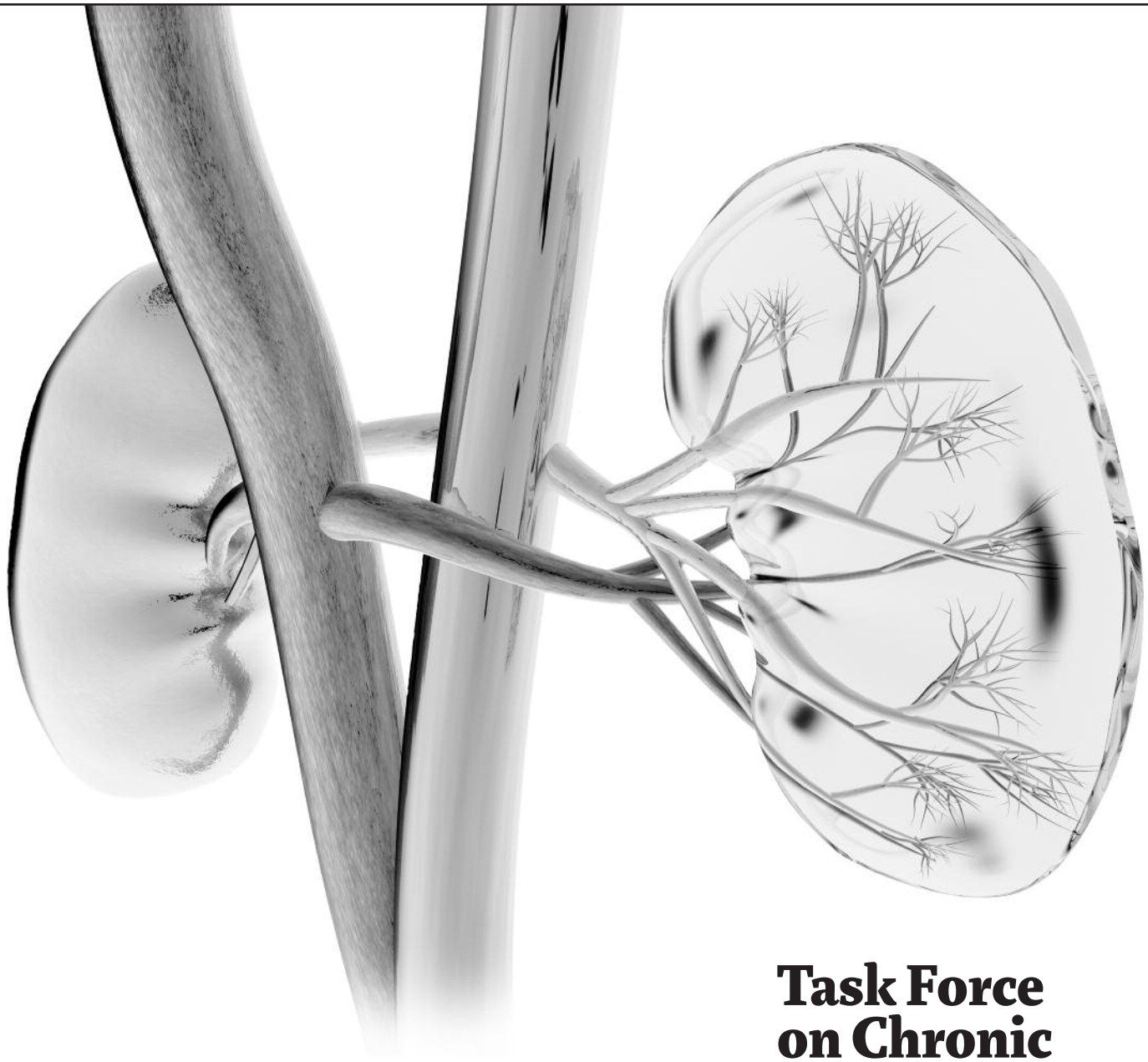

Task Force on Chronic Kidney Disease

Addressing Chronic Kidney Disease in North Carolina

May 2008

North Carolina Institute of Medicine

This Task Force was convened at the request of North Carolina General Assembly.

NC IOM Task Force on Chronic Kidney Disease

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NC IOM Task Force on Chronic Kidney Disease

Acknowledgements

The North Carolina Institute of Medicine (NC IOM) convened this Task Force at the request of North Carolina General Assembly.

The NC IOM would like to extend sincere appreciation to the Task Force Co-Chairs, Marcus Plescia, MD, MPH, Chief, Chronic Disease and Injury Section, Division of Public Health, NC Department of Health and Human Services; and Leanne Skipper, Chief Executive Officer, National Kidney Foundation of NC. They provided guidance to the work of the Task Force and helped direct its progress. The success of the work would not have been possible without their contributions. The NC IOM also wants to thank the 38 members of the Task Force and Steering Committee (listed below) who gave freely of their time and expertise over the past 18 months to try to address the important issue.

In addition to select Task Force and Steering Committee members, three individuals participated in the two workgroups focused on primary care and estimated glomerular filtration rate (eGFR) reporting. Bilenna Richardson, BSW, MPA, and Denise Rouse, BSN, both from Access Care - Robeson County, Community Care of North Carolina; and Michael Hitchcock, MBChB, President, North Carolina Society of Pathologists provided unique perspectives to the respective workgroups and much needed input for Task Force discussion.

Pam Silberman, JD, DrPH, President and CEO of the North Carolina Institute of Medicine, guided the work of the Task Force, led the workgroup meetings, and served as the primary author of the final Task Force report. Vice President Mark Holmes, PhD, helped facilitate Task Force meetings and assisted in the writing and editing of the report. Project Director Kimberly Alexander-Bratcher, MPH, also helped write and edit the report, was the primary author of an issue brief on this topic for the *North Carolina Medical Journal*, and assisted with logistical arrangements of the meetings. Phyllis Blackwell, Editorial Assistant,

Acknowledgements

and Jennifer Hastings, MS, MPH, Director of Communications and Project Director assisted with editing the report. Key staff support was provided by Adrienne Parker, Director of Administrative Operations, and Thalia Fuller, Administrative Assistant.

The Task Force would like to recognize the following people for making presentations to the Task Force and providing background information: Linda Upchurch, MBA, MHA, former Renal Consultant/Group Marketing, Baxter Healthcare Corporation; Laura Edwards, RN, NC Kidney/Epilepsy Program Coordinator, NC Division of Public Health, NC Division of Health and Human Services; Leanne Skipper, Chief Executive Officer, National Kidney Foundation of NC; Donna Harward, Director of Education, UNC Kidney Center; Thomas DuBose, MD, Harrison Chair of Internal Medicine, Wake Forest University School of Medicine; Ronald Falk, MD, Distinguished Professor, Chief, Nephrology and Hypertension Division, UNC School of Medicine; Annette DuBard, MD, MPH, Associate Medical Director for Quality, Evaluation, and Health Outcomes, NC Division of Medical Assistance; Anne Rogers, BSN, MPH, Disease & Health Care Management Coordinator, NC State Health Plan; Abhijit Kshirshagar, MD, MPH, Department of Medicine, Division of Nephrology and Hypertension, UNC School of Medicine; James Fleming, PhD, Vice President and Director, Department of Science and Technology; Laboratory Corporation of America; Cynda Ann Johnson, MS, MBA, former Senior Associate Vice Chancellor for Clinical and Translational Research, Division of Research and Graduate Studies, East Carolina University; Samuel Cykert, MD, Associate Director, Medical Education and Quality Improvement, North Carolina Area Health Education Center Program; Ann Lefebvre, MSW, CPHQ, Project Director, Improving Performance in Practice, NC Academy of Family Physicians Foundation; Paula Szypko, MD, FACP, North State Pathology Associates, former President, NC Society of Pathologists, Chair, Federal and State Affairs Committee, College of American Pathologists; Marcus Plescia, MD, MPH, Chief, Chronic Disease and Injury Section, NC Division of Public Health, Department of Health and Human Services; Maria Ferris, MD, MPH, PhD, Associate Professor of Clinical Medicine, UNC Kidney Center; Monique Winslow, PhD, Children with Special Health Needs, Women and Children's Health Section, NC Division of Public Health, Department of Health and Human Services; Barbara Pullen Smith, MPH, Director, Office of Minority Health and Health Disparities, NC Department of Health and Human Services; Jim Keene, former Planner, Medical Facilities Planning Section, Division of Health Service Regulation, NC Department of Health and Human Services; Kristina Ernst, RN, CDE, BSN, Public Health Advisor and Program Consultant, The Kidney Disease Initiative, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, Steering Committee Member, National Kidney Disease Education Program, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health; Thomas Hoerger, PhD, Senior Fellow in Health Economics, Director, Health Economics and Financing Program, Director, RTI-UNC Center for

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Excellence in Health Promotion Economics, RTI International; Caroline Jennette, MSW, Social Research Specialist, Kidney Education Outreach Program, UNC Kidney Center; Susan Johnson, RN, Home Training Nurse Manager, Independent Nephrology Services; Deidre Hall, Founder, The Kidney Coaching Foundation; and Celeste Castillo Lee, former Administrative Manager, Interdisciplinary Programs, Office of the Provost, Duke University.

The North Carolina Institute of Medicine would like to thank the graduate students who helped assist with the work of this Task Force. Jennifer Bonds performed the initial literature review and helped with preparation of some of the earlier Task Force meetings. Sarah Haseltine and Daniel Shive helped with preparation for some of the later Task Force meetings.

Finally, the Task Force would like to dedicate this report to the memory of Janet Reaves, RN, MPH, former Chronic Disease Manager, NC Division of Public Health. She served on both the Steering Committee and Primary Care Workgroup, actively participated in Task Force meetings, and was always willing to share her expertise and enthusiasm. Janet had a tireless zeal for public health and a passion for helping the people of North Carolina.

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Chapter One
Introduction

The kidneys play an integral role in removing waste products and drugs from the body, balancing the body's fluids, regulating blood pressure, promoting strong bones, and controlling the production of red blood cells. Kidney damage can cause health problems like high blood pressure (hypertension) and cardiovascular disease, blood or protein in the urine, waste products in the blood, frequent urination, difficulty or pain with urination, and swelling or puffiness around the eyes, hands, and feet.[1]

Chronic kidney disease (CKD) is a health condition that encompasses various levels of kidney damage ranging from a decline in function to kidney failure. It is estimated that over 13% of the US population has CKD, amounting to 26 million people.[2] There are just under one million people with CKD in North Carolina not including those with kidney failure.[3] The elderly and people with certain chronic diseases such as diabetes, high blood pressure, and cardiovascular disease are also more likely to develop CKD.

As described more fully in Chapter 2, the loss of kidney functioning can lead to a decline in other bodily functions. Kidney disease contributes to high blood pressure, high blood sugar, high lipid levels, anemia, and bone disease. In fact, people with kidney disease are more likely to die from cardiovascular disease than from kidney failure. However, many people with chronic kidney disease do progress to kidney failure, the most severe form of CKD. These patients need treatment including dialysis or transplantation to avoid the build up of toxins that can lead to death.[4] People who receive treatment for their kidney failure are considered to have end-stage kidney disease (ESKD).[a,b] According to the United States Renal Data System (USRDS), more than 1.8 million people suffer from ESKD worldwide including 387,000 people in the United States and 11,000 people in North Carolina. The number of people with ESKD per population in North Carolina has been consistently higher than the national average. In 2004, North Carolina ranked 10th highest for the number of people per population living with ESKD and 12th highest

a End-stage kidney disease (ESKD) and end-stage renal disease (ESRD) refer to the same condition. Throughout the report we use the term *end-stage kidney disease* as the term *kidney* is more widely understood by the public than *renal*. We use the term ESKD rather than ESRD except when referring specifically to a publication or report that uses the term *end-stage renal disease*.

b Kidney failure includes those patients who are not treated with dialysis or transplantation while the term ESKD does not.[7]

for new cases of ESKD among the state's population for the 50 states and the District of Columbia. The risk of developing ESKD is not uniform across the population and imposes considerable disparities across race and ethnicity. African Americans have 3.7 times the risk of developing kidney failure, as do Caucasians. Other racial and ethnic groups are also at greater risk; Native Americans have 1.9 times and Asians have 1.3 times the risk of developing kidney failure as Caucasians.[5]

The USRDS shows that from the 1980s through 2004 the incidence and prevalence of ESKD have been increasing both nationally and statewide. Nationally, the number of ESKD cases has doubled since 1990, although the number of new cases has begun to level off in recent years. Nonetheless, as people live longer with this disease, the overall number of people (prevalence) with ESKD is expected to rise.

The costs of providing health care services to people with ESKD alone exceeded $30 billion in 2006, and these costs are expected to grow.[5] A relatively small number of patients account for these high health care expenditures. According to 2005 USRDS data, ESKD patients represent only 1.2% of the Medicare population but account for 6.4% of Medicare expenditures.[5] Together, CKD and ESKD account for 19% of general Medicare expenditures. Moreover, CKD increases the costs of treating people with diabetes or congestive heart failure, further increasing costs to the health care system.

The growing prevalence of chronic kidney disease can be characterized as a public health threat. To qualify as a public health threat, the following four conditions must be met: (1) the condition must have a high burden of disease, (2) there must be unfair distribution of the problem, (3) there must be evidence that upstream prevention strategies could reduce the burden of the condition, and (4) prevention strategies must not yet be in place.[6] CKD meets all four of these conditions. The impact of CKD, both in terms of health care consequences and economic costs, is enormous. However, there is reason for hope. We can do more as a state and as a society to prevent kidney disease from occurring and to delay the progression of kidney disease to kidney failure. This Task Force report provides a framework for addressing this public health threat.

Legislative Charge To The Task Force

The North Carolina General Assembly asked the North Carolina Institute of Medicine (NC IOM) to convene a Task Force to study Chronic Kidney Disease (Section 48 of Session Law 2006-248). Specifically, the NC IOM was asked to develop a plan to:

(1) Reduce the occurrence of chronic kidney disease by controlling the most common risk factors, diabetes and hypertension, through preventive efforts at the community level and disease management efforts in the primary care setting.

(2) Educate the public and health care professionals about the advantages and methods of early screening, diagnosis, and treatment of chronic kidney disease and its complications based on Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for chronic kidney disease or other medically recognized clinical practice guidelines.

(3) Educate health care professionals about early renal replacement therapy education for patients (including in-center dialysis, home hemodialysis, peritoneal dialysis, vascular access options, and transplantation) prior to the onset of end-stage renal disease when kidney function is declining.

(4) Make recommendations on the implementation of a cost-effective plan for prevention, early screening, diagnosis, and treatment of chronic kidney disease and its complications for the state's population.

(5) Identify current barriers to adoption of best practices and potential policy options to address these barriers.

The Task Force was co-chaired by Marcus Plescia, MD, MPH, chief of the Chronic Disease and Injury Section, North Carolina Division of Public Health, and Leanne Skipper, chief executive officer of the National Kidney Foundation of North Carolina. The Task Force had 33 additional members including state policy makers, legislators, primary care physicians, nephrologists, clinical laboratory operators, nurses, dietitians, social workers, and persons with CKD. (See pages 9-11 for a complete list of Task Force members.)

Although the Task Force examined some issues as they relate to chronic kidney disease in children, the Task Force focused most of its work on care for adults with chronic kidney disease. Kidney damage is far more prevalent in adults than it is in children, and the likelihood of developing chronic kidney disease increases as a person ages beyond 65 years old.[c] In addition, the evidence-based guidelines are not as well-developed for children.[d]

The Task Force met 8 times over an 18-month period to study CKD and to develop a plan to address it. In addition, the Task Force held three subcommittee meetings to focus on care for people with

c According to the Southeastern Kidney Council, the data as of July 30, 2007 show that there were 12,691 people 18 years of age or older who were receiving dialysis in North Carolina and 8,152 people 18 years or older living in North Carolina with a functioning kidney transplant. In contrast, there are only 38 people under age 18 who were receiving dialysis in North Carolina and 135 who are living in North Carolina with a functioning kidney transplant.

d According to the American Society of Pediatric Nephrology, there is a lack of evidence-based outcomes in pediatric patients with chronic kidney disease. In the original KDOQI documents (discussed more fully in Chapter 2), pediatric guidelines were either not discussed or incorporated into the adult guidelines, and the clinical practice guidelines do not provide specific provisions for many areas of pediatrics. Children and adolescents have some strategies of care that are similar to adult strategies and others that are age-specific. One significant area of divergence is the expectation of long-term survival, making the emphasis on growth, development, and preparation for self-directed care of particular importance.

CKD in primary care settings and on screening of CKD through use of an estimated glomerular filtration rate (eGFR). (See Chapter 4.) This report culminates the work of the Task Force. Chapter 2 includes an overview of chronic kidney disease and the evidence-based guidelines for identifying, screening, and treating people with kidney disease. Chapter 3 describes the economic consequences of kidney disease. Chapter 4 describes the current system of care for chronic kidney disease and includes recommendations about how to improve care for people with chronic kidney disease. Chapter 5 summarizes the findings and recommendations that address the legislative charge to the Task Force and includes a chart that includes all of the recommendations along with organizations and/or professionals with responsibility for implementing the recommendations of the Task Force.

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Chapter Two
Overview of Chronic Kidney Disease

Role Of The Kidneys

The kidneys are two bean-shaped, fist-sized organs located near the middle of the back below the rib cage. Daily, these small organs filter approximately 200 quarts of blood to remove 2 quarts of waste products and extra water.[1] The waste that is removed is what remains after the body processes food and liquids for energy and repair. Extra water and waste products from the blood become urine, which flows through tubes called ureters into the bladder for storage. Ineffective removal of waste products can lead to waste product build-up in the blood and cause damage to the kidneys and other organs. The kidneys also produce hormones that help make red blood cells, regulate blood pressure, maintain calcium for bones, and regulate normal chemical balance in the body.

The ability of the kidneys to perform their work is referred to as *kidney function*.[1] Most people are born with two healthy kidneys; however, people do not need two healthy kidneys to lead normal lives. Some people are born with only one kidney and live normal lives. Others donate a kidney to a person in need and still have adequate kidney function. A small decrease in kidney function may not cause a problem. A more significant decline in kidney function, however, can lead to serious consequences.

Some people develop acute kidney diseases that can be cured with their kidneys returning to normal function. Others develop chronic kidney disease (CKD), which persists and worsens over time. Serious medical problems arise when kidney function falls below 25% of normal kidney functioning.[1] People with less than 15% of function are considered to have kidney failure and need therapy to sustain their lives. This therapy may be in the form of dialysis or kidney transplant.

Risk Factors

Some people have clinical or sociodemographic risks that increase their likelihood of developing CKD.[2] For example, people with diabetes, high blood pressure (hypertension), cardiovascular disease, an autoimmune disease (eg, lupus), systemic infections, urinary

tract infections, urinary stones, lower urinary tract obstruction, cancer, a family history of CKD, a history of acute kidney failure, decreased kidney size, exposure to drugs toxic to the kidneys, or low birth weight are at increased risk of developing CKD.[2,3] Similarly, people who are older adults, have low incomes or low educational achievement, or have had exposure to certain chemical and environmental conditions are in higher risk categories. Although some studies indicate certain racial and ethnic minorities (African American, Native American, Hispanic/Latino, and Asian or Pacific Islander) have a higher prevalence of CKD, other studies suggest otherwise.[4-6] One study reported "metabolic abnormalities were more common in minority populations, and low GFR appeared to have a multiplicative effect. Defining CKD using a single GFR threshold may be disadvantageous for minority populations because metabolic abnormalities are present at higher levels of GFR."[7] Other risk factors for CKD include male gender, obesity, high protein intake, anemia, and dyslipidemia (abnormal levels of cholesterol, LDL, and triglycerides).[3] Large numbers of people have one or more of these risk factors, placing them at greater risk of developing chronic kidney disease. In the 2006 Behavioral Risk Factor Surveillance Survey, 9.1% of North Carolina adults reported being told they had diabetes, and 9.3% had a history of cardiovascular disease.[8] Of these different risk factors, diabetes, hypertension, and cardiovascular diseases are considered to be the primary risk factors that increase a person's likelihood of developing CKD.

Measuring, Defining, and Staging Of Chronic Kidney Disease

There are several tests that may be performed to measure kidney function. A health care professional may use a urine dipstick to test for protein in the urine, referred to as proteinuria, that may result from decreased kidney function.[9] Proteinuria, however, can also be caused by other conditions such as cardiovascular disease, diabetes, hypertension, and other forms of kidney disease, so the urine dipstick is not considered the best test of kidney function.[10] Albumin is the protein most likely to be found in the urine if there is a problem with kidney function, and a very small amount of this protein in the urine, called microalbuminuria, is one of the first signs of kidney disease.[11] A urine test for this protein may be performed on people with an increased risk for CKD.

A more specific test for kidney function is measurement of creatinine. Creatinine is a waste product in the blood that comes from muscle activity. It is normally removed by the kidneys, but people have increased creatinine levels when kidney function declines. The glomerular filtration rate (GFR), a calculation of how efficiently the kidneys filter waste from the blood, can be calculated by analyzing all of a person's urine over a 24-hour period. An *estimated* glomerular filtration rate (eGFR) can be calculated by analyzing a person's blood for serum creatinine.[10] The blood is tested in a laboratory to determine how many milligrams of creatinine are in one deciliter of blood

(mg/dL). The creatinine measure is then converted to an estimated glomerular filtration rate using age, gender, and race.[a] Given the relative convenience of the blood test approach and the reliability of the eGFR, this test is widely accepted as the best overall measure of kidney function.

The National Kidney Foundation (NKF) convened panels of experts to review the current evidence on kidney disease and dialysis in adult patients.[12] A separate workgroup was convened to study pediatric kidney disease and dialysis. In 1997, the workgroups published the Dialysis Outcomes Quality Initiative (DOQI) guidelines. In 1999, the NKF focused its attention on earlier kidney disease and developed staging of chronic kidney disease as well as clinical treatment guidelines. The Kidney Disease Outcomes Quality Initiative (KDOQI) was the product of their work.

The KDOQI guidelines define chronic kidney disease as either kidney damage or glomerular filtration rates less than 60 for more than 3 months.[2] Based on glomerular filtration rates (GFR), KDOQI guidelines classify people into one of five stages of CKD that range from kidney damage with normal or elevated GFR to kidney failure.[b] People with increased risk for CKD who have GFR values greater than 90 can be classified as pre-CKD. Stage 1 CKD is described as kidney damage with GFR values greater than or equal to 90. Kidney function steadily declines until Stage 5, kidney failure. Kidney failure includes patients who may or may not be treated with dialysis or transplantation.[13] In contrast, the term "end-stage kidney disease" (ESKD) includes only those individuals with kidney failure who have had a kidney transplant or who are undergoing dialysis.

Using the national prevalence estimates of kidney functioning, the University of North Carolina at Chapel Hill (UNC) Kidney Center was able to estimate the number of people in North Carolina at each stage of CKD.[14] In total, UNC estimated that there were 941,770 North Carolinians with non-ESKD CKD (Stages 1 – 4). According to the United States Renal Data System (USRDS), more than 11 000 people in North Carolina suffer from ESKD. The numbers of new cases and people living with ESKD have steadily increased since 1994, and the state is higher than the national average. Table 2.1 lists the different stages of chronic kidney disease, the estimated national prevalence of the disease, and the estimated number of people in North Carolina at each stage of the disease.

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a The most commonly used equations to estimate glomerular filtration rate are the Modification of Diet in Renal Disease (MDRD) study equation and the Cockcroft-Gault (CG) equation. The MDRD equation estimates eGFR using creatinine value, age, race, and gender, while the CG equation uses creatinine value, age, gender, and weight. The MDRD equation is validated for values <60 in adults. [22]

b The level of GFR may vary by patient. Some progress through stages more quickly while others never move past an intermediate stage. The health care provider will consider the specific risk factors of each patient to determine a treatment plan.

