Chapter X

The Cost Effectiveness of Alternative Types of Vascular Access and the Economic Cost of ESRD

As part of the expanded scope of the USRDS to conduct analyses of cost and cost effectiveness in the ESRD program, this is the first Annual Data Report of the USRDS to conduct detailed empirical analysis of the cost effectiveness of ESRD therapies.

This chapter is divided into two sections. The first section compares patient outcomes and Medicare costs for the two primary access types used in hemodialysis patients, the arteriovenous (AV) fistula and a polytetrafluoroethylene (PTFE) graft (USRDS 1994). This study combines the 1990 incident patient data from the USRDS Casemix Adequacy Study with the HCFA billing data. The primary outcomes include patient survival and vascular access survival (through first revision), with corresponding estimates of Medicare reimbursements. This information is then used in a preliminary evaluation of the relative cost effectiveness of each type of vascular access. The current study is intended as a demonstration of how cost effectiveness can be applied to ESRD therapy in a way that combines powerful epidemiologic and economic data from several sources.

The second section presents estimates of the total direct monetary cost of the ESRD program in the United States, including a discussion of recent trends. This material in previous reports was contained in the “Prevalence and Cost of ESRD” chapter.

Cost Effectiveness and Vascular Access

INTRODUCTION

Since vascular access is a requirement for hemodialysis, maintenance of a functioning vascular access is a major issue for hemodialysis patients. Vascular access revision is the single most common reason for hospitalization of hemodialysis patients and is very costly both in monetary terms and as a morbidity burden on patients.

Further, there is some evidence that the utilization of arteriovenous (AV) fistulas is declining relative to polytetrafluoroethylene (PTFE) grafts (see Chapter IV) despite many clinicians’ beliefs that AV fistula is the preferred type of access for many patients. If fistulas are found to be more cost effective than grafts in some patients, it may be worthwhile to take steps such as revising reimbursement rates to encourage use of the fistula.

This chapter reports on the first USRDS project that employs Medicare Claims data linked to the USRDS Case Mix Adequacy sample (USRDS, 1994). The goals of this project are:

- To demonstrate the use of these Special Study and Medicare Claims data for a project focusing on both the patient outcomes and cost of medical care.
- To demonstrate the techniques used in this type of analysis by estimating the technical efficacy of an AV fistula vs. a PTFE graft in both the analysis of patient survival and survival of the vascular access itself.
To perform a cost effectiveness analysis (Held, 1992) of these two alternative types of vascular access both with regards to patient and vascular access survival.

This study has relied on extensive data processing of HCFA Standard Analysis Files (H-SAFs) of the inpatient and outpatient billing records which have been made available to the USRDS as part of the pursuit of economic analyses related to ESRD. (At the time of this writing, a third H-SAF, Physician and Supplier claims, were only available for 1992. Future work will include these additional Medicare Claims that amount to approximately 20 percent of total Medicare spending for ESRD patients.) The technical design of this project has relied extensively on prior work by Held et al. (1992). The current task has been unusually complex, involving many different disciplines including medicine, epidemiology, statistics, economics and computer science.

This chapter is designed to show the feasibility of this type of study, rather than to provide a final analysis of this question. This preliminary study is limited primarily by the absence of important and major adjustments for the likely selection of “sicker” patient to the PTFE graft over the fistula. The final evaluation of this question will depend on future work which incorporates comorbidities as well as analyses which utilize the proposed Dialysis Morbidity and Mortality Study (DMMS), a new USRDS special study. The DMMS is discussed in Chapter XIII.

METHODS AND MATERIALS

Sample Selection

This study of the efficacy and cost effectiveness of vascular access analyzed patient survival and Medicare costs (reimbursements) for hemodialysis patients treated with either of the two main alternative types of access: AV-fistula and PTFE graft. Subsequent analyses focused on the time to first access revision for patients treated with these two accesses and the corresponding Medicare costs (reimbursements) for the treatment of these patients.

The analysis started with the 1990 incident sample of new ESRD patients that survived until 12/31/90. The data are from the USRDS Special Study of Case Mix Adequacy (CMA; the study is described further in Chapter XIII, and the questionnaire is reprinted in Appendix B). For this subset of patients, we estimated the time and aggregate cost to death, or censor at transplant or end of the study. We employed this same sample of patients to estimate the parameters of time and resource utilization (Medicare reimbursement) to first access revision for both fistulas and PTFE grafts.

The type of vascular access in use on day 30 after the start of ESRD was recorded in the CMA questionnaire for 1990 incident patients. Patients with a temporary type of vascular access as the type of access in use on day 30 were excluded from the primary analysis as we could not reliably determine if a subsequent vascular access procedure was for creation of the initial permanent type of access or for revision of a type of access created prior to day 30. Only results for an initial type of access of an AV fistula or PTFE graft were included in this study, but descriptive statistics are presented for four classifications of vascular access among patients in the CMA study (Table X-1).

The study sample was restricted to patients in the 65 to 79 year age group at time of incidence. Patients who have private insurance would not be likely to satisfy the inclusion criteria (discussed below) relating to Medicare eligibility and those who would satisfy these criteria are likely to be a non-random sample of the incident population. Since the vast majority of individuals age 65 and older were eligible for Medicare prior to ESRD, including only patients who were at least 65 substantially reduces this problem. Patients over 79 years of age were excluded to make the study population as homogeneous as possible.

The study start date for a given patient was defined as the latest of the following plus thirty days (thirty days allows for the Medicare procedure of starting entitlement on the first day of the month in which a patient becomes eligible):

• The first dialysis date as recorded on the CMA questionnaire.
• The first ESRD service date in the USRDS database for the patient.
• The Medicare Part B entitlement date from the USRDS database.
• The date of the first dialysis bill encountered in the Quarterly Dialysis Record of the USRDS database.

