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Research Report

2002 Organ and Tissue Transplant Costs and Discussion

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Consultants and Actuaries

2002 ORGAN AND TISSUE TRANSPLANT COSTS AND DISCUSSION

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INTRODUCTION

This report updates our 1999 report and summarizes projected 2002 costs for organ and tissue transplants. Organ transplants include heart, lung, heart-lung, liver, kidney, pancreas, kidney-pancreas, and intestine transplants. Tissue transplants include cornea and bone marrow transplants. We split bone marrow costs by donor method: autologous, where the donor is the recipient; or allogeneic, either from a related or unrelated donor.

Highlights of the report include:

- Estimated per member per month (PMPM) costs equal $3.45 and $1.93 for under age 65 and ages 65 and over transplant recipients, respectively, as shown in Section II, Table 1.
- Based on an overall assessment of the organ-by-organ detail included in Section III, the number of transplants provided to those ages 65 and older is increasing at a faster rate than for other ages. Conversely, the number of transplants provided to children is growing at a slower rate than average.
- Billed charges, discussed in Section V, have increased significantly.
- Hospital lengths of stay have declined, with a number of transplants showing substantial length of stay reductions, as shown in Section V, Table 18.
- Survival rates, discussed in detail in Section VI, have increased for virtually all transplants, with the exception of heart-lung transplants.
- Median waiting times for patients on transplant waiting lists have significantly increased for several organs, as mentioned in Section VII.

New sections of the report include:

- Section IV: High volume transplant centers by organ, based on the number performed in 1999.
- Section VII: 1999 waiting list information, including patient characteristics, median waiting times, number of registrations, and deaths and death rates.
- Section VIII: Cadaveric and living donor characteristics and issues.

We have updated the utilization and average charge assumptions, and transplant recipient demographic data, diagnosis, information, and survival rates.

We based the utilization estimates on our judgment, and data from the United Network for Organ Sharing (UNOS), the Eye Bank Association of America (EBAA), the National Marrow Donor Program (NMDP), the International Bone Marrow Transplant Registry (IBMTR), and the Autologous Blood and Marrow Transplant Registry (ABMTR).

We developed average charges per transplant based primarily on data from Solucient, Florida, Washington, and Wisconsin hospital data, Milliman USA data, and our judgment.

The estimated 2002 costs and the number of transplants in the United States assume the existing trend of organ donation continues. "Costs" means the product of frequency and average charges. "Charges" refers to the amount billed, and may not be the actual expense incurred by the payer in performing the services, due to the presence of discounts or other negotiated reimbursement arrangements.

PMPM COSTS AND DISCUSSION

Table 1 summarizes the projected 2002 PMPM transplant costs in the United States, for the under age 65 and ages 65 and over populations. The total cost for all transplants assumes full coverage for heart, lung, heart-lung, liver, kidney, pancreas, kidney-pancreas, cornea, bone marrow, and intestine transplants.

Patient cost-sharing, maximum benefit limitations, and provider discounts would reduce these costs. Also, administration costs and margins for variation and profit would need to be considered.

Private insurance programs do not cover all of the transplants. For example, Medicare covers a significant portion of kidney transplants through the end stage renal disease (ESRD) program.

Costs may vary by geographic area and transplant center. Lower volume areas or centers may be more costly due to additional complications. Those same complications may not arise, all else being equal, in higher volume/higher quality areas or centers.[1] Growth in the number of transplant centers will have the potential for changing transplant costs, too, as long as suitable donor organs and tissue can be found.

Costs may vary also by market, such as for Medicaid and the uninsured population. The number of transplants for persons ages 65 and over continues to increase rapidly, and this demographic shift could also affect costs.

The reader should also consider several other items related to cost variation, items beyond the scope of this report:

- Costs will vary by underlying diagnosis and/or disease stage.
- Transplant charges per patient may be different for pediatric and adult populations.
- The degree of medical management can have a significant impact on costs, particularly with respect to hospital charges.
- Negotiated charges may result in substantially lower costs PMPM, compared with our estimated billed costs PMPM of $3.45 and $1.93 for the under age 65 and ages 65 and over populations, respectively.
- New immunosuppressant drugs, treatment patterns, and other innovations can have a significant impact on costs, with potentially higher or lower costs as a result.

Estimated first-year charges do not reflect differences in transplant charges due to age. Although transplant charges will vary by age group, we believe these variations will have minimal impact on costs PMPM, due to the low frequency of transplants.

We based Table 1 costs on the estimated number of organ transplants in 2002 from Table 4, shown later in this report, after removing transplants for foreign citizens. We then separated the foreign citizen-adjusted total by age group for Table 1.

We estimated the under age 65 and ages 65 and over resident populations of the United States to be 244,821,000 and 35,449,000 in 2002, respectively, for purposes of determining the PMPM costs.

TABLE 1

Projected 2002 U.S. Transplant Costs Per Member Per Month (PMPM)

Transplant	Estimated First-Year Charges	Ages <65		Ages 65+	
		Estimated Annual Utilization Per 1,000	Estimated Cost PMPM	Estimated Annual Utilization Per 1,000	Estimated Cost PMPM
Heart	$391,800	0.0080	$0.26	0.0065	$0.21
Lung	343,000	0.0041	0.12	0.0011	0.03
Heart-Lung	504,400	0.0002	0.01	0.0000	0.00
Liver	313,600	0.0203	0.53	0.0105	0.27
Kidney	143,300	0.0553	0.66	0.0346	0.41
Pancreas	148,900	0.0028	0.03	0.0000	0.00
Kidney-Pancreas	195,500	0.0037	0.06	0.0000	0.00
Cornea	14,200	0.0633	0.07	0.5298	0.63
Bone Marrow—Autologous	243,800	0.0408	0.83	0.0147	0.30
Bone Marrow—Allogeneic Related	362,100	0.0200	0.60	0.0019	0.06
Bone Marrow—Allogeneic Unrelated	447,300	0.0068	0.25	0.0006	0.02
Intestine	814,500	0.0004	0.03	0.0000	0.00
Total		0.2257	$3.45	0.5997	$1.93

The estimated PMPM amounts are relatively small, in relation to total per capita health care expenditures in the United States. However, organ and tissue transplants are costly procedures, with average billed charges ranging from $143,300 to $814,500, other than cornea transplants.

The $3.45 and $1.93 per capita costs, for the under age 65 and ages 65 and over populations, respectively, should be adjusted to develop costs for insured plans. These adjustments should reflect the anticipated impact of benefit limitations, margins for frequency and charge variation, negotiated charges or discounts, demographics, underlying diagnosis, and other payers. Relaxed selection criteria for transplant recipients and donors may also impact costs.

Follow-up charges continue after the first year for many transplant patients, and may include immunosuppressant drugs, continued testing and evaluation, and medical services for transplant rejection. Many follow-up charges may not fall under a negotiated arrangement with a transplant center, but will instead be provided by the patient's normal provider network.

We no longer estimate transplant related costs after the first year following the transplant, due to a lack of data and a lack of general interest in these values. Any estimate of long-term costs associated with a transplant should reflect appropriate adjustments for trend, survival, and probability of re-transplantation.

The cost of organ transplants will also need to be reassessed if, or when, mechanical, artificial, or cloned organs become widely available for transplant. For example, two surgeons from the University of Louisville implanted the world's first totally implantable replacement heart at Jewish Hospital on July 2, 2001, and performed the procedure again on September 13, 2001. Could such a mechanical replacement, like the AbioCor™ Implantable Replacement Heart, become more prominent in the future, perhaps for other organs, as well?

Differences from Milliman 2002 Health Cost Guidelines

Users of both the Milliman 2002 Health Cost Guidelines (HCGs) and this report may notice differences in the estimated first-year charges between the two sources.

Overall, all first-year, billed charge estimates increased in this report, compared with the 2002 HCGs. The overall increases better reflect research completed after the development of the 2002 HCG values.

Specific estimates by charge category (Evaluation, Procurement, etc., discussed in greater detail in Section V) and by organ may have increased, decreased, or remained unchanged, when compared with the 2002 HCG estimates.

Alternative Treatment Modality Costs

The costs of alternative treatment modalities are generally less than the costs of a transplant. The treatment of ESRD and intestinal failure represent two notable exceptions.

Even with long-term immunosuppressive medication costs, kidney transplants cost just a fraction of chronic hemodialysis and peritoneal dialysis treatments. In a May 1999 release, based on 1993 figures, the University of Maryland estimated a medical cost break-even point (where non-transplant costs surpass transplant-related costs) of 2.7 years, with annual savings of about $28,000 after the break-even point.

The Transplant Video Journal[1] compared intestinal transplant and transplant-related maintenance costs with total parenteral nutrition (TPN) costs, and estimated a medical cost break-even point between one and three years. The annual savings estimates, after the break-even point, ranged from $85,000 to $190,000, depending on the intestinal transplant and TPN annual cost assumptions.

However, as reported by the Intestinal Transplant Registry, intestinal transplants must offer better survival, better quality of life, and lower costs than TPN, to make intestinal transplants a more routine surgical procedure.

PROJECTED NUMBER AND DEMOGRAPHICS OF TRANSPLANT RECIPIENTS

The number of transplant center programs in the UNOS registry has increased from 566 in 1990 to 842 in 2000, an average increase of 4.1% per year. However, the growth in programs at transplant centers appears to have slowed down recently. The number of programs, by organ, decreased between 1997 and 2000 for all organs, except pancreas and intestine.

Table 2 shows the number of transplant programs, for the organs with available information, performing various transplants during 1990 through 2000. A single center can have several transplant programs for different types of transplants.

TABLE 2

NUMBER OF TRANSPLANT CENTER PROGRAMS

Organ	1990	1994	1997	2000
Heart	135	165	155	141
Lung	38	85	89	76
Heart-Lung	19	92	94	82
Liver	83	117	123	122
Kidney	231	248	250	245
Pancreas	60	116	122	137
Intestine	NA	NA	32	39

The annual percentage change in the number of programs, and the number of transplants by organ, often show similar changes in direction, increase or decrease, and magnitude, size of the increase or decrease.

The average number of transplants per program has increased steadily since 1994 for all transplants except heart-lung. Greater success in locating donor organs may be a primary reason for the increase. Liver and kidney transplants also showed greater annual increases between 1997 and 2000, compared with prior history.

Overall, the number of centers has been relatively stable, while the average number of programs per center has generally increased since 1997. It is likely established programs have increased the number of transplants they perform, whereas new programs are likely to perform less than the average. However, the limiting factor in determining the number of transplants is the availability of donor organs and tissue.

Table 3 shows the average number of transplants per program, for the organs with available information, over several years.

TABLE 3

Average Number of Transplants Per Program				
Organ	1990	1994	1997	2000
Heart	15.6	14.2	14.8	15.6
Lung	5.3	8.5	10.5	12.6
Heart-Lung	2.7	0.8	0.6	0.6
Liver	32.4	31.2	34.0	40.6
Kidney	40.8	42.9	46.7	54.6
Pancreas	1.2	0.8	1.7	3.2
Intestine	NA	NA	2.1	2.0

Number of Transplants-Summary

Table 4 shows the annual number of major organ and tissue transplants performed in the U.S. for all ages and citizens from 1995 to 2000, as well as the estimated number of organ transplants in 2001 and 2002. We also estimated all bone marrow transplants (1995 through 2002).

Looking back, historical numbers can change due to reporting lags and corrections. Looking forward, further success using living donors could increase the number of transplants, as could other factors.

TABLE 4

Annual Number of Organ and Tissue Transplants in the U.S. All Ages										
	Organ									
Year	Heart	Lung	Heart-Lung	Liver	Kidney	Pancreas	Kidney-Pancreas	Cornea	Bone Marrow	Intestine
1995	2,357	870	69	3,924	11,051	107	917	35,300	11,250	45
1996	2,342	814	39	4,072	11,363	165	860	34,668	12,600	45
1997	2,294	931	60	4,176	11,674	208	851	35,209	13,950	68
1998	2,344	864	47	4,502	12,375	245	971	35,861	21,150	68
1999	2,181	886	49	4,707	12,527	362	932	33,020	18,540	70
2000	2,198	956	48	4,954	13,372	435	911	33,260	15,930	79
2001 *	2,209	1,004	48	5,202	14,107	544	916	33,759	16,530	87
2002 *	2,220	1,054	48	5,462	14,883	680	921	34,265	17,160	96

* 2001 and 2002 values are Milliman estimates.[3]

For transplants other than cornea and bone marrow, 1995 through 2000 Table 4 data is from the UNOS Scientific Registry Newsroom, Critical Data as of August 3, 2001. We based the 2001 and 2002 data on our projections.

Multi-organ transplants of a single organ type, such as a double kidney or double lung transplant, are counted once. Heart-lung and kidney-pancreas transplants are also counted once, but other multi-organ transplants of two different organ types appear in each organ-specific column.

We based the cornea data for 1995 through 2000 on information from the Eye Bank Association of America (EBAA), which includes cornea transplants performed in the U.S. only. We estimated the 2001 and 2002 cornea transplants.

The bone marrow transplant data for 1995 through 2002 includes autologous and allogeneic, related and unrelated, transplants. We based the bone marrow transplant estimates for 1995 through 2002 on Milliman projections and data obtained from the IBMTR, ABMTR, and the NMDP. The Advisory Committee of the IBMTR and ABMTR has not reviewed or approved our bone marrow transplant estimates.

Number of Transplants-Rate of Change

Table 5 shows the percentage change in the number of transplants over the last several years, including the projections made in this report.

