Data sources .................. 140
Database definitions ...... 141
Précis ......................... 142
Chronic kidney disease in adult NHANES participants ............ 142
Chapter One
Renal function measures in adolescents .................. 143
Chapter Two
Chronic kidney disease identified in the claims data ............ 143
Chapter Three
Care of patients with CKD .................. 144
Chapter Four
Morbidity & mortality ....... 145
Chapter Five
Cardiovascular disease in CKD patients ............ 146
Chapter Six
Transition to ESRD ........... 148
Chapter Seven
Acute kidney injury ........ 149
Chapter Eight
Costs of CKD .................. 151
Chapter Nine

The sorest misfortune is when your views are in advance of your work.

Leonardo da Vinci
In this appendix we describe the datasets and methods used for the CKD analyses in this volume. Appendix B includes information on all USRDS products and services. Data management and preparation, database definitions, and the data sources used for ESRD analyses are described in the appendix of Volume Two.

Data sources

The USRDS maintains a stand-alone database with data on diagnoses and demographic characteristics of CKD and ESRD patients, along with biochemical data, dialysis claims, and information on treatment and payor histories, hospitalization events, deaths, physician/supplier services, and providers.

CMS MEDICARE ENROLLMENT DATABASE

The Enrollment Database (EDB) of the Centers for Medicare and Medicaid Services (CMS) is the designated repository of all Medicare beneficiary enrollment and entitlement data, and provides current and historical information on residence, Medicare as secondary payor (MSP) and employer group health plan (EGHP) status, and Health Insurance Claim/Beneficiary Identification Code (HIC/BIC) cross-referencing.

ESRD MEDICAL EVIDENCE FORM (CMS 2728)

The ESRD Medical Evidence (ME) form is used as the official form for registering individual patients at the onset of ESRD. This form must be submitted by dialysis or transplant providers within 45 days of ESRD initiation. The CMS, USRDS, and renal research communities rely on this form to ascertain basic patient demographic attributes, the primary cause of renal failure, major comorbidities, and biochemical test results at the time of ESRD initiation.

The third major revision of the ME form, released in May, 2005, was intended to remedy several shortcomings found in the 1995 form and its earlier version. Key additions target pre-ESRD care and vascular access use, and additional new fields collect information on glycosylated hemoglobin and lipid testing, on the frequency of hemodialysis sessions, and on whether patients are informed of transplant options. This new form will help federal and private researchers gain better insights into the health and care of ESRD patients prior to their entry into the program.

ESRD DEATH NOTIFICATION FORM (CMS 2746)

The ESRD Death Notification form is used as the official form for reporting the death of individual patients with ESRD. According to CMS policy, this form must be submitted by dialysis or transplant providers within 30 days of a patient’s death, and provides the date and causes of death (primary and secondary), reasons for discontinuation of renal replacement therapy, if applicable, and evidence of hospice care prior to death. It is the primary source of death information for CMS and the USRDS, identifying more than 99 percent of deaths. The USRDS also utilizes the Social Security Administration’s (SSA) Death Master File as a supplemental data source for ascertaining death in a small group of lost-to-follow-up ESRD patients; this file, however, identifies only all-cause deaths.

CMS 5 PERCENT STANDARD ANALYTICAL FILES (SAFs)

These files contain billing data from final action claims, submitted by Medicare beneficiaries, in which all adjustments have been resolved. The claims data are selected randomly from general Medicare claims (i.e. final action claims) using five combinations of the last two-digit numbers are used each year to create the 5 percent general Medicare SAWS, one should expect to see the same beneficiaries in these annual datasets. These claims are categorized into the inpatient (IP), outpatient (OP), home health agency (HHA), hospice (HS), skilled nursing facility (SNF), physician/supplier (PB), and durable medical equipment (DME) SAWS.

The files are updated each quarter through June of the next year, when the annual files are finalized. Datasets for the current year are created six months into the year and updated quarterly until finalized at 18 months, after which they are not updated to include late arriving claims. Annual files are thus approximately 98 percent complete. The USRDS 2009 ADR includes all claims up to December 31, 2007.

MEDICARE CURRENT BENEFICIARY SURVEY (MCBS)

The Medicare Current Beneficiary Survey is a longitudinal survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries. The MCBS contains information on the health status, health care use and expenditures, drug prescriptions, health insurance coverage, and socioeconomic and demographic characteristics of the entire spectrum of Medicare beneficiaries. Data are made available by CMS in two datasets: Access to Care (1992–2006), and Cost and Use (1992–2005), with the 2006 and 2005 files, respectively, the latest updates for the 2009 ADR.

In the fall of 1991, the MCBS began to be conducted three times per calendar year (winter, summer, and fall), and in 1994 a sample rotation scheme was introduced. Survey participants are kept in the sample for four years, with approximately one-third rolling off, and with new participants added each fall to keep the overall sample size at approximately 12,000 each calendar year.

THOMSON REUTERS MARKETSCAN DATA

The Thomson Reuters MarketScan Commercial Claims and Encounters Database includes specific health services records for employees
and their dependents in a selection of large employers, health plans, and government and public organizations. The database includes nine files: Annual Enrollment Summary Table, Enrollment Detail Table, Inpatient Admissions Table, Inpatient Services Table, Outpatient Services Table, Outpatient Pharmaceutical Claims Table, Facility (Inpatient and Outpatient) Header Table, AggregatedPopulations Table, and the RED BOOK (prescription drug information by National Drug Code). The strength of this database lies in the quality of its cost information, where claims data include actual paid dollars and net payments by the insurer.

The MarketScan database links billing and encounter data to detailed patient demographic and enrollment information across sites and types of providers, and over time from 1999 to 2007, and includes commercial health data from approximately 100 payors. About 80 percent of those covered are self-insured. Each year the insurer discloses only charged dollars without actual paid amounts or the portion paid by the insurer. The strength of this database lies in the quality of its cost information, where claims data include actual paid dollars and net payments by the insurer.

The MarketScan database contains health data for about 10.5 million people. For details about the MarketScan data, please visit www.usrds.org.

**INGENIX i3 DATA**

The Ingenix i3 database is a commercial and non-capitated health plan database covering employees from multiple employers within a single insurer. In addition to the usual service encounter and drug data, similar to that of the MarketScan database, this database also includes laboratory data, allowing for comparisons between claims-based and lab-based definitions of diseases. In order to protect the discount structure of its business, the billing data of this single insurer discloses only charged dollars without actual paid amounts or the portion paid by the insurer.

The Ingenix i3 database links billing and encounter data to detailed demographic and enrollment information of individual employees from 2000 to 2007, and contains health data for about 14 million people annually. For details about what is contained in the Ingenix i3 data, please visit our website at www.usrds.org.

**NATIONAL HEALTH & NUTRITION EXAMINATION SURVEY (NHANES)**

NHANES is a series of health examination surveys conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). Begun in 1959, NHANES is designed to monitor the health and nutritional status of the non-institutionalized civilian population in the United States. NHANES III was conducted in two phases between 1988 and 1994. In 1999, NHANES III became a continuous annual survey to allow annual estimates, with release of public-use data files every two years. Both NHANES III and NHANES 1999–2006 were nationally representative cross-sectional surveys and used a complex, stratified, multi-stage probability cluster sampling design that included selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households. Survey participants were interviewed in their homes and/or received standardized medical examinations in mobile examination centers. Both surveys over-sampled African Americans, Mexican Americans, and individuals age 60 or older to improve the estimates for these subgroups.

**PAYORS**

Information on payors is obtained from the CMS EDB. We also examine Medicare outpatient claims to identify patients for whom the EDB does not indicate Medicare as primary payor (MPP), but who have at least three consecutive months of dialysis treatment covered by Medicare; these patients are also designated as having MPP coverage. From these two data sources we construct a payor sequence file to define payor history, and, starting with the 2003 ADR, we use this file to identify Medicare eligibility status and other payors.

The construction of this file is similar to that of the treatment history file. Payor status is maintained for each ESRD patient from the first ESRD service date until death or the end of the study period. Payor data are used to categorize a patient as MPP, Medicare as secondary payer (MSP) with EGBP, MSP non-EGHP, Medicare Advantage (Medicare + Choice), Medicaid, or a combination of payers. With this approach, the USRDS is now able to apply payor status information in all outcome analyses using the “as-treated” model (see the discussion of Chapter Eleven in Volume Two).

**UNITED STATES CENSUS**

In rate calculations throughout this year’s ADR we use data from the 2000 U.S. Census, and incorporate CDC population estimates by race.

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**Database definitions**

**EGHP DATA**

To examine the demographic segment represented by the EGHP data, we use enrollment information to construct yearly cohorts of enrollees younger than 65. To ensure that we select enrollees with the potential to generate claims evidence appropriate to the demands of analytical methods, rules for inclusion also include 12 months of continuous coverage in a commercial fee-for-service plan, and, for medication analyses, continuous prescription drug coverage. Comorbidities are identified using claims. Patients with at least one inpatient claim or at least two outpatient claims during the period of interest and with a diagnosis code of a particular comorbidity are identified as having that comorbidity.

**ESRD COHORT IN THE EGHP POPULATION**

Because the MarketScan and Ingenix i3 databases do not provide identifiable data elements, we are unable to link them directly to the USRDS ESRD registry. To identify ESRD patients, we therefore use a process similar to that used in the registry. Transplant patients are identified by evidence of a kidney transplant procedure or an adverse graft event, and chronic dialysis patients by evidence of continuous history of dialysis therapy, with at least three consecu-
The surveys used in this chapter include NHANES III (1988–1994), 60 and older. Race/ethnicity is defined as non-Hispanic white, non-Hispanic black, and other, and ethnicity as Hispanic (including Mexican-American and other Hispanic) and non-Hispanic only. Hispanic black, and other, and ethnicity as Hispanic (including Mexican-American and other Hispanic) and non-Hispanic only.

The first ESRD service date is set to the earliest of the first dialysis service date or the transplant date. If neither is available, the start of enrollment is used. Incidence is defined by a first ESRD service date at least 60 days after the start of enrollment.

**Précis**

For a description of analytical methods related to age, gender, race, ethnicity, comorbidities, and CKD stages in Table p.a, please see the discussion for Chapter One, below. The glomerular filtration rate (ml/min/1.73 m²) is estimated by the MDRD method, based on the standardized creatinine value for NHANES III and NHANES 1999–2000, 2001–2002, 2003–2004, and 2005–2006, separately, as based on NCHS recommendations.

Additional figures and tables in the Précis are taken directly from the chapters; methods can be found in the chapter discussions.

**CKD in adult NHANES participants**

**Chapter One**

**DATABASE DESIGN, SETTING, & STUDY PARTICIPANTS**


**MEASUREMENTS**

In this chapter age is defined as the participant’s age at the time of the household interview, and grouped into ages 20–39, 40–59, and 60 and older. Race/ethnicity is defined as non-Hispanic white, non-Hispanic black, and other, and ethnicity as Hispanic (including Mexican-American and other Hispanic) and non-Hispanic only.

Obesity is defined as a BMI of 30 kg/m² or above. Participants with self-reported diabetes are those ever told by a doctor that they have diabetes or sugar diabetes (other than during pregnancy). In NHANES 1999–2006, participants answering “borderline” are classified as non-diabetic. Participants with self-reported congestive heart failure are those ever told by a doctor that they have congestive heart failure. And participants with self-reported cardiovascular disease are those with at least one of the following self-reported diseases: coronary heart disease, angina/angina pectoris, heart attack, congestive heart failure, or stroke.

Smokers are identified by an affirmative answer to the question: “Have you smoked at least 100 cigarettes during your entire life?” then further classified by their answer to the question: “Do you smoke cigarettes now?” Those with affirmative answers are classified as smokers; others are defined as non-smokers.

Who anemia is defined as a hemoglobin less than 13 g/dl in males and less than 12 g/dl in females.

Self-reported hypertension is identified by an affirmative answer to the question: “Have you ever been told by a doctor that you had hypertension, also called high blood pressure?”

Connective tissue disorder is identified by an affirmative answer to the question: “Has a doctor ever told you that you had arthritis?”

Hip fracture is identified by an affirmative answer to the question: “Has a doctor ever told you that you had a broken or fractured hip?”

Cancer is identified by an affirmative answer to the question: “Has a doctor ever told you that you had cancer or malignancy?”

Participants with self-reported COPD are those with at least one of the following self-reported diseases: asthma, chronic bronchitis, or emphysema.

Hepatitis C disease is defined as a confirmed hepatitis C antibody. In NHANES 1999–2006, systolic blood pressure (SBP) / diastolic blood pressure (DBP) for each participant is calculated as the mean of all measured SBP / DBP.

Microalbuminuria is defined by the ratio of urinary albumin (mg/l) to urinary creatinine (mg/dl; ACR). Participants with a valid ACR are classified as having microalbuminuria if this value is not less than 30 mg/g.

The glomerular filtration rate (ml/min/1.73 m²) is estimated by two methods. The first is the MDRD method, based on the standardized creatinine value for NHANES III and NHANES 1999–2000, 2001–2003, 2003–2004, and 2005–2006, separately, based on NCHS recommendations. The formula used to estimate the GFR is as follows (Levey et al.): estimated GFR = 175 * (standardized serum creatinine in mg/dl)**(-1.154) * age**(-0.203) * (0.742 if female) * (1.212 if black).

The second method is based on cystatin C only (Stevens et al.), which is available only for NHANES III, NHANES 1999–2000, and NHANES 2001–2002: estimated GFR = 76.7 * cystatin C **(-1.19).

**CKD is defined as an eGFR less than 60 ml/min/1.73 m², or an eGFR ≥ 60 in the presence of microalbuminuria. CKD stages are defined as follows: Stage 5, eGFR < 15; Stage 4, 15 ≤ eGFR < 30; Stage 3, 30 ≤ eGFR < 60; Stage 2, ACR ≥ 30 and 60 ≤ eGFR ≤ 89; and Stage 1, ACR ≥ 30 and eGFR ≥ 90. These are the standard CKD definitions used in this chapter.**

**STATISTICAL ANALYSIS**

To obtain national estimates of each statistic, odds ratios, sampling weights, and survey design are implemented by SUDAAN (Research Triangle Institute, Research Triangle Park, NC). Standard errors
are estimated using the Taylor Series Linearization method for NHANES III and NHANES 1999–2006. GFR is estimated either by the MDRD (creatinine) method or by cystatin C, as indicated in the figure titles. CKD includes Stages 1–5; all other comorbidities are self-reported.

