



Chronic Kidney Failure and Commercial Motor Vehicle Driver Safety

April, 2008



Expert Panel Recommendations

Chronic kidney failure and commercial
vehicle driver safety

Federal Motor Carrier Safety Administration

Presented by
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Introduction

- Mission of FMCSA – reduce crashes, injuries and fatalities among commercial motor vehicles in the USA
- Vehicle operators must be physically qualified
- Develop physical qualification standards for individuals with CKD

A close-up, black and white photograph of a dialysis machine. The image shows several circular, textured components, likely part of the dialyzer or filter, arranged in a row. The lighting is dramatic, highlighting the metallic and plastic surfaces.

Facts about kidney disease

- There are approximately 20 million Americans with CKD
- There are 340,057 prevalent patients on dialysis
- There are 106,912 new patients per year
- The rate is slowing - better management is paying off
- Mortality rate for ESRD fell from 21.7 percent to 16.4 percent

Source: USRDS

Incident patient morbidity

Morbidity (in percent %)	2006
Congestive heart failure	34.2
Atherosclerosis	2.5
Other cardiac disease	15.1
Cerebrovascular	9.8
Peripheral vasc disease	14.8
Hypertension	83.4
Amputation	3.1
Diabetes	52.5
Tobacco	6.0

Source: USRDS 2007



Definition of CKD

- Chronic kidney disease is defined as either kidney damage or $\text{GFR} < 60 \text{ cc/min/1.73m}^2$ for ≥ 3 months.
- Kidney damage is defined as pathologic abnormalities or markers of damage, including abnormalities in blood or urine tests or imaging studies

A close-up, grayscale photograph of a dialyzer filter, showing its circular, textured surface and the internal structure. The filter is part of a dialysis machine, with various components and tubing visible in the background.

CKD Stages

- **Stage 1 – GFR ≥ 90 cc/min/1.73m²**
 - Kidney Damage with normal or high GFR
- **Stage 2 – GFR – 60 to 89 cc/min/1.73m²**
 - Kidney Damage with mildly decreased GFR
- **Stage 3 – GFR – 30 to 59 cc/min/1.73m²**
 - Moderate decreased GFR
- **Stage 4 – GFR – 15 to 29 cc/min/1.73m²**
 - Severely decreased GFR
- **Stage 5 – GFR - < 15 cc/min/1.73m²**
 - Kidney failure



Methodology

- Comprehensive evidence report
 - Review of medical literature from several electronic databases
- MEP Meeting and discussing
 - Based on scientific evidence whenever possible
 - Concise and explicit
 - Actionable



Present status

- FMCSA does not have physical qualifications standards that speak specifically to CKD
- No guidance to medical examiners on certifying individuals with CKD
- Evidence is sparse, but CKD individuals constitute a risk to road safety

Recommendation 1





Recommendations 1: Identification of individuals with CKD

- Instruct medical examiners to determine kidney function status of all potential commercial motor vehicle drivers
- Ideally, all individuals should have a serum creatinine, calculation of the electronic glomerular filtration rate (MDRD GFR)
- At the very least individuals with risk factors should have an MDRD calculated from the serum creatinine



Who is at risk for CKD

- Individuals with a known history of CKD
- Individuals with a family history of CKD
- Individuals over 65 years of age
- Diabetics
- Hypertensive patients
- Individuals with proteinuria

Where to find the MDRD GFR

MDRD GFR Calculator - (With SI Units)

by Stephen Z. Fadem, M.D., FACP, FASN

Serum creatinine

mg/dL $\mu\text{mol/L}$

1.1

Creatinine methods recalibrated to be traceable to IDMS.

Age

30 years

Race

African American All other races*

Gender

Male Female

GFR Value: 101 mL/min/1.73 m²

(Age, Race, Gender, Plasma creatinine)

Chronic kidney disease (GFR less than 60 or kidney damage for at least three months)

*All ethnic groups other than African American

NOTE: The estimated GFR values above 60 mL/min/1.73 m² should be interpreted as "above 60 mL/min/1.73 m²," not an exact number.

