

End Stage Renal Disease

Key Findings:

- Almost 90% of in-center hemodialysis patients are receiving adequate dialysis.
- Over 75% of ESRD patients have good anemia management.
- Only 1 in 5 ESRD patients is placed on a transplant waiting list. This measure reflects whether doctors are referring patients for a transplant workup evaluation.

Background and Impact

Chronic kidney disease (CKD)ⁱ is a progressive failure of the kidneys to filter waste and fluid from the body.¹ Nearly 20 million (19.2 million) Americans are living with this condition.²

Although CKD cannot be cured, the progression of this condition may be slowed with early intervention.^{3,4} Left untreated, CKD can lead to a complete shutdown of kidney function, a condition known as end stage renal disease (ESRD). Because CKD shows no symptoms in its early stages, many people who have the condition do not seek treatment until after they begin to experience the symptoms associated with advanced stages of the disease.^{5,6} ESRD is on the rise.^{7,8,9}

The large number of people with CKD is partly attributable to an increase in the rates of diabetes (especially type 2 diabetes) and hypertension.¹⁰ Forty percent of all CKD patients have diabetes, while 26% suffer from hypertension.^{11,12} The growing number of people with these two diseases is due in part to lifestyle factors, such as obesity and lack of exercise.

CKD is also associated with cardiovascular disease.^{13,14,15,16} Almost 40% of patients who begin dialysis are found to have cardiovascular disease, and over half of ESRD mortality is caused by cardiovascular disease.^{17,18} Populations at risk for CKD, and ultimately ESRD, include not only those with diabetes and hypertension, but also certain racial and ethnic groups. The incidence of ESRD among African Americans, American Indians/Alaska Natives, Asians/Pacific Islanders, and Hispanics is approximately four times greater, three times greater, 50 percent greater, and 40 percent greater than it is for white Americans, respectively.¹⁹

Routine screening and treatment with currently available therapies can reduce the morbidity and mortality of CKD and slow the advance towards ESRD. Treating ESRD requires renal replacement therapy (either a kidney transplant or dialysis). Without one of these therapies, the disease is fatal. Even with dialysis, the annual mortality rate is about 20%.^{20,21}

ⁱ Clinical definitions of CKD include an elevated serum creatinine or the presence of microalbuminuria. More recently, the National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) defined CKD in terms of the glomerular filtration rate, the best overall measure of kidney function.

The human toll is substantial not only in terms of lives lost, but also in quality of life lived. The majority of ESRD patients are on hemodialysis at dialysis centers. These patients must get dialysis 4 days a week, 4 hours a day, making it difficult for them to continue to work or go to school.²² ESRD patients with a kidney transplant generally experience better quality of life, living from 8 to 25 years longer than those without.²³ For many patients, transplant is the treatment of choice.

CKD, including ESRD, is expensive to treat. In 2000, almost \$19 billion was spent treating the disease, with the Medicare program paying some \$14 billion of that total.²⁴ Between 1991 and 2001, Medicare spending for outpatient dialysis services increased about 10% per year, the fastest growing expenditure of the Medicare program.²⁵ The Medicare program has been the primary bill-payer for ESRD treatment since 1972, when Medicare began providing coverage for individuals with ESRD, regardless of age. Currently, Medicare covers 93% of the ESRD patient population.^{26,27}

How the NHQR Measures ESRD Quality of Care

Well-established measures exist for tracking quality of care for ESRD patients, particularly measures relating to adequacy of dialysis and management of anemia. These measures, based on the National Kidney Foundation (NKF) Dialysis Outcome Quality Initiative Clinical Practice Guidelines, were developed and fully endorsed by the renal community, as well as by public- and private-sector partners. This was done under the auspices of the Medicare program's Clinical Performance Measures Project, known as the CPM Project.^{28,29} National data for this set of measures, with the exception of the vascular access measures, have been collected and reported annually since 1994. Vascular access measures have been collected by the CPM Project since 1999.

A 1997 Congressional directive to develop public reporting measures that would help consumers choose a dialysis facility led to development of three facility-level measures. All three have been reported (and updated annually) on Medicare's consumer Web site, Dialysis Facility Compare (DFC, at www.medicare.gov/Dialysis/Home.asp), since January 2001. Two are comparable to similar measures collected under the CPM Project; the third addresses the relatively high rate of mortality within the dialysis population. Both national and State level data are available for the DFC measures, while national and regional, but not State data are available for the CPMs. Because of the lack of State data for the CPMs, the DFC measures were chosen for inclusion in this report.

