

Chapter IX

DonorNet and the Potential Effects on Organ Utilization

Overview

- The evolution of communication as donor data flows from OPO to transplant centers has evolved with the incorporation of DonorNet 2007® into the UNetSM system. The ensuing study looks at DonorNet's impact on this process.
- Defined time periods were established for comparison purposes. The study looked at match number for organ placement and overall organ utilization with a focus on ischemia time and graft outcomes.
- The results of the study demonstrate no significant change in the median match number of organ placement in liver or kidney transplantation.
- Changes in discard rates were varied amongst transplanted organs and there were noticeable changes in organ sharing with an increase in local allocation for kidney and liver and an ensuing decrease in regional and national distribution.
- There were no significant differences in the outcomes of livers and kidneys with low offer numbers compared with those with high offer numbers.
- Overall the study suggests a modest impact by DonorNet on organ placement and utilization, but a longer term study would need to be done to fully evaluate its impact.

Introduction

UNetSM is the Organ Procurement and Transplantation Network's (OPTN) primary instrument for transplant data collection and verification. Upon its implementation on October 25, 1999, UNet represented a 2-and-1-half year, 30,000 person-hour effort by the United Network for Organ Sharing (UNOS) to update the OPTN information system. UNOS undertook the UNet development project in 1997 to meet the following goals: 1) resolve Year 2000 issues with the legacy mainframe system; 2) increase integration of the allocation and research data collection systems, eliminating parallel systems; 3) increase member access and functionality in the system; 4) allow for faster implementation of system changes; 5) increase system security and 6) increase the OPTN's ability to utilize emerging technologies. UNOS incorporated DonorNet® (a registered trademark of UNOS) into the UNetSM system on July 16, 2003. This system added several enhancements to the primary features previously included in the UNet Placement section including: allowing organ procurement organizations (OPOs) to add or modify information on donors and donor organs, initiate the donor-recipient matching process, and record organ placement information. The donor-recipient match process ranks all acceptable, active candidates with the specific information entered for a given donor. The resulting match list is the guideline by which all organs are offered to transplant centers for waiting transplant candidates. New features added in this section allowed OPOs to post donor information in an electronic file format for review by transplant personnel. Such files may include the OPO's donor information form, ancillary confirmatory information such as ABO confirmation documents or serology results, digital images of X-rays of the donor, and short video images of echocardiograms, angiograms or bronchoscopies. The belief was that by viewing posted source documents; transplant center personnel can reach an informed decision of whether to accept the organ for their transplant candidate. By adding these new features, the goal of the DonorNet system was to increase the efficiency and accuracy of the organ placement process (1).

At its September 20, 2006 meeting, the OPTN/UNOS Board of Directors unanimously approved a recommendation presented by the OPTN/UNOS Operations Committee to establish a national mandatory use date for the new electronic organ placement system on April 30, 2007. On December 9, 2006, UNOS released DonorNet 2007®, for voluntary use (1). The stated goal of DonorNet 2007 was to “facilitate and expedite organ placement” (2). Through this system, a “national list” is generated for the organ, and offers must be made to patients at centers based on the order of this list. At the local level, the offering OPO determines the number of offers to make with each notification. At the regional and national level, offers can be made to an unlimited number of patients up to 3 programs simultaneously for pre-recovery offers and up to 5 programs simultaneously for post-recovery offers. By permitting the simultaneous electronic notification of organ offers, this system represents a fundamental change in the organ placement process, with a focus on improving efficiency and organ utilization. Prior to DonorNet 2007, match lists were generated electronically but the organ offers were made manually based on contemporary OPTN guidelines and local practice. In the period before DonorNet, the transplant center for the potential recipient received donor information by telephone that involved either the on-site OPO professional or through a telephone intermediary. During that period there were

challenges transmitting a detailed clinical picture of the donor and there were limitations that prevented the transplant center from going back to reference the information during the period between donor offer and organ retrieval.

The design of DonorNet 2007 makes it possible to “send” multiple offers simultaneously. This initially led to an extraordinary increase in the volume of unwanted offers to many centers. Incremental upgrades were incorporated into DonorNet 2007 as a result of feedback provided to the OPTN staff and the Electronic Organ Placement Working Group. Changes in 2007 included limits on maximum miles the organ or recovery team will travel for select candidates. It also delineated if a center would accept a Hepatitis B core antibody positive donor or Hepatitis C antibody positive donor. Additional screening criteria: 1) allowed for differentiation between local and import values; 2) added screening for donors after cardiac death (DCD) donors with differentiation between local and import offers. In 2008 additional screening features were added: 1) maximum acceptable cold ischemic time (CIT), 2) maximum donor body mass index (BMI), 3) donor history of hypertension, diabetes, coronary artery disease, etc. The current emphasis is on the addition of capabilities to allow centers to restrict organ offers to those they are most likely to accept.

This study looks at several defined time periods to gauge the initial and subsequent impact of DonorNet on organ allocation efficiency, as iterative changes have occurred within the DonorNet system. It also looks at the impact of DonorNet on organ utilization along with a focus on ischemia time of transplanted organs and graft outcomes.