Table 1.f and Figures 1.12–15 present data on awareness, treatment, and control of metabolic markers. Patients are classified as hypertensive if measured systolic blood pressure (BP) is \( \geq 140 \text{ mmHg} \) (\( \geq 130 \text{ mmHg} \) for CKD or diabetic patients) or measured diastolic BP is \( \geq 90 \text{ mmHg} \) (\( \geq 80 \text{ mmHg} \) for CKD or diabetic patients), or if the patient self-reports currently taking a prescription to control hypertension. Patients are classified as being aware of hypertension if they report having been told they have high BP, are classified as being treated for hypertension if they report currently taking a prescription to control hypertension, and are considered in control of hypertension if current BP is \(< 140/90 \) (\(< 130/80 \) for CKD or diabetic patients).

Control of hypercholesterolemia is assessed in a similar way. Hypercholesterolemia is defined as a measured LDL cholesterol above the ATP III target range (\( \geq 160 \text{ mg/dl} \) for patients with 0–1 risk factors, \( \geq 130 \text{ mg/dl} \) for patients with two or more risk factors, \( \geq 100 \text{ mg/dl} \) for patients with coronary heart disease (CHD) and CHD risk equivalents). CKD is classified as a CHD risk equivalent. Awareness of hypercholesterolemia is assessed by self-report of being told by a doctor that blood cholesterol level is high, and a patient is classified as being treated for hypercholesterolemia if he or she reports currently taking a cholesterol medication or dieting to control cholesterol. Control is defined as meeting the ATP III LDL target for the appropriate risk category, as described above. Current control of HDL cholesterol and total cholesterol are also presented here; awareness and treatment, however, are not assessed, since LDL cholesterol is currently the recommended target of therapy.

Diabetic patients are identified by self-report, as described above. Control of diabetes is assessed as a glycosylated hemoglobin (A1c) of less than 7 percent, as recommended by the American Diabetes Association.

In Figures 1.16–18, SAS survey procedures are used and survey design and weights are considered to calculate C-statistic, sensitivity, and specificity.

Renal function measures in adolescents

Chapter Two

The NHANES dataset is described in the methods for Chapter One. For Chapter Two, the population is restricted to participants ages 12–17. Measurements are defined as in Chapter One, with the following additions.

Age is defined as the participant’s age at the time of the household interview, and grouped into ages 12–13, 14–15, and 16–17. Race/ethnicity is defined as non-Hispanic white, African American, Hispanic, and other.

Obesity is defined as a z-score for weight-to-height of 1.645 on the CDC growth reference table, 2000.

The status of current pregnancy for females participants is based on self-report, while current menstruation is a response of “Having it now” to the question “When did you have your last menstrual period?”

The glomerular filtration rate (GFR; ml/min/1.73 m²) is estimated by the Schwartz formula (Schwartz et al.), based on the standardized creatinine value for NHANES 1999–2000, 2001–2002, 2003–2004, and 2005–2006, separately, from NCHS recommendations. The formula used to estimate the GFR is as follows: estimated GFR = k * \( (\text{height (cm)}) / \text{serum creatinine (mg/dl)} \), where the constant k is 0.55 in children age 1–13, 0.70 in adolescent males (because of the presumed increase in male muscle mass), and 0.55 for adolescent females.

For analytical methods, please refer to the description of Chapter One, above. In Tables 2.b–d, a linear model is fitted to find the association between each risk factor and renal function, either by single predictor (unadjusted) or multivariates (adjusted by all variables in the table). The regression coefficient and its standard error are estimated. Predicted variables are eGFR in Table 2.c, cystatin C in Table 2.c, and log-transformed ACR in Table 2.d. In Table 2.e, a linear regression is fitted to find the impact of each renal function measurement on blood pressure and laboratory abnormalities, either by single renal function measurement (unadjusted) or adjusted by age, gender, and race/ethnicity.

CKD identified in the claims data

Chapter Three

Figure 3.1 illustrates the burden of new and prevalent diabetes, chronic obstructive pulmonary disease, and cardiovascular disease in the Medicare CKD population. Methods are those described for Figure 9.1.

Table 3.a compares the characteristics of prevalent general Medicare, MarketScan, and Ingenix i3 CKD patients by age, gender, comorbidity, and occupation in 2007. Each comorbidity is defined by medical claims (one inpatient or two outpatient) during each calendar year; identification of hepatitis C also requires that the two outpatient claims be at least 30 days apart. Cardiovascular disease is defined as any of the following claims-defined diseases: atherosclerotic heart disease, congestive heart failure, cerebrovascular accident, dysrhythmia, other cardiovascular disease, or peripheral vascular disease.

Maps in Figure 3.2 include 2007 patients, age 20–64, in the MarketScan and Ingenix i3 databases, while Figures 3.3–4 include 2007 incident and prevalent CKD patients, age 65 and older, in the general Medicare data. CKD is defined by medical claims (one inpatient or two outpatient) during each calendar year; ESRD patients are excluded.

In Figures 3.5–12, the 5 percent Medicare sample includes patients who are age 65 and older, without ESRD, and who sur-
The Kaplan-Meier method is used to calculate the cumulative probability of CKD patients with different comorbidities, defined as in Table 3.a. For the general Medicare data, patients are age 65 and above, and have both inpatient/outpatient and physician/supplier coverage during the calendar year. MarketScan patients are age 20–64, with fee-for-service coverage during the calendar year. Ingenix i3 patients are age 20–64 and are under coverage with business type classified as commercial. Both hospital days and hospital admissions per patient year are assessed during the calendar year. All patients must survive to the end of each calendar year; ESRD patients are excluded.

In Table 3.c and Figures 3.20–25, CKD is defined as follows: Stage 5: eGFR < 15; Stage 4: 15 ≤ eGFR < 30; Stage 3: 30 ≤ eGFR < 60; Stage 3–5: eGFR < 60. Comorbidities such as hypertension, cardiovascular disease, chronic obstructive pulmonary disease, hepatitis C, cancer, anemia, liver disease, and hospitalization are defined from claims, and metabolic abnormalities are defined from laboratory test results.

Figure 3.19 presents distribution of eGFR by CKD identification codes, including CKD defined using all codes, CKD stage diagnosis code (585.X), diabetes with renal manifestations (250.4), and hypertensive kidney disease with CKD (403.X).

### Care of patients with CKD

#### Chapter Four

Figure 4.1 shows the cumulative probability of non-CKD patients receiving a first urinary microalbumin measurement. The general Medicare population includes patients continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program during 2006, age 65 or older at the beginning of the year. Patients are excluded if they are enrolled in a managed care program (HMO), acquire Medicare as secondary payor, die, are diagnosed with CKD or ESRD during 2006, have a missing date of birth, or do not live in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Racial and ethnic categories are mutually exclusive.

Ingenix i3 patients are those continuously enrolled in a fee-for-service plan in 2006 and 2007, and age 50–64 during that year. Patients are excluded if they are diagnosed with CKD or ESRD during 2006.

For both populations, patients are followed from January 1 to December 31, 2007 for the first urinary microalbumin measurement. The Kaplan-Meier method is used to calculate the cumulative probability. Patients are censored at death, development of ESRD, and payor status change for the Medicare population, while patients are censored at development of ESRD for the Ingenix i3 population.

CPT codes used to define urinary microalbumin measurement are 82042, 82043, 82044, and 84196. Diabetes and hypertension are defined in 2006. Methods of defining CKD, diabetes, and hypertension are the same as those described for Chapter Six, below.

Figure 4.2 includes patients from the 5 percent Medicare sample, age 66 and older, who survive all of 2007 with Medicare as primary payor and are not enrolled in Medicare Advantage. Patients with CKD or ESRD in 2006 are excluded. The first CKD claim is identified in 2007 by the regular CKD diagnosis codes, excluding 584. The calendar year 2006 is used to define diabetes and cardiovascular disease by the standard method, and the Kaplan-Meier method is used to obtain the cumulative probability. The MarketScan and Ingenix i3 cohorts are constructed in a similar fashion, but restricted to patients age 50–64 who are enrolled in a fee-for-service plan. Figure 4.3 uses a similar cohort, but excludes only ESRD patients. The first nephrologist claim in 2007 is identified for Medicare patients from the physician specialty codes on physician/supplier claims, for MarketScan patients from provider codes on inpatient and outpatient claims, and for Ingenix i3 patients from provider category codes on inpatient, outpatient, or physician/supplier claims. Figure 4.4 is similar to 4.3, but restricted to patients with CKD in 2006.

Figure 4.5 includes patients from the 5 percent Medicare sample, age 66 and older, who survive all of 2006 with Medicare as primary payor, are not enrolled in Medicare Advantage, and develop CKD in 2006; patients with CKD in 2005 or ESRD in 2006 are excluded. Calendar year 2006 is used to define CKD by the standard method, while calendar year 2005 is used to define diabetes and cardiovascular disease by the standard method; the Kaplan-Meier method is used to obtain the cumulative probability within one year of CKD diagnosis. MarketScan and Ingenix i3 cohorts are constructed in a similar fashion, but restricted to patients age 50–64 who are enrolled in a fee-for-service plan. The first nephrologist claim, primary care claim, or cardiology claim is identified for Medicare patients from the physician specialty codes on physician/supplier claims, for MarketScan patients from provider codes on inpatient and outpatient claims, and for Ingenix i3 patients from provider category codes on inpatient, outpatient, or physician/supplier claims. Constructed in a similar fashion, Figure 4.6 is restricted to 2006 CKD patients with diabetes, Figure 4.7 to 2006 CKD patients with cardiovascular disease, and Figure 4.8 to 2006 CKD patients with both diabetes and cardiovascular disease.

Figures 4.9–14 include CKD patients in 2002, 2004, and 2006; and show the cumulative probability of testing during one year. The 2007 cohort for Figures 4.9–12 and 4.14 is the same as that described for Figure 4.4; the cohort in Figure 4.13 is similar, but limited to diabetic CKD patients. Patients are followed from January 1, 2007 to December 31, 2007, and the Kaplan-Meier method is used to obtain the cumulative probability. Cohorts and follow-up are similar for 2003 and 2005. Tests are identified from outpatient and physician/supplier claims during the year, and identified as follows: creatinine
testing, HCPCS codes 80048, 80050, 80053, 80069, and 82565; calcium/phosphorus testing, HCPCS codes 82310, 80048, 80050, 80053, 80069, and 84100; parathyroid hormone testing, HCPCS code 83970; lipid testing, HCPCS codes 80061, 82465, 83700, 83701, 83715, 83716, 83717, 83718, 83719, 83720, 83721, and 84478; glycosylated hemoglobin testing, HCPCS codes 83036 and 83037; and hemoglobin testing, HCPCS codes 8003, 80014, 80018, 8025, 80227, 80505, and 8055.

Figures 4.15–22 include CKD patients in the entry periods of 2002, 2004, and 2006, and show the cumulative probability of medication use during the 12-month study periods of 2003, 2005, and 2007, separately. The study cohort includes MarketScan and Ingenix i3 patients age 20–64; MarketScan patients have fee-for-service coverage during the entry period and medical coverage and drug insurance during the study period, while Ingenix i3 patients have coverage with business type classified as commercial during both the entry and study periods. Both CKD and diabetes are defined by medical claims (one inpatient or two outpatient) during the entry period. CKD of Stages 3–5 is defined by the 585 stage code.

Figures 4.23–24 include 2007 CKD Ingenix i3 patients, age 50–64. Patients survive all of 2007, are enrolled in a fee-for-service plan for the entire year, and use a statin at least once during the year. Calendar year 2007 is used to define CKD, diabetes, and cardiovascular disease by the standard method. For CKD patients on a statin, the controlled total cholesterol is less than 200 mg/dl and the controlled LDL is less than 100 mg/dl. Figures 4.25–26 use a similar cohort, but include only 2007 CKD patients with diabetes and with at least one use of diabetic drugs in 2007. The controlled glycosylated hemoglobin level is less than 7 percent.

Morbidity & Mortality

Chapter Five

HospitaLization

New to this year’s ADR, adjusted admission rates in this chapter include adjustment for baseline comorbidities and prior hospitalization in addition to patient demographics. A model-based adjustment method is used with a Poisson assumption, and includes data from the current and previous two years, with respective weights of 1, ¼, and ¼. Adjusted rates reflect the distribution of a reference cohort: in this case, Medicare patients in 2005. With this method, the parameter estimates from the model are used to calculate an estimated admission rate for each patient in the reference cohort. Adjusted rates are then computed as the weighted average of these individual rates, using as the weight the time at risk of each patient in the reference cohort.

Figure 5.1 compares all-cause hospital admission rates in CKD and non-CKD patients in prevalent Medicare and MarketScan cohorts. The study design consists of a one-year period during which CKD, comorbidities, and prior hospitalization are defined from claims, followed by the cohort year when follow-up for admissions begins on January 1. The Medicare cohort includes patients age 66 and older on December 31 of the prior year, who are residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories, are continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, are without HMO coverage, are without ESRD, and who survive the complete year prior to follow-up. The MarketScan cohort includes patients age 50–64 on December 31 of the prior year who remain without ESRD and enrolled in a fee-for-service commercial health plan during the prior year. Patients are followed for admissions from January 1 of the follow-up year, and are censored at ESRD initiation, end of plan coverage, or December 31; Medicare patients are also censored at death. Rates are adjusted for gender, prior hospitalization, diabetes, COPD, hypertension, liver disease, gastrointestinal disease, cancer, anemia, and cardiovascular disease, which is defined by at least one of the following conditions: peripheral vascular disease, CVA/TIA, atherosclerotic heart disease, congestive heart failure, dysrhythmia, and other cardiac disease.

Table 5.a shows predictors of hospitalization in Medicare patients age 66 and older. Study design, censoring, and inclusion criteria generally follow those described above for the Medicare cohort in Figure 5.1, with the additional exclusion of patients with a bridge hospitalization spanning January 1. Groups for CKD, diabetes, and cardiovascular disease are mutually exclusive. Follow-up for first hospital admission starts on January 1 of 2003, 2005, and 2007, and Cox proportional hazards regression models are used. Adjustment factors include those listed for Table 5.a.

