# NATIONAL QUALITY FORUM

#### Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the <u>submitting standards web page</u>.

#### NQF #: 1668 NQF Project: Renal Endorsement Maintenance 2011

(for Endorsement Maintenance Review) Original Endorsement Date: Most Recent Endorsement Date:

# **BRIEF MEASURE INFORMATION**

De.1 Measure Title: Laboratory Testing (Lipid Profile)

Co.1.1 Measure Steward: American Medical Association

**De.2 Brief Description of Measure:** Percentage of patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) who had a fasting lipid profile performed at least once within a 12-month period

2a1.1 Numerator Statement: Patients who had a fasting lipid profile performed at least once within a 12-month period

2a1.4 Denominator Statement: All patients aged 18 years and older with a diagnosis of CKD (stage 3, stage 4 or 5, not receiving RRT)

Defintion:

RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation

2a1.8 Denominator Exclusions: Documentation of patient reason(s) for not performing a fasting lipid profile (eg, patient declined, other patient reasons)

1.1 Measure Type: Process

2a1. 25-26 Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry, Paper Records 2a1.33 Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (*title and NQF number if endorsed*): This measure has a companion (paired) measure that is designated for Quality Improvement only. That measure title is: Laboratory Testing (Calcium, Phosphorus, and Intact Parathyroid Hormone (iPTH)).

### **STAFF NOTES** (*issues or questions regarding any criteria*)

Comments on Conditions for Consideration:

Is the measure untested? Yes No If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (check De.5):
5. Similar/related endorsed or submitted measures ( <i>check 5.1</i> ):

Other Criteria:

Staff Reviewer Name(s):

# 1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence. Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria) 1a. High Impact: (The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.) De.4 Subject/Topic Areas (Check all the areas that apply): Renal, Renal : Chronic Kidney Disease (CKD) De.5 Cross Cutting Areas (Check all the areas that apply): 1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Frequently performed procedure, High resource use, Patient/societal consequences of poor quality, Severity of illness 1a.2 If "Other," please describe: 1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data): Chronic kidney disease (CKD), affects approximately 13.1% of United States adults and leads to end-stage renal disease (ESRD), cardiovascular disease (CVD), and premature death.(1) CKD affects up to 5% of the population and 25% of those aged 70 years or older. An additional 6% of the population has signs of kidney damage, which may progress to ESRD.(2) CKD is now recognized as a major public health concern. It is estimated that approximately 26.3 million adults in the U.S. have nondialysis dependent kidney disease and over 470,000 have ESRD, collectively representing over 13% of the US population. In the next 20 years, the burden of CKD is expected to increase, with over 2 million individuals projected to be receiving renal replacement therapy (dialysis or kidney transplant) by 2030.(3) CKD is a world-wide public health problem, with increasing incidence and prevalence, high cost, and poor outcomes. The major outcomes of CKD are loss of kidney function and development of cardiovascular disease (CVD). Increasing evidence indicates that the adverse outcomes of CKD can often be prevented or delayed through early detection and treatment. (4) Currently, patients with CKD are five to 10 times more likely to die than to reach ESRD.(5) Costs for CKD patients are now 23 percent of Medicare expenditures in the fee-for-service sector; when added to costs for ESRD patients, it appears that 31 percent of all Medicare expenditures are incurred by patients with a diagnosis of kidney disease.(6) In 1993, costs for Medicare patients with CKD accounted for 3.8 percent of overall Medicare expenditures. By 2008, this had grown to 14.2 percent, in part reflecting growth in the number of recognized CKD patients.(6) 1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. Snyder JJ, Collins AJ. Association of Preventive Health Care with Atherosclerotic Heart Disease and Mortality in CKD. J Am Soc Nephrol. 2009 July; 20(7): 1614–1622. 2. Alves TP, Lewis, J. Racial differences in chronic kidney disease (CKD) and end-stage renal disease (ESRD) in the United States: a social and economic dilemma. Clinical Nephrology.2010;74(1):S72-S77. 3. Choi AI, Rodriguez RA, Bacchetti P, Bertenthal D, et al. White/Black Racial Differences in Risk of End-Stage Renal Disease and Death. Am J Med. 2009 July;122(7):672-678. 4. National Kidney Foundation. (2004) K/DOQI clinical practice guidelines on hypertension and antihypertensive agents in chronic kidney disease. Am J Kidney Dis. May:43(5 Suppl 1):S1-S290.

5. Gilbertson DT, Liu J, Xue JL, Louis TA, et al. Projecting the Number of Patients with End-Stage Renal Disease in the United States to the Year 2015. J Am Soc Nephrol 16:3736-3741, 2005.

6. U S Renal Data System, USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2010.

1b. Opportunity for Improvement: H M L I

(There is a demonstrated performance gap - variability or overall less than optimal performance)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:

This measure is aimed at increasing the number of patients with CKD who have a lipid profile performed. The principal reason to evaluate dyslipidemias in patients with CKD is to detect abnormalities that may be treated to reduce the incidence of atherosclerotic CVD (ACVD). A number of observational studies have reported that various dyslipidemias are associated with decreased kidney function in the general population and in patients with CKD. Many factors influence the prevalence of dyslipidemias in CKD. Changes in proteinuria, GFR, and treatment of CKD may alter lipoprotein levels. Therefore, it is prudent to evaluate dyslipidemias more often than is recommended in the general population.

There are 2 major overlapping categories of CVD: (1) disorders of cardiovascular perfusion, which include atherosclerotic CVD (ACVD); and (2) disorders of cardiac function, such as heart failure and left ventricular hypertrophy. Some risk factors are unique to each category of CVD, and some risk factors are shared by both categories of CVD. The National Kidney Foundation (NKF) Task Force on CVD concluded that the incidence of ACVD is higher in patients with CKD compared to the general population. The Task Force concluded that patients with CKD should be considered to be in the highest risk category, ie, a CHD risk equivalent, for risk factor management. This measure hopes to help reduce the incidence of ACVD in the CKD population by encouraging regular evaluation of dyslipidemias.

Reference: National Kidney Foundation. KDOQI Clinical Practice Guidelines for Managing Dyslipidemias in Chronic Kidney Disease. Am J Kidney Dis 41(4):S1-S91, 2003 (suppl 3).

1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers): [For <u>Maintenance</u> – Descriptive statistics for performance results <u>for this measure</u> - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

Testing to identify the usual complications of progressive kidney disease is

lacking, with low rates of calcium/phosphorus, parathyroid hormone, lipid,

and glycemic testing.(1) Among CKD patients with recognized cardiovascular disease, 61 percent use a lipid lowering agent.(1) In a study, as part of the Healthy People 2010 Initiative administered by The Centers for Disease Control and Prevention, using data of a random sample of 5% Medicare patients, focusing on preventative care of CKD patients, lipid screenings were performed for only 65% of CKD patients. Lipid monitoring was also associated with a 20% decrease in harmful events.(2)

In a database analysis to assess practice patterns and conformance to clinical practice guidelines among nephrologists and nonnephrologists who care for patients with advanced CKD, data shows that management of advanced CKD is suboptimal for all patients but is particularly poor for patients who are treated solely by non-nephrologists.(3) Out of 1933 patients total, only 52.3% of patients were regularly monitored for dyslipidemias; out of 1131 patients treated by nephrologists and 802 patients treated by nonnephrologists, only 60.9% and 40.1% (respectively) were regularly monitored for dyslipidemias.(3)

This measure was used in the CMS Physician Quality Reporting Initiative, in the claims option (2008, 2009, 2010) as well as the Registry and Measure Group options (2009, 2010) and it will be used in the CMS Physician Quality Reporting System for 2011. This measure was also included in the Final Rule for Stage 1 of Meaningful Use.

There is a gap in care as shown by this 2008 data; 56.7% of patients reported on did not receive the optimal care.(4) 10th percentile: 5.7% 25th percentile: 18.5% 50th percentile: 46.7% 75th percentile: 66.7% 90th percentile: 90.0%

1b.3 Citations for Data on Performance Gap: [*For <u>Maintenance</u> – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*] (1) U S Renal Data System, USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2010.

(2) Snyder JJ, Collins AJ. Association of Preventive Health Care with Atherosclerotic Heart Disease and Mortality in CKD. J Am Soc Nephrol. 2009 July; 20(7): 1614–1622.

(3) Patwardhan MB, Samsa GP, Matchar DB, Haley WE. Advanced Chronic Kidney Disease Practice Patterns among Nephrologists and Non-Nephrologists: A Database Analysis. Clin J Am Soc Nephrol 2: 277–283, 2007.

(4) Confidential CMS PQRI 2008 Performance Information by Measure. Jan-Sept TAP file.

