The USRDS: What You Need to Know about What It Can and Can’t Tell Us about ESRD

Robert N. Foley*† and Allan J. Collins*†

Summary
This article summarizes the administrative structure underlying the United States Renal Data System (USRDS); summarizes incidence, prevalence, patient characteristics, and treatment modalities; and describes data regarding clinical indicators and preventive care, hospitalization, survival, and costs. The USRDS recently instituted a comprehensive assessment system to characterize the transition to the new Centers for Medicare & Medicaid Services Prospective Payment System, which bundles into a single payment several integral components of dialysis care. This challenging initiative will be an important component of future USRDS Annual Data Reports. The main strengths of the USRDS are its size and representativeness, nearly complete inclusion of the US end-stage renal disease population, and linkage to Medicare claims. Limitations include lack of continuous validation of its methods, lack of complete comorbidity and laboratory data at registration, an initial survival bias, and lack of accuracy of cause-of-death reporting.

Renal Replacement Therapy in the United States: Medicare, the Networks, the Medical Evidence Report, and the U.S. Renal Data System
Insights into the strengths, weaknesses, and quirks of the U.S. Renal Data System (USRDS) (1) and its Annual Data Report (2) are greatly facilitated by an overview of the underlying administrative landscape. Medicare is a national health insurance program in the United States that is available to people age 65 years or older and to people younger than age 65 years who qualify for Social Security Disability insurance benefits or in whom ESRD requiring maintenance renal replacement therapy (RRT) is diagnosed (3).

Medicare has several distinct components. In contrast to Part A (hospital insurance available to all beneficiaries), Part B is optional and carries a monthly premium. Part B covers care such as physician services, outpatient hospital care, physical and occupational therapy, and some elements of home health care deemed medically necessary. Since 1997, Medicare benefits can be administered through private plans, an option termed Medicare Advantage, previously termed Medicare + Choice or Part C. Since 2006, Part D, a broad suite of premium-requiring prescription drug coverage options, has also been available.

Because all elements of treatment require claims for reimbursement, Medicare databases are potentially rich sources of information about health system encounters. In practice, only permanent residents and citizens of the United States who have paid 40 quarters (10 years) of Social Security tax are eligible for Medicare. Even though Medicare is not used as insurance in situations that do not meet these criteria, treating physicians are required to complete a Centers for Medicare & Medicaid (CMS) Medical Evidence Report (form CMS-2728) for these patients. In theory, therefore, patients with alternative or no forms of insurance should be identified and key clinical events, such as dialysis initiation and death, should be known. However, concern remains that enrollment rates are far from complete in some important segments of the dialysis population of the United States, particularly undocumented immigrants.

Eighteen regional ESRD network organizations are under contract with CMS to facilitate interactions between providers of RRT and the federal government (4). The networks play several important roles, including assessing quality of care and collecting data needed to administer the ESRD program. Ongoing quality-of-care programs such as Dialysis Facility Reports or Dialysis Facility Compare do not fall under the remit of the USRDS and are administered by CMS (5). CROWNWeb (Consolidated Renal Operations Network) is also a CMS-based initiative. CROWNWeb is a system in which comprehensive clinical information, including key laboratory results, is submitted electronically; when data retrieval and cleaning systems have been fully operationalized, these data will be available to the USRDS (6).

The interplay between starting maintenance RRT, Medicare, and the USRDS is somewhat complex. Regardless of future intention to use Medicare as payer, a CMS Medical Evidence Report must be filed within 45 days of the first maintenance RRT session, even for patients who die before 45 days have elapsed (7). Similarly, a Death Notification (form CMS-2746) is required when patients die, regardless of payer status (8). The Medical Evidence Report performs the dual role of tracking the size and composition of...
the national RRT program and potential enrollment in Medicare for coverage of medical care. Importantly, Medicare coverage differs slightly for peritoneal dialysis and hemodialysis. Medicare coverage is available from day 1 of peritoneal dialysis, home hemodialysis, and transplant, but not until 3 months of in-center hemodialysis. The 3-month delay may have led to the unfortunate misconception that the USRDS is unable to study mortality in the first 3 months of RRT. The date of first RRT is an integral part of all USRDS datasets, and early mortality findings have been reported in the Annual Data Report for several years. Nonfatal clinical events, however, are a different story. Even among patients age 65 years or older at RRT inception, the rate of Medicare take-up is variable and never complete. Especially in studies of incident RRT patients, it is important to check whether the study population is restricted to patients actually receiving Medicare coverage.

