely. Their ability to drive private vehicles can best be determined by a driver examiner. Patients wearing braces or body casts must be evaluated on the basis of their ability to move free of pain, operate the controls, and observe approaching vehicles.			
Lumbar		Applicants for a license to drive a passenger transport or heavy commercial vehicle should be free of back pain that limits movement, attention, or judgment. Less stringent standards may be applied to private-vehicle drivers. However, this group may need to be restricted to driving vehicles with power-assisted brakes.			

Musculoskeletal Disorder	Australia	Canada	UK	New Zealand	Sweden
Paraplegia and quadriplegia		On the basis of a favorable recommendation from a medical specialist in physical medicine and rehabilitation, patients with new paraplegia or quadriplegia (below C4) may receive a learner's license. With the permit, these patients may then take driving lessons in an adapted vehicle fitted with special, modified controls.			
Hemiplegia/cerebral palsy			Driving is possible in both static and progressive or relapsing disorders, but vehicle modification may be needed.		
Pain or severe discomfort	Individuals should not drive with severe pain from spinal conditions that interfere with movement of the spine or shoulder of pelvic girdles.			Some discomfort from joints may be severe enough to distract an individual's attention and thus pose a danger on the road. Acute neck pain, severe back pain, and knee or elbow problems—especially when associated with locking—may present situations where it may be necessary to recommend the individual refrain from driving—especially for drivers of heavy vehicles or those driving commercially.	
General	In the case of commercial vehicle drivers, the opinion of a medical specialist is required for recommendation of a conditional license. This requirement reflects the higher safety risk for commercial vehicle drivers and the consequent importance of expert opinion. The Driver Licensing Authority may consider issuing a conditional commercial vehicle license in certain circumstances. For example, in situations where crash risk exposure is reduced: ▪ "off road" driving of commercial vehicle (e.g., in quarries or other properties where public vehicle access is limited).		Refusal or revocation of license if muscle or movement disorder is likely to affect vehicle control because of impairment of coordination and muscle power. If driving would not be impaired and condition stable, licensing will be considered subject to satisfactory reports and annual review. At age 70, the DVLA requires confirmation that no medical disability is present. After age 70, the maximum licence period is 3 years, subject to a satisfactory completion of medical questions. Drivers have an obligation to declare medical conditions that may affect driving safety.		

Methods

The *Methods* section provides a synopsis of how we identified and analyzed information for this report. The section briefly covers the key questions addressed, literature searches performed, the criteria used. The criteria includes studies, evaluation of study quality, assessment of the strength of the evidence base for each key question, and the methods used for abstracting and analyzing available data. Specific details of literature searches, study quality assessment, statistical approaches used, etc., are documented in appendices.

Key Questions

This evidence report addresses four key questions. Each of these key questions was developed by the FMCSA so that the answers would provide information that would be useful in updating its current medical examination guidelines. The four key questions addressed in this evidence report are as follows:

Key Question 1: Do musculoskeletal disorders of the hand, wrist, elbow, or shoulder (specifically carpal tunnel syndrome, cubital tunnel syndrome, radial tunnel syndrome, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

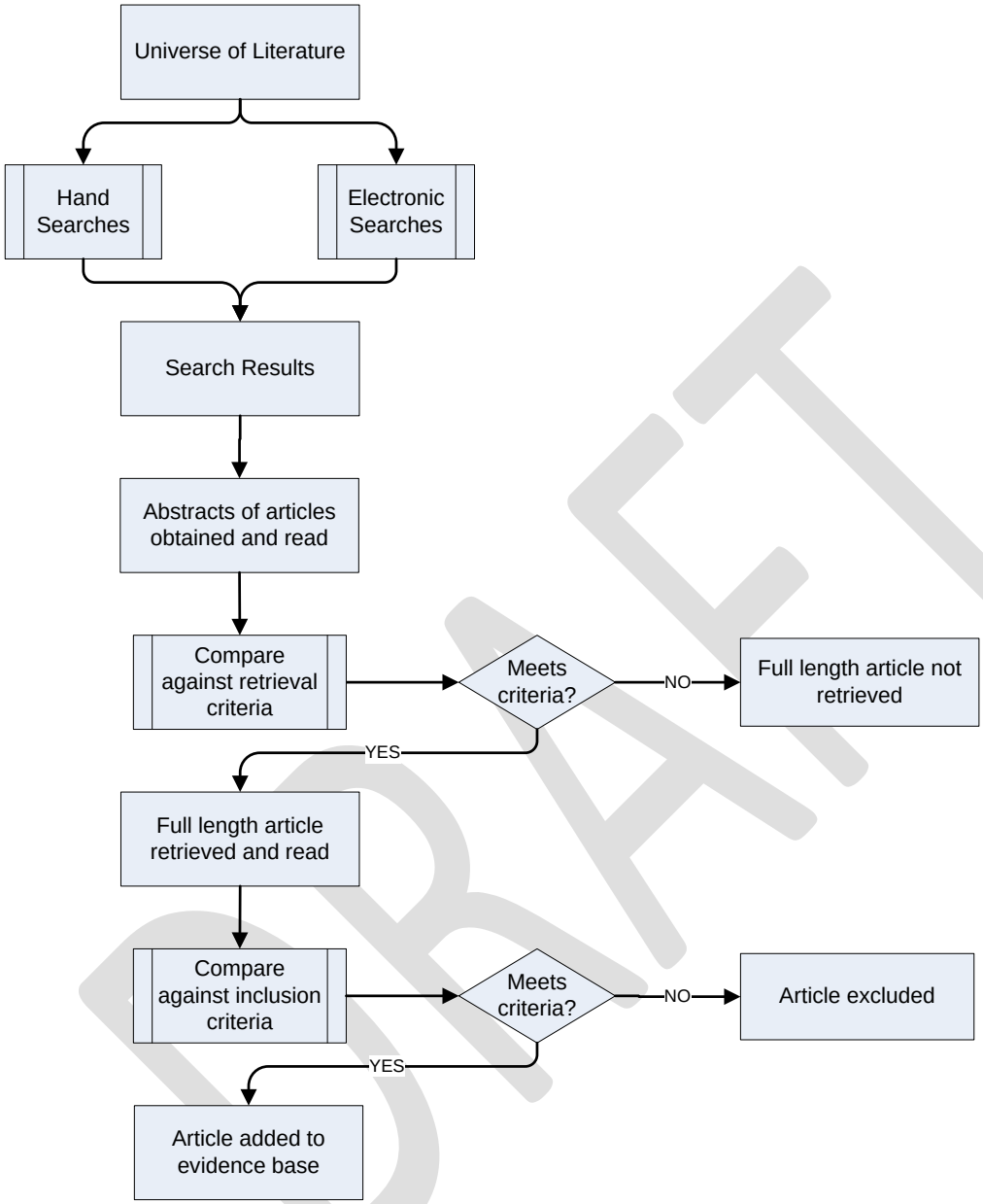
Key Question 2: Do musculoskeletal disorders of the foot, ankle, or knee (specifically plantar fasciitis, tarsal tunnel syndrome, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

Key Question 3: Does reduced limb mobility and/or control resulting from spinal cord injury increase crash risk and/or affect driving ability?

Identification of Evidence Bases

The individual evidence bases for each of the three key questions addressed in this evidence report were identified using the multistage process captured by the algorithm presented in Figure 2. The first stage of this process consists of a comprehensive search of the literature. The second stage of the process consists of the examination of abstracts of identified studies in order to determine which articles will be retrieved. The final stage of the process consists of the selection of the actual articles that will be included in the evidence base.

Figure 2. Evidence Base Identification Algorithm



Searches

One characteristic of a good evidence report is a systematic and comprehensive search for information. Such searches distinguish systematic reviews from traditional literature reviews, which use a less rigorous approach to identifying and obtaining literature, thereby allowing a reviewer to include only articles that agree with a particular perspective and to ignore articles that do not. Our approach precludes this potential reviewer bias, because we obtain and include articles according to explicitly determined *a priori* criteria. Full details of the search strategies used in this report are presented in Appendix A.

Electronic Searches

We performed comprehensive searches of the electronic databases listed in Table 10.

Table 10. Electronic Databases Searched

Name of Database	Date Limits	Platform/Provider
The Cochrane Central Register of Controlled Trials (CENTRAL)	through 2009 Issue 1	www.thecochranelibrary.com
The Cochrane Database of Methodology Reviews (Methodology Reviews)	through 2009 Issue 1	www.thecochranelibrary.com
The Cochrane Database of Systematic Reviews (Cochrane Reviews)	through 2009 Issue 1	www.thecochranelibrary.com
Database of Abstracts of Reviews of Effects (DARE)	through 2009 Issue 1	www.thecochranelibrary.com
EMBASE (Excerpta Medica)	1980 through March 14, 2009	OVID
Health Technology Assessment (HTA) Database	through 2009 Issue 1	www.thecochranelibrary.com
Healthcare Standards	Searched January 7, 2009	ECRI Institute
International Health Technology Assessment (IHTA)	Searched January 7, 2009	ECRI Institute
MEDLINE	1950 through March 14, 2009	OVID
National Guideline Clearinghouse™ (NGC)	Searched March 10, 2009	www.ngc.gov
NHS Economic Evaluation Database (NHS EED)	through 2009 Issue 1	www.thecochranelibrary.com
PubMed (PreMEDLINE)	Searched March 14, 2009	www.pubmed.gov
TRIS Online (Transportation Research Information Service Database)	Searched March 10, 2009	http://ntlsearch.bts.gov/tris/index.do

Manual Searches

We reviewed journals and supplements maintained in ECRI Institute's collections of more than 1,000 periodicals. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. In addition, we examined the reference lists of all obtained articles with the aim of identifying relevant reports not identified by our electronic searches. In order to retrieve additional relevant information, we also performed hand searches of the "gray literature." Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. The latter documents do not appear in the peer-reviewed journal literature.

Retrieval Criteria

Retrieval criteria were used to determine whether a full-length version of an article identified by our searches should be ordered. Decisions pertaining to whether a full-length article should be retrieved are usually based on a review of available abstracts. For this project, retrieval criteria were determined *a priori* in conjunction with the FMCSA. The retrieval criteria are presented in Appendix B.

If an article did not meet the retrieval criteria for this evidence report, the full-length version of the article was not obtained. If it was unclear whether a potentially relevant article met our retrieval criteria (e.g., no abstract was available for evaluation), the full-length version of that article was to be obtained.

Inclusion and Exclusion Criteria

Each retrieved article was read in full by an ECRI Institute analyst who determined whether that article met a set of predetermined, question-specific, inclusion criteria. As was the case for the retrieval criteria, the inclusion criteria for this evidence report were determined *a priori* in conjunction with the FMCSA. These inclusion and exclusion criteria are presented in Appendix C.

If an article did not to meet the question-specific inclusion criteria listed in Appendix C, the article was excluded from the analysis. Each excluded article, along with the reason(s) for its exclusion, are presented in Appendix D.

Evaluation of Quality and Strength of Evidence

Rather than focus on the quality of the individual studies that comprise an evidence base, our approach to assessing the quality of evidence focused on the overall *body* of the available evidence that was used to draw an evidence-based conclusion.(68) Using this approach, which is described briefly in Appendix E, we took into account not only the quality of the individual studies that comprise the evidence base for each key question, but we also considered the interplay between the quality, quantity, robustness, and consistency of the overall body of evidence.

Our approach to assessing the strength of the body of evidence makes a clear distinction between a qualitative conclusion (e.g., “Individuals with musculoskeletal disorders are at increased risk for a motor vehicle crash”) and a quantitative conclusion (e.g., “When compared to individuals who do not have musculoskeletal disorders, the risk ratio for a motor vehicle crash among individuals with the disorder is 1.37; 95% CI: 1.03 to 1.74; P <0.005.”). As shown in Table 11, we assigned a separate strength-of-evidence rating to each type of conclusion. Evidence underpinning a qualitative conclusion was rated according to its strength, and evidence underpinning a quantitative conclusion was rated according to the stability of the effect-size estimate that was calculated.

Table 11. 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.

The definitions presented in the table above are intuitive. Qualitative conclusions that are supported by strong evidence are less likely to be overturned by the publication of new data than conclusions supported by weak evidence. Likewise, quantitative effect-size estimates that deemed to be stable are more unlikely to change significantly with the publication of new data than are unstable effect-size estimates.

