

September 2007

# END-STAGE RENAL DISEASE

## Characteristics of Kidney Transplant Recipients, Frequency of Transplant Failures, and Cost to Medicare





Highlights of [GAO-07-1117](#), a report to congressional requesters

## Why GAO Did This Study

For individuals with end-stage renal disease (ESRD), the permanent loss of kidney function, Medicare covers kidney transplants and 36 months of follow-up care. Kidney transplant recipients must take costly medications to avoid transplant failure. Unless a transplant recipient is eligible for Medicare other than on the basis of ESRD, Medicare coverage, including that for medications, ends 36 months posttransplant. Pediatric transplant recipients, including those who were under 18 when transplanted but are now adults (transitional recipients), may be more likely than their adult counterparts to lose access to medications once Medicare coverage ends because they may lack access to other health insurance coverage. GAO was asked to examine (1) the percentage of transplant failures and subsequent outcomes—retransplant, dialysis, or death—among pediatric, transitional, and adult kidney transplant recipients and (2) how the cost to Medicare for a beneficiary with a functioning transplant compares with the cost for a beneficiary with a transplant failure. To do this, GAO analyzed 1997 through 2004 data from the United States Renal Data System (USRDS) and interviewed officials from pediatric transplant centers.

The Centers for Medicare & Medicaid Services—the agency that administers Medicare—commented that it is concerned about beneficiary outcomes and has an education program to help them.

To view the full product, including the scope and methodology, click on [GAO-07-1117](#). For more information, contact Laurie E. Ekstrand at (202) 512-7114 or [ekstrand@gao.gov](mailto:ekstrand@gao.gov).

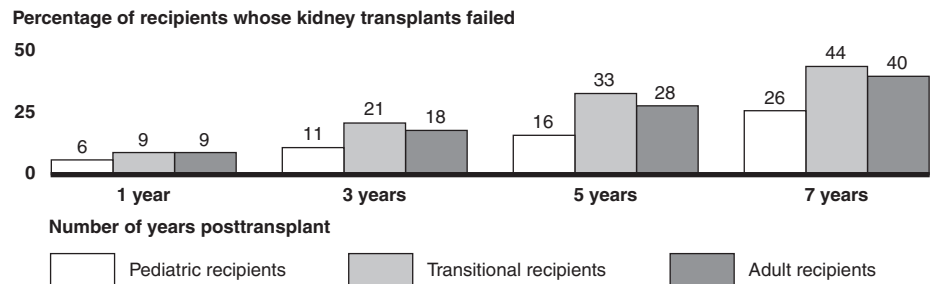
## END-STAGE RENAL DISEASE

### Characteristics of Kidney Transplant Recipients, Frequency of Transplant Failures, and Cost to Medicare

#### What GAO Found

The percentage of kidney transplant recipients who experience a transplant failure varies by age group as do the percentages who experience dialysis, retransplant, or death. After the first year posttransplant, a higher percentage of transitional recipients (those younger than 18 at the time of their transplants and at least 18 as of December 31, 2004) experienced a transplant failure and subsequently received dialysis compared with their pediatric (those younger than 18 as of December 31, 2004) and adult (those at least 18 at the time of their transplants) counterparts. By 5 years posttransplant, the percentage of transitional recipients who experienced a transplant failure (33 percent) was about twice as high as pediatric recipients (16 percent) and somewhat higher than adult recipients (28 percent). The largest increase in transplant failures for each age group occurred in the first 3 years posttransplant—before the termination of Medicare coverage on the basis of ESRD—and the increase was substantially higher for transitional recipients (133 percent) than for pediatric (83 percent) and adult (100 percent) recipients.

**Percentage of Kidney Transplant Recipients Whose Transplants Failed, by Age Group and Number of Years Posttransplant, 1997-2004**



Source: GAO analysis of USRDS data.

Medicare beneficiaries with functioning transplants cost substantially less per year to treat than those who experienced a transplant failure. GAO found that the median annual Medicare cost for a beneficiary whose transplant failed (\$50,938) was 500 percent more than the median annual Medicare cost for a beneficiary with a functioning transplant (\$8,550). This percentage difference was consistent across transplant recipient age groups.

The substantial cost of treating transplant recipients who experience a transplant failure underscores the importance of maintaining functioning kidney transplants. While there are many reasons that could account for transplant failures, the large percentage increase in transplant failures from 1 year to 3 years posttransplant for transitional recipients cannot be attributed to an inability to access medications due to a lack of Medicare coverage.

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## Abbreviations

ARF	Area Resource File
CMS	Centers for Medicare & Medicaid Services
ESRD	end-stage renal disease
HHS	Department of Health and Human Services
NIH	National Institutes of Health
SCHIP	State Children's Health Insurance Program
USRDS	United States Renal Data System

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United States Government Accountability Office  
Washington, DC 20548

September 28, 2007

The Honorable Max Baucus  
Chairman  
The Honorable Charles E. Grassley  
Ranking Member  
Committee on Finance  
United States Senate

The Honorable Christopher J. Dodd  
Chairman  
Subcommittee on Children and Families  
Committee on Health, Education, Labor, and Pensions  
United States Senate

Regardless of age, most individuals with end-stage renal disease (ESRD), the permanent loss of kidney function, are covered under Medicare.<sup>1</sup> Individuals with ESRD must either receive kidney transplants or undergo regular dialysis treatments,<sup>2</sup> which remove excess fluids and wastes from the blood, in order to survive. Medicare covers kidney transplants and 36 months of follow-up care, and for individuals who do not receive kidney transplants, Medicare covers regular dialysis treatments.<sup>3</sup> In the long term, dialysis is associated with a lower quality of life and higher mortality rates than kidney transplants and is considered a less desirable treatment option.

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<sup>1</sup>Generally, individuals with ESRD are eligible for benefits under Medicare if they (1) are entitled to monthly insurance benefits under Title II of the Social Security Act (or an annuity under the Railroad Retirement Act of 1974), (2) meet certain work requirements under the Social Security or Railroad Retirement programs, or (3) are the spouse or dependent child of a person who meets at least one of the first two requirements. 42 U.S.C. § 426-1 (2000). In addition to Medicare, individuals with ESRD may also be covered by other public or private health insurance, including Medicaid.

<sup>2</sup>Individuals with ESRD typically receive dialysis treatments three times per week.

<sup>3</sup>For the first 30 months of an individual's Medicare coverage, Medicare is the secondary payer for individuals with employer-sponsored group health insurance coverage.

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Kidney transplant recipients must take immunosuppressive medications<sup>4</sup> for the life of the transplant to avoid transplant failure, and the cost of these medications is substantial—ranging from \$5,000 to \$13,000 annually. Transplant recipients who stop taking immunosuppressive medications (referred to as medication noncompliance) and experience transplant failure must, absent a retransplant, receive regular dialysis treatments in order to survive.<sup>5</sup> Transplant failures may be particularly problematic for pediatric recipients<sup>6</sup> because long-term dialysis can lead to developmental problems, such as inhibited growth, as well as poor academic performance and delayed social development.

Unless a transplant recipient is eligible for Medicare<sup>7</sup> other than because of ESRD, coverage of immunosuppressive medications, along with follow-up care, ends 36 months posttransplant. Pediatric transplant recipients may be more likely than their adult counterparts to lose access to immunosuppressive medications once Medicare coverage for ESRD ends because they may lack access to other health insurance coverage. Access to health insurance may be particularly problematic for those individuals who are 18 or older but were under 18 at the time of their transplants—for the purposes of this report, we refer to these individuals as transitional recipients. While some pediatric recipients may be covered by their parents' health insurance, family insurance coverage often does not extend to children over 18 unless they are full-time students. While a lack of health insurance is one reason transplant recipients may stop taking their medication, studies have reported that there are numerous other reasons for medication noncompliance, including avoidance of adverse side effects associated with immunosuppressive medications and difficulty following complex treatment regimens.