<http://mdrd.com>

Where to find the MDRD GFR



National Kidney Foundation™

Calculators for Health Care Professionals

Glomerular filtration rate (GFR) is the best overall index of kidney function. Normal GFR varies according to age. NKF's KDOQI clinical practice guidelines recommend the MDRD Study equation to estimate GFR. Other useful calculators are available below.

MDRD GFR Calculator - (With SI Units)

by Stephen Z. Fadem, M.D., FACP, FASN

Serum creatinine

mg/dL $\mu\text{mol/L}$

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Creatinine methods recalibrated to be traceable to IDMS.

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Male Female

GFR Value: 101 mL/min/1.73 m²

(Age, Race, Gender, Plasma creatinine)

Chronic kidney disease (GFR less than 60 or kidney damage for at least three months)

*All ethnic groups other than African American

NOTE: The estimated GFR values above 60 mL/min/1.73 m² should be interpreted as "above 60 mL/min/1.73 m²," not :

http://www.kidney.org/professionals/KDOQI/gfr_calculator.cfm

Where to find the MDRD GFR

Plasma creatinine (mg/dL)

Age*

African American Yes No

Gender Male Female

GFR value: mL/min/1.73 m²**

*This equation should only be used for patients 18 and older.

The NKDEP presently recommends reporting estimated GFR values **greater than or equal to 60 mL/min/1.73 m² simply as "≥60 mL/min/1.73 m²", not an exact number.

http://www.nkdep.nih.gov/professionals/gfr_calculators/orig_con.htm



The Nephron Information Center

<http://nephron.com>

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CR	<input type="text" value="1.1"/>	<input checked="" type="radio"/> mg/dL	
<input type="checkbox"/> IDMS		<input type="radio"/> μ mol/L	
	AGE	<input type="text" value="30"/> yrs	
		W <input type="radio"/>	F <input type="radio"/>
		B <input checked="" type="radio"/>	M <input checked="" type="radio"/>
		MDRD	GFR: 101mL/min/1.73 m ²

<http://nephron.com>

<http://nephron.org>

Where to find the MDRD GFR



Justification: Recommendation 1

- Possibility of a crash in a kidney patient is not supported by direct evidence
- Indirect evidence suggests CKD drivers may represent a threat to road safety.(Noble et al., 2007)
- Individuals with chronic kidney disease demonstrate impaired neurocognition.(Madero et al. 2008; Noble et al., 2007; Madan et al., 2006; Kurella et al., 2004)
- Weak evidence suggests individuals with CKD at high risk for sleep disordered breathing,(Noble et al. 2007; Markou et al., 2006)
- Sleep disordered breathing is associated with increased risk of crash.(Tregear et al., 2007)



Justification - Recommendation 1 (Continued)

- CKD may have a deleterious impact on road safety that may increase as kidney function deteriorates
- CKD should identified and disease extent quantified.
- Approach 1:
 - All individuals applying for medical certification required to have a serum creatinine for calculation of the Modification of Diet in Renal Disease (MDRD) Glomerular Filtration Rate (GFR) to
 - Determine presence and stage of CKD
 - Serum creatinine test becomes a mandatory part of the medical examination for CMV drivers.
 - U.S. Preventive Health Services Task Force presently does not recommend urinalysis or measurement of serum creatinine in otherwise seemingly healthy adults.



Can we justify making a GFR determination a mandatory part of the medical examination for commercial motor vehicle drivers?

- Active testing is necessary in healthy adults because many unaware of condition.
 - NHANES, a large population-based study, suggests nearly 24% of CKD patients unaware (Coresh et al., 2005).
 - NHANES also found 70% with stage 2, 78% with stage 3, and 55% with stage 4 were not aware of CKD .(Nikolas et al., 2004)
 - Singh demonstrated 75.3% stage-3 and 42.4% stage-4 CKD unaware of condition.(Singh et al., 2005)
 - Hsu: 92% of individuals with stage-3, 75% of individuals with stage 4, and 29% of individuals with stage-5 unaware they had CKD .(Hsu et al., 2006)



Contingency Recommendation 1

- Limits the requirement for a GFR measurement to only those individuals who are considered to be at risk for chronic kidney disease



Justification - Recommendation 1 (Continued)

