# Establishing a Surveillance System for Chronic Kidney Disease in the U.S. The CKD Surveillance Project

## 2008 Interim Report

September 30, 2008

Johns Hopkins University Baltimore, Maryland University of Michigan Ann Arbor, Michigan

### **CKD Surveillance Project** Personnel and Grant Support

### Johns Hopkins University

Neil R. Powe, MD, MPH, MBA,

Principal Investigator

Professor, Departments of Medicine, Epidemiology and Health Policy and Management Director, Welch Center for Prevention, Epidemiology, and Clinical Research Johns Hopkins School of Medicine and Johns Hopkins Bloomberg School of Public Health

L. Ebony Boulware, MD, MPH,

Co-Investigator

Assistant Professor, Department of Medicine Johns Hopkins School of Medicine

Josef Coresh, MD, PhD, *Co-Investigator* Professor, Departments of Epidemiology, Medicine, and Biostatistics Johns Hopkins School of Medicine and Johns Hopkins Bloomberg School of Public Health

- Edgar R. Miller, III, MD, *Co-Investigator* Associate Professor, Department of Medicine Johns Hopkins School of Medicine
- Laura Plantinga, ScM, *Project Coordinator* Research Associate, Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health
- Andrew Levey, MD, Consultant Professor, Department of Medicine Tufts Medical Center
- Lesley Stevens, MD, MS, *Consultant* Assistant Professor, Department of Medicine Tufts Medical Center
- April Lawner, BS, BA, *Research Assistant* Academic Program Administrator, Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health

### University of Michigan

Rajiv Saran, MBBS, MD, MRCP, MS, *Principal Investigator* Associate Professor, Division of Nephrology, Department of Internal Medicine Associate Director, University of Michigan-Kidney Epidemiology and Cost Center

- Brenda W. Gillespie, PhD, *Co-Investigator* Assistant Professor of Biostatistics University of Michigan
- Friedrich K. Port, MD, MS, *Co-Investigator* President, Arbor Research Collaborative for Health
- Bruce Robinson, MD, MS, *Co-Investigator* Vice President for Research Arbor Research Collaborative for Health
- Vahakn B. Shahinian, MD, MS, Co-Investigator Department of Internal Medicine and Nephrology University of Michigan
- Jerry Yee, MD, *Co-Investigator* Division Head, Nephrology and Hypertension Henry Ford Hospital
- Eric W. Young, MD, MS, *Co-Investigator* Professor, Internal Medicine Assistant Dean, Clinical Affairs Chief of Staff, VA Medical Center University of Michigan
- William Herman, MD, MPH, *Consultant* Professor of Epidemiology and Internal Medicine University of Michigan

Kassandra L. Messer, BA, *Project Coordinator* Programmer/Analyst University of Michigan-Kidney Epidemiology and Cost Center

#### University of Michigan, continued

Meggy Yin, MS Programmer Arbor Research Collaborative for Health

Philip Boonstra, BA Department of Biostatistics University of Michigan

<u>Acknowledgment of Grant Support:</u> This pilot report of the CKD Surveillance Project was supported by American Association of Medical Colleges-Centers for Disease Control and Prevention (AAMC-CDC) Cooperative Agreements MM-0996-07/07 (University of Michigan) and MM-0997-07/07 (Johns Hopkins University).

### CKD Surveillance Project Steering Committee

### **Centers for Disease Control and Prevention**

Desmond Williams (Technical Advisor) Sabitha Dasari Mark Eberhardt (National Center for Health Statistics) Paul Eggers (National Institute of Diabetes and Digestive and Kidney Diseases) Kristina Ernst Nicole Flowers Linda Geiss Regina Jordan Nilka Rios Burrows Juanita Mondeshire Bernice Moore Gary Myers Meda Pavkov Deborah Rolka Sharon Saydah (National Center for Health Statistics) Anton Schoolwerth Rodolfo Valdez Larry Waller

#### Johns Hopkins University

Neil Powe (Co-Chair) L. Ebony Boulware Josef Coresh Deidra Crews April Lawner Andrew Levey Edgar R. Miller, III Laura Plantinga Lesley Stevens

### University of Michigan

Rajiv Saran (Co-Chair) Philip Boonstra Brenda Gillespie William Herman Kassandra Messer Bruce Robinson Vahakn Shahnian Randall Webb Jerry Yee Meggy Yin Eric Young

