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Report to Congressional Requesters

September 2001

ORGAN TRANSPLANTS

Allocation Policies Include Special Protections for Children

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Abbreviations

AOPO	Association of Organ Procurement Organizations
EPSDT	Early and Periodic Screening, Diagnostic and Treatment Program
ESRD	end-stage renal disease
FPL	federal poverty level
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
OPTN	Organ Procurement and Transplantation Network
UNOS	United Network for Organ Sharing

GAO
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United States General Accounting Office
Washington, DC 20548

September 28, 2001

Congressional Requesters

Organ transplantation can offer individuals with end stage organ disease the opportunity for a healthy life. Organ transplants can be particularly beneficial for children with organ failure. However, pediatric organ transplants involve some special considerations.[1] Children with end stage organ disease face different medical consequences than adults. Disease progression can be faster in children, and their physical and mental development may be affected if they do not receive an organ transplant early in their illness.

With the scarcity of donor organs, children, as well as adults, may wait a long time for a transplant or die while waiting. You raised concerns about the supply of organs and the number of pediatric organs that are allocated to adults. You also raised concerns about how children in need of an organ transplant are faring in comparison with adults waiting for a transplant and whether organ allocation policies sufficiently recognize the unique needs of children. Specifically, you asked us to determine (1) the trends in organ donation and demand among adults and children and the factors that affect pediatric donation, (2) the extent to which pediatric organs are transplanted into adults, (3) whether pediatric patients are disadvantaged in terms of waiting times and survival, and (4) how the national organ allocation policies compare for adult and pediatric patients.

In conducting this study, we interviewed officials and obtained documents from the Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA), which regulates and provides oversight of the Organ Procurement and Transplantation Network (OPTN). We also interviewed officials and obtained documents on organ allocation policies and data on donation, transplant, survival, and waiting times from the United Network for Organ Sharing (UNOS), the organization that coordinates the OPTN for HHS. The OPTN develops policies for organ allocation, maintains the waiting list, and tracks the OPTN data on each patient. We also interviewed officials from the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) about coverage criteria for organ transplants and

[1]The pediatric population includes children aged 17 and younger.

medication therapy because of Medicare coverage for disabled children and children with end stage renal disease. Additionally, we visited six transplant centers that represented different geographic locations and perform a high volume of pediatric organ transplants. At these centers, we interviewed medical and other transplant services personnel and obtained relevant documents about donation and allocation issues, survival measures, and coverage for medication therapy. Representatives from the local organ procurement organization attended meetings we held at four centers, and we separately interviewed officials from two other organ procurement organizations. We also obtained and analyzed data on the causes of death most likely to result in organ donation from the Centers for Disease Control and Prevention's mortality and population database. Because the overwhelming majority of the organs used in transplant operations come from cadaveric donors, the discussion on donor organs in this report is limited to cadaveric organs. We conducted our work from March 2000 through September 2001 in accordance with generally accepted government auditing standards.

Results in Brief

Pediatric patients in need of an organ transplant continue to face a shortage of donated organs. From 1991 through 2000, the number of pediatric organ donors each year has remained relatively constant, despite a drop in the number of potential donors. The number of adult donors has increased 45 percent during the same period, in large part because donor eligibility criteria have been expanded to include older donors and donors with certain diseases that were not accepted in the past. Simultaneously, the demand for organs for pediatric patients has grown substantially, with the number of children on waiting lists for organ transplants more than doubling. However, compared to adults, children account for a small number of transplant candidates. Several factors can prevent the recovery of organs from a potential donor, such as refusal by the family to give consent for donation, failure by health professionals to identify potential donors or approach families, and refusal by medical examiners and coroners to release the body. Nonetheless, organs are recovered from a higher proportion of potential pediatric donors than potential adult donors.

Most pediatric organs are transplanted into adults because adults make up the vast majority of patients waiting for an organ transplant and therefore are more likely to be at a higher status on local organ waiting lists than children. The degree to which pediatric organs are transplanted into adults varies by organ. In particular, adult patients receive more pediatric kidneys than pediatric patients do, partly because of the importance of

tissue-type matching criteria in the allocation of kidneys. The picture differs for livers and hearts, where organs from children aged 11 to 17 are often transplanted into adults, because of size considerations, but organs from children under 10 are usually transplanted into pediatric patients. Adult organs are also transplanted into children, but in much smaller numbers because of size and matching criteria.

Pediatric patients appear to be faring as well as or better than adult patients, both while on the waiting list and after transplantation. On key measures such as time on the waiting list, deaths while waiting for a transplant, and post-transplant survival, children do as well as or better than adults, with some exceptions for very young patients and heart transplant patients. Pediatric patients generally wait fewer days on average than adults for transplants, have lower death rates on the waiting list, and have equivalent or better rates for 1- and 5-year post-transplant survival.

Allocation policies for kidneys, livers, and hearts provide a number of protections for children awaiting transplants. The organ transplant community has recognized the distinctive needs of children waiting for a transplant, and the OPTN has revised organ allocation policies over the past decade to consider the pediatric patient. The priority a child receives takes into account differences between children and adults in the progression and treatment of end stage organ disease, with the policies differing for each organ. For example, the kidney policy strives to reduce waiting time for pediatric patients, in part because of the difficulties they experience with dialysis, and pediatric liver patients now receive priority for livers from pediatric donors because research has shown that pediatric livers will improve pediatric patients' chances of survival after transplant.

HHS and UNOS provided technical comments on a draft of the report which we incorporated, where appropriate.

Background

Transplants are performed for organs such as kidney, liver, heart, intestine, pancreas, heart-lung, and kidney-pancreas. However, the kidney, liver, and heart are the most commonly transplanted organs. In 2000, doctors performed 13,333 kidney, 4,950 liver, and 2,197 heart transplants.[2]

[2]Approximately 39 percent of the kidney transplants and 7 percent of the liver transplants were from living donors.

Of these, children made up 617 of the kidney recipients, 569 of the liver recipients, and 274 of the heart recipients. Organ transplants were performed at 261 centers, which had one or more specific organ transplant programs, in 1998. Some of these centers accept both adults and children, and others are for children only.[3] In 1998, pediatric kidney transplants were performed at 129 of the 241 centers that performed kidney transplants; pediatric liver transplants were performed at 77 of the 116 centers that transplanted livers; and pediatric heart transplants were performed at 54 of the 134 centers that transplanted hearts.

In 1984, Congress enacted the National Organ Transplant Act (P.L. 98-507), which requires HHS to establish the OPTN. In 1986, HHS awarded the OPTN contract to UNOS, which operates the network under HRSA's oversight. The OPTN develops national transplantation policy, maintains the list of patients waiting for transplants, and fosters efforts to increase the nation's organ supply.[4] OPTN members include all transplant centers, organ procurement organizations, and tissue-typing laboratories.

Organ Donation and Allocation

Only a small fraction of those who die are considered for organ donation. Most cadaveric organs derive from donors who have been pronounced brain-dead as a result of a motor vehicle collision, stroke, violence, suicide, or severe head injury.

When an organ becomes available, staff from the local organ procurement organization typically identify potential recipients from the OPTN computerized waiting list. Patients are ranked on the OPTN waiting list according to points assigned on the basis of time waiting, medical urgency,[5] organ size, and the quality of the tissue-type match between the donor and the potential recipient, as determined by antigen matching.[6] The criteria that determine the order of candidates on the list are applied or

[3]No count is maintained of the number of programs that are specifically for pediatric patients.

[4]HHS issued final regulations governing the operation of the OPTN, which became effective on March 16, 2000. Because of concern over geographic disparities in organ allocation, the Final Rule authorizes continuous evaluation and revision of organ allocation policies to achieve an equitable national allocation system.

[5]Medical urgency is measured differently for different organs and may include such factors as life expectancy and intensity of current treatment.

[6]Tissue type is determined by identification of six human-leukocyte-associated antigens.

defined differently for each type of organ and for pediatric versus adult patients. With certain limitations, organs from pediatric donors can be transplanted into adults, and vice versa. The UNOS computer matches each patient in the OPTN database against a donor's characteristics and then generates a different ranked list of potential recipients for each transplantable organ from the donor. Organs are generally allocated first to patients waiting in the local organ procurement organization's service area, with priority based on a patient's severity of illness. If a matching recipient is not found locally, the organ is offered regionally and then nationally.[7] Organ allocation policies are revised from time to time to reflect advancements in medical science and technology.

Children's Health Act of 2000

Title XXI of the Children's Health Act of 2000 (P.L. 106-310, October 17, 2000) requires the OPTN to recognize the differences in organ transplantation needs between children and adults and adopt criteria, policies, and procedures that address the unique health care needs of children. In addition, the OPTN is to carry out studies and demonstration projects for improving procedures for organ procurement and allocation, including projects to examine and to increase transplantation among populations with special needs, such as children and racial or ethnic minority groups. Finally, the act requires the Secretary of HHS to conduct a study and make recommendations regarding the (1) special growth and developmental issues that children have before and after transplant; (2) extent of denials by medical examiners and coroners to allow donation of organs; (3) other special health and transplantation needs of children; and (4) costs of the immunosuppressive drugs that children must take after receiving a transplant and the extent of their coverage by health plans and insurers. (For a discussion of children's access to these necessary medications, see app. I.) The Secretary must report to the Congress by December 31, 2001.

[7]The OPTN has divided the country into 11 regions for allocating organs. Under certain circumstances, regional or national sharing may occur from the outset when medically appropriate or when interregional sharing arrangements exist. For example, regional sharing is allowed for the highest-priority liver patients.

Demand for Organs for Pediatric Patients Continues to Outpace Supply

Pediatric patients in need of an organ transplant continue to face a shortage of donated organs. From 1991 through 2000, the number of pediatric organ donors each year has remained relatively constant, even though the number of potential pediatric donors decreased. The number of adult donors has increased significantly during the same period, in large part because donor eligibility criteria have been expanded to include older donors and donors with certain diseases that were not accepted in the past. Simultaneously, the demand for organs for pediatric patients has grown substantially, with the number of children on waiting lists for organ transplants more than doubling. However, compared to adults, children account for a small number of transplant candidates. Several factors can prevent the recovery of organs from a potential donor. Refusal by the family to give consent for donation is the primary reason for nonrecovery of an organ, but failure by health professionals to identify potential donors or approach families and refusal by medical examiners and coroners to release the body also account for significant losses of transplantable organs. Nonetheless, organs are recovered from a higher proportion of potential pediatric donors than potential adult donors.

Number of Pediatric Organ Donors Has Remained Relatively Constant

The number of pediatric donors has held relatively steady despite a drop in the number of potential donors. Our analysis of 1989 through 1997 mortality data for children showed a 20-percent decline in deaths of the kinds that are most likely to result in organ donation, such as those resulting from head trauma, motor vehicle collisions, and violence. (See app. II for a complete list of these causes of death.) Mortality for potential donors up to age 19 years declined from 24,069 deaths in 1989 to 19,327 in 1997, the latest data available at the time of our analysis (see table 1).