Statistical Methods

The set of analytic techniques used in this report was extensive. In summary, random- and fixed-effects meta-analyses were used to pool data from different studies.(69-78) Important differences in the findings of different studies (heterogeneity) were identified using I^2.(74,79-84) Whenever appropriate, heterogeneity was explored using meta-regression techniques.(85-87) Sensitivity analyses, aimed at testing the robustness of our findings, were performed using cumulative random-effects meta-analyses.(88-94) If a meta-analysis had 10 or more studies, the presence of publication bias was tested for using the "trim and fill" method.(95) All meta-analyses in this evidence report were performed using Comprehensive Meta-Analysis software.(96-98)

We calculated several different estimates of effect. The choice of effect-size estimate depended on the purpose of the studies we assessed, their design, and whether reported outcome data were continuous or dichotomous. Between-group differences in outcome measured using continuous data were analyzed in their original metric (if all included studies reported on the same outcome using the same metric), or the data were standardized into a common metric known as the standardized mean difference (SMD). Dichotomous data were analyzed using the rate ratio (RR) or the odds ratio (OR). Time-to-event data were analyzed using the hazard ratio (HR). The formulae for these effect sizes and their variance are

presented in Table 12. If means and standard deviations were not available for continuous data, every effort was made to determine an estimate of treatment effect from reported statistics (e.g., t-values, f-values) or from p-values using methods described in detail elsewhere.(99)

Table 12. Effect-size Estimates Used in Evidence Report and their Variance

Effect Size	Formula (Effect Size)	Formula (Variance)
WMD	$\mu_{TG} - \mu_{CG}$	$\left(\sqrt{\frac{(n_{TG}-1)(s_{TG})^2+(n_{CG}-1)(s_{CG})^2}{n_{TG}+n_{CG}-2}}\right)\left(\frac{1}{n_{TG}}+\frac{1}{n_{cg}}\right)$
SMD	$\frac{\mu_{TG}-\mu_{CG}}{\left(\sqrt{\frac{(n_{TG}-1)(s_{TG})^2+(n_{CG}-1)(s_{CG})^2}{n_{TG}+n_{CG}-2}}\right)}$	$\frac{n_{TG}+n_{CG}}{n_{TG}n_{CG}}+\frac{SMD^2}{2(n_{TG}+n_{CG})}$
Where: μ_{TG} = mean (treatment group); μ_{CG} = mean (control group); S_{TG} = standard deviation (treatment group); S_{CG} = standard deviation (control group); n_{TG} = enrollees (treatment group); n_{CG} = enrollees (control group)		
Event Rate	$a/a+b$	$\ln\left[\frac{1}{a}+\frac{1}{a+b}\right]$
Where: a = number of individuals in cohort experiencing an event; b = number of individuals in cohort who did not experience an event		
RR (incidence)	$\left(\frac{a_{msd}}{pt_{msd}}\right) \Big/ \left(\frac{b_{control}}{pt_{control}}\right)$	$\ln\left[\frac{1}{a_{msd}}+\frac{1}{b_{control}}\right]$
Where: a = number of individuals with musculoskeletal disorders who crashed; pt_{msd} = rate denominator (musculoskeletal disorder group); b = number of individuals without musculoskeletal disorders who crashed; $pt_{control}$ = rate denominator (control group)		
OR	$\left(\frac{a}{b}\right) \Big/ \left(\frac{c}{d}\right) = \left(\frac{ad}{bc}\right)$	$\frac{1}{a}+\frac{1}{b}+\frac{1}{c}+\frac{1}{d}$
RR	$\left(\frac{a}{a+c}\right) \Big/ \left(\frac{b}{b+d}\right)$	$\frac{1}{a}+\frac{1}{a+c}+\frac{1}{b}+\frac{1}{b+d}$
Where: a = number of individuals with musculoskeletal disorders who crashed; b = number of individuals without musculoskeletal disorders who crashed; c = number of individuals with musculoskeletal disorders who did not crash; d = number of individuals without musculoskeletal disorders who did not crash.		
HR	$\frac{O_{pi}/E_{pi}}{O_{ci}/E_{ci}}$	$\exp\left(\ln\left[\frac{1}{E_{pi}}+\frac{1}{E_{ci}}\right]\right)$
Where O_{pi} = observed number of events in treatment group; O_{ci} = observed number of events in control group; E_{pi} = logrank expected number of events in treatment group; E_{ci} = logrank expected number of events in control group		

HR = Hazard ratio; OR = Odds ratio; RR = Rate ratio; SMD = Standardized mean difference; WMD = Weighted mean difference

Evidence Synthesis

This section summarizes the findings of our systematic review of the evidence pertaining to each of the key questions asked by the FMCSA.

Key Question 1: Do musculoskeletal disorders of the hand, wrist, elbow, or shoulder (specifically carpal tunnel syndrome, cubital tunnel syndrome, radial tunnel syndrome, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

Musculoskeletal disorders of the upper extremities are a concern to those responsible for road safety as physical/structural changes present in the conditions may culminate in problems in mechanical function which can contribute to the potential for crash, injury, and death. These mechanical problems may include difficulty in gripping the steering wheel, mirror adjustment, use of gears, and steering/cornering due to pain or weakness in the hands or upper limbs. For CMV drivers, musculoskeletal disorders of the upper extremities may also affect the ability to lift cargo and to secure loads in the vehicle. Jensen et al.(26) assessed the risks of hospitalization for musculoskeletal disorders among long- haul truck drivers and other truck drivers in Denmark. They reported higher relative risk rates of hospitalization (standardized hospital treatment ratio) for heavy road vehicle professional drivers with upper limb disorders, including mononeuropathies of the upper limb, carpal tunnel syndrome, synovitis and bursitis, and olecranon bursitis compared to the general population.(26) Therefore, continued CMV driving ability could potentially be affected by these disorders.

In this section we attempted to review evidence pertaining to the crash risk and/or effect on driving ability associated with selected musculoskeletal disorders of the hand, wrist, elbow, or shoulder. The purpose of this review is to determine whether any of these disorders poses a risk to road safety inasmuch as they may impact the ability to perform the functions required to operate a CMV.

Identification of Evidence Base

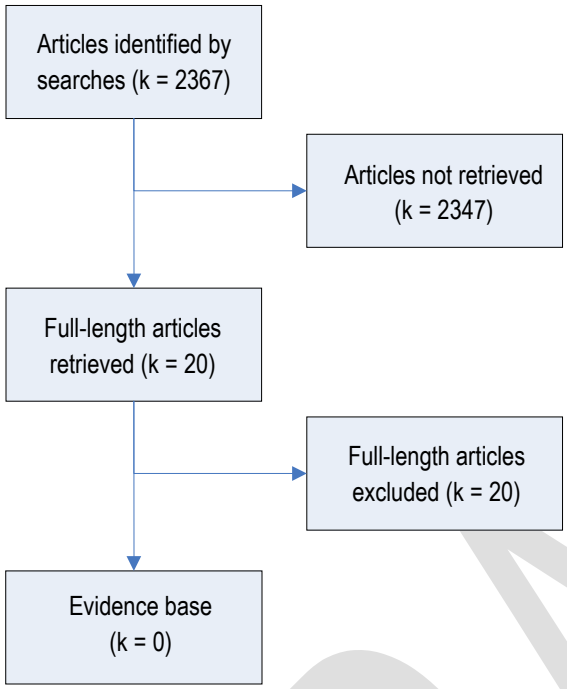
To meet the aims of this section of the evidence report, we searched for trials that compared crash risk or driving ability among individuals with musculoskeletal disorders of the upper extremities and otherwise comparable individuals without these disorders. In addition, we looked for studies that compared the prevalence of these disorders among cohorts of individuals who had or had not experienced a crash or among individuals who had or had not scored poorly on road tests, simulated driving, or functional tests.

The evidence-base identification pathway for Key Question 1 is summarized in Figure 3. Our searches[2] identified a total of 2367 articles that appeared relevant to this key question. Following application of the retrieval criteria for this question, 20 full-length articles were retrieved and read in full. None of

[2] See Appendix A for search strategies

these 20 retrieved articles were ultimately found to meet the inclusion criteria[3] for Key Question 1. Table D-1 of Appendix D lists the 20 articles that were retrieved, read in full, and then excluded.

Figure 3. Development of Evidence Base for Key Question 1



Although no study met our inclusion criteria, two excluded studies are worthy of discussion. Both studies presented epidemiological information concerning musculoskeletal disorders in CMV driver populations.

The large population study of hospitalization rates for long-haul and other truck drivers with various musculoskeletal disorders in Denmark has been summarized in Table 2 in the Background section. Hospitalization rates for carpal tunnel syndrome and elbow bursitis were significantly higher among long-haul truckers than the expected rates in the general population.(26) This study did not meet our inclusion criteria for this question because it did not report any relevant driving outcomes among truck drivers with musculoskeletal disorders. Hospital treatment indicates that the symptoms were bothersome, and lends plausibility to the notion that these disorders might influence driving ability. However, this is insufficient to infer that the symptoms actually have a negative impact on driving ability.

Another study surveyed 481 bus drivers in Hong Kong to determine rates of musculoskeletal disorders in that population. The study did not provide rates for specific musculoskeletal disorders, only by

[3] See Appendix C for inclusion criteria

groupings based on anatomical discomfort. The only upper extremity area addressed in the survey is the shoulder. The study did not meet the inclusion criteria for this question in part because of the lack of description of specific musculoskeletal disorders, but even more importantly because of the lack of relevant driving outcomes. A percentage of patients (16.7%) reported that work performance was affected by shoulder discomfort, but no description was provided of how the work performance was affected.(100)

Section Summary

There is insufficient evidence to determine whether any musculoskeletal disorders of the upper extremities assessed in this report increase crash risk and/or decrease driving performance.

Our searches did not identify any studies providing crash or driving performance data addressing Key Question 1. One excluded study reported that rates of hospital treatment for carpal tunnel syndrome and elbow bursitis among long-haul truck drivers were significantly higher than the expected rates in the general population.(26) *However, hospital treatment is insufficient to infer that these disorders affected the ability to drive safely. Another excluded study reported the percentage of urban bus drivers whose work performance was affected by discomfort in the shoulder area.(100) However, the data presented did not specify how work performance was affected or the type of disorder and thus did not meet the inclusion criteria for this question.*

Key Question 2: Do musculoskeletal disorders of the foot, ankle, or knee (specifically plantar fasciitis, tarsal tunnel syndrome, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

Musculoskeletal disorders of the lower extremities are a concern to those responsible for road safety as physical/structural changes present in the conditions may culminate in problems in mechanical function which can contribute to the potential for crash, injury, and death. These mechanical problems may include difficulty in braking and accelerating, affecting the ability to safely operate the vehicle. The potential effects of musculoskeletal disorders of the lower extremities in truck drivers also include driver's ability to jump from cab or trailer level (risky activities that can result in the onset of these disorders in the lower extremities due to high forces required). Jensen et al.'s study of truck drivers in Denmark found a significantly higher relative risk of hospitalization with prepatellar (knee) bursitis among long-haul truck drivers compared to the general population.(26)

In this section we attempted to review evidence pertaining to the crash risk and/or effect on driving ability associated with selected musculoskeletal disorders of the foot, ankle, or knee. The purpose of this review is to determine whether any of these disorders poses a risk to road safety among CMV drivers.

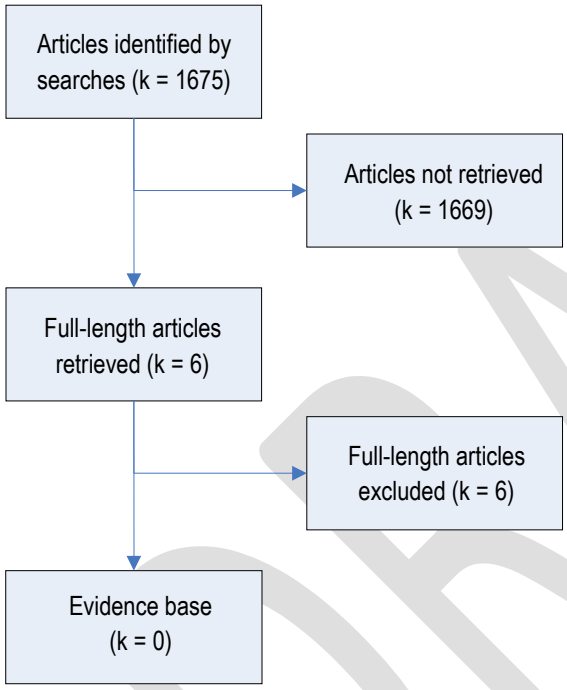
Identification of Evidence Base

We searched for trials that compared crash risk or driving performance among individuals who had musculoskeletal disorders of the lower extremities with otherwise comparable individuals who did not have these disorders. In addition, we looked for studies that compared the prevalence of these

disorders among cohorts of individuals who had or had not experienced a crash or those who had or had not scored poorly of road tests, simulated driving, or driving-related functional tests.