### CKD Surveillance Project Advisory Group

### Agency for Healthcare Research and Quality (AHRQ):

Shilpa Amin, MD, Staff Medical Officer, Center for Outcomes and Evidence Yen-pin Chiang, PhD, Agency on the inter-agency workgroup on kidney disease and education

### American Association of Kidney Patients (AAKP):

Kris Robinson, Executive Director/CEO

### American Society of Pediatric Nephrology (ASPN);

Susan Furth, MD, Associate Professor of Pediatrics, Johns Hopkins School of Medicine

### American Heart Association (AHA):

Frank Brosius, MD, Chair, Council on the Kidney in Cardiovascular Disease

### Centers for Medicare & Medicaid Services (CMS):

Diane Frankenfield, DrPH, Office of Research, Development, and Information

### Health Resources and Services Administration (HRSA):

Ahmed Calvo, MD, Chief, Clinical Quality Improvement Branch

Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7):

George Bakris, MD, FACP, Professor of Medicine, University of Chicago School of Medicine

### National Kidney Disease Education Program (NKDEP):

Andrew S. Narva, MD, Director

<u>National Kidney Foundation (NKF):</u> Joseph A. Vassalotti, MD, FASN, Chief Medical Officer

### Veterans Affairs (VA):

Ann O'Hare, MD, Assistant Professor of Medicine, University of Washington

### Unaffiliated Experts:

Alan S. Go, MD, Assistant Director for Clinical Research, Division of Research at Kaiser Permanente of Northern California

William McClellan, MD, MPH, Professor of Medicine, Rollins School of Public Health, Emory University

## **Table of Contents**

Personnel and Grant Support	<i>ii</i>
Steering Committee	iv
Advisory Group	
List of Figures	
List of Tables	
List of Abbreviations	
List of Appendices	XVIII
1. Executive Summary	1-2
1.A. Introduction	
1.B. Overview of Approach and Methods	
1.C. Key Findings	
1.D. Methodologic Challenges	1-8
1.E. Recommendations	1-9
1.F. Policy Implications	
2. Introduction and Background	
2.A. General Principles of Chronic Disease Surveillance Relevant to the CKD Project	
2.B. Rationale for a National CKD Surveillance System	
2.C. Efforts Related to CKD by Organizations within the United States	
2.E. Characteristics of an Ideal CKD Surveillance System	
2.F. General Approach to Population-based CKD Surveillance in the CKD	
System	
3. Approach and Methods	
3.A. Introduction and Aims of Project	
3.B. Topics and Priority Measures for CKD Surveillance	
3.C. Investigation of Data Sources for CKD Surveillance	
3.D. Analytic Methods	3-11
4. Burden of CKD (Incidence/Prevalence)	4-2
4.A. Introduction.	
4.B. Prevalence of CKD Stages 1-4 by Kidney Function (eGFR).	4-3
4.C. Prevalence of CKD Stage 5 by Treatment	4-37
4.D. Prevalence of CKD by ICD-9 Codes	
4.E. Incidence of CKD by Kidney Function (eGFR)	
4.F. Incidence of CKD Stage 5 by Treatment	
4.G. Burden of CKD: Discussion	
5. Awareness of CKD	
5.A. Introduction.	
5.B. Awareness of CKD in the General Population	5-2
5.C. Health Care System/Provider Awareness of CKD	
5.D. Awareness of CKD: Discussion	
6. Burden (Prevalence) of Risk Factors for CKD	
6.A. Introduction	
6.B. Prevalence of Diabetes Mellitus	
6.C. Prevalence of Hypertension	
6.D. Race/Ethnicity 6.E. Burden (Prevalence) of Risk Factors for CKD: Discussion	
U.L. DUINETT (FTEVALETINE) UT RISK FANIUTS INT URD. DISCUSSIUT	

# Chapter 1

# **Executive Summary**

### 1. Executive Summary

### **1.A. Introduction**

Chronic kidney disease (CKD) is an important public health problem and has been recognized as a national health priority. It is defined by the presence of kidney damage or reduced kidney function for a period of at least 3 months. The level of disease severity has been used to classify CKD into various stages, from persistent kidney damage only (stage 1) to mild reduction in kidney function (stage 2) to moderate to severe reduction in kidney function (stage 3 and 4). Stage 5 refers to the advanced stage of CKD also termed "kidney failure," which can progress to end-stage renal disease (ESRD), a term that implies kidney failure has reached the point of requiring dialysis therapy or kidney transplantation to maintain life.