- Second approach -
 - Measure GFR only in individuals considered at risk for chronic kidney disease.
 - According to evidence-based guidelines from the National Kidney Foundation risk factors for chronic kidney disease include susceptibility factors and initiation factors.
 - The onset of chronic kidney disease is difficult to determine (some risk factors for faster progression may appear to be to susceptibility or initiation factors)

Example Risk Factors

Table 39. Types and Examples of Risk Factors for Chronic Kidney Disease

	Definition	Examples
Susceptibility factors	Increase susceptibility to kidney damage	Older age, family history
Initiation factors	Directly initiate kidney damage	Diabetes, high blood pressure, autoimmune diseases, systemic infections, urinary tract infections, urinary stones, lower urinary tract obstruction, drug toxicity
Progression factors	Cause worsening kidney damage and faster decline in kidney function after initiation of kidney damage	Higher level of proteinuria, higher blood pressure level, poor glycemic control in diabetes, smoking

Recommendation 2





Recommendation 2: Certification of individuals with stages 1, 2 or 3

- Individuals with CKD in stages 1, 2 or 3 may be considered as physically qualified to drive a commercial motor vehicle
- Provided they are not restricted for another reason (example: related to cardiovascular disease, etc)
- Stages 1 and 2 Evaluate/recertify every two years
- Stage 3 Evaluate/recertify every one year



Justification: Recommendation 2

- No evidence (either direct or indirect) suggests stage-1, -2, or -3 CKD individuals at increased risk for a motor vehicle crash.(Noble et al., 2005)
- Clinical signs and symptoms of CKD do not usually appear during stage 3.
- Given the lack of evidence that individuals with early CKD are a safety risk, restriction of driving privileges in stage 3 would be inappropriate.
- Kidney function progressively declines in approximately 85% of patients with CKD. (NKF KDOQI Guidelines, 2002; Hunsicker et al.,1997)



Justification: Recommendation 2

- If the underlying disease does not resolve, CKD becomes self-perpetuating and ultimately leads to kidney failure - “end-stage kidney disease” (ESRD).
- Average rate of decline in GFR is approximately 4 mL/min/year and unrelated to the baseline level of GFR.(MDRD: Hunsicker et al.,1997)
- But, GFR decline is highly variable, ranging from slowly progressive over decades, to rapidly progressive over months. (NKF KDOQI Guidelines, 2002)
- Stage-3 chronic kidney failure require closer monitoring than individuals with stage-1 and 2.
- The inherent and independent risks of cardiovascular disease in CKD makes it imperative to monitor this population of patients closely (**Go AS, Chertow GM, Fan D, McCulloch CE, Hsu CY. Chronic kidney disease and the risks of death, cardiovascular events, and hospitalization. N Engl J Med. 2004;351(13):1296-305**)



Recommendation 3



Recommendation 3: Certification of individuals with stage 4 CKD

- Normal EKG and a blood pressure less than 140/90 mm Hg: may be certified for a period not to exceed 6 months, whereupon the individual must present for re-certification
- Normal EKG and blood pressure 140-180 mm Hg (systolic) or 90-110 (diastolic): may be certified for a period not to exceed 3 months, whereupon the individual must present for re-certification
- An EKG or echogram that reveals left ventricular hypertrophy or a blood pressure that is greater than or equal to 180 mm Hg systolic or greater than or equal to 110 mm Hg diastolic disqualifies one from driving a CMV



Justification - Recommendation 3

- No direct evidence to suggest stage 4 CKD individuals at increased risk for a motor vehicle crash, (Noble et al., 2007)
- Sparse evidence suggests stage 4 CKD patients at increased risk for cognitive (Hailpurn et al., 2007) and sleep disturbances. (Markou et al., 2006)
- Whether the deficits observed in this population are severe enough to impact driver safety is not known, but plausible that driving ability may be impaired in some individuals.