TABLE 5

Percentage Change in the Number of Transplants

Transplant	1999/1998	2000/1999	Projected 2001/2000	Projected 2002/2001
Heart	-7%	1%	1%	0%
Lung	3	8	5	5
Heart-Lung	4	-2	0	0
Liver	5	5	5	5
Kidney	1	7	5	6
Pancreas	48	20	25	25
Kidney-Pancreas	-4	-2	1	1
Cornea	-8	1	2	1
Bone Marrow	-12	-14	4	4
Intestine	3	13	10	10

The UNOS Scientific Registry Newsroom, Critical Data as of July 6, 2001, provides demographic data, waiting list data, and overall counts for heart, lung, heart-lung, liver, kidney, pancreas, kidney-pancreas, and intestine transplants. The types of data available include gender, race, age, previous transplant status, and citizenship of recipient at the time of the transplant, in addition to other information.

Heart

As shown in Table 6, 73.3% of heart transplant recipients are men, with over 60% of all the recipients ages 50 and older.

The distribution of heart transplant recipients by age has shifted somewhat toward those ages 65 and older. The percentage of recipients ages 65 or older was 9.8% in 2000, a 40% increase from 7.0% in 1996.

We estimate 2,220 heart transplants will be performed in 2002, based on historical patterns. The number of heart transplants performed over the last five years has remained fairly constant, around 2,200 to 2,300. Figure 1 shows a graph of historical and projected number of transplants since 1995.

FIGURE 1

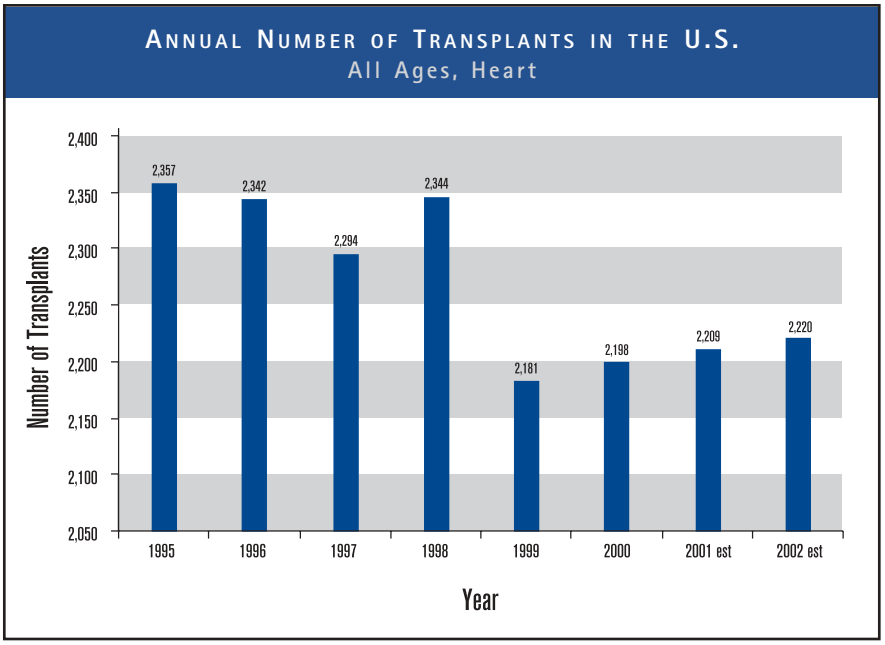


TABLE 6

2000 Transplant Recipient Demographics, Heart

Gender	Percentage
Male	73.3%
Female	26.7
Total	100.0%
Race	
White	76.5%
Black	13.2
Hispanic	7.0
Asian	1.8
Other	1.5
Total	100.0%
Age (at time of transplant)	
0	3.4%
1-5	2.6
6-10	2.1
11-17	4.3
18-34	7.6
35-49	19.1
50-64	50.9
65+	9.8
Total	100.0%
Previous Transplants	
No	96.9%
Yes	3.1
Total	100.0%
Citizenship	
U.S. Citizen	97.8%
Resident Alien	1.4
Non-Resident Alien	0.8
Total	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

Lung

Table 7 shows the gender, race, age, previous transplant status, and citizenship distributions of lung transplant recipients in 2000.

From 1996 to 1999, lung transplant recipients receiving double lungs made up a declining percentage of all lung transplants, decreasing from 47.3% in 1996 to 40.5% in 1999. This is in contrast to the period 1992 to 1996, when the double lung recipient percentage increased from 31.8% in 1992, to 47.3% in 1996.

The highest percentages reported in 2000 for lung transplant recipients were for whites (89.4%) and ages 50-64 (53.3%), with gender mix essentially even between males and females.

The trend of males receiving an increasing percentage of lung transplants seems to have flattened out, with 1996-2000 values hovering in the 49%-52% range. The percentage receiving lung transplants by race has remained steady since 1996, and the percentage of recipients ages 50 and older has increased.

Since 1995, the number of lung transplants has fluctuated from a six-year low of 814 in 1996, to a six-year high of 956 in 2000. Based on historical trends, we estimate 1,054 lung transplants in 2002. We show the historical and projected numbers of lung transplants in Figure 2.

TABLE 7

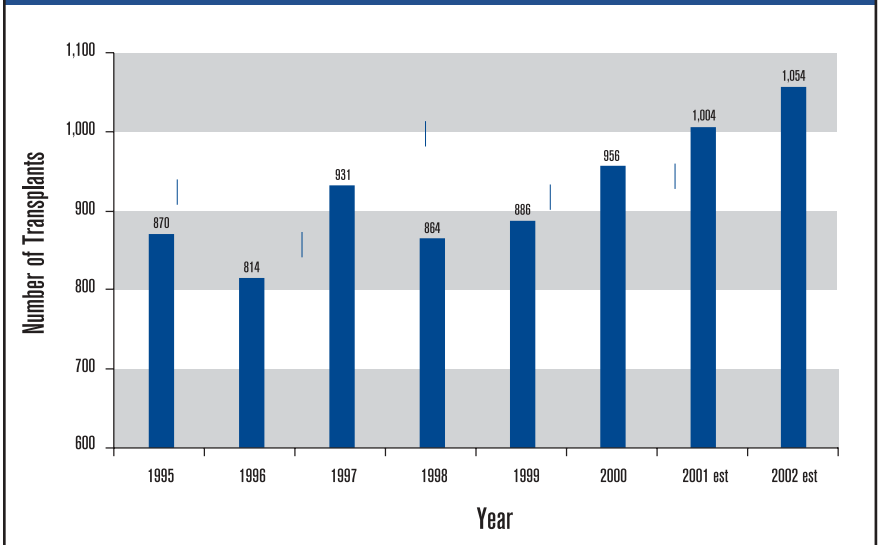
2000 Transplant Recipient Demographics, Lung

Gender	Percentage
Male	49.9%
Female	50.1
Total	100.0%
Race	
White	89.4%
Black	6.8
Hispanic	2.9
Asian	0.0
Other	0.8
Total	100.0%
Age (at time of transplant)	
0	0.4%
1-5	0.3
6-10	1.0
11-17	3.6
18-34	13.5
35-49	24.7
50-64	53.3
65+	3.1
Total	100.0%
Previous Transplants	
No	97.9%
Yes	2.1
Total	100.0%
Citizenship	
U.S. Citizen	99.4%
Resident Alien	0.1
Non-Resident Alien	0.5
Total	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

FIGURE 2

Annual Number of Transplants in the U.S.
All Ages, Lung



Heart-Lung

The UNOS Scientific Registry Newsroom, Critical Data as of July 6, 2001, reports heart-lung transplants as one transplant.

Table 8 shows the gender, race, age, previous transplant status, and citizenship distributions of the heart-lung transplant recipients in 2000. The sample size was 48 transplants in 2000.

The highest percentages of transplant recipients were female (64.6%), white (81.3%), and ages 18-34 (33.3%) and 35-49 (31.3%).

It is difficult to characterize changes since 1996 as distinct trends because there were so few heart-lung transplants. However, the following changes occurred from 1996 to 2000:

- The number of recipients ages 50-64 increased from 2, or 5.0%, in 1996 to 9, or 18.8%, in 2000.
- A greater percentage of females have been recipients in recent years, with over 60% in 1997, 1999, and 2000.
- The racial mix of recipients has fluctuated in the range of 73%-90%, 2%-13%, and 3%-10% for white, black, and Hispanic races, respectively, from 1996 to 2000.

The number of heart-lung transplants has remained at about the same level since 1998, with some fluctuation prior to 1998. Based on these historical trends, we estimate 48 combined heart-lung transplants in 2002. Figure 3 shows the historical and projected numbers of heart-lung transplants.

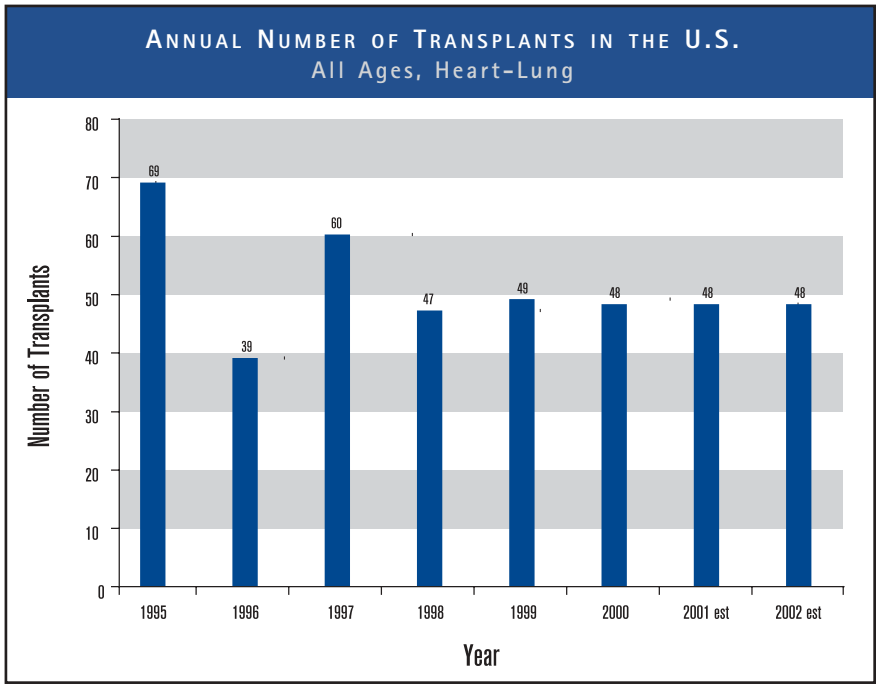
TABLE 8

2000 Transplant Recipient Demographics, Heart-Lung

Gender	Percentage
Male	35.4%
Female	64.6
Total	100.0%
Race	
White	81.3%
Black	8.3
Hispanic	10.4
Asian	0.0
Other	0.0
Total	100.0%
Age (at time of transplant)	
0	0.0%
1-5	2.1
6-10	4.2
11-17	10.4
18-34	33.3
35-49	31.3
50-64	18.8
65+	0.0
Total	100.0%
Previous Transplants	
No	100.0%
Yes	0.0
Total	100.0%
Citizenship	
U.S. Citizen	100.0%
Resident Alien	0.0
Non-Resident Alien	0.0
Total	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

FIGURE 3



Liver

For 2000, 92.5% of all liver transplant recipients received livers from cadaveric donors. This represents a decline from 98.1% in 1998 and 95.2% in 1999.

Table 9 displays the demographic characteristics of 2000 liver transplant recipients. Of these recipients, 60.9% were male, 73.3% were white, and 75.4% were ages 35-64.

There has been a slight shift toward older liver transplant recipients since 1996. Adults ages 35 and older have seen their relative percentage increase by 3%, from 80.3% to 82.7%. Adults ages 18-34 have seen their relative percentage decrease by 16% since 1996, from 6.9% to 5.8%.

Based on the past trend of liver transplants and transplant programs in the U.S. and availability of donor organs, we estimate 5,462 liver transplants will be performed in 2002. We summarize the historical and projected numbers of liver transplants in Figure 4.

FIGURE 4

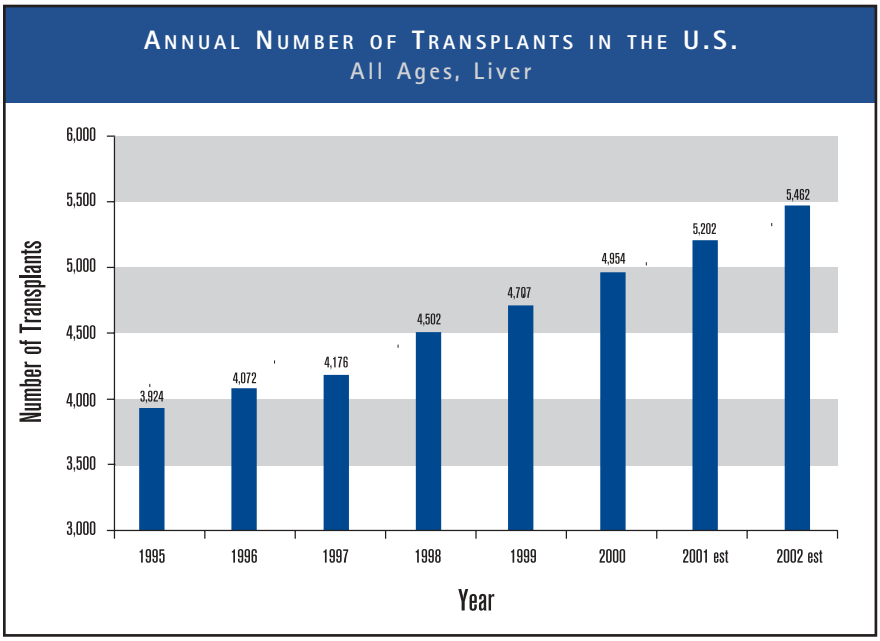


TABLE 9

2000 Transplant Recipient Demographics, Liver

Gender	Percentage
Male	60.9%
Female	39.1
Total	100.0%
Race	
White	73.3%
Black	8.6
Hispanic	12.7
Asian	3.1
Other	2.4
Total	100.0%
Age (at time of transplant)	
0	3.4%
1-5	4.0
6-10	1.8
11-17	2.4
18-34	5.8
35-49	34.4
50-64	41.0
65+	7.3
Total	100.0%
Previous Transplants	
No	90.9%
Yes	9.1
Total	100.0%
Citizenship	
U.S. Citizen	95.8%
Resident Alien	2.0
Non-Resident Alien	2.2
Total	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

Kidney

For 2000, 60.6% of all kidney transplant recipients received kidneys from cadaveric donors. The cadaveric donor percentage has declined every year since 1990, when the percentage equaled 77.8%.

