

OPTN/UNOS: PEDIATRIC DATA ONLY
Deceased Donor Liver Transplants by Era: Liver-Intestine Transplants EXCLUDED

Waiting List Status Code at Transplant	Era		Total
	27Aug00-26Feb02	27Feb02-27Aug03	
Frequency			
Unknown	1	2	3
Status 1	311	276	587
Status 2B	261	2	263
Status 3	72	0	72
MP <= 6	1	111	112
MP7-15	0	88	88
MP16-25	1	96	97
MP26-35	0	62	62
MP>35	0	41	41
Inactive	2	1	3
Total	649	679	1328

OPTN/UNOS: PEDIATRIC DATA ONLY
Deceased Donor Liver Transplants by Era: Liver-Intestine Transplants EXCLUDED

Diagnosis @ Tx	Era		Total
	27Aug00-26Feb02	27Feb02-27Aug03	
Frequency			
Acute Hepatic Necrosis	75	89	164
Benign Neoplasms	1	5	6
Biliary Atresia	236	240	476
Cholestatic Liver Disease/Cirrhosis	34	31	65
Malignant Neoplasms	18	37	55
Metabolic Disease	68	71	139
Non-Cholestatic Cirrhosis	71	60	131
Not Reported	0	4	4
Other	85	90	175
Other Liver Disease	61	52	113
Total	649	679	1328

OPTN/UNOS: PEDIATRIC DATA ONLY
Deceased Donor Liver Transplants by Era: Liver-Intestine Transplants EXCLUDED

Era	Status 1 Criteria		Total
	Exception	Standard	
27Aug00-26Feb02	71	238	309
27Feb02-27Aug03	76	199	275
Total	147	437	584

Statistic	DF	Value	Prob
Chi-Square	1	1.6768	0.1953
Likelihood Ratio Chi-Square	1	1.6747	0.1956
Continuity Adj. Chi-Square	1	1.4386	0.2304
Mantel-Haenszel Chi-Square	1	1.6740	0.1957
Phi Coefficient		-0.0536	
Contingency Coefficient		0.0535	
Cramer's V		-0.0536	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	71
Left-sided Pr <= F	0.1152
Right-sided Pr >= F	0.9177
Table Probability (P)	0.0330
Two-sided Pr <= P	0.2147

Final Analysis for Data Requests from the OPTN Liver-Intestine Transplantation Committee Meeting of May 20, 2004

**Prepared by Robert Merion, M.D., Robert Wolfe, Ph.D., Nathan Goodrich, M.S.,
and Dawn Zinsser of the Scientific Registry of Transplant Recipients**

This final analysis is submitted by the Scientific Registry of Transplant Recipients (SRTR) in response to the data request from the OPTN Liver-Intestine Transplantation Committee, dated May 28, 2004.

Data Request Routing Information and Analysis Timeline:

OPTN Liver-Intestine Committee meeting date: May 20, 2004
 OPTN Liver-Intestine Committee request made: May 28, 2004
 Analysis plan submitted: June 15, 2004
 Draft Analysis submitted: June 29, 2004
 Final Analysis to be submitted to Committee: July 9, 2004
 Next Committee Date: July 22, 2003

Table of Contents

ANALYTICAL/INFERENCEIAL REQUEST #1.....	2
STUDY POPULATION.....	2
ANALYTICAL APPROACH.....	2
RESULTS.....	2
<i>Table 1.1 Waiting List Death Rates for Pediatric Candidates by PELD Scores and Status1 Categories (for listings between 2/27/02 - 9/30/03 and followed through 12/31/03)</i>	3
<i>Figure 1.1 Waiting List Death Rates for Pediatric Candidates by PELD Score (for listings between 2/27/02 - 9/30/03 and followed through 12/31/03)</i>	3
<i>Figure 1.2 Waiting List Death Rates for Pediatric Candidates by PELD Score (For listings between 2/27/02 - 9/30/03 and followed through 12/31/03)</i>	4
ANALYTICAL/INFERENCEIAL REQUEST #2.....	4
STUDY POPULATION.....	4
ANALYTICAL APPROACH.....	4
RESULTS.....	4
<i>Table 2.1 Waiting List Death Rates for Pediatric Candidates by Age and Status1 Category (for listings between 2/27/02 - 9/30/03 and followed through 12/31/03)</i>	5
<i>Figure 2.1 Waiting List Death Rates for Pediatric Candidates by Age and Status1 Category (for listings between 2/27/02 - 9/30/03 and followed through 12/31/03)</i>	5
ANALYTICAL/INFERENCEIAL REQUEST #3.....	6
STUDY POPULATION.....	6
ANALYTICAL APPROACH.....	6
RESULTS.....	6
<i>Table 3.0 Median MELD at Transplant, Rate (per 100 patient days) and Adjusted* Relative Rate of Deceased Donor Transplantation by DSA and MELD Category (2/27/02-3/31/04)</i>	7

