



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

February 19, 2015

<u>Purpose</u>: Provide an early look at high-level metrics revealing performance of the system, and potentially identify patterns that suggest unintended consequences that may require changes to policy, programming, or clinical practice. 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 OPTN/UNOS Kidney Transplantation 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 approximately the same rate as before?
- 2. How many candidates have verified data for calculating their Estimated Post-Transplant Survival (EPTS) score?
- 3. How many CPRA 99+ candidates have both approver names entered for receiving additional priority?
- 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 are the characteristics transplant recipients now compared to before?
- 3. What is the geographic distribution of transplants (local/regional/national)?
- 4. Are there noticeable changes from before KAS (expected or unexpected) related to geographic distribution of transplants?
- 5. What proportion of transplants are going to EPTS 0-20% patients compared with patients with EPTS 21-100%?
- 6. Is there evidence of decreased longevity-mismatching due to the new policy?

Kidney utilization

- 1. Has the rate of recovering deceased kidney donors changed?
- 2. Are there any changes in the kidney discard rate, in particular for high KPDI kidneys?
- 3. Has there been a rise in the number of kidneys accepted for a candidate but ultimately either discarded or transplanted into a different candidate, in particular for kidneys allocated non-locally (outside of the recovery donor service area) to highly sensitized patients?





Executive Summary

In the first two months after implementation of KAS, three sharp changes are evident in the types of transplants being performed: an approximately 6-fold increase in transplants for CPRA 99-100 patients; an increase in non-local transplants from around 20% to over 30%; and a drop in the proportion of longevity-mismatched transplants. 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. Compared to results from December, two of these changes – the proportion of high CPRA and non-local transplants – lessened to some extent in January. (**Figure 4a, Table 2**)

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. Though the proportion of transplants to pediatric (age<18) recipients decreased from approximately 5.0% to 2.2% in the first four weeks after implementation, this proportion rebounded in January to 3.6%. Still, these results suggest a potential decrease in transplants to pediatric recipients has occurred under the new system, a trend that demands close monitoring and requires additional months of data for validation. (**Figure 4b**, **Table 2**)

The proportion of transplants being performed in black recipients has increased. However, since this trend appears to have begun prior to implementation, further months of data and additional analyses are necessary to better understand the drivers of this increase and whether it will be sustained. It is possible that the increase is at least partially a result of the new system's awarding of waiting time points for time spent on dialysis prior to being registered on the waitlist. (**Figure 4b**, **Table 2**)

A statistically significant drop in zero-mismatch transplants, from approximately 8% to 5%, has been observed since implementation. (**Figure 4b**, **Table 2**) It is likely that this trend, along with the decrease in pediatric transplants, is at least in part due to the increased priority for very high CPRA patients.

The overall number of deceased donor kidneys being recovered (**Figure 5**) and kidney transplants being performed (**Figure 2**) do not appear to have changed. However, registrations to the kidney waitlist have slowed moderately in the two months after implementation. Though seasonality may partially explain this slowdown, and registrations for all other organs dropped in January as well, it is possible that centers may have changed listing practices in light of the new policy's awarding of waiting time points based on dialysis time prior to being added to the list.

Though kidney discard rates increased moderately in the first four weeks after implementation to 22.9%, the discard rate tempered in January to 19.5%, a rate more in line with the recent historical average of 18.5%. The increase in December and





subsequent drop in January can be largely explained by the usual variations in the characteristics of donors recovered each month; for example, far fewer low KDPI donors were recovered in December compared to January. Still, the mere possibility of a small, residual increase in discard rates that may be attributable to KAS demands continued close monitoring. Additional months of data are necessary before more definitive conclusions can be reached, however.

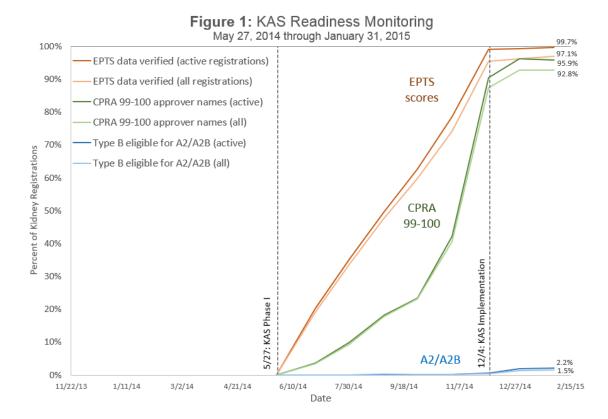
December data suggest that there has *not* been a systematic increase in the percentage of cases in which a kidney was accepted for one candidate but then transplanted into a different candidate or discarded (**Table 3**). These data contain important limitations that are described later in this report; still, the absence of a measurable increase is encouraging in light of anecdotal reports of such cases in the post-KAS period.