Methods

To compare changes following DonorNet’s implementation, 3 time periods were defined. They were selected for consistency and to avoid months where DonorNet was being modified. The Pre-DonorNet period was April 30, 2006 to October 31, 2006, immediately prior to any regional DonorNet testing. The Early DonorNet period was April 30, 2007 to October 31, 2007 and corresponds to the national launch on April 30, 2007. The Later-DonorNet period was April 30, 2008 to October 31, 2008, after the majority of the initial improvements to DonorNet were implemented. An additional period, “Historical,” April 30, 2005 to October 31, 2005, helps identify trends that preceded and may have been occurring independently of the DonorNet implementation. As few meaningful trends were identified that predated DonorNet implementation, these data are not presented but described in the text where applicable.

Organ Placement - Match Runs

The data on the distribution of the sequence number of the acceptor were assessed based on either number of patient specific offers or center specific offers. This was performed for each time period and was adjusted for the exclusion of bypasses. For instance, if the acceptor was number 201 on the match run, but offers were not made to patients 150 to 200 for some reason (aggressive placement, multi-organ placement, etc.) then the acceptor was considered to be offer 150 for that organ. In addition, for accepted organs the calculation of offer number ends with the match sequence number of the acceptor, regardless of the actual number of offers made. The calculation was defined in this manner because centers may accept or refuse organ offers for

their entire waiting list, and match run data do not distinguish between those center acceptances and refusals that are entered in response to an offer for a particular candidate, and those in response to an offer for a candidate higher up on the match run.

Data provided on the number of waiting list candidates excluded those patients waiting in an inactive status on October 31st of each year, and only counted those patients listed at multiple centers once.

Organ Recovery and Discard

All organs recovered for the purpose of transplantation during the defined periods were included in the analyses. The percentage of recovered organs that were discarded was calculated for all organ types. Additionally, kidney, liver, and pancreas results are stratified by organ-specific Donor Risk Index (DRI) quartiles, which are a measure of donor quality, with lower quartiles indicating a better donor (3,4,5). The DRI concept, originally introduced for liver donors, has also been adopted and developed for kidney and pancreas donors. DRIs use donor and transplant factors from Cox regression models that predict graft failure or death after liver, kidney or pancreas transplantation. In the case of liver transplantation, donor age over 40 years, donation after cardiac death and split/partial grafts are strongly associated with graft failure. In the kidney DRI, additional factors such as history of hypertension, history of diabetes, serum creatinine, cerebrovascular cause of death and human leukocyte antigen-B and donor risk mismatch are important factors that impact graft function. Statistically significant differences in the discard percentage by time period were evaluated via chi-square test.

Regional and National Sharing

All organs transplanted during the time periods were included in the analyses except zero mismatch and payback kidneys, as the policy for sharing of zero-mismatch kidneys changed during the study period. The exclusion of payback kidneys accounted for <4 percent of the total matches during the period. Organs were classified as local, if the donor and recipient were in the same OPO; regional, if the donor and recipient were in the same OPTN region but not the same OPO; or national, if the donor and recipient were in different OPTN regions. Statistically significant differences in the sharing percentages by time period were evaluated via chi-square test.

Ischemic Time

All organs transplanted during the periods under study were included in the analyses. The mean ischemia time is reported by period. For kidneys and livers, these data are collected as CIT and for all other organs as total ischemia time (cold + warm + anastamotic). Differences between time periods were compared via ANOVA test.

Outcomes of Organs Transplanted

Kidneys and livers that were transplanted in the post-DonorNet era between 11/1/2007 and 10/31/2008 were included in this analysis. These organs were divided into groups by offer number of the acceptor (excluding any bypasses). Unadjusted graft survival rates for each group were calculated with a Kaplan-Meier model. Adjusted graft survival rates for each group were

calculated with a Cox proportional hazards model, adjusted for recipient age, race, sex, and diagnosis. Statistical Analysis was performed using SAS Version 9.2., Cary, NC, USA.

RESULTS AND DATA ANALYSIS

Organ Placement - Match Runs

Liver Data

Liver match runs created between April 30, 2008 and October 31, 2008 were examined. Excluded from the analysis were match runs created by an importing OPO (instead of the recovering OPO), organs allocated for split liver, and cases with at least 1 refusal for directed donation. The calculation for the number of offers made during the placement of each liver excluded any refusals where the transplant center was not contacted (aggressive placement efforts, multi-organ candidate, etc.). The results of this analysis are shown in Tables IX-1 and IX-2.

Table IX-1. Liver Allocation Match Run - Number of Patient Specific Offers

Number of Offers	Number of Matches	Percentage Accepted
50+	880	20.6%
75+	742	19.4%
100+	649	18.8%
250+	342	16.1%
500+	183	13.1%
750+	84	14.3%

Table IX-2. Liver Allocation Match Run - Number of Center Specific Offers

Number of Centers Offered the Liver	Number of Matches	Percentage Accepted
5+	1138	28.1
10+	649	22.0
15+	404	18.8
20+	302	17.2
30+	156	10.3

To evaluate changes in the number of registrations on the match run the 3 DonorNet cohorts (Pre-DonorNet, Early DonorNet and Later-DonorNet) were analyzed (Tables IX-3 and IX-4). While the number of active candidates on the liver waiting list was essentially the same during these 3 time intervals, the median number of registrations on liver match runs (excluding bypass

offers) declined from 5245 in the 6 months after DonorNet implementation to 4763 for the same 6 months the following year (Later-DonorNet), (Table IX-3).

