The National Summit on Home Dialysis Policy

Horizon Ballroom
The Ronald Reagan Building
& International Trade Center
Washington, DC

March 29th, 2012

HONORARY CONGRESSIONAL CO-CHAIRS

Congressman Tom Marino            Congressman Jim McDermott
Congressman Jesse Jackson Jr.      Congressman John Fleming

Background Materials
Background Materials

Section One: Agenda

Section Two: General Background Information

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Ronald Reagan Building and International Trade Center  
March 29, 2012  
8:00 am - 4:00 pm  

Agenda  

8:00 AM  REGISTRATION  

8:30 AM  WELCOME  

8:45 AM  OPENING SESSION: LAYING THE FOUNDATION FOR HOME DIALYSIS  
Panelist: James Sloand, MD, Senior Medical Director, North American Renal Division, Baxter Healthcare Corporation  
Panelist: Christopher Blagg, MD, FRCP, Professor Emeritus of Medicine, University of Washington; Executive Director Emeritus, Northwest Kidney Centers  
Panelist: Captain Herman Phillips, U.S. Navy (retired), Board of Directors, National Kidney Foundation Serving the National Capital Area  
Panelist: Beth Piraino, MD, Professor of Medicine, University of Pittsburgh  

9:30 AM  REMARKS FROM CONGRESSMAN JIM McDERMOTT (D-WA)  
Honorary Summit Co-Chair and Congressional Kidney Caucus Co-Chair  

9:40 AM  PANEL DISCUSSION: EDUCATIONAL, TRAINING AND IMPLEMENTATION CHALLENGES  
Panelist: Rudolph Rodriguez, MD, Professor of Medicine, University of Washington; Director, Nephrology and Renal Dialysis Unit, Veterans Affairs Puget Sound Medical Center  
Panelist: Lisa Koester, Renal Nurse Practitioner, Washington University School of Medicine  
Panelist: Vanessa Evans, Patient Ambassador, Dialysis Patient Citizens  
Panelist: Juan Ordonez, MD, Clinical Professor of Medicine, University of California, San Francisco; Chair of the Chiefs of Nephrology, Kaiser Permanente Medical Care Program of Northern California  
Moderator: Troy Zimmerman, Vice President Government Relations, National Kidney Foundation
10:20 AM  **DELEGATE DISCUSSION**

11:00 AM  **BREAK**

**11:15 AM  **PANEL DISCUSSION: THE IMPACT OF THE NATIONAL REIMBURSEMENT SYSTEM**

Panelist: Richard Rettig, PhD, Adjunct Senior Social Scientist, Research and Development (RAND) Corporation

Panelist: Allan Collins, MD, Director, United States Renal Data System Coordinating Center

Panelist: Robert J. Kossmann, MD, President Elect, National Renal Physicians Association; Clinical Nephrologist, Nephrophiles, LLC

Moderator: Leslie Norwalk, Strategic Counsel, Epstein Becker Green; former Acting Administrator for the Centers for Medicare & Medicaid Services

11:45 AM  **DELEGATE DISCUSSION**

**12:30 PM  **LUNCHEON PANEL DISCUSSION: THE INNOVATION ENVIRONMENT**

Panelist: Susan Crowley, MD, National Program Director for Kidney Disease & Dialysis, Veterans Health Administration

Panelist: Mark Shapiro, MD, National Peritoneal Dialysis Advisor, DaVita Inc.

Panelist: Daya Ranamukhaarachchi, PhD, Senior Advisor for Innovation, Food and Drug Administration, Center for Devices and Radiological Health

Moderator: Hrant Jamgochian, JD, LLM, Executive Director, Dialysis Patient Citizens

**1:10 PM  **DELEGATE DISCUSSION**

**2:00 PM  **PANEL BRIEFING: QUALITY MEASURES AND INITIATIVES**

Panelist: Jean Moody Williams, Centers for Medicare and Medicaid Services, Director, Quality Improvement Group, Office of Clinical Standards and Quality

Panelist: Rajnish Mehrotra, MD, Professor of Medicine, David Geffen School of Medicine at University of California, Los Angeles (UCLA); Associate Chief of the Division of Nephrology and Hypertension, Harbor UCLA Medical Center

Panelist: Suhail Ahmad, MD, Chief Medical Officer, Northwest Kidney Centers

Panelist: Kathe LeBeau, Patient Advocate, Northeast Kidney Foundation

Moderator: Leslie Wong, MD, Vice President of Clinical Affairs, Satellite Healthcare

**2:40 PM  **DELEGATE DISCUSSION**

**3:15 PM  **CONSENSUS DISCUSSION & WRAP UP**

Moderator: Hrant Jamgochian, JB, LLM, Executive Director, Dialysis Patient Citizens

Moderator: Leslie Wong, MD, Vice President of Clinical Affairs, Satellite Healthcare
Section Two
General Background Information

Articles


Outpatient dialysis services
The Congress should update the outpatient dialysis payment rate by 1 percent for calendar year 2013.
Outpatient dialysis services

Chapter summary

Outpatient dialysis services are used to treat the majority of individuals with end-stage renal disease (ESRD). In 2010, more than 355,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from about 5,500 ESRD facilities. In that year, Medicare expenditures for outpatient dialysis services, including separately billable drugs administered during dialysis, were $9.5 billion, an increase of 4 percent from 2009 spending levels. For most facilities, 2010 is the last year that Medicare paid them a prospective payment for each dialysis treatment furnished and separate payments for furnishing certain drugs during dialysis. The modernized prospective payment system began in 2011 and includes dialysis drugs for which facilities previously received separate payments in the payment bundle.

Assessment of payment adequacy

Our payment adequacy indicators for outpatient dialysis services are generally positive.

Beneficiaries’ access to care—Measures include examining the capacity and supply of providers, beneficiaries’ ability to obtain care, and changes in the volume of services.

In this chapter

- Are Medicare payments adequate in 2012?
- How should Medicare payments change in 2013?
• **Capacity and supply of providers**—Dialysis facilities appear to have the capacity to meet demand. Growth in the number of dialysis treatment stations has generally kept pace with growth in the number of dialysis patients.

• **Volume of services**—Between 2009 and 2010, the number of FFS dialysis patients and dialysis treatments grew at similar rates (4 percent and 5 percent, respectively). Per capita use of erythropoiesis-stimulating agents, the drug class accounting for three-quarters of dialysis drug spending, declined during this time. This decline is linked to clinical evidence showing that higher use of these drugs is associated with increased risk of cardiovascular events. It also may be linked to facilities’ and physicians’ modifying their prescribing patterns in anticipation of the new payment method that began in 2011 that no longer pays separately for these drugs.

**Quality of care**—Dialysis quality has improved over time for some measures, such as use of the recommended type of vascular access—the site on the patient’s body where blood is removed and returned during hemodialysis. Other measures, such as rates of rehospitalization within 30 days, suggest that improvements in quality are still needed.

**Providers’ access to capital**—Information from investment analysts suggests that dialysis providers continue to have adequate access to capital. The number of facilities, particularly for-profit facilities, continues to increase.

**Medicare payments and providers’ costs**—In 2010, the Medicare margin for dialysis services and drugs was 2.3 percent for freestanding dialysis facilities. We project the Medicare margin for outpatient dialysis services will be 2.7 percent in 2012. This projection reflects payment updates of 2.5 percent in 2011 and 2.1 percent in 2012; the 2 percent reduction in total spending that the Medicare Improvements for Patients and Providers Act of 2008 mandated in 2011; the 3.1 percent transitional budget-neutrality adjustment in effect between January and March 31, 2011; the estimated 0.2 percent payment reduction due to Medicare’s quality incentive program in 2012; and a conservative behavioral offset to account for efficiencies in the use of drugs that are anticipated under the new dialysis payment method.
**Background**

End-stage renal disease (ESRD) is the last stage of chronic kidney disease and is characterized by permanent irreversible kidney failure. ESRD patients include those who are treated with dialysis—a process that removes wastes and fluid from the body—and those who have a functioning kidney transplant. Because of the limited number of kidneys available for transplantation and because of potential patients’ suitability for transplantation, 70 percent of ESRD patients undergo dialysis. The text box (above) summarizes the different types of dialysis. Patients receive additional items and services related to their dialysis treatments, including dialysis drugs to treat conditions such as anemia and bone disease resulting from the loss of kidney function.

The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD who are eligible for Social Security benefits, including those under age 65 years. To qualify for the ESRD program, individuals must be fully or currently insured under the Social Security or Railroad Retirement program, entitled to benefits under the Social Security or Railroad Retirement program, or the spouse or dependent child of an eligible beneficiary. ESRD patients entitled to Medicare due to kidney disease alone have the same benefits as other Medicare patients.

For individuals entitled to benefits due to ESRD alone, Medicare coverage does not begin until the fourth month after the start of dialysis, unless the individual had a kidney transplant or began training for self-care, including those dialyzing at home. About half of new ESRD patients each year are under age 65 and thus are entitled to Medicare because they have chronic renal failure. In 2009, there were about 113,000 new dialysis patients, inclusive of individuals covered by Medicare and those not covered by Medicare. According to the U.S. Renal Data System (USRDS), between 2008 and 2009, the rate of new ESRD cases increased by 1 percent to 355 per million population (United States Renal Data System 2011).

Most dialysis patients—more than 355,000 patients in 2010—are covered by fee-for-service (FFS) Medicare as the primary or secondary payer (Figure 6-1, p. 144). Compared with all Medicare patients, FFS dialysis patients are disproportionately younger and African American (Table 6-1, p. 145). Nearly three-quarters of FFS dialysis patients are less than 75 years old and 36 percent are African American. About 91 percent of FFS dialysis patients are covered by Medicare as the primary payer (Figure 6-1). This trend is especially pronounced among African Americans (Table 6-1).
dialysis patients are enrolled in Part D plans or have other sources of creditable drug coverage.

To help pay for Part A and Part B cost sharing, most FFS dialysis patients have supplemental insurance. About 47 percent of patients are dually eligible for Medicare and Medicaid. According to the 2008 Medicare Current Beneficiary Survey, 11 percent of Medicare ESRD patients lack supplemental insurance. Medicare is the secondary payer (for Part A and Part B) for 7 percent of FFS dialysis patients who are insured by an employer group health plan (EGHP) at the time they are diagnosed with ESRD. If an EGHP covers a beneficiary at the time of ESRD diagnosis, it is the primary payer for the first 33 months of care (as long as the individual maintains the EGHP coverage). EGHPs include health plans that beneficiaries were enrolled in through their own employment or through a spouse’s or parent’s employment before becoming eligible for Medicare due to ESRD.

Although most dialysis patients who are entitled to Medicare are enrolled in FFS, in recent years, the share of Medicare dialysis patients in Medicare Advantage (MA) plans has increased. In 2009, nearly 13 percent of Medicare dialysis patients were enrolled in MA plans, an increase from 7 percent in 2005 (United States Renal Data System 2011).

According to CMS’s renal facility survey, about 96 percent of all patients are covered by Medicare. The share of dialysis patients not covered by Medicare (as either the primary or the secondary payer) between 2004 and 2009 (the most recent five-year period for which data are available) remained relatively steady, ranging between 4 percent and 5 percent.

The two principal providers of dialysis care are the facilities that furnish dialysis treatments and the physicians (often nephrologists, who specialize in the treatment of kidney diseases) who prescribe and manage the provision of dialysis and establish the patient’s plan of care. Medicare uses separate methods to pay for these services. Under the new payment method, Medicare pays facilities a prospective payment for each dialysis treatment they furnish. By contrast, physicians and practitioners are paid a monthly rate for outpatient dialysis-related management services. The monthly payment amount varies based on the number of visits provided each month, the age of the beneficiary, and whether the patient is receiving dialysis in a facility or at home. While this chapter focuses on the fee that Medicare pays to facilities, it is important to recognize that facilities and physicians collaborate to care for dialysis patients and only together can they improve quality in the long term.

In 2011, CMS paid most dialysis facilities under a new outpatient dialysis payment policy

In 2011, to improve efficiency, Medicare began to phase in a new prospective payment system (PPS) for dialysis facilities. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) updated the outpatient dialysis payment method by broadening the payment bundle in 2011 to include dialysis drugs and laboratory tests that were previously separately billable and implementing a pay-for-performance program in 2012. MIPPA’s provisions are consistent with the Commission’s long-standing recommendation to modernize the outpatient dialysis payment system (Medicare Payment Advisory Commission 2001). We contended that Medicare could provide incentives for controlling costs and
promoting quality care by broadening the payment bundle to include drugs, laboratory services, and other commonly furnished items that providers formerly billed separately and by linking payment to quality. The new bundled rate is designed to create incentives for facilities to furnish services more efficiently by reducing incentives inherent in the former payment method to overutilize drugs.

Table 6-2 (p. 146) compares features of the new and former payment methods. Like the new method, the previous one pays facilities for a single dialysis treatment by using a prospective payment—often referred to as the composite rate. However, the new payment method differs from the former one in the following ways: (1) it uses a broader payment bundle, (2) it sets payment using a greater number of patient-level payment adjusters, (3) it provides an outlier payment for high-cost patients, (4) it increases the base rate by a low-volume adjustment for certain low-volume facilities, and (5) it links facilities’ payments to the quality of care they furnish. The Commission’s Payment Basics provides more information about Medicare’s former and new methods for paying for outpatient dialysis services (available at http://medpac.gov/documents/MedPAC_Payment_Basics_11_dialysis.pdf).

In 2011, most dialysis facilities (about 87 percent), including the two largest dialysis organizations, elected to be paid under the new PPS instead of the four-year transition (Centers for Medicare & Medicaid Services 2011b). In 2012, under the new PPS, the base prospective payment is $234.81 per treatment, which includes all ESRD-related services, including injectable drugs and selected laboratory services that were previously separately billable. For the 13 percent of all dialysis facilities that are paid under the four-year transition to the new payment method, in 2012, 50 percent of their payment is based on the new payment method and 50 percent of their payment is based on the former payment method. In 2012, under the former method (i.e., basic case-mix adjusted composite rate system), the base composite rate (including the drug add-on payment) is about $162 per treatment. Separately billable dialysis drugs are paid according to the Part B average sales price, and separately billable laboratory tests are paid according to the laboratory fee schedule.

**Concerns about the new dialysis prospective payment method**

We have identified three issues concerning the new payment method that we intend to continue to follow. We anticipate addressing them again in 2012 after we evaluate the first-year experience with the new payment method using 2011 claims and cost report data. These issues are:

- **Lower use of dialysis drugs:** If the trend in the decline in the use of dialysis drugs continues, Medicare might consider using some of the associated savings...
### TABLE 6–2

New dialysis payment method broadens the payment bundle and includes more beneficiary-level adjustments, a low-volume adjustment, and payment for high-cost outliers

|------------------------|------------------------------------------|---------------------------------------------|
| **Payment bundle**     | Composite rate services, which include: nursing, dietary counseling and other clinical services, dialysis equipment and supplies, social services, and certain laboratory tests and drugs | • Composite rate services  
• Separately billable (Part B) injectable dialysis drugs and their oral equivalents  
• ESRD-related laboratory tests  
• Selected renal-related oral-only Part D drugs (in 2014) |
| Unit of payment        | Single dialysis treatment                 | Single dialysis treatment                    |
| Drug add-on payment to the composite rate | Yes                                      | None                                        |
| Self-dialysis training services adjustment | Yes                                      | Yes                                         |
| Beneficiary-level adjustments | • For adults: age, body surface area, and body mass  
• For pediatric beneficiaries: none | • For adults: age, dialysis onset, body surface area, body mass, and 6 comorbidities*  
• For pediatric patients: age and dialysis method |
| Facility-level adjustments | • Wage index                             | • Wage index  
• Low-volume adjustment |
| Outlier policy         | None                                     | Applies to the portion of the broader payment bundle comprising the drugs and services that were formerly billed separately |
| Quality incentive program | None                                    | • Begins in 2012, uses 3 measures: percentage of patients with hemoglobin less than 10.0 g/dL, percentage of patients with hemoglobin greater than 12.0 g/dL, percentage of patients with URR greater than 65 percent  
• In 2013, uses 2 measures: percentage of patients with hemoglobin greater than 12.0 g/dL and percentage of patients with URR greater than 65 percent  
• In 2014 uses 6 measures: percentage of patients with URR greater than 65 percent, percentage of patients with hemoglobin greater than 12 g/dL, percentage of patients receiving treatment through an AV fistula or catheter, whether the facility reports certain dialysis-related infections to the CDC’s National Healthcare Safety Network, whether the facility administers a patient experience of care survey, whether the facility monitors phosphorus and calcium levels on a monthly basis |
| Update                 | No statutory provision                   | Begins in 2012, set at ESRD market basket less productivity adjustment |

Note: PPS (prospective payment system), ESRD (end-stage renal disease), URR (urea reduction ratio), AV (arteriovenous), g/dL (grams/deciliter), CDC (Centers for Disease Control and Prevention).

*Payment for adults is not adjusted by dialysis method.

to pay for other renal-related services, such as the oral-only Part D drugs that CMS intends to include in the payment bundle in 2014 and more frequent hemodialysis.

- **The quality incentive program (QIP):** In 2013 and 2014, the QIP lacks measures that hold providers accountable for undertreatment of anemia and bone disease, two common renal comorbidities.

- **The low-volume adjuster:** This adjuster does not yet consider the distance between a low-volume facility and the next closest facility. Consequently, Medicare may be subsidizing some low-volume facilities, particularly those located in urban and rural micropolitan areas, which are near another facility.

In addition to these three issues, industry representatives of dialysis facilities are concerned that they often lack the necessary documentation to bill Medicare for the six patient-level comorbidity adjustments under the requirements of the new payment method. CMS requires dialysis facilities to provide documentation in the patient’s medical record to support any diagnosis recognized for a payment adjustment (Centers for Medicare & Medicaid Services 2010). As a result, they contend that Medicare’s payments for dialysis services may be less than what was intended in 2011.

**Lower use of dialysis drugs** Since 2009, per capita use of certain dialysis drugs, particularly erythropoiesis-stimulating agents (ESAs), which are used to treat anemia, declined. Our analysis of Medicare claims data shows that between 2009 and 2010, the average erythropoietin dose per patient per week declined by 1.4 percent. Between January 2010 and December 2010, our analysis finds that the average dose per patient declined by 7 percent. According to industry data, between January and June 2011, the erythropoietin dose per patient per week fell by an additional 4 percent for the two largest dialysis organizations (Dialysis Outcomes and Practice Patterns Study 2011).

If the trend in lower drug use continues, some of the potential savings might offset some of the cost associated with including the oral-only Part D drugs in the bundle, which CMS intends to do in 2014.6 (CMS delayed including the oral-only Part D drugs in the bundle in order to complete an evaluation of the drugs’ pricing data and address operational concerns.) Some of the savings might also be used to pay for more frequent hemodialysis.

**The quality incentive program** Under the new payment method, with dialysis drugs in the broader payment bundle, some providers may have an incentive to reduce their use to the extent clinically possible. However, the QIP in 2013 and 2014 does not include measures that hold facilities accountable for the undertreatment of anemia and bone disease.

In 2012, the QIP measures the undertreatment of anemia—expressed as the percentage of patients receiving ESAs with an average hemoglobin less than 10.0 grams per deciliter (g/dL) of blood. CMS is not using this measure in the 2013 and 2014 QIPs because (1) it cannot identify a specific hemoglobin lower bound level that has been proven safe for all patients treated with ESAs and (2) it contends that, based on the revision of the ESA label by the Food and Drug Administration (FDA) in 2011, it would not be appropriate for the QIP to continue encouraging providers to achieve hemoglobin levels above 10 g/dL in all patients. In addition, the QIP does not hold dialysis providers accountable for the outcomes of undertreatment of anemia, such as blood transfusions and hospitalizations. CMS proposed, but did not implement, a standardized hospitalization ratio measure for the 2014 QIP.

In 2014, the QIP will measure whether facilities monitor two clinical outcomes (phosphorus and calcium levels) of bone disease and mineral management. But the QIP will not require that facilities submit data on mineral metabolism levels nor will it hold providers accountable for the outcomes of undertreatment.

**The low-volume adjuster** Low-volume facilities meeting CMS’s definition are paid an 18.9 percent adjustment to the base payment rate to account for the higher costs they incur. CMS defined a low-volume facility as one that furnishes fewer than 4,000 treatments (including those for non-Medicare patients) in each of the three years before the payment year and that has not opened, closed, or received a new provider number due to a change in ownership during the three-year period. Facilities under common ownership and within 25 road miles of each other are treated as if they are one unit when applying the low-volume adjustment; facilities certified for Medicare participation before January 1, 2011, are exempt from this provision.

Our analysis of 2007–2009 cost reports submitted by facilities to CMS found that (1) 25 percent of low-volume facilities were within 1.2 miles of the next facility and (2) low-volume facilities located in urban and rural micropolitan areas were more likely to be in close...
Medicare spending on outpatient dialysis services

In 2010, Medicare spending for dialysis services, including dialysis drugs, totaled about $9.5 billion, an increase of 4 percent compared with 2009. Freestanding facilities accounted for 91 percent of the spending total (about $8.7 billion in 2010). Payments for composite rate services accounted for 69 percent of the total, and separately billable dialysis drugs accounted for the remainder. Three drug classes accounted for nearly all (98 percent) dialysis drug spending:

- ESAs accounted for 73 percent of total dialysis drug spending and nearly one-quarter of total dialysis spending.
- Injectable vitamin D agents accounted for 15 percent of dialysis drug spending and 5 percent of total dialysis spending.
- Injectable iron agents accounted for 10 percent of dialysis drug spending and 3 percent of total dialysis spending.

In 2010, total dialysis spending averaged $26,575 per FFS dialysis patient (Figure 6-2), a 0.5 percent decline from 2009. This modest decline in total per capita spending resulted from dialysis drug spending decreasing by nearly 5 percent; by contrast, composite rate per capita spending increased by 1 percent. The decline in per patient spending for dialysis drugs was primarily due to the lower volume of ESAs furnished to patients in 2010.

### Table 6-3

<table>
<thead>
<tr>
<th>Facility location</th>
<th>Percent of all low-volume facilities</th>
<th>Distance to closest facility (in miles)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>All low-volume facilities</td>
<td>100%</td>
<td>18.0</td>
</tr>
<tr>
<td>Urban county</td>
<td>57%</td>
<td>5.9</td>
</tr>
<tr>
<td>Rural county, micropolitan</td>
<td>17%</td>
<td>38.4</td>
</tr>
<tr>
<td>Rural county, adjacent to urban</td>
<td>17%</td>
<td>23.7</td>
</tr>
<tr>
<td>Rural county, not adjacent to urban</td>
<td>10%</td>
<td>43.9</td>
</tr>
</tbody>
</table>

Note: Urban counties contain a core area with 50,000 or more population, rural micropolitan counties contain at least one cluster of at least 10,000 and less than 50,000 population, rural counties adjacent to urban areas do not have a city of 10,000 people in the county, and rural counties not adjacent to urban areas do not have a city of 10,000 people.

Source: Data compiled by MedPAC from 2007–2009 cost reports submitted by facilities to CMS.

proximity to another facility (Table 6-3). Medicare and dialysis patients might be better served by an adjuster that targets low-volume facilities that are not in close proximity to another facility.

Industry concerns about patient comorbidity payment adjusters

Under the new payment method, CMS has designated three chronic conditions—hereditary hemolytic or sickle cell anemia, myelodysplastic syndromes, and monoclonal gammopathy—and three acute conditions—bacterial pneumonias, gastrointestinal tract bleeding with hemorrhage, and pericarditis—as beneficiary payment adjusters. These adjusters were intended to recognize the increased costs incurred by facilities when treating patients with these conditions. Some industry representatives contend that (1) they lack sufficient documentation (e.g., chest X-ray for bacterial pneumonia) to bill CMS for a comorbidity adjustment, as these conditions are typically diagnosed at other provider sites (e.g., hospital, physician office), and (2) the high labor costs incurred to collect the documentation often offset Medicare’s comorbidity payment adjustments.7

CMS included these conditions as case-mix adjusters based on regression analyses assessing the relationship between facilities’ cost per treatment for composite rate services and facilities’ payment per treatment for separately billable drugs and labs. These comorbidities had a statistically significant association with facilities’ costs and payments. Once 2011 claims data become available, the Commission intends to analyze the billing patterns of facilities under the new payment method and the prevalence of these conditions across other Part B providers.
The decrease in the use of ESAs in 2010 is partly linked to some physicians and facilities phasing in new prescribing protocols for dialysis drugs in anticipation of Medicare’s change to a bundled payment method in 2011. However, between 2006 and 2008, on a per patient basis, the mean dose per week of erythropoietin declined (by 3 percent annually) because of new clinical evidence demonstrating an association between higher use of ESAs and increased risk of cardiovascular morbidity and mortality (Food and Drug Administration 2011, United States Renal Data System 2011).

**Providers of outpatient dialysis services**

In 2011, there were nearly 5,600 dialysis facilities in the United States (Table 6-4, p. 150). Since the late 1980s, for-profit, freestanding facilities have provided the majority of dialysis treatments (Rettig and Levinsky 1991). In 2011, freestanding facilities furnished 91 percent of FFS treatments and for-profit facilities furnished 83 percent. The share of facilities that are for profit and freestanding increased from 66 percent of all facilities in 1996 to nearly 85 percent in 2011.

Although Medicare is the primary payer for the majority of dialysis patients that facilities cared for in 2010 (Figure 6-1, p. 144), information from the two largest dialysis organizations suggests that Medicare revenues accounted for only 53 percent to 63 percent of their revenues (DaVita Inc. 2010, Fresenius Medical Care AG & Co. KGaA 2010). One of the large dialysis organizations states that “although commercial payment rates vary significantly, average commercial payment rates are generally significantly higher than Medicare rates” (DaVita Inc. 2010).

Chain organizations have also dominated this sector, with the first one established in 1970. In 2011, 81 percent of facilities were affiliated with a chain organization (i.e., multifacility enterprise), and chains furnished 86 percent of FFS treatments. In 2011, the two largest dialysis chains (Fresenius Medical Care North America and DaVita) were for profit; each owned more than 1,600 clinics, which accounted for nearly 70 percent of freestanding facilities and 60 percent of all facilities, and they furnished 66 percent of FFS treatments. In 2011, 9 of the 10 largest chains were for profit.

The distribution of facilities located in urban and rural areas is generally consistent with where FFS dialysis patients live (Table 6-1, p. 145):

- 81 percent of FFS dialysis patients reside in and 78 percent of facilities are located in urban areas,
- 11 percent of FFS dialysis patients reside in and 14 percent of facilities are located in rural micropolitan areas,
- 5 percent of FFS dialysis patients reside in and 5 percent of facilities are located in rural counties adjacent to urban areas, and
- 3 percent of FFS dialysis patients reside in and 3 percent of facilities are located in rural counties not adjacent to urban areas.

