

KIDNEY ALLOCATION SYSTEM (KAS) “OUT-OF-THE-GATE” MONITORING REPORT

January 15, 2015

Purpose: Provide an early look at high-level metrics revealing performance of the system, and detect unanticipated patterns that suggest early, severe unintended consequences that may warrant near-term course corrections. A goal is also to have information on hand for responding to the media, general public, and transplant community in the wake of KAS implementation on December 4, 2014. This report will serve as a complement to the more extensive analyses that will be performed for the kidney committee at 6 months, 1 year, and 2 years post-implementation.

This monitoring plan is aimed at addressing these types of high-level questions:

Waitlist

1. Is the kidney waitlist growing at about the same rate as before?
2. How many candidates still don't have an EPTS score due to unverified data?
3. How many CPRA 99+ candidates don't have both approver names entered?
4. How many blood type B candidates are eligible to receive A2/A2B kidneys?

Transplants

1. Is the rate of deceased donor kidney transplants about the same as before?
2. What types of candidates are being transplanted?
3. What is the geographic distribution of transplants (local/regional/national)?
4. Are there noticeable changes from before KAS (expected or unexpected) related to access to and geographic distribution of transplants?
5. What proportion of transplants are going to EPTS Top 20% patients vis-à-vis Bottom 80% patients?
6. Is there evidence of decreased age or longevity-mismatching due to the new policy?

Kidney utilization

1. Is the rate of recovering deceased kidney donors about the same as before?
2. Is the number of kidneys recovered for transplantation as expected?
3. Do we see any sharp changes in the kidney discard rate, in particular for high KPDI kidneys?
4. Do we see a sharp rise in the number of kidneys accepted for a candidate but ultimately either discarded or transplanted into a different candidate, in particular, for (non-local) CPRA 99-100 patients? (starting in February, pending data availability)

Executive Summary

In the first approximately one month after implementation of KAS, three sharp changes are evident in the types of transplants being performed: a 7-fold increase in transplants for CPRA 99-100 patients; an increase in non-local transplants from around 20% to 35%; and a drop in the number of age-mismatched (and longevity-mismatched) transplants (**Figure 4 and Table 2**). These changes were expected based on core components of the new system such as the CPRA sliding scale, broader sharing for very highly sensitized patients, and longevity-matching using EPTS and KDPI.

The distribution of transplants by candidate age appears to have shifted moderately, with an increase observed for candidates ages 18-49 and a decrease for candidates over age 50. Pediatric transplants have decreased from approximately 5.0% to 2.2%, a trend that demands close monitoring. Fewer zero-mismatch transplants (5.2%) have been performed in the first month post-KAS since beforehand (~8%). These early data do not reveal any marked changes in the distribution of transplants by candidate race/ethnicity. (**Table 2**)