Lastly, **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 January 31, 99.7% of active kidney registrations had data elements needed to calculate their EPTS score verified by the transplant hospital, and over 95.9% of active, very highly sensitized (CPRA 99-100) kidney registrations were eligible for increased priority due to centers having entered the required approver names into UNetSM. However, only 2.2% of blood type B registrations have been indicated as willing to accept an A₂/A₂B-subtyped kidney, a low signup rate that should be investigated to ensure this aspect of the system reaches its full potential to increase transplant opportunities for these patients.





Waitlist



Interpretation

The six-month preparation phase (KAS Phase I) beginning on May 27, 2014 proved highly successful in allowing centers to update and verify data needed for calculating candidates' EPTS and to input approver names for CPRA 99-100% patients eligible for increased priority (**Figure 1**).

As of January 31, 2015, 99.7% of active kidney registrations and 97.1% of all registrations had data elements needed to calculate their EPTS score verified by the transplant center. Approver names had been entered for 95.9% of active and 92.8% of all kidney registrations with CPRA of 99 or 100%.

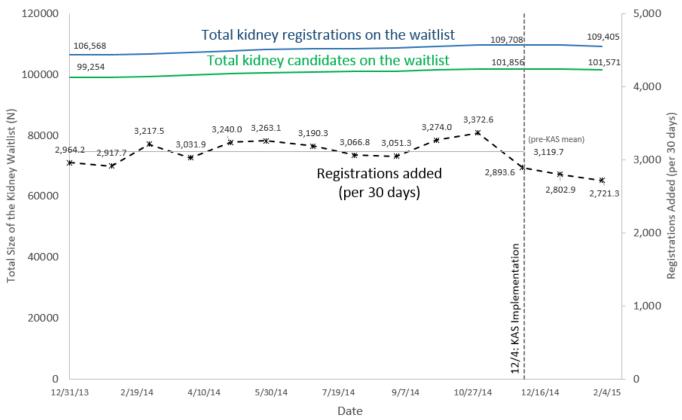
However, strikingly few (239 of 10,945, or 2.2%) active blood type B registrations were listed as willing to accept an A_2 or A_2B kidney as of January 31. Far more have been reported as ineligible (N=1,425; 13%), while the vast majority still have unknown status (N=9,266; 85%)¹. Participation in the $A_2/A_2B \rightarrow B$ aspect of the new system is optional.

¹ Also, 15 registrations had their eligibility – which must be reconfirmed every 90 days – expire as of Jan 31, 2015.





Figure 2: Pre/Post-KAS Growth in the Kidney Waitlist December 1, 2013 through January 31, 2015



Interpretation

In the first two months after KAS implementation, the number of registrations added to the kidney waitlist (normalized per 30 days) declined marginally to 2,802.9 and 2,721.3 in December and January, respectively, compared to a rate of 3,119.7 in the year prior to KAS. This post-KAS decrease is attributable, at least in part, to normal seasonal variation, as registration totals tend to be lower in some months compared to others. Though the December rate was on par with seasonally-adjusted projections, January was 6% lower, a trend that warrants continued close monitoring (**Figure 2**).

The total size of the kidney waitlist has actually decreased slightly since KAS implementation. On December 3, 2014, the kidney waitlist had 109,708 registrations. Due to a combination of a moderately lower rate of registrations being added to the list, and patients being removed due to transplantation or other reasons, the waitlist had 303 fewer kidney registrations – 109,405 – as of January 31, 2015. The slight decline in the size of the list actually began just prior to KAS implementation (**Table 1**).





Table 1: Waitlist Growth and KAS Readiness Metrics June 30, 2014 through January 31, 2015