Table IX-3. Registrations on Match Run for Liver Offers

Period	Number of Active Candidates on the waitlist on 10/31	Median Number of Registrations on Match Run (Excluding Bypass Offers)	Match Sequence Number of Acceptor (Excluding Bypass Offers)						
			N	P25	Median	P75	P90	P95	P99
4/30/06 - 10/31/06	12,603	5261	3301	2.0	4.0	9.0	40.0	98.0	488.0
4/30/07 - 10/31/07	12,279	5245	3062	1.0	3.0	7.0	29.0	86.0	558.0
4/30/08 - 10/31/08	12,369	4763	2961	1.0	3.0	7.0	25.0	71.0	433.0

The median match sequence number of the acceptor decreased from #4 in the Pre-DonorNet dataset to #3 in both periods after DonorNet was initiated. Furthermore, the 75th, 90th, and 95th percentile values of match sequence number have all progressively decreased over time. In contrast, the median distribution of the sequence number of the center accepting the liver did not change, except at the 95th and 99th percentiles, where it increased under DonorNet (Table IX-4).

Table IX-4. Registrations on Match Run - Liver Offers, Center Data

Period	Number of Active Candidates on the waitlist on 10/31	Median Number of Registrations on Match Run (Excluding Bypass Offers)	Center Number Accepting Organ (Excluding Bypass Offers)						
			N	P25	Median	P75	P90	P95	P99
4/30/06 - 10/31/06	12,603	5261	3301	1	2	3	6	8	15
4/30/07 - 10/31/07	12,279	5245	3062	1	2	3	6	10	25
4/30/08 - 10/31/08	12,369	4763	2961	1	2	3	6	10	25

Substantial differences in the mechanics of organ placement preclude meaningful comparisons of offer number data between pre- and post DonorNet cohorts. However the aggregate data within 1 cohort allows us to analyze organ placement activity. During the Later-DonorNet, the number of livers with >50 offers was more than twice the number of those with >250 offers, and 10 times the number with >750 offers. While liver placement rates declined with increasing numbers of offers, livers with more than 750 offers were still placed 14.3 percent of the time, compared with 16.1 percent of livers with more than 250 offers (Table IX-1). Acceptance rates for livers with higher numbers of center offers were lower than for those with fewer offers (Table IX-2).

Kidney Data

Kidney match runs created between April 30, 2008 and October 31, 2008 were examined. Match runs created by an importing OPO (not the recovering OPO); cases with documented placement on multiple local match runs, and cases with at least 1 refusal for directed donation were excluded from the analysis. The calculation for the number of offers excluded any refusals where the transplant center was not contacted. For this analysis, when donors resulted in at least 1 kidney acceptance, the sequence number of the acceptor refers to the last kidney placed, and this also determines the offer number; results are shown in Tables IX-5 and IX-6.

Table IX-5. Kidney Offers Match Run - Patient Specific Offers

Donor Type								
Overall			DCD		ECD		SCD	
Number of Offers	Number of Matches	Percentage Accepted	Number of Matches	Percentage Accepted	Number of Matches	Percentage Accepted	Number of Matches	Percentage Accepted
75+	1077	52.5	145	61.4	442	40.3	490	60.8
100+	951	51.7	132	59.8	401	39.4	418	61.0
250+	647	45.7	100	52.0	258	28.3	289	59.2
500+	430	40.5	71	46.5	171	22.8	188	54.3
750+	326	33.4	58	41.4	129	16.3	139	46.0
1000+	268	29.9	52	36.5	105	13.3	111	42.3
1500+	196	24.5	41	24.4	70	5.7	85	40.0

Table IX-6. Kidney Offers Match Run - Center Offers

Donor Type								
Overall			DCD		ECD		SCD	
Number of Centers Offered Kidney	Number of Matches	Percentage Accepted	Number of Matches	Percentage Accepted	Number of Matches	Percentage Accepted	Number of Matches	Percentage Accepted
10+	823	47.9	104	50.0	328	35.1	391	58.1
15+	589	41.9	82	43.9	251	31.9	256	51.2
20+	455	41.3	73	39.7	190	33.7	192	49.7
30+	281	33.8	49	32.7	121	25.6	111	43.2
40+	181	29.3	35	17.1	74	23.0	72	41.7
50+	132	28.8	27	14.8	49	14.3	56	48.2
60+	92	27.2	20	10.0	35	11.4	37	51.4

During the Later-DonorNet cohort the number of kidneys with >75 offers was 50 percent greater than the number of kidneys with >250 offers, and more than 3 times the number with >750 offers (Table IX-5). Acceptance rates for kidney offers were much higher than for livers; kidneys with >75 offers were placed 52.5 percent of the time, and those with >500 offers were still placed 40.5 percent of the time. Overall, acceptance rates were lowest for expanded criteria donor (ECD) kidneys, and highest for standard criteria donor (SCD) kidneys; the decrease in acceptance rates with increasing offer number was greater for ECD and DCD kidneys than for SCD kidneys. Similar trends by donor type and offer number were observed in the center analysis, except that SCD kidney acceptance rates changed very little with increasing center offer number (Tables IX-5 and IX-6).

The number of active candidates on the kidney waiting list increased during the time intervals studied while the median number of registrations on kidney match runs (excluding bypass offers) declined (Tables IX-7 and IX-8). For SCD kidneys the median match sequence number of the acceptor decreased from 11 in the Pre-DonorNet group to 6 in the Later-DonorNet group. The median sequence number declined similarly for SCD and DCD kidneys, but not ECD kidneys. In contrast the median center number did not change appreciably under DonorNet, either overall or by any donor type. However, the 90th, 95th and 99th percentiles of center number increased under DonorNet, for ECD and DCD kidneys. This data suggests either an increase in efficiency of placement or an effect of the wider use of screening criteria.