In light of these concerns, you asked us to describe certain aspects of kidney transplant recipients, determine the extent to which they

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<sup>4</sup>Immunosuppressive medications diminish an individual's natural immune response to the presence of foreign objects so that the body does not reject the newly transplanted kidney.

<sup>5</sup>Medicare covers the cost of a retransplant and regular dialysis treatments if kidney transplant recipients experience a transplant failure.

<sup>6</sup>For the purposes of this report, we define pediatric transplant recipients as those younger than 18 years old as of December 31, 2004.

<sup>7</sup>In general, Medicare coverage is available to individuals who are 65 years or older or are disabled and who qualify for benefits under the Social Security Act or Railroad Retirement Act. 42 U.S.C. § 426 (2000).

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experience transplant failure and subsequent outcomes, and calculate the cost associated with their treatment. In this report, we (1) compare certain demographic characteristics and types of health insurance coverage of pediatric, transitional, and adult kidney transplant recipients; (2) examine the percentage of transplant failures and subsequent outcomes—retransplant, dialysis, or death—among pediatric, transitional, and adult kidney transplant recipients; (3) determine how the percentage of transplant failures and subsequent outcomes of kidney transplant recipients compare by type of health insurance coverage; and (4) examine how the cost to Medicare for a beneficiary with a functioning transplant compares with the cost for a beneficiary with a transplant failure.

To determine the characteristics of pediatric, transitional, and adult kidney transplant recipients,<sup>8</sup> we used 2004 data—the latest data available—on recipient age, sex, race, and type of health insurance coverage<sup>9</sup> from the United States Renal Data System (USRDS). The USRDS is a national data system maintained by the Department of Health and Human Services' (HHS) National Institutes of Health (NIH) that contains data on individuals with ESRD collected from many sources, including HHS's Centers for Medicare & Medicaid Services (CMS), the agency that administers Medicare, and the United Network for Organ Sharing. We used USRDS to define three age groups: pediatric recipients are those who were younger than 18 years old as of December 31, 2004, transitional recipients are those who were younger than 18 years old at the time of their transplants and at least 18 years old as of December 31, 2004, and adult recipients are those who were at least 18 years old at the time of their transplants. We used USRDS data to compare the distribution of sex, race, and income levels among pediatric, transitional, and adult recipients who had a functioning transplant as of December 31, 2004. There were 3,675 pediatric recipients, 4,608 transitional recipients, and 110,762 adult recipients in the USRDS data who met this criterion. We also compared the demographic characteristics of the three age groups to those found in the general U.S. population, using data from the 2000 U.S. Census. To estimate the income levels for recipients in each of our three age groups, we matched recipients' zip codes and federal information processing

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<sup>8</sup>We did not have information on the health status of the transplant recipients beyond the fact that they had ESRD.

<sup>9</sup>For the purposes of this objective, for each recipient, we determined the type of health insurance coverage as of December 31, 2004, and as of the recipient's transplant date.

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standards codes using the 2002 median household income for the county<sup>10</sup> of their residence as published in the 2005 Area Resource File (ARF), the latest data available.<sup>11</sup> The USRDS maintains health insurance information under three categories: Medicare but not Medicaid, Medicare and Medicaid, and Other. The Other category is defined as those who do not have Medicare coverage but are covered by private health insurance, Medicaid, or other governmental health insurance or are uninsured or whose health insurance status is unknown. Our analysis is based on recipients who had a functioning kidney-only transplant as of December 31, 2004.<sup>12</sup>

To examine the percentage of transplant failures and subsequent outcomes among pediatric, transitional, and adult kidney transplant recipients, we used data through December 31, 2004, from the USRDS on individuals who received kidney-only transplants from 1997 through 2000.<sup>13</sup> There were 1,218 pediatric recipients, 2,148 transitional recipients, and 49,940 adult recipients who met this criterion. We analyzed data separately for pediatric, transitional, and adult recipients. We determined the frequency of transplant failures among each of the three age groups at 1 year, 3 years, 5 years, and 7 years after the transplant using the date of failure reported in the USRDS, and we grouped the frequencies by age group and these follow-up periods.<sup>14</sup> For recipients whose transplants failed, we determined the percentage who died,<sup>15</sup> received retransplants, or

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<sup>10</sup>Median annual household income estimates are county-level averages and are not calculated from actual annual household incomes of transplant recipients. Data on individual recipients' household income levels are not available.

<sup>11</sup>The ARF is a database containing information on every county in the United States. It is maintained by Quality Resource Systems, Inc., which is under contract with the National Center for Health Workforce Analysis within HHS's Health Resources and Services Administration.

<sup>12</sup>We excluded those who received kidney-pancreas transplants. According to data from the Organ Procurement and Transplant Network, kidney-pancreas transplants represent less than 5.7 percent of all kidney transplants performed since 1988.

<sup>13</sup>We included individuals who received initial kidney transplants as well as those who received retransplants from 1997 through 2000. We did not have information on the health status of the transplant recipients beyond the fact that they had ESRD.

<sup>14</sup>For those who received transplants in 1997, we report at 1 year, 3 years, 5 years, and 7 years after the transplant. For those who received transplants in 1998 and 1999, we report at 1 year, 3 years, and 5 years after the transplant. For those who received transplants in 2000, we report at 1 year and 3 years after the transplant.

<sup>15</sup>These recipients could have died for causes other than transplant failure because USRDS also categorizes death with a functioning transplant as a transplant failure.



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received dialysis during the follow-up periods, by age group. These outcome groups are not mutually exclusive; for example, if an individual received both dialysis and a subsequent retransplant, the individual is counted in both groups. A recipient who died after a transplant failure could have received dialysis or a retransplant between date of failure and date of death. Those recipients who had dates of failure but no subsequent treatment information or dates of death were excluded from our analysis. We included only transplant recipients in the 50 states and the District of Columbia.

To compare the percentage of transplant failures and subsequent outcomes of kidney transplant recipients by type of health insurance coverage, we used data through December 31, 2004, from the USRDS on individuals who received kidney-only transplants from 1997 through 2000.<sup>16</sup> The USRDS maintains health insurance information under three categories: Medicare but not Medicaid, Medicare and Medicaid, and Other. There were 33,702 recipients with Medicare but not Medicaid, 12,139 recipients with Medicare and Medicaid, and 7,465 recipients in the Other category who met this criterion. Using the same three categories, we determined the frequency of transplant failures by type of health insurance coverage at 1 year, 3 years, 5 years, and 7 years after the transplant and we grouped the frequencies by the follow-up periods.<sup>17</sup> For recipients whose transplants failed, we determined the percentage who died,<sup>18</sup> received retransplants, or received dialysis during the follow-up periods. As described above, these outcome groups are not mutually exclusive.

To examine how the cost to Medicare for a beneficiary with a functioning transplant compares with the cost for a beneficiary with a transplant failure, we used data through December 31, 2004, from the USRDS on individuals who received kidney-only transplants from 1997 through 2000

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<sup>16</sup>We included individuals who received initial kidney transplants as well as those who received retransplants from 1997 through 2000. We did not have information on the health status of the transplant recipients beyond the fact that they had ESRD.