Analytical/Inferential Request #1

Please update the analysis of pediatric waiting list mortality rates in Status 1 stratified by the following categories:

- a. Fulminant candidates*
- b. Candidates with PNF/HAT*
- c. Candidates by exception*
- d. Other Status 1 candidates*

For the analysis, candidates should be categorized according to the information provided on the Status 1 justification form. Candidates removed for "too sick" should be counted as events in the mortality analysis. Liver-intestine candidates should be excluded.

Study Population

Pediatric candidates added to the liver waiting list from 2/27/02 to 9/30/03 with follow up through 12/31/03 were included in the study. Candidates listed on both the liver and the intestine waiting lists were excluded from the analysis.

Analytical Approach

The mortality rates while on the liver waiting list will be tabulated for the following pediatric status 1 categories:

1. Fulminant candidates
2. Candidates with PNF/HAT
3. Candidates by exception
4. Other Status 1 candidates

Candidates were followed from the time of first active status until the earliest of death, transplant, end of study, or censoring date. In order to avoid missing deaths that occur shortly after removal from the waiting list or switching to inactive status, candidates were followed for 30 days after moving to inactive status or removal from the waiting list for reasons other than transplant. If the patient was alive at the end of 30 days they were censored at that time. Within a given PELD or status1 category the death rates were calculated as follows:

$$\text{Death Rate} = \frac{\text{\# of Deaths}}{\text{Total \# of Patient Years Spent in Category}}$$