**1b.4 Summary of Data on Disparities by Population Group:** [*For <u>Maintenance</u> – Descriptive statistics for performance results for this measure by population group*]

In a case presentation of health and health care disparities, Neil R. Powe from Johns Hopkins University School of Medicine describes an African American man who had not had the opportunity for early intervention to delay progression of chronic kidney disease or to prepare for eventual renal replacement therapy.(1) Powe explains that lack of health insurance coupled with the silent nature of hypertension and chronic renal insufficiency are major culprits in the late presentation to medical care for individuals with known risk factors for chronic renal disease.(1) There is little opportunity to attend early to comorbid conditions occurring before end-stage renal disease (ESRD), including coronary artery disease, hypertension, anemia, and hyperlipidemia.(1) Decisions about the choice of renal replacement therapy sometimes must be made in an accelerated fashion. This haste raises concerns about whether the health care providers, the patient, and the family have adequately considered the different treatment options. The case presented also illustrates the special plight of African American patients, whose risk factors make them more likely to develop progressive renal insufficiency and who are less likely to receive peritoneal dialysis or undergo renal transplantation.(1)

To demonstrate disparities in regular monitoring for dyslipidemias (which is part of attending early to comorbid conditions occurring before end-stage renal

disease (ESRD)), one should look at differences in CKD progression to ESRD. African-Americans have the highest reported prevalence and incidence of treated ESRD.(2) Overall, African-Americans are four times more likely to progress to ESRD compared to whites (988 vs. 254 patients per million) and at a higher-than-average risk for developing ESRD in the Southeastern US.(2) Diabetes is the leading cause of ESRD in all racial and ethnic groups, but occurs at a much higher rate among African-Americans, Hispanics and Native Americans (422,382.9, and 307.2 vs. 115 per million, respectively) compared to whites. In addition, African-Americans have the highest rate of hypertension-related ESRD, which far exceeds other racial and ethnic groups. As a result, hypertension remains a close second to Diabetes Mellitus as the leading cause of ESRD in the African-American community.(2)

Hispanic-Americans have a diabetes rate more than twice that of whites, and are twice as likely to progress to ESRD than whites. Furthermore, the higher prevalence of diabetes among Hispanic individuals is only partially explained by the increased rate of ESRD progression.(2) Registry level data from the USRDS show that US Asians have a 34% higher age and gender adjusted risk of ESRD compared to US whites and have a 12-fold increase in the prevalence of ESRD since 1980.(2)

A prospective study of 300,645 white and 20,222 black men screened for enrollment in the Multiple Risk Factor Intervention Trial showed over 16 years of follow-up that for each of several levels of systolic blood pressure, African American men were more likely to develop ESRD than were white men.(3, in 1) An age-adjusted 3.2-fold greater relative risk of developing ESRD for African Americans versus whites was reduced to 1.9-fold after adjustment for differences between African Americans and whites in blood pressure, income, and risk factors such as cholesterol, cigarette smoking, diabetes, and history of myocardial infarction.(1)

A recent nationally representative, prospective study of 9082 adult men and women, ages 30 to 74, enrolled in the Second National Health and Nutrition Examination Survey II examined the cumulative incidence of chronic kidney disease by linking data from baseline interviews, physical examinations, and laboratory tests performed at baseline from 1976 to 1980 with the Medicare ESRD registry and the National Death Index.(4, in 1) This study examined whether socioeconomic status, lifestyle, or clinical factors would

explain the excess incidence of chronic kidney disease among African Americans. Eleven percent of the excess risk was accounted for by socioeconomic status, 24% by lifestyle factors, and 32% of by clinical factors such as control of blood pressure. All three factors combined accounted for more than 40% of the excess risk.(1)										
A similar study of diabetic renal disease in 1434 diabetic adults in four United States communities examined factors that might explain why African Americans compared to whites have an age- and gender-adjusted three-and- one-half-fold higher risk of early renal function decline during 3 years of follow-up (defined as an increase in serum creatinine of 0.4 mg/dL).(5, in 1) The relative odds of early renal function decline decreased by 15% when health behaviors were taken into account, by 45% when physiologic factors were taken into account, by 52% when socioeconomic status was taken into account, and by 83% when all three factors were combined.(1) These studies suggest that genetic factors are not the predominant reason for the										
greater bu interventio	rden of re ns.(1)	nal disease am	ong minorities, at least am	nong African Americans, and provide attractive targets for						
1b.5 Citat reported in included	<b>ions for E</b> n 1b.4 incl	Data on Dispar Uding number of	ities Cited in 1b.4: [ <i>For <u>I</u> of measured entities; numb</i>	Maintenance – Description of the data or sample for measure results ber of patients; dates of data; if a sample, characteristics of the entities						
(1) Powe, chronic kia (2003), pp	Neil R. To Iney disea . 763–772	have and have se. Johns Hop	e not: Health and health ca kins University School of N	are disparities in Aedicine, Baltimore, Maryland, USA, Kidney International, Vol. 64						
(2) Alves States: a s	P, Lewis, social and	J. Racial differ economic diler	ences in chronic kidney di nma. Clinical Nephrology.2	sease (CKD) and end-stage renal disease (ESRD) in the United 2010;74(1):S72-S77.						
(3) Klag M JAMA 277	U, Whelto 1293–129	n PK, Randall E 98, 1997.	BL, et al: End-stage renal c	disease in African-American and white men. 16-year MRFIT findings.						
(4) Tarver subjects in	Carr ME, the Unite	Powe NR, Ebe d States: A po	rhardt MS, et al: Excess ri pulation-based study of po	sk of chronic kidney disease among African-American versus white tential explanatory factors. J Am Soc Nephrol 13:2363–2370, 2002.						
(5) Krop J function de 1783, 199	S, Coresh ecline in b 9.	J, Chambless lacks vs whites	LE, et al: A community-ba: with diabetes: The Athero	sed study of explanatory factors for the excess risk for early renal sclerosis Risk in Communities Study. Arch Intern Med 159:1777–						
1c. Evider Is the mea	nce ( <i>Meas</i> asure foc	<i>sure focus is a</i> us a health ou	health outcome OR meets tcome? Yes No	the criteria for quantity, quality, consistency of the body of evidence.) If not a health outcome, rate the body of evidence.						
Quantity:	H M		Quality: H M L	I Consistency: H M L I						
Quantity	Quality	Consistency	Does the measure pass s	subcriterion1c?						
M-H	M-H	M-H	Yes							
L	M-H	М	Yes IF additional resea harms: otherwise No	rch unlikely to change conclusion that benefits to patients outweigh						
M-H	L	M-H	Yes IF potential benefit	s to patients clearly outweigh potential harms: otherwise No						
L-M-H	L-M-H	L	No 🗌							
Health out one health	t <b>come</b> – ra care struct	itionale support ure, process, in	s relationship to at least tervention, or service	Does the measure pass subcriterion1c? Yes IF rationale supports relationship						
1c.1 Structure-Process-Outcome Relationship (Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome): This process measure is aimed at increasing the number of patients with CKD who have a lipid profile performed. The principal reason to evaluate dyslipidemias in patients with CKD is to detect abnormalities that may be treated to reduce the incidence of the										

health outcome, atherosclerotic CVD (ACVD). A number of observational studies have reported that various dyslipidemias are associated with decreased kidney function in the general population and in patients with CKD. Many factors influence the prevalence of dyslipidemias in CKD. Changes in proteinuria, GFR, and treatment of CKD may alter lipoprotein levels. Therefore, it is prudent to evaluate dyslipidemias more often than is recommended in the general population. The National Kidney Foundation (NKF) Task Force on CVD concluded that the incidence of ACVD is higher in patients with CKD compared to the general population. The Task Force concluded that patients with CKD should be considered to be in the highest risk category, ie, a CHD risk equivalent, for risk factor management. This process measure hopes to help reduce the incidence of the health outcome, ACVD, in the CKD population by encouraging regular evaluation of dyslipidemias.

Reference: National Kidney Foundation. KDOQI Clinical Practice Guidelines for Managing Dyslipidemias in Chronic Kidney Disease. Am J Kidney Dis 41(4):S1-S91, 2003 (suppl 3).

1c.2-3 Type of Evidence *(Check all that apply)*: Clinical Practice Guideline

1c.4 Directness of Evidence to the Specified Measure (State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population):

The guideline recommendations supporting this measure are focused on the evaluation of dyslipidemias in patients with CKD. The guideline focuses on the adult CKD population but also includes special considerations for the adolescent CKD population. This measure specifically focuses on patients with CKD stages 3-5 that are not receiving renal replacement therapy. The principal reason to evaluate dyslipidemias in patients with CKD is to detect abnormalities that may be treated to reduce the incidence of the health outcome, atherosclerotic CVD (ACVD). This process measure aims to reduce the incidence of the health outcome, ACVD, in the CKD population by encouraging regular evaluation of dyslipidemias. The KDOQI guideline recommends that all adults and adolescents with CKD should be evaluated for dyslipidemias, and that for adults and adolescents with CKD, the assessment of dyslipidemias should include a complete fasting lipid profile with total cholesterol, LDL, HDL, and triglycerides. The measure numerator captures patients with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) who had a fasting lipid profile performed at least once within a 12-month period.

There were no guidelines that were assigned an "A" level recommendation. The key guideline statements for this measure were graded "B." Some would argue that no guideline statements should be made in the absence of evidence

from randomized trials in patients with CKD (yielding level "A" recommendations). However, it was decided that when the strength of evidence for treatment efficacy was strong—based on trials in the general population—this

evidence might be reasonably extrapolated to patients with CKD. Specifically, it was assumed that similar treatment efficacy as reported reported in the general population would be found if the trials were carried out in patients with CKD. This also assumes, of course, that treatment is safe and effective in ameliorating dyslipidemias in patients with CKD. The principal results of large multicenter trials in the general population have generally been applicable to most, if not all, major subgroups of patients that have been examined. For

example, the benefit of reducing LDL cholesterol extends to men and women; old and middleaged; smokers and non-smokers; hypertensive and non-hypertensive patients; diabetics and nondiabetics; and individuals with higher or lower LDL, higher or lower total cholesterol, higher or lower triglycerides, and higher or lower HDL. In other words, the results of lipid-lowering trials are usually generalizable to population subgroups. Therefore, it was reasonable to assume that the major findings from randomized trials in the general population are applicable to patients with CKD, until proven otherwise.

Reference: National Kidney Foundation. KDOQI Clinical Practice Guidelines for Managing Dyslipidemias in Chronic Kidney Disease. Am J Kidney Dis 41(4):S1-S91, 2003 (suppl 3).

1c.5 Quantity of Studies in the Body of Evidence (*Total number of studies, not articles*): Overall, for KDOQI's Clinical Practice Guidelines for Managing Dyslipidemias in Chronic Kidney Disease, 10,363 abstracts were screened, 642 articles were retrieved, and 258 articles were subjected to structured review by members of the Work Group. Although systematic, manual searches were not conducted, members of the Work Group supplied a number of articles that were not located by the MEDLINE searches. Total number of studies reviewed was not specified.