Table IX-7. Registrations on Kidney Offer Match Run by Donor Type

Donor Type	Period	Number of Active Candidates on the waitlist on 10/31 (same for all donor types)	Median Number of Registrations on Match Run (Excluding Bypass Offers)	Match Sequence Number of Acceptor (Excluding Bypass Offers)						
				N	P25	Median	P75	P90	P95	P99
DCD	4/30/06 - 10/31/06	49,026	12473	308	10	26.5	103	313	545	2442
	4/30/07 - 10/31/07	50,564	12213	333	6	17	56	480	893	2585
	4/30/08 - 10/31/08	52,103	9680	371	5	13	71	441	1026	2959
ECD	4/30/06 - 10/31/06	49,026	4311	491	7	22	93	293	522	1269
	4/30/07 - 10/31/07	50,564	3932	521	7	30	166	518	795	1735
	4/30/08 - 10/31/08	52,103	3811	546	6	26	121	350	570	1378
SCD	4/30/06 - 10/31/06	49,026	12582	2302	4	11	35	139	392	1387
	4/30/07 - 10/31/07	50,564	12486	2188	3	8	30	144	418	1664
	4/30/08 - 10/31/08	52,103	12307	2134	3	6	27	141	480	1933

Table IX-8. Registrations on Kidney Offer Match Run by Donor Type, Center Number of Acceptor

Donor Type	Period	Number of Active Candidates on the waitlist on 10/31 (same for all donor types)	Median Number of Registrations on Match Run (Excluding Bypass Offers)	Center Number of Acceptor (Excluding Bypass Offers)						
				N	P25	Median	P75	P90	P95	P99
DCD	4/30/06 - 10/31/06	49,026	12473	308	2	4	8	12	16	31
	4/30/07 - 10/31/07	50,564	12213	333	2	3	7	14	31	79
	4/30/08 - 10/31/08	52,103	9680	371	2	3	6	14	27	54
ECD	4/30/06 - 10/31/06	49,026	4311	491	2	4	8	16	24	43
	4/30/07 - 10/31/07	50,564	3932	521	2	5	11	27	38	71
	4/30/08 - 10/31/08	52,103	3811	546	2	4	9	24	33	54
SCD	4/30/06 - 10/31/06	49,026	12582	2302	2	3	6	9	14	37
	4/30/07 - 10/31/07	50,564	12486	2188	2	3	5	10	17	41
	4/30/08 - 10/31/08	52,103	12307	2134	2	3	5	11	19	54

Organ Recovery

During the Pre-DonorNet period there was a peak of activity with a total of 14,141 organs recovered; followed by a decrease in total organ recovery during the subsequent 2 periods (Table IX-9). Lung recoveries increased in the Early DonorNet period and declined in the following year. Heart and intestine recoveries were the most stable over all periods compared with kidney, liver, pancreas and lung.

Table IX-9. Number of Recovered Organs by Time Period

Organ	Pre-DonorNet	Early DonorNet	Later-DonorNet
Kidney	7,271	7,152	7,094
Liver	3,667	3,557	3,408
Heart	1,210	1,169	1,160
Pancreas	1,073	1,002	943
Lung	817	835	800
Intestine	103	106	103
Total	14,141	13,821	13,508

There are many influences on organ utilization which makes it challenging to isolate the individual impact of DonorNet. However, as organ recovery, discard, and transplant rates all contribute to an assessment of utilization; the recovery rates provide perspective to the assessment of discard rates.

Organ Discard

Liver discard rates were significantly greater during the DonorNet periods (11.95 percent and 11.3 percent for Early and Later DonorNet, respectively) compared with the periods prior to DonorNet (9.8 percent) (Table IX-10). This was especially true for livers in the highest quartile of liver donor risk index (LDRI) (Quartile 4).

Table IX-10. Liver: Percentage Discarded by DRI Quartile and Time Period

DRI	Pre-DonorNet (n=3,667)	Early DonorNet (n=3,557)	Later-DonorNet (n=3,408)	Overall p-value
Q1 (Lowest DRI)	0.21	0.24	0.13	0.87
Q2	4.07	4.20	5.76	0.17
Q3	8.99	11.24	10.79	0.24
Q4 (Highest DRI)	26.30	30.40*	28.29	0.015
All	9.84	11.95**	11.33*	0.01

*p <0.05 vs Pre-DonorNet period

**p <0.01 vs Pre-DonorNet period

Livers in the lowest quartile of LDRI were discarded less in the Later DonorNet period (0.13 percent) compared with the previous 2 time periods (0.21 percent-0.24 percent). The decline in discards may represent improvements in liver placement, or may be a consequence of the reduction in liver recoveries over this time period. National sharing of livers decreased from Pre-DonorNet to the Later-DonorNet period, while local use increased over the same time periods (Table IX-11).