| # Metric | 30JUN14 | 31JUL14 | 31AUG14 | 30SEP14 | 310CT14 | 03DEC14 | 31DEC14 | 31JAN15 |
|------------------------------------|---------|---------|---------|---------|---------|---------|---------|---------|
| 1 Total KI registrations on list | 108,545 | 108,669 | 108,877 | 109,373 | 109,861 | 109,708 | 109,800 | 109,405 |
| 2 Total KI candidates on list | 100,953 | 101,066 | 101,188 | 101,568 | 101,963 | 101,856 | 101,918 | 101,571 |
| 3 % w/active status | 60.9% | 60.8% | 60.8% | 60.8% | 60.7% | 60.6% | 60.2% | 59.9% |
| 4 KI Registrations added | 3,139 | 3,169 | 3,153 | 3,274 | 3,485 | 3,183 | 2,616 | 2,812 |
| 5 KI regs added per 30 days | 3,139.0 | 3,066.8 | 3,051.3 | 3,274.0 | 3,372.6 | 2,893.6 | 2,802.9 | 2,721.3 |
| 6 Number with EPTS score | 20,885 | 36,729 | 52,044 | 65,390 | 81,500 | 104,795 | 105,790 | 106,230 |
| 7 Number without EPTS score | 87,660 | 71,940 | 56,833 | 43,983 | 28,361 | 4,913 | 4,010 | 3,175 |
| 8 % with EPTS score | 19.2% | 33.8% | 47.8% | 59.8% | 74.2% | 95.5% | 96.3% | 97.1% |
| 9 % Active with EPTS score | 20.5% | 35.3% | 49.8% | 62.8% | 78.7% | 99.1% | 99.4% | 99.7% |
| 10 Number CPRA 99-100 regs | 9,305 | 9,288 | 9,310 | 9,305 | 9,222 | 9,147 | 8,987 | 8,846 |
| 11 %with approvers names | 3.5% | 9.5% | 17.8% | 23.3% | 40.7% | 87.4% | 92.8% | 92.8% |
| 12 # of blood type B registrations | 17,801 | 17,847 | 17,894 | 18,002 | 18,067 | 18,086 | 18,110 | 18,013 |
| 13 % eligible for A2/A2B KI | 0.03% | 0.07% | 0.13% | 0.16% | 0.25% | 0.45% | 1.40% | 1.52% |

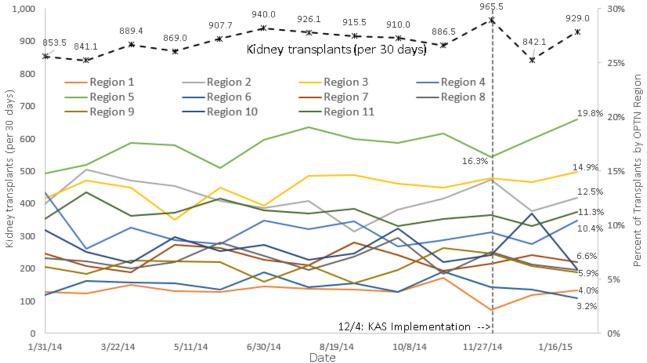




Transplants

Figure 3: Pre vs. Post-KAS Deceased Donor Kidney Transplant Volume, O∨erall and % by Region

Jan 1, 2014 through Jan 31, 2015 910.0 889.4



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). In January, the rate increased to 929.0. The overall post-KAS rate of transplantation is similar and not statistically different (p=0.69) from the transplant rate in the year prior to KAS. 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. Though Region 5 has seen an early increase in transplants (16.3% to 19.8% of total) and other regions have seen either a slight increase or decrease, none of these differences are statistically significant. These early results suggest access to transplantation by OPTN Region will not change substantially due to KAS, although additional months of data are needed to reach a more definitive conclusion.





Recipient Characteristics 60% <--12/4: KAS Implementation Jan 1, 2014 through Jan 31, 2015 Percent of Deceased Donor Kidney Transplants % % % % % % 49.5% 50.2% Donor/recipient age difference > 15 years 11.7% 43.6% 35.8% 31.9% 19.6% Non-local 19.7% 15.7% CPRA 99-100 2.4% 1.6% 0% 1/31/2014 3/22/2014 5/11/2014 6/30/2014 8/19/2014 10/8/2014 11/27/2014 1/16/2015 Date

Figure 4a: Pre vs. Post KAS Deceased Donor Kidney Transplant

Interpretation

The three sharp changes in the types of kidney transplants being performed that were previously identified based on December data persisted into January (**Figure 4a**). However, two of these trends tempered slightly in January compared to December. All three (pre vs. post-KAS) changes are highly statistically significant (p<0.001).

Firstly, and most dramatically, the percentage of transplants going to CPRA 99-100 patients jumped from about 2.5% to 17.7% in December and remained high at 15.7% in January, an approximately 6-fold increase. This rise was expected due to the CPRA sliding scale, coupled with regional and national priority for CPRA 99-100 patients. Simulations performed on behalf of the OPTN/UNOS Kidney Transplantation Committee predicted an approximately 5-fold increase in the number of transplants going to these most highly sensitized patients. Simulations also suggested the presence 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.

Table 1 shows that the number of CPRA 99-100 registrations on the waitlist has dropped, but only slightly, from over 9,100 to about 8,800 in the two months after implementation. Reaching a state of equilibrium, where a possible bolus effect has resolved and the percentage of transplants to very high CPRA patients has stabilized, may take a significant amount of time.