Reference: National Kidney Foundation. KDOQI Clinical Practice Guidelines for Managing Dyslipidemias in Chronic Kidney

Disease. Am J Kidney Dis 41(4):S1-S91, 2003 (suppl 3).

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events)*: All adults and adolescents with CKD should be evaluated for dyslipidemias (Moderately Strong). For adults and adolescents with CKD, the assessment of dyslipidemias should include a complete fasting lipid profile with total cholesterol, LDL, HDL, and triglycerides (Moderately Strong). These recommendations are "Moderately Strong," indicating that evidence is sufficient to determine effects on health outcomes in the target population, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; OR evidence is from a population other than the target population, but from well-designed, well-conducted studies; OR evidence is from studies with some problems in design and/or analysis; OR evidence is from well-designed, well-conducted studies on surrogate endpoints for efficacy and/or safety in the target population.

The incidence of ACVD is very high in patients with CKD. Therefore, the NKF Task Force on CVD and the KDOQI Work Group on CKD both concluded that, in the management of risk factors such as dyslipidemia, patients with CKD should be considered to be in the highest risk category, ie, equivalent to that of patients with known CHD. There is very strong evidence from the general population that dyslipidemias cause ACVD, and this evidence has led to the ATP III guidelines for evaluation and treatment. It is conceivable that the pathogenesis of ACVD is different in patients with CKD, and that dyslipidemias do not contribute to ACVD in CKD. However, the relationship between dyslipidemias and ACVD in the general population is robust, ie, it is valid in men and women; old and middle-aged; smokers and non-smokers; hypertensive and non-hypertensive patients; diabetics and nondiabetics; and individuals with higher or lower LDL, higher or lower total cholesterol, higher or lower triglycerides, and higher or lower HDL. There are no compelling reasons to assume that dyslipidemias do not contribute to ACVD in patients with CKD as well.

There are no randomized, controlled, intervention trials testing the hypothesis that dyslipidemias cause ACVD in patients with CKD. However, in an observational study of 3,716 patients initiating treatment for Stage 5 CKD in 1996, the use of statins in 362 (9.7%) was independently associated with lower all-cause mortality and a reduction in CVD deaths during follow-up. Unfortunately, it is likely that the patients using statins had other favorable characteristics that were not accounted for in the adjusted analysis, but may have explained their reduced risk for CVD independent of their use of statins. Therefore, these study results are consistent with, but do not prove, the hypothesis that dyslipidemias contribute to ACVD in patients with CKD.

The principal reason to evaluate dyslipidemias in patients with CKD is to detect abnormalities that may be treated to reduce the incidence of ACVD. However, there may be other reasons to evaluate and treat dyslipidemias in CKD. A number of observational studies have reported that various dyslipidemias are associated with decreased kidney function in the general population and in patients with CKD. It is impossible to determine from these studies whether dyslipidemias cause reduced kidney function, result from reduced kidney function, or whether other conditions such as proteinuria cause both reduced kidney function and dyslipidemias. Each of these explanations is plausible, and only randomized, controlled trials can adequately test the hypothesis that dyslipidemias cause a decline in kidney function.

Unfortunately, there are no large, adequately powered, randomized, controlled trials testing the hypothesis that treatment of dyslipidemia preserves kidney function. However, there have been several small studies, and a meta-analysis of these studies. This meta-analysis included prospective, controlled trials published before July 1, 1999. Three trials published only in abstract form were included in this meta-analysis; one of these studies has subsequently been published in a peer-reviewed journal. All patients were followed for at least 3 months, but in only 5 studies were patients followed for at least 1 year. Statins were used in 10 studies, gemfibrozil in 1 study, and probucol in 1 study. Altogether, 362 patients with CKD were included in the meta-analysis. The results suggested that the rate of decline in GFR was significantly less in patients treated with a cholesterol-lowering agent compared to placebo. No significant heterogeneity in treatment effect was detected between the studies. However, the quality of the studies was generally low, and their small sample sizes and relatively short duration of follow-up make it difficult to conclude that lipid-lowering therapies reduce the rate of decline in GFR in CKD. Therefore, the primary or secondary prevention of ACVD remains the principal reason to evaluate and treat dyslipidemias in patients with CKD.

There were no guidelines that were assigned an "A" level recommendation. The key guideline statements in this document were graded "B" or "C." Some would argue that no guideline statements should be made in the absence of evidence from randomized trials in patients with CKD (yielding level "A" recommendations). However, it was decided that when the strength

of evidence for treatment efficacy was strong-based on trials in the general population-this

evidence might be reasonably extrapolated to patients with CKD. Specifically, it was assumed that similar treatment efficacy as reported reported in the general population would be found if the trials were carried out in patients with CKD. This also assumes, of course, that treatment is safe and effective in ameliorating dyslipidemias in patients with CKD. The principal results of large multicenter trials in the general population have generally been applicable to most, if not all, major subgroups of patients that have been examined. For

example, the benefit of reducing LDL cholesterol extends to men and women; old and middleaged; smokers and non-smokers; hypertensive and non-hypertensive patients; diabetics and nondiabetics; and individuals with higher or lower LDL, higher or lower total cholesterol, higher or lower triglycerides, and higher or lower HDL. In other words, the results of lipid-lowering trials are usually generalizable to population subgroups. Therefore, it was reasonable to assume that the major findings from randomized trials in the general population are applicable to patients with CKD, until proven otherwise.

Nevertheless, there are reasonable doubts as to whether trial results from the general population can be extrapolated to all patients with CKD, and most major trials in the general population have excluded patients with elevated serum creatinine and Stage 5 CKD. It is possible that, in some subpopulations of CKD patients, dyslipidemias may not play as large a role in the pathogenesis of CVD as they do in the general population. Therefore, it was concluded that additional studies are needed in patients with CKD. However, pending the results of these trials, the recommendations were based on the evidence from the general population.

Reference: National Kidney Foundation. KDOQI Clinical Practice Guidelines for Managing Dyslipidemias in Chronic Kidney Disease. Am J Kidney Dis 41(4):S1-S91, 2003 (suppl 3).

1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect): There is very strong evidence from the general population that dyslipidemias cause ACVD, and this evidence has led to the ATP III guidelines for evaluation and treatment. It is conceivable that the pathogenesis of ACVD is different in patients with CKD, and that dyslipidemias do not contribute to ACVD in CKD. However, the relationship between dyslipidemias and ACVD in the general population is robust, ie, it is valid in men and women; old and middle-aged; smokers and non-smokers; hypertensive and non-hypertensive patients; diabetics and nondiabetics; and individuals with higher or lower LDL, higher or lower total cholesterol, higher or lower triglycerides, and higher or lower HDL. There are no compelling reasons to assume that dyslipidemias do not contribute to ACVD in patients with CKD as well.

There are no randomized, controlled, intervention trials testing the hypothesis that dyslipidemias cause ACVD in patients with CKD. However, in an observational study of 3,716 patients initiating treatment for Stage 5 CKD in 1996, the use of statins in 362 (9.7%) was independently associated with lower all-cause mortality and a reduction in CVD deaths during follow-up. Unfortunately, it is likely that the patients using statins had other favorable characteristics that were not accounted for in the adjusted analysis, but may have explained their reduced risk for CVD independent of their use of statins. Therefore, these study results are consistent with, but do not prove, the hypothesis that dyslipidemias contribute to ACVD in patients with CKD.

Unfortunately, there are no large, adequately powered, randomized, controlled trials testing the hypothesis that treatment of dyslipidemia preserves kidney function. However, there have been several small studies, and a meta-analysis of these studies. This meta-analysis included prospective, controlled trials published before July 1, 1999. Three trials published only in abstract form were included in this meta-analysis; one of these studies has subsequently been published in a peer-reviewed journal. All patients were followed for at least 3 months, but in only 5 studies were patients followed for at least 1 year. Statins were used in 10 studies, gemfibrozil in 1 study, and probucol in 1 study. Altogether, 362 patients with CKD were included in the meta-analysis. The results suggested that the rate of decline in GFR was significantly less in patients treated with a cholesterol-lowering agent compared to placebo. No significant heterogeneity in treatment effect was detected between the studies. However, the quality of the studies was generally low, and their small sample sizes and relatively short duration of follow-up make it difficult to conclude that lipid-lowering therapies reduce the rate of decline in GFR in CKD. Therefore, the primary or secondary prevention of ACVD remains the principal reason to evaluate and treat dyslipidemias in patients with CKD.

Reference: National Kidney Foundation. KDOQI Clinical Practice Guidelines for Managing Dyslipidemias in Chronic Kidney Disease. Am J Kidney Dis 41(4):S1-S91, 2003 (suppl 3).

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit

- benefit over harms):

The principal reason to evaluate dyslipidemias in patients with CKD is to detect

abnormalities that may be treated to reduce the incidence of atherosclerotic CVD

(ACVD). A number of observational studies have reported that various dyslipidemias are associated with decreased kidney function in the general population and in patients with CKD. Many factors influence the prevalence of dyslipidemias in CKD. Changes in proteinuria, GFR, and treatment of CKD may alter lipoprotein levels. Therefore, it is prudent to evaluate dyslipidemias more often than is recommended in the general population.

There are 2 major overlapping categories of CVD: (1) disorders of cardiovascular perfusion, which include atherosclerotic CVD (ACVD); and (2) disorders of cardiac function, such as heart failure and left ventricular hypertrophy. Some risk factors are unique to each category of CVD, and some risk factors are shared by both categories of CVD. The National Kidney Foundation (NKF) Task Force on CVD concluded that the incidence of ACVD is higher in patients with CKD compared to the general population. The Task Force concluded that patients with CKD should be considered to be in the highest risk category, ie, a CHD risk equivalent, for risk factor management.