The evidence base identification pathway for Key Question 2 is summarized in Figure 4. Our searches (Appendix A) identified a total of 1675 articles that appeared relevant to this key question. Following application of a set of retrieval criteria (Appendix B), 5 full-length articles were retrieved and read in full. Of these 5 retrieved articles, none were found to meet the inclusion criteria for Key Question 2 (Appendix C). Table D-2 of Appendix D lists the 6 articles that were retrieved but then excluded from the evidence base for Key Question 2, along with the reason for their exclusion.

Figure 4. Development of Evidence Base for Key Question 2



As in Key Question 1, no study met our inclusion criteria for key question 2. However, the same two excluded studies that were discussed under key question 1 are worthy of discussion here as well.

Jensen et al.'s study of hospitalization rates for long-haul and other truck drivers with various musculoskeletal disorders in Denmark has been summarized in Table 2 in the Background section. The hospitalization rate for kneecap bursitis was significantly higher among long-haul truckers than the expected rate in the general population.(26) This study did not meet our inclusion criteria for this question because it did not report any relevant driving outcomes among truck drivers with musculoskeletal disorders. Again, hospital treatment for symptoms of a disorder does not allow sufficient inference regarding the effect of those symptoms on driving ability.

Szeto and Lam surveyed bus drivers in Hong Kong to determine rates of musculoskeletal disorders in that population. As noted earlier, the study did not provide rates for specific musculoskeletal disorders, only for discomfort in specific anatomical areas. The only lower extremity area evaluated in the survey is the thigh/knee (combined). The study did not meet the inclusion criteria for this question in part because of the lack of description of specific musculoskeletal disorders, but mainly due to the lack of relevant driving outcomes. A percentage of patients (16.3%) reported that work performance was affected by thigh or knee discomfort, but no description was provided of how the work performance was affected.(100)

Section Summary

There is insufficient evidence to determine whether any musculoskeletal disorders of the lower extremities assessed in this report increase crash risk and/or decrease driving performance.

Our searches identified no relevant articles that addressed this question. One excluded study reported that the rate of hospital treatment for kneecap bursitis among long-haul truck drivers was significantly higher than the expected rate in the general population.(26) *However, hospital treatment is insufficient to infer that these disorders affected the ability to drive safely. Another excluded study reported the percentage of urban bus drivers whose work performance was affected by discomfort in the thigh/knee area.(100) The data presented did not specify how work performance was affected or the type of disorder and thus did not meet the inclusion criteria for this question.*

Key Question 3: Does reduced limb mobility and/or control resulting from spinal cord injury increase crash risk and/or affect driving ability?

SCI is a condition usually associated with permanent disability and substantial neurologic deficits.(58) The two major types of SCI include paraplegia (which affects lower limb function) and tetraplegia (which affects upper and lower limb function). The majority of SCIs are traumatic, most commonly caused by motor vehicle crash.(52) SCI impairs normal driving ability as a result of reduced limb mobility or control. However, the use of adaptive equipment and vehicle modifications (e.g., hand and foot controls) permits driving for certain individuals with SCI. Based upon the adaptation required, SCI licensed drivers (non-CMV) may also be granted restricted licenses.(101) A patient's driving ability is strongly influenced by SCI level and age as reported in a recent study of non-CMV drivers with SCI. For individuals with SCI, it is possible for new patients with injury below C4 level to receive a learner's license for lessons in adapted vehicle-independent driving contingent upon medical provider recommendation.(102) Studies of driving performance for SCI drivers have reported conflicting findings regarding the highest vertebral level of injury permitting functional driving. One study reported that functional driving was possible for injury levels as high as C5,(103) while another study reported that the highest neurological level for independent driving was C6, specifically C6A (weak wrist extension).(104)

Identification of Evidence Base

We searched for trials that compared crash risk or driving performance (on-road or simulated) between individuals with SCI (paraplegia or tetraplegia) and able-bodied individuals. We also searched for studies

that compared the prevalence of SCI among drivers who had or had not crashed or those who had or had not scored poorly on driving performance tests. Presently, there is no evidence from our searches of crash rates or driving performance rates in device-adapted CMV use for this driving population.

The evidence identification pathway for Key Question 3 is presented in Figure 5. Our searches identified a total of 885 articles that appeared relevant to Key Question 3. Twenty-two articles were retrieved and read in full. Of these 22 articles, three were found to meet the inclusion criteria for this question. These three included studies are listed in Table 13. Details of the 19 retrieved articles that did not meet our inclusion criteria are presented in Table D- 3 of Appendix D, along with the reasons for their exclusion.

Figure 5. Evidence Base Development Process

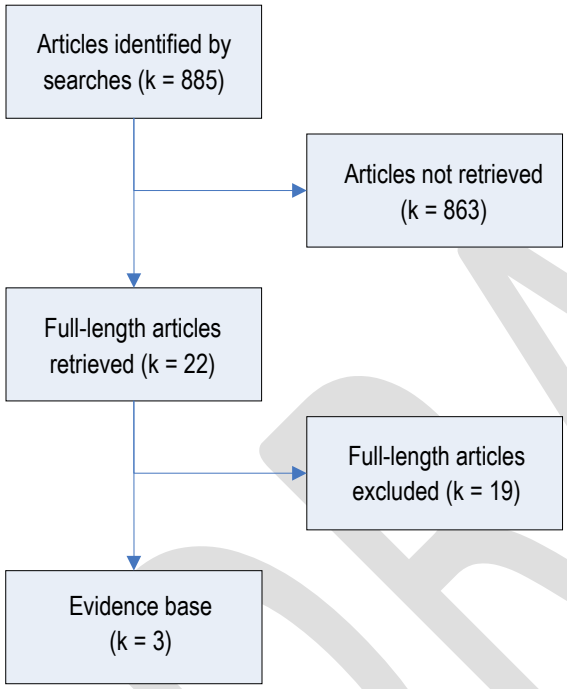


Table 13. Evidence Base

Primary Reference	Year	Study Location	Country
Studies that Examined Driving Performance			
Ku et al.(105)	2002	Seoul	Korea
Peters(103)	2001	Linkoping	Sweden
Sivak et al.(106)	1981	Ann Arbor, Michigan	USA

Evidence Base

The key attributes of the three studies that met the inclusion criteria for this key question are summarized in Table 14. None of the included studies directly examined the association between SCI and crash risk in any driver population. Consequently, the available evidence will only allow an assessment of whether individuals with SCI have impaired driving performance as measured by simulators or on-road tests.

Of the three included studies, one study(105) focused on the impact of thoracic and lumbar SCI on driving, which included the impact of the injury on one's ability to use adapted hand controls for braking and accelerating. Another study(103) examined the impact of tetraplegia resulting from SCI on driving performance and workload. Similar to Ku et al.,(105) this cohort study assessed the impact of tetraplegia on one's ability to use adapted hand controls for braking and accelerating. Both of these studies evaluated performance on driving simulators. The remaining study (Sivak et al.) did not report the type of SCI of their enrollees, and this was the only study that evaluated driving performance in an adapted vehicle (closed course and open road driving).(106)

Table 14. Key Study Design Characteristics of Studies that Address Key Question 3

Reference	Year	Study Design	Comparison	Factors Controlled For	Primary Outcome	Comorbidities	Adapted Device Used	Outcomes Self-reported
Spinal Cord Injury and Driving Ability/Performance								
Ku et al.(105)	2002	Cohort	Patients(TLCI) vs. normal drivers	NR	Driving performance (simulated)	NR	Hand controls for braking and accelerating	No
Peters(103)	2001	Cohort	Tetraplegia vs. able-bodied drivers	NR	Driving performance (simulated)	NR	Two hand controls for braking and accelerating	No
Sivak et al.(106)	1981	Cohort	Spinal cord injury (undefined) vs. able-bodied drivers	NR	Driving performance (closed and open road driving)	NR	Hand controls for braking and accelerating and (if desired) a steering knob	No

NR: Not reported
TLCI: Thoracic or Lumbar Cord Injury

Quality of the Evidence Base

The results of our analysis of the overall quality of the evidence base for Key Question 3 are presented in Table 15. Our analysis using the Newcastle Ottawa Scale for Cohort Studies concluded that the quality of two included studies was moderate and the third was low. Although observational studies often statistically adjust for known confounding factors, only random allocation can control for unknown confounding; however, random allocation is not possible in this study design. Therefore, the quality rating of cohort studies can never be high. Although all studies were prospective, the study by Sivak et al. did not report the type of SCI in their patient population. Complete details of our quality assessment can be found in Appendix G.

Table 15. Quality of Included Studies

Reference	Year	Quality Scale Used	Quality
Spinal Cord Injury and Driving Ability/Performance			
Ku et al.(105)	2002	Revised Newcastle-Ottawa Quality Assessment Scale Cohort Studies	Moderate
Peters(103)	2001	Revised Newcastle-Ottawa Quality Assessment Scale Cohort Studies	Moderate
Sivak et al.(106)	1981	Revised Newcastle-Ottawa Quality Assessment Scale Cohort Studies	Low

Generalizability of Evidence Base to Target Population

The characteristics of the individuals enrolled in the three included studies are summarized in Table 16. The generalizability of the findings of these studies to CMV drivers is unclear. All studies included private motor vehicle license holders. Exposure to risk is lower among noncommercial vehicle drivers, because their driving exposure is lower than that of CMV drivers. In two studies more than 90% of enrollees were men, a percentage which is comparable to the percentage of men among CMV drivers; the remaining study had only 50% men. The ages of the private motor vehicle license holders included in these studies are likely to be slightly younger, on average, when compared to those of CMV drivers. It is unclear whether the ethnicity of the private motor vehicle license holders included in these studies is representative of CMV drivers due to lack of reporting.

Table 16. Individuals with Spinal Cord Injury Enrolled in Studies that Address Key Question 3

Reference	Year	N	SCI Type	Number Driving vs. Number Not Driving	Age Distribution	% Male	% CMV Drivers	Driving Exposure	Ethnicity	Generalizability to Target Population
Spinal Cord Injury and Driving Performance										
Ku et al.(105)	2002	25 (15 SCI, 10 controls)	Thoracic and lumbar cord injuries (paraplegia)	NR. All had prior driving experience	SCI: 20-29: n = 5 30-39: n = 2 40-49: n = 6 50-59: n = 2 Normal: Mean (SD): 31.4 (1.3)	96% overall SCI Group: 100% Normal Driver Group: 90%	0	SCI: NR** Normal Mean (SD): 8.9 (3.4)	NR	Unclear
Peters(103)	2001	52 (26 SCI, 26 controls)	Tetraplegia, C5-C7, complete and incomplete	NR	SCI: Median 36 (Range 22-60 years Able-bodied: Median 37 (Range 24-56)	SCI: 92.3* Able-bodied: 92.3*	0	SCI: 4-40 years (17 years median); 10,000-45,000 km (15,500 median)	NR	Unclear
Sivak et al.(106)	1981	18 (8 SCI, 10 controls)	NR	NR	SCI: Mean (SD): 27.5 (7.8) Range: 20-48 Able-bodied: Mean (SD): 24.2 (5.4) Range: 19-38	SCI: 50% Able-bodied: 60%	0	NR	NR	Unclear

* Calculated by ECRI Institute.
**Not reported though 12 out of 15 members of patient group had driving licenses.

SCI: Spinal Cord Injury
NR: Not Reported

Findings

All studies examined whether SCI affected the ability to carry out driving-related tasks. No studies directly examined whether SCI was associated with an increase in an individual's risk for a motor vehicle crash. Two studies evaluated performance on a driving simulator, while the remaining study evaluated performance during closed course and open road driving.

Indirect Evidence – Studies of Driving Performance (On Road or Simulated)

Table 17 shows results from one study(105) comparing the driving performance, i.e., driving speeds, between lumbar and thoracic SCI (paraplegic) patients (with adapted device) to normal drivers using a driving simulator. Eighteen sections were included in the simulator consisting of speed-limited road, straight road, curved road and left turn types. Driving section outcomes suggest that spinal injury group tend to practice careful driving. The average speeds (in road sections 1,2,3,4,8,10,12 and 13) for the patient group and the normal group were 45.6km/ hr and 61.2 km/hr, respectively ($p < 0.05$). This difference in performance outcomes may have resulted from the complexity of these road sections for the patient. However, this does not necessarily indicate that patients have a reduced ability to drive safely. Other driving skill measures, including steering stability, centerline violations, traffic signal violations, and driving time, showed no statistically significant difference between the patient and normal groups.