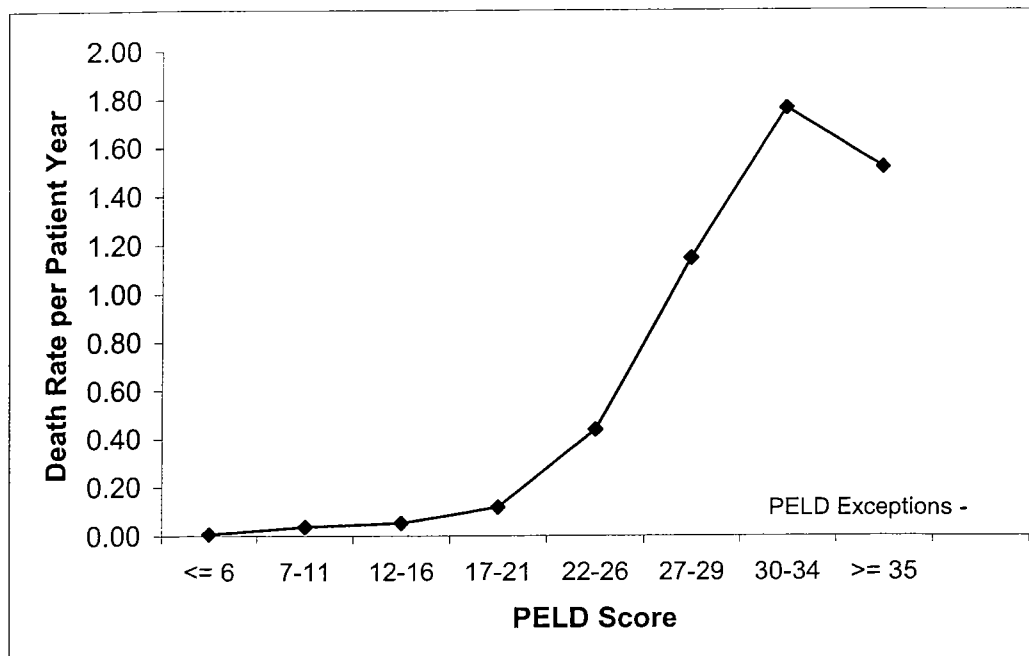
Results

Table 1.1 lists the death rates per patient year for pediatric candidates on the liver waiting list by PELD scores and status1 Categories. Figure 1.1 displays the death rates graphically by PELD score. Figure 1.2 shows the death rates for the various status1 categories. The fulminant and PNF/HAT status1 candidates have very similar death rates at just over 5 deaths per patient year. The exception status1 category had the lowest death rate at about .5 deaths per patient year. Overall the 'other' status1 category had a death rate of about 3 deaths per patient year. Candidates in the 'other' status1 category with a PELD score ≥ 25 had a death rate of about 4.6 deaths per patient year. Candidates in the 'other' status1 category with a PELD score < 25 had a death rate of about 2.4 deaths per patient year.

Table 1.1 Waiting List Death Rates for Pediatric Candidates by PELD Scores and Status1 Categories (for listings between 2/27/02 - 9/30/03 and followed through 12/31/03)

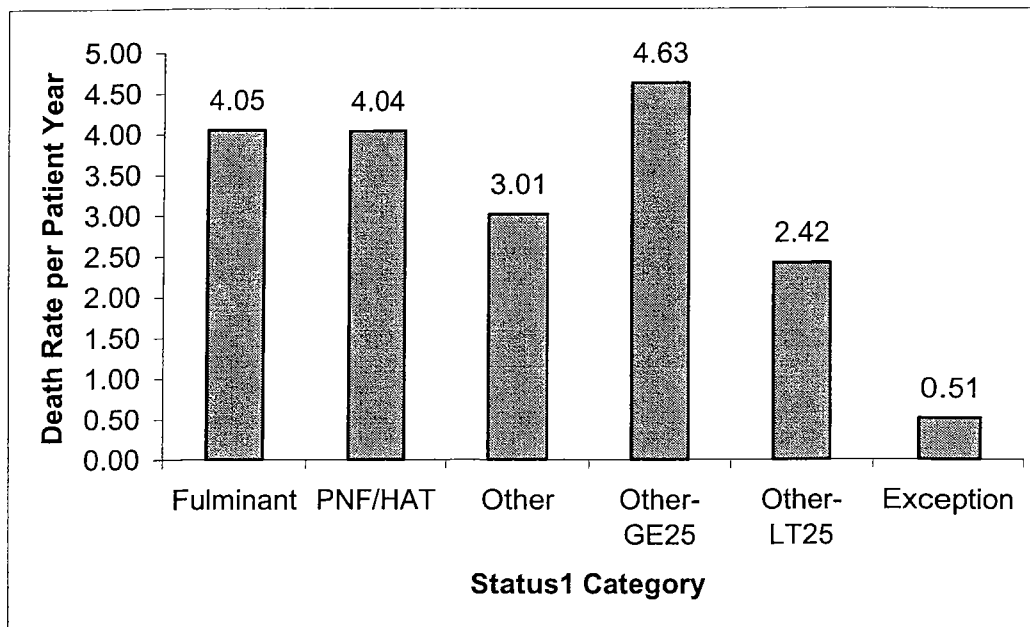
Status Category	Number of Patient Years	Number of Deaths	Death Rate per Year	Median PELD Score
PELD <= 6	160.8	1	0.006	-1
PELD 7-11	55.0	2	0.036	9
PELD 12-16	38.4	2	0.052	14
PELD 17-21	25.6	3	0.117	19
PELD 22-26	11.4	5	0.439	24
PELD 27-29	3.5	4	1.146	28
PELD 30-34	2.3	4	1.764	31
PELD >= 35	1.3	2	1.519	41
PELD-Exception	30.3	3	0.099	6
Status1-FUL	5.9	24	4.055	29
Status1-PNF/HAT	3.0	12	4.040	23
Status1-Other	5.6	17	3.014	17
Status1-Other-GE25	1.5	7	4.632	32
Status1-Other-LT25	4.1	10	2.422	8
Status1-Exception	3.9	2	0.508	8
Total	347.1	81	0.233	15