We show the gender, race, age, previous transplant status, and citizenship distributions of kidney transplant recipients in Table 10. Overall, the demographic profile of kidney transplants, with the exception of the age distribution, has changed very little over the last several years.

The age distribution shows older kidney transplant recipients in 2000, where 42.4% are ages 50 and older, versus 1998 (38.9%) and 1996 (34.7%). Over 95% of all kidney transplant recipients are ages 18 or older, in total.

Why are most patients adults before requiring either dialysis or a kidney transplant? ESRD, the major cause of kidney transplants, is generally the result of a progressive disease process.

Based on kidney transplant trends in the United States and current availability of donor organs, we estimate 14,883 kidney transplants will be performed in 2002. Figure 5 shows the recent number of actual kidney transplants performed, as well as our projections for 2001 and 2002.

FIGURE 5

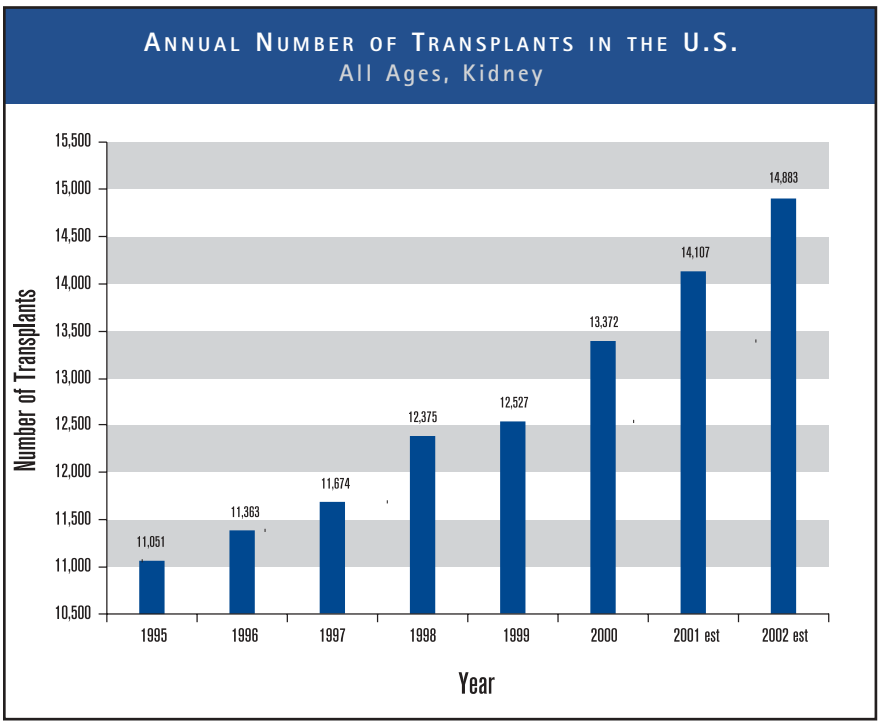


TABLE 10

2000 Transplant Recipient Demographics, Kidney
Cadaveric and Living Donor

Gender	Percentage
Male	59.4%
Female	40.6
Total	100.0%
Race	
White	60.0%
Black	22.5
Hispanic	11.5
Asian	3.9
Other	2.0
Total	100.0%
Age (at time of transplant)	
0	0.0%
1-5	0.8
6-10	0.9
11-17	2.9
18-34	18.9
35-49	34.1
50-64	33.4
65+	9.0
Total	100.0%
Previous Transplants	
No	88.1%
Yes	11.9
Total	100.0%
Citizenship	
U.S. Citizen	96.5%
Resident Alien	2.7
Non-Resident Alien	0.8
Total	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

TABLE 11

2000 Transplant Recipient Demographics, Pancreas

Gender	Percentage
Male	53.6%
Female	46.4
Total	100.0%
Race	
White	92.6%
Black	3.7
Hispanic	3.0
Asian	0.5
Other	0.2
Total	100.0%
Age (at time of transplant)	
0	0.5%
1-5	0.5
6-10	0.2
11-17	0.2
18-34	23.9
35-49	58.2
50-64	16.6
65+	0.0
Total	100.0%
Previous Transplants	
No	81.6%
Yes	18.4
Total	100.0%
Citizenship	
U.S. Citizen	99.2%
Resident Alien	0.6
Non-Resident Alien	0.2
Total	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

Pancreas

Pancreas transplant recipients are usually under age 50, with 83% under age 50 in 2000. The number of pancreas recipients ages 50 and older is growing, from 2% in 1996, to 9% in 1998, to 17% in 2000.

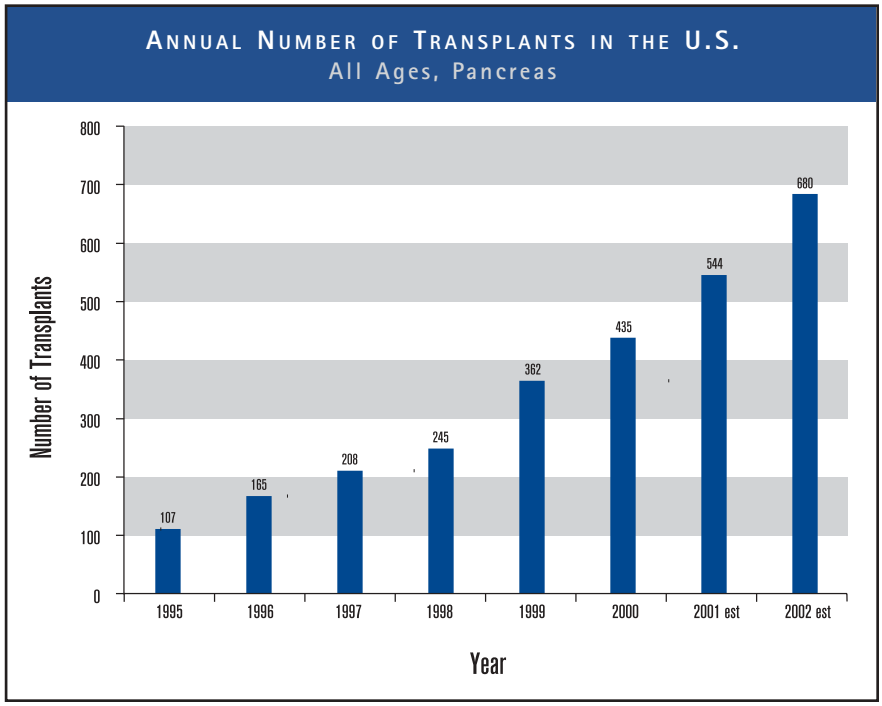
The vast majority of pancreas transplants are performed on diabetics, who are generally under the age of 60, with imminent kidney failure or who no longer respond to insulin therapy.[2] Generally speaking, patients have to be on insulin for at least 10 years before being considered for a pancreas transplant.[2]

We show the gender, race, age, previous transplant status, and citizenship distributions for pancreas transplant recipients in Table 11. The majority of the reported recipients were male (53.6%), white (92.6%), and ages 35-49 (58.2%).

Since 1996, as just mentioned, there has been a sizable shift in the percentage of transplant recipients, from ages 18-49 to ages 50-64. In 1996, 94.5% of recipients were age 18-49, and 2.4% were age 50-64. The comparable 2000 percentages were 82.1% and 16.6%, respectively.

We estimate the number of pancreas transplants in 2002 to be 680. Figure 6 shows the actual number of pancreas transplants during 1995 through 2000, and our projections for 2001 and 2002.

FIGURE 6



Kidney-Pancreas

We show the gender, race, age, previous transplant status, and citizenship distributions of kidney-pancreas transplant recipients in Table 12.

The kidney-pancreas demographics differ from the kidney demographics in the following ways:

- Kidney-pancreas recipients show a greater percentage of white recipients - 85.0%, versus 60.0% for kidney.
- Kidney-pancreas recipients demonstrate minimal previous transplant experience - 0.8%, versus 11.9% for kidney.

How do the kidney-pancreas demographics differ from the pancreas demographics?

- Kidney-pancreas recipients demonstrate greater diversity by race than pancreas recipients - 92.6% of pancreas recipients are white, versus 85.0% for kidney-pancreas.
- Kidney-pancreas recipients show minimal previous transplant experience - 0.8%, versus pancreas recipients with 18.4%.

FIGURE 7

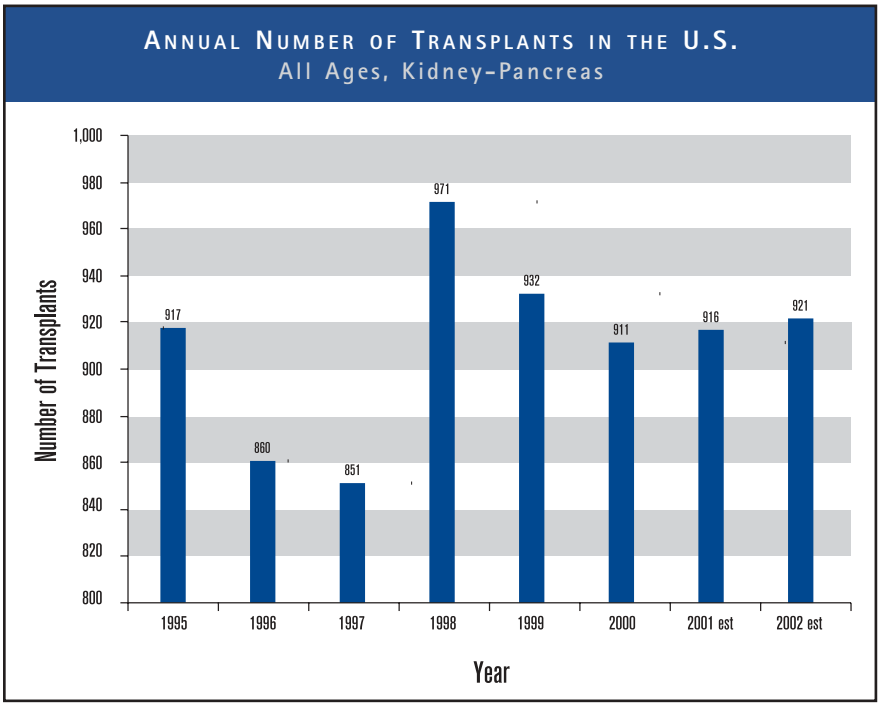


TABLE 12

2000 Transplant Recipient Demographics, Kidney-Pancreas

Gender	Percentage
Male	57.2%
Female	42.8
Total	100.0%
Race	
White	85.0%
Black	9.2
Hispanic	4.8
Asian	0.4
Other	0.5
Total	100.0%
Age (at time of transplant)	
0-17	0.0%
18-34	25.1
35-49	61.0
50-64	13.6
65+	0.2
Total	100.0%
Previous Transplants	
No	99.2%
Yes	0.8
Total	100.0%
Citizenship	
U.S. Citizen	99.3%
Resident Alien	0.4
Non-Resident Alien	0.3
Total	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

Cornea-Overall

We were not able to obtain current gender, race, and age distributions for cornea transplant patients. Table 13 shows 1997 data previously included in our 1999 report.

We have assumed Eye Bank Association of America (EBAA) members will provide 34,265 cornea transplants in the U.S. in 2002. Figure 8 shows the historical and projected numbers of cornea transplants.

Cornea-1999 Report versus 2002 Report

Figure 8 appears to indicate a substantial decrease in cornea transplants, compared with data in the 1999 Research Report. For example, the 1999 report shows 45,493 transplants in 1997, compared with 35,209 transplants in 1997 now. In reality, the apparent difference is a result of the use of a different subset of data now, versus what was used in 1999.

The 1999 report actually summarized all corneal transplants, provided by U.S. and International Eye Banks. The transplants provided by U.S. Eye Banks can further be separated into transplants performed in the U.S., and transplants exported internationally.

This report now properly reflects only those corneal transplants provided by U.S. Eye Banks and performed in the U.S.