Table 1: Mortality Rates in Children by Age for Deaths Most Likely to Result in Organ Donation, 1989 and 1997

	1989		1997	
Age, years	Number of deaths	Mortality rate[a]	Number of deaths	Mortality rate[a]
Under 1	6,604	163	3,958	102
1-4	2,032	14	1,566	10
5-9	1,712	10	1,328	7
10-14	2,242	13	2,143	11
15-19	11,479	63	10,332	54
Total deaths	**24,069**		**19,327**	

[a]The Centers for Disease Control and Prevention calculates death rates for infants (aged less than 1 year) as the number of deaths per 100,000 live births. For other ages, the mortality rate is based on the number of deaths per 100,000 population.

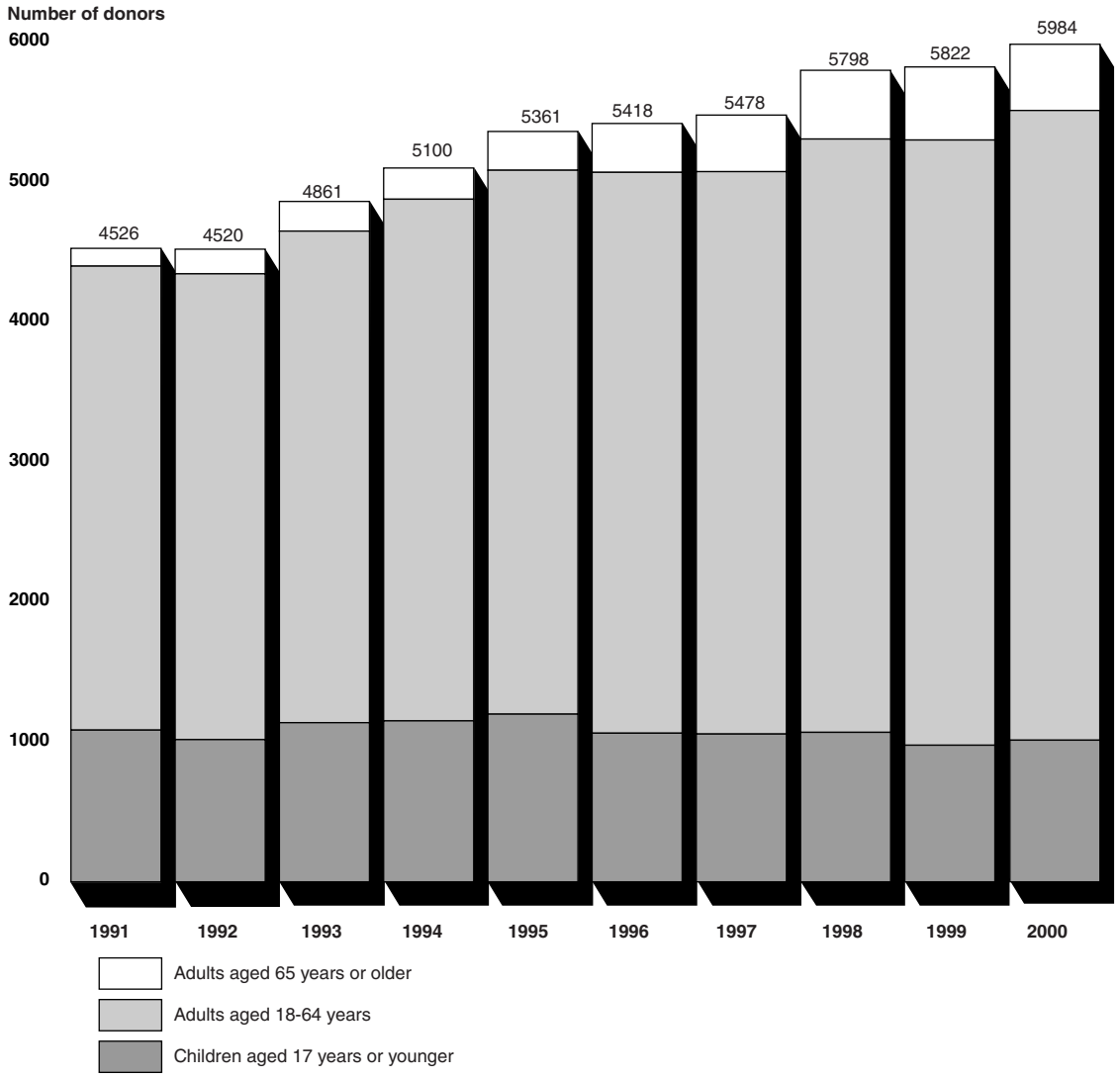
Source: Centers for Disease Control and Prevention, "Compressed Mortality File, CDC Wonder on the Web" (http://wonder.cdc.gov), Apr. 13, 2000.

OPTN data show that from 1991 through 2000, while the number of pediatric donors remained relatively constant, the number of adult donors increased 45 percent (see fig. 1).[8] The large increase in the number of adult donors is primarily due to changes in the criteria for accepting organs from a donor. At one time, organs were accepted only from someone who had been declared brain-dead and was relatively young and free from diseases that could affect organ quality. However, because of the continuing shortage of transplantable organs, transplant professionals have gradually expanded the criteria for acceptable organs. Older individuals and persons with certain medical conditions who previously would have been excluded from donating organs can now be donors.[9] From 1991 through 2000, the number of cadaveric donors aged 50 to 64 increased 108 percent, and the number of cadaveric donors aged 65 or older increased 272 percent.

[8]Throughout this report, we use OPTN data that were current as of the date cited. These data are subject to change based on future data submissions or corrections.

[9]Individuals not routinely considered for organ donation include diabetics and those with systemic infections or abnormal organ functions.

Figure 1: Pediatric and Adult Cadaveric Donors, 1991 Through 2000



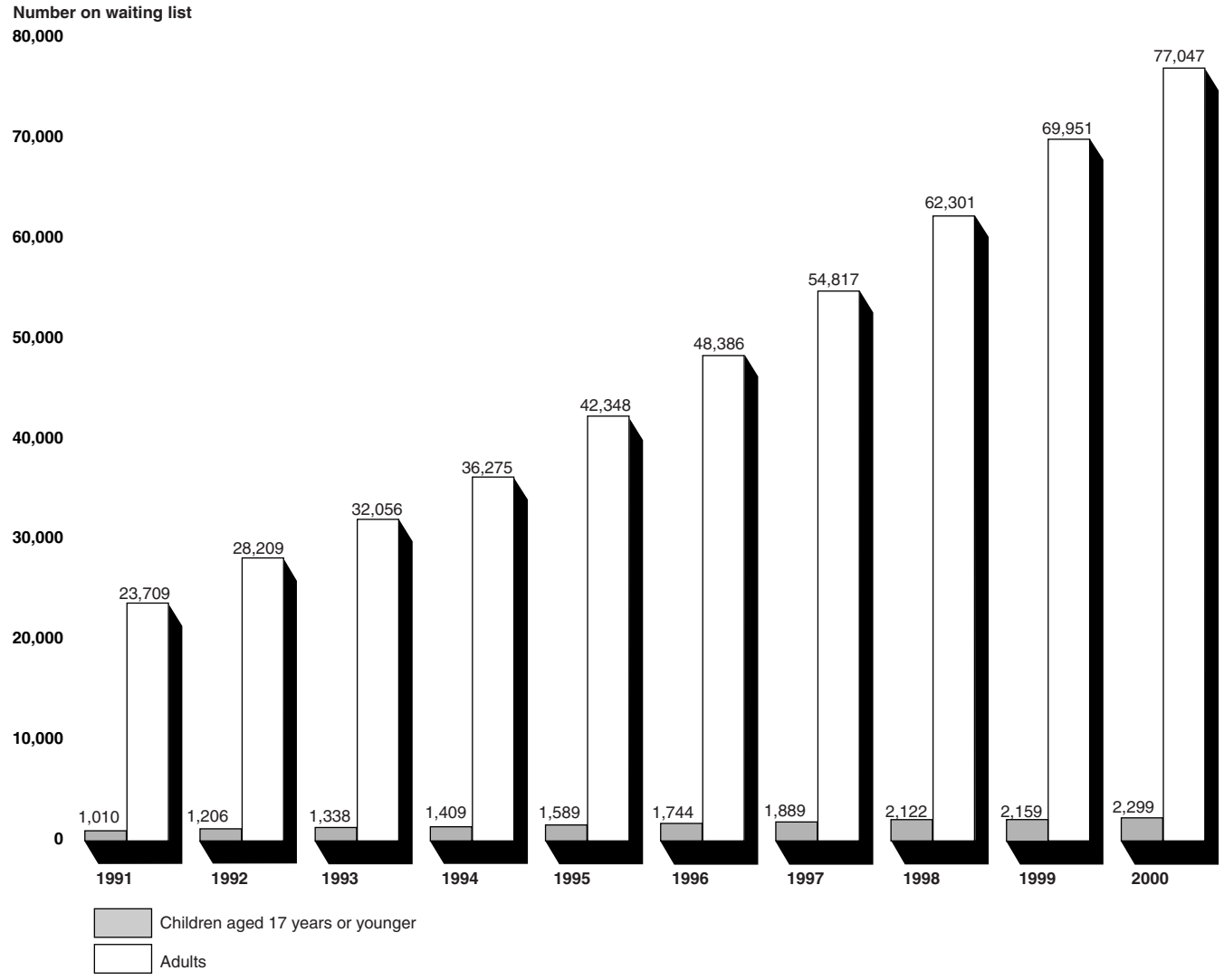
Source: OPTN, June 4, 2001.

Demand for Pediatric Transplants Has More Than Doubled Over the Past Decade

The number of children waiting for a transplant has increased over time, but not as much as for adults (see fig. 2). OPTN data show that the number of pediatric patients awaiting transplants increased from 1,010 in 1991 to 2,299 in 2000, a 128-percent increase. The number of adults on the waiting list has increased even faster, from 23,709 in 1991 to 77,047 in 2000, a 225-percent increase. These increases have been spurred by advances in

medical science and technology, which have made transplantation a more acceptable medical procedure; improvements in immunosuppressive medications, which have increased survival rates; and an increase in the incidence of certain diseases that lead to end stage organ failure. Despite these increases, the proportion of patients awaiting transplant who are children has remained fairly constant from 1991 through 2000, at between 3 and 4 percent overall.

Figure 2: Numbers of Pediatric and Adult Patients on Waiting Lists, 1991 Through 2000



Source: OPTN, June 4, 2001.