There were no guidelines that were assigned an "A" level recommendation. The key guideline statements in this document were graded "B" or "C." Some would argue that no guideline statements should be made in the absence of evidence from randomized trials in patients with CKD (yielding level "A" recommendations). However, it was decided that when the strength of evidence for treatment efficacy was strong—based on trials in the general population—this

evidence might be reasonably extrapolated to patients with CKD. Specifically, it was assumed that similar treatment efficacy as reported reported in the general population would be found if the trials were carried out in patients with CKD. This also assumes, of course, that treatment is safe and effective in ameliorating dyslipidemias in patients with CKD. The principal results of large multicenter trials in the general population have generally been applicable to most, if not all, major subgroups of patients that have been examined. For

example, the benefit of reducing LDL cholesterol extends to men and women; old and middleaged; smokers and non-smokers; hypertensive and non-hypertensive patients; diabetics and nondiabetics; and individuals with higher or lower LDL, higher or lower total cholesterol, higher or lower triglycerides, and higher or lower HDL. In other words, the results of lipid-lowering trials are usually generalizable to population subgroups. Therefore, it was reasonable to assume that the major findings from randomized trials in the general population are applicable to patients with CKD, until proven otherwise.

Nevertheless, there are reasonable doubts as to whether trial results from the general population can be extrapolated to all patients with CKD, and most major trials in the general population have excluded patients with elevated serum creatinine and Stage 5 CKD. It is possible that, in some subpopulations of CKD patients, dyslipidemias may not play as large a role in the pathogenesis of CVD as they do in the general population. Therefore, it was concluded that additional studies are needed in patients with CKD. However, pending the results of these trials, the recommendations were based on the evidence from the general population.

Reference: National Kidney Foundation. KDOQI Clinical Practice Guidelines for Managing Dyslipidemias in Chronic Kidney Disease. Am J Kidney Dis 41(4):S1-S91, 2003 (suppl 3).

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: The Co-Chairs of the KDOQI Advisory Board selected the Work Group Chair and Director of the Evidence Review Team, who then assembled groups to be responsible for the development of the guidelines and the evidence report, respectively. These groups collaborated closely throughout the project.

The Work Group consisted of "domain experts," including individuals with expertise in nephrology, nutrition, pediatrics, transplantation medicine, epidemiology, and cardiology. In addition, the Work Group included a liaison member from the Renal Physicians Association. The Evidence Review Team consisted of nephrologists and methodologists from Tufts-New England Medical Center with expertise in systematic review of the medical literature.

Guideline Development Work Group Members:

Bertram Kasiske, MD, Chair Hennepin County Medical Center Minneapolis, MN

Fernando G. Cosio, MD, Vice-Chair Mayo Clinic Rochester, MN

Judith Beto, PhD, RN, FADA Loyola University Medical Center Maywood, IL

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Richard Grimm, Jr, MD, PhD Hennepin County Medical Center Minneapolis, MN

Adeera Levin, MD, FRCPC St Paul's Hospital University of British Columbia Vancouver, Canada

Bassem Masri, MD Cornell University New York, NY

Rulan Parekh, MD, MS Johns Hopkins Medical Institutions Baltimore, MD

Christoph Wanner, MD University of Würzburg Würzburg, Germany

David Wheeler, MD, MRCP Royal Free and University College Medical School London, United Kingdom

Peter Wilson, MD Boston University School of Medicine Boston, MA

Liaison Member: Kline Bolton, MD, FACP (RPA)

Methodology Consultants:

Joseph Lau, MD, Director New England Medical Center Boston, MA Vaidyanatha Balakrishnan, MD, PhD Bruce Kupelnick, BA Caroline McFadden, MD Kimberly Miller, BA

All work group members completed a disclosure statement certifying that any potential conflict of interest would not influence their judgment or actions concerning the KDOQI.

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: These guidelines were developed using 4 basic principles set forth by the KDOQI:

1. The guidelines were developed using a scientifically rigorous process, and the rationale and evidentiary basis for each guideline is clearly explained.

A multidisciplinary Work Group, with expertise in the management of CKD, dyslipidemias, and ACVD developed the guidelines.
 The Work Group members worked independently from any organizational affiliations and had final responsibility for determining guideline content.

4. The guidelines underwent widespread critical review before being finalized.

The guidelines were developed using an evidence-based approach similar to that endorsed by the Agency for Health-Care Research and Quality. The Work Group reviewed all pertinent, published evidence, and critically appraised the quality of studies and the overall strength of evidence supporting each recommendation.

The strength of evidence was assessed using a rating system that takes into account (1) methodological quality of the studies; (2) whether or not the study was carried out in the target population, ie, patients with CKD, or in other populations; and (3) whether the studies examined health outcomes directly, or examined surrogate measures for those outcomes, eg, improving dyslipidemia rather than reducing CVD. These 3 separate study characteristics were combined in rating the strength of evidence provided by pertinent studies.

Strong-Evidence includes results from well-designed, well-conducted study/studies in the target population that directly assess effects on health outcomes.

Moderately strong-Evidence is sufficient to determine effects on health outcomes in the target population, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; OR evidence is from a population other than the target population, but from well-designed, well-conducted studies; OR evidence is from studies with some problems in design and/or analysis; OR evidence is from well-designed, well-conducted studies on surrogate endpoints for efficacy and/or safety in the target population.

Weak-Evidence is insufficient to assess the effects on net health outcomes because it is from studies with some problems in design and/or analysis on surrogate endpoints for efficacy and/or safety in the target population; OR the evidence is only for surrogate measures in a population other than the target population; OR the evidence is from studies that are poorly designed and/or analyzed.

1c.13 Grade Assigned to the Body of Evidence: Moderately strong

1c.14 **Summary of Controversy/Contradictory Evidence:** Unfortunately, there are no randomized controlled intervention trials in CKD patients showing that the treatment of dyslipidemias reduces the incidence of ACVD. Moreover, it is possible that trial results from the general population may not be applicable to all patients with CKD. It is also possible that in some subpopulations of CKD patients, treatment of dyslipidemias may not be as safe—or as effective—in reducing the incidence of ACVD, as it is in the general population. This may be due to the unique complications of CKD (eg, anemia, calcium and phosphorus metabolic abnormalities) that may contribute to the risk of ACVD in CKD.

There were no guidelines that were assigned an "A" level recommendation. The key guideline statements in this document were graded "B" or "C." Some would argue that no guideline statements should be made in the absence of evidence from randomized trials in patients with CKD (yielding level "A" recommendations). However, it was decided that when the strength of evidence for treatment efficacy was strong—based on trials in the general population—this

evidence might be reasonably extrapolated to patients with CKD. Specifically, it was assumed that similar treatment efficacy as reported reported in the general population would be found if the trials were carried out in patients with CKD. This also assumes, of course, that treatment is safe and effective in ameliorating dyslipidemias in patients with CKD. The principal results of large multicenter trials in the general population have generally been applicable to most, if not all, major subgroups of patients that have been examined. For

example, the benefit of reducing LDL cholesterol extends to men and women; old and middleaged; smokers and non-smokers; hypertensive and non-hypertensive patients; diabetics and nondiabetics; and individuals with higher or lower LDL, higher or lower total cholesterol, higher or lower triglycerides, and higher or lower HDL. In other words, the results of lipid-lowering trials are usually generalizable to population subgroups. Therefore, it was reasonable to assume that the major findings from randomized trials in the general population are applicable to patients with CKD, until proven otherwise.

Nevertheless, there are reasonable doubts as to whether trial results from the general population can be extrapolated to all patients with CKD, and most major trials in the general population have excluded patients with elevated serum creatinine and Stage 5 CKD. It is possible that, in some subpopulations of CKD patients, dyslipidemias may not play as large a role in the pathogenesis of CVD as they do in the general population. Therefore, it was concluded that additional studies are needed in patients with CKD. However, pending the results of these trials, the recommendations were based on the evidence from the general population.

Reference: National Kidney Foundation. KDOQI Clinical Practice Guidelines for Managing Dyslipidemias in Chronic Kidney Disease. Am J Kidney Dis 41(4):S1-S91, 2003 (suppl 3).

1c.15 Citations for Evidence other than Guidelines *(Guidelines addressed below)*: Not applicable.

1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #): All adults and adolescents with CKD should be evaluated for dyslipidemias. (B) (Guideline 1)

For adults and adolescents with CKD, the assessment of dyslipidemias should include a complete fasting lipid profile with total cholesterol, LDL, HDL, and triglycerides. (B) (Guideline 1)

1c.17 Clinical Practice Guideline Citation: National Kidney Foundation. KDOQI Clinical Practice Guidelines for Managing Dyslipidemias in Chronic Kidney Disease. Am J Kidney Dis 41(4):S1-S91, 2003 (suppl 3).

1c.18 National Guideline Clearinghouse or other URL: http://www.kidney.org/professionals/kdoqi/guidelines\_commentaries.cfm#guidelines

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: Guideline Development Work Group and Evidence Review Team members are described and listed in 1c.10.

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: The [Guideline Development] Work Group rated the strength of each guideline using a modification of a system originally adopted by the Canadian Task Force on the Periodic Health Examination. Accordingly, recommendations were graded A, B, or C when:

(A) It is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is strong evidence that the practice improves net health outcomes.