TABLE 13

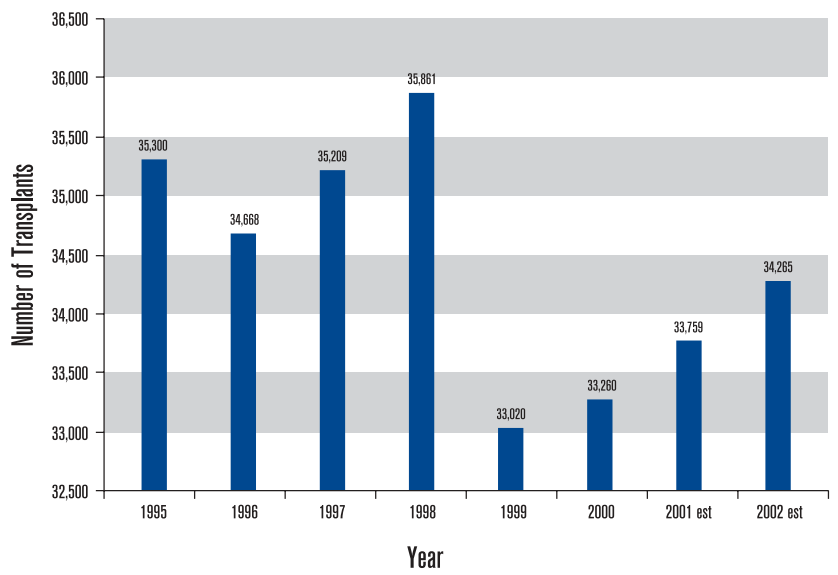
1997 Transplant Recipient Demographics, Cornea

Gender	Percentage
Male	44.8%
Female	55.2
Total	100.0%
Race	
White	76.1%
Black	9.8
Hispanic	8.5
Asian	3.5
Other	2.1
Total	100.0%
Age (at time of transplant)	
0	0.5%
1-10	1.1
11-20	2.4
21-40	12.9
41-60	17.8
61-70	17.8
71+	47.5
Total	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

FIGURE 8

Annual Number of Transplants in the U.S.
All Ages, Cornea



Cornea-Decrease from 1998 to 1999

Figure 8 demonstrates a material decrease in corneal transplants from 1998 to 1999 in the U.S. The decrease from 1998 to 1999 is a result of a minimal increase in the total number of transplants provided by U.S. Eye Banks, but a substantial increase in the number of U.S. Eye Bank transplants exported internationally, as shown in Table 13A.

TABLE 13A

Corneal Transplants Provided by U.S. Eye Banks

Year	Total	Performed in U.S.	Exported Internationally
1998	45,579	35,861	9,718
1999	45,765	33,020	12,745

Bone Marrow

We obtained sample demographic data for bone marrow transplant patients from Solucient[3], shown in Table 14. The data includes allogeneic and autologous bone marrow transplants. Males (53.8%), whites (79.2%, excluding unrecorded cases), and ages 40-64 (50.6%) most commonly receive bone marrow transplants.

TABLE 14

2000 Transplant Recipient Demographics, Bone Marrow

Gender	Percentage
Male	53.8%
Female	46.2
Total	100.0%
Race	
White	47.2%
Black	6.3
Hispanic	0.5
Asian	0.7
Other	4.9
Unrecorded	40.4
Total	100.0%
Age (at time of transplant)	
0-17	20.8%
18-39	23.7
40-64	50.6
65+	4.9
Total	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

Similar to other transplants, there has been a trend, over time, toward older individuals receiving bone marrow transplants. In 1994, 31.0% of all recipients were 0-19 years old, and 16.3% were over age 50. The comparable values in 1997 were 20.3% and 29.3%, respectively. A shift toward older recipients appears to have continued in 2000.

From 1998 to 2000, the number of allogeneic transplants in North America remained flat - 7,000 in 1998, versus 6,700 in 1999 and 2000. IBMTR cites two reasons the number of allogeneic transplants remained flat:

1. There is a finite availability of donors.

2. Expansion into new diseases has slowed-in other words, there are no new diseases on which to perform these transplants.

Autologous transplants in North America showed material increases from 1996 to 1998 - 9,000 in 1996, to 10,000 in 1997, to 16,500 in 1998 - followed by material decreases from 1998 to 2000 - 16,500 in 1998, to 14,000 in 1999, to 11,000 in 2000. Autologous transplants increased, and then declined, because of issues related to breast cancer:

- Through 1998 and driven by marketplace pressure on insurers, high-dose chemotherapy, followed by a bone marrow transplant, became a common treatment for women with advanced breast cancer or a high chance of recurrence, despite the lack of data or studies demonstrating the procedure's clinical effectiveness.

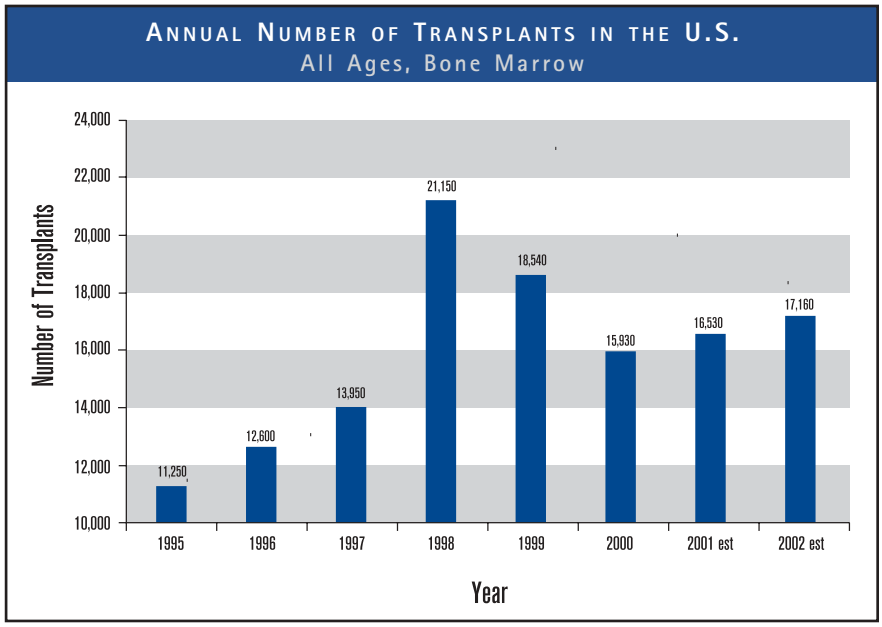
- In 1999, four major studies showed high-dose chemotherapy, followed by a bone marrow transplant, for breast cancer patients resulted in no change in patient survival, compared with those patients receiving conventional chemotherapy without a bone marrow transplant.[4] Marketplace pressure on insurers, to provide coverage for such high-dose chemotherapy procedures requiring a bone marrow transplant, then subsided.

In 2002, we estimate the number of U.S. bone marrow transplants to be 17,160. Of this number, about 29% are expected to be allogeneic related transplants, 61% autologous transplants, and 10% allogeneic unrelated donor transplants.

Our analysis relied on North American data from the International Bone Marrow Transplant Registry (IBMTR), the Autologous Blood & Marrow Transplant Registry (ABMTR), and the National Marrow Donor Program (NMDP). The Advisory Committee of the IBMTR and ABMTR has not reviewed or approved our analysis.

We based the number of bone marrow transplants in the U.S. for each year, 1995-2002, on our judgment. We summarize these values in Figure 9.

FIGURE 9



Intestine

We included intestine transplant information for the first time in our 1999 report. Physicians performed few intestine transplants before 1990. Since then, the number performed has been increasing, with significant increases in 1995 and 1997.

Significant increases may also be coming in the near future, given the new April 1, 2001 legislation. The Centers for Medicare and Medicaid Services (CMS), as of April 1, 2001, will provide national Medicare intestinal transplant coverage, for those suffering irreversible intestinal failure.

Over 40%, down from about 50%, of all intestine transplants involve both small bowel and liver grafts. According to the University of Nebraska, all intestine transplant patients are required to be on total parenteral nutrition (TPN) therapy to be considered a transplant candidate. TPN can cause liver damage for patients, resulting in the need for both a small bowel and liver transplant.

Table 15 shows the 2000 demographic profile of intestine transplants, according to the UNOS Scientific Registry Newsroom, Critical Data as of June 1, 2001. Since 1996, more males than females have received intestine transplants. Over 60% of all recipients are under age 18. The ages 35-49 and 50-64 groups are also receiving more transplants, increasing from 13% to 19%, and 2% to 5%, respectively, from 1997 to 2000.

We estimate 96 intestine transplants will be performed in 2002 in the United States. Figure 10 shows the actual number of intestine transplants performed during 1995 through 2000, and our projections for 2001 and 2002.

FIGURE 10

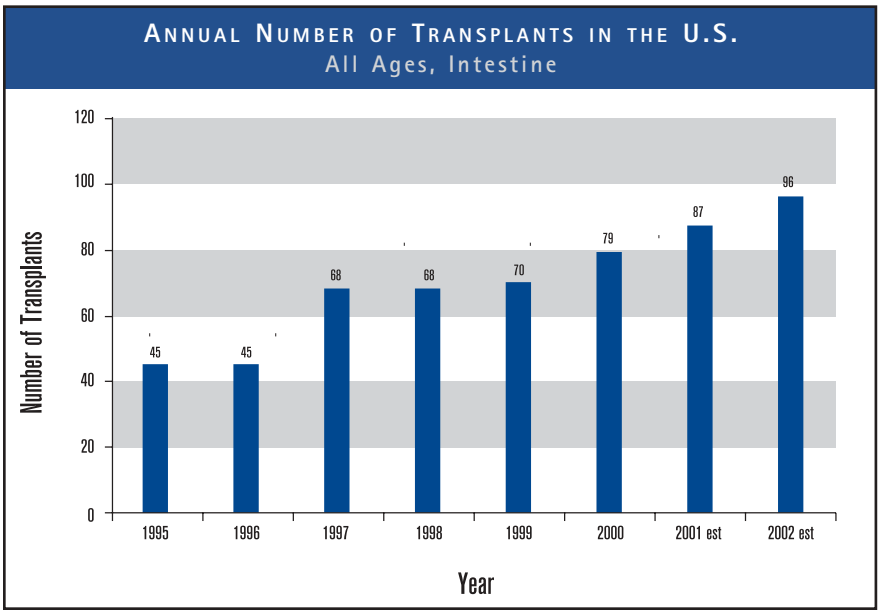


TABLE 15

2000 Transplant Recipient Demographics, Intestine

Gender	Percentage
Male	54.4%
Female	45.6
Total	100.0%
Race	
White	64.6%
Black	12.7
Hispanic	19.0
Asian	2.5
Other	1.3
Total	100.0%
Age (at time of transplant)	
0	12.7%
1-5	35.4
6-10	8.9
11-17	3.8
18-34	15.2
35-49	19.0
50-64	5.1
Total	100.0%
Previous Transplants	
No	92.4%
Yes	7.6
Total	100.0%
Citizenship	
U.S. Citizen	93.1%
Resident Alien	0.0
Non-Resident Alien	6.9
Total	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

HIGH VOLUME TRANSPLANT CENTERS-1999

Where are the transplants, summarized in Table 4, performed most often? Tables 16a-h highlight, by 1999 organ counts, the top 10 transplant-providing states and centers.[5] We did not have cornea and bone marrow transplant information at this level of detail.

TABLE 16A

1999 U.S. Transplants, High Volume States and Centers, Heart

High Volume States and Counts		High Volume Centers and Counts	
California	237	UCLA Med Ctr-Los Angeles	89
Pennsylvania	206	Presbyterian Hosp-New York City	81
Texas	189	Cleveland Clinic Foundation-Cleveland	76
Ohio	147	Hosp of the Univ of PA-Philadelphia	59
Florida	116	Temple Univ Hosp-Philadelphia	51
New York	114	Univ of MI Med Ctr-Ann Arbor	40
Missouri	79	Tampa General Hosp-Tampa	37
Wisconsin	77	St. Luke's Med Ctr-Milwaukee	36
North Carolina	74	Stanford Univ Med Ctr-Stanford	36
Illinois	73	Ochsner Foundation Hosp-New Orleans	35
		St. Luke's Episcopal Hosp-Houston	35

TABLE 16B

1999 U.S. Transplants, High Volume States and Centers, Lung

High Volume States and Counts		High Volume Centers and Counts	
California	73	Duke Univ Med Ctr-Durham	52
Pennsylvania	73	Barnes-Jewish Hosp-St. Louis	47
North Carolina	69	Fairview Univ Med Ctr-Minneapolis	39
Missouri	67	Univ of WI Hosp and Clinics-Madison	35
Texas	56	Univ of Pittsburgh Med Ctr-Pittsburgh	34
Ohio	45	Loyola University Med Ctr-Maywood, IL	33
Illinois	44	Cleveland Clinic Foundation-Cleveland	32
Wisconsin	42	Univ of AL Hosp-Birmingham	31
Minnesota	40	Johns Hopkins Hosp-Baltimore	29
Michigan	34	Univ of WA Med Ctr-Seattle	26

TABLE 16C

1999 U.S. Transplants, High Volume States and Centers, Heart-Lung

High Volume States and Counts		High Volume Centers and Counts	
Pennsylvania	14	Children's Hosp-Philadelphia	7
California	11	Stanford Univ Med Ctr-Stanford	7
Missouri	3	Children's Hosp-Pittsburgh	4
New York	3	Presbyterian Hosp-New York City	3
Alabama	2	Duke Univ Med Ctr-Durham	2
Colorado	2	St. Louis Univ Hosp-St. Louis	2
North Carolina	2	UCSD Med Ctr-San Diego	2
Tennessee	2	Univ of AL Hosp-Birmingham	2
Texas	2	Univ of Pittsburgh Med Ctr-Pittsburgh	2
Wisconsin	2	Univ of WI Hosp and Clinics-Madison	2
		Univ Hosp-Denver	2
		Vanderbilt Univ Med Ctr - Nashville	2