Patients with CKD suffer considerable morbidity as well as high rates of mortality. While progression to ESRD is a well-known and serious complication of CKD, it is now well-recognized that premature death and morbidity (especially cardiovascular morbidity) are far more frequent outcomes compared to ESRD. Despite the tremendous impact of CKD on health, quality of life, and healthcare costs, the United States has thus far not developed a comprehensive, systematic surveillance program to monitor this important condition. Such a system would help not only in documenting the burden of CKD and its risk factors in the U.S. population over time, but also in tracking the progress of our efforts to prevent, detect, and manage CKD and its complications. It would also provide the means for evaluation, monitoring and implementation of quality improvement efforts by both federal and non-federal agencies. The CKD Surveillance Project was designed and implemented to address these issues.

### 1.B. Overview of Approach and Methods

Our specific aims in this project were to:

1. Identify and prioritize broad topics (*e.g.*, burden of disease), measures within each topic (*e.g.*, proportion of subjects with CKD by estimated kidney function), and indicators (*e.g.*, estimated glomerular filtration rate, a specific indicator of kidney function).

2. Identify existing national and regional data sources that would allow an assessment of the identified topics, measures, and indicators for CKD surveillance. This would include data sources both within and outside the U.S. healthcare system.

3. Evaluate each data source/topic-measure-indicator combination using available scientific evidence and achieve consensus as to which data sources should be included in a CKD surveillance system.

4. Develop a comprehensive plan for integration of all the data source/topic-measure-indicator combinations into a functional national surveillance system.

5. Conduct a pilot and feasibility test of the system by procuring, analyzing, and synthesizing results obtained from a variety of data sources and comparing findings from different data sources, which alone or in combination provide a picture of the state of CKD in the United States.

6. Identify gaps and deficiencies in examined data sources and assess the need for development of new data sources.

7. Assess the feasibility of integration of all the data sources into a functional national surveillance system.

8. Produce a final report of CKD surveillance with recommendations toward the implementation of a national CKD surveillance system.

This project has three phases. The first two phases are described in this report. In Phase 1, we established the topics, measures, and data sources of highest priority. In Phase 2, we performed a pilot and feasibility test of a sample of data sources. In Phase 3, we will integrate these data sources, investigate additional data sources to address already examined and other high-priority measures, and prepare the results for optimal dissemination.

Topics and priority measures were selected by first identifying all important broad topics and possible measures under each topic for comprehensive CKD surveillance. Significant input was obtained from an external Advisory Group on the relative importance of each of these measures for a surveillance system; and a priority list of measures was established and pursued in the pilot and feasibility phase of this project.

We developed a comprehensive list of potential data sources for the highest-rated topics and measures, including: national government data, registries, population-based and prospective cohort studies, state & local health departments, private industry (*e.g.*, national laboratories), and healthcare system data (*e.g.*, administrative healthcare data from managed care plans, the Department of Veterans Affairs or VA, and Centers for Medicare and Medicaid Services). A number of potential data sources were assessed by a standardized interview designed to assess their key attributes pertinent to CKD surveillance. A summary of this information was provided to our external Advisory Group, who rated each of the data sources by measure and overall. Using this information, we prioritized the data sources for initial analyses.

Through data procurement, analysis, and synthesis of the results, we tested the feasibility of our CKD surveillance system. This report represents our pilot test of the system.

### 1.C. Key Findings

### 1.C.1. Burden of CKD

**Prevalence in the General Population.** CKD prevalence, or number of CKD cases in a given population at a specific period of time, was estimated using data from the National Health and Nutrition Examination Survey (NHANES). In 1999-2006, 13.1% of adult NHANES participants, representing ~26 million non-institutionalized U.S. civilian residents aged 20+ years, had CKD stages 1-4; of these, ~17 million had CKD stage 3 or 4. Overall, the prevalence or amount of CKD stages 1-4 in the general population increased 30%, from 1994 to 2006. CKD was more common in those who were older, females, and non-Hispanic whites, compared to minorities. Persons with diabetes and hypertension had far greater prevalence of CKD than those without these conditions. The prevalence of kidney damage was high in 1999-2006, with nearly 10% (~19 million adult residents) showing some degree of albuminuria.