Several Factors Can Inhibit Both Pediatric and Adult Organ Donation

Several factors can prevent the recovery of organs from potential pediatric and adult donors and thus contribute to the continuing shortage of transplantable organs for both children and adults. For example, for many potential donors, families refuse to give consent for organ donation. For others, health care professionals may fail to offer the families the opportunity to donate.[10] Further, some medical examiners and coroners believe that the need to preserve forensic evidence in certain types of cases, such as suspected child abuse and sudden infant death syndrome, makes it impossible for them to allow organ donation to proceed.

The Association of Organ Procurement Organizations (AOPO) recently conducted a study at 31 organ procurement organizations on the reasons why potential adult and pediatric donors do not become organ donors. The study found that consent was not given for 39 percent of potential donors and only 41 percent of suitable individuals actually become organ donors.[11]

AOPO provided us with the survey data from the referral, request, and organ recovery processes for the pediatric patients. As our analysis shows in table 2, of the 2,420 potential pediatric donors, organs were recovered in 1,230 cases, or about 51 percent of pediatric cases, a rate higher than the overall donation rate. Family refusal (25 percent) was the most common obstacle to organ recovery, but this occurred less frequently for potential pediatric donors than for the entire group of potential donors.

[10]Centers for Medicare and Medicaid Services regulations require hospitals that participate in Medicare and Medicaid to refer all deaths and imminent deaths to organ procurement organizations as potential donors.

[11]S. Conrad, L. Brigham, E. Sheehy, Association of Organ Procurement Organizations (AOPO) Death Record Review Study. Paper presented at AOPO Briefing of Federal Officials; Nov. 15, 2000, Rockville, Md.

Table 2: Organ Recovery from Potential Pediatric Donors at 31 Organ Procurement Organizations, and Reasons for Nonrecovery, 1997 and 1998

	Number	Percentage of total
Total potential pediatric donors	2,420	
Recovery of at least one organ	1,230	51
No organ recovery	1,190	49
Reason for nonrecovery[a]		
No referral to organ procurement organization	291[b]	12
Referred to organ procurement organization but family not approached	153[c]	6
Referred to organ procurement organization but family refused	597	25
Consent obtained but organs not recovered	136[d]	6

[a]Numbers do not total to 1,190 because of missing information for 13 records.

[b]Hospital staff ruled out 123 cases; families denied consent in 97 cases; medical examiners or coroners refused referral in 14 cases; and 57 cases were not referred for other reasons.

[c]The potential donor was determined to be medically unsuitable in 60 cases; medical examiner and coroner refusals occurred in 38 cases; cardiac arrest occurred before the request could be made in 18 cases; no placement could be made for the organ prior to the request in 5 cases; and the request was not made for other reasons in 32 cases.

[d]The organs were determined to be medically unsuitable in 47 cases; cardiac arrest occurred prior to recovery in 36 cases; unsuccessful placement occurred in 21 cases; medical examiner or coroner denials occurred in 18 cases; and the organs were not recovered for other reasons in 14 cases.

Source: GAO analysis of data from the AOPO Death Record Review Project.

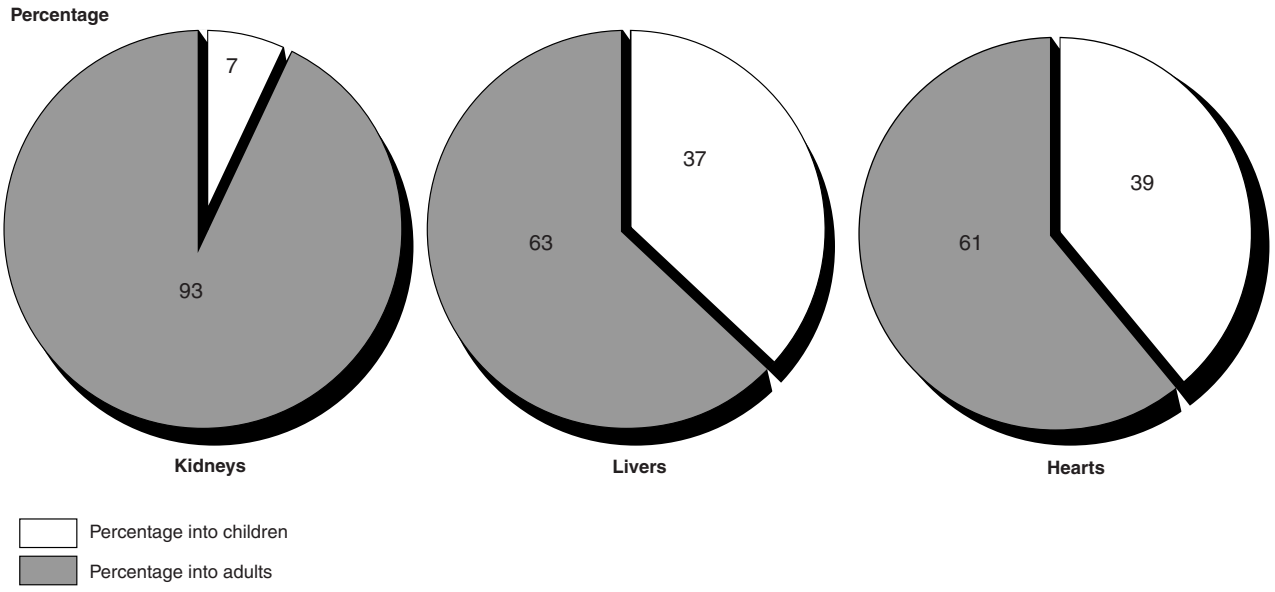
Most Pediatric Organs Are Transplanted Into Adults

Most pediatric organs are transplanted into adults because adults make up the vast majority of patients waiting for an organ transplant and therefore are more likely to be at a higher status on local organ waiting lists than children. However, the degree to which pediatric organs are transplanted into adults varies by organ. In particular, adult patients receive more pediatric kidneys than pediatric patients do, partly because of the importance of tissue-type matching criteria in the allocation of kidneys.[12] While most pediatric kidneys are transplanted into adults, adult kidneys are sometimes transplanted into children. The situation is different for livers and hearts, where organ size is an important determinant of suitability. Livers and hearts from children under 10 are usually transplanted into pediatric patients, whereas those from children aged 11

[12]Although first priority is given to patients for whom a donor kidney is a perfect match, antigen-matching criteria are becoming less important because of improvements in immunosuppressive therapies.

to 17 are usually transplanted into adults. Figure 3 shows the distribution of pediatric kidneys, livers, and hearts to pediatric and adult recipients. (See app. III for a detailed listing of the distribution of kidneys, livers, and hearts by age of donor and recipient.) Pediatric livers and hearts that are given to adults have sometimes been refused beforehand for a pediatric patient by the patient's physician for various medical or logistical reasons.[13] Adult organs are also transplanted into children, but in much smaller numbers.

Figure 3: Distribution of Pediatric Kidneys, Livers, and Hearts by Age of Recipient, 1994 Through 1999



Source: OPTN, June 17, 2000.

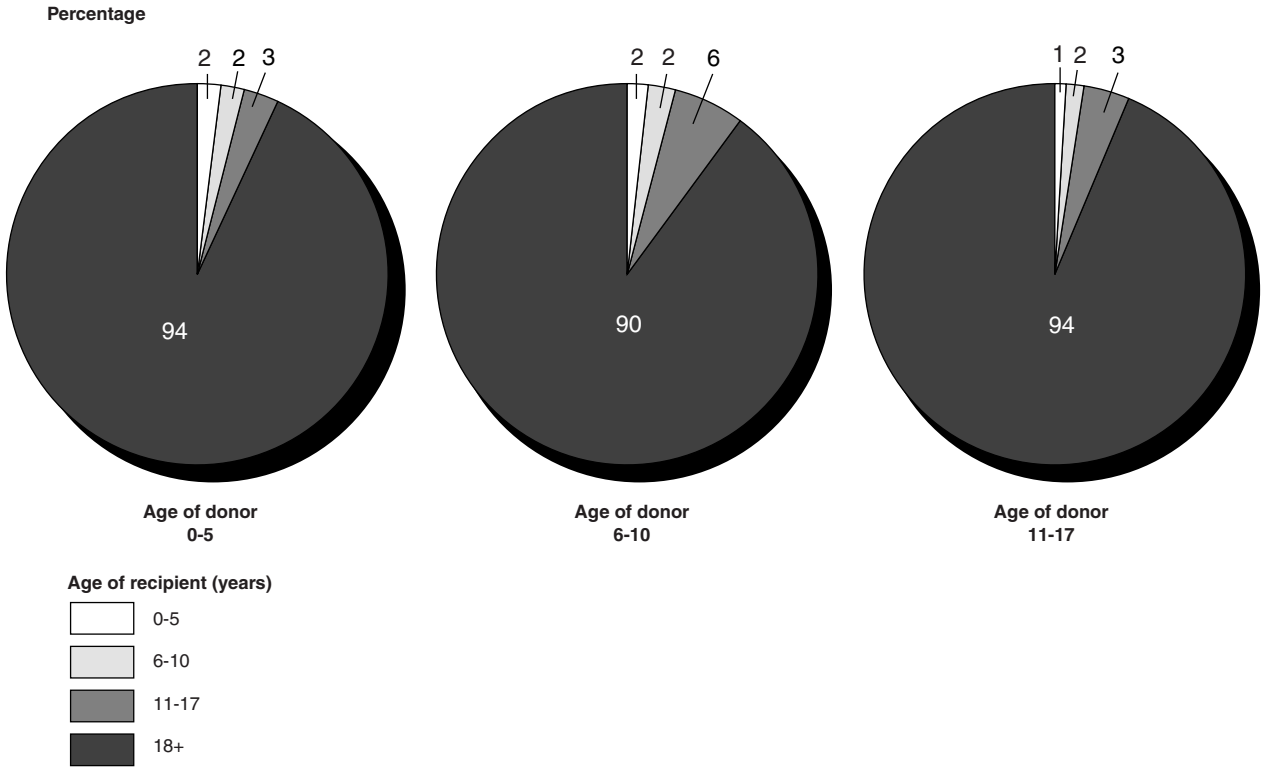
Most Pediatric Kidneys Are Transplanted Into Adults, While Most Pediatric Patients Receive Kidneys From Adults

Although the majority of pediatric kidneys are transplanted into adults, some adult kidneys are transplanted into children. From 1994 through 1999, adult donors provided 81 percent of the kidneys procured and pediatric donors provided 19 percent (see table 4 in app. III). Of the adult kidneys, 4 percent were transplanted into children. Of the pediatric kidneys, 93 percent were transplanted into adults. Figure 4 shows the

[13]Comparable refusal data are not available for kidney transplants.

distribution of pediatric kidneys by age of donor and recipient. During that period, 32 percent of the kidneys given to pediatric recipients came from children, and 68 percent came from adults.