Table 2.1.
Five Stages of Chronic Kidney Disease

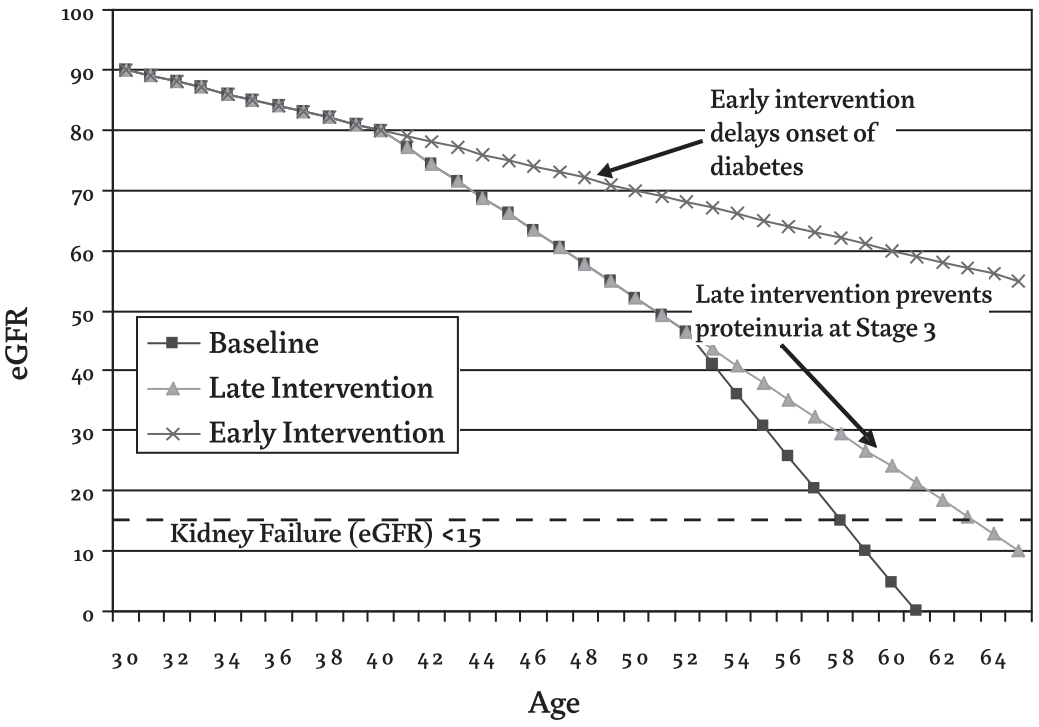
Stage	Description	GFR (mL per minute per 1.73 m^2)	US prevalence, percentage of affected patients (%)[4]	Estimated NC prevalence (see Appendix A)	Estimated number of North Carolinians with CKD by stage
—	At increased risk for chronic kidney disease	No CKD via KDOQI staging, but with risk factors for chronic kidney disease	Unknown	25.3%	1,636,629
1	Kidney damage with normal or elevated GFR	≥90	1.8%	1.8%	110,000
2	Kidney damage with mildly decreased GFR	60 to 89	3.2%	3.4%	208,000
3	Moderately decreased GFR	30 to 59	7.7%	8.1%	503,000
4	Severely decreased GFR	15 to 29	0.4%	0.4%	27,000
5	Kidney failure	<15 (or dialysis)	0.1%	—	>11,000

Despite the large number of people living with CKD, there is an overall lack of knowledge about the disease even among people who have CKD. Nationally, only about 25% of Americans diagnosed with CKD reported awareness about weak or failing kidneys.[5] Among the general population, there is even less awareness. Preliminary data from a UNC Kidney Center study shows that people do not know the risk factors for CKD and associate the factors with unrelated behaviors.[15] A telephone survey was conducted among North Carolina citizens in three counties targeted by the UNC Kidney Education Outreach Program (KEOP). Respondents were provided a list of several items and were asked whether each was a risk factor for kidney disease. The most popular responses for risk factors were not drinking enough water and drinking dark sodas, although neither is directly related to CKD. In addition, many people in the state who have CKD do not receive treatment for the condition until the disease is in the advanced stages. According to 2003 North Carolina Medicaid data, only 30% of Medicaid recipients who presented in the emergency department with acute kidney episodes had received kidney-related treatment from a health care professional within the past 60 days.[16] Furthermore, nationally over one-quarter of patients admitted to the hospital for dialysis enter through the emergency department, suggesting that the patient may not have been seeing a health care provider regularly.[17]

Complications

If not controlled, CKD can lead to rapidly deteriorating kidney function. As kidney function declines, patients develop complications related to fluid overload, chemical imbalance, and waste buildup.[18] These problems may lead to high blood pressure, high blood sugar, high lipid levels, anemia, and bone disease. Patients with CKD should receive evaluation and treatment for these complications including routine blood sugar and blood pressure testing. Figure 2.1 shows a sample of GFR decline based on published estimates of average decline and two theoretical interventions including an early intervention that prevents diabetes and a late intervention that prevents proteinuria.

Figure 2.1.
Sample eGFR Decline



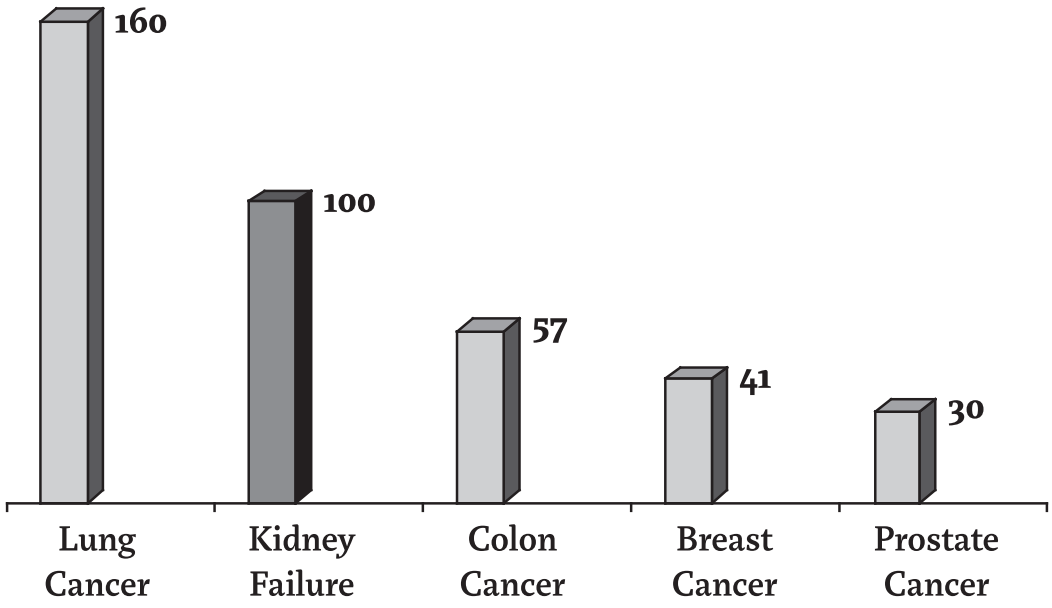
Source: NC Institute of Medicine calculations based on sample GFR decline values presented in Table 3 of Boulware et al, *JAMA*, 2003. Assumptions: Early intervention prevents onset of diabetes at age 40, patient would develop proteinuria at onset of Stage 3 unless he receives late intervention.

Most patients with CKD do not die from kidney failure. Rather, the decreased kidney function leads to failure of other organs. CKD patients are more likely to die from comorbidities of kidney disease than to progress to ESKD.[19] As GFR decreases, the rates of cardiovascular events, hospitalizations, and death increase substantially.[20] Dialysis patients are 5 to 30 times more likely to die from cardiovascular disease than are people from the general population who are the same age, race, and gender. Cardiovascular disease is the leading cause of death both for patients on

dialysis and people with chronic kidney disease. The risk of death increases sharply as estimated GFR declines even after adjusting for differences in socioeconomic status, prior cardiovascular disease, prior hospitalization, diabetes, hypertension, abnormal lipid levels, lung or liver disease, cancer, dementia, proteinuria, and dialysis.[21]

Although kidney failure is not the most common cause of death for people with CKD, it is nonetheless a common cause of death. Death from kidney failure occurs more frequently than death from many of the most prevalent forms of cancer. (See figure 2.2.)

Figure 2.2.
Sample eGFR Decline



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Clinical Guidelines

Evidence-based clinical guidelines are established to provide standards to treat patients with different health conditions. These guidelines change over time, and new ones are developed as health professionals gather new evidence about what treatments work best for different conditions. The *KDOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification* provides 15 recommendations for early identification and appropriate treatment to improve patient outcomes.[2] The KDOQI guidelines focus on assessment and classification of CKD, associations between level of kidney function and complications, and risk for progression of the disease. Guidelines 1-15 cover the following: (1) the definition and stages of chronic kidney disease; (2) evaluation

and treatment; (3) individuals with increased risk for chronic kidney disease; (4) estimation of GFR; (5) assessment of proteinuria; (6) markers of kidney damage other than proteinuria; (7) high blood pressure; (8) anemia; (9) malnutrition; (10) bone diseases and disorders of calcium and phosphorus metabolism; (11) neuropathy; (12) functioning and well-being; (13) loss of kidney function; (14) diabetic complications; and (15) cardiovascular disease. (See Appendix B for complete KDOQI guidelines.)

The Task Force is supportive of all KDOQI guidelines but focused on those guidelines that assisted in developing recommendations for identification and screening of people at risk for CKD (Guidelines 3, 4, 5) and recommendations for appropriate treatment plans for the primary health problems that exacerbate CKD (Guidelines 7, 14, 15). The KDOQI evidence-based guidelines that the Task Force focused on can be summarized into the following categories.

- ***Testing.*** Some individuals without kidney damage and with normal or elevated GFR are at increased risk for development of chronic kidney disease. All individuals at increased risk for CKD should be assessed using a spot urine sample as part of routine health encounters to determine whether they are at increased risk of developing chronic kidney disease.[c] The recommended urine test varies based on clinical and sociodemographic factors.[d] Individuals at increased risk of developing chronic kidney disease should undergo testing to estimate kidney function. Individuals found to have chronic kidney disease should be evaluated and treated. Individuals at increased risk but not found to have chronic kidney disease, should be advised to follow a program of risk factor reduction, if appropriate, and undergo repeat periodic evaluation.

- ***Measuring kidney function.*** Estimates of GFR are the best overall indices of the level of kidney function. The level of GFR should be estimated from prediction equations that take into account the serum creatinine concentration and some or all of the following variables: age, gender, race, and body size.[e] The serum creatinine concentration alone should not be used to assess the level of kidney function. Clinical laboratories should report an estimate of GFR using a prediction equation in addition to reporting the serum creatinine measurement.[f]

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c The 1996 release of the United States Preventive Services Task Force recommended urinalysis only for individuals with hypertension or diabetes but no longer has any recommendations related to proteinuria screening. KDOQI recommendations acknowledge this difference but point out that broader screenings will detect CKD earlier. [Guide to Clinical Preventive Services, 2nd ed, 1996. Report of the US Preventive Services Task Force. Alexandria, VA: International Medical Publishing; 1996. Accessed at http://www.ahrq.gov/clinic/cpsix.htm on 19 May 2003])

d It is usually not necessary to obtain a timed urine collection (overnight or 24-hour) for these evaluations.

e The following equations provide useful estimates of GFR: In adults, the Modification of Diet in Renal Disease (MDRD) Study and Cockcroft-Gault equations, and in children, the Schwartz and Counahan-Barratt equations.

f Autoanalyzer manufacturers and clinical laboratories should calibrate serum creatinine assays using an international standard. Measurement of creatinine clearance using timed (for example, 24-hour) urine collections does not improve the estimate of GFR over that provided by prediction equations. A 24-hour urine sample provides useful information for estimation of GFR in individuals with exceptional dietary intake (eg, vegetarian diet, creatinine supplements) or muscle mass (eg, amputation, malnutrition, muscle wasting), assessment of diet and nutritional status, and the need to start dialysis.

- ***Treatment of patients with high blood pressure.*** High blood pressure is both a cause and a complication of chronic kidney disease. As a complication, high blood pressure may develop early during the course of chronic kidney disease and is associated with adverse outcomes—in particular, faster loss of kidney function. In addition, patients with chronic kidney disease—irrespective of diagnosis—have a high risk of developing cardiovascular disease (CVD) including coronary heart disease, cerebrovascular disease, peripheral vascular disease, and heart failure. Blood pressure should be closely monitored in all patients with chronic kidney disease. Treatment of high blood pressure in chronic kidney disease should include a multifaceted approach. Target blood pressure levels should be specified. Antihypertensive medicines should be given to prevent the progression of kidney disease and the development of cardiovascular disease. Specific examples of these medications include angiotensin-converting enzyme (ACE) inhibitors and angiotensin-2 receptor blockers (ARB). Finally, in addition to medication, other therapeutic interventions should be used.

- ***Treatment of patients with diabetes.*** The risk of cardiovascular disease, retinopathy, and other diabetic complications is higher in diabetic patients with kidney disease than in diabetic patients without kidney disease. Prevention, detection, evaluation, and treatment of diabetic complications in patients with chronic kidney disease should follow published guidelines and position statements including strict glucose control in diabetes. Guidelines regarding angiotensin-converting enzyme inhibitors or angiotensin receptor blockers and strict blood pressure control are particularly important since these agents may prevent or delay some of the adverse outcomes of both kidney and cardiovascular disease.

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Chapter Three
Economics of Chronic Kidney Disease

Chronic kidney disease imposes a significant burden of suffering. Modest decreases in quality of life can be identified in even moderate stages of CKD.[1,2] Further, many patients experience marked decreases in their quality of life from the comorbid conditions that can be created or exacerbated from CKD.[3,4] Beyond the effects on personal well-being, CKD imposes significant financial costs on individuals and the overall health care system.

Because CKD patients often have multiple chronic conditions, it is often difficult to identify the cost increases resulting from CKD alone. Indeed, a number of studies have found that the comorbidities have a multiplicative effect; a given comorbidity often leads to larger cost increases among CKD patients than among non-CKD patients.[5] Furthermore, the systematic underdiagnosis of early CKD also is problematic in developing estimates.

Despite these difficulties, researchers have tried to develop cost estimates because they have recognized that understanding the economic costs imposed by chronic kidney disease is critical to developing strategies to decrease the burden of CKD. In order to develop population-based cost estimates, it is necessary to develop prevalence estimates for all stages of CKD. The more accurate prevalence estimates are those based on populations systematically tested for CKD. For example, the National Health and Nutrition Examination Survey (NHANES) is a national survey that performs serum creatinine measurements on all respondents. Because NHANES collects creatinine data, it is possible to calculate estimated GFR to make population-based estimates of the prevalence of CKD.[a] With population prevalence estimates in hand, population cost estimates can be developed by using per-person cost estimates.

Naturally, when describing the costs of medical interventions (such as dialysis), there are ethical concerns since most people are uncomfortable thinking about lives in

a NHANES data are the best source for calculating population-based estimates of CKD. However, ideally, CKD staging would be based on multiple serum creatinine tests. There is no data source which includes multiple samples of creatinine for respondents over time.

dollar terms. Part of the problem is the difference between an *individual* life and a *statistical* life; dialysis saves an individual life, but better traffic signals or safer cars save *statistical* lives (we never know whose life is saved, but we know that on average we saved X lives/year with better traffic signals). Often, when discussing the cost-effectiveness of medical interventions, we use *quality adjusted life years* which measures both the number of years as well as the quality of those years. For example, one study estimated that the quality of life for patients with CKD Stages 2-4 was about 95% of people without CKD (meaning only a modest decrease), but the quality of life for Stage 5 patients was 70% of people without CKD.[2] For context in the following discussion, over a host of medical treatments, those interventions that cost more than $100,000 per quality adjusted life year (QALY) are generally considered not cost-effective,[6] while those that cost less than $50,000 are considered "good bargains," although there is controversy about whether these values are too low.[7]

Costs of CKD and ESKD

The costs associated with CKD and ESKD are largely borne by different payers. People in the non-kidney failure stages of CKD (Stages 1-4) generally have the same insurance coverage as the general population. These individuals may have employer-based coverage, private non-group coverage, public coverage (eg, Medicaid, Medicare, or Veterans), or they may be uninsured. There is no special insurance coverage until a person needs kidney replacement therapy (either dialysis or transplant). Most people who need kidney replacement therapy will qualify for Medicare coverage. In most instances, Medicare coverage begins in the fourth month following initiation of dialysis (however, there are certain instances involving home dialysis or transplantation when coverage can begin earlier). Once Medicare coverage begins, there are special rules for people who have insurance coverage under an employer- or union-based health plan. Employer- or union-based coverage is the primary payer of health bills for the first 30 months (Medicare is the secondary payer and will pay the bills not covered by the employer- or union-based plan). After 30 months, Medicare becomes the primary payer, and the other insurance coverage becomes the secondary payer. Medicare coverage continues for as long as the person receives dialysis or for 36 months following transplantation.[b]

The costs associated with end-stage kidney disease (ESKD) are considerable, although costs vary widely by dialysis modality. One meta-analysis found that the cost per life year saved varies from roughly $55,000-$80,000 per life year for in-center hemodialysis, $33,000-$50,000 for home hemodialysis, and approached $10,000 per life year for transplantation.[8] As noted more fully in

b Centers for Medicare and Medicaid Services. Medicare Coverage of Kidney Dialysis and Kidney Transplant Services. CMS Publication No. 10128. September 2007. http://www.medicare.gov/Publications/Pubs/pdf/10128.pdf.

Chapter 4, transplantation is the most cost-effective treatment for patients with ESKD. Further, peritoneal dialysis is more cost-effective than hemodialysis, although less commonly used. It should be noted that all treatments are cost-effective using commonly used cost-effectiveness standards.[c]

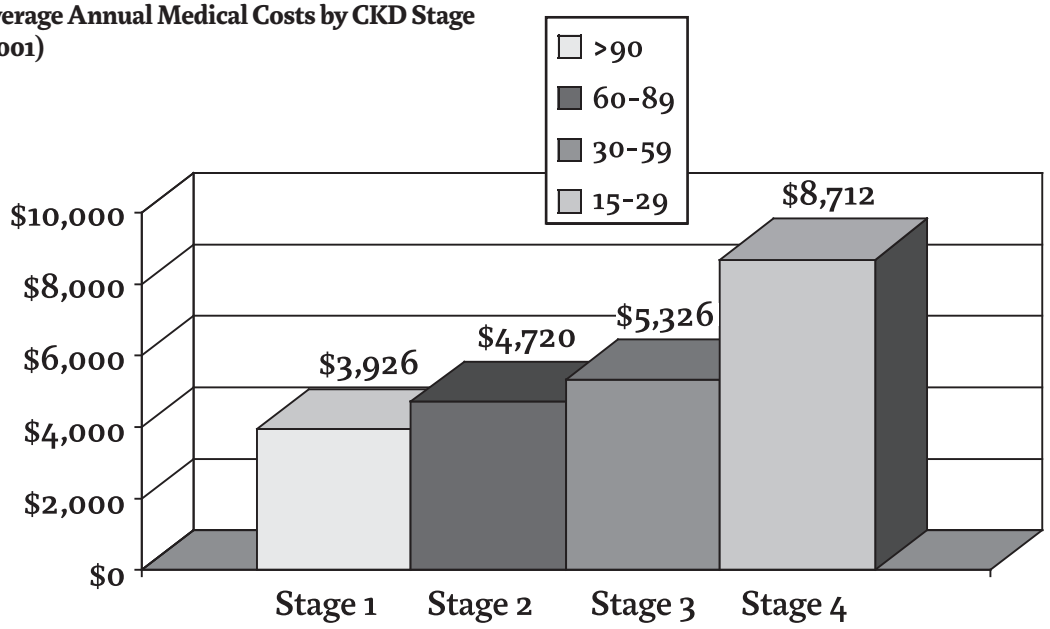
As discussed in Chapter 1, Medicare costs for ESKD have increased considerably over the past few years. ESKD costs represent 6.4% of the Medicare budget, but ESKD patients represent only 1.2% of the Medicare population.[9] The cost of dialysis in the Medicare population was nearly $250,000 per person in 2003. Although Medicare pays for approximately two-thirds of the health care costs for people with ESKD, the state Medicaid program also helps pay for some of the costs. In State Fiscal Year 2006, there were 7,592 North Carolina Medicaid enrollees who received services for ESKD.[10] ESKD patients incurred $839 million in total medical spending—an average annual cost per patient of more than $110,000 (excluding pharmacy costs covered under Part D). Though most Medicaid recipients with ESKD are also covered by Medicare, over half of these costs were incurred by Medicaid patients.

The metaphor of an iceberg is commonly used when describing the epidemiology of the early stages of asymptomatic CKD since the highly visible ESKD population represents but a small fraction of the whole population with CKD. This metaphor is also appropriate when describing the economics of CKD. Total Medicare costs associated with non-ESKD CKD were roughly equal to the Medicare costs of ESKD in 2005. Thus, although ESKD costs are considerable (representing 6.4% of all Medicare costs in 2005), the costs associated with pre-ESKD CKD patients are also considerable. Given that approximately 20% of individuals with Stages 3 and 4 in the 2003-2004 NHANES had private insurance but not Medicare, total costs for CKD will be higher than those incurred by Medicare alone.

Nationally representative data on CKD costs are unavailable, but one study of a large HMO provides some important information on CKD costs. CKD patients experienced an increased cost of as much as $4,676 per person per year, depending on stage of disease.[5] The following chart demonstrates the effect CKD stage has on overall costs. Average annual costs adjusted for age and gender are shown below by stage of CKD. Note that costs for Stage 3 patients were roughly one-third higher than for Stage 1 patients, and costs for Stage 4 were over double. Patients with CKD had 2.5 times as many prescriptions, 1.9 times as many office visits, and were 2.2 times as likely to be hospitalized as non-CKD patients of similar age and gender.

c This is, indeed, by definition as the standard of $50,000-$100,000 commonly used throughout the literature derives from the cost of dialysis.[15]

Figure 3.1.
Average Annual Medical Costs by CKD Stage (2001)



Source: Smith DH, Gullion CM, Nichols G, Keith DS, Brown JB. Cost of medical care for chronic kidney disease and comorbidity among enrollees in a large HMO population. *J Am Soc Nephrol*. 2004;15(5):1300-1306.

The US Renal Data System reports that for CKD patients who never reach ESKD, the average cost in the month prior to death is $12,405.[d] That figure has increased from $4,174 in 1994. Inpatient costs per patient are eight times higher for those with ESKD than for CKD. Often this is a consequence of dialysis beginning when the patient presents in an emergency room setting; this type of dialysis initiation is the most expensive. In 2005, average costs during the first month of dialysis were approximately $15,000 while annual costs were approximately $60,000 (USRDS). As expected, patients with comorbidities cost much more to treat than those with CKD alone; the average costs for inpatient and outpatient services for CKD patients with heart failure were over twice that of a CKD patient with no heart failure. Diabetes increased the costs slightly for a CKD patient without heart failure, but dramatically for patients with heart failure ($1,782 for a CKD patient with diabetes but without congestive heart failure compared to $2,113 for a patient with both diabetes and congestive heart failure).[9]

The costs of CKD have been increasing steadily over the last decade or so. Average costs for people with CKD have increased from approximately $800 per month in 1993 to more than $1,200 in 2005 (adjusted for inflation).[9] Available evidence suggests that one major driver of the cost increases is higher prevalence of comordibity in the CKD population. For example, one study

d United States Renal Data System. USRDS 2006 Annual Data Report: Atlas of End-Stage Renal Disease in the United States. National Institutes of Health. National Institute of Diabetes and Digestive and Kidney Diseases. Bethesda, MD; 2006.

tracked prevalence of selected comorbidities in a sample of new dialysis patients. From 1995 to 1998 the proportion of dialysis patients with heart failure increased significantly from 59.2% to 64.7%, a history of heart attack from 16.0% to 19.4%, diabetes from 54.9% to 58.9%, and hypertension from 73.2% to 81.1%.[11]

Of course, it would be better if we could manage the progression of CKD more effectively and slow the progression of the disease. Early screening in high-risk populations (that is, case-finding), identification, and treatment of CKD can help people prevent ESKD and reduce health care expenditures. For example, as recommended in the KDOQI guidelines, the use of angiotensin-2 receptor blockades and angiotensin-converting enzyme inhibitors in the treatment of CKD can both slow the progression of CKD to more advanced stages as well as inhibit the development of significant comorbidities.[12] Other research has found that proteinuria screening may be appropriate (using conventional levels of cost-effectiveness) but only for certain populations at higher risk for CKD.[13,14,e]

RTI International is currently conducting analyses for the Centers for Disease Control and Prevention on the cost-effectiveness of alternative interventions. *Very few medical interventions are cost-saving*. Cost-effectiveness studies in the health care context evaluate which intervention provides the best health outcomes (ie, extended life or improved quality of life) per cost of the health care intervention. Unfortunately, the research is just beginning, but the types of interventions being considered are similar to those proposed by the Task Force. RTI is also examining whether early intervention and treatment programs lead to sufficient improvements in length and quality of life to warrant the increased health care expenditures. Early results suggest that early CKD intervention and treatment, like many other health care interventions, may not lead to an overall reduction in health care expenditures per patient. Instead, the early intervention and treatment may lead to better health outcomes, improved health status, and functioning and longer lives.

e Proteinuria leads to a larger average annual eGFR decrement for patients with diabetes than without. Thus, it may be more cost effective to screen patients with diabetes for proteinuria than to screen otherwise similar non-diabetics for proteinuria.