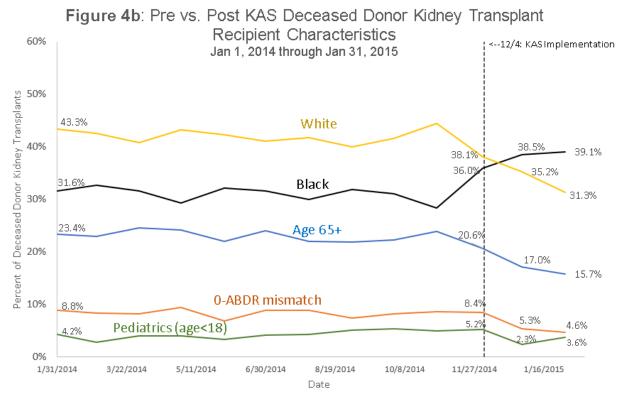
$\overline{\mathrm{OPTN}}$ The Organ Procurement and Transplantation Network



Secondly, the percentage of non-local kidney transplants – defined as those in which the recipient hospital was located outside of the recovering OPO's donor service area (DSA) – increased from about 20% to over 30%. 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 of these elements of the new policy are contributing to this increase in non-local transplants, as evidenced by the aforementioned 6-fold increase in CPRA 99-100 transplants, as well as a shift from 30% to 50% of KDPI 86-100 transplants going outside the local DSA. Table 2 indicates that despite the increase in non-local transplants, about one-fourth of local transplants are being performed utilizing the highest quality donors (KDPI<=20%), a percentage very similar to the pre-KAS period.

Thirdly, the percentage of *longevity-mismatched* transplants – defined here as those in which the donor and recipient age difference exceeded 15 years – fell from 50% to 41.7% in December and to 43.6% in January. Similarly, the percentage of transplants in which the recipient was age 65+ and the donor KDPI was less than 35% decreased from 6% to approximately 3%. In addition, the average donor-recipient age difference dropped from over 18 years to about 16 years. (**Table 2**) These trends were expected since the new system incorporates longevity-matching by prioritizing those kidneys expected to last the longest (low KDPI score) to those candidates most expected to need a long-lasting kidney (low EPTS score).

Several other pre vs. post-KAS changes are also being closely monitored (Figure 4b).



9





Interpretation:

The distribution of candidate race/ethnicity appears to have changed moderately. Black patients have represented a higher percentage of kidney recipients in the early post-KAS era (about 39%) compared to before KAS. Though this change is statistically significant (p<0.001), further analysis is necessary to better understand its cause, since this shift seems to have begun prior to KAS implementation. A contributing factor to this change may be the awarding of waiting time points based on time spent on dialysis prior to being registered on the waitlist. Candidates who previously experienced delayed referrals for transplantation may now be more likely to receive kidney offers due to this back-dating of waiting time.

The distribution of transplants by candidate age also appears to have shifted moderately, with increases observed for candidates ages 18-49 (**Table 2**) and decreases for candidates age 50-64 and 65+ (**Table 2**, **Figure 4b**). Pediatric transplants decreased from approximately 5.0% to 2.3% in the four weeks immediately post-KAS, but rebounded to 3.6% in January. The pre vs. post-KAS change in pediatric transplants is of borderline² statistical significance (p=0.01) and will continue to be monitored closely.

Fewer zero-mismatch transplants (about 5%) have been performed in the first month post-KAS since prior to KAS (about 8%); this change is highly statistically significant (p<0.0001). It is likely that this decrease is being 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 regardless of donor KDPI. This elevated prioritization for very high CPRA patients is also likely a contributing factor toward the observed decrease in pediatric transplants.

Despite the small percentage of blood group B candidates listed as eligible to receive a blood type A_2 or A_2 B kidney (Figure 1, Table 1), row 40 of **Table 2** shows that fourteen $A_2/A_2B \rightarrow B$ transplants occurred during the two months after KAS implementation, compared to just six during the prior six months. Though small in absolute numbers, this increase is statistically significant (p<0.0001) and suggests that this aspect of the policy has already started to make a difference. Finally, Table 2 shows that the proportion of kidneys being used in multi-organ transplants (e.g. simultaneous liver-kidney (SLK), kidney-pancreas (KP), heart-kidney) has not changed appreciably in the two months since KAS was implemented.

-

² Typically, p-values less than 0.05 (or 0.01) are considered clearly statistically significant. However, since this analysis involves performing a large number of hypothesis tests, some of which are suggested by changes observed in the data, additional caution is needed to avoid declaring that a change has occurred when it really hasn't (Type I error). When testing many hypotheses simultaneously, p-values should be extremely low (e.g., <0.001) before declaring with confidence that a true change has been identified.