As of December 31, 2005, nearly 0.5 million patients were being treated for ESRD in the United States [as reflected in Medicare kidney replacement therapy records, tracked by the United States Renal Data System (USRDS)], giving a prevalence of 1,585 per million population; prevalence of dialysis treatment was 1,116 per million, whereas prevalence of functioning kidney transplant was 469 per million. The prevalence of ESRD more than doubled between 1990 and 2005. Increased age, African-American race, and geography were associated with ESRD.

The prevalence of both CKD stages 1-4 and ESRD in the general population are high and have been increasing over time. Prevalence of both is associated with diabetes, hypertension, and older age; while whites are more likely to have CKD, African-Americans are more likely to have ESRD.

**Prevalence in a Healthcare System.** Among patients seeking health care in the Veterans Affairs (VA) health system, the prevalence (%) of CKD stages 3-5 by eGFR was 15.0% in 2005, and slightly higher (16.0%) in 2007. Risk groups were similar to the NHANES participants. Prevalence estimates of CKD stages 3-5 were low (0.69% in 2004 and 1.6% in 2006) in an employer-based regional health care plan (M-CARE) but higher in those with diabetes mellitus (3.0% of in 2004 and 5.6% in 2006) or hypertension (2.6% in 2004 and 5.7% in 2006).

Using ICD-9 diagnosis codes (rather than laboratory tests or the receipt of kidney replacement therapy) to indicate the presence of diagnosed CKD among persons seeking outpatient care in the VA, the overall percentages with a CKD diagnosis were 6.3% in 2005 and 7.3% in 2007. The percentages of M-CARE patients with ICD-9 diagnosis codes for CKD were 0.45% in 2004 and 0.79% in 2006.

The prevalence of CKD was slightly higher in the VA healthcare system and much lower in an employer-based regional health care plan than in the general population, but high-risk groups were similar. These differences may be due to the characteristics of persons seeking care in these systems as well as physician practice styles with regard to testing and identification of disease.

**Incidence in the General Population.** There is a lack of available data to estimate U.S. incidence of CKD stages 1-4, or number of new-onset CKD cases in a specified period in a specific population. However, we do have estimates of the incidence or amount of new-onset ESRD from the USRDS. In 2005, 106,912 patients initiated treatment for ESRD patients, 104,488 of whom were initiated on dialysis (2,424 started with a kidney transplant). ESRD incidence increased by ~150% from 1990 to 2005, but the proportion starting with a transplant remained ~2% over the entire period. Advanced age, male sex, and African-American race were associated with a higher incidence of ESRD. Diabetes and hypertension were the most common assigned causes of incident ESRD. New-onset ESRD varied widely by state. The occurrence of new-onset ESRD in the general population has increased over time and the vast majority of these patients have been treated by dialysis therapies rather than kidney transplantation.

**Incidence in a Healthcare System.** The incidence of CKD stages 3-5 in the VA was 5.6% in 2006 and 7.0% in 2007. The incidence of CKD stages 3-5 in the M-CARE managed care plan was 1.3% in 2005 and 1.2% in 2006. The incidence of CKD stages 3-5 (combined) was higher in females, older adults, and persons with diabetes or hypertension

The incidence of CKD stages 3-5 through 9 years of follow-up among 45- to 64-year old participants in the population-based Atherosclerosis Risk in Communities (ARIC) study was 10.4 per 1,000 person-years and was higher among older, white, and female participants; incidence was double among those with diabetes or hypertension, relative to those without these conditions.

The incidence of CKD was higher in the VA healthcare system than in an employer-based regional health care plan and a prospective, population-based cohort study, but high-risk groups were similar.