<sup>17</sup>For those who received transplants in 1997, we report at 1 year, 3 years, 5 years, and 7 years after the transplant. For those who received transplants in 1998 and 1999, we report at 1 year, 3 years, and 5 years after the transplant. For those who received transplants in 2000, we report at 1 year and 3 years after the transplant.

<sup>18</sup>These recipients could have died from causes other than transplant failure because USRDS also categorizes death with a functioning transplant as a transplant failure.

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and for whom Medicare reported costs.<sup>19</sup> There were 669 pediatric beneficiaries, 1,264 transitional beneficiaries, and 33,557 adult beneficiaries who met this criterion. For beneficiaries with functioning transplants, we summed the Medicare costs from their posttransplant hospital discharge dates through December 31, 2004. For beneficiaries whose transplants failed and who subsequently died, we summed the Medicare costs from their transplant failure dates through the dates of death and annualized any portion incurred during a period that was less than a full year. For beneficiaries whose transplants failed but who did not die, we summed the Medicare costs from their transplant failure dates through December 31, 2004.<sup>20</sup> For beneficiaries with functioning transplants and for those whose transplants failed, we calculated the median annual cost per beneficiary in each age group. For each of the four objectives, we included only transplant recipients in the 50 states and the District of Columbia. We reviewed relevant documentation and spoke with knowledgeable officials to determine the reliability of the USRDS and ARF. Based on this, we found the USRDS and ARF suitable for our purposes.

We conducted a literature search of reported studies related to ESRD and pediatric, transitional, and adult kidney transplant recipients and conducted interviews with officials from CMS; the Health Resources and Services Administration, a federal agency focused on access to health care services; and NIH, the primary federal agency that conducts and supports medical research and maintains the USRDS. We also interviewed representatives of the National Kidney Foundation, the Forum of ESRD Networks, and the American Society of Pediatric Nephrology. Of the 251 pediatric transplant centers in the United States, we interviewed representatives from 6 centers that treat a high number of pediatric recipients. Those 6 centers accounted for about 10 percent of the 13,560 pediatric kidney transplants performed since 1988.<sup>21</sup> We performed our

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<sup>19</sup>We included individuals who received initial kidney transplants as well as those who received retransplants from 1997 through 2000. We did not have information on the health status of the transplant recipients beyond the fact that they had ESRD.

<sup>20</sup>If USRDS did not report Medicare cost data on a beneficiary through December 31, 2004, we summed cost data from hospital discharge date following the transplant to the latest date with available cost data.

<sup>21</sup>We interviewed representatives from transplant centers in California, Texas, Pennsylvania, Illinois, and Florida.

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work from October 2006 through August 2007 in accordance with generally accepted government auditing standards.

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## Results in Brief

Pediatric, transitional, and adult transplant recipients were similar with respect to demographic characteristics such as sex, race, and income level but differed in their types of health insurance coverage. As of December 31, 2004, recipients in all three age groups were predominately male, white, and lived in counties with a median annual household income of \$25,000 to less than \$50,000. Unlike the demographic characteristics, recipients' type of health insurance coverage varied by age group. While more than two-thirds of adult recipients had health insurance coverage under Medicare, just over one-third of pediatric recipients and less than half of transitional recipients were covered under Medicare. At the time of their transplants, the percentage of recipients covered by Medicare was higher for all age groups, although the percentages of pediatric (67 percent) and transitional (81 percent) recipients with Medicare coverage were still lower than adult recipients (87 percent). It is not known why these differences in Medicare coverage existed, given that most individuals who have ESRD are eligible for Medicare coverage.

After the first year posttransplant, a higher percentage of transitional recipients experienced a transplant failure and subsequently received dialysis compared with their pediatric and adult counterparts. For example, by 5 years posttransplant, the percentage of transitional recipients who experienced a transplant failure (33 percent) was about twice as high as pediatric recipients (16 percent) and somewhat higher than adult recipients (28 percent). The largest increase in transplant failures for each age group occurred during the first 3 years posttransplant—before the termination of Medicare coverage on the basis of ESRD—and the increase was substantially higher for transitional recipients (133 percent) than for pediatric (83 percent) and adult (100 percent) recipients. Compared to adult and pediatric recipients, a higher percentage of transitional recipients received dialysis after experiencing a transplant failure. A higher percentage of pediatric recipients received retransplants after the first year posttransplant, compared with adult and transitional recipients, and a higher percentage of adult recipients died after experiencing a transplant failure.

Recipients who had both Medicare and Medicaid coverage experienced a higher percentage of transplant failures than those who had Medicare but not Medicaid coverage or were in the Other category. For example, by 7 years posttransplant, the percentage of recipients covered by both

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Medicare and Medicaid who experienced a transplant failure (56 percent) was more than three times as high as the percentage of recipients in the Other category (16 percent). In addition, after experiencing a transplant failure, a higher percentage of recipients who had both Medicare and Medicaid coverage received dialysis when compared with recipients who had Medicare but not Medicaid coverage or were in the Other category. Throughout the 7 years of posttransplant follow-up, the percentage of recipients covered by both Medicare and Medicaid who received dialysis was substantially higher than the percentage for recipients in the Other category.

Medicare beneficiaries with functioning transplants cost substantially less per year to treat than those beneficiaries who experienced transplant failures. Specifically, we found that the median annual Medicare cost for a beneficiary whose transplant failed (\$50,938) was 500 percent more than the median annual Medicare cost for a beneficiary with a functioning transplant (\$8,550).

The substantial cost of treating transplant recipients who experience transplant failures underscores the importance of maintaining functioning kidney transplants. While there are many reasons that could account for transplant failures during the first 3 years posttransplant—including medication noncompliance—the large percentage increase in transplant failures from 1 year to 3 years posttransplant for transitional recipients cannot be attributed to an inability to access immunosuppressive medications due to a lack of Medicare coverage.

In commenting on a draft of this report, CMS stated that it appreciated our interest in kidney transplant patients and in the cost of care provided to those receiving transplants or dialysis. CMS stated that it was concerned about the quality of care and the outcomes experienced by Medicare beneficiaries, including the higher rate of transplant failure among transitional patients. CMS also pointed out that it engages in numerous educational and outreach efforts targeted to beneficiaries, providers, and national organizations that represent renal patients.

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## Background

ESRD occurs when an individual's kidneys have regressed to less than 10 percent of normal baseline function. Without functioning kidneys, excess wastes and fluids in the body rise to dangerous levels, and certain hormones are no longer produced. Individuals with ESRD must undergo either regular dialysis treatments or receive kidney transplants to survive. As of the end of 2004, of the approximately 480,000 adults with ESRD

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(those at least 18 years old), just over one-fourth (about 130,000) had functioning kidney transplants and two-thirds (about 330,000) were receiving dialysis treatments.<sup>22</sup> In addition, of the almost 5,700 pediatric individuals with ESRD (those younger than 18 years old), approximately two-thirds (about 3,800) had functioning transplants and less than one-third (about 1,700) were receiving dialysis treatments.<sup>23</sup>

A kidney transplant is the preferred method of treatment for individuals with ESRD because it increases an individual's quality of life and decreases long-term mortality rates compared with lifetime dialysis treatments. Studies have reported that pediatric ESRD patients tend to perform better developmentally with transplants than on dialysis. For example, one study reported improvement in neurological development in infants aged 6-11 months following transplantation.<sup>24</sup> Another study showed that transplantation increased the rate at which pediatric ESRD patients improved on measures of intelligence and mathematical skills.<sup>25</sup>

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## Medicare Coverage for Individuals with ESRD

Medicare covers over 80 percent of all individuals with ESRD. For these individuals, Medicare covers the cost of lifetime dialysis treatments, or for individuals who receive kidney transplants, the cost of the transplants and 3 years of follow-up care—including immunosuppressive medications needed to sustain the transplants. Medicare also covers hospital inpatient services and outpatient services, such as physician visits and laboratory tests, as well as medical evaluations provided to living donors and recipients in anticipation of transplants. In addition to Medicare, individuals with ESRD may be covered by other public or private health insurance, such as Medicaid or an employer-sponsored health plan. For individuals who are eligible for Medicare on the basis of ESRD, Medicare is the secondary payer if the individuals have employer-sponsored group health insurance coverage during the first 30 months of Medicare coverage. After the first 30 months, Medicare becomes the primary payer for these beneficiaries until they are no longer entitled to Medicare. For an

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<sup>22</sup>The remaining approximately 20,000 adults with ESRD were lost to follow-up.