Table 2: Pre vs. Post-KAS Transplant Volume and Characteristics June 30, 2014 through January 31, 2015

| # Metric | 30JUN14 | 31JUL14 | 31AUG14 | 30SEP14 | 310CT14 | 03DEC14 | 31DEC14 | 31JAN15 |
|---|---------|---------|---------|---------|---------|---------|---------|---------|
| 1 Total # deceased donor kidney transplants | 940 | 957 | 946 | 910 | 916 | 1,062 | 786 | 960 |
| 2 Total # deceased donor kidney transplants per 30 days | 940.0 | 926.1 | 915.5 | 910.0 | 886.5 | 965.5 | 842.1 | 929.0 |
| 3 % Transplants: age 0-17 | 4.1% | 4.3% | 5.1% | 5.3% | 4.9% | 5.2% | 2.3% | 3.6% |
| 4 % Transplants: age 18-34 | 7.9% | 10.3% | 10.0% | 9.6% | 9.3% | 8.6% | 13.1% | 14.2% |
| 5 % Transplants: age 35-49 | 23.4% | 25.6% | 25.6% | 21.4% | 23.9% | 23.5% | 28.9% | 30.3% |
| 6 % Transplants: age 50-64 | 40.6% | 37.8% | 37.4% | 41.5% | 38.0% | 42.1% | 38.7% | 36.1% |
| 7 % Transplants: age 65+ | 23.9% | 21.9% | 21.9% | 22.2% | 23.9% | 20.6% | 17.0% | 15.7% |
| 8 % Transplants: Ethnicity - White | 41.1% | 41.8% | 40.0% | 41.5% | 44.4% | 38.1% | 35.2% | 31.3% |
| 9 % Transplants: Ethnicity - Black | 31.6% | 30.0% | 31.8% | 31.0% | 28.3% | 36.0% | 38.5% | 39.1% |
| 10 % Transplants: Ethnicity - Other | 27.3% | 28.2% | 28.2% | 27.5% | 27.3% | 25.9% | 26.2% | 29.7% |
| 11 % Transplants: Blood Type A | 35.1% | 35.7% | 36.8% | 34.7% | 37.1% | 40.0% | 36.1% | 35.1% |
| 12 % Transplants: Blood Type AB | 5.5% | 5.2% | 5.5% | 4.5% | 4.7% | 5.6% | 5.9% | 7.1% |
| 13 % Transplants: Blood Type B | 12.1% | 12.4% | 12.1% | 13.1% | 14.1% | 12.2% | 13.6% | 12.8% |
| 14 % Transplants: Blood Type O | 47.2% | 46.6% | 45.7% | 47.7% | 44.1% | 42.1% | 44.4% | 45.0% |
| 15 % Transplants: CPRA 0 | 61.0% | 59.7% | 58.5% | 63.1% | 62.2% | 60.6% | 56.7% | 54.5% |
| 16 % Transplants: CPRA 1-79 | 25.9% | 24.1% | 24.1% | 22.7% | 21.4% | 24.3% | 17.0% | 21.8% |
| 17 % Transplants: CPRA 80-94 | 8.5% | 9.2% | 11.1% | 8.9% | 10.2% | 10.1% | 4.2% | 4.8% |
| 18 % Transplants: CPRA 95-98 | 2.9% | 3.6% | 3.5% | 2.7% | 3.4% | 2.6% | 4.3% | 3.2% |
| 19 % Transplants: CPRA 99-100 | 1.8% | 3.4% | 2.9% | 2.5% | 2.8% | 2.4% | 17.7% | 15.7% |
| 20 % Transplants: EPTS 0-20 | | | | | | | 23.2% | 25.8% |
| 21 % Transplants: EPTS 21-100 | | | | | | | 74.3% | 70.3% |
| 22 % Transplants: EPTS Missing (including peds) | | | | | | | 2.5% | 3.9% |
| 23 % Transplants: 0MM | 8.8% | 8.9% | 7.4% | 8.1% | 8.6% | 8.4% | 5.3% | 4.6% |
| 24 % Transplants: Placement- Non-Local | 21.6% | 22.3% | 21.7% | 22.0% | 23.4% | 19.7% | 35.8% | 31.9% |
| 25 % Transplants: recip age 65+ w/ donor KDPI < 35 | 5.0% | 5.6% | 5.5% | 6.6% | 6.7% | 6.5% | 3.3% | 2.6% |
| 26 % Transplants: absolute age diff. donor/recip >15 | 46.7% | 51.7% | 50.2% | 52.7% | 51.0% | 49.5% | 41.7% | 43.6% |
| 27 Mean absolute age diff. between recip/donor | 17.8 | 18.8 | 18.8 | 19.1 | 18.6 | 18.4 | 15.5 | 16.4 |
| 28 % KDPI>85% Transplants: Local | 72.4% | 62.7% | 69.4% | 76.3% | 66.0% | 64.1% | 50.0% | 47.5% |
| 29 % KDPI>85% Transplants: Regional | 13.8% | 17.6% | 22.2% | 10.2% | 16.0% | 9.0% | 39.6% | 40.7% |
| 30 % KDPI>85% Transplants: National | 13.8% | 19.6% | 8.3% | 13.6% | 18.0% | 26.9% | 10.4% | 11.9% |
| 31 % Local Transplants: KDPI 0-20 | 20.8% | 23.3% | 25.6% | 24.2% | 24.5% | 24.2% | 17.8% | 26.5% |
| 32 % Local Transplants: KDPI 21-34 | 14.4% | 16.3% | 15.8% | 20.3% | 15.7% | 17.7% | 22.2% | 15.1% |
| 33 % Local Transplants: KDPI 35-85 | 56.3% | 56.2% | 51.8% | 49.2% | 55.1% | 52.3% | 55.2% | 54.1% |
| 34 % Local Transplants: KDPI 86-100 | 8.5% | 4.3% | 6.7% | 6.3% | 4.7% | 5.9% | 4.8% | 4.3% |
| 35 % CPRA 99-100% Transplants: Local | 47.1% | 51.5% | 37.0% | 73.9% | 65.4% | 60.0% | 9.4% | 11.3% |
| 36 % CPRA 99-100% Transplants: Regional | 11.8% | 15.2% | 7.4% | 4.3% | 0.0% | 0.0% | 32.4% | 27.8% |
| 37 % CPRA 99-100% Transplants: National | 41.2% | 33.3% | 55.6% | 21.7% | 34.6% | 40.0% | 58.3% | 60.9% |
| 38 # multi-organ kidney transplants | 102 | 99 | 108 | 139 | 119 | 146 | 95 | 122 |
| 39 # multi-organ kidney transplants per 30 days | 102.0 | 95.8 | 104.5 | 139.0 | 115.2 | 132.7 | 101.8 | 118.1 |
| 40 # A2/A2B kidney transplants to blood type B recipients | 0 | 2 | 1 | 0 | 0 | 3 | 7 | 7 |