**Incidence, Prevalence, Patient Characteristics, and Treatment Modalities at RRT Inception**

In 2009, 116,395 patients began RRT therapy, an unadjusted incidence rate of 371 per million. This rate was 363, 362, 366, and 354 per million, respectively, for the preceding 4 years; 326 per million in 2000; 258 per million in 1995; and 199 per million in 1990. Trends were similar after adjustment for population demographic characteristics, suggesting that new starts have been comparatively stable since 2000, in distinct counterpoint to the two-thirds increased incidence in the preceding decade. Figure 1 shows incidence of ESRD treated by RRT and prevalent counts for hemodialysis, peritoneal dialysis, and transplant, 1978–2008.

When incidence rates in 2009 were compared by age, sex, race, ethnicity, and cause of ESRD, the lowest/highest rates for age were as follows: lowest, <20 years (15.8 per million person-years)/highest, ≥75 years (1522.8 per million person-years). Low/high findings for the other categories were the following: men (426.1)/women (317.4), white (304.0)/black (783.3), Hispanic (305.0)/non-Hispanic (383.4), and other urologic disease (5.1)/diabetic renal disease (162.2). Applying an otherwise similar approach to the absolute change between 2000 and 2009 showed the following low/high contrasts: age < 20 years (1.2 per million person-years)/age ≥ 75 years (168.7 per million person years), women (18.9)/men (71.1), Native American (2.5)/Asian (77.2), Hispanic (4.1)/non-Hispanic (53.5), and unknown cause (0.8)/hypertension (17.9). Thus, without statistical adjustment, current incident disease burden is characterized by older age, male sex, black race, non-Hispanic ethnicity, and diabetic renal disease, whereas the most rapidly growing disease burden is characterized by older age, male sex, Asian race, non-Hispanic ethnicity, and hypertensive renal disease.

All of these findings were from unadjusted analyses. Although incidence rates differed clearly by age and race, adjustment for these factors had little effect on incidence rate patterns. Geographic variation was apparent, with the highest adjusted incidence rates in 2009 occurring in the Ohio Valley, parts of Texas and California, and the southwestern states. Prevalence trends for RRT generally mirror incidence trends. In 2009, 0.17% of the population of the United States was receiving RRT, a relative increase of 2.1% over the previous year; much of the year-on-year increase in prevalence was explicable by increasing survival rates.

Some characteristics of the 2009 RRT populations are worth highlighting. Among incident patients, proportions were as follows: age < 20 years, 1.1%; age ≥ 75 years, 25.1%; men, 56.7%; African American, 28.2%; Hispanic, 13.0%; diabetic renal disease, 43.7%; and hypertensive renal disease, 28.4%. Initial RRT modality was 91.7% for hemodialysis, 5.3% for peritoneal dialysis, and 2.2% for preemptive transplant. Proportions using peritoneal dialysis were higher for the following subgroups than for the overall population: age 0–19 years, 5.1 times higher; age 20–44 years, 1.5 times higher; ESRD attributed to GN, 2.0 times higher; and ESRD attributed to cystic disease, 2.8 times higher. Characteristics associated with lower proportions included age ≥ 75 years (0.5 times higher) and African American race (0.7 times higher). Characteristics

![Figure 1](image-url)
associated with higher proportions of pre-emptive transplant included younger age (0–19 years, 7.5 times higher; 20–44 years, 2.1 times higher; and 45–64 years, 1.3 times higher); Native American (2.3 times higher) and Asian (4.3 times higher) race; and GN, cystic kidney disease, and other urologic disease (2.9, 7.2, and 1.8 times higher, respectively). Characteristics associates with lower proportions were age 65–74 years (0.6 times higher) and age ≥ 75 years (0.1 times higher); African American race and Hispanic (0.3 and 0.4 times higher) ethnicity; and diabetic (0.4 times higher) and hypertensive (0.5 times higher) renal disease. The total prevalence of RRT continues to increase at about 2% per year, reaching 557,263 in 2009. The percentages of patients undergoing hemodialysis, peritoneal dialysis, and transplant were 65.1, 4.8, and 30.1, respectively, and subgroups associated with atypical proportions of peritoneal dialysis and transplant mirrored those in the incident population.