The purpose of using the last date encountered was to exclude those patients who at study start date had Medicare as Secondary Payer (MSP) for medical insurance. For the same reason patients for whom there was insufficient activity (defined as having inpatient plus outpatient, less physician supplier, Medicare reimbursement bills for dialysis averaging
less than $30 per day) over the follow-up period following study start date were excluded. Given a possible 90 day waiting period for Medicare eligibility following the onset of ESRD, and the thirty day period allowed for Medicare’s policy of always starting eligibility on the first of the month, we expect that all patients with Medicare as primary insurance payer would have significant (substantial) dialysis bills within 120 days of the CMA date. Therefore, patients whose first actual dialysis payment by Medicare occurred more than 120 days after the first dialysis date recorded in the CMA study were excluded. Of the sample of patients age 65-79 that was selected for analysis (n=580), 17.5 percent of patients were excluded due to insufficient billings or a delay in the first dialysis bill as defined above. See the Statistical Methods section below for the censoring procedures followed.

**Defining Vascular Access Revision**

The analysis of vascular access failure was performed as a ‘time to first event.’ This methodology has been used previously by the USRDS in analyzing the time to first episode of peritonitis in CAPD patients (Port 1992). The timing of a vascular revision was determined by the date associated with a free-standing outpatient procedure code (CPT-4, 1992) or a hospital outpatient or inpatient procedure code (ICD-9-CM, 1992) captured from the HCFA Standard Analysis Files (H-SAF; as distinct from USRDS SAF’s described in Chapter I). These procedure codes were used to indicate an actual or incipient access failure during the period from 1990 to 1992.

On the basis of the procedure codes and dates indicated, it was difficult in some cases to distinguish whether the revision procedure codes indicated a continuing event as distinct from a second access revision. Therefore the current study focuses on time to first revision.

The date for first revision was right censored by the earliest of the study end period (December 31, 1992), date of death, or date of the first transplant occurring after the start of the study. The inpatient and outpatient H-SAFs were used for this analysis. These files indicate that nearly all procedures were performed on an inpatient or outpatient basis. (At the time of this writing the Physician/Supplier H-SAF was only available to the USRDS for 1992). The physician supplier files contain approximately 20 percent of total Medicare billings measured in total dollar reimbursements (Table X-2). We believe that the two H-SAF files (inpatient and outpatient) identified nearly all access revisions since revision procedures are performed primarily in outpatient and inpatient settings. A test of a sample of patients (approximately 10 percent subsample) indicated that all of the procedures found were performed in a hospital inpatient or outpatient department. Future work will include physician and supplier reimbursements which will increase total dollar reimbursements, but not necessarily different relative amounts.

The relevant vascular access revision codes were obtained from the Physicians’ Current Procedural Terminology (CPT-4, 1992) coding of procedures and services or as a procedure code from the International Classification of Diseases, 9th Revision (ICD-9-CM, 1992). An access failure was considered to have occurred when a code identifying a thrombectomy, thrombolysis, major revision or removal of a vascular access was found. An access failure was also considered to have occurred when a temporary or permanent venous hemodialysis catheter or a peritoneal dialysis catheter was inserted, or when a new vascular access was created. A total of 18 ICD-9 procedure codes and 59 CPT-4 procedure codes were used to identify billings for vascular access revisions. In addition to the date performed and reimbursement for such procedures, the location of the service was also recorded as inpatient or outpatient.

**Defining Time to Events**

Time to death was defined as the number of days from study start date to the earliest of death or censor for transplant or end of the study (December 31, 1992). Time to first revision was calculated as the date of the first revision minus the study start date with censoring for transplant, death or end of the study. We choose to censor at death, rather than treat as if a failure, in order to focus specifically on the mechanisms of access failure, rather than on patient outcome. (While we did not censor at the time of a switch in modality from hemodialysis to peritoneal dialysis, only two percent of patients switched to peritoneal dialysis during the study).

A vascular revision event was defined at the time of the first vascular access revision, whether as an inpatient or outpatient service. The date of the first revision procedure was determined from Medicare payment claims. The other dates were determined by data contained in the USRDS, including the Case Mix Adequacy Study.
Defining Medicare Reimbursements and “Allowed Charges”

Medicare reimbursements for all outpatient and inpatient services for patients included in this study were aggregated to the date of the first revision procedure or censoring event (transplant, death, or end of the study). Separately these same reimbursements were aggregated to time of death or censor at transplant or end of the study.

“Allowed charges” are approximately Medicare reimbursements plus patient obligations. Medicare outpatient reimbursements (Part B including physician supplier services) are approximately 80 percent of the “allowed charge”. (An annual patient deductible for part B of $100 was ignored in converting reimbursement to “allowed charge”). Medicare inpatient reimbursements are determined by a DRG payment code together with additions for “outlier” cases. Medicare patient obligations for inpatient services are a deductible per hospitalization. We assumed 2 hospitalizations per year at risk and used the 1991 deductible of $628 and for 1992 $652.

For a number of reasons, including the fact that most patient obligations are paid by a third party (Medicaid, private insurance, philanthropy) we have used “allowed charges” as an approximation of the cost (Held, 1992). Thus, the cost effectiveness study takes a payer perspective.

Medicare reimbursements for insurance claims that spanned the study start date or stop date of the analysis were prorated using the average cost per day between the “from” date and the “to” date on the claim. For example, we assumed that hospital stays beyond the nine days of the revision were for reasons beyond the access revision, since 75 percent of hospital stays with access revisions were nine days or less. We therefore prorated reimbursements in hospital bills and outpatient dialysis bills to the date of the access procedure plus nine days, based on the average cost per day over the full period covered by the claim. Measures of cost were not adjusted for inflation and measures of cost and outcomes were not discounted (Held, 1992). The follow-up time on average was just over one year which would suggest that discounting and inflation adjustments are not likely to materially affect the results.