Figure 1.1 Waiting List Death Rates for Pediatric Candidates by PELD Score* (for listings between 2/27/02 - 9/30/03 and followed through 12/31/03)



*Does not include status1; candidates granted exception scores are considered separately

Figure 1.2 Waiting List Death Rates for Pediatric Candidates by PELD Score (For listings between 2/27/02 - 9/30/03 and followed through 12/31/03)



Analytical/Inferential Request #2

Tabulate overall death rates for Status 1 candidates by age (0-2 years and 3-17 years).

Study Population

Pediatric candidates added to the liver waiting list from 2/27/02 to 9/30/03 with follow up through 12/31/03 were included in the study. Candidates listed on both the liver and the intestine waiting lists were excluded from the analysis.

Analytical Approach

The mortality rates while on the liver waiting list will be tabulated for status 1 candidates 0-2 years and status 1 candidates 3-17 years. The death rates for this request were calculated in the same manner as those given in request #1.

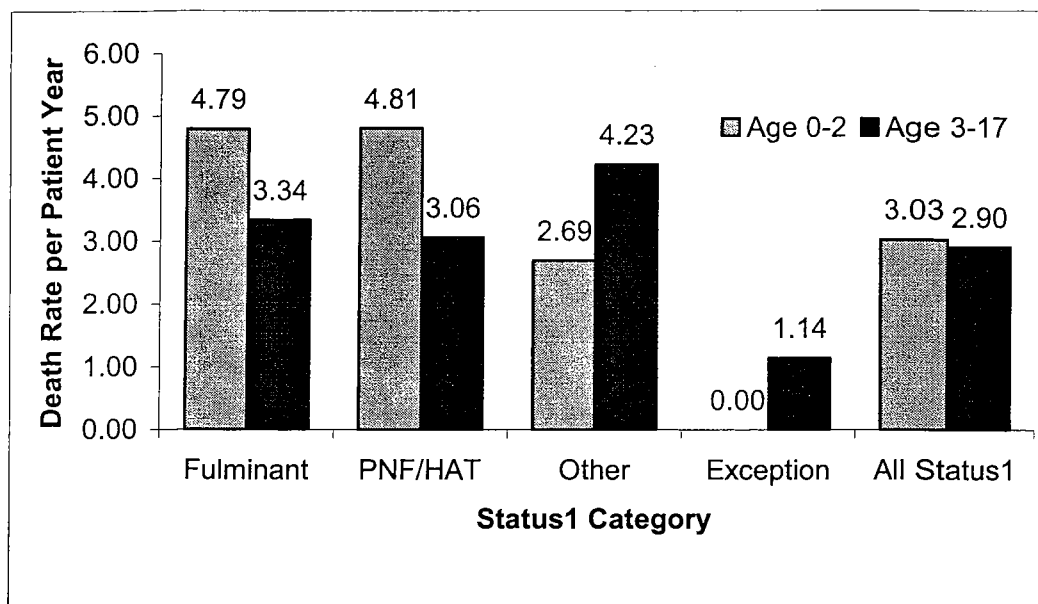
Results

Table 2.1 shows the waiting list death rates for pediatric status1 candidates by age (0-2 and 3-17 years) and reason for status1. Figure 2.1 displays the same information graphically. There is some variation within specific status1 categories between the two age groups, but overall the death rates are very similar.