Not surprisingly, the average number of dialysis treatment stations decreases as the area where facilities are located becomes more rural. On average, urban facilities had 19 treatment stations, facilities in rural micropolitan areas had 16 stations, facilities in rural counties adjacent to urban areas had 13 stations, and facilities in rural counties not adjacent to urban areas had 12 stations.
There has been significant industry consolidation in this sector. In 2005 and 2006, the four largest dialysis chains merged into two chains (referred to as the two largest dialysis organizations). Before the mergers (in 2004), the largest two organizations accounted for 37 percent of all facilities; after the mergers (in 2007), the largest two organizations accounted for nearly 60 percent of all facilities.

In addition to operating most dialysis facilities in 2011, the two largest dialysis organizations are vertically integrated. One of the largest dialysis organizations is the leading supplier of dialysis products, such as hemodialysis machines and dialyzers, and develops and distributes renal-related pharmaceutical products (e.g., phosphate binders) (Fresenius Medical Care AG & Co. KGaA 2006). Each of the two largest dialysis organizations (1) operates an ESRD-related laboratory, a pharmacy, and one or more centers that furnish vascular access services; (2) provides ESRD-related disease management services; and (3) operates dialysis facilities internationally.

Although large-chain organizations dominate this sector, an individual dialysis facility is relatively small compared with other institutional providers, such as PPS hospitals. On average, in 2010, a facility provided nearly 10,600 treatments to 75 patients per year. Smaller facilities (in the 25th percentile of all treatments and patients) provided about 5,560 treatments to 40 patients per year, while...
larger facilities (in the 75th percentile of all treatments and patients) provided nearly 14,000 treatments to nearly 100 patients per year.

As mentioned earlier, physicians collaborate with facilities to care for dialysis patients. As we describe in the online appendix to this chapter (available at http://www.medpac.gov), in many instances, this collaboration includes physicians having financial or ownership interests in dialysis facilities that chain organizations operate. The statute permits physicians who refer patients to a dialysis facility to have financial and ownership interests in the facility. For example, joint ventures are a common business model in the dialysis sector, in which physicians own a minority stake and chain organizations own a majority stake in a dialysis facility. Physicians with financial and ownership interests share similar incentives with the dialysis chains to be efficient in furnishing services. Such incentives could affect the delivery of services, such as leading to overfurnishing dialysis drugs under the former payment method (when Medicare paid for them on a per unit basis) and underfurnishing them under the new payment method (when Medicare pays for them in the payment bundle). Such incentives may also affect the type of dialysis that is recommended to the patient. Complete data are lacking to assess the specific financial relationships between physicians and dialysis chain organizations. Disclosure of such information, as recommended by the Commission in 2009, would help CMS and other payers determine whether physician ownership might influence the quality of care and overall spending.

Are Medicare payments adequate in 2012?

To address whether payments for 2012 are adequate to cover the costs that efficient providers incur and how much providers’ costs should change in the update year (2013), we examine several indicators of payment adequacy. Specifically, we assess patients’ access to care by examining the capacity of dialysis providers and changes over time in the volume of services provided, quality of care, providers’ access to capital, and the relationship between Medicare’s payments and providers’ costs. Most of our payment adequacy indicators for dialysis services are positive: Provider capacity is sufficient, volume growth (the number of dialysis treatments) has kept pace with growth in the number of beneficiaries, some improvements in quality have occurred, and provider access to capital is sufficient. In 2010, we estimate the Medicare margin for composite rate services and dialysis services was 2.3 percent, and we project it will be 2.7 percent in 2012.

Beneficiaries’ access to care: Indicators continue to be favorable

Our analysis of access indicators—including the capacity of providers to meet patient demand, changes in patients’ ability to obtain different types of dialysis, and changes in the volume of services—shows that patients’ access to care remains favorable.

Capacity of facilities that are freestanding, for profit, and affiliated with a chain is growing and has kept pace with patient demand

From 2006 to 2011, the number of facilities and their capacity to furnish care, as measured by dialysis treatment stations, each increased by 4 percent annually (Table 6-4). During this period, the capacity of facilities that were freestanding, for profit, and affiliated with a chain organization grew by 5 percent per year. By contrast, the annual growth in the capacity of facilities that are hospital based, nonprofit, and not affiliated with a chain decreased or remained about the same (–2 percent, 0.2 percent, and 0.2 percent, respectively). Between 2006 and 2011, the capacities of urban and rural facilities grew at similar rates. The capacities of urban facilities grew by 4 percent per year while the capacities of rural facilities grew at an average annual rate of 4 percent to 5 percent. Between 2010 and 2011, the growth in dialysis capacity grew by 3 percent, 1 percentage point slower than the growth in capacity between 2006 and 2011.

Growth in the numbers of dialysis stations and dialysis patients suggests that provider capacity kept up with demand for care between 2005 and 2010. During this period, the numbers of all dialysis patients (those in FFS Medicare, in MA, and not eligible for Medicare) and dialysis treatment stations increased by 4 percent per year (Figure 6-3, p. 152). Annual growth in the number of treatment stations was faster than the 2 percent annual growth in the number of FFS dialysis beneficiaries.

Most dialysis patients continue to receive thrice weekly in-center hemodialysis, but interest in other dialysis methods continues

During the most recent five-year period for which data are available (2006–2011), at least 96 percent of facilities
are certified to offer in-center hemodialysis and 46 percent are certified to offer some type of peritoneal dialysis—continuous cycle peritoneal dialysis or continuous ambulatory peritoneal dialysis (Centers for Medicare & Medicaid Services 2011a). Between 2006 and 2011, the proportion of facilities certified to offer home hemodialysis training increased from 13 percent to 23 percent. According to CMS, since 2006, facilities certified to offer home hemodialysis dialysis training programs grew by 17 percent per year, while facilities offering peritoneal dialysis grew by 4 percent annually. Industry data examining trends in home hemodialysis suggest greater growth in the number of midsized and large facilities offering more frequent home hemodialysis (five or more times weekly) than conventional home hemodialysis (three times per week) (Home Dialysis Central 2011). Between 2006 and 2011, the number of midsized and large facilities offering nocturnal home hemodialysis, short daily home hemodialysis, and conventional home hemodialysis grew annually by 38 percent, 52 percent, and 21 percent, respectively.

As we describe in the text box (opposite page), interest in the use of more frequent hemodialysis (administered at a patient’s home or in a facility) has grown because of studies showing favorable clinical outcomes and quality of life compared with conventional hemodialysis. Nonetheless, relatively few patients receive more frequent hemodialysis. According to CMS, in 2009, about 2,600 patients received hemodialysis more than four times per week. In the coming year, the Commission intends to discuss obstacles in the diffusion of more frequent hemodialysis with clinicians and other dialysis representatives.

There is continued interest in the use of home dialysis methods. Compared with in-center dialysis, studies conclude that home-based dialysis offers patients greater autonomy, improved quality of life, and enhanced satisfaction. Nonetheless, most patients receive dialysis in facilities. In 2009 (the most recent year for which data are available), 92 percent of dialysis patients received hemodialysis in a facility, while 7 percent received peritoneal dialysis (at home), and 1 percent received home hemodialysis (United States Renal Data System 2011). Between 1999 and 2009, the number of patients receiving hemodialysis in a facility increased by 4 percent per year, while the number of patients treated at home grew by 1 percent per year.

Factors contributing to greater use of in-center dialysis include patients’ preference for in-center versus home dialysis, availability of caregivers, patients’ lack of knowledge about home-based dialysis, and some physicians’ lack of familiarity with home modalities, which may make them less likely to discuss this option with their patients. Medicare’s former dialysis payment method was also a factor in the decline in home-based methods. The profitability of separately billable dialysis drugs provided an incentive to focus on in-center programs rather than on home-based ones. On average, peritoneal dialysis patients use fewer dialysis drugs than in-center hemodialysis patients. The new payment method might result in increased use of home methods over time. Providers’ costs to furnish the most common home-based method—peritoneal dialysis—are less than for in-center hemodialysis. In addition, in 2010, Medicare began to pay for educating pre-ESRD beneficiaries about kidney disease. Researchers report that inadequate education is one of the barriers to increasing the use of home dialysis (Golper et al. 2011).
Use of more frequent hemodialysis by Medicare patients

During the past few years, the use of more frequent hemodialysis (furnished at home or in a center five or more times per week compared with the thrice-weekly regimen) has modestly increased. According to CMS, the number of patients receiving hemodialysis more than four times per week increased from 1,700 patients in 2007 to about 2,600 patients in 2009.

Interest in more frequent hemodialysis regimens has grown during the past decade because of studies showing improved outcomes and quality of life. By smoothing out fluctuations in fluid levels and toxins between dialysis sessions, hemodialysis five or more times per week may better approximate the organic kidney than thrice-weekly treatment. Until 2007, the body of evidence demonstrating improved clinical outcomes and quality of life associated with more frequent hemodialysis consisted of uncontrolled studies. However, two randomized controlled studies—one conducted between 2004 and 2006 and the other conducted between 2006 and 2010—demonstrated improved clinical outcomes and quality of life associated with more frequent hemodialysis compared with thrice-weekly hemodialysis.

The first controlled trial compared outcomes of 52 patients randomized to receive either frequent nocturnal hemodialysis or conventional hemodialysis (Culleton et al. 2007). Compared with conventional hemodialysis, frequent nocturnal hemodialysis improved left ventricular mass, reduced the need for blood pressure medications, improved some measures of mineral metabolism, and improved selected measures of quality of life.

The second controlled trial, funded by the National Institutes of Health (NIH), found that 125 patients randomized to receive short daily hemodialysis (six times per week) had improvements in the coprimary outcomes (which include mortality, left ventricular mass, and self-reported physical health) compared with the 120 patients who received hemodialysis thrice weekly (National Institutes of Health 2010). The more frequent treatments helped avoid excessive phosphate levels in the blood (hyperphosphatemia) and improved control of blood pressure, which are often problems for patients on dialysis. The only downside was that access to blood vessels needed to be adjusted about twice as often in patients who received more treatments.

However, a related NIH-sponsored study reported no differences in the coprimary outcomes among 87 patients randomized to receive either nocturnal hemodialysis six times per week or conventional hemodialysis (Rocco et al. 2011). The researchers found that patients in the nocturnal group had improved control of hyperphosphatemia and hypertension (secondary outcome measures).

Despite these generally favorable findings, relatively few patients receive this type of dialysis. One obstacle in the diffusion of more frequent hemodialysis is CMS’s policy of capping payment for dialysis services at a rate of thrice weekly. Medicare’s contractors have the discretion to pay for a fourth dialysis treatment if there is sufficient medical justification, such as fluid overload and congestive heart failure.

Finally, researchers might be better able to retrospectively evaluate the outcomes of patients on more frequent hemodialysis using the claims facilities submit for payment if the coding (based on the Healthcare Common Procedure Coding System) is more specific about the dialysis type. Although Medicare uses codes differentiating hemodialysis from peritoneal dialysis, specific codes are lacking to distinguish among patients on nocturnal, short daily, and conventional hemodialysis.

Types of facilities that closed and their effect on beneficiaries’ access to care

Each year, we assess whether specific groups of patients are disproportionately affected by facility closures. Specifically, we compare the characteristics of dialysis patients treated by facilities that were open in 2009 and 2010, that newly opened in 2010, and that closed in 2009. This analysis uses claims submitted by facilities to CMS and CMS’s Dialysis Compare database and the ESRD facility survey.

Compared with facilities that remained open, facilities that closed in 2009 (90 units) were more likely to be...
hospital based and nonprofit, which is consistent with long-term trends in supply (as shown in Table 6-4, p. 150). In contrast, facilities that opened in 2010 (260 units) were more likely to be freestanding and for profit, which is also consistent with the long-term trends in supply.

On net, between 2009 and 2010, the number of dialysis treatment stations, a measure of providers’ capacity, increased by 4 percent. On average, facilities that closed had less capacity than new facilities and those that remained open in both years. In 2009, closures disproportionately occurred in more rural areas. Of closed facilities, 16 percent were located in rural (micropolitan) counties with a town of 10,000 people or more, 9 percent were located in rural counties adjacent to urban areas, and 6 percent were in rural counties not adjacent to urban counties. By comparison, among facilities that remained open in 2009 and 2010, 14 percent were in rural micropolitan counties, 5 percent were in rural counties adjacent to urban areas, and 3 percent were in rural counties not adjacent to urban counties.

Facility closures in 2009, which affected about 3,600 FFS dialysis patients, did not appear to affect any demographic group disproportionately, including the elderly, females, and patients dually eligible for Medicare and Medicaid. In contrast to last year’s findings, this year’s analysis does not find that African Americans were disproportionately affected by facility closures. African American patients represented 38 percent of patients treated at facilities that remained in business and 30 percent of patients treated at facilities that closed. About 1,000 FFS dialysis patients were affected by rural facilities that closed in 2009.

Finally, 61 percent of facilities in business in 2009 and 2010 were operated by the two largest dialysis chains; only 29 percent of facilities that closed in 2009 were operated by the two largest organizations. Consistent with our findings from last year’s analysis, all demographic groups continued to obtain care from the two largest dialysis organizations that serve the majority of FFS beneficiaries.

Volume of services

To assess changes in the volume of dialysis services, we examined trends in the number of dialysis treatments furnished to beneficiaries and in the use of drugs administered during dialysis between 2009 and 2010. Between 2009 and 2010, dialysis treatments grew at an average annual rate that kept pace with the growth in the number of FFS dialysis patients. During this period, the number of dialysis treatments grew by 5 percent per year, while the number of FFS dialysis patients grew by 4 percent per year.

Between 2009 and 2010, the mean weekly erythropoietin dose per patient declined by 1.4 percent. The slowdown in the volume of ESAs administered is linked to some physicians and facilities phasing in new prescribing protocols for dialysis drugs in anticipation of Medicare’s change to a bundled payment method in 2011. In addition, new clinical evidence that demonstrated an association between higher use of ESAs and increased risk of cardiovascular morbidity and mortality may have contributed to the slowdown, as it did between 2006 and 2008 when the mean dose per patient fell by 3 percent per year (United States Renal Data System 2011).

Our analysis finds that erythropoietin use declined in 2010 across all demographic groups. We examined the subset of FFS dialysis patients who received erythropoietin in January and December 2010. There was an overall 7 percent decline in the units of erythropoietin per patient per month (Table 6-5). The decline was slightly larger for younger patients than for older patients and for African Americans than for whites.

Since 2011, industry data suggest that erythropoietin use continues to decline. Between January and June 2011, the average erythropoietin dose per patient per week furnished by the two largest dialysis chains decreased by 4 percent (Dialysis Outcomes and Practice Patterns Study 2011).

Between 2009 and 2010, the volume of all other dialysis drugs also declined (by 1 percent). For this analysis, we held the drug payment rate constant and looked at the dollar change in the total volume of the products. Rates of volume change differed by drug class. The volume of vitamin D analogs fell by 2 percent, while the volume of iron agents increased by 1 percent. The increase in iron volume is not unexpected, as researchers have shown that its use is associated with reduced average ESA dose (Hasegawa et al. 2010).

Quality of care: Some measures show progress, others need improvement

The Commission assesses quality of care furnished to dialysis patients using a variety of measures (clinical performance measures and beneficiaries’ outcomes) and
Use of the recommended type of vascular access—an arteriovenous (AV) fistula—also improved during this period. Hemodialysis patients require vascular access—the site on the patient’s body where blood is removed and returned during dialysis. The three basic types of vascular access are AV fistulas, AV grafts, and catheters. For most patients, the AV fistula is considered the best long-term vascular access for hemodialysis because it provides adequate blood flow, lasts a long time, and has a lower complication rate than other types of access (National Institute of Diabetes and Digestive and Kidney Diseases 2008). The goal of Fistula First—CMS’s quality improvement initiative that promotes use of AV fistulas—is for 66 percent of all hemodialysis patients to have an AV fistula. Factors affecting the use of AV fistulas include certain medical contraindications preventing their use (e.g., small or weak veins) and patients’ attitudes from different perspectives (trends for all patients and patients according to type of facility).

To assess how facilities meet Medicare’s clinical performance measures, we used data from the Elab Project, in which nearly all dialysis facilities provide the ESRD networks with patient-level laboratory data on clinical indicators, such as dialysis adequacy and anemia status. We used data from CMS’s quality project, Fistula First, to monitor changes in the types of vascular access hemodialysis patients used. To assess trends in hospitalization, mortality, and renal transplantation overall for all patients and by facility type, we used data from the USRDS. We used industry data from the Dialysis Outcomes and Practice Patterns Study (DOPPS) to assess clinical outcomes under the new payment method (since 2011).

The conclusions of this year’s assessment of changes in quality are consistent with those in last year’s report. Dialysis adequacy remains high and improvements have been made in the proportion of all patients meeting the FDA’s anemia status recommendations and using the type of vascular access recommended by renal clinicians. Between 2003 and 2009, mortality, while high, trended downward and hospitalization rates remained about the same. Rates of kidney transplantation increased for Asian Americans and Native Americans, remained about the same for African Americans, and decreased for whites. Some types of facilities achieved statistically significantly lower rates of standardized hospitalization and mortality rates than others.

**Trends in clinical indicators of dialysis quality**

Between 2003 and 2010, the quality of some aspects of dialysis care remained high. The proportion of dialysis patients receiving adequate dialysis (a measure of the effectiveness of the dialysis treatment in removing waste products from the body) remained high (Table 6-6, p. 156). According to this measure, from 93 percent to 95 percent of hemodialysis patients and 88 percent to 90 percent of peritoneal dialysis patients received adequate dialysis.

Also during this period, increasing proportions of dialysis patients had their anemia under control (i.e., with a mean hemoglobin between 10 g/dL and 12 g/dL). Nearly all dialysis patients have anemia because diseased kidneys typically do not produce sufficient amounts of a hormone that stimulates production of red blood cells, leading to the development of anemia. Providers furnish ESAs and injectable iron to treat anemia.

Use of the recommended type of vascular access—an arteriovenous (AV) fistula—also improved during this period. Hemodialysis patients require vascular access—the site on the patient’s body where blood is removed and returned during dialysis. The three basic types of vascular access are AV fistulas, AV grafts, and catheters. For most patients, the AV fistula is considered the best long-term vascular access for hemodialysis because it provides adequate blood flow, lasts a long time, and has a lower complication rate than other types of access (National Institute of Diabetes and Digestive and Kidney Diseases 2008). The goal of Fistula First—CMS’s quality improvement initiative that promotes use of AV fistulas—is for 66 percent of all hemodialysis patients to have an AV fistula. Factors affecting the use of AV fistulas include certain medical contraindications preventing their use (e.g., small or weak veins) and patients’ attitudes from different perspectives (trends for all patients and patients according to type of facility).

**TABLE 6-5**

| Monthly units of erythropoietin declined between January and December 2010 |
| Change in monthly units between January and December 2010 |
| All FFS patients | −7% |
| Age |
| Under 45 years | −8 |
| 45–64 years | −7 |
| 65–74 years | −6 |
| 75+ years | −6 |
| Sex |
| Male | −7 |
| Female | −7 |
| Race |
| White | −5 |
| African American | −8 |
| Affiliated with one of 2 largest chains | −6 |
| All other freestanding facilities | −9 |

Note: FFS (fee-for-service). Analysis includes FFS dialysis patients who received erythropoietin in January and December 2010 at a freestanding dialysis facility.

Source: Compiled by MedPAC from 2010 claims submitted by freestanding dialysis facilities to CMS.
### TABLE 6-6
Dialysis clinical indicators and outcomes continue to improve for some measures

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>2003</th>
<th>2005</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Percent of in-center hemodialysis patients:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receiving adequate dialysis</td>
<td>94%</td>
<td>93%</td>
<td>94%</td>
<td>95%</td>
<td>95%</td>
<td>95%</td>
</tr>
<tr>
<td>Anemia measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean hemoglobin 10–12 g/dL</td>
<td>48</td>
<td>44</td>
<td>49</td>
<td>57</td>
<td>62</td>
<td>68</td>
</tr>
<tr>
<td>Mean hemoglobin ≥ 13 g/dL</td>
<td>15</td>
<td>17</td>
<td>14</td>
<td>9</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Mean hemoglobin &lt; 10 g/dL*</td>
<td>6</td>
<td>5</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Dialyzed with an AV fistula</td>
<td>33</td>
<td>39</td>
<td>47</td>
<td>50</td>
<td>53</td>
<td>56</td>
</tr>
<tr>
<td>Nutritional status</td>
<td>37</td>
<td>33</td>
<td>34</td>
<td>35</td>
<td>35</td>
<td>39</td>
</tr>
<tr>
<td>Phosphorus and calcium management</td>
<td>39</td>
<td>42</td>
<td>46</td>
<td>45</td>
<td>46</td>
<td>47</td>
</tr>
<tr>
<td><strong>Percent of peritoneal dialysis patients:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receiving adequate dialysis</td>
<td>N/A</td>
<td>90%</td>
<td>89%</td>
<td>88%</td>
<td>89%</td>
<td>89%</td>
</tr>
<tr>
<td>Anemia measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean hemoglobin 10–12 g/dL</td>
<td>45%</td>
<td>44</td>
<td>48</td>
<td>52</td>
<td>57</td>
<td>58</td>
</tr>
<tr>
<td>Mean hemoglobin ≥ 13 g/dL*</td>
<td>21</td>
<td>22</td>
<td>18</td>
<td>14</td>
<td>12</td>
<td>11</td>
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<tr>
<td>Mean hemoglobin &lt; 10 g/dL*</td>
<td>7</td>
<td>7</td>
<td>7</td>
<td>9</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Nutritional status</td>
<td>21</td>
<td>20</td>
<td>20</td>
<td>19</td>
<td>18</td>
<td>20</td>
</tr>
<tr>
<td>Phosphorus and calcium management</td>
<td>40</td>
<td>44</td>
<td>46</td>
<td>45</td>
<td>47</td>
<td>47</td>
</tr>
<tr>
<td><strong>Percent of prevalent dialysis patients wait-listed for a kidney:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>15.2%</td>
<td>15.9%</td>
<td>16.3%</td>
<td>16.8%</td>
<td>17.0%</td>
<td>17.3%</td>
</tr>
<tr>
<td>White</td>
<td>14.2%</td>
<td>14.8%</td>
<td>15.2%</td>
<td>15.7%</td>
<td>15.9%</td>
<td>16.2%</td>
</tr>
<tr>
<td>African American</td>
<td>15.5%</td>
<td>16.3%</td>
<td>16.7%</td>
<td>17.3%</td>
<td>17.5%</td>
<td>17.7%</td>
</tr>
<tr>
<td>Native American</td>
<td>14.0%</td>
<td>14.2%</td>
<td>14.3%</td>
<td>15.0%</td>
<td>15.4%</td>
<td>14.9%</td>
</tr>
<tr>
<td>Asian American</td>
<td>24.4%</td>
<td>25.2%</td>
<td>25.2%</td>
<td>25.6%</td>
<td>25.6%</td>
<td>25.7%</td>
</tr>
<tr>
<td><strong>Renal transplant rate per 100 dialysis patient years:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>4.8</td>
<td>4.8</td>
<td>4.8</td>
<td>4.4</td>
<td>4.2</td>
<td>4.1</td>
</tr>
<tr>
<td>White</td>
<td>5.9</td>
<td>5.7</td>
<td>5.6</td>
<td>5.1</td>
<td>4.8</td>
<td>4.6</td>
</tr>
<tr>
<td>African American</td>
<td>3.1</td>
<td>3.2</td>
<td>3.2</td>
<td>3.0</td>
<td>2.9</td>
<td>2.9</td>
</tr>
<tr>
<td>Native American</td>
<td>3.3</td>
<td>3.4</td>
<td>4.6</td>
<td>4.4</td>
<td>4.3</td>
<td>4.9</td>
</tr>
<tr>
<td>Asian American</td>
<td>5.3</td>
<td>5.5</td>
<td>6.6</td>
<td>7.5</td>
<td>7.2</td>
<td>7.3</td>
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<td><strong>One year survival for new dialysis patients</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>All</td>
<td>78.1%</td>
<td>78.9%</td>
<td>79.6%</td>
<td>79.9%</td>
<td>80.6%</td>
<td>N/A</td>
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<tr>
<td>White</td>
<td>77.0</td>
<td>77.7</td>
<td>78.5</td>
<td>78.6</td>
<td>79.3</td>
<td>N/A</td>
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<tr>
<td>African American</td>
<td>79.3</td>
<td>80.3</td>
<td>81.0</td>
<td>81.5</td>
<td>82.6</td>
<td>N/A</td>
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<tr>
<td>Other race</td>
<td>84.2</td>
<td>85.0</td>
<td>85.3</td>
<td>86.1</td>
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<tr>
<td>45-64 years</td>
<td>84.6</td>
<td>85.3</td>
<td>85.9</td>
<td>86.0</td>
<td>86.7</td>
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<tr>
<td>65-74 years</td>
<td>75.5</td>
<td>76.5</td>
<td>77.5</td>
<td>77.5</td>
<td>77.9</td>
<td>N/A</td>
</tr>
<tr>
<td>75+ years</td>
<td>64.0</td>
<td>64.7</td>
<td>65.2</td>
<td>65.8</td>
<td>67.2</td>
<td>N/A</td>
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<tr>
<td><strong>Annual mortality rate per 100 dialysis patient years</strong></td>
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<td></td>
<td></td>
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<tr>
<td>All</td>
<td>21.4</td>
<td>20.5</td>
<td>20.0</td>
<td>19.2</td>
<td>18.5</td>
<td>18.0</td>
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<tr>
<td>White</td>
<td>23.2</td>
<td>22.2</td>
<td>21.6</td>
<td>20.8</td>
<td>20.1</td>
<td>19.6</td>
</tr>
<tr>
<td>African American</td>
<td>19.2</td>
<td>18.7</td>
<td>18.1</td>
<td>17.3</td>
<td>16.5</td>
<td>16.0</td>
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<td>Other race</td>
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<td>14.8</td>
<td>14.1</td>
<td>13.7</td>
<td>13.4</td>
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<td>45-64 years</td>
<td>17.4</td>
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<td>16.3</td>
<td>15.6</td>
<td>15.0</td>
<td>14.5</td>
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<tr>
<td>65-74 years</td>
<td>28.4</td>
<td>27.4</td>
<td>26.4</td>
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<td>23.8</td>
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<tr>
<td>75+ years</td>
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<td>41.0</td>
<td>40.3</td>
<td>39.2</td>
<td>38.0</td>
<td>37.0</td>
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<tr>
<td><strong>Inpatient admission rate per dialysis patient</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>2.0</td>
<td>2.0</td>
<td>1.9</td>
<td>1.9</td>
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<td>White</td>
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<td>1.9</td>
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<td>1.8</td>
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</tr>
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<td>Native American</td>
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<td>1.9</td>
<td>1.8</td>
<td>1.7</td>
<td>1.7</td>
<td>1.8</td>
</tr>
<tr>
<td>Asian American</td>
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<td>1.4</td>
<td>1.4</td>
<td>1.4</td>
<td>1.4</td>
<td>1.3</td>
</tr>
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<td>45-64 years</td>
<td>1.9</td>
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<td>1.8</td>
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<td>1.8</td>
</tr>
<tr>
<td>65-74 years</td>
<td>2.0</td>
<td>2.0</td>
<td>1.9</td>
<td>1.9</td>
<td>1.9</td>
<td>1.8</td>
</tr>
<tr>
<td>75+ years</td>
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<td>2.2</td>
<td>2.1</td>
<td>2.0</td>
<td>2.1</td>
<td>1.9</td>
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<tr>
<td><strong>Percent of discharges that were rehospitalized within 30 days</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>35.8%</td>
<td>36.1%</td>
<td>N/A</td>
<td>35.8%</td>
<td>N/A</td>
<td>35.9%</td>
</tr>
<tr>
<td>Cardiovascular (index hospitalization)</td>
<td>37.2</td>
<td>37.7</td>
<td>N/A</td>
<td>37.5</td>
<td>N/A</td>
<td>37.6</td>
</tr>
<tr>
<td>Infection (index hospitalization)</td>
<td>33.6</td>
<td>33.9</td>
<td>N/A</td>
<td>33.7</td>
<td>N/A</td>
<td>33.8</td>
</tr>
<tr>
<td>Vascular access (index hospitalization)</td>
<td>32.0</td>
<td>31.9</td>
<td>N/A</td>
<td>31.7</td>
<td>N/A</td>
<td>31.1</td>
</tr>
</tbody>
</table>

Note: g/dL (grams/deciliter), N/A (not available), AV (arteriovenous). Other includes Asian Americans and Native Americans. Data on dialysis adequacy, use of fistulas, and anemia management represent percent of patients meeting CMS’s clinical performance measures. United States Renal Data System (USRDS) adjusts data by age, gender, race, and primary diagnosis of end-stage renal disease.