Figure 4: Distribution of Pediatric Kidneys by Age of Donor and Recipient, 1994 Through 1999



Note: Percentages may exceed 100 due to rounding.

Source: OPTN, June 17, 2000.

Kidneys from pediatric donors are most often transplanted into adults because children make up only a small portion of the kidney waiting list[14] and because of the importance of antigen matching as a ranking factor for this organ. Also, the matching criteria for kidneys generally do not include the size (weight and height) of the donor and recipient. When kidneys

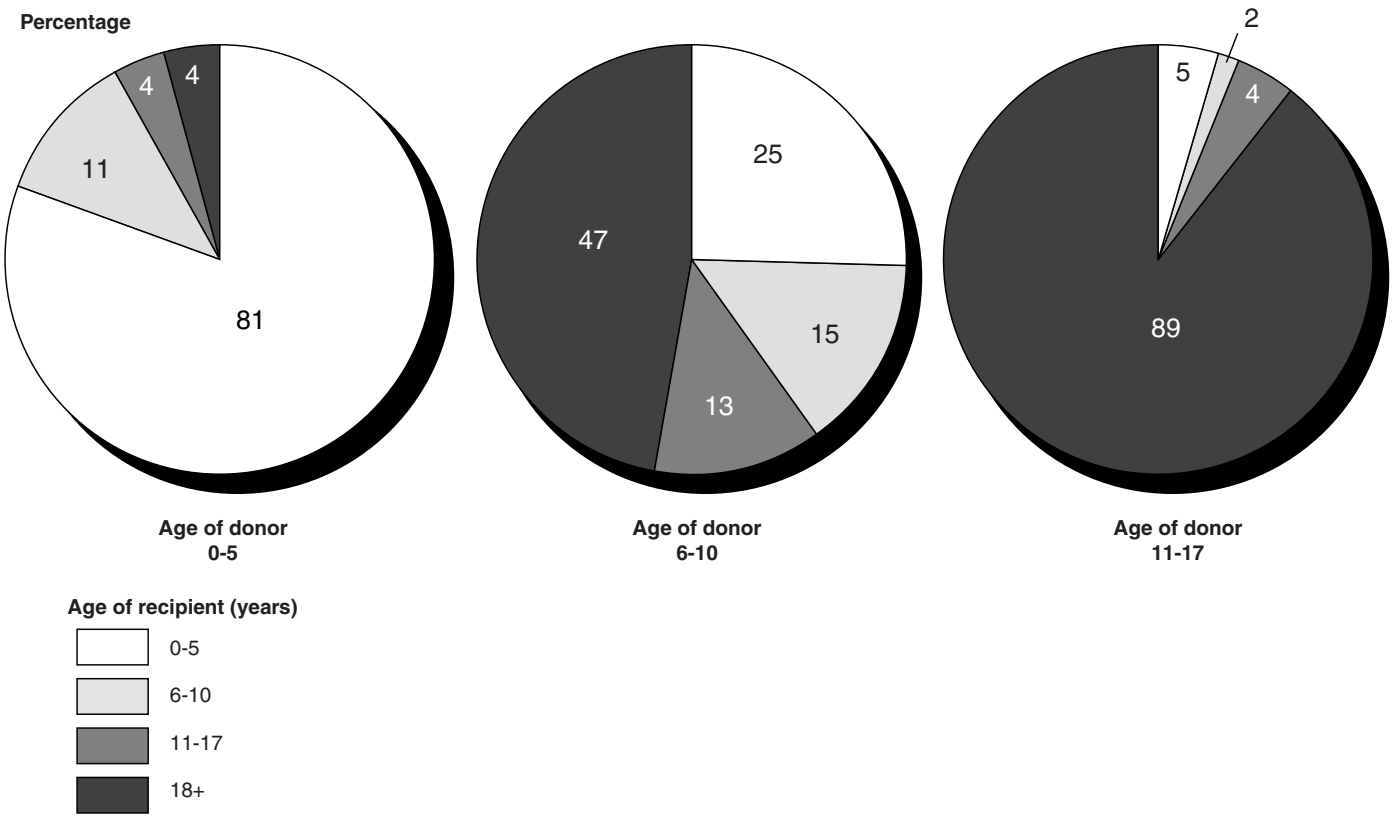
[14]At the end of 1998, 648 children were on the waiting list, compared to 41,744 adults.

from small children are given to adults, they are typically transplanted *en bloc*, meaning that both kidneys are transplanted into the recipient. Transplant center representatives told us that adult kidneys are often preferred for children because of the larger kidney mass. If complications occur, the larger kidney is more apt to continue functioning than a small, pediatric kidney.

Liver Transplants Present a More Varied Picture, but Most Children Receive Pediatric Livers

For liver transplants, the sizes of the donor and the recipient are factors that are considered to obtain an organ of compatible size. From 1994 through 1999, adult donors provided 78 percent of the livers procured and pediatric donors provided 22 percent (see table 5 in app. III). Of the adult livers, 4 percent were transplanted into children. Of the pediatric livers, 63 percent were transplanted into adults, but this varied greatly by age of the donor. Most livers (81 percent) from donors aged 5 years or younger went to recipients in the same age group, and 4 percent went to adults. For the 6- to 10-year-old donors, 47 percent of the livers went to adult recipients, and for the 11- to 17-year-old donors, 89 percent of the livers went to adult recipients. Figure 5 shows the distribution of pediatric livers by age of donor and recipient from 1994 through 1999. During that period, 72 percent of the livers given to pediatric recipients came from children, and 28 percent came from adults.

Figure 5: Distribution of Pediatric Livers by Age of Donor and Recipient, 1994 Through 1999



Note: Percentages may exceed 100 due to rounding.

Source: OPTN, June 17, 2000.

Unlike kidneys and hearts, livers can be reduced in size or split to accommodate the size of the recipient. A reduced-size liver from an adult donor can be transplanted into a pediatric patient. A split liver can yield a portion for an adult and a portion for a child.[15] However, the number of livers that are either reduced or split is small. From 1994 through 1999, fewer than 2 percent of donor livers were reduced for transplantation, and

[15]The liver consists of a right and left lobe. A reduced-size liver graft consists of the left lobe of an adult liver, with the right lobe discarded. In split-liver transplantation, the left lobe of an adult liver is transplanted into a child, and the right lobe is transplanted into an adult.

about 1 percent were split for transplantation. Although using reduced or split livers can provide a needed transplant for children, initial studies found that survival rates were lower for pediatric recipients of these types of liver transplants.[16] However, a recent OPTN analysis of 1997-99 transplants has shown similar 1-year survival rates for whole and split-liver transplants.

Sometimes an organ from a pediatric donor is transplanted into an adult even though there is a higher-ranking pediatric patient waiting. This only occurs if the transplant center refuses the organ for the higher-ranked patient. According to OPTN data, 1,122 liver transplants occurred during 1997 and 1998 in which an adult recipient received a pediatric organ. Of these, 222 livers were each refused for at least one potential pediatric recipient who was ranked higher on the waiting list than the adult recipient. The most common reasons for refusing the pediatric liver for a pediatric patient involved administrative reasons (e.g., medical judgment, transportation, logistics, and distance concerns) (33 percent), donor size and/or weight (26 percent), and poor donor quality (18 percent).[17]

Heart Transplants Are Highly Dependent on Organ Size

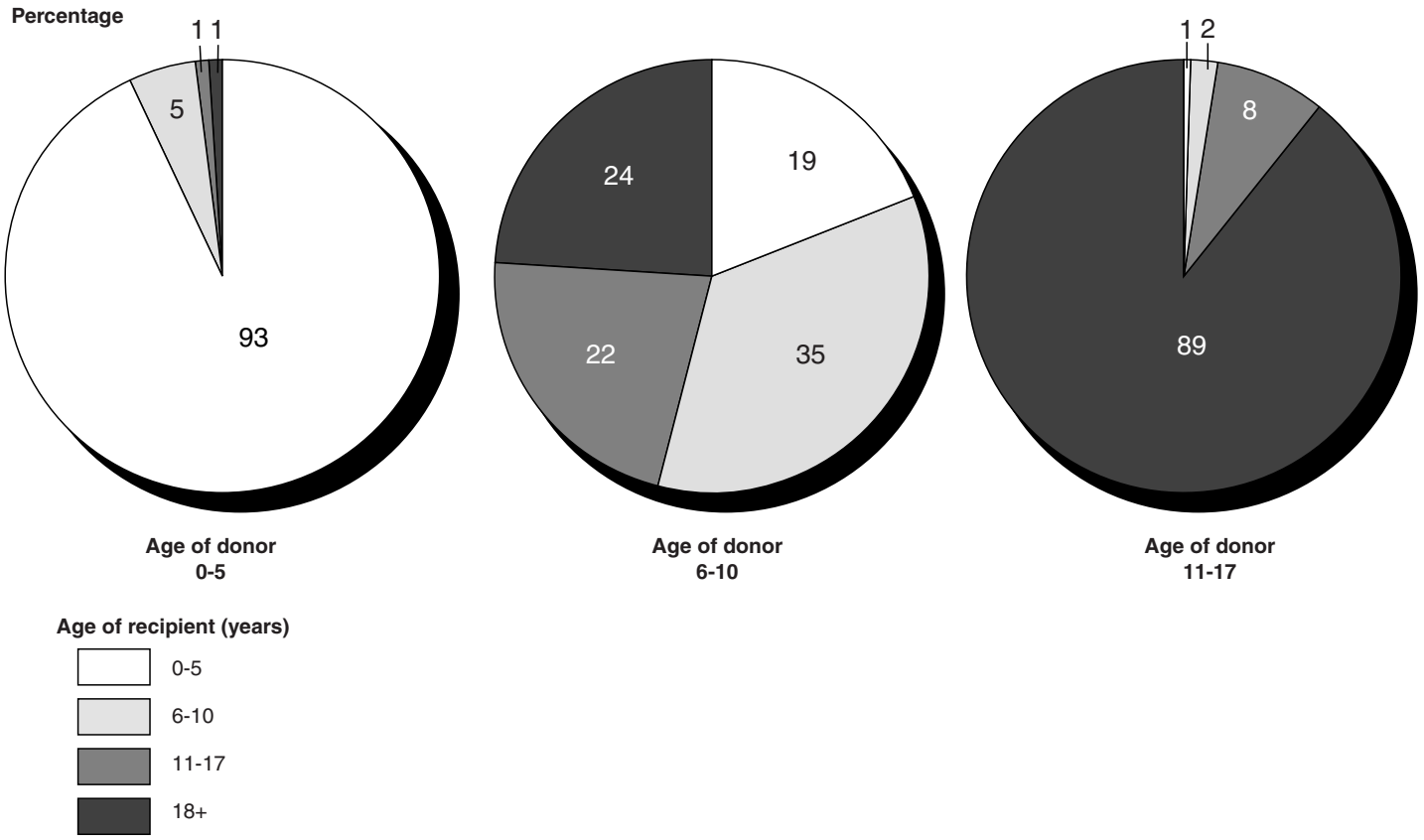
From 1994 through 1999, adult donors provided 75 percent of the hearts procured and pediatric donors provided 25 percent (see table 6 in app. III). Of the adult hearts, 3 percent were transplanted into children. Of the pediatric hearts, 39 percent were transplanted into adults, but this varied greatly by age of donor. For heart transplants, organ size is critically important both to proper functioning and to proper fit into the chest cavity. Hearts from small children, aged 5 years or younger, are therefore likely to be transplanted into children of the same age group. Of the hearts recovered from donors aged 5 years and younger, 93 percent were transplanted into recipients in the same age group, and 1 percent went to adults. During the same period, adults received about 24 percent of the hearts from donors aged 6 through 10 years, and 89 percent from donors aged 11 through 17 years. Figure 6 shows the distribution of pediatric hearts by age of donor and recipient. During that period, 83 percent of the