<sup>23</sup>The remaining approximately 200 pediatric individuals with ESRD were lost to follow-up.

<sup>24</sup>M.S. Polinsky et al., "Neurologic Development of Children with Severe Chronic Renal Failure from Infancy," *Pediatric Nephrology*, vol. 1 (1987), 157-165 (citing endnote 6).

<sup>25</sup>R.S. Fennell III et al., "Effects of Kidney Transplantation on Cognitive Performance in a Pediatric Population," *Pediatrics*, vol. 74 (1984), 273-278.

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individual who is eligible for Medicare solely because of ESRD and who has a kidney transplant, Medicare coverage ends on the last day of the 36th month after the individual receives the transplant unless the individual is entitled to Medicare other than because of ESRD.<sup>26</sup> However, after 36 months, a transplant recipient can become eligible for Medicare again after a transplant failure and subsequently receive a retransplant or dialysis.

Following termination of Medicare coverage, individuals who are unable to pay for immunosuppressive medications and other transplant-related follow-up care must rely on other public or private health insurance or charity care. Pediatric recipients have several potential sources of coverage when their Medicare coverage ends: private health insurance—generally, a parent’s employer-sponsored coverage;<sup>27</sup> Medicaid;<sup>28</sup> the State Children’s Health Insurance Program (SCHIP);<sup>29</sup> and charity care. However, once individuals turn 19, they may lose access to their parents’ private insurance coverage as well as coverage under SCHIP and Medicaid.

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## Posttransplant Immunosuppressive Therapy

Individuals who receive kidney transplants require immunosuppressive therapy—usually a combination of at least two different immunosuppressive medications—as well as regular laboratory tests to monitor and maintain their transplants. Although the frequency of laboratory tests decreases over time, the need for immunosuppressive medications continues for the life of the transplant.

Recipients who do not take their immunosuppressive medications according to the prescribed regimens are more likely to have their transplanted kidneys fail. Studies have shown that not only does medication noncompliance cause 13 to 35 percent of transplants to fail,

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<sup>26</sup>For beneficiaries with ESRD who are also eligible for Medicare due to age or disability, Medicare covers the immunosuppressive medications for the life of the individual.

<sup>27</sup>Some private health insurance plans provide coverage for dependants until age 23 if the dependant is a full-time student.

<sup>28</sup>Medicaid provides health care coverage to eligible low-income people and is jointly financed by the federal government and the states.

<sup>29</sup>SCHIP provides health care coverage to uninsured children in families whose incomes exceed the eligibility requirements of Medicaid. SCHIP has a capped allotment to states. States have some flexibility in how they design their programs.

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one of the studies indicated that it also causes recipients to die at rates fourfold greater than compliant recipients.<sup>30</sup> One recent study showed that about 23 percent of recipients with failed transplants who returned to dialysis died within 2 years.<sup>31</sup>

Several studies have reported that there are a number of reasons why some transplant recipients do not comply with their medication regimens. More specifically, one study reported that adverse side effects of the medications,<sup>32</sup> difficulty following complex treatment regimens that involve several drugs and varying schedules of dosing, and an inability to pay for medications due to a lack of health insurance coverage, among other reasons, can contribute to medication noncompliance.<sup>33</sup> Other studies have reported that medication noncompliance can be unpredictable, often without an identifiable reason.<sup>34</sup>

Studies have also shown that adolescent recipients are especially prone to medication noncompliance or partial compliance. For example, one study showed that for individuals aged 12 to 19 years, dissatisfaction with body image and the physical side effects of medications have been linked to poor compliance with prescribed transplant medication regimens.<sup>35</sup> Another study found that 57 percent of participating recipients under

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<sup>30</sup>E. F. Yen et al., "Cost-Effectiveness of Extending Medicare Coverage of Immunosuppressive Medications to the Life of a Kidney Transplant," *American Journal of Transplantation*, vol. 4 (2004): 1703-1708 (citing endnotes 4-7 (reported from 1989, 1990, 1992, and 1999)), and S.D. Geest et al., "Incidence, Determinants, and Consequences of Subclinical Noncompliance with Immunosuppressive Therapy in Renal Transplant Recipients," *Transplantation*, vol. 59, no. 3 (1995): 340-347 (citing endnotes 18-19 (1992)).

<sup>31</sup>Yen et al., "Cost-Effectiveness of Extending Medicare Coverage of Immunosuppressive Medications to the Life of a Kidney Transplant."

<sup>32</sup>Immunosuppressive medications can increase patients' risk of developing infections and can cause weight gain, cataracts, diabetes, high blood pressure, bone disease, and damage to the liver and kidney.

<sup>33</sup>M. A. Chisholm, "Issues of Adherence to Immunosuppressant Therapy After Solid-Organ Transplantation," *Drugs*, vol. 62, no. 4 (2002): 567-575.

<sup>34</sup>See, for example, R. T. Schweizer et al., "Noncompliance in Organ Transplant Recipients," *Transplantation*, vol. 49, no. 2 (1990): 374-377, and Chisholm, "Issues of Adherence to Immunosuppressant Therapy After Solid-Organ Transplantation."

<sup>35</sup>M. E. Ferris et al., "Trends in Treatment and Outcomes of Survival of Adolescents Initiating End-Stage Renal Disease Care in the United States of America," *Pediatric Nephrology*, vol. 21 (2006): 1020-1026 (citing endnote 16).

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20 years old were not compliant with their medication regimens, compared with only 15 percent of participants over 40 years old.<sup>36</sup>

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## Transplant Recipients in All Age Groups Had Similar Demographic Characteristics, but Fewer Pediatric and Transitional Recipients Had Medicare Coverage

Pediatric, transitional, and adult kidney transplant recipients were similar with respect to sex, race, and income level. As of December 31, 2004, all three age groups were predominately male, white, and lived in counties with a median annual household income of \$25,000 to less than \$50,000. However, the three groups differed in terms of their types of health insurance coverage, with a smaller percentage of pediatric and transitional recipients covered by Medicare compared to their adult counterparts.

## Pediatric, Transitional, and Adult Transplant Recipients Were Similar with Respect to Sex, Race, and Income Level

Based on our analyses of USRDS and ARF data, we found that pediatric, transitional, and adult recipients were similar with respect to sex, race, and income level, as of December 31, 2004. All three age groups were predominantly male, and the proportion of males in each age group was higher than that found in the general U.S. population—49 percent (see table 1). Approximately 59 percent of individuals with ESRD are male.

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**Table 1: Distribution of Pediatric, Transitional, and Adult Kidney Transplant Recipients by Sex**

Sex	Percentage of pediatric recipients	Percentage of transitional recipients	Percentage of adult recipients
Male	62	57	59
Female	39	43	41

Source: GAO analysis of USRDS data.