* Lower values indicate higher quality.


Between 2009 and 2010, there was a modest increase in the proportion of patients achieving the mean albumin level that equals or exceeds the recommendation of the National Kidney Foundation. The level of albumin in the blood has been used by CMS and ESRD networks as a marker of nutritional status for patients. Researchers find a strong inverse correlation between albumin levels and mortality. Inflammation and infection can also affect albumin levels.

Clinical indicators related to the management of bone and mineral disorders, a frequent comorbidity of kidney failure, suggest some improvement between 2003 and 2010. About 47 percent of hemodialysis and peritoneal dialysis patients achieved the recommended range for phosphorus and calcium levels. Since 2007, the percentage of dialysis patients achieving the recommended range for these two measures has remained constant.

Finally, because data from our traditional sources (Elab Project, USRDS) end in 2009 or 2010, we used DOPPS, an industry-sponsored effort that samples, since 2010, representative facilities to obtain clinical outcome data on adequacy of dialysis, management of anemia, and management of bone disease. According to DOPPS, between January and April 2011:

- Across all patients, dialysis adequacy was unchanged after implementation of the new payment bundle. This finding held when the data were analyzed by race.
- Across all patients, mean hemoglobin measures (an assessment of anemia status) trended slightly down from 11.43 g/dL to 11.39 g/dL. By race, the proportion of patients with hemoglobin levels between 10.0 g/dL and 12.0 g/dL remained steady at between 75 percent and 79 percent for African Americans and at 79 percent for non-African Americans. Among patients who have hemoglobin levels outside of this range, a greater proportion of them have higher levels (greater than 12.0 g/dL) versus lower levels (less than 10.0 g/dL).
- Overall, mean serum calcium values, a measure of bone disease, decreased from 9.07 mg/dL to 9.04 mg/dL. Mean serum calcium values trended down for both African Americans and whites from January through March 2011 and then increased slightly in April 2011.

**Trends in outcomes for dialysis patients**

In general, trends in outcomes—including mortality, hospitalization, and access to kidney transplantation—suggest that improvements in dialysis quality are still needed.

Between 2003 and 2009, overall adjusted mortality rates decreased but remained high among dialysis patients. By race, dialysis patients included in the “other” category (which includes Asian Americans and Native Americans) had the lowest adjusted mortality rate; this finding is a function of the lower mortality rate among Asian Americans. In contrast to the pattern seen in the general population, adjusted mortality was lower among African American dialysis patients than among white dialysis patients (16.0 vs. 19.6 per 100 patient years, respectively, in 2009) (United States Renal Data System 2011). However, new research has demonstrated an age-based effect in the racial differences in mortality. Kucirka and colleagues found that among patients new to dialysis, African Americans under age 50 years had significantly higher mortality than their white counterparts (Kucirka et al. 2011). The authors suggest that several factors, including the differential access to kidney transplantation and socioeconomic factors, may contribute to the higher mortality rates among young, but not old, African Americans compared with whites.

Mortality rates for dialysis patients increase with age, from 14.5 per 100 patient years at risk for patients between 45 and 64 years to 37.0 per 100 patient years at risk for patients 75 years or older. Similarly, one-year survival decreases with increasing age.

Overall rates of hospitalization remained steady at about two admissions per dialysis patient per year. With the exception of lower rates for Asian Americans, hospitalization rates do not vary substantially by age and race. Between 2003 and 2009, conditions related to ESRD—cardiovascular conditions, infections, and vascular access complications—accounted for the majority of inpatient admissions for dialysis patients. In 2009, among hemodialysis patients: cardiovascular conditions accounted for about 29 percent of admissions, infections accounted for 25 percent, and vascular access complications accounted for 12 percent (United States Renal Data System 2011). According to USRDS, 30-day rates of rehospitalization for dialysis patients remained high and unchanged. For example, between 2003 and 2009, hospital stays with a primary diagnosis of infection had a 30-day rehospitalization rate of about 34 percent.
Kidney transplantation is a lifesaving medical procedure for which the demand far exceeds the transplantable organ supply. Transplantation improves clinical outcomes compared with dialysis. When no living kidney donor is available, end-stage renal disease (ESRD) patients must rely on the limited supply of cadaveric donor organs.

Multiple factors affect access to kidney transplantation: (1) a kidney allocation policy that uses immunologic factors to match kidneys to potential recipients; (2) the rate of kidney transplants from living donors; (3) patients’ attitudes and preferences, clinical characteristics, and socioeconomic status; (4) patients’ education and referral to a transplant center by the physicians and dialysis facilities who treat dialysis and predialysis patients; and (5) the criteria used by transplant centers that determine placement on the kidney waiting list (such as physical health, mental health, social support, insurance status, and financial support).

Although the principle of equity is emphasized in the distribution of this limited resource, several studies document that kidney transplantation rates differ by patients’ demographic and socioeconomic characteristics.

For example, access to kidney transplantation and organ donation rates vary by race. Data from the United States Renal Data System show that in 2009:

- White ESRD patients accounted for 61 percent of ESRD patients and received 64 percent of transplants.
- African Americans accounted for 32 percent of ESRD patients and received 25 percent of transplants.
- Asian Americans and Native Americans together accounted for 7 percent of the ESRD population and accounted for 11 percent of transplant recipients.

Researchers also find differences in access to kidney transplantation based on patients’ sex and income. Compared with whites, men, and higher income patients, African Americans, women, and lower income patients were less likely to complete the pretransplant workup (Alexander and Sehgal 1998).

From the patient’s perspective, the transplantation process involves a series of steps that include: (1) being educated about transplantation, (2) being interested in transplantation and referred to a transplant center, (3) completing the transplant center’s workup and being placed on at least one kidney waiting list, and (4) moving up the waiting list and receiving a transplant. The factors affecting this process are complex. Unequal transplantation rates reflect (1) the matching process that considers the immunologic compatibility of donor kidneys with potential recipients; (2) patient-level factors, including patients’ knowledge of renal

We looked at several measures that examine access to kidney transplantation, because it is widely considered the best treatment option for ESRD patients. Transplantation reduces mortality and improves patients’ quality of life (Eggers 1988, Kasiske et al. 2000, Laupacis et al. 1996, Ojo et al. 1994). The proportion of dialysis patients accepted on the kidney transplant waiting list showed little change over time, increasing from 17.0 percent of dialysis patients in 2008 to 17.3 percent in 2009 (Table 6-6, p. 156).

We also examined rates of kidney transplantation from 2003 to 2009. In 2009, the USRDS reported that 17,736 individuals underwent transplantation, which represents about 25 percent of the ESRD patients wait-listed for a kidney in that year. Between 2003 and 2006, rates of kidney transplantation remained relatively steady (Table 6-6) (United States Renal Data System 2011). However, between 2006 and 2009, the rate of kidney transplantation and the total number of procedures declined. Between 2006 and 2009, African Americans and whites experienced a decrease in the rate of kidney transplantation while
treatment options, their preferences, and their clinical characteristics; and (3) provider-level factors, including the process by which nephrologists and dialysis facilities educate patients about different treatment opportunities and the evaluation process that transplant centers use to place patients on the kidney waiting list.

Lower rates of renal transplantation, particularly among African Americans, partly reflect the immunologic (including blood type and antibodies in the blood) matching process of donors to recipients. Reducing the number of biological mismatches improves the outcomes of kidney transplantation; as a result, the matching process gives priority to candidates who have fewer mismatches. Researchers report that because of racial and ethnic differences in the frequency of alleles (any one of two or more genes) at a given site on a chromosome, whites are more likely than people in other racial and ethnic groups to find a good match in the cadaver kidney pool (Roberts et al. 2004). This difference, coupled with the matching process, increases the transplantation rate among white candidates and reduces access for candidates with less common blood types and antibodies in the blood, including those who are members of minority groups (Roberts et al. 2004).

A recent study shows the importance of these immunologic factors on access to kidney transplantation. According to Hall and colleagues, a change in the relative priority given to tissue matching in 2003 significantly decreased, but did not eliminate, racial disparity in access to transplantation for individuals on the kidney waiting list (Hall et al. 2011). In 2003, the United Network for Organ Sharing, the private nonprofit organization that manages the U.S. organ transplant system, eliminated giving priority to a specific immunologic factor (HLA-B antigen) in the process that matches cadaver kidneys to potential recipients. These researchers estimate a 23 percent reduction in the disparity for wait-listed African Americans and whites after the policy change in 2003.

Differences in access may also stem from differences in transplants from live donors, which, in 2009, accounted for about 36 percent of all transplant procedures (United States Renal Data System 2011). By race, whites accounted for 73 percent of live donor procedures, compared with 13 percent for African Americans, 11 percent for Asian Americans, and 2 percent for Native Americans. Researchers note that there are fewer living donors among African Americans, increasing the dependence of African American patients on cadaver organs (Young and Gaston 2000). According to some researchers, interventions that attempt to reduce transplant disparities should prioritize the improvement of live donation rates for African Americans (Hall et al. 2011).

Differences in kidney transplantation rates may also reflect patient factors, such as lack of knowledge about transplantation, concerns about surgery and adverse

Native Americans and Asian Americans experienced a rate increase. During that period, kidney transplants from living donors declined by 4 percent, while transplants from deceased donors declined by 1 percent. The text box summarizes issues related to the distribution of kidney transplantation across the ESRD population.

**Dialysis quality varies by type of organization in 2009**

According to USRDS, dialysis quality, as measured by standardized hospitalization and mortality ratios, varies across types of dialysis organizations, including large dialysis chains, smaller dialysis chains, independent facilities, and hospital-based facilities (Table 6-7, p. 161).

In 2009, for all patients, small dialysis chains had slightly lower standardized hospitalization and mortality ratios than large dialysis chains; independent (i.e., freestanding nonchain) facilities had higher standardized hospitalization ratios. Although hospital-based facilities had lower hospitalization ratios, they had the highest standardized mortality ratios among the different facility types.

Outcomes by race varied between and within organizations. Some organizations had lower
Trends in kidney transplantation (cont.)

effects of medication, and mistrust of the medical system. In addition, some patients are not able to receive a transplant because of the presence of medical contraindications, such as a recent history of substance abuse, cancer, a serious infection (including from dental disease), and significant cardiovascular disease.

Provider-level factors can also affect access to kidney transplantation. Dialysis facilities and physicians who treat dialysis patients have an important role in educating patients about renal treatment options, including transplantation and home dialysis, and referring patients to a transplant center. The literature on the relationship between the role of the dialysis facility and access to transplantation is mixed. Some researchers have found that patients treated at for-profit facilities are less likely to undergo transplantation, while other researchers have not reached this conclusion. Some dialysis providers contend that the decision about whether patients are included on the transplant wait list and ultimately undergo transplantation is the responsibility of the transplant center. Because these factors are outside of their purview, dialysis providers argue that these measures should not be used to assess their quality.

The process used by transplant centers plays an important role in determining which candidates are placed on the kidney waiting list. For most transplant centers, the process for placing individuals on the waiting list includes evaluating the patient’s physical and mental health (American Society of Transplantation 2006, National Institute of Diabetes and Digestive and Kidney Diseases 2008). Other factors that transplant centers consider are the patient’s ability to carry out necessary posttransplant treatment plans, patient’s education, and patient’s financial resources, including insurance covering the transplant procedure and the anti-rejection medicines needed after transplantation (Volk et al. 2011). According to experts in the field, transplant centers’ selection committees rule out patients with psychosocial barriers, including lack of or inadequate social support (no spouse, family, or friends).

In the coming year, the Commission intends to review quality improvement initiatives sponsored by the Secretary of Health and Human Services that have focused on reducing racial disparities in kidney transplantation. For example, the Centers for Disease Control and Prevention’s Healthy People 2020 initiative includes objectives to increase the proportion of dialysis patients on the kidney wait list (by 10 percent to 18.8 percent) and to increase the proportion of patients with treated chronic kidney disease who receive a kidney transplant (Department of Health and Human Services 2011a). Nonetheless, neither this initiative nor the recent initiative by the Secretary to address racial disparities in minority health includes activities specific to reducing racial disparities in transplantation (Department of Health and Human Services 2011b). The Commission also intends to assess the literature on the effectiveness of public and private campaigns to reduce racial disparities in transplantation. To increase kidney transplantation rates, quality improvement efforts must be multifaceted to address the varied provider and patient factors that affect access. Recently, some researchers concluded that little is known about effective strategies for improving patients’ and families’ early consideration of live kidney transplantation.

hospitalization and mortality ratios for African Americans and higher ones for whites. By contrast, in hospital units, standardized hospitalization ratios were lower for whites and higher for African Americans. In 2009, the largest freestanding nonprofit dialysis chain, DCI, had the lowest standardized hospitalization and mortality ratios for all patients as well as separately for whites and African Americans. These data show the opportunity for quality improvement across different facility types and the role of the QIP in ensuring dialysis quality.

Providers’ access to capital: Growth trends suggest access is adequate

Providers need access to capital to improve their equipment and open new facilities so they can accommodate the growing number of patients requiring dialysis. Between 2010 and 2011, the large and small dialysis chains showed similar growth rates, which suggests that both small and large providers have adequate access to capital. During this period, the number
announced that he is partnering with a private equity firm to create a new dialysis company that will acquire and build centers nationally (Nephrology News & Issues 2011).

- In December 2011, Ambulatory Services of America acquired Renal CarePartners. Once the acquisition is complete, Ambulatory Services of America will operate 62 facilities.

In addition to these mergers, a small chain was created as a consequence of DaVita’s acquisition of DSI. To preserve competition and proceed with its acquisition of DSI, the Federal Trade Commission required DaVita to sell 30 facilities. Frazier Healthcare and New Enterprise Associates purchased the 30 facilities for $91 million and plans to operate them as one company called DSI.

These current trends in the profit status and consolidation among dialysis providers suggest that the dialysis industry is an attractive business to for-profit providers and that there are efficiencies and economies of scale in providing dialysis care. The attractiveness of these ventures is suggested by the statement from a midsized dialysis chain that new clinics become “EBITDA (earnings before interest, taxes, depreciation, and amortization) positive” within an average of 12 months of opening (American Renal Holdings 2011).

TABLE 6–7

<table>
<thead>
<tr>
<th>Provider</th>
<th>All patients</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hospitalization</td>
<td>Mortality</td>
<td>Hospitalization</td>
<td>Mortality</td>
<td>Hospitalization</td>
</tr>
<tr>
<td>Fresenius</td>
<td>0.99</td>
<td>1.00</td>
<td>1.02</td>
<td>1.00</td>
<td>0.96</td>
</tr>
<tr>
<td>DaVita</td>
<td>1.01</td>
<td>0.97</td>
<td>1.02</td>
<td>0.99</td>
<td>1.01</td>
</tr>
<tr>
<td>DCI</td>
<td>0.91</td>
<td>0.96</td>
<td>0.93</td>
<td>0.97</td>
<td>0.88</td>
</tr>
<tr>
<td>Other freestanding chains</td>
<td>0.99</td>
<td>0.98</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Independent freestanding facilities</td>
<td>1.02</td>
<td>1.00</td>
<td>0.97</td>
<td>0.98</td>
<td>1.07</td>
</tr>
<tr>
<td>Hospital-based facilities</td>
<td>1.01</td>
<td>1.08</td>
<td>0.95</td>
<td>1.04</td>
<td>1.09</td>
</tr>
</tbody>
</table>

Note: The standardized hospitalization (or mortality) ratio compares the actual number of hospital admissions (or deaths) for the provider and the number of admissions that would be expected if patients under the care of that provider experienced admissions (or deaths) at the national rate for patients with similar characteristics (age, gender, race, and number of years on dialysis). A value of less than 1.0 indicates that a provider’s total number of events was less than expected, based on national rates, whereas a value of greater than 1.0 indicates that a provider had a rate of total events higher than the national average. The reference cohorts are all 2009 Medicare hemodialysis patients for the standardized hospitalization ratio and all 2009 hemodialysis patients (Medicare and non-Medicare) for the standardized mortality ratio.

Source: United States Renal Data System 2011.
Medicare payments and providers’ costs

Each year, we assess the relationship between Medicare’s provider payments and freestanding providers’ costs by considering whether current costs approximate what efficient providers are expected to spend on delivering high-quality care. The latest and most complete data available on freestanding providers’ costs are from 2010.

For most facilities, 2010 is the last year that Medicare paid a prospective payment for each dialysis treatment furnished and separate payments for furnishing certain drugs during dialysis. In 2011, nearly 90 percent of all facilities were paid under a new PPS that includes dialysis drugs for which facilities previously received separate payments.

Appropriateness of current costs

Between 2005 and 2010, the cost per treatment for services paid for under the former payment system using the composite rate rose by an average 2.5 percent per year. Variation from this average across freestanding dialysis facilities shows that some facilities were able to hold their cost growth well below that of others. For example, between 2005 and 2010, per treatment costs increased by 0.7 percent per year for facilities in the 25th percentile of cost growth, compared with 4.2 percent for facilities in the 75th percentile.

Differences exist in cost growth trends and adjusted cost per treatment (adjusted for differences in labor costs and patient case mix) between the two largest dialysis organizations and all other freestanding facilities. Between 2005 and 2010, cost per treatment increased by 2.6 percent per year for facilities affiliated with the two largest chains and by 2.0 percent for all other freestanding facilities. In 2010, the cost per treatment for composite rate services standardized for differences in labor costs and patient case mix for the two largest dialysis organizations was 1 percent lower than for all other freestanding facilities.

The growth in cost per treatment between 2005 and 2010 partly stemmed from rising general and administrative costs, which increased by 4 percent per year and accounted for about 27 percent of the total cost per treatment in 2010. General and administrative costs include expenses associated with legal and accounting services, record-keeping and data-processing tasks, telephone and other utilities, home office costs, and malpractice premiums. By contrast, between 2005 and 2010, capital and labor costs (associated with direct patient care) increased by 3 percent and 2 percent per year, respectively; other direct medical costs increased by 0.5 percent per year. In 2010, capital, labor, and other direct medical costs accounted for 22 percent, 40 percent, and 11 percent, respectively, of the total cost per treatment. Cost report data do not permit us to assess which cost elements contributed to the high rate of cost growth within the general and administrative cost category.

Medicare margin for freestanding providers

For 2010, the Commission assessed payments and costs for dialysis services for freestanding dialysis facilities by comparing Medicare’s payments for composite rate services and dialysis drugs with providers’ Medicare-allowable costs.

For 2010, we estimate that the aggregate Medicare margin for composite rate services and dialysis drugs was 2.3 percent (Table 6-8). The distribution of margins in 2010 shows wide variation in performance among freestanding facilities. One-quarter of facilities had margins at or below –6.7 percent and one-quarter of facilities had Medicare margins of at least 11.9 percent.

In 2008 and 2009, the aggregate Medicare margins were 3.2 percent and 3.1 percent, respectively. The modest decline in the Medicare margin in 2010 is explained by the change in drug payment and cost per treatment. Between 2009 and 2010: (1) drug payment per treatment dropped by about 5 percent and (2) drug cost per treatment declined by 3.5 percent. During this period, the volume of

### Table 6-8

Medicare margin in 2010 varies by type of freestanding provider

<table>
<thead>
<tr>
<th>Provider type</th>
<th>Percent of spending</th>
<th>Medicare margin</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>100%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Affiliated with one of the two largest dialysis organizations</td>
<td>69</td>
<td>3.4%</td>
</tr>
<tr>
<td>All others</td>
<td>31</td>
<td>0.1%</td>
</tr>
<tr>
<td>Urban</td>
<td>85</td>
<td>3.4%</td>
</tr>
<tr>
<td>Rural</td>
<td>15</td>
<td>–3.7%</td>
</tr>
<tr>
<td>More than 10,000 treatments</td>
<td>54</td>
<td>7.7%</td>
</tr>
<tr>
<td>Less than or equal to 10,000 treatments</td>
<td>46</td>
<td>–2.3%</td>
</tr>
</tbody>
</table>

Source: Compiled by MedPAC from 2010 cost report and outpatient claims submitted by facilities to CMS.
ESAs and vitamin D analogs declined. As in earlier years, urban facilities had higher margins than rural facilities (3.4 percent and –3.7 percent, respectively), and facilities affiliated with the two largest dialysis organizations tended to have higher margins than other freestanding facilities (3.4 percent and 0.1 percent, respectively). The number of treatments a facility furnishes also affects the Medicare margin; in 2010, the margin for higher volume facilities was 7.7 percent, compared with –2.3 percent for lower volume facilities.

The Commission is concerned that the gap in the Medicare margin widened between urban and rural facilities between 2009 and 2010 (Medicare Payment Advisory Commission 2010). We will continue to monitor the adequacy of Medicare’s payments for rural and urban facilities in the coming years. The low-volume adjuster in the new payment method should disproportionately benefit rural facilities. Our analysis of 2007–2009 cost reports finds that while 22 percent of all facilities are rural, 44 percent of facilities meeting CMS’s definition of low volume are rural. We are also analyzing changes that would better target the low-volume adjuster to facilities that are both isolated and low volume, which would also benefit rural facilities.

On the basis of 2010 payment and cost data, we project that the 2012 aggregate margin will be 2.7 percent. This estimate reflects:

- the 2 percent reduction in total spending that MIPPA mandated to begin in 2011,
- the 3.1 percent budget-neutrality adjustment in 2011 that CMS applied between January and April 2011,
- the 2011 payment update of 2.5 percent and the 2012 payment update of 2.1 percent,
- the reduction of 0.2 percent of payments due to implementation of the QIP in 2012, and
- a conservative behavioral offset to account for efficiencies anticipated under the new payment method.

The conservative behavioral offset included in the 2011 margin projection is based on industry data that providers have become more efficient in the delivery of drugs under the new payment method (Dialysis Outcomes and Practice Patterns Study 2011). The high rate of facilities opting into the new payment method (nearly 90 percent) suggests that most can operate within the provisions of the new payment method. Published studies also suggest that providers can decrease costs while maintaining quality (Hasegawa et al. 2010, Kaufman et al. 1998, Pizzi et al. 2006). Charytan summarized the following selected strategies to maximize efficiencies in the management of anemia: switching from intravenous to subcutaneous routes, lowering hemoglobin targets and doses in hyporesponsive patients, increasing administration of intravenous iron, increasing use of home dialysis, and optimizing ESA dosing intervals (Charytan 2010).

### How should Medicare payments change in 2013?

The effect of the QIP in 2013 on Medicare’s payments to dialysis facilities is not modeled in the Commission’s projection of the 2012 aggregate Medicare margin. In 2013, the year of the Commission’s update recommendation, CMS predicted that the impact of the QIP would decrease total payments by 0.29 percent (Table 6–9). CMS estimated that reductions would be greater in 2013 and 2014 compared with 2012. In addition, the full impact of the QIP—a reduction of up to 2 percent—will affect more facilities in 2013 than in 2012 and 2014.

<table>
<thead>
<tr>
<th>Estimated reduction in payments due to QIP</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total impact</td>
<td>–0.19%</td>
<td>–0.29%</td>
<td>–0.27%</td>
</tr>
<tr>
<td>Percent of facilities, by estimated reduction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0%</td>
<td>74</td>
<td>82</td>
<td>70</td>
</tr>
<tr>
<td>0.5% to 1%</td>
<td>21</td>
<td>5</td>
<td>23</td>
</tr>
<tr>
<td>1.5%</td>
<td>4</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>2%</td>
<td>1</td>
<td>7</td>
<td>3</td>
</tr>
</tbody>
</table>

Note: QIP (quality improvement program).

Source: CMS 2011 final rules.
Update recommendation

The evidence on payment adequacy suggests that a moderate update of the outpatient dialysis payment rate is in order to ensure continued beneficiary access to outpatient dialysis services. Therefore, the Commission recommends that the Congress update the outpatient dialysis payment rate by 1 percent for calendar year 2013.

RECOMMENDATION 6

The Congress should update the outpatient dialysis payment rate by 1 percent for calendar year 2013.

RATIONALE 6

Most of our indicators of payment adequacy are positive, including beneficiaries’ access to care, the supply and capacity of providers, volume of services, quality of care, and access to capital. The Medicare margin in 2010 was 2.3 percent, and we project that it will be 2.7 percent in 2012.