Table 17. Speed Assessment by Road Sections

Reference	Year	Speeds in Sections			
		Sections	Normal (n = 15) Mean (SD)	Patient (n = 10) Mean (SD)	P
Ku et al.(105)	2002	1 (road entrances)	36.8 (12.1)	22.6 (7.1)	0.005*
		2 (speed-limited road)	47.6 (13.7)	31.1 (11.5)	0.017*
		3 (sharp curves)	53.4 (9.9)	33.4 (16.5)	0.021*
		4 (sharp curves)	70.6 (9.6)	50.0 (20.4)	0.046*
		5**	57.0 (10.5)	52.5 (20.7)	0.652
		6**	85.0 (11.6)	62.3 (23.1)	0.052
		7**	58.8 (22.8)	46.8 (20.4)	0.285
		8**	57.6 (9.3)	52.8 (10.5)	0.213
		9**	52.2 (15.3)	39.9 (14.5)	0.123
		10 (left-turn sections)	44.2 (9.3)	26.4 (8.8)	0.001*
		11 (left-turn sections)	61.2 (5.6)	45.6 (13.6)	0.024*
		12 (left-turn sections)	30.8 (7.9)	21.8 (6.2)	0.017*
		13 (left-turn sections)	26.8 (7.8)	21.8 (6.7)	0.001*
		14**	52.2 (9.9)	51.8 (6.8)	0.184
		15**	52.6 (5.2)	52.8 (15.6)	0.978
		16**	63.0 (9.3)	48.8 (16.9)	0.095
		17**	71.2 (12.9)	58.1 (19.4)	0.181
		18**	31.8 (13.3)	22.0 (4.3)	0.019*

*p <0.05
** Road section was not defined in the article
SD: Standard Deviation

Table 18 shows the results from another study(103) comparing the driving performance (choice reaction braking task) between individuals with tetraplegia and able-bodied individuals on a driving simulator. The study found a statistically significant difference between tetraplegic drivers and able-bodied drivers [0.10 seconds, $F(1,50) = 6.53$, $p = 0.014$], indicating a slightly longer brake reaction time for tetraplegic drivers. In Table 19, only one statistically significant difference (dual lever sub-group: [$F(1,24) = 4.35$, $p = 0.048$]) resulted from comparisons of the single lever (combined lever hand controls for accelerating and braking) and dual lever (two separate lever hand controls for accelerating and braking) tetraplegia driver groups to coordinating control driver groups. Conversely, no statistically significant difference was found between single and dual-lever groups when compared by driver group.

Table 18. Choice Reaction Braking Task

Reference	Year	Choice Reaction Braking Task-Brake Reaction Times		
		Tetraplegic Drivers (n = 26)	Able-bodied Drivers (n = 26)	Findings Significant? (p <.05)
		Total Mean Reaction Time		
Peters et al.(103)	2001	0.90s	0.80s	Yes; F(1,24) = 4.35 p = 0.014

NS: Not significant
s: Seconds

Table 19. Brake Reaction Times by Lever

Reference	Year	Choice Reaction Braking Task-Brake Reaction Times by Lever Type			
		Lever Type	Tetraplegic Drivers (n = 26)	Able-bodied Drivers (n = 26)	Findings Significant? (p <.05)
		Mean Brake Reaction Times			
Peters et al.(103)	2001	Single	0.88	0.81	NS
		Dual	0.93	0.79	Yes; p = 0.048

NS: Not significant

Table 20 shows group means for six workload factors from the NASA-Raw Task Load Index (NASA-RTLX) scale: mental demand, physical demand, time pressure, performance, effort and frustration. The difference between tetraplegia and control groups' subjective estimates were only significant for time pressure[$F(1,24) = 4.35$, $p = 0.048$)] and effort workload tasks [$F(1,50) = 4.01$, $p = 0.050$)].

Table 20. Workload Factors

Reference	Year	NASA-RTLX Scale Group Averages		
		Tetraplegic Drivers (n = 26)	Able-bodied Drivers (n = 26)	Findings Significant? (p <.05)
Peters et al.(103)	2001	**Mental Demand**		
		39.0	42.0	NS
		Physical Demand		
		20.0	23.5	NS
		Time Pressure		
		27.5	16.0	p = 0.006
		Performance		
		67.0	70.5	NS
		Effort		
		53.0	41.0	p = 0.050
		Frustration		
		29.0	32.0	NS

NASA-RTLX: Nasa-Raw Task Load Index workload measurement scale
NS: Not Significant; author only indicates not significant, no p values or data provided for calculation

Sivak et al. was the only study that compared non-simulated (closed course and open road) driving performance in a specially-modified car for individuals with spinal cord injuries and able-bodied individuals. No statistically significant between-group differences were found for any driving performance measure on the closed course or open road. The findings for open-road driving appear in Table 21. The major limitation of this study is the failure to report the type of spinal cord injury experienced by the enrollees. Driving performance for individuals with paraplegia cannot be extrapolated to individuals with tetraplegia, because the latter have more extensive limitations in functional ability. Not knowing what type of injury these individuals had limits the ability to make inferences from the study's findings.

Table 21. Open-road Driving Performance

Reference	Year	Spinal Cord Injury Drivers (n = 8)	Able-bodied Drivers (n = 10)	Findings Significant? (p <.05)
Sivak et al.(106)	1981	**Observation on Turns**		
		100.0	100.0	NS
		Observation on Straight Portions		
		84.0 (18.4)	82.0 (26.3)	NS
		Path on Turns		
		88.8 (7.4)	90.7 (6.8)	NS
		Path on Straight Portions		
		98.6 (3.9)	97.5 (7.9)	NS
		Speed on Turns		
		100.0	96.9 (8.5)	NS

Reference	Year	Spinal Cord Injury Drivers (n = 8)	Able-bodied Drivers (n = 10)	Findings Significant? (p <.05)
		Speed on Straight Portions		
		92.5 (7.1)	86.7 (17.0)	NS
		Gap Acceptance		
		100.0	100.0	NS
		Limit Line Behavior		
		96.9 (8.8)	97.4 (5.5)	NS
		Composite Driving Index		
		95.1 (2.8)	93.9 (2.3)	NS

NS: Not statistically significant

Although these studies suggest that certain patients with SCI may have acceptable driving performance in adapted smaller vehicles, none of the studies tested driving performance in an adapted CMV. Driving a large truck would present greater challenges to an individual with SCI than driving a smaller vehicle. An additional consideration is the FMCSA regulation 9 CFR 392 (Inspection of cargo, cargo securement devices and systems)(http://www.fmcsa.dot.gov/rules-regulations/administration/fmcsr/fmcsrruletext.asp?reg=r49CFR392.9-a#r49CFR392.9-a). This regulation states that truck drivers must "Inspect the cargo and the devices used to secure the cargo within the first 50 miles after beginning a trip and cause any adjustments to be made to the cargo or load securement devices as necessary". It further states that reexamination and any necessary adjustments must occur when the truck has been driven for 3 hours or 150 miles, whichever comes first. If cargo adjustments are needed during a trip, a lone driver with SCI would be unable to perform this task. Driving an adapted vehicle with a partner might be a possible option for certain individuals with SCI and acceptable levels of functional ability to perform driving tasks. Alternatively, driving a sealed vehicle would not require inspection and adjustment during a trip and thus might be within the capability of certain individuals with SCI. However, there is no evidence to support or disprove this supposition.

Section Summary

Certain individuals with SCI appear to have adequate driving ability in specially-modified cars. Individuals with paraplegia are less likely to have limitations that decrease driving ability than individuals with tetraplegia. However, certain requirements that CMV drivers must meet (e.g., inspecting and adjusting loads during a long trip) would exceed the capabilities of a lone individual with SCI (the possible exception might be a sealed vehicle that did not require inspection during a trip). Driving a specially-modified CMV with a partner might be a possible option for certain individuals with enough functional ability to perform driving tasks.

Indirect Evidence-Studies of Driving Performance

Three studies evaluated driving performance (simulated or on-road) among non-CMV driver populations with SCI. Two moderate quality studies evaluated outcomes associated with simulated driving performance. One of these studies assessed driving performance outcomes for road sections on a driving

simulator. This study found that patients with thoracic or lumbar cord injuries (paraplegia) drove at significantly slower speeds than uninjured drivers in several sections of the simulated course. However, slower speed does not necessarily indicate a reduced ability to drive safely. In addition, no statistically significant between-group difference was observed for steering stability, centerline violations, traffic signal violations, and driving time. The other simulation study showed significantly slower brake reaction times and workload factors (time pressure, effort) among tetraplegic individuals compared to able-bodied individuals. Whether these statistically significant differences in simulated driving outcomes have any relationship to the ability to safely drive a motor vehicle remains uncertain. The remaining study found no statistically significant difference in driving performance measures during closed-course or open-road driving with a specially-modified car between individuals with SCI (type not reported) and able-bodied individuals. However, driving a large truck would require greater functional abilities than driving smaller vehicles. Whether the magnitude of difficulty of large truck driving would make the task impractical for individuals with SCI has not been addressed or discussed in the existing literature. The requirement to check and adjust loads during a long trip would be beyond the ability of a lone driver with SCI (the exception would be a sealed vehicle that did not require inspection during a trip). Driving a modified CMV with a partner might be a possible option to overcome this problem.

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Appendix A: Search Summaries

Search Summary for Key Questions 1 through 3

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

Electronic Database Searches

The following databases have been searched for relevant information:

Name of Database	Date Limits	Platform/Provider
The Cochrane Central Register of Controlled Trials (CENTRAL)	Through 2009 Issue 1	www.thecochranelibrary.com
The Cochrane Database of Methodology Reviews (Methodology Reviews)	Through 2009 Issue 1	www.thecochranelibrary.com
The Cochrane Database of Systematic Reviews (Cochrane Reviews)	Through 2009 Issue 1	www.thecochranelibrary.com
Database of Abstracts of Reviews of Effects (DARE)	Through 2009 Issue 1	www.thecochranelibrary.com
EMBASE (Excerpta Medica)	1980 through March 14, 2009	OVID
Health Technology Assessment (HTA) Database	Through 2009 Issue 1	www.thecochranelibrary.com
Healthcare Standards	Searched January 7, 2009	ECRI INSTITUTE
International Health Technology Assessment (IHTA)	Searched January 7, 2009	ECRI INSTITUTE
MEDLINE	1950 through March 14, 2009	OVID
NHS Economic Evaluation Database (NHS EED)	Through 2009 Issue 1	www.thecochranelibrary.com
PubMed (PreMEDLINE)	Searched March 14, 2009	www.pubmed.gov
TRIS Online (Transportation Research Information Service Database)	Searched March 10, 2009	http://ntlsearch.bts.gov/tris/index.do
U.S. National Guideline Clearinghouse™ (NGC)	Searched March 10, 2009	www.ngc.gov

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI Institute's collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature (gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature).

Search Strategies

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE and MEDLINE. A parallel strategy was used to search the databases comprising the Cochrane Library.