### 1.C.2. Awareness of CKD

<u>Awareness in the General Population</u>. Among NHANES participants in 1999-2006, <5% of those with eGFR  $\geq$ 60 ml/min/1.73 m<sup>2</sup> with proteinuria (single measurement) reported being aware of having CKD; of those with CKD stage 3, awareness was only 7.5%; for stage 4,

awareness was still only less than half (40%). Younger (15%) and male (13%) participants and those who were non-Hispanic black (21%) had the greatest levels of awareness relative to their counterparts, among those with CKD stage 3 or 4. Awareness rates for CKD stage 3 or 4 were higher in those with comorbid diagnoses of diabetes and hypertension, but still quite low (20% and 12%, respectively). Persons with CKD in the community are unlikely to be aware of their disease and seek appropriate treatment.

In a National Kidney Disease Education Program (NKDEP) survey, very few African-Americans (2.8%) considered CKD to be an important health problem in African-American community. Only one-third (33%) of surveyed African-Americans with diabetes named diabetes as a risk factor for CKD; furthermore, only 17% of those with hypertension and 4% of those with family history named these risk factors for CKD. Only one-quarter (26%) of surveyed African-Americans with risk factors perceived their CKD risk to be higher than average. Knowledge of CKD and its risk factors are low, even among those at highest risk for developing CKD.

<u>Healthcare System/Provider Awareness of CKD.</u> Overall, for VA patients with evidence of CKD stages 3-5 based on available outpatient serum creatinine values, the percentages who also had a provider-coded ICD-9 diagnosis for CKD ranged from 27.0% in 2005 to 29.0% in 2007. Persons with diabetes or hypertension and men with evidence of CKD were more often assigned a diagnosis of CKD.

In a NKDEP survey of primary care physicians, one-third did not perceive family history to be a risk factor for CKD, while almost one-quarter did not perceive African-American race to be a CKD risk factor; however, nearly all perceived diabetes and hypertension to be CKD risk factors. Only 22% reported using the CKD-specific National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines. In a national survey of primary care providers and nephrologists, only about two-thirds of surveyed primary care providers correctly identified CKD in a hypothetical patient with CKD progressing to stage 4, compared to nearly all surveyed nephrologists. Many primary care providers, who are most likely to initially treat patients with CKD, do not appear to have optimal knowledge of CKD and its risk factors.

### 1.C.3. Burden of risk factors for CKD

**Prevalence of Diabetes Mellitus.** The prevalence of diabetes in U.S. adults (NHANES) ranged from 4.7% to 10.2% in 1999-2006, depending on the definition; 7.5% reported having diabetes, while 7.1% had fasting glucose levels indicating diabetes. The burden of diabetes is high in the U.S. general population, especially among the elderly, non-Hispanic blacks, and the overweight and obese. Because we expect this prevalence to remain steady, if not increase as the age and race distribution of the population change and rates of obesity continue to increase, we also expect to have many future cases of CKD from this population with diabetes.

In the healthcare system, prevalence of diabetes was higher: approximately one-quarter of VA patients had either an ICD-9 diagnosis and/or medication code related to diabetes mellitus in 2007 whereas ~9% of patients within M-CARE had an ICD-9 diagnosis code for diabetes mellitus in 2006.

**Prevalence of Hypertension.** The prevalence of hypertension in U.S. adults (NHANES) ranged from 18.3% to 46.3% in 1999-2006, depending on the definition; 43.4% either reported having hypertension or had measured blood pressures ≥140/≥90 mmHg. Hypertension is highly prevalent in the general U.S. population, with nearly half reporting hypertension or having high blood pressures and prevalence remaining steady over recent years. As with diabetes, the prevalence was highest in the elderly, non-Hispanic blacks, and the overweight and obese.

Thus, we expect prevalence of future CKD related to hypertension to remain steady, or even increase as the population ages, the race distribution changes, and the rates of overweight and obesity continue to climb.

Prevalence of hypertension was even higher in the older VA population: approximately twothirds of VA patients had an ICD-9 diagnosis codes or medication codes related to hypertension in 2007. In the younger M-CARE population, a smaller proportion (~18%) of patients had an ICD-9 diagnosis code for hypertension from medical claims in 2006.

**<u>Race/Ethnicity</u>**. By U.S. Census estimates, by the year 2050, the U.S. population is estimated to be greater than 400 million persons. In 2000, 13% of the U.S. population was black; by 2050, this percentage is expected to reach 15%. In 2000, 12% of the U.S. population was Hispanic; by 2050, this percentage is expected to reach 22%.