Table 2.1 Waiting List Death Rates for Pediatric Candidates by Age and Status1 Category (for listings between 2/27/02 - 9/30/03 and followed through 12/31/03)

Age	Status1 Category	Number of Patient Years	Number of Deaths	Death Rate per Patient Year	Median PELD Score
0-2	Fulminant	2.9	14	4.792	33
0-2	PNF/HAT	1.7	8	4.806	26
0-2	Other	4.5	12	2.692	18
0-2	Exception	2.2	0	0.000	12
0-2	All Status1	11.2	34	3.027	21
3-17	Fulminant	3.0	10	3.336	26
3-17	PNF/HAT	1.3	4	3.063	19
3-17	Other	1.2	5	4.227	11.5
3-17	Exception	1.7	2	1.145	2
3-17	All Status1	7.2	21	2.903	19

Figure 2.1 Waiting List Death Rates for Pediatric Candidates by Age and Status1 Category (for listings between 2/27/02 - 9/30/03 and followed through 12/31/03)



Data Requested by the Joint Pediatric/Liver Subcommittee at July 21, 2004 Subcommittee Meeting

Prepared by Robert Merion, M.D., Robert Wolfe, Ph.D., Nathan Goodrich, M.S.,
and Dawn Zinsser of the Scientific Registry of Transplant Recipients

Table of Contents

ANALYTICAL/INFERENTIAL REQUEST.....	1
STUDY POPULATION.....	1
ANALYTICAL APPROACH.....	1
RESULTS.....	1
Table 1.1 Waiting List Death Rates for Pediatric Candidates by PELD Scores and Status 1 Categories (for listings between 2/27/02 - 9/30/03 and followed through 12/31/03)	2
Table 1.2 Time from Listing to Death for Status 1 Candidates Who Died on the Liver Waiting List by Status 1 Category (for listings between 2/27/02 - 9/30/03 and followed through 12/31/03).....	2
Table 1.3 List of the Number of Days from Listing to Death for Status 1 Deaths	2
Table 1.4 Number of Patients Who Were <u>Ever Listed</u> as Status 1 by the Most Recent Status 1 Category	3

Analytical/Inferential Request

Report the median time to death for pediatric status 1 deaths from the previous analysis by the following categories.

- a. Fulminant candidates
- b. Candidates with PNF/HAT
- c. Candidates by exception
- d. Other Status 1 candidates

Study Population

Pediatric candidates added to the liver waiting list from 2/27/02 to 9/30/03 with follow up through 12/31/03 were included in the study. Candidates listed on both the liver and the intestine waiting lists were excluded from the analysis.

Analytical Approach

The median time from listing to death of the deaths reported in the previous status 1 mortality analysis were tabulated. The number of patients who were ever listed as status 1 are also reported.

Results

Table 1.1 lists the death rates per patient year for pediatric candidates on the liver waiting list by PELD scores and status 1 Categories (reproduced from the previous analysis). Table 1.2 lists the median time to death for the deaths listed in table 1.1. The PNF/HAT category had the shortest median time to death at 4.5 days from listing until death,

followed by the fulminant candidates with a median of 5 days. The status 1 other and exception categories had medians of 18 and 24 days respectively.

Table 1.1 Waiting List Death Rates for Pediatric Candidates by PELD Scores and Status1 Categories (for listings between 2/27/02 - 9/30/03 and followed through 12/31/03)

Status Category	Number of Patient Years	Number of Deaths	Death Rate per Year	Median PELD Score
Status1-FUL	5.9	24	4.055	29
Status1-PNF/HAT	3.0	12	4.040	23
Status1-Other	5.6	17	3.014	17
Status1-Other-GE25	1.5	7	4.632	32
Status1-Other-LT25	4.1	10	2.422	8
Status1-Exception	3.9	2	0.508	8

Table 1.2 Time from Listing to Death for Status 1 Candidates Who Died on the Liver Waiting List by Status 1 Category (for listings between 2/27/02 - 9/30/03 and followed through 12/31/03)

Category	Number of Deaths	Median Days	Minimum Days	Maximum Days
Status1-FUL	24	5.5	0	29
Status1-PNF/HAT	12	4.5	2	21
Status1-Other	17	18.0	1	127
Status1-Other-GE25	7	21.0	15	74
Status1-Other-LT25	10	15.5	1	127
Status1-Exception	2	24.0	12	36