IMPLICATIONS 6

Spending

- Under current law, if current projections were used, the payment rate would be updated by the ESRD market basket less a productivity adjustment, an update of 1.9 percent. This recommendation would decrease federal program spending relative to current law by between $50 million and $250 million in 2013 and by less than $1 billion over five years. The spending implication of this recommendation is based on Medicare spending projections that were made prior to a sequester, as the recommendation was developed and voted on before the sequester was triggered and became current law. If a Medicare sequester does occur, it will change the spending implication of the recommendation.

Beneficiary and provider

- We do not anticipate any negative effects on beneficiary access to care. This recommendation is not expected to affect providers’ willingness or ability to serve beneficiaries.
To be eligible for Medicare ESRD benefits: (1) the individual must file an application for Medicare with Social Security; (2) a physician must certify that the individual requires chronic dialysis or a kidney transplant to maintain life; and (3) the individual must be entitled to a monthly benefit under Social Security, be fully or currently insured under Social Security, or be the spouse or dependent child of a person meeting these Social Security requirements. Individuals qualify for Social Security by earning Social Security credits when employed in a job that pays Social Security taxes. Generally, individuals are fully insured under Social Security if they have 40 credits of covered employment. Individuals are currently insured under Social Security if they have a minimum of 6 credits of covered employment in the three years before ESRD diagnosis (http://www.ssa.gov/pubs/10072.html). Individuals who are not eligible for Social Security have not earned a minimum of credits toward retirement under Social Security.

New dialysis patients include those who are not eligible for Medicare either because they do not meet the eligibility criteria (explained in Endnote 1) or because they have not yet applied for Medicare coverage.

The proportion of all dialysis patients and FFS patients with Medicare as the secondary payer may be underestimated because of the extent to which Medicare’s enrollment databases do not identify patients with private insurance.

Beneficiaries with ESRD on dialysis cannot join an MA plan unless they developed ESRD while already enrolled in an MA plan. Enrollment in an ESRD special needs plan or the ESRD demonstration program are exceptions to this statutory provision.

The base prospective payment under the former payment method of $162 per treatment is inclusive of the drug add-on payment of about $20 per treatment.

Some observers are concerned that CMS’s proposed approach for updating the base rate per dialysis treatment (by dividing the sum of Part D payments in 2007 by total treatments) may not reflect their cost of furnishing these drugs. They contend that the agency’s proposed approach will not cover their costs because the Part D spending data do not reflect the drug use of dialysis FFS patients who are not enrolled in a Part D plan.

CMS requires that dialysis facilities provide documentation in the patient’s medical record to support any diagnosis recognized for a payment adjustment (Centers for Medicare & Medicaid Services 2010).

Medicare pays for a maximum of six kidney disease education sessions for beneficiaries with stage IV chronic kidney disease, the precursor to kidney failure. The statute permits only qualified persons to furnish such education services, such as physicians, physician assistants, nurse practitioners, and clinical nurse specialists. In addition, providers of services (e.g., hospitals, critical access hospitals) in rural areas can furnish kidney disease services. The statute precludes dialysis facilities from providing kidney disease education sessions regardless of the provider’s geographic location (Centers for Medicare & Medicaid Services 2009).

For 2010, the Elab Project collected laboratory data (for the fourth calendar quarter) from 5,472 facilities for about 97 percent of all dialysis patients in the United States. Facilities submit the first laboratory value of the month for October, November, and December of each year (Renal Network of the Upper Midwest 2011).

Physicians create an AV fistula by joining an artery to a vein under the patient’s skin (frequently in the forearm). A few months are usually needed to allow the AV fistula to properly develop before it can be used during dialysis. Physicians may implant an AV graft for certain patients (including those with small or weak veins) who are not candidates for an AV fistula. Like AV fistulas, AV grafts are implanted under the skin, usually in the patient’s forearm. AV grafts use a soft plastic tube to join an artery and a vein. Compared with AV fistulas, AV grafts can be used sooner after placement, often in two to three weeks. A catheter placed in the patient’s neck, chest, or leg is used as a temporary access when a patient needs dialysis immediately and is waiting for an AV fistula or AV graft to mature. A catheter is also used when an AV fistula or AV graft fails.

DOPPS is based on a sample of about 145 facilities and is designed to provide results representative nationally and by dialysis organization size, location of facility (rural versus urban), and facility type (freestanding versus hospital based). Laboratory data (e.g., hemoglobin levels) are generally based on a monthly value reported by sampled facilities (Robinson et al. 2011).

Since 2011, the FDA no longer recommends a target hemoglobin range for dialysis patients with ESAs. According to the FDA, providers should initiate ESA therapy when a patient’s hemoglobin level is less than 10.0 g/dL and reduce or interrupt the ESA dose when a patient’s hemoglobin level approaches or exceeds 11.0 g/dL. By contrast, the National Kidney Foundation recommends a target hemoglobin range of 11.0 g/dL to 12.0 g/dL.

Medicare covers anti-rejection medicines. However, for beneficiaries under age 65 entitled to Medicare because of ESRD alone, their Medicare entitlement ends 36 months after the month of the transplant.
References


American Association of Kidney Patients. 2011. *Understanding your hemodialysis access options*. Tampa, FL: AAKP.


Short daily haemodialysis: survival in 415 patients treated for 1006 patient-years

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Abstract

Background. Survival statistics for daily haemodialysis are lacking as most centres providing this have treated only a small number of patients for short observation times. We pooled our 23-year, 1006-patient-year, five-centre experience of 415 patients treated by short daily haemodialysis.

Methods. One hundred and fifty patients were treated in-centre, most because of medical complications and 265 by home or self-care haemodialysis. Patients were on daily haemodialysis for 29 ± 31 (0–272) months. Forty-two percent had primary and 31% had secondary renal failure. Treatment time was 136 ± 35 min, frequency 5.8 ± 0.5 times/week and weekly stdKt/V 2.7 ± 0.55.

Results. Eighty-five patients (20%) died; 5-year cumulative survival was 68 ± 4.1% and 10-year survival was 42 ± 9%. Age, secondary renal failure and in-centre dialysis were associated with mortality, while gender, frequency of dialysis (5, 6 or 7 per week), continent, country and blood access were not. Survival was compared with matched patients from the USRDS 2005 Data Report using the standardized mortality ratio and cumulative survival curves. Both comparisons showed that the survival of the daily haemodialysis patients was 2–3 times higher and the predicted 50% survival time 2.3–10.9 years longer than that of the matched US haemodialysis patients. Survival of patients dialyzing daily at home was similar to that of age-matched recipients of deceased donor renal transplants.

Conclusions. Survival of patients on short daily haemodialysis was 2–3 times better than that of matched three times weekly haemodialysis patients reported by the USRDS.

Keywords: daily haemodialysis; mortality rate; short; survival comparisons

Introduction

In 1960, the Quinton–Scribner shunt solved the problem of treating patients with chronic renal failure [1]. Initially, 24 h of haemodialysis was done once weekly after patients developed symptoms of uraemia and fluid overload. To prevent these symptoms the regime soon was changed to twice-weekly dialysis for 16–23 h. This in turn was changed to three times weekly overnight nocturnal dialysis. Each increase in dialysis frequency led to further improvements, and so logic would have indicated proceeding to daily haemodialysis. However, because patients were reasonably well and because of financial problems, no further increase in dialysis frequency was undertaken [2].

In the 1950s, Teschan et al. started daily haemodialysis for acute renal failure [3], and the first study of daily dialysis in patients with end-stage renal disease (ESRD) began four decades ago in 1967 [4]. Since then many have studied daily haemodialysis and reported improvements in biochemistry, cardiovascular physiology, clinical symptoms and quality of life.

Reimbursement problems, the virtual disappearance of home haemodialysis training programs in the USA and other countries, difficult logistics, physician and patient reluctance and conservatism have limited adoption of daily dialysis. Reliable patient survival data for this have not been published, and so we decided to pool our clinical experience with this treatment, analyse survival and make comparisons to other treatments for end-stage renal failure.

Patients were converted to daily dialysis for two reasons. Most were chosen as daily treatment was thought to improve well-being, quality of life and survival. Others were started on daily dialysis because of serious medical complications and/or cardiovascular instability during dialysis. Many of these regularly required a fourth weekend dialysis, and most of these were considered unsuitable for home haemodialysis.
Statistical analysis and comparisons

Patient data were entered on an Excel spreadsheet (Microsoft Inc., WA, USA) and imported to the Statview 5 (SAS., NC, USA) statistical program for analysis. Data are presented as mean ± SD unless otherwise stated.

Kaplan–Meier and Cox–Mantel log rank analyses were used for comparisons of survival [5]. Error bars on survival graphs are standard error of the mean (SEM).

Backward stepwise Cox proportional hazard analysis was used to study variables influencing survival. The confidence interval (CI) was 95%.

Categorical variables were analysed using the chi square and Fisher’s exact probability tests and continuous variables with one sample and unpaired t-tests. A P-value <0.05 was used for statistical significance.

Standardized mortality rates (SMRs) were calculated according to the technique described by Wolfe et al. for comparing survival among groups of dialyzed patients [6,7].

Data from the USRDS 2005 Annual Data Report for period prevalent haemodialysis patients [8], matched for age as of 1 January 2003, gender, race and primary diagnosis, were used to calculate an estimated annual mortality rate for each of the 224 short daily haemodialysis patients observed in the same time period.

For comparison of projected daily survival by the Kaplan–Meier technique, we used survival probabilities for incident haemodialysis patients published by the USRDS in 2005 [8]. We compared survival probabilities after 5 years of dialysis for the 1998 cohort reported by the USRDS in 2005, the last cohort contributing 5-year-survival data. The comparison is reported as the relative risk (RR) of death. We also compared the number of years after which 50% of patients were projected to have died for matched patient groups. Finally, we compared projected life expectancy of daily haemodialysis patients to that of patients on conventional haemodialysis, recipients of deceased donor transplants and the US population published by the USRDS [8].

The efficiency of urea removal was calculated from pre- and post-dialysis BUN and used to calculate spKt/V by Daugirdas’ second equation [9] and weekly stdKt/V by the equation of Leypoldt [10].

Results

Patients

The age of patients when they started daily dialysis was 52 ± 15, range 13–89 years. There were 120 females and 295 males. Forty-three percent had primary renal disease (glomerulonephritis, interstitial nephritis and obstructive uropathy) and 30% had secondary renal disease [15% had diabetes, 9% had hypertensive nephrosclerosis and 6% had other secondary diseases (amyloid, myeloma, cholesterol emboli, systemic lupus erythematosus—SLE)] and in 27% the diagnosis was unknown. Patient characteristics are shown in Table 1.

Two hundred and sixty-five of the 415 patients treated themselves at home, and 150 were treated in a centre. The

<table>
<thead>
<tr>
<th>Variable</th>
<th>USA</th>
<th>Italy</th>
<th>France and UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>169</td>
<td>165</td>
<td>81</td>
</tr>
<tr>
<td>Mean age, years</td>
<td>55 ± 15</td>
<td>51 ± 15</td>
<td>45 ± 14</td>
</tr>
<tr>
<td>Female (%)</td>
<td>35</td>
<td>26</td>
<td>21</td>
</tr>
<tr>
<td>Home (%)</td>
<td>70</td>
<td>46</td>
<td>88</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>24</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>Primary RF (%)</td>
<td>41</td>
<td>34</td>
<td>68</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>21</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Secondary RF other (%)</td>
<td>7</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Unknown (%)</td>
<td>7</td>
<td>55</td>
<td>11</td>
</tr>
<tr>
<td>Deaths/patient-years</td>
<td>40/279</td>
<td>37/560</td>
<td>8/167</td>
</tr>
<tr>
<td>Deaths/1000 patient-years</td>
<td>143</td>
<td>66</td>
<td>48</td>
</tr>
</tbody>
</table>

RF = renal failure.

Dialysis

Dialysis data are given in Table 2. European patients dialyzed fewer minutes per dialysis (106 ± 28 versus 143 ± 36, P < 0.0001) but with a higher frequency per week (5.9 ± 0.4 versus 5.6 ± 0.5, P < 0.0001). There was no difference in spKt/V, but US patients had a higher mean weekly stdKt/V (2.9 ± 0.6 versus 2.6 ± 0.5, P = 0.0001).

Clinical course

One hundred and sixty-nine (41%) of the patients continued short daily dialysis, 75 (18%) had a renal transplant, 85 (20%) died, 78 (19%) returned to conventional in-centre haemodialysis and in 8 (2%) patients the continued
Short daily haemodialysis

Fig. 1. Survival of all 415 short daily haemodialysis patients, upper panel. The 5-year survival is 65% and 50% have died at 9 years. Comparison of survival of the daily haemodialysis patients by site of dialysis and to the USRDS survival data, lower panel. The 5-year mortality of daily haemodialysis patients treating at home is one-third and of those treated in centre ∼2/3 of that of the patients on conventional three times per week haemodialysis.

Factors influencing survival

In a Cox proportional hazards analysis including all 415 patients, three factors were independently associated with mortality—secondary renal disease (HR 2.72, CI 1.76–4.20, \( P < 0.0001 \)), age more than the mean of 52 years (HR 2.39, CI 1.49–3.83, \( P = 0.0003 \)) and in-centre dialysis (HR 2.42, CI 1.54–3.79, \( P = 0.0001 \)). Gender, vascular access, duration of renal failure treatment before start of daily dialysis, centre, year of starting daily dialysis, era, country or continent were not associated with mortality. The European patients were younger, had less secondary disease and less often dialyzed at home and had a lower incidence of deaths per 1000 patient-years. (Table 1). When age, diagnosis and place of dialysis were included in Cox proportional hazards analysis, there was no difference in mortality between the countries or continents. (Table 3). The similarity of mortality rate between countries and continents remained the same even when including differences in dialysis frequency, Kt/V or time on dialysis (data not shown).

We had data on the duration of each dialysis in 259 patients and repeated Kt/V determinations in 139 patients. Backward stepwise Cox proportional hazard analyses were done using age, dialysis place, secondary/primary renal disease, individual dialysis duration, weekly dialysis hours, frequency per week of dialysis, spKt/V and weekly stdKt/V as covariates. Three factors were independently associated with survival in this analysis: weekly dialysis hours (HR 0.72, CI 0.58–0.89, \( P = 0.002 \)), secondary renal disease (HR 3.23, CI 1.39–7.52, \( P = 0.007 \)) and weekly stdKt/V (HR 0.43, CI 0.19–0.98, \( P = 0.045 \)).

Comparison to dialyzed patients in the USRDS

We did three comparisons to survival as reported in the USRDS 2005 Annual Data Report matching the patients by age, diagnosis and place of dialysis.

At 5 years, the RR of mortality of daily haemodialysis patients was 0.35–0.83 of that of the matched USRDS haemodialysis patients, Table 4, upper panel. The time to 50% mortality was more than double for the short daily haemodialysis patients. The daily haemodialysis patients have a 50% survival 2.5–10.9 years longer than in matched USRDS patients, (Table 4, lower panel). As daily home dialysis patients had a better outcome than in-centre daily dialysis patients, we also compared the daily dialysis patients treated in-centre to all USRDS patients. More than 99% of US haemodialysis patients are treated in a centre. The in-centre daily dialysis patients had a much better survival than the USRDS patients—Figure 1 and Table 4. Cumulative survival curves comparing the patients on short daily haemodialysis to survival of patients in the USRDS matched for age are shown in Figure 2 and matched for diagnosis in Figure 3.

With the SMR technique, the number of expected deaths over the 2 years was 50.5, and the number of actual deaths was 17. The SMR was 0.34 (CI 0.20–0.54). The chi square
Table 4. Matched comparisons to the 2005 USRDS incident haemodialysis patients

<table>
<thead>
<tr>
<th>Category</th>
<th>Percent</th>
<th>Daily haemodialysis</th>
<th>USRDS</th>
<th>Category</th>
<th>Percent ± SEM</th>
<th>RR ± SEM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(A) Percent surviving 5 years of haemodialysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>31</td>
<td>In-centre</td>
<td>50 ± 6</td>
<td></td>
<td>0.73 (0.69–0.81)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>27</td>
<td>Diabetes</td>
<td>38 ± 16</td>
<td></td>
<td>0.83 (0.59–1.06)</td>
<td></td>
</tr>
<tr>
<td>Glomeruloneph.</td>
<td>49</td>
<td>Primary RF</td>
<td>74 ± 5</td>
<td></td>
<td>0.52 (0.42–0.61)</td>
<td></td>
</tr>
<tr>
<td>Age 20–44</td>
<td>58</td>
<td>Age 20–44</td>
<td>82 ± 7</td>
<td></td>
<td>0.35 (0.26–0.51)</td>
<td></td>
</tr>
<tr>
<td>Age 45–64</td>
<td>41</td>
<td>Age 45–64</td>
<td>71 ± 5</td>
<td></td>
<td>0.49 (0.41–0.58)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(B) Years until 50% mortality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>2.8</td>
<td>In-centre</td>
<td>5.1 ± 0.8</td>
<td></td>
<td>2.3 (1.3–3.1)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>2.1</td>
<td>Diabetes</td>
<td>4.6 ± 0.6</td>
<td></td>
<td>2.5 (1.9–3.1)</td>
<td></td>
</tr>
<tr>
<td>Glomeruloneph.</td>
<td>4.8</td>
<td>Primary RF</td>
<td>10.5 ± 2.2</td>
<td></td>
<td>5.9 (3.7–8.1)</td>
<td></td>
</tr>
<tr>
<td>Age 20–44</td>
<td>6.5</td>
<td>Age 20–44</td>
<td>17.4 ± 6.1</td>
<td></td>
<td>10.9 (4.8–17.0)</td>
<td></td>
</tr>
<tr>
<td>Age 45–64</td>
<td>4.0</td>
<td>Age 45–64</td>
<td>9.8 ± 0.7</td>
<td></td>
<td>5.8 (5.1–6.5)</td>
<td></td>
</tr>
</tbody>
</table>

Glomeruloneph = Glomerulonephritis, RF = renal failure, RR = percent surviving at 5 years, USRDS = patients divided by daily haemodialysis patients.

Life expectancy and comparison to transplanted patients in the USRDS

We also compared survival of all the daily home haemodialysis patients to that of US patients receiving a deceased donor transplant. The mean age of US patients receiving a transplant was similar to that of the daily home dialysis patients, 50 versus 49 years ($P = 0.280$). Survival curves of patients on home daily dialysis are almost identical to those of recipients of cadaveric kidney transplants, Figure 4.

The estimated life expectancies of the daily haemodialysis dialysis patients, patients on conventional dialysis, recipients of deceased donor transplants and the US population are shown in Figure 5. The life expectancies are 9–15 years longer than those of the age-matched US haemodialysis patients and the same as in deceased donor recipients in the USRDS.

Discussion

The survival of these 415 patients strongly suggests that short daily dialysis offers much longer survival than conventional three times weekly haemodialysis. Survival of any group of patients is much influenced by selection. However, one-third of the daily dialysis patients were selected because of serious complications or serious co-morbidities and a poor prognosis and often needed a fourth dialysis for congestive heart failure or dangerous metabolic derangements developing over the weekend. The increasing age and numbers with secondary renal disease over time among these daily dialysis patients also paralleled that of all dialysis patients. As a result, these 415 patients represent a wide spectrum of chronic dialysis patients and are a representative group for survival comparisons using techniques similar to those used in comparisons of different groups of dialyzed and transplanted patients [5–7].

We used three methods to compare survival. First, we matched patients by age and diagnosis and compared projected survival curves to those of comparable haemodialyzed patients from the USRDS 2005 Annual Data Report.
Short daily haemodialysis

Second, we compared patients by the standardized mortality rate technique. With both methods, survival was 2–3 times higher than that of patients dialyzing three times weekly. The time to 50% mortality was prolonged by 2.3–10.9 years in the daily dialysis patients. Third, we compared survival with that of transplanted patients. Dialysis patients are carefully selected before acceptance to a transplant waiting list, and selected again when a kidney becomes available for transplant. Currently, <15% of patients starting dialysis receive a transplant. Dialysis patients on a transplant waiting list have an RR of ~0.5 compared to those not on the list, and the RR of those finally selected for a transplant is only 0.5 of those on the waiting list but who are not selected for a transplant [8,11,12]. Survival of daily haemodialysis patients was similar to that of transplanted patients of comparable age receiving a deceased donor transplant who have been shown to have a mortality of only one-third that of matched patients on conventional three times-weekly dialysis [11].

This study has several limitations. It is difficult to compare survival among different patient groups when the patients are from different countries with different selection criteria and practice patterns [12,13]. However, both the

Cox proportional hazards analysis and the SMR comparison indicated there was no difference in the outcome of daily dialysis between European and the US patients once age, diagnosis and site of treatment had been considered. It would also have been better if co-morbidities had been considered, but these details were not available for all of our patients. However, in survival comparisons among haemodialysis patients it has been shown that once age and diagnosis are considered, including co-morbidity adds only little additional information [14]. Based on the similar results of all three comparisons, each using a different methodology to normalize survival, we conclude that the improved survival is a result of the short daily haemodialysis modality itself, and not of patient selection.

We found, as have others, that patients on home haemodialysis survived better than patients dialyzing in centre [14–16]. The RR of death of our patients dialyzed daily at home, compared to the in-centre daily dialysis patients, was 0.44 when correcting for differences in age and diagnosis. A high percentage of our patients were on home haemodialysis, 64% compared to the 0.7% of US haemodialysis patients, but this difference by itself does not explain the better survival in the daily dialysis patients, as those treated by daily dialysis in-centre also had a much better survival than all USRDS patients.

More hours of dialysis weekly were associated with longer survival, and thus, the higher frequency of dialysis, the positive influence of dialyzing at home and the longer hours the patient could spend on dialysis, apparently, all contribute to the much lower mortality of patients on short daily haemodialysis when compared to three times weekly haemodialysis patients.

There are a number of reasons why daily haemodialysis might improve patient survival. It minimizes the oscillations in body chemistry and fluid volumes seen with three times weekly dialysis [17,18]. The dangers of three times a week haemodialysis are shown by the 2–3 times increase in sudden and cardiac deaths on Mondays and Tuesdays after the long weekend interval without dialysis compared with deaths on the other weekdays [19,20].

Several abnormal physiological parameters associated with a high mortality are improved by daily dialysis. Fluid
overload quickly decreases to 50% of that on three times weekly haemodialysis patients; blood pressure normalizes and antihypertensive drugs can be decreased or discontinued in most patients [18]. Left ventricular hypertrophy, an important predictor of mortality, regresses; levels of brain natriuretic peptide normalize; pulmonary fluid overload disappears and cardiac output increases [4,18,21–31].

Many metabolic markers that are associated with mortality also improve in patients on daily dialysis. These include hyperhomocysteinaemia, dyslipidaemia, malnutrition and hypoalbuminaemia and hormonal abnormalities. The need for erythropoietin may decline, vascular calcification is reduced and baroreceptor function is normalized [4,18,29–35).

Quality of life has uniformly been reported to improve as painful and dangerous complications during dialysis markedly decrease, the profound fatigue between dialyses disappears and appetite and physical strength return [4,18,21,23,25,26,33,34,37,38].

Both standardized mortality rate and actuarial comparisons with matched patients allow survival comparison among different patient groups, but the gold standard is the prospective randomized clinical trial. The National Institutes of Health is conducting such a study to compare short daily in-centre haemodialysis and long nightly home haemodialysis patients to patients on three times weekly in-centre haemodialysis. It will be several years before the results of this study are known. While this randomized study will be a valuable contribution, even such studies are affected by unanticipated problems. A recent comparison of the predictive value of randomized prospective studies and carefully conducted clinical analyses found no superiority of large-scale randomization over clinical analyses [39].

More than 300 publications of clinical observations spanning over four decades have shown much better metabolic and physiologic parameters and quality of life measures with short daily dialysis when compared to three times weekly haemodialysis. Our pooled data suggest that the survival of short daily dialysis patients is also much superior to that of conventional haemodialysis patients. Logistical problems, conservatism by physicians and nurses, worries about expenses by government, businessmen and administrators, the decline in training of physicians and nurses and training units for home haemodialysis, unavailability of haemodialysis machines suitable for the use at home and patient worries have made the introduction of daily haemodialysis slow and difficult.

We believe that daily haemodialysis presently is the best dialysis modality for patients willing to undertake this and should be considered the gold standard of dialysis to which other dialysis methods should now be compared.

Acknowledgements. This study is based on careful records and observations by colleagues and nurses at many clinics who cooperated with us in offering daily haemodialysis. Special thanks are due to the clinical and research nurses at the dialysis units at HS Silvestrini, Perugia, Italy; El Camino Hospital, Mountain View, CA, USA; Claude Bernard University, Lyon, France; University Hospital of Turin, Italy; AURAL-Lyon, France; Northwest Kidney Centers and the University of Washington, Seattle, WA, USA and Aksys Ltd, Lincolnshire, IL, USA. We are grateful for valuable statistical input and discussions from Per Kjellstrand, Senior Scientist Emeritus at Gambro Inc., Lund, Sweden. The now defunct Aksys Ltd Company paid for the dialyses of some of the US patients as part of an FDA mandated clinical trial for approval for commercialization of the Aksys PHD haemodialysis machine, no longer available.