Insurance coverage of patients with ESRD has changed substantially over the years. For example, among incident hemodialysis patients, Medicare Advantage coverage climbed to 15.3% in 2009, dual Medicare/Medicaid coverage decreased to 13.5%, and Medicare fee-for-service coverage decreased to 45%. Thus, one in four new hemodialysis patients have no insurance coverage of any type via Medicare, compared with 1 in 20 in 1978. Trends were similar but less marked in prevalent patients, with 89.3%, 89.7%, and 66.2% Medicare coverage of the hemodialysis, peritoneal dialysis, and transplant populations, respectively.

Since 2005, the Medical Evidence Report for incident RRT includes fields for targeted elements of predialysis nephrology care. Predialysis care remains inadequate for broad swathes of the incident dialysis population; 24.5% had received specialist nephrology care for a year or more, and 82.5% initiated hemodialysis with a catheter in 2009. Mean initiation hemoglobin levels decreased slightly from a 2006 peak of 10.2 to 9.9 g/dl in 2009, and the proportions using an erythropoiesis-stimulating agent decreased from 10.5% to 9.9% in the same period. The trend toward higher estimated GFR continues; 29% of patients started RRT with levels between 10 and 14.9 g/dl; 51.8% of diabetic RRT patients had four or more glycosylated hemoglobin and two lipid measurements per year, and 64.3% received influenza vaccinations. As examples of the latter, 30.8% of hemodialysis patients had a fistula present at dialysis initiation, and pneumococcal and hepatitis penetration estimates were 25.8% and 22.1%, respectively.

Information on Medicare Part D prescription drugs in the RRT population is a new initiative for the USRDS. We are in the early stages of understanding Part D data and have not yet formally compared the populations. However, most CKD patients with Medicare coverage participate in Part D and are unlikely to be super-selected. In 2008, dialysis patients with this benefit used an average of 13.6 different medications a year, compared with 12.4 in transplant patients. In a given month, patients filled an average of five prescriptions; antihypertensive medications account for one-fifth of the total. The types of vasoactive medications prescribed mirror what might be expected after overt cardiac disease; 64.1% of the dialysis population shows prescription activity for β-blockers; 45.0%, dihydropyridine calcium-channel blockers; and 50.7%, angiotensin-converting enzyme inhibitors, angiotensin-receptor blockers, or renin inhibitors. In light of findings from large randomized trials showing lack of efficacy in hemodialysis patients, it was notable that 40.9%, 4.6%, and 49.2% of Part D—dialysis patients were prescribed statins, ezetimibe, and sevelamer, respectively (10–13).

**Clinical Indicators and Preventive Care**

Dialysis patients in the United States do increasingly well by some quality indicators and poorly by others. As examples of the former, in 2008 or 2009, 95% of hemodialysis patients had urea reduction ratios ≥ 65%; 87.1% of peritoneal dialysis patients had weekly Kt/V ≥ 1.7; 55.0% of prevalent hemodialysis patients had a fistula for dialysis access and 77.2% had hemoglobin levels between 10 and 12 g/dl; 51.8% of diabetic RRT patients had four or more glycosylated hemoglobin and two lipid measurements per year, and 64.3% received influenza vaccinations. As examples of the latter, 30.8% of hemodialysis patients had a fistula present at dialysis initiation, and pneumococcal and hepatitis penetration estimates were 25.8% and 22.1%, respectively.

Hospitalization

Cause-specific hospitalization has received more attention in recent iterations of the Annual Data Report. Although hospitalization rates have been largely stable for decades, at just under 2 per 100 person-years in the RRT population, causes of hospitalization have changed dramatically. For example, in hemodialysis patients, admission rates for infection (0.33 per 100 person-years in 1993 and 0.46 in 2009) now rival those for cardiovascular disease (0.50 and 0.53, respectively). Vascular access hospitalizations, in contrast, were halved during this time (from 0.44 to 0.23 per 100 person-years), suggesting that progress is possible, at least with regard to using less expensive settings to address vascular access interventions. Catheters remain the dominant risk factor for infection, and it is disappointing that the increased prevalence of fistulas has yet to reverse the trends for catheter use and infection-related hospitalization.

