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Elsewhere the sky is the roof of the world; but here the earth was the floor of the sky.

Willa Cather, Death Comes for the Archbishop

In this appendix we describe the datasets and methods used for the analyses in this volume. Appendix B includes information on 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 the official form for registering ESRD patients, and must be submitted by dialysis or transplant providers within 45 days of ESRD initiation. The CMS, USRDS, and renal research communities rely on the ME 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 key revision of the ME form, released in May, 2005, was meant 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.

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 digits of the CMS Health Insurance Claims (HIC) number: 05, 20, 45, 70, and 95. Since the same two-digit numbers are used each year to create the 5 percent general Medicare SAFS, 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) SAFS.

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 2010 ADR includes all claims up to December 31, 2008.

MEDICARE CURRENT BENEFICIARY SURVEY (MCBS)

The MCBS is a longitudinal survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries. It 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

(1992–2007), and Cost and Use (1992–2006), with the 2007 and 2006 files, respectively, the latest updates for the 2010 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 new participants added each fall to keep the overall sample size at approximately 12,000 each calendar year.

CMS PRESCRIPTION DRUG EVENT (PDE) FILE

In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), amending the Social Security Act by adding Part D under Title XVIII. With this new Part D coverage, health plans must submit a summary record called the prescription drug event (PDE) record to CMS whenever a Medicare beneficiary fills a prescription. The PDE record contains 37 data elements; the USRDS receives PDE records with 30 elements, excluding a few non-critical fields. Each drug is identified by a National Drug Index (NDC) code; the record also contains prescription dosing information, drug costs above and below the out-of-pocket threshold, other true out-of-pocket (TrOOP) amounts, plan paid amounts, and low-income cost-sharing subsidy amounts.

Due to delays in the availability of the data, only the 2006 and 2007 PDE files were available for the 2010 ADR. The USRDS will, however, include both 2008 and 2009 PDE data in its 2011 ADR.

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, Aggregated Populations 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 includes commercial health data from approximately 100 payors; about 80 percent of those covered are self-insured. Each year the 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, non-capitated health plan database covering employees from multiple employers within a single insurer. In addition to the usual service encounter and drug data, it also includes laboratory data, allowing for comparisons between claims-based and lab-based definitions of diseases. 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 2008, 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 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 oversampled 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 EGHP, MSP non-EGHP, Medicare Advantage (Medicare + Choice), Medicaid, or a combination of payors. 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.

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 consecutive months of dialysis service and with dialysis service claims in at least 70 percent of treatment months. Treatment months are defined by the period from the first dialysis claim to the earliest of kidney transplant, death, or end of enrollment. Both inpatient and outpatient claims are evaluated for evidence of dialysis service history.

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.

IDENTIFICATION OF MAJOR COMORBIDITIES

According to a previously validated method for using Medicare claims to identify diabetic patients, a patient is diabetic if, within a one-year observation period, he or she has a qualifying ICD-9-CM diagnosis code of diabetes on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or two or more institutional outpatient claims and/or physician/supplier claims. We employ the same methodology to identify major comorbidities, using the following codes: diabetes, 250.xx, 357.2, 362.0x, and 366.41; hypertension, 362.11, 401.x–405.x, 437.2; CKD, 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 403.x1, 403.x0 (after October 1, 2006), 404.x2, 404.x3, 404.x0 and 404.x1 (after October 1, 2006), 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; congestive heart failure, 398.91, 402.x1, 404.x3, 422.xx, 425.xx 428.xx, V42.1; and CVD (other than CHF), 404.x1, 410–414, 420–421, 423–424, 426–427, 429, 430–438, 440–444, 447, 451–453, 557, 785.0–785.3, V42.2, V43.3, V45.0, V45.81, V45.82, and V53.3.

PRÉCIS

For a description of analytical methods related to age, gender, race, ethnicity, comorbidity, CKD stage, and estimated glomerular filtration rate in Table p.a, see the discussion for Chapter One, below.

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

CHRONIC KIDNEY DISEASE IN THE GENERAL POPULATION

CHAPTER ONE

DATABASE DESIGN, SETTING, & STUDY PARTICIPANTS

The surveys used in this chapter include NHANES III (1988–1994), NHANES 1999–2000, NHANES 2001–2002, NHANES 2003–2004, and NHANES 2005–2006, and populations are limited to participants age 20 and older. The public use NHANES III Linked Mortality File provides mortality follow-up data from the date of NHANES III survey participation (1988–1994) through December 31, 2006. Study populations using these data are limited to participants age 20 and older, and the mortality follow-up month is greater than zero.

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 African American, 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?"

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 three methods. The first is the MDRD method, using the standardized creatinine value for NHANES III and NHANES 1999–2000, 2001–2002, 2003–2004, and 2005–2006, separately, based on NCHS recommendations. The equation 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 African American).

Second is the CKD-EPI method, based on the standardized creatinine value for the NHANES cohorts, as listed above. The equation is as follows (Levey et al.): estimated GFR = 141 * min(Scr /κ, 1)**α * max(Scr/κ, 1)**(-1.209) * 0.993**age * 1.018 [if female] * 1.159 [if African American], where Scr is standardized serum creatinine in mg/dl, κ is 0.7 for females and 0.9 for males, α is -0.329 for females and -0.411 for males, min indicates the minimum of Scr/ κ or 1, and max indicates the maximum of Scr/κ or 1.

The third 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 of 60 or greater 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, the 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 by the method indicated in the figure titles. CKD includes Stages 1–5; all other comorbidities are self-reported.

Table 1.e and Figure 1.10 present data on awareness, treatment, and control of various metabolic markers by CKD stage. Patients are classified as hypertensive if measured systolic blood pressure is ≥ 140 mmHg (≥ 130 mmHg for CKD or diabetic patients) or measured diastolic blood pressure is ≥ 90 mmHg (≥ 80 mmHg for CKD or diabetic patients), or if they self-report currently taking a prescription to control hypertension. Patients are classified as being aware of hypertension if they report having been told they have high blood pressure, 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 blood pressure is < 140/< 90 (< 130/< 80 for CKD or diabetic patients).

Control of hyperlipidemia is assessed in a similar fashion. Hyperlipidemia is defined as a measured LDL cholesterol above the ATP III target range (≥ 160 mg/dl for patients with 0–1 risk factors, ≥ 130 mg/dl for patients with two or more risk factors, ≥ 100 mg/dl for patients with coronary heart disease (CHD) and CHD risk equivalents). CKD is classified as a CHD risk equivalent. Awareness of hyperlipidemia is assessed by self-report of being told by a doctor that blood cholesterol level is high, and patients are classified as being treated for hyperlipidemia if they report 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 in Table 1.e and Figure 1.11–12; awareness and treatment, however, are not assessed, since LDL cholesterol is currently the recommended target of therapy.

Control of diabetes is presented in Table 1.e and Figure 1.13. 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.

CHRONIC KIDNEY DISEASE IDENTIFIED IN THE CLAIMS DATA

Chapter Two

Figure 2.1 illustrates the extent of point prevalent diabetes, cancer, congestive heart failure, and CKD in the general Medicare population. Methods are the same as those described at the beginning of Chapter Nine.