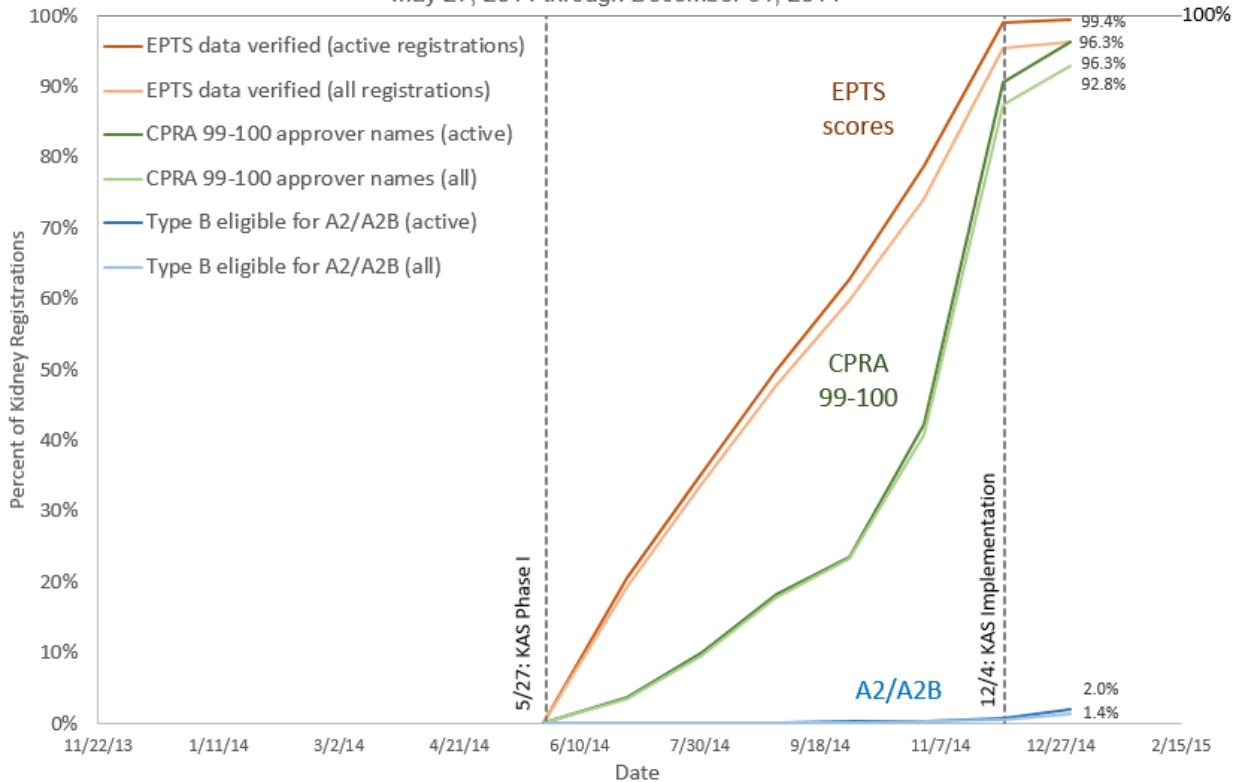
Though **Figure 3** suggests the number of transplants has decreased, the 30-day transplant rate of 878.6 is on par with December 2013 through February 2014. Though **Figure 2** shows a decrease in kidney registrations since implementation, the rate of registrations per 30 days only 3% less than the rate seen in the month leading up to KAS. Though this trend warrants continued close monitoring, these data should not be a cause for alarm due to the small size of the drop, limited sample size, and known influence of the December holidays on registration activity.

The rate of kidneys being recovered for transplantation has not changed (**Figure 5**). Though overall discard rates are up slightly (22.4%, compared to a recent historical rate of about 19%), sample sizes are too limited to draw conclusions. Discard rates for high KDPI kidneys (86-100) have not changed markedly compared to pre-KAS rates. The mere possibility of an increase in discard rates demands continued close monitoring.

Figure 1 highlights the success of the six-month, KAS Phase I period in guiding centers to update and verify candidate data in preparation for KAS. As of December 31, over 99% of active kidney registrations had an EPTS score, and over 96% of active, very highly sensitized (CPRA 99-100) kidney registrations are eligible for increased priority due to centers entering approver names into UNetSM. However, only 2% of blood type B candidates have been indicated as willing to accept an A2/A2B-subtyped kidney, a low signup rate that should be studied to ensure this aspect of the system reaches its full potential to increase transplant opportunities for these patients.