Comorbid and Risk Factor Adjustments

The only adjustments for comorbid/risk factors were to stratify the analysis by diabetic status and to impose a restriction on patient age. Diabetic status was determined based on the primary cause of renal failure, and does not consider diabetes that may be present as a complicating condition in patients with another reported cause of renal failure. The current study focuses on diabetes as the primary diagnosis since sensitivity analysis and prior research (Held, 1994) have indicated that patients with diabetes listed as a complicating condition in the Case Mix studies experienced lower mortality rates than did patients for whom diabetes was the primary cause of renal failure. No other adjustments for risk factors except age and diabetes were made in this preliminary analysis. Since the selection of patients to receive a particular therapy depends on risk factors beyond age and diabetes, particularly with regard to the type of vascular access, e.g. peripheral vascular disease, is very likely, the results of this paper should be interpreted most cautiously. Thus, this chapter serves primarily as a demonstration of the capability of USRDS cost and cost effectiveness studies.

Statistical Methods

Time to death, time to first revision (in days) and Medicare reimbursements (in dollars) to both death and first access revision were all estimated as right-censored parameters (Held, 1992). Kaplan-Meier (1958) estimates were derived using the LIFETEST routine contained in the SAS programs (SAS, 1990) Version 6.10. Parameter estimates of the median (50th percentile) of the distribution of times to events and corresponding reimbursements were used for all analyses. When the 50th percentile was either not reached by the end of the study or when the median was believed to be unreliable because of small sample size, the 60th percentile was used for both survival and cost. Cost effectiveness literature has not developed hypothesis testing and other statistical tests. Consequently such tests were not performed for this analysis.
RESULTS

Characteristics of CMA Patients by Vascular Access

Patient demographic characteristics and cause of renal failure are provided in Table X-1 for all incident patients in the CMA study. These data serve two purposes. First, they describe many of the factors correlated with the probability that incident CMA patients have particular types of vascular access at 30 days after beginning hemodialysis. Second, before considering patient survival, vascular access failures, and associated Medicare reimbursements, it is useful to examine the characteristics of patients receiving different types of vascular access. Demographics, and basic measures of comorbidity, might influence both the likelihood of receiving a particular type of vascular access, the chance of death, and the chance and costs of access failure. Estimates of treatment effects derived from observational studies (such as this one) which fail to adequately account for the choice of modality can be biased. Thus, the revision failure, patient survival and cost estimates presented below should be considered descriptive rather than causal.

Table X-1 contains descriptive statistics for four types of vascular access in use at 30 days after the start of hemodialysis: AV fistula, PTFE graft, temporary lines and other types of access. The findings highlight the differences between patients with the two most common modalities: PTFE graft and AV-fistula. These modalities account for 82.4 percent of these 1990 incident patients. Overall,
PTFE grafts were 1.7 times as prevalent as fistulas (51.9 percent vs. 30.5 percent).

Several demographic characteristics are correlated with the type of vascular access. Patients with fistulas are on average 4.5 years younger, slightly more likely to be white and substantially more likely to be male. There were no notable differences in anthropometric measures (height, weight, and body mass index).

Patients with fistulas and PTFE grafts have different distributions of causes of ESRD. Diabetics were 2.3 times more likely to receive a PTFE graft than a fistula (56.7 percent vs. 25.0 percent). Fistula to PTFE graft ratios for ESRD caused by hypertension, glomerulonephritis and other causes are 1.6, 1.2, and 1.4, respectively. Given the large difference by diabetes, the estimates of time and reimbursement to death, and time and reimbursements to first access failure presented below were stratified by diabetes as cause of ESRD.

**Medicare Reimbursements and “Allowed Charges”**

Average Medicare reimbursement per day are shown in Table X-2 by year (1991 and 1992) and age (all ages and the current subset of ages 65-79). Dollar amounts are presented separately for outpatient, inpatient, and physician/supplier categories (in the last case currently available for 1992 only). For the 1990 CMA incident hemodialysis sample of patients determined to be accruing regular Medicare dialysis bills by day 120 (as defined above in Methods), average reimbursements for 1991 were $48.40 per day for outpatient services (i.e., primarily for dialysis) and $41.50 per day for inpatient services. Similar estimates were obtained for the subset of patients age 65-79 years for both outpatient ($48.60 per day) and inpatient ($41.70 per day) services. Among patients alive sometime during 1992, average outpatient reimbursements per day at risk were approximately 5 percent higher while average inpatient services were slightly lower than in 1991. Physician and supplier reimbursements averaged $24.50 per day for all ages and $25.10 for ages 65-79 in 1992, or 21 percent of total Medicare spending. Total Medicare reimbursements, including outpatient, inpatient and physician/supplier bills, averaged $116.30 per day in 1992, corresponding to $39,500 in estimated “allowed charges” per 365 day year. Comparable

### Medicare Reimbursements and "Allowed Charges"

**By Bill Type and Year for 1990 Cohort of Incident Hemodialysis Patients**

<table>
<thead>
<tr>
<th>Type</th>
<th>Mean $'s per Day at Risk</th>
<th>1991</th>
<th>1992</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Ages (n=1053)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Age 65-79 (n=606)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reimbursements:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outpatient</td>
<td>48.4</td>
<td>48.6</td>
<td>51.1</td>
</tr>
<tr>
<td>Inpatient</td>
<td>41.5</td>
<td>41.7</td>
<td>40.7</td>
</tr>
<tr>
<td>Physician/Supplier</td>
<td>n.a.</td>
<td>n.a.</td>
<td>24.5</td>
</tr>
<tr>
<td>Total Reimbursements</td>
<td>89.9²</td>
<td>90.3²</td>
<td>116.3</td>
</tr>
<tr>
<td>Total &quot;Allowed Charges&quot;³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per Day</td>
<td>105.4²</td>
<td>105.9²</td>
<td>108.1</td>
</tr>
<tr>
<td>Per Year ($1000)</td>
<td>38.5²</td>
<td>38.7²</td>
<td>39.5</td>
</tr>
</tbody>
</table>

¹Includes patients who survived through 12/31/90. Reimbursements for 1992 apply to patients who survived through 12/31/91.
²Does not include physician/supplier reimbursements.
³See Methods section for calculation.
figures for patients aged 65-79 were reimbursements: $116.70 per day and “allowed charges” of $39,400 per year.