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Chapter Four
Coordinated System Of Care

People in the United States with chronic kidney disease progress to kidney failure more frequently than in other countries, even though the prevalence of chronic kidney disease in the United States is similar to that in other countries.[1] One of the reasons for the rapid deterioration in the health status of people with chronic kidney disease is the lack of a comprehensive system of care, especially for individuals at earlier stages of kidney disease.[2] Curtin et al. describes the current fragmented system of care for people with chronic kidney disease in the United States:

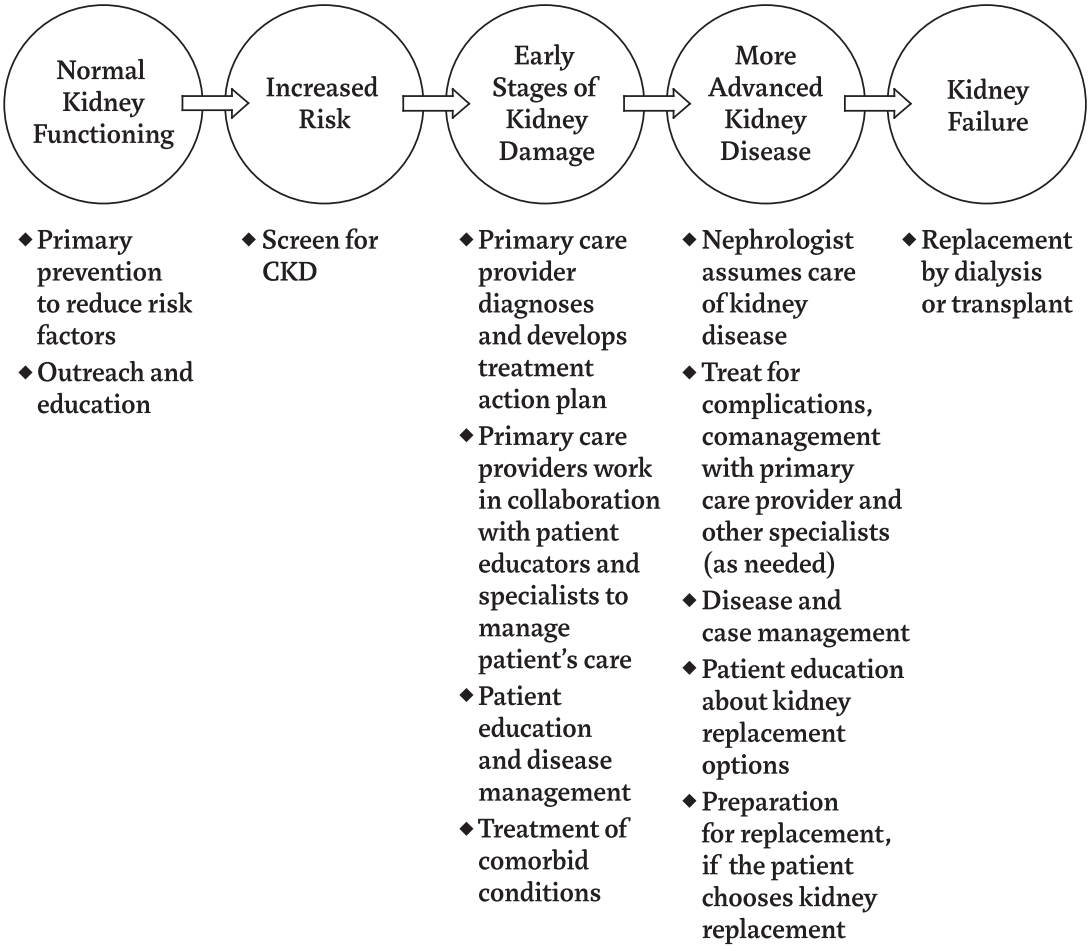
> Many believe, care delivered during CKD stages 1-4 is uncoordinated and suboptimal [citations omitted]. Kidney disease is often diagnosed relatively late in its course [citations omitted]. In many cases, interventions to delay progression may not be instituted in a timely fashion, albumin levels may be allowed to fall in the pre-ESRD period, and anemia and cardiovascular disease may be undertreated [citations omitted]. Additionally, patient education is not likely to be instituted during the pre-ESRD period, modality choice may be less than optimally 'informed' and access may not be placed in advance of dialysis [citations omitted]. Renal replacement therapy itself often occurs late and on an emergent basis [citations omitted].
>
> Some of the problems with the delivered treatment might be attributed to the disjointed nature of the care. Patients with early stage CKD are usually treated by primary care physicians and referral to nephrologists frequently occurs late in the course of the disease [citations omitted]. Dialysis and transplant patients tend to be treated by different "teams," even within the same health care setting. Moreover, communication/coordination between these health care teams that might smooth the transitions through CKD and deliver continuous care does not occur with regularity [citations omitted].[3]

Studies suggest that our fragmented system of care leads to worse health outcomes for people with chronic kidney disease. Hallan et al. conducted a cross-country comparison to examine the prevalence of chronic kidney disease in the United States and Norway,

both countries with large data sets that could be used to identify people with CKD.[1] The prevalence of early stages of CKD is similar in the two countries even after adjusted for age, race, and diabetes status. People in Norway, however, have a much lower risk of progressing to ESKD than do people in the United States. The researchers compared the care system offered in Norway to care in the United States and concluded that the difference in the prevalence of ESKD between the two countries is due to differences in management of patients with earlier stages of CKD. Norwegian patients were referred to nephrologists earlier in the course of their disease and had more visits prior to renal failure. As a result, patients were less likely to be anemic when starting dialysis and had better nutritional status than patients with kidney disease in the United States. Patients were more likely to receive transplantation services in Norway, reducing the need for dialysis. Because of this more coordinated system of care, the people with chronic kidney disease in Norway were able to maintain higher kidney function for longer periods of time than were people in the United States.

North Carolina needs a comprehensive system of care to ensure that people with chronic kidney disease are identified early and receive the services needed to help them manage their chronic health problem.[4] The system of care can be conceptualized as addressing five subpopulations defined by their risk for and stage of CKD. An effective system of care would ensure that the general population with normal kidney functioning has a basic understanding of kidney health and risk factors for kidney disease. Those with normal kidney function should be screened for CKD risk factors such as diabetes and hypertension. Better detection of CKD risk factors would help practitioners target the people at most risk for CKD. Individuals at higher risk for CKD (such as those with hypertension, diabetes, cardiovascular disease, or a family history of CKD) would be screened specifically for chronic kidney disease. Those with early stage kidney damage would have a treatment action plan, be treated for comorbid conditions (eg, hypertension or diabetes), and receive ongoing care to slow the progression of the disease. Numerous studies have demonstrated that treatment with specific agents such as inhibitors of the angiotensin converting enzyme (ACE-I) slow progression of CKD effectively. Unfortunately, one study of Medicare patients admitted to a hospital with diabetic- or hypertensive-related kidney disease showed that less than one-third of patients with CKD receive appropriate therapy.[5] Although proven strategies are available, they are simply not being utilized with sufficient frequency to slow progression in the population with CKD. Further, since CKD is an independent risk factor for accelerated cardiovascular disease, and most patients with CKD die of cardiovascular events before reaching end stage kidney disease, insufficient attention is being directed to treating cardiovascular disease in this subset of patients. As a person's kidney function declines further, he or she would be treated for complications (eg, anemia), educated about kidney replacement options, and begin early preparations for kidney replacement therapy. Finally, those who have kidney failure would receive appropriate kidney replacement therapy.

Chart 4.1.
Coordinated System of Care for Patients as They Progress with Kidney Disease



Adapted from National Kidney Foundation. KDOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. *Am J Kidney Dis*. 2002;39(suppl. 1):S1-S266.p.6 Figure 1.

Chart 4.1 lays out a comprehensive system of care for people at risk of kidney disease or for people who have chronic kidney disease. A comprehensive system of care prior to kidney failure needs to have at least six elements:

(1) ***Primary prevention.*** North Carolina can help reduce the occurrence of chronic kidney disease by controlling the most common risk factors that can lead to or exacerbate chronic kidney disease including diabetes and hypertension.

(2) ***Outreach and education.*** The general public should be educated about chronic kidney disease, its risk factors, and the need to be screened for chronic kidney disease if they fall into a high-risk group. This is similar to health outreach and education efforts to encourage women to receive annual pap smears or mammograms or to encourage people over age 50 to obtain periodic colorectal cancer screening tests.

(3) ***Screen high-risk individuals.*** Primary care providers should routinely screen people who are at risk for developing chronic kidney disease including people with diabetes, hypertension, cardiovascular disease, a family history of chronic kidney disease, or other evidence-based risk factors which have been demonstrated to contribute to the development of CKD.

(4) ***Primary care providers and collaborative care teams.*** A person with chronic kidney disease should have a regular primary care provider who serves as the patient's medical home. The primary care provider should monitor the patient's kidney function, develop a care management plan using evidence-based clinical practice guidelines, treat the patient for comorbid conditions, and refer the patient to a nephrologist for consultation or ongoing care as the patient's kidney function declines and to other specialists for consultation or care to manage other comorbid conditions and complications.

(5) ***Patient education, disease management, and care management services.*** The care from the primary care provider should be augmented, when necessary, with a trained case manager or disease management specialist.

(6) ***Nephrologists.*** Nephrologists and other specialists should be available to provide consultative services to primary care providers to help the primary care provider manage patients with early stages of chronic kidney disease and the associated complications such as accelerated cardiovascular disease. Nephrologists, working collaboratively with the primary care provider and other specialists as needed, should be available to oversee the care of patients with more advanced stages of kidney disease or renal failure. Nephrologists should help provide early education regarding the different types of renal replacement therapies including kidney transplant, peritoneal dialysis, and hemodialysis, and ensure that vascular access is established prior to the need for kidney replacement therapy.

Although North Carolina has some of the necessary ingredients of a coordinated system of care, we lack many of the other essential elements needed to effectively reduce the occurrence of chronic kidney disease and to appropriately manage people with the disease. The NC IOM Task Force on Chronic Kidney Disease identified gaps in the existing health care system and made specific recommendations to address these problems. Each of the six elements outlined above is described in greater detail below.

Primary Prevention

Diabetes mellitus and hypertension are major causes of chronic kidney disease and kidney failure. Diabetes is an underlying cause of CKD in 42% of new patients diagnosed annually with CKD.[7] Most of these patients (90%) have Type 2 diabetes mellitus, the prevalence of which is growing rapidly. In addition, people with uncontrolled hypertension (high blood pressure) have a greater risk of developing chronic kidney disease (as well as heart disease, stroke, and myocardial infarction).[8] Not only do these chronic health conditions increase the risk of someone developing chronic kidney disease, they are also major contributors to kidney *failure*. Together, diabetes

mellitus and hypertension help contribute to approximately 60% of new cases of people with kidney failure.[9] North Carolina can help prevent chronic kidney disease by reducing risk factors that lead to diabetes or hypertension such as obesity, poor nutrition, and lack of exercise.

Reducing the number of people with chronic kidney disease or kidney failure will have a positive spillover effect on other health conditions. Decreased kidney function can lead to complications in all organ systems.[10] This is particularly true for cardiovascular disease (CVD). Patients with CKD are 5 to 10 times more likely to die—primarily from cardiovascular causes—than to progress to kidney failure, and the rate of sudden death for this population is more than 3 times greater than that seen in individuals without CKD.[11] Thus, controlling kidney disease in earlier stages may prevent comorbidities as well as prevent or slow the progression to kidney failure.[10] Additional education is necessary to make physicians more aware of the independent influence of CKD on CVD and other vascular complications so that management of these comorbidities can be integrated into the patient's health plan in a coordinated manner.

North Carolina already has many primary prevention programs aimed at reducing risk factors that lead to obesity, diabetes, and hypertension. For example, Eat Smart, Move More NC is a statewide social marketing campaign aimed at helping North Carolina citizens eat healthier and exercise more by changing social norms and practices in schools, worksites, communities, and healthcare settings. The NC Statewide Health Promotion Program provides funding to local health departments to focus on barriers to physical activity and good nutrition at the community level. The Office of Minority Health and Health Disparities provides grants to community-based organizations to address health disparities. In addition, Healthy Carolinians supports local coalitions that assess and address community health priorities, which may include primary prevention.

Unfortunately, these programs are predominantly federally funded and lack adequate resources to accomplish even a modest fraction of their ambitious agendas. Obesity rates continue to rise across North Carolina. The state was recently ranked 5th worse for childhood obesity rates,[12] and the state's adult obesity rate is higher than the national average (CDC BRFSS). The prevalence of diabetes, a potent risk factor for kidney disease, has doubled over the last 10 years in North Carolina. In addition, the incidence of diabetes is 50% higher in our minority populations.[13] The dramatic increase in obesity in North Carolina also parallels a rapid increase in the prevalence of metabolic syndrome, an additional risk factor for CKD.

Recommendation 4.1

The Task Force supports ongoing efforts by the North Carolina Division of Public Health, the North Carolina Department of Public Instruction, and other state and local organizations to enhance community education about and reduce the risk factors for chronic kidney disease.

Recommendation 4.2

The North Carolina General Assembly should increase funding to the Division of Public Health to build statewide capacity for chronic disease prevention programs that reduce the risk factors that may lead to chronic kidney disease by funding implementation of the Eat Smart, Move More NC objectives and by increasing funding to local communities through the Statewide Health Promotion, Healthy Carolinians, and Health Disparities programs.

Outreach And Education

The National Kidney Foundation estimates that most of the nation's 20 million adults with CKD are unaware of it.[14] Chronic kidney disease is largely asymptomatic. In fact, most people do not experience health symptoms until their kidney functioning has deteriorated to a very low level. Thus, most people are unaware of the need to monitor their kidney health.

Certain groups are at increased risk of developing chronic kidney disease but often are unaware of these health risks. These groups include people diagnosed with diabetes or hypertension, people aged 65 or older, and people with a family history of kidney failure. In addition, certain racial and ethnic minorities face increased risks of developing CKD and progressing to kidney failure. For example, African Americans have a 3.8 times greater likelihood of having kidney failure than do whites. When compared to whites, American Indians have a 2 times higher risk of kidney failure, and Hispanics have a 1.5 times higher risk.[15] Many of these individuals, however, do not seek care for their kidney condition until they have extensive kidney damage and are experiencing kidney failure. Broad-based health education campaigns are needed to educate at-risk populations and the general public about kidney health, risk factors for kidney disease, and the need to monitor kidney functioning. These broad-based public health investments in communication programs aimed at increased awareness would be similar to the strategy adopted for other conditions such as high cholesterol and hypertension.

Many complementary outreach strategies are needed to educate the public about kidney health and chronic kidney disease. Broad-based health education efforts can be effective in reducing the primary risk factors that ultimately lead to chronic kidney disease, especially when these approaches are combined with policy and environmental change interventions.[16] Further, disease management programs coupled with educational materials tailored to populations with low health literacy levels can be particularly effective.[17] In addition, health education provided by health care professionals has been shown to be effective in educating people who are already seeking care. For example, counseling by health care professionals on specific risk factors such as smoking cessation is effective.[18,19] However, different strategies are needed to broadly reach individuals who do not frequently use the health care system.

Many people rely on friends and family for their health information.[20,21] The use of lay health advisors has also been effective in communicating health information.[22] This is particularly true for underserved populations including the uninsured and other groups that have less access to or who are less likely to utilize health care services. People most at risk for chronic kidney disease are frequently those that clinicians find difficult to reach. Community-based cooperative outreach and education efforts have been shown to be successful in reaching underserved populations.[23]

There are already several community-based health education efforts that could be expanded to reach more people or different at-risk populations. Some of these initiatives are designed to increase awareness of kidney health and related risk factors for CKD; others work with the targeted population around diabetes or other health conditions.

- **National Kidney Foundation Kidney Early Evaluation Program (KEEP).** KEEP is a free kidney health screening program designed to raise awareness about kidney disease among high-risk individuals and provide free testing and educational information so that kidney disease and its complications can be prevented or delayed. KEEP targets adults with diabetes, high blood pressure, or a family history of chronic kidney disease, and provides follow-up referrals to providers when needed. The North Carolina affiliate of the National Kidney Foundation (NKF) will provide a screening anywhere in the state based on expressed interest from a local community group. However, the NKF KEEP program does not have a continuous outreach and screening program in any county in the state. Recently, the North Carolina NKF affiliate received a $75,000 grant from the Office of Minority Health and Health Disparities, NC Department of Health and Human Services, to conduct focus groups, educational interventions, and screenings in 11 counties in eastern North Carolina including Beaufort, Cumberland, Durham, Edgecombe, Granville, Greene, Lee, Lenoir, Nash, Wake, and Wilson. The project began September 1, 2007 and will end on June 30, 2008.

- **National Kidney Foundation North Carolina Chapter (NKFNC) "Know Your Score" Public Education Campaign.** The "Know Your Score" public awareness campaign ran on radio stations throughout North Carolina from October through December, 2007. Paid advertising schedules were placed on leading news talk stations in Raleigh and Charlotte. This campaign encouraged listeners to speak with their doctors and "get the score" on their kidney health. Radio public service announcements featured celebrity spokespeople including North Carolina Commissioner of Labor Cherie Berry and Carolina Panther Brad Hoover. The NKFNC continues to work with regional and ethnic print publications such as *PRIDE* magazine and *La Noticia* to include stories about kidney health and the importance of monitoring estimated glomerular filtration rate (eGFR) on a regular basis.

- **UNC Kidney Center Kidney Education Outreach Program (KEOP).** KEOP has four components: (1) primary care provider surveys to assess their skills in managing and identifying early stages of CKD; (2) focus groups to assess high risk individuals' knowledge of the risk factors for CKD; (3) outreach activities aimed at educating at-risk populations and health care professionals about the importance of screening before clinical symptoms appear; and (4) free screenings to identify and provide interventions for people who are at higher risk of developing CKD. KEOP uses trained community-based leaders to assist in education and outreach efforts. In its first 18 months, KEOP screened 1,000 at-risk citizens, conducted 14 focus groups, and participated in 25 outreach activities across Anson, Bertie, Edgecombe, Martin, and Montgomery counties. KEOP will expand to an additional 12 counties including Bladen, Camden, Caswell, Chowan, Greene, Hyde, Moore, Northampton, Pamlico, Perquimans, Swain, and Washington. In addition, KEOP, in partnership with the Kate B. Reynolds Foundation, UNC Health Care, and citizen donors, has purchased a mobile outreach unit. Designed to provide stand-alone capability to host screenings, provide clinical follow-up, and promote citizen awareness about the risk factors for developing CKD, this mobile unit will facilitate KEOP's ability to provide screenings and outreach across all of North Carolina.

  The UNC Kidney Center also initiated a public education campaign to promote understanding of kidney disease called "HEY DOC, HOW ARE MY KIDNEYS?™" This campaign includes billboards and television ads that use local citizens as spokespersons to promote awareness about the major risk factors for developing CKD and the importance of being screened before clinical symptoms appear. Advertising campaigns have occurred in Anson, Edgecombe, and Montgomery counties and are currently being initiated in Bertie County.

- **Office of Minority Health and Health Disparities (OMHHD) Community Health Ambassador Program (CHAP).** The CHAP program trains trusted leaders in the African American, American Indian, and Hispanic/Latino communities to serve as lay health advisors in their communities. OMHHD partners with the North Carolina Community College System, Community Care of North Carolina, the Old North State Medical Society, the University of North Carolina at Greensboro Nursing Program, and community- and faith-based organizations to help identify and train Community Health Ambassadors (CHAs). These volunteers help bridge the gap between community members, their health concerns, and health service providers. CHAs educate community members about how to prevent illnesses, recognize early warning signs, and access services. The goal of the program is help community members prevent chronic diseases and decrease morbidity and mortality.

Currently, CHAP focuses on diabetes and cancer education. However, there are plans to develop modules to address other health disparity issues including CKD, cardiovascular disease, and HIV/AIDS. CHAP began in the spring of 2006. CHAs must successfully complete 20 hours of classroom education and pass a competency examination. The program has trained more than 300 CHAs from the following counties: Buncombe, Mecklenburg, Guilford, Durham, Wake, Lee, Cumberland, Pitt, Martin, Bertie, Hertford, Gates, Greene, Lenoir, Nash, Robeson, and Wilson. There are plans to expand the program statewide as funding becomes available.

- **Division of Public Health Diabetes Today Program.** Diabetes Today focuses on the strengths of communities and their ability to work creatively to deal with problems associated with diabetes. Local health departments serve as lead agencies and collaborate with surrounding health departments to increase the spread of community-based programs focused on reducing the burden of diabetes through awareness, education, and prevention strategies. Currently there are 4 lead Diabetes Today programs in local health departments in Hertford, Robeson, Surry, and Wake counties. Through the collaborative efforts of each of these departments within its region, Diabetes Today initiatives are implemented in 29 counties in North Carolina.[a]

- **Division of Public Health WISEWOMAN Program.** The North Carolina WISEWOMAN (Well-Integrated Screening and Evaluation for Women Across the Nation) program provides expanded cardiovascular disease screening, intervention, counseling, and referral services to women age 40 and older who are at or below 250% of the Federal Poverty Guidelines (FPG), uninsured or underinsured, and eligible for the Breast and Cervical Cancer Control Program (BCCCP). Special emphasis is placed on the population of women 50-64 years of age, especially minorities. WISEWOMAN is administered locally through 39 North Carolina county or district health departments and community health centers.[b]

a The counties currently covered by the initiative are Ashe, Alleghany, Surry, Stokes, Watauga, Wilkes, Yadkin, Forsyth, Guilford, Davie, Davidson, Chatham, Durham, Granville, Vance, Franklin, Nash, Wilson, Wake, Johnston, Harnett, Lee, Scotland, Hoke, Robeson, Bladen, Columbus, Halifax, Northampton, Hertford, Martin, Washington, and Tyrrell.

b The counties currently covered by the initiative are Ashe, Alleghany, Watauga, Buncombe, Cabarrus, Caldwell, Cleveland, Columbus, Cumberland, Forsyth, Duplin, Graham, Granville, Vance, Guilford, Halifax, Haywood, Hyde, Jackson, Johnston, Lincoln, Martin, Mecklenburg, Moore, New Hanover, Northampton, Pamlico, Pasquotank, Perquimans, Chowan, Person, Richmond, Robeson, Surry, Swain, Union, Vance, Wayne, Yadkin, and Yancey. In November 2007 Ashe, Catawba, and Robeson will be added.

- **Division of Public Health Heart Disease and Stroke Prevention (NC HDSP) Program.** The NC HDSP Program is a state-based cardiovascular health program that focuses on systems-level change to create communities, work places, schools, and health care systems that are supportive of cardiovascular health promotion and cardiovascular disease prevention. The NC HDSP Program works with 4 lead counties (Henderson, Cabarrus, Hertford, and Pitt) to facilitate and coordinate the work among key health promotion and disease prevention partners and to serve as a resource for technical assistance for policy and environmental change interventions to prevent heart disease and stroke.

These 7 programs help reach the public with information about kidney disease or with information on other health conditions such as diabetes that can lead to kidney disease. However, more is needed to reach target populations throughout the state. In order to reach more of the at-risk population, the NC IOM Chronic Kidney Disease Task Force recommends:

Recommendation 4.3 (PRIORITY RECOMMENDATION)

(a) The North Carolina General Assembly should appropriate $500,000 in recurring funding to the Division of Public Health and the Office of Minority Health and Health Disparities to expand diabetes prevention and control funding. Funding should be limited to programs that are built on evidence-based or promising practices that educate at-risk populations about chronic kidney disease and the importance of early screening. Funding priority should be given to programs that:

(1) Increase outreach in existing counties and expand outreach to counties that are not being adequately served by existing programs.

(2) Include a plan for ongoing evaluation of effectiveness.

(3) Target populations at increased risk for developing chronic kidney disease and incorporate local partners such as faith-based health ministries, beauty salons/barber shops, civic and senior citizen groups, public health departments, and primary care practitioners.