Waitlist

Figure 1: KAS Readiness Monitoring
May 27, 2014 through December 31, 2014



Interpretation

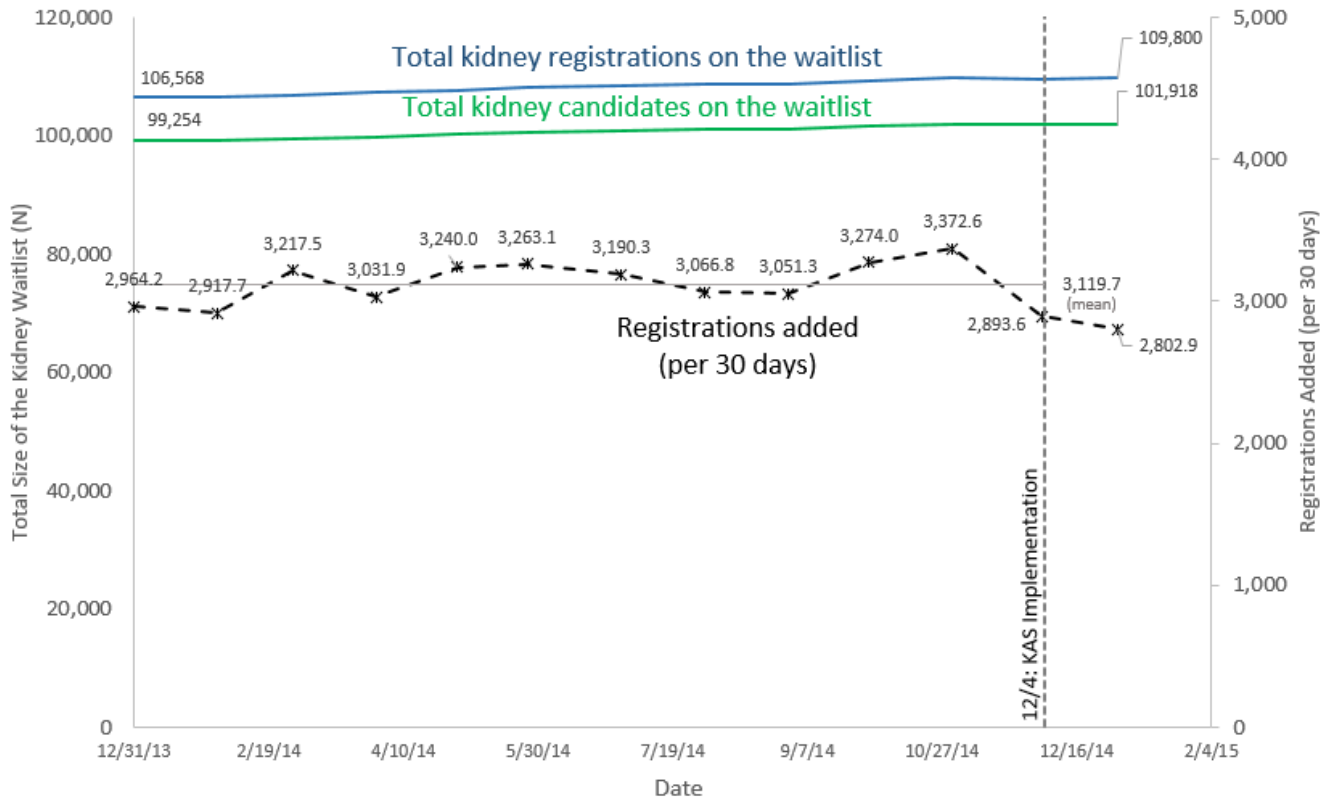
The six-month preparation phase (KAS Phase I) beginning on May 27 proved highly successful in allowing centers to update and verify data needed for calculating candidates' Estimated Post Transplant Survival (EPTS) and to input approver names for CPRA 99-100% patients eligible for increased priority (**Figure 1**).

As of December 31, 99.4% of active kidney registrations and 96.3% of all registrations had EPTS scores. Approver names have been entered for 96.3% of active and 92.8% of all kidney registrations with CPRA of 99 or 100%.

However, strikingly few (222 of 11,064, or about 2%) active blood type B registrations were listed as willing to accept an A2 or A2B kidney as of December 31. Far more have been reported as ineligible (N=1,214; 11%), and the vast majority still have unknown status (N=9,615; 87%)¹. Participation in the A2/A2B→B aspect of KAS is optional.

¹ Also, 13 registrations had their eligibility – which must be reconfirmed every 90 days – expire as of Dec 31, 2014.

Figure 2: Pre/Post-KAS Growth in the Kidney Waitlist
December 1, 2013 through December 31, 2014



Interpretation

The number of kidney registrations added dropped slightly in the weeks prior to KAS implementation (12/4), perhaps owing to the Thanksgiving holiday. In the first 28 days after KAS implementation, 2,616 kidney registrations were added. Normalized to a 30-day period, this early post-KAS rate of 2,802.9 registrations added is slightly lower than the average of 3,119.7 observed in the prior year. The rate of 2,802.9 represents a 3% decrease from the immediate pre-KAS period. Though it is likely that this drop is influenced by random variation and the December holidays and may not reflect a real trend, it warrants continued close monitoring (**Figure 2**).