Figure 5.2 displays unadjusted and adjusted all-cause admission rates by CKD stage for prevalent Medicare patients, 2007, age 66 and older. Study design, censoring, and inclusion criteria generally follow the description for the Medicare cohort in Figure 5.1. Here, however, CKD patients without indication of CKD stage from 585 ICD-9-CM diagnosis codes are excluded. Follow-up begins on January 1, 2007. Admission rates are adjusted for age, gender, race, prior hospitalization, cardiovascular disease, diabetes, COPD, hypertension, liver disease, gastrointestinal disease, cancer, and anemia. Rates shown by hypertension, cardiovascular disease, or COPD, respectively, include the subgroup of patients with the comorbidity, and are adjusted for all factors except the respective comorbidity. Rates are adjusted using the model-based adjustment method described above, except that for CKD patients, due to the availability of CKD stage data, only 2007 data are used, without weighting the previous two years.

Figures 5.3–6 show adjusted all-cause and cause-specific admission rates by CKD status and dataset. Again, study design, censoring, and inclusion criteria generally follow the description for the Medicare and MarketScan cohorts in Figure 5.1. Additionally, Ingenix i3 data include point prevalent patients on January 1 of the year, continuously enrolled in a fee-for-service or commercial health plan and without ESRD during the prior year, and age 50–64 on December 31 of the prior year. The group labeled “CKD” includes those with claims-based evidence of CKD in the prior year, while
“non-CKD” is defined as patients without claims-based evidence of CKD. For the CKD group identified from Ingenix i3 lab data, patients without at least one serum creatinine value during the prior year are excluded. The MDRD equation is used to compute eGFR, and an eGFR less than 60 ml/min/1.73 m² defines CKD from lab data. One limitation of this application of the eGFR calculation is that race data are unavailable in the Ingenix i3 dataset; therefore, in the absence of race information, the eGFR equation assumes all patients are not African Americans. Rates are adjusted for gender, prior hospitalization, cardiovascular disease, diabetes, COPD, hypertension, liver disease, gastrointestinal disease, cancer, and anemia. Cause-specific rates reflect hospital admissions for the purpose of the stated condition, and are identified by principal ICD-9-CM diagnosis codes for cardiovascular and infectious admissions listed in the description of Figure 6.2 in Volume Two.

Figures 5.7–9 illustrate geographic variations in hospital admissions for pneumonia, bacteremia/septicaemia, and urinary tract infection among Medicare CKD patients, point prevalent on January 1, 2007. Included patients are age 66 and older on December 31, 2006, and, during 2006, have a claims-based CKD diagnosis, are without ESRD, and are continuously enrolled in Medicare parts A and B, with no HMO coverage. Residents of Puerto Rico and the Territories are excluded. Follow-up begins on January 1, 2007, and unadjusted admission rates are presented by state. Cause-specific admissions are based on principal ICD-9-CM codes as follows: pneumonia, 480–486 and 487.0; bacteremia/septicaemia, 038.0–038.9 and 790.7; and urinary tract infection, 590–590.9, 595–595.4, 597–597.89, 598, 599.0, 601–601.9, 604–604.9, 607.1–2, 608.0, 608.4, 616.1, 616.3–4, and 616.8.

Figures 5.10–18 present cause-specific hospital admission rates from various data sources. Again, for the Medicare (Figures 5.10–12) and MarketScan (Figures 5.13–15) cohorts, study design, censoring, and inclusion criteria follow the description for Figure 5.1. Ingenix i3 data (Figures 5.16–18) include point prevalent patients on January 1 of the year who, during the prior year, are age 50–64 on December 31, continuously enrolled in a fee-for-service or commercial health plan, and without ESRD. Admissions for pneumonia, bacteremia/septicemia, and urinary tract infection are identified by the principal ICD-9-CM diagnosis codes listed for Figures 5.7–9. In Figures 5.14–15, rates in 2002 for female CKD patients are not available due to insufficient events for model-based estimates. Figures 5.10–18 are comparable since they use the same adjustment factors and reference cohort. Rates are presented by gender and adjusted for prior hospitalization, cardiovascular disease, diabetes, COPD, hypertension, liver disease, gastrointestinal disease, cancer, and anemia.

Mortality
Figures 5.19–21 illustrate trends, by CKD status, in unadjusted and adjusted all-cause mortality from 1995 through 2007 by age, gender, and race, respectively. The study cohort for 1995 represents point prevalent Medicare patients on January 1, 1995, age 66 or older. CKD status is identified from 1994 Medicare claims, and the cohort excludes patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD in 1994. Follow-up extends from January 1, 1995 to December 31, 1995, and is censored at the ESRD date and the end of Medicare entitlement. Patients not living in the 50 states or the District of Columbia are excluded. Cohorts for 1996–2007 are constructed in a similar manner. Adjusted mortality is based on a Cox regression model and adjusted for demographics, hospitalization in the prior year, and comorbidities and sources of comorbidities defined in the prior year. Medicare patients from 2005 are used as the reference cohort.

Table 5.b shows adjusted relative risks for death in 2003, 2005, and 2007. The cohort definitions are same as those defined in Figures 5.19–21. A proportional hazards model is used to obtain the relative risks, and covariates include age, gender, race, and comorbidities. Reference groups are those age 66–69 at the beginning of each period, females, whites, and non-comorbid patients. Figure 5.22 is based on the results obtained from Table 5.b.

STROKE & MORTALITY
In Figures 5.23–26 and Table 5.c, strokes are identified using ICD-9-CM codes 430.x–434.x and 436.x, and patients are required to have one inpatient claim or two outpatient claims with a diagnosis to be identified as having had a stroke. For Figures 5.23–24, prevalent CKD patients are identified for 2005, and only those without a stroke in 2005 are eligible for an incident stroke in 2006. For those without prevalent CKD in 2005 (and without a stroke in 2005), CKD and stroke are identified in 2006, and any time at risk for a stroke prior to a CKD diagnosis is attributed to the non-CKD group. For Figure 5.25 we use incident ESRD patients in 2006 without any stroke codes in the 12–24 months prior to initiation, and then look at claims starting 12 months prior to initiation. Figure 5.26 uses the same cohort as Figure 5.24.

Cardiovascular disease in CKD patients

Chapter Six
Figure 6.1 illustrates the percentage of patients with incident congestive heart failure (CHF) receiving an echocardiogram, nuclear imaging, or coronary angiography at or up to 90 days after CHF diagnosis. It uses a subset of the population in Table 6.a and Figure 6.2 (described below), restricted to Medicare patients with a first diagnosis of cardiovascular disease or a first procedure/device during the follow-up period in 2007. Any stress test includes stress echocardiograms, stress nuclear imaging, stress test, and stress electrocardiograms (ECGs). Patients receiving these tests are identified through procedure codes using the same method described below. Follow-up for testing begins on the CHF diagnosis date and ends at the earliest of death, ESRD diagnosis, change of enrollment status, 90 days after CHF diagnosis, or December 31, 2007. The percentage
Table 6.6 presents information on the risk of incident CHF, cerebrovascular accident/transient ischemic attack (CVA/TIA), peripheral arterial disease (PAD), cardiac arrest, acute myocardial infarction (AMI), first percutaneous coronary interventions (PCI), coronary artery bypass graft surgery (CABG), and use of implantable cardioverter defibrillators and cardiac resynchronization therapy with defibrillator (ICD/CRT-D), by CKD stage, in both Medicare and Ingenix i3 patients. Medicare patients include point prevalent patients on December 31, 2006, age 66 and older, residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories, continuously enrolled in Medicare inpatient/outpatient & physician/supplier coverage, and not enrolled in an HMO in 2006 (baseline). Ingenix i3 patients include point prevalent patients on December 31, 2006, age 20–64, who are continuously enrolled in a fee-for-service commercial health plan in 2006. Patients diagnosed with ESRD prior to January 1, 2007, or with changed coverage on January 1, 2007, are excluded. In estimating the risk of incident CHF in 2007, patients diagnosed with CHF at baseline are also excluded. Similar exclusion criteria are applied for each of the other endpoints. This method, however, is not used to identify patients with cardiac arrest. A patient with cardiac arrest at baseline is identified through an ICD-9-CM diagnosis code of cardiac arrest on a claim from either inpatient/outpatient institutional claims or physician/supplier claims. PCI and CABG are identified through ICD-9-CM procedure codes in inpatient/outpatient claims. PAD is defined through either diagnosis codes or procedure codes. If PAD is defined through diagnosis codes, we use the standard method. If PAD is defined through procedure codes, we use the same method used for PCI and CABG.

Cardiovascular events of CHF, CVA/TIA, PAD, cardiac arrest, AMI, first PCI and CABG surgery, and first use of ICD/CRT-D are defined as the date of the first appearance of diagnosis or procedure codes in the claims during the follow-up period. For each event except AMI, the data sources and methods used to define the event are the same as those used in defining the condition at baseline. The event of AMI is defined as the first appearance of the diagnosis code on an inpatient claim. The same codes are used to define PAD, PCI, CABG, and ICD/CRT-D at baseline and during follow-up, while different codes are used for CHF, CVA/TIA and AMI. Codes used to identify cardiovascular disease, procedures, and device use are as follows:

- CHF: 398.91, 422.xx, 425.x, 428.xx, 402.x1, 404.x3, and V42.1 for condition at baseline (ICD-9-CM diagnosis codes); 398.91, 425.x, 428.xx, 402.x1, 404.x1, and 404.x3 for event during follow-up (ICD-9-CM diagnosis codes)
- PAD: 440–444.4, 447, and 557 (ICD-9-CM diagnosis codes); 84.0, 84.1, 84.91, 39.25, 39.26, and 39.29 (ICD-9-CM procedure codes); 24900, 24920, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, 28805, 34900, 35131, 35132, 35141, 35142, 35151, 35152, 34051, 34451, 34201, 34203, 34800–34834, 35081–35103, 35331, 35341, 35351, 35355, 35357.
CVA/TIA: 430–438 for condition at baseline; 430–437 for event
cardiac arrest: 427.4 and 427.5 (ICD-9-CM diagnosis codes)
CRT-D: 00.51 (ICD-9-CM procedure code)
PCI: 00.66, 36.01, 36.02, 36.05, and 36.06 (ICD-9-CM procedure
cABG surgery: 36.1x (ICD-9-CM procedure codes); 33510–33523
ICD: 37.94 (ICD-9-CM procedure code)

Figures 6.3–10 shows geographic variations in incident rates for
each cardiovascular disease/procedure. For the 2007 maps, the pop-
ulation is a subset of the population used in Table 6.a and Figure
6.2, restricted to those diagnosed with CHF at baseline and residing
in the 50 states and the District of Columbia. Rates are incident events
or first procedures per 1,000 patient years in 2007. Similar meth-
ods are applied to identify point prevalent Medicare patients with
CHF on December 31, 1996, to evaluate the event/procedure rate in
1997. For ICD/CRT-D, point prevalent Medicare patients with CHF on
December 31, 2002, are used because the ICD–9–CM procedure code
for CRT-D was not available prior to January 1, 2002.

Figures 6.11–13 use a subset of the population in Table 6.a and
Figure 6.2, restricted to Medicare patients who had a first diagnosis
of cardiovascular disease or received a first procedure/device dur-
ing the follow-up period in 2007. These figures evaluate diagnostic
testing, survival, physician care, and per person per month costs
after the first cardiovascular event or procedure during the follow-
up period in 2007. CKD patients and CKD stage are defined through
ICD–9–CM diagnosis codes on inpatient/outpatient or physician/sup-
plier claims from January 1, 2006, to the date of first cardiovascular
disease diagnosis, procedure, or device use in 2007, using the same
method described for Chapter Three.

Figure 6.11 presents survival, by CKD stage, after each cardio-
vascular event or procedure. For survival after CHF, incident CHF
patients in 2007 are included. Follow-up begins on the CHF diagnosis
date and ends on the earliest of death, ESRD diagnosis, or December
31, 2007. Using the model-based adjustment method (described in
the section on statistical methods in the Volume Two appendix), sur-
ival probabilities are estimated with the Cox proportional haz-
ards model, and adjusted for age. The reference group includes point
prevalent Medicare patients on December 31, 2006, who are age 66
and older; residing in the 50 states, the District of Columbia, Puerto
Rico, or the Territories; continuously enrolled in Medicare inpa-
tient/outpatient and physician/supplier coverage; and not enrolled
in an HMO in 2006. Patients diagnosed with ESRD prior to January
1, 2007, or with changed coverage on January 1, 2007, are excluded.

Figure 6.12 illustrates physician care of CKD patients during and
after hospitalization for each cardiovascular event and procedure.
To evaluate physician care during and after hospitalization for CHF,
included patients are those whose first diagnoses of CHF in 2007
are from inpatient claims, and who are diagnosed with CKD at
the time of hospital admission, discharged alive, not diagnosed with
ESRD, and do not have a change in enrollment status at the time of
discharge. The time period for evaluating care after hospitalization
begins on the day after discharge and ends on the earliest of death,
ESRD diagnosis, change of enrollment status, 90 days after discharge,
or December 31, 2007. A similar method is used for the other events
or procedures. For first PCI and first use of ICD/CRT-D, patients with
first claims from outpatient institutional claims or physician/sup-
plier claims are also included in the analysis. For these patients, the
time period for evaluating physician care after the procedure begins
on the day after the claim–from date on the outpatient or physician/
supplier claims and ends on the earliest of death, ESRD diagnosis,
change of enrollment status, 90 days after the procedure, or Decem-
ber 31, 2007. Patients receiving primary, cardiology, and nephrology
care during and up to 90 days after hospitalization are examined to
identify those with a first diagnosis of CHF or AMI, receiving their
first PCI or CABG surgery, or receiving their first ICD/CRT-D device.
Neurology is added for patients with CVA/TIA and cardiac arrest,
while radiology and vascular surgery are added for those with PAD.
The physician specialty codes on physician/supplier claims are used
to identify primary care (01, general practice; 08, family practice;
and 11, internal medicine), cardiology (06), nephrology (39), neu-
rology (19), radiology (94), and vascular surgery (77).