(b) Programs must be evaluated in a timely fashion to demonstrate effectiveness in order to receive continued funding.

(c) In order to ensure that the most effective elements of programs are emulated appropriately, the Division of Public Health and the Office of Minority Health and Health Disparities should work with existing grantees and others to foster inter-program collaboration. Collaborative activities should include, but not be limited to, sharing of appropriately privacy-protected evaluative data to allow improvement in a program's current (or potential) design.

Collaboration should ensure that the program messages are coordinated to minimize confusion among the targeted populations.

Recommendation 4.4

Public and private insurers should examine patient-level eligibility and claims data to identify people who are at risk of or diagnosed with chronic kidney disease. Insurers should explore mechanisms to increase awareness of chronic kidney disease among consumers at risk, such as targeted messaging that encourages consumers to be screened for kidney function.

Screening High-Risk Individuals

As noted previously, the National Kidney Foundation estimates that most people with chronic kidney disease are unaware of having it. Chronic kidney disease is not often recognized or treated by primary care physicians. In fact, although being diabetic and older than age 65 are two of the primary risk factors for having chronic kidney disease, one study found that primary care practices screen fewer than 20% of Medicare patients with diabetes for kidney disease.[24]

More effort is needed to screen people who are high risk for developing chronic kidney disease. The KDOQI evidence-based guidelines suggest primary care providers should routinely screen people with diabetes, hypertension, or a family history of kidney disease, and should monitor kidney functioning over time.[c,6]

More recent research shows that cardiovascular disease is also a risk factor which contributes to CKD, and thus patients with CVD should also be screened for chronic kidney disease.[25,26] The National Kidney Foundation's KDOQI evidence-based guidelines recommend that providers obtain a "spot" urine sample to measure the microalbumin to creatinine ratio and a blood test to obtain the serum creatinine. The urine microalbumin to creatinine ratio checks for abnormal levels of protein in the urine (microalbuminuria) which is a marker of kidney damage. Serum creatinine can be used to measure the estimated glomerular filtration rate (eGFR),[d] which measures how well the kidney is eliminating waste from the blood.[27] Screening for proteinuria may alert physicians to the presence of CKD before changes in GFR.[28] These helpful tests are widely available, easily obtained, and relatively inexpensive.

People with health insurance generally will have coverage for screening if their provider orders it, but there is no statewide screening program for people who are uninsured. The National Kidney Foundation's KEEP program and the UNC Kidney Center's KEOP program provide screenings to individuals who have been identified as high risk in 26 counties throughout the state. However, uninsured individuals in other areas of the state may not have access to regular screenings.

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a The CDC will be providing funds to 4 states for targeted screening. Pilots will start next year.

b Serum creatinine can be used to measure the estimated glomerular filtration rate using the Modification Diet in Renal Disease (MDRD) prediction formula.[75]

To compound this problem, uninsured individuals who have been diagnosed with CKD may not have a source of coverage to pay for the care and treatment needed to slow the progression of the disease. There are safety net programs in certain communities that provide ongoing primary care services on a sliding fee scale to the uninsured.[e,29] However, these organizations do not serve all areas of the state, and not all safety net organizations have the capacity to provide comprehensive and ongoing primary care services to people with chronic illnesses. The North Carolina General Assembly created the Community Health Center Grants program to help increase access to preventive and primary care services for low-income uninsured. Last year (2007), the General Assembly appropriated $2 million on a recurring basis and $5 million in nonrecurring funds to the Office of Rural Health and Community Care to create or expand safety net organizations.[f] However, these funds are not sufficient to ensure sufficient primary care safety net capacity throughout the state.

In addition to the Community Health Center grants program, the North Carolina General Assembly funds special programs (eg, Purchase of Medical Care program) to help pay for services for uninsured individuals with certain chronic illnesses or health problems. Generally, these programs operate through the Division of Public Health (DPH). For example, DPH operates a program (State Kidney Program) which provides funding to help pay for limited services for people with end stage kidney disease.[g] However, funding is limited to people with ESKD and is not available to manage the care of uninsured individuals with less advanced stages of CKD. In contrast, the state does have some funding to help pay for screening and limited treatment services for people with cancer, epilepsy and neurological diseases, HIV/AIDS, sickle cell syndrome, sexually transmitted diseases, tuberculosis, and vision problems.[h]

To address this issue, the Task Force recommends:

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e Certain health care organizations have a legal responsibility or mission to provide ambulatory health care services to the uninsured for free or on a sliding fee scale basis. These include community and migrant health centers (federally qualified health centers), state-funded rural health clinics, free clinics, local health departments, hospital emergency departments or outpatient clinics, and other nonprofit community organizations. However, certain organizations—including many free clinics, health departments, and hospital emergency rooms—are not set up to provide ongoing comprehensive primary care services to individuals to help them manage their chronic conditions.

f Sec. 10.6(a) of Session Law 2007-323. Funding is available on a competitive basis to federally qualified health centers, state-designated rural health centers, free clinics, public health departments, school-based health centers and other nonprofit organizations that provide primary and preventive services to low-income uninsured patients.

g NCGS §130A-220.

h NCGS §130A-205, 130A-206 (Cancer Control Program); NCGS §130A-223 (Epilepsy and Neurological Disease Program); NCGS §130A-5(3) (AIDS Drug Assistance Program); NCGS §130A-124 (Hemophilia program); NCGS §130A-135, 130A-144 (Sexually Transmitted Disease Control); NCGS §130A-129 (Sickle Cell program); NCGS §130A-144 (Tuberculosis Control), NCGS §111-8, 143B-157 (Medical Eye Care Program).

Recommendation 4.5 (PRIORITY RECOMMENDATION)

(a) The North Carolina General Assembly should provide $550,000 in recurring funding to the Division of Public Health to help pay for the screenings of uninsured patients who are at high risk for developing kidney disease including people with diabetes, hypertension, cardiovascular disease, family history of chronic kidney disease, or other evidence-based risk factors which have been demonstrated to contribute to the development of chronic kidney disease.[i]

(b) The North Carolina General Assembly should appropriate an additional $2,400,000 to the Community Health Center grants program to expand care to uninsured individuals with chronic kidney disease.[j] **Priorities should be given to:**

(1) Areas of the state that do not have sufficient safety net capacity.

(2) Programs that provide primary care, disease management, and care management to patients with chronic kidney disease.

(3) Organizations that provide comprehensive services, including pharmaceuticals, to the uninsured with incomes <200% FPG.

(c) The North Carolina General Assembly should appropriate an additional $15 million to the Community Health Center grants program to expand care to the uninsured with other chronic illnesses that can lead to chronic kidney disease.[k] **Priorities should be given to:**

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i This cost estimate assumes that the Division of Public Health will screen 5% of the uninsured population with hypertension. The Division of Public Health estimated there are approximately 328,000 uninsured adults with hypertension. The current combined cost for a urine microalbumin and serum creatinine laboratory report is approximately $38. Multiplying these figures indicates a total cost of close to $11.5 million. The Division estimates they may be able to screen approximately 5% of these individuals for a cost of $550,000.

j Combining information from a variety of data sources including the Behavioral Risk Factor Surveillance Survey (BRFSS) and the National Health and Nutrition Examination Survey (NHANES), the NC IOM estimates there are approximately 40,000 uninsured North Carolinians with stage 3 or higher CKD. Furthermore, the same analysis estimates that approximately 16,000 of the uninsured with CKD indicate they have no usual source of care; they would need to be linked with a primary care medical home. The Bureau of Primary Health Care suggests that community health centers use a standard budget of approximately $150 per year per patient to provide primary care services to the uninsured (New Access Points (NAP) Grant Competition Announcement Number HRSA08-077. Health Resources and Services Administration. US Department of Health and Human Services. http://www.hrsa.gov/grants/. Accessed November 1, 2007). Using $150 as a per person estimate, primary care services for these 16,000 uninsured are estimated at $2,400,000. This cost estimate is conservative since providing services to the uninsured with chronic illnesses will be more expensive than providing services to the uninsured without chronic illnesses. Further, this includes only the estimated cost of providing primary care services to people with CKD and does not include other uninsured individuals with diabetes, hypertension, cardiovascular disease, or other chronic illnesses who do not also have CKD. Providing a primary care home to other people with chronic illnesses would require additional funds. For more details on estimation see Appendix.

k BRFSS data suggest there are approximately 250,000 uninsured North Carolinians with diabetes, hypertension, or cardiovascular disease who do not have CKD; 100,000 of this number have no usual source of care. The Bureau of Primary Health Care estimates that community health centers should budget approximately $150 per year per patient to provide primary care services to the uninsured (New Access Points (NAP) Grant Competition Announcement Number HRSA08-077. Health Resources and Services Administration. US Department of Health and Human Services. http://www.hrsa.gov/grants/. Accessed November 1, 2007). Using $150 as a per person estimate, primary care services for these 100,000 uninsured are estimated at $15,000,000. This cost estimate is conservative since providing services to the uninsured with chronic illnesses will be more expensive than providing services to the uninsured without chronic illnesses.

(1) Areas of the state that do not have sufficient safety net capacity.

(2) Programs that provide primary care, disease management, and care management to patients with high-cost chronic illnesses including, but not limited to, diabetes, hypertension, cardiovascular disease, and other evidence-based risk factors which have been demonstrated to contribute to the development of chronic kidney.

(3) Organizations that provide comprehensive services, including pharmaceuticals, to the uninsured with incomes <200% FPG.

(d) The North Carolina General Assembly should provide $5 million to the Division of Public Health Purchase of Medical Care (POMC) program to help pay for nephrologist consults for uninsured patients with incomes <200% FPG.[l] Funding should be used to:

(1) Pay for nephrology consultations that follow the Renal Physicians Association consultation standards for patients with chronic kidney disease with <30 eGFR or other patients with higher eGFR if a clinical action plan cannot be prepared or the appropriate evaluation performed.

(2) Support a coordinated system of care between the primary care provider and nephrologist.

Primary Care And Collaborative Care Teams

People obtain most of their outpatient health care services through primary care providers. Primary care providers (PCPs), including physicians, nurse practitioners, or physician assistants, are trained to provide comprehensive care that meets most of a patient's health care needs. PCPs provide preventive, primary, and acute medical services and help coordinate the care that people with complex or chronic illnesses receive from specialists. Optimal primary care is comprehensive, accessible to the patient, coordinated, and continuous.[30] Primary care providers are generally more widely disbursed than are specialists; thus people have more ready access to primary care providers than to most specialists. Approximately 60% of office visits in 2005, including 55% of the office visits for people with chronic illnesses, were to primary care providers.[31]

While primary care providers are the principal source of outpatient medical care for most patients, PCPs face significant challenges providing all the recommended care to their patients. The practice of medicine is constantly evolving with new clinical guidelines for different health conditions. There are more than 1800 evidence-based clinical guidelines to treat patients with different health

l The NC IOM estimates there are approximately 40,000 uninsured individuals with CKD who are in stages 3-5 and who are not receiving dialysis. For purposes of this estimate, we assumed that all of the uninsured would need access to a nephrology consult once a year even if they otherwise had access to primary care providers for the ongoing management of their health problem. Medicaid pays between $49.50-$202.50 to nephrologists for consultations depending on the CPT code. For purposes of this estimate, we assumed that each patient would receive 1 consult per year with an average cost of $125.

conditions.[32] These guidelines change over time, and new ones are developed as health professionals gather new evidence about what treatments work best for different conditions. Research suggests that it would take more than 7 hours a day for primary care providers to provide all the recommended evidence-based preventive services to a typical daily panel of patients and another 10 hours a day to provide recommended services to patients with chronic illnesses.[33-35] Practice redesign and other supports are needed to help primary care providers provide optimal care. (See Rec. 4.8 and 4.9 below.)

Ideally, primary care providers should screen people at high risk and identify patients with chronic kidney disease. However, national screening programs suggest that chronic kidney disease is often not detected even when patients have access to primary care.[28] PCPs may be unaware of all the risk factors for CKD.[36] Further, many primary care providers are unaware of existing clinical guidelines for care of people with CKD.[37]

The Task Force recognized the need to provide further education to primary care providers about chronic kidney disease, risk factors which can make people more likely to develop chronic kidney disease, the impact of CKD on overall health care spending, death and comorbidities, and evidence-based treatment of people with chronic kidney disease. Studies have shown that primary care providers who are aware of the KDOQI guidelines were more likely to have knowledge of all of the risk factors[36] and more likely to follow the recommendations.[37] Therefore, the Task Force recommends:

Recommendation 4.6

The North Carolina Area Health Education Centers program, the National Kidney Foundation (NC Chapter), the UNC Kidney Center, North Carolina Renal Care, the North Carolina Medical Society, the North Carolina Academy of Family Physicians, the North Carolina Chapter of the American College of Physicians, the Old North State Medical Society, the North Carolina Academy of Physician Assistants, the North Carolina Nurses Association Council of Nurse Practitioners, the North Carolina Association of Pharmacists, and Community Care of North Carolina should collaborate to provide targeted chronic kidney disease educational programs for primary care providers. The education should include information about the importance of early screening for at-risk populations, the use of the eGFR to identify people with chronic kidney disease, stages of the disease, diagnosing the etiology of the disease, and evidence-based treatment guidelines for people with the disease. Education should be provided in a variety of settings including, but not limited to, health professional training schools, residency programs, continuing medical or nursing education programs, practice consultants, and quality improvement initiatives.

Once identified, most people with chronic kidney disease continue to be treated by primary care providers.[38] Primary care providers are appropriate sources of care for people in the early stages of the disease and can help manage patients' kidney disease along with other comorbidities. PCPs who identify patients with CKD should determine the type of kidney disease, comorbid conditions, and severity of the disease using the KDOQI stages of chronic kidney disease.[10] (See Chart 2.1 in Chapter 2.) Physicians can use the stages of CKD to help explain the disease process to their patients and to develop care plans. PCPs should also assess potential complications such as development of cardiovascular disease and risk of kidney failure.

The evidence-based clinical guidelines for chronic kidney disease will vary somewhat depending on the etiology of the disease. In general, patients should be prescribed ACE inhibitors or angiotensin receptor blockers (ARBs) to control blood pressure, aspirin to lower the risk of cardiovascular disease, and cholesterol-lowering therapy when their LDL is elevated.[39] Patients need to control their hypertension (to achieve a blood pressure of <130/80 mm Hg) and manage their lipids in order to slow progression of CKD to more advanced stages.[40] Successful hypertension control and lipid management could slow the progression toward kidney failure and limit the damage caused by cardiovascular diseases. Patients should also be encouraged to implement lifestyle changes to support their treatment regimen including smoking cessation and a light-to-moderate exercise program three to five times a week.

Primary care providers should monitor the progress of the disease and treat complications of decreased kidney failure. PCPs should work in a collaborative care team involving patient educators, disease management or case management staff, and appropriate specialists as needed to manage comorbid conditions. Primary care providers may need to consult with nephrologists or other specialists to develop care plans for patients with CKD and any incident comorbidities. The National Kidney Disease Education Program and Renal Physicians Association have developed a model template nephrology consult letter to provide information about a patient's level of kidney disease and treatment recommendations.[m]

As the kidney function declines further (to <30 eGFR), patients should be referred to nephrologists for clinical management of kidney disease. Even after referral, the primary care provider will still play an important role in serving as the patient's medical home and helping to manage the patient's comorbid conditions.

Nephrologists and other trained kidney educators should help patients prepare for kidney failure and replacement of kidney function by dialysis or transplantation.[10] Patients need better modality education of different renal replacement options in advance of when their kidney failure reaches

m See http://nkdep.nih.gov/professionals/consult/consult.pdf.

stage 5. (See Recommendation 4.15 below.) Unfortunately, many patients with chronic kidney disease do not see nephrologists until advanced stages of their disease. More than one-fifth (22%) of all patients do not see a nephrologist until they are almost ready to begin dialysis (less than four months prior to initiating dialysis).[41] African Americans are much more likely to be evaluated late in the progression of their disease with 42.4% receiving their first consult from nephrologists within four months of beginning dialysis compared to 27.7% of whites. Patients who receive these late evaluations are more likely to die than those who receive earlier evaluations even after controlling for comorbid conditions, type of dialysis, demographic characteristics, and socioeconomic factors. Because of the lack of nephrologists in certain communities, it may not be possible for nephrologists to assume the care of all the patients in later stages of the disease. In these instances, the primary care provider and nephrologist should develop models of shared clinical care to provide treatment and care management to the patients.[42]

While much is known about effective treatment which could delay the deterioration of kidney function, this evidence-based care is not often provided. To encourage more widespread adoption of evidence-based care for people with chronic kidney disease, the Task Force recommends:

Recommendation 4.7 (PRIORITY RECOMMENDATION)

(a) Primary care providers should routinely screen their patients who are at high risk for chronic kidney disease including patients with diabetes mellitus, hypertension, cardiovascular disease, family history of chronic kidney disease, or other evidence-based risk factors which have been demonstrated to contribute to the development of the disease. Screening should include albumin measurement from a spot urine sample[n] and serum creatinine to obtain the estimated GFR.

(b) Patients who have been identified with chronic kidney disease should be staged using the National Kidney Foundation 5 stages of disease categories.

(c) Health care providers who have patients who have been diagnosed with chronic kidney disease should follow the KDOQI or other evidence-based guidelines to manage and slow the progression of the disease. These guidelines include, but are not limited to:

- **(1) Treating patients to achieve a target blood pressure of <130/80.**
- **(2) Prescribing an ACE inhibitor or ARB as specific therapy to slow the progression of kidney disease as well as control blood pressure.**
- **(3) Using combination hypertensive therapy which should include a diuretic.**
- **(4) Evaluating patients with eGFR<60 mL/min/1.73m2 for anemia.**
- **(5) Treating to ensure strict glucose control in diabetes.**
- **(6) Detecting and managing other cardiovascular risk factors, particularly cholesterol and tobacco use.**

n The KDOQI guidelines state that albumin should be measured in a spot urine sample using either albumin-specific dipstick or albumin-to-creatinine ratio.

(7) Monitoring the rate of eGFR decline in patients with chronic kidney disease at least yearly and more often for patients with rapid decline or specific risk factors.

(8) Referring patients to registered dietitians for nutrition therapy when appropriate.

(d) Primary care providers should refer patients with eGFR <30 to nephrologists for ongoing care. Other patients, with higher eGFR, should also be referred to a nephrologist for consultation or comanagement if a clinical action plan cannot be prepared or the appropriate evaluation performed or if a patient is experiencing rapid decline in kidney function. There should be sustained coordination between the primary care provider, disease management or care management staff, the nephrologist, and other specialists.

Primary care practitioners need to actively monitor the rate of decline of kidney function in their patients. The risk of progression to kidney failure can vary markedly across patients, based on the stage of the disease, comorbidities, racial and ethnic and other sociodemographic factors.[43] While many practitioners are aware of certain requirements within the diabetes and hypertension guidelines, many are unaware of the chronic kidney disease guidelines.[38] Both the American Diabetes Association's evidence-based guidelines for treatment of patients with diabetes[44] and the Joint National Committee on Prevention, Detection and Treatment of High Blood Pressure report (JNC 7) on evidence-based guidelines for treatment of patients with hypertension[8] recommend that practitioners obtain a serum creatinine to calculate the estimated GFR. The serum creatinine alone is simply too imprecise, too dependent on a number of variables, and has too wide a range of "normal" values to be clinically useful in patients with mild to moderate chronic kidney disease. As noted earlier, the KDOQI guidelines also recommend screening high-risk individuals including those with diabetes, hypertension, or a family history of kidney disease.[6] Despite these guidelines, it appears that few providers are specifically requesting an eGFR routinely when a serum creatinine is ordered as part of a basic or complete metabolic profile even among high-risk individuals.[45]

The Task Force considered a variety of alternative mechanisms to facilitate primary care providers in obtaining eGFR results. Theoretically, PCPs could calculate the results themselves using various prediction equations including the Modification of Diet in Renal Disease (MDRD) equation.[o] The MDRD equation is based on the following 4 factors: the serum creatinine level, age, gender, and race (with a correction factor for African Americans). For most individuals, the eGFR is a far

o There are two commonly used measurements to estimate GFR: Cockroft-Gault and MDRD. The MDRD estimation is superior to the Cockroft-Gault calculation in adults. [76]

more accurate measure than other tests of kidney function and is more revealing of kidney disease.[p] Realistically, however, primary care providers have little time to do everything else that is required of them. Therefore, it is unlikely that primary care providers will routinely calculate the eGFR on all at-risk patients.

One promising method to increase physician awareness of chronic kidney disease and identification of patients with CKD is to automatically calculate and report the eGFR on all adult clinical laboratory creatinine determinations. Automatic reporting, coupled with an educational program, has been shown to lead to increased CKD recognition by primary care providers.[q,46]

Some states have implemented statutory language to require eGFR calculation on all creatinine determinations.[47] The College of American Pathologists and the National Kidney Foundation issued a joint statement and the American Medical Association adopted a resolution opposing statutorily mandating automatic reporting of eGFR for all creatinine measurements because of their concerns regarding legislative mandates of clinical practice.[48,49] While not opposing the use of eGFR, these groups opposed legislatively mandating how medicine is practiced; as clinical practice evolves and improves over time, legislation does not always keep pace with these changes. Because of the national controversy, the NC IOM Task Force on Chronic Kidney Disease convened a separate workgroup to explore automatic eGFR reporting.

After considering different options, the workgroup and the full Task Force recommended that clinical laboratories in North Carolina be encouraged to report eGFR values on all creatinine determinations voluntarily rather than requiring a legislative mandate. Because of the importance of identifying people with chronic kidney disease, the full Task Force strongly supported that laboratories automatically calculate eGFR whenever the provider orders a creatinine measurement. If North Carolina laboratories do not voluntarily begin computing the eGFR on all creatinine determinations, then the Task Force recommended that the General Assembly mandate this practice. Simultaneously, the Task Force members recommended that primary care providers receive education about CKD and the use of the eGFR as a measure of kidney function. (See Recommendation 4.6.)

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p While the eGFR is the best measurement of kidney function for most people, it may not be appropriate for everyone, particularly those who have abnormal production of basal creatinine (ie, the morbidly obese or severely malnourished, amputees, paraplegics, or those with other muscle wasting diseases), are on unusual diets (ie, taking creatinine supplements), or are under age 18. However, the eGFR may be useful as a reference among some of these populations to measure changes over time.

q Although there are no data on the cost of implementing these changes into the laboratory reporting software, most people familiar with these information systems indicate that the cost of adding an eGFR would be relatively low(J. Keene, personal communication, February 26, 2008).

Given concerns about the precision of current estimating equations (such as the MDRD formula) for eGFR values above 60 mL/min/1.73 m², [50] the Task Force recommends that laboratories should report the calculated eGFR levels that exceed 60 mL/min/1.73 m² as ">60" rather than denoting the calculated value. Laboratories that already report calculated values greater than 60 should educate providers about the lack of precision for values greater than 60.

Recommendation 4.8 (PRIORITY RECOMMENDATION)

The estimated glomerular filtration rate (eGFR) values should be computed and reported on all creatinine determinations by clinical laboratories in North Carolina.

(a) Hospital and commercial clinical laboratories should incorporate a calculated eGFR on all patient laboratory data that includes measurement of the serum creatinine. Carolina Renal Care, the College of American Pathologists, and the National Kidney Foundation North Carolina Chapter should work collaboratively to educate clinical laboratories of the importance of reporting the eGFR when a provider orders a serum creatinine or when the creatinine is part of a metabolic panel.

(b) Payers and insurers should require that all serum creatinine determinations for their members and dependents automatically include the eGFR.

(c) The Division of Public Health along with Carolina Renal Care should monitor the clinical laboratories to determine if reporting of GFR has become standard practice throughout the state when a serum creatinine is ordered. If the preceding recommendations are insufficient to make eGFR reporting standard practice throughout the state within one year for all laboratories, the General Assembly should amend the General Statutes to require all creatinine laboratory reports to include eGFR values.

In addition to automatically reporting eGFR when a provider orders a creatinine, certain practice redesigns (eg, disease registries) can assist primary care providers in identifying patients with specific chronic illnesses and trigger periodic screening and evidence-based treatment guidelines. Some providers have electronic health records (EHRs) with the capacity to identify patients with chronic illnesses and which include clinical decision support prompts. However, EHRs do not universally have this capacity. Further, one study found that in 2005 less than one-quarter of practices had electronic health records. [51]

The Task Force recognized the need for practice redesign to support care of patients with chronic kidney disease. Thus, the Task Force recommends:

Recommendation 4.9

Businesses and organizations that develop electronic health records should provide the capacity for chronic disease registries and clinical decision support prompts that incorporate chronic kidney disease screening and treatment measures for at-risk groups.