Table 2.a compares the characteristics of prevalent general Medicare, MarketScan, and Ingenix i3 CKD patients by age, gender, comorbidity, and occupation in 2008. Each comorbidity is defined by medical claims (one inpatient or two outpatient) during each calendar year. Figures 2.2–3 include prevalent Medicare (age 65 and older) and MarketScan and Ingenix i3 (age 20–64) patients, without ESRD, and surviving 2008; Figure 2.2 also excludes patients with CKD in 2007. CKD is also defined by medical claims (one inpatient or two outpatient) during each calendar year.

Figures 2.4–6 and 2.10–13 illustrate the incidence, and Figures 2.7–9 and 2.14–17 the prevalence, of recognized CKD in the Medicare, Marketscan, and Ingenix i3 datasets. The 5 percent Medicare sample includes patients age 65 and older, without ESRD, surviving throughout the cohort year with Medicare as primary payor, and not enrolled in Medicare Advantage. The MarketScan and Ingenix i3 cohorts are constructed in a similar fashion, but restricted to patients age 20–64, enrolled in a fee-for-service plan, and without ESRD. Patients with CKD in the prior year are excluded when defining incident CKD.

Table 2.b and Figures 2.18–19 illustrate the percentage of prevalent CKD patients with different comorbidities, and include general Medicare patients age 65 and older with both inpatient/outpatient and physician/supplier coverage during the calendar year. All patients survive to the end of each calendar year; ESRD patients are excluded. All comorbidities are identified by claims (one inpatient or two outpatient) during each calendar year.

In Table 2.c and Figure 2.21–26, CKD is defined as follows: Stage 5: eGFR < 15 ml/min/1.73 m^2; Stage 4: 15 ≤ eGFR < 30; Stage 3: 30 ≤ eGFR < 60; stage 3-5: eGFR <60. Comorbidities such as hypertension, CVD, COPD, hepatitis C, cancer, anemia, and liver disease, along with hospitalization, are defined from claims; other metabolic abnormalities are defined from laboratory test results. GFR is estimated using both the MDRD and the CKD-EPI equations.

Figure 2.20 illustrates the distribution of eGFR by CKD diagnosis codes, and includes CKD defined using all codes, CKD stage diagnosis codes (585.x), diabetes with renal manifestations (250.4), and hypertensive kidney disease with CKD (403.x1). GFR is estimated using both the MDRD and the CKD-EPI equations.

CARE OF PATIENTS WITH CHRONIC KIDNEY DISEASE

Chapter Three

Figure 3.1 shows the cumulative probability of non-CKD patients receiving a first urinary microalbumin measurement at month 12 in the second year of each two-year period. The general Medicare population includes patients continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program during the first year, and age 65 or older at the beginning of that 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 the first year, have a missing date of birth, or do not live in the 50 states, the District of Columbia, Puerto Rico, or the Territories. The Ingenix i3 population includes patients continuously enrolled in a fee-for-service plan in the first year and age 50–64 during that year; patients diagnosed with CKD or ESRD during that year are excluded.

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

CPT codes used to define urinary microalbumin measurement are 82042, 82043, 82044, and 84156. Diabetes and hypertension are defined in the first year. Methods of defining CKD, diabetes, and hypertension are the same as those described above in the section titled "identification of major comorbidities."

Figure 3.2 includes patients from the 5 percent Medicare sample, age 66 and older, who survive all of 2008 with Medicare as primary payor and are not enrolled in Medicare Advantage; patients with CKD or ESRD in 2007 are excluded. The first CKD claim is identified in 2008 by the regular CKD diagnosis codes, excluding 584. Calendar year 2007 is used to define diabetes and congestive heart failure by the standard method, and the Kaplan-Meier method is used to obtain the cumulative probability. The same method is used for 2002 and 2005. 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.

A similar cohort is used in Figure 3.3, but only ESRD patients are excluded. The first nephrologist claim in 2002, 2005, and 2008 is identified for Medicare patients from the physician specialty codes on physician/supplier claims, for MarketScan patients from pro-

vider codes on inpatient and outpatient claims, and for Ingenix i3 patients from provider category codes on inpatient, outpatient, or physician/supplier claims. Figure 3.4 is similar, but restricted to patients with CKD.

Figure 3.5 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, and who develop CKD in 2007; patients with CKD in 2006 or ESRD in 2007 are excluded. Calendar year 2007 is used to define CKD by the standard method, while calendar year 2006 is used to define diabetes and congestive heart failure, also by the standard method. The Kaplan-Meier method is then used to obtain the cumulative probability of a physician visit 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 as described for Figure 3.3. Constructed in a similar fashion, Figure 3.6 is restricted to 2007 CKD patients with diabetes, Figure 3.7 to 2007 CKD patients with congestive heart failure, and Figure 3.8 to 2007 CKD patients with both diabetes and CHF.

Figures 3.9–16 include 2007 CKD patients; and show the cumulative probability of testing during one year. The cohort for Figures 3.9–12 and 3.14–16 is the same as that described for Figure 3.4; the cohort in Figure 3.13 is similar, but limited to diabetic CKD patients. Patients are followed from January 1, 2008, to December 31, 2008, and the Kaplan-Meier method is used to obtain the cumulative probability. Tests are identified from HCPCS codes in outpatient and physician/supplier claims during the year, as follows: microalbumin testing, 82042, 82043, 82044, and 84156; creatinine testing, 80048, 80050, 80053, 80069, and 82565; calcium/phosphorus testing, 82310, 80048, 80050, 80053, 80069, and 84100; parathyroid hormone testing, 83970; lipid testing, 80061, 82465, 83700, 83701, 83715, 83716, 83717, 83718, 83719, 83720, 83721, and 84478; glycosylated hemoglobin testing, 83036 and 83037; hemoglobin testing, 85013, 85014, 85018, 85025, 85027, 80050, and 80055; and iron saturation testing, 83550, 83540, and 84466.

Figures 3.17–24 include CKD patients in the 2007 entry period, and show the cumulative probability of medication use during the 12-month study period in 2008. 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. All comorbidities are defined by medical claims (one inpatient or two outpatient) during the entry period.

Figures 3.25–26 include 2008 CKD Ingenix i3 patients, age 50–64. Patients survive all of 2008, are enrolled in a fee-for-service plan for the entire year, and use a statin at least once during the year. Calendar year 2008 is used to define CKD, diabetes, and CHF by the standard method. For CKD patients on a statin, controlled total cholesterol is less than 200 mg/dl and controlled LDL is less than 100 mg/dl. Figures 3.27–28 use a similar cohort, but include only 2008 CKD patients with diabetes and with at least one use of diabetic drugs in 2008. The controlled A1c level is less than 7 percent.