In addition, because transplantation is the preferred treatment choice for so many ESRD patients, the NHQR also includes two quality measures for tracking transplantation. Thus the NHQR uses these five measures to track care for patients with ESRD:

- Percent of hemodialysis patients with a urea reduction ratio (or URR) equal to or greater than 65; this measures how well urea, a waste product in the blood, is eliminated.

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- Percent of patients with a hematocrit of 33 or greater; this measure tracks how well the patient's anemia (low blood count) is managed.
- Patient standardized mortality ratio,ⁱⁱ which compares actual with expected rates of survival at both the national and State levels.
- Percent of dialysis patients on a waiting list for transplantation. This measure reflects whether doctors are referring patients for a transplant workup evaluation.
- Percent of patients with treated chronic kidney failure who receive a transplant within 3 years of entry on the waiting list.

No system exists to collect data on early stage CKD patients that is comparable to that used for ESRD. There is no agreement on a core set of measures for tracking quality of care for patients with early stage CKD.

How the Nation Is Doingⁱⁱⁱ

Impressive gains have been made in the quality of care for kidney dialysis patients since measurement began in the early 1990s.³⁰ Currently, almost 90% of in-center hemodialysis patients are receiving adequate dialysis (as measured by either urea reduction ratio [URR] of 65% or greater or a comparable measure).^{iv} Tracking of this measure began in 1994. The rate has increased from about 74% in 1996 to 89% in 2000. This gain is evidenced for both sexes and across all ages and races (University of Michigan, 2000).

Over 75% of ESRD patients have good anemia management (measured as either hematocrit of 33% or higher or a comparable measure) (University of Michigan, 2000).

One in five ESRD patients reports being registered on a transplant waiting list. States vary substantially in registration rates for transplantation (USRDS, 2000). States also vary significantly in the proportion of ESRD patients with transplants, with the best performing States achieving a rate that is more than double the national average.

ⁱⁱ On CMS's Dialysis Facility Compare Web site, this measure is converted into "Patient Survival Rate."

ⁱⁱⁱ Adjusting for known contributing factors, such as gender, age, and insurance status (multivariate analysis) would allow for more detailed exploration of the data, but this generally was not feasible for this report. Any adjustments that were done are noted in the detailed tables. The data presented in this report do not imply causation.

^{iv} The CPM project uses Kt/V, while DFC uses URR. The measures are comparable, but due to differences in the measures themselves, as well as their data sources, percentages reported may not be identical. The same is true for hemoglobin and hematocrit.

What We Don't Know

Measures for tracking quality of care for early stage CKD are needed. Spurred by clinical performance guidelines released in 2000 by the National Kidney Disease Outcomes Quality Initiative, greater emphasis is now being placed on treatments for earlier stages of the disease, as well as on prevention. Two areas that show the most promise for development of candidate performance measures are:

- Early detection of kidney malfunction with calculation of the glomerular filtration rate (GFR)—a measure of overall kidney health—from serum creatinine measurement.
- Proportion of patients diagnosed with CKD who are referred to a nephrologist early. Early referral is associated with lower mortality, greater rates of treatment for anemia, and higher rates of permanent vascular access (so that the risk of infection and clots from dialysis can be kept low).³¹

In addition, baselines are not established in the following areas:

- Blood pressure control through the appropriate use of prescription drugs.
- Blood sugar, salt, potassium, and cholesterol control through dietary changes.
- Malnutrition prevention.^{v,vi}

What Can Be Done

Rapid progress is being made in many areas of CKD.

First, progress is being made in available therapies. The Food and Drug Administration (FDA) reports that improved hemodialysis machines are being reviewed.³² Initial clinical trials have been completed for a new therapy that apparently works well to reduce anemia and may also eliminate the need for frequent repeated injections. Early treatment of anemia can result in reduced morbidity and mortality for patients with CKD, including reduction in the need for blood transfusions, fewer hospitalizations, fewer problems in heart function, and increased energy. The treatment of choice has been recombinant human erythropoietin (r-HuEPO), which requires frequent re-injection because of its short half-life (4 to 8-1/2 hours). Repeated injections cause pain and discomfort to the patient.³³

^v Albumin level, an approximate indicator of nutrition, is part of the CPMs collected by the Medicare program. Because of its interaction with c-reactive protein, an indicator of inflammation which raises a patient's score on serum albumin, this measure is being re-evaluated.