Table IX-11. Liver: Sharing of Transplanted Organs

Sharing	Pre-DonorNet (n=3,306)	Early DonorNet (n=3,132)	Later-DonorNet (n=3,022)	Overall p-value
Local %	66.58	67.34	69.03*	0.17
Regional %	24.53	24.78	23.36	
National %	8.89	7.89	7.61	

*p<0.05 compared to Pre-DonorNet period

While kidney discard rates increased to 17.7 percent in the Early DonorNet period from 16.2 percent in the Pre-DonorNet period ($p < 0.05$), (Table IX-12), they decreased to 16.9 percent in the Later-DonorNet period, which suggests a possible improvement in utilization during DonorNet. Among kidneys in the highest quartile of kidney donor risk index (KDRI), discard rates decreased to 36 percent ($p < 0.05$ compared to Pre-DonorNet) in the Later-DonorNet period. Kidney recoveries with high KDRI increased from the Early DonorNet period to the Later-DonorNet period, suggesting a potential improvement in placement of high DRI quartile kidneys with DonorNet (SRTR Special Analysis 2009, not shown). A similar pattern was observed with kidneys with low KDRI. However, since kidney discards in the lowest quartile of KDRI also decreased from the Historical period to the Pre-DonorNet (not shown), the overall impact of DonorNet on these kidneys is difficult to assess. Discard rates of kidneys in the middle quartiles of KDRI (Q2 and Q3) increased, albeit not significantly, from the Early to Later-DonorNet periods, and are currently greater than historical rates.

Table IX-12. Kidney: Percentage Discarded by DRI Quartile and Time Period

DRI	Pre-DonorNet (n=7,271)	Early DonorNet (n=7,152)	Later- DonorNet (n=7,094)	Overall p-value
Q1 (Lowest DRI)	2.25	3.80**	3.30†	0.03
Q2	6.43	7.21	7.83	0.28
Q3	16.79	16.06	17.36	0.58
Q4 (Highest DRI)	39.66	42.71†	36.38*	0.0006
All	16.22	17.70*	16.94	0.059

†p < 0.10 vs Pre-DonorNet period

*p < 0.05 vs Pre-DonorNet period

**p < 0.01 vs Pre-DonorNet period

Non-mandatory sharing of kidneys increased under DonorNet (Table IX-13). While national sharing of kidneys increased from 7.3 percent to 8.6 percent between Pre-DonorNet and Early DonorNet, this declined to 8.0 percent in the Later-DonorNet period. This latter decrease corresponds to an increase in regional sharing in the Later-DonorNet period.

Table IX-13. Kidney: Sharing of Transplanted Organst

Sharing	Pre-DonorNet (n=5,151)	Early DonorNet (n=4,887)	Later- DonorNet (n=4,881)	Overall p-value
Local %	85.58	84.12*	83.96*	0.06
Regional %	7.14	7.33	8.03	
National %	7.28	8.55*	8.01	

† Excludes zero mismatch and payback organs

*p < 0.05 compared to Pre-DonorNet period

Pancreas discard rates, which had increased Pre-DonorNet, decreased (not significantly) after DonorNet implementation (Table IX-14). There were no specific trends observed by quartiles of pancreas donor risk index (PDRI). National sharing of pancreata has increased under DonorNet (Table IX-15).

Table IX-14. Pancreas: Percentage Discarded by DRI Quartile and Time Period

DRI	Pre-DonorNet (n=1,073)	Early DonorNet (n=1,002)	Later- DonorNet (n=943)	Overall p-value
Q1 (Lowest DRI)	17.13	13.14	16.22	0.44
Q2	19.09	21.05	22.41	0.67
Q3	33.20	28.40	28.45	0.41
Q4 (Highest DRI)	49.83	54.62	45.22	0.13
All	30.29	28.94	27.89	0.49

Table IX-15. Pancreas: Sharing of Transplanted Organs

Sharing	Pre-DonorNet (n=748)	Early DonorNet (n=712)	Later- DonorNet (n=680)	Overall p-value
Local %	74.06	68.68*	69.26*	0.03
Regional %	12.57	11.94	12.50	
National %	13.37	19.38*	18.24*	

*p<0.05 compared to Pre-DonorNet period

Discard rates of hearts and intestines have declined (Table IX-16). Sharing of thoracic organs has increased under DonorNet (Tables IX-17, Table IX-18), but it should be noted that the implementation of DonorNet coincided with changes in heart allocation which expanded sharing of cardiac allografts for Status 1A and 1B candidates. Sharing of intestinal organs, after an initial shift away from local allocation to national allocation in the Early DonorNet period, subsequently returned to percentages comparable to Pre-DonorNet (Table IX-19).

Table IX-16. Heart, Lung, Intestine: Percentage Discarded by Time Period

Organ	Pre-DonorNet	Early DonorNet	Later- DonorNet	Overall p-value
Heart (n=3,539)	1.07	0.77	0.78	0.66
Lung (n=2,452)	4.53	4.79	4.38	0.92
Intestine (n=312)	6.80	1.89†	2.91	0.15

†p <0.10 vs Pre-DonorNet period

Table IX-17. Heart: Sharing of Transplanted Organs

Sharing	Pre-DonorNet (n=1,197)	Early DonorNet (n=1,160)	Later- DonorNet (n=1,151)	Overall p-value
Local %	53.30	46.90*	45.87*	0.002
Regional %	15.96	18.10	16.85	
National %	30.74	35.00*	37.27*	

*p<0.05 compared to Pre-DonorNet period

Table IX-18. Lung: Sharing of Transplanted Organs

Sharing	Pre-DonorNet (n=780)	Early DonorNet (n=795)	Later- DonorNet (n=765)	Overall p-value
Local %	48.85	43.02*	47.19	0.006
Regional %	17.56	14.47	14.51	
National %	33.59	42.52*	38.30	