TABLE 16D

1999 U.S. Transplants, High Volume States and Centers, Liver

High Volume States and Counts		High Volume Centers and Counts	
California	598	UCLA Med Ctr-Los Angeles	209
Florida	442	Jackson Memorial Hosp-Miami	190
Pennsylvania	434	Mt. Sinai Med Ctr-New York	181
New York	365	Univ of Pittsburgh Med Ctr-Pittsburgh	151
Texas	356	Baylor Univ Med Ctr-Dallas	147
Illinois	232	Hosp of the Univ of PA-Philadelphia	106
Ohio	179	Shands Hosp at Univ of FL-Gainesville	105
Minnesota	127	St. Luke's Hosp-Jacksonville	97
North Carolina	121	NE Health System-Univ Hosp-Omaha	93
Wisconsin	121	UCSF Med Ctr-San Francisco	91

TABLE 16E

1999 U.S. Transplants, High Volume States and Centers, Kidney

High Volume States and Counts		High Volume Centers and Counts	
California	1,273	Univ of MD Med System-Baltimore	329
Texas	898	Univ of AL Hosp-Birmingham	271
New York	810	Univ of WI Hosp and Clinics-Madison	246
Pennsylvania	774	UCLA Med Ctr-Los Angeles	211
Florida	694	UCSF Med Ctr-San Francisco	192
Ohio	534	Univ of MI Med Ctr-Ann Arbor	189
Maryland	493	Tampa General Hosp-Tampa	185
Michigan	466	Fairview Univ Med Ctr-Minneapolis	169
Illinois	465	Johns Hopkins Hosp-Baltimore	164
Minnesota	405	St. Barnabas Med Ctr-Livingston, NJ	164

TABLE 16F

1999 U.S. Transplants, High Volume States and Centers, Pancreas

High Volume States and Counts		High Volume Centers and Counts	
Minnesota	123	Fairview Univ Med Ctr-Minneapolis	105
Maryland	80	Univ of MD Med System-Baltimore	69
Pennsylvania	20	Rochester Methodist Hosp-Rochester, MN	18
Wisconsin	19	Univ of WI Hosp and Clinics-Madison	18
Tennessee	14	Univ of TN Med Ctr-Memphis	14
New York	12	Univ of Pittsburgh Med Ctr-Pittsburgh	13
California	11	Jackson Memorial Hosp-Miami	11
Florida	11	Johns Hopkins Hosp-Baltimore	11
Michigan	10	Univ of WA Med Ctr-Seattle	10
Ohio	10	Univ of MI Med Ctr-Ann Arbor	9
Washington	10		

TABLE 16G

1999 U.S. Transplants, High Volume States and Centers, Kidney-Pancreas

High Volume States and Counts		High Volume Centers and Counts	
California	112	Univ of WI Hosp and Clinics-Madison	57
Illinois	79	Fairview Univ Med Ctr-Minneapolis	53
Pennsylvania	79	Univ of Pittsburgh Med Ctr-Pittsburgh	40
Wisconsin	72	Northwestern Memorial Hosp-Chicago	33
Minnesota	64	Ohio State Univ Hosp-Columbus	32
Ohio	61	Univ of Chicago Med Ctr-Chicago	29
Texas	57	Jackson Memorial Hosp-Miami	23
New York	38	UCLA Med Ctr-Los Angeles	23
Florida	33	Univ of TN Med Ctr-Memphis	20
Tennessee	27	St. Vincent Med Ctr-Los Angeles	17

TABLE 16H

1999 U.S. Transplants, High Volume States and Centers, Intestine

High Volume States and Counts		High Volume Centers and Counts	
Florida	19	Jackson Memorial Hosp-Miami *	19
Nebraska	14	NE Health System-Univ Hosp-Omaha *	14
Pennsylvania	14	Mt. Sinai Med Ctr-New York *	11
New York	12	Univ of Pittsburgh Med Ctr-Pittsburgh *	9
California	5	Children's Hosp-Pittsburgh	5
Minnesota	3	UCLA Med Ctr-Los Angeles	5
Wisconsin	2	Fairview Univ Med Ctr-Minneapolis	3
		Univ of WI Hosp and Clinics-Madison	2

* Approved for CMS accreditation

AVERAGE BILLED CHARGES

Considerations in Evaluating Charges

According to Evans, organ transplant costs should not be estimated as the total costs associated with the procedure. Rather, the cost of a transplant should be "...the added marginal costs of caring for a patient with an end-stage disease had the transplant not been performed."[6]

Evans devised a scheme to calculate the marginal cost, organizing costs into five categories:

- Pre-transplant costs
- Evaluation and screening costs
- Candidacy costs
- Transplant costs
- Post-transplant costs

While we agree with the Evans concept of marginal costs, such calculations are outside the scope of this paper. However, we used categories similar to the Evans charge categories as a convenient way to track charges.

We estimated first-year billed charges for each type of transplant, by the categories similar to those above. We no longer estimate follow-up charges for each succeeding year, due to lack of data for, and low interest in, costs after one year. We used various data sources to estimate the charge information, as well as our judgment. We then trended all charges to July 1, 2002.

Organ transplant charges vary tremendously. Most of the variation is associated with the hospital stay and resulting length of stay. For example, Solucient reports a standard deviation of $125,000 or more for a majority of organ and tissue transplants in 2000.[3]

We used mean charges, which are significantly greater than median charges in some cases, reflecting the effect the skewness (lack of symmetry) of the charge distribution can have on insurance benefits.

Some transplant centers have addressed the variation in charges by developing separate payment rates, by diagnosis or patient disease stage. The charges shown in this report may require adjustment to reflect diagnosis, disease stage, or other variables specific to a given situation.

Transplant charges can often be negotiated with transplant networks or centers. Significant charge reductions may be obtained, and treatment success maximized, by directing patients to specific transplant centers.

Typically, hospitals charge a case rate or single amount for the hospital admission for the transplant. This charge usually includes physician charges during the transplant admission. Organ procurement charges could be included in the case rate, but most often these charges reflect slight, if any, discounts from billed levels.

In addition to the case rate, an outlier provision provides additional payment to the transplant center. The outlier provision may start after a specified number of days in the hospital, or after a certain level of billed charges. After the outlier starts, the outlier provision may pay for hospital days at either a discount from billed charges, or at a set per diem rate. Transplant centers may request outlier payments for physician services, as well.

Pre- and post-transplant services are usually provided at discounted charge levels, although they could be included in the case rate. Outpatient immunosuppressant drugs are not usually covered, at least in the negotiated transplant arrangements we have observed.

Most formal negotiated arrangements between transplant centers and payers tend to cease one year following the transplant. Our research indicates a significant portion of follow-up costs occur within the first 90 days after discharge for most transplants.

Immunosuppressant and other charges can certainly continue past the first year following transplant. However, charges related to the transplant after the first year may occur within a patient's normal provider network.

Estimated 2002 Billed Charges

Table 17 shows estimated average 2002 first-year charges associated with each type of transplant. These charges reflect our estimate of 2002 billed, not negotiated, charges. Our estimates also reflect more up-to-date information, particularly related to procurement, hospital, and immunosuppressant charges.

TABLE 17

Estimated U.S. Average Billed Charges Per Transplant as of July 1, 2002
First Year Following Transplant

Transplant	Evaluation	Procurement	Hospital	Physician	Follow- Up	Immuno-suppressants	Total
Heart	$16,800	$57,000	$210,400	$29,300	$68,100	$10,200	$391,800
Lung	17,400	58,200	170,400	27,100	57,100	12,800	343,000
Heart-Lung	17,100	115,200	253,800	37,400	68,100	12,800	504,400
Liver	17,200	54,100	131,800	42,700	58,400	9,400	313,600
Kidney	9,500	45,700	32,800	13,500	31,200	10,600	143,300
Pancreas	9,500	43,900	40,200	15,200	31,200	8,900	148,900
Kidney-Pancreas	9,500	89,600	39,400	15,200	31,200	10,600	195,500
Cornea	0	0	7,900	6,300	0	0	14,200
BMT - Autologous	15,100	33,000	122,500	16,000	57,200	0	243,800
BMT - Allogeneic Related	15,100	33,000	188,500	9,800	106,700	9,000	362,100
BMT - Allogeneic Unrelated	15,100	33,000	257,500	9,800	122,900	9,000	447,300
Intestine	31,000	69,600	593,500	55,100	58,400	6,900	814,500

Note: "BMT" is Bone Marrow Transplant

Charge Category Definitions

We defined the categories comprising total charges as follows:

- *Evaluation:* Detailed history of the transplant candidate, noting indications and contraindications for the transplant. The transplant recipient may receive comprehensive physical, psychological, and laboratory evaluations, including blood and tissue typing and serum and cell compatibility matching. Living donor

evaluation costs are also included, if applicable, and may cover blood testing, tissue typing, crossmatching for donor-recipient compatibility, antibody screening, medical and psychological testing, lab tests, X-rays, and other services.

- *Procurement:* Donated organ or tissue recovery services, which may include retrieval, preservation, transportation, and other acquisition costs.

- *Hospital:* Facility charges only, with any re-admissions not involving re-transplantation classified under "Follow-Up." Re-admissions including re-transplantation are classified here. Hospital services may include room and board and ancillary services such as use of surgical and intensive care facilities, inpatient nursing care, pathology and radiology procedures, drugs, supplies, and other facility-based services.

- *Physician:* Professional (i.e., non-facility) services while the transplant recipient is in the hospital, including surgery procedures and other services, and using CPT-4 or HCPCS procedure codes.

- *Follow-Up:* Post-discharge facility and professional services, including any re-admissions to the hospital which do not include re-transplantation. Follow-up services may also include regular lab tests, regular outpatient visits, and evaluation and treatment of any transplant-related complications.

- *Immunosuppressants:* Drugs used, after discharge from the hospital, to reduce the immune system's ability to reject a transplanted organ or tissue. Some examples include cyclosporine (Sandimmune®, Neoral®), mycophenolate mofetil (CellCept), and tacrolimus (Prograf).

General Discussion

We developed evaluation cost estimates by trending past estimates and adjusting the trended estimates, where appropriate, to more closely reflect Milliman managed care research data.

Unlike in prior reports, we have excluded candidacy charges. One could argue candidacy charges should not be allocated to the cost of transplant, since they would be incurred, at any rate, to maintain the patient or keep the patient alive, regardless of whether the patient is waiting for a transplant or not.

We based procurement cost estimates on 2000 data from Washington hospitals, adjusted to national levels. We evaluated the bone marrow procurement cost estimates versus information from the NMDP. We used our judgment in setting the final procurement charge levels based on the data sources used.

We based hospital charges on 2000 Solucient data,[3] and Florida and Wisconsin hospital data.

Physician charges are composed of two pieces, surgeon and other. We based physician surgeon charges on Medicare's 2002 RBRVS unit values, Milliman managed care research data, and judgment. We developed other physician charges based on their estimated relationship to surgeon charges, using Milliman managed care research data and judgment.

We developed follow-up charges based on Milliman managed care research data and our judgment.

Immunosuppressants and Other Drugs Discussion

We developed first-year outpatient immunosuppressant charges using the cyclosporine dosing regimen from RxList, and the estimated 2002 average wholesale price for Sandimmune®. We then adjusted the immunosuppressant estimates using Milliman managed care research data and judgment. We estimated the start of outpatient immunosuppressant coverage using available average inpatient length of stay information.

Actual immunosuppressant charges will be lower than those developed in this report for several reasons:

- We have stated charges on a billed, rather than a discounted, basis.
- We have used Sandimmune® as the basis for billed immunosuppressant charges, because Sandimmune® continues to be a prominent immunosuppressant. However, Sandimmune® is, by no means, the only immunosuppressant alternative. Milliman managed care research data indicated we would calculate only somewhat different estimates if we incorporated other brand-name immunosuppressants (such as Neoral®, CellCept, or Prograf) or generic equivalents, and their recommended dosing regimens, into our analysis.
- We have not fully reflected reduced costs associated with emerging treatment pattern trends. For example, RxList reports a growing trend toward use of lower initial doses, and reduced maintenance doses, for kidney transplants.

In addition, we have not evaluated charges associated with other, non-immunosuppressant drugs, used as a result of transplantation. Antivirals, colony stimulating factors, steroids, antifungal antibiotics, gastrointestinal drugs, hypertension drugs, and post-operative pain management drugs are just some examples of other drugs which could be used as part of a transplant patient's treatment.

Cornea-Specific Information

We developed cornea transplant charges from year 2000 Wisconsin hospital data for inpatient and outpatient procedures, adjusted to national levels. The 2000 Wisconsin data showed physicians perform over 99% of cornea transplants on an outpatient basis, with outpatient cornea transplants representing nearly 98% of billed charges.

Bone Marrow-Specific Information

We based bone marrow and peripheral stem cell hospital charges on separate Solucient data[3] for allogeneic and autologous transplants. We based allogeneic procurement charges on 2000 Washington hospital data. We assumed procurement and evaluation charges for autologous transplants were the same as for allogeneic transplants.

However, the timing of when evaluation and cell collection charges are incurred may be different for autologous, versus allogeneic, bone marrow transplants. For example, cells for an autologous transplant are usually collected shortly before the procedure.

Total first-year autologous bone marrow transplant charges are about 50% of allogeneic-related charges and about 60% of allogeneic-unrelated charges. The differences are due primarily to lower hospital charges and shorter lengths of stay, and no need for immunosuppressant drug charges.

Data for outpatient bone marrow transplants is limited, at best. As a result, the bone marrow charge levels in this report do not reflect any savings from outpatient treatment methods.

Decreasing Lengths of Stay

Since our 1999 report, hospital lengths of stay have decreased for most transplants. Table 18 compares 2000 lengths of stay with 1998 lengths of stay.[3] The lung transplant information in Table 18 comes from Solucient's *Length of Stay* series of printed resources.