**Characteristics of Study Patients by Vascular Access**

Descriptive statistics for the patients selected in this study are presented in Table X-3. The sample sizes, after the restrictions that were applied with regard to age, access type and reimbursement requirements, are reasonably small. The average ages across the four groupings of diabetic and non-diabetic by fistula and PTFE graft indicate that diabetic patients using the PTFE grafts are 2 years younger than the other three groups.

Mean follow-up for survival was 1.8 to 1.9 years; mean follow-up for first vascular access revision was 1.0 to 1.2 years. Hospital admissions averaged approximately 2.0 per patient year at risk and were similar across all groups, although diabetic patients generally experienced 10 percent higher admissions than the non-diabetic patients. Reimbursements were very similar across the four groups with approximately $88 per day at risk for the study of mortality and $79 per day at risk for the study of vascular revision. The higher costs found in the mortality study (a difference of approximately $5K per year between the two samples) may partially reflect the cost of medical services rendered shortly before death.
Patient Survival and Cost Effectiveness by Vascular Access

Kaplan-Meier estimates of patient survival are shown in Figure X-1 for diabetic patients and in Figure X-2 for non-diabetic patients. Separate estimates are obtained for patients using either a fistula or PTFE graft at 30 days past first dialysis.

Among diabetic patients (Figure X-1), patient survival is longer for patients with a graft for the first two years of dialysis; thereafter the two survival curves intersect, with a small sample remaining in the fistula group by 2.5 years of follow-up.
**Cost Effectiveness (CE) Parameters For Patient Lifetimes by Primary Diagnosis (DM or Non-DM) and Vascular Access Type, 1990 Incident Patients, with No Adjustment for Comorbid/Risk Factors**

**Age: 65-79**
Percentile of Survival: 60th

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Diabetic Fistula</th>
<th>PTFE Graft</th>
<th>Non-Diabetic Fistula</th>
<th>PTFE Graft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Survival</td>
<td>698</td>
<td>771</td>
<td>838</td>
<td>754</td>
</tr>
<tr>
<td>Difference (days)</td>
<td>-73</td>
<td></td>
<td></td>
<td>84</td>
</tr>
<tr>
<td>Reimbursement per patient ($1,000)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 60th percentile</td>
<td>72.8</td>
<td>70.2</td>
<td>70.0</td>
<td>71.2</td>
</tr>
<tr>
<td>Difference ($1,000)</td>
<td>2.6</td>
<td></td>
<td>-1.2</td>
<td></td>
</tr>
<tr>
<td>Difference ($1,000/year)</td>
<td><em>not applicable</em></td>
<td></td>
<td><em>not applicable</em></td>
<td></td>
</tr>
<tr>
<td>Dominant solution¹ (yes/no)</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

**Method #1: Compare CE at same percentile of survival**

**Method #2: Compare CE over same survival period by pro-rating costs²**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Diabetic Fistula</th>
<th>PTFE Graft</th>
<th>Non-Diabetic Fistula</th>
<th>PTFE Graft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Survival</td>
<td>{771}</td>
<td>771</td>
<td>838</td>
<td>{838}</td>
</tr>
<tr>
<td>Difference (days)</td>
<td>0</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Reimbursement per patient ($1,000)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delta $1,000</td>
<td>(80.4)</td>
<td>70.2</td>
<td>70</td>
<td>{79.1}</td>
</tr>
<tr>
<td>Dominant Solution¹ (yes/no)</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

"More cost effective" using Methods 1 and 2  
PTFE Graft  
Fistula

¹A dominant solution occurs when one technique is associated with 1) longer survival and similar or lower costs or 2) similar or longer survival and lower costs.

²The survival period is determined by the 60th percentile of survival for the technique with longer survival. Costs with shorter survival are then pro-rated based on average costs to the 60th percentile for that group; e.g., for diabetics, 72.8+(73*(72.8/698)) = {80.4}.

Table X-4

Patient survival of non-diabetics (Figure X-2) is slightly longer through approximately 2.5 years of follow-up for patients with a fistula compared to a PTFE graft. Medical resources were measured as median “lifetime costs”, or total Medicare reimbursements accrued over fully observed patient lifetimes. As with survival, lifetime costs are estimated using right-censored Kaplan-Meier techniques to account for patients who were alive at the end of the follow-up period or who were transplanted.

The estimates of patient survival (Figures X-1 and X-2) and corresponding estimates of total Medicare reimbursements were used to compare the cost effectiveness of each therapy over the full lifetime of patients. In this case the 60th rather than the 50th percentile of survival was used as the basis for comparing survival, since the estimated median
survival was based on a small sample size and appeared to be unstable.

The intersection of the horizontal lines drawn at the 60th percentile in Figures X-1 and X-2 determine the survival estimates reported in the first row of Table X-4. Among diabetic patients, survival was 73 days longer for patients with a PTFE graft (771 days) compared to a fistula (698 days). At the same (60th) percentile of total reimbursements, spending was slightly lower (by $2,600) for patients with a PTFE graft ($70,200) compared to patients with a fistula ($72,800). When measured on this basis, the PTFE graft would appear to be preferred to the fistula, yielding longer patient survival at a similar or slightly lower cost. However, as discussed below, patients with fistulas remained access free for a longer period of time. Thus, the lower quantity of life for these patients might be accompanied by a higher quality of life due to the avoidance of revision procedures.

It is also instructive to compare costs for patient survival for the two access types over an identical time period. A simple estimate of costs that would have been incurred (at the 60th percentile) by diabetic fistula patients had they survived as long as the 60th percentile PTFE recipient was constructed using average reimbursements per day for patients with a fistula. Through the 60th percentile of survival for fistula patients (698 days), the average daily cost for fistula patients was $80.40 ($72,800/698 days). Adding $80.40 per day for the 73 days necessary to bring fistula patients to the 60th percentile survival experience of PTFE patients (771 days) yielded a total reimbursement of $80,400, which exceeds reimbursements in the PTFE group by $10,200. This estimate of extra spending is conservative however since it is likely that average cost per day would have been higher on days 699 to 771 post-study start than during the first 698 days. This likely bias only strengthens the conclusion that PTFE grafts appear more cost effective than fistulas among diabetic patients.