(B) It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderate evidence that the practice

mproves net health outcomes.
(C) It is recommended that clinicians consider following the guideline for eligible patients. This recommendation is based on either weak evidence, poor evidence, or on the opinions of the Work Group and reviewers, that the practice might improve net health outcomes.
Health outcomes are conditions or healthrelated events that can be perceived by individuals to have an important effect on their ives. Improving net health outcomes implies that benefits outweigh risks, and that the action is costeffective. The strength of evidence was assessed taking into account (1) methodological quality of the studies; (2) whether or not the study was carried out in the target population, ie, patients with CKD, or in other populations; and (3) whether the studies examined health outcomes directly, or examined surrogate measures for those outcomes, eg, improving dyslipidemia rather than reducing CVD.
1c.23 Grade Assigned to the Recommendation: Grade B
1c.24 Rationale for Using this Guideline Over Others: It is the PCPI policy to use guidelines, which are evidence-based, applicable to physicians and other health-care providers, and developed by a national specialty organization or government agency. In addition, the PCPI has now expanded what is acceptable as the evidence base for measures to include documented quality mprovement (QI) initiatives or implementation projects that have demonstrated improvement in quality of care.
KDOQI was founded on the principles of structured review of the literature, with data abstraction of pertinent articles. All of the KDOQI guidelines were developed in this manner. Since the first guideline was published, additional refinement and maturation of this process has occurred. This rigorous process of guideline development has been well received as both credible and transparent.
National Kidney Foundation. KDOQI Guideline Process. http://www.kidney.org/professionals/KDOQI/guidelines_process.cfm. Accessed: May 19, 2011.
Based on the NQF descriptions for rating the evidence, what was the <u>developer's assessment</u> of the quantity, quality, and consistency of the body of evidence? 1c.25 Quantity: <u>Moderate</u> 1c.26 Quality: <u>Moderate1c.27</u> Consistency: <u>Moderate</u>
Was the threshold criterion, <i>Importance to Measure and Report</i> , met? ( <i>1a &amp; 1b must be rated moderate or high and 1c yes</i> ) Yes No Provide rationale based on specific subcriteria:
For a new measure if the Committee votes NO, then STOP. For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

# 2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See <u>guidance on measure testing</u>.

S.1 Measure Web Page (In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained). Do you have a web page where current detailed specifications for this measure can be obtained? Yes

S.2 If yes, provide web page URL: physicianconsortium.org

2a. RELIABILITY. Precise Specifications and Reliability Testing: H M L I

2a1. Precise Measure Specifications. (The measure specifications precise and unambiguous.)

2a1.1 Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome): Patients who had a fasting lipid profile performed at least once within a 12-month period 2a1.2 Numerator Time Window (The time period in which the target process, condition, event, or outcome is eligible for inclusion): Once during the measurement period 2a1.3 Numerator Details (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses: See attached for EHR specifications. For Claims/Administrative: Report CPT II code 4XXXF: Fasting Lipid Profile performed, results documented 2a1.4 Denominator Statement (Brief, narrative description of the target population being measured): All patients aged 18 years and older with a diagnosis of CKD (stage 3, stage 4 or 5, not receiving RRT) Definition: RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation 2a1.5 Target Population Category (Check all the populations for which the measure is specified and tested if any): Adult/Elderly Care 2a1.6 Denominator Time Window (The time period in which cases are eligible for inclusion): 12 consecutive months 2a1.7 Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses): See attached for EHR specifications. For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT) 2a1.8 Denominator Exclusions (Brief narrative description of exclusions from the target population): Documentation of patient reason(s) for not performing a fasting lipid profile (eg, patient declined, other patient reasons) 2a1.9 Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses): Append modifier to CPT II code 4XXXXF- 2p 2a1.10 Stratification Details/Variables (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses ): We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected. 2a1.11 Risk Adjustment Type (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in *2a1.13*): No risk adjustment or risk stratification 2a1.12 If "Other," please describe: 2a1.13 Statistical Risk Model and Variables (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.): As a process measure, no risk adjustment is necessary. 2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please

supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

2a1.19 Interpretation of Score (*Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score*): Better quality = Higher score

2a1.20 Calculation Algorithm/Measure Logic (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):

Calculation algorithm is included in data dictionary/code table attachment (2a1.30).

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

2a1.24 **Sampling (Survey) Methodology.** If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate): Our measure does not require sampling or a survey.

2a1.25 **Data Source** *(Check all the sources for which the measure is specified and tested*). If other, please describe: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry, Paper Records

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): N/A

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment: Attachment AMA-PCPI\_AKID-3\_LipidProfile.pdf

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested*): Clinician : Group/Practice, Clinician : Individual, Clinician : Team

2a1.34-35 Care Setting (Check all the settings for which the measure is specified and tested): Ambulatory Care : Clinician Office, Dialysis Facility, Home Health, Laboratory, Other:Domicillary, Rest Home or Custodial Care Services, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility

**2a2**. **Reliability Testing**. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability*.)

2a2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

• Four nephrology practice sites representing various types, locations and sizes were identified to participate in testing the measures

o The number of physicians per site ranged from 5-62 physicians

- o The sites were located in four different regions: Midwestern, Western, Eastern, and Southern
- o Patient visit volume ranged from 60-2,250 CKD patients
- Sample size per physician organization ranged from 24-30 (as shown below) for a total of 112 patients with Chronic
- Kidney Disease (CKD).
- o Site 1: 24 CKD patients
- o Site 2 : 29 CKD patients
- o Site 3 : 29 CKD patients
- o Site 4 : 30 CKD patients
- Sample selection: Data were collected from the medical records of the first 35 patients seen at each site after July 1, 2007
- Data abstraction was performed in 2008

# 2a2.2 Analytic Method (Describe method of reliability testing & rationale):

Data abstracted from patient records were used to calculate inter-rater reliability for the measure. Patients were randomly selected from visits for chronic kidney disease.

Data analysis included:

- Percent agreement
- Kappa statistic to adjust for chance agreement

2a2.3 Testing Results (*Reliability statistics, assessment of adequacy in the context of norms for the test conducted*): Measure (N, % Agreement, Kappa (95% Confidence Interval))

Laboratory Testing: Ca+, P, iPTH, Lipid Profile (112, 98.2%, (0.9602, 0.9055 - 1.0000))

This measure is highly reliable, as shown in results from the inter-abstrator analysis (above).

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H M L I

2b1.1 Describe how the measure specifications (measure focus, target population, and exclusions) are consistent with the evidence cited in support of the measure focus (criterion 1c) and identify any differences from the evidence: The evidence cited in support of the measure, demonstrates the association between patients with CKD and atherosclerotic CVD (ACVD). The principal reason to evaluate dyslipidemias in patients with CKD is to detect abnormalities that may be treated to reduce the incidence of ACVD. A number of observational studies have reported that various dyslipidemias are associated with decreased kidney function in the general population and in patients with CKD. Many factors influence the prevalence of dyslipidemias in CKD. Changes in proteinuria, GFR, and treatment of CKD may alter lipoprotein levels. Therefore, it is prudent to evaluate dyslipidemias more often than is recommended in the general population.

The National Kidney Foundation (NKF) Task Force on CVD concluded that the incidence of ACVD is higher in patients with CKD compared to the general population. The Task Force concluded that patients with CKD should be considered to be in the highest risk category, ie, a CHD risk equivalent, for risk factor management. The KDOQI guideline recommends that all adults and adolescents with CKD should be evaluated for dyslipidemias, and that for adults and adolescents with CKD, the assessment of dyslipidemias should include a complete fasting lipid profile with total cholesterol, LDL, HDL, and triglycerides. The measure numerator captures patients with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) who had a fasting lipid profile performed at least once within a 12-month period. There are no differences between the evidence and our measure focus, target population, or exclusions.

2b2. Validity Testing. (Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)

**2b2.1 Data/Sample** (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

An expert panel was used to assess face validity of the measure. This panel consisted of 21 members, with representation from the following specialties: nephrology, pediatric nephrology, endocrinology, nursing, methodology, internal medicine, preventive medicine and family medicine.

Louis H. Diamond, MBChB, FCP (SA), FACP, FHIMSS (Work Group Co-Chair) (Nephrology, Methodology) President, Quality Healthcare Consultants, Rockville, MD

Barbara Fivush, MD (Work Group Co-Chair) (Nephrology - Pediatrics) Professor of Pediatrics, Division Chief of Pediatric
Paul M. Palevsky, MD, FACP, FCCD, FASN (Work Group Co-Chair) (Nephrology - Adult) Professor of Medicine, University of
Pittsburgh School of Medicine, Chief, Renal Section, VA Pittsburgh Healthcare System, Pittsburgh, PA
Eileen D. Brewer, MD (Nephrology - Pediatrics) Professor and Head, Pediatric Renal Section, Baylor College of Medicine Chief,
Renal Service, Lexas Children's Hospital, Houston, LX John W. Foreman, MD (Nenhrology - Pediatrics) Department of Pediatrics, Professor of Pediatrics, Duke University, Durham, NC
Richard S. Goldman, MD (Nephrology - Adult, Methodology) Nephrology and Internal Medicine, Albuguergue, NM
Stuart L. Goldstein, MD (Nephrology - Pediatrics) Director, Center for Acute Care Nephrology, Cincinnati Children's Hospital
Medical Center; Medical Director, Pheresis Service, Professor of Pediatrics, University of Cincinnati College of Medicine, Cincinnati, OH
John Hartman, MD (Nephrology - Adult) CEO, Visonex, LLC, Treasurer, Wisconsin Medical Society, Green Bay, WI
Richard Hellman, MD, FACP, FACE (Endocrinology, Methodology) Clinical Professor of Medicine, University of Missouri-Kansas
City School of Medicine, Private Practice, Diabetes & Endocrinology, North Kansas City, MU Joan L. Holloy, MD, EACD (Nonbrology, Adult) Clinical Professor of Modicino, University of Illinois, Urban Champaign and Carlo
Physician Group Tribana II
Edward R. Jones, MD (Nephrology - Adult) Self-Employed, Delaware Valley Nephrology Associates, Philadelphia, PA
Karen M. Kolbusz, RN, BSN, MBA, (Nursing, Joint Commission Liaison) Associate Project Director, The Joint Commission,
Oakbrook Terrace, IL
Craig B. Langman, MD (Nephrology - Pediatrics) The Isaac A. Abt MD Professor of Kidney Diseases and Head, Kidney Diseases,
Feinberg School of Medicine, Northwestern University, and Children's Memorial Hospital, Chicago, IL Painish Mahrotra, MD (Nanhrology - Adult) Professor of Medicine at David Caffen School of Medicine at LICLA and Associate
Chief. Div of Nephrology and Hypertension. Harbor-UCI A Medical Center. Torrance. CA
Alvin H. Moss, MD (Nephrology - Adult) Professor of Medicine, West Virginia University, Morgantown, WV
Sharon A. Perlman, MD (Nephrology - Pediatrics) USF Pediatric Nephrology, All Children's Hospital, St. Petersburg, FL
Paul D. Rockswold, MD, MPH (Preventive Medicine and Family Medicine) Physician Epidemiologist, Head of Health Analysis, Navy
and Marine Corps Public Health Center, Suffolk, VA
Candace C. Walworth, MD (Nephrology - Aduit) Nephrology and Internal Medicine, Lewiston, ME Bradley Warady, MD (Nephrology - Pediatrics) Chief, Pediatric Nephrology, Children's Mercy Hospitals and Clinics, Kansas City
MO
Steven J. Wassner, MD, FAAP (Nephrology - Pediatrics) Professor of Pediatrics, Vice-Chair for Education, Chief, Division of
Nephrology & Hypertension, Hershey, PA
Jerry Yee, MD (Nephrology - Adult) Division Head, Nephrology and Hypertension, Henry Ford Hospital, Detroit, MI
2b2.2 Analytic Method (Describe method of validity testing and rationale; if face validity, describe systematic assessment):
Face validity of the measure score as an indicator of quality was systematically assessed as follows:
After the measure was fully specified, the expert panel (work Group membership) was asked to rate their agreement with the following statement:
Please rate your agreement with the following statement for each measure:
The scores obtained from the measure as specified will accurately differentiate quality across providers.
Scale 1-5, where 1=Strongly Disagree; 3=Neither Disagree nor Agree; 5=Strongly Agree
2D2.3 Testing Results (Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment):
The results of the expert papel rating of the validity statement were as follows: $N = 19$ : Mean rating = 4.32
The results of the onport participating of the valuery statement work as follows: W = 17, mountaining = 1.02.
Frequency Distribution of Ratings
1 – 0 (Strongly Disagree)
z - 1 3 - 1 (Neither Disagree nor Agree)