*p<0.05 compared to Pre-DonorNet period

Table IX-19. Intestine: Sharing of Transplanted Organs

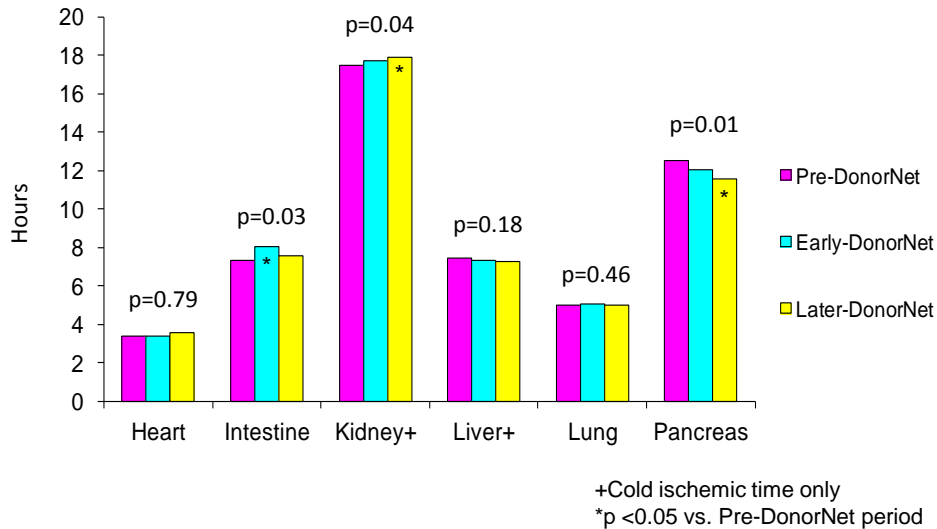
Sharing	Pre DonorNet (n=96)	Early DonorNet (n=104)	Later DonorNet (n=100)	Overall p-value
Local %	27.08	13.46*	23.00	0.052
Regional %	20.83	14.42	15.00	
National %	52.08	72.12*	62.00	

*p<0.05 compared to Pre-DonorNet period

Ischemia Times

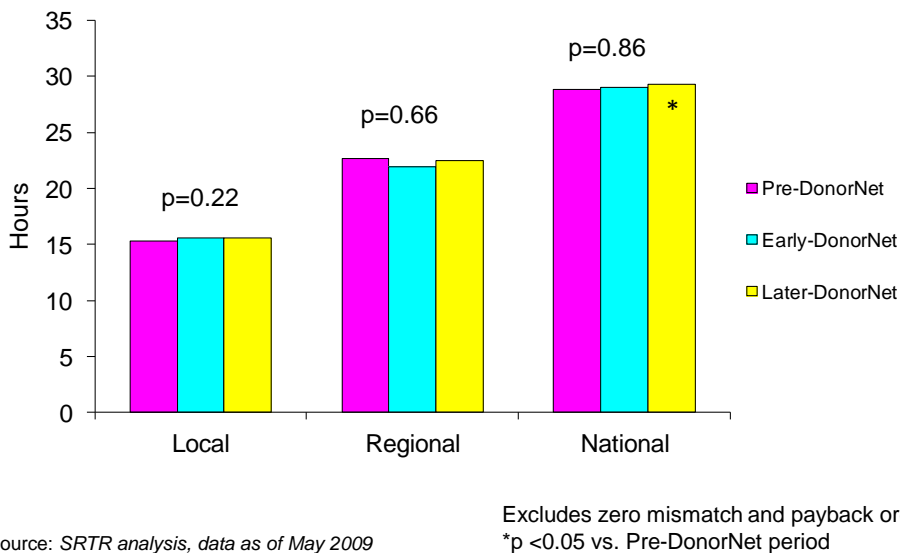
The mean length of ischemia time for individual organs was evaluated (Figure IX-1). There is no difference in total ischemia time for heart or lung transplants across cohorts. A gradual decline was found in CIT for liver transplants from 7.5 hours in the Pre-DonorNet time to 7.3 hours in the Later-DonorNet period. In the kidney cohort there was an increase in CIT in the Later-DonorNet period compared with the Pre-DonorNet time, 17.9 hours and 17.5 hours, respectively. Pancreas ischemia times decreased from 12.5 hours in the Pre-DonorNet period to 11.6 hours in the Later-DonorNet period. Since increases in CIT from increased sharing could potentially obscure potential improvements in efficiency under DonorNet, changes in CIT were evaluated by sharing status; for kidney and intestine, no significant changes in CIT were observed at any level of sharing (Figures IX-2, IX-3).

Figure IX-1. Mean Ischemic Time for Transplanted Organs, by Organ and Time Period



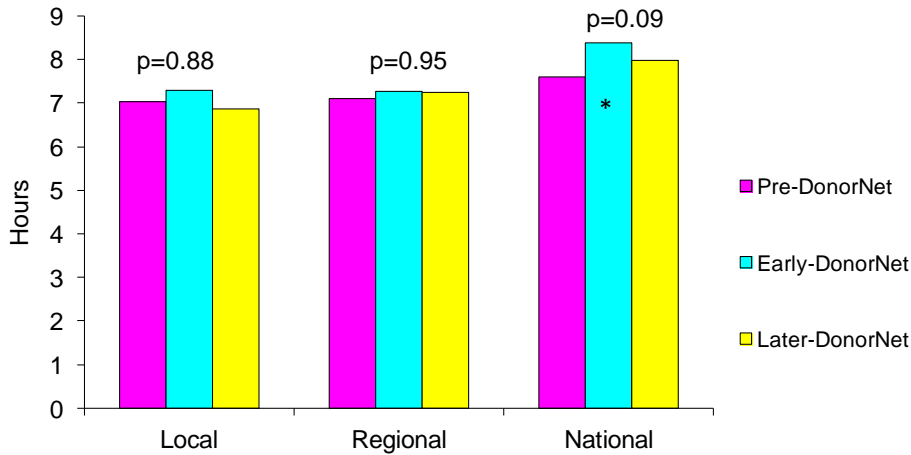
Source: SRTR analysis, data as of May 2009