Figure 6.13 presents, by CKD stage and for Medicare patients, per
person per month (PPPM) inpatient/outpatient and physician/sup-
plier expenditures related to cardiovascular diagnoses and proce-
dures. The time period for calculating the cost begins on the first
cardiovascular diagnosis or procedure date and ends on the earliest
of death, ESRD diagnosis, change of enrollment status, or Decem-
ber 31, 2007. The actual Medicare PPPM payment is calculated by
dividing the total Medicare payment in the follow-up period by
the total follow-up time.

**Transition to ESRD**

**Chapter Seven**

Figures 7.2–6 include incident ESRD patients (Medicare patients
are limited to those age 67 and older). For Figures 7.3–6, physician
specialty is identified from claims; physician visits in Figure 7.3
include those to a primary care physician, cardiologist, or nephrol-
ologist, while in Figure 7.6 primary care represents family practice,
general practice, and internal medicine. Inpatient and outpatient
locations are identified by location code or the source of the claim, depending on the dataset.

Figures 7.7–12 include incident ESRD patients in 2003, 2005, and 2007, and show the percentage of patients with at least one test during the eight quarters before the first ESRD service date. Tests are identified from outpatient and physician/supplier claims during the two years, as follows: parathyroid hormone testing, HCPCS code 83970; creatinine testing, HCPCS codes 80048, 80050, 80053, 80069, and 82565; lipid testing, HCPCS codes 80061, 82465, 83715, 83716, 83717, 83718, 83719, 83720, 83721, and 84478; hemoglobin testing, HCPCS codes 85013, 85014, 85018, 85025, 85027, 80050, and 80055; and glycylated hemoglobin testing, HCPCS codes 83036 and 83037. For glycosylated hemoglobin testing, patients must be defined with diabetes during the 24 months before incident ESRD. The ESRD cohort includes patients age 67 and older; the MarketScan cohort includes all ESRD patients with fee-for-service coverage during the study period, and the Ingenix I3 cohort includes all ESRD patients under coverage with business type classified as commercial.

Figures 7.13–20 show the percentage of patients on specific drugs during the eight quarters prior to and the one quarter after ESRD initiation. The cohort includes MarketScan and Ingenix I3 incident ESRD patients age 20–64. MarketScan patients have fee-for-service coverage and drug insurance during the nine quarters, while Ingenix I3 patients have coverage with business type classified as commercial during the same period.

Table 7.7 and Figures 7.21–23 illustrate the percentage of patients on specific drugs prior to and after ESRD initiation, and uses the same study cohort as Figures 7.13–20. Figure 7.23 shows medication use in the quarter after ESRD initiation in patients using the medication three quarters prior to ESRD. All diabetic drugs (insulin, sulfonylureas, and potassium-sparing diuretics) are analyzed for ESRD patients with diabetes, which is defined by medical claims (one inpatient or two outpatient) during the year of ESRD incidence.

Figures 7.24–26 include ESRD patients who have Medicare as primary payer coverage (Medicare) or are eligible (MarketScan and Ingenix I3) for two years prior to ESRD; Figure 7.27 is limited to Medicare patients, because data on dialysis type is not available in the other datasets. Medicare patients include those age 67 or older at initiation. Methods used to identify vascular access insertions and to calculate rates are the same as in those used in Volume Two, Chapter Five. Vascular access procedures are obtained from Part B revenue line item files in the Medicare population and from physician’s claims in the Ingenix I3 and MarketScan data. Data from Part B and physician claims files can reflect procedures done in either the inpatient or outpatient setting.

**Acute kidney injury**

Chapter Eight

In this chapter, patients with an acute kidney injury (AKI) hospitalization are identified from inpatient claims by the presence of ICD-9-CM code 584.x. AKI that requires dialysis (AKI-D) is identified by the additional presence of any of the following: ICD-9-CM procedure codes 39.95 and 54.98; ICD-9-CM diagnosis codes V45.1, V56.0, and V56.1; CPT codes 90935, 90937, 90945, and 90947; and revenue codes 0800–0809. Patients with ESRD diagnosed before the AKI hospitalization discharge are omitted, except as indicated. For patients with multiple AKI hospitalizations through the years, the first one in the timeframe is counted. The event rate is estimated as the number of events per 1,000 patient years at risk.

Figure 8.1 displays the percentage of patients hospitalized for AKI or AKI-D in a given year. The cohort includes general Medicare patients age 66 or older on December 31 of the cohort year, continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, with no HMO coverage, and who survive and are without ESRD in the cohort year.

**Characteristics of AKI Patients**

Figure 8.2, Table 8.7, and Figures 8.5–6 describe the demographic characteristics of patients suffering AKI. The study cohort includes the general Medicare patients described for Figure 8.1 (Figure 8.2 uses the 2007 cohort), along with MarketScan and Ingenix I3 patients age 20–64 on December 31 of the cohort year who are enrolled in a fee-for-service plan. Contrast is received during the two weeks prior to AKI hospitalization, and ACE-Is/ARBs and statins are taken in the three months prior to AKI hospitalization.

Figures 8.3–4 use the same cohort described for Figure 8.1. Figure 8.3 shows the type of dialysis used by hospitalized AKI-D patients. Modality is defined as follows: peritoneal dialysis, CPT codes 90945 or 90947 and 49420; continuous venous to venous hemodialysis (CVVHD), dialysis with CPT codes 90945 or 90947 but without 49420; intermittent hemodialysis (IHD), dialysis with CPT codes 90935 or 90937 and intermittent in the first three days; and daily hemodialysis (DHD), dialysis with CPT codes 90935 or 90937 and with three consecutive dialysis sessions in the first three days. To define modality, we first determine if there is any peritoneal dialysis during the period of the AKI event, and then look for continuous dialysis to identify hemodialysis or DHD. Those who are not identified by the above methods are categorized as having an unknown dialysis type. Figure 8.4 shows the percentage of hospitalized AKI patients who receive contrast in the two weeks prior to AKI admission.

**Overall Rates of Acute Kidney Injury**

Figure 8.7 presents rates of acute kidney injury, and Figure 8.8 shows the adjusted hazard ratios for AKI hospitalization, adjusted for age, gender, and race. The study cohort for both includes point prevalent general Medicare patients on January 1, 2007, age 66 and older on December 31, 2007, along with point prevalent MarketScan and Ingenix I3 patients age 20–64 on December 31, 2007. Patients with ESRD before January 1, 2007, are excluded. Each patient is followed from January 1, 2007, to the earliest of death.
The methods for identifying the types of physician visits in Figure 8.1 and MarketScan and Ingenix i3 patients, 2006. Each patient is followed from January 1, 2007 to the earliest of death (for Medicare patients only), ESRD diagnosis, change of enrollment, or December 31, 2007. CKD is identified with one or more Part A institutional claims (inpatient hospitalization, skilled nursing facility, or home health agency), or two or more Part A institutional claims (outpatient) or physician/supplier claims, with codes as follows: 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 403.21, 404.X2, 404.33, 440.1, 442.1, 4473, 572.4, 580–583, 585–588, 591, 642.1, 646.2, 753.12–753.17, 753.19, 753.2, and 794.4. The codes for the remaining comorbidities are the same as those indicated elsewhere.

Figures 8.10–11 illustrate geographic variations in unadjusted rates of AKI and AKI-D in 2006 for the Medicare patient sample. Patients are followed from AKI discharge (for those with AKI) or January 1, 2007 (for those without) to the earliest of death, ESRD diagnosis, end of Medicare coverage, or one year after AKI discharge. The Kaplan-Meier method is used to estimate the probability of death in Figure 8.19 and the probability of ESRD in Figure 9.20.

Table 8.d includes all patients in the 5 percent Medicare sample who are age 66 and older and who have hospitalized AKI events in 2006 or 2007. Hospitalized AKI is defined by ICD-9-CM diagnosis code 584 in inpatient claims, and discharge status in these claims is used to determine discharge status during hospitalization. The previous year of each AKI event is used to define diabetes, hypertension, and CKD. A logistic model is used to obtain the odds ratios of in-hospital death, adjusting for age, gender, diabetes, hypertension, and CKD (and, in the Medicare cohort, for race). The MarketScan cohort is constructed in a similar fashion, but restricted to patients age 20–64 who are enrolled in a fee-for-service plan.

Table 8.e includes all patients in the 5 percent Medicare sample who are age 66 and older and who have hospitalized AKI events in 2005 or 2006. Hospitalized AKI is again defined by ICD-9-CM diagnosis code 584 in inpatient claims, and the previous year of each AKI event is used to define diabetes, hypertension, and CKD. Patients are followed from the discharge date until the earliest of one year, ESRD, death, December 31, 2007, or loss of insurance coverage. The Cox model is used to obtain hazard ratios of death after discharge, adjusting for age, gender, race, diabetes, hypertension, and CKD. Patients are restricted to Medicare patients age 20–64 who are enrolled in a fee-for-service plan. The Cox model is used to obtain hazard ratios of ESRD after discharge, with the same adjustments used in Table 8.d.

PATIENT CARE & OUTCOMES

The methods for identifying the types of physician visits in Figures 8.12 and 8.13 are the same as those described in the methods for Chapter Seven. In Figure 8.15, multiple physician claims for the same specialty during the same inpatient stay are counted only once. Testing in Figures 8.13–14 is identified as follows: creatinine testing, HCPCS codes 80048, 80050, 80053, 80069, and 82565; microalbumin testing: CPT codes 82042, 82043, 82044, and 84566.

Figures 8.16–17 examine the use of ACE-Is/ARBs and statins before and after AKI hospitalization in both AKI and AKI-D patients, and include 2006 Ingenix i3 patients, identified as in Figure 8.2. Medication treatment is identified in the three months before and after admission for AKI.

Figure 8.18 demonstrates the probability of patients receiving follow-up testing after hospitalization for AKI. Testing includes glycosylated hemoglobin (A1c) testing and eye examinations (diabetic patients only), along with influenza vaccinations. Patients with AKI are identified from the Ingenix i3 dataset in 2006, and are followed from the AKI admission until ESRD diagnoses, end of fee-for-service coverage, or one year after AKI admission. Diabetic status is determined from the one-year entry period before the AKI admission. Codes for testing are as follows: A1c tests, CPT code 83016 (at least two tests); eye examinations, CPT codes 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, 92287, 67101, 67105, 67107, 67108, 67110, 67112, 67141, 67145, 67208, 67210, 67218, 67227, and 67228; and influenza vaccinations, CPT codes 90724, 90737, 90645, 90646, 90647, 90648, 90655, 90656, 90657, 90658, 90659, and 90660. The Kaplan-Meier method is used to calculate the cumulative unadjusted probability of testing during the one-year follow-up period.

Figures 8.19–20 display outcomes among survivors of an episode of hospitalized AKI, by AKI and CKD status. General Medicare patients age 66 and older on December 31, 2006, continuously enrolled in Medicare coverage, and without HMO coverage are included, and we identify administrative claims for AKI in 2006. CKD is defined by searching claims in the one year prior to the AKI admission. Patients are followed from AKI discharge (for those with AKI) or January 1, 2007 (for those without AKI), to the earliest of death, ESRD diagnosis, end of Medicare coverage, or one year after AKI discharge. The Kaplan-Meier method is used to estimate the probability of death in Figure 8.19 and the probability of ESRD in Figure 9.20.

Figures 8.21–22 present unadjusted rates and hazard ratios of ESRD and death by AKI and CKD status, using the same cohort as in Figures 8.19–20. Patients are followed from AKI admission (for those with AKI) or January 1, 2007 (for those without) to the earliest of death, ESRD diagnosis, end of Medicare coverage, or one year after AKI admission. Hazard ratios are estimated using Cox proportional hazard models, adjusted for age, gender, and race.

Table 8.d includes all patients in the 5 percent Medicare sample who are age 66 and older and who have hospitalized AKI events in 2006 or 2007. Hospitalized AKI is defined by ICD-9-CM diagnosis code 584 in inpatient claims, and discharge status in these claims is used to determine discharge status during hospitalization. The previous year of each AKI event is used to define diabetes, hypertension, and CKD. A logistic model is used to obtain the odds ratios of in-hospital death, adjusting for age, gender, diabetes, hypertension, and CKD (and, in the Medicare cohort, for race). The MarketScan cohort is constructed in a similar fashion, but restricted to patients age 20–64 who are enrolled in a fee-for-service plan.

Table 8.e includes all patients in the 5 percent Medicare sample who are age 66 and older and who have hospitalized AKI events in 2005 or 2006. Hospitalized AKI is again defined by ICD-9-CM diagnosis code 584 in inpatient claims, and the previous year of each AKI event is used to define diabetes, hypertension, and CKD. Patients are followed from the discharge date until the earliest of one year, ESRD, death, December 31, 2007, or loss of insurance coverage. The Cox model is used to obtain hazard ratios of death after discharge, adjusting for age, gender, race, diabetes, hypertension, and CKD.

The Medicare cohort in Table 8.f is same as that used in Table 8.e. The MarketScan and Ingenix i3 cohorts are constructed in a similar fashion, but restricted to patients age 20–64 who are enrolled in a fee-for-service plan. The Cox model is used to obtain hazard ratios of ESRD after discharge, with the same adjustments used in Table 8.d.
The cohorts and adjustments in Table 8.g are same as those used in Table 8.f, and the Cox model is used to obtain hazard ratios of recurrent AKI hospitalization after discharge. Recurrent AKI events are defined as those more than 30 days after the first AKI event.

Table 8.h is similar to Table 8.d, but includes only hospitalized AKI patients with dialysis. Hospitalized AKI is defined as in Table 8.d, while dialysis is identified by any of the following codes: CPT codes 90935, 90937, 90945, and 90947; ICD-9-CM procedure codes 39.95 and 54.98; revenue codes 0800–0809; and ICD-9-CM diagnosis codes V45.1, V56.0, and V56.1. Table 8.i is similar to Table 8.e, Table 8.j is similar to Table 8.f, and Table 8.k is similar to Table 8.g. Tables 8.i–k, however, include only hospitalized AKI patients with dialysis.

**Costs of CKD**

**Chapter Nine**

**POPULATIONS**

Using the methodology described below, Figure 9.1 compares populations and costs in 2007 for Medicare patients (based on the 5 percent Medicare sample) and MarketScan patients, while Figures 9.2–7, 9.12–13, and Table 9.a compare costs for these populations.

Figures 9.8–11 are based on the Medicare and MarketScan incident 2006 ESRD populations during the transition to ESRD. Medicare patients here are ages 67 and older, with Medicare as primary payor for the entire transition period (six months before through six months after the initiation of renal replacement therapy), and not enrolled in a managed care program (HMO) during the transition period. The MarketScan patients include those younger than 65 and continuously enrolled in a fee-for-service plan for the entire transition period.