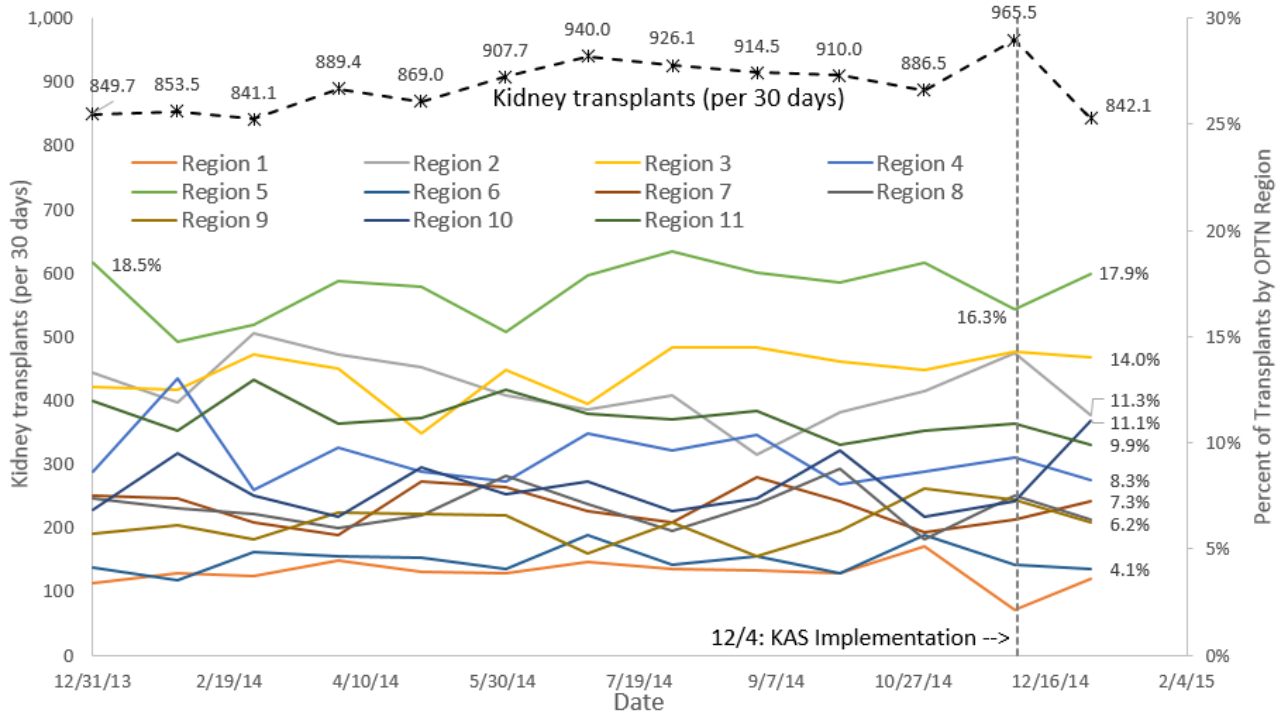
The size of the kidney waitlist continues to grow, with nearly 110,000 registrations – nearly 102,000 unique patients – on the list as of December 31, 2014.

Table 1: Waitlist Growth and KAS Readiness Metrics
June 30, 2014 through December 31, 2014

#	Metric	30JUN14	31JUL14	31AUG14	30SEP14	31OCT14	03DEC14	31DEC14
1	Total KI registrations on list	108,545	108,669	108,877	109,373	109,861	109,708	109,800
2	Total KI candidates on list	100,953	101,066	101,188	101,568	101,963	101,856	101,918
3	% w/active status	60.9%	60.8%	60.8%	60.8%	60.7%	60.6%	60.2%
4	KI Registrations added	3,139	3,169	3,153	3,274	3,485	3,183	2,616
5	KI regs added per 30 days	3139	3066.8	3051.3	3274	3372.6	2893.6	2802.9
6	Number with EPTS score	20,885	36,729	52,044	65,390	81,500	104,795	105,790
7	Number without EPTS score	87,660	71,940	56,833	43,983	28,361	4,913	4,010
8	% with EPTS score	19.2%	33.8%	47.8%	59.8%	74.2%	95.5%	96.3%
9	% Active with EPTS score	20.5%	35.3%	49.8%	62.8%	78.7%	99.1%	99.4%
10	Number CPRA 99-100 regs	9,305	9,288	9,310	9,305	9,222	9,147	8,987
11	%with approvers names	3.5%	9.5%	17.8%	23.3%	40.7%	87.4%	92.8%
12	# of blood type B registrations	17,801	17,847	17,894	18,002	18,067	18,086	18,110
13	% eligible for A2/A2B KI	0.028%	0.067%	0.129%	0.161%	0.249%	0.448%	1.403%