[16]For the period 1990 through 1996, the rate of graft survival for children at 1 year for whole-liver grafts was 70.9 percent, whereas the rates for reduced-liver grafts and split-liver grafts were 61.1 and 60.3 percent, respectively (N. Scott Adzick and Michael L. Nance, "Pediatric Surgery, Second of Two Parts," *New England Journal of Medicine*, Vol. 342, No. 23 (2000), pp. 1726-32).

[17]Poor donor quality can result from problems with a donor's medical condition, such as hypertension, cardiac arrest, evidence of infection, or diabetes.

hearts given to pediatric recipients came from children, and 17 percent came from adults.

Figure 6: Distribution of Pediatric Hearts by Age of Donor and Recipient, 1994 Through 1999



Note: Percentages may exceed 100 due to rounding.

Source: OPTN, June 17, 2000.

OPTN data indicate that 664 heart transplants occurred during 1997 and 1998 in which a pediatric organ was transplanted into an adult. Of these, 75 hearts were each refused for at least one pediatric patient who was ranked higher on the waiting list than the adult recipient. In these instances, the most common refusal reasons were donor quality (17 percent), donor size and/or weight (17 percent), administrative reasons (14 percent), and abnormal echocardiogram (14 percent).

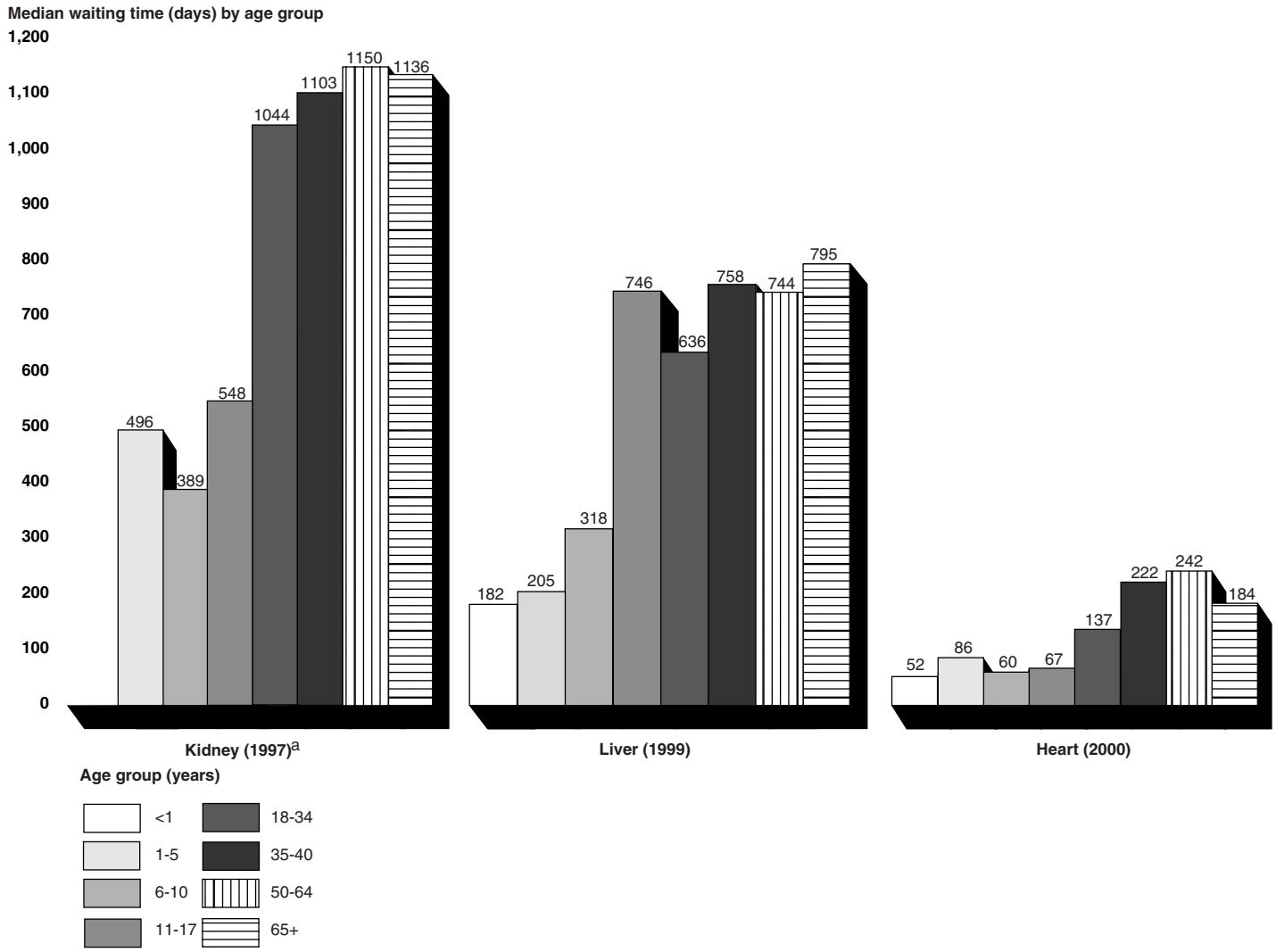
Pediatric Patients Generally Fare As Well As or Better Than Adult Patients on Critical Measures

Although the patterns vary by organ and present a complex picture, pediatric patients appear to be faring as well as or better than adult patients, both while on the waiting list and after transplantation. Data from the OPTN and HHS on four key measures—time on the waiting list, deaths while waiting for a transplant, and 1- and 5-year post-transplant survival—show that children appear to fare as well as or better than adults, with some exceptions for very young patients and heart transplant patients. Other measures of importance for pediatric patients, such as growth and development, are not routinely part of the current OPTN data collection. Pediatric patients wait fewer days on average than adults for transplants. With the exception of infants under 1 year of age and heart transplant patients, death rates for pediatric patients on the waiting list are lower than those for adults. Again with the exception of infants under 1 year old, post-transplant survival rates for children generally appear to be equivalent to or better than those for adult patients at the 1- and 5-year post-transplant points. However, because the number of pediatric patients is small, variation across time by even a few pediatric patients on any of these measures could result in relatively large changes in the percentages. We report on the most current data available.

Pediatric Patients Generally Spend Less Time on the Waiting List Than Adults

In general, pediatric patients wait fewer days than adults for transplants (see fig. 7). Adults are likely to wait about twice as long as children for a kidney transplant. For patients added to the waiting list for a transplant in 1997, the median waiting time for pediatric kidney recipients ranged from 389 days for 6- to 10-year-olds to 548 days for 11- to 17-year-olds, while for adults the range was from 1,044 days for 18- to 34-year-olds to 1,150 days for 50- to 64-year-olds. For livers and hearts, the median waiting time for adult candidates was two to three times as long as it was for children. For livers, median waiting times for patients added to the waiting list in 1999 ranged across age subgroups from 182 to 318 days for children through age 10. For children aged 11 to 17 years, however, the waiting time was similar to waiting times for adults. Candidates aged 11 through 17 years waited 746 days, whereas adult waiting times ranged across age subgroups from 636 to 795 days. Across all age groups, waiting times for hearts were much shorter than they were for kidneys and livers because survival is lower without a transplant. Among heart transplant candidates added to the waiting list in 2000, median waiting times for children ranged from 52 to 86 days and for adults from 137 to 242 days across the different age subgroups.

Figure 7: Median Waiting Times by Organ and Age



[a]Median waiting time for kidney patients under 1 year of age was not calculated owing to the small number of patients.

Note: Data are for patients added to the waiting list for a transplant for a kidney in 1997, a liver in 1999, or a heart in 2000.