Conflict of interest statement. Some of these data have been published in abstract form and presented at the Annual Dialysis Conference, Tampa Florida, February 2005, at the annual meeting of the American Society of Nephrology in Philadelphia, PA, November 2005, and at the Annual Dialysis Conference in San Francisco, February 2006, and in Denver, CO, February 2007. Carl M. Kjellstrand is a freelance consultant to...
<table>
<thead>
<tr>
<th></th>
<th>Transplant</th>
<th>Peritoneal Dialysis (PD)</th>
<th>Home Hemodialysis† (HHD)</th>
<th>In-center Hemodialysis (ICHD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Known As</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preferred treatment</td>
<td></td>
<td>Most utilized home therapy</td>
<td>Most flexible Hemodialysis</td>
<td>Currently most utilized treatment for kidney disease in the U.S.</td>
</tr>
<tr>
<td><strong>How it Works</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• A donated kidney is surgically placed in your body.</td>
<td></td>
<td>Dialysis is done by you at home using a special solution that goes into your abdomen through a tube called a catheter.</td>
<td>Dialysis is done by you and a trained partner at home. Blood is removed from the body, usually through an access point in your arm. The blood is cleaned by a home dialysis machine with a special filter, before being returned to your body.</td>
<td>Dialysis is done by nurses and technicians in a clinic. Blood is removed from the body, usually by an access point in your arm. The blood is cleaned by a machine with a special filter before being returned to your body.</td>
</tr>
<tr>
<td><strong>Pros &amp; Cons</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>✔ No longer need dialysis</td>
<td>✔ Can help you preserve any remaining kidney function(^1,2)</td>
<td>✔ Fewer fluid and dietary restrictions(^4,5)</td>
<td>✔ Have four days off from dialysis</td>
<td></td>
</tr>
<tr>
<td>You have a functioning kidney again</td>
<td>Preserves access to veins</td>
<td>Fewer blood pressure and phosphorus medications(^4,5)</td>
<td>No dialysis supplies in your home</td>
<td></td>
</tr>
<tr>
<td>Have more energy and feel better than compared to dialysis</td>
<td>Flexible dialysis schedule</td>
<td>Strengthens your heart and makes your heart better able to manage excess fluid(^4,5,6)</td>
<td>Interact with other dialysis patients</td>
<td></td>
</tr>
<tr>
<td>✗ Requires anti-rejection medications which may be costly and have side effects</td>
<td>Have more energy and feel better than compared to In-center Hemodialysis(^3)</td>
<td>Have more energy and feel better than compared to In-center Hemodialysis(^3)</td>
<td>Many restrictions on fluid and diet compared to all other treatments</td>
<td></td>
</tr>
<tr>
<td>Requires surgery</td>
<td>Less fatigue and fewer daily peaks and valleys with how you feel compared to In-center Hemodialysis(^3)</td>
<td>Fewer daily peaks and valleys with how you feel than compared to In-center Hemodialysis(^3)</td>
<td>Limited flexibility and control over dialysis schedule and amount of dialysis</td>
<td></td>
</tr>
<tr>
<td>May have to wait for a kidney</td>
<td>Must keep dialysis supplies and equipment at your home</td>
<td>Must keep dialysis supplies and equipment at your home</td>
<td>May feel bad and tired between and following dialysis treatments</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Have a catheter (tube) in your abdomen</td>
<td>Must have a trained partner</td>
<td>You or your partner must perform needlestick</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Exchange of blood occurs in your home</td>
<td></td>
</tr>
<tr>
<td><strong>Sources</strong></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>United States Renal Data System (USRDS)</td>
<td>United States Renal Data System (USRDS)</td>
<td>United States Renal Data System (USRDS)</td>
<td>United States Renal Data System (USRDS)</td>
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</tr>
<tr>
<td>Transplant</td>
<td>Peritoneal Dialysis (PD)</td>
<td>Home Hemodialysis’ (HHD)</td>
<td>In-center Hemodialysis (ICH)</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------</td>
<td>--------------------------</td>
<td>-----------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Key Facts</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of people on therapy in the U.S. as of December, 2008</td>
<td>165,639(^7)</td>
<td>28,291(^8)</td>
<td>4,141(^9)</td>
<td>339,483(^8)</td>
</tr>
<tr>
<td>% of patients “satisfied” with their treatment</td>
<td>87(^%)</td>
<td>75(^%)</td>
<td>85(^%)</td>
<td>52(^%)</td>
</tr>
<tr>
<td>Survival rate after</td>
<td>1 year: 92.4(^%)^{10##}</td>
<td>1 year: 87.3(^%)^{10}</td>
<td>U.S. survival data is not currently available</td>
<td>1 year: 79(^%)^{10}</td>
</tr>
<tr>
<td>% of waste and excess fluids removed from body - goal is 100%</td>
<td>15(^%) - 100(^%) (depending on the function of the transplanted kidney)</td>
<td>15(^%)^{11##}</td>
<td>15(^%)^{12##}</td>
<td>19(^%)^{13##}</td>
</tr>
<tr>
<td>% of patients requiring hospital stay due to serious infection (bacteremia/septicemia) or peritonitis (exit-site infection)</td>
<td>3.3(^%)^{14}</td>
<td>6(^%) - sepsis(^14)</td>
<td>U.S. data is not currently available</td>
<td>10.5(^%)^{14}</td>
</tr>
<tr>
<td>% receiving a transplant within 2 years (Data from 2003-2005)</td>
<td>Not applicable</td>
<td>9.3(^%)^{15}</td>
<td>2.5(^%)^{15}</td>
<td>2.9(^%)^{15}</td>
</tr>
<tr>
<td>% of nephrologists who would choose this dialysis while waiting for transplant</td>
<td>Preferred treatment</td>
<td>43(^%)^{16}</td>
<td>50(^%)^{16}</td>
<td>5(^%)^{16}</td>
</tr>
<tr>
<td>Time spent connected to dialysis equipment</td>
<td>No dialysis needed</td>
<td>CAPD: 30-40 minutes per day, four times per day APD: 8-10 hours per night</td>
<td>Short daily: 2-3 hours a day, 4-6 days week Nighttime: 8-10 hours a day, 5-7 days a week</td>
<td>3-5 hours a day, 3 days a week</td>
</tr>
<tr>
<td>Days per week waste and fluids are removed from the body</td>
<td>7 days</td>
<td>7 days</td>
<td>Short daily: 4-6 days Nocturnal: 5-7 days</td>
<td>3 days</td>
</tr>
<tr>
<td>Recovery time after each dialysis treatment</td>
<td>Not applicable</td>
<td>Typically no recovery time</td>
<td>Short daily: 16-67 minutes(^3); Nocturnal: 2-20 minutes(^3)</td>
<td>397-460 minutes (7 hours)(^3)</td>
</tr>
<tr>
<td>% of patients employed 90 days after starting of dialysis*</td>
<td>Not applicable</td>
<td>32.4(^%)^{17}</td>
<td>Not applicable</td>
<td>16.2(^%)^{17}</td>
</tr>
</tbody>
</table>
Frequent monthly time in clinic + travel time to clinic (does not include time dialyzing at home)***

<table>
<thead>
<tr>
<th>Transplant</th>
<th>Peritoneal Dialysis (PD)</th>
<th>Home Hemodialysis (HHD)</th>
<th>In-center Hemodialysis (ICHD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequent visits post-transplant for first year</strong></td>
<td><strong>3 hours per month</strong></td>
<td><strong>3 hours per month</strong></td>
<td><strong>60 hours per month</strong></td>
</tr>
<tr>
<td><strong>Annual visit every year thereafter</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Dialysis Facility Compare at www.medicare.gov in Resources>Dialysis Facilities

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**Is home dialysis right for you?**

While home dialysis has many advantages and is a viable option for most people, there are some exceptions. You must be healthy enough to provide care for yourself. In some cases, you may need to have a caregiver. You will also need to have a home or place suitable for home dialysis. If you’ve had previous abdominal surgeries or the presence of intestinal diseases, such as inflammatory bowel disease or diverticulitis, your doctor might not prescribe home dialysis. Home dialysis may also not be an option if you’ve had a recent history of seizures or memory difficulties. In addition, there are sanitary precautions that must be taken before, during and after dialysis, and you must be prepared for occasions or incidents that, if not recognized and responded to promptly, may be hazardous to your health. Remember, every patient is different so it is important to talk to your doctor, nurse or social worker to determine if there are other reasons home dialysis may not be right for you.

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Section Three
Education, Training, and Implementation Challenges

Articles


American Journal of Kidney Diseases

Special Article

Systematic Barriers to the Effective Delivery of Home Dialysis in the United States: A Report From the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis

Thomas A. Golper, MD, Anjali B. Saxena, MD, Beth Piraino, MD, Isaac Teitelbaum, MD, John Burkart, MD, Fredric O. Finkelstein, MD, and Ali Abu-Alfa, MD

Abstract

Home dialysis, currently underused in the United States compared with other industrialized countries, likely will benefit from the newly implemented US prospective payment system. Not only is home dialysis less expensive from the standpoint of pure dialysis costs, but overall health system costs may be decreased by more subtle benefits, such as reduced transportation. However, many systematic barriers exist to the successful delivery of home dialysis. We organized these barriers into the categories of educational barriers (patient and providers), governmental/regulatory barriers (state and federal), and barriers specifically related to the philosophies and business practices of dialysis providers (eg, staffing, pharmacies, supplies, space, continuous quality improvement practices, and independence). All stakeholders share the goal of delivering home dialysis therapies in the most cost- and clinically effective and least problematic manner. Identification and recognition of such barriers is the first step. In addition, we have suggested action plans to stimulate the kidney community to find even better solutions so that collectively we may overcome these barriers.


To read full article (requires paid subscription) visit:
Insights into nephrologist training, clinical practice, and dialysis choice

Joseph R. MERIGHI,1 Dorian R. SCHATELL,2 Jennifer L. BRAGG-GRESHAM,2 Beth WITTEN,2 Rajnish MEHROTRA3,4
1School of Social Work, Boston University, Boston, Massachusetts, USA; 2Medical Education Institute, Inc., Madison, Wisconsin, USA; 3Los Angeles Biomedical Research Institute at Harbor-UCLA, Torrance, California, USA; 4David Geffen School of Medicine at UCLA, Los Angeles, California, USA

Abstract
There is variable emphasis on dialysis-specific training among US nephrology fellowship programs. Our study objective was to determine the association between nephrology training experience and subsequent clinical practice. We conducted a national survey of clinical nephrologists using a fax-back survey distributed between March 8, 2010 and April 30, 2010 (N = 629). The survey assessed the time distribution of clinical practice, self-assessment of preparedness to provide care for dialysis patients at the time of certification examination, distribution of dialysis modality among patients, and nephrologists’ choice of dialysis modality for themselves if their kidneys failed. While respondents spent 28% of their time caring for dialysis patients, 38% recalled not feeling very well prepared to care for dialysis patients when taking the nephrology certification examination. Sixteen percent obtained additional dialysis training after fellowship completion. Only 8% of US dialysis patients use home dialysis; physicians very well prepared to care for dialysis patients at the time of certification or who obtained additional dialysis training were significantly more likely to provide care to home peritoneal dialysis patients. Even though 92% of US dialysis patients receive thrice weekly in-center hemodialysis, only 6% of nephrologists selected this for themselves; selection of therapy for self was associated with dialysis modalities used by their patients. Nephrology training programs need to ensure that all trainees are very well prepared to care for dialysis patients, as this is central to nephrology practice. Utilization of dialysis therapies other than standard hemodialysis is dependent, in part, on training experience.

Key words: Training, certification examination, end-stage renal failure, hemodialysis, peritoneal dialysis, home hemodialysis

INTRODUCTION
End-stage renal disease (ESRD) afflicts more than a half-million Americans; about two-thirds receive maintenance dialysis.1 Although treated ESRD incidence has plateaued in the United States, continued population growth and reduced mortality among current patients will likely increase the number of dialysis patients.3 Hence, the care of maintenance dialysis patients is and will remain a key component of clinical nephrology. Yet, at 210 per 1000 patient-years, mortality of US dialysis patients is significantly higher than in Europe or Japan.2 Moreover, utilization of both peritoneal dialysis (PD) and home hemodialysis (HD) is one of the lowest of any developed nation.1 Thus, it is imperative for nephrology training programs to ensure that trainees are prepared to care for dialysis patients and improve their outcomes.1–3 However, in a recent survey of US nephrologists who graduated

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between 2004 and 2008, 20% recalled not feeling well trained and competent to provide care for in-center HD, a therapy utilized by 92% of US dialysis patients. Training programs are even more limited in ensuring competency in home dialysis; many programs have insufficient patients or time for trainees to learn about PD, the dominant home dialysis modality. As a result, more than 44% of recent US nephrology graduates responding did not feel well-trained and competent to provide care to PD patients; more than 84% reported this to be the case for home HD patients.

Taking the certification examination administered by the American Board of Internal Medicine has become a “rite of passage” for graduates of nephrology fellowship programs. It is conceivable that acquisition of medical knowledge while preparing for the certification examination may help bridge the gap in fellowship training with regard to the care of dialysis patients. At this time, however, there are no data on the nephrologists’ self-assessment of preparedness for caring for dialysis patients at the time of taking the certification examination. Further, whether low utilization of home dialysis in the United States is, in part, a result of the training experience has not been examined. We undertook this study to determine nephrologists’ self-assessment of preparedness for providing care to dialysis patients, their need for additional dialysis-specific training after completing fellowship, and the relationship between dialysis therapies used by their patients and selection of dialysis therapies for themselves if they had ESRD. Together, this information provides an important opportunity to assess how well current nephrology fellowship training and certification processes prepare physicians for the clinical practice of the sub-specialty.

MATERIALS AND METHODS

Survey sample

The mailing list of US nephrologists was obtained from American Medical Information, a proprietary health-care marketing firm. The list contained addresses for 6827 US nephrologists as of February 2010. We identified 17 incorrect addresses, for a final total of 6810 nephrologists; 665 respondents completed and returned the questionnaire (10%). We restricted our analyses to nephrologists who reported “clinical practice” as their primary work role (n = 629, 95%). The Medical Education Institute (MEI) was solely responsible for all aspects of data collection and analysis and provided the first author with summary findings. Boston University Institutional Review Board granted this study exempt status.

Survey design and testing

Data were collected using a 13-item, self-administered, paper-and-pencil fax-back survey of US nephrologists (Appendix 1). This survey assessed: clinical practice (years of nephrology practice, types of dialysis patients seen in practice, hours per week spent on nephrology-specific medical concerns); nephrology training and certification (perceived level of preparedness for providing care to dialysis patients at the time of board certification examination, and post-fellowship dialysis training); patient employment and entitlements (data not presented herein); and dialysis modality choice for self (dialysis modality the nephrologist would select in the event of a 5-year wait for a kidney transplant).

MEI staff developed the survey items. To assess the clarity and accuracy of the survey, 12 nephrologists with clinical practice or research expertise were asked to review and critique each item. All items were deemed appropriate and no substantive changes were recommended by the nephrologists. Prior to national distribution, the survey was pilot-tested with a sample of nephrologists employed by a large dialysis organization (n = 131) to identify potential problems with response categories and question phrasing. No problems or concerns were identified.

Survey administration

MEI distributed a cover letter and a one-page fax-back survey by US mail to all nephrologists on the mailing list. The cover letter described the research aim, informed prospective respondents that MEI would donate $2 to the American Kidney Fund for each survey that was returned, and listed study endorsements by the American Association of Kidney Patients, Dialysis Patient Citizens, Renal Support Network, and the International Society for Hemodialysis. The packet was mailed on March 8, 2010, and a reminder packet was mailed on April 1, 2010. Data collection ended on April 30, 2010.

Statistical analysis

Chi-squared tests and t-tests were used to compare the distributions and frequencies of descriptive variables. Years of practice was dichotomized as 10 years or fewer (≤10) and 11 years or more (>11) for examining differences in this measure by other characteristics of the respondents. Logistic regression (adjusted for sex, years of practice, preparedness for the certifying exam in nephrology, and
post-fellowship dialysis training) was used to examine associations between these variables and types of patients seen by the nephrologists. The “types of patients treated” variable was collapsed into three categories: any home HD (three times weekly, daily, or nocturnal), PD, and any in-center HD (three times weekly or nocturnal). Multinomial logistic regression, adjusted for the same variables listed earlier, was used to compare the odds of the nephrologists’ modality choice for self. PD was chosen as the reference category. Multinomial logistic regression was also used when examining the association between types of patients seen and the nephrologists’ modality choice for self, using the same outcome categories and adjustments. All analyses were performed using SAS 9.2 (Cary, NC, USA).

RESULTS

Sample characteristics

Characteristics of the respondents and the distribution of responses are summarized in Table 1. Most respondents were males (80%); 64% of all respondents had been practicing for \( +11 \) years. The distribution of responses grouped by years in practice is summarized in Table 2.

Time distribution of clinical practice

Care of maintenance dialysis patients accounted for 28% of nephrologists’ time providing clinical care. There was no significant difference in distribution of time across different clinical domains by sex. However, respondents who had been in practice for \( \leq 10 \) years spent more time providing care to dialysis patients and less time providing care to those with acute kidney injury than those who had been in practice for \( +11 \) years (Table 2).

Self-assessment of preparedness to provide care for dialysis patients at the time of taking the certification examination in nephrology

Among respondents, 62% recalled feeling very well prepared to care for dialysis patients at the time of the nephrology certification examination (Table 1). There was no significant difference in self-assessment of preparedness to care for dialysis patients by sex. However, significantly more respondents who had been in practice for \( \leq 10 \) years recalled feeling very well prepared to provide care to dialysis patients than those in practice for \( +11 \) years (Table 2).

<table>
<thead>
<tr>
<th>Measure</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex: ( n = 604 )</td>
<td></td>
</tr>
<tr>
<td>Male (%)</td>
<td>80</td>
</tr>
<tr>
<td>Female (%)</td>
<td>20</td>
</tr>
<tr>
<td>Years of nephrology practice: ( n = 628 )</td>
<td></td>
</tr>
<tr>
<td>( +21 )</td>
<td>39</td>
</tr>
<tr>
<td>11–20</td>
<td>25</td>
</tr>
<tr>
<td>5–10</td>
<td>24</td>
</tr>
<tr>
<td>Fewer than 5</td>
<td>12</td>
</tr>
<tr>
<td>Percentage of time spent in seeing patients with the following conditions: ( n = 505 )</td>
<td></td>
</tr>
<tr>
<td>Predialysis chronic kidney disease</td>
<td>31</td>
</tr>
<tr>
<td>Dialysis (all types)</td>
<td>28</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>19</td>
</tr>
<tr>
<td>Fluids and electrolyte disorders</td>
<td>14</td>
</tr>
<tr>
<td>Transplant</td>
<td>8</td>
</tr>
<tr>
<td>After passing the nephrology exam, how prepared did Nephrologist feel to care for dialysis patients? ( n = 617 )</td>
<td></td>
</tr>
<tr>
<td>Very well prepared</td>
<td>62</td>
</tr>
<tr>
<td>Somewhat prepared</td>
<td>36</td>
</tr>
<tr>
<td>Not at all prepared</td>
<td>2</td>
</tr>
<tr>
<td>Additional training in dialysis ( % ) yes: ( n = 625 )</td>
<td></td>
</tr>
<tr>
<td>Dialysis modalities used by patients ( % ) yes: ( n = 626 )</td>
<td></td>
</tr>
<tr>
<td>Standard in-center hemodialysis (3×week)</td>
<td>99</td>
</tr>
<tr>
<td>Peritoneal dialysis (any type)</td>
<td>85</td>
</tr>
<tr>
<td>Daily home hemodialysis</td>
<td>42</td>
</tr>
<tr>
<td>Standard home hemodialysis (3×week)</td>
<td>23</td>
</tr>
<tr>
<td>Nocturnal in-center hemodialysis</td>
<td>21</td>
</tr>
<tr>
<td>Nocturnal home hemodialysis</td>
<td>8</td>
</tr>
<tr>
<td>If nephrologists’ kidneys failed and there was a 5-year wait for a transplant, which type of dialysis would they choose: ( n = 624 )</td>
<td></td>
</tr>
<tr>
<td>Standard in-center hemodialysis (3×week)</td>
<td>6</td>
</tr>
<tr>
<td>Peritoneal dialysis (any type)</td>
<td>45</td>
</tr>
<tr>
<td>Daily home hemodialysis</td>
<td>25</td>
</tr>
<tr>
<td>Standard home hemodialysis (3×week)</td>
<td>3</td>
</tr>
<tr>
<td>Nocturnal in-center hemodialysis</td>
<td>3</td>
</tr>
<tr>
<td>Nocturnal home hemodialysis</td>
<td>18</td>
</tr>
</tbody>
</table>

After fellowship training, 16% of respondents sought additional dialysis-specific training. A higher percentage of nephrologists practicing for \( \leq 10 \) years sought additional dialysis-specific training (20% vs. 8%, \( p < 0.0001 \)). Individuals who reported that they did not feel very well prepared to care for dialysis patients at the time of certification examination were more likely to
seek additional post-fellowship training in dialysis (64% vs. 56%; \(p = 0.02\)).

**Utilization of different dialysis modalities by their patients**

The overwhelming majority of respondents provided care to in-center HD or PD patients (Table 1). Fewer than half reported caring for daily home HD or nocturnal HD patients treated at home or in-center (Table 1). There were differences in patients’ dialysis modalities by respondents’ sex; male nephrologists were significantly more likely to care for thrice-weekly home HD patients than female nephrologists (\(p = 0.0003\)) (Figure 1). Nephrologists practicing for \(\leq 10\) years were significantly more likely to treat patients with daily, thrice-weekly, nocturnal home HD, or nocturnal in-center HD than nephrologists practicing for \(+11\) years (all \(p < 0.02\), Table 2). Table 3 displays nephrologist characteristics that were associated with treating PD patients (Table 3). The nephrologist’s sex was not associated with treating PD patients (Table 3).

### Choice of dialysis modality for themselves if faced with ESRD

When asked what dialysis modality they would choose if their kidneys failed and the wait-list for a transplant was 5 years, 45% of respondents chose PD, 25% preferred daily home HD, 18% elected nocturnal home HD, 3% chose standard home HD, and 3% selected nocturnal in-center

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**Table 2** Descriptive statistics by number of years of practice (10 years or fewer vs. 11 or more years)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Practice 10 years or fewer (n = 229)</th>
<th>Practice 11 or more years (n = 399)</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of time spent in seeing patients with the following conditions: ((n = 505))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Predialysis chronic kidney disease</td>
<td>31</td>
<td>31</td>
<td>0.68</td>
</tr>
<tr>
<td>Dialysis (all types)</td>
<td>30</td>
<td>25</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>17</td>
<td>23</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Fluids and electrolyte disorders</td>
<td>14</td>
<td>15</td>
<td>0.04</td>
</tr>
<tr>
<td>Transplant</td>
<td>8</td>
<td>6</td>
<td>0.03</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Measure</th>
<th>Practice 10 years or fewer (n = 229)</th>
<th>Practice 11 or more years (n = 399)</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very well prepared</td>
<td>69</td>
<td>59</td>
<td>0.05</td>
</tr>
<tr>
<td>Not at all or somewhat prepared</td>
<td>31</td>
<td>41</td>
<td></td>
</tr>
<tr>
<td>Additional training in dialysis (% yes): ((n = 625))</td>
<td>20</td>
<td>8</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Dialysis modalities used by patients (% yes): ((n = 626))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard in-center hemodialysis (3x/week)</td>
<td>99</td>
<td>100</td>
<td>0.40</td>
</tr>
<tr>
<td>Peritoneal dialysis (any type)</td>
<td>86</td>
<td>82</td>
<td>0.15</td>
</tr>
<tr>
<td>Daily home hemodialysis</td>
<td>45</td>
<td>35</td>
<td>0.02</td>
</tr>
<tr>
<td>Standard home hemodialysis (3x/week)</td>
<td>26</td>
<td>17</td>
<td>0.004</td>
</tr>
<tr>
<td>Nocturnal in-center hemodialysis</td>
<td>24</td>
<td>16</td>
<td>0.02*</td>
</tr>
<tr>
<td>Nocturnal home hemodialysis</td>
<td>11</td>
<td>4</td>
<td>0.003</td>
</tr>
</tbody>
</table>

*\(P\) value cut-point to account for multiple comparisons using Bonferroni correction is \(p < 0.0025\).
Only 6% chose thrice weekly (“standard”) in-center HD (Table 1). Female respondents were significantly more likely to select PD and less likely to choose daily home HD for themselves (Figure 2). Nephrologists practicing for +11 years were significantly more likely to prefer PD for themselves; those practicing ≤10 years were more likely to prefer nocturnal in-center or standard home HD for themselves (Table 4).

Table 5 shows which nephrologists would prefer home HD or in-center HD for themselves compared to those who would prefer PD. In adjusted multinomial regression analyses using PD as a reference group, female nephrologists were significantly less likely to prefer any form of home HD for themselves if they had ESRD (Table 5). Nephrologists who had been in practice for ≤10 years were significantly more likely to prefer PD for themselves (Table 5).

Table 6 displays the associations between the modality preferred by nephrologists for themselves and the modalities of patients they see in clinical practice. Nephrologists who treat in-center HD patients were four times more likely to choose home HD for themselves, while nephrologists who treat PD patients were half as likely to choose home HD (Table 6). Also, nephrologists who treat patients using nocturnal HD were seven times more likely to choose in-center HD (either standard or nocturnal) for themselves if their kidneys failed (Table 6).

DISCUSSION

The results of this largest survey of US nephrologists to date allow us to make a few important observations, some of which have not been reported previously. First, provision of care to dialysis patients accounts for more than one-quarter of nephrologists’ time in clinical practice. Yet, more than one-third of respondents recalled not feeling very well prepared to provide such care when they took the nephrology certification examination. Second, one of every six nephrologist respondents in clinical practice, and one of every five who had been in practice for ≤10 years, obtained additional training to care for dialysis patients after completing their fellowships. Third, a higher self-assessment of preparedness and additional post-fellowship training was associated with a higher likelihood of providing treatment to PD patients—a modality currently used by only 7% of US dialysis patients.1 Finally, only 6% of respondents selected standard in-center HD for themselves if their kidneys failed, while 92% of US dialysis patients are dialyzed with this modality.1

The annual death risk of patients with ESRD undergoing maintenance dialysis exceeds 20%, which is higher than the death risk for some diseases like colon cancer. Moreover, these patients experience considerable morbidity and report significantly impaired health-related quality of life.1,2,8–10 Medical care of dialysis patients is central to clinical nephrology practice, and to our knowledge, this is the first study to quantify the time nephrologists spend in this activity. The high morbidity and mortality of US dialysis patients and the observation that more than one-quarter of nephrologists’ clinical time is spent caring for them underscores the importance of ensuring that trainees feel very well prepared and competent to manage this sub-

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Adjusted odds ratio (95% confidence interval)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female (Ref.: male)</td>
<td>0.98 (0.55–1.74)</td>
<td>0.93</td>
</tr>
<tr>
<td>Years of practice (Ref.: 21+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11–20</td>
<td>0.91 (0.49–1.70)</td>
<td>0.53</td>
</tr>
<tr>
<td>5–10</td>
<td>0.91 (0.48–1.71)</td>
<td>0.54</td>
</tr>
<tr>
<td>&lt;5</td>
<td>0.45 (0.23–0.89)</td>
<td>0.02</td>
</tr>
<tr>
<td>Felt very prepared for providing care to dialysis patients at time of certification examination (Ref.: somewhat or not well prepared)</td>
<td>1.59 (1.00–2.54)</td>
<td>0.05</td>
</tr>
<tr>
<td>Received additional dialysis training after completion of fellowship training (Ref.: no additional training)</td>
<td>4.07 (1.44–11.5)</td>
<td>0.008</td>
</tr>
</tbody>
</table>

Adjusted for all covariates listed in the table.