Note: Our analysis is based on kidney transplant recipients who had functioning transplants as of December 31, 2004. The percentages may not total 100 because of rounding.

All three age groups were also predominantly white, and the percentage distribution of other races among the three groups was similar (see table 2). Although a higher percentage of transitional recipients were white and a lower percentage were black compared with pediatric and

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<sup>36</sup>Schweizer et al., “Noncompliance in Organ Transplant Recipients.”



adult recipients, the differences were not substantial. In addition, the distribution of racial groups among pediatric, transitional, and adult transplant recipients was similar to that found in the general U.S. population.

**Table 2: Distribution of Pediatric, Transitional, and Adult Kidney Transplant Recipients by Race**

Race	Percentage of pediatric recipients	Percentage of transitional recipients	Percentage of adult recipients
White	77	82	74
Black	16	12	19
Asian	3	3	5
Native American	1	1	1
Other	2	1	1
Not available	1	0	0

Source: GAO analysis of USRDS data.

Note: Our analysis is based on kidney transplant recipients who had functioning transplants as of December 31, 2004. The percentages may not total 100 because of rounding.

Pediatric, transitional, and adult transplant recipients were similar in terms of their household income level (see table 3). Seventy-five percent of recipients in each age group resided in counties with a median annual household income of \$25,000 to less than \$50,000, which is almost three times the percentage for the general U.S. population (27 percent). When compared to the general U.S. population, a very small percentage of recipients in each of the three age groups resided in counties with the lowest and highest median annual household incomes—less than \$25,000 or \$75,000 or more, respectively. About 27 percent of the U.S. population resided in counties with a median annual household income of less than \$25,000 and about 28 percent resided in counties with a median annual household income of \$75,000 or more.

**Table 3: Distribution of Pediatric, Transitional, and Adult Kidney Transplant Recipients by Median Annual County-Level Household Income**

Median annual county-level household income	Percentage of pediatric recipients	Percentage of transitional recipients	Percentage of adult recipients
Less than \$10,000	0	0	0
\$10,000 to less than \$25,000	2	2	1
\$25,000 to less than \$50,000	75	75	75
\$50,000 to less than \$75,000	18	20	21
\$75,000 or more	1	1	1
Not available	5	3	1

Source: GAO analysis of USRDS data and the 2005 ARF of 2002 median annual county-level household income.

Note: Our analysis is based on kidney transplant recipients who had functioning transplants as of December 31, 2004. The percentages may not total 100 because of rounding.

### A Smaller Percentage of Pediatric and Transitional Recipients Had Medicare Coverage

While pediatric, transitional, and adult transplant recipients were similar in terms of sex, race, and income, they were less similar in terms of their health insurance coverage. As of December 31, 2004, while more than two-thirds of adult recipients had coverage under Medicare, just over one-third of pediatric recipients and slightly less than half of transitional recipients were covered under Medicare (see table 4). Although each group had about the same percentage of recipients with both Medicare and Medicaid coverage, almost three times as many adult recipients had Medicare but not Medicaid coverage compared with pediatric recipients, and almost twice as many adult recipients had Medicare but not Medicaid coverage compared with transitional recipients.

**Table 4: Distribution of Pediatric, Transitional, and Adult Kidney Transplant Recipients by Insurance Coverage**

<b>Insurance coverage</b>	<b>Percentage of pediatric recipients</b>	<b>Percentage of transitional recipients</b>	<b>Percentage of adult recipients</b>
Medicare but not Medicaid	20	30	55
Medicare and Medicaid	15	17	15
Other <sup>a</sup>	65	53	30

Source: GAO analysis of USRDS data.

Note: Our analysis is based on the latest reported health insurance coverage by kidney transplant recipients who had functioning transplants as of December 31, 2004.

<sup>a</sup>Other is defined as those who do not have Medicare coverage but are covered by private health insurance, Medicaid, or other governmental health insurance or are uninsured or whose health insurance status is unknown.

Although still smaller than the percentage of adult recipients, based on our analysis of USRDS data, a larger percentage of pediatric and transitional recipients had Medicare coverage at the time of their transplants—67 percent and 81 percent, respectively, compared to 87 percent. It is not known why these differences in Medicare coverage existed, given that most individuals who have ESRD are eligible for Medicare coverage.

## A Higher Percentage of Transitional Recipients Experienced Transplant Failure and Received Dialysis

Our analysis of data from the USRDS show that after the first year posttransplant, a higher percentage of transitional recipients experienced a transplant failure compared with their pediatric and adult counterparts. In addition, the largest increase in transplant failure among the three age groups occurred in the first 3 years posttransplant—before termination of Medicare coverage—and the increase was substantially higher for transitional recipients than for pediatric and adult recipients. After experiencing a transplant failure, a higher percentage of transitional recipients received dialysis, a higher percentage of pediatric recipients received retransplants after the first year posttransplant, and a higher percentage of adult recipients died.

## A Higher Percentage of Transitional Recipients Experienced Transplant Failure Compared with Pediatric and Adult Recipients

Based on our analysis of USRDS data, we found that after the first year posttransplant, a higher percentage of transitional recipients experienced a transplant failure when compared with their pediatric and adult counterparts (see fig. 1). For example, we found that by 5 years posttransplant, the percentage of transitional recipients who experienced a transplant failure (33 percent) was about twice as high as the percentage of pediatric recipients (16 percent) and somewhat higher than adult recipients (28 percent). According to several representatives of pediatric kidney transplant centers that we interviewed, adolescent kidney transplant recipients—who generally populate our transitional age group—are less likely than other age groups to comply with their medication regimens, which, among other things, can lead to transplant failure.

**Figure 1: Percentage of Kidney Transplant Recipients Whose Transplants Failed, by Age Group and Number of Years Posttransplant**



Source: GAO analysis of USRDS data.

Notes: Our analysis is based on individuals who received kidney transplants from 1997 through 2000. The percentage of kidney transplant failures is equal to the number of recipients whose transplants failed in that time period divided by the total number who received transplants during the same time period.

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The largest increase in the percentage of transitional recipients who experienced a transplant failure occurred in the first 3 years posttransplant, and this increase was substantially higher than the increase for pediatric and adult recipients. Specifically, the percentage of failures for transitional recipients increased by 133 percent between 1 and 3 years posttransplant, while the percentage increases for pediatric and adult recipients were 83 and 100 percent, respectively.

After 3 years posttransplant, all three age groups showed a smaller increase in transplant failures when compared with the period between 1 and 3 years posttransplant. Between 3 and 5 years posttransplant, the percentage increase in transplant failures was 45 percent for pediatric, 57 percent for transitional, and 56 percent for adult recipients. The percentage increase in failures remained lower during the 5 to 7 years posttransplant period—63 percent, 33 percent, and 43 percent for pediatric, transitional, and adult recipients, respectively. Failure to see a large percentage increase of transplant failures in pediatric and transitional recipients beyond 3 years posttransplant, when Medicare coverage terminates for many recipients, may be explained by the practices of transplant centers. Representatives from pediatric kidney transplant centers with whom we spoke stated that once Medicare coverage ends, they either help recipients to acquire other health insurance coverage or provide them with free or reduced-cost immunosuppressive medications if they lack health insurance coverage or otherwise cannot afford the medications. They also stated that the percentage of recipients who experience transplant failures because of an inability to pay for their medications after Medicare coverage ends (3 years posttransplant) is low.