The general Medicare population includes persons age 65 and older who survive for at least the last three months of year one, are continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage for this time period, with censoring at the earliest of death, development of ESRD, change in payor status, or the end of year two. In addition, the cohorts include those who survive at least three months during year two, are enrolled at least three months during the year in Medicare inpatient/outpatient and physician/supplier coverage, are not enrolled in an HMO, and do not have ESRD during year two. Costs for this portion of the cohort are aggregated for year two, with censoring at the earliest of death, development of ESRD, change in payor status, or the end of year two. In addition, the cohorts include those who survive at least three months during year two, are enrolled at least three months during the year in Medicare inpatient/outpatient and physician/supplier coverage, are not enrolled in an HMO, and do not have ESRD during year two. Costs are also aggregated for year two for this portion of the cohort.

Important comorbidities (diabetes mellitus, chronic kidney disease (CKD), chronic obstructive pulmonary disease (COPD), and cardiovascular disease (CVD)) are determined for these cohorts from Medicare claims using a previously validated method. A patient is defined as having one of these comorbidities if, within the one-year observation period (year one or year two), he or she has a qualifying ICD-9-CM diagnosis code on one or more institutional claims (inpatient, skilled nursing facility, or home health agency) or two or more institutional outpatient claims and/or physician/supplier claims. Qualifying diagnosis codes are as follows: diabetes, 250.xx, 357.2, 362.0x, and 366.41; CKD, 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 255.0, 271.4, 274.1, 283.11, 403.x1, 404.x2, 404.x3, 440.1, 442.1, 447.3, 572.4, 580–588, 591, 642.1, 646.2, 753.12–753.17, 753.19, 753.2, and 794.4; COPD, 491–494, 496, 510; and CVD, 398.91, 402.x1, 404.x1, 404.x3, 425.x, 426–427, 428.x, 429, 430–438, 440–444, 447, 451–453, 557, 785.0–785.3, V42.1, V42.2, V43.3, V45.0, V45.81, V45.82, and V53.3. Costs are presented for the 1992–1993 through 2006–2007 cohorts. The cost year is always year two of the cohort.

The MarketScan population includes patients age 50–64, and is constructed in the same fashion as that described for the Medicare population, requiring continuous enrollment in a fee-for-service health plan. Patients identified as having ESRD are excluded. The cohorts are from 1999–2000 to 2006–2007.

**COST CATEGORIES**

Costs are categorized in several ways. For Figures 9.1–5, costs are simply total claims-based expenditures, while those in 9.6–11 are claims-based expenditures expressed per person per month (PPPM). Costs for Figures 9.12–13 are defined by the type of claim—either inpatient, outpatient, and physician/supplier—and expressed as PPPM expenditures. MarketScan also has a separate claim set for drug claims, and these claims are included in the outpatient category. Costs are further broken down for Table 9.a, using diagnosis-related groupings (DRGs) for inpatient claims; revenue codes, current procedural terminology (CPT) codes, and healthcare common procedure coding system (HCPCS) codes for outpatient claims; and CPT, HCPCS, provider specialty, and place of service codes for physician/supplier claims.
Products and services provided by the United States Renal Data System to support the work of the renal community are detailed in Table b.a. The entire ADR is available at www.usrds.org, with PowerPoint slides of all figures and Excel files of the data behind the graphs; included as well are PDF files of the Researcher’s Guide. The site’s Render system allows users to create customized data sets and regional maps. Data on website use are presented in Figure b.1.

Data requests
Making information on ESRD available to the renal community is a primary objective of the USRDS, and we are committed to the timely fulfillment of data requests. In many cases requests can be answered through data published in the ADR or elsewhere. Requests for data not available in material published by the USRDS, but that require two hours or less of staff time, are fulfilled by the Coordinating Center without charge, usually within one week. More complex requests — requiring more than two hours of staff time — as well as requests for Standard Analysis Files and custom files, must be accompanied by a written proposal (see details below), and will be completed only upon written approval by the NIDDK Project Officer.

Research files
The Coordinating Center maintains a set of Standard Analysis Files (SAFs) to meet diverse research needs and provide easy access to data used in the ADR. The SAFs were introduced in 1994, as the NIDDK began awarding new grants focusing on research using the USRDS data. The result has been an annual increase in the number of files provided by the USRDS.

Prior to 1994, all researcher files were created for specific projects. Since the introduction of the SAFs, however, custom files are generally limited to cases in which a researcher provides a patient finder file to be matched with the USRDS database. For more information on merged data requests, please contact the Coordinating Center at usrds@usrds.org.

The three-CD Core SAF set contains basic patient data, and is needed to use any of the other SAFs. Included are each patient’s demographic information, payor and treatment history, limited transplant data, provider data, and all data from the USRDS Special Studies. Approximately half of the researchers using the USRDS SAFs need only this CD set. Full transplant information is provided on a separate CD that contains detailed transplant and transplant follow-up data collected by CMS and UNOS. Data on hospital inpatient stays are found on the hospitalization CD. All Medicare billing data are available by individual year (see Table b.c).

Standard Analysis Files (SAFs)
SAF use is governed by the USRDS policy on data release for investigator-initiated research, found later in these appendices. Research proposals must be approved by a USRDS Project Officer, and researchers must sign the USRDS “Agreement for Release of Data,” on the same page. File prices are listed in Table b.c.

Most SAFs provide patient-specific data. All patient identifiers are removed or encrypted, but data confidentiality remains a serious concern. The USRDS “Agreement for Release of Data” describes restrictions on SAF use and disposition. The SAFs include an encrypted ID number to allow patient data from multiple SAFs to be merged.

CORE CDS
The Core Standard Analysis File CDs contain the most frequently used SAFs, including those from the Special Studies, and are needed for use of the Transplant and Hospital CDs, or any CD based on Medicare claims data. Included files are as follows (also listed in Table b.b).

- Patient Contains one record per patient in the USRDS database, and gives basic demographic and ESRD-related data.
- Residence A longitudinal record, to zip code, of residence.
- Payor History Contains a new record for each patient at each change in insurance payor.
- Treatment History Modality Sequence Contains a new record for each patient at each change in modality or dialysis provider.
- Medical Evidence Contains full data from the 1995 version of the CMS Medical Evidence form. In April 1995 a new version of the form went into use, with data on comorbidity, employment status, lab values at initiation, and Hispanic ethnicity.
- Transplant Contains basic data for all transplants (reported by CMS and UNOS), including the date of graft failure (detailed transplant data are contained on a separate transplant CD).
- Transplant Wait List Beginning with 2001 data (used in the 2002 ADR), this CD has been updated to include basic patient demographic and, from UNOS, all unique wait-list periods for each dialysis patient.
- Facility Conducted annually, the CMS End-Stage Renal Disease Facility Survey is the source of data for the Facility SAF, which can be linked to the Facility Cost Report files using the USRDS provider ID. Geographic variables that could identify facilities are deleted. The survey period is January 1 through December 31.

- Facility Cost Reports CMS hospital and independent facility cost reports for 1989–1995 and 1989–1993, respectively, are available as SAFs. All geographic variables are deleted to ensure confidentiality. The files may be linked to the Facility SAF using the USRDS provider ID, though analyses at less than a regional or network level are not possible. Because these files are rarely used, additional data will be added only if there is sufficient demand.
DATA FROM SPECIAL STUDIES

Topics for USRDS Special Studies are approved by the NIDDK, with recommendations from CMS, the Scientific Advisory Committee, the ESRD networks, and the Renal Community Council. Design and sampling plans are developed, samples are selected, and data collection forms and instructions are drafted, tested, and finalized. The main studies to date are summarized below, and are detailed in the Researcher’s Guide.

Dialysis Morbidity & Mortality Study (DMMS) The DMMS was a USRDS Special Study in which data on demographics, comorbidity, laboratory values, treatment, socioeconomic factors, and insurance were collected, using dialysis records, for a random sample of U.S. patients. Waves 1, 3, and 4 are historical prospective studies in which data were collected for patients on in-center hemodialysis on December 31, 1993. Data were abstracted from medical records, and patients were followed to the earliest of data abstraction, death, transplant, change in modality, or transfer to another facility. Wave 2 is a prospective study of incident hemodialysis and peritoneal dialysis patients for 1996 and early 1997.

Case Mix Adequacy Study of Dialysis The objectives of this USRDS Special Study were to establish the relationship between the dose of delivered dialysis therapy and mortality, determine the strength of this relationship when data are adjusted for comorbidity, assess how this relationship changes with dialysis dose, assess how this relationship is affected by dialyzer reuse, and examine the impact of different dialysis membranes on patient morbidity and mortality.

The study consisted of two groups: an incident sample of ESRD patients who began hemodialysis in 1990, and a prevalent sample of hemodialysis patients whose ESRD began prior to 1990. A total of 7,096 patients from 523 dialysis units were included, with approximately 3,300 patients having both the pre- and post-BUN values needed to calculate delivered dialysis dose. Ninety-four percent of these cases were matched to the USRDS database. The ESRD networks collected these data in conjunction with their Medical Case Review data abstraction.

Case Mix Severity Study For this USRDS Special Study, data were collected on 5,235 patients incident in 1986–87 at 328 dialysis units nationwide. Objectives were to estimate the correlation of comorbidity and other factors existing at the onset of ESRD to mortality and hospitalization rates, while adjusting for age, gender, race, and primary diagnosis; evaluate possible associations of these factors with reported causes of death; assess the distribution of comorbidity and other factors among patients on different modalities; and compare relative mortality rates by treatment modality, adjusting for comorbid conditions and other factors.

Pediatric Growth & Development The objectives of the USRDS Pediatric Growth and Development Study were to establish a baseline for assessing the relation of patient growth and sexual maturation to modality, and establish a prototype for the ongoing collection of pediatric data. All patients prevalent in 1990 and born after December 31, 1970, were included in the study, a total of 3,067 patients at 548 units.

CAPD & Peritonitis Study The USRDS CAPD and Peritonitis Study examined the relation of peritonitis episodes in CAPD patients to connection device technology and other factors. The study population included all patients newly starting CAPD in the first six months of 1989, a maximum of 14 patients per dialysis unit. All units providing CAPD training participated in the study. The sample contains data on 3,385 patients from 706 units.

TRANSPLANT CDS

Due to changes in data collection sources over the years, data related to transplants are now presented in eight separate SAFs. The first two are included on the Core CD, and the remaining six are included on two separate Transplant CDs.

- TX contains minimum details on all transplants from all sources
- TXWAIT contains one record for each patient in the USRDS database per wait list event
- TXHCF contains transplant information collected by CMS’s Pmmis system prior to 1994
- TXUNOS includes transplant information collected since 1987 by UNOS, currently the main source of transplant data for the USRDS
- TXRUS contains information on immunosuppressive drugs collected by UNOS at the time of transplantation events
- TXFUCFA contains transplant follow-up reports collected by CMS prior to 1994; reports are completed at discharge, six months, each year post-transplant, and at graft failure
- TXFUNOS includes transplant follow-up reports collected by UNOS since 1988
- TX IFUNOS includes information on immunosuppressive drugs, collected by UNOS at follow-up visits

Tables in Reference Sections E and F are produced primarily from the CMS and UNOS transplant files.

In July of 1994, CMS and the Health Resources Services Administration (HRSA) consolidated transplant data into a single collection by UNOS under its HRSA contract. Expanded transplant data are shared among HRSA, CMS, and the NIH, and are thus available to the USRDS. This has resulted in the addition of data on a substantial number of non-Medicare transplant patients, including children. CMS and UNOS transplant files overlap for 1988–1993, and some Medical Evidence (ME) forms and institutional claims records indicate transplants not included in either file. To resolve conflicts among the sources and create the transplant SAF, all UNOS transplants are first accepted into the file, with all pre-1988 CMS transplants accepted next. CMS transplants from 1988–1993 are then accepted if there is no transplant in the file for that patient within 30 days of the CMS transplant (it is common for dates between sources to differ by one day). Finally, transplants indicated on the ME form are accepted if no transplant is listed for the patient within 30 days of the Medical Evidence transplant date.

HOSPITAL CDs

Hospitalization inpatient data are a subset of the data in the Institutional Claims file. No payment or cost variables are included on this two-CD set, which is for researchers who need data on hospital inpatient stays and on diagnoses and procedures for those stays, but who do not need payment data.

COMPREHENSIVE DIALYSIS STUDY CD

This CD contains data from the Comprehensive Dialysis Study (CDS), a new USRDS special data collection study to assess rehabilitation/
App B

pg 154

b

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ii

ii

USRDS products & services

Reports & guides

Annual Data Reports Available from the National Kidney and Urologic Disease Information Clearinghouse, 3 Information Way, Bethesda, MD 20892-3560; 301.654.4415; nkudic@info.niddk.nih.gov. ADR material is also published in the American Journal of Kidney Diseases.

Annual Data Report CD Contains the text and graphics of the ADR, data tables, PowerPoint slides, and the Researcher's Guide.

Researcher's Guide to the USRDS database Provides a detailed description of the USRDS database and of the USRDS Standard Analysis Files; the basic reference for researchers who use USRDS data files.

www.usrds.org Contains PDF files of the chapters, reference tables, and the Researcher's Guide; PowerPoint slides of atlas figures and USRDS conference presentations; Excel files of the data tables; notices regarding current news and analyses; links to related Internet sites; and email addresses for contacting the USRDS.

RenDER The USRDS Renal Data Extraction and Referencing (RenDER) System is a querying application that allows users to create data tables and interactive maps. It can be accessed at www.usrds.org/odr/xrender_home.asp following a short registration; a tutorial is also available on this site to help new users.

Requests for data Data requests: two-hour Questions and data requests that are not answered directly by the ADR can be addressed to the Coordinating Center; those that require less than two hours of staff time to fulfill will be processed without charge.

Data requests: more than two hours Questions and data requests that require over two hours of staff time must be submitted in writing and approved by the NIDDK Project Officer. Fulfillment of these requests is subject to staff availability, and costs are assessed on a case-by-case basis.

Standard Analysis Files SAFs provide patient-specific data from the USRDS to support ESRD research. A standard price list has been established for the files (Table b.c), and users must sign a Data Release Agreement with the NIDDK.