Table 3 Adjusted odds of currently providing care to patients treated with peritoneal dialysis

Figure 2 Distribution of nephrologists’ modality choice for themselves by sex.
group of patients. Yet, a study of recent graduates of US nephrology training programs reported that one in five respondents did not feel well prepared and competent to provide care to in-center HD patients, a therapy used by more than 92% of dialysis patients in the country. The gap in training is even more substantial for home dialysis, particularly home HD. Our observation that more than one-third of practicing nephrologist respondents did not feel well prepared to provide care to dialysis patients at the time they took their certification examination and that one out of six undertook additional dialysis training upon completion of their fellowship builds upon the results of previous studies. Physicians spend considerable time during and shortly after completing fellowship to prepare for the examination. Our study demonstrates that this preparation does not compensate for limitations in the treatment of dialysis patients.

Table 4 Nephrologists' dialysis modality choice by years of practice (10 years or fewer vs. 11 or more years)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Practice 10 years or fewer (n = 229)</th>
<th>Practice 11 or more years (n = 399)</th>
<th>P value</th>
</tr>
</thead>
</table>
| If nephrologists' kidneys failed and there was a 5-year wait for a transplant, which type of dialysis would they choose: (n = 624)
  Standard *in-center* hemodialysis (3×/week) | 7 | 5 | 0.19 |
  Peritoneal dialysis (any type) | 39 | 56 | <0.0001 |
  Daily *home* hemodialysis | 27 | 21 | 0.06 |
  Standard *home* hemodialysis (3×/week) | 4 | 1 | 0.007 |
  Nocturnal *in-center* hemodialysis | 5 | 0.4 | 0.003 |
  Nocturnal *home* hemodialysis | 18 | 17 | 0.82 |

*Chi-squared test of independence, p < 0.0001.

bP value cut-point to account for multiple comparisons using Bonferroni correction is p < 0.0025.

Table 5 Adjusted odds of currently choosing home hemodialysis or in-center hemodialysis (reference: peritoneal dialysis) for treatment if nephrologist had kidney failure

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Prefers home hemodialysis (thrice weekly, daily, or nocturnal) vs. peritoneal dialysis</th>
<th>Prefers in-center hemodialysis (nocturnal or standard thrice weekly) vs. peritoneal dialysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adjusted odds ratio (95% confidence interval)</td>
<td>P value</td>
</tr>
<tr>
<td>Female (Ref.: male)</td>
<td>0.60 (0.38–0.95)</td>
<td>0.03</td>
</tr>
</tbody>
</table>
| Years of practice (Ref.: 21+)
  11–20 | 0.65 (0.41–1.04) | 0.36 | 0.62 (0.30–1.31) | 0.17 |
  5–10 | 0.46 (0.29–0.75) | 0.03 | 0.38 (0.16–0.88) | 0.03 |
  <5 | 0.64 (0.36–1.14) | 0.85 | 0.12 (0.03–0.55) | 0.03 |
| Felt very prepared for providing care to dialysis patients at time of certification examination (Ref.: somewhat or not well prepared) | 1.00 (0.69–1.45) | 0.99 | 1.25 (0.66–2.37) | 0.49 |
| Received additional dialysis training after completion of fellowship training (Ref.: no additional training) | 0.80 (0.48–1.35) | 0.40 | 1.24 (0.54–2.84) | 0.62 |

Adjusted for all covariates listed in the table.
clinical experience of caring for dialysis patients during training.

The high prevalence of self-reported inadequate preparation to care for dialysis patients at the time of the certification examination raises concern that many nephrology training programs do not have the resources (faculty or patients) or do not invest adequate time to ensure the competence of their trainees.3,4,6 Our finding draws attention to the importance of ensuring that the nephrology certification examination itself incorporates sufficient questions to test knowledge about the care of dialysis patients. The blueprint published by the American Board of Internal Medicine does not specifically define what proportion of the examination tests medical knowledge about in-center or home dialysis.7 Given how central dialysis care is to nephrology and how often trainees recalled feeling that they were not well prepared to provide such care, the American Board of Internal Medicine may wish to consider increasing the proportion of the examination that tests knowledge in this domain.

Our study also demonstrates for the first time that the training experience may help explain the very low utilization of dialysis modalities other than thrice weekly in-center HD in the United States. Manual and cycler ambulatory PD has been used for the long-term treatment of uremia for more than three decades, and in contemporary cohorts from around the world, the 4-, 5-, and 10-year survival of patients treated with this therapy are similar to those achieved with in-center HD.1,11,12 At 7%, US PD utilization is one of the lowest of any developed economy in the world.1 Home HD has been used for ESRD patients since the early 1960s. There has been a recent resurgence in interest in longer and/or more frequent HD in the dialysis facility and at home. At least two clinical trials have demonstrated a greater regression of left ventricular hypertrophy with more frequent HD.13,14 While there are no reliable estimates of the proportion of in-center HD patients who dialyze more often than three times a week or for longer than the typical 3–4 h, only about 1% of US dialysis patients are treated with home HD.1 Our study demonstrates that physicians who reported feeling very well prepared to provide dialysis care or who undertook post-fellowship training were more likely to currently provide care to PD patients. In a cross-sectional study, it is not possible to conclude causality. However, it is conceivable that better training may have increased nephrologists’ comfort level with alternate modalities and allowed these physicians to offer a wider variety of dialysis modalities to their patients. Put differently, the training experience may, in part, be responsible for the low utilization of dialysis modalities other than thrice weekly standard in-center HD in the United States. This, in turn, may come at the cost of denying patients the dialysis modality that may better fit their lifestyle, or be associated with better outcomes.

To our knowledge, this is the first study to report on the dialysis modality nephrologists would prefer for themselves if they had kidney failure. The decision about dialysis modality for self may have been dictated by perceptions of medical outcomes with the therapy and how the dialysis modality was expected to fit the nephrologists’ own lifestyles. The most striking observation was that only 6% of the respondents selected thrice weekly in-center HD even though 92% of US dialysis patients are treated with this modality. We did not explore the reasons

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### Table 6

Adjusted odds of currently choosing home hemodialysis or in-center hemodialysis (reference: peritoneal dialysis) for treatment if nephrologist had kidney failure

<table>
<thead>
<tr>
<th>Types of patients cared for</th>
<th>Prefers home hemodialysis (thrice weekly, daily, or nocturnal)</th>
<th>Prefers in-center hemodialysis (nocturnal or standard thrice weekly)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adjusted odds ratio (95% confidence interval) P value</td>
<td>Adjusted odds ratio (95% confidence interval) P value</td>
</tr>
<tr>
<td>Standard home hemodialysis</td>
<td>1.11 (0.71–1.73) 0.65</td>
<td>1.46 (0.71–3.02) 0.30</td>
</tr>
<tr>
<td>(3×/week)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily home hemodialysis</td>
<td>1.37 (0.94–2.01) 0.11</td>
<td>0.72 (0.36–1.45) 0.36</td>
</tr>
<tr>
<td>Nocturnal home hemodialysis</td>
<td>2.74 (1.26–5.96) 0.01</td>
<td>7.00 (2.59–18.9) 0.0001</td>
</tr>
<tr>
<td>Standard in-center hemodialysis (3×/week)</td>
<td>4.37 (0.34–55.6) 0.26</td>
<td>—</td>
</tr>
<tr>
<td>Nocturnal in-center hemodialysis</td>
<td>0.80 (0.51–1.25) 0.33</td>
<td>1.08 (0.50–2.32) 0.85</td>
</tr>
<tr>
<td>Peritoneal dialysis</td>
<td>0.50 (0.29–0.86) 0.01</td>
<td>0.19 (0.09–0.42) &lt;0.0001</td>
</tr>
</tbody>
</table>

Adjusted for gender, years of practice, self-assessment of preparedness for providing care to dialysis patients at the time of taking the certification examination, and additional dialysis training after completing fellowship.
for this substantial discordance, but it does raise the question of whether virtually all nephrologists in the country believe the dialysis modality utilized by the overwhelming majority of patients is simply an inadequate or inappropriate way to treat ESRD or whether they underestimate patients' ability to be successfully treated with the modalities they would choose for themselves. The association between dialysis modalities utilized by their patients currently and the therapy they would choose for themselves, particularly in the case of nocturnal HD, may suggest that the respondents believe alternative dialysis modalities are superior to thrice weekly in-center HD.

**Study limitations**

The results of our study should be interpreted in light of its limitations. The low response rate to the survey is the most important factor that limits the generalizability of our findings. However, with more than 600 respondents, this is the largest survey of practicing US nephrologists ever to be undertaken or published. The design of our study did not allow us to juxtapose the components of the clinical practice of nephrology against the blueprint published by the American Board of Internal Medicine. Nearly 40% of the respondents took the certification exam more than 20 years ago, which may constrain the interpretation of findings regarding preparation to care for dialysis patients due to recall bias. There may be selection bias in our sample; however, we are unable to assess for this bias because data on non-respondents are not available. Despite these limitations, using a respondent-administered questionnaire and self-report items are acceptable data collection methods in survey research. Finally, we did not ask the nephrologists to explain the reasons for their selection of dialysis modality for themselves. This should be explored in future studies in addition to reason(s) why the treatments preferred by the nephrologists for themselves are used so infrequently by US dialysis patients.

**CONCLUSION**

To conclude, this national survey of practicing clinical nephrologists highlights the need for nephrology training programs to consistently ensure that their graduates have received ample training to provide care to dialysis patients on all modalities. The training experience seems to impact whether nephrologists offer dialysis modalities other than thrice weekly standard in-center HD to their patients. Although this survey tested the perceived preparedness of practicing nephrologists, it highlights the importance of evaluating the preparedness of other subspecialists for managing the common diseases or therapies they are likely to encounter in their clinical practice.

**ACKNOWLEDGMENTS**

This study was funded by Medical Education Institute.

**DISCLOSURES**

Rajnish Mehrotra has received grant support and/or honoraria from Amgen, Baxter Healthcare, DaVita, Genzyme, Mitsubishi, Shire, Takeda, and Vifor. The other authors have no conflicts of interests related to the findings reported in this work.
APPENDIX 1

National Nephrologist Dialysis Practice Survey

Medical Education Institute, Inc.

1. At what school did you do a nephrology fellowship?

2. Are you:  
   □ 1 Male  □ 2 Female

3. How long have you practiced nephrology?
   □ 1 < 4 years
   □ 2 5–10 years
   □ 3 11–20 years
   □ 4 21+ years

4. Which one area of nephrology takes most of your time:
   □ 1 Clinical practice
   □ 2 Research
   □ 3 Teaching
   □ 4 Administration

5. How many hours per week do you see patients with the following medical concerns?
   □ 1 I don’t see patients
   □ 2 Acute kidney injury  _____ hours
   □ 3 Fluid & electrolyte disorders  _____ hours
   □ 4 Predialysis CKD  _____ hours
   □ 5 Dialysis (all types)  _____ hours
   □ 6 Transplant  _____ hours

6. When you passed the Nephrology Board exam, how prepared did you feel to care for dialysis patients? (Fellows: please skip items 6 & 7)
   □ 1 Not at all prepared
   □ 2 Somewhat prepared
   □ 3 Very well prepared

7. Did you obtain additional training in dialysis after completing your fellowship training?
   □ 0 No
   □ 1 Yes: (Please specify)

8. To best prepare new nephrologists for dialysis care, how many of the ~240 items on the Nephrology Board exam should focus on the topics below?
   ▶ Hemodialysis
   ▶ Peritoneal dialysis
   ▶ Chronic kidney disease
   ▶ Diabetes

9. How important is a patient’s ability to keep a job when you advise about a dialysis modality?
   □ 1 I don’t know the patient’s job status
   □ 2 Of minor importance
   □ 3 Somewhat important
   □ 4 Very important

10. Who most often asks you to sign disability forms?
    □ 1 Patient
    □ 2 Social Worker
    □ 3 Social Security
    □ 4 Employer/Worker’s Compensation
    □ 5 I offer this to my patients
    □ 6 I don’t routinely sign these forms

11. What percent of a patient’s income is provided by Social Security Disability Income (SSDI)?
    □ 1 20%
    □ 2 35%
    □ 3 66%
    □ 4 Don’t know

12. Which type(s) of dialysis patients do you see? (Check all that apply):
    □ 1 Standard in-center hemodialysis (3x/wk)
    □ 2 Nocturnal in-center hemodialysis
    □ 3 Peritoneal dialysis (any type)
    □ 4 Daily home hemodialysis
    □ 5 Nocturnal home hemodialysis
    □ 6 Standard home hemodialysis (3x/wk)

13. If your kidneys failed and you had a 5-year wait for a transplant, which type of dialysis would you choose?
    □ 1 Standard in-center hemodialysis (3x/wk)
    □ 2 Nocturnal in-center hemodialysis
    □ 3 Peritoneal dialysis (any type)
    □ 4 Daily home hemodialysis
    □ 5 Nocturnal home hemodialysis
    □ 6 Standard home hemodialysis (3x/wk)

Thank you for your time!  
Please fax this survey to 608-833-8366
REFERENCES


Section Four
The Impact of the National Reimbursement System

Articles


END-STAGE RENAL DISEASE

CMS Should Monitor Effect of Bundled Payment on Home Dialysis Utilization Rates

May 2009
END-STAGE RENAL DISEASE

CMS Should Monitor Effect of Bundled Payment on Home Dialysis Utilization Rates

What GAO Found

The self-reported cost information GAO obtained from dialysis providers—including a large chain provider, small nonprofit providers, and a hospital-based provider—indicated variation in the costs to provide home dialysis when compared with costs to provide dialysis in their facility. The six dialysis providers reported lower costs per treatment to provide home dialysis than to provide dialysis at a facility, though the amount by which home dialysis costs were lower varied widely among the providers. Because patients who dialyze at home typically receive dialysis treatments more than three times per week, some providers’ costs to provide home dialysis on a weekly basis can be higher than their costs to provide dialysis at a facility. However, other dialysis providers reported lower costs per week to provide home dialysis compared with dialysis provided in a facility. Additionally, several dialysis providers indicated that, for home dialysis patients, the costs of a dialysis treatment with a training session were significantly higher than the costs of a dialysis treatment without a training session.

At the time of GAO’s review CMS officials said they are considering factoring the costs of home dialysis treatments and training into the expanded bundled payment, but the details for the expanded bundled payment are still under development and subject to change. CMS officials told GAO that the expanded bundled payment would create incentives for providers to offer home dialysis instead of dialysis at a facility, because although some costs associated with home dialysis may be higher for providers, other efficiencies will offset those costs. For example, although supply costs may be higher for home dialysis, other costs of providing home dialysis—such as drugs, staff, and overhead—will be lower, and thus, in CMS’s view, will encourage providers to offer home dialysis. However, concerns have been raised that the way that CMS is considering accounting for the costs of home dialysis in the expanded bundled payment might not encourage providers to offer home dialysis, as CMS expects. For example, some dialysis providers raised concerns that because home dialysis generally consists of more than three dialysis treatments per week—which may result in higher weekly costs to provide home dialysis compared with dialysis received in a facility—providers may not be encouraged to offer home dialysis. CMS officials indicated that CMS intends to assess the effect of the expanded bundled payment on home dialysis utilization rates, but CMS has not established formal plans to monitor this effect.

What GAO Recommends

GAO recommends that CMS establish and implement a formal plan to monitor the expanded bundled payment system’s effect on home dialysis utilization rates. CMS agreed with GAO’s recommendation.
Abbreviations

CMS  Centers for Medicare & Medicaid Services
ESRD  end-stage renal disease
HHS  Department of Health and Human Services
HMO  Health Maintenance Organization
MedPAC  Medicare Payment Advisory Commission
MIPPA  Medicare Improvements for Patients and Providers Act of 2008
NIH  National Institutes of Health
UM-KECC  University of Michigan Kidney Epidemiology and Cost Center
USRDS  United States Renal Data System

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May 22, 2009

Congressional Committees

End-stage renal disease (ESRD) is a chronic illness characterized by permanent kidney failure. Regardless of age, most individuals with ESRD are eligible for Medicare coverage. Individuals with ESRD can receive a kidney transplant or undergo dialysis—a process that removes wastes and fluid from the body to replace kidney functioning. In 2006, about 70 percent of patients with ESRD underwent dialysis and Medicare was the primary payer for approximately 84 percent of dialysis patients nationwide. In 2005, Medicare spending on dialysis and dialysis-related drugs totaled about $7.9 billion.

Individuals with ESRD may receive dialysis treatments in a dialysis facility or be trained to perform dialysis treatments at home. Patients who receive dialysis at a facility receive hemodialysis, a process where blood is allowed to flow, a few ounces at a time, through a special filter that removes wastes and extra fluids and then returns the blood to the body. Patients who conduct dialysis at home perform either home hemodialysis or peritoneal dialysis—which uses the individual’s own peritoneal membrane, located within the abdomen, as the filter for screening toxins from the body. Figure 1 describes the two types of dialysis.

1For individuals who have employer group coverage, Medicare is the secondary payer for 30 months, after which Medicare becomes the primary payer. 42 U.S.C. § 1395y(b)(1)(C).

2According to the United States Renal Data System (USRDS), about 53 percent of dialysis patients live for 3 years after being diagnosed with end-stage renal disease (ESRD), and the 10-year survival rate is less than 12 percent.

3GAO analysis of 2006 USRDS data. Data from 2006 were the most recent data available from USRDS.


5Dialysis facilities can be freestanding dialysis facilities, which are not associated with hospitals, or can be hospital-based facilities.

6Some dialysis facilities allow patients to self-perform hemodialysis in a dialysis facility. We do not address this type of dialysis in this report.
According to the United States Renal Data System (USRDS)—a national data system that collects, analyzes, and distributes information about ESRD in the United States—use of peritoneal dialysis peaked in the mid-1990s—reaching about 14.4 percent of the dialysis population—but has since declined. Utilization of home hemodialysis declined steadily from 1985 to 2002, when the home hemodialysis population began to increase. In 2006, of the 355,000 individuals with ESRD nationwide who received dialysis treatments—including both patients who were covered by Medicare and patients who had other insurance coverage—approximately 92 percent received dialysis in a facility, while about 7.4 percent received dialysis in the home.
performed peritoneal dialysis at home, and 0.7 percent performed home hemodialysis.\textsuperscript{7,8}

The Centers for Medicare & Medicaid Services (CMS)—the agency that administers the Medicare program—has made an effort to promote home dialysis,\textsuperscript{9} whenever clinically appropriate. In April 2008, CMS issued a final rule establishing new conditions of coverage for Medicare dialysis facilities.\textsuperscript{10} It requires such facilities to inform patients about the options of home and facility dialysis treatments, and the patients’ care team—which includes the patients, their physician, and nurses—to identify a plan for each patient’s home dialysis treatments or explain why the patient is not a candidate for home dialysis. According to CMS, one of the goals of the rule is to foster patient independence by encouraging ESRD patients to receive dialysis at home. Some medical experts and dialysis providers have estimated that anywhere from less than 10 percent to up to 50 percent of all patients who receive dialysis nationwide could be good candidates for home dialysis.\textsuperscript{11}

As CMS takes steps to promote home dialysis, the agency also is required by law to change the way Medicare pays for dialysis and other ESRD services. Currently, Medicare pays dialysis providers a prospective payment—known as a composite rate—for three dialysis treatments per week, whether the treatment is provided at home or in a facility.\textsuperscript{12,13} The composite rate covers a partial bundle of dialysis services, including items associated with dialysis treatments, such as certain tests, drugs, and

\textsuperscript{7}Roughly 355,000 patients with ESRD were receiving dialysis services on December 31, 2006.

\textsuperscript{8}GAO analysis of USRDS data from 2006.

\textsuperscript{9}We use the term home dialysis when referring to both home hemodialysis and peritoneal dialysis.

\textsuperscript{10}Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule, 73 Fed. Reg. 20370, 20475 (Apr. 15, 2008) (to be codified at 42 C.F.R. pt. 494). Among other things, the conditions for coverage require that all dialysis facilities providing services to Medicare patients meet specified patient safety and care standards.

\textsuperscript{11}Many of the experts and providers we interviewed provided estimates that from 15 to 35 percent of all dialysis patients would be good candidates for home dialysis.

\textsuperscript{12}A dialysis provider can operate multiple dialysis facilities.

\textsuperscript{13}Some dialysis patients may receive more than three dialysis treatments per week, but Medicare typically does not reimburse for more than three treatments per week.
supplies that are frequently used during dialysis. In addition to the composite rate, providers can also receive additional Medicare reimbursements for separately billable ESRD services, which include other injectable drugs (such as Epogen, vitamin D, and iron), laboratory tests, supplies, and blood products that are often used during the course of dialysis. Providers can also receive additional Medicare reimbursements for training patients to dialyze at home.\textsuperscript{14}

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires CMS to implement a new, expanded bundled payment for dialysis services by January 1, 2011.\textsuperscript{15,16} MIPPA requires that the expanded bundled payment for ESRD services include a payment for providing both composite rate services and separately billable services. This would include the costs of providing home dialysis.\textsuperscript{17}

As we have previously reported, an expanded bundled payment for ESRD services should promote efficient care delivery, as providers retain the difference if Medicare’s payment exceeds the costs they incur to provide dialysis services. We also reported that an expanded bundled payment would afford clinicians more flexibility in decision making because incentives to provide a particular drug or treatment would be reduced.\textsuperscript{18} According to the Secretary of the Department of Health and Human Services’ (HHS) 2008 Report to Congress that outlined CMS’s proposed design for the expanded bundled payment for ESRD services, the new payment is intended to eliminate incentives for providers to overutilize certain services that are separately billable, to target higher payments to

\textsuperscript{14}Currently, dialysis facilities can bill separately and receive payments for training patients how to dialyze at home. Facilities can receive $12 per training session to train a patient how to manually conduct peritoneal dialysis, for up to 15 training sessions. Facilities can receive $20 per training session to train a patient how to use a machine to conduct peritoneal dialysis, for up to 15 training sessions. Facilities can receive $20 per training session to train a patient how to conduct hemodialysis, for three sessions per week for up to 3 months.


\textsuperscript{16}In 2006, we reported that Congress should consider establishing a fully bundled payment system for dialysis services that would eliminate separate payments for ESRD services that are now separately billable. See GAO-07-77.

\textsuperscript{17}The Medicare Payment Advisory Commission (MedPAC)—an agency that advises Congress on issues affecting the Medicare program—noted in its 2009 Report to Congress that CMS could consider setting different payment rates for different methods of dialysis.

\textsuperscript{18}See GAO-07-77.
providers that treat more costly patients, and to create incentives for efficiencies.

The Tax Relief and Health Care Act of 2006 required us to review and report on the costs associated with providing home hemodialysis and patient training for home hemodialysis and peritoneal dialysis. Several congressional committees also asked us to review the implications of the expanded bundled payment for home dialysis. For our review, we examined (1) the extent to which the costs of home dialysis differ from the costs of dialysis provided in a facility, and (2) CMS's plans to account for home dialysis costs in the expanded bundled payment for ESRD services.

To examine the extent to which the costs of home dialysis differ from the costs to provide dialysis in a facility, we conducted interviews with officials from 12 dialysis providers, including large chain providers, small nonprofit providers, and a hospital-based provider. Additionally, we obtained self-reported cost information from 6 of the 12 dialysis providers we interviewed that offered both home and facility dialysis. The 6 providers shared with us annual cost information (which ranged from August 2006 to June 2008), including their average cost per treatment and total annual costs for specific cost categories associated with providing dialysis services (such as supplies, overhead, equipment, drugs, laboratory, staff, and administrative costs). In total, we obtained cost information from the providers on the costs for dialysis services provided in nearly 1,600 facilities to approximately 130,000 dialysis patients, including almost 11,000 peritoneal dialysis patients and over 850 home hemodialysis patients.

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20Some home dialysis patients choose not to be associated with a facility and make independent arrangements with a supplier to receive equipment and supplies. Payment to these suppliers is known as Method II. For these patients, the supplier is required to maintain a written agreement with a dialysis facility to provide back-up and support services. We do not discuss this type of payment in the report because dialysis providers only offer back-up and support services to these patients.

21Some of the dialysis providers that we contacted operated multiple dialysis facilities.
hemodialysis or peritoneal dialysis and calculated the percentage difference in average self-reported costs between home dialysis and dialysis provided in a facility (or chain of facilities). We also used the cost information reported to us to calculate the providers’ weekly costs for providing home dialysis and dialysis in a facility. We regard the cost information reported to us as testimonial and we did not independently assess the accuracy of that information. We identify the cost information as self-reported throughout this report, and we did not aggregate or average the self-reported costs across different providers. We also conducted interviews with representatives from the Medicare Payment Advisory Commission (MedPAC) and professional organizations, and we conducted site visits to two dialysis facilities that offered both home dialysis and dialysis in a facility. In addition, to obtain information on the costs of home dialysis, we examined over 30 articles about the costs of home dialysis published between 2002 and 2008, obtained through a MEDLINE literature search or recommended by representatives we interviewed.

To examine CMS’s plans to account for the costs of home dialysis in the expanded bundled payment, we reviewed the Secretary of HHS’s 2008 Report to Congress on the Proposed Design for a Bundled ESRD Prospective Payment System and conducted interviews with CMS officials. We also conducted interviews with CMS’s contractor, the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC), dialysis facilities, dialysis equipment suppliers, and medical experts on home dialysis. We also interviewed dialysis providers to learn their views on home dialysis issues that CMS should consider when developing the expanded bundled payment for ESRD services. Appendix I provides more detailed information on our methodology. We conducted our work from October 2008 through May 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit

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22 Of the six dialysis providers that reported cost information to us, five providers had 20 or more patients on peritoneal dialysis, and thus, were included in our review. Separately, five of the six providers had 20 or more patients on home hemodialysis, and thus, were included in our review.

23 The average costs per treatment for home hemodialysis and peritoneal dialysis did not include the costs of training patients to receive dialysis at home. The dialysis providers reported cost information about training patients separately.
objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Individuals diagnosed with ESRD may be influenced by a variety of factors when choosing the type of dialysis to receive. One factor that may influence the individual’s choice of dialysis is the individual’s awareness about the different types of dialysis available. For example, some individuals may not be aware that peritoneal dialysis is an option to replace kidney functioning and, as a result, would not choose to undergo peritoneal dialysis. The individual’s choice of which dialysis to perform can also be influenced by the type of dialysis that the individual’s physician recommends and if the individual has a partner to assist with dialysis treatments. Additionally, some individuals may have physical conditions that prevent them from self-performing dialysis—such as vision problems or dexterity issues. The individual’s choice may also be influenced by how quickly the dialysis treatments need to begin—as individuals who need to urgently start dialysis may not have time to be trained in conducting dialysis at home.