MeSH, EMTREE, and Keywords

Conventions:

OVID

$ = truncation character (wildcard)

exp = "explodes" controlled vocabulary term. (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)

.de. = limit controlled vocabulary heading

.fs. = floating subheading

.hw. = limit to heading word

.md. = type of methodology

.mp. = combined search fields (default if no fields are specified)

.pt. = publication type

.ti. = limit to title

.tw. = limit to title and abstract fields

PubMed

[mh] = MeSH heading

[majr] = MeSH heading designated as major topic

[pt] = publication type

[sb] = subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)

[sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)

[tiab] = keyword in title or abstract

[tw] = text word

Topic-specific Search Terms

Concept	Controlled Vocabulary	Keywords
Direct crash risk	Accident Accident prevention Accidents Accidents, occupational Accidents, traffic Highway safety Motor traffic accidents Occupational health Occupational safety Safety Traffic accident Traffic safety Transportation accidents	Accident$ Citation$ Collision$ Crash$ Ticket$ Wreck$

Concept	Controlled Vocabulary	Keywords
Driving	Automobile driver examination Automobile driving Car driving Driv$.hw. Driver license Driving ability Driving behavior Drivers	Driver$ Driving[ti] Drive Highway Licens$
Motor vehicles	Automobiles Motor vehicle Motor vehicles	Bus Buses Car Cars Haul Long distance Lorry Lorries Motor$ Semi-trailer$ Truck$1 Vehicle$
Cumulative trauma disorders	Exp cumulative trauma disorder/ Exp cumulative trauma disorders/	Cumulative trauma Nerve entrapment Occupation-related syndromes Overuse syndrome Repetitive motion Repetitive strain Work-related musculoskeletal disorders
Musculoskeletal disorders		Ankle$ Arm$ Digit$ Feet Finger$ Foot Hand$ Hip Injur$ Knee$ Leg$ Musculoskeletal disorder$ Shoulder$ Stenos$ Wrist$
Nerve entrapment		Elbow Entrap$ Median Radial Wrist

Concept	Controlled Vocabulary	Keywords
Paralysis	Paralysis Paraplegia Quadriplegia	Paraly$ Parapleg$ Quadripleg$
Specific musculoskeletal disorders	Bursitis Carpal tunnel syndrome Cubital tunnel syndrome Plantar fasciitis Tarsal tunnel syndrome Tennis elbow Tenosynovitis	Bursitis Carpal tunnel syndrome$ Cubital tunnel syndrome$ Epicondylitis De Quervain Golfer's elbow Plantar fasciitis Radial tunnel syndrome$ Tarsal tunnel syndrome$ Tendinitis Tendonitis Tennis elbow Tenosynovitis Tenovaginitis Trigger finger Trigger wrist
Spinal cord injury	Spinal cord injury	Spinal cord injur$

Key Question 1

EMBASE/MEDLINE
English language, human

Set Number	Concept	Search Statement	Number Identified
1	Musculoskeletal disorders - general	Exp cumulative trauma disorders/ or exp cumulative trauma disorder/ or cumulative trauma or work-related musculoskeletal disorder$ or occupation-related syndrome$	14,299
2	Musculoskeletal disorders – upper limb	(Carpal tunnel syndrome or cubital tunnel syndrome or tennis elbow or tendinitis or tenosynovitis or bursitis).de.	17,177
3		Carpal tunnel syndrome$ or cubital tunnel syndrome$ or radial tunnel syndrome$ or tendinitis or tendonitis or tenosynovitis or tenovaginitis or bursitis or epicondylitis or tennis elbow or golfer$ elbow or trigger wrist or trigger finger	20,974
4		((1 or (musculoskeletal and disorder$) or injur$ or stenos$) and (finger$ or digit$ or hand$ or wrist$ or elbow$ or arm$ or shoulder$))	80,184
5		De Quervain or DeQuervain	124
6		(median or ulnar) and entrap$ and (wrist$ or elbow$)	617
7	Combine sets	or/2-6	94,028
8	Limit by publication type	7 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.)	77,188
9	Limit by population	8 and (exp child/ or adolescent.de. or child$ or pediatr$ or paediatr$ or juvenile$ or adolescen$ or teen$ or youth$)	17,173
10		9 and adult	10,992
11		9 not 10	6181
12		8 not 11	71,007
13	accidents	12 and (accident or accidents or accidents, traffic or traffic accident or motor traffic accidents or accidents, occupational or accident prevention or occupational accident or transportation accidents).de.	2,870
14		12 and ((accident$ and (motor or traffic)) or collision$ or crash$ or wreck$ or citation$ or ticket$)	1,666
15	Driving	12 and (Automobiles or Motor vehicles or Motor vehicle or Automobile driving or Car driving or Driving ability or Driving behavior or Drivers).de.	245
16		12 and (driver$ or driving$ or drive or licens$ or highway$ or car or cars or motor$ or vehicle$ or semi-trailer$ or bus or buses or truck$1 or lorry or lorries or haul or (long adj distance)).ti.	1,047
17		12 and (Automobile driver examination or Licensure or Driver license or Safety or Traffic safety or Highway safety or Occupational safety or Occupational Health or Occupational disease).de.	1,985
18	Combine sets	or/13-17	5,835
19	Limit by study type	18 and ((Randomized controlled trials or random allocation or double-blind method or single-blind method or placebos or cross-over studies or crossover procedure or double blind procedure or single blind procedure or placebos or latin square design or crossover design or double-blind studies or single-blind studies or triple-blind studies or random assignment or exp controlled study/ or exp clinical trial/ or exp comparative study/ or cohort analysis or follow-up studies.de. or intermethod comparison or parallel design or control group or prospective study or retrospective study or case control study or major clinical study).de. or Case control studies/ or Cohort/ or Longitudinal studies/ or Evaluation studies/ or Follow-up studies/ or Prospective studies/ or Retrospective studies/ or Case control study/ or Cohort analysis/ or Longitudinal study/ or Follow up/ or Cohort analysis/ or Followup studies/ or random$.hw. or random$.ti. or placebo$.mp. or ((singl$ or doubl$ or tripl$ or trebl$) and (dummy or blind or sham or mask)).mp. or latin square.mp. or (time adj series) or (case adj (study or studies) or ISRCTN$.mp. or ACTRN$.mp. or (NCT$ not nctc$)))	2,656
20	Eliminate overlap	Remove duplicates from 15	**2,367**

Key Question 2

EMBASE/MEDLINE
English language, human

Set Number	Concept	Search Statement	Number Identified
1	Musculoskeletal disorders – general	Exp cumulative trauma disorders/ or exp cumulative trauma disorder/ or cumulative trauma or work-related musculoskeletal disorder$ or occupation-related syndrome$	14,299
2	Musculoskeletal disorders – lower limb	Tarsal tunnel syndrome.de. or plantar fasciitis or tarsal tunnel syndrome$	1,535
3		((1 or (musculoskeletal and disorder$) or injur$ or stenos$) and (toe$ or foot or feet or ankle$ or shin$ or hip$ or leg$ or knee$))	69,972
4	Combine sets	2 or 3	71,204
5	Limit by publication type	4 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.)	59,243
6	Limit by population	5 and (exp child/ or adolescent.de. or child$ or pediatr$ or paediatr$ or juvenile$ or adolescen$ or teen$ or youth$)	15,718
7		6 and adult	10,358
8		6 not 7	5,360
9		5 not 8	53,883
10	accidents	10 and (accident or accidents or accidents, traffic or traffic accident or motor traffic accidents or accidents, occupational or accident prevention or occupational accident or transportation accidents).de.	2,879
11		10 and ((accident$ and (motor or traffic)) or collision$ or crash$ or wreck$ or citation$ or ticket$)	2,332
12	Driving	10 and (Automobiles or Motor vehicles or Motor vehicle or Automobile driving or Car driving or Driving ability or Driving behavior or Drivers).de.	340
13		10 and (driver$ or driving$ or drive or licens$ or highway$ or car or cars or motor$ or vehicle$ or semi-trailer$ or bus or buses or truck$1 or lorry or lorries or haul or (long adj distance)).ti.	864
14		10 and (Automobile driver examination or Licensure or Driver license or Safety or Traffic safety or Highway safety or Occupational safety or Occupational Health or Occupational disease).de.	1,024
15	Combine sets	or/10-14	4,484
16	Limit by study type	14 and ((Randomized controlled trials or random allocation or double-blind method or single-blind method or placebos or cross-over studies or crossover procedure or double blind procedure or single blind procedure or placebos or latin square design or crossover design or double-blind studies or single-blind studies or triple-blind studies or random assignment or exp controlled study/ or exp clinical trial/ or exp comparative study/ or cohort analysis or follow-up studies.de. or intermethod comparison or parallel design or control group or prospective study or retrospective study or case control study or major clinical study).de. or Case control studies/ or Cohort/ or Longitudinal studies/ or Evaluation studies/ or Follow-up studies/ or Prospective studies/ or Retrospective studies/ or Case control study/ or Cohort analysis/ or Longitudinal study/ or Follow up/ or Cohort analysis/ or Follow up studies/ or random$.hw. or random$.ti. or placebo$.mp. or ((singl$ or doubl$ or tripl$ or trebl$) and (dummy or blind or sham or mask)).mp. or latin square.mp. or (time adj series) or (case adj (study or studies) or ISRCTN$.mp. or ACTRN$.mp. or (NCT$ not nctc$)))	1,899
17	Eliminate overlap	Remove duplicates from 15	**1,675**

Key Question 3

EMBASE/MEDLINE
English language, human

Set Number	Concept	Search Statement	Number Identified
1	Spinal injury	exp Spinal cord injury/ or spinal cord injur$ or SCI	45,974
2	Limit by publication type	1 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.)	37,510
3	Limit by population	2 and (exp child/ or adolescent.de. or child$ or pediatr$ or paediatr$ or juvenile$ or adolescen$ or teen$ or youth$)	6,678
4		3 and adult	4,796
5		3 not 4	1,882
6		3 not 5	35,628
7	accidents	6 and (accident or accidents or accidents, traffic or traffic accident or motor traffic accidents or accidents, occupational or accident prevention or occupational accident or transportation accidents).de.	730
8		6 and ((accident$ and (motor or traffic)) or collision$ or crash$ or wreck$ or citation$ or ticket$)	890
9	Driving	6 and (Automobiles or Motor vehicles or Motor vehicle or Automobile driving or Car driving or Driving ability or Driving behavior or Drivers).de.	68
10		6 and (driver$ or driving$ or drive or licens$ or highway$ or car or cars or motor$ or vehicle$ or semi-trailer$ or bus or buses or truck$1 or lorry or lorries or haul or (long adj distance)).ti.	679
11		6 and (Automobile driver examination or Licensure or Driver license or Safety or Traffic safety or Highway safety or Occupational safety or Occupational Health or Occupational disease).de.	206
12	Combine sets	or/7-11	1,822
13	Limit by study type	12 and ((Randomized controlled trials or random allocation or double-blind method or single-blind method or placebos or cross-over studies or crossover procedure or double blind procedure or single blind procedure or placebos or latin square design or crossover design or double-blind studies or single-blind studies or triple-blind studies or random assignment or exp controlled study/ or exp clinical trial/ or exp comparative study/ or cohort analysis or follow-up studies.de. or intermethod comparison or parallel design or control group or prospective study or retrospective study or case control study or major clinical study).de. or Case control studies/ or Cohort/ or Longitudinal studies/ or Evaluation studies/ or Follow-up studies/ or Prospective studies/ or Retrospective studies/ or Case control study/ or Cohort analysis/ or Longitudinal study/ or Follow up/ or Cohort analysis/ or Followup studies/ or random$.hw. or random$.ti. or placebo$.mp. or ((singl$ or doubl$ or tripl$ or trebl$) and (dummy or blind or sham or mask)).mp. or latin square.mp. or (time adj series) or (case adj (study or studies) or ISRCTN$.mp. or ACTRN$.mp. or (NCT$ not nctc$)))	843
14	Eliminate overlap	Remove duplicates from 15	**698**

EMBASE/MEDLINE

English language, human

Set Number	Concept	Search Statement	Number Identified
1	Spinal injury	(paraplegia or quadriplegia).de. or (parapleg$ or quadripleg$ or paraly$).ti.	49,804
2	Limit by publication type	1 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.)	37,862
3	Limit by population	2 and (exp child/ or adolescent.de. or child$ or pediatr$ or paediatr$ or juvenile$ or adolescen$ or teen$ or youth$)	8,220
4		3 and adult	4,149
5		3 not 4	4,071
6		3 not 5	33,791
7	accidents	6 and (accident or accidents or accidents, traffic or traffic accident or motor traffic accidents or accidents, occupational or accident prevention or occupational accident or transportation accidents).de.	417
8		6 and ((accident$ and (motor or traffic)) or collision$ or crash$ or wreck$ or citation$ or ticket$)	431
9	Driving	6 and (Automobiles or Motor vehicles or Motor vehicle or Automobile driving or Car driving or Driving ability or Driving behavior or Drivers).de.	47
10		6 and (driver$ or driving$ or drive or licens$ or highway$ or car or cars or motor$ or vehicle$ or semi-trailer$ or bus or buses or truck$1 or lorry or lorries or haul or (long adj distance)).ti.	691
11		6 and (Automobile driver examination or Licensure or Driver license or Safety or Traffic safety or Highway safety or Occupational safety or Occupational Health or Occupational disease).de.	110
12	Combine sets	or/7-11	1,318
13	Limit by study type	12 and ((Randomized controlled trials or random allocation or double-blind method or single-blind method or placebos or cross-over studies or crossover procedure or double blind procedure or single blind procedure or placebos or latin square design or crossover design or double-blind studies or single-blind studies or triple-blind studies or random assignment or exp controlled study/ or exp clinical trial/ or exp comparative study/ or cohort analysis or follow-up studies.de. or intermethod comparison or parallel design or control group or prospective study or retrospective study or case control study or major clinical study).de. or Case control studies/ or Cohort/ or Longitudinal studies/ or Evaluation studies/ or Follow-up studies/ or Prospective studies/ or Retrospective studies/ or Case control study/ or Cohort analysis/ or Longitudinal study/ or Follow up/ or Cohort analysis/ or Followup studies/ or random$.hw. or random$.ti. or placebo$.mp. or ((singl$ or doubl$ or tripl$ or trebl$) and (dummy or blind or sham or mask)).mp. or latin square.mp. or (time adj series) or (case adj (study or studies) or ISRCTN$.mp. or ACTRN$.mp. or (NCT$ not nctc$)))	448
14	Eliminate overlap	Remove duplicates from 15 Limited to human and english	**309** (**187** unique to this search – 3 downloaded)

Total Identified	Total Downloaded	Total Retrieved	Total Cited in Report	Total Included in Evidence Base
4,927 (includes overlap between sets of search results)	**564 (unique citations)**	**109**	**77**	**3**

145 cited (includes 68 citations retrieved for previous DOT task orders)

Appendix B: Retrieval Criteria

Appendix B will list the retrieval criteria for each key question. An example of a small set of retrieval criteria are presented below.