Table 1.3 List of the Number of Days from Listing to Death for Status 1 Deaths

Status 1 Category at Time From Listing	Time of Death to Death	Listing Date	Death Date
Status1-Exception	12	8/10/2003	8/22/2003
Status1-Exception	36	1/24/2003	3/1/2003
Status1-FUL	0	6/30/2003	6/30/2003
Status1-FUL	1	3/21/2002	3/22/2002
Status1-FUL	1	11/7/2002	11/8/2002
Status1-FUL	1	1/27/2003	1/28/2003
Status1-FUL	1	6/27/2003	6/28/2003
Status1-FUL	1	9/12/2003	9/13/2003
Status1-FUL	2	3/31/2002	4/2/2002
Status1-FUL	2	6/13/2002	6/15/2002
Status1-FUL	3	5/21/2002	5/24/2002
Status1-FUL	4	3/23/2003	3/27/2003
Status1-FUL	4	7/5/2003	7/9/2003
Status1-FUL	5	4/12/2002	4/17/2002
Status1-FUL	6	6/20/2002	6/26/2002
Status1-FUL	8	4/26/2003	5/4/2003
Status1-FUL	9	8/7/2002	8/16/2002
Status1-FUL	9	12/22/2002	12/31/2002

Status1-FUL	11	9/7/2002	9/18/2002
Status1-FUL	11	6/12/2003	6/23/2003
Status1-FUL	13	3/19/2003	4/1/2003
Status1-FUL	19	6/20/2003	7/9/2003
Status1-FUL	25	2/12/2003	3/9/2003
Status1-FUL	25	9/8/2003	10/3/2003
Status1-FUL	26	8/29/2002	9/24/2002
Status1-FUL	29	12/24/2002	1/22/2003
Status1-Other-GE25	15	5/7/2002	5/22/2002
Status1-Other-GE25	15	2/17/2003	3/4/2003
Status1-Other-GE25	18	2/27/2002	3/17/2002
Status1-Other-GE25	21	6/6/2003	6/27/2003
Status1-Other-GE25	42	5/13/2003	6/24/2003
Status1-Other-GE25	50	7/15/2002	9/3/2002
Status1-Other-GE25	74	3/22/2002	6/4/2002
Status1-Other-LT25	1	9/30/2003	10/1/2003
Status1-Other-LT25	6	12/23/2002	12/29/2002
Status1-Other-LT25	8	9/19/2003	9/27/2003
Status1-Other-LT25	10	12/25/2002	1/4/2003
Status1-Other-LT25	14	7/21/2003	8/4/2003
Status1-Other-LT25	17	1/10/2003	1/27/2003
Status1-Other-LT25	23	7/10/2003	8/2/2003
Status1-Other-LT25	28	11/7/2002	12/5/2002
Status1-Other-LT25	52	11/14/2002	1/5/2003
Status1-Other-LT25	127	11/8/2002	3/15/2003
Status1-PNF/HAT	2	4/26/2002	4/28/2002
Status1-PNF/HAT	2	6/7/2002	6/9/2002
Status1-PNF/HAT	2	7/12/2002	7/14/2002
Status1-PNF/HAT	2	8/28/2002	8/30/2002
Status1-PNF/HAT	4	2/2/2003	2/6/2003
Status1-PNF/HAT	4	4/4/2003	4/8/2003
Status1-PNF/HAT	5	12/4/2002	12/9/2002
Status1-PNF/HAT	7	5/15/2003	5/22/2003
Status1-PNF/HAT	8	9/2/2002	9/10/2002
Status1-PNF/HAT	11	9/22/2003	10/3/2003
Status1-PNF/HAT	15	12/18/2002	1/2/2003
Status1-PNF/HAT	21	8/1/2003	8/22/2003

Table 1.4 Number of Patients Who Were Ever Listed as Status1 by the Most Recent Status 1 Category

Category	Frequency	Percent
Status1-FUL	175	39.24
Status1-PNF/HAT	72	16.14
Status1-Other-LT25	89	19.96
Status1-Other-GE25	42	9.42
Status1-Exception	68	15.25