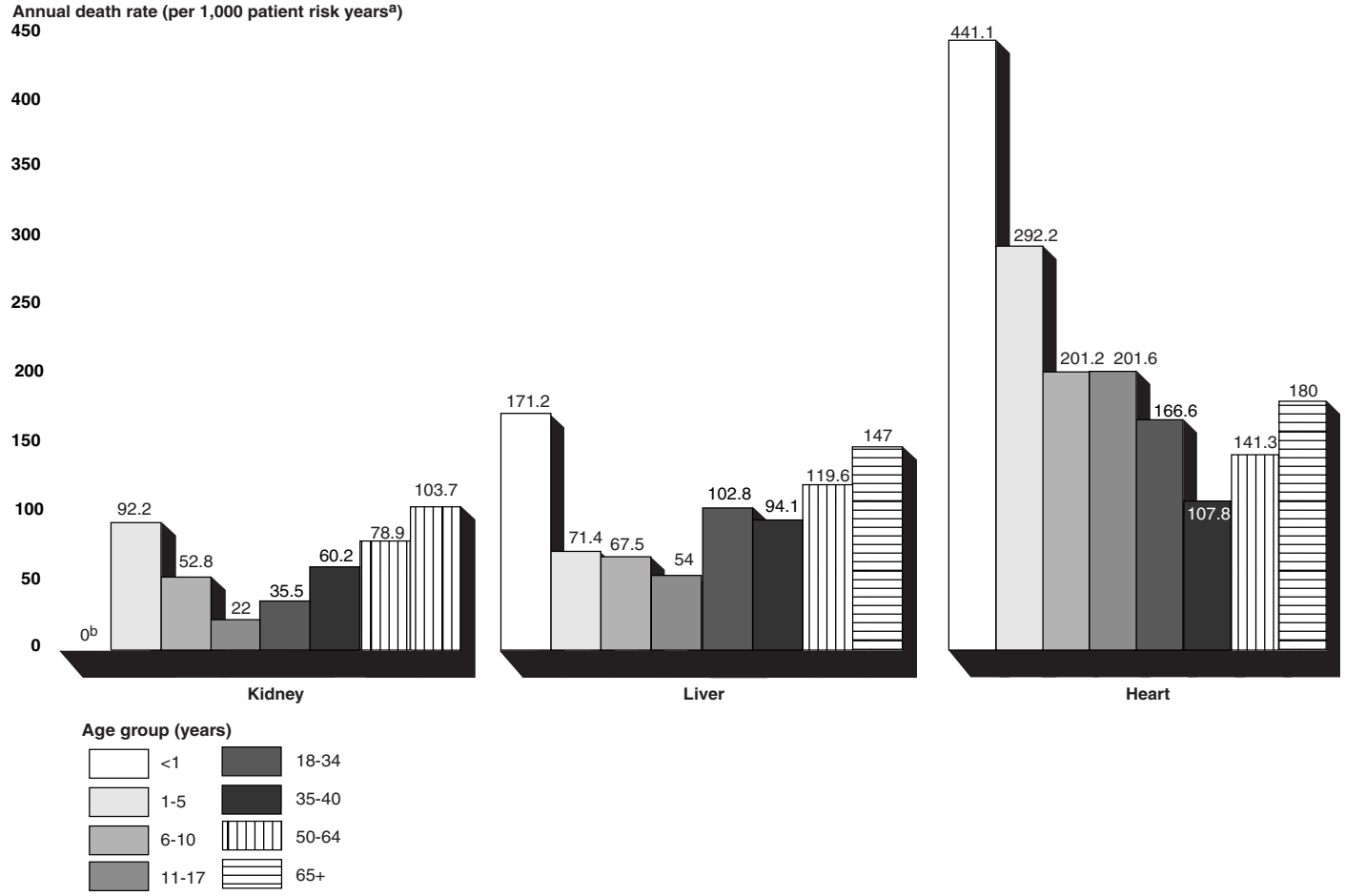
Source: OPTN, June 8, 2001.

Pediatric Deaths While Waiting Vary by Organ

The death rates for pediatric patients on the waiting list vary considerably by organ, with pediatric patients having slightly lower rates than adults for kidneys and livers, but higher rates than adults for hearts (see fig. 8). In

2000, death rates for children waiting for a kidney transplant ranged from 0 to 92 per 1,000 patient risk years (i.e., years on the waiting list), whereas for adults they ranged from 36 to 104. Infants under 1 year old who were awaiting liver or heart transplants had considerably higher death rates than other pediatric or adult age groups; however, pediatric patients aged 1 year or older waiting for a liver transplant had lower death rates than adults. For patients waiting for a heart transplant, pediatric patients of all age groups had higher death rates than did adults.

Figure 8: Deaths on the Waiting List, 2000



[a]Patient-years at risk is calculated as the number of deaths for every 1,000 patient years on the waiting list, based on the actual time waiting for each patient listed.

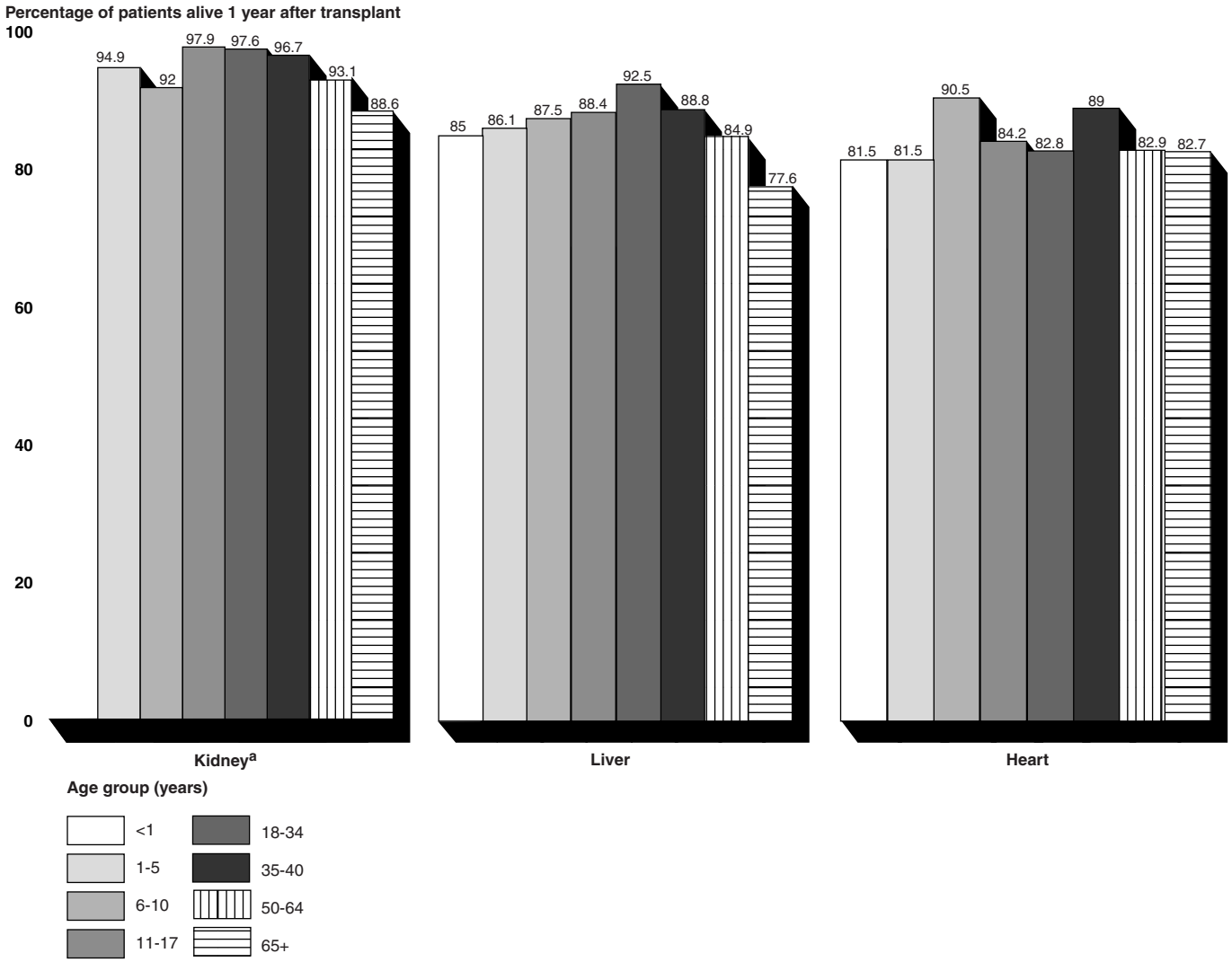
[b]Of 16 kidney patients under age 1, none died while on the waiting list.

Source: OPTN, June 8, 2001.

Pediatric Survival After Transplant Is Generally As Good As or Better Than That for Adults

With the exception of infants under 1 year old, post-transplant survival rates (i.e., the percentage of patients alive at 1 and 5 years after transplant) for children generally appear to be as good as or better than those for adults (see figs. 9 and 10). In general, 1-year survival rates vary more by type of organ than they do by age group, with kidney transplant recipients having the highest survival rates and heart transplant patients having the lowest survival rates. Overall, survival rates for children at 5 years after transplant are better than adult survival for kidneys and livers. Children 5 years old and younger have lower 5-year survival rates for heart transplants.

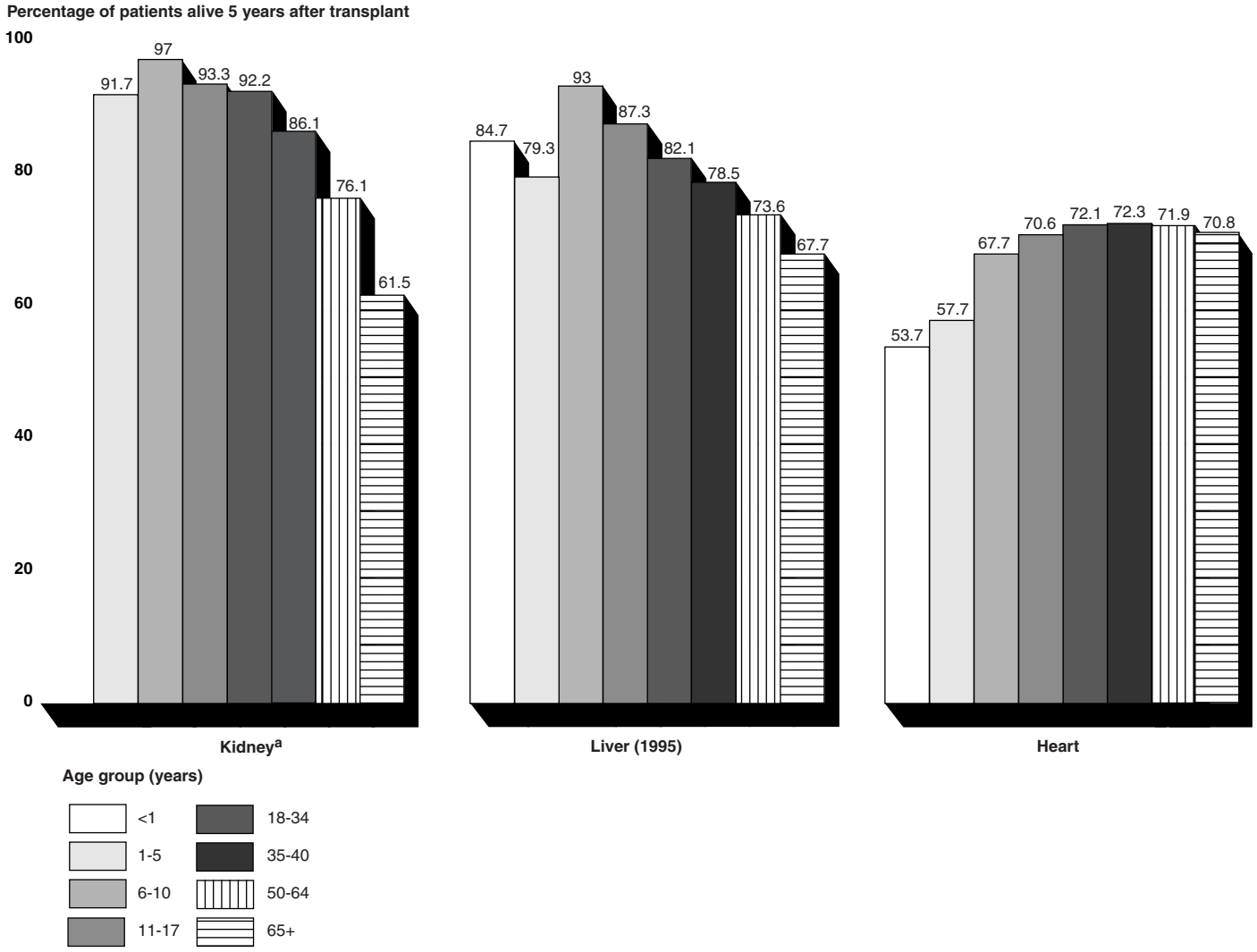
Figure 9: One-Year Survival Rates for Transplants Performed in 1999



[a]Survival rates for infants under 1 year of age for kidney transplants could not be calculated because of an insufficient number of patients.