Utilization

Jan 1, 2014 through Jan 31, 2015 1,750 100% 12/4: KAS Implementation --> 1,500 Kidneys recovered (per 30 days) 1,320,0 1,268.6 Kidneys and Donors Recovered (N) 1,221.3 1.250 65.2% 65,2% 64.2% Kidney discard rate (KDPI 86-100 58.6% 1,000 59.4% Discard rate 50% 750 674.5 663.9 Kidney donors recovered (per 30 days) 636.4 613.5 500 22.5% 25% 22,9% 21.0% 19.5% Kidney discard rate (overall) 16.69 250 Kidney discard rate (KDPI 0-20) 2.1% 0 0% 1/31/14 3/22/14 5/11/14 6/30/14 8/19/14 10/8/14 11/27/14 1/16/15 Date

Figure 5: Pre vs. Post-KAS Kidney Recovery and Discard Rates

Interpretation

Figure 5 shows no appreciable change in the rate of deceased kidney donors (p=0.45) or kidneys (p=0.29) recovered per 30 days in the two-month post-KAS period compared to the prior year.

The discard rate – the proportion of kidneys not transplanted among those recovered for the purpose of transplantation – increased modestly from a recent historical rate of 18.5% to 22.9% in December. However, this increase tempered substantially in January with an observed rate of 19.5%, a rate more closely in line with recent history.

In addition to random variation caused by modest sample sizes, the increase in December and subsequent drop in January is at least partially explained by the change in the distribution of kidneys recovered by donor KDPI, which is highly associated with discard rates. **Table 3** shows that in December, only 16% of kidneys recovered were from the highest quality donors (those with KDPI \leq 20%), while nearly 22% of kidneys recovered in January had KDPI \leq 20%. By comparison, in April 2014 only 15.6% of kidneys recovered had KDPI \leq 20%, and the discard rate was very similar (22.5%) to the rate seen in the first four weeks post implementation (22.9%).

OPTN The Organ Procurement and Transplantation Network



Among recovered kidneys with KDPI of 86-100%, the discard rate increased from about 58% before KAS to 65% in the two months following implementation. This difference is of borderline² statistical significance (p=0.02).

Though the observed increase in discard rates in the first two months post implementation appears to be, in large part, explained by variations in the characteristics of recovered kidney donors, further close monitoring and analytical investigation into a possible residual increase in discard rates due to KAS is imperative. Since the potential increase in discard rates appears to be small, additional months of data are needed before more definitive conclusions can be reached.