Hemodialysis conducted in a facility typically consists of three dialysis treatments per week. Peritoneal dialysis is conducted daily. Recent technological changes in hemodialysis equipment have occurred, making it easier for hemodialysis to be done more frequently. For example, a new hemodialysis machine—designed for use at home—requires patients to dialyze five to seven times per week and is reported by some dialysis providers to be more user-friendly than traditional dialysis machines. As a result, most home hemodialysis patients dialyze five to seven times per week.

Data from USRDS show that, compared to patients who dialyzed in a facility, in 2006, home dialysis patients were more likely to be younger, white, located in rural areas, employed, and have employer or group health insurance coverage, and were less likely to be Hispanic. USRDS data for 2006 also indicate that patients who received home dialysis may be healthier than patients who dialyzed in a facility. Home dialysis patients were more likely to be on the wait-list for a kidney transplant (which requires a certain level of health status) and had lower rates of diabetes
and hypertension as the primary disease that caused their ESRD compared with patients who received dialysis in a facility.\textsuperscript{24}

Limited evidence suggests and several dialysis provider officials and medical experts we interviewed believe that home dialysis results in better clinical outcomes for individuals with ESRD. These better clinical outcomes include better control over fluid levels, less need for dialysis drugs, fewer hospitalizations, and better quality of life. Improved clinical outcomes may be due to the features of home dialysis that its supporters believe more closely mimic natural kidney functioning—home dialysis can be done more frequently with less time between treatments, for longer periods of time than dialysis received in a facility, three times a week. Perhaps as a result of this more frequent dialysis, USRDS reported that the overall Medicare costs for peritoneal dialysis patients—including hospitalization costs as well as costs for dialysis services—were about 26 percent less than the total Medicare costs for hemodialysis patients in 2006. Similarly, a Medicare health maintenance organization (HMO) reported to us that moving some of its patients from facility hemodialysis to home hemodialysis has substantially reduced hospitalizations, and overall health costs, for those patients. That HMO has also published a study documenting relatively low hospitalization rates for its home hemodialysis patients.\textsuperscript{25}

However, in general, it is challenging to determine the causes of differences in clinical outcomes between patients who receive dialysis at home versus in a facility because—as we previously noted—the characteristics of patients who dialyze at home are different than those who dialyze in a facility. The National Institutes of Health (NIH) is conducting randomized clinical trials that are intended to provide information on the clinical outcomes associated with more frequent dialysis received in a facility compared to dialysis received three times a week in a facility, and with home nocturnal hemodialysis compared to

\textsuperscript{24}With one exception, USRDS data from 2006 describe patients with ESRD on December 31, 2006. USRDS data on ESRD patients’ employment describes patients who were diagnosed with ESRD sometime during 2006.

three times weekly home hemodialysis. Results from the NIH trials are expected to be available in 2010.

Selected Dialysis Providers Reported Wide Variation in the Costs of Providing Dialysis at Home Compared to Facility Dialysis

The self-reported cost information we obtained from the six dialysis providers indicated variation in the cost to provide home dialysis when compared with dialysis provided in a facility. The six dialysis providers reported lower costs per treatment to provide home dialysis than to provide dialysis at a facility, though the amount by which home dialysis costs were lower varied widely among the providers. Because patients who dialyze at home typically receive dialysis treatments more than three times per week, some providers' costs to provide home dialysis on a weekly basis can be higher than their costs to provide dialysis at a facility. However, other dialysis providers reported lower costs per week to provide home dialysis compared with dialysis provided in a facility. Additionally, several dialysis providers indicated that, for home dialysis patients, the costs of a dialysis treatment with a training session were significantly higher than the costs of a dialysis treatment without a training session.

Six Dialysis Providers Reported a Range of Lower Costs per Treatment for Home Dialysis When Compared with the Costs per Treatment for Dialysis Provided in a Facility

The self-reported cost information that we obtained from six dialysis providers indicated that the average costs per treatment for home dialysis were lower than the average costs per treatment for dialysis provided in a facility. However, there was a wide range among the dialysis providers in terms of how much lower the average costs per treatment for home dialysis were than dialysis provided in a facility. For home hemodialysis, dialysis providers reported to us that their average costs per treatment were 17 to 50 percent lower than the average costs per treatment for dialysis provided in a facility. For peritoneal dialysis, dialysis providers reported to us that their average costs per treatment were 48 to 68 percent lower.


The average costs per treatment that the dialysis providers self-reported to us did not include the costs to train patients to conduct home dialysis. The dialysis providers reported cost information about training patients separately.
lower than the average costs per treatment for hemodialysis provided in a facility.  

The average costs per treatment that the dialysis providers reported to us include costs for certain items associated with providing dialysis services, including supplies, equipment, drugs, overhead, and staff. Officials from dialysis providers indicated to us that supply costs are higher for home dialysis compared with dialysis provided in a facility. One reason that supply costs for home dialysis patients are higher is because certain supplies that can be reused for patients who receive dialysis in a facility often cannot be reused by home patients. For example, patients who receive dialysis in a facility can reuse their own dialyzer—the artificial kidney used to filter the blood during hemodialysis—because the facility is able to sterilize the dialyzer between dialysis treatments. Patients who dialyze at home need to use dialyzers that are intended for one-time use, which results in higher supply costs. In contrast, other cost items (such as drugs and staff) were reported to be lower for home dialysis than for dialysis provided in a facility. For example, after home dialysis patients have been trained to conduct dialysis, there are lower staffing costs associated with home dialysis because patients require less staffing resources—as the patients (or their caregiver) are performing the dialysis treatments at home that are performed by staff for dialysis provided in a facility.  

Table 1 provides one dialysis provider’s self-reported average costs per treatment in 2008 for hemodialysis provided in a facility compared to hemodialysis provided at home, which indicates that the supply costs are higher for home hemodialysis while the other items are lower for home hemodialysis compared with hemodialysis provided in a facility.

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28Peritoneal dialysis is performed continually throughout the day, as patients repeatedly fill their abdomen with dialysis solution, allow the dialysis solution to remain in their abdomen for several hours, and then drain the dialysis solution. As a result, we report that the average cost per treatment for peritoneal dialysis equals 1 day of peritoneal dialysis.

29Staffing costs for home dialysis include the costs of nurses, dieticians, and social workers who meet with home dialysis patients.
Table 1: Self-Reported Average Costs per Treatment for Hemodialysis in a Facility and Home Hemodialysis from One Dialysis Provider, 2008

<table>
<thead>
<tr>
<th></th>
<th>Hemodialysis in a facility</th>
<th>Hemodialysis at home</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplies</td>
<td>$27</td>
<td>$41</td>
</tr>
<tr>
<td>Equipment</td>
<td>$7</td>
<td>$5</td>
</tr>
<tr>
<td>Drugs</td>
<td>$63</td>
<td>$19</td>
</tr>
<tr>
<td>Laboratory</td>
<td>$7</td>
<td>$5</td>
</tr>
<tr>
<td>Staff</td>
<td>$66</td>
<td>$20</td>
</tr>
<tr>
<td>Other (including overhead)</td>
<td>$72</td>
<td>$41</td>
</tr>
<tr>
<td><strong>Total average cost per treatment</strong></td>
<td><strong>$243</strong></td>
<td><strong>$133</strong></td>
</tr>
</tbody>
</table>

Sources: Self-reported cost information provided by one dialysis provider.

Note: Entries may not sum to the total because of rounding. The average costs per treatment that the dialysis providers self-reported to us did not include the costs to train patients to conduct home dialysis.

Table 2 provides another dialysis provider’s self-reported average costs per treatment in 2006 for hemodialysis provided in a facility compared to peritoneal dialysis provided at home. The provider reported that its supply costs were higher for peritoneal dialysis provided at home, while the other items were lower for peritoneal dialysis compared with hemodialysis provided in a facility.

Table 2: Self-Reported Average Costs per Treatment for Hemodialysis in a Facility and Peritoneal Dialysis from One Dialysis Provider, 2006

<table>
<thead>
<tr>
<th></th>
<th>Hemodialysis in a facility</th>
<th>Peritoneal Dialysis at home</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplies</td>
<td>$22</td>
<td>$45</td>
</tr>
<tr>
<td>Equipment</td>
<td>$11</td>
<td>$0</td>
</tr>
<tr>
<td>Drugs</td>
<td>$80</td>
<td>$18</td>
</tr>
<tr>
<td>Laboratory</td>
<td>$1</td>
<td>$0</td>
</tr>
<tr>
<td>Staff</td>
<td>$70</td>
<td>$16</td>
</tr>
<tr>
<td>Other (including overhead)</td>
<td>$68</td>
<td>$15</td>
</tr>
<tr>
<td><strong>Total average cost per treatment</strong></td>
<td><strong>$251</strong></td>
<td><strong>$94</strong></td>
</tr>
</tbody>
</table>

Sources: GAO analysis of self-reported cost information provided by one dialysis provider.

Note: Entries may not sum to the total because of rounding. The average costs per treatment that the dialysis providers self-reported to us did not include the costs to train patients to conduct home dialysis.
Some Dialysis Providers Reported Higher Costs per Week for Home Dialysis Compared to Dialysis Provided in a Facility, While Other Dialysis Providers Reported Lower Costs per Week for Home Dialysis

All six dialysis providers in our review reported lower average costs per treatment for home dialysis when compared to dialysis provided in a facility; however, some dialysis providers reported higher costs per week for home dialysis compared with dialysis provided in a facility, while others reported lower costs per week for home dialysis. For home hemodialysis, three of the five dialysis providers included in our review reported higher costs per week for providing home hemodialysis compared with the costs per week of providing dialysis in a facility. Officials from these three dialysis providers indicated that the costs per week for patients who dialyze at home were higher because these patients typically dialyze more frequently than three times per week. Home hemodialysis is often performed five to seven times per week. For example, using one provider’s self-reported average costs per treatment from table 1, the average costs per treatment for home hemodialysis were lower ($133 per treatment) compared with dialysis provided in a facility ($243 per treatment); however, for patients who received six dialysis treatments per week, the provider’s weekly costs for home hemodialysis were higher ($798 for six treatments during the week) compared with dialysis provided in a facility ($729 for three treatments per week). The other two providers reported lower costs per week for home hemodialysis compared with dialysis provided in a facility. However, one of these providers indicated that their home hemodialysis patients only dialyze three times per week, which is not more frequent than patients who dialyze in a facility.

Providers also reported varying costs per week for peritoneal dialysis compared to dialysis provided in a facility. Of the five dialysis providers in our review, two providers indicated that their costs per week for providing peritoneal dialysis were higher than the weekly costs of providing dialysis in a facility. In contrast, three of the five dialysis providers in our review indicated that the costs per week of providing peritoneal dialysis were lower than the weekly costs of providing dialysis in a facility. Using one provider’s self-reported average costs per treatment from table 2, the average costs per treatment for peritoneal dialysis were

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30Six dialysis providers self-reported costs to us; however, only five dialysis providers had 20 or more patients on home hemodialysis and were included in our review for home hemodialysis.

31Six dialysis providers self-reported costs to us; however, only five dialysis providers had 20 or more patients on peritoneal dialysis and were included in our review for peritoneal dialysis.
lower ($94 per treatment) compared with dialysis provided in a facility ($251 per treatment) and the weekly costs of peritoneal dialysis were also lower ($658 for 7 days of peritoneal dialysis during the week) compared with dialysis provided in a facility ($753 for three treatments per week). Based on self-reported cost information from dialysis providers, the costs per week of providing peritoneal dialysis were lower than the costs of providing hemodialysis in a facility, in part, because costs for drugs, staff, and overhead were lower for peritoneal dialysis patients.

As indicated by the dialysis providers’ self-reported cost information, the higher weekly costs of home dialysis for some providers may be due—in part—to the increased frequency of dialysis. For hemodialysis, this is consistent with a 2001 MedPAC report, which estimated that the weekly costs to provide hemodialysis more than three times a week were 15 to 20 percent higher than the weekly costs to provide hemodialysis three times per week.

### Several Dialysis Providers Reported That Training Costs for Home Dialysis Patients Are Significant

According to dialysis providers, the costs of training patients to dialyze at home can be significant. These costs are exclusively for home dialysis patients as patients who receive dialysis in a facility do not need to be trained. Dialysis providers reported to us that the costs of training patients to dialyze at home are significant because it typically takes 3 to 6 weeks, with up to 5 training sessions a week, to train a patient to perform home hemodialysis (approximately 15 to 30 sessions) and 1 to 2 weeks (approximately 5 to 10 sessions) to train a patient to perform peritoneal dialysis. In addition, training sessions are costly because they require the dedicated attention of one nurse for each training session. Table 3 shows an example of one dialysis provider’s self-reported average costs for a home hemodialysis training session (which includes a dialysis treatment) compared with the average costs of a home hemodialysis treatment session during 2008.
### Table 3: Self-Reported Average Cost for One Home Hemodialysis Training and Treatment Session, and One Home Hemodialysis Session from One Dialysis Provider, 2008

<table>
<thead>
<tr>
<th></th>
<th>Home hemodialysis training session + treatment</th>
<th>Home hemodialysis treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplies</td>
<td>$41</td>
<td>$41</td>
</tr>
<tr>
<td>Equipment</td>
<td>$5</td>
<td>$5</td>
</tr>
<tr>
<td>Drugs</td>
<td>$19</td>
<td>$19</td>
</tr>
<tr>
<td>Laboratory</td>
<td>$5</td>
<td>$5</td>
</tr>
<tr>
<td>Staff</td>
<td>$150</td>
<td>$20</td>
</tr>
<tr>
<td>Other (including overhead)</td>
<td>$41</td>
<td>$41</td>
</tr>
<tr>
<td><strong>Total average cost per treatment</strong></td>
<td><strong>$263</strong></td>
<td><strong>$133</strong></td>
</tr>
</tbody>
</table>

Sources: GAO analysis of self-reported cost information provided by one dialysis provider.

Note: Entries may not sum to the total because of rounding.

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**CMS Is Considering Factoring Current Home Dialysis Costs into the Expanded Bundled Payment, but Concerns Have Been Raised That Home Dialysis May Not Be Encouraged as CMS Expects**

At the time of our review CMS officials indicated that they are considering factoring the costs of home dialysis treatments and training into the expanded bundled payment, but the details for the expanded bundled payment are still under development. CMS officials told us that the expanded bundled payment could create incentives for providers to offer home dialysis instead of dialysis in a facility, because although some costs associated with home dialysis may be higher for providers, other efficiencies will offset those costs. However, concerns have been raised that the way in which the expanded bundled payment may account for home dialysis costs might not encourage providers to offer home dialysis, as CMS expects. CMS officials indicated that it intends to assess the effect of the expanded bundled payment on home dialysis utilization rates, but CMS has not established formal plans to monitor this utilization.
CMS is Considering Factoring Home Dialysis Costs into Calculation of Expanded Bundled Payment

In order to fulfill the requirements of MIPPA, CMS is developing an expanded bundled payment for ESRD services. Beginning in 2011, Medicare will pay for dialysis services using an expanded bundled payment, which will include both services currently paid under the composite rate and services that are separately billable. Although the details of the expanded bundled payment are still under development and subject to change, at the time of our review CMS officials said they were considering giving providers the same payment regardless of whether the dialysis treatments are provided in the patient’s home or at a facility. They noted that a base payment for dialysis services—based on several factors—could be calculated by totaling providers’ costs, including costs for home hemodialysis, peritoneal dialysis, and dialysis in a facility.32

CMS officials and an official from UM-KECC, the contractor assisting CMS with developing the expanded bundled payment, told us that they will obtain cost information from cost reports that dialysis providers are required to submit to CMS and from Medicare claims for separately billable ESRD-related services.33 Since dialysis providers submit cost reports to CMS, which include the costs of home dialysis, CMS officials told us that the costs associated with home dialysis could be factored into the development of the expanded bundled payment.

CMS officials told us that when implemented, the expanded bundled payment could create incentives for providers to offer home dialysis. CMS officials explained that while some costs associated with home dialysis may be higher for providers (such as supplies), these costs will be offset by efficiencies created by lower cost categories for such items as drugs, staff, and overhead expenses. However, CMS officials said they have not conducted an analysis to determine whether these cost assumptions are accurate.

32MIPPA requires CMS to adjust its bundled payment to dialysis facilities based on several factors, including adjustments for the characteristics of patients that dialyze at that facility (such as patient’s age, weight, and comorbidities); for higher costs in dialyzing certain patients due to unusual variations in medically necessary care; for low-volume facilities; and for other items as determined appropriate by the HHS Secretary.

33In developing the expanded bundled payment, CMS is required to use data from the year in which per dialysis patient utilization was the lowest among 2007, 2008, or 2009.
Concerns Have Been Raised That the Way CMS Is Considering Accounting for Home Dialysis Costs in the Expanded Bundled Payment May Not Encourage Home Dialysis as CMS Expects

Some home dialysis providers and officials we interviewed have raised concerns that the way that CMS is considering accounting for the costs of home dialysis may not encourage use of home dialysis. In particular, concerns have been raised that the cost information CMS and its contractor are using to develop the expanded bundled payment may not account for all of the costs associated with providing home dialysis. For example, one analysis of CMS cost reports found that some providers only report cost information to CMS for the three treatments per week for which Medicare reimburses, even though some home dialysis patients receive more frequent treatments. Also, USRDS officials reported to us that the claims information CMS is using to develop its expanded bundled payment does not always reliably distinguish between the costs for separately billable items and services for home hemodialysis and facility hemodialysis.

Concerns have also been raised that the expanded bundled payment might not encourage providers to offer home dialysis depending on how home dialysis training costs are accounted for in the bundled payment. At the time of our review, CMS officials noted that they are considering factoring providers’ costs associated with training patients to dialyze at home into the expanded bundled payment rather than providing a separate, additional payment for training patients to dialyze at home. As we noted previously, some providers reported significant up-front costs to start a patient on home dialysis, in part because training for home dialysis requires one nurse to train one patient.

Moreover, some home dialysis providers are also concerned that providers will not have an incentive to provide home dialysis if the expanded bundled payment restricts reimbursement to three dialysis treatments per week. Indeed, under the current partially bundled payment system, we found that some home dialysis providers now have been granted medical necessity exceptions to receive Medicare reimbursements for additional

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34 This analysis was commissioned by a dialysis equipment manufacturer.

35 Some dialysis facilities have received payments in addition to the training reimbursement (called exceptions) for training patients to dialyze at home if the costs of training their patients exceed the typical Medicare reimbursement for home dialysis training. CMS officials told us that they are unlikely to grant these exceptions under the expanded bundled payment.
dialysis treatments beyond three per week. CMS officials told us that they are unlikely to allow these additional reimbursements under the expanded bundled payment system.

CMS officials indicated that, after the expanded bundled payment system has been implemented, they plan to assess its effect on home dialysis utilization rates and, if necessary, adjust the expanded bundled payment accordingly. However, CMS officials said that no formal plan to assess the bundled payment system’s effect on home dialysis utilization rates has been established.

Some dialysis experts and officials from dialysis providers have estimated that anywhere from less than 10 percent to up to 50 percent of patients could be good candidates to perform dialysis at home—higher than the current home dialysis utilization rate of about 8 percent. In its April 2008 final rule, CMS took steps to encourage home dialysis for appropriate patients, including requiring that patients be informed of all types of dialysis treatments (including home dialysis). CMS officials told us that they believe that home dialysis could be encouraged under the forthcoming expanded bundled payment if providers receive the same reimbursement under the expanded bundled payment for dialysis provided in a facility or at home, because the reduced costs of home dialysis for drugs and staff would make home dialysis less costly to provide than dialysis in a facility. However, CMS has not independently verified if these assumptions are correct. Additionally, some home dialysis providers and officials we interviewed raised concerns about whether a bundled payment would encourage home dialysis, including concerns that the sources of cost information used to calculate the expanded bundled payment rate may not include all of the costs of providing home dialysis, such as the up-front costs associated with training patients to conduct home dialysis, and its increased frequency. Furthermore, although CMS has said it plans to monitor the effect of the expanded bundled payment system on utilization of home dialysis, it has not specified how this will be done. For these reasons, we believe that the effect of the expanded bundled payment system on home dialysis utilization rates is uncertain.

Conclusions

Dialysis facilities receive Medicare reimbursements for providing dialysis services from CMS contractors. These contractors have some flexibility about what services they will reimburse. We found that at least two of these contractors have policies that grant reimbursements for additional dialysis treatments—beyond three treatments per week—for home dialysis patients based on medical necessity.
and that it is important to monitor its effect on the utilization of home dialysis.

**Recommendation for Executive Action**

To determine the effect of the expanded bundled payment system on home dialysis utilization rates, CMS should establish and implement a formal plan to monitor the expanded bundled payment system’s effect on home dialysis utilization rates to determine whether home dialysis utilization rates have increased as CMS expects.

**Agency Comments and Our Evaluation**

In written comments on a draft of this report, CMS concurred with our recommendation to establish and implement a formal plan to monitor the expanded bundled payment system’s effect on home dialysis utilization rates. CMS agreed with the need to establish a monitoring plan under the expanded bundled payment system and expects to establish a formal plan after it has promulgated the final rule associated with the ESRD bundled payment system. CMS also commented that our draft report implied that final decisions have been reached by CMS and the Secretary of HHS regarding the details of the expanded bundled payment system. We revised our draft report to clarify that the details of the expanded bundled payment are tentative and still subject to change.

CMS also provided a few additional comments. First, CMS noted that one dialysis provider that operates multiple dialysis facilities has recently trained patients to conduct and self-perform hemodialysis in a dialysis facility. We added a reference to this option for dialysis treatment in the report. CMS requested that we clarify information in reference to a MedPAC report on the costs of frequent home dialysis. We made changes as appropriate. Additionally, CMS stated that Medicare claims submitted by dialysis facilities do distinguish home hemodialysis from facility hemodialysis. However, we confirmed with USRDS officials that the claims information does not always reliably make this distinction for separately billable items and services and we clarified this in the report. Finally, CMS noted that when dialysis providers have presented information to CMS regarding the percentage of patients who would be good candidates for home dialysis, these percentages are usually closer to 10 to 15 percent of all dialysis patients. However, medical experts and dialysis providers we interviewed indicated a range of less than 10 percent to up to 50 percent of all dialysis patients could be good candidates for home dialysis, although many of the experts and providers we interviewed estimated that from 15 to 35 percent of all dialysis patients would be good
candidates for home dialysis. We have clarified this in the report. CMS’s written comments are reprinted in appendix II.

We are sending copies of this report to the Administrator of CMS. In addition, the report is available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or kohnl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff that made major contributions to this report are listed in appendix III.

Linda T. Kohn
Director, Health Care
List of Committees

The Honorable Max Baucus
Chairman
The Honorable Chuck Grassley
Ranking Member
Committee on Finance
United States Senate

The Honorable Edward M. Kennedy
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, & Pensions
United States Senate

The Honorable Henry A. Waxman
Chairman
The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Charles B. Rangel
Chairman
The Honorable Dave Camp
Ranking Member
Committee on Ways and Means
House of Representatives
This report examines (1) the extent to which the costs of home dialysis differ from the costs of dialysis provided in a facility, and (2) the Centers for Medicare & Medicaid Services’ (CMS) plans to account for home dialysis costs in the expanded bundled payment for end-stage renal disease (ESRD) services.

To meet our objectives, we conducted interviews with representatives from 12 dialysis providers—including large chain providers, small nonprofit providers, and a hospital-based provider. Based on the officials’ self-reported estimates, these dialysis providers offered dialysis services to approximately 68 percent of all dialysis patients—including an estimated 77 percent of peritoneal dialysis patients and roughly all home hemodialysis patients.¹

To examine the extent to which the costs of home dialysis differ from the costs of dialysis provided in a facility, we obtained cost information from six dialysis providers that we interviewed—including average costs per treatment reported in CMS’s renal facility cost reports for home dialysis and dialysis provided in a facility. Additionally, we requested that the dialysis providers include annual cost information for specific categories of costs associated with providing dialysis. The cost categories that we requested were supplies, overhead, equipment and maintenance, drugs, laboratory tests, staff, and administrative costs. We included descriptions of what services should be included in each cost category, basing the descriptions on CMS definitions from the renal facility cost reports. The average costs per treatment reported to us by the dialysis providers did not include the costs of training patients to dialyze at home. At our request, the dialysis providers gave us separate information on the costs of training patients to conduct home dialysis.

Six of the 12 dialysis providers we interviewed shared with us cost information for a 12-month period, which ranged from August 2006 through June 2008. In total, we obtained cost information from these 6 providers on the costs for dialysis services provided in nearly 1,600 facilities to approximately 130,000 dialysis patients, including almost 11,000 peritoneal dialysis patients and over 850 home hemodialysis patients. We analyzed the cost information each provider sent to us if the

¹We compared 2006 data on the number of dialysis patients to 2008 estimates from dialysis providers on the number of patients that they provided dialysis services to in order to estimate the percentages of patients who received dialysis services from the providers we interviewed.
provider had 20 or more patients on either home hemodialysis or peritoneal dialysis. Using this self-reported cost information from the providers, we calculated the percentage difference in average costs per treatment between dialysis provided at home and dialysis provided in a facility (or chain of facilities). We also used the cost information reported to us to calculate the providers’ weekly costs for providing home dialysis and dialysis in a facility. To calculate the weekly costs of home dialysis and dialysis provided in a facility, we multiplied the average cost per treatment by the frequency of the specific type of dialysis.

We regard the cost information reported to us as testimonial and we did not independently assess the accuracy of that information. We identify the cost information as self-reported throughout the report, and we did not aggregate or average the self-reported costs across providers.

We also conducted interviews with representatives from the Medicare Payment Advisory Commission and professional organizations, including the National Kidney Foundation, the Renal Physicians Association, the National Renal Administrators Association, and the American Association of Kidney Patients. We also conducted site visits to two dialysis facilities that offered both home dialysis and dialysis in a facility to obtain additional information on how patients are trained to conduct home dialysis as well as obtain patients’ perspectives on factors associated with performing home dialysis.

Additionally, to obtain information on the extent to which the costs of home dialysis are different than the costs of dialysis provided in a facility, we examined over 30 articles about the costs of home dialysis published between 2002 and 2008, obtained through a MEDLINE literature search or

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2Five of the six providers had 20 or more patients on home hemodialysis, and thus, were included in our review.

3Five of the six providers had 20 or more patients on peritoneal dialysis, and thus, were included in our review.