Source: OPTN, June 8, 2001.

Figure 10: Five-Year Survival Rates for Transplants Performed in 1994 and 1995



[a]Survival rates for infants under 1 year of age for kidney transplants could not be calculated because of an insufficient number of patients.

Source: OPTN, June 16, 2001.

Allocation Policies Aim to Provide Protection for Pediatric Patients

Organ allocation policies provide a number of protections for children awaiting transplants. The organ transplant community has recognized the distinctive needs of children waiting for a transplant, and the OPTN has revised organ allocation policies over time to consider the pediatric patient. The priority a child receives takes into account differences between children and adults in the progression and treatment of end stage organ disease. Prolonged waiting times can be more harmful for children than for adults because disease progression in children can be faster and their growth and development can be compromised without timely transplantation. The policies differ for each organ. For example, waiting time requirements for kidney transplants are less stringent for pediatric patients than for adult patients because of the unique problems children experience with end stage renal disease, including difficulties with dialysis. For livers, research showing better survival for pediatric patients who received a pediatric liver led to a policy change giving priority for pediatric livers to pediatric patients. For hearts, medical urgency status is determined differently for pediatric patients because pretransplant treatments appropriate for adults, such as heart assist devices, cannot always be used for children who are waiting for transplants.

Kidney Allocation Policy Geared to Reduce Waiting Time for Pediatric Patients

Current kidney allocation policy provides several protections for pediatric kidney patients because of the unique problems they experience in association with end stage renal disease. These problems include dialysis difficulties and disruption of growth and development due to renal failure. Early transplantation can avoid or ameliorate many of the effects of end stage renal disease experienced by pediatric patients.

One advantage the allocation policy gives to pediatric patients concerns waiting time, one factor in determining priority for obtaining a transplant. Waiting time for children is measured from when they are placed on the waiting list, whereas, since changes to the adult kidney allocation policy in January 1998, waiting time for adults begins when they reach a certain stage of disease. Therefore pediatric patients can begin moving up in priority on the waiting list at an earlier point in their disease progression than can adult patients.

In addition, pediatric patients receive higher priority for kidney allocation at the time of listing and until they reach 18 years of age, based on their age at listing. The criteria for granting this priority were first implemented by the OPTN in 1990 and have been altered several times, most recently in November 1998. Kidney transplant candidates less than 11 years of age at

listing are assigned four additional points, and candidates aged 11 through 17 years are assigned three additional points.[18]

Another advantage was introduced by the OPTN in November 1998. It provides that patients who are less than 18 years old at listing, and have not received a transplant within a specified amount of time, must be the first in line to receive available kidneys, except for those that must be allocated to a patient with a perfect antigen match, to a patient needing a kidney plus a nonrenal organ, or to a patient whose immune system makes it difficult to receive organs. These specified times are within 6 months of listing for candidates up to and including 5 years of age, 12 months for those from 6 to 10 years, and 18 months for those from 11 to 17 years.

Liver Allocation Policy Seeks to Provide Pediatric Patients With Pediatric Organs

The liver allocation policy for pediatric patients has been revised several times since 1994 to address conditions and challenges unique to pediatric patients. Children with chronic liver disease may deteriorate rapidly and unpredictably. Their growth and development may also be affected. The policy revisions redefine medical urgency criteria, focus on disease progression in children, and recognize factors distinctive to pediatric liver candidates.

In June 2000, the OPTN approved a policy to give pediatric liver transplant patients preference over adult patients for livers from pediatric donors. Prior to the implementation of this change, the age of the donor was not a factor. Now, a pediatric liver is offered to a pediatric patient before an adult patient with the same medical urgency within the same organ distribution area. If no local matches occur in a given medical urgency category, the pediatric liver will be offered to a pediatric patient before an adult patient with the same medical urgency at the regional level. This change was made in response to the finding that pediatric liver transplant recipients have higher survival rates and better graft survival[19] if they are transplanted with a pediatric liver rather than an adult liver. A study showed that pediatric patients receiving livers from pediatric donors during 1992 through 1997 had a 3-year graft survival rate of 81 percent,

[18]According to current allocation policies, patients are ranked on the OPTN waiting list according to points assigned on the basis of time waiting and medical urgency.

[19]Graft survival refers to the length of time the transplanted organ continues to function.

compared to 63 percent for children receiving an adult liver. Adults, however, had similar 3-year graft survival rates regardless of donor age.[20]

The OPTN policy also provides an advantage for pediatric patients with chronic liver failure. The policy places these patients at the highest medical urgency level when their condition worsens, a provision that is not in place for adult patients with chronic liver failure. Moving pediatric patients to the highest category provides the advantage of access to donated organs locally and regionally before all patients in lower categories.

Heart Allocation Policy Gives Some Priority to Pediatric Patients

The heart allocation criteria have also been revised recently to reflect differences in treatment and progression of heart disease between children and adults. Before these revisions, the use of certain mechanical assist devices or other monitoring and treatment therapies was required for any patient to be included in the highest medical urgency categories. However, because some of these devices and therapies are generally not used with pediatric patients, the OPTN removed this requirement for pediatric patients in January 1999. The OPTN implemented two further revisions in May 2000. One change allows pediatric patients on the waiting list for a heart to retain their medical urgency status when they turn 18 rather than being subject to adult criteria. Another revision gives priority to pediatric heart transplant candidates, within each medical urgency category, for hearts recovered from 11- to 17-year-old donors.

Concluding Observations

Children constitute a small proportion of patients in need of an organ transplant, but organ allocation policies have been designed to provide this vulnerable population with some special protections. Our examination of transplantation patterns across age groups and recent data on waiting times and death and survival rates indicates that pediatric patients do not appear to be at a disadvantage in the competition for scarce organs. These data show comparable or better outcomes for pediatric patients even before the most recent policy changes, such as the change to prioritize pediatric livers for pediatric recipients.

[20]Sue V. McDiarmid, Darcy B. Davis, Eric B. Edwards, "Improved Graft Survival of Pediatric Liver Recipients Transplanted With Pediatric-Aged Liver Donors," *Transplantation*, Vol. 70, No. 9 (Nov. 15, 2000), pp. 1283-91. Data from this study were presented to OPTN for consideration prior to publication.

Agency Comments

We provided HHS with the opportunity to comment on a draft of this report. HHS provided technical comments, which we have incorporated where appropriate. We also provided a draft of the report to UNOS, and it provided technical comments, which we have incorporated where appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this letter. We will then send copies to others who are interested and make copies available to others who request them. If you or your staffs have any questions about this report, please call me at (202) 512-7119. Another contact and key contributors to this report are listed in appendix IV.

Janet Heinrich
Director, Health Care—Public Health Issues

List of Requesters

The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce

The Honorable Sherrod Brown
The Honorable William J. Coyne
The Honorable Diana L. DeGette
The Honorable Frank R. Mascara
The Honorable John E. Peterson
The Honorable Henry A. Waxman
House of Representatives

Appendix I: Insurance Coverage for Immunosuppressive Drugs for Children

Coverage for immunosuppressive medications may be extended to children under Medicare, Medicaid, and private insurance. Pediatric patients may also gain access to prescription drug coverage through special state insurance programs for children. However, both adults and children may have difficulty in obtaining and retaining insurance coverage for the expensive immunosuppressive medications[1] necessary for survival following transplantation. Further, gaps in coverage may occur during a transition from one type of insurance to another. For example, if a parent loses Medicaid eligibility, a child's eligibility status could also be affected. In addition, coverage problems can arise for both Medicaid- and private-insurance-covered pediatric patients when they reach adulthood. Transplant recipients covered by Medicaid as children may become ineligible for continued coverage if they are able to obtain employment as they reach adulthood. Children covered by private insurance under a parent's policy may be unable to afford coverage, given their expensive preexisting medical condition, when they grow too old to be covered by a parent's policy. Data on the costs of immunosuppressive medications, actual payments, and patient cost-sharing by the various insurers are not readily available, so the level of the coverage cannot be specified with certainty.

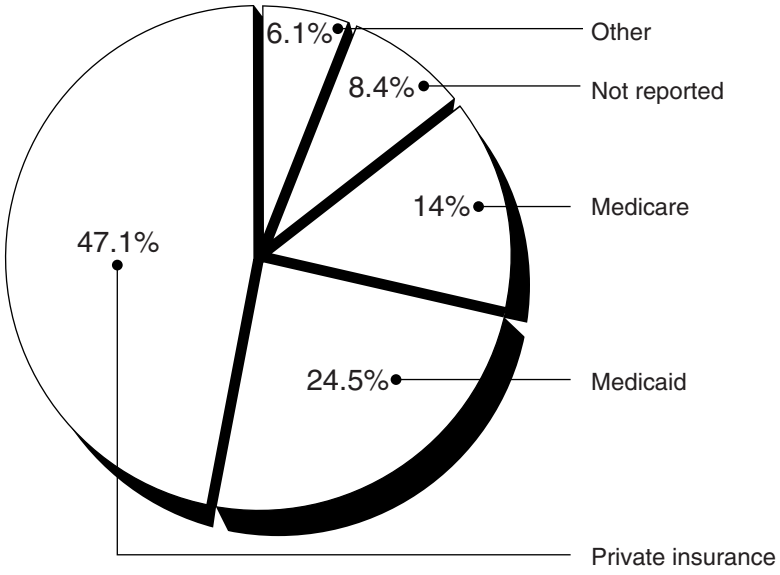
Sources of Payment for Transplants

The proportion of transplant patients covered by different insurance programs can be used to derive an indication of coverage for immunosuppressive medications. Data from the Organ Procurement and Transplantation Network (OPTN) on the expected sources of payment for the pediatric transplants performed from 1997 through 1999 may serve as a general estimate of the share of immunosuppressive medications for children paid for by Medicare, Medicaid, and private insurance. OPTN data show that 4,835 transplants were performed on children up to age 17 from 1997 to 1999. Of these, 2,775 transplants were for livers and hearts, and 2,060 were for kidneys. As figure 11 shows, private insurance paid for almost half of the pediatric transplants for these three organs performed from 1997 through 1999, while Medicaid paid for 25 percent and Medicare paid for 14 percent of these transplants. For the same period, Medicare paid for an estimated 30 percent of pediatric kidney transplants because of

[1]In 1999, the average annual charges for immunosuppressive medications for kidney, liver, and heart transplant recipients ranged from $11,400 to $13,600 (Richard H. Hauboldt, *Cost Implications of Human Organ and Tissue Transplantations, An Update: 1999* (Brookfield, Wisc.: Milliman & Robertson, Inc., 1999)).

its special coverage for kidney patients under the End-Stage Renal Disease (ESRD) program.