A similar comparison was performed in the right side of Table X-4 for non-diabetic patients. Patient survival was 84 days longer for non-diabetic patients with a fistula compared to a PTFE graft, while total spending was also slightly lower for the fistula group (by $1,200). The combined result of longer patient survival and a similar (or slightly lower) level of reimbursements would argue for selecting the fistula as the “more cost effective” therapy in non-diabetic patients. Any reduction in the frequency of access revisions in the fistula group would reinforce this conclusion.

Performing the “experiment” of comparing costs over the same time interval also enhanced the finding that fistula appears to be the more cost effective type of access for non-diabetics. Based on the average cost per day of $94.40 for PTFE grafts at the 60th percentile of survival (754 days), reimbursements would rise to $79,100 over the 838 day survival experience of the 60th percentile fistula patient, exceeding reimbursements for fistula patients by $9,100.

As noted above, any discussion of which therapy is “more cost effective” must be regarded with caution, for several reasons. In the absence of adjustments for other patient characteristics and comorbid conditions, differences in patient survival or reimbursement may be attributable to factors not measured by this analysis. In the current example the relative effectiveness of each therapy may also perhaps be more directly measured by the survival of the original vascular access and any costs incurred through the first vascular revision. An example of this related but distinct approach to cost effectiveness is presented below.

Estimates of Vascular Access Survival

Kaplan-Meier survival curves for the vascular access to the first revision is shown in Figure X-3 for diabetic patients and in Figure X-4 for non-diabetic patients. For diabetic patients the two vascular access survival curves were nearly identical through the first third of a year. PTFE grafts continued on the same general rate of decline as before, but the fistula patients appear to have had improved access survival comparatively. The plot of access survival for diabetic patients with a fistula suggested that the small sample size begins to generate unstable estimates below the 70th percentile. But the two curves suggest that in diabetic patients access survival is higher for the fistula group.

Access survival for non-diabetics in Figure X-4 showed a similar pattern by access type as did the comparison among diabetics. At close to six months, the two curves separate, with the fistulas having higher survival than the graft thereafter.

Estimates of Costs and Reimbursements through First Revision

The estimates of cost and survival for patients through the first access revision are shown in Table X-5. These data are also the working ingredients for a cost effectiveness analysis (Held, 1992).
The median time to first revision, indicated by a horizontal line in Figures X-3 and X-4, is presented in the first row of Table X-5. The second row indicates that the first revision for the median diabetic patient with a fistula occurred 184 days later than for the median patient with a graft. The difference in median access survival for the non-diabetic patients was smaller at 130 days.

Median reimbursements to first access revision were $35,300 and $26,100 in diabetic patients, with the fistula patients incurring higher reimbursements than did the graft patients. This is as one could expect, since the fistula patients reached the first access failure at a later time. A similar pattern was

**Figure X-3**

*Kaplan-Meier vascular access (revision-free) survival in hemodialysis patients with an AV fistula or a PTFE graft. Includes diabetic patients ages 65 to 79 years. Based on a national sample of 1990 incident patients from the USRDS Casemix/Adequacy Special Study.*

**Figure X-4**

*Kaplan-Meier vascular access (revision-free) survival in hemodialysis patients with an AV fistula or a PTFE graft. Includes non-diabetic patients ages 65 to 79 years. Based on a national sample of 1990 incident patients from the USRDS Casemix/Adequacy Special Study.*
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observed for non-diabetic patients, with median reimbursements to first revision amounting to $32,700 and $25,400 for patients with a graft and fistula, respectively.

Cost Effectiveness of Vascular Access through First Revision

A cost effectiveness analysis, based on Medicare reimbursements, comparing access survival and relative spending for fistulas with grafts indicates that for diabetic patients the additional 184 days with no revision of the vascular access is associated with an additional $9,200 in Medicare reimbursements for both inpatient and outpatient accounts. Annualizing this $9,200 for 184 days leads to an estimated reimbursement of $18,300 per year. For an additional $18,300 the median fistula patient can have Medicare ESRD services and remain revision free for an extra half-year. Is this cost effective?

The choice presented is an example of the more difficult comparisons for cost effectiveness analyses. The fistula patient had less need of revision, but incurred greater spending. However, Medicare payments do not end with first access revision, suggesting that a more appropriate comparison would be spending for graft and fistula patients for an identical duration of follow-up period. Even under the conservative assumption that graft recipients’ post-access failure per day costs are identical to their pre-failure costs, we would expect to see Medicare reimbursements $4,600 higher for diabetic graft patients than for diabetic fistula patients over the 532 day period representing median fistula survival. This comparison for diabetic patients indicates that the fistula is more cost effective even without accounting

Table X-5
for reduced patient morbidity associated with longer access survival (at 532 days, 50 percent of fistulas had failed compared to 59 percent of PTFE grafts).

The estimates for the non-diabetic patients comparing fistula and graft survival and associated resource use yielded similar conclusions as the results for diabetic patients. The median fistula patient is revision free 130 days longer than is the median graft patient. The differences in spending are such that graft recipients cost HCFA $3,700 more than fistula patients when pro-rating graft reimbursements to standardize the comparison at 429 days (median fistula survival time). Furthermore, when the median (50th percentile) fistula patient has their first revision, the 66th percentile graft patient is having their first revision. Thus, the fistula vascular access appears more cost effective than PTFE graft for access revision in non-diabetic patients. The spending is lower for the fistula patient for the same follow-up time and there is less morbidity as well.

The results presented above for diabetic patient survival suggest an inconsistency. The parameters presented in Table X-4 suggested that a graft was more cost effective than a fistula for patient survival. In contrast the parameters presented in Table X-5 suggest that a fistula is more cost effective for vascular revision.