Transplants

Figure 3: Pre vs. Post-KAS Deceased Donor Kidney Transplant Volume, Overall and % by Region
Dec 1, 2013 through Dec 31, 2014

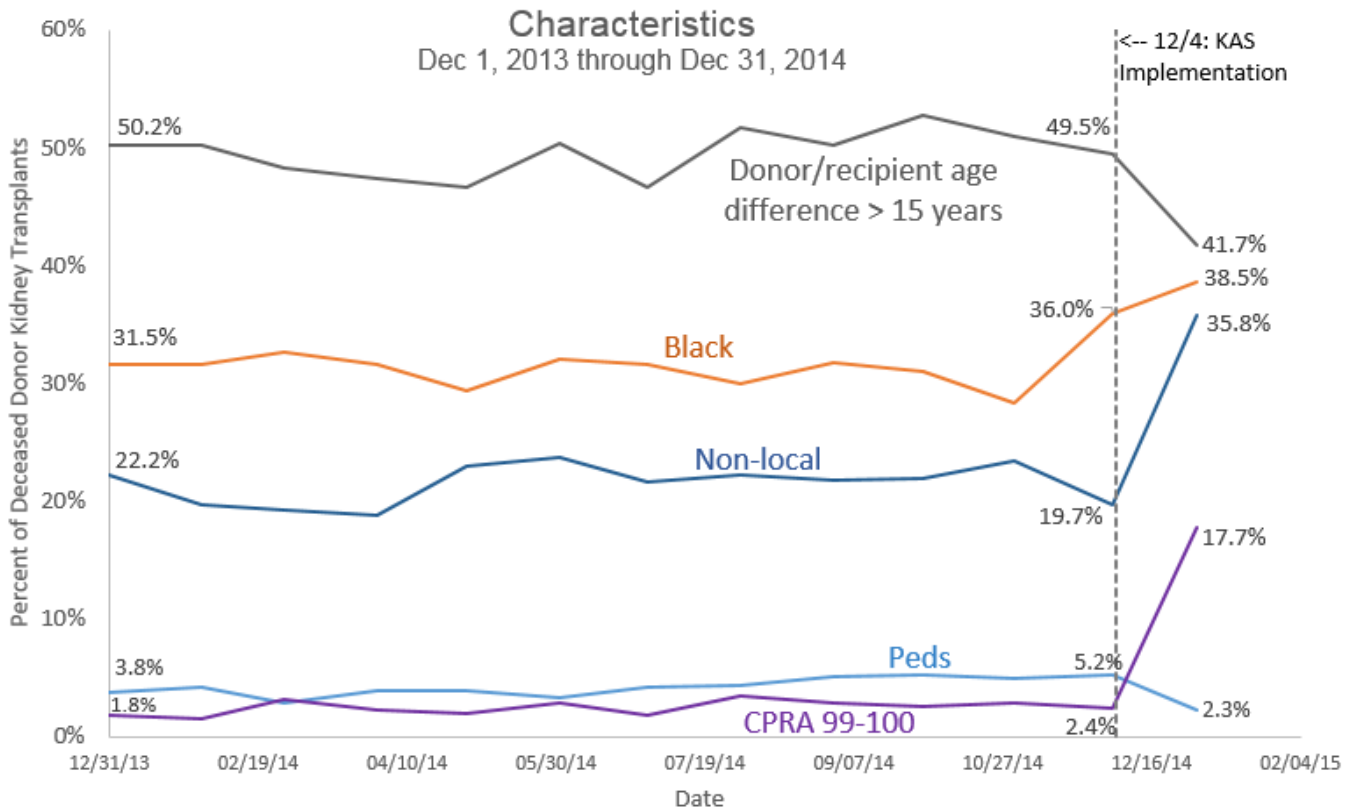


Interpretation

In the first 28 days after KAS implementation (Dec 4 through Dec 31), 786 deceased donor kidney transplants were performed, a rate of 842.1 per 30 days (**Figure 3**). Though this represents a decrease from the months immediately preceding KAS, is it on par with the rate of transplants that occurred in December 2013 and early 2014. Based on these findings, there is no initial cause for concern about a decrease in transplant volume due to KAS.