## 4 - 8 5 - 9 (Strongly Agree)

POTENTIAL THREATS TO VALIDITY. (All potential threats to validity were appropriately tested with adequate results.)

**2b3**. **Measure Exclusions**. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

**2b3.1 Data/Sample for analysis of exclusions** (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):

• Four nephrology practice sites representing various types, locations and sizes were identified to participate in testing the measures

- o The number of physicians per site ranged from 5-62 physicians
- o The sites were located in four different regions: Midwestern, Western, Eastern, and Southern
- o Patient visit volume ranged from 60-2,250 CKD patients

• Sample size per physician organization ranged from 24-30 (as shown below) for a total of 112 patients with Chronic Kidney Disease (CKD).

- o Site 1: 24 CKD patients
- o Site 2 : 29 CKD patients
- o Site 3 : 29 CKD patients
- o Site 4 : 30 CKD patients
- Sample selection: Data were collected from the medical records of the first 35 patients seen at each site after July 1, 2007
- Data abstraction was performed in 2008

**2b3.2 Analytic Method** (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference*):

Exclusions included medical reasons and patient reason- they were analyzed for frequency and variability across providers.

2b3.3 Results (*Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses*): The exception rate for this measure was 0%.

**2b4. Risk Adjustment Strategy**. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included): This measure is not risk adjusted.

**2b4.2 Analytic Method (***Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables*):

This measure is not risk adjusted.

2b4.3 Testing Results (*Statistical risk model*: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. <u>Risk stratification</u>: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata): This measure is not risk adjusted.

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: As a process measure, no risk adjustment is necessary.

**2b5. Identification of Meaningful Differences in Performance**. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included): PCPI Testing Project:

Four nephrology practice sites representing various types, locations and sizes were identified to participate in testing the measures

- The number of physicians per site ranged from 5-62 physicians 0
- 0 The sites were located four different regions: Midwestern, Western, Eastern, and Southern
- Patient visit volume ranged from 60-2,250 CKD patients and 240-2,800 ESRD patients seen per month 0
- Sample size per practice site ranged from 24-30 (as shown below) for a total of 112 patients with Chronic Kidney Disease (CKD)

- Site 1: 24 CKD patients 0
- Site 2 : 29 CKD patients 0
- Site 3 : 29 CKD patients 0
- Site 4 : 30 CKD patients 0
- Sample selection: Data were collected from the first 35 patients seen at the site after July 1, 2007

CMS 2009 Physician Quality Reporting Initiative: Clinical Condition and Measure: #121 Laboratory Testing

5,829 patients were reported on for the 2008 program, the most recent year for which data are available

# Eligible Professionals: 45,994

# Professionals Reporting >=1 Valid QDC: 554

% Professionals Reporting >=1 Valid QDC: 1.2%

- # Professionals Satisfactorily Reporting: 203
- % Professionals Satisfactorily Reporting: 36.6%

2b5.2 Analytic Method (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance):

The inter-quartile range (IQR) was calculated, which provides a measure of the dispersion of performance.

2b5.3 Results (Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance): PCPI Testing Project Results: Scores on this measure: N = 112 Mean = 67.0 %, Range (27.0% - 88.0%)

CMS Physician Quality Reporting Initiative:

This measure was used in the CMS Physician Quality Reporting Initiative, in the claims option (2008, 2009, 2010) as well as the Registry and Measure Group options (2009, 2010) and it will be used in the CMS Physician Quality Reporting System for 2011. This measure was also included in the Final Rule for Stage I of Meaningful Use.

There is a gap in care as shown by this 2008 data; 56.7% of patients reported on did not receive the optimal care.

10th percentile: 5.7% 25th percentile: 18.5% 50th percentile: 46.7% 75th percentile: 66.7% 90th percentile: 90.0%

The inter-quartile range (IQR) provides a measure of the dispersion of performance. The IQR is 48.2, and indicates that 50% of physicians have performance on this measure ranging from 18.5% and 66.7%. A guarter of reporting physicians have performance on this measure which is greater than 66.7%, while a guarter have performance on this measure less than 18.5%.

Reference: Confidential CMS PQRI 2008 Performance Information by Measure. Jan-Sept TAP file.

2b6. Comparability of Multiple Data Sources/Methods. (If specified for more than one data source, the various approaches result in comparable scores.)

2b6.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a

*sample, characteristics of the entities included)*: This measure has not been compared across data sources.

**2b6.2 Analytic Method** (*Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:

This measure has not been compared across data sources.

**2b6.3 Testing Results** (*Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted*):

This measure has not been compared across data sources.

2c. Disparities in Care: H M L I NA (If applicable, the measure specifications allow identification of disparities.)

2c.1 If measure is stratified for disparities, provide stratified results (*Scores by stratified categories/cohorts*): We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected.

# 2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:

The PCPI advocates that performance measure data should, where possible, be stratified by race, ethnicity, and primary language to assess disparities and initiate subsequent quality improvement activities addressing identified disparities, consistent with recent national efforts to standardize the collection of race and ethnicity data. A 2008 NQF report endorsed 45

practices including stratification by the aforementioned variables. (1) A 2009 IOM report "recommends collection of the existing Office of Management and Budget (OMB) race and Hispanic ethnicity categories as well as more fine-grained categories of ethnicity (referred to as granular ethnicity and based on one's ancestry) and language need (a rating of spoken English language proficiency of less than very well and one's preferred language for health-related encounters)."(2)

References:

(1)National Quality Forum Issue Brief (No.10). Closing the Disparities Gap in Healthcare Quality with Performance Measurement and Public Reporting. Washington, DC: NQF, August 2008.

(2)Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. March 2010. AHRQ Publication No. 10-0058-EF. Agency for Healthcare Research and Quality, Rockville, MD. Available at: http://www.ahrq.gov/research/iomracereport. Accessed May 25, 2010.

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met? (*Reliability and Validity must be rated moderate or high*) Yes No Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

# 3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

C.1 Intended Purpose/ Use (Check all the purposes and/or uses for which the measure is intended): Professional Certification or Recognition Program, Public Reporting, Quality Improvement (Internal to the specific organization)

3.1 Current Use (Check all that apply; for any that are checked, provide the specific program information in the following *questions*): Public Reporting, Professional Certification or Recognition Program, Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H M L I (The measure is meaningful, understandable and useful for public reporting.) 3a.1. Use in Public Reporting - disclosure of performance results to the public at large (If used in a public reporting program, provide name of program(s), locations, Web page URL(s)). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered. This measure was used in the CMS Physician Quality Reporting Initiative, in the claims option (2008, 2009, 2010) as well as the Registry and Measure Group options (2009, 2010) and it will be used in the CMS Physician Quality Reporting System for 2011. This measure was also included in the Final Rule for Stage I of Meaningful Use. The results from the 2010 PQRS program can be found on the CMS website: http://www.cms.gov/PQRS// This measure has been used in the CMS Physician Quality Reporting Initiative since 2008. 3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: The PCPI, RPA and ASPN believe that the reporting of participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is appropriate since the measure has been tested and the reliability of the performance data has been validated. NQF endorsement will facilitate our ongoing progress toward this public reporting objective. 3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): This measure may be used in a Maintenance of Certification program. 3b. Usefulness for Quality Improvement: H M L (The measure is meaningful, understandable and useful for quality improvement.) 3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s): [For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement. All PCPI measures are suitable for use in quality improvement initiatives and are made freely available on the PCPI website and through the implementation efforts of medical specialty societies and other PCPI members. The PCPI strongly encourages the use of its measures in QI initiatives and seeks to provide information on such initiatives to PCPI members. 3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results: The PCPI, RPA and ASPN believe that the use of PCPI measures in guality improvement initiatives is a beneficial way to gather scientific data with which to improve physician performance. This is appropriate since the measure has been tested and the reliability of the performance data has been validated. NQF endorsement will facilitate our ongoing progress toward this quality improvement objective. Overall, to what extent was the criterion, Usability, met? H M L Provide rationale based on specific subcriteria: 4. FEASIBILITY Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria) 4a. Data Generated as a Byproduct of Care Processes: H M L 4a.1-2 How are the data elements needed to compute measure scores generated? (Check all that apply). Data used in the measure are: generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition

4b.1 Are the data elements needed for the measure as specified available electronically (Elements that are needed to compute measure scores are in defined, computer-readable fields): ALL data elements in electronic health records (EHRs)

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H M L

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results: We are not aware of any unintended consequences related to this measurement.