Figure IX-2. Mean Cold Ischemic Time for Transplanted Kidneys, by Sharing and Time Period



Source: SRTR analysis, data as of May 2009

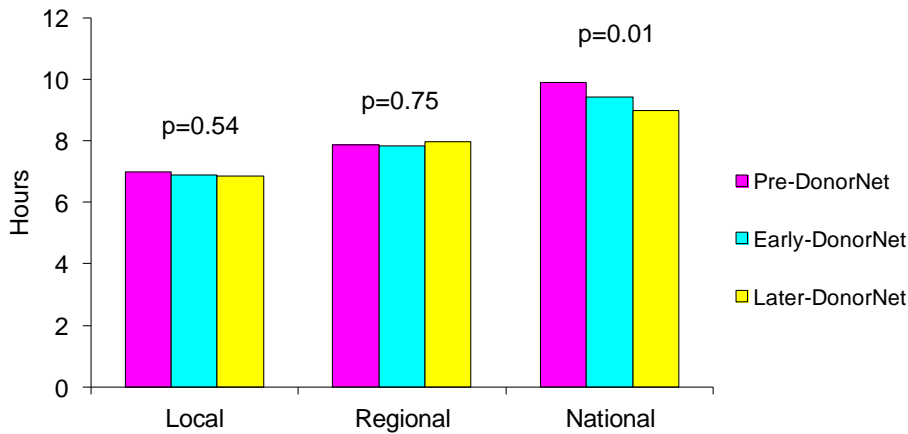
Figure IX-3. Mean Ischemic Time for Transplanted Intestines, by Sharing and Time Period



*p <0.05 vs. Pre-DonorNet period

Source: SRTR analysis, data as of May 2009

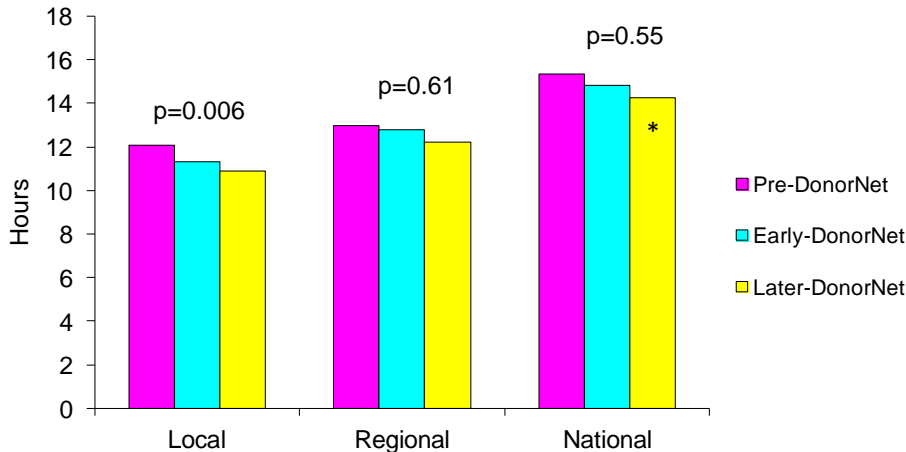
Figure IX-4. Mean Cold Ischemic Time for Transplanted Livers, by Sharing and Time Period



*p <0.05 vs. Pre-DonorNet period

Source: SRTR analysis, data as of May 2009

Figure IX-5. Mean Ischemic Time for Transplanted Pancreas, by Sharing and Time Period



*p <0.05 vs. Pre-DonorNet period

Source: SRTR analysis, data as of May 2009

Figure IX-4 demonstrates little difference in mean CIT for livers allocated locally or regionally, but there was a decline in CIT at the national level from Pre-DonorNet to Later-DonorNet. For pancreas transplantation there were significantly shorter total ischemia times in the locally allocated transplants in the post-DonorNet era, with similar but non-significant decreases in regional and national organs (Figure IX-5).

Organ Outcomes

Liver Results

No significant differences were seen in unadjusted or adjusted liver graft survival based on offer number. The 1-year adjusted graft survival for transplanted livers with >50 offers was slightly worse than those with <50 offers, though not statistically different (SRTR Special Analysis 2009, not shown). Among organs with <50 offers, there was no difference in graft survival for those with ≤3 offers, 21-50 offers, or intermediate offer number categories (Table IX-20). Among those with >50 offers, both the unadjusted and adjusted 1-year graft survival decreased slightly with increasing offer number, though these differences are not statistically significant. This indicates that transplanted organs with high offer numbers appear to have similar outcomes compared to those with lower offer numbers.