TABLE 18

1998 AND 2000 LENGTHS OF STAY

Transplant	1998 Lengths of Stay	2000 Lengths of Stay
Heart	34.9	29.3
Lung	17.8	19.0
Heart-Lung	31.7	32.1
Liver	21.1	18.8
Kidney	9.2	8.6
Pancreas	13.9	10.8
Kidney-Pancreas	NA	NA
Cornea	2.8	2.0
Bone Marrow		
Allogeneic	36.0	32.6
Autologous	25.5	25.2
Peripheral Stem Cell	20.0	19.7
Intestine	NA	NA

COMMON DIAGNOSES AND SURVIVAL RATES

Summary

Table 19 summarizes one-, three-, and five-year patient survival rates by type of transplant. Most of these values are from the UNOS 2000 Annual Report[5]. We based bone marrow transplant survival on information from the ABMTR, IBMTR, and our judgment. Cornea transplant survival is not a significant factor.

Virtually all survival rates, with the exception of heart-lung transplants, have shown improvement since our last report in 1999, as shown in Table 19.

TABLE 19

Transplant Patient Survival Rates, 1997 and 2000

Organ/Tissue	One-Year		Three-Year		Five-Year	
	1997	2000	1997	2000	1997	2000
Heart	85%	86%	76%	77%	69%	70%
Lung	77	77	58	58	43	44
Heart-Lung	75	60	52	51	42	42
Liver	87	88	77	79	72	74
Kidney	96	96	90	91	84	85
Pancreas	93	93	86	89	81	84
Kidney-Pancreas	94	94	87	88	81	83
Cornea	100	100	100	100	100	100
Bone Marrow	71	71	51	51	44	42
Intestine	70	79	44	62	N/A	50

Heart

According to the UNOS 2000 Annual Report[5], the most common primary diagnoses for heart transplants were coronary artery disease and cardiomyopathy, which have consistently accounted for about 86%-88% of 1995-1999 heart transplants. Each indication has consistently been in the 42%-46% range. Congenital and valvular heart disease have accounted for another 7%-8% of cases.

The UNOS 2000 Annual Report[5] indicated 86% of heart transplant patients survive one year, 77% survive three years, and 70% survive five years. The 2000 values are similar to the UNOS 1997 Annual Report data.

Lung

The primary diagnosis for 1999 lung transplants was emphysema/chronic obstructive pulmonary disease, accounting for 42% of lung transplant recipients. Idiopathic pulmonary fibrosis and cystic fibrosis accounted for about 17% and 16% of long transplants, respectively. Other prominent diagnoses included alpha-1 antitrypsin deficiency (7%), primary pulmonary hypertension (4%), retransplant/graft failure (3%), and congenital disease (2%).[5]

In 1999, lung transplant recipients receiving a double lung transplant made up 40.5% of all lung transplants, down from a high of 47.3% UNOS reported in 1996.

According to the 2000 Annual Report from UNOS, one-, three-, and five-year survival rates for lung transplants equaled 77%, 58%, and 44%, respectively.[5] These rates are consistent with data from the UNOS 1997 Annual Report.

Heart-Lung

Congenital disease was the primary diagnosis for heart-lung transplants 33% of the time in 1999, according to the UNOS 2000 Annual Report.[5] Additional prominent indications included primary pulmonary hypertension (18%), emphysema/chronic obstructive pulmonary disease (6%), retransplant/graft failure (6%), and cystic fibrosis (2%). "Other" represented the primary diagnosis for 35% of 1999 heart-lung transplants.

The UNOS 2000 Annual Report reported one-, three-, and five-year patient survival rates of 60%, 51%, and 42%, respectively. These values represented a decline in survival rates from the rates UNOS shows for 1990 through 1995. The 1996 and later survival rates have been consistently, significantly lower than 1990-1995.

UNOS did not risk-adjust the survival rate data for the many factors influencing transplant outcomes. Therefore, it would be inappropriate to infer any variables studied (e.g., donor age, recipient race), by themselves, cause the outcomes shown.

That said, some observations about the declining heart-lung survival rates include:

- *Three-year rates:* 38% of recipients were ages 35-49, and this was the only age group with a survival rate below the composite of 51%; "not hospitalized at the time of transplant" recipients made up 75% of the recipients, and showed a lower survival rate than "hospitalized at the time of transplant" recipients.

- *Five-year rates:* Of the ages measured, rates declined at each successive older age group; a primary diagnosis of "primary pulmonary hypertension," making up 22% of recipients, demonstrated lower survival rates at three and five years, than a congenital disease diagnosis, representing 45% of recipients.

Liver

Non-cholestatic cirrhosis was the most common primary diagnosis for liver transplants, accounting for 62.0% of 1999 liver transplants. Cholestatic liver disease/cirrhosis was the primary diagnosis for 11.0% of 1999 liver transplants. Other common diagnoses included acute hepatic necrosis, biliary atresia, metabolic disease, and malignant neoplasms, which account for about 8%, 5%, 4%, and 3%, respectively, of 1999 liver transplants.[5]

Children and adults have different underlying disease states and problems. The Gale Encyclopedia of Medicine reports, "Biliary atresia is the most common lethal liver disease in children." Adults have different causes of liver failure. Cirrhosis, the eighth leading cause of death by disease, is most commonly caused by chronic alcoholism and hepatitis C.

Nineteen years ago, the Consensus Development Panel on Liver Transplantation, convened by the National Institutes of Health, concluded, "... patients who are judged likely to abstain from alcohol and who have established clinical indicators of fatal outcome may be candidates for transplantation."[7]

A few years later, the Massachusetts Task Force on Organ Transplantation reported active alcoholism should not be an absolute contraindication to liver transplantation, it recommended active alcoholism "... be taken into account insofar as it might affect the (patient's) longevity and prospects for functional rehabilitation..."[8]

One-year, three-year, and five-year survival rates have improved since 1994, and equaled 88%, 79%, and 74%, respectively, using data from the UNOS 2000 Annual Report[5]. According to the University of Pittsburgh, the advent of the immunosuppressant drug Tacrolimus, formerly known as FK506, has contributed to this improvement in survival.

The UNOS 2000 Annual Report[5] indicated adult, ages 18 and over, survival rates equal about 101% and 85% of the pediatric, ages 17 and under, survival rate at one and five years, respectively.

Kidney

The most common primary diagnosis for kidney transplants is glomerular diseases, accounting for about 27% of 1999 kidney transplants. Diabetes was the primary diagnosis for approximately 21% of 1999 kidney transplants. Other prominent diagnoses included hypertensive nephrosclerosis, polycystic kidneys, retransplant/graft failure, tubular and interstitial diseases, and renovascular and other vascular diseases, which accounted for about 14%, 9%, 6%, 6%, and 5%, respectively, of 1999 kidney transplants.[5]

Kidney transplants have long been recognized as a successful treatment for patients with end stage renal disease (ESRD). Many of the current potential candidates for a transplant developed ESRD a number of years ago.

Since dialysis is a viable alternative to a transplant, many candidates are able to survive by using dialysis. However, the number of dialysis patients in Medicare's ESRD program has been growing at a rate of about 8% per year since 1990. As of December 31, 1999, there were over 344,000 enrollees in the Medicare ESRD program.

Graft retention rates were somewhat lower than patient survival rates, reflecting the fact kidney transplant recipients can turn to dialysis in the event of rejection of the transplanted organ. Using data in the UNOS 2000 Annual Report[5], we estimate one-, three-, and five-year graft survival rates to be 91%, 80%, and 69%, respectively. These rates are for kidney transplants only, and include kidneys from living and cadaveric donors.

One-, three-, and five-year survival rates, for recipients of kidneys from living and cadaveric donors, are about 96%, 91% and 85%, respectively, using data from the UNOS 2000 Annual Report[5].

Pancreas and Kidney-Pancreas

In the UNOS 2000 Annual Report, no specific diagnosis categories were listed for pancreas or kidney-pancreas transplants because nearly all pancreas and kidney-pancreas recipients have diabetes as their primary diagnosis. In 1999, diabetes accounted for more than 93% of all kidney-pancreas recipient diagnoses, with another 6% listed as unreported.[5]

Table 20 summarizes the UNOS 2000 Annual Report one-, three-, and five-year pancreas graft survival rates, for pancreas-only and kidney-pancreas transplants:

TABLE 20

UNOS 2000 Annual Report, Graft Survival Rates

Transplant	One-Year	Three-Year	Five-Year
Pancreas-Only	76%	50%	42%
Kidney-Pancreas	84%	74%	67%

The patient survival rates were higher than graft survival rates, reflecting the fact patients with a non-functioning pancreas transplant can return to insulin use for controlling diabetes mellitus. The 2000 UNOS Annual Report showed one-, three-, and five-year pancreas transplant patient survival rates of about 93%, 89%, and 84%, respectively, with kidney-pancreas transplants showing similar results.

Successful pancreas transplant recipients no longer need daily insulin shots, and diabetes-related diseases like eye and nerve degeneration can either stabilize or improve.[2]

Cornea

The most common indications in the United States in 2000 for corneal transplants were pseudophakic corneal edema (19.6%), endothelial corneal dystrophies (14.9%), and ectasias/thinnings (14.5%).[9] Regrafts represent 12.1% of all corneal transplant procedures.

Other diagnosis-related items noted in the 2000 Eye Banking Statistical Report[9] include:

- Fuchs' dystrophy and keratoconus show a slight increasing trend in recent years.
- Infectious causes-viral, syphilitic, and bacterial-continue to show small numbers with little change, as do traumatic causes, mechanical and chemical.

Corneal transplants are the most frequently performed organ transplant procedure. Members of The Eye Bank Association of America provided corneas for 46,949 transplants in 2000, of which 33,260, or about 71%, were performed in the U.S.[9]

Successful corneal transplants depend on a variety of factors, including the surgical technique used, the quality of the donor cornea, the underlying cause of corneal clouding, and the follow-up regimen.

Treatment of graft rejection, within 48 hours, usually reverses the process and maintains a clear cornea. Not all corneal transplants are successful, with re-transplantation necessary in certain cases and an overall vision restoration rate of over 90%.

Most corneal transplant operations are done on an outpatient basis, under local anesthesia. There appears to be minimal follow-up cost necessary, beyond the first year after transplant. We have assumed a 100% patient survival rate.

Bone Marrow

Bone marrow transplants can be classified according to the patient-donor relationship: allogeneic related, allogeneic unrelated, and autologous.

Allogeneic transplants involve receiving stem cells or bone marrow which have been donated by another person. Allogeneic related transplants involve a donation from a genetically matched family member. The most suitable related donor is usually a brother or sister.

A subset of allogeneic related transplants is the syngeneic transplant, which involves identical twins as donor and recipient. Allogeneic unrelated transplants may also be considered, if an unrelated donor's cells are a good match with the recipient.

On the other hand, the patient donates his or her own bone marrow or blood stem cells prior to treatment, for later infusion, in what is known as an autologous transplant.

The most common indications for allogeneic and autologous transplants differ, as follows[10]:

- *Allogeneic:* Acute and chronic leukemias, myelodysplasia (MDS), and non-malignant diseases (aplastic anemia, immune deficiencies, and inherited metabolic disorders).
- *Autologous:* Breast, ovarian, and other solid malignancies, Hodgkin and non-Hodgkin lymphomas, and multiple myeloma.

Overall 1998 common indications for transplant in North America, starting with the most common indication, include breast cancer (nearly one-third of all transplants), non-Hodgkin lymphoma, acute myelogenous leukemia (AML), multiple myeloma, and chronic myelogenous leukemia (CML).[10]

Autologous transplantation is indicated in patients with solid tumor malignancy, the most common being breast cancer and lymphoma.[11] Chemotherapy and/or radiotherapy can be harmful to the patient's bone marrow. To obtain the necessary cells, a portion of the patient's own bone marrow is obtained by needle aspirations, usually from the iliac crest, and placed in storage.

Alternatively, the needed cells can be collected from the blood. The cells are later infused intravenously, after the patient has received chemotherapy and/or radiotherapy. The transplant serves to repopulate the marrow.

The most pressing problem with autologous bone marrow transplants is purging the harvested marrow of tumor cells that may be present. However, the use of autologous, rather than allogeneic, marrow can help avoid the complications of graft-versus-host disease (GVHD).

Bone marrow transplants can also be classified according to whether bone marrow cells or peripheral stem cells (PSC) are used. PSC transplants continue to be the most common type of bone marrow transplant. The advantages of PSC transplants include shorter lengths of stay in the hospital, and less follow-up care required. We estimate about 71% of all bone marrow transplants are PSC transplants.

The development of generalized overall bone marrow transplant survival rates is difficult. Survival depends heavily on the advancement of the underlying disease at the time of transplant.

For example, survival rates are fairly high for autologous bone marrow transplants for Hodgkin's disease, and quite low for acute lymphoblastic leukemia and metastatic breast cancer. The survival rate for bone marrow transplants can also vary significantly, due to the stage of cancer for the patient.

In addition, the bone marrow transplant survival data available to us consisted primarily of studies of sample patient groups suffering from a specific disease. In aggregate, we estimate one-, three-, and five-year survival rates to be 71%, 51%, and 42%, respectively, for bone marrow transplants performed, for all causes combined.

We based the survival rate estimates on information from ABMTR, IBMTR, and our judgment. These rates haven't essentially changed from our 1999 Report, where the survival rates equaled 71%, 51%, and 44%.

Bone Marrow Mini-Transplants[12]

Mini-transplant is the term used to describe several different types of transplant, sharing one common feature - they use lower dosages of chemotherapy and/or radiation than those given to patients who undergo a standard stem cell transplant. As a result, mini-transplants are less toxic and can be tolerated more easily by older people, and those who are too frail to undergo a standard transplant.