A important concern identified in the wake of KAS implementation was the potential for an increase in the rate of kidneys being accepted for transplant by a non-local candidate, and then transplanted into a different recipient or discarded due to the inability to find a suitable back-up recipient. This concern was linked in particular to the increased priority for very high CPRA candidates, who may have a higher likelihood of an unacceptably positive crossmatch, coupled with the increased rates of kidneys being sent outside of the local DSA for these candidates.

However, **Table 3** indicates that the percentage (11.2%) of kidneys reported as having a "final acceptance" on a match run in DonorNet® but which were not transplanted into the accepting candidate did not change appreciably in the first four weeks post implementation³. The percentages of kidneys with "final acceptance" that were ultimately transplanted into a different candidate (7.8%) or discarded (3.4%) were both similar to recent historical percentages. No increase was observed in these percentages for the subpopulation of kidneys that were accepted by non-local CPRA 99-100% candidates (Table 3, rows 29-33).

Thirty-nine different transplant hospitals accounted for the 103 kidneys that were reported as accepted but then not transplanted into the originally accepting candidate, so these occurrences are not isolated among a very small number of programs. However, three transplant hospitals accounted for 37% of these cases. These three programs also had a disproportionate number of such cases in the pre-KAS period.

These results suggest that there has *not* been a systemic increase in the percentage of cases in which a kidney was accepted for one candidate but then transplanted into a different candidate or discarded. However, it is essential to recognize the limitations inherent in the statistics reported in the last fifteen rows of Table 3, which are derived from reporting of final acceptances and refusals on match runs for potential transplant recipients (PTR)⁴.

³ These cases are typically reported to be caused by candidate illness or a positive crossmatch. All allocations, including those in which the actual recipient differs from the initially accepting patient, are reviewed by the OPTN for potential policy violations.

⁴ The primary purpose of data collected in DonorNet® is to facilitate organ allocation, not to provide reliable data for research. Consequently, statistics derived from this data source must be interpreted





Table 3: Pre vs. Post-KAS Kidney Recovery and Discard Rates April 30, 2014 through January 31, 2015