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### A Higher Percentage of Transitional Recipients Received Dialysis Compared with Pediatric and Adult Recipients

Based on our analysis of USRDS data, we found that after experiencing transplant failures, a higher percentage of transitional recipients received dialysis, a higher percentage of pediatric recipients received retransplants after the first year posttransplant, and a higher percentage of adult recipients died (see figs. 2, 3, and 4).<sup>37</sup> By 7 years posttransplant, the percentage of transitional recipients who received dialysis after experiencing a transplant failure was nearly 30 percent higher than that of pediatric recipients and nearly 60 percent higher than that of adult

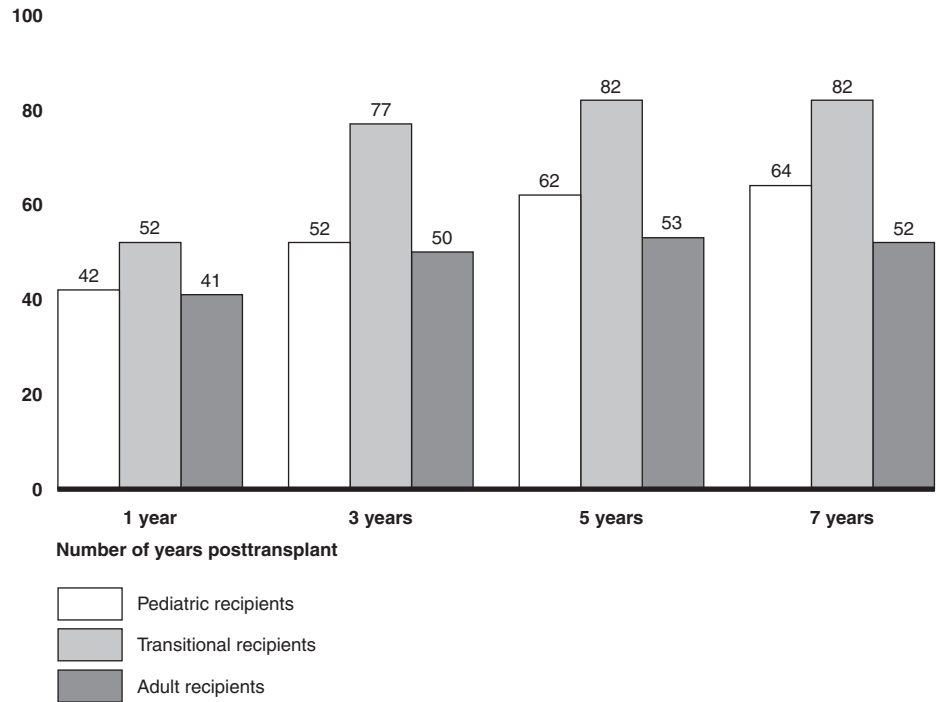
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<sup>37</sup>After experiencing a transplant failure, the outcome for an individual can be dialysis, retransplant, or death.

recipients. In addition, at 7 years posttransplant, the percentage of pediatric recipients who received retransplants after experiencing a transplant failure was over 25 percent higher than that of transitional recipients and more than twice the percentage of adults who received retransplants. The percentage of adults who died following a transplant failure was about twice as high as the percentage of pediatric recipients and about three times as high as transitional recipients.

**Figure 2: Percentage of Kidney Transplant Recipients Who Received Dialysis after Transplant Failure, by Age Group and Number of Years Posttransplant**

Percentage of recipients who received dialysis after a transplant failure

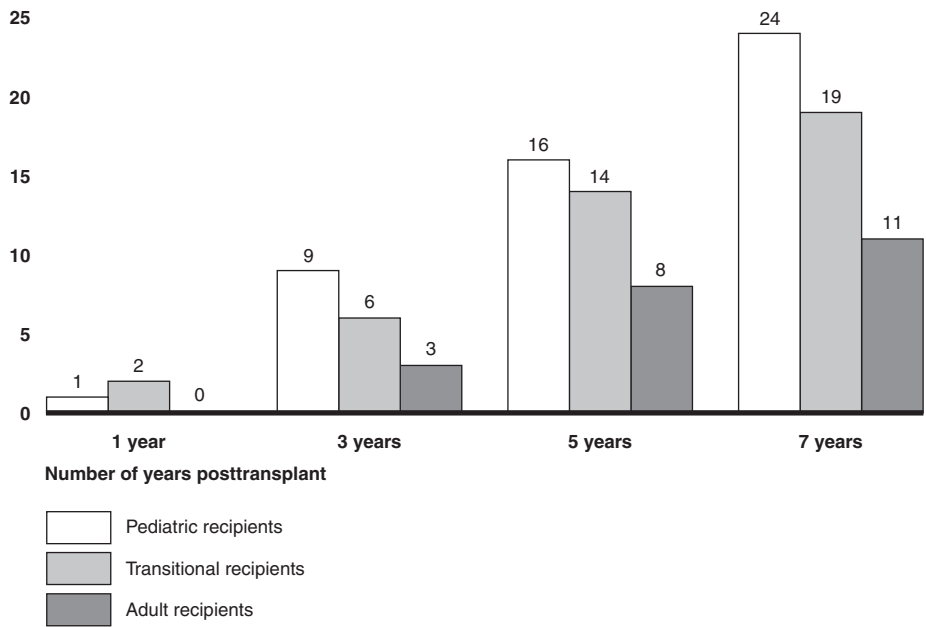


Source: GAO analysis of USRDS data.

Notes: Our analysis is based on individuals who received kidney transplants from 1997 through 2000. The percentage of kidney transplant recipients who received dialysis is equal to the number of transplant recipients on dialysis in that time period divided by the total number of recipients whose transplants failed during the same time period.

**Figure 3: Percentage of Kidney Transplant Recipients Who Received Retransplants after Transplant Failure, by Age Group and Number of Years Posttransplant**

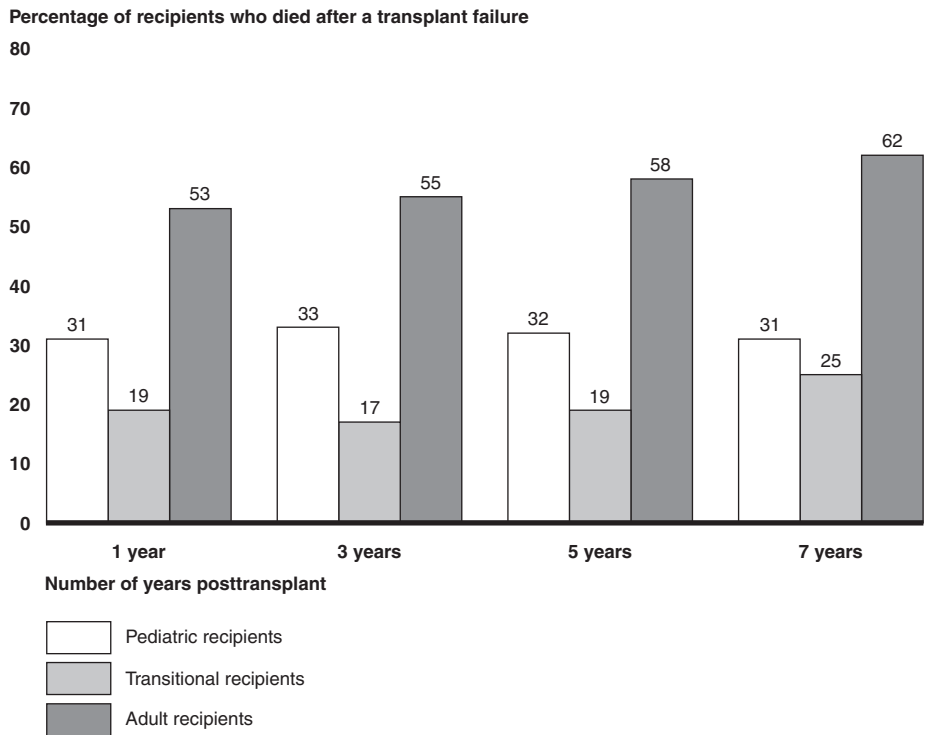
Percentage of recipients who received retransplants after a transplant failure



Source: GAO analysis of USRDS data.