4d. Data Collection Strategy/Implementation: H M L

4b. Electronic Sources: H M L I

A.2 Please check if either of the following apply (*regarding proprietary measures*):

4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (*e.g., fees for use of proprietary measures*): The measure was tested looking for laboratory test orders only, not specifically if the test was actually preformed. The updated measures include looking to see if the test was performed. We do not believe that this modification changed the data necessary to

calculate the measures.

Overall, to what extent was the criterion, *Feasibility*, met? H M L I Provide rationale based on specific subcriteria:

# OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes No Rationale:

If the Committee votes No, STOP.

If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

# 5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population)*, list the NQF # and title of all related and/or competing measures: 0063 : Diabetes: Lipid profile

0074 : Chronic Stable Coronary Artery Disease: Lipid Control

0616 : Atherosclerotic Disease - Lipid Panel Monitoring

0626 : Chronic Kidney Disease - Lipid Profile Monitoring

### 5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as <u>NQF-endorsed measure(s)</u>: Are the measure specifications completely harmonized?

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures *(e.g., a more valid or efficient way to measure quality);* OR provide a rationale for the additive value of endorsing an additional measure. *(Provide analyses when possible)*: Our measure is specified at the clinician level, but measure results can be aggregated at a higher level of measurement.

We have developed and will maintain specifications for multiple data sources, including Electronic Health Records (EHRs) and Claims-Based Reporting. Our specifications for EHRs are developed in accordance with the terminology standards (eg, SNOMED, RxNorm, LOINC) named in the Meaningful Use Program (CMS EHR Incentive Program).

In regards to NQF #0626 Chronic Kidney Disease - Lipid Profile Monitoring (also undergoing maintenance), the data source for ActiveHealth measures is what they call "level 2 clinically enriched data" (including data from claims & pharmacy). Our measure is specified for use in administrative claims (using CPT II codes) as well as integration into EHRs. The implementation of measures that are specified using clinically enriched data is significantly limiting in that it would only apply to those groups/settings with access to that type of information (ie, pharmacy data).

NQF staff have noted that the ActiveHealth measures are in use by health plans – a 3 million patient database system. By comparison, our measures are in CMS's PQRS program providing an incentive payment to eligible professionals who satisfactorily report data on quality measures for services furnished to 46 million Medicare beneficiaries.

# CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): American Medical Association, 515 N State St, Chicago, Illinois, 60654

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Co.3 Measure Developer if different from Measure Steward: American Medical Association, 515 N State St, Chicago, Illinois, 60654

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Co.5 Submitter: Diedra, Joseph, MPH, diedra.joseph@ama-assn.org, 312-464-4904-, American Medical Association

Co.6 Additional organizations that sponsored/participated in measure development: Renal Physicians Association, American Society of Pediatric Nephrology

Co.7 Public Contact: Mark, Antman, DDS, MBA, mark.antman@ama-assn.org, 312-464-5056-, American Medical Association

# ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

Louis H. Diamond, MBChB, FCP (SA), FACP, FHIMSS (Work Group Co-Chair) (Nephrology, Methodology) President, Quality Healthcare Consultants, Rockville, MD

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#### Ad.8 Disclaimers:

Ad.9 Additional Information/Comments: The next scheduled review/update for this measure will be in 2014.

The following updates were made on 11/08/11:

**Specifications** 

De.2 The measure description was updated and the words "results documented" removed. 2a1.1 The numerator language was updated, as indicated above.

Importance:

1c.4 The directness of evidence to the specified measure was updated as indicated above.

Scientific Acceptability:

2b1.1 The consistency of the evidence with the measure specifications was updated, as indicated above.

Date of Submission (MM/DD/YY): 06/08/2011

# **PCPI eSpecification**

<b>Clinical Topic</b>	Adult Kidney Disease
Measure Title	Laboratory Testing (Lipid Profile)
Measure #	AKID-3
Measure Description	Percentage of patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, 5, not receiving RRT) who had a fasting lipid profile performed and results documented at least once within a 12-month period
Measurement Period	Twelve consecutive months
Initial Patient Population	<ul> <li>Patient Age: Patients aged 18 years and older starts before the start of the measurement period</li> <li>Diagnosis Active: Patient has a diagnosis of CKD (stage 3, 4, or 5, not receiving RRT) starts before or during encounter during measurement period</li> <li>Encounter: At least two visits with the physician, physician's assistant, or nurse practitioner during the measurement period</li> </ul>
Denominator Statement	All patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) Definition: RRT (Renal Replacement Therapy): For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation
Numerator Statement	Patients who had a fasting lipid profile performed and results documented at least once within a 12-month period
Denominator Exceptions	Documentation of patient reason(s) for not performing a fasting lipid profile (eg, patient declined, other patient reasons)

#### Adult Kidney Disease DRAFT Data Elements for PCPI eSpecification

Measure #3 : Laboratory Testing (Lipid Profile)

QDM* Standard Category	QDM* Data Type	Standard Terminology	Constraints	Value Set Name	Value of Data Element	Data Source	Comments/Rationale
Measure Timing	N/A	N/A	TBD by measure implementer	Measurement Start Date			
Measure Timing	N/A	N/A	TBD by measure implementer	Measurement End Date			
Individual Characteristic	Patient Characteristic	TBD	during measurement period	Gender		<ul><li>Electronic Administrative Claims</li><li>Electronic Health Record (EHR)</li></ul>	This data element is collected for the purpose of stratifying results in an effort to highlight disparities.
Individual Characteristic	Patient Characteristic	TBD	during measurement period	Race		Electronic Health Record (EHR)	This data element is collected for the purpose of stratifying results in an effort to highlight disparities.
Individual Characteristic	Patient Characteristic	TBD	during measurement period	Ethnicity		Electronic Health Record (EHR)	This data element is collected for the purpose of stratifying results in an effort to highlight disparities.
Individual Characteristic	Patient Characteristic	TBD	during measurement period	Primary Language		Electronic Health Record (EHR)	This data element is collected for the purpose of stratifying results in an effort to highlight disparities.
Individual Characteristic	Patient Characteristic	LN	starts before the start of measurement period	Date of Birth		Electronic Administrative Claims     Electronic Health Record (EHR)	
Individual Characteristic	Patient Characteristic	Calculated	starts before the start of measurement period	Age	≥ 18	Electronic Administrative Claims     Electronic Health Record (EHR)	Measurement start date minus Date of Birth must be greater than or equal to 18 years.
Condition / Diagnosis / Problem	Diagnosis, Active	19, 110, SNM	starts before or during encounter during measurement period	Chronic Kidney Disease, Stage III		Electronic Administrative Claims     Electronic Health Record (EHR)	
Condition / Diagnosis / Problem	Diagnosis, Active	19, 110, SNM	starts before or during encounter during measurement period	Chronic Kidney Disease, Stage IV		<ul> <li>Electronic Administrative Claims</li> <li>Electronic Health Record (EHR)</li> </ul>	
Condition / Diagnosis / Problem	Diagnosis, Active	19, 110, SNM	starts before or during encounter during measurement period	Chronic Kidney Disease, Stage V		<ul> <li>Electronic Administrative Claims</li> <li>Electronic Health Record (EHR)</li> </ul>	
Encounter	Encounter, Performed	СРТ	during measurement period	Encounter, Outpatient	count ≥ 2	Electronic Administrative Claims     Electronic Health Record (EHR)	
Laboratory Test	Laboratory Test, Result	LN, CPT II, CPT	during measurement period	Lipid Panel	Value Present	<ul> <li>Electronic Administrative Claims</li> <li>Electronic Health Record (EHR)</li> </ul>	
				total cholesterol	Value Present		
Laboratory Test	Laboratory Test. Result	LN. CPT	during measurement period	LDL	Value Present	Electronic Administrative Claims	
	, ee, ee, ee, ee, ee, ee, ee, ee, e		during measurement period	HDL	Value Present	Electronic Health Record (EHR)	
				triglycerides	Value Present		
Negation Rationale	Laboratory Test, Not Done	SNM	during measurement period	Patient Reason(s)		Electronic Health Record (EHR)	

\*The Quality Data Model (QDM), Version 2.1, was developed by National Quality Forum (NQF).

