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ANALYSIS OF CHANGES TO TRANSPLANTATION PRACTICES IN THE PERIOD SURROUNDING THE INITIATION OF MEDICARE CONDITIONS OF PARTICIPATION FOR ORGAN TRANSPLANT PROGRAMS

FINAL REPORT

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EXECUTIVE SUMMARY

In 2007, CMS implemented Hospital Conditions of Participation (CoPs) – requirements for approval and re-approval of transplant centers to perform organ transplants.[1] These CoPs include requirements for utilization of data from the Scientific Registry of Transplant Recipients (SRTR) semi-annual Program-Specific Reports (PSRs) to compare observed to expected post-transplant 1-year patient and graft survival. Programs that do not meet specified performance standards are flagged for performance review and risk losing CMS certification.

To account for disparities in program outcomes that might result from differences in recipient or donor case mix, the expected graft and patient outcomes generated by the SRTR are risk adjusted for a broad range of recipient, donor and transplant-related factors. However, the increased oversight of transplant programs under the CoPs may have prompted some programs, unconfident of the extent and adequacy of SRTR risk adjustment, to modify their selection criteria for donor organs and transplant candidates in an effort to avoid CMS flagging. Anecdotal evidence suggests that the implementation of the CoPs has prompted some low-performing transplant programs to alter the candidates that they choose for wait-listing and the organs and recipients that they ultimately select for transplantation,[2] although it is unknown whether this has occurred in a systemic way.

As a first step, this report presents a preliminary examination of the trends in kidney transplantation and wait-listing practices preceding and following introduction of these CoPs. Evidence was sought that might indicate the existence of a systematic response to the CoPs by organ transplant programs. Specifically, the present analysis is focused on changes in transplant practices and outcomes at an aggregate level, rather than the variation between individual transplant programs, and attempts to address the question of whether significant overall trends are apparent. This report is in no way intended to examine more specific changes in practice at the program level that may be tied to a variety of triggers including revision of allocation policy, changes in practice and specific cycle of review. This approach is observational in nature and therefore cannot be used to infer causation. In addition, the precise time points of interest are likely to differ depending on the transplant program. Some programs may have responded to the announcement of the regulations by examining their outcomes and acting on them, preemptively, while others may not have taken action until they were contacted by CMS.

[1] Federal Register Vol 72, No. 61, March 30, 2007. Rule and Regulations Part II, Department of Health & Human Services, Centers for Medicare & Medicaid Services: 42 CFR Parts 405, 482, 488 and 498 Medicare Programs. Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; Final Rule.

[2] Schold JD, Arrington CJ, Levine G. Significant alterations in reported clinical practices associated with increased oversight of transplant center performance. Progress in Transplantation; Sep 2010; 20(3):279-287.

SRTR data were analyzed for changes in transplant practices and outcomes over the 10-year period (2001-2010) surrounding the implementation of the CoPs. Key outcomes for this initial assessment focused on select parameters felt to be potentially most reflective of the perceived impact on outcomes and the CoP's. These included whether:

- There was evidence of a decline in the number of ECD transplants performed among kidney transplant programs that were flagged compared with programs that were not flagged;
- Poorer ECD graft outcomes were observed for flagged programs;
- There was evidence of a shift towards lower risk donors and/or lower risk recipients;
- Wait-listing practices changed in association with the implementation of Medicare CoPs, or subsequent to citation for outcomes under the CoPs;
- There was evidence of kidney candidates being discouraged from ECD transplants, or conversely of inappropriate candidates being encouraged to accept ECD organs; or
- There was any evidence of shifts in access to the transplant wait-list according to socioeconomic factors associated with the implementation of Medicare CoPs, or subsequent to citation for outcomes under the CoPs.

We examined the data for the 221 adult kidney transplant programs active during 2007. Programs were classified according to whether they were flagged in any of the first three SRTR PSRs that were released after the CoPs went into effect (July 2007, January 2008 and July 2008 - Period 1), and again by whether they were flagged in any of the four subsequent PSRs (January 2009, July 2009, January 2010 and July 2010 -Period 2).[3] These seven available PSRs were collapsed into two periods in order to evaluate general trends before and after flagging in the absence of precise data on the dates of program practice changes that, if available, might inform additional analyses.

An examination of trends in kidney transplant volume showed that the total number of kidney transplants per annum grew by 16% from 2001 to 2006, fell slightly in 2007, and remained relatively stable thereafter through 2010. Unadjusted graft survival increased from 92.4% to 93.5% during the period from 2006 through 2010, which translates to an increasing number of functioning grafts despite the leveling off of total number of transplants performed.