| # Metric | 04/30/14 | 05/31/14 | 06/30/14 | 07/31/14 | 08/31/14 | 09/30/14 | 10/31/14 | 12/03/14 | 12/31/14 | 01/31/15 |
|--|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| 1 Kidney donors recovered for transplantation | 654 | 670 | 639 | 666 | 653 | 654 | 639 | 742 | 594 | 686 |
| 2 Kidney donors recovered for tx (per 30 days) | 654.0 | 648.4 | 639.0 | 644.5 | 631.9 | 654.0 | 618.4 | 674.5 | 636.4 | 663.9 |
| 3 Kidneys recovered for transplantation | 1,300 | 1,331 | 1,273 | 1,329 | 1,298 | 1,303 | 1,271 | 1,474 | 1,184 | 1,364 |
| 4 Kidneys recovered for tx (per 30 days) | 1,300.0 | 1,288.1 | 1,273.0 | 1,286.1 | 1,256.1 | 1,303.0 | 1,230.0 | 1,340.0 | 1,268.6 | 1,320.0 |
| 5 Discarded kidneys | 292 | 246 | 215 | 243 | 219 | 236 | 224 | 245 | 271 | 266 |
| 6 Kidney discard rate | 22.5% | 18.5% | 16.9% | 18.3% | 16.9% | 18.1% | 17.6% | 16.6% | 22.9% | 19.5% |
| 7 Kidneys recovered (KDPI 0-20) N | 202 | 229 | 237 | 252 | 287 | 270 | 275 | 325 | 189 | 295 |
| 8 Kidneys recovered (KDPI 21-34) N | 171 | 200 | 159 | 202 | 180 | 242 | 161 | 213 | 204 | 191 |
| 9 Kidneys recovered (KDPI 35-85) N | 683 | 683 | 685 | 711 | 634 | 625 | 659 | 702 | 612 | 691 |
| 10 Kidneys recovered (KDPI 86-100) N | 207 | 183 | 160 | 131 | 164 | 136 | 151 | 197 | 148 | 158 |
| 11 Kidneys recovered (KDPI 0-20) % | 15.6% | 17.2% | 18.6% | 19.0% | 22.2% | 20.7% | 21.8% | 22.1% | 16.0% | 21.7% |
| 12 Kidneys recovered (KDPI 21-34) % | 13.2% | 15.0% | 12.5% | 15.2% | 13.9% | 18.6% | 12.7% | 14.5% | 17.4% | 14.0% |
| 13 Kidneys recovered (KDPI 35-85) % | 54.4% | 53.2% | 55.7% | 55.5% | 50.5% | 49.4% | 52.8% | 49.5% | 53.5% | 52.1% |
| 14 Kidneys recovered (KDPI 86-100) % | 16.9% | 14.6% | 13.2% | 10.4% | 13.4% | 11.2% | 12.7% | 13.9% | 13.1% | 12.2% |
| 15 Kidney discard rate (KDPI 0-20) | 2.5% | 3.1% | 0.8% | 2.4% | 3.5% | 3.0% | 1.8% | 3.7% | 2.1% | 4.1% |
| 16 Kidney discard rate (KDPI 21-34) | 7.6% | 6.5% | 8.2% | 7.4% | 4.4% | 6.2% | 3.7% | 5.2% | 8.8% | 6.3% |
| 17 Kidney discard rate (KDPI 35-85) | 18.6% | 16.3% | 18.1% | 18.7% | 16.7% | 20.6% | 16.5% | 13.5% | 23.7% | 18.8% |
| 18 Kidney discard rate (KDPI 86-100) | 65.2% | 60.1% | 43.1% | 62.6% | 53.0% | 55.1% | 64.2% | 59.4% | 64.2% | 65.2% |
| 19 Overall: Number of kidneys with "final acceptance" | 1,018 | 1,103 | 1,081 | 1,109 | 1,083 | 1,062 | 1,057 | 1,201 | 923 | * |
| 20 Overall: # accepted kidneys not transplanted to accepting candidate | 116 | 135 | 124 | 124 | 108 | 125 | 124 | 109 | 103 | * |
| 21 Overall: % accepted kidneys not transplanted to accepting candidate | 11.4% | 12.2% | 11.5% | 11.2% | 10.0% | 11.8% | 11.7% | 9.1% | 11.2% | * |
| 22 Overall: % accepted kidneys transplanted to a different candidate | 8.6% | 8.8% | 8.1% | 7.5% | 6.7% | 8.6% | 8.5% | 6.7% | 7.8% | * |
| 23 Overall: % accepted kidneys discarded | 2.8% | 3.4% | 3.3% | 3.7% | 3.2% | 3.2% | 3.2% | 2.3% | 3.4% | * |
| Non-local: Number of kidneys with "final acceptance" | 328 | 354 | 323 | 336 | 329 | 318 | 340 | 331 | 397 | * |
| 25 Non-local: # accepted kidneys not transplanted to accepting candidate | 114 | 133 | 119 | 124 | 103 | 121 | 122 | 105 | 100 | * |
| 26 Non-local: % accepted kidneys not transplanted to accepting candidate | 34.8% | 37.6% | 36.8% | 36.9% | 31.3% | 38.1% | 35.9% | 31.7% | 25.2% | * |
| Non-local: % accepted kidneys transplanted to a different candidate | 26.2% | 27.4% | 26.0% | 24.7% | 21.3% | 27.4% | 25.9% | 23.9% | 17.6% | * |
| Non-local: % accepted kidneys discarded | 8.5% | 10.2% | 10.8% | 12.2% | 10.0% | 10.7% | 10.0% | 7.9% | 7.6% | * |
| Non-local 99-100 CPRA: Number of kidneys with "final acceptance" | 14 | 16 | 12 | 22 | 25 | 9 | 13 | 13 | 159 | * |
| 30 Non-local 99-100 CPRA: # accepted kidneys not transplanted to accepting candidate | 2 | 5 | 3 | 5 | 9 | 2 | 3 | 4 | 29 | * |
| 31 Non-local 99-100 CPRA: % accepted kidneys not transplanted to accepting candidate | 14.3% | 31.3% | 25.0% | 22.7% | 36.0% | 22.2% | 23.1% | 30.8% | 18.2% | * |
| 32 Non-local 99-100 CPRA: % accepted kidneys transplanted to a different candidate | 7.1% | 18.8% | 25.0% | 18.2% | 28.0% | 22.2% | 23.1% | 23.1% | 15.1% | * |
| 33 Non-local 99-100 CPRA: % accepted kidneys discarded | 7.1% | 12.5% | 0.0% | 4.5% | 8.0% | 0.0% | 0.0% | 7.7% | 3.1% | * |

^{*} Results not yet available due to usual lags associated with the reporting of offer acceptance data in DonorNet®.

cautiously. More specifically, these data will not include cases in which the allocating OPO does not enter a "final acceptance" for a candidate. For example, if the recovering OPO places and ships a kidney to a non-local transplant hospital, but the kidney is subsequently refused (e.g., positive crossmatch) and shipped back to the recovering OPO's DSA, the case will not be captured in Table 3 if the recovering OPO continues allocating the kidney using the same match run; the reason the case is not included is because a final acceptance will not have been reported for the initially accepting candidate. Also, an underlying assumption in analysis of trends in these cases is that OPOs' practices for entering final acceptance data has not changed over time.