4We determined the frequency of each type of dialysis based on interviews with officials from the dialysis providers, in which they indicated how often their patients typically dialyzed per week. The providers indicated that most of their patients who received dialysis in a facility did so three times per week. As a result, we calculated the weekly costs of providing dialysis in a facility by multiplying the average costs per treatment by 3. For home hemodialysis and peritoneal dialysis, we multiplied the average costs per treatment by the frequency of dialysis, based on information from the providers about how frequently their home dialysis patients received dialysis treatments during the week.
Appendix I: Scope and Methodology

recommended by representatives we interviewed. We also examined over 27 articles about the clinical outcomes associated with home dialysis published between 2002 and 2008, obtained through a MEDLINE literature search.

To examine CMS's plans to account for the costs of home dialysis in the expanded bundled payment, we reviewed CMS's proposed design for the expanded bundled end-stage renal disease (ESRD) payment, outlined in the Secretary of the Department of Health and Human Services' 2008 Report to Congress on the Proposed Design for a Bundled ESRD Prospective Payment System. Additionally, to obtain information on how the costs of home dialysis would be included in the expanded bundled payment, we conducted interviews with CMS and CMS's contractor—the University of Michigan Kidney Epidemiology and Cost Center. We also conducted interviews with dialysis facilities' officials, dialysis equipment suppliers, and medical experts on home dialysis to obtain their perspective on the expanded bundled payment.

We conducted our work from October 2008 through May 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.
Appendix II: Comments from the Centers for Medicare & Medicaid Services

MAY 8 2009

Linda T. Kohn
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Kohn:

Enclosed are the Department’s comments on the U.S. Government Accountability Office’s (GAO) draft report entitled: “END-STAGE RENAL DISEASE: Although Costs of Home Dialysis Will Be Included in Bundled Payment, CMS Should Monitor Effect on Home Dialysis Utilization Rates (GAO-09-537).

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

Barbara Pisaro Clark
Acting Assistant Secretary for Legislation

Attachment
Appendix II: Comments from the Centers for Medicare & Medicaid Services

DATE: MAY 8, 2009

TO: Barbara Pisuro Clark
Acting Assistant Secretary for Legislation
Office of the Secretary

FROM: Charlene Frizzera
Acting Administrator


Thank you for the opportunity to review and comment on the GAO draft report entitled, “End-Stage Renal Disease: Although Costs of Home Dialysis Will Be Included in Bundled Payment, CMS Should Monitor Effect on Home Dialysis Utilization Rates.” We appreciate GAO’s interest in ensuring the bundled payment system for End-Stage Renal Disease (ESRD) currently under development provides incentives to encourage more home dialysis for ESRD patients. The GAO analyzed self-reported cost information from dialysis providers and determined that dialysis providers reported lower costs per treatment for home dialysis. However, several dialysis providers indicated that home dialysis patients who dialyze more than 3 times per week may be more costly than in-center patients, and that dialysis sessions with training were more costly than dialysis sessions without training.

While the Centers for Medicare & Medicaid Services (CMS) appreciates GAO’s efforts in reviewing this topic, we are very concerned that the draft report implies, in many places, that final decisions have been reached by CMS and the Secretary regarding the ESRD prospective payment system (PPS). For example, the discussion that begins on page 17, describes specific details about the system design which the report attributes to CMS officials.

It is important for CMS to note that no final decisions have been made by CMS or the Department of Health and Human Services’ officials regarding the details of this new system, and that CMS has not even published a proposed rule, as of this date. Further, we do not believe this report should offer speculation to the public regarding details of the new system prior to issuance of the ESRD PPS proposed rule based on GAO’s interviews with CMS staff.
Appendix II: Comments from the Centers for Medicare & Medicaid Services

GAO Recommendation

GAO recommends that CMS establish and implement a formal plan to monitor the expanded bundled payment system’s effect on home dialysis utilization rates.

CMS Response

The CMS concurs with the GAO’s recommendation and intends to assess the effect of the expanded bundled payment on home dialysis utilization rates. We agree with GAO on the need to establish a monitoring plan under the new ESRD bundled payment system that includes an examination of home dialysis utilization. We expect to establish such a plan once we have received and analyzed public comments on a proposed rule, and developed and promulgated the final ESRD bundled payment system.

We have a few specific comments for your consideration.

Additional Comments

1. We note that one dialysis chain has recently developed an option for in-center self-hemodialysis. Although the report does not include costs of in-center hemodialysis, we believe the introductory remarks should acknowledge that it exists.

2. On page 15 in the discussion of the 1991 Medicare Payment Advisory Commission (MedPAC) report, reference is made to providing more frequent home dialysis when the MedPAC report was addressing home hemodialysis. Please review other references to verify that references to home dialysis are appropriate.

3. On page 18, there is information attributed to United States Renal Data System officials indicating that ESRD facility claims data do not distinguish between home hemodialysis and in-facility hemodialysis. In fact, ESRD facilities report revenue codes that identify the modality and the setting of hemodialysis and the separately billable services on that claim are related to the treatments.

4. In the discussion on page 4 and the conclusion section beginning on page 19, you indicate that medical experts and dialysis providers have estimated that anywhere from less than 10 percent to up to 50 percent of all patients who receive dialysis could be good candidates for home dialysis. We note that dialysis providers and medical experts who have discussed this issue with CMS have never indicated that up to 50 percent of patients could perform home dialysis. The percentage presented to us has generally been much lower, closer to 10-15 percent.

Thank you again for the opportunity to review this report.
Appendix III: GAO Contact and StaffAcknowledgments

<table>
<thead>
<tr>
<th>GAO Contact</th>
<th>Linda T. Kohn, (202) 512-7114 or <a href="mailto:kohnl@gao.gov">kohnl@gao.gov</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledgments</td>
<td>In addition to the contact named above, Martin T. Gahart, Assistant Director; George Bogart; Christie Enders; Krister Friday; and Hillary Loeffler made key contributions to this report.</td>
</tr>
</tbody>
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Home hemodialysis was introduced because it was less expensive than center dialysis, so allowing more patients to be treated with the limited funds available in the 1960s. The start of the Medicare ESRD Program in July 1973, with almost universal entitlement, removed the financial barriers, and had many other effects including reducing the use of home dialysis. Bundled payment for dialysis, including necessary dialysis supplies and laboratory tests, was introduced as the “composite” rate in 1983. Over the ensuing years, the costs of providing dialysis treatment increased, and expensive new drugs were introduced, particularly erythropoietin. As a result, the government introduced a more extensive bundle at the beginning of this year, aimed at better control of costs. This article considers the potential effect of this reimbursement change on home dialysis.
Section Five
The Innovation Environment

**Articles**


More Frequent Dialysis Improves Health of Kidney Patients

Kidney patients fare better on an almost-daily hemodialysis regimen than on the standard 3-times-a-week plan, according to a new study. While more research is needed, the finding could lead to changes in the standard of care for patients who need dialysis treatment.

Nearly 400,000 Americans depend on dialysis to survive. These treatments are necessary when the kidneys fail and waste products build up in the body. In the most common kind of dialysis, hemodialysis, your blood flows through a special filter that removes wastes and extra fluids. The clean blood is then returned to your body.

Despite recent advancements in technology and medication, 18% to 20% of patients still die from kidney disease. Previous studies suggested that higher doses of dialysis may improve patient survival. However, increasing the dose during the usual 3 sessions per week showed no benefit.

Some small studies have suggested that the dialysis dose could be greatly increased by adding more dialysis sessions. Researchers from the Frequent Hemodialysis Network Daily Trial Group set out to investigate whether adding more dialysis sessions could improve patients’ survival and well-being. Their work was partially funded by NIH’s National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

The scientists randomly assigned almost 250 patients from more than 60 different dialysis treatment facilities to 2 groups—one receiving 6 treatments a week and one receiving 3. They used MRI to determine the size of the patients' left ventricles as a measure of heart health. They also asked the patients to complete a widely used clinical survey to assess how well they felt and functioned.

The results appeared online on November 20, 2010, in the New England Journal of Medicine. Patients receiving more frequent dialysis had improvements in heart health and blood pressure, as well as in overall health. The more frequent treatments also helped avoid excessive phosphate levels in the blood, which is often a problem for patients on dialysis. The only downside was that access to blood vessels needed to be adjusted about twice as often in patients who received more treatments.

"We confirmed that by administering dialysis more often, although with a smaller dose each time, we could effectively deliver a higher weekly dose overall. As a result, patients' hearts remained healthier, they enjoyed better blood pressure control and they enjoyed better physical health than those receiving the standard 3 treatments per week," says NIDDK Director Dr. Griffin P. Rodgers.
The scientists couldn't draw conclusions about whether more frequent treatments affected death rates. Nevertheless, this study offers hope that simple changes to current dialysis treatments could substantially improve the health of the patients who depend on them.
More Kidney Dialysis Is Better, Research Finds

Four studies found frequent and longer sessions helped patients

February 23, 2012

By Serena Gordon
HealthDay Reporter

THURSDAY, Feb. 23 (HealthDay News) -- If you're receiving kidney dialysis, four new studies suggest that you could benefit from longer or more frequent dialysis sessions.

The treatments can be done at home or at a dialysis center, but it appears that more time spent doing dialysis can reduce mortality rates and improve quality of life, according to the research published online and in the March issue of the Journal of the American Society of Nephrology.

"What all of these studies show is that the more time your kidneys are getting cleaned, the better off you are," said Dr. Robert Provenzano, chairman of the department of nephrology at St. John Providence Health System in Detroit. Provenzano was not involved in the research.

When someone's kidneys fail, the only options are dialysis or a kidney transplant. Because there aren't enough donor kidneys to give transplants to everyone who needs one, many people must turn to dialysis. In dialysis, a machine takes over many of the jobs of the kidneys, such as filtering excess fluid and waste. In the United States, almost 400,000 people undergo dialysis every year, according to the U.S. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). In 2008, fewer than 18,000 people received a kidney transplant, according to NIDDK.

But, dialysis isn't perfect. It may not remove enough fluid, and levels of important nutrients can get out of balance for people on dialysis, according to background information in one of the studies. In addition, people on dialysis have to eat a limited diet.

Provenzano said improving dialysis is a big issue, and one of the biggest questions has been whether more dialysis is better. And, he said, "If it's true that more is better, is it longer individual sessions or more frequent dialysis that's most beneficial?"
Previous research has suggested that longer dialysis sessions seem to provide a benefit without increasing the risks of complications. One past study found that more frequent dialysis could increase the risk of problems with the dialysis access area.

Here's what the current studies found:

- One study included 1,873 daily home dialysis patients and 9,365 people undergoing in-center hemodialysis three times a week. "In general, we saw a 13 percent reduction in mortality in the home hemodialysis patients," said study author Eric Weinhandl, an epidemiologist at the Chronic Disease Research Group at the Minneapolis Medical Research Foundation. The survival benefit of daily home dialysis was seen across different groups of people -- different sexes, races, weights and more. One area that wasn't improved with more frequent dialysis was the number of people who died from infections. That rate was slightly higher for the more frequent dialysis group, though Weinhandl said it wasn't clear why that was the case.
- The second study compared standard hemodialysis, which is usually three sessions a week for between 2.5 and 5.5 hours a session, to intensive home hemodialysis for almost five sessions a week for more than seven hours each session. Almost 340 people received home treatment compared to about 1,400 people receiving standard care. People who received intensive dialysis at home were 45 percent less likely to die than patients receiving conventional dialysis over the nearly two-year study period.
- In the third study, researchers compared the health of 746 patients who received hemodialysis treatments at a clinic three nights per week for about eight hours each night to 2,062 similar patients who received conventional dialysis care. As with the other studies, the researchers saw a significant benefit from the longer dialysis sessions. During a two-year follow-up period, those on night-time dialysis had a 25 percent reduced risk of dying. The night-time group also had benefits such as lower weight, blood pressure and blood phosphorous levels. (Dialysis patients have difficulty maintaining proper phosphorous levels, putting them at risk of serious complications such as heart disease. Diet and medications help to control these levels.)
- The last study reexamined the results of two previous studies. They looked at frequent (six times per week) treatments vs. conventional dialysis. The researchers concluded that more frequent dialysis treatments helped lower patients' blood phosphorus levels over 12 months. And, more frequent dialysis reduced their need for phosphorus-lowering medications, and might also allow people on dialysis to ease some of their dietary restrictions.

The bottom line, Provenzano said, is to "dialyze the maximum amount of time you possibly can, based on your lifestyle. Get your family actively involved in your care and, if you can, keep working. Quality of life is significantly improved if you keep working. Dialysis is not a reason to stop working or doing activities. Stay active. You'll feel better."

**More information**

Learn more about hemodialysis from the [U.S. National Institute of Diabetes and Digestive and Kidney Diseases](https://www.niddk.nih.gov/).
Innovation Challenge: End-Stage Renal Disease

For more information about the application process, email FDA at:
InnovationChallenge@fda.hhs.gov

Appropriate Candidates
Guiding Principles
Nominations
Entry Discussion
FDA Consideration
Sponsor/Requestor — Roles and Responsibility
Duration of Solicitation
Evaluation

The FDA is announcing an Innovation Challenge — a pilot program for real-time review of devices that address end-stage renal disease (ESRD), a disease that affects hundreds of thousands of Americans, disproportionately impacts minorities, and is increasing among people ages 45 to 64.

It is hoped that this pilot will ultimately help people living with ESRD as well as other medical conditions.

This pilot will test the tools and processes being developed for the Innovation Pathway and possible application to other pre-market programs. It will help the FDA assess the strengths and weaknesses of these innovative tools and fine-tune them for broader application.

The Innovation Challenge focuses on ESRD for a number of reasons:

- ESRD is managed almost entirely using medical devices.
- ESRD management is costly, and it negatively impacts the patient's quality of life.
- ESRD is a growing public health care concern in the U.S.
- ESRD could benefit from innovative devices and transformative improvements.

The FDA encourages interested sponsors who believe their devices are appropriate candidates for the Innovation Challenge and would like to explore participating, to contact FDA at InnovationChallenge@fda.hhs.gov for more information.

Appropriate Candidates

Appropriate candidates are those with new medical device technologies for which the sponsor has expectation of beneficially impacting the morbidity or mortality rates of patients with ESRD
and for which an original or supplemental application for premarket approval (PMA), investigational device evaluation (pre-IDE, IDE) or petition for de novo review may be required.

The agency encourages interested sponsors who believe their devices are appropriate candidates and would like to explore the use of the innovation pathway pilot challenge for ESRD to contact the FDA by e-mail at: InnovationChallenge@fda.hhs.gov

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**Guiding Principles**

The following guidelines are intended to create a common understanding between the sponsor/requester and the FDA about the goals and parameters of the Innovation Pathway Pilot Challenge for ESRD:

- Participation in the solicitation will not change any review standards for device approval by the FDA.
- The agency will adhere to all current statutory and regulatory requirements.
- A sponsor/requester may enter or withdraw from, and the FDA or sponsor may terminate participation at any time prior to the initiation of any form of regulatory application such as investigational device exemption (IDE) or pre market approval application (PMA).
- The agency will not publicly disclose participation of a sponsor/requester in the solicitation, unless the sponsor/requestor agrees to allow public disclosure by the agency.
- Due to agency resource issues, the FDA expects to accept no more than six candidates per year at the present time.

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**Nominations**

Interested sponsors may request additional information regarding innovation pathway pilot challenge for ESRD nominations by e-mail at: InnovationChallenge@fda.hhs.gov

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**Entry Discussion**

The FDA intends to acknowledge receipt of nominations by email. The two parties will then agree upon a time to conduct an entry discussion. During the discussion, potential applicants should be prepared to disclose the following:

- Name of the sponsor/requester and relevant contact information;
- Name of the product;
- Expectations for clinical impact, risk and benefit including unmet public needs for their product;
- The technology and condition the devices is intended to diagnose or treat;
• Stage of development of the technology (that is, in preclinical testing, in clinical trials);
• Why the device is an appropriate candidate for the solicitation as described under the section of this document entitled "appropriate candidates;" and
• The sponsor should demonstrate that they plan to comply with all the requirements necessary for FDA review of an IDE and the ensuing PMA or DeNovo petition.

FDA Consideration

Within 30 days of the completion of the entry meeting(s) and agency decision, the FDA will notify the sponsor/requester whether the product is an appropriate candidate for the ESRD solicitation.

If deemed an appropriate candidate, the FDA will meet with the product sponsor/requester, either in person or by phone.

Participation in the program will not affect user fees, review timeframes or procedures or the FDA standard of approval, which is reasonable assurance of safety and effectiveness, unless explicitly agreed upon by the FDA.

Sponsor/Requester — Roles and Responsibilities

The sponsor/requester initiates consideration by submitting a nomination as outlined previously under "Nominations" section of this document.

Once a nomination has been submitted, an entry discussion will be held with the sponsor/requester who should be able to discuss the information outlined in the section "Entry Discussion" above.

Duration of Solicitation

The FDA intends to accept requests for participation in the ESRD pilot solicitation until Feb. 15, 2012, unless the FDA has selected six candidates prior to that date. In addition, in the case of unforeseen program considerations or needs the FDA may terminate the solicitation before the closure of the period or may extend the solicitation beyond February 15.

Evaluation
The FDA intends to use the lessons learned from this pilot to develop additional Innovation Pathway Challenge solicitations. In addition, in an effort to enhance our understanding of the advantages and shortcomings of this pilot, the FDA plans to solicit feedback from participants to determine among other things, whether the pilot should be extended or modified.
Section Six
Quality Measures and Initiatives

**Articles**


Medicare sets framework for the ESRD Quality Incentive Program for PYs 2013 and 2014

OVERVIEW

On Nov. 1, 2011, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that would update payment policies and rates for dialysis services furnished to Medicare beneficiaries that are paid under the End-Stage Renal Disease Prospective Payment System (ESRD PPS). The final rule also includes provisions for strengthening the ESRD Quality Incentive Program (QIP), under which payments to dialysis facilities are reduced if they do not achieve a high enough total performance score based on their performance on measures that assess the quality of dialysis care. Both the ESRD PPS and the QIP were mandated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

BACKGROUND

Over the past 35 years, CMS has instituted a series of quality initiatives to improve dialysis care. The ESRD QIP builds upon and enhances CMS’ commitment to improve quality by allowing CMS for the first time to tie ESRD facility payments to their performance on measures of quality.

The QIP is designed to improve patient outcomes by establishing payment incentives for dialysis facilities to meet performance standards established by CMS. Under the ESRD QIP, for the first time, payments are tied to the quality of care beneficiaries receive at the facilities.

By law, the QIP must include measures of dialysis adequacy and anemia management. These measures were incorporated into the payment year (PY) 2012 program and low facility performance on those measures could affect payments for services furnished by these facilities beginning on Jan. 1, 2012. In addition, the statute requires that, to the extent feasible, the program must include measures of patient satisfaction, iron management, bone mineral metabolism, and vascular access.

-More-
CMS published the final rule that initially implemented the ESRD QIP in the Federal Register on Jan. 5, 2011. Today’s final rule would update the QIP measures and scoring methodologies that would affect payments to dialysis facilities in PY 2013 and PY 2014.

**DETERMINING TOTAL PERFORMANCE SCORES FOR PY 2013 AND PY 2014**

Dialysis facility performance will be evaluated based on a set of quality measures established by CMS. These measures focus on core aspects of the quality of care for patients with ESRD and can significantly impact their quality of life. Under the ESRD QIP, CMS will compare facility performance on these quality measures against performance standards to generate a performance score. The performance scores for individual measures will then be weighted and summed to calculate a total performance score that determines whether the facility will receive a payment reduction. Payments will be reduced on a sliding scale basis, up to a maximum of two percent, to ensure that reductions are proportionate to the degree a facility’s total performance score fails to meet the minimum total performance score needed to avoid a payment reduction.

In an effort to bring accountability to the ESRD QIP, facilities are also required to display certificates containing their performance scores prominently in the facility. This certificate serves to notify patients about the facility’s performance on the ESRD QIP and how CMS used quality measures to evaluate the quality of care at the facility. ESRD QIP performance information will also be published online at CMS’ Dialysis Facility Compare website.

As part of today’s final rule, CMS revised its scoring method and performance standards for PYs 2013 and 2014.

**ESRD QIP MEASURES AND SCORING FOR PY 2013**

For the PY 2013 program, CMS will measure facility performance on two measures:

- An anemia management measure that assesses the percentage of patients with a hemoglobin level greater than 12 g/dL (for which a lower percentage indicates better performance on the measure); and
- A hemodialysis adequacy measure which assesses the percentage of patients with a urea reduction ratio (URR) of at least 65 percent (for which a higher percentage indicates better performance on the measure).

In addition, CMS is retiring the anemia management measure that assesses the percentage of patients with a hemoglobin level below 10 g/dL, because the medical evidence does not show that targeting a hemoglobin level of at least 10 g/dL is the most appropriate treatment option for many dialysis patients. This decision will allow for more individualized treatment of anemia in ESRD and will not encourage overuse of these medications. This decision is also consistent with
the label recently approved by the U.S. Food and Drug Administration for erythropoietin-stimulating agents (ESAs) when used to treat anemia in patients with chronic kidney disease.

CMS is actively monitoring anemia management practices and outcomes. We will continue to post information on the Dialysis Facility Compare website, and we will also explore additional ways to make anemia management data publicly available.

With respect to the PY 2013 ESRD QIP, CMS set the performance standards as the lesser of:

- The facility’s own performance in the year that was selected for purposes of the ESRD PPS based on lowest per patient utilization (CY 2007) or
- A standard based on the national performance rates in a selected period (CY 2009).

To calculate the total performance score for PY 2013, CMS will weight each of these measures equally at 50 percent and to use CY 2011 as the performance period. CMS will score the total performance of facilities from 0 to 30 points and apply payment reductions on a sliding scale. A facility will need to earn a total performance score of 30 points in order to avoid a payment reduction in PY 2013. Payment reductions for PY 2013 will range from 1.0 to 2.0 percent.

**ESRD QIP MEASURES AND SCORING FOR PY 2014**

CMS has finalized three clinical measures and three reporting measures for the PY 2014 ESRD QIP. The three clinical measures are:

- The anemia management measure (the percentage of patients with a hemoglobin greater than 12 g/dL);
- Dialysis adequacy (as determined through the percentage of patients in a facility whose Urea Reduction Ratio is at least 65 percent); and
- Type of vascular access, which encourages the use of arteriovenous fistulae and discourages the use of catheters because of the high rate of infections and complications associated with catheter use.

The three reporting measures will capture whether a facility:

- Reports dialysis infection events to the Centers for Disease Control and Prevention’s National Healthcare Safety Network;
- Surveys patients to learn about their experience of care; and
- Monitors patients for abnormalities in phosphorus and calcium levels.

For the PY 2014 ESRD QIP, CMS will score facilities on both achievement and improvement for each of the three clinical measures. A facility’s achievement score will be determined based
on comparing its score to the scores of facilities in the 15th to 90th percentiles during the baseline period. A facility’s improvement score is then determined based on where its actual performance falls on a scale ranging between its performance during the baseline period and the 90th percentile (the national benchmark). The baseline period for the PY 2014 ESRD QIP is July 1, 2010, through June 30, 2011, while the performance period is CY 2012.

Scores for the three clinical measures for which a facility is eligible are weighted equally to make up 90 percent of the facility’s total performance score. Scores from the reporting measures for which a facility is eligible are weighted equally to make up the remaining 10 percent of the total performance score. If a facility is eligible for only one type of measure, the measure will comprise 100 percent of the total performance score.

CMS will reduce payments to facilities that do not meet a minimum total performance score. Facilities whose total performance score falls below the minimum total performance score by up to 10 points will receive a 0.5 percent payment reduction; 11 to 20 points below will receive a 1.0 percent payment reduction; 21 to 30 points below will receive a 1.5 percent payment reduction; and greater than 30 points below will receive a 2.0 percent payment reduction. CMS estimates that the minimum total performance score, based on 9 months of baseline data, will be 56 points. This minimum total performance score will be updated to reflect the full 12 months of baseline data no later than January 31, 2012 at http://www.dialysisreports.org/ESRDMeasures.aspx.

The ESRD QIP supports the importance of a meaningful relationship between physicians, caregivers, and patients with ESRD. As a result of the ESRD QIP, patients on dialysis may notice a change at their facilities, such as staff seeking better ways to do their jobs safely and efficiently. However, the ESRD QIP will not change patients’ rights, such as their power to decide how and where to be treated. Patients should also expect that their dialysis facilities will continue to respect their rights and address their concerns. For more information about resources for patients with ESRD, please visit Medicare’s Dialysis Facility Compare website at http://www.medicare.gov/dialysis.

For more information about the final rule, please see:


The final rule will appear in the Nov. 10, 2011, Federal Register.

For more information about the ESRD PPS and QIP, please see:

http://www.cms.gov/center/esrd.asp

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Long Interdialytic Interval and Mortality among Patients Receiving Hemodialysis

Robert N. Foley, M.B., David T. Gilbertson, Ph.D., Thomas Murray, M.S., and Allan J. Collins, M.D.

Abstract

**Background**
Patients with end-stage renal disease requiring dialysis have limited tolerance of metabolic and volume-related deviations from normal ranges; in addition, the prevalence of cardiovascular disease is high among such patients. Given these problems, we hypothesized that a long interdialytic interval is associated with adverse events in patients receiving hemodialysis.

**Methods**
We studied 32,065 participants in the End-Stage Renal Disease Clinical Performance Measures Project, a nationally representative sample of U.S. patients receiving hemodialysis three times weekly, at the end of calendar years 2004 through 2007. We compared rates of death and cardiovascular-related hospital admissions on the day after the long (2-day) interdialytic interval with rates on other days.

**Results**
The mean age of the cohort was 62.2 years; 24.2% of the patients had been receiving dialysis treatment for 1 year or less. Over a mean follow-up interval of 2.2 years, the following event rates were higher on the day after the long interval than on other days: all-cause mortality (22.1 vs. 18.0 deaths per 100 person-years, P<0.001), mortality from cardiac causes (10.2 vs. 7.5, P<0.001), infection-related mortality (2.5 vs. 2.1, P = 0.007), mortality from cardiac arrest (1.3 vs. 1.0, P = 0.004), mortality from myocardial infarction (6.3 vs. 4.4, P<0.001), and admissions for myocardial infarction (6.3 vs. 3.9, P<0.001), congestive heart failure (29.9 vs. 16.9, P<0.001), stroke (4.7 vs. 3.1, P<0.001), dysrhythmia (20.9 vs. 11.0, P<0.001), and any cardiovascular event (44.2 vs. 19.7, P<0.001).

**Conclusions**
The long (2-day) interdialytic interval is a time of heightened risk among patients receiving hemodialysis. (Funded by the National Institutes of Health.)

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