Figure 11: Expected Sources of Payment for Pediatric Kidney, Liver, and Heart Transplants, 1997 Through 1999



Source: OPTN, April 23, 2000.

Medicare Coverage for Immunosuppressive Drugs

Medicare coverage for transplants and the associated medications is provided to children either under a special entitlement to the Medicare program created by the Congress for those diagnosed with ESRD or by virtue of a parent's enrollment as an eligible Medicare beneficiary.

The Medicare program has special entitlement rules for patients with ESRD, the stage of kidney impairment that is considered irreversible and requires either regular dialysis or a kidney transplant to maintain life. To be eligible for Medicare entitlement as an ESRD patient, the patient generally must have been on dialysis for 3 months and must be (1) entitled to a monthly insurance benefit under title II of the Social Security Act (or an annuity under the Railroad Retirement Act), (2) fully or currently insured under Social Security, or (3) the spouse or dependent child of a

person who meets at least the first 2 requirements.[2] Currently, ESRD patients' entitlement to Medicare—and thus coverage for immunosuppressive medications—ends 36 months after a transplant is performed.[3]

In contrast, individuals who are eligible for Medicare under other entitlement rules—that is, age 65 or disabled, and eligible for Social Security or Railroad Retirement benefits—currently receive unlimited coverage for immunosuppressive drug medications for the life of the transplant under Part B.[4] Originally, Medicare limited immunosuppressive drug coverage to 1 year. However, the Omnibus Budget Reconciliation Act of 1993 (P.L. 103-66) expanded this coverage with a series of annual 6-month increases beginning in 1995. As a result, by 1998, Medicare patients received immunosuppressive medication coverage for 36 months after a transplant operation. In 1999, the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (P.L. 106-113) extended this immunosuppressive drug coverage benefit for an additional 8 months. Most recently, the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (P.L. 106-554) eliminated all time limits for immunosuppressive drug coverage under Part B of Medicare.

Medicaid Coverage for Immunosuppressive Drugs

Medicaid is a joint federal/state entitlement that annually finances health care coverage for more than 40 million low-income individuals, over half of whom are children. Medicaid coverage for children is comprehensive, offering a wide range of medical services and mandating coverage based upon family income in relation to the federal poverty level (FPL). Federal law requires states to cover children up to age 6 from families with incomes up to 133 percent of the FPL, and children ages 6 to 15 for incomes up to 100 percent of the FPL. Medicaid benefits are particularly important for children because of Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Program. EPSDT, which is

[2]For ESRD participants, Medicare pays secondary to employer-sponsored group health plans for the first 30 months.

[3]An ESRD patient may be eligible for immunosuppressive drug coverage if, after 36 months, the patient is otherwise entitled to Medicare based on age and/or disability.

[4]Medicare insurance consists of two parts, Part A, which covers in-patient hospital expenses, and Part B, which covers other medical expenses including physician, outpatient hospital, laboratory, and other services such as immunosuppressive drug therapy. Beneficiaries must pay a premium for Part B coverage, currently $50 per month, and are also responsible for Part B deductibles, coinsurance, and copayments.

mandatory for categorically needy children, provides comprehensive, periodic evaluations of health and developmental history, as well as vision, hearing, and dental screening services to most Medicaid-eligible children.[5] Under EPSDT, states are required to cover any service or item that is medically necessary to correct or ameliorate a condition detected through an EPSDT screening, regardless of whether the service is otherwise covered under a state Medicaid program. This would include immunosuppressive drugs.[6]

Private Insurance Coverage for Immunosuppressive Drugs

Private insurance, such as employer-sponsored health plans, generally covers all aspects of organ transplants, including follow-up care and necessary medications. Information is not readily available on private insurance coverage specifically for immunosuppressive medications. However, according to a 1998 national survey of employer-sponsored health plans, nearly all employers that offer health benefits include benefits for outpatient prescription drugs.[7] In addition, a Kaiser Family Foundation survey of employer health benefits found that 96 percent of all firms with conventional fee-for-service plans and 99 percent of those with managed care plans cover prescription drugs.[8]

[5]The categorically needy includes low-income children; pregnant women; aged, blind, or disabled people meeting Supplemental Security Income program requirements; and individuals who are eligible to receive federally assisted income maintenance payments. The EPSDT benefit is optional for the medically needy population, who generally have too much income to quality for Medicaid, but have "spent down" their income by incurring medical and/or remedial care expenses. See 42 USC 1396(a)(10)(C). If a state chooses to provide one EPSDT service, it must provide all EPSDT services to medically needy individuals under age 21. The medically needy comprise individuals whose income, resources, or both exceed the levels for the categorically needy, but who cannot afford to pay their medical bills.

[6]The Institute of Medicine reported that kidney, heart, and liver transplants are covered services under Medicaid in nearly all states. See *Organ Procurement and Transplantation, "Assessing Current Policies and the Potential Impact of the DHHS Final Rule,"* (Washington, D.C.: National Academy Press, 1999). Generally, once a transplant is approved, immunosuppressive drugs and medications to maintain the organ are also approved.

[7]Mercer/Foster Higgins, *National Survey of Employer-Sponsored Health Plans 1998*, a survey of all U.S. employers with 10 or more employees.

[8]The Kaiser Family Foundation and Health Research and Educational Trust, *Employer Health Benefits, Annual Survey, 1999* (Menlo Park, Calif., and Chicago, Ill., 1999).

Privately insured organ transplant patients most likely will incur additional expenses for medications, however, such as out-of-pocket expenses for deductibles and copayments, because of limits on coverage. A recent survey of employers with 1,000 or more employees on strategies to control prescription drug expenditures found that 6 percent of employers cap annual benefits and 10 percent are considering doing so.[9] The study also found that 41 percent of employers limit the quantities of prescription drugs and 7 percent are considering it. Moreover, 40 percent of employers now require higher copayments than previously, and 39 percent are considering it.

[9]Hewitt Associates, *Health Care Expectations: Future Strategy and Direction, 2001* (Lincolnshire, Ill.: 2001).

Appendix II: Causes of Death Most Likely to Result in Organ Donation

The causes and circumstances of death that could reasonably result in a declaration of brain death and from which organ donation might be possible are listed in table 3.[1] We used the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes to classify deaths by causes and circumstances.[2]

[1]See *Organ Procurement Organizations: Alternatives Being Developed to More Accurately Assess Performance* (GAO/HEHS-98-26, Nov. 26, 1997), where we developed this list.

[2]Medical staff use ICD-9-CM codes at the time of death to indicate cause of death on the death certificate.

Table 3: Causes of Death Most Likely to Result in Organ Donation

ICD-9 CM Code	Description
430-438	Cerebrovascular disease
798.0	Sudden infant death syndrome
E810-E825[a]	Motor vehicle accident
E830	Accident of watercraft causing submersion
E832	Other accidental submersion or drowning in water transport accident
E850-E858	Accidental poisoning by drugs, medicinal substances, and biologicals
E910-E913	Accidental submersion, suffocation, and other foreign bodies
E920	Accidents caused by cutting and piercing instruments or objects
E922	Accidents caused by firearm missile
E930-E950.5	Drugs, medicinal and biological substances causing adverse effects in therapeutic use, suicidal and self-inflicted poisoning by solid or liquid substances
E953-E955.4, E956, E958.5	Suicide
E962.0	Assault by poisoning
E963	Assault by hanging and strangulation
E964	Assault by drowning
E965-E965.4	Assault by firearms and explosives
E966	Assault by cutting and piercing instrument
E970	Injury due to legal intervention by firearms
E974	Injury due to legal intervention by cutting and piercing instrument
E980.0-E980.5	Poisoning, undetermined whether accidentally or purposely inflicted
E983	Hanging, strangulation, or suffocation undetermined whether accidentally or purposely inflicted
E984	Drowning, undetermined whether accidentally or purposely inflicted
E985-E985.4	Injury by firearms, undetermined whether accidentally or purposely inflicted
E986	Injury by cutting, piercing instruments, undetermined whether accidentally or purposely inflicted

[a]E codes permit the classification of environmental events, circumstances, and conditions as the cause of injury, poisoning, and other adverse effects.

Appendix III: Distribution of Kidneys, Livers, and Hearts, 1994 Through 1999

The following tables show the distribution of kidneys, livers, and hearts procured from all donors from 1994 to 1999, by age of donor and recipient.

Table 4: Distribution of Kidneys, 1994 through 1999

	Recipients					
Donors	0-5 years	6-10 years	11-17 years	Total children	Total adults, 18 and over	Total recipients
0-5 years	27	23	47	97	1,412	1,509
6-10 years	29	38	99	166	1,479	1,645
11-17 years	55	88	227	370	5,477	5,847
Total children	111	149	373	633	8,368	9,001
Total adults, 18 and over	168	272	902	1,342	36,449	37,791
Total	**279**	**421**	**1,275**	**1,975**	**44,817**	**46,792**

Source: OPTN, June 17, 2000.

Table 5: Distribution of Livers, 1994 through 1999

	Recipients					
Donors	0-5 years	6-10 years	11-17 years	Total children	Total adults, 18 and over	Total recipients
0-5 years	1,052	148	51	1,251	55	1,306
6-10 years	215	124	107	446	399	845
11-17 years	151	53	149	353	2,982	3,335
Total children	1,418	325	307	2,050	3,436	5,486
Total, adults, 18 and over	326	128	341	795	18,128	18,923
Total	**1,744**	**453**	**648**	**2,845**	**21,564**	**24,409**

Source: OPTN, June 17, 2000.

Table 6: Distribution of Hearts, 1994 through 1999

	Recipients					
Donors	**0-5 years**	**6-10 years**	**11-17 years**	**Total children**	**Total adults, 18 and over**	**Total recipients**
0-5 years	752	44	3	799	9	808
6-10 years	66	118	76	260	81	341
11-17 years	11	44	180	235	1,959	2,194
Total children	829	206	259	1,294	2,049	3,343
Total adults, 18 and over	8	20	236	264	9,978	10,242
Total	**837**	**226**	**495**	**1,558**	**12,027**	**13,585**

Source: OPTN, June 17, 2000.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse, (202) 512-3407

Acknowledgments

In addition to the above, Donna Bulvin, Charles Davenport, Roy Hogberg, Behn Miller, and Roseanne Price made key contributions to this report.

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