The distribution of race and ethnicity in the U.S. population is expected to change dramatically over the next ~40 years. Non-Hispanic blacks and Hispanic whites will together comprise the majority of the population by 2050. Additionally, they will make up more of the elderly population. Because these individuals are at higher risk for CKD, we expect that the prevalence of CKD will rise as the U.S. population undergoes this transformation.

### 1.C.4. Health consequences in CKD patients

**Progression of CKD in the General Population.** CKD progression refers to moving to a more severe stage, or worsening of the disease. The treated ESRD incidence through 2000 among non-institutionalized U.S. adult residents (NHANES) aged 20+ with normal kidney function in 1988-1994 was 0.8 per 1,000 person-years; among those with CKD stage 3, it was 4.1 per 1,000 person-years; and for those with stage 4 or 5, it was 59.6 per 1,000 person-years. Incidence of ESRD was dramatically higher in those participants with CKD stage 3 who were younger and in those who were non-Hispanic black or Mexican-American. These populations should be targeted more aggressively to prevent progression to ESRD.

**Progression of CKD in a Healthcare System.** In the VA healthcare system, a large number of patients appear to remain in the same eGFR category/CKD stage the following year, suggesting stability or slow rates of progression (54% and 42% remained in stage 3 and 4, respectively, between 2005 and 2006). Of those in CKD stage 3 in 2005, 14.6% appeared to move to eGFR category 60-89 from CKD stage 3, while only 1.9% moved to stage 4 from stage 3, A significant number of M-CARE patients also appear to remain in the same eGFR category/CKD stage the following year.(42% and 50% remained in stage 3 and 4, respectively, between 2004 and 2005). Of those in CKD stage 3 in 2004, 28.6% appeared to move to eGFR category 60-89 from CKD stage 3 in 2004, 28.6% appeared to move to eGFR category 60-89 from CKD stage 3 in 2004, 1000 from stage 3. Among those younger than 60 years and those with diabetes or hypertension, a greater percentage of patients showed a decline in eGFR over a 1-year period. It appears that a substantial number of patients move to a less severe CKD stage over time. This phenomenon requires further investigation and may or may not represent true improvement in the underlying CKD.

**Mortality in CKD.** The adjusted all-cause mortality rate among non-institutionalized U.S. adult residents aged 20+ (NHANES) with CKD stage 3 and 4 and macroalbuminuria in 1988-1994 (88 per 1,000 person-years) was far greater than that among those with normal kidney function and no albuminuria (18 per 1,000 person-years). Albuminuria appeared to be more strongly associated with mortality than reduced eGFR.In the VA healthcare system mortality was higher for worse CKD stage and highest for those with CKD stage 5 (non-dialysis). The adjusted all-cause mortality rate in ARIC study participants was 2-4 times greater for those with

macroalbuminuria than those with microalbuminuria or no albuminuria among those with CKD stage 3 or 4 and those with normal kidney function. Both declines in kidney function and evidence of kidney damage should be considered in estimating risk of mortality in CKD.

### 1.C.5. CKD processes and quality of care

**Serum Creatinine Testing by Healthcare Providers.** Serum creatinine testing allows estimation of kidney function in the clinical setting. Overall, the percentages of VA patients who had serum creatinine tested in the outpatient setting (as determined by CPT codes) were ~60-75% in 2005-2007. Testing was highest among those with diabetes, hypertension, or older age. In the M-CARE regional employer-based health plan the percentages of patients who had serum creatinine tested in the outpatient setting were lower (approximately one-third of patients in 2006), but were highest among those with diabetes, hypertension, or older age. As expected, those at highest risk for CKD in the healthcare system are the most likely to have serum creatinine tested.

<u>Urine Protein Testing by Healthcare Providers.</u> Urine protein testing allows assessment of kidney damage in the clinical setting. Overall, the percentages of VA patients with data on laboratory results for urine albumin (microalbumin or microalbumin:creatinine ratio) were 11-13% in 2005-2007. Testing was greatest among patients with diabetes. Approximately one quarter of M-CARE patients had evidence of urine protein testing in this health care plan in 2004-2006. Again, testing was greatest in those with diabetes. Fewer M-CARE patients had undergone urine albumin:creatinine testing in the healthcare system compared with testing for urine protein (~2.5%). Urine protein testing is fairly low in the healthcare system, even among those with diabetes.