Figure 3 also shows the percentage of transplants across the 11 OPTN regions. These early findings suggest that the proportion of transplants by OPTN region will not be substantially affected by KAS. Though Region 10 has seen an early increase in transplants (about 7% to 11.1% of total) and Region 8 a slight decrease (7.5% to 6.4%), sample sizes are too small to draw conclusions regarding sustained changes in access to transplants across the 11 regions.

Figure 4: Pre vs. Post KAS Deceased Donor Kidney Recipient



Interpretation

Figure 4 reveals three sharp changes in the characteristics of deceased donor kidney transplants immediately post-KAS implementation.

Firstly, and most dramatically, the percentage of transplants going to CPRA 99-100 patients has jumped from about 2.5% to 17.7%, a 7-fold increase. This rise was expected due to the CPRA sliding scale, coupled with regional and national priority for CPRA 99-100 patients. SRTR’s KPSAM simulation results predicted about a 5-fold increase in the number of transplants going to these most highly sensitized patients. Simulations also suggested the occurrence of a “bolus” effect: a large initial number of CPRA 99-100 transplant recipients that would gradually decrease as these patients, many of whom have been on the waitlist for many years, would comprise a smaller proportion of the waitlist over time.

Secondly, the percentage of kidney transplants in which the kidney was shipped outside the local donor service area (DSA) increased from about 20% to 35.8%. An increase in non-local transplants was expected due to regional and national priority for CPRA 99-100 patients as well as combined local/regional distribution of high KDPI kidneys. Early data suggest that both elements of the new policy are contributing to this increase in

non-local transplants, due to the following: the aforementioned 7-fold increase in CPRA 99-100 transplants; a shift from 30% to 50% of KDPI 86-100 transplants going outside the local DSA.

Thirdly, the percentage of transplants in which the donor and recipient age differed by more than 15 years dropped from about 50% to 41.7%; this trend was expected since the new system incorporates longevity-matching. Similarly, as shown in **Table 2**, the mean donor-recipient age difference dropped from over 18 to 15.5 years. Likewise, the percentage of *longevity-mismatched* transplants – defined here as those in which the recipient was age 65+ and the donor KDPI was less than 35% – fell from 6.5% to 3.3% in the immediate pre vs. post-KAS periods.

The distribution of transplants by candidate age appears to have shifted moderately, with increases observed for candidates ages 18-49 and decreases for candidates over age 50. Pediatric transplants decreased from approximately 5.0% to 2.3%. Fewer zero-mismatch transplants (5.3%) have been performed in the first month post-KAS since prior to KAS (8-9%). It is conceivable that the decreases in pediatric and zero-mismatch transplants have been driven by the sharp increase in the proportion of transplants for very high CPRA patients, who appear at the very top of the allocation sequence.