Justification – Recommendation 3

- **Primary reason to restrict driving privileges
CKD 4 is the high risk for sudden incapacitation or death.**
- **CKD is an independent risk factor for coronary artery disease, left ventricular hypertrophy (LVH) and sudden death, even before dialysis.**
- **The American Heart Association published a statement in 2003 recommending that patients with chronic kidney disease are in the “highest risk group” for subsequent cardiovascular disease.(Sarnak et al., 2003)**



Justification – Recommendation 3

- LVH ranges from 8 to 40% in patients with CKD not on dialysis (Levin, 2003).
- In an epidemiological study from Japan LVH was present in 40% of patients studied. 22.7% in Stage 3 and 43.6% in Stage 4.(Kimura et al., 2007)
- CKD without diabetes:
 - Atherosclerosis risk is 35.7%
 - congestive failure 30.7%
 - death 17.7%
- CKD and diabetes
 - atherosclerosis 49.1%
 - congestive heart failure 52.3%
 - death 19.9% (Foley et al., 2005)

A black and white photograph featuring an anatomical model of a human heart in the foreground. The heart is dark-colored with visible coronary arteries. In the background, there is a blood pressure monitor with a digital display and a cuff. The monitor's display is blank. Text on the monitor includes "READY TO MEASURE" and "SYSTOLIC mmHg". The text "Recommendation 4" is overlaid in white on the heart model.

Recommendation 4



Recommendation 4: Certification of individuals with stage 5 CKD

- Individuals who require renal replacement therapy (excluding renal transplant) and those with stage 5 CKD not receiving renal replacement (hemodialysis or peritoneal dialysis) cannot be considered fit for duty and should be disqualified from operating a commercial motor vehicle



Justification – Recommendation 4

- No direct evidence demonstrating that individuals with stage 5 CKD are at increased risk for a motor vehicle crash
- Indirect evidence consistently demonstrates that, on average, individuals with renal failure exhibit cognitive impairments across several domains thought to be associated with decreased driving performance. (Noble et al., 2007)
- There is an association between renal failure, dialysis, and disturbed sleep.(Noble et al., 2007)
- Driving long distances maintaining compliance with dialysis regimens is logistically unsound



Justification – Recommendation 4

- Dialysis has been shown to be associated with several conditions that potentially preclude the safe operation of a CMV.
- Neurological complications associated with dialysis include dialysis dementia, disequilibrium syndrome, cerebrovascular accidents, hypertensive encephalopathy, Wernicke's encephalopathy, hemorrhagic stroke, intracranial hypertension, and aggravation of pre-existing atherosclerosis.
- Hemodialysis patients may also experience muscle atrophy and related weakness and impaired movement that may impede an individual's ability to safely operate a CMV.



Justification – Recommendation 4

- Risk of sudden cardiac death is associated with left ventricular hypertrophy and cardiovascular disease.
- Dialysis *per se* causes changes to the heart. Hypotension, transient myocardial ischemia and the potential for arrhythmias may accompany this procedure.
- It will be impossible to control the timing of the dialysis treatment and the activity of driving, and thus, the MEP strongly recommends that patients undergoing dialysis not be certified as physically qualified to operate commercial motor vehicles for the purposes of interstate commerce. (Mohiuddin et al., 2005; Santoro et al., 2008; Selby and McIntyre, 2007)

Recommendation 5





Recommendation 5: Individuals with renal transplants

- Individuals who have undergone successful renal transplantation may operate a CMV 90 days post operatively provided they have been cleared as fit-for-duty by their transplant physician
- With the exception of differences in recertification periods (see below), individuals who have undergone successful renal transplantation should be assessed as per recommendations 1 through 4 (see earlier slides)
- All individuals who have undergone successful renal transplantation should be re-certified at 3 months, 6 months and 12 months postoperatively. Thereafter, they should be re-certified on an annual basis



Justification – Recommendation 5

- Although management of maintenance immunosuppression varies from center to center, it is common practice to taper therapy after the first month.
- By the end of the first year, most patients should be on stable doses of therapy.
- Due to the higher risk of infection, it is advisable that patients not return to active driving until initial therapy has been tapered or until after the physician feels their condition is stable. (Hricik et al., 1994; Schiff et al., 2007; Ciancio et al., 2004; Gaston et al., 2006; Chan et al. 2001).



Justification – Recommendation 5

- Most employed recipients of a kidney transplant should be able to return to work at one year.(van der Mei et al., 2007)
- Close follow-up during the first year is prudent. (At three months and six months).
- Rationale : at the end of the first three months the patient should be approaching maintenance therapy, and at the end of six months should be stable on therapy.
- At the end of one year, it is likely that transplant recipients will have resumed previous job duties.

Questions?





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The End



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