Patient Education, Disease Management, And Case Management Services

People with chronic kidney disease should be involved in their own self-management at all stages of the disease.[10] A survey of research studies suggests individuals who have been trained in effective self-management techniques generally have better health outcomes than those who have not.[52] People need to be taught the information and skills necessary to manage their own health. In addition, some individuals may need additional assistance maneuvering through the health care system to ensure that their chronic health care needs can be met.

In general, all patients who have health problems should be educated about the course of their disease, treatment options, and management of their health condition. Patients with chronic kidney disease need education about the role of the kidneys in maintaining their overall health, the progression of the disease, risk factors that can exacerbate CKD, and recommended treatment, medications, and diet. The goal is to give patients the skills to better manage their own health.

Primary care providers and nephrologists can assist in the patient education process. However, individuals often need more intensive health education than can be provided in a physician's office. Patient education, disease management, and case management services can augment the information and services provided by physicians.

Disease management activities are generally targeted to individuals with specific health conditions or diseases such as diabetes, asthma, congestive heart failure, coronary artery disease, or hypertension. Disease management activities are designed to provide individuals with these conditions with the information and support necessary to assist them in monitoring their own care and adhering to recommended treatment guidelines. Disease management is typically offered through insurance coverage. Nationally, approximately one-fourth of all firms that offered health insurance in 2006 included at least one disease management program.[r,53] Disease management activities can be delivered in person through community networks of care or can be provided through mail or telephone contact. As described below, both types of disease management activities are operational in North Carolina.

r Nationally, among firms offering health benefits that include a disease management program, 95% offer disease management for diabetes, 87% for asthma, 88% for hypertension, and 88% for high cholesterol.

Case management activities can be offered in conjunction with, or separate from, disease management efforts. Case management is often targeted to individuals with multiple chronic diseases and/or costly health problems, those patients most at risk of hospitalizations or other costly care.[54] Case managers help patients obtain care for unmet needs, coordinate the care they receive, and may assist patients in addressing other non-health related needs that prevent individuals from properly managing their health condition. Case management of patients undergoing dialysis has been shown to lead to mortality reductions and other positive outcomes.[55] Case management is generally more customized to the individual needs of the patient. Case managers who can help the patient manage multiple conditions may be more effective than multiple disease managers each trained in the management of one disease affecting the patient.

North Carolina insurers offer both disease management and case management activities for selected individuals. Typically, these initiatives do not specifically target people with chronic kidney disease, although they may target individuals with comorbid conditions such as diabetes or hypertension which could lead to or exacerbate chronic kidney disease. For example:

- ***Medicaid.*** The North Carolina Division of Medical Assistance and the North Carolina Office of Rural Health and Community Care developed a comprehensive disease management and quality improvement initiative focused on care of Medicaid recipients with certain chronic illnesses. Community Care of North Carolina (CCNC) provides disease and case management services to certain Medicaid recipients with chronic or complex health conditions. CCNC is built around provider-led community networks that include, at a minimum, primary care physicians, specialists, hospitals, departments of social services, and health departments. There are currently 14 networks that cover the state. In September 2007 there were approximately 890 000 Medicaid recipients enrolled in CCNC.56 Medicaid pays participating providers $2.50 per member per month (PMPM) to serve as the patient's medical home and an additional $3.00 PMPM for the network to hire nurses or social work case managers to help patients manage their health conditions.

  CCNC uses nationally recognized evidence-based guidelines to help patients with chronic conditions manage their health. CCNC currently operates a statewide disease management and quality improvement initiative for people with diabetes and is in the process of developing similar statewide initiatives to help people with hypertension or cardiovascular disease manage their health problems. CCNC disseminates evidence-based clinical guidelines for the care of patients with these conditions to the primary care practices and then collects performance measure data to determine how well practices are doing in providing evidence-based standards of care. CCNC does not currently have a specific disease management or quality improvement initiative targeting people with chronic kidney disease. However, people with diabetes, hypertension, and cardiovascular disease

are at greater risk of developing chronic kidney disease. Thus, CCNC could augment their current quality improvement initiatives to develop strategies to identify, monitor, and manage the care of people with chronic kidney disease. Further, CCNC should consider adding performance measures to ensure that people who are at risk of developing CKD or who have been diagnosed with CKD are receiving evidence-based standards of care.

- ***Blue Cross and Blue Shield of North Carolina (BCBSNC).*** BCBSNC offers disease and lifestyle management programs and quality improvement initiatives that focus on certain health conditions that are risk factors for chronic kidney disease. In addition, BCBSNC offers case management services to people with risk factors for ESKD. The Member Health Partnership Program is a lifestyle management program that provides targeted information and services to help patients manage their health needs. The program focuses on several health conditions that either contribute to CKD or exacerbate the condition including diabetes, weight, high blood pressure, high cholesterol, heart failure, and tobacco use. Members receive educational materials targeted to their specific condition. They can also receive one-on-one assistance through a nurse or case manager (for high-risk patients). Members who are enrolled in this lifestyle promotion program are eligible to receive up to 6 nutritional counseling sessions per year.

  In addition to the disease and lifestyle management programs, BCBSNC also contracts with Health Dialog to help ensure members receive appropriate care based on nationally recognized evidence-based standards of care. BCBSNC has quality improvement initiatives for people with diabetes, coronary heart disease, and congestive heart failure, each of which would also benefit people with CKD. BCBSNC's quality improvement initiative ensures that:
  - Patients with diabetes or coronary artery disease (CAD) receive lipid profile tests and cholesterol lowering medications.
  - Patients with diabetes, congestive heart failure, or CAD receive ACE/ARB therapy.
  - Patients with diabetes are tested for microalbuminuria and hemoglobin A1C (HbA1C).

  BCBSNC also provides case management services for their members with risk factors for ESKD. Case managers collaborate with other clinical staff, medical directors, providers, vendors, family, and hospital/facility staff to provide individual health coaching, coordination of care, and decision support to the members. Case managers work directly with the BCBSNC member and his or her physician to develop a care plan for the treatment of ESKD as needed. The goal is to ensure that the member receives medically appropriate care in the right setting in order to increase the member's quality of health care and achieve improved health outcomes.

- *North Carolina State Health Plan (SHP).* The State Health Plan has 2 programs that help identify and educate patients with kidney disease. Health Dialog is the SHP's chronic disease management vendor. Health Dialog offers disease management services targeting members with diabetes and coronary artery disease (among other conditions). Health coaches provide members with patient education materials and support to help them manage their health problems. For example, members with diabetes are sent patient education materials related to chronic kidney disease. SHP members with coronary artery disease receive information about hypertension control. In addition, Health Dialog includes a quality improvement initiative targeted at providers. Twice a year, primary providers are given information about clinical gaps related to microalbuminuria testing for members with diabetes as part of the Health*Smart* Registry. Health Dialog does not currently have performance measures related to collection of creatinine or eGFR to measure kidney disease.

  In addition to the disease management services offered through Health Dialog, the State Health Plan offers more intensive case management services to patients with more advanced stages of CKD. The SHP contracts with Renaissance Health Care to provide patient education, disease management, and case management services to patients with an eGFR less than or equal to 45 (stage 3 of KDOQI guidelines).[s] Renaissance Health Care helps identify clinical gaps in the care provided to patients with CKD. Renaissance works with the members and treating providers to improve blood pressure control as well as blood glucose control for people with diabetes. In addition, each identified SHP member is offered more intensive case management and education to help members prepare to transition into renal replacement therapy. As a part of the needs assessment, members are screened for depression and are referred to treatment as needed.

  Renaissance Health Care identifies members with more advanced stages of CKD through claims data. Because the claims data do not identify all patients with CKD, the SHP has worked with the UNC Kidney Center to develop alternative methods of identifying patients with CKD. The Kidney Center has identified SHP members with eGFR of 45 or less and referred those patients to Renaissance Health Care for case management services. Within the first 3 months of the program (3rd quarter 2007), there were over 30 referrals with the majority screened and engaged with a case manager. The SHP is evaluating this model to determine whether it could be duplicated with other kidney clinics throughout the state.

s Renaissance targets individuals with an eGFR of 45 or less because it is at this time people need to start thinking of transitions to renal replacement therapy and need more intensive case management and education.

Of the members who have been in Renaissance Health Care case management for at least 180 days:

- 80% of members have completed educational modules on dialysis modalities.
- 90% of members have an appropriate hemoglobin level.
- 80% of members have a fistula placed to allow vascular access before the inception of dialysis, without the use of a central venous catheter.
- 50% of members transition to dialysis on an outpatient basis in contrast to requiring emergency inpatient hospitalization to begin dialysis.

In addition, inpatient admission rates for SHP members with ESKD have declined by more than 35% since the inception of intensive case management and the implementation of the patient education program with Renaissance Health Care.

Naturally, it will be important that these and other disease management programs are consistent with their messages to minimize confusion among the public. If programs offer differing messages as patients move between multiple insurers and case managers, the patient may become confused about his or her best course of action. Coordination across multiple insurers will be important.

Although many insurers and payers offer disease management and quality improvement efforts targeting people with diabetes, hypertension, or cardiovascular disease, these initiatives do not always measure how well providers screen high-risk individuals for chronic kidney disease. Further, there are few quality initiatives focused on the care that patients with identified CKD are receiving. Nationally, fewer than one-third of people with diabetes or hypertension identified with chronic kidney disease are receiving an ACE inhibitor.5 The Task Force recognized the need to focus additional attention on chronic kidney disease prevention, screening, and management. Thus, the Task Force recommends:

Recommendation 4.10

(a) Public and private insurers, payers, and other organizations that offer disease management or quality improvement initiatives targeted at people with diabetes, hypertension, or cardiovascular disease should give greater emphasis to chronic kidney disease prevention, screening, and management.

(1) Payers, insurers, and other organizations should remind patients and providers to obtain regular screenings for chronic kidney disease including urine microalbumin and estimated GFR from serum creatinine.

(2) Payers, insurers, and other organizations should adopt evidence-based clinical practice recommendations for screening and management of chronic kidney disease (including those referenced in Recommendation 4.7) and should develop and include performance measures relevant to chronic kidney disease detection and treatment in quality improvement and quality assurance programs.

(b) Public and private payers and insurers should provide targeted disease management or case management services and medical nutrition therapy to all patients with chronic kidney disease once patients have progressed to stage 4. Patients should be provided information about different types of renal replacement therapy.

Disease management and quality initiatives such as those provided through Community Care of North Carolina, BCBSNC, or the North Carolina State Health Plan rely on nationally recognized evidence-based performance measures to evaluate quality of care. These include measures that may be recognized by the National Quality Forum or the National Committee for Quality Assurance or by disease-specific organizations such as the National Kidney Foundation or the American Diabetes Association (ADA). North Carolina health care professionals are more likely to adopt new performance measures if they have been nationally recognized. While KDOQI has developed evidence-based standards of care for people with chronic kidney disease, performance measures to assess whether these standards are being applied have not been incorporated into care of people with diabetes, hypertension, or cardiovascular disease. Thus, for example, the ADA and the Joint National Committee on Prevention, Detection and Treatment of High Blood Pressure recommend that providers obtain a serum creatinine in order to calculate the eGFR. (See Appendix C for a comparison of the KDOQI, ADA, and JNC guidelines.) These guidelines also recommend the use of ACE inhibitors or ARBs to control blood pressure. However, while quality measures assessing providers' performance in appropriately prescribing ACE inhibitors or ARBs are commonly used in the United States, there is no quality measure assessing whether providers collect eGFR on CKD patients, although the British Medical Association has developed a quality measure for eGFR calculation for patients with diabetes. Thus, to assure that providers routinely collect eGFR to identify people with chronic kidney disease, the Task Force recommends:

Recommendation 4.11

The National Kidney Foundation, the American Society of Nephrology, the American Society of Pediatric Nephrology, and the American Dietetic Association should work with national quality and standard setting organizations to devise quality performance measures that assess the degree to which practitioners screen and manage patients with or at risk of developing chronic kidney disease in accordance with nationally recognized guidelines.

The Task Force also recommends that Medicaid develop a specific disease management and quality improvement initiative for people with chronic kidney disease. North Carolina is currently seeking a Section 646 Medicare demonstration waiver to improve the care delivered to North Carolina Medicare beneficiaries.[57] North Carolina Community Care Networks, Inc., the statewide parent organization of the local CCNC networks, applied for a waiver to manage the care of Medicare recipients using the CCNC disease management and quality improvement model.

Initially, the program would focus on dual eligibles (ie, individuals who receive both Medicare and Medicaid) but the initiative would soon be expanded to include Medicare beneficiaries not eligible for Medicaid. These individuals are generally 65 years or older, although the dual eligibles also include some younger individuals with disabilities. Because kidney functioning normally declines with age, approximately 17% of people age 60 years or older have mild to severe kidney disease.[58] This means that the population that would be served by the waiver will have a high risk of CKD.

Medicare is the primary insurer after kidney transplantation or at onset of dialysis.[t] More than one-third of people with kidney failure are over 65, and many also have insurance coverage under Medicaid. Kidney failure is a major cost to the Medicare program, accounting for approximately 6.4% of all Medicare payments in 2005 for only 1.2% of the Medicare population.[59]

More than 80% of Medicaid-eligible older adults (age 50 or older) have been diagnosed with hypertension.[60] The Task Force recommends that CCNC create a separate CKD disease management initiative for the dually eligible since this is the group that is most likely to have chronic kidney disease. Focusing on the care of people with chronic kidney disease should be cost-effective for the dual eligibles given that kidney functioning naturally declines as people age, and better management of people with chronic kidney disease can help reduce the incidence of ESKD (and thereby reduce Medicare and Medicaid costs).

To improve the care provided to Medicare recipients with or at risk of developing chronic kidney disease, the Task Force recommends:

Recommendation 4.12

Community Care of North Carolina (CCNC) should create a disease management initiative for chronic kidney disease as part of its §646 Medicare waiver, if approved, which will focus on older adults age 65 or older or people with disabilities who are also receiving Medicare. CCNC should incorporate evidence-based treatment of people with chronic kidney disease into the initiative and identify clinical performance measures to assess the quality of care provided to patients with the disease.

In order for patient educators, case managers, or disease management professionals to appropriately provide services for people with chronic kidney disease, they must first be educated about the

t There is a 30-month waiting period for individuals with employer-sponsored group health insurance during which Medicare is the secondary payer.

disease and the evidence-based guidelines for care of the disease. Individuals can receive certification in diabetes disease management.[u] However, there is no similar certification or recognized training program for people working with chronic kidney disease patients.

The University of North Carolina at Chapel Hill, in collaboration with the North Carolina Community College System, has developed a proposal to create a kidney disease certification program, the Kidney Care Prevention Program (KCPP). The KCPP would be offered throughout the 58 North Carolina community college campuses. The community colleges would offer a kidney education curriculum similar to the diabetes education curriculum so that people can be certified as having the skills necessary to monitor the risk profiles of patients with chronic kidney disease (including clinical, behavioral, and demographic factors) and certified to provide patients with self-management education and skills. The intent is to train local kidney disease educators who can be cross-trained in the management of other comorbid diseases as well as trained to provide patient education and disease management to at-risk individuals in their communities. Funding would be used to support curriculum development, to provide salaries for community college faculty, and to secure an external evaluation of the effectiveness of KCPP.

The goal is to test the cost-effectiveness of providing CKD education and case management early in the progression of the disease to determine if it can help prevent the more costly progression to kidney failure (requiring dialysis or transplant). Insurers and payers should reimburse appropriately trained CKD educators if the pilot is shown to be effective in helping to improve patient self-management and slow the progression of the disease to more advanced stages of kidney disease. This is similar to the reimbursement provided to diabetes educators. Insurers and payers should require that CKD educators meet certain competency requirements, either through certification or another mechanism to demonstrate appropriate knowledge of CKD self-management education and skills.

To further this initiative, the Task Force recommends:

Recommendation 4.13

(a) North Carolina foundations and/or national foundations should provide funding to the University of North Carolina at Chapel Hill to pilot test and evaluate the effectiveness of the Kidney Care Prevention Program (KCPP), a chronic kidney disease certification program being developed in conjunction with the North Carolina Community College System. People who are trained for disease management of

u Diabetes education certification is through the National Certification Board for Diabetes Educators (NCBDE). There is no national certification for asthma education, but the National Respiratory Training Center conducts training that is accredited by multiple organizations including but not limited to the American Academy of Nurse Practitioners. See http://www.nrtc-usa.org/trainingcourses.html.

chronic kidney disease should also be cross-trained for diabetes, hypertension, and cardiovascular disease.

(b) Public and private payers and insurers should provide funding for chronic kidney disease trained educators if determined to be effective and cost efficient[v] in slowing the progression of the disease or improving health.

The Task Force also recommends that disease management professionals or case managers who manage patients with diabetes, hypertension, or cardiovascular disease be cross-trained in the management of people with chronic kidney disease. People with multiple health problems generally benefit by having one disease management expert who can help them manage all their health problems rather than multiple individuals who help them with different diseases. One key element in effective disease management is the coordination among the multiple caregivers (eg, case/disease managers, primary care providers, specialist providers).[61] Many researchers have thus advocated a "generalist" case management approach.[62-65] Indeed, researchers note that single-disease management would not be effective for the care of patients with comorbid health conditions.[66] Managers should be required to consider all of a patient's comorbidities and diseases.[67] Further, it may not be cost-effective to have multiple case managers/disease educators in all communities. Many communities, particularly rural communities, cannot support separately trained individuals. North Carolina needs care coordinators/educators with multi-disease training. However, once a person with CKD reaches stage 4, he or she needs a care manager with specialized training in the care of people with kidney disease.

The Division of Public Health has applied to the American Diabetes Association to become an umbrella organization that is recognized to provide diabetes self-management education including education about kidney disease.[w] Medicare, Medicaid, and many private insurers limit reimbursement for diabetes self-management education to entities that have been recognized by either the American Diabetes Association or Indian Health Services. Once DPH receives ADA recognition, it can include additional local health departments under the DPH umbrella, enabling the local health departments to receive reimbursement for diabetes self-management education. Although this reimbursement is limited to people with diabetes, it is a source of funding to support CKD education as diabetes educators must include information about kidney disease as a potential complication of diabetes. The goal is to get more diabetes educators who can focus on kidney disease in clinical settings. The division is piloting this initiative for the 2007-2008 fiscal year in five local

v The term *cost efficient* here means "leads to a generally accepted reasonable cost per unit of improvement in health." This is a lower standard of effectiveness than *cost-saving* (meaning the program leads to overall cost decreases). For more discussion see Chapter 3.

w In order to obtain ADA recognition, the division must meet certain staffing requirements including having a registered nurse (RN) and a registered dietitian (RD). As an umbrella program, DPH will be responsible for other health departments or programs that come under its umbrella to assure that program criteria are met. Local health departments would qualify for reimbursement for the diabetes self-management education provided by an RN, RD, pharmacist, or certified diabetes educator.

health departments in Brunswick, Clay, Robeson, Rockingham, and Wake counties. Additional funding would allow the project to expand to additional health departments across the state more rapidly, thus providing increased access to diabetes self-management education.

Recommendation 4.14 (PRIORITY RECOMMENDATION)

(a) Disease managers or case managers who manage patients with diabetes, hypertension, or cardiovascular disease should be cross-trained in the management of people with chronic kidney disease.

(b) Existing programs that provide disease management education and/or certification for diabetes, hypertension, or cardiovascular disease management should ensure that the curriculum includes information about prevention, screening, treatment, and self-management skills for people with chronic kidney disease.

(c) The North Carolina General Assembly should provide funding to the Department of Health and Human Services to support the infrastructure needed to expand the Division of Public Health Diabetes Education Recognition Program with a special focus on chronic kidney disease screening and management. The General Assembly should appropriate $150,000 in FY 2008-2009, $300,000 in FY 2009-2010, and $450,000 in FY 2010-2011 and thereafter to support this program.[x]

In addition to disease management services, many patients with kidney disease need nutrition therapy. For example, many patients with CKD need to monitor their protein intake. Medicare and many private providers will pay for medical nutrition therapy services for people with an eGFR of 13-50 ml/min/1.73m^2 or with diabetes.[y] In order to be covered, medical nutrition therapy must be prescribed by a physician and provided by a registered dietitian or another qualified nutrition professional. Nephrologists and other primary care providers managing patients with more advanced stages of CKD should refer patients for medical nutrition therapy when appropriate. (See Recommendation 4.15 below.)

Nephrologists

Nephrologists play a critical role in the effective management of patients with kidney disease, although there are too few nephrologists to assume the care of everyone with chronic kidney disease. In North Carolina, there are 215 nephrologists[68] or about 3.4 nephrologists per 10,000 people with CKD stages 2-5. In contrast, there are approximately 9 primary care providers for every 10 000 people in North Carolina.[69] Because of the relative dearth of nephrologists, most of

x The main difference between 4.3(a) and 4.14(c) is that the former is geared toward expansion of existing programs that educate and screen at-risk populations through community education and partnerships, and the latter expands a new program that specifically targets persons diagnosed with diabetes through a formal diabetes education program with a component that focuses on CKD as a complication of diabetes.

y Information about Medicare coverage of medical nutrition therapy is available at http://www.cms.hhs.gov/MedicalNutritionTherapy/.

their work is concentrated with people who have more advanced forms of kidney disease. Although the supply of nephrologists in North Carolina increased 105% between 1984 and 2005, the ratio of nephrologists per patient with ESKD declined by 40% because of the 240% increase in the prevalence of people with ESKD during that time period.[z] The Health Professions Data System (HPDS) at the Cecil G. Sheps Center for Health Services Research also shows that nephrologists are concentrated around academic medical centers, leaving 44 counties where there are no nephrologists practicing regularly. Because of this maldistribution and the overall shortage of nephrologists, primary care providers will continue to play a key role in the management of patients with chronic kidney disease. However, nephrologists should assist primary care providers in the care of patients with CKD by providing easy referrals and consultation.

The relative supply of nephrologists in North Carolina is nearly identical to the nation as a whole. Using 2005 data from the American Medical Association, there were 218 North Carolina physicians indicating nephrology as their primary specialty.[aa] The US Renal Data System reports 16,071 North Carolina residents with ESKD in 2005, which amounts to approximately 135.6 nephrologists per 10,000 ESKD patients. National data from this same time period puts the supply across the country at 136.1, so North Carolina has essentially the same ratio as the rest of the country. Our 4 border states are also highlighted in Figure 4.1. Although Tennessee has more nephrologists per ESKD patient, North Carolina has more nephrologists than South Carolina, Virginia, and Georgia.

The KDOQI guidelines recommend that patients with <30 GFR be referred to nephrologists for clinical management. However, many patients do not receive their first evaluation with a nephrologist until they are almost ready to begin dialysis, and their health care outcomes suffer as a result of the late evaluations.[41] One study found that mortality during the first year of dialysis was about 20% overall, but those seeing a nephrologist more than one month prior to the initiation of dialysis had a 35% lower mortality rate in the first 120 days of dialysis.[70] Further, the Task Force heard from some primary care providers that it is sometimes difficult to obtain a nephrology consultation, especially in rural areas. Even when a patient obtains a nephrology consultation, the information that the primary care provider receives back from the nephrologist is not always helpful to the ongoing management of the patient with chronic kidney disease. The Renal Physicians Association and the National Kidney Disease Education Program developed a model consultation letter that helps nephrologists communicate information to primary care providers.[bb] However, nephrologists do not always use this letter or provide all the recommended information to primary care providers.