Considered organ by organ, hospitalization rates for skin and lung infections have been increasing since 1993 in hemodialysis patients; corresponding rates have remained static and decreased in peritoneal dialysis patients, and both have decreased in transplant patients. Admissions for musculoskeletal infections, such as osteomyelitis and septic arthritis, are almost twice as common in hemodialysis
patients as in peritoneal dialysis and transplant patients. Abdominal infections are much more frequent in peritoneal dialysis than in hemodialysis patients, but temporal trends have been running in opposing directions, with rates per 100 person-years of 159.7 in 1993 and 128.2 in 2009 for peritoneal dialysis patients, and 17.0 and 27.1 in hemodialysis patients. In the absence of parallel prospective nationally representative studies, it is impossible to quantify the contribution of differing claim submission strategies to these trends.

Avoidable readmissions to hospital are indicators of poor quality of care and have a profound economic impact. For example, it has been estimated that nearly 20% of Medicare beneficiaries were rehospitalized within 30 days of discharge in 2009, at a cost of $17 billion per year (14). Under the Affordable Care Act, CMS calculates average 30-day hospital readmission rates for patients with myocardial infarction, pneumonia, or heart failure from claims data, and hospitals with above-average readmission rates receive a proportionate revenue penalty in the following year (15). Of note, 36% of hemodialysis patients were readmitted within 30 days in 2009, a value that increased to 42.6% among those age 20–44 years.

Likelihood of hospitalization is one of several important considerations affecting the decision between modes of RRT as dissimilar as hemodialysis and peritoneal dialysis. Traditional comparisons include combined examination of both populations en bloc, and adjustment of hospitalization rates for age, demography, and known comorbid illnesses. Realization is growing that this approach may not be entirely realistic because for substantial numbers of hemodialysis patients no identical peritoneal dialysis counterparts could ever be found. With traditional comparison methods, hospitalization rates in the first and second years are substantially higher for hemodialysis patients than for peritoneal dialysis patients. When peritoneal dialysis patients are matched by an extensive array of comorbid conditions, these disparities dissipate, especially after a year of follow-up. Thus, compared with peritoneal dialysis, unadjusted 2006–2007 hospitalization ratios in the unmatched and matched hemodialysis populations were 1.43 and 1.25 in the first year after RRT initiation, compared with 1.16 and 1.05, respectively, in year 2.

**Survival**

Mortality rates in RRT populations remain much higher than in the general population. Among Medicare beneficiaries aged ≥ 65 years, for example, adjusted mortality rates were 6.5 and 1.6 times higher than expected, respectively, in the prevalent dialysis and transplant populations. Mortality rates are especially high early in the course of dialysis treatment (Figure 2). For example, adjusted mortality rates in 2008 were 27 per 100 person-years in month 1, peaked at 44 per 100 person-years in month 2, and gradually decreased to 21 per 100 person-years by month 12 of dialysis treatment. Survival rates, however, have been improving annually in the United States for decades. Among incident hemodialysis patients, for example, first- through fourth-year mortality rates all peaked in the mid-to-late 1980s and all except the first of these declined steadily on a close-to-annual basis in the next 2 decades. First-year all-cause adjusted mortality rates, which peaked at 31 per 100 person-years in 1985, had remained at approximately 26 per 100 person-years between 1995 and 2003. Encouragingly, first-year mortality rates in hemodialysis patients showed year-on-year declines from 2004 through 2008. Among incident RTT patients, followed from day 90, first-year adjusted mortality rates are 23 per 100 person-years in hemodialysis patients, 13 per 100 person-years in peritoneal dialysis patients, and 0.6 per 100 person-years in transplant patients; corresponding values are 19, 18, and 4 in year 2 and 21, 22, and 4 in year 3. Thus, the initial apparent survival advantage of peritoneal dialysis over hemodialysis appears to have reversed by year 3. Survival trends among prevalent RRT patients largely mirror those in incident analyses; adjusted all-cause mortality rates peaked at 27 per 100 person-years in 1988 and declined annually to 21 per 100 person-years in 2009. Regarding trends in reported cause of death, rates of death from cardiovascular disease have declined more quickly than those from other causes, and deaths related to infection are a cause for concern.