Retrieval Criteria for Key Question 1

- Article must have been published in the English language.
- Article must have enrolled 10 or more individuals.
- Article must describe a study that attempted to determine the risk for a motor vehicle crash associated with musculoskeletal disorders of the hand, wrist, elbow, or shoulder directly (crash data) or indirectly (road test, simulated driving, driver-related functional tasks).
- Article must describe a study that includes a comparison group comprised of comparable subjects without these disorders.

Retrieval Criteria for Key Question 2

- Article must have been published in the English language.
- Article must have enrolled 10 or more individuals.
- Article must describe a study that attempted to determine the risk for a motor vehicle crash associated with musculoskeletal disorders of the foot, ankle, or knee directly or indirectly (road test, simulated driving, driver-related functional tasks).
- Article must describe a study that includes a comparison group comprised of comparable subjects without these disorders.

Retrieval Criteria for Key Question 3

- Article must have been published in the English language.
- Article must have enrolled 10 or more individuals.
- Article must describe a study that attempted to determine the risk for a motor vehicle crash associated with spinal cord injury directly (crash data) or indirectly (road test, simulated driving, driver-related functional tasks).
- Article must describe a study that includes a comparison group comprised of comparable subjects without spinal cord injury.

Appendix C: Inclusion Criteria

Appendix C will list the inclusion criteria for each of the four key questions addressed in this evidence report.

Inclusion Criteria for Key Question 1

- Article must have been published in the English language.
- Article must be a full-length article. Abstracts and letters to the editor will not meet this inclusion criterion.
- Article must have enrolled 10 or more individuals (at least 5 per group in a controlled study).
- Article must have enrolled subjects aged ≥18 years.
- Studies must include individuals with musculoskeletal disorders of the hand, wrist, elbow, and shoulder.
- Article must describe a study that attempted to determine the risk for a motor vehicle crash associated with musculoskeletal disorders of the hand, wrist, elbow, or shoulder directly or indirectly (road test, simulated driving, or driver-related functional tasks).
- Article must describe a study that includes a comparison group comprised of comparable subjects without these disorders.
- Article must present data in a manner that will allow ECRI Institute to calculate (directly or through imputation) effect-size estimates and CIs.
- If the same study is reported in multiple publications, the most complete publication will be the primary reference. Data will be extracted so as to avoid double-counting individuals.

Inclusion Criteria for Key Question 2

- Article must have been published in the English language.
- Article must be a full-length article. Abstracts and letters to the editor will not meet this inclusion criterion.
- Article must have enrolled 10 or more individuals (at least 5 per group in a controlled study).
- Article must have enrolled subjects aged ≥18 years.
- Studies must include individuals with musculoskeletal disorders of the foot, ankle, or knee.
- Article must describe a study that attempted to directly determine the risk for a motor vehicle crash associated with musculoskeletal disorders of the foot, ankle, or knee directly or indirectly (road test, simulated driving, driver-related functional tasks).
- Article must describe a study that includes a comparison group comprised of comparable subjects without these disorders.

- Article must present data in a manner that will allow ECRI Institute to calculate (directly or through imputation) effect-size estimates and CIs.
- If the same study is reported in multiple publications, the most complete publication will be the primary reference. Data will be extracted so as to avoid double-counting individuals.

Inclusion Criteria for Key Question 3

- Article must have been published in the English language.
- Article must be a full-length article. Abstracts and letters to the editor will not meet this inclusion criterion.
- Studies must include individuals with spinal cord injuries.
- Article must have enrolled 10 or more individuals (at least 5 per group in a controlled study).
- Article must have enrolled subjects aged ≥18 years.
- Article must describe a study that attempted to determine the risk for a motor vehicle crash associated with spinal cord injury directly (crash data) or indirectly (road test, simulated driving, driver-related functional tasks).
- Article must describe a study that includes a comparison group comprised of comparable subjects without these disorders.
- Article must present data in a manner that will allow ECRI Institute to calculate (directly or through imputation) effect-size estimates and CIs.
- If the same study is reported in multiple publications, the most complete publication will be the primary reference. Data will be extracted so as to avoid double-counting individuals.

Appendix D: Excluded Articles

Table D-1. Key Question 1

Reference	Year	Reason for Exclusion
Jensen(26)	2008	No relevant outcome data
Palmer(107)	2008	No relevant outcome data
Miranda(108)	2007	No relevant outcome data
Szeto(100)	2007	No relevant outcome data
Kuijpers(109)	2006	No relevant outcome data
Acharya(110)	2005	Background
Lotters(111)	2005	No relevant outcome data
Kashima(112)	2003	No relevant outcome data
Costa(113)	2001	No relevant outcome data
Courtney(114)	2001	No relevant outcome data
Pascarelli(115)	2001	No relevant outcome data
Atroshi(116)	1998	No relevant outcome data; no comparison data
Fougeyrollas(117)	1998	No relevant outcome data
Mackinnon(118)	1997	Narrative review
Tanaka(119)	1995	No relevant outcome data
Levine(120)	1993	No relevant outcome data
Stock(121)	1991	No relevant outcome data
Gouvier(122)	1989	No relevant outcome data
Hedberg(123)	1989	No relevant outcome data; no specific musculoskeletal disorders discussed
Tanaka(124)	1988	No relevant outcome data

Table D-2. Key Question 2

Reference	Year	Reason for Exclusion
Jensen(26)	2008	No relevant outcome data
Szeto(100)	2007	No relevant outcome data
Lotters(111)	2005	No relevant outcome data
Tanaka(35)	2001	No relevant outcome data
de Zwart(125)	1997	No relevant outcome data
Hedberg(123)	1989	No relevant outcome data; no specific musculoskeletal disorders discussed

Table D- 3 Key Question 3

Reference	Year	Reason for Exclusion
Letts(126)	2007	No relevant outcome data
Biering-Sorenson(127)	2004	No relevant outcome data
Henriksson(128)	2004	No relevant outcome data; no separate spinal cord injury outcomes
Krause(129)	2004	No relevant outcome data
Bock(130)	2002	Narrative review
Kiyono(104)	2001	No comparison group
Taricco(131)	2000	No relevant outcome data
Noreau(132)	1999	No relevant outcome data
Peters(133)	1998	Only Abstract in English; Full article in Swedish
Krause(134)	1997	No relevant outcome data
Laaperi(135)	1997	No relevant outcome data
Orne(136)	1997	Unable to locate full article
Mizukami(137)	1995	No relevant outcome data
Taricco(138)	1992	No relevant outcome data
Siösteen(139)	1990	No relevant outcome data
Hedberg(123)	1989	No relevant outcome data; no specific musculoskeletal disorders discussed
Welch(140)	1986	No relevant outcome data
Jenik(141)	1982	No relevant outcome data
Richter(142)	1974	No relevant outcome data; no relevant comparison data

Appendix E: Determining the Stability and Strength of a Body of Evidence

As stated in the main text, ECRI Institute evidence reports differ substantially from other systematic reviews in that we provide two types of conclusion; qualitative conclusions and quantitative conclusions. In order to reach these conclusions we use an algorithm developed by ECRI Institute to guide the conduct and interpretation of the analyses performed during the development of this evidence report.(68) The algorithm, which is presented in Figure E-2 through Figure E-5, formalizes the process of systematic review by breaking the process down into several discrete steps. At each step, rules are applied that determine the next step in the systematic review process and ultimately to the stability and strength of evidence ratings that are allocated to our conclusions. Because the application of the rules governing each step in the algorithm (henceforth called a decision point) guide the conduct of the systematic review process and how its findings are interpreted, much time and effort was spent in ensuring that the rules and underlying assumptions for each decision point were reasonable.

The algorithm is comprised of three distinct sections: a *General* section, a *Quantitative* section, and a *Qualitative* section. The system employs 14 decision points (Table 22). Four of them are listed in the General section because they apply to both quantitative conclusions as well as qualitative conclusions. The other 10 apply specifically to either quantitative conclusions (Decision Points 5-9) or qualitative conclusions (Decision Points 10-14). The rest of this appendix defines these decision points and describes how we resolved them for this report. After these descriptions, the pathways for the full system appear in Figure E-2 through Figure E-5.

Note that we applied this system separately for each outcome of interest. This is because many aspects of the evidence (quality, consistency, etc.) can vary by outcome.

Table 22. Decision Points in the ECRI Institute System

Category	Decision Point
General	1) What is the quality of individual studies?
	2) What is the overall quality of evidence?
	3) Is a quantitative estimate potentially appropriate?
	4) Are data informative?
Quantitative	5) Are data quantitatively consistent (homogeneous)?
	6) Are findings stable (quantitatively robust)?
	7) Are there sufficient data to perform meta-regression?
	8) Does meta-regression explain heterogeneity?
	9) Is the meta-regression model robust?
Qualitative	10) Are data qualitatively robust?
	11) Is meta-analysis possible?
	12) Are data qualitatively consistent?
	13) Was at least one study a multicenter study?
	14) Is the magnitude of effect extremely large?

Decision Point 1: Acceptable Quality?

Decision Point 1 serves two purposes: (1) to assess the quality of each included study; (2) to provide a means of excluding studies that are so prone to bias that their reported results cannot be considered useful. To aid in assessing the quality of each of the studies included in this evidence report, we used two study quality assessment instruments. The choice of which instrument to use was based on the design of the study used to address the key questions of interest. In this evidence report we used a revised version of the Newcastle-Ottawa Quality Assessment Scale (for cohort studies).(143) This instrument is presented in Appendix F. To assess the quality of an individual study, we computed a normalized score so that a perfect study received a score of 10, a study for which the answers to all items was "No" received a score of 0, and a study for which the answers to all questions was "NR" was 2.5. Quality scores were converted to categories as shown in Table 11 (see Methods section of main document). The definitions for what constitutes low, moderate, or high quality evidence were determined *a priori* by a committee of four methodologists. Because the quality was determined separately for each outcome, a study that scored as high quality for one outcome might score as moderate or low quality for another outcome.

Decision Point 2: Determine Quality of Evidence Base

We classified the overall quality of each key question's specific evidence base into one of three distinct categories; high, moderate or low quality. Decisions about the quality of each evidence base were based on data obtained using the quality assessment instruments described above using the criteria presented in Table E-1.

Table E-1. Criteria Used to Categorize Quality of Evidence Base

Category	Median NOQAS Score (cohort)
High Quality	
Moderate Quality	≥8.0
Low Quality	<8.0

NOQAS: Newcastle-Ottawa quality assessment scale

Decision Point 3: Is a Quantitative Analysis Potentially Appropriate?

The answer to Decision Point 3 depends upon the adequacy of reporting in available studies as well as the number of available studies. In order to permit a quantitative estimate of an effect size for a given outcome, the data for that outcome must be reported in at least three studies in a manner that allows the data to be pooled in a meta-analysis. If less than three studies are available, no quantitative estimate is usually appropriate, regardless of reporting. Another situation that does not permit a quantitative estimate is when at least three studies are relevant to the general topic, but fewer than 75% of them reported the outcome and as well as sufficient information for determination of the effect size and its dispersion, either by direct reporting from the trial or calculations based on reported

information. If no quantitative estimate would be appropriate, then one moves directly to Decision Point 10 to determine whether the evidence supports a qualitative conclusion.

Decision Point 4: Are Data Informative?

When there are only a small number of patients in an evidence base, statistical tests generally do not perform well. Under such circumstances, statistics cannot determine whether a true difference exists between treatments. This means that no clear conclusion can be drawn. For this decision point, we determined whether the precision of an evidence base was sufficient to permit a conclusion. Statistically significant results are informative because they mean that a treatment effect may exist. Statistically non-significant results are also potentially informative, but only if they exclude the possibility that a clinically significant treatment effect exists.