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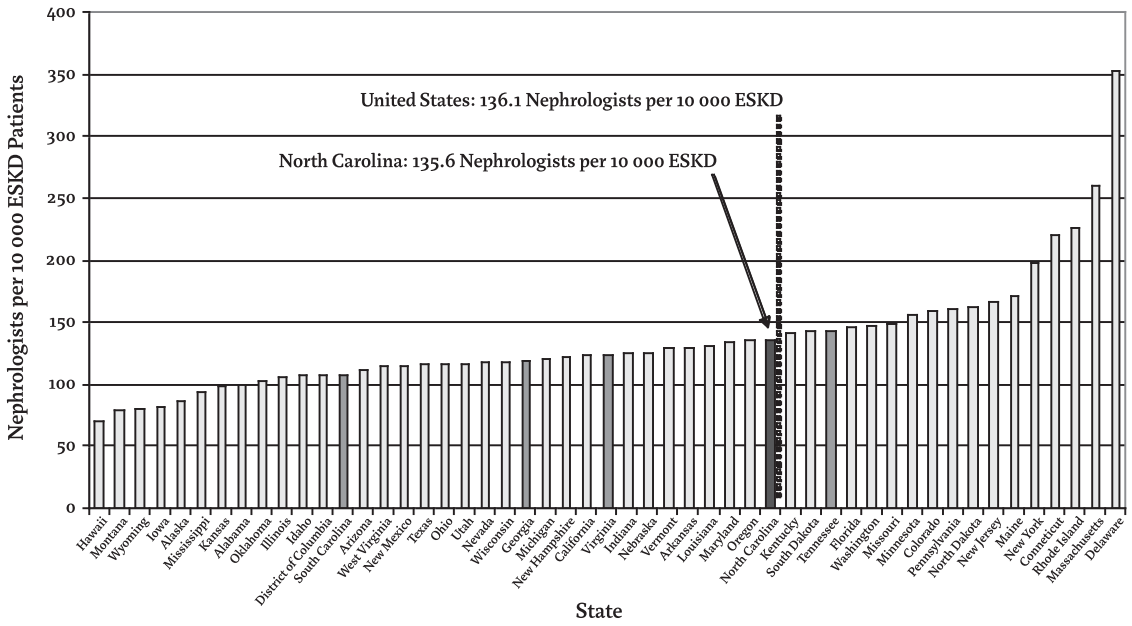
z United States Renal Data System. USRDS 2006 Annual Data Report: Atlas of End-Stage Renal Disease in the United States. National Institutes of Health. National Institute of Diabetes and Digestive and Kidney Diseases:Bethesda, MD; 2006.

aa Note this differs slightly from the 215 reported by the HPDS. When using interstate comparisons, AMA data are used; HPDS data are used for North Carolina analyses.

bb The consultation letter can be accessed online at http://www.renalmd.org/consult/index.cfm.

Figure 4.1.
Nephrologist Availability By State (2005)



Sources: AMA, USRDS

Patients who have reached stage 4 and who are approaching kidney failure should receive education about kidney replacement options including in-center hemodialysis (dialysis provided in a licensed dialysis center), home hemodialysis (dialysis using equipment in the person's home), peritoneal dialysis (dialysis in the patient's abdominal cavity), or preemptive transplantation. Patients should also be informed of the option not to have kidney replacement therapy and the consequences of this choice. This patient education should assist patients in making informed choices about the type of renal replacement therapy, or lack thereof, which reflects their needs and preferences. Studies have shown that the clinical outcomes are similar among different dialysis modalities, but satisfaction is higher and costs are lower with peritoneal dialysis than with in-center hemodialysis or kidney transplants.[71,72]

Typically, kidney replacement therapies other than in-center hemodialysis are not offered to most ESKD patients when considering renal replacement options.[73] The duration of time spent in discussing treatment options and discussion of peritoneal dialysis as one of the options for renal replacement therapy increases the likelihood of patients selecting home kidney replacement therapy.[72] Further, the lack of education about kidney transplant options earlier in the disease process effectively excludes the possibility of preemptive transplantations, which has been shown to have better health outcomes than waiting until the patient has total kidney failure.[73] Because of the

overall lack of patient education, more than 90% of dialysis patients receive in-center hemodialysis. In North Carolina, the percentage of patients who have chosen in-center hemodialysis has increased slightly over the last 5 years, from 89.7% (2001) to 91.5% (2006).[74]

In addition, patients with earlier stages of chronic kidney disease need to be educated about the importance of protecting their veins to support vascular access in the event that their kidneys fail, and they need dialysis. CKD and ESKD patients will need reliable intravenous access for their treatment, especially if the patient later needs dialysis.[75] Patients who have their blood drawn frequently or have central venous catheters or peripherally inserted central catheters (PICC) can experience damage to veins and prevent the placement of fistulas or other venous equipment needed for later treatment.[cc]

Further, for optimal care patients should have a fistula placed prior to the initiation of dialysis. A fistula is an operation which makes it easier to allow blood to flow from the patient's veins to the dialysis machine.[dd] Studies show that patients who have a fistula placed prior to initiating dialysis have fewer complications and lower hospital rates for infection in the first 12 months of therapy.[59] Conversely, the lack of permanent access to the veins (typically a fistula) prior to initiation of dialysis leads to higher hospitalizations, higher costs, and higher mortality.[71] Patients who are receiving ongoing care from nephrologists prior to kidney failure are much more likely to have had a fistula placed prior to ESKD initiation.

Recommendation 4.15 (PRIORITY RECOMMENDATION)

(a) Nephrologists should actively build collaborative relationships with primary care providers in their referral base and provide consultations when requested to help in developing care management plans. Nephrologists should also help educate primary care providers and other health care professionals on current recommendations regarding detection and management of people with chronic kidney disease and the accompanying vascular complications including cardiovascular disease.

(b) Academic health centers, Area Health Education Centers, and Carolina Renal Care should widely disseminate the Renal Physicians Association toolkit to all nephrologists across the state to promote better understanding of chronic disease management and to incorporate this knowledge into management of patients with

cc There is a nationwide effort to increase the preservation of vascular access through the NKF KDOQI Clinical Practice Guidelines for Vascular Access, the Centers for Medicare and Medicaid Services, and regional ESRD networks.

dd A fistula involves a small operation to join an artery and vein which allows arterial blood to flow directly into the vein. The purpose is to make it easier to place a needle into the vein to allow blood to flow to the dialysis machine. Optimally it should be created using the patient's own veins and arteries (arterial venous fistula); however, when that is not possible, it can be established using a graft of synthetic material. NKF KDOQI Guidelines 2000. Guidelines for Vascular Access.

chronic kidney disease. Specifically, nephrologists should be referred to the model consultation template and other tools for communicating effectively with primary care providers.

(c) The American Society of Nephrology should provide educational programs to nephrologists pertaining to chronic kidney disease management, the need for early collaborative relations with primary care providers, and information that should be included in any nephrology consultation letter for a primary care provider.

(d) Nephrologists and/or primary care providers who are managing the care of patients with later stages of chronic kidney disease should refer patients for medical nutrition therapy, when appropriate.

(e) Nephrologists, in conjunction with disease management or patient educators, primary care providers, and private dialysis centers should provide patients with early education prior to the onset of kidney failure including:

(1) All options of kidney therapy including transplantation, home dialysis (including hemodialysis and peritoneal dialysis), in-center hemodialysis and supportive therapy only.

(2) The need to protect veins prior to the need for dialysis.

(f) Nephrologists should work with patients in stage 4 to ensure they are offered transplantation or timely placement of peritoneal or vascular access to prevent possible medical complications from emergency treatment for kidney failure and to reduce the utilization of temporary catheters for access to circulation for renal replacement unless there is no other option.

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Chapter Five
Conclusions

Chronic kidney disease (CKD) is a major public health problem facing the state. There are a little less than a million people in North Carolina with different stages of chronic kidney disease. Many people do not realize they have CKD, especially in the early stages. Kidney disease is the 10th leading cause of death in our state, but the impact of this disease is actually far greater. A person's kidneys filter out toxins and other waste from their body. Improperly functioning kidneys can lead to damage in other body organs. Thus, people with kidney disease die more often of cardiovascular diseases than through complete kidney failure.

Like many other diseases, chronic kidney disease is largely preventable. Public health campaigns that help reduce the incidence of diabetes and hypertension will lead to reductions in the number of people with CKD. In addition, with early intervention and treatment people with CKD can learn to manage their chronic health problems. The treatment of kidney disease is often the same or complimentary to the treatment prescribed for high blood pressure or diabetes. Therefore, helping people with CKD manage their health problems will also lead to improvements in other comorbid conditions.

The North Carolina General Assembly has recognized the growing prevalence of kidney disease and identified it as a health challenge facing the state. In 2006 the General Assembly directed the North Carolina Institute of Medicine to study this problem and develop recommendations to implement a cost effective plan for prevention, early screening, diagnosis, and treatment of chronic kidney disease and its complications.

The Task Force organized its recommendations around a comprehensive system of care for people at various stages of kidney disease. These recommendations also address the legislative charge to the Task Force:

(1) **Reduce the occurrence of chronic kidney disease by controlling the most common risk factors, diabetes and hypertension, through preventive efforts at the community level and disease management efforts in the primary care setting.**

The Task Force identified a number of public and private initiatives that are aimed at controlling some of the common risk factors that contribute to CKD (including diabetes and hypertension). However, these programs are not available statewide. In Recommendations 4.1-4.3 the Task Force recommended continuation of these programs and further expansion of educational efforts. The Task Force specifically recommended increasing appropriations to the Division of Public Health by $500,000 annually to expand diabetes prevention and control with these funds targeted to community-based programs that educate at-risk populations about CKD and the importance of early screening.

(2) Educate the public and health care professionals about the advantages and methods of early screening, diagnosis, and treatment of chronic kidney disease and its complications based on Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines for chronic kidney disease or other medically recognized clinical practice guidelines.

The Task Force recognized that more work is needed to educate the public and primary care providers about the importance of early screening. Recommendations 4.3 and 4.4 are targeted at educating the public about CKD and early intervention while Recommendation 4.6 targets health care professionals.

As noted previously, the Task Force recommended that the General Assembly appropriate $500,000 to implement community-based diabetes prevention and control programs that target at-risk populations for CKD (Rec. 4.3). Part of these funds would be used to educate at-risk populations about chronic kidney disease and the importance of early screening. Similarly, Recommendation 4.4 asks public and private payers to examine their claims data to identify people who may be at-risk of or diagnosed with CKD in order to send targeted patient education materials to educate their enrollees about this condition.

The Task Force identified the need to provide more targeted education to primary care providers about the importance of early screening, the use of the eGFR to "stage" people with chronic kidney disease, and the application of evidence-based treatment guidelines for people with CKD. Strategies to provide more intensive education were identified in Recommendation 4.6.

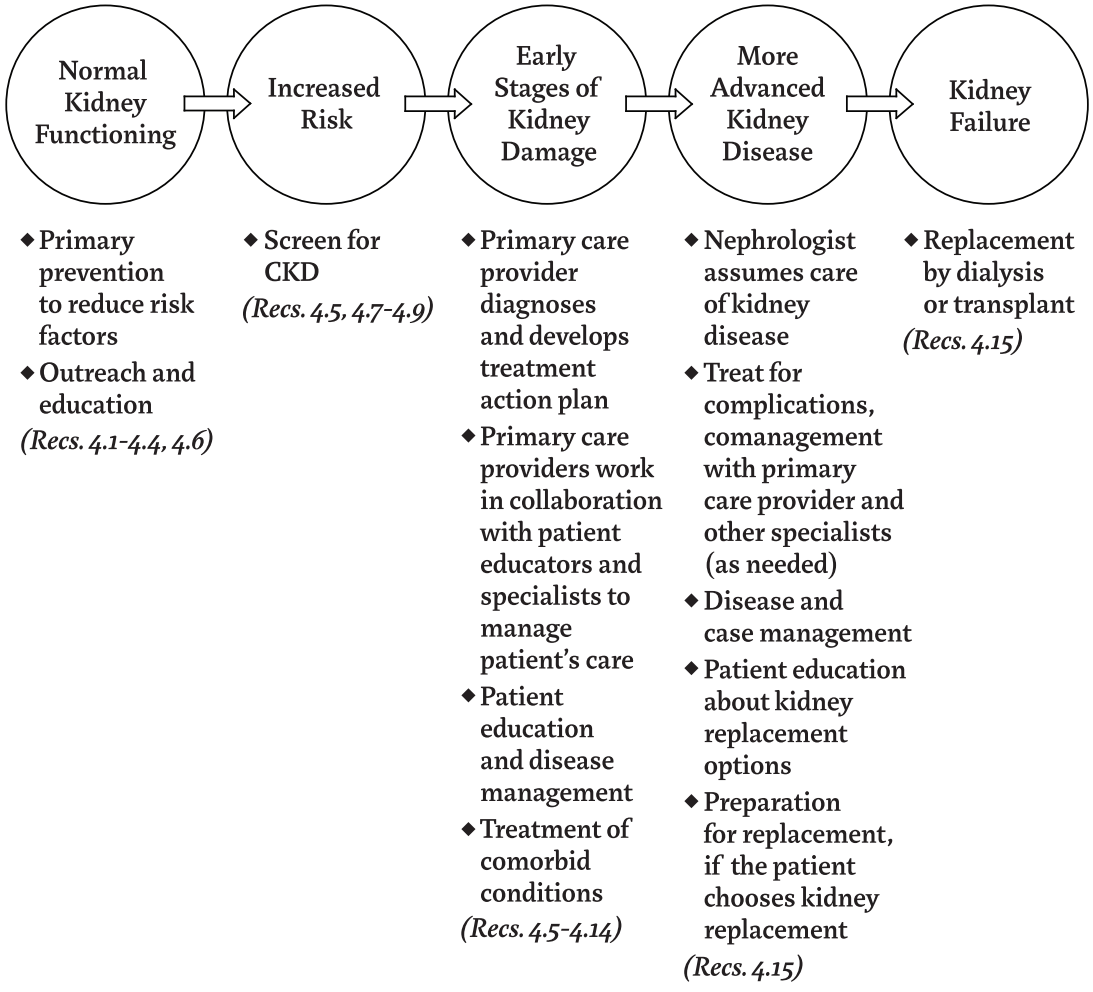
(3) Educate health care professionals about early renal replacement therapy education for patients (including in center dialysis, home hemodialysis, peritoneal dialysis as well as vascular access options and transplantation) prior to the onset of end-stage kidney disease when kidney function is declining.

The Task Force spent a great deal of time examining ways to prevent kidney disease or delay the progression of the disease through better disease management. Inevitably, there will be some individuals with CKD who progress to kidney failure. These patients need better education about all their choices of kidney therapy—including transplantation, home dialysis, in-center dialysis, and supportive therapy only—as well as education about the importance of protecting their veins prior to the need for dialysis. In addition, the Task Force recognized the importance of providing patients with early vascular access to support dialysis (if that is the option chosen by the patient) in order to reduce the need for more expensive emergency placement of vascular access. These issues are addressed in Recommendation 4.15.

(4) Make recommendations on the implementation of a cost-effective plan for prevention, early screening, diagnosis, and treatment of chronic kidney disease and its complications for the State's population.

The Task Force considered ways to implement a cost-effective plan for the prevention, early screening, diagnosis, and treatment of chronic kidney disease. The goal was to either prevent CKD from occurring or to identify patients early in the disease so as to provide appropriate treatment to manage their health problems. The higher costs of dialysis and treatment of complications from comorbid conditions could be reduced by funding efforts to lower the prevalence of diseases and conditions that can lead to CKD, that accelerate progression in the GFR decline, and/or that lead to complications in CKD. Thus, the Task Force recommended a system of care encompassing prevention, early identification, and treatment to prevent or delay the progression of kidney disease to kidney failure. The first three elements of the coordinated system of care focus on people with normal kidney functioning, increased risk, or early stages of kidney damage. The goal is to prevent more advanced kidney disease or kidney failure.

Chart 4.1.
Coordinated System of Care for Patients as They Progress with Kidney Disease



Adapted from National Kidney Foundation. KDOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. *Am J Kidney Dis*. 2002;39(suppl. 1):S1-S266.p.6 Figure 1.

The Task Force focused on identifying people who are at high-risk for developing kidney disease and screening them (Rec. 4.5) by obtaining a spot urine albumin to creatinine ratio and a serum creatinine to obtain the estimated GFR (Recs. 4.7 and 4.8). Patients who have been identified as having CKD should have their disease "staged" using the National Kidney Foundation's five stages of disease categories (Rec. 4.7). Providers should follow the KDOQI or other evidence-based guidelines to manage or slow the progression of the disease and should refer the patients to nephrologists in the early stages for consults or in the later stages for more active management of

kidney disease (Rec. 4.7). In addition, public and private payers and insurers should develop disease management systems and quality improvement initiatives to ensure that patients receive evidence-based standards of care and that they are educated appropriately to manage their health problems (Recs. 4.10, 4.11, 4.12, 4.13, 4.14).

(5) Identify current barriers to adoption of best practices and potential policy options to address these barriers.

Primary care providers are currently faced with enormous challenges providing the most up-to-date evidence-based care to all of their patients. The Task Force recognized that the time and resource constraints facing most primary care providers were one of the greatest barriers which prevented patients with CKD from receiving evidence-based care. Thus, the Task Force recommended system supports to facilitate primary care practitioners in the adoption of best practices. First, the Task Force recommended that all laboratories in the state report the eGFR anytime a practitioner requests a serum creatinine measurement (Rec. 4.8). Second, the Task Force recommended that all businesses that develop electronic health records include clinical decision supports to help identify patients at risk for developing CKD and to help manage patients with the condition (Rec. 4.9).

The second barrier that the Task Force identified was the lack of insurance coverage. The Task Force recognized that some of the at-risk populations identified with CKD will be uninsured. These uninsured patients will need access to ongoing primary care, medications, and nephrology consults (when necessary) in order to manage their chronic health problem. The Task Force recommended that the General Assembly appropriate additional funds to expand the health care safety net and pay for nephrology consults for the uninsured who have been identified with CKD (Rec. 4.5).

In total, the Task Force made 15 recommendations, 6 of which were considered high priority. These recommendations, if implemented, will lead to reductions in the incidence of chronic kidney disease in the future. Equally important, ensuring that people with chronic kidney disease are identified early and provided appropriate education, support and treatment to manage their health problems should lead to improved health status, increased productivity, and the reduced disability that results if their conditions progress to kidney failure.

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
Rec. 4.1 The Task Force supports ongoing efforts by the North Carolina Division of Public Health, the North Carolina Department of Public Instruction, and other state and local organizations to enhance community education about and reduce the risk factors for chronic kidney disease.		✓				
Rec. 4.2 The North Carolina General Assembly should increase funding to the Division of Public Health to build statewide capacity for chronic disease prevention programs that reduce the risk factors that may lead to chronic kidney disease by funding implementation of the Eat Smart, Move More NC objectives and by increasing funding to local communities through the Statewide Health Promotion, Healthy Carolinians, and Health Disparities programs.	✓	✓				
Rec. 4.3 (PRIORITY) (a) The NC General Assembly should appropriate $500,000 in recurring funding to the Division of Public Health and the Office of Minority Health and Health Disparities to expand diabetes prevention and control funding. Funding should be limited to programs that are built on evidence-based or promising practices that educate at-risk populations about CKD and the importance of early screening. Funding priority should be given to programs that: (1) Increase outreach in existing counties and to expand to counties that are not being adequately served by existing programs. (2) Include a plan for ongoing evaluation of effectiveness.	✓ $500K	✓				✓ (Community-based program)

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
(3) Target populations at increased risk for developing CKD, and incorporate local partners such as faith-based health ministries, beauty salons/barber shops, civic and senior citizen groups, public health departments, and primary care practitioners. (b) Programs must be evaluated in a timely fashion to demonstrate effectiveness in order to receive continued funding. (c) In order to ensure that the most effective elements of programs are emulated appropriately, the Division of Public Health and Office of Minority Health and Health Disparities should work with existing grantees and others to foster inter-program collaboration. Collaborative activities should include, but not be limited to, sharing of appropriately privacy-protected evaluative data to allow improvement in a program's current (or potential) design.						
Rec. 4.4 Public and private insurers should examine patient-level eligibility and claims data to identify people who are at risk of or diagnosed with CKD. Insurers should explore mechanisms to increase awareness of CKD among consumers at risk, such as targeted messaging that encourage consumers to be screened for kidney function.					✓	
Rec. 4.5 (PRIORITY) (a) The North Carolina General Assembly should provide $550,000 in recurring funding to the Division of Public Health to help pay for the screenings of uninsured patients who are at high-risk for developing kidney disease,	✓ $22.9 M	✓				

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
including people with diabetes, hypertension, cardiovascular disease, family history of CKD, or other evidence-based risk factors which have been demonstrated to contribute to the development of CKD.[a] (b) The North Carolina General Assembly should appropriate an additional $2,400,000 to the Community Health Center grants program to expand care to uninsured individuals with CKD.[b] Priorities should be given to: (1) Areas of the state that do not have sufficient safety net capacity. (2) Programs that provide primary care, disease management, and care management to patients with CKD.						

a This cost estimate assumes that the Division of Public Health will screen 5% of the uninsured population with hypertension. The Division of Public Health estimated that there are approximately 328,000 uninsured adults with hypertension. The current combined cost for a urine microalbumin and serum creatinine laboratory report is approximately $38. Multiplying these figures indicates a total cost of close to $11.5 million. The Division estimates that they may be able to screen approximately 5% of these individuals for a cost of $550,000.

b Combining information from a variety of data sources including the Behavioral Risk Factor Surveillance Survey (BRFSS) and the National Health and Nutrition Examination Survey (NHANES), the NC IOM estimates that approximately 40,000 North Carolinians uninsured with stage 3 or higher CKD.
Furthermore, the same analysis estimates that approximately 16,000 of these uninsured with CKD indicate they have no usual source of care; they would need to be linked with a primary care medical home. The Bureau of Primary Health Care suggests that community health centers use a standard budget of approximately $150 per year per patient to provide primary care services to the uninsured (New Access Points (NAP) Grant Competition Announcement Number HRSA08-077. Health Resources and Services Administration. US Department of Health and Human Services. http://www.hrsa.gov/grants/. Accessed November 1, 2007.) Using $150 as a per-person estimate, primary care services for these 16,000 uninsured are estimated at $2,400,000. This cost estimate is very conservative since providing services to people with chronic illnesses will be more expensive than providing services to uninsured without chronic illness. Further, this only includes the estimated cost of providing primary care services to people with CKD and does not include other uninsured individuals with diabetes, hypertension, cardiovascular disease, or other chronic illnesses who do not also have CKD. Providing a primary care home to other people with chronic illnesses would require additional funds. For more details on estimation see Appendix 2.

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
(3) Organizations that provide comprehensive services, including pharmaceuticals, to the uninsured with incomes <200% FPG. (c) The North Carolina General Assembly should appropriate an additional $15 million to the Community Health Center grants program to expand care to the uninsured with other chronic illnesses that can lead to CKD.[c] Priorities should be given to: (1) Areas of the state that do not have sufficient safety net capacity. (2) Programs that provide primary care, disease management, and care management to patients with high-cost chronic illnesses, including but not limited to: diabetes, hypertension, cardiovascular disease, and other evidence-based risk factors which have been demonstrated to contribute to the development of CKD (3) Organizations that provide comprehensive services, including pharmaceuticals, to the uninsured with incomes <200% FPG. (d) The North Carolina General Assembly should provide $5 million to the NC Division of Public						

c BRFSS data suggest there are approximately 250,000 uninsured North Carolinians with diabetes, hypertension, or cardiovascular disease who do not have CKD; 100,000 of this number have no usual source of care. The Bureau of Primary Health Care estimates that community health centers should budget approximately $150 per year per patient to provide primary care services to the uninsured (New Access Points (NAP) Grant Competition Announcement Number HRSA08-077. Health Resources and Services Administration. US Department of Health and Human Services. http://www.hrsa.gov/grants/. Accessed November 1, 2007.). Using $150 as a per person estimate, primary care services for these 100,000 uninsured are estimated at $15,000,000. This cost estimate is conservative since providing services to the uninsured with chronic illnesses will be more expensive than providing services to the uninsured without chronic illnesses.

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
Health Purchase of Medical Care (POMC) program to help pay for nephrologist consults for uninsured patients with incomes <200% FPG.[d] Funding should be used to: (1) Pay for nephrology consultations that follow the Renal Physicians' Association consultation standards for patients with chronic kidney disease with <30 eGFR, or other patients with higher eGFR if a clinical action plan cannot be prepared or the appropriate evaluation performed. (2) Support a coordinated system of care between the primary care provider and nephrologist.						
Rec. 4.6 The NC Area Health Education Centers program, the National Kidney Foundation (NC Chapter), the UNC Kidney Center, NC Renal Care, the NC Medical Society, the NC Academy of Family Physicians, the NC Chapter of the American College of Physicians, the Old North State Medical Society, the NC Academy of Physician Assistants, the NC Nurses Association Council of Nurse Practitioners, the NC Association of Pharmacists, and Community Care of NC should collaborate to provide targeted CKD educational programs for primary care providers. The education should include information about the importance						✓ (AHEC, NKF, other academic health programs, provider associations)

d The NC IOM estimates there are approximately 40,000 uninsured individuals with CKD who are in stages 3-5 and who are not receiving dialysis. For purposes of this estimate, we assumed that all of the uninsured would need access to a nephrology consult once a year even if they otherwise had access to primary care providers for the ongoing management of their health problem. Medicaid pays between $49.50-$202.50 to nephrologists for consultations, depending on the CPT code. For purposes of this estimate, we assumed that each patient would receive one consult/year with an average cost of $125.