Custom data files Custom files can be created by the Coordinating Center for projects requiring data other than those provided in the Standard Analysis Files. An hourly rate of $119.57 will be assessed for time spent on the request, and users must sign a data release agreement with the NIDDK.

Publications & presentations Most USRDS research studies result in published papers or presentations at national meetings. Figures from abstracts and presentations can be found on the website, while published abstracts and papers can be found in the relevant journals.

Contact information Data requests & publication orders USRDS Coordinating Center 914 South 8th Street, Suite S-206 Minneapolis, MN 55404 612.347.7776 or 1.888.99-USRDS Fax 612.347.5878 usrds@usrds.org

Data file contacts Shu-Cheng Chen, MS; schen@usrds.org

Beth Forrest, BBA; bforrest@usrds.org

Contents of the USRDS Core Standard Analysis CD-ROM

File name unit of observation & uses • This two-CD set is needed in order to use any of the other Standard Analysis Files.

Patient one record for each ESRD patient • Incidence, prevalence, patient survival. Most other files will need to be linked to this file using the encrypted patient ID.

Residence for each patient, one record for each period in a different residence • Regional analyses.

Treatment History one record for each period a patient is on one modality • Modality distribution and treatment patterns.

Payor History one record for each period a patient is covered by one payor; each patient can have many records • The impact of insurance payors on clinical outcomes.

Medical Evidence one record for each 2728 form filed (1995 version) • ESRD first service date, initial treatment modality, comorbid conditions, patient status at start of ESRD.

Transplant one record for each transplant event; patients can have multiple events • Transplant and transplant outcome analyses.

Transplant Wait List one or more records for each patient ever on list • Comparison of transplanted patients to dialysis patients who are transplant candidates. Patient selection to wait list.

Dialysis Morbidity and Mortality (DMMS; Special Study) Wave 1: 5,670 patients; Wave 2: 4,024 patients; Wave 3: 11,142 patients Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values, nutrition, vascular access.

Case Mix Adequacy (Special Study) 7,046 patients • Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.

Case Mix Severity (Special Study) 5,255 patients • Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.

Pediatric Growth and Development (Special Study) 3,067 patients • Growth, development, and other issues relating to pediatric ESRD patients.

CAPD Peritonitis (Special Study) 3,385 patients • CAPD and peritonitis.

Facility one record for each facility has operated • Merge with the treatment history, transplant, or annual summary SAFs for analyses involving provider characteristics by encrypted ID.

Facility Cost Reports one record per facility per year (1989–2005) • Costs and staffing of dialysis facilities.

Dialyzers information on dialyzer characteristics to be matched to patient dialyzer information in other files on CD • Relation of dialyzer characteristics to patient outcomes.

CLMCODES one record for each diagnosis, procedure, or HCPCS code appearing in claims file • Frequency of occurrence of each code. A starting point for analyses that will use diagnosis and procedure codes.

Formats.sci all USRDS-defined SAS formats used by SAFs • Format library used to format values of categorical variables.
quality of life and nutrition issues in incident dialysis patients. The study was conducted between 2005 and 2008. All 1,677 participants answered questions on physical activity level, health-related quality of life, and work/disability status during the first six months after the initiation of ESRD therapy. In a subset of 400 participants, dietary intake and nutritional status were also assessed.

**DIALYSIS MORBIDITY & MORTALITY CLAIMS CD**

This CD contains files from the Dialysis Morbidity and Mortality Study, with data extracted from all CMS Medicare payment data for the study patients. Data are followed to the currently reported claims year.

**CASE MIX ADEQUACY CLAIMS CD**

This CD contains the Case Mix Adequacy Special Study file, and extracts data for the study patients from all CMS Medicare payment data. Medicare payment data for these patients are followed to the currently reported claims year. This file is useful for developing analyses to be run on full Medicare payment files.

**MEDICARE PAYMENT DATA CDs**

Medicare payment data on institutional claims are available for pre-1989 through 2007, while data on physician/supplier claims are available for 1991–2007. The 2007 claims will be available, along with other updated USRDS SAF CDs, by the end of 2009.

Institutional claims consist of all inpatient/outpatient claims (inpatient, outpatient, skilled nursing facility, home health agency, and hospice), including outpatient dialysis claims. Physician/supplier claims account for 80 percent of claims but only 20 percent of dollars. The structure and content of the two types of claims differ, as do the files derived from them. Institutional claims are provided in two types of files: the Institutional Claims file, indicating claim type, dollar amounts, DRG code, type of dialysis involved (if any), and dates of service; and the Institutional Claims Detail file, containing details such as diagnosis and procedure codes. Many analyses require only the Institutional Claims files. Physician/supplier claims are contained in one type of file with one record for each claim line-item. The file includes dollar amounts, dates of service, diagnosis and procedure codes, and type and place of service.

**CLINICAL PERFORMANCE MEASURES SURVEY CDs**

The Clinical Performance Measures (CPM) data is a CMS project developed to collect information on the quality of care provided to the dialysis population. The data originates from yearly surveys of approximately 10,000 patients completed by the primary care facilities, and was formerly known as the ESRD Core Indicators Project. This project results in a rich source of detailed information, useful in analyses of healthcare delivery in a sample of the dialysis population.

To further expand the value and use of the CPM data, we have linked patient data from the USRDS SAFs, enabling complete claims extraction from the SAFs for all identified patients. The resulting claims history has been combined with the CPM data to form a complete mini-set of the USRDS data products with supporting files. This enables researchers to add patient-level laboratory and dialysis prescription detail to a broad range of healthcare service event data over many years.

The USRDS Coordinating Center has made the CPM data available as SAFs. The dataset contains CPM data collected in surveys from 1994–2007. A listing of available files and the corresponding costs can be found in Table b.e, or you may contact the USRDS Coordinating Center for further information.

**DISEASE-BASED COHORT CDs & 5 PERCENT GENERAL MEDICARE PAYMENT DATA CDs**

Three disease-based cohort CD sets — for CKD, diabetes, and CHF — are built from the 5 percent general Medicare Claims SAFs. Each CD contains a patient master file, a payor sequence file, and a set of comorbidity files.

Separately, 5 percent general Medicare claims SAFs (inpatient, outpatient, skilled nursing facility, home health, hospice, Part B, and durable medical equipment) are also available for single or multiple years from 1992 to 2005. Data are derived from the IP claims SAF files. No payment or cost variables are included, so these data are for researchers who need data on hospital inpatient stays and on diagnoses and procedures for those stays, but do not need payment data.

**PRE-ESRD MEDICARE CLAIMS CDs**

The pre-ESRD claims (also known as the back-casted claims) are a collection of Medicare institutional and physician/supplier (Part B, durable medical equipment) billing records incurred prior to the onset of ESRD. Included in these claims are any and all claims available from Medicare for incident patients during their incident year and the two prior calendar years.

The USRDS has made the pre-ESRD data available as SAFs. This dataset includes Medicare claims of ESRD patients from incident years 1995–2005. The structure of the claims file is identical to the ESRD claims files and organized by calendar year. In addition, a pre-ESRD payor sequence is provided so researchers can determine
### Medicare payment data

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Pre-ESRD claims available for 1993 to 2007; price ranges $200–600 per year and claim type.

Prices subject to change.

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</table>
Medicare enrollment for the periods prior to first ESRD service date. A listing of available files and the corresponding costs can be found in Table b.e.

**FILE MEDIA & FORMATS**

SAFS are provided on CDs and DVDs as SAS files, and can be used by SAS on any 386 or Pentium PC with a CD/DVD reader. The SAS format is widely used, easily transported, and largely self-documenting. SAS is a commercially available data management and statistical analysis software system that runs on most computers, and is almost universally available on university computer systems. The SAFS take full advantage of the program’s ability to incorporate detailed documentation into the file. Researchers needing another format or medium must arrange for the conversion.

**COSTS**

File prices cover file reproduction, documentation, administrative costs, and costs of technical support. Prices are subject to change.

**DOCUMENTATION**

The Researcher’s guide to the USRDS database provides most of the SAF documentation. It includes a codebook of variables, copies of data collection forms used by CMS, UNOS, and the USRDS Special Studies, and a chapter on using the SAFS in SAS. The guide may be downloaded from the USRDS website, and a copy on CD-ROM will be sent to researchers with the purchase of the SAFS.

**Data usage acknowledgement**

Publications using USRDS data should include an acknowledgment and this notice: The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. government.

**Data release policy**

Since the SAFS and custom data files contain confidential, patient-specific data, their release requires the approval process described here. Investigators may contact the USRDS Project Officer (PO) at the NIDDK to discuss requests before preparing a proposal. To request and use USRDS data files, investigators must provide the PO with a detailed description of the proposed investigation (see Table b.d). The summary must include goals, background data, an in-depth description of study design and methodology, and resources available for completing the project, and may be the description from a grant proposal or other application. The project must comply with the Privacy Act of 1974, and the summary should provide enough information to enable assessment of compliance. Guidelines for Privacy Act adherence are found in the “Agreement for Release of Data,” later in the appendices. With your completed research proposal, please include a signed agreement for release of information from each investigator and analyst who will use the data files.

Investigators must also indicate needed USRDS SAFS by name. If these files cannot meet requirements of the proposed research, investigators must specify precisely which data elements are needed, and budget for a substantially higher cost.

The investigator and the Coordinating Center (CC) will resolve any technical questions. The investigator will arrange payment with the CC, and payment must be received before the files will be released. Checks must be made payable to the Minneapolis Medical Research Foundation.

The NIH will review the project for technical merit and for conformity with the Privacy Act. The PO will notify the investigator(s) in writing of the outcome, and if the project is not approved will discuss reasons for the decision. The PO will send a copy of the approval letters to the CC. When payment for the files has been received by the CC, the CC will prepare the files and documentation and send them to the investigator.

Any reports or articles resulting from use of USRDS data must be submitted to the PO prior to submission for publication to assure adherence to the Privacy Act. The PO must respond within 30 days. If a report or article is determined not to adhere to the Privacy Act, it shall not be published until compliance is achieved. Assessment of compliance will not depend on the opinions and conclusions expressed by the investigators, nor will the PO’s approval indicate government endorsement of the investigator’s opinions and conclusions.

All publications using released data must contain the standard acknowledgement and disclaimer presented above. Investigators are requested to send copies of all final publications resulting from this research to both the PO and the CC.

**Caveats**

This policy establishes conditions and procedures for the release of data from the USRDS, and is intended to ensure that data are made available to investigators in the pursuit of legitimate biomedical, cost-effectiveness, or other economic research.

The USRDS will not release data that identify individual patients, providers, or facilities. Since it might be possible, however, to infer identity from SAF data, these data are considered confidential. The USRDS “Agreement for Release of Data” contains a number of general and specific restrictions on the use of USRDS data, and investigators are expected to abide by these restrictions. If individually identifiable data are needed, the request should be submitted directly to CMS. Use of these data to identify and/or contact patients, facilities, or providers is prohibited by USRDS policy and by the Privacy Act of 1974.

The USRDS CC will provide data in any of the usual media (tape, disk, or hard copy). Analytical services other than review of the proposal and preparation of the data file will not be provided under the USRDS contract, though CC personnel may participate in analyses funded by other sources.

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### Prices for the ESRD CPM/USRDS files (checks must be made payable to the Minneapolis Medical Research Foundation)

<table>
<thead>
<tr>
<th>ESRD CPM/SAF linked files</th>
<th>Cost</th>
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<tr>
<td>Core files</td>
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<td>Hospital</td>
<td>$150</td>
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<td>Transplant</td>
<td>$100</td>
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<td>DMMS/Case Mix Adequacy claims</td>
<td>$100</td>
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</table>

**ESRD CPM Survey data**


**ESRD CPM Medicare participant**

Institutional & Physician/Supplier claims are available for the years pre-1989 through 2004; $100–300 per year
Acute kidney injury (AKI) Also known as acute kidney failure or acute renal failure is a sudden decline in renal function triggered by a number of acute occurrences such as shock, trauma, drug toxicity, or kidney stones.

Acute myocardial infarction (AMI) An event causing injury to the heart muscle.

Adult polycystic kidney disease An inherited disease in which the kidneys contain multiple cysts.

Anemia A condition marked by a reduced number of red cells in the bloodstream.

Angiography A radiographic procedure where a radio-opaque contrast material is injected into a blood vessel for the purpose of identifying its anatomy.

Angioplasty A procedure in which a balloon catheter is inserted into a blocked or narrowed vessel in order to reopen the vessel and allow normal blood flow.

Angiotensin converting enzyme (ACE) inhibitor An antihypertensive agent that inhibits the production of angiotensin II. Can delay progression to diabetes or kidney disease.

Angiotensin II receptor blocker (ARB) An antihypertensive agent that inhibits the actions of angiotensin II, a substance which causes narrowing of blood vessels.

Arteriovenous fistula A type of vascular access used in hemodialysis patients, and created by the anastomosis of the radial artery and the cephalic vein.

Arteriovenous graft A type of vascular access used in hemodialysis patients and created via a connection between an artery and vein using either a native vessel (saphenous vein) or a synthetic material such as Teflon.

Atherosclerotic heart disease (ASHD) A disease of the arteries of the heart, characterized by a thickening and/or loss of elasticity of the arterial walls.

Beta blockers Antihypertensive medications that block production of noradrenaline, slowing the heart rate and preventing the constriction of blood vessels.

Blood urea nitrogen (BUN) A by-product of the breakdown of amino acids and endogenous and ingested protein.

Body mass index (BMI) A measure of height to weight ratio: weight (kg)/height (m²).

Creatine A protein produced by the liver in response to infection or injury; high levels are associated with an increased risk of heart disease and stroke.

Calcium channel blockers Antihypertensive agents that work by blocking the access of calcium to muscle cells in artery walls.

Cardiac arrest A complete cessation of cardiac activity.

Cardiac resynchronization therapy defibrillator (CRT-D) A device designed to arrest the fibrillation of (heart muscle) by applying electric shock across the chest, thus depolarising the heart cells and allowing normal rhythm to return.

Cardiomyopathy A general diagnostic term indicating a primary non-inflammatory disease of the heart muscle.

Catheter A vascular access used in hemodialysis patients, commonly implanted into the jugular or subclavian vein.