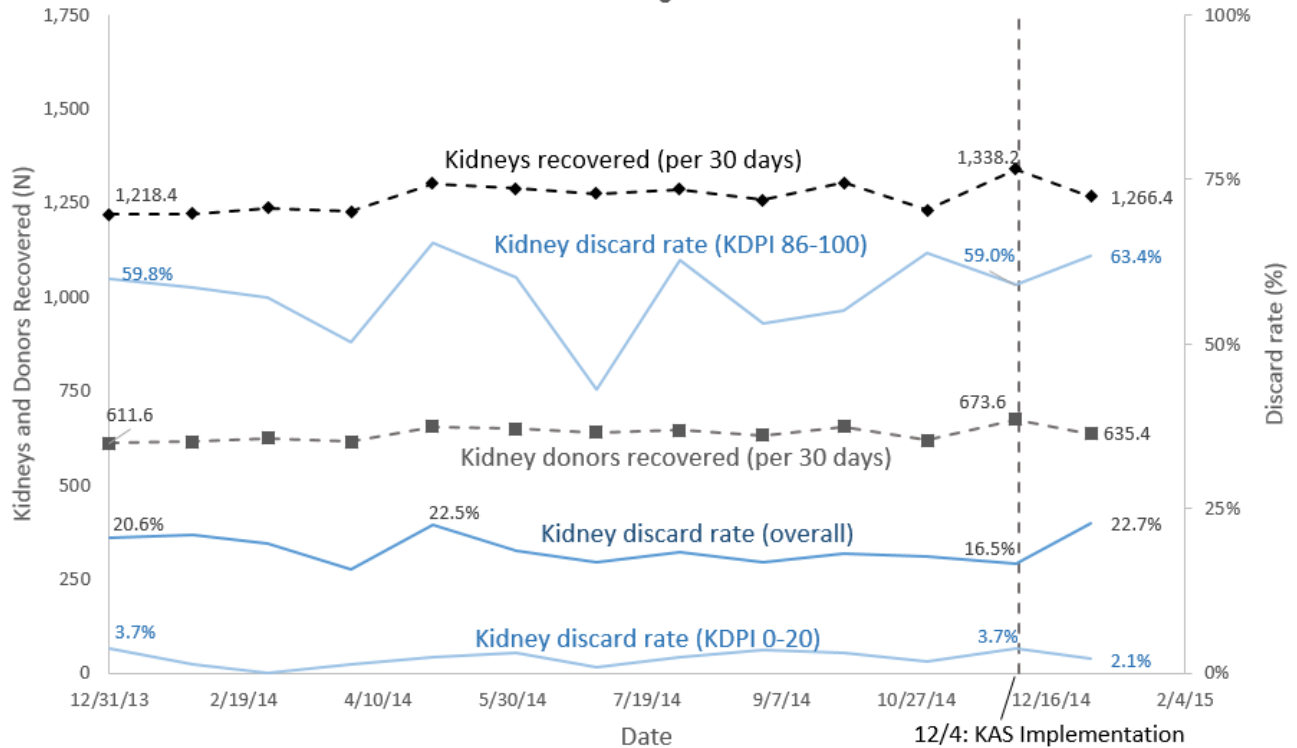
Given the modest sample sizes, some of these initial pre vs. post-KAS differences may not be real, but rather manifestations of natural, month-to-month variability. As further data are collected, we will be able to more reliably distinguish true signals from random noise. Future versions of this report will include statistical tests and confidence intervals to help assess whether observed effects are real.

Table 2: Pre vs. Post-KAS Transplant Volume and Characteristics
June 30, 2014 through December 31, 2014

#	Metric	30JUN14	31JUL14	31AUG14	30SEP14	31OCT14	03DEC14	31DEC14
1	Total # deceased KI-alone transplants	940	957	945	910	916	1062	786
2	Total # deceased KI-alone transplants per 30 days	940.0	926.1	914.5	910.0	886.5	965.5	842.1
3	% Transplants: age 0-17	4.1%	4.3%	5.1%	5.3%	4.9%	5.2%	2.3%
4	% Transplants: age 18-34	7.9%	10.3%	10.1%	9.6%	9.3%	8.6%	13.1%
5	% Transplants: age 35-49	23.4%	25.6%	25.5%	21.4%	23.9%	23.5%	28.9%
6	% Transplants: age 50-64	40.6%	37.8%	37.5%	41.5%	38.0%	42.1%	38.7%
7	% Transplants: age 65+	23.9%	21.9%	21.9%	22.2%	23.9%	20.6%	17.0%
8	% Transplants: Ethnicity - White	41.1%	41.8%	40.0%	41.5%	44.4%	38.1%	35.2%
9	% Transplants: Ethnicity - Black	31.6%	30.0%	31.7%	31.0%	28.3%	36.0%	38.5%
10	% Transplants: Ethnicity - Other	27.3%	28.2%	28.3%	27.5%	27.3%	25.9%	26.2%
11	% Transplants: CPRA 0	61.0%	59.7%	58.5%	63.1%	62.2%	60.6%	56.7%
12	% Transplants: CPRA 1-79	25.9%	24.1%	24.1%	22.7%	21.4%	24.3%	17.0%
13	% Transplants: CPRA 80-94	8.5%	9.2%	11.0%	8.9%	10.2%	10.1%	4.2%
14	% Transplants: CPRA 95-98	2.9%	3.6%	3.5%	2.7%	3.4%	2.6%	4.3%
15	% Transplants: CPRA 99-100	1.8%	3.4%	2.9%	2.5%	2.8%	2.4%	17.7%
16	% Transplants: EPTS 0-20	23.2%
17	% Transplants: EPTS 21-100	74.3%
18	% Transplants: EPTS Missing (including peds)	2.5%
19	% Transplants: OMM	8.8%	8.9%	7.4%	8.1%	8.6%	8.4%	5.3%
20	% Transplants: Placement- Non-Local	21.6%	22.3%	21.7%	22.0%	23.4%	19.7%	35.8%
21	% Transplants: recip age 65+ w/ donor KDPI < 35	5.0%	5.6%	5.5%	6.6%	6.7%	6.5%	3.3%
22	% Transplants: absolute age diff. donor/recip >15	46.7%	51.7%	50.3%	52.7%	51.0%	49.5%	41.7%
23	Mean absolute age diff. between recip/donor	17.8	18.8	18.8	19.1	18.6	18.4	15.5