^{vi} Updated clinical practice guidelines have been released by KDOQI on nutrition; these may form the basis for creation of appropriate performance measures.

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Second, new research efforts have been initiated in a number of areas related to CKD. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is funding several studies:

- The Prospective Cohort Study of Chronic Renal Insufficiency is designed to provide new information on the risk factors for progression to kidney failure and for cardiovascular disease in people with CKD.
- A study of the longitudinal aspects of pediatric kidney disease. Such a study is important because some of the issues affecting children with CKD differ substantively from those of adults. Moreover, there is little information available concerning both the etiology and the magnitude of some of the impairments that affect children with CKD.³⁴
- In conjunction with the Department of Veterans Affairs (VA), NIDDK is also funding a study on strategies for managing renal support in critically ill acute renal failure (ARF) patients. The study will be a multicenter, prospective, randomized, parallel-group trial that will compare intensive renal support with conventional management of the disease.³⁵

Third, CKD educational efforts also continue to grow and improve. These efforts include a national program designed to raise awareness about CKD and the importance of proper kidney care, entitled “Kidney Care: Finding Your Strength.”³⁶ Another major educational effort was launched in 2001 by NIDDK, called the National Kidney Disease Education Program, which includes among its goals slowing the progression of kidney disease in its early stages and preventing kidney disease in those at risk.³⁷

Fourth, demonstration projects are planned. CMS is encouraging innovative approaches to ESRD through a new disease management demonstration program. This program will include a focus on the use of evidence-based practice guidelines, services that facilitate greater patient education and self-care, nephrologist involvement, protocols for anemia and diabetes management, coordination of care and attention to comorbidities (e.g., hypertension), and experienced care managers who will oversee the patient’s overall well-being.³⁸ The program includes three different delivery models and two different payment options (capitation and fee for service bundled payment), along with an incentive payment for quality. The quality incentive payment is based on two kinds of targets according to specific algorithms: one, an improvement target (for those who show marked improvement over time), and two, a threshold target (set relative to a national performance level).

Lessons Learned—CMS' ESRD Health Care Quality Improvement Program

In the Medicare ESRD program, steady improvement has been made in the quality of care provided to dialysis patients. In the early 1990s, spurred to action by evidence of poor quality care, Medicare initiated the new Health Care Quality Improvement Program (HCQIP) to be implemented through its contractors, the Networks. The program, using data to identify important variations in processes of care and focusing on the provision of technical assistance to improve those processes, began with a meeting of the Federal partners with the renal community. The two pronged approach of data and assistance worked. In 1993, only 43% of adult hemodialysis patients had a URR of 65 or above; but as reported in this report, by 2000 that figure rose to 89%. How did they do it? According to McClellan et al., 2003:

First, full participation: the renal community and the Federal government worked side by side from the start, collaborating and reaching agreement on the problems to be tackled and the methods to be employed. For example, a workgroup chose the initial indicators, seeking expert input and using available guidelines.

Second, the central role of uniform, annual data collection that helped both to highlight problem areas and track improvement over time. Frequent updates keep the renal community informed of progress and pitfalls, helping to mobilize their support and enthusiasm.

Third, the HCQIP is dynamic. When new guidelines were published, the existing structure was able to readily adapt and issue new performance measures.

Fourth, and finally, this project has demonstrated that it is possible to analyze large amounts of data and disseminate the results in a timely manner.

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List of Measures

Chronic Kidney Disease

Measure Title	National	State
Management of End Stage Renal Disease:		
Process: % of dialysis patients registered on a waiting list for transplantation	Table 1.15a	Table 1.15 b(00)
Process: % of patients with treated chronic kidney failure who receive a transplant within three years of renal failure	Table 1.16a	Table 1.16b (97)
Outcome: % of hemodialysis patients with URR of 65 or greater	Table 1.17a(00)	Table 1.17b(00)
Outcome: % of patients with hematocrit of 33 or greater	Table 1.18a(00)	Table 1.18b(00)
Outcome: Patient survival rate	XXX	Table 1.19(00)

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