Notes: Our analysis is based on individuals who received kidney transplants from 1997 through 2000. The percentage of kidney transplant recipients who received retransplants is equal to the number of transplant recipients who received retransplants in that time period divided by the total number of recipients whose transplants failed during the same time period.

**Figure 4: Percentage of Kidney Transplant Recipients Who Died after Transplant Failure, by Age Group and Number of Years Posttransplant**



Source: GAO analysis of USRDS data.

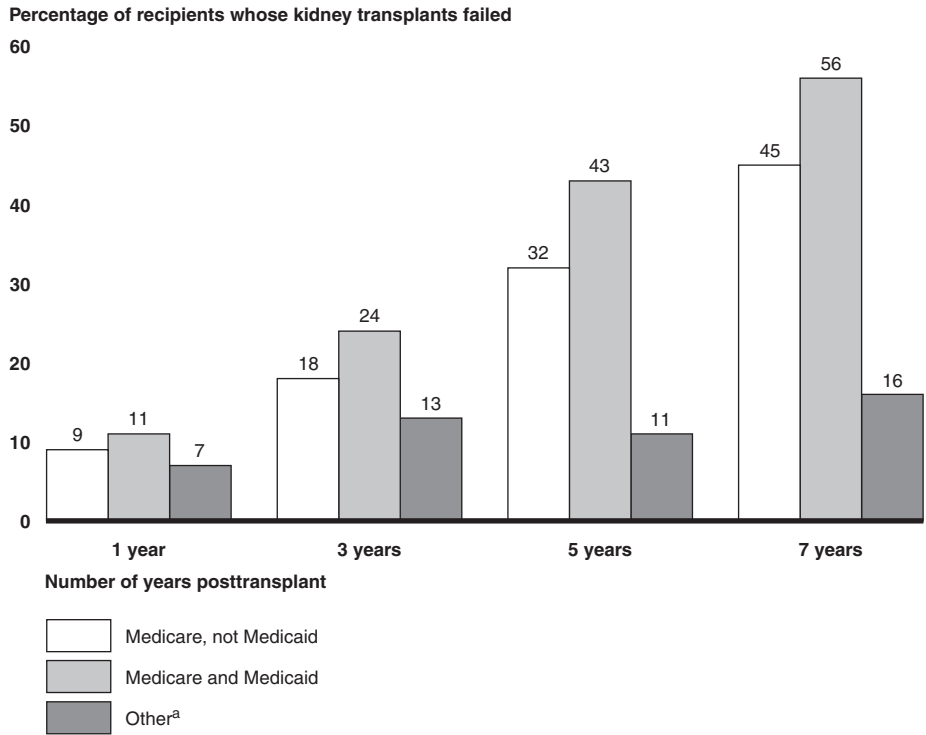
Notes: Our analysis is based on individuals who received kidney transplants from 1997 through 2000. The percentage of kidney transplant recipients who died is equal to the number of recipients who died in that time period divided by the total number of recipients whose transplants failed during the same time period.

## A Higher Percentage of Recipients with Both Medicare and Medicaid Coverage Experienced Transplant Failure and Received Dialysis

Based on our analysis of USRDS data, we found that recipients who had both Medicare and Medicaid coverage experienced a higher percentage of transplant failures compared with those who had Medicare but not Medicaid coverage or were in the Other category (see fig. 5). By 7 years posttransplant, the percentage of recipients covered by both Medicare and Medicaid who experienced a transplant failure was slightly higher (24 percent) than recipients covered by Medicare but not Medicaid and was more than three times as high as the percentage of recipients in the Other category.



**Figure 5: Percentage of Kidney Transplant Recipients Whose Transplants Failed, by Type of Health Insurance Coverage and Number of Years Posttransplant**



Source: GAO analysis of USRDS data.

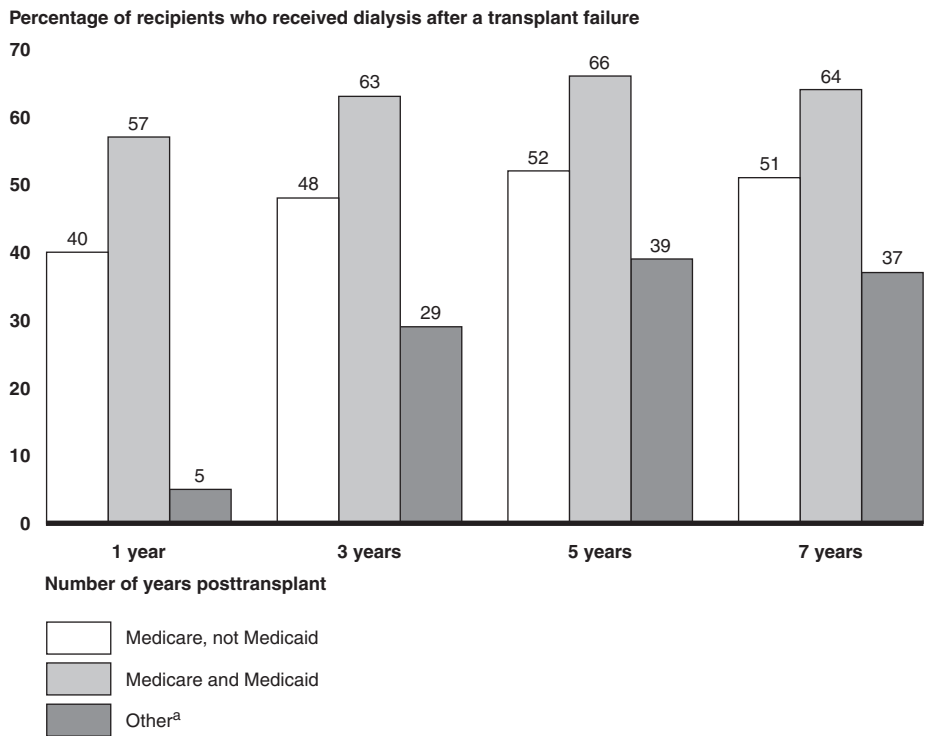
Notes: Our analysis is based on individuals who received kidney transplants from 1997 through 2000. The percentage of kidney transplant failures is equal to the number of recipients whose transplants failed in that time period divided by the total number who received transplants during the same time period.

<sup>a</sup>Other is defined as those who do not have Medicare coverage but are covered by private health insurance, Medicaid, or other governmental health insurance or are uninsured or whose health insurance status is unknown.

After experiencing a transplant failure, a higher percentage of recipients who had both Medicare and Medicaid coverage received dialysis when compared with recipients who had Medicare but not Medicaid coverage or were in the Other category (see fig. 6). For example, by 7 years posttransplant, the percentage of recipients covered by both Medicare and Medicaid who received dialysis after experiencing a transplant failure was about 70 percent higher than recipients in the Other category. After the first year posttransplant, the percentage of recipients covered by both Medicare and Medicaid who received dialysis after a transplant failure was

substantially higher than the percentage for recipients in the Other category.

**Figure 6: Percentage of Kidney Transplant Recipients Who Received Dialysis after Transplant Failure, by Type of Health Insurance Coverage and Number of Years Posttransplant**



Source: GAO analysis of USRDS data.