With respect to ECD utilization, we found that as a group the programs flagged in Period 1 only increased their percentage of ECD transplants between 2006 and 2010, while those flagged in both periods tended to perform fewer ECD transplants after 2006.

Based on organ acceptance rates calculated between July 2006 and January 2011, programs that were not flagged in either period had a higher average acceptance rate when compared to the average acceptance rates observed for the two groups of flagged centers. Programs that

[3] The PSRs covered rolling 2.5 year cohorts in which data from transplants performed in the most distant 6 month period of the previous report were removed from analysis and data from transplants performed in the most recent 6 month period were added

were flagged in Period 1 only raised their average kidney acceptance rate in 2009, whereas programs that were flagged in both periods neither increased nor decreased their acceptance over the period subsequent to the introduction to the Medicare CoPs, providing some evidence that flagging did not have the effect of causing 'good' organs to be turned down by these programs.

The group flagged in both periods would of course be expected to have higher graft failure rates overall, and subset analysis revealed poorer-than-expected kidney graft survival for each donor type (ECD, DCD, SCD and Living donors) over the entire period from Jan 2006 to Jan 2011. Notably, however, the one-year standardized graft failure ratio for ECD kidney transplants actually worsened until 2009 for the group that was flagged in both periods, after this point the group saw a strong improvement in graft survival. Similarly, the group flagged in Period 1 only showed a steady improvement in the standardized graft failure ratio for ECD kidney transplants after July 2007. This suggests that some program improvements may have occurred following flagging leading to improved ECD transplant graft survival.

Several recipient and donor characteristics were analyzed to assess trends in donor and recipient risk characteristics. The risk associated with these factors was modeled and compared over time to see whether any changes in risk coincided with the introduction of the Medicare CoPs. The overall transplant risk, calculated using a model combining donor and recipient risk factors, increased approximately 13% between 2001 and 2010. This reflects a 6% increase in donor risk and 7% increase in recipient risk, calculated using separate donor and recipient models, over the decade. These trends were consistent among all the groups studied and there was no evidence that flagged programs changed their practice to perform less risky transplants.

Candidates newly added to the kidney waiting list were also evaluated as a program practice that may have been influenced by flagging. It was found that the flagged and non-flagged groups all followed the same trend over the ten-year time period for patient age, with the exception of the programs that were flagged in Period 1 only. The average percent of newly wait-listed adult patients, 65 or older, for these 17 programs was significantly lower than the other group, most notably from 2006 to 2008.

Trends did not differ among groups for the other characteristics that were studied among newly listed patients, including BMI, education, income or prior kidney transplant. However, the level of ECD-designation among new listings did vary widely according to whether or not the programs were flagged. The programs flagged in Period 1 only and the programs flagged in both periods had the highest percentage of newly listed patients designating willingness to accept an ECD kidney between 2003 and 2005. This perhaps suggests that flagged programs were more aggressive in influencing patient ECD willingness during this time.

The programs flagged in Period 1 only initially demonstrated the highest level of ECD designation among new candidates, but later dropped below the overall average. The percent of newly wait-listed candidates under 40 and non-diabetic candidates that the program indicated were willing to accept an ECD organ, while differing somewhat among groups prior to

the CoPs, diminishes over the remaining years so that by 2010 there is no distinguishable difference between groups.

A detailed summary of these findings can also be found in the table at the end of this report.

INTRODUCTION

Background and Rationale

In 2007, CMS implemented regulations under which organ transplant programs must meet Conditions of Participation (CoPs) for the safety and quality of transplantation services delivered in Medicare-participating facilities. Central to the implementation of the CoPs is the ongoing evaluation of post-transplant patient and graft survival. For this purpose, data from the Scientific Registry of Transplant Recipients (SRTR) semi-annual Program-Specific Reports (PSRs) are used to determine expected patient outcomes, which are then evaluated against observed post-transplant patient and graft survival data. The expected patient outcomes generated by the SRTR are risk adjusted for a broad range of recipient, donor and transplant-related factors; therefore, when comparing observed versus expected patient and graft survival outcomes, many differences due to recipient and donor case mix are taken into account. Although outcomes are risk adjusted, there is anecdotal evidence suggesting that the implementation of the CoPs has prompted some transplant programs to alter the candidates that they select for wait-listing and the organs and patients that they ultimately choose for transplantation in an effort to improve post-transplant results and avoid flagging for CMS review.