Centers for Disease Control & Prevention (CDC) The lead federal agency for protecting the health and safety of people at home and abroad; develops and applies programs designed to improve the health of the people of the United States.

Centers for Medicare and Medicaid Services (CMS) Formerly the Health Care Financing Administration (HCFA). Federal agency that administers Medicare, Medicaid, and State Children’s Health insurance programs.

Cerebrovascular accident (CVA) A general descriptor that encompasses such problems as stroke and cerebral hemorrhage.

Cerebrovascular disease A disease that causes narrowing or occlusion of the arteries supplying blood to the brain.

Chain provider A single business entity that at years end owns or operates 20 or more freestanding dialysis units. This definition applies to all chain affiliation references in the USRDS Annual Data Reports. An alternative definition from the Centers for Medicare and Medicaid Services can be found under “definitions” in the Health Care Provider/Supplier Application Form, CMS 855.

Chronic kidney disease (CKD) A condition in which there is a progressive loss of kidney function which over time may lead to end-stage renal disease.

Chronic obstructive pulmonary disease (COPD) A progressive disease characterized by coughing, wheezing, or difficulty in breathing.

Clinical Performance Measures (CPM) Project Formerly the Core Indicator Project. A project in which CMS and the ESRD networks cooperatively maintain a clinical database of key elements related to the quality of dialysis care. These elements are used as indicators in quality improvement initiatives.

Common Working File (CWF) System The Medicare inpatient/outpatient and physician/supplier benefit coordination and claims validation system. Under the CWF, CMS maintains both institutional and physician supplier claims-level data. CWF claims records are the data source for most claims and utilization files used by the USRDS.

Comprehensive Dialysis Study (CDS) A special data collection study that focuses on physical activity level, health-related quality of life, and work/disability status reported by patients who have recently started maintenance dialysis.

Congestive heart failure (CHF) A condition caused by ineffective pumping of the heart and subsequent fluid accumulation in the lungs.

Continuous ambulatory peritoneal dialysis (CAPD) A type of dialysis in which dialysate is continuously present in the abdominal cavity. Fluid is exchanged by using gravity to fill and empty the cavity 4–5 times each day.

Continuous cycler-assisted peritoneal dialysis (CCPD) A type of dialysis in which the abdominal cavity is filled and emptied of dialysate using an automated cycler machine.

Creatinine A waste product of protein metabolism found in the urine; often used to evaluate kidney function. Abnormally high creatinine levels indicate kidney failure or renal insufficiency.

Creatinine clearance Used as an indicator to predict the onset of uremia, which develops when creatinine clearance falls below 10 ml/minute/1.73 m².

Darbepoetin alfa (DPO) One of a class of medications called erythropoietic proteins. Used to treat anemia in patients with serious kidney disease.

Death Notification Form (CMS-2740) A form submitted following the death of an ESRD patient, and containing basic patient demographic information in addition to information on the primary cause of death.

Diabetes mellitus, insulin-dependent A condition in which insulin is necessary to regulate abnormally high levels of glucose (sugar) in the blood.

Diagnosis Related Groups (DRGs) Used by Medicare to determine payment for inpatient hospital stays; based on diagnosis, age, gender, and complications.

Employer group health plan (EGHP) A health plan of or contributed to by an employer, providing medical care directly or through other methods such as insurance or reimbursement to current or former employees, or to these employees and their families.

End-stage renal disease (ESRD) A condition in which a person’s kidney function is inadequate to support life.

Eprenolol stimulating agent (ESA) Used to increase the production of red blood cells; includes erythropoetin (EPO) and darbepoetin alfa (DPO).

Erythropoietin (EPO) A hormone secreted chiefly by the adult kidney; acts on bone marrow to stimulate red cell production. Also produced in a formulated version to treat anemia.
ESRD Facility Survey Data for this survey are collected annually by CMS from all facilities certified to provide Medicare-covered renal dialysis and transplantation. The survey uses CMS form 2744, and encompasses the full calendar year. Geographic data are included to the level of facility ZIP code. Each record contains facility information and data on the number of patients served, dialysis treatments provided, and kidney transplants performed. The data include services to both Medicare and non-Medicare patients.

ESRD networks Regional organizations, established by law in 1978, contracted by CMS to perform quality oversight activities to assure the appropriate-ness of services and protection for dialysis patients.

Expanded criteria donors (ECDs) Older kidney donors or donors whose health issues in the past would have prevented their acceptance into the donor program.

Glomerular filtration rate (GFR) Estimated rate in ml/min/1.73 m² of the volume of plasma filtered by the kidney. Rates of filtration are based on an individu-al’s age, gender, and height, and on levels of serum creatinine, blood urea nitrogen, and serum albumin. GFR is traditionally considered the best over-all index to determine renal function.

Glycosylated hemoglobin (HbA1c) test Used to help determine how well a patient’s diabetes is being controlled, this test measures the level of glucose-bound hemoglobin in the bloodstream.

Health Maintenance Organization (HMO) A competitive medical plan, such as Medicare+Choice, that has contracts with CMS on a prospective capitation payment basis for providing health-care to Medicare beneficiaries.

Health Service Area (HSA) A group of counties described by the authors of the CDC Atlas of United States Mortality as “an area that is relatively self contained with respect to hospital care.”

Healthy People 2020 A national agenda for health promotion and disease prevention, with objectives and goals aimed at improving the health of the Ameri-can people (www.health.gov/healthypeople).

Hemodialysis The process of removing toxins from the blood by diffusion through a semi-permeable membrane.

Hemoglobin Oxygen-carrying protein in the erythrocyte (red blood cell).

Hepatitis An inflammation of the liver that may be caused by a viral infec-tion, poisons, or the use of alcohol or other drugs. Forms include Hepatitis A, usually transmitted by contaminated food or water; Hepatitis B, more seri-ous than Hepatitis A and transmitted through blood and body fluids; Hepa-titis C, also transmitted through blood and body fluids; and Hepatitis D, which causes symptoms only when an indi-vidual is already infected with the Hepatitis B virus.

Hospital-based facility A dialysis unit attached to or located in a hospital and licensed to provide outpatient dialysis services directly to ESRD patients.

Implantable cardioverter defibrillator (ICD) An implantable device designed to ar-rest the fibrillation of (heart muscle) by applying electric shock thus depolarizing the heart cells and allowing nor-mal rhythm to return.

Incident ESRD patient A patient starting renal replacement therapy for ESRD during a calendar year. Excludes pa-tients with acute renal failure, those with chronic renal failure who die before starting ESRD treatment, and those whose treatments are not re-ported to CMS.

Incident population The people in a pop-ulation who are newly diagnosed with a disease in a given time period, typ-ically a year.

Independent unit A unit licensed to pro-vide outpatient and home mainte-nance dialysis, and not affiliated with a chain.

Ischemic heart disease (ISHD) A disease of the heart evidenced by a lowered oxy-gen supply to the heart tissue, caused by occlusion or narrowing of the arter-ies supplying the heart muscle.

Kidney Disease Outcomes Quality Initiative (KDQI) Established in 1995 by the Na-tional Kidney Foundation to improve patient outcomes and survival by pro-viding recommendations for optimal clinical practices in the areas of dialysis adequacy, vascular access, and anemia.

Kt/V An indicator of the dialysis dose per treatment, calculated by multiply-ing the urea clearance (K) by the treat-ment duration (t) and dividing by the urea distribution (V). The urea distribu-tion volume is approximately equal to the volume of total body water.

Medical Evidence form (CMS-2728) A form which provides source data about ESRD patients, including information on demographics, primary cause of re-nal disease, comorbidity, biochemical data, dialysis treatment, transplant, di-aalysis training, employment status, ini-tial insurance coverage, and first ESRD service date.

Medicare as Secondary Payor (MSP) patient A Medicare beneficiary with a health insurer other than Medicare (e.g. an Employer Group Health Plan) that has primary responsibility for payment of the beneficiary’s medical bills.

Medicare Current Beneficiary Survey (MCBS) An ongoing national survey of aged, disabled, and institutionalized Medi-care beneficiaries. Sponsored by the Centers for Medicare and Medi-care Services, and used to study the health status, health care use and ex-penditures, health insurance coverage, and socioeconomic and demograph-ic characteristics of Medicare bene-ficiaries.

Microalbuminuria A condition in which small amounts of albumin are pres-ent in the urine; indicates early kid-ney damage.

Modality A method of treatment. Treat-ment for end-stage renal disease (ESRD) is comprised of three modalities: hemodialysis, peritoneal dialysis, and transplantation.

National Health and Nutrition Examination Survey (NHANES) A survey conducted by the National Center for Health Statis-tics (NCHS) at the Centers for Disease Control and Prevention; uses home interviews and health tests to collect information on health and diet in the United States.

National Institutes of Health (NIH) The fed-eral focal point for medical research in the U.S. and one of eight health agencies of the Public Health Servic-es, which are part of the Department of Health and Human Services.

Organ Procurement and Transplantation Network (OPTN) The unified transplant network established by the United States Congress under the National Organ Transplant Act (NOTA) of 1984. A private, non-profit organization ad-ministered by the United Network for Organ Sharing, under contract with the Health Resources and Services Ad-ministration of the U.S. Department of Health and Human Services.

Percutaneous coronary intervention (PCI) A therapeutic procedure to treat the ste-notic (narrowed) coronary arteries of the heart found in coronary heart dis-ease. Commonly known as coronary angioplasty or simply angioplasty.

Period prevalent patient A patient re-ceiving treatment for ESRD at some point during a period of time, usually six months or a year. Patients may die during the period or be point preva-lent at the end of the period. Period prevalence is a useful measure for cost analysis, since it indicates total disease burden over the course of a year.

Peripheral vascular disease (PVD) A progres-sive disease that causes narrowing or occlusion of the arteries supplying the extremities of the body.

Peritoneal dialysis Dialysis in which fl uid (dialysate) is introduced into the ab-dominal cavity and uremic toxins are removed across the peritoneum.

Point prevalent patient A patient report-ed as receiving treatment for ESRD on a particular day of the calendar year (e.g. December 31).

Program Medical Management and Informa-tion System for ESRD, and Renal Benefi ciary and Utilization System (PMMIS/REBUS) The major source of data for the USRDS. This CMS file incorporates data from the Medical Evidence form (CMS-2728), the Death Notification form (CMS-2746), the Medicare Enrollment Database, CMS paid claims records, and the UNOS transplant database.

Prevalent ESRD patient A patient on renal replacement therapy or with a func-tioning kidney transplant (regardless of the transplant date). This defini-tion excludes patients with acute re-nal failure, those with chronic renal failure who die before receiving treat-ment for ESRD, and those whose ESRD treatments are not reported to CMS.

Prevalent population The people in a population who have a disease at a given point in time (point prevalence) or during a given time period (period prevalence).

Proteinuria The existence of protein in the urine; indicative of kidney damage.

Recombinant human growth hormone (rGH) Also called somatropin; a substance identical in its amino acid sequence to human growth hormone, and used to treat growth hormone deficiency.

REMS CMS’s Renal Management In-formation System (REMS), which has replaced the Renal Beneficiary and Utilization System (REBUS). Includes an operational interface to the SIMS Central Repository.

Renin Inhibitors A class of drugs used to lower blood pressure by blocking the renin-angiotensin system which regul-ates blood volume and systemic vas-cular resistance.

SIMS CMS’s Standard Information Man-agement System (SIMS), which became operational at the beginning of 2000. Supports CMS reporting requirements.
and the business processes of the ESRD networks; provides communication and data exchange links for the networks, CMS, and other parts of the renal community; supplies standard core data functionality for previous network data systems; and provides improved electronic communication capabilities, data standardization, and information management tools.

**Standard Analysis Files (SAFs)** CMS files containing final action Medicare inpatient/outpatient claims data: Inpatient, Outpatient, Home Health Agency, Hospice, Skilled Nursing Facility, Clinical Laboratory, Durable Medical Equipment, and 5 percent Sample Beneficiary.

**Standardized hospitalization ratio (SHR)**
Used to compare hospitalization rates for a selected group of patients by computing the ratio of the group's observed hospitalization rate to the expected hospitalization rate for the national ESRD population.

**Standardized mortality ratio (SMR)**
Used to compare dialysis patient mortality rates from year to year. Mortality rates for a subgroup of patients are compared to a set of reference rates, with adjustments for age, gender, race, primary diagnosis, and ESRD vintage.

**Standardized transplantation ratio (STR)**
Used to compare transplant rates for a subgroup of patients to national transplant rates.

**Statin**
Medications that lower cholesterol through action on an enzyme in the liver.

**Transient ischemic attacks (TIA)**
A temporary loss of neurological function caused by a brief period of inadequate blood supply in a portion of the brain supplied by the carotid or vertebral basilar arteries.

**United Network for Organ Sharing (UNOS)**
A private, non-profit organization that maintains the organ transplant list for the nation and coordinates the matching and distribution of organs to patients awaiting transplant.

**Urea reduction ratio (URR)**
A means of measuring dialysis dose by calculating the change in BUN over the course of a dialysis treatment. URR = (pre-dialysis – post-dialysis BUN) / pre-dialysis BUN * 100.

**Vintage**
Time in years that a patient has had ESRD.

**Wait list**
A list of patients awaiting an organ transplant; maintained by the United Network for Organ Sharing (UNOS).

Some of these definitions are obtained from the Monofacto Medical Dictionary, found at www.mondofacto.com/dictionary.