MORBIDITY & MORTALITY

CHAPTER FOUR

HOSPITALIZATION

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 ⅛. However, since stage-specific ICD-9-CM codes for CKD do not appear until 2006, models for adjusted rates by CKD stage (Table 4.a and Figures 4.2–6) include only two years of data: 2007 and 2008 point prevalent patients with CKD defined in 2006 and 2007, respectively, with weights of 1 and ¼. Adjusted rates reflect the distribution of a reference cohort specified below in the discussion of the respective figures. 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 4.1 compares all-cause hospital admission rates for 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 who are age 66 and older on December 31 of the prior year, residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories, continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, without HMO coverage, and 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, peripheral vascular disease, CVA/TIA, atherosclerotic heart disease, congestive heart failure, dysrhythmia, and other cardiac disease. The reference cohort includes Medicare patients in 2005, age 66 and older.

Table 4.a and Figure 4.2 show adjusted admission rates in Medicare patients age 66 and older. Study design, censoring, and inclusion criteria generally follow those described for the Medicare cohort in Figure 4.1. Groups for diabetes and congestive heart failure are mutually exclusive. Follow-up for hospital admissions starts on January 1, 2008, with the model-based adjustment method described above. Adjustment factors include those listed for Figure 4.1 in addition to age and race, and with diabetes and congestive heart failure combinations rather than as separate factors. Rates presented by one factor are adjusted for the others. The reference cohort includes Medicare patients in 2008, age 66 and older.

Figures 4.3–6 show adjusted all-cause and cause-specific admission rates by CKD diagnosis code and dataset. Again, study design, censoring, and inclusion criteria generally follow the description for the Medicare and MarketScan cohorts in Figure 4.1. Additionally, Ingenix i3 data include point prevalent patients on January 1, 2008, continuously enrolled in a fee-for-service or commercial health plan and without ESRD during 2007, and age 50–64 on December 31, 2007. The group labeled "CKD" includes those with claims-based evidence of CKD in 2007, while "non-CKD" is defined as patients without claims-based evidence of CKD. Rates are adjusted for the same factors listed for Figure 4.1. 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. The reference cohort includes Medicare patients in 2008, age 66 and older.

Figures 4.7–12 illustrate geographic variations in admissions for pneumonia, bacteremia/septicemia, and urinary tract infection among Medicare patients point prevalent on January 1, 2008. Patients are 66 or older on December 31, 2007, and, during 2007, classified by their claims-based CKD status, without ESRD, and 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, 2008, 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/septicemia, 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 4.13–15 present cause-specific hospital admission rates for Medicare patients age 66 and older. Study design, censoring, and inclusion criteria again follow the description for Figure 4.1. Admissions for pneumonia, bacteremia/septicemia, and urinary tract infection are identified by the principal ICD-9-CM diagnosis codes listed for Figures 4.7–12. Rates are presented by race and adjusted for age, gender, prior hospitalization, peripheral vascular disease, CVA/TIA, atherosclerotic heart disease, congestive heart failure, dysrhythmia, other cardiac disease, diabetes, COPD, hypertension, liver disease, gastrointestinal disease, cancer, and anemia. The reference cohort includes Medicare patients in 2005, age 66 and older.

MORTALITY

Figures 4.16–18 illustrate trends, by CKD status, in unadjusted and adjusted all-cause mortality by age, gender, and race. The study cohort for 1995 includes 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 ESRD and the end of Medicare entitlement. Patients not living in the 50 states or the District of Columbia are excluded. Cohorts for 1996–2008 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 4.b shows adjusted rates of mortality per 1,000 patient years at risk in 2008 for patients with and without CKD, and by CKD stage. The cohort definitions are same as those defined in Figures 4.16–18. Adjusted mortality is based on a Cox regression model; rates by age are adjusted for gender, race, and comorbidities; rates by gender are adjusted for age, race, and comorbidities; and rates by race are adjusted for age, gender, and comorbidities. All 2008 patients are used as reference. Figure 4.19 is based on the results obtained from Table 4.b; adjusted mortality is adjusted for all of the above covariates.

CARDIOVASCULAR DISEASE IN PATIENTS WITH CHRONIC KIDNEY DISEASE

CHAPTER FIVE

Figure 5.1 illustrates cardiovascular prescription drug use in 2007 Medicare enrollees with chronic kidney disease. Patients are alive and at least 66 years of age on January 1, 2007, survive and carry Medicare Parts A, B, and D during all of 2007, and are not enrolled in an HMO during 2007. Chronic kidney disease is defined from Medicare claims during 2006, and drug use by at least one prescription fill during 2007. Particular agents are identified from National Drug Codes on Part D claims, linked to the 2007 edition of Red Book.

Table 5.a describes prescription drug therapy in Medicare enrollees with their first diagnosis for cardiovascular disease (CVD) or receiving their first treatment for CVD in 2007. The index events for CVD include acute myocardial infarction (AMI), atrial fibrillation (AF), cerebrovascular accident/transient ischemic attack (CVA/TIA), congestive heart failure (CHF), and peripheral arterial disease (PAD), while the index events for CVD treatment include 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).

For each of the index events, a study cohort is identified from the 2007 general Medicare database. Patients have the index event during 2007, are continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, are not enrolled in an HMO during the one-year period before the index event, are 66 or older on the date of the index event, and reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients diagnosed with ESRD prior to the index event are excluded. The twelve-month period prior to the index event is the baseline period, and CKD patients and CKD stage are identified based on Medicare claims during this period, using the same methodology described for Chapter Two. Patients with a pre-existing condition of the index event are also identified during the baseline period, but are not excluded in the analysis for Table 5.a.

Using the method employed to identify patients with CKD, we identify those with pre-existing AMI, AF, CVA/TIA, or CHF during the baseline period. ICD/CRT-D is defined through ICD-9-CM procedure codes in inpatient/outpatient claims, and PCI and CABG are identified through ICD-9-CM procedure codes in inpatient/outpatient claims or CPT codes in physician/supplier claims. PAD is defined through either diagnosis codes or procedure codes; if defined through diagnosis codes, we use the standard method; if defined through procedure codes, we employ the method used for PCI and CABG. AMI, AF, CVA/TIA, CHF, PAD, first PCI and CABG surgery, and the first use of ICD/CRT-D are defined on the date of the first appearance of diagnosis or procedure codes in the 2007 claims.

With the exception of AMI, the data sources and methods used to define each event are the same as those used in defining the pre-existing condition at baseline. The AMI event is defined as the first appearance of the diagnosis code on an inpatient claim.