Notes: Our analysis is based on those who received kidney transplants from 1997 through 2000. The percentage of kidney transplant recipients who received dialysis is equal to the number of transplant recipients on dialysis in that time period divided by the total number of recipients whose transplants failed during the same time period.

<sup>a</sup>Other is defined as those who do not have Medicare coverage but are covered by private health insurance, Medicaid, or other governmental health insurance or are uninsured or whose health insurance status is unknown.

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## Beneficiaries with Functioning Transplants Were Substantially Less Costly to Medicare Than Those with Transplant Failures

Based on our analysis of USRDS data, we found that Medicare beneficiaries with functioning transplants cost substantially less per year to treat than those beneficiaries who experienced transplant failures. Specifically, we found that overall, the median annual Medicare cost for a beneficiary with a functioning transplant was \$8,550, compared with a median annual Medicare cost of \$50,938 for a beneficiary after a transplant failure—a difference of 500 percent. For pediatric beneficiaries, the percentage difference was even higher—the median annual Medicare cost after a transplant failure was 750 percent higher than for a functioning transplant (see table 5). The differences for transitional and adult beneficiaries were 550 percent and 500 percent, respectively.<sup>38</sup>

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**Table 5: Median Annual Medicare Cost per Beneficiary with a Functioning Transplant and after a Transplant Failure, by Age Group**

Age group	Median annual cost per beneficiary to maintain a functioning transplant	Median annual cost per beneficiary after transplant failure
All	\$8,550	\$50,938
Pediatric	4,916	41,929
Transitional	6,714	43,678
Adult	8,708	51,755

Source: GAO analysis of USRDS data.

Note: Our analysis is based on those who received kidney transplants from 1997 through 2000.

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## Concluding Observations

The substantial cost of treating transplant recipients who experience transplant failures underscores the importance of maintaining functioning kidney transplants. While there are many reasons that could account for transplant failures during the first 3 years posttransplant—including medication noncompliance—the large percentage increase in transplant failures from 1 year to 3 years posttransplant for transitional recipients cannot be attributed to an inability to access immunosuppressive medications due to a lack of Medicare coverage.

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<sup>38</sup>Although the percentage difference for pediatric and transitional recipients was well above 500 percent, the overall percentage is virtually the same as the adult percentage because adults account for 95 percent of all recipients.

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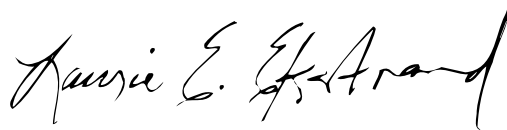
## Agency Comments

In commenting on a draft of this report, CMS stated that it appreciated our interest in kidney transplant patients and in the cost of care provided to those receiving transplants or dialysis. CMS stated that it was concerned about the quality of care and the outcomes experienced by Medicare beneficiaries, including the higher rate of transplant failure among transitional patients. CMS also stated that educating beneficiaries with kidney failure is critical to improving beneficiaries' ability to actively participate in and make informed decisions about their care. As a result, the agency engages in numerous educational and outreach efforts targeted to beneficiaries, providers, and national organizations that represent renal patients. CMS's comments are reprinted in appendix I.

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As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this letter. At that time, we will send copies of this report to the Secretary of HHS and to other interested parties. In addition, this report will be available at no charge on GAO's Web site at <http://www.gao.gov>. We will also make copies available to others upon request.

If you or your staff have any questions about this report, please call me at (202) 512-7114 or [ekstrandl@gao.gov](mailto:ekstrandl@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 who made major contributions to this report are listed in appendix II.



Laurie E. Ekstrand  
Director, Health Care

# Appendix I: Comments from the Centers for Medicare & Medicaid Services



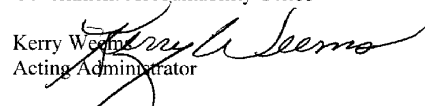
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

SEP 07 2007

Office of the Administrator  
Washington, DC 20201

**TO:** Laurie E. Ekstrand  
Director, Health Care  
Government Accountability Office

**FROM:** Kerry Wehler   
Acting Administrator

**SUBJECT:** Government Accountability Office's (GAO) Draft Report: END-STAGE RENAL DISEASE: Characteristics of Kidney Transplant Recipients, Frequency of Transplant Failures, and Cost to Medicare (GAO-07-1117)

Thank you for the opportunity to review and comment on the above referenced subject final report. We appreciate the GAO's interest in transplant patients and the cost of care provided to those receiving a transplant or dialysis. The Centers for Medicare & Medicaid Services (CMS) is, as always, concerned about the quality of care and the outcomes experienced by Medicare beneficiaries. Since transplant failure affects the quality of life of patients as well as a return to a significantly more costly treatment modality, the higher rate of transplant failure in transitional patients is an important concern for both patients and CMS. Consequently, CMS engages in numerous educational and outreach activities targeted to beneficiaries, renal providers, and a variety of national organizations that represent renal patients and the renal community.

Education of all Medicare beneficiaries with kidney failure is critical to their ability to actively participate in their care and make informed healthcare decisions. Consequently, the ESRD Networks, who are CMS contractors, distribute the New ESRD Patient Orientation Package to all new Medicare enrollees with ESRD when they receive their Medicare ESRD eligibility form. This orientation package includes the "Medicare Coverage of Kidney Dialysis and Kidney Transplant Services" handbook, which includes a transplant chapter with information on immunosuppressive drugs, their use and the possible ramifications if a kidney transplant patient stops taking their immunosuppressive medicines as prescribed. This chapter also includes information on Medicare prescription drug plan coverage for ESRD patients. In addition, the package contains the guide, "You Can Live: Your Guide to Living with Kidney Failure", which provides information on treatment options for kidney failure including transplantation. Both of these publications can also be found on [www.medicare.gov/dialysis](http://www.medicare.gov/dialysis) under resources. The ESRD Networks have also focused some of their efforts on transplantation by carrying out follow-up transplant data collection, conducting transplant education and promotion, as well as encouraging dialysis facilities to conduct and follow through on patient assessments for transplantation.

Page 2 – Laurie E. Ekstrand

In addition to these educational activities, both CMS and the ESRD Networks have developed strong, active partnerships with the National Kidney Foundation (NKF), the American Kidney Fund (AKF), and the American Association of Kidney Patients (AAKP). All three of these organizations are influential kidney patient advocates and provide significant outreach to the renal community. For example, CMS partnered with the NKF for a series of seven teleconferences specific to the implementation of Medicare Part D. Participation for each of the seven calls was high, with approximately 400 lines in use. Subsequent to the calls, NKF has continued to convey information to their membership as well as alert CMS to issues as they arise. On another occasion, CMS partnered with NKF, AKF, AAKP, and 80 other individuals and organizations to form the Kidney Community Emergency Response Coalition in order to assure that all kidney patients in time of disaster or emergency receive the care, treatment, drugs, and services that they need to remain healthy. This coalition is in its second year and remains active and committed to its original purpose.

Again, we appreciate GAO's interest in transplant patients and the cost of care provided to those receiving a transplant or dialysis. We look forward to working together to make improvements to the quality of care and the outcomes experienced by Medicare beneficiaries.

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# Appendix II: GAO Contact and Staff Acknowledgments

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## GAO Contact

Laurie Ekstrand, (202) 512-7114 or [ekstrandl@gao.gov](mailto:ekstrandl@gao.gov)

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## Acknowledgments

In addition to the contact named above, Nancy Edwards, Assistant Director; Kelly DeMots; Krister Friday; Joanna Hiatt; Xiaoyi Huang; Martha Kelly; and Ba Lin made key contributions to this report.

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