In a sensitivity analysis, we tested another approach to the cost effectiveness comparison for vascular access revisions, by treating both death and a revision as a failure in the analysis of time to first vascular revision. In this alternative model the conclusion we reach regarding cost effectiveness does not change for non-diabetic patients, as the fistula appears to be relatively more cost effective. However, the cost effectiveness analysis among diabetic patients is such that the PTFE graft is more cost effective than is the fistula when treating both death and a revision as events, although the difference in survival is relatively small (an advantage of 29 days for the graft, or approximately 10 percent higher than for the fistula). This appears to be the combined result for the fistula of relatively lower patient survival (at least in the short term in Figure X-1) and relatively higher access survival (Figure X-3). This alternative model appears to provide more consistency in that when accounting for potential differences in both patient and access survival, PTFE grafts, when compared to fistulas, appear to be more cost effective for diabetic patients in the 65-79 age group.

**DISCUSSION**

**Purpose**

The purpose of this chapter was to explore the possibilities of cost effectiveness analyses applied to the choice of vascular access and to revision free survival for hemodialysis patients using the Special Study of Case Mix Adequacy and Medicare payment records for procedures performed on both an inpatient and outpatient basis. The emphasis was more on data sources and statistical technique rather than conclusive results. We have not evaluated our confidence in the specific parameter estimates of efficacy and cost effectiveness. Our main concern was the limited statistical control we applied to the preselection of patients to a particular type of vascular access device.

**Billing Records As A Source of Economic Data**

One of the principal realities of this work is the fact that the billing records would not permit one to identify what vascular access device a patient had. It was necessary to use specially abstracted data from the USRDS Casemix Adequacy Study to identify the particular vascular access device(s) a patient was using at a defined point in time. The matching between this information for particular incident patients with their billing data determined the time to first revision. Cumulative Medicare reimbursements to the same follow-up period for these patients permitted cost effectiveness analyses to be estimated for both patient survival and revision-free vascular access survival.

Another empirical difficulty is the precise identification of patients who had Medicare as their secondary insurance payer. HCFA billing records are incomplete for Medicare secondary payer (MSP) patients during the period of time in which the Medicare and private group health insurance coordinate the payment of benefits. (In the early period of this study, the length of the coordination time for new patients was one year after Medicare eligibility. In the latter period the coordination period was 18 months).

The Medicare billing system has an uncertain set of indicators for MSP status. In this analysis, we selected patients for inclusion on the basis of the amount of Medicare payments for outpatient dialysis since it is expected that this is one service that Medicare is unlikely to pay for if the patient has MSP.
Unfortunately, the required criteria excluded a sizable number of patients from the analysis, resulting in a small sample size. Our selection criteria excluded 39 percent of all cases and 18 percent of patients in the 65-79 age group. The lesson is that the MSP identification in the Medicare billing records may be a limitation in this type of analysis for these otherwise very useful data.

Social Cost of Vascular Access Revision

These analyses have shown that vascular revision is a major problem for hemodialysis patients, for their providers and for Medicare insurance. Half of this entire sample of 1990 incident patients (n=1700) experienced at least one access revision before the end of the study. The experience in this study sub-sample of patients aged 65-79 was similar, with 50 percent experiencing a first revision by 299 to 532 days.

We did not estimate reimbursements or hospital and outpatient clinic days as a function of the number of vascular revisions, but one can easily speculate that “allowed charges” per day and morbidity will not decline after initial access revisions. Overall approximately 40 percent of first vascular revisions among the study sample were performed on an inpatient basis.

Cost Effectiveness Analyses

The analyses of cost effectiveness presented above generally provided credible estimates of the potential answer to some difficult questions. In general AV fistulas were found to be more cost effective than were PTFE grafts for both patient and access survival. But this was not always the case.

The analyses for diabetic patients (Table X-4 and Table X-5) provided an inconsistent answer. For 65-79 year old diabetics, in the patient survival analysis, fistulas were more cost effective than was the PTFE graft. The opposite was the case for vascular access survival. It would seem inconsistent for the one type of access to be associated with higher mortality and yet have a longer interval to first access failure.

In the analysis of patient survival the fistula was also associated with higher lifetime Medicare reimbursements when estimated over the same survival period for patients with a PTFE graft. This appears to be inconsistent with the evidence that there were fewer first access revisions in diabetics with a fistula compared to a graft. As a result of the reduced risk of a first revision we might have expected corresponding declines in spending for the fistula patients of treating the first and any subsequent revisions.

These apparent inconsistencies in the current preliminary analysis for diabetic patients suggests there are other factors for which may influence the relative cost effectiveness of each type of vascular access for which the current analysis does not adjust. The potential effect of other factors such as comorbidity and geography on patient outcomes and costs will need to be considered in any definitive evaluation of these data. Further, the sample sizes in the current study are in some cases relatively small, providing limited statistical power in particular for analyses of diabetic patients with a fistula.

Summary

This study provides preliminary results on vascular access survival, patient survival and cost effectiveness for the two major types of vascular access used in a national sample of 1990 incident patients. More importantly, however, this study demonstrates the feasibility of linking data on patient outcomes and cost from multiple sources to compare the cost effectiveness of alternative therapies for ESRD. It is our hope that this will be the first of many empirical studies of patient outcomes and cost effectiveness conducted by the USRDS to provide information that is timely and useful to medical providers, public policy makers, researchers and ultimately to patients.

The Direct Monetary Cost of ESRD

Patients receiving dialysis or a kidney transplant usually require both intensive medical care to initiate treatment and regular maintenance therapy. For example, as described earlier in this chapter for hemodialysis patients, hospitalization is often necessary to insert access devices for dialysis patients. Major surgery is required for a kidney transplant recipient (and in some cases the living donor). Chronic dialysis treatments must be provided on a regular basis, requiring several sessions per week. Daily drug regimens such as erythropoietin, used to treat anemia in dialysis patients, and immunosuppression therapy, used to prevent rejection of a transplanted kidney, are used regularly in either preventing or treating complications of ESRD. The many dimensions of ESRD therapy can result in substantial direct medical costs, many of them reimbursed (and consequently measurable) through the Medicare insurance program.
Estimated Medicare Expenditures for ESRD, 1992

A preliminary estimate of the total estimated direct medical charges for ESRD by public and private payers was $9.47 billion during 1992 (Table X-6 and Figure X-5). Approximately $6.8 billion was paid by the Federal government through the Medicare system who were either not yet Medicare eligible or were no longer Medicare eligible (“will be” and “no longer”) from 195.8K yields 175.8K. The 10.2 percent estimate is based on a 12/31/90 calculation of prevalent ESRD patients who were not yet Medicare eligible or no longer Medicare eligible.