The same codes are used to define AF, PAD, PCI, CABG, and ICD/CRT-D as pre-existing conditions at baseline and as an event in 2007, while different codes are used for CHF, CVA/TIA and AMI:

- AF: 427.3 (ICD-9-CM diagnosis codes)
- AMI, 410 and 412 for condition at baseline; 410, 410.x0, and 410.x1 for event (ICD-9-CM diagnosis codes)
- CHF: 398.91, 422.xx, 425.x, 428.xx, 402.x1, 404.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 (ICD-9-CM diagnosis codes)
- CVA/TIA: 430–438 for condition at baseline; 430–437 for event (ICD-9-CM diagnosis codes)
- PAD: 440–444, 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, 34151, 34201, 34203, 34800–34834, 35081–35103, 35331, 35341, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35450, 35452, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35480, 35481, 35482,35483, 35485, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35663, 35665, 35666, and 35671 (CPT codes)

- CABG surgery: 36.1x (ICD-9-CM procedure codes); 33510–33523 and 33533–33536 (CPT codes)
- PCI: 00.66, 36.01, 36.02, 36.05, and 36.06 (ICD-9-CM procedure codes); 92980–92982, 92984, and 92995–92996 (CPT codes)
- ICD: 37.94 (ICD-9-CM procedure code)
- CRT-D: 00.51 (ICD-9-CM procedure code)

Table 5.a and Figures 5.2–5 include Medicare enrollees with a CVD event between January 1, 2007, and November 30, 2007, discharged within two weeks of the date of the index event (if the enrollee was hospitalized at the time of the event), remaining outside the hospital at one month after the date of the index event, and carrying continuous Medicare Part D coverage during the interval from one month before to one month after the date of the index event; use of a particular drug is defined by at least one filling of a prescription for the drug during this interval. Drugs are identified from National Drug Codes included on Part D claims, and linked with the 2007 edition of Red Book.

Figure 5.6 describes all-cause survival in Medicare patients with a first diagnosis of CHF, AMI, AF, or CVA/TIA (index event) in 2007–2008. The study cohorts are constructed as for Table 5.a., except that the period searched for the index event extends to 2008. To estimate all-cause survival after CHF, patients with pre-existing CHF are excluded. Follow-up begins on the CHF diagnosis date and ends at the earliest of death, ESRD diagnosis, one year after CHF diagnosis, or December 31, 2008. The Kaplan-Meier method is used to estimate all-cause survival.

Figure 5.7 presents rates of rehospitalization for any disease and for rehospitalization/death in CKD patients with a first hospitalization or treatment for CVD (as described for Table 5.a) during 2007–2008. The cohorts are constructed as for Table 5.a, except that we first search Medicare Part A inpatient claims in 2007–2008 to identify Medicare enrollees who are admitted to the hospital for CVD or receiving CVD treatment (index hospitalization event) for the first time, and who are discharged alive. Patients diagnosed with ESRD prior to or on the discharge date are excluded. CKD patients are identified during the one-year period prior to the discharge date using the methodology described for Chapter Two. Patients with a pre-existing condition of the same index disease or treatment are identified during the one-year period prior to the admission date using the method described for Table 5.a.

To examine rates in patients admitted to the hospital for CHF, patients with pre-existing CHF are excluded. To track the occurrence of rehospitalization, follow-up begins on the day after the discharge date and ends at the earliest of rehospitalization for any disease, death, ESRD diagnosis, change of Medicare inpatient/outpatient and physician/supplier coverage, enrollment in an HMO, one year after discharge, or December 31, 2008. To track the occurrence of death, follow-up does not end at the admission date of rehospitalization; the combined event of rehospitalization and death is defined as the occurrence of either rehospitalization or death, and time to the combined event is time to rehospitalization or time to death, whichever is shorter. The event rate is calculated by dividing the total number of events by the total person-time at risk. The same method is then used to calculate rates after each of the other index hospitalization events.

Figure 5.8 presents, by CKD status and stage, the cumulative probability of rehospitalization for any disease and for the combined event of rehospitalization/death in Medicare patients with a first hospitalization for CHF, AMI, AF, or CVA/TIA during 2007–2008. Study cohorts are constructed as for Figure 5.7, including Medicare patients without CKD during one year prior to the index event. The follow-up time and the occurrence of outcomes are defined using the method employed in Figure 5.7, and the Kaplan-Meier method is used to estimate probabilities.

Figures 5.9–12 show geographic variations in rates of prevalent CHF, cardiac arrest, AMI, and CVA/TIA in 2008 for Medicare CKD and non-CKD patients. The study cohort includes point prevalent Medicare enrollees on December 31, 2007, age 66 and older, residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories, continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, and not enrolled in an HMO in 2007. Patients diagnosed with ESRD are excluded; those with CKD are identified using the method described for Chapter Two. To track the occurrence of CHF, AMI, CVA/TIA, and cardiac arrest, patients are followed from January 1, 2008, to the earliest of death, ESRD diagnosis, change of Medicare inpatient/outpatient and physician/supplier coverage, enrollment in an HMO, or December 31, 2008. Patients with CHF, AMI, and CVA/TIA are identified using the methods described for Table 5.a. Patients with cardiac arrest are identified through an ICD-9-CM diagnosis code of cardiac arrest (427.4 and 427.5) on a claim from either inpatient/outpatient institutional claims or physician/supplier claims. The proportion of patients with each of the four events in 2008 is calculated for each HSA or state by CKD status, and presented per 1,000 patients. HSA-level map data are smoothed using a Bayesian spatial hierarchical model (described in the section on statistical methods in the Volume Two appendix).

Figures 5.13–16 illustrate geographic variations in prescription drug use in Medicare CKD and non-CKD patients with a first diagnosis for CHF or AF in 2007. Methods for cohort construction and identification of prescription drug use are those used in Table 5.a. CHF medications include angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, and beta blockers, while atrial fibrillation medications include warfarin, clopidogrel, and amiodarone.

Figures 5.17–19 illustrate the distribution of prescription drug use in Medicare CKD and non-CKD patients with a first diagnosis for CHF, AMI, or AF in 2007. Methods for cohort construction and identification of prescription drug use are as those used in Table 5.a.

Total solar eclipse photographed by Charles A. Herzog, MD, on March 7, 1970, Virginia Beach, Va. Nikkormat FTN with 90–230mm Soligor zoom lens and 2X "Tel-extender" for effective focal length of 460mm. Exposure: ½ second at F9; film: high speed Ektachrome (400 ASA).

OUTCOMES IN THE TRANSITION ZONE IN NURSING HOME PATIENTS WITH CKD

CHAPTER SIX

ESRD PATIENTS

The ESRD cohort in this chapter includes nursing home patients initiating ESRD in 2004–2006, age 65 and older at the time of ESRD, and in the nursing home at least 90 days, with at least one Minimum Data Set (MDS) assessment prior to ESRD. Included patients either

die or remain in the nursing home for one year after ESRD. Baseline and follow-up are as follows:

- baseline: up to 180 days prior to ESRD. Assessment used is the last one prior to ESRD.
- follow-up period one: Assessment used is the first one at least 10 days after ESRD, but allowed to be as late as 60 days after ESRD.
- follow-up period two: Assessment used is the closest one to 180 days (six months) after ESRD, but allowed to be as early as 150 days (five months) after ESRD. If there is no valid assessment during that period, the first assessment between 180 and 210 days after ESRD is used.
- follow-up period three: Assessment used is the closest one to 360 days (12 months) after ESRD, but allowed to be as early as 330 days (11 months) after ESRD. If there is no valid assessment during that period, the first assessment between 360 and 390 days after ESRD is used.