**<u>Referral to a Nephrologist Prior to ESRD.</u>** Nephrology is a branch of medicine concerned with the kidneys. Based on an analysis of national Medicare data files, 60% of incident ESRD patients had some duration of pre-ESRD nephrology care. Females, persons with diabetes, whites, non-Hispanics, and older patients were more likely to have received pre-ESRD care by a nephrologist. Patients starting treatment on hemodialysis with a fistula were also more likely to have received pre-ESRD care by a nephrologist. Earlier referral to a nephrologist prior to dialysis has been associated with better survival after initiation of therapy for ESRD.

### 1.C.6. Health system capacity for CKD

**eGFR Reporting and Creatinine Standardization.** Patterns of automatic laboratory reporting of eGFR were recently reported by two independent surveys, one performed by the College of American Pathologists (CAP) on its accredited chemistry laboratories (2003-2007), and another performed by the National Kidney Disease Education Program (NKDEP) on a variety of U.S. laboratories that performed creatinine testing, including independent, hospital, physician office, insurance, and health fair laboratories (2006-2007). Reporting of eGFR with serum creatinine has increased in recent years: overall, half (50%) of surveyed CAP-accredited laboratories (38%) surveyed by NKDEP reported eGFR with serum creatinine in 2007, up from only 3% in 2003; fewer laboratories (38%) surveyed by NKDEP reported eGFR with serum creatinine in 2007. The percentage of M-CARE patients with eGFR reported when serum creatinine test results were reported was 20% in 2006, up from <2% in 2004. Although NKDEP-recommended protocols for eGFR reporting and creatinine standardization are being increasingly adopted by U.S. laboratories, there is ample room for improvement.

<u>Adequacy of Insurance Coverage.</u> In 1999-2006, 81.6% of the U.S. population <65 years of age reported having insurance; those with diabetes (84.1%), hypertension (84.1%) and CKD (87.1%) were more likely than those without these conditions to report having health insurance. For those <65 years of age with CKD (eGFR <60 ml/min/1.73 m<sup>2</sup>), younger age and Mexican-American race were associated with far lower rates of self-reported health insurance (70% and 63%, respectively). These patients may be at high risk for complications and progression of their CKD due to lack of access to appropriate care.

**Dialysis and Transplant Facilities.** In 2005, there were 4,683 dialysis facilities in the United States, at which 332,790 patients were being dialyzed; in contrast, there were only 242 transplant facilities, at which 17,260 patients received kidney transplants in the same year. The numbers of facilities will need to increase even further to accommodate the increasing numbers of elderly patients at high risk for ESRD.

**Providers of CKD Care.** In 2008, there were 229,872 primary care providers and 7,965 physicians claiming nephrology as their specialty in the United States. This translates to ~1 primary care provider per 150 U.S. residents with CKD stages 1-4 and ~1 per 4000 U.S. residents with CKD. There is a clear need for not only greater numbers of nephrology specialty care providers but also primary care physicians capable of treating these patients.

### 1.D. Methodologic Challenges

Although some of the data sources we examined have great strengths, we found that no one data source is sufficient to build a CKD surveillance system. General limitations include representativeness of the data, lack of longitudinal data, lack of data in a data source for particular measures, missing or incomplete data on particular variables, and diagnostic inaccuracies.

Data from some important sources were more difficult to obtain within the time frame of our study than we originally anticipated. Health care plans were challenging to enlist because of privacy issues, perception of time involved, personnel required, and cost. Cohort studies in particular were sometimes reticent to share unpublished data, as they have their own investigators who must be given the first opportunity to publish in scientific journals. Finally, data from surveys were often provided in the form of results, rather than raw data, which gave us little or no control over the analyses.

Our main analytic challenges included making key decisions about the most appropriate denominator within the different data sources, especially those derived from the administrative sources within the healthcare system. The differing denominators between data sources meant that data could not be combined or pooled for analysis. Missing laboratory and race information was a limitation in some data sources and will need to be addressed in future versions of this surveillance system. A greater body of programmatic and analytic personnel will be key to the future success of this project in order to deal effectively with even larger data files from multiple and disparate data sources, as envisaged in a comprehensive, national CKD surveillance system.