The distribution of the total estimated point prevalence of ESRD in the U.S. in 1992 by Medicare eligibility status is shown in Table X-6, and serve as the basis for estimating total expenditures per patient.

Table X-6

Note: The cells surrounded by a box indicate the primary data inputs that are used in all calculations in the above table. Note that the total estimated mid-year point prevalent count of Medicare ESRD patients (195.8 K) was estimated as the mean of 12/31/91 and 12/31/92 point prevalence counts, for the 50 states, D.C., Puerto Rico and U.S. territories (Source: Reference Table B.1). These estimates do not include patients lost to follow-up (see Chapter XIV for details). Subtracting an estimated 10.2 percent of patients in the Medicare system who were either not yet Medicare eligible or were no longer Medicare eligible (“will be” and “no longer”) from 195.8K yields 175.8K. The 10.2 percent estimate is based on a 12/31/90 calculation of prevalent ESRD patients who were not yet Medicare eligible or no longer Medicare eligible.

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Table X-6

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a. Based on a HCFA file update of June 1994. The mid-year 1992 point prevalence count of Medicare ESRD patients (195.8 K) was estimated as the mean of 12/31/91 and 12/31/92 point prevalence counts, for the 50 states, D.C., Puerto Rico and U.S. territories (Source: Reference Table B.1). These estimates do not include patients lost to follow-up (see Chapter XIV for details). Subtracting an estimated 10.2 percent of patients in the Medicare system who were either not yet Medicare eligible or were no longer Medicare eligible (“will be” and “no longer”) from 195.8K yields 175.8K. The 10.2 percent estimate is based on a 12/31/90 calculation of prevalent ESRD patients who were not yet Medicare eligible or no longer Medicare eligible.

b. Estimated as 7.6 percent of total dialysis patients and transplant recipients. This estimate is derived from the 1993 HCFA Facility Survey and is based on the ratio of non-Medicare to Medicare dialysis patients. It is assumed that the proportion of ESRD patients, including those with a functioning transplant, who are not insured by Medicare is similar to the proportion observed for dialysis patients. This estimate (16.1K) is based on the USRDS estimate of the total mid-year Medicare dialysis population (195.8K), including “will be” and “no longer” Medicare eligible patients.

c. Unpublished data. Personal communication (3/30/95) from Frank Jones, Bureau of Data Management and Strategy, and Paul Eggers, Office of Research and Demonstrations, HCFA (HCFA 1995). Mr. Jones and Dr. Eggers estimate $6.8 billion Medicare expenditures for the ESRD program for 1992. This estimate is divided by the 1992 mid-year point prevalent estimate of the Medicare eligible population (195.8K) to estimate Medicare expenditures per patient per year ($38.7K).

d. Non-Federal includes all patient obligations, including private payments and private and public insurance (e.g., Medicaid, a state program that insures medical care for the poor).

e. Estimated as 22.4 percent of Medicare payments. The factor 22.4 percent is an estimate of patient obligations and private insurance obligations which has two components. The first component is Medicare coinsurance provisions, which is estimated to be 21.1 percent. The second component of the patient obligations is the Medicare Secondary Payor (MSP) provision, whereby private employer group health insurance becomes the primary insurer of medical care for an initial period (up to one year during 1989). This is estimated to be 1.3 percent of total HCFA reimbursements (see USRDS 1991 ADR for estimation). A recent General Accounting Office (GAO) report suggested that the increase in the time period for MSP from 12 months to 18 months shifted about one percent of costs to private group insurance. Extrapolation of this estimate to the period of 1 to 12 months indicates that the total shift of cost from Medicare to private group health insurance would be approximately three percent of total ESRD expenditures.

f. Estimated as 140 percent of the average Medicare total payments (38.7K), i.e. Federal plus patient obligations. This estimate is based on results from HCFA Contract 500-90-0050 with the Urban Institute (Washington, D.C.) which showed that for patients 65 years of age and older, the payment rate per day during the first 90 days was 55 percent greater than during the remaining three quarters of the first year of eligibility. Average Medicare payments were assumed to be 40 percent greater because this estimate applies to patients less than 65 years of age, for whom HCFA has limited data during the first 90 days and who are assumed to have fewer and less severe complications than older patients.

g. This estimate is based on results from HCFA Contract 500-90-0050 with the Urban Institute (Washington, D.C.) which showed that payments (Federal plus other) per day for maintenance of patients with a functioning kidney graft totals approximately $20.

h. Assumed to be the same as the average total charges for Medicare patients (47.3K). See footnotes c and d to this table.

i. The sum of Federal and non-federal charges.

Medicare program. The estimate of $6.8 billion is obtained from HCFA (HCFA 1995), and includes inpatient ($2.9 billion), outpatient ($2.2 billion) and physician/supplier and other home health care expenditures ($1.7 billion). It is estimated that patient and private obligations represented an additional $2.7 billion, or 28 percent of total expenditures, during 1992. Note that ESRD expenditures include all types and locations of services, not just dialysis.

An estimate of mid-point prevalence (July 1, 1992) was used to approximate the number of patients treated under the Medicare program during any week of the year in 1992. This was calculated as the average of the two end-of-year Medicare point prevalence estimates for 1991 and 1992 (see Reference Table B.1).
As shown in Table X-6 and Figure X-6, estimated Medicare payments (Federal only) averaged $38,700 per capita during 1992. Patient and private insurance obligations represented an additional $8,700 per patient, or 18 percent of the total per patient per year.