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
of early screening for at-risk populations, the use of the eGFR to identify people with CKD, stages of the disease, diagnosing the etiology of the disease, and evidence-based treatment guidelines of people with the disease. Education should be provided in a variety of settings including, but not limited to, health professional training schools, residency programs, continuing medical or nursing education, practice consultants, and quality improvement initiatives.						
Rec. 4.7 (PRIORITY) (a) Primary care providers should routinely screen their patients who are at high risk for chronic kidney disease including patients with diabetes mellitus, hypertension, cardiovascular disease, family history of CKD, or other evidence-based risk factors which have been demonstrated to contribute to the development of the disease. Screening should include albumin measurement from a spot urine sample[e] and serum creatinine to obtain the estimated GFR. (b) Patients who have been identified with CKD should be staged using the NKF 5 stages of disease categories. (c) Health care providers who have patients who have been diagnosed with CKD should follow the KDOQI or other evidence-based guidelines to manage and slow the progression of CKD. These guidelines include, but are not limited to:			✓	✓		✓ (Nutritionist)

e The KDOQI guidelines state that albumin should be measured in a spot urine sample using either albumin-specific dipstick or albumin-to-creatinine ratio.

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
(1) Treating patients to achieve a target blood pressure of <130/80. (2) Prescribing an ACE inhibitor or ARB as specific therapy to slow the progression of kidney disease as well as control blood pressure. (3) Using combination hypertensive therapy, which should include a diuretic. (4) Evaluating patients with eGFR<60 mL/min/1.73m² for anemia. (5) Treating to ensure strict glucose control in diabetes. (6) Detecting and managing other cardiovascular risk factors, particularly cholesterol and tobacco use. (7) Monitoring the rate of eGFR decline in patients with CKD at least yearly and more often for patients with rapid decline or specific risk factors. (8) Referring patients to registered dietitians for nutrition therapy when appropriate. (d) Primary care providers should refer patients with eGFR <30 to nephrologists for ongoing care. Other patients, with higher eGFR, should also be referred to a nephrologist for consultation or comanagement if a clinical action plan cannot be prepared or the appropriate evaluation performed, or if a patient is experiencing rapid decline in kidney function. There should be sustained coordination between the primary care provider, disease management or care management staff, nephrologists and other specialists.						

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
Rec. 4.8 (PRIORITY) The estimated GFR values should be computed and reported on all creatinine determinations by clinical laboratories in North Carolina. (a) Hospital and commercial clinical laboratories should incorporate a calculated eGFR on all patient laboratory data that includes measurement of the serum creatinine. Carolina Renal Care, the College of American Pathologists, and the National Kidney Foundation NC Chapter should work collaboratively to educate clinical laboratories of the importance of reporting the eGFR when a provider orders a serum creatinine or when the creatinine is part of a metabolic panel. (b) Payers and insurers should require that all serum creatinine determinations for their members and dependents automatically include the eGFR. (c) The NC Division of Public Health along with Carolina Renal Care should monitor the clinical laboratories to determine if reporting of eGFR has become standard practice throughout the state when a serum creatinine is ordered. If the preceding recommendations are insufficient to make eGFR reporting standard practice throughout the state within 1 year for all laboratories, the General Assembly should amend the General Statutes to require all creatinine laboratory reports to include eGFR values.	✓	✓	✓	✓	✓	✓ (Lab)
Rec. 4.9 Businesses and organizations that develop electronic health records should provide the capacity for						✓ (Electronic Health Records)

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
chronic disease registries and clinical decision support prompts that incorporate CKD screening and treatment measures for at-risk groups.						
Rec. 4.10 (a) Public and private insurers, payers, and other organizations that offer disease management or quality improvement initiatives targeted at people with diabetes, hypertension, or cardiovascular disease should give greater emphasis to CKD prevention, screening and management. (1) Payers, insurers, and other organizations should remind patients and providers to obtain regular screenings for CKD including urine microalbumin and estimated GFR from serum creatinine. (2) Payers, insurers, and other organizations should adopt evidence-based clinical practice recommendations for screening and management of CKD (including those referenced in Recommendation 4.7), and should develop and include performance measures relevant to CKD detection and treatment in quality improvement and quality assurance programs. (b) Public and private payers and insurers should provide targeted disease management or case management services and medical nutrition therapy to all patients with CKD once they have progressed to Stage 4. Patients should be provided information about different types of renal replacement therapy.					✓	

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
Rec. 4.11 The National Kidney Foundation, the American Society of Nephrology, the American Society of Pediatric Nephrology, and the American Dietetics Association should work with national quality and standard setting organizations to devise quality performance measures that assess the degree to which practitioners screen and manage patients with or at risk of developing CKD in accordance with nationally recognized guidelines.				✓		✓ (NKF, Other organizations)
Rec. 4.12 Community Care of North Carolina (CCNC) should create a CKD disease management initiative as part of its §646 Medicare waiver, if approved, which will focus on older adults age 65 or older or people with disabilities who are also receiving Medicare. CCNC should incorporate evidence-based treatment of people with CKD into the initiative, and identify clinical performance measures to assess the quality of care provided to patients with the disease.					✓ CCNC	
Rec. 4.13 (a) North Carolina foundations and/or national foundations should provide funding to the University of North Carolina at Chapel Hill to pilot test and evaluate the effectiveness of the Kidney Care Prevention Program (KCPP), a chronic kidney disease certification program being developed in conjunction with the NC Community College System. People who are trained for disease management of CKD should also be cross trained for diabetes, hypertension, and cardiovascular disease. (b) Public and private payers and insurers should provide funding for CKD trained educators if						✓ (Foundations, UNC-CH)

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
determined to be effective and cost efficient[f] in slowing the progression of the disease or improving health.						
Rec. 4.14 (PRIORITY) (a) Disease managers or case managers who manage patients with diabetes, hypertension, or cardiovascular disease should be cross-trained in the management of people with chronic kidney disease. (b) Existing programs that provide disease management education and/or certification for diabetes, hypertension, or cardiovascular disease management should ensure that the curriculum includes information about prevention, screening, treatment and self-management skills for people with chronic kidney disease. (c) The North Carolina General Assembly should provide funding to the Department of Health and Human Services to support the infrastructure needed to expand the DPH Diabetes Education Recognition Program with a special focus on CKD screening and management. The General Assembly should appropriate $150,000 in FY 2008-2009, $300 000 in FY 2009-2010, and $450,000 in FY 2010-2011 and thereafter to support this program.	✓ $150K - $450K	✓				✓ (Disease and case managers)

f The term cost efficient here means "leads to a generally accepted reasonable cost per unit of improvement in health." This is a lower standard of effectiveness than cost-saving (meaning the program leads to overall cost decreases). For more discussion see Chapter 3.

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
Rec. 4.15 (PRIORITY) (a) Nephrologists should actively build collaborative relationships with primary care providers in their referral base and provide consultations when requested to help in developing care management plans. Nephrologists should also help educate primary care providers and other health care professionals on current recommendations regarding detection and management of people with chronic kidney disease and the accompanying vascular complications including cardiovascular disease. (b) Academic health centers, AHEC, and Carolina Renal Care should widely disseminate the Renal Physicians Association toolkit to all nephrologists across the state to better understanding of chronic disease management and to incorporate this knowledge into management of patients with CKD. Specifically, nephrologists should be referred to the model consultation template and other tools for communicating effectively with primary care providers. (c) The American Society of Nephrology should provide educational programs to nephrologists pertaining to CKD management, the need for early collaborative relations with primary care providers, and information that should be included in any nephrology consultation letter for a primary care provider. (d) Nephrologists and/or primary care providers who are managing the care of patients with later stages of CKD should refer patients for medical nutritional therapy, when appropriate.			✓	✓		

	General Assembly	DHHS	Primary Care Providers	Nephrologists	Insurers and Payers	Other
(e) Nephrologists, in conjunction with disease management or patient educators, primary care providers, and private dialysis centers should provide patients with early education prior to the onset of kidney failure including: (1) All options of kidney therapy including transplantation, home dialysis (including hemodialysis and peritoneal dialysis), in-center hemodialysis and supportive therapy only. (2) The need to protect veins prior to the need for dialysis. (f) Nephrologists should work with patients in stage 4 to ensure that they are offered transplantation or timely placement of peritoneal or vascular access to prevent possible medical complications from emergency treatment for kidney failure and to reduce the utilization of temporary catheters for access to circulation for renal replacement unless there is no other option.						

Appendix A
Estimation Methods

As has been documented throughout the report, available evidence on the prevalence of CKD in NC is limited, primarily because it is underdiagnosed, awareness is low, and it is difficult to obtain serum creatinine measures on a generalizable sample of the NC population. In order to inform the Task Force on the scope and magnitude of the problem, and to help develop cost estimates for some of the recommendations, North Carolina specific prevalence estimates were developed. The general method for developing these estimates is outlined below.

Step 1: Classify NHANES respondents by CKD Stage

National Health and Nutrition Examination Survey data from the 2001-2002 and 2003-2004 interview periods were used to generate national CKD prevalence estimates. The approach follows those used in published analyses.[1,2] Estimated GFR was calculated using the MDRD equation. Also following that work, persistent albuminuria was operationalized by assuming specified fractions of the microalbunuria cases were persistent (50.9% for those with microalbuminuria and an eGFR>90 ml/min/1.73 m^2; 75.0% for those with microalbuminuria and an eGFR of 60 to 89 ml/min/1.73 m^2; 100% of all macroalbuminuria cases).[2] This was accomplished by randomly selecting 50.9% of cases in which eGFR was greater than 90 ml/min/1.73 m^2 and microalbuminuria was present and labeling these cases "Stage 1." The remaining 49.1% of eGFR>90 ml/min/1.73 m^2 and microalbuminuria cases were not classified as having CKD. This process was repeated for the eGFR between 60 and 89 ml/min/1.73m^2 and microalbuminuria cases. All macroalbuminuria cases were classified as CKD with stage depending on the eGFR.

Prevalence estimates by stage are presented below in Table A-1. Note that Coresh et al ignore NHANES respondents classified as Stage 5 due to an eGFR<15. The identical approach is taken here.

Step 2: Develop prediction model for CKD Stage

With the Stage assignment in hand, prediction models were performed to ascertain the association between CKD Stage and commonly observed characteristics. The final

prediction model included age, gender, race (African-American non-Hispanic or otherwise), self-reported diabetes status, and self-reported hypertension status.

Multiple models were considered, including one logistic model predicting CKD Stage 1-4, another predicting CKD stage 3-4, and an ordered probit predicting stage of CKD. All models used the NHANES survey weights.

After model estimation, these parameter estimates were set aside.

Step 3: Assign CKD probabilities to BRFSS respondents

The Centers for Disease Control and Prevention annually performs a survey of adults that includes questions on factors, such as high blood pressure and diabetes, known to be associated with CKD. This survey, the Behavioral Risk Factor Surveillance System (BRFSS) is designed to be representative at the state level; North Carolina has roughly 17,000 respondents to the survey in any given year. Thus, we can apply the national prevalence estimates for CKD from NHANES to the NC population based on state specific health characteristics. For the final model used here, age, gender, history of hypertension, history of diabetes, and race of African-American were used as predictors.

The data from the 2005 BRFSS were formatted to correspond with the NHANES data. (High blood pressure awareness was not asked in the 2006 data, so 2005 was the most recent data available). With the data formatted in the same manner, predictions can be generated using the average associations between observed factors and CKD stage at a national level. A simplified example may be helpful in illustrating this approach. For purposes of the example, assume that a survey reveals that 20 percent of males and 60 percent of females have a certain characteristic. If a group of similar people is 50 percent male and 50 percent female, one estimate is that .5 x 20% + .5 x 60% = 40% of the group has the characteristic. If a second group is 80 percent male and 20 percent female, an estimate would be .8 x 20% + .2 x 60% = 28%. Assuming that the relationships in the development (here, NHANES) dataset is similar to the relationships in the *estimation* (here, NC using BRFSS) population, then we are able to estimate a valid prevalence rate of CKD in NC using this approach.[3]

Table A-1 presents 5 different sets of estimates. Column A is the prevalence as presented in Coresh using 1999-2004 data. Column B is the NC IOM's analysis based on 1999-2004. Both these are standardized to the 2000 standard population. Overall, the predictions are quite similar between the Coresh et al model analysis and the replication by the Task Force. Column C uses the weights in the NHANES data, meaning the predictions apply to a 1999-2004 population. This slightly lowers the estimated prevalence of CKD. Column D applies the estimated relationship in NHANES and looks at the in-sample predictive power. The in-sample predictive power, as expected, is overall quite good – the predicted prevalence is very similar to the estimated

prevalence. Column E applies the prediction model to the national BRFSS data (out-of-sample prediction). Applying the model to the BRFSS data increases the prevalence; one reason is the much higher prevalence of diabetes (7.7 in BRFSS vs. 6.8 in NHANES). Finally, Column F limits the prediction to only the North Carolina BRFSS data. Note the highly similar prevalence estimates for the US and North Carolina. Although North Carolinians have a higher estimated prevalence of CKD due to higher rates of diabetes and hypertension, our age profile is younger and this tends to lower the estimated prevalence.

Table A.1.
Comparison of Prevalence Estimates

Column	A	B	C	D	E	F
Area:	*National*	*National*	*National*	*National*	*National*	*North Carolina*
Population	*2000*	*2000*	*1999-2004*	*1999-2004*	*2005*	*2005*
Analysts:	*Coresh et al*	*NCIOM*	*NCIOM*	*NCIOM*	*NCIOM*	*NCIOM*
Data:	*NHANES*	*NHANES*	*NHANES*	*NHANES*	*BRFSS*	*BRFSS*
Type:	*Actual*	*Actual*	*Actual*	*Predicted*	*Predicted*	*Predicted*
No CKD	86.94%	86.68%	87.62%	87.48%	86.40%	86.32%
Stage 1	1.78%	1.64%	1.68%	1.69%	1.76%	1.77%
Stage 2	3.24%	3.16%	3.05%	3.18%	3.34%	3.36%
Stage 3	7.69%	8.13%	7.31%	7.30%	8.07%	8.11%
Stage 4	0.35%	0.38%	0.34%	0.35%	0.42%	0.43%

Step 4: Estimate prevalence for subcategories of the population

With these prevalence estimations in hand, other estimates can be derived in a relatively straightforward manner. The prevalence estimation yields a probability of the respondent having each of the 5 CKD stages (0-4) considered here. BRFSS asks other questions such as insurance status and whether the respondent has a usual source of care. Using the answers to these questions, the number of CKD patients who are uninsured, or who are uninsured and do not have a usual source of care, or the number of people with CKD or at high risk for CKD who are uninsured and have no usual source of care, can be estimated. The estimated number of people with CKD is estimated by summing the individual probabilities. Likewise, other estimates – such as the number of people with diabetes without CKD – are computed similarly by summing probabilities for individual respondents.

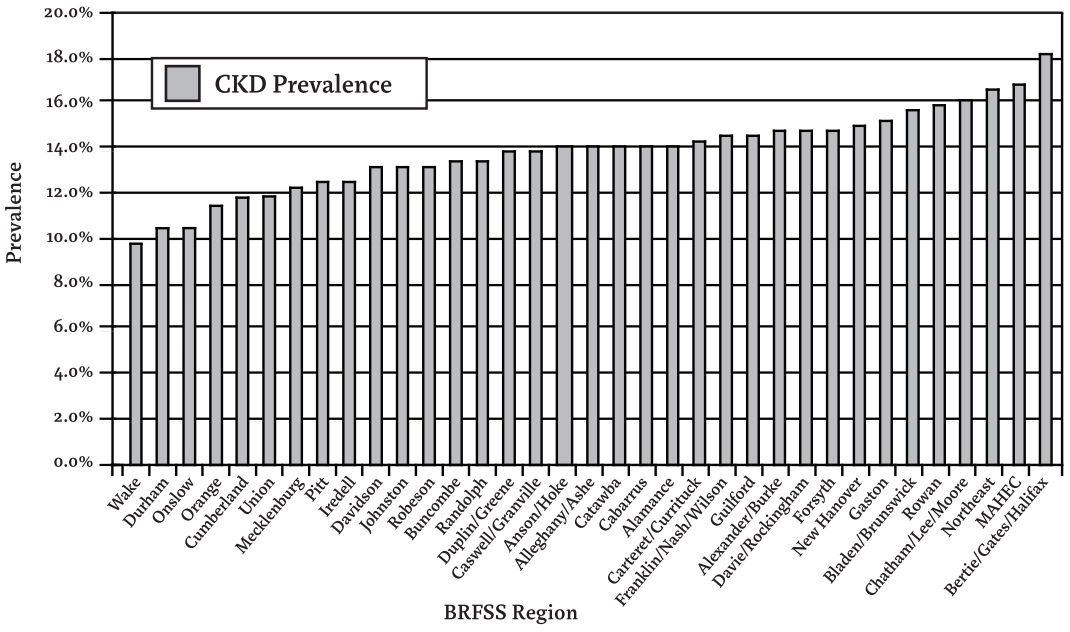
Step 5: Compute estimated costs

With subpopulation estimates in hand, estimated statewide costs can be derived by including per person costs from other sources. For example, for the Recommendation on purchase of medical care for nephrologists, multiplying the number of North Carolinians who are (a) uninsured (b) have no usual source of care and (c) have CKD by the average cost of a nephrologist visit yields the recommended appropriation.

Table A.2.
Estimated CKD Prevalence by Cardiovascular Disease (CVD), Diabetes, & Hypertension (HTN) Status

	Without CVD			With CVD			Total		
	With Diabetes	*Without Diabetes*	*Total*	*With Diabetes*	*Without Diabetes*	*Total*	*With Diabetes*	*Without Diabetes*	*Total*
Estimated North Carolinian Adults with CKD Stage 3-4									
No HTN	145,713	20,857	166,570	17,183	8,314	25,497	162,896	29,171	192,067
HTN	168,312	73,229	241,540	55,253	40,521	95,774	223,565	113,750	337,315
Total	314,025	94,086	408,110	72,436	48,835	121,271	386,461	142,921	529,382
Total North Carolinian Adults									
No HTN	4,015,397	135,574	4,150,971	157,160	31,652	188,812	4,172,557	167,226	4,339,783
HTN	1,231,064	257,322	1,488,386	246,155	122,782	368,937	1,477,219	380,104	1,857,323
Total	5,246,461	392,896	5,639,357	403,315	154,434	557,749	5,649,776	547,330	6,197,106
Percent with CKD Stage 3-4									
No HTN	3.6%	15.4%	4.0%	10.9%%	26.3%	13.5%	3.9%	17.4%	4.4%
HTN	13.7%	28.5%	16.2%	22.4%	33.0%	26.0%	15.1%	29.9%	18.2%
Total	6.0%	23.9%	7.2%	18.0%	31.6%	21.7%	6.8%	26.1%	8.5%

Chart A.3.
Estimated CKD Prevalence



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Appendix B
KDOQI Guidelines

KDOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification

Guideline 1.

Definition and Stages of Chronic Kidney Disease (p. S46)

Adverse outcomes of chronic kidney disease can often be prevented or delayed through early detection and treatment. Earlier stages of chronic kidney disease can be detected through routine laboratory measurements.

- The presence of chronic kidney disease should be established, based on presence of kidney damage and level of kidney function (glomerular filtration rate [GFR]), irrespective of diagnosis.
- Among patients with chronic kidney disease, the stage of disease should be assigned based on the level of kidney function, irrespective of diagnosis, according to the KDOQI CKD classification:

Table B.1.
Stages of Chronic Kidney Disease

Stage	Description	GFR (mL per minute per 1.73 m^2)
1	Kidney damage with normal or ↑ GFR	≥90
2	Kidney damage with mild ↓ GFR	60-89
3	Moderate ↓ GFR	30-59
4	Severe ↓ GFR	15-29
5	Kidney failure	<15 (or dialysis)

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

Guideline 2.
Evaluation and Treatment (p. S65)
The evaluation and treatment of patients with chronic kidney disease requires understanding of separate but related concepts of diagnosis, comorbid conditions, severity of disease, complications of disease, and risks for loss of kidney function and cardiovascular disease.

Patients with chronic kidney disease should be evaluated to determine:

- Diagnosis (type of kidney disease);
- Comorbid conditions;
- Severity, assessed by level of kidney function;
- Complications, related to level of kidney function;
- Risk for loss of kidney function;
- Risk for cardiovascular disease.

Treatment of chronic kidney disease should include:

- Specific therapy, based on diagnosis;
- Evaluation and management of comorbid conditions;
- Slowing the loss of kidney function;
- Prevention and treatment of cardiovascular disease;
- Prevention and treatment of complications of decreased kidney function;
- Preparation for kidney failure and kidney replacement therapy;
- Replacement of kidney function by dialysis and transplantation, if signs and symptoms of uremia are present.

A clinical action plan should be developed for each patient, based on the stage of disease as defined by the KDOQI CKD classification (see table below).

Review of medications should be performed at all visits for the following:

- Dosage adjustment based on level of kidney function;
- Detection of potentially adverse effects on kidney function or complications of chronic kidney disease;
- Detection of drug interactions; and
- Therapeutic drug monitoring, if possible.

Self-management behaviors should be incorporated into the treatment plan at all stages of chronic kidney disease.

Patients with chronic kidney disease should be referred to a specialist for consultation and co-management if the clinical action plan cannot be prepared, the prescribed evaluation of the patient cannot be carried out, or the recommended treatment cannot be carried out. In general, patients with GFR <30 mL/min/ 1.73 m^2 should be referred to a nephrologist.

Guideline 3.
Individuals at Increased Risk of Chronic Kidney Disease (p. S72)
Some individuals without kidney damage and with normal or elevated GFR are at increased risk for development of chronic kidney disease.

- All individuals should be assessed, as part of routine health encounters, to determine whether they are at increased risk of developing chronic kidney disease, based on clinical and sociodemographic factors.
- Individuals at increased risk of developing chronic kidney disease should undergo testing for markers of kidney damage and to estimate the level of GFR.
- Individuals found to have chronic kidney disease should be evaluated and treated as specified in Guideline 2.
- Individuals at increased risk, but found not to have chronic kidney disease, should be advised to follow a program of risk factor reduction, if appropriate, and undergo repeat periodic evaluation.

Table B.2.
Stages of Chronic Kidney Disease: A Clinical Action Plan

Stage	Description	GFR (mL/min/1.73 m^2)	Action*
1	Kidney damage with normal or ↑ GFR	≥90	Diagnosis and treatment, Treatment of comorbid conditions, Slowing progression, CVD risk reduction
2	Kidney damage with mild ↓ GFR	60-89	Estimating progression
3	Moderate ↓ GFR	30-59	Evaluating and treating complications
4	Severe ↓ GFR	15-29	Preparing for kidney replacement therapy
5	Kidney failure	<15 (or dialysis)	Replacement (if urernia present)

Chronic kidney disease is defined as either kidney damage or GFR <60 mL/min/1.73 m^2 for ≥3 months. Kidney damage is defined as pathologic abnormalities or markers of damage, including abnormalities in blood or urine tests or imaging studies.
*Includes actions from preceding stages.
Abbreviations: CVD, cardiovascular disease

Evaluation of Laboratory Measurements for Clinical Assessment of Kidney Disease (Part 5, P. S76)
The definition and staging of chronic kidney disease depends on the assessment of GFR, proteinuria, and other markers of kidney disease. The goals of Part 5 are to evaluate the accuracy of prediction equations to estimate the level of GFR from serum creatinine, the accuracy of ratios of protein-to-creatinine concentration in untimed ("spot") urine samples to assess protein excretion rate, and the utility of markers of kidney damage other than proteinuria. As described

in Appendix 1, Table 151, the Work Group evaluated studies according to accepted methods for evaluation of diagnostic tests. To provide a more comprehensive review, the Work Group attempted to integrate the systematic review of specific questions with existing guidelines and recommendations.

Guideline 4.
Estimation of GFR (p. S76)
Estimates of GFR are the best overall indices of the level of kidney function.