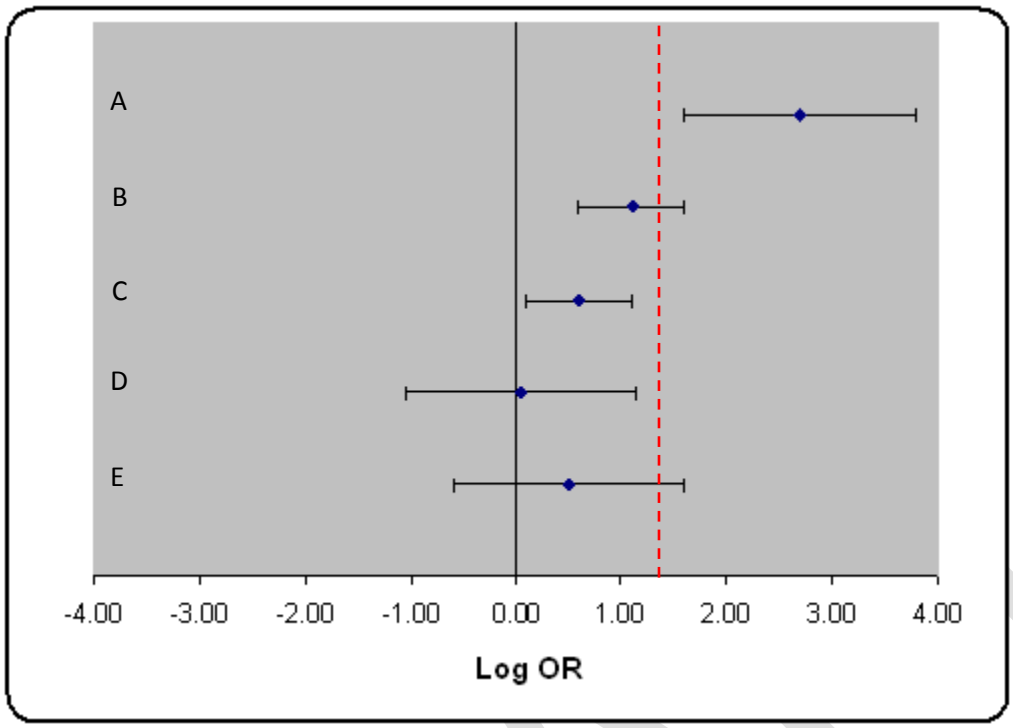
When a meta-analysis is performed, a key concern is the confidence interval around the random-effects summary statistic. If this interval is so wide that it is includes a clinically significant (or substantial) effect in one direction *and also an effect in the opposite direction*, then the evidence is inconclusive, and therefore uninformative.(144)

Thus, when considering the summary effect size from a meta-analysis (or the effect size from a single study), there are three ways in which the effect can be "informative":

1. The effect size is statistically significantly different from 0. This would be indicated whenever the confidence interval does not overlap 0.
2. The confidence interval is narrow enough to exclude the possibility that a *clinically significant difference* exists.
3. The confidence interval is narrow enough to exclude the possibility that a *substantial difference* exists. This possibility is included to address situations when even a very small effect can be considered "clinically significant" (e.g., a difference in mortality rates), but the effect may not be "substantial".

Consider Figure E-1. Four of the findings in this figure are informative (A to D). Only finding E is non-informative.

Figure E-1. Informative Findings



Dashed Line = Threshold for a clinically significant difference.

Finding A shows that the treatment effect is statistically significant and clinically important. Finding B shows that the treatment effect is statistically significant but it is unclear whether this treatment effect is clinically important. Finding C shows that the treatment effect is statistically significant but that the treatment effect is too small to be considered clinically important. Finding D shows that it is unclear whether there is a statistically important treatment effect, but regardless, this treatment effect is not clinically important. Finding E shows that it is unclear whether there is a statistically important treatment effect and it is also unclear whether the treatment effect is clinically important. This latter finding is thus non-informative.

Note that when the evidence base consists of one or two studies, and the only usable data from one study consists of a p-value that was calculated using the wrong statistical test, then the data cannot generally be considered "informative." If, however, the study reported sufficient information for one to perform the correct test, then informativeness can be determined.

Decision Point 5: Are Data Quantitatively Consistent (Homogeneous)?

This decision point was used only when the answer to Decision Point 3 was affirmative and a quantitative analysis was performed. Quantitative consistency refers to the extent to which the quantitative results of different studies are in agreement. The more consistent the evidence, the more precise a summary estimate of treatment effect derived from an evidence base will be. Quantitative

consistency refers to consistency tested in a meta-analysis using a test of homogeneity. For this evidence report we used Higgins and Thompson's I^2 statistic.(81) By convention, we considered an evidence base as being quantitatively consistent when I^2 <50%.

If the findings of the studies included were homogeneous (I^2 <50%), we obtained a summary effect size estimate by pooling the results of these studies using random-effects meta-analysis (REMA). If the findings were not homogeneous, we moved on to Decision Point 7 (exploration of heterogeneity, if ≥10 studies) or Decision Point 9 (qualitative analysis).

Decision Point 6: Are Findings Stable (Quantitatively Robust)?

If the findings of the random-effects meta-analysis were found to be homogeneous, we next assess the stability of the summary effect size estimate obtained. Stability refers to the likelihood that a summary effect estimate will be substantially altered by changing the underlying assumptions of the analysis. Analyses that are used to test the stability of an effect size estimate are known as sensitivity analyses. Clearly, ones confidence in the validity of a treatment effect estimate will be greater if sensitivity analyses fail to significantly alter the summary estimate of treatment effect.

We utilize three different sensitivity analyses. These sensitivity analyses are:

1. *Removal of one study and repeat meta-analysis.* The purpose of this sensitivity analysis is to determine whether a meta-analysis result is driven by a particular trial. For example, a large trial may have a very strong impact on the results of a meta-analysis because of its high weighting.
2. *Publication bias test.* If a meta-analysis has 10 or more studies we perform a test to determine the likelihood of publication bias. The publication bias test used in this evidence report was that of Duval and Tweedie.(95-98) Based on the degree of asymmetry in a funnel plot constructed from the findings of the included studies, this test(97,98) estimates the number of unpublished studies (and their effect sizes). After addition of any "missing" data to the original meta-analysis, the overall effect size is estimated again. If evidence of publication bias was identified and the summary effect size estimate, adjusted for "missing" studies, differed from the pooled estimate of treatment effect determined by the original random-effects meta-analysis by >±5%, we determined that the findings of our original analysis are not robust and the effect size estimate is not stable.
3. *Cumulative random-effects meta-analysis.* Cumulative meta-analysis provides a means by which one can evaluate the effect of the size of the evidence base (in terms of the number of individuals enrolled in the included studies and the number of included studies) on the stability of the calculated effect size estimate. We typically perform two different cumulative random-effects meta-analyses:
    a. Studies are added cumulatively to a random-effects meta-analysis by date of publication-oldest study first.

b. Studies are added cumulatively to a random-effects meta-analysis by date-newest study first.

In each instance, the pooled effect size estimate was considered unstable if any of the last three studies to be added resulted in a change in the cumulative summary effect size estimate effect of >±5%.

The prespecified tolerance levels for each of the potential effect size estimates we could have utilized in this evidence report are presented in Table E-2.

Table E-2. Prespecified Tolerance Levels

Effect Size Estimate	WMD	SMD	% of individuals	RR	OR
Tolerance	±5%	±0.1	±5%	±0.05	±0.05

OR: Odds ratio
RR: Rate ratio
SMD: Standardized mean difference
WMD: Weighted mean difference

Decision Point 7: Are There Sufficient Data to Perform Meta-regression?

We required a minimum of 10 studies before attempting meta-regression.

Decision Points 8 and 9: Exploration of Heterogeneity

We will always attempt to determine the source of heterogeneity when the evidence base consists of 10 or more studies using meta-regression. In preparing this evidence report we did not encounter any situations where we had a heterogeneous evidence base consisting of at least 10 studies. Consequently, Decision Points 8 and 9 are irrelevant to the present report and we do not discuss them further.

Decision Point 10: Are Qualitative Findings Robust?

Decision Point 10 allows one to determine whether the qualitative findings of two or more studies can be overturned by sensitivity analysis. The same sensitivity analyses used to test quantitative robustness were used to test qualitative robustness. We considered our qualitative findings to be overturned only when the sensitivity analyses altered our qualitative conclusion (i.e., a statistically significant finding became non-significant as studies were added to the evidence base). Otherwise, we concluded that our qualitative findings were robust.

Decision Point 11: Is Meta-analysis Possible?

This Decision Point is used only when the evidence base for an outcome consists of two studies.

A meta-analysis is possible if each study reports an effect size and its standard error, or if each study reports sufficient information for the reader to calculate these values. Note that meta-analysis is never appropriate if two studies have statistically significant effect sizes in opposite directions.

Decision Point 12: Are Data Qualitatively Consistent?

This Decision Point is used only when the evidence base for an outcome consists of two studies.

The purpose of this decision point is to determine whether the qualitative findings of an evidence base consisting of only two studies are the same. For example one might ask, "When compared to drug-free controls, do all included studies find that cannabis abuse is a significant risk factor for a motor vehicle crash?"

Decision Point 13: Is at Least One Study a Multicenter Study?

Multicenter trials may increase the strength of a one or two-study evidence base because they demonstrate partial replication of findings; they have shown that different investigators at different centers can obtain similar results using the same protocol. We defined a multicenter trial as any trial that met the following two conditions: (1) ≥3 centers and (2) either ≥100 patients or at least 3 centers enrolled ≥20 patients/center.

Decision Point 14: Is Magnitude of Treatment Effect Large?

When considering the strength of evidence supporting a qualitative conclusion based on only one or two studies, magnitude of effect becomes very important. The more positive the findings, the more confident one can be that new evidence will not overturn ones qualitative conclusion.

The algorithm divides the magnitude of effect into two categories–large and not large. Determining the threshold above which the observed magnitude of effect can be considered to be "large" cannot usually be determined *a priori*. In cases where it is necessary to make judgments about whether an estimate of treatment effect is extremely large, the project director will present data from the two studies to a committee of three methodologists who will determine whether an effect size estimate is "extremely large" using a modified Delphi technique.

Additional Consideration: Evidence from Indirect or Surrogate Outcomes

In certain instances when an evidence base includes only one or two studies with direct evidence (e.g., crash data), the strength of evidence may be increased by additional studies of indirect outcomes (e.g., driving simulator tests, visual function tests) that show findings consistent with the direct evidence study findings.