Table IX-20. Liver Graft Survival by Offer Number of Acceptor

Offer Number	N	Unadjusted 1 year graft survival (95% CI)	Adjusted 1 year graft survival * (95% CI)
1-3	3,464	86.0 (84.3, 87.5)	85.7 (83.9, 87.6)
4-10	1,320	86.6 (83.6, 89.1)	86.3 (83.3, 89.5)
11-20	386	83.7 (78.1, 88.0)	83.6 (78.1, 89.4)
21-50	313	88.1 (82.5, 92.0)	87.6 (82.0, 93.7)
51-100	122	81.3 (67.6, 89.7)	78.8 (67.2, 92.5)
101-250	118	82.2 (68.6, 90.3)	81.0 (68.8, 95.3)
251+	127	83.1 (72.7, 89.8)	85.9 (79.0, 93.4)

*Adjusted for recipient age, race, gender, and diagnosis

Renal Results

Among transplanted kidneys, the 1-year unadjusted graft survival rates of kidneys for recipients with offer numbers >50 were significantly lower than those with offer numbers 1-10 (Table IX-21); however, after adjusting for recipient age, race, gender and diagnosis, there were no significant differences among the groups. There were no significant differences in kidney graft survival associated with increasing numbers of offers among those kidneys transplanted after >300 offers. These results suggest that kidneys transplanted into candidates with high offer numbers have acceptable short-term graft outcomes.

Table IX-21. Kidney Graft Survival by Offer Number of Acceptor

Offer Number	N	Unadjusted 1 year graft survival (95% CI)	Adjusted 1 year graft survival * (95% CI)
1-10	5,575	93.6 (92.6, 94.5)	93.5 (92.3, 94.7)
11-50	2,282	92.4 (90.8, 93.7)	92.4 (90.6, 94.2)
51-100	595	88.0 (83.7, 91.2)	88.9 (85.1, 93.0)
101-300	725	88.5 (84.6, 91.4)	91.0 (87.9, 94.3)
301-500	298	88.0 (81.3, 92.4)	87.9 (81.7, 94.5)
501-1000	242	92.6 (86.6, 95.9)	94.5 (91.3, 97.8)
1000+	241	87.5 (79.6, 92.4)	88.5 (81.4, 96.3)

*Adjusted for recipient age, race, gender, and diagnosis

Discussion

The mandatory incorporation of an electronic organ offer system was met with angst by some members of the transplant community. Initial surveys completed by transplant practitioners and administrators expressed frustration with: the sudden increase in the number of organ offers that did not lead to transplants, the change in mechanisms for communication and challenges with the methodologies needed to access the system (personal communication D Gerber, ASTS survey-2008). After iterative changes were made to DonorNet 2007, a follow-up survey demonstrated a mix of positive and negative attitudes towards the technology (personal communication D Gerber, ASTS Survey-2009). The transparency in the system and the availability of detailed donor data is portrayed as a key positive role in transplant activities.

This study was designed to objectively assess the impact of DonorNet 2007 with respect to achieving its stated goals while analyzing for any causality related to DonorNet. How well does DonorNet meet its intended goals of facilitating and expediting organ placement? The data demonstrates improvements in the efficiencies of organ placement, including a decrease in the accepted organ offer number for select kidney match runs. Interestingly this was not demonstrated in the liver data. There was a generalized increase in local and regional allocation except for heart where changes in the national allocation policy overlap this study. The transition in organ sharing towards local and regional distribution suggests that organs are currently offered based on the intended allocation sequence. Organ utilization has been further optimized with the ability to place additional filters for organ offers at the center level.

The data also suggests that DonorNet has the intended consequence of decreasing the OPO practice of bypassing local or regional centers for an “aggressive” national center. This is apparent in Tables IX-7 and IX-8 where the 90th-99th percentiles of center number increased for ECD and DCD kidneys with the start of DonorNet. One possible explanation for this increase is that DonorNet was continually used for placement rather than short-circuiting the process by subjectively looking for an “aggressive” center. The subsequent decrease in center number in the Later-DonorNet would reflect a time when centers added additional filters to determine which offers they were interested in evaluating. The historic arguments that “aggressive” centers drove organ utilization in the pre-DonorNet period is not supported by the data, as this study found no significant increase in discard rates for most organs and only a slight increase in discard rates for livers. This suggests that organs are being successfully placed with the electronic offer process of DonorNet.

With iterative improvements and efficiencies in DonorNet the data doesn’t demonstrate any unintended consequences on ischemia time. In liver transplantation there is a 0.2 hour decrease in CIT with a 0.4 hour increase in CIT for kidneys when comparing Historical to Later-DonorNet periods (data not shown). This increase in CIT is potentially a function of sharing. Other factors including the recipient center and patient need for dialysis pre-transplant can also contribute to duration of ischemia time, so no definitive conclusions can be drawn about DonorNet’s efficiency of kidney placement. Presumably these changes in ischemia time have little impact on graft outcomes. One-year graft survival analyses by offer number suggest that there is no pure

cut-off for select organs beyond which an organ's lack of function could be predicted, which has potentially important implications for organ acceptance behavior.

The complexity of the processes that surround organ allocation and transplantation, and that have evolved under DonorNet, make data assessment and establishing causality a challenging process. For example, whether the decrease in acceptor match sequence number for SCD kidneys is due to greater efficiency of offer or is due to simply better use of screening criteria is unknown. While the data suggest that DonorNet has achieved an impact at facilitating organ placement, further study will permit clarification of these effects and identification of refinements that will improve the efficiency of DonorNet.

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