- The level of GFR should be estimated from prediction equations that take into account the serum creatinine concentration and some or all of the following variables: age, gender, race and body size. The following equations provide useful estimates of GFR:
  - In adults, the MDRD Study and Cockcroft-Gault equations;
  - In children, the Schwartz and Counahan-Barratt equations.
- The serum creatinine concentration alone should not be used to assess the level of kidney function.
- Clinical laboratories should report an estimate of GFR using a prediction equation, in addition to reporting the serum creatinine measurement.
- Autoanalyzer manufacturers and clinical laboratories should calibrate serum creatinine assays using an international standard.
- Measurement of creatinine clearance using timed (for example, 24-hour) urine collections does not improve the estimate of GFR over that provided by prediction equations. A 24-hour urine sample provides useful information for:
  - Estimation of GFR in individuals with exceptional dietary intake (vegetarian diet, creatine supplements) or muscle mass (amputation, malnutrition, muscle wasting);
  - Assessment of diet and nutritional status;
  - Need to start dialysis.

Guideline 5.
Assessment of Proteinuria (p. S93)
Normal individuals usually excrete very small amounts of protein in the urine. Persistently increased protein excretion is usually a marker of kidney damage. The excretion of specific types of protein, such as albumin or low molecular weight globulins, depends on the type of kidney disease that is present. Increased excretion of albumin is a sensitive marker for chronic kidney disease due to diabetes, glomerular disease, and hypertension. Increased excretion of low molecular weight globulins is a sensitive marker for some types of tubulointerstitial disease. In this guideline, the term "proteinuria" refers to increased urinary excretion of albumin, other specific proteins, or total protein; "albuminuria" refers specifically to increased urinary excretion of albumin. "Microalbuminuria" refers to albumin excretion above the normal range but below the level of detection by tests for total protein. Guidelines for detection and monitoring of proteinuria in adults and children differ because of differences in the prevalence and type of chronic kidney disease.

Guidelines for Adults and Children:

- Under most circumstances, untimed ("spot") urine samples should be used to detect and monitor proteinuria in children and adults.
- It is usually not necessary to obtain a timed urine collection (overnight or 24- hour) for these evaluations in either children or adults.
- First morning specimens are preferred, but random specimens are acceptable if first morning specimens are not available.
- In most cases, screening with urine dipsticks is acceptable for detecting proteinuria:
- Standard urine dipsticks are acceptable for detecting increased total urine protein.
- Albumin-specific dipsticks are acceptable for detecting albuminuria.
- Patients with a positive dipstick test (1+ or greater) should undergo confirmation of proteinuria by a quantitative measurement (protein-to-creatinine ratio or albumin-to-creatinine ratio) within 3 months.
- Patients with two or more positive quantitative tests temporally spaced by 1 to 2 weeks should be diagnosed as having persistent proteinuria and undergo further evaluation and management for chronic kidney disease as stated in Guideline 2.
- Monitoring proteinuria in patients with chronic kidney disease should be performed using quantitative measurements.

Specific Guidelines for Adults:

- When screening adults at increased risk for chronic kidney disease, albumin should be measured in a spot urine sample using either:
  - Albumin-specific dipstick;
  - Albumin-to-creatinine ratio.
- When monitoring proteinuria in adults with chronic kidney disease, the protein to-creatinine ratio in spot urine samples should be measured using:
  - Albumin-to-creatinine ratio;
  - Total protein-to-creatinine ratio is acceptable if albumin-to-creatinine ratio is high (>500 to 1,000 mg/g).

Specific Guidelines for Children Without Diabetes:

- When screening children for chronic kidney disease, total urine protein should be measured in a spot urine sample using either:
  - Standard urine dipstick;
  - Total protein-to-creatinine ratio.
- Orthostatic proteinuria must be excluded by repeat measurement on a first morning specimen if the initial finding of proteinuria was obtained on a random specimen.
- When monitoring proteinuria in children with chronic kidney disease, the total protein-to-creatinine ratio should be measured in spot urine specimens.

Specific Guidelines for Children With Diabetes:

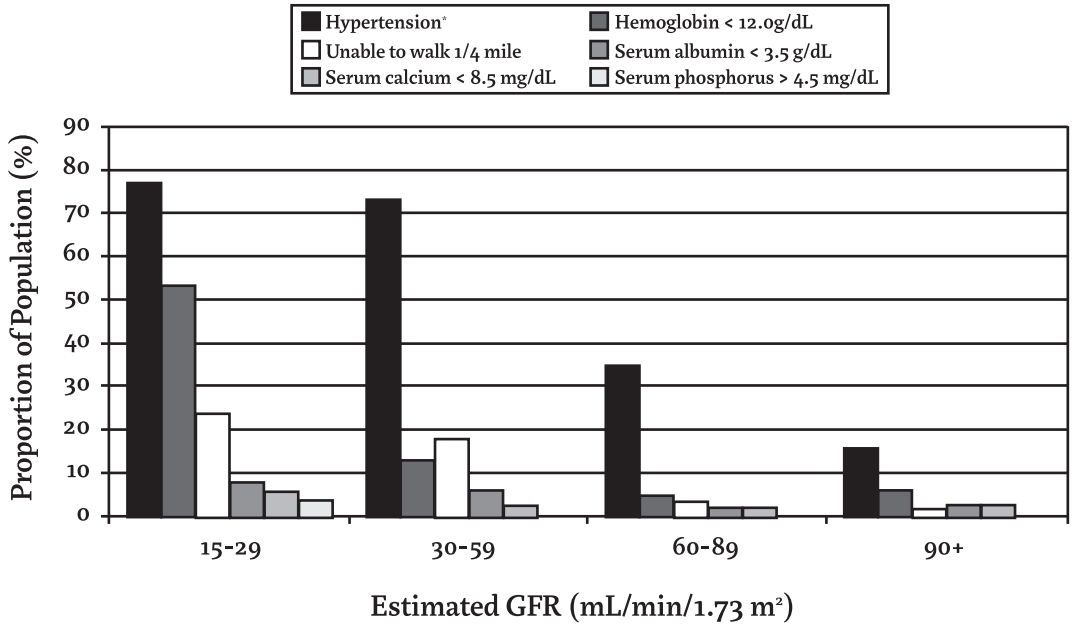
- Screening and monitoring of post-pubertal children with diabetes of 5 or more years of duration should follow the guidelines for adults.
- Screening and monitoring other children with diabetes should follow the guidelines for children without diabetes.

Guideline 6.
Markers of Chronic Kidney Disease Other Than Proteinuria (p. S103)
Markers of kidney damage in addition to proteinuria include abnormalities in the urine sediment and abnormalities on imaging studies. Constellations of markers define clinical presentations for some types of chronic kidney disease. New markers are needed to detect kidney damage that occurs prior to a reduction in GFR in other types of chronic kidney diseases.

- Urine sediment examination or dipstick for red blood cells and white blood cells should be performed in patients with chronic kidney disease and in individuals at increased risk of developing chronic kidney disease.
- Imaging studies of the kidneys should be performed in patients with chronic kidney disease and in selected individuals at increased risk of developing chronic kidney disease.
- Although several novel urinary markers (such as tubular or low-molecular weight proteins and specific mononuclear cells) show promise of future utility, they should not be used for clinical decision-making at present.

Association of Level of GFR with Complications in Adults (Part 6, P. S111)
Many of the complications of chronic kidney disease can be prevented or delayed by early detection and treatment. The goal of Part 6 is to review the association of the level of GFR with complications of chronic kidney disease to determine the stage of chronic kidney disease when complications appear. As described in Appendix 1, Table 152, the Work Group searched for crosssectional studies that related manifestations of complications and the level of kidney function. Data from NHANES III were also analyzed, as described in Appendix 2.

Chart B.3.
Lower eGFR is Associated with Poorer Health Outcomes

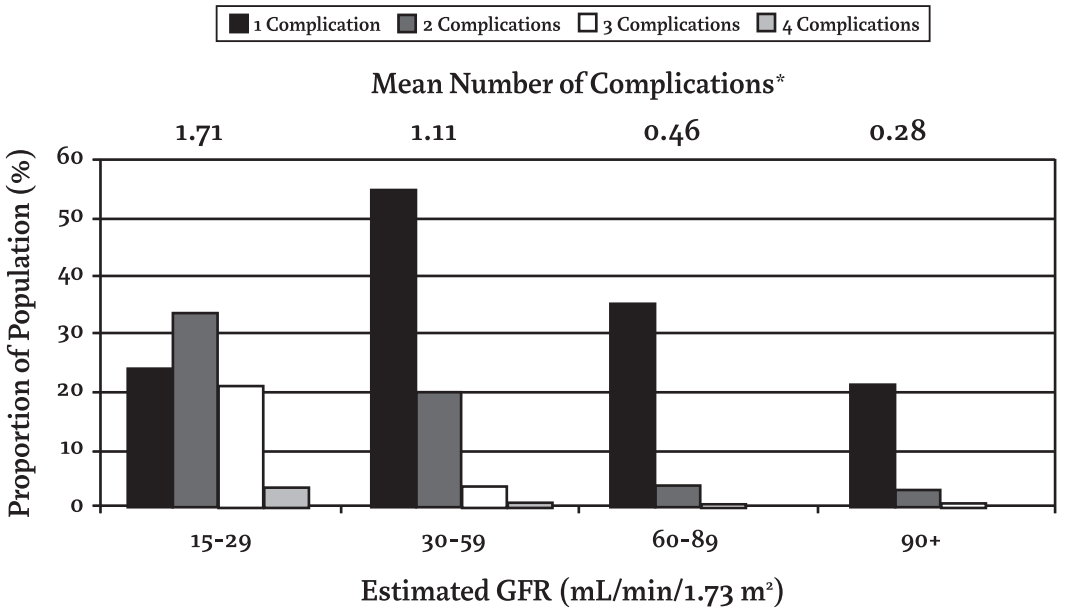


* ≥140/90 or antihypertensive medication

p-trend <0.001 for each abnormality

Estimated prevalence of selected complications, by category of estimated GFR, among participants age 20 years in NHANES III, 1988 through 1994. These estimates are not adjusted for age, the mean of which is 33 years higher at an estimated GFR of 15 to 29 mL/min/1.73 m² than that at an estimated GFR 90 mL/min/1.73 m².

Chart B.4.
Lower eGFR is Associated with More Complications



* ≥140/90 or antihypertensive medication

p-trend <0.001 for each abnormality

Estimated distribution of the number of complications shown in figure by category of estimated GFR among participants age 20 years in NHANES III, 1988 through 1994. These estimates are not adjusted for age, the mean of which is 33 years higher at an estimated GFR of 15 to 29 mL/min/1.73 m² than that at an estimated GFR of 90 mL/min/1.73 m².

Because of different manifestations of complications of chronic kidney disease in children, especially in growth and development, the Work Group limited the scope of the review of evidence to adults. A separate Work Group will need to address this issue in children.

The Work Group did not attempt to review the evidence on the evaluation and management of complications of chronic kidney disease. This is the subject of past and forthcoming clinical practice guidelines by the National Kidney Foundation and other groups, which are referenced in the text.

Representative findings are shown by stage of chronic kidney disease in the figures above and below, showing a higher prevalence of each complication at lower GFR, and a larger mean number of complications per person and higher prevalence of multiple complications at lower GFR. These and other findings support the classification of stages of chronic kidney disease and are discussed in detail in Guidelines 7 through 9.

Guideline 7.
Association of Level of GFR with Hypertension (p. S112)
High blood pressure is both a cause and a complication of chronic kidney disease. As a complication, high blood pressure may develop early during the course of chronic kidney disease and is associated with adverse outcomes—in particular, faster loss of kidney function and development of cardiovascular disease.

- Blood pressure should be closely monitored in all patients with chronic kidney disease.
- Treatment of high blood pressure in chronic kidney disease should include specification of target blood pressure levels, nonpharmacologic therapy, and specific antihypertensive agents for the prevention of progression of kidney disease (Guideline 13) and development of cardiovascular disease (Guideline 15).

Guideline 8.
Association of Level of GFR with Anemia (p. S120)
Anemia usually develops during the course of chronic kidney disease and may be associated with adverse outcomes.

- Patients with GFR <60 mL/min/1.73 m² should be evaluated for anemia. The evaluation should include measurement of hemoglobin level.
- Anemia in chronic kidney disease should be evaluated and treated (see KDOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease, Guidelines 1-4).

Guideline 9.
Association of Level of GFR with Nutritional Status (p. S128)
Protein energy malnutrition develops during the course of chronic kidney disease and is associated with adverse outcomes. Low protein and calorie intake is an important cause of malnutrition in chronic kidney disease.

- Patients with GFR <60 mL/min/1.73 m² should undergo assessment of dietary protein and energy intake and nutritional status (see KDOQI Clinical Practice Guidelines for Nutrition in Chronic Renal Failure, Guidelines 23 and 26).
- Patients with decreased dietary intake or malnutrition should undergo dietary modification, counseling and education, or specialized nutrition therapy (see KDOQI Clinical Practice Guidelines for Nutrition in Chronic Renal Failure, Guidelines 24 and 25).

Guideline 10.
Bone Disease and Disorders of Calcium and Phosphorus Metabolism (p. S143)
Bone disease and disorders of calcium and phosphorus metabolism develop during the course of chronic kidney disease and are associated with adverse outcomes.

- Patients with GFR <60 mL/min/1.73 m² should be evaluated for bone disease and disorders of calcium and phosphorus metabolism.
- Patients with bone disease and disorders of bone metabolism should be evaluated and treated (see forthcoming KDOQI Clinical Practice Guidelines on Bone Metabolism and Disease in Chronic Kidney Disease).

Guideline 11.
Neuropathy (p. S156)
Neuropathy develops during the course of chronic kidney disease and may become symptomatic.

- Patients with chronic kidney disease should be periodically assessed for central and peripheral neurologic involvement by eliciting symptoms and signs during routine office visits or exams.
- Specialized laboratory testing for neuropathy in patients with chronic kidney disease is indicated only in the presence of symptoms.

Guideline 12.
Association of Level of GFR with Indices of Functioning and Well-Being (p. S161)
Impairments in domains of functioning and well-being develop during the course of chronic kidney disease and are associated with adverse outcomes. Impaired functioning and well-being may be related to sociodemographic factors, conditions causing chronic kidney disease, complications of kidney disease, or possibly directly due to reduced GFR.

- Patients with GFR <60 mL/min/1.73 m² should undergo regular assessment for impairment of functioning and wellbeing:
    - To establish a baseline and monitor changes in functioning and well-being over time;
    - To assess the effect of interventions on functioning and well-being.

Stratification of Risk for Progression of Kidney Disease and Development of Cardiovascular Disease (Part 7, P. S170)
The major outcomes of chronic kidney disease are loss of kidney function, leading to complications and kidney failure, and development of cardiovascular disease. The goals of Part 7 are to define risk factors for progression of chronic kidney disease and to determine whether chronic kidney disease is a risk factor for cardiovascular disease. Because of the well-known association of cardiovascular disease and diabetes, the Work Group considered patients with chronic kidney disease due to diabetes separately from patients with chronic kidney disease due to other causes. As described

in Appendix 1, Table 153, the Work Group searched primarily for longitudinal studies that related risk factors to loss of kidney function (Guideline 13) and that related proteinuria and decreased GFR to cardiovascular disease (Guidelines 14 and 15). It was beyond the scope of the Work Group to undertake a systematic review of studies of treatment. However, existing guidelines and recommendations were reviewed, as were selected studies, to provide further evidence of efficacy of treatment.

Guideline 13.

Factors Associated with Loss of Kidney Function in Chronic Kidney Disease (p. S170)

The level of kidney function tends to decline progressively over time in most patients with chronic kidney diseases.

- The rate of GFR decline should be assessed in patients with chronic kidney disease to:
  - Predict the interval until the onset of kidney failure;
  - Assess the effect of interventions to slow the GFR decline.
- Among patients with chronic kidney disease, the rate of GFR decline should be estimated by:
  - Computing the GFR decline from past and ongoing measurements of serum creatinine;
  - Ascertaining risk factors for faster versus slower GFR decline, including type (diagnosis) of kidney disease and nonmodifiable and modifiable factors.
- Interventions to slow the progression of kidney disease should be considered in all patients with chronic kidney disease.
  - Interventions that have been proven to be effective include:
    (1) Strict glucose control in diabetes;
    (2) Strict blood pressure control;
    (3) Angiotensin-converting enzyme inhibition or angiotensin-2 receptor blockade.
  - Interventions that have been studied, but the results of which are inconclusive, include:
    (1) Dietary protein restriction;
    (2) Lipid-lowering therapy;
    (3) Partial correction of anemia.

- Attempts should be made to prevent and correct acute decline in GFR. Frequent causes of acute decline in GFR include:
  - Volume depletion;
  - Intravenous radiographic contrast;
  - Selected antimicrobial agents (for example, aminoglycosides and amphotericin B);
  - Nonsteroidal anti-inflammatory agents; including cyclo-oxygenase type 2 inhibitors;
  - Angiotensin-converting enzyme inhibition and angiotensin-2 receptor blockers;
  - Cyclosporine and tacrolimus;
  - Obstruction of the urinary tract.
- Measurements of serum creatinine for estimation of GFR should be obtained at least yearly in patients with chronic kidney disease and more often in patients with:
  - GFR <60 mL/min/1.73 m^2;
  - Fast GFR decline in the past (>4 mL/ min/1.73 m^2 per year);
  - Risk factors for faster progression;
  - Ongoing treatment to slow progression;
  - Exposure to risk factors for acute GFR decline.

Guideline 14.
Association of Chronic Kidney Disease with Diabetic Complications (p. S198)
The risk of cardiovascular disease, retinopathy, and other diabetic complications is higher in patients with diabetic kidney disease than in diabetic patients without kidney disease.

- Prevention, detection, evaluation, and treatment of diabetic complications in patients with chronic kidney disease should follow published guidelines and position statements.
- Guidelines regarding angiotensin-converting enzyme inhibitors or angiotensinreceptor blockers and strict blood pressure control are particularly important since these agents may prevent or delay some of the adverse outcomes of both kidney and cardiovascular disease.

Application of published guidelines to diabetic patients with chronic kidney disease should take into account their "higher risk" status for diabetic complications.

Guideline 15.
Association of Chronic Kidney Disease with Cardiovascular Disease (p. S204)
Patients with chronic kidney disease, irrespective of diagnosis, are at increased risk of cardiovascular disease (CVD), including coronary heart disease, cerebrovascular disease, peripheral vascular disease, and heart failure. Both traditional and "chronic kidney disease related (nontraditional)" CVD risk factors may contribute to this increased risk.

- All patients with chronic kidney disease should be considered in the "highest risk" group for cardiovascular disease, irrespective of levels of traditional CVD risk factors.
- All patients with chronic kidney disease should undergo assessment of CVD risk factors, including:
    - Measurement of "traditional" CVD risk factors in all patients;
    - Individual decision-making regarding measurement of selected "CKD-related" CVD risk factors in some patients.
- Recommendations for CVD risk factor reduction should take into account the "highest-risk" status of patients with chronic kidney disease.

Available at http://www.kidney.org/professionals/kdoqi/guidelines_ckd/ex2.htm#ckdex1

Appendix B is an Executive Summary of the National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification. Am J Kidney Dis 39:S1-S000, 2002 (suppl 1). Reprinted with permission of the National Kidney Foundation.

The full text of these guidelines with references can be accessed at:
http://www.kidney.org/professionals/KDOQI/guidelines_ckd/toc.htm

Appendix C
Guideline Comparison

Comparison of KDOQI, ADA, and JNC-VII Guidelines. Focus on CKD-Related Guidelines

KDOQI (NGC, from Am J Kidney Dis 2002 Feb)	ADA (in "Standards of Medical Care," Diabetes Care 30 (supp1) 2007 Jan)	JNC-VII
#1: Definition and Stages of CKD defined by GFR		
#2: Evaluation and Treatment. 1. CKD patients should be evaluated for diagnosis, comorbidities, severity, complications, risk for loss of kidney function, risk for CVD 2. Treatment of CKD should include dx-based therapy, E&M of comorbidities, slowing loss of kidney function, prevention and treatment for CVD, cx of dec. kidney function, preparation for replacement, and replacement/transplant 3. Develop clinical action plan. 4. Review medication 5. Incorp. S/M into tx plan 6. Referral to nephrologist for eGFR<30	V.A. The comprehensive diabetes examination includes, among other components, tests for microalbuminuria and serum creatinine (and calculation of eGFR)	Physical exam should include… examination of the abdomen for enlarged kidneys, masses, and abnormal aortic pulsation… Routine laboratory tests recommended before initiating therapy include …blood glucose and hematocrit; serum potassium, creatinine (or the corresponding estimated glomerular filtration rate [GFR]), and calcium; and a lipid profile… Optional tests include measurement of urinary albumin excretion or albumin/creatinine ratio..
#3: Patients at increased risk for CKD should be assessed		

KDOQI (NGC, from Am J Kidney Dis 2002 Feb)	ADA (in "Standards of Medical Care," Diabetes Care 30 (suppl) 2007 Jan)	JNC-VII
#4: eGFR should be used for assessment. Serum creatinine alone is insufficient Labs should report eGFR in addition to creatinine Timed GFR necessary only in exceptional circumstances		
#5: Assessment of proteinuria. Spot urine for most circumstances Dipsticks acceptable in most; if positive, confirm using quantitative w/in 3 mos. Adults: screen using albumin-specific of albumin to creatinine; monitor CKD patients using albumin-to-creatinine *More details that specifically relate to children*		Serum potassium and creatinine should be monitored at least 1–2 times/year.
#6: CKD markers other than proteinuria a. urine sediment or red/white blood dipstick for CKD or at risk for CKD b. kidney imaging for CKD or at risk for CKD c. other markers show promise; not ready yet		
#7: GFR and HTN a. monitor BP for all with CKD b. treat HTN using target BP, nonpharm therapy, and specific Rx agents (see GL 13 and GL 15)	VI.A.1 Measure BP at each visit Goal of 130/80 ACE/ARB	
#8: GFR and anemia Evaluate GFR<60 for anemia, incl. hemoglobin		
#9: GFR and nutrition GFR<60 assess protein and energy intake	V.D. Consultation with RD, weight loss, reduce fat/carb intake	
#10: Bone disease and Ca and Ph metabolism GFR<60 evaluate for bone disease		

KDOQI (NGC, from Am J Kidney Dis 2002 Feb)	ADA (in "Standards of Medical Care," Diabetes Care 30 (suppl) 2007 Jan)	JNC-VII
#11: Neuropathy Assess CKD patients for neurologic involvement	VI.D Annual screen	
#12: GFR and functioning GFR<60 assess for functioning and well-being		
#13: CKD progression a. assess GFR decline b. estimate rate of decline c. intervene with all CKD patients: glucose control for diabetics, BP control, ACE/ARB. (Protein restriction, lipid-lowering, and partial correction of anemia inconclusive) d. Prevent and correct acute decline due to common causes: volume depletion, IV radio contrast, some antimicrobial Rx, NSAIDs, use of ACE/ARBs, cyclosporine/ tacrolimus, urinary tract obst. e. Annually measure eGFR, more often for GFR<60, history of rapid decline (>4/year), risk factors for rapid progression, treatment for progression, risk of acute GFR decline	VI.A.1 Measure BP at each visit Goal of 130/80. ACE/ARB VI.B To slow CKD progression, optimize glucose and BP control. All diabetics: annual test for microalbuminuria; annual serum creatinine (to yield eGFR, the best method for evaluating kidney function)	CKD defined by eGFR<60 and/or albuminuria Target BP 130/80. ACE/ARB recommended; temporary creatinine increase of up to 35 percent OK unless hyperkalemia develops. For eGFR<30, loop diuretics recommended.
#14: CKD & diabetes a. CKD with diabetes: follow published guidelines for diabetics b. ACE/ARB particularly important c. CKD have "higher risk" of diabetic c/c	VI.B. For treating micro/macroalb., ACE/ARB unless pregnant. Reduce protein intake Monitor serum potassium if taking ACE/ARB Cont. surv. of microalb/proteinuria Refer to expert in diabetic/renal if eGFR<60. *Refer to nephrologist if eGFR<30 (in text, not a guideline)*	Thiazide diuretics, BBs, ACEs, ARBs, and CCBs
#15: CKD and CVD CKD are highest risk for CVD Measure CKD for "traditional" CVD risk	VI.A annual lipid panel. Statins recommended for most patients.	