Utilization

Figure 5: Pre vs. Post-KAS Kidney Recovery and Discard Rates
Dec 1, 2013 through Dec 31, 2014



Interpretation

Figure 5 shows no changes in the rate of deceased donor kidneys recovered per 30 days in the immediate post-KAS period. The discard rate – kidneys not transplanted among those recovered for the purpose of transplantation – increased modestly from a recent historical rate of about 19% to 22.7%; however, this increase is within the range of month-to-month variation typically observed for kidney discard rates (April 2014 had a discard rate of 22.4%). Some of this modest increase in the overall discard rate may be due to slightly fewer low-KDPI kidney donors having been recovered during the 28-day post-KAS period (**Table 3**). Though the possibility of an increase in discard rates demands continued close monitoring, this observed change and sample sizes are both too small to conclude that rates have changed post-KAS. Furthermore, the discard rate for KDPI 86-100 kidneys (63.4%) appears little changed from the pre-KAS period.

Once sufficient data are available, future editions of this report will include trends in kidneys being accepted for one patient but either transplanted into another patient or discarded. Increased shipping of kidneys for high CPRA patients has the potential for increasing rates of offer refusal due to positive crossmatches, which could lead to increased kidney discard rates if back-up recipients are not routinely identified.

Table 3: Pre vs. Post-KAS Kidney Recovery and Discard Rates
June 30, 2014 through December 31, 2014

Metric	06/30/14	07/31/14	08/31/14	09/30/14	10/31/14	12/03/14	12/31/14
Kidney donors recovered for transplantation	639	666	653	654	639	741	593
Kidney donors recovered for tx (per 30 days)	639.0	644.5	631.9	654.0	618.4	673.6	635.4
Kidneys recovered for transplantation	1,273	1,329	1,298	1,303	1,271	1,472	1,182
Kidneys recovered for tx (per 30 days)	1,273.0	1,286.1	1,256.1	1,303.0	1,230.0	1,338.2	1,266.4
Discarded kidneys	215	243	219	236	224	243	268
Kidney discard rate	16.9%	18.3%	16.9%	18.1%	17.6%	16.5%	22.7%
Kidneys recovered (KDPI 0-20) N	237	252	287	270	275	325	189
Kidneys recovered (KDPI 21-85) N	844	913	814	867	821	915	817
Kidneys recovered (KDPI 86-100) N	160	131	164	136	152	195	145
Kidneys recovered (KDPI 0-20) %	18.6%	19.0%	22.2%	20.7%	21.8%	22.1%	16.0%
Kidneys recovered (KDPI 21-85) %	68.2%	70.7%	64.4%	68.1%	65.5%	64.0%	71.0%
Kidneys recovered (KDPI 86-100) %	13.2%	10.4%	13.4%	11.2%	12.7%	13.8%	13.0%
Kidney discard rate (KDPI 0-20)	0.8%	2.4%	3.5%	3.0%	1.8%	3.7%	2.1%
Kidney discard rate (KDPI 21-85)	16.2%	16.2%	14.0%	16.6%	14.0%	11.6%	20.0%
Kidney discard rate (KDPI 86-100)	43.1%	62.6%	53.0%	55.1%	63.8%	59.0%	63.4%