The term mini-transplant, however, is somewhat misleading. "Reduced intensity" transplant, referring to the less toxic dosages of chemotherapy and/or radiation, may be a more accurate description.

Since 1997, researchers have been investigating whether reduced intensity transplants might be a viable alternative to a standard stem cell transplant. Preliminary results have been encouraging. The number of reduced intensity transplants performed in the US over the past three years has risen dramatically, from a few in 1997 to more than 1,000 in 2000.

There are several different types of reduced intensity transplants currently under investigation. Although reduced intensity transplants are still in an early stage of study, results thus far suggest they may be a promising treatment option for patients with CML, chronic lymphocytic leukemia (CLL), mantle cell lymphoma, and low-grade lymphoma.

Results in patients with AML, intermediate grade lymphoma, multiple myeloma, and Hodgkin's disease have varied, depending on the type of reduced intensity transplant used.

Researchers have urged caution when interpreting data from the various ongoing trials. The small number of transplants performed and short follow-up periods are the primary reasons for caution.

Although patients receive less toxic dosages of chemotherapy and/or radiation, they are still at risk of developing some serious side effects. Chief among these is graft-versus-host disease (GVHD). GVHD occurs when the donor's immune system cells attack the patient's organs and tissues. More severe cases of GVHD can cause life-threatening liver, stomach, and intestinal problems.

GVHD following a reduced intensity transplant is a major problem to resolve. Managing GVHD can also be tricky, since the same drugs used to prevent GVHD also interfere with the ability of the donor's white blood cells to destroy cancer cells that remain in the patient's body after transplant.

Intestine

According to the Intestinal Transplant Registry, the common indications for intestinal transplants vary for children versus adults. Results presented at the 6th International Small Bowel Transplant Symposium, University of Nebraska Medical Center, October 6-8, 1999, included the following indications:

- Children: volvulus (22%), gastroschisis (22%), necrotizing enterocolitis (12%), and pseudo-obstruction (10%).
- Adults: ischemia (21%), Crohn's disease (16%), desmoid tumor (14%), trauma (12%), and Gardner's disease/familial polyposis (10%).

Based on the UNOS 2000 Annual Report[5], prominent primary diagnoses for 1999 intestinal transplants included short gut syndrome (64%), functional bowel problems (26%), and retransplant/graft failure (6%). Unknown diagnoses represented 20 of the 70, or 28.6%, of 1999 intestine transplants.

Successful intestinal transplants were first performed in the mid-1980's. However, the Intestinal Transplant Registry reports successful transplants have been difficult to achieve for the following reasons:

- The large number of white cells in the bowel provides a strong stimulus for rejection.
- The large number of bacteria in the gut increases the risk of infection after the transplant.

On the other hand, several sources report increases in the number of successful intestinal transplants and improved intestinal transplant survival rates:

- The University of Pittsburgh reports survival over the last five years has improved significantly, due to improvements in surgical technology, the advent of improved immunosuppressant drugs such as CellCept and Zenapax, and better post-operative management.

- The Intestinal Transplant Registry reports improved anti-rejection drugs, refined surgical procedures, and a greater understanding of immunology have contributed to successful intestinal transplants.

- The Transplant Video Journal cites more experienced programs for improvements in outcomes over the last ten years.[1]

The UNOS 2000 Annual Report[5] showed one-, three-, and five-year patient survival rates of 79%, 62%, and 50%, respectively. The Intestinal Transplant Registry showed survival rates about 10%-15% lower, but reported it will take more time to obtain reliable data on long-term results.

Though not shown here, survival rates for pediatric transplant recipients are generally comparable to adult survival rates.

UNOS did not risk-adjust the survival rate data for the many factors that may influence transplant outcomes. Therefore, exercise caution when analyzing survival rate data by variables such as donor age, recipient race, etc. It is inappropriate to infer the variables analyzed by themselves cause the outcomes shown.

Correlation Between Survival Rates and Transplants Performed

Dr. John Roberts, Professor of Surgery at the University of California-San Francisco, coordinated a study of the correlation between survival rates and transplants performed.[1]

Dr. Roberts studied liver transplants, using the following definition for volume:

- High volume: Centers performing 20 or more transplants per year

- Low volume: Centers performing less than 20 transplants per year

Statistical techniques indicated lower survival rates at low volume centers. Possible reasons cited for this correlation include:

- More experienced surgeons and anesthesiologists at the high volume centers

- Greater exposure, with the higher volume, to unique occurrences during transplant, yielding an improvement in techniques and outcomes moving forward

Questions for the Future

Some questions for the future may arise, as we consider the high volume states and centers from Tables 16a through 16h in Section IV, and the information from Dr. Roberts' study:

- What about future quality and outcomes issues, perhaps tied in with volume?

- How could the apparent correlation between survival rates and transplant center volume be used?

Closing transplant centers with poor, or poorer, outcomes could be a future option. However, center closure must be weighed versus patient unwillingness to go too far away from home. Generally speaking, patients still stay close to home, even with lower quality and volumes at the nearest center.[1]

WAITING LIST INFORMATION-1999

The UNOS 2000 Annual Report[5] includes the following 1999 waiting list information, by organ and overall:

- Waiting list patient characteristics, including time waiting, overall counts, and splits by gender, race, age, previous transplant experience, and residency.
- Median waiting times and new registrations based on Organ Procurement and Transplantation Network (OPTN) data.
- Patients ever on the waiting list, reported deaths, and annual death rates per 1,000 patient years at risk.

National Patient Waiting List-1999 versus 11/2/01

Table 21 summarizes the UNOS national patient waiting list at year-end 1999, and as of November 2, 2001:

All waiting lists have increased, with the exception of heart-lung. Out of those transplants with increased waiting lists, only heart transplants have not shown a significant increase in 2001 versus 1999.

For cornea patients, the 2000 Eye Banking Statistical Report[9] reports the number of persons on waiting lists for corneal tissue in the U.S., as of December 31, 2000, equaled 1,125.

TABLE 21

PATIENTS WAITING FOR TRANSPLANT

Organ	Year-End 1999	November 2, 2001
Heart	4,121	4,162
Lung	3,491	3,795
Heart-Lung	232	212
Liver	14,710	18,557
Kidney	46,489	50,305
Pancreas	725	1,169
Kidney-Pancreas	2,225	2,486
Intestine	116	179

Waiting Time Distributions

Table 22 summarizes waiting times from the OPTN waiting lists, as of December 31, 1999. We show kidney transplants separately because of the different measure of waiting times used for kidney transplants.

TABLE 22

YEAR-END 1999, OPTN WAITING LIST, WAITING TIMES

Characteristic	Organ							
	Heart	Lung	Heart-Lung	Liver	Kidney	Pancreas	Kidney-Pancreas	Intestine
Waiting Times								
0 - 30 Days	5.9%	4.4%	2.2%	5.2%		8.0%	7.6%	8.6%
31 - 60 Days	4.4	4.1	2.2	4.5		6.8	8.1	5.2
61 - 90 Days	4.3	4.1	2.5	4.0		5.4	6.0	8.6
3 - 6 Months	10.1	10.3	5.2	11.6		16.8	16.9	16.4
6 - 12 Months	17.2	19.4	15.1	18.9		16.1	21.2	17.2
1 - 2 Years	21.4	26.6	22.0	22.0		18.9	22.1	19.0
2+ Years	36.6	31.2	50.9	33.7		28.0	17.9	25.0
0 - 6 Months					21.2%			
6 - 12 Months					17.6			
1 - 2 Years					24.2			
2 - 3 Years					14.8			
3 - 5 Years					14.4			
5+ Years					7.8			
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Percentages exclude unknown cases and may not add to one due to rounding.

UNOS listed some patients at different centers for the same organ type or for multiple organs. The totals reflect the number of registrations, rather than number of candidates, because the data are not adjusted for multiple candidate listings. UNOS estimates the number of listings, for the same patient at different centers, to be 5% or less of total registrants.

Median Waiting Times

Table 23 summarizes the median waiting times in days, by organ, based on data taken from the OPTN waiting list and removal files as of September 5, 2000, and summarized in the 2000 UNOS Annual Report.[5] We used pre-1999 median waiting times for lung, heart-lung, liver, and kidney transplants, because of cohort sizes less than ten.

TABLE 23

MEDIAN WAITING TIMES BY ORGAN, MEASURED IN DAYS *

1999 Heart	1998 Lung	1997 Heart-Lung	1998 Liver	1997 Kidney	1999 Pancreas	1999 Kidney-Pancreas	1999 Intestine
206	704	889	517	1,099	179	442	285

*All median waiting times are measured in days, using the most recent year with a cohort of at least ten transplants.

The median waiting times are estimates of the length of time by which at least 50% of all patients in the category have received a transplant. If a median waiting time for a category of patients starting in a given year equals 180 days, then a patient starting in that year, with that characteristic, is estimated to have a 50% chance of being transplanted within 180 days.

As with new registrations, the data has not been adjusted for multiple listings, and all calculations are based on patient registrations, not patients.

Each registration's waiting time is defined as the number of days between the date of entry onto the waiting list, and one of the following possibilities:

- September 5, 2000, for registrants still waiting on that date.
- Date of removal from the waiting list due to transplant, or any other reason.

Waiting times continue to increase across all organs, except pancreas. Median waiting time extremes, by organ and by age, include:

Heart: 49 days for ages 1-5, to 269 days for ages 35-49.

Lung (1998 data): 140 days for ages less than one, to 821 days for ages 18-34.

Heart-Lung (1997 data): 289 days for ages 1-5, to 918 days for ages 50-64.

Liver (1998 data): 140 days for ages less than one, to 628 days for ages 50-64.

Kidney (1997 data): 389 days for ages 6-10, to 1,242 days for ages 65 and over.

Pancreas: 157 days for ages 35-49, to 196 days for ages 18-34.

Kidney-Pancreas: 429 days for ages 35-49, to 491 days for ages 50-64.

Intestine: 85 days for ages 35-49, to 396 days for ages 1-5.

New Registrations

Table 24 summarizes the number of new registrations by organ in 1999, based on data taken from the OPTN waiting list and removal files as of September 5, 2000.

TABLE 24

NEW REGISTRATIONS BY ORGAN, 1999

Organ							
Heart	Lung	Heart-Lung	Liver	Kidney	Pancreas	Kidney-Pancreas	Intestine
3,536	2,154	109	10,498	20,946	523	1,806	149

UNOS listed some patients at different centers for the same organ type or for multiple organs. UNOS did not adjust the data for multiple listings. Each cohort consists of patient registrations, rather than patients.

The number of new registrants overall continues to increase. However, new heart and heart-lung registrants actually declined about 10% and 21%, respectively, from 1998 to 1999, with new intestine registrants remaining flat.

Deaths and Death Rates on the Waiting List

Table 25 shows the number of patients ever on the waiting list and the number of patients reported to have died awaiting a transplant, by organ, for 1999. Table 25 also includes the 1999 annual death rates per 1,000 patient years at risk on an overall basis and by organ. Table 25 reflects OPTN data as of September 5, 2000, as taken from the 2000 UNOS Annual Report.[5]

TABLE 25

1999 Patients, Reported Deaths, and Death Rates on the Waiting List by Organ

	Organ								
	Heart	Lung	Heart–Lung	Liver	Kidney	Pancreas	Kidney–Pancreas	Intestine	Total
Patients	7,546	5,074	353	21,267	57,403	952	3,357	229	95,908
Deaths	712	591	53	1,756	3,073	18	169	44	6,143
Annual Death Rate Per 1,000 Patient Years	172.4	181.9	229.8	137.8	78.5	39.5	93.9	416.9	99.4

"Patient years" describes the actual amount of time each patient spends on the waiting list. For example, a patient spending six months on the waiting list contributes one-half year to the calculation.

The annual death rate per 1,000 patient years at risk is calculated as follows:

$$1{,}000^{*}x \quad \frac{\text{Number of patients who died in a given year}}{\text{Sum of years (and partial years) patients spent waiting in a category}}$$

* UNOS chose 1,000 because death rates in some categories could, otherwise, be so low that they produce fractional percentages.

UNOS adjusted the data for multiple reporting of deaths for the same patient, due to multiple registrations for the same patient. So, deaths are not counted more than once for any organ. Also, the number of waiting list deaths does not include patients removed from the waiting list because they are too ill to receive a transplant, and who subsequently die.

Tables 22-25, Additional Data

Additional data, underlying Tables 22-25, may be found in the 2000 UNOS Annual Report.[5] UNOS separates the data into gender, race, age, previous transplant experience, and residency subsets.

DONOR CHARACTERISTICS AND ISSUES

Cadaveric Donors[5]

We obtained cadaveric donor data, as of September 5, 2000, from the UNOS Cadaver Donor Registration Form. The cadaveric donor data only reflects donors recovered by U.S. Organ Procurement Organizations (OPOs).

UNOS defines a recovered, cadaveric donor as one from whom at least one vascularized solid organ-heart, lung, liver, kidney, pancreas, or intestine-was recovered for transplantation.

Organ-specific donors are those from whom at least one organ of that type was recovered. In other words, a kidney donor is one who donated at least one kidney. On the other hand, for example, hearts recovered for heart values are not counted. Also, not all recovered organs are transplanted.

Table 26 summarizes cadaveric donor counts by organ and overall from 1995 to 1999. Liver, kidney, and pancreas donations have increased each year from 1995 to 1999, while heart and lung donations are down from their peaks in the mid-1990's. Intestine donations appear to be rebounding from their 1996 low of 48.