### 1.E. Recommendations

Based upon our findings and experience gained during the pilot and feasibility phase of this surveillance project, we have the following recommendations for future surveillance of CKD in the United States.

#### Recommendation 1: Exploration of new measures for CKD surveillance and refinement of

<u>measures previously examined in the pilot phase.</u> Many measures beyond the initial subset examined in the pilot phase of this project could be explored. Additionally, new measures that were not part of our comprehensive list of measures in the pilot phase could be developed, based upon recent advances in CKD such as changes in laboratory technology, pharmacology, clinical guidelines, or the identification of novel risk factors.

**Recommendation 2: Continued selection of priority measures for a national CKD surveillance system.** While exploration of new measures is clearly important as outlined above, a formal process of continued prioritization of measures for an ongoing CKD surveillance system should be initiated and subjected to greater scrutiny by the community. This process should give greater weight to those measures that are clinically relevant, widely applicable/time tested, and supported by published evidence.

<u>Recommendation 3: Improve or expand currently used data sources.</u> Data sources that were used in this pilot phase of the report provided invaluable information. However, further improvements could be made to increase the breadth of the CKD surveillance system.

**Recommendation 4: Explore important existing/new data sources not thus far explored.** Data sources that were not fully explored, or even identified, in the pilot phase of the project could be explored as possible sources of data for CKD surveillance in the future.

**Recommendation 5: Integrate data sources for future CKD surveillance.** Integration could be accomplished sequentially: (*i*) comparison of measures across data sources and (*ii*) exploration of the feasibility of creating a pooled patient-level database from several disparate data sources (*e.g.*, a variety of regional healthcare system sources) with common data elements. In addition to testing the feasibility of integration of data sources, data procurement and its integration with the surveillance system over time could be tested.

Recommendation 6: Develop partnerships with other chronic disease surveillance

**systems.** Dialogues with other related surveillance systems, including those for ESRD (United States Renal Data System), diabetes, and other chronic diseases, should be initiated. Common interest, potential areas of collaboration, and potential cross-walks between systems could be explored. The gaps in knowledge not currently filled by any of the existing surveillance systems and how the current project could fill those gaps could be further explored.

### Recommendation 7: Explore alternate (e.g., web-based) dissemination channels for CKD

<u>surveillance report.</u> In order to reach a wider audience for the results presented in this pilot report and any future updates to these results, alternate dissemination channels could be explored. The possibility of including a searchable database within a web-based report (a data base that could, for example, be queried for prevalence of CKD by age in male, diabetics across data sources) could be explored. A web-based report could also include the production of a brief CKD fact sheet, similar to those already produced by the CDC for diabetes and hypertension, intended for the lay public.

### **1.F. Policy Implications**

From this initial report, we believe that there are several ways in which data and policy could help lessen the burden of CKD in the United States. This initial attempt to bring together important national information on CKD surveillance in the United States should help in targeting efforts toward improving health through the prevention and reduction of morbidity and mortality associated with CKD. First, there is an obvious need to increase awareness and knowledge of CKD and its risk factors both in the community and among providers. Continued efforts by the National Kidney Disease Education Program (NKDEP), National Kidney Foundation (NKF), and other entities are warranted. Additionally, efforts targeting both patients and providers should emphasize not only prevention of disease (through identification and proper treatment of risk factors) but also prevention of its progression. These benefits of increasing the numbers of persons identified with CKD should be weighed against possible risks.

Encouraging providers to improve their care for those at risk of developing CKD as well as those CKD, especially those with diabetes and hypertension, might decrease the number of newonset cases of CKD as well as significantly reduce associated morbidity and mortality. Given the increasingly high burden of CKD in the United States, efforts to increase urine testing among those at risk and increase eGFR reporting and creatinine standardization by laboratories would help providers better identify and treat those with early-stage CKD. Finally, there is a need for better recruitment and education of primary care providers and nephrologists, given that the current demand on the system by those with CKD is quite high and likely to increase. This CKD surveillance system, once developed and disseminated, will serve as an important resource for tracking the nation's progress in implementation and achievement of health goals. In the next phase of this project we plan to integrate the promising data sources we have identified, explore other data sources for additional measures and wider representativeness, and prepare our work for greater dissemination to the public, practitioners, and policymakers.