![Figure 2](image-url)  
**Figure 2.** Mortality rates trajectories after initiation of hemodialysis in 2008. Adjustment factors for incidence rates are age, sex, race, and primary renal disease.
Lengthening survival estimates are certainly encouraging, but it is slightly perplexing that no single intervention, to date, has been shown in a large multicenter trial to extend survival. Although unlikely, the salutary trends might reflect diminishing severity of comorbid conditions at inception of dialysis therapy. One useful data source that tends to mitigate against this possibility involves dialysis patients on the transplant waiting list. Both adjusted (9.3–7.7 per 100 person-years) and unadjusted (7.3–6.5) mortality rates in dialysis patients on the waiting list decreased noticeably between 2004 and 2009. Another potentially explanatory hypothesis could be described as the “rising tide lifts all boats” hypothesis, with lengthening survival in RRT patients (a boat) explained by survival trends in the general population (the rising tide). To date, little or no research has confirmed whether this is the case in the United States.

Interdialytic Interval and Hemodialysis Outcomes

Long-term hemodialysis in the United States is usually delivered three times weekly, even though ESRD severely limits the fluid and electrolyte homeostatic capacity and most patients begin maintenance dialysis with pre-existing heart disease. Hence, we recently examined the mortality and morbidity implications of the long interdialytic interval with data from the End-Stage Renal Disease Clinical Performance Measures project, a nationally representative sample of patients receiving hemodialysis three times per week, from 2004 to 2007 (16). The average age of the study population was 62.2 years, and 24.2% of the patients had RRT duration <1 year. All-cause mortality, cardiac mortality, infectious mortality, and mortality from cardiac arrest and myocardial infarction were all substantially higher than expected on the day after the 2-day interdialytic interval, as were admissions for myocardial infarction, congestive heart failure, stroke, and dysrhythmia. Although these data immediately suggest a testable hypothesis for a randomized trial, it might be worth noting that the excess mortality attributable to a particular day of the week needs to be amortized over all 7 days to judge the potential effect on overall death rates. Nevertheless, these data suggest that nonpharmacologic treatment interventions hold promise in the hemodialysis population.

Costs

Total Medicare costs, including the new Part D prescription drug benefit, were $491 billion in 2009. The exact proportion attributable to RRT is not yet known because Part D data availability for this subgroup lags a year behind availability for the general Medicare population. However, RRT accounted for 6.7% of the $434.5 billion cost of combined Medicare Parts A, B, and C in 2009, a proportion that has remained stable since the end of the last millennium. In 2009, 470,063 prevalent RRT patients in the United States billed Medicare. Thus, excluding Part D expenditures, which are likely to be large given use of 12–14 separate medications per year, the cost per RRT Medicare beneficiary was just under $62,000 per year. These costs were distributed as follows: inpatient, 38.1%; outpatient, 34.8%; physician supplier, 20.7%; skilled nursing facility, 3.6%; home health, 2.4%; and hospice, 0.4%. Hemodialysis, peritoneal dialysis, and transplant accounted for 85.6%, 4.5%, and 9.9%, respectively, of expenditures, equivalent to $82,000, $62,000, and $30,000 per patient. Injectable medications were responsible for almost $2.8 billion in 2009; 67.9%, 18.3%, and 10.3% were attributable to erythropoiesis-stimulating agents, vitamin D analogues, and iron, respectively, representing increases of 5.0%, 3.7%, and 7.0% compared with 2008.

To date, the USRDS has received Part D Medicare data for 2006, 2007, and 2008. The entire program for 2008 cost $51 billion, with dialysis and transplant accounting for 2.5% and 0.6%. Although USRDS analyses of this important program are in their infancy, some important insights have already been gained. For example, by prescription frequency, the top five medications were metoprolol, insulin, amlodipine, sevelamer hydrochloride, and lisinopril. Ranked in terms of outlay, the top five medications were sevelamer hydrochloride ($260 million), cinacalcet ($227 million), insulin ($72 million), calcium acetate ($50 million), and lanthanum carbonate ($50 million). It is quite striking, for example, that >$600 million was expended on bone and mineral disorder treatments that lack compelling evidence-based rationale for treatment.