While it is not known precisely how many of these patient obligations are paid, it is likely that the majority are paid by the patient or by an insurance company, either public or private. A portion of these charges are paid by Medicaid, a Federal/state program that insures medical care for the poor.

Results from the USRDS Casemix Severity Special Study of 1986-87 incident Medicare patients indicate that 69 percent of patients had either private or Medicaid insurance just before onset of ESRD (USRDS 1991). Medicare eligibility rules also may delay benefits during the first 21 months of therapy, particularly for patients under age 65 years.

The estimates shown in Table X-6 and in Figure X-5 and Figure X-6 do not include a number of direct cost items, some medical and some non-medical. For example, patient travel costs, the cost of almost all outpatient drugs, lost labor production in and out of the home and some costs associated with the Department of Veterans Affairs are not included in these estimates. Also excluded from the charges estimated in Table X-6 are “transfer payments” such as Social Security payments.


The change in USRDS estimates of mid-year prevalent Medicare ESRD patient counts and Medicare payments for ESRD between 1991 and 1992 is shown in Figure X-7. Trends in aggregate Medicare payments and expenditures per capita were considered in both nominal terms (not adjusted for inflation) and in real terms (adjusted for inflation).
The adjustments for inflation account for the change in the purchasing power of a dollar that occurs as overall consumer price levels rise over time. The inflation-adjusted, or real, price level more accurately reflects the current value of goods and services than the nominal price level, and can then be compared with the estimated value of those same goods and services in earlier or later years. “Real” Medicare expenditures in each year were estimated by adjusting expenditures to the price level in an arbitrary baseline year, in this case 1990. The inflation adjustment was performed using the general (overall) Consumer Price Index.

Figure X-6

Estimated monetary charges per Medicare ESRD patient, 1992. Includes Medicare, other public (e.g., Medicaid) and private obligations. See Table X-6 for methodology and original sources.

Percent annual change in mid-year Medicare ESRD point prevalent counts (estimated as the average of counts on 12/31 of that year, e.g. 1991 and 1992, and the preceding year, e.g. 1990 and 1991), average Medicare payments per patient and total Medicare payments from 1991 to 1992. Medicare payments include all services provided in all locations. Changes in Medicare payments are expressed in nominal (i.e., without adjustment for inflation) and in real terms. The change in the general CPI during 1992 (2.9 percent) was used to adjust 1992 Medicare payments to 1990 dollars. Prevalent counts exclude patients lost to follow-up but include patients in Puerto Rico and the U.S. Territories. Medicare patients only.

Figure X-7
The prevalence of treated ESRD is growing at approximately 11 percent per year. As shown in Figure X-7, the mid-year Medicare point prevalence count increased 11.2 percent between 1991 and 1992. Comparable growth in the Medicare ESRD population has been sustained over the last five years at a compound annual average of 10.4 percent per year since 1987.

Nominal per capita Medicare payments for ESRD were relatively unchanged between 1991 and 1992. With adjustment for inflation, however, per capita Medicare ESRD payments appear to be declining. Trends in per capita Medicare expenditures are shown in nominal terms (not adjusted for inflation) on the left side of Figure X-7 and in real terms (adjusted for inflation) on the right side of Figure X-7. Average Medicare payments per Medicare patient per year (without adjustment for inflation) decreased slightly from $38.9K to $38.7K between 1991 and 1992, or 4.5 percent (Figure III-11). Similar growth in Medicare ESRD per capita expenditures was observed over the 1987-92 period (3.8 percent per patient per year, not shown). With adjustment for the overall change in consumer prices, per capita Medicare expenditures for ESRD decreased 3.4 percent per year from 1991-92 and by an annual average of 0.2 percent from 1987-92.

Aggregate Medicare payments for ESRD are higher in 1992 compared to 1991 in both nominal dollars and in real (inflation-adjusted) dollars. It appears that this is entirely due to the increasing number of treated patients. Without adjustment for inflation, total Medicare payments in 1992 ($6.80 billion) were 10.5 percent higher than in 1991 ($6.15 billion). This growth is slightly lower than the average annual increase of 14.6 percent from 1987-92 (not shown). During the most recent year, the increase in aggregate expenditures was entirely a result of growth in the ESRD population, as nominal per capita expenditures appeared to be relatively constant. Over the recent five-year period the growth in overall Medicare expenditures for ESRD was the combined result of slow growth in nominal expenditures per patient per year and relatively faster growth in the size of the Medicare ESRD patient population.

As shown in Figure X-7, inflation-adjusted total Medicare ESRD payments increased 7.4 percent from 1991-92. This annual increase is lower than the average annual increase of 10.2 percent from 1987-92 (not shown).

While real Medicare payments per year for ESRD continue to rise in response to a growing ESRD population, average payments per patient per year show little or no growth in the last five years. The real level of reimbursement per dialysis treatment, determined through the composite rate schedule, has been declining for almost two decades. However, outpatient services represent only one third of total Medicare expenditures for ESRD (HCFA 1993, Held 1992). Expenditures for other medical goods and services, including inpatient, physician and other supplier charges, are also reflected in total Medicare payments. This trend of little or no growth in “real” per capita Medicare payments for all ESRD patients is particularly surprising since Medicare coverage was recently expanded to include EPO (9/89), which is now used in 90 percent of center hemodialysis patients and 57 percent of peritoneal dialysis patients in the U.S. (see Chapter IV).

Summary

While total Medicare ESRD expenditures continue to increase in real terms, the growth is primarily due to growth in the number of treated ESRD patients. Growth in ESRD expenditures per patient has changed little during the last year and has only just matched the overall rate of inflation over the last five years. Understanding the reasons for growth in the patient population is the key to understanding recent growth in total Medicare expenditures for ESRD.
References

HCFA, 1995. Personal communication from Frank Jones, B.S., Chief, ESRD Information Analysis Branch, Bureau of Data Management and Strategy, HCFA; and Paul Eggers, Ph.D., Chief, Program Evaluation Branch, Office of Research and Demonstrations, HCFA.