CKD & NON-CKD PATIENTS

The CKD and non-CKD cohorts in this chapter include Medicare patients from the 5 percent sample, 2004–2005, in the nursing home and age 65 and older as of December 31 of those years. CKD is identified from claims (one inpatient or two or more outpatient/Part B claims) during 2004 or 2005. Included patients either die or remain in the nursing home for the entire calendar year; those who progress to ESRD are excluded. MDS data during 2004–2006 are then used, and baseline and follow-up are as follows:

- baseline: up to 180 days prior to January 1 of the year. Assessment used is the last one prior to January 1 of the year.
- follow-up periods one to three: the same methodology is used as for the ESRD patients, substituting January 1 of the appropriate year for the ESRD date.

Demographic information in Figure 6.1 is obtained from either the USRDS demographic profile (ESRD patients), or the 5 percent denominator file (CKD and non-CKD patients). Comorbidity is obtained from MDS assessments from up to one year prior to baseline.

There are several types of scores calculated from the MDS assessments at each time period: memory scores in Figures 6.2–4, decision scores in Figures 6.5–7, scores related to making oneself understood in Figures 6.8–10, and Activities of Daily Living (ADL) scores in Figures 6.11–14 and Table 6.a. These are calculated as follows:

- memory score (0–6 points): B2a = 0 (1 point), B2b = 0 (1 point), B3a–d (1 point for each checked answer)
- decision score (0–3 points): B4 = 0 (3 points), 1 (2 points), 2 (1 point), 3 (0 points)
- understood score (0–3 points): C4 = 0 (3 points), 1 (2 points), 2 (1 point), 3 (0 points)
- ADL score (0–28 points): 0–4 points from each of the following questions, based on what was reported. 0 = independent (0 points), 1 = supervision (1 point), 2 = limited assistance (2 points), 3 = extensive assistance (3 points), 4 = total dependence (4 points).
  - G1a: bed mobility
  - G1b: transfer
  - G1c: walk in room (a value of 8 = 'did not occur in last 7 days' was given 4 points)
  - G1g: dressing
  - G1h: eating
  - G1i: toilet use
  - G1j: personal hygiene

Most figures are self-explanatory. For Figures 6.4, 6.7, 6.10, 6.13, and 6.14, patients are required to survive with an assessment for the two periods being compared. That is, some of the patients included in the calculation of "average change" from "baseline to follow-up one" may die in follow-up periods two or three.

The distribution of ADL scores in Figure 6.11 for each time period excludes patients who die during or prior to that particular period.

Unadjusted survival in Figure 6.15 is from Kaplan-Meier methods. The overall adjusted relative risk of death in Figure 6.16 is adjusted for age, race, and gender; the RR for one category is adjusted for the remaining ones. In Figures 6.15–16 and Table 6.b, patients are considered to have died during a follow-up period if they die before the end of the period (60, 210, or 390 days) and have no valid assessment in that period prior to death.

THE TRANSITION TO END-STAGE RENAL DISEASE

CHAPTER SEVEN

Figures 7.1–6 include incident ESRD patients (Medicare patients are limited to those age 67 and older). For Figure 7.2, the type of CKD claim represents the code present on the first CKD claim. If there are multiple CKD claims and/or codes on the same date as the first claim, the type of claim is determined by the following hierarchy: 585.4, 585.3-5, 585.1-2, 585.9/other. In Figures 7.3–6, CKD stage, identified from claims, is defined using the highest coded stage in quarters -8 to -5. Physician specialty is identified from claims; physician visits in Figure 7.3 include those to a primary care physician, cardiologist, or nephrologist, 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 2008, and show the cumulative percentage of patients with at least one test during the four quarters before the first ESRD service date. Tests are identified from outpatient and physician/supplier claims during the two years, as follows: microalbumin, HCPCS codes 82042, 82043, 82044, and 84156; parathyroid hormone, HCPCS code 83970; creatinine, HCPCS codes 80048, 80050, 80053, 80069, and 82565; lipid, HCPCS codes 80061, 82465, 83715, 83716, 83717, 83718, 83719, 83720, 83721, and 84478; and glycosylated hemoglobin, 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, based on CKD diagnosis codes. The cohort includes 2008 incident MarketScan and Ingenix i3 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.

Figures 7.21–22 and Table 7.a illustrate the percentage of patients on specific drugs prior to and after ESRD initiation, and use the same study cohort as Figures 7.13–20.

ACUTE KIDNEY INJURY

CHAPTER EIGHT

In this chapter, patients with a hospitalization for acute kidney injury (AKI), or for AKI requiring dialysis (AKI-D) are identified from inpatient claims by the presence of ICD-9-CM code 584.x or by indi-

cation of dialysis through 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 time frame 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.

Figure 8.2 shows 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 2008 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.

Figures 8.3–7 use the same cohorts described for Figure 8.1. Figures 8.3–4 show rates per time at risk, while Figure 8.5 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 8.6 shows the percentage of hospitalized AKI patients who receive ACEs/ARBs or statins during the same year as their AKI, and Figure 8.7 illustrates the principle diagnosis that appears on AKI claims.

Figures 8.8–11 present hazard ratios for AKI hospitalization, adjusted for age, gender, and race. The study cohort includes 2007 general Medicare patients age 66 and older, along with 2007 MarketScan and Ingenix i3 patients age 20–64. Patients with ESRD before January 1, 2008, are excluded. Each patient is followed from this date to the earliest of death (Medicare patients only), ESRD diagnosis, change of enrollment, or December 31, 2008.

Figure 8.12 illustrates geographic variations in unadjusted rates of AKI and AKI-D in 2003 and 2008 for general Medicare patients. The cohort is constructed as in Figure 8.2, but is restricted to those residing in the 50 states and the District of Columbia.

Methods of identifying the type of physician visit for Figures 8.13–14 are the same as those described in the methods for Chapter Seven. In Figure 8.14, multiple physician claims for the same specialty during the same inpatient stay are counted only once.

Testing in Figures 8.15–16 is identified as follows: creatinine testing, HCPCS codes 80048, 80050, 80053, 80069, and 82565; urine protein testing: CPT codes 82042, 82043, 82044, and 84156.

Figure 8.17 examines the use of ACEIs/ARBs and statins before and after AKI hospitalization, and includes 2007 Medicare patients with Part D coverage, identified as in Figure 8.2.

Figures 8.18 and 8.20 demonstrate the probability of patients having a recurrent AKI hospitalization. The Kaplan-Meier method is used to calculate the cumulative unadjusted probability of testing during the one-year follow-up period.

Figure 8.19 displays changes in CKD status following an AKI hospitalization in 2007, based on CKD claims before and after the hospitalization. The cohort includes all Medicare patients age 66 or older on December 31, 2007. CKD claims are identified in the one year prior and one year following the AKI admission date, and CKD stage is defined with the method described above, under "identification of major comorbidities." ESRD is defined by the ESRD date.

Figure 8.21 shows the distribution of patients by CKD stage prior to an AKI hospitalization in 2007, along with discharge status and outcomes. Patients are from the 5 percent Medicare sample. CKD stage is obtained from 2007 claims prior to the admission date, and nephrologist care is determined from claims in the year following discharge. Creatinine testing during the three months after discharge, and albumin in the one year following discharge, are identified from claims using the method described for Chapter Three.