Figure E-2. General Section

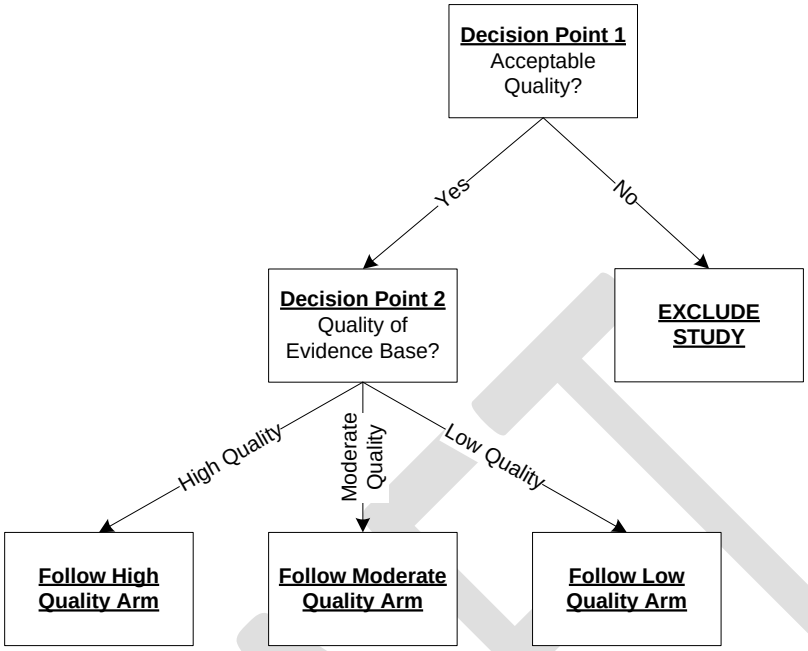


Figure E-3. High Quality Pathway

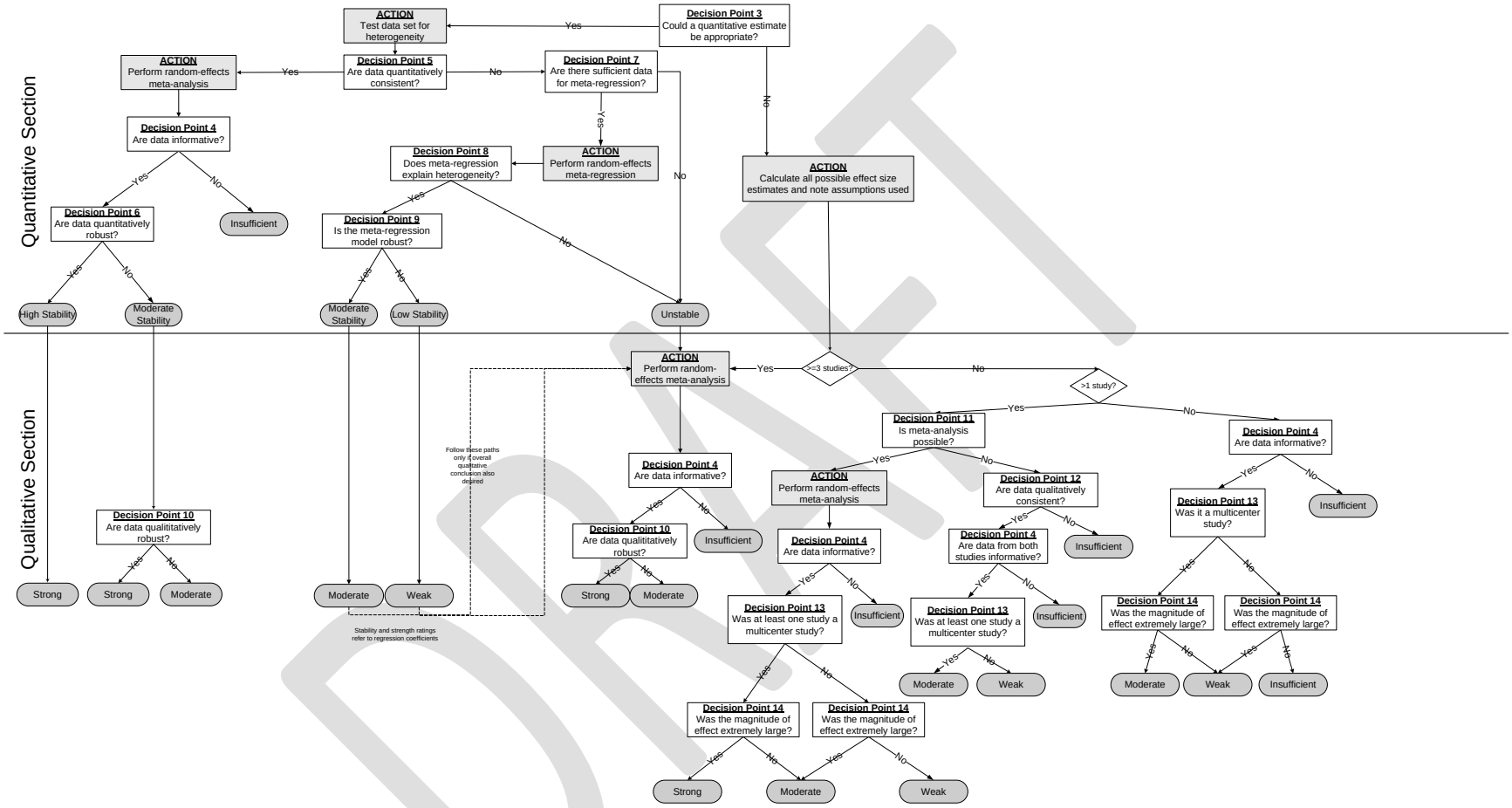


Figure E-4. Moderate Quality Pathway

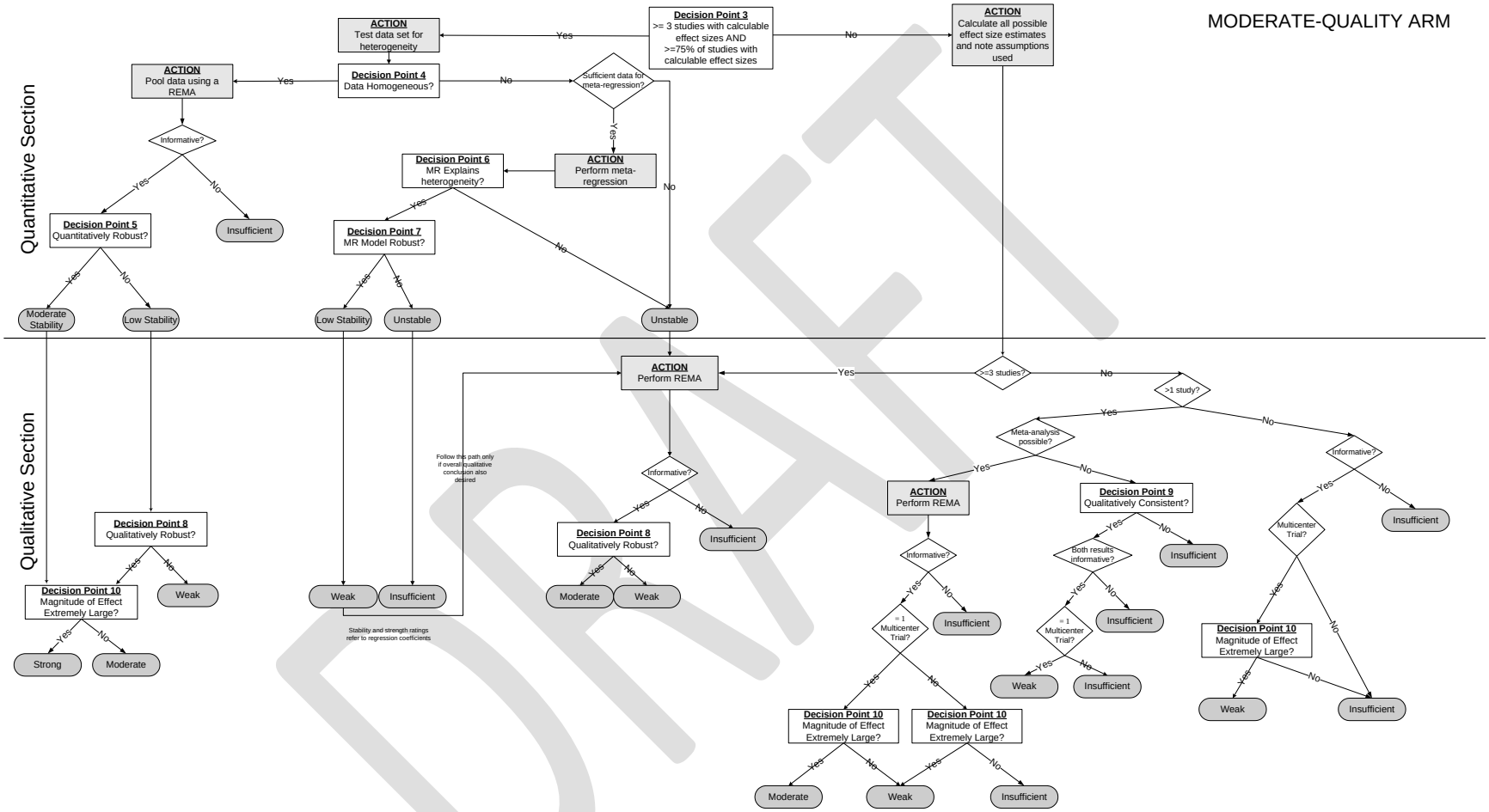
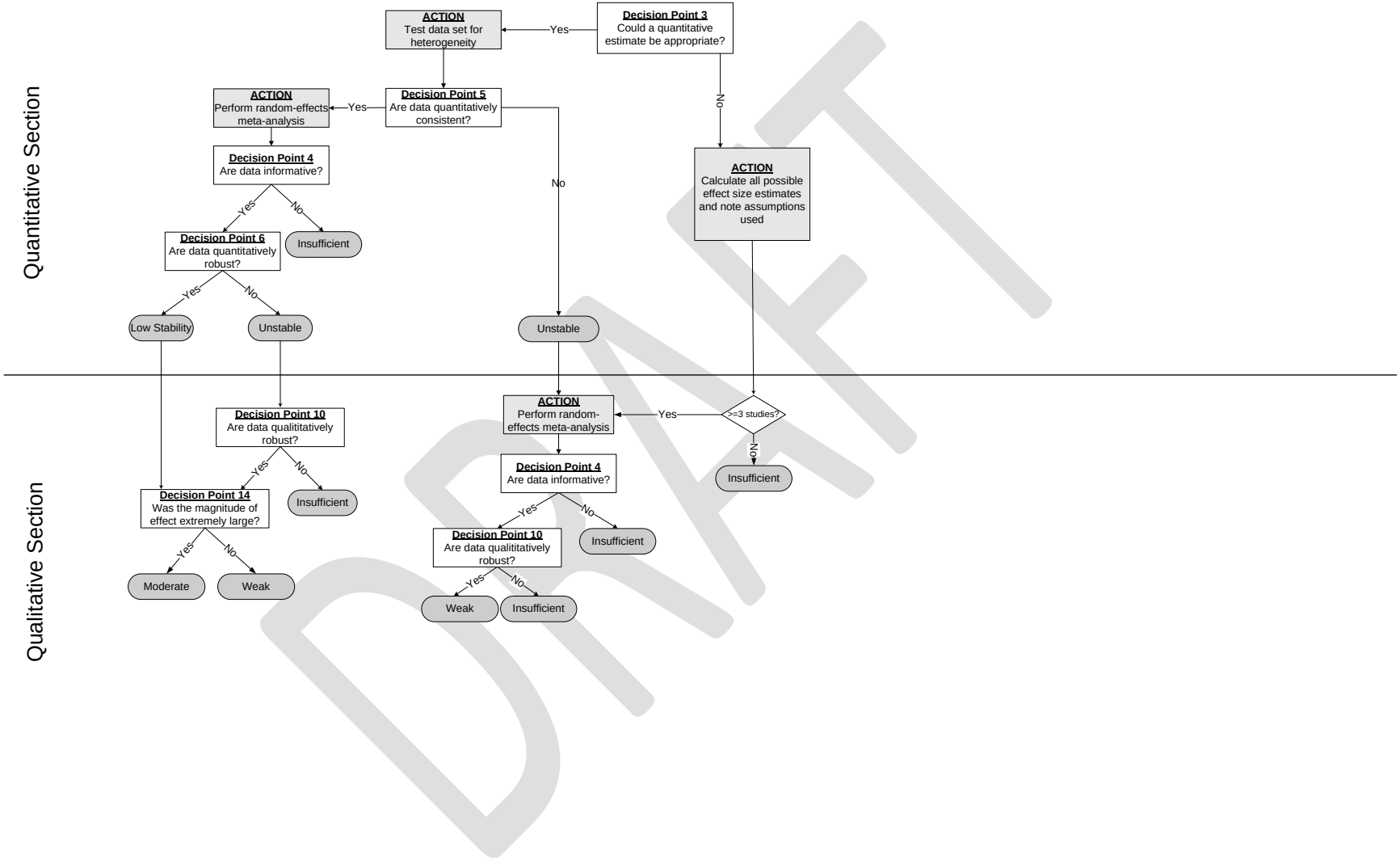


Figure E-5. Low Quality Pathway



Appendix F: Quality Assessment Instruments Used

One assessment instrument was used to assess the quality of the studies included in the evidence bases for the key questions addressed in this evidence report. The assessment instrument is a revised version of the Newcastle-Ottawa Quality Assessment Scale for Cohort Studies.(143)

Revised Newcastle-Ottawa Quality Assessment Scale for Cohort Studies

Question #	Question
1	Representativeness of the exposed cohort?
2	Are the non-exposed cohorts representative?
3	How was exposure determined?
4	At the designated start of the study, were the controls free of the outcome of interest?
5	What is the comparability of the cohorts on the basis of design or analysis?
6	How was the outcome assessed?
7	Was follow-up adequate for outcome to occur?
8	Was the follow-up adequate for both exposed and non-exposed cohorts?
9	Was the funding free of financial interest?
10	Were the conclusions supported by the data

Appendix G: Quality Score Tables

Key Question 3

Table G-1. Quality Assessment Table for Cohort Studies

Reference	Year	Items										Quality Category
		1	2	3	4	5	6	7	8	9	10	
Ku et al.(145)	2002	Y	S	Y	Y	N	Y	Y	Y	Y	Y	Moderate
Peters et al.(103)	2001	Y	S	Y	Y	N	Y	Y	Y	Y	Y	Moderate
Sivak et al.(106)	1981	N	S	Y	Y	N	Y	Y	Y	Y	Y	Low

N: No
S: Selected from a different source than the exposed cohort
Y: Yes