The present report was commissioned by CMS for the purpose of evaluating changes to transplantation practices that have occurred in the five years since the implementation of Medicare COPs for organ transplant programs. The aims of this report are to:

1. Describe transplant program practices and outcomes in aggregate over time, and identify whether any observed changes occur contemporaneously with the era surrounding the introduction of the CoPs, or after flagging for non-conformance with the Medicare CoPs;
2. Evaluate trends over the past ten years in the utilization of ECD kidneys and in ECD graft outcomes, according to program performance;
3. Evaluate trends in graft survival over the past decade, looking for improvements, deterioration or maintenance of outcomes particularly as they coincide with the era surrounding the introduction of the CoPs and following flagging;
4. Describe any shifts in the risk profile of donors and recipients indicative of changing program practices with respect to organ acceptance and recipient selection;
5. Evaluate the number and characteristics of candidates wait-listed over the past 10 years, according to program performance;
6. Evaluate trends in candidate designation of willingness to accept an ECD kidney, according to program performance;
7. Describe any shift in access to the kidney transplant waiting list associated with socioeconomic status.

In consultation with CMS, we have focused our report on kidney transplantation, as this involves the greatest number of transplant patients and is performed at nearly all transplant centers. Focusing on the most commonly performed type of transplant allows for an efficient appraisal of significant trends. Furthermore, one of the most important trends in organ transplantation over the past decade has been the increasing utilization of expanded criteria donor (ECD) kidneys, and it was of particular interest to CMS to evaluate whether there is evidence of changing acceptance practices with respect to ECD kidneys associated with the implementation of the CoPs. Associations, if any, with the implementation of the CoPs or citation by CMS for non-conformance with outcomes measures may be evaluated for other types of organ transplant programs in a future study.

Context

The Medicare CoPs were introduced in 2007, contemporaneously with other initiatives and policy revisions aimed at improving access to organ transplantation. Such initiatives and policy changes, together with developments in clinical practice over the past decade, have exerted their own influence on transplant volumes and outcomes, and on practices with respect to wait-listing, organ allocation and recipient selection. It is beyond the scope and resources of this report to confidently distinguish changes in program behavior and outcomes possibly attributable to the CoPs from those resulting from other initiatives and policies implemented during this same era.

Of particular relevance is the Organ Donation Breakthrough Collaborative. The Collaborative, announced by the Department of Health and Human Services (HHS) in April 2003, was aimed to increase organ transplantation rates through identification, evaluation and dissemination of practices common to hospitals with high donor consent and conversion rates. [1] This Collaborative was completed in 2006, a few months prior to the implementation of the CoPs.

Evaluation of the Breakthrough Collaborative has determined that a substantial and statistically significant increase in the conversion rate (actual donors divided by total eligible donors) occurred among Collaborative hospitals in the 12 months following implementation of the initiative. Overall, the number of organ donors increased by 10.7% from 2003 to 2004 (versus an average annual increase in organ donors of 2.2% for the five preceding years).[2]

An ECD allocation system was implemented by OPTN in October, 2002. While ECD utilization has increased significantly since that time, the rate at which ECD kidneys are discarded has remained unchanged at approximately four-times that of SCD kidneys.[3] Pulsatile perfusion is

[1] http://www.lewin.com/content/publications/OrganDonationBreakthroughCollaborative.pdf

[2] Howard DH, Siminoff LA, McBride V, Lin M. Does quality improvement work? Evaluation of the Organ Donation Breakthrough Collaborative. Health Services Research 42:6, Part 1 (December 2007):2160-2173

[3] Sung RS, Christensen LL, Leichtman AB et al. Determinants of discard of expanded criteria donor kidneys: impact of biopsy and machine perfusion. Am J Transplant 2008; 8:783-792.

increasingly utilized to preserve ECD kidneys. Trials have shown that pulsatile perfusion preservation is superior to static cold storage in reducing delayed graft function in ECD kidney transplantation,[4] and the rate of discard of ECD kidneys is shown to be nearly 50% lower when pulsatile perfusion is employed, compared to when it is not.[6] Still, discard rates vary widely among donor services areas, possibly reflecting local attitudes towards ECD transplantation and differing need for ECD organs based upon wait-list composition and the availability of non-ECD kidneys.[6]

Several policy changes also affected allocation and wait-listing practices over the past decade. OPTN policy was revised in November, 2003 to allow for the accrual of waiting time during the entire interval that wait-listed candidates are designated as inactive (Status 7). It appears that the removal of this previous restriction, which meant candidates ceased accruing waiting time after being inactive for 30 days, has led to more candidates being listed in inactive status. Certainly there has been an increased in the use of the inactive designation since 2003 (see Appendix Figure 32), and the probability of an inactive patient becoming active has declined.[5] In May 2003, in an effort to redress disparities in transplant rates by race/ethnicity, the OPTN changed deceased donor kidney allocation policy to eliminate priority based on HLA-B matching. Analyses indicated that assigning points for HLA-B similarity disadvantaged non-white transplant candidates.[6] Since the HLA-B policy change, racial disparities in deceased donor kidney transplantation have been reduced (although not eliminated), with no adverse effect on graft survival.[7] Additionally, in 2006 and 2007, the OPTN introduced the national electronic organ offer system, DonorNet®, To-date, evaluation of the impact of DonorNet in facilitating and expediting organ placement has documented an increase in local allocation for kidneys and livers, with a commensurate decline in regional and national distribution.[8]