COSTS OF CHRONIC KIDNEY DISEASE

CHAPTER NINE

The general Medicare point prevalent cohort used in Figures 9.1–4 includes persons age 65 and older who survive all of year one, are continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage for this period, are not enrolled in an HMO, and do not have ESRD during year one. Costs 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. Figure 9.2 also features the MarketScan point prevalent CKD population, constructed in a similar fashion, but limited to patients aged 50–64.

Figure 9.1 also illustrates estimated populations and costs from the 1 percent Taiwan National Health Insurance (NHI) dataset,

which, like Medicare claims data, employs ICD-9-CM diagnosis to identify the presence of CKD and key comorbid conditions. Patients age 65 and older with CKD (without ESRD), CVD, or diabetes are determined from claims in year one, and costs are aggregated for calendar year two, 2008.

Figures 9.5–8 look at 2007 incident Medicare and MarketScan ESRD patients during the transition to ESRD. Medicare patients here are age 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.

Costs are categorized in several ways throughout this chapter. For Figures 9.1, 9.12, and 9.18–20, and for Table 9.b, costs are simply total claims-based expenditures, while those in 9.2–4 and 9.9–11 are claims-based expenditures PPPY. Figures 9.5 and 9.20–21 display costs as PPPM claims-based totals, and Figures 9.13–17 show PPPM costs for Part D claims. Costs for Figures 9.6–8 are limited to inpatient claims, and expressed PPPM. 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.

Using the point prevalent methodology described above, Figure 9.1 compares populations and costs in 2008 for Medicare patients (based on the 5 percent Medicare sample) and patients from the 1 percent random sample of the Taiwan National Health Insurance (NHI) population, while Figures 9.18–21 show expenditures for point prevalent populations (described above) drawn from these same sources. Figures 9.22–23 show overall and inpatient PPPM expenditures during the transition for Medicare and NHI patients initiating ESRD in 2007.

Important comorbidities (diabetes, CKD, and CHF) are determined for these cohorts from Medicare claims using a previously validated method, as described earlier in this appendix in the section "identification of major comorbidities." Costs are presented for the 1992–2007 cohorts. The cost year is always the year after the cohort year.

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, and the cohorts are from 1999 to 2007.

Figures 9.9–17 and Table 9.b present Medicare Part D costs. Populations used in these figures are derived from the point prevalent Medicare population (described above), with the further restriction that each individual included in the population is enrolled in Part D for the full 12 months of the analysis year and has a qualifying diagnosis of CKD. Costs are estimated Medicare net pay, which is the sum of plan covered payments and low income subsidy payments. Costs do not include out of pocket expenditures. Table 9.b and Figure 9.12 show total expenditures, while the other figures use per person per month PPPM or PPPY expenditures.

In Figures 9.18–21 we again use data from the NHI dataset. To allow comparisons with Medicare data, the cohort includes only patients age 65 and older. Patient counts are estimated using the methods defined for Figure 9.1.

Figures 9.22–23 illustrate expenditures during the six months before and six months after initiation of dialysis among incident ESRD patients in the U.S. and Taiwan. Total and inpatient hospitalization costs PPPM are calculated for Medicare patients age 67 and older, MarketScan patients younger than 65, and NHI patients.

REFERENCE TABLES

Tables B.1–6 present estimated point December 31 prevalent counts of the general Medicare non-ESRD population, based on the 5 percent Medicare sample.

Tables B.7–10 present estimated counts by age, gender, race, ethnicity, and comorbidity in the non-institutionalized U.S. population, using NHANES 1999–2006 data. CKD status is based on eGFR and ACR, and eGFR is estimated by the MDRD and CKD-EPI equations, using standardized serum creatinine as suggested by NCHS. Both diabetes and CHF are self-reported.

Tables K.1–5 present estimates of per person per year costs for general Medicare patients, also derived from the 5 percent Medicare sample. The cohorts include those who survive all of year one, are continuously enrolled with Medicare inpatient/outpatient and physician/supplier coverage, are not enrolled in a managed care program (HMO), and do not have ESRD during year one. Costs 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. Important comorbidities are determined for these cohorts from Medicare claims using a previously validated method, as described earlier in this appendix in the section on identification of major comorbidities. PPPY expenditures are presented for the 1992–2007 cohorts. The cost year is always the calendar year after the cohort year.

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 tables 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 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 data from many of the USRDS Special Studies. Approximately half of the researchers using the USRDS SAFs need only this data set. The Transplant data set contains detailed transplant and transplant follow-up data collected by CMS and UNOS. Data on hospital inpatient stays are found on the Hospital data set. All Medicare billing data are available by individual year (see Table b.c).

STANDARD ANALYSIS FILES

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 DATASET

The Core Standard Analysis Files contain the most frequently used data and are needed for use of the Transplant and Hospital datasets, or any data based on Medicare claims. 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 data set).

Transplant Wait List Beginning with 2001 data (used in the 2002 ADR), this file has been updated to include basic patient demographic data 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. 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.

Dialyzers The Case Mix Severity, Case Mix Adequacy, and DMMS Special Studies collected information on patient dialyzers. SAFs for these studies describe the dialyzer through a code, which must be matched to information in the Dialyzer file to find the manufacturer and model along with characteristics such as membrane type and clearance. We believe that these data, from published sources available at the time of the study, accurately represent the dialyzer characteristics, but they should be used with caution.

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 on a total of 16,812 participants 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 and included 4,024 participants. 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 5,255 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 DATASET

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 SAF, and the remaining six are included inthe Transplant data set.

- **TX** includes minimum details on all transplants from all sources
- **TXWAIT** contains one record for each patient in the USRDS database per wait list event
- **TXHCFA** includes 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
- **TXIRUNOS** includes information on immunosuppressive drugs collected by UNOS at the time of transplantation events
- **TXFUHCFA** includes 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
- **TXFUUNOS** includes transplant follow-up reports collected by UNOS since 1988
- **TXIFUNOS** 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 ac-

b a 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 1.888.99USRDS
Fax 612.347.5878
usrds@usrds.org

Data file contacts Shu-Cheng Chen, MS; schen@usrds.org
Beth Forrest, BBA; bforrest@usrds.org

b b 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 3–4: 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) 7,096 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 year 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 (1989–1995). 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 files. Frequency of occurrence of each code. A starting point for analyses that will use diagnosis and procedure codes.

Formats.SC2 all USRDS-defined SAS formats used by SAFs. Format library used to format values of categorical variables.

cepted 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 DATASET

Hospitalization inpatient data are a subset of the data in the Institutional Claims file. No payment or cost variables are included on this data 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

This data set contains information from the Comprehensive Dialysis Study (CDS), a USRDS special data collection study to assess rehabilitation/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 of after the initiation of ESRD therapy. In a subset of 400 participants, dietary intake and nutritional status were also assessed.

DIALYSIS MORBIDITY & MORTALITY CLAIMS

This data setcontains Medicare claims for participants in the Dialysis Morbidity and Mortality Studies. Data are followed to the currently reported claims year.