# **PCPI eSpecification**



PARAMETER SPECIFICATIONS (Value Sets are found in the Coding Appendices):

IPP: <sup>1</sup> Patient Age: measurement start date minus birth date (value set 000307) ≥ 18 years starts before the start of measurement period; <sup>234</sup> Diagnosis, Active: starts before or during measurement period; <sup>5</sup> Encounter: count ≥ 2 during measurement period;

E: <sup>6</sup> Patient Exception: during measurement period;

# **PCPI eSpecification**



PARAMETER SPECIFICATIONS (Value Sets are found in the Coding Appendices):

N: 89 10 11 All in (N) occuring during measurement period;

Basic Measure Cal (N) (D) – (E) The PCPI strongly alongside perform Exception Calculat	culation: = % recommends that exce ance rates as follows: tion:	ption rates also be cor	nputed and reported
(D) Exception Types: E= E1 (Medical Exc For patients who h be counted when	= % eptions) + E2 (Patient Ex ave more than one vali calculating the exception	<pre>kceptions) + E3 (System id exception, only one d on rate</pre>	Exceptions) exception should be
Initial Patient Population (IPP) Definition: The initial patient population identifies the general group of patients that the performance measureis designed to address; usually focused on a specific clinical condition (e.g., coronary artery disease, asthma). For example, a patient aged 18 years and older with a diagnosis of CADwho has at least 2 Visits during the measurement period.	Definition: The denominator defines the specific group of patients for inclusion in a specific performance measure based on specific criteria (e.g., patient's age, diagnosis, prior MI). In some cases, the denominator may be I dentical to the initial patient population.	Numerator (N) Definition: The numerator defines the group of patients in the denominator for whom a process or outcome of care occurs (e.g., flu vaccine received).	Denominator Exceptions (E) The finition: Denominator exceptions are the valid reasons why patients who are included in the fonominator population did not receive a process or outcome of care (described in the numerator). Patients may have Denominator Exceptions for medical reasons (e.g., patient has an egg allergy so they did not receive flu vaccine); patient reasons (e.g., patient did not receive flu vaccine due to vaccine shortage). These cases are removed from the denominator population for the performance calculation, however the number of patients with valid exceptions should be calculated and reported. This group of patients constitutes the Denominator Exception reporting population – patients for whom the numerator was not achieved and a there is a valid Denominator Exception.
Find the patients who meet the Initial Patient Population criteria (IPP)	<ul> <li>Find the patients who qualify for the denominator (D):</li> <li>From the patients within the Patient Population criteria (IPP) select those people who meet Denominator selection criteria.</li> <li>(In some cases the IPP and D are identical).</li> </ul>	<ul> <li>Find the patients who qualify for the Numerator (N):</li> <li>From the patients within the Denominator</li> <li>(D) criteria, select those people who meet Numerator selection criteria.</li> <li>Validate that the number of patients in the number of patients in the denominator</li> </ul>	From the patients who did not meet the Numerator criteria, determine if the patient meets any criteria for the Denominator Exception (E1 + E2+E3). If they meet any criteria, they should be removed from the Denominator for performance calculation. As a point of reference, these cases are removed from the denominator population for the performance calculation, however the number of patients with valid exceptions should be calculated and reported.

#### ADULT KIDNEY DISEASE Coding Spreadsheet for PCPI eSpecification AKID-3 : Laboratory Testing (Lipid Profile)

Value Set ID	Clinical Topic	Topic Indicator	Measure Component	Standard Concept	Standard Category	Taxonomy	Code	Code Descriptor
000307	AKID	3	IPP	Birth Date	Individual Characteristic	LN	21112-8	Birth date: TmStp:Pt:^Patient:Qn:
000284	AKID	3	IPP	Chronic Kidney Disease, Stage III	Condition / Diagnosis / Problem	19	585.3	Chronic Kidney Disease, Stage III (Moderate)
000284	AKID	3	IPP	Chronic Kidney Disease, Stage III	Condition / Diagnosis / Problem	l10	N18.3	Chronic Kidney Disease, Stage III (moderate)
000284	AKID	3	IPP	Chronic Kidney Disease, Stage III	Condition / Diagnosis / Problem	SNM	433144002	Chronic kidney disease stage 3 (disorder)
000285	AKID	3	IPP	Chronic Kidney Disease, Stage IV	Condition / Diagnosis / Problem	19	585.4	Chronic Kidney Disease, Stage IV (Severe)
000285	AKID	3	IPP	Chronic Kidney Disease, Stage IV	Condition / Diagnosis / Problem	l10	N18.4	Chronic Kidney Disease, Stage IV (severe)
000285	AKID	3	IPP	Chronic Kidney Disease, Stage IV	Condition / Diagnosis / Problem	SNM	431857002	Chronic kidney disease stage 4 (disorder)
000286	AKID	3	IPP	Chronic Kidney Disease, Stage V	Condition / Diagnosis / Problem	19	585.5	Chronic Kidney Disease, Stage V
000286	AKID	3	IPP	Chronic Kidney Disease, Stage V	Condition / Diagnosis / Problem	l10	N18.5	Chronic Kidney Disease, Stage V
000286	AKID	3	IPP	Chronic Kidney Disease, Stage V	Condition / Diagnosis / Problem	SNM	433146000	Chronic kidney disease stage 5 (disorder)
000002	AKID	3	IPP	Encounter	Encounter	CPT	99201	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99202	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99203	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99204	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99205	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99211	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99212	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99213	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99214	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99215	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99241	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99242	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99243	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99244	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99245	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99304	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99305	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99306	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99307	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99308	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99309	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99310	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99324	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99325	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99326	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99327	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99328	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99334	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99335	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99336	
000002		3	IPP	Encounter	Encounter	CPT	99337	
000002	AKID	3	IPP	Encounter	Encounter	CPT	99341	
000002		3	IPP	Encounter	Encounter	CPT	99342	
000002		3	IPP	Encounter	Encounter	CPT	99343	
000002		3	IPP	Encounter	Encounter	CPT	99344	
000002		3	IPP	Encounter	Encounter	CPT	99345	
000002		3	IPP	Encounter	Encounter	CPT	99347	
000002		3	IPP	Encounter	Encounter	CPT	00318	
000002		3	IPP	Encounter	Encounter	CPT	002/0	
000002		3	IFF	LIICOUIILEI	LICOUIILEI		33343	Į

#### ADULT KIDNEY DISEASE Coding Spreadsheet for PCPI eSpecification AKID-3 : Laboratory Testing (Lipid Profile)

Value Set ID	Clinical Topic	Topic Indicator	Measure Component	Standard Concept	Standard Category	Taxonomy	Code	Code Descriptor
000002	AKID	3	IPP	Encounter	Encounter	CPT	99350	
000302	AKID	3	N	Lipid Panel	Laboratory Test	CPT	80061	
000302	AKID	3	N	Lipid Panel	Laboratory Test	SNM	16254007	lipid panel
000302	AKID	3	N	Lipid Panel	Laboratory Test	SNM	252150008	fasting lipid profile
000303	AKID	3	N	Triglyceride Level	Laboratory Test	CPT	84478	
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	14740000	triglycerides measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	104586006	cholesterol/triglyceride ratio measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	412827004	fluid sample triglyceride measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	167082000	plasma triglyceride measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	271245006	measurement of serum triglyceride level
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	443915001	measurement of total cholesterol and triglycerides
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	167084004	plasma fasting triglyceride measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	167083005	plasma random triglyceride measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	166849007	serum fasting triglyceride measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	166850007	serum random triglyceride measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	104991000	triglyceride and ester in IDL measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	104993002	triglyceride and ester in VLDL measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	104784006	lipids, triglycerides measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	313830003	plasma VLDL triglyceride measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	313551005	serum VLDL triglyceride measurement
000303	AKID	3	N	Triglyceride Level	Laboratory Test	SNM	250742000	high density lipoprotein/triglyceride ratio measurement
000304	AKID	3	N	HDL-C	Laboratory Test	CPT	83718	
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	17888004	high density lipoprotein measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	121791001	high density lipoprotein 2 measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	121792008	high density lipoprotein 3 measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	28036006	high density lipoprotein cholesterol measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	104583003	HDL/total cholesterol ratio measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	314035000	plasma HDL cholesterol measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	167073006	plasma fasting HDL cholesterol measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	167072001	plasma random HDL cholesterol measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	166832000	serum HDL cholesterol measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	166838001	serum fasting HDL cholesterol measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	166839009	serum random HDL cholesterol measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	313811003	cholesterol/HDL ratio measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	166854003	lipoprotein electroph HDL
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	313989009	serum cholesterol/HDL ratio measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	313990000	plasma cholesterol/HDL ratio measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	166842003	total cholesterol:HDL ratio measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	271059008	serum HDL/non-HDL cholesterol ratio measurement
000304	AKID	3	N	HDL-C	Laboratory Test	SNM	104990004	triglyceride and ester in HDL measurement
000305	AKID	3	N	LDL-C	Laboratory Test	CPT	83721	
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	166855002	lipoprotein electroph LDL
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	22644003	low density lipoprotein measurement
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	77068002	cholesterol measurement
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	113079009	low density lipoprotein cholesterol measurement
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	314036004	plasma LDL cholesterol measurement
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	167075004	plasma fasting LDL cholesterol measurement
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	167074000	plasma random LDL cholesterol measurement
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	166833005	serum LDL cholesterol measurement
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	166840006	serum fasting LDL cholesterol measurement
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	166841005	serum random LDL cholesterol measurement
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	314012003	serum LDL/HDL ratio measurement
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	314013008	plasma LDL/HDL ratio measurement
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	313991001	serum cholesterol/LDL ratio measurement
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	313992008	plasma cholesterol/LDL ratio measurement

#### ADULT KIDNEY DISEASE Coding Spreadsheet for PCPI eSpecification AKID-3 : Laboratory Testing (Lipid Profile)

Value Set ID	Clinical Topic	Topic Indicator	Measure Component	Standard Concept	Standard Category	Taxonomy	Code	Code Descriptor
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	395065005	calculated LDL cholesterol level
000305	AKID	3	N	LDL-C	Laboratory Test	SNM	104992007	triglyceride and ester in LDL measurement
000306	AKID	3	N	Total Cholesterol	Laboratory Test	CPT	82465	
000306	AKID	3	N	Total Cholesterol	Laboratory Test	SNM	121868005	total cholesterol measurement
000306	AKID	3	N	Total Cholesterol	Laboratory Test	SNM	412808005	serum total cholesterol measurement
000306	AKID	3	N	Total Cholesterol	Laboratory Test	SNM	390956002	plasma total cholesterol level
000289	AKID	3	E	Patient Exception	Negation Rationale	SNM	511000124109	Exclusion from performance measure for patient reason (finding)