Potentially influencing observed kidney transplant outcomes is a progressive increase during the last decade in the number of combined kidney-liver transplants and combined kidney-heart transplants performed. Some transplant physicians and surgeons have speculated that these combined transplants diverted many of the “better” deceased donor kidneys away from kidney-alone candidates and towards multi-organ recipients.

Finally, while difficult to quantify, ongoing improvements in the clinical care of the patient pre- and post-transplant are likely to drive improvement in patient and graft survival over time,

[4] Abboud I, Antoine C, Gaudez F et al. Pulsatile perfusion preservation for expanded-criteria donor kidneys: Impact on delayed graft function rate. In J Artf Organs 2011;34(6):513-518; Moers C, Amits JM, Maathuis MH et al. Machine perfusion or cold storage in deceased-donor kidney transplantation. N Engl J Med 2009;360(1):7-19.

[5] Leichtman AB, Cohen D, Keith D, O’Connor K, Goldstein M, McBride V, Gould CJ, Christensen LL, Ashby VB. Kidney and pancreas transplantation in the United States, 1997-2006: The HRSA Breakthrough Collaborative and the 58 DSA Challenge. American Journal of Transplantation 2008; 8(Part 2): 946-957

[6] Roberts JP, Wolfe RA, Bragg-Gresham JL, Rush SH, Wynn JJ, Distant DA, et al. Effect of changing the priority for HLA matching on the rates and outcomes of kidney transplantation in minority groups. *N Engl J Med* 2004; 350: 545-551.

[7] Ashby VB, Port FK, Wolfe RA, Wynn JJ, Williams WW, Roberts JP, Leichtman AB. Transplanting kidneys without points for HLA-B matching: consequences of the policy change. American Journal of Transplantation 2011; 11:1712-1718

[8] Gerber DA, Arrington CJ, Taranto SE, Baker T, Sung RS. DonorNet and the Potential Effects on Organ Utilization. Am J Transplant 2010;10 (Part 2): 1081-1089.

independent of trends in donor and recipient selection. This examination of transplant practices before and after the implementation of the CoPs focuses on donor and recipient characteristics and the composition of wait-listed candidates. However, improved transplant outcomes are likely to reflect a combination of improvements in organ and recipient selection and the application of technological and medical advances to improve patient care.

National Trends in Transplantation Outcomes

First overall trends in kidney transplantation, organ acceptance, and kidney graft survival were examined. We defined groups by program performance during specified intervals and analyzed their differences as well as any differences in the overall trends over time. In doing this, special consideration is paid to any changes that occurred contemporaneously with the introduction of the CoPs and the time following their implementation.

Ultimately, the purpose of the Medicare CoPs is to ensure that all transplant programs are providing safe and high quality transplant services. This report examines overall one-year graft survival – both observed graft survival and expected graft survival (expected survival adjusted for patient characteristics) – following kidney transplantation over past decade.

Expanded Criteria Donors

An “expanded” criteria donor (ECD) kidney is defined by the Organ Procurement and Transplantation Network (OPTN) as a kidney recovered from a donor of age 60 years or greater, or a donor between 50 and 59 years of age who meets at least two of the following criteria: a terminal pre-recovery serum creatinine > 1.5 mg/dl, a cerebrovascular accident as the cause of death, or a history of hypertension. Kidneys transplanted from an ECD have a relative risk (RR) of allograft failure that is 70% greater than that of kidneys transplanted from an “ideal” reference group of non-hypertensive donors between the ages of 10 and 39 years with a terminal serum creatinine of less than 1.5 mg/dl and death from a cause other than a cerebral vascular accident. While the ECD designation is a dichotomous classification of several risk factors, it does represent a discrete and easily identifiable subset of donor organs that might be preferentially the focus for center driven changes. In addition to the ECD designation, we also evaluate changes related to specific components of the donor risk index.

While the number of ECD transplants has increased by more than 50% over the past decade, transplant programs that have fallen out of compliance with the outcomes CoPs, or been in jeopardy of doing so, may consider changing their acceