FINAL REPORT

OPTN/UNOS *OPO Committee*Descriptive Data Request

Imminent Neurological and Eligible Death Definitions

Prepared for: I & E Death Definition Subcommittee December 15, 2010

Updated with additional information on January 6, 2010

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Background/Purpose

The Committee is in the process of trying to improve the eligible and imminent neurological death definitions. They are concerned that the definitions are being applied inconsistently across DSAs and would like to tighten up the definitions to reduce the variability and better measure the eligible death/donor potential. To help guide those discussions the Committee would like to request the following data.

Committee Request

- 1. To help guide the discussion on the lower bound of what is considered an eligible/imminent death, analyze donors over the last 3 years by donor age and weight. This should include the number of donors and donor yield as age or weight increase.
 - 1-6-2011 Update: do the above for donor BMI also.
- 2. To help determine the upper bound of what is considered an eligible/imminent death, analyze the number of donors and donor yield over the last 3 years to help determine if increasing the age bound will be worth the added burden of data collection on the OPOs. Also, look to external sources of data to estimate the added burden by increasing the upper bound on age.
- 3. Determine how many pancreas only and intestine only donors were recovered over the last 3 years.
- 4. To help guide the discussion of which organs are "transplantable," analyze the ages of liver, lung, heart, and kidney donors.
- 5. To help guide the discussion of which organs are "transplantable" analyze the match run data for kidney, liver, heart, and lung to assess when transplanted organs are placed (offers, centers).
- 6. (Additional Request from the "Below the Diaphragm" group) To help guide the discussion of "transplantable" kidneys and livers, provide the following (edited based on what we actually collect on the DDR) for donors recovered from 2008 to Date.
 - a. Livers transplanted with Total Bilirubin > 10 mg/dl
 - b. Livers transplanted with Macro vesicular fat $\geq 50\%$
 - c. Livers transplanted with Micro vesicular fat $\geq 50\%$
 - d. Kidneys transplanted by % Glomerulosclerosis category
 - 1-6-2011 Update: do the above for the following:
 - a. Livers transplanted with SGOT/AST > 5000
 - b. Livers transplanted with SGPT/ALT > 5000
 - c. Livers transplanted with Macro vesicular fat > 60%

Data and Methods

All of the committee requests are based on OPTN data as of November 19, 2010. Committee requests 1-4 are based on actual deceased donors (at least one organ recovered for the purpose of transplantation) recovered in the three year period from September 1, 2007 to August 31, 2010. Transplant donors are actual donors that had at least one organ transplanted. An organ specific

transplant donor (i.e. Kidney Transplant Donor) is a donor from whom that specific organ was recovered and transplanted (i.e. at least one kidney transplanted).

Committee request 5, which is an analysis of organ offers, uses potential transplant recipient (PTR) data for matches that were run between September 1, 2007 and August 31, 2010. The analysis includes only organs that were eventually transplanted. Since the goal of the analysis is to help guide the discussion of organs that are "transplantable" based on the "effort" to place and organ, we only include offers up to the candidate in which an organ was accepted. This comes into play with kidney and lung where two organs can be placed from the one match run. For example, on a kidney match run if the first kidney was accepted for the 5th candidate and the second kidney was accepted for the 10th candidate, only the offers up to the 5th candidate are included in the analysis. For the purpose of this analysis, we excluded for which the OPO marked the candidate as "bypassed." In addition, candidates that had any of the following refusal reasons reported (most likely non-offers) were excluded:

- 802 Multiple organ transplant or different laterality needed
- 810 Positive crossmatch
- 813 Unacceptable Antigens
- 850 Multi-organ placement
- 851 Directed donation
- 852 Military donor
- 853 ALU, Sharing Agreement, Variance
- 860 Medical urgency of another potential recipient
- 861 Operational OPO
- 862 Donor medical urgency
- 863 Offer not made due to expedited placement attempt
- 880 Kidney placed with extra-renal
- 881 Maximum 0mm offer limits exceeded
- 882 Not offered non facilitated pancreas center
- 883 Not offered minimum acceptance criteria not met

For this analysis, "Offers" is the number of candidates that were offered the organ (those not excluded based on the above) up to and including the candidate for which the organ was accepted. "Centers" are the number of unique transplant programs that were include in the number of "Offers."

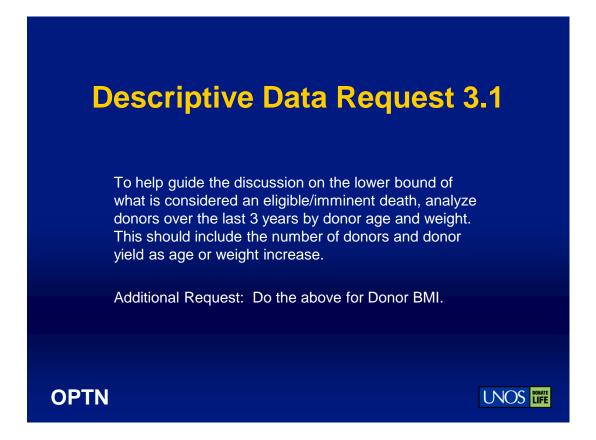
Example:

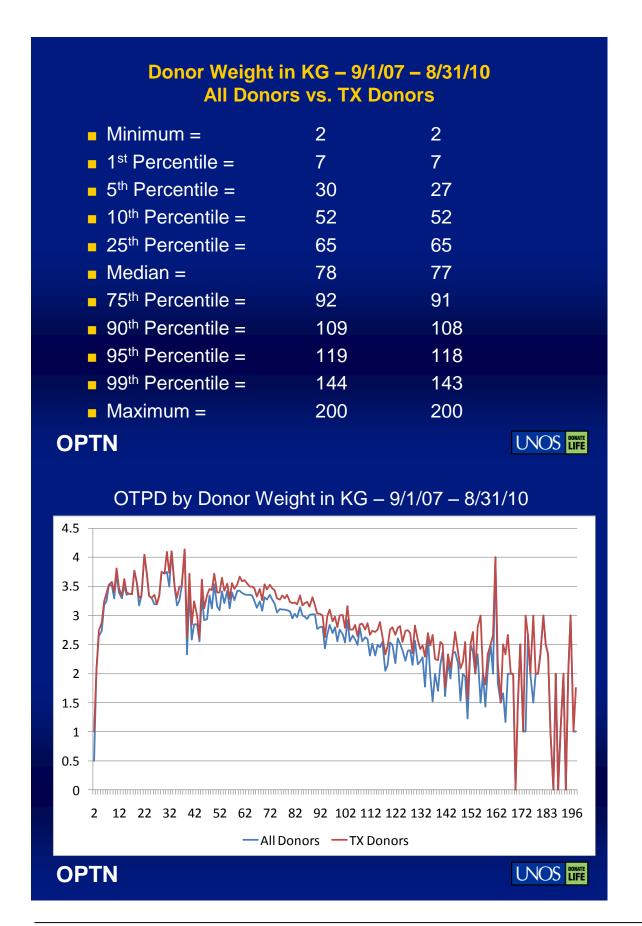
Litampic.		
Candidate #	Center	Accepted?
1	A	No
2	A	No
3	В	No
4	A	No
5	C	No
6	C	Yes
Offers $= 6$		

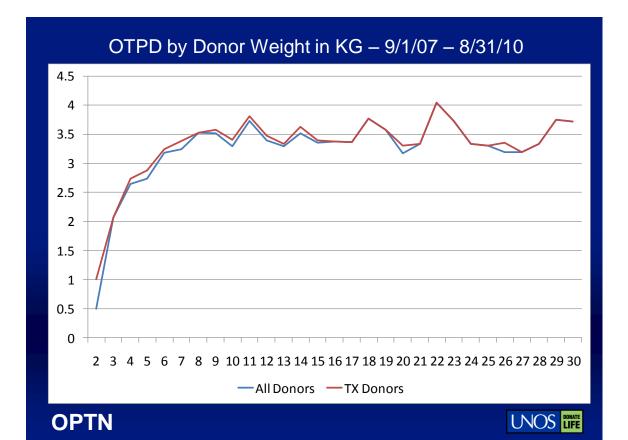
Centers = 3

Committee request #6 was based on actual donors recovered during the 32 month period from January 1, 2008 to August 31, 2010. The bilirubin data are based on all donors. The biopsy analyses are based only on those donors for whom a kidney or liver biopsy was performed.

Results







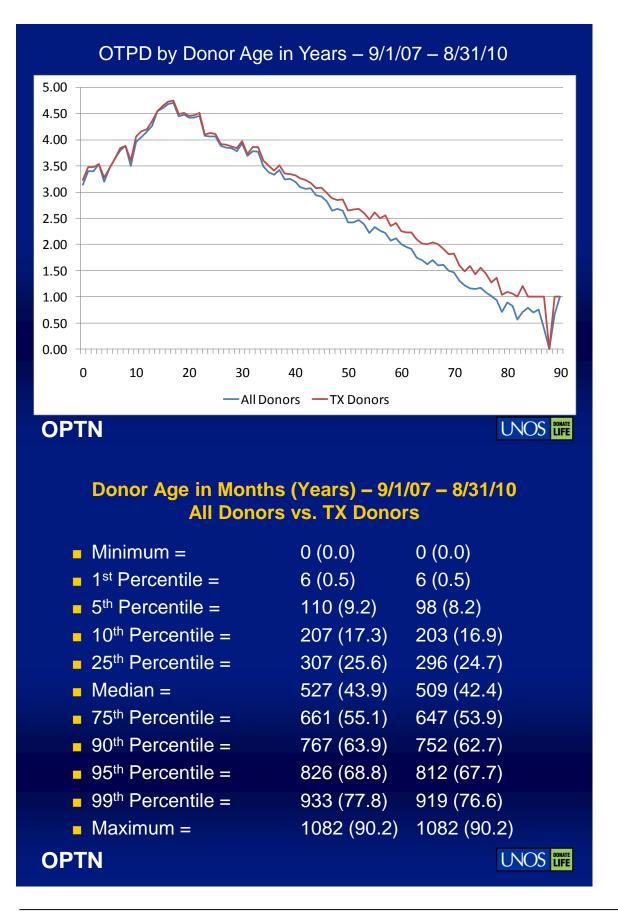
Transplant Donors Weight – 9/1/07 – 8/31/10

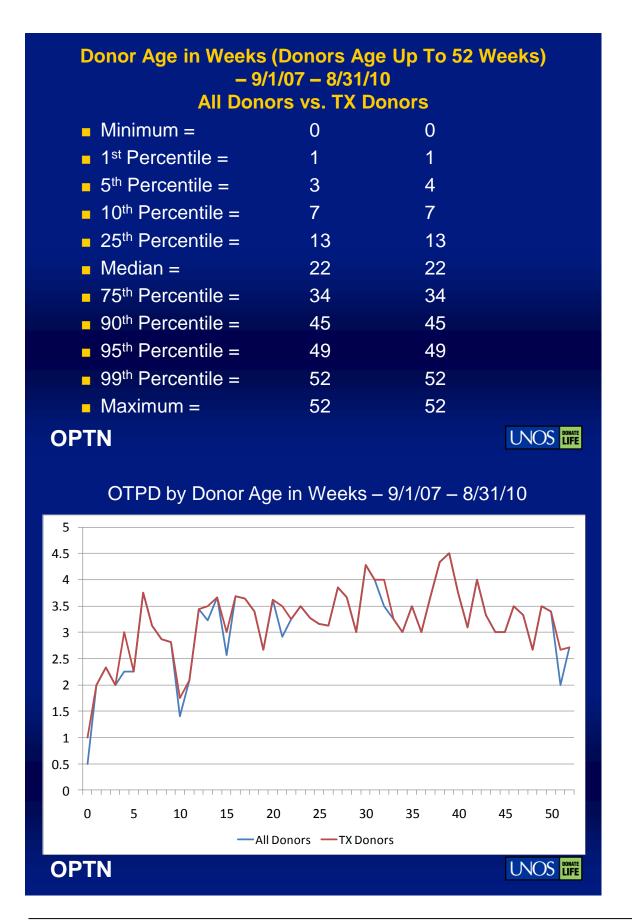
KG	Donors	OTPD	KG	Donors	OTPD
2	1	1.00	17	36	3.36
3	15	2.07	18	35	3.77
4	30	2.73	19	21	3.57
5	58	2.88	20	50	3.30
6	59	3.24	21	9	3.33
7	70	3.39	22	26	4.04
8	63	3.52	23	11	3.73
9	59	3.58	24	24	3.33
10	88	3.41	25	39	3.31
11	46	3.80	26	20	3.35
12	85	3.47	27	21	3.19
13	68	3.34	28	15	3.33
14	64	3.63	29	20	3.75
15	86	3.40	30	53	3.72
16	37	3.38			

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NOS DONATE LIFE





Transplant Donors Age in Weeks – 9/1/07 – 8/31/10

Age in Weeks	Donors	OTPD	Age in Weeks	Donors	OTPD	Age in Weeks	Donors	OTPD
0	1	1.00	18	10	3.40	36	5	3.00
1	8	2.00	19	9	2.67	37	3	3.67
2	6	2.33	20	8	3.63	38	3	4.33
3	3	2.00	21	10	3.50	39	6	4.50
4	3	3.00	22	12	3.25	40	4	3.75
5	8	2.25	23	8	3.50	41	11	3.09
6	4	3.75	24	11	3.27	42	1	4.00
7	8	3.13	25	6	3.17	43	3	3.33
8	8	2.88	26	8	3.13	44	7	3.00
9	11	2.82	27	7	3.86	45	4	3.00
10	8	1.75	28	9	3.67	46	4	3.50
11	11	2.09	29	6	3.00	47	6	3.33
12	9	3.44	30	7	4.29	48	3	2.67
13	12	3.50	31	8	4.00	49	8	3.50
14	6	3.67	32	7	4.00	50	5	3.40
15	6	3.00	33	4	3.25	51	3	2.67
16	13	3.69	34	4	3.00	52	7	2.71
17	14	3.64	35	6	3.50			

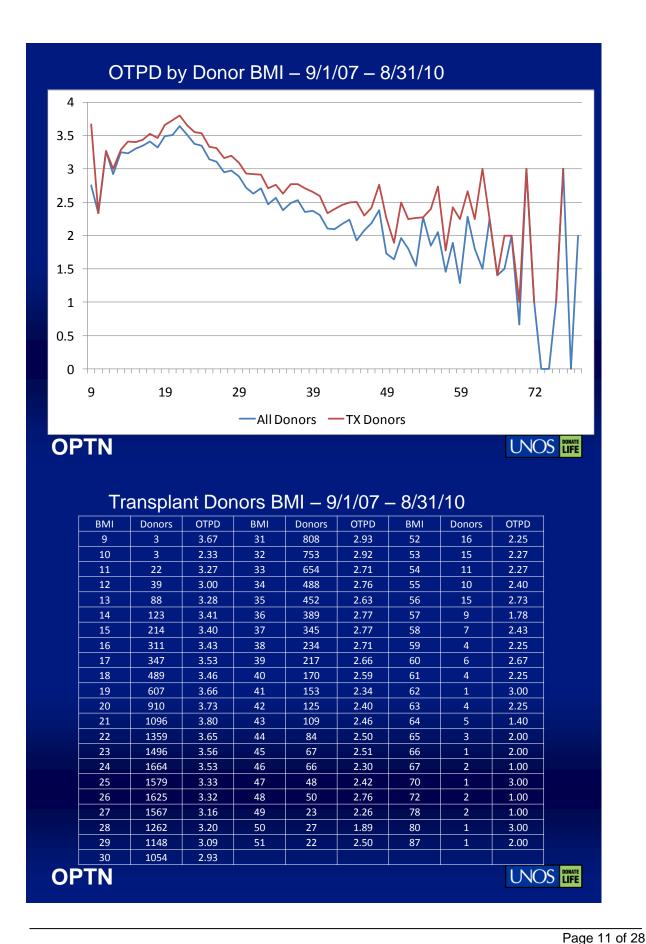
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Minimum =	8.6	8.6	
1st Percentile =	14.2	14.1	
■ 5 th Percentile =	17.5	17.4	
■ 10 th Percentile =	19.6	19.5	
25 th Percentile =	22.6	22.5	
Median =	26.1	26.0	
■ 75 th Percentile =	30.5	30.3	
■ 90 th Percentile =	35.8	35.5	
95 th Percentile =	39.7	39.2	
■ 99 th Percentile =	48.7	47.8	
Maximum =	86.6	86.6	





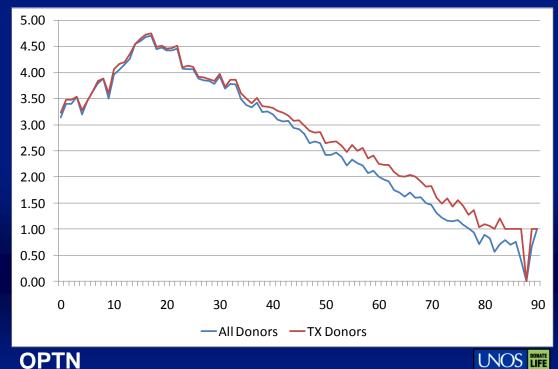
Descriptive Data Request 3.2

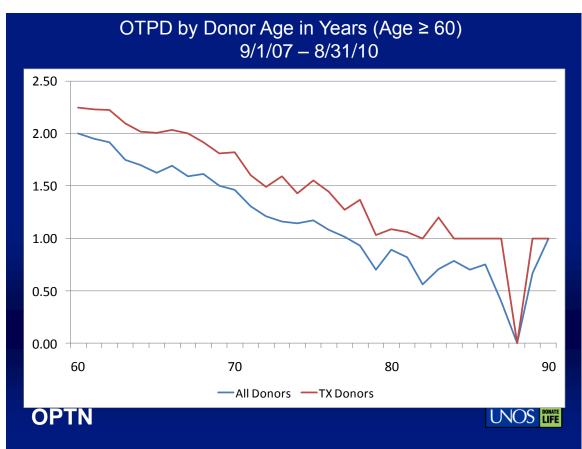
To help determine the upper bound of what is considered an eligible/imminent death, analyze the number of donors and donor yield over the last 3 years to help determine if increasing the age bound will be worth the added burden of data collection on the OPOs. Also, look to external sources of data to estimate the added burden by increasing the upper bound on age.







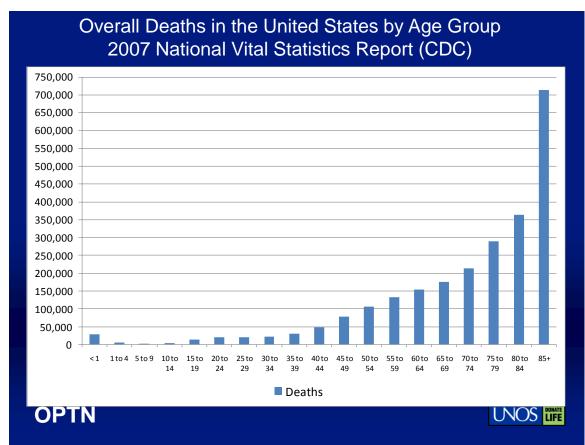




Transplant Donors Age in Years (Age ≥ 60) 9/1/07 - 8/31/10

Donor Age	Donors	OTPD	Donor Age	Donors	OTPD
60	355	2.25	75	78	1.55
61	352	2.23	76	56	1.45
62	284	2.23	77	44	1.27
63	254	2.09	78	41	1.37
64	223	2.02	79	30	1.03
65	205	2.00	80	23	1.09
66	216	2.03	81	17	1.06
67	181	2.00	82	9	1.00
68	166	1.92	83	10	1.20
69	131	1.81	84	11	1.00
70	85	1.82	85	7	1.00
71	96	1.60	86	6	1.00
72	100	1.49	87	2	1.00
73	76	1.59	89	2	1.00
74	89	1.43	90	1	1.00





Overall Deaths in the United States by Age Group 2007 National Vital Statistics Report (CDC)

Age Group	Deaths	Age Group	Deaths
< 1	29,138	45 to 49	77,738
1 to 4	4,703	50 to 54	106,948
5 to 9	2,711	55 to 59	132,458
10 to 14	3,436	60 to 64	154,652
15 to 19	13,299	65 to 69	174,991
20 to 24	20,683	70 to 74	214,247
25 to 29	20,931	75 to 79	289,029
30 to 34	21,641	80 to 84	363,653
35 to 39	30,881	85+	713,647
40 to 44	48,725		



Descriptive Data Request 3.3

Determine how many pancreas only and intestine only donors were recovered over the last 3 years.

For the "Above the Diaphragm" group do this same analysis for heart only and lung only donors.

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Transplant Donors September 1, 2007 - August 31, 2010

- Pancreas Only Donors = 1
- Intestine Only Donors = 3
- Heart Only Donors = 136
- Lung Only Donors = 78
- Total Transplant Donors = 22,410



Descriptive Data Request 3.4 To help guide the discussion of which organs are "transplantable," analyze the ages of liver, lung, heart, and kidney donors. **OPTN** UNOS LIFE **HEART Donor Age in Years - 9/1/07 - 8/31/10** All Heart Donors vs. Heart TX Donors Minimum = 0 1st Percentile = 0 0 5th Percentile = 1 1 ■ 10th Percentile = 9 10 25th Percentile = 19 19 Median = 26 26 75th Percentile = 39 39 90th Percentile = 48 48 95th Percentile = 52 52 99th Percentile = 58 58 Maximum = 67 64 **OPTN** UNOS LIFE

LUNG Donor Age All Lung Dono			
Minimum =	0	0	
1st Percentile =	7	7	
5 th Percentile =	15	15	
10 th Percentile =	17	17	
25 th Percentile =	21	21	
Median =	31	30	
75 th Percentile =	45	45	
90 th Percentile =	54	54	
95 th Percentile =	58	58	
99 th Percentile =	66	66	
Maximum =	78	78	
OPTN			UNOS LIFE
LIVER Donor Age	in Years -	014107 010	
All Liver Dono		9/1/0 <i>7 –</i> 8/3 TX Donors	
■ Minimum =			
	rs vs. Liver	TX Donors	
Minimum =	ors vs. Liver	TX Donors	
Minimum =1st Percentile =	ors vs. Liver 0 0	TX Donors 0 0	
 Minimum = 1st Percentile = 5th Percentile = 	ors vs. Liver 0 0 9	TX Donors 0 0 8	
 Minimum = 1st Percentile = 5th Percentile = 10th Percentile = 	o rs vs. Live r 0 0 9 17	• TX Donors 0 0 8 16	
 Minimum = 1st Percentile = 5th Percentile = 10th Percentile = 25th Percentile = 	ors vs. Liver 0 0 9 17 24	0 0 0 8 16 23	
 Minimum = 1st Percentile = 5th Percentile = 10th Percentile = 25th Percentile = Median = 	ors vs. Liver 0 0 9 17 24 42	0 0 8 16 23 40	
 Minimum = 1st Percentile = 5th Percentile = 10th Percentile = 25th Percentile = Median = 75th Percentile = 	ors vs. Liver 0 0 9 17 24 42 54	0 0 8 16 23 40 53	
 Minimum = 1st Percentile = 5th Percentile = 10th Percentile = 25th Percentile = Median = 75th Percentile = 90th Percentile = 	0 0 9 17 24 42 54 64	0 0 8 16 23 40 53 63	
 Minimum = 1st Percentile = 5th Percentile = 10th Percentile = 25th Percentile = Median = 75th Percentile = 90th Percentile = 95th Percentile = 	0 0 9 17 24 42 54 64 69	0 0 8 16 23 40 53 63 68	

KIDNEY Donor Age in Years – 9/1/07 – 8/31/10 All Kidney Donors vs. Kidney TX Donors						
Minimum =	0	0				
1st Percentile =	0	1				
5 th Percentile =	10	8				
10 th Percentile =	17	16				
25 th Percentile =	24	23				
Median =	43	39				
75 th Percentile =	54	51				
90 th Percentile =	62	59				
95 th Percentile =	67	63				
99 th Percentile =	75	71				
Maximum =	88	83				
OPTN			UNOS LIFE			

Descriptive Data Request 3.5

To help guide the discussion of which organs are "transplantable" analyze the match run data for kidney, liver, heart, and lung to assess when transplanted organs are placed (offers, centers).

OPTN



Match Run Analysis

- Include only transplanted organs
- For kidney and lung analysis count offers/centers until the first kidney/lung was accepted
- Do not include "offers" to candidates reported as bypassed
- Exclude candidates with the following refusal reasons given (most likely non-offers)
 - 802, 810, 813, 850, 851, 852, 853, 860, 861, 862, 863, 880, 881, 882, 883 see next slide for reasons



Match Run Analysis con't

- Refusal reasons excluded
 - 802 Multiple organ transplant or different laterality needed
 - 810 Positive crossmatch
 - 813 Unacceptable Antigens
 - 850 Multi-organ placement
 - 851 Directed donation
 - 852 Military donor
 - 853 ALU, Sharing Agreement, Variance
 - 860 Medical urgency of another potential recipient
 - 861 Operational OPO
 - 862 Donor medical urgency
 - 863 Offer not made due to expedited placement attempt
 - · 880 Kidney placed with extra-renal
 - 881 Maximum 0mm offer limits exceeded
 - 882 Not offered non facilitated pancreas center
 - 883 Not offered minimum acceptance criteria not met

OPTN

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Number of Offers Made and Centers Contacted to Place an Organ* - 9/1/07 - 8/31/10 **Kidney**

	Offers	Centers	
Minimum =	1	1	
1st Percentile =	1	1	
■ 5 th Percentile =	1	1	
■ 10 th Percentile =	1	1	
25 th Percentile =	1	1	
Median =	3	2	
■ 75 th Percentile =	12	3	
■ 90 th Percentile =	79	7	
■ 95 th Percentile =	291	13	
99th Percentile =	1394	36	
Maximum =	18311	226 _{UN}	IOS DONATE LIFE

*Includes only match runs for organs that were transplanted

Number of Offers Made and Centers Contacted to Place an Organ* – 9/1/07 – 8/31/10 Kidney-Pancreas					
To the second	Offers	Centers			
Minimum =	1	1			
1st Percentile =	1	1			
5 th Percentile =	1	1			
10 th Percentile =	1	1			
25 th Percentile =	1	1			
■ Median =	1.5	1			
■ 75 th Percentile =	3	2			
90 th Percentile =	9	3			
95 th Percentile =	23	6			
99 th Percentile =	67	24			
OPTN Maximum =	226	59 UNOS LIFE			
*Includes only match runs	for organs that were				
Number of Offers Made Place an Organ ^a L					
	Offers	Centers			
Minimum =	1	1			
1st Percentile =	1	1			
5th Percentile =	1	1			
10th Percentile =	1	1			
25th Percentile =	1	1			
■ Median =	2	2			
75 th Percentile =	5	3			
90 th Percentile =	21	5			
95 th Percentile =	57	9			
99 th Percentile =	457	26			
OPTN Maximum = *Includes only match runs	5980 for organs that were	113 UNOS LIFE			

Number of Offers Made and Centers Contacted to Place an Organ* – 9/1/07 – 8/31/10 Heart					
· ·	Offers	Centers			
Minimum =	1	1			
1st Percentile =	1	1			
■ 5 th Percentile =	1	1			
■ 10 th Percentile =	1	1			
25 th Percentile =	1	1			
■ Median =	2	2			
75 th Percentile =	6	4			
90 th Percentile =	19	10			
95 th Percentile =	31	15			
99 th Percentile =	87	29			
OPTN Maximum =	382	45 UNOS DOMATE			
*Includes only match runs	for organs that were				
Number of Offers Made Place an Organ*					
	ung	0/31/10			
	Offers	Centers			
Minimum =	1	1			
1st Percentile =	1	1			
5 th Percentile =	1	1			
10 th Percentile =	1	1			
25 th Percentile =	1	1			
■ Median =	3	2			
■ 75 th Percentile =	10	4			
90 th Percentile =	28	8			
95 th Percentile =	49	12			
99 th Percentile =	141	21			
OPTN Maximum =	430	40 UNOS DOMATE LIFE			
*Includes only match runs	for organs that were				

Number of Offers Made and Centers Contacted to Place an Organ* – 9/1/07 – 8/31/10 Heart-Lung			
	Offers	Centers	
Minimum =	1	1	
1 st Percentile =	1	1	
5 th Percentile =	1	1	
10 th Percentile =	1	1	
25 th Percentile =	1	1	
■ Median =	2	2	
75 th Percentile =	6	4	
90 th Percentile =	18	9	
95 th Percentile =	31	15	
99 th Percentile =	78	27	
OPTN Maximum =	567	74 LNOS TOR	TE F
*Includes only match runs for organs that were transplanted			

Additional Requests from the "Below the Diaphragm" Group

To help guide the discussion of "transplantable" kidneys and livers, provide the following (edited based on what we actually collect on the DDR) for donors recovered from 2008 to Date.

- 1. Livers transplanted with Total Bilirubin > 10 mg/dl
- 2. Livers transplanted with Micro vesicular fat ≥ 50%
- 3. Livers transplanted with Macro vesicular fat ≥ 50%
- 4. Livers transplanted with Macro vesicular fat > 60%
- 5. Livers transplanted with SGOT/AST > 5000
- 6. Livers transplanted with SGPT/ALT > 5000
- 7. Kidneys transplanted by % Glomerulosclerosis category

OPTN



21,341 Donors Recovered January 1, 2008 – August 31, 2010

Total Dilimbia	Liver Transplanted	
Total Bilirubin	Yes	No
≤ 10	15,957	5,200
> 10	9	41
Missing	43	91
Total	16,009	5,332



21,341 Donors Recovered January 1, 2008 – August 31, 2010

7,630 with Liver Biopsy = "Yes" 1,572 with Micro Vesicular Fat = "Not Reported"

% Micro	Liver Transplanted	
Vesicular Fat	Yes	No
< 50	4566	1092
≥ 50	219	181
Total	4785	1273



21,341 Donors Recovered January 1, 2008 – August 31, 2010

7,630 with Liver Biopsy = "Yes"
1,200 with Macro Vesicular Fat = "Not Reported"

% Macro	Liver Transplanted	
Vesicular Fat	Yes	No
< 50	4990	1146
≥ 50	68	226
Total	5058	1372

OPTN



21,341 Donors Recovered January 1, 2008 – August 31, 2010

7,630 with Liver Biopsy = "Yes"
1,200 with Macro Vesicular Fat = "Not Reported"

% Macro	Liver Transplanted	
Vesicular Fat	Yes	No
≤ 60	5036	1308
> 60	22	64
Total	5058	1372



21,341 Donors Recovered January 1, 2008 – August 31, 2010

SGOT/AST	Liver Transplanted		
	Yes	No	
≤ 5000	15,975	5,213	
> 5000	1	33	
Missing	33	86	
Total	16,009	5,332	

OPTN



21,341 Donors Recovered January 1, 2008 – August 31, 2010

SGPT/ALT	Liver Transplanted		
	Yes	No	
≤ 5000	15,976	5,213	
> 5000	0	18	
Missing	33	83	
Total	16,009	5,332	



21,341 Donors Recovered January 1, 2008 - August 31, 2010

9,175 with Left Kidney Biopsy = "Yes"

% Glomerulosclerosis	Left Kidney Transplanted	
	Yes	No
Missing	0	19
0 to 5	4593	1139
6 to 10	880	444
11 to 15	338	309
16 to 20	149	228
20+	247	694
Indeterminate	67	68
Total	6274	2901

OPTN





21,341 Donors Recovered January 1, 2008 - August 31, 2010

9,278 with Right Kidney Biopsy = "Yes"

% Glomerulosclerosis	Right Kidney Transplanted	
	Yes	No
Missing	0	22
0 to 5	4617	1204
6 to 10	856	470
11 to 15	322	297
16 to 20	180	2 53
20+	255	662
Indeterminate	61	79
Total	6291	2987