A New Medicare Payment System for RRT: The Bundle

The USRDS recently instituted a comprehensive assessment system to characterize the transition to the new CMS Prospective Payment System (17). Although a detailed description of the nuances of this system is beyond the purview of this article, we can say that it differs radically from the previous system. It bundles into a single payment, per treatment, several integral components of dialysis care, including intravenous medications, such as erythropoiesis-stimulating agents, vitamin D analogues, iron, antibiotics for vascular access infection, and additional laboratory testing, potentially limiting the ability to track these components separately. Clearly, understanding the trajectories of cost to Medicare and quality of dialysis care will be important as the new system rolls out. To assess the effect of this payment system in a timely manner, Quarterly Standard Analytic Files have been obtained from CMS. Balanced against the attractiveness of up-to-date information is the labor intensiveness of getting this information; finder files must be constructed four times per year to collect dialysis services and hospitalization claims from the overall body of Medicare claims. This challenging initiative will be an important component of Annual Data Reports for the foreseeable future.

Limitations of the USRDS

The main strengths of the USRDS are its size and representativeness, nearly complete inclusion of the ESRD population in the United States, and linkage to Medicare claims. However, it is limited in many ways. For example, prospective validation of its methods is not performed on a continuous basis. The Dialysis Morbidity and Mortality studies of the 1990s were very helpful resources for checking the validity of the larger USRDS datasets and for testing research hypotheses by researchers. In the current era, the
only large equivalent is the Comprehensive Dialysis Study, whose data are available to researchers. This study collected data on patient demographic characteristics, contact information, treatment, laboratory values, quality-of-life survey interviews, and nutrition survey interviews for dialysis patients in the United States who started treatment between 2005 and 2007 at 335 randomly selected dialysis facilities.

Data completeness of the Medical Evidence Report at initiation of RRT is also an underappreciated issue. Although basic demographic factors are close to complete, the same cannot be said about several key laboratory variables. For example, baseline serum albumin values are missing for about 23% of new patients entering the system since 2005 compared with 28% before 2005. The attention given to defining cause of ESRD can also lead to concerns. For example, we studied temporal trends regarding the epidemiology of atherosclerotic renovascular disease in dialysis populations between 1996 and 2007. Specifically, USRDS data were used to identify patients age 67 years or older at dialysis inception, and Medicare claims in the preceding 2 years were used to identify renovascular disease and revascularization procedures. Although the pre-ESRD atherosclerotic renovascular disease burden appeared to increase from 7.1% to 11.2%, the proportion of patients with renovascular disease listed as cause of ESRD on the Medical Evidence Report at dialysis inception remained unchanged at approximately 5.0% (18). As with all registry studies based on ESRD as entry point, it is impossible to know the interplay between AKI, ESRD, inclusion in and exclusion from the USRDS, and how this has evolved over time. In this regard, it is notable that whereas estimated GFRs at dialysis initiation have been increasing steadily over the years, an inverse relationship exists between initial GFR and survival. Data fields examining pre-RRT care and initial vascular access have been available since 2007. Unfortunately, the options available to rate these items are somewhat problematic. For example, the question “Was the patient under care of a nephrologist?” can be answered “Yes,” “No,” or “Unknown.” If “Yes” is selected, the rater is asked to indicate 6–12 months or >12 months. For patients with care duration known to be <6 months, or known care of unknown duration, for example, one could envisage a large potential for ambiguity. There is also concern that patients who die very soon after developing true dialysis-requiring ESRD may not be enrolled in the USRDS database, a survival bias that may underlie the frequently reported observation that the lowest and highest mortality rates in the dialysis population in the United States occur in the first and sixth weeks of therapy.

Medicare claims are the main source available to the USRDS for studying quality of care and nonfatal clinical events. It is important to know that among incident and prevalent populations, only about 50% and 80% of patients have Medicare as their insurer. Many claims-based analyses examining clinical care have selection criteria stipulating that Medicare claims were made in each month of follow-up. This approach is likely to introduce a degree of survival bias in a population known to have a high mortality. In general, population denominators and follow-up strategies need to be examined closely in claims-based analyses with USRDS datasets. Finally, although the accuracy of cause-of-death reporting has not been studied recently, previous studies have shown it to be highly inaccurate, and this inaccuracy is highly likely to remain in effect (19).

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Disclosures

None.

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