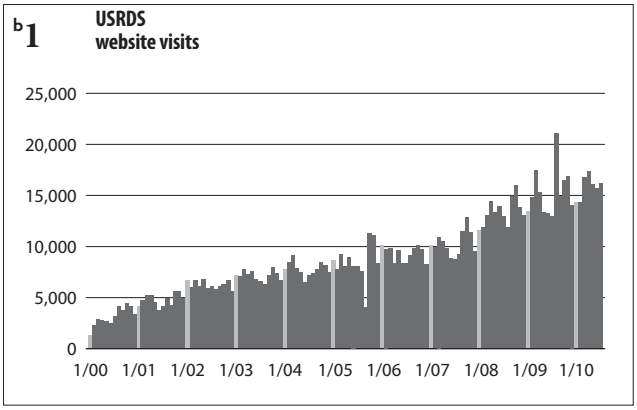
CASE MIX ADEQUACY CLAIMS

This data set contains Medicare claims for particiants in the Case Mix Adequacy Special Study,. Medicare payment data for these patients are followed to the currently reported claims year.

MEDICARE PAYMENT DATA

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 2008 claims will be available, along with other updated USRDS SAFs, by the end of 2010.

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

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 dialysis 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 1994–2008. 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 DATA & 5 PERCENT GENERAL MEDICARE PAYMENT DATA

Three disease-based cohort data sets — for CKD, diabetes, and CHF — are built from the 5 percent general Medicare Claims SAFs. Each data set 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 2007; 2008 claims will be available by the end of 2010. 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

The pre-ESRD claims (also known as the back-casted claims) are a collection of Medicare institutional and physician/supplier 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 1995–2007 with 2008 data available by the end of 2010. 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 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.

[b]c Prices for the USRDS Standard Analysis Files (checks must be made payable to the Minneapolis Medical Research Foundation)

Standard Analysis Files

Core dataset	$1,275	Needed in order to use the other files.
Transplant dataset	$500	Detailed transplant data from CMS and UNOS.
Hospital dataset	$500	Derived from the institutional claims; contains diagnosis and surgical procedure codes for each stay but does not include the cost data from the institutional claims records.
CDS survey dataset	$750	Survey information and laboratory values from the Comprehensive Dialysis Survey
DMMS claims	$500	Contains all of the Institutional and Physician/Supplier claims data for the patients in the USRDS Dialysis Morbidity and Mortality (DMMS) Special Study. Survey data are included in the Core dataset.
Case Mix Adequacy claims	$125	Contains all institutional and physician/supplier claims data for patients in the USRDS Case Mix Adequacy Special Study. Survey data are included in the Core dataset.

Pre-ESRD claims available for 1993 to 2008; price ranges from $200 to $600 per year and claim type. Prices subject to change.

Medicare payment data

	Institutional	Physician/ supplier
pre-1989	$250	
1989	$250	
1990	$250	
1991	$375	$500
1992	$375	$500
1993	$375	$500
1994	$375	$625
1995	$500	$625
1996	$500	$750
1997	$500	$875
1998	$500	$875
1999	$500	$875
2000	$750	$875
2001	$875	$875
2002	$875	$1,000
2003	$1,000	$1,125
2004	$1,125	$1,125
2005	$1,250	$1,250
2006	$1,250	$1,250
2007	$1,750	$1,375
2008	$1,875	$1,500

[b]d Prices for the 5 percent Medicare Sample Standard Analysis File CD-ROMs (checks must be made payable to the Minneapolis Medical Research Foundation)

	CKD		Diabetes		Congestive heart failure	
	Institutional	Physician/ supplier	Institutional	Physician/ supplier	Institutional	Physician/ supplier
1992	$375	$375	$375	$500	$375	$625
1993	$375	$375	$375	$500	$500	$625
1994	$375	$375	$375	$500	$500	$625
1995	$375	$375	$500	$625	$500	$625
1996	$375	$500	$500	$625	$500	$750
1997	$375	$500	$500	$625	$500	$750
1998	$375	$500	$500	$625	$625	$750
1999	$500	$500	$500	$625	$625	$750
2000	$500	$500	$500	$625	$625	$750
2001	$500	$500	$625	$750	$625	$750
2002	$500	$500	$625	$750	$625	$750
2003	$500	$500	$625	$750	$625	$750
2004	$500	$500	$625	$875	$625	$750
2005	$625	$625	$750	$875	$750	$875
2006	$750	$625	$750	$1,000	$750	$875
2007	$875	$625	$875	$1,000	$750	$875
2008	$1,000	$750	$1,000	$1,125	$875	$1,000

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

ESRD CPM Survey data

Includes 1994–2008 hemodialysis survey years and 1995–2008 peritoneal dialysis survey years $1,250

ESRD CPM/SAF linked files

Core files	$400
Hospital	$200
Transplant	$200

ESRD CPM Medicare participant Institutional & Physician/Supplier claims

are available for the years pre-1989 through 2007; $100–300 per year

[b]f Outline for research proposals using USRDS data

A data request applies only to the project stated in the proposal; a new proposal must be submitted for each additional use of the data

I Research topic title and submission date.

II Background information.

III Study design: objectives, hypothesis(es), analytical methods.

IV Data being requested: 1) List of Standard Analysis Files needed (if multiple years, please specify), or fields needed in custom data file. 2) Description of data security: responsible party, computer access, etc. 3) Time frame for the project. 4) Statement that data will be returned to the USRDS or destroyed at the end of the project.

V To address patient privacy issues, to be consistent with HIPAA policies, and to insure that researchers are adhering to local privacy standards as well as to USRDS and CMS privacy policies, the USRDS now requires IRB approval for all research proposals. IRB approval is not required from those requesting aggregate data.

VI Outline of estimated costs of requested data; source of funding.

VII Agreement for Release of Data, signed by all researchers.

VIII Investigator information. For Principal Investigator and co-authors, supply:
- Name
- Affiliation
- Business address
- Business phone & fax
- Email address

Submit to

Paul Eggers, PhD
NIDDK
6707 Democracy Blvd, Room 615
Bethesda, MD 20892-5458
Phone 301.594.8305
Fax 301.480.3510
eggersp@extra.niddk.nih.gov

FILE MEDIA & FORMATS

SAFs are provided on CDs and DVDs as SAS files, and can be used by SAS on any 486 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 USE 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 on CD or DVD. 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.

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.

Albumin/creatinine ratio (ACR) A screening test used to assess chronic conditions such as diabetes and hypertension that can put patients at risk for chronic kidney failure.

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 norepinephrine, 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 (m^2).

C-reactive protein 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 depolarizing 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 the Medicare, Medicaid, and State Childrens' 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 Kidney Disease Epidemiology Collaboration (CKD-EPI) A method used to estimate glomerular filtration rate (GFR) using a single serum creatinine. Yields a lower CKD prevalence than the Modification of Diet in Renal Disease (MDRD) Study equation.

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 m^2.

Cystatin-C equation A method which uses the laboratory marker cystatin-C for estimating glomerular filtration rate (GFR).

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

Death Notification Form (CMS-2746) 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.