TABLE 26

U.S. Cadaveric Donor Counts by Organ and Overall, 1995 – 1999

	Organ						
Year	Heart	Lung	Liver	Kidney	Pancreas	Intestine	Overall
1995	2,495	880	4,324	4,998	1,277	121	5,358
1996	2,474	758	4,462	5,038	1,294	48	5,418
1997	2,425	836	4,600	5,082	1,319	71	5,477
1998	2,449	764	4,846	5,346	1,458	78	5,801
1999	2,316	781	4,954	5,396	1,627	97	5,849

Cadaveric donors often donate more than one organ. In 1999, an average of 3.6 organs per donor was recovered. Recovered organs may then be:

- Transplanted
- Used for research
- Not used for a variety of reasons, such as organ damage, poor function, or biopsy findings

Table 27 shows the overall number of cadaveric donors and organ transplants over the last five years. In general, the number of cadaveric organ transplants has been about three times greater than the number of cadaveric donors.

Table 28 shows specific cadaveric donor characteristics by organ and overall for 1999. Generally speaking, the gender, race, and age splits have remained consistent over the last five years. We noted no significant changes.

TABLE 27

U. S. Cadaveric Donors and Organ Transplants, 1995 – 1999

Year	Cadaveric Donors	Cadaveric Organ Transplants
1995	5,358	15,783
1996	5,418	15,783
1997	5,477	16,040
1998	5,801	16,752
1999	5,849	16,802

TABLE 28

U.S. Cadaveric Donor Characteristics by Organ and Overall, 1999

Characteristic	Organ						
	Heart	Lung	Liver	Kidney	Pancreas	Intestine	Overall
Count Total	2,316	781	4,954	5,396	1,627	97	5,849
Gender							
Male	66.0%	57.9%	58.0%	57.4%	64.4%	63.9%	57.3%
Female	34.0	42.1	42.0	42.6	35.6	36.1	42.7
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Race							
White	74.8%	75.5%	76.4%	76.6%	77.2%	65.6%	75.9%
Black	11.7	14.0	11.0	10.5	10.4	19.8	11.2
Hispanic	11.5	7.8	10.0	10.2	10.4	13.5	10.3
Asian	1.5	1.6	1.8	1.9	1.2	1.0	1.9
Other	0.5	1.1	0.8	0.8	0.8	0.0	0.8
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Age							
0	2.2%	0.6%	1.2%	0.7%	0.3%	19.8%	1.3%
1 - 5	3.5	1.7	3.4	3.4	0.9	25.0	3.6
6 - 10	2.9	2.8	3.0	2.9	2.5	12.5	2.8
11 - 17	13.7	14.4	9.6	9.5	18.2	6.3	9.1
18 - 34	39.0	37.7	26.3	25.8	42.2	15.6	25.1
35 - 49	28.7	30.6	26.4	27.6	29.9	10.4	27.3
50 - 64	9.6	11.5	20.9	22.2	5.8	7.3	21.9
65+	0.4	0.6	9.2	7.9	0.2	3.1	9.0
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

Table 29 summarizes 2000 cornea transplant donor characteristics:[9]

TABLE 29

U.S. Donor Characteristics, 2000, Cornea

Characteristic	Count or %
Total Donations	85,548
Total Donors	43,432
Gender	
Male	63.3%
Female	36.7
Total	100.0%
Race	
White	91.4%
Black	4.6
Hispanic	3.0
Asian	0.6
Other	0.4
Total	100.0%
Age	
0	0.1%
1-10	1.2
11-20	4.1
21-40	9.7
41-60	33.1
61-70	27.9
71+	23.8
Total	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

Living Donor Data[5]

UNOS based living donor data, as of September 5, 2000, solely on UNOS Living Donor Registration Forms. The living donor data include living donors from whom organs were transplanted in the U.S.

There are a few reasons why the number of transplants using living donors may be different from the number of living donors:

• There is a small number of multi-organ living donors-a living donor might donate a kidney and pancreas segment.

• There is a small number of multiple donors for one transplant-two living donors might each donate a lung lobe for one transplant procedure.

Table 30 summarizes living donor counts from 1995 to 1999. Liver donations have climbed steadily, with a 156% increase, 85 to 218, from 1998 to 1999. Kidney donations have also increased steadily, but more modestly than liver donations.

TABLE 30

U.S. Living Donor Counts by Organ and Overall, 1995 – 1999

	Organ						
Year	Heart	Lung	Liver	Kidney	Pancreas	Intestine	Overall
1995	0	45	46	3,364	7	1	3,457
1996	1	41	56	3,656	11	2	3,757
1997	0	34	76	3,909	6	2	4,022
1998	0	47	85	4,341	2	1	4,475
1999	2	26	218	4,466	5	0	4,712

Table 31 highlights specific 1999 living donor characteristics by the organs studied in detail, liver and kidney, and overall. The numbers of living heart, lung, pancreas, and intestine donors were too small to offer meaningful information and, therefore, are not presented in detail.

The splits by characteristic have remained relatively consistent over time, though the liver characteristics have demonstrated greater fluctuation. In part, greater fluctuation occurs because of the smaller counts involved, where a slight shift represents a larger percentage shift.

TABLE 31

U.S. Living Donor Characteristics by Organ and Overall, 1999

Characteristic	Organ						
	Heart	Lung	Liver	Kidney	Pancreas	Intestine	Overall
Count Total	2	26	218	4,466	5	0	4,712
Gender							
Male	–	–	53.2%	42.1%	–	–	42.7%
Female	–	–	46.8	57.9	–	–	57.3
Total	–	–	100.0%	100.0%	–	–	100.0%
Race							
White	–	–	72.7%	71.8%	–	–	71.9%
Black	–	–	4.9	13.6	–	–	13.2
Hispanic	–	–	16.8	10.3	–	–	10.5
Asian	–	–	2.1	2.4	–	–	2.4
Other	–	–	3.5	2.0	–	–	2.1
Total	–	–	100.0%	100.0%	–	–	100.0%
Age							
0 - 17	–	–	0.0%	0.0%	–	–	0.0%
18 - 34	–	–	51.8	33.6	–	–	34.3
35 - 49	–	–	42.3	47.1	–	–	47.0
50 - 64	–	–	5.8	18.4	–	–	17.9
65+	–	–	0.0	0.8	–	–	0.8
Total	–	–	100.0%	100.0%	–	–	100.0%
Donor Relation							
Parent	–	–	31.4%	17.7%	–	–	18.3%
Offspring	–	–	25.5	17.2	–	–	17.5
Identical Twin	–	–	0.0	0.2	–	–	0.2
Full Sibling	–	–	16.8	35.5	–	–	34.6
Half Sibling	–	–	0.7	1.8	–	–	1.7
Other Relative	–	–	12.4	7.2	–	–	7.4
Spouse Unrelated	–	–	5.1	12.1	–	–	11.8
Other Unrelated	–	–	8.0	8.3	–	–	8.3
Total	–	–	100.0%	100.0%	–	–	100.0%

Percentages exclude unreported cases and may not add to one due to rounding.

Living Donor Facts[5]

Living donors have been used for heart, lung, liver, kidney, pancreas, bone marrow, and intestine transplants, as well as multi-organ transplants including one or more of these organs.

A living donor may donate any of the following:

- Single kidney
- Lobe of a lung
- Segment of the liver
- Portion of the pancreas

A "domino transplant" makes some heart-lung recipients living heart donors. Upon receiving a heart-lung "bloc" from a cadaveric donor, the patient's healthy heart may be given to someone waiting for a heart transplant. Physicians use this procedure when they determine the cadaveric donor lungs will function best if they are used in conjunction with the cadaveric donor heart.

Living donor transplants are a viable alternative for patients needing new organs. There is little danger, for the donor, in living with one kidney. The remaining kidney enlarges to do the work both kidneys previously shared. The liver can regenerate the donated segment, while lung lobes do not regenerate.

Living Donor Advantages

UNOS mentions several advantages to living donation:[5]

1. Living donation may eliminate the recipient's need for placement on the national waiting list. Transplant surgery can be scheduled at a mutually agreed upon time, rather than performed as an emergency operation. The recipient may begin taking immunosuppressant drugs two days before the operation, because the operation can be scheduled in advance. The recipient also has a decreased risk of organ rejection, by taking immunosuppressants ahead of the operation.

2. Transplants from living donors are often more successful, because there is a better tissue match between the living donor and the recipient. The higher rate of organ compatibility also decreases the risk of organ rejection.

3. There can be a psychological benefit in living donation. The recipient may experience positive feelings, knowing the gift came from a loved one or a caring stranger. The donor experiences the satisfaction of knowing he or she has contributed to the improved health of the recipient.

Living Donor Risks and Issues

According to UNOS[5], the Transplant Video Journal[1], and the National Kidney Foundation, there are several ethical and medical risks and issues to keep in mind, related to living donations:

- *Donor Evaluation:* Make sure the donor candidate is physically and psychologically healthy. Living donors must be made aware of the physical and psychological risks involved, before consenting to organ donation.

  Physically, all patients experience some pain and discomfort after an operation, and infections, bleeding, or other injuries are possible.

  Psychologically, living donors may feel pressured by family members to donate, may feel guilty if they are reluctant to go through with the procedure, or may feel resentment if the donated organ is rejected.

- *Anonymity:* Ensure anonymity for the donor and recipient, to keep the donation process purely altruistic.

- *Reimbursement:* Reimburse the donor for expenses only, again to ensure altruism.

- *Health Care Costs and Coverage:* Provide coverage equal to that of cadaveric donation. Health insurance coverage currently varies for living donation. If the recipient is covered by a private insurance plan, most insurance companies pay 100% of the donor's expenses.

  If the recipient is covered by Medicare's end-stage renal disease (ESRD) program, Medicare Part A pays all of the donor's medical expenses, including preliminary testing, the transplant operation, and post-operative recovery costs. Medicare Part B pays for physician services during the hospital stay.

  Medicare covers follow-up care for one full year beyond the donation. Medicare coverage may be extended if complications arise following the donation.

- *Donation Allocation:* Develop and refine workable allocation models, particularly for non-related, also called non-directed, donors.

Donor Registries

Donor registries are another issue important to cadaveric and living donation.

Currently, only 22 states have some form of a donor registry, and these registries exist without national funding, consistency, uniformity, or universal accessibility.[13]

The National Donor Registry Forum, held in late 2001, focused on the following donor registry critical issues: [13]

- Funding - Primarily needed for marketing and education initiatives.

- Education - Needed to increase awareness, to ultimately increase the number of potential donors. For example, only 2% of New York State residents are currently registered as potential donors.

- Structure - Portals of entry currently vary by state, as different states have prospective donors register via state Health Departments, state OPOs, private organizations, or even state Departments of Motor Vehicle.

- Coordination - No coordination exists between existing registries, and OPOs need access, which they do not yet have, to those existing registries.

- Donor Intent versus Consent - Registries need a consistent policy regarding binding consent of prospective donors, to ensure the donor's intent is met.

In addition, the National Donor Registry Forum, while rejecting a National Donor Registry, may look to the federal government for funding and support to coordinate and enhance state-based registries. Specific points related to a coordinated donor registry include:

- Establish minimum guidelines, and states must meet those guidelines to receive federal funding.
- Wait until minimum guidelines are established in the 28 states currently without registries.
- Clarify donor intent versus consent.
- Respect states' autonomy to establish registries.
- Establish a process for registry evaluation and accountability.
- Conduct a national study to address all important registry issues.

Initiatives for Increasing Donation

In an interview with the Transplant Video Journal, Health and Human Services Secretary Tommy G. Thompson summarized the five initiatives for increasing organ and tissue donation:[1]

- Build partnerships with businesses, labor unions, and other organizations to encourage greater donation and improve recruitment.
- Create a National Donor Card, with two family member signatures included on the card to ensure the donor's wishes are clearly known to family members.
- Honor donors and/or their families with a National Gift of Life medal and ceremony.
- Encourage a national dialogue by bringing the transplant community together with state legislators and governors, and discuss such issues as a National Donor Registry.
- Require all driver education courses to include 30 minutes of instruction relating to organ and tissue donation and donation procedures, modeled after the 1999 Wisconsin Act 124, effective July 1, 2000.

Thompson and the Organ Transplant Advisory Committee have also emphasized that making more organs available through increased donation is their shared top priority.[13]

MILESTONES

Transplant milestones in the United States and Canada include:

1954 -	First successful kidney transplant * *Dr. Joseph E. Murray, Brigham & Women's Hospital,*	Boston, MA
1966 -	First simultaneous kidney-pancreas transplant *Drs. Richard Lillehei and William Kelly, University of Minnesota,*	Minneapolis, MN
1967 -	First successful liver transplant * *Dr. Thomas Starzl, University of Colorado Health Sciences Center,*	Denver, CO
1968 -	First isolated pancreas transplant *Dr. Richard Lillehei, University of Minnesota,*	Minneapolis, MN
1968 -	First successful heart transplant *Dr. Norman Shumway, Stanford University Hospital,*	Stanford, CA
1981 -	First successful heart-lung transplant *Dr. Bruce Reitz, Stanford University Hospital,*	Stanford, CA
1983 -	First successful single lung transplant *Dr. Joel Cooper, Toronto Lung Transplant Group, Toronto General Hospital,*	Toronto, CANADA
1986 -	First successful double lung transplant * *Dr. Joel Cooper, Toronto Lung Transplant Group, Toronto General Hospital,*	Toronto, CANADA
1989 -	First successful living-related liver transplant *Dr. Christoph Broelsch, University of Chicago Medical Center,*	Chicago, IL
1990 -	First successful living-related lung transplant *Dr. Vaughn A. Starnes, Stanford University Medical Center,*	Stanford, CA

** First of its kind in the world.*

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