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**Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<td>Ac</td>
<td>glycosylated hemoglobin</td>
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<tr>
<td>AAPCC</td>
<td>average annual per capita cost</td>
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<td>ACE-I</td>
<td>angiotensin converting enzyme inhibitor</td>
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<td>ACR</td>
<td>albumin/creatinine ratio</td>
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<td>AKI</td>
<td>acute kidney injury</td>
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<tr>
<td>AMI</td>
<td>acute myocardial infarction</td>
</tr>
<tr>
<td>ARB</td>
<td>angiotensin receptor blocker</td>
</tr>
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<td>arteriosclerotic heart disease</td>
</tr>
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<td>arteriovenous</td>
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<td>Behavioral Risk Factor Surveillance System</td>
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<tr>
<td>BUN</td>
<td>blood urea nitrogen</td>
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<td>continuous ambulatory peritoneal dialysis</td>
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<tr>
<td>CCPD</td>
<td>continuous cycler peritoneal dialysis</td>
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<td>creatinine clearance rate</td>
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<td>Comprehensive Dialysis Study</td>
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<td>CPM</td>
<td>Clinical Performance Measures Project</td>
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<td>CVA/TIA</td>
<td>cerebrovascular accident/transient ischemic attack</td>
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<td>CPT</td>
<td>Current Procedure and Terminology</td>
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<td>CRT-D</td>
<td>cardiac resynchronization therapy defibrillator</td>
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<td>cerebrovascular disease</td>
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<td>DM</td>
<td>diabetes, diabetic</td>
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<td>DPO</td>
<td>darbepoetin alfa</td>
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<td>DRG</td>
<td>diagnosis related group</td>
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<td>ECD</td>
<td>expanded criteria donor</td>
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<td>employer group health plan</td>
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<td>erythropoiesis stimulating agent</td>
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<td>ESRD</td>
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<td>eGFR</td>
<td>estimated glomerular filtration rate</td>
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<td>GN</td>
<td>glomerulonephritis</td>
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<td>HEDIS</td>
<td>Health Plan Employer Data Information Set</td>
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<td>Health Service Area</td>
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<td>hypertension</td>
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<tr>
<td>ICD</td>
<td>implantable cardioverter defibrillator</td>
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<td>ICD-9-CM</td>
<td>International Classification of Diseases, 9th revision, Clinical Modification</td>
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<tr>
<td>IPD</td>
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<td>ISHD</td>
<td>ischemic heart disease</td>
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<tr>
<td>KDOQI</td>
<td>Kidney Disease Outcomes Quality Initiative</td>
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<tr>
<td>MCBS</td>
<td>Medicare Current Beneficiary Survey</td>
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<td>ME</td>
<td>Medical Evidence form (2728)</td>
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<td>MI</td>
<td>myocardial infarction</td>
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<td>MPP</td>
<td>Medicare as primary payor</td>
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<td>MSP</td>
<td>Medicare as secondary payor</td>
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<td>National Kidney Foundation</td>
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<td>OPTN</td>
<td>Organ Procurement and Transplantation Network</td>
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<td>PCI</td>
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<td>PPPM</td>
<td>per person per month</td>
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<td>Pppy</td>
<td>per person per year</td>
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<td>PAD</td>
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<td>peripheral vascular disease</td>
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<td>rHGH</td>
<td>recombinant human growth hormone</td>
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<td>SMR</td>
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<td>standardized transplantation ratio</td>
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<td>UNOS</td>
<td>United Network for Organ Sharing</td>
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<td>WHO</td>
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United States Renal Data System (USRDS)  
Agreement for Release of Data

Project title ____________________________________________

In this agreement, “Recipient” means ____________________________________________

A. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), through the United States Renal Data System (USRDS) Coordinating Center (CC), will provide the Recipient with tapes, disks, and/or hard copies containing data extracted from the USRDS research database.

B. The sole purpose of providing the data is the conduct of legitimate and approved biomedical, cost-effectiveness, and/or other economic research by the Recipient.

C. The Recipient shall not use the data to identify individuals on the file.

D. The Recipient shall not combine or link the data provided with any other collection or source of information that may contain information specific to individuals on the file, except where written authorization has been obtained through the approval process.

E. The Recipient shall not use the data for purposes that are not related to biomedical research, cost-effectiveness, or other economic research. Purposes for which the data may not be used include, but are not limited to,  
   • the identification and targeting of under- or over-served health service markets primarily for commercial benefit  
   • the obtaining of information about providers or facilities for commercial benefit  
   • insurance purposes such as redlining areas deemed to offer bad health insurance risks  
   • adverse selection (e.g., identifying patients with high risk diagnoses)

Any use of the data for research not in the original proposal must be approved by the USRDS Project Officer (PO).

F. The Recipient shall not publish or otherwise disclose the data in the file to any person or organization unless the data have been aggregated (that is, combined into groupings of data such that the data are no longer specific to any individuals within each grouping), and no cells (aggregates of data) contain information on fewer than ten individuals or fewer than five providers or facilities. The Recipient shall not publish or otherwise disclose data that identify individual providers or facilities, or from which such identities could be inferred. However, the Recipient may release data to a contractor for purposes of data processing or storage if (1) the Recipient specified in the research plan submitted to the USRDS Project Officer that data would be released to the particular contractor; or the Recipient has obtained written authorization from the PO to release the data to such contractor; and (2) the contractor has signed a data release agreement with the PO.

G. A copy of any aggregation of data intended for publication shall be submitted to the PO for review for compliance with the confidentiality provisions of this agreement prior to submission for publication and, if not approved, shall not be published until compliance is achieved. The PO must respond within 30 days.

H. Appropriate administrative, technical, procedural, and physical safeguards shall be established by the Recipient to protect the confidentiality of the data and to prevent unauthorized access to it. The safeguards shall provide a level of security outlined in OMB Circular No. A-130, Appendix III — Security of Federal Automated Information System, which sets forth guidelines for security plans for automated information systems in Federal agencies.

I. No copies or derivatives shall be made of the data in this file except as necessary for the purpose authorized in this agreement. The Recipient shall keep an accurate written account of all such copies and derivative files, which will be furnished upon request to the PO. The USRDS data files covered in this data use agreement may be retained by the Recipient until ________________. At the completion of the activities in the research plan, the file shall be returned to the USRDS CC at the Recipient’s expense, and any derivative files and copies shall be destroyed.

J. For the purpose of inspecting security procedures and arrangements, authorized representatives of the PO and/or of CMS will, upon request, be granted access to premises where data in this file are kept.
Lawrence Y. C. Agodoa, MD, NIDDK, NIH or Paul W. Eggers, PhD, NIDDK, NIH
USRDS Project Officer
Bayesian mortality ratios: /E.sc/S.sc/R.sc/D.sc
Bayesian hospitalization ratios: /E.sc/S.sc/R.sc/D.sc
bacteremia/septicemia
atherosclerotic heart disease (/A.sc/S.sc/H.sc/D.sc).
angioplasty: /E.sc/S.sc/R.sc/D.sc /two.oldstyle/six.oldstyle/nine.oldstyle, /two.oldstyle/seven.oldstyle/eight.oldstyle
alpha-/one.oldstyle acid glycoprotein /three.oldstyle/two.oldstyle/three.oldstyle
albumin/creatinine ratio (/A.sc/C.sc/R.sc): /C.sc/K.sc/D.sc
admission rates.
/A.sc/C.sc/E.sc inhibitors
pre-ESRD 112, 114, 115
ESRD 209, 313, 315–317
rates 124, 125, 127
pre-ESRD 112, 114, 115
ESRD 215
CKD 98, 99, 101–103
ESRD 313, 315–317
cardiovascular disease: /E.sc/S.sc/R.sc/D.sc
CKD 98–100, 102, 103
ESRD 313, 316, 317
cardiac resynchronization therapy
CKD 98, 99, 101–103
ESRD 313, 315–317
cardiovascular disease: /E.sc/S.sc/R.sc/D.sc
CKD 78
pre-ESRD 112, 114, 115
body mass index: /E.sc/S.sc/R.sc/D.sc
bypass, coronary: /E.sc/S.sc/D.sc
calcineurin inhibitors: /E.sc/S.sc/R.sc/D.sc
calcium channel blockers
CKD 78
pre-ESRD 112, 114, 115
calcium/phosphorus testing
CKD 76
ESRD 330
pre-ESRD 110
cancer: /E.sc/S.sc/R.sc/D.sc
CAPD. See dialysis cardiac arrest. See also cardiovascular disease
CKD 98–100, 102, 103
ESRD 313, 314, 316, 317
cardiac resynchronization therapy
CKD 98, 99, 101–103
ESRD 313, 315–317
cardiovascular disease: /E.sc/S.sc/R.sc/D.sc
across datasets 66, 67
albumin/creatinine ratio and 41
CKD claims and 74
CKD prevalence and 38
CKD stage and 40, 41
expenditures 133–135
glomerular filtration rate and 41
hospitalization and 86
patient distribution 37, 61
CKD claims
prior to ESRD 108
quality 74
CKD stage
cardiovascular disease and 98, 99, 102, 103
clinical and biochemical parameters and 42, 43
comorbidity and 38, 40, 44, 45
expenditures and 103
hospitalization and 86
ICD-9-CM codes 64, 65, 68
metabolic abnormalities and 68, 69
survival and 102
Comprehensive Dialysis Study
318–323
congestive heart failure (CHF)
CKD 98–100, 102, 103
ESRD 313, 314, 316, 317
coronary angiography: /E.sc/S.sc/R.sc/D.sc
CKD 98, 99, 101–103
ESRD 313, 315–317
c-reactive protein: /E.sc/S.sc/R.sc/D.sc
creatinine, serum
acuerdo kidney injury 126
CKD 38–40, 42, 44–47, 51–57, 76
ESRD 248
pre-ESRD 110
cystatin C: /E.sc/S.sc/R.sc/D.sc
37–39, 43–47, 51–57
Cystic kidney disease: /E.sc/S.sc/R.sc/D.sc
at initiation 208
ESRD 231, 237, 239
transplantation and 212
EsrD
266, 331
survival and 277
transplantation and 212, 289, 295
transport wait list and 212
diabetes: general population 208, 230
diabetes: /E.sc/S.sc/R.sc/D.sc
prescription drug therapy and 114, 115
diabetes
acute kidney injury and 129
adequacy 99, 263
cardiovascular disease and 331–337
ESRD network populations 241
expenditures 202, 203, 332, 340, 342
hospitalization and 200, 274, 275
infection and 274, 275
international comparisons 353
mortality and 210, 273, 276
patient counts
incident 194, 196, 251, 254
prevalent 194, 252, 256
patients returning from transplant 195, 295
prevalent 194, 196, 251, 255
transplantation and 212
physical activity 320–323
survival and 201, 277
transplant and 290
VolumEs One & Two of the 2009 AdR. Pages 17–138 are found in Volume One, & pages 189–354 in Volume Two.
iron therapy and 329
modality and 254, 256
mortality ratios and 314, 335
patient counts and 327, 328
preventive care and 331
time managed 328
transfusions and 329
unit counts and 328
dietitian care, pre-ESRD 210, 302
diuretics: CKD 79, 113
donation rates, transplant 288
drug therapy, prescription
acute kidney injury and 126
CKD 78, 79
ESRD 203, 215
pre-ESRD 112–115
eCD donors 287, 289
ECHO cardiograms: CKD 97
employment 318, 319
erythropoiesis stimulating agents (ESA): CKD 79
erthropoiesis stimulating agents
(expands): ESRD
expenditures 203, 322, 342
hemoglobin levels and 264
at initiation 247
in pediatric patients 303
pre-ESRD use 98
weekly dose 264
erthropoiesis stimulating agents
(expands): pre-ESRD 113
ESRD networks
HP2010 objectives and 218, 219
patient counts, growth in 240
providers and 328
expected remaining lifetimes: ESRD 276
expenditures. See also Medicare
expenditures
expenditures: CKD
cardiovascular disease 103, 133,
135, 137
chronic obstructive pulmonary
disease 133–135
diabetes 133–135, 137
overall 136, 193
expenditures: ESRD
before and after initiation 203
cardiovascular disease and 317
injectables 203
inpatient 342
non-Medicare 310, 340
outpatient 342
overall 193, 202, 203
physician/supplier 342
during transition to ESRD 341
expenditures: pre-ESRD 135
eye examinations, diabetic: ESRD 215,
216, 265, 266, 331, 333
ferritin testing: ESRD 330
Ferrlecit: ESRD 329
fistulas, arteriovenous. See
also vascular access
ESRD 245, 246, 263, 268, 278, 305,
341
prior to ESRD 116, 211
glomerular filtration rate, estimated
(eGFR): CKD
CKD prevalence and 38, 40, 53
cKd screening and 38
clinical and biochemical
parameters and 42, 43, 52,
54, 55
mortality and 47
patient distribution and 39, 52, 53
renal function measures and 54, 55
risk factors and 41
chronic obstructive pulmonary
disease and 86
CKD stage and 68
days 66, 68
hypertension and 86
infection and 87
for pneumonia 88, 89
predictors 86
for urinary tract infection 88, 89
hospitalization: ESRD
admissions 274, 275, 278
all-cause 200, 274, 275, 341
for bacteremia/sepsis 275
cardiovascular disease and 200,
226, 227, 294, 341
case-specific 200, 278
dialysis unit admission and 334, 335
expenditures 341
first-year 226, 227
hospital days 274
infection and 210, 226, 227, 278,
294
modality and 274, 275
in pediatric patients 306
for peritonitis 275
for pneumonia 275
rates 354, 335
in transplant recipients 294
vascular access and 200, 274, 275,
278
hyperlipidemia: CKD 44, 45
hypertension: CKD
cross datasets 66
albumin/creatinine ratio and 41
CKD prevalence and 38
CKD stage and 38, 40, 41, 44, 45, 68
glomerular filtration rate and 41
hospitalization and 86
hypertension: ESRD
ESRD networks and 240
at initiation 208
modality and 254, 256
patient counts 194, 237, 239
rates of ESRD due to 194, 237, 239,
340
survival and 277
glomerulonephritis: ESRD
preclinical networks 240
at initiation 208
cases and 329
count and 334
survival 332
survival and 334
survival 277
transplantation and 212, 289
immunizations
CKD 127
ESRD 207, 209, 215, 265, 301, 306
immunosuppression medications
292
implantable cardioverter
defibrillators
CKD 98, 99, 101–103
ESRD 313, 355–317
incidence: CKD
ICD-9-CM codes and 64, 65
patient rates 65
incidence: ESRD
after acute kidney injury 128, 129
diabetes and 214, 219, 231, 237
ESRD network populations 240, 241
international comparisons 347, 348,
350, 351
mean age and 240
median age and 237
modality and 194, 196, 197, 254, 255,
300, 301
patient counts 194, 196, 236, 237, 254
pediatric 194, 236, 254, 300
patient rates 194, 196, 197, 208, 218,
236, 237, 254, 347, 350
pediatric 194, 208, 236, 254
by payer 237
primary diagnosis and 194, 237
preclinical networks 239
infection: CKD
hospitalization and 87–89
during transition to ESRD
transplant 202
vascular access 343
metabolic abnormalities: CKD 68, 69
microalbumin testing
acute kidney injury 126
CKD 71
ESRD 216
modality: ESRD