Erythropoiesis stimulating agent (ESA) Used to increase the production of red blood cells; includes erythropoietin (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 appropriateness 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 (eGFR) Estimated rate in ml/min/1.73 m^2 of the volume of plasma filtered by the kidney. Rates of filtration are based on an individual's age, gender, and height, and on levels of serum creatinine, blood urea nitrogen, and serum albumin. GFR is traditionally considered the best overall 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 healthcare 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 2010 A national agenda for health promotion and disease prevention, with objectives and goals aimed at improving the health of the American 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 infection, poisons, or the use of alcohol or other drugs. Forms include Hepatitis A, usually transmitted by contaminated food or water; Hepatitis B, more serious than Hepatitis A and transmitted through blood and body fluids; Hepatitis C, also transmitted through blood and body fluids; and Hepatitis D, which causes symptoms only when an individual 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 arrest the fibrillation of (heart muscle) by applying electric shock thus depolarizing the heart cells and allowing normal rhythm to return.

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

Incident population The people in a population who are newly diagnosed with a disease in a given time period, typically a year.

Independent unit A unit licensed to provide outpatient and home maintenance dialysis, and not affiliated with a chain.

Ischemic heart disease (ISHD) A disease of the heart evidenced by a lowered oxygen supply to the heart tissue, caused by occlusion or narrowing of the arteries supplying the heart muscle.

Kidney Disease Outcomes Quality Initiative (KDOQI) Established in 1995 by the National Kidney Foundation to improve patient outcomes and survival by providing 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 multiplying the urea clearance (K) by the treatment duration (t) and dividing by the urea distribution (V). The urea distribution volume is approximately equal to the volume of total body water.

Modification of Diet in Renal Disease (MDRD) Study equation A method used to estimate glomerular filtration (GFR) using a single serum creatinine.

Medical Evidence form (CMS-2728) A form which provides source data about ESRD patients, including information on demographics, primary cause of renal disease, comorbidity, biochemical data, dialysis treatment, transplant, dialysis training, employment status, initial 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 Medicare beneficiaries. Sponsored by the Centers for Medicare and Medicaid Services, and used to study the health status, health care use and expenditures, health insurance coverage, and socioeconomic and demographic characteristics of Medicare beneficiaries.

Microalbuminuria A condition in which small amounts of albumin are present in the urine; indicates early kidney damage.

Modality A method of treatment. Treatment 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 Statistics (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 federal focal point for medical research in the U.S. and one of eight health agencies of the Public Health Services, 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 administered by the United Network for Organ Sharing, under contract with the Health Resources and Services Administration of the U.S. Department of Health and Human Services.

Part D Medicare coverage A U.S. government program which subsidizes the costs of medications for Medicare beneficiaries.

Percutaneous coronary intervention (PCI) A therapeutic procedure to treat the stenotic (narrowed) coronary arteries of the heart found in coronary heart disease. Commonly known as coronary angioplasty or simply angioplasty.

Period prevalent patient A patient receiving 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 prevalent 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 progressive disease that causes narrowing or occlusion of the arteries supplying the extremities of the body.

Peritoneal dialysis Dialysis in which fluid (dialysate) is introduced into the abdominal cavity and uremic toxins are removed across the peritoneum.

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

Program Medical Management and Information System for ESRD, and Renal Beneficiary 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 functioning kidney transplant (regardless of the transplant date). This definition excludes patients with acute renal failure, those with chronic renal failure who die before receiving treatment 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 (rhGH) Also called somatropin; a substance identical in its amino acid sequence to human growth hormone, and used to treat growth hormone deficiency.

REMIS CMS's Renal Management Information System (REMIS), 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 regulates blood volume and systemic vascular resistance.

SIMS CMS's Standard Information Management 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.

Statins 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 Mondofacto Medical Dictionary, found at www.mondofacto.com/dictionary.

abbreviations

A1c	glycosylated hemoglobin
AAPCC	average annual per capita cost
ACEI	angiotensin converting enzyme inhibitor
ACR	albumin/creatinine ratio
AKI	acute kidney injury
AKI-D	acute kidney injury with dialysis
AMI	acute myocardial infarction
ARB	angiotensin receptor blocker
ASHD	atherosclerotic heart disease
AV	arteriovenous
BMI	body mass index
BRFSS	Behavioral Risk Factor Surveillance System
BUN	blood urea nitrogen
CAPD	continuous ambulatory peritoneal dialysis
CCPD	continuous cycler peritoneal dialysis
CCR	creatinine clearance rate
CDC	Centers for Disease Control and Prevention
CDS	Comprehensive Dialysis Study
CHF	congestive heart failure
CK	cystic kidney disease
CKD	chronic kidney disease
CKD-EPI	Chronic Kidney Disease Epidemiology Collaboration
CMS	Centers for Medicare & Medicaid Services
COPD	chronic obstructive pulmonary disease
CPM	Clinical Performance Measures Project
CVA/TIA	cerebrovascular accident/transient ischemic attack
CPT	Current Procedure and Terminology
CRT-D	cardiac resynchronization therapy defibrillator
CVD	cerebrovascular disease
DCD	donation after cardiac death
DGF	delayed graft function
DM	diabetes, diabetic
DPO	darbepoetin alfa
DRG	diagnosis related group
ECD	expanded criteria donor
EGHP	employer group health plan
EPO	erythropoietin
ESA	erythropoiesis stimulating agent
ESRD	end-stage renal disease
eGFR	estimated glomerular filtration rate
GN	glomerulonephritis
HCPCS	healthcare common procedure coding system
HD	hemodialysis
HEDIS	Health Plan Employer Data Information Set
HMO	health maintenance organization
HSA	Health Service Area
HTN	hypertension
ICD	implantable cardioverter defibrillator
ICD-9-CM	International Classification of Diseases, 9th revision, Clinical Modification
IPD	intermittent peritoneal dialysis
ISHD	ischemic heart disease
KDOQI	Kidney Disease Outcomes Quality Initiative
MCBS	Medicare Current Beneficiary Survey
MDRD	Modification of Diet in Renal Disease
ME	Medical Evidence form (2728)
MI	myocardial infarction
MPP	Medicare as primary payor
MSP	Medicare as secondary payor
NDC	National Drug Code
NDM	non-diabetic
NHANES	National Health and Nutrition Examination Survey
NKF	National Kidney Foundation
OPTN	Organ Procurement and Transplantation Network
PCI	percutaneous coronary intervention
PD	peritoneal dialysis
PPPM	per person per month
PPPY	per person per year
PAD	peripheral arterial disease
PVD	peripheral vascular disease
SCD	standard criteria donor
SHR	standardized hospitalization ratio
SMR	standardized mortality ratio
STR	standardized transplantation ratio
Tx	transplant
UNOS	United Network for Organ Sharing
WHO	World Health Organization

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.

Recipient typed name, title, & organization

Recipient telephone number

Recipient signature & date

Contractor typed name, title, & organization, as appropriate

Contractor telephone number

Contractor signature & date

Lawrence Y. C. Agodoa, MD, NIDDK, NIH or
Paul W. Eggers, PhD, NIDDK, NIH
USRDS Project Officer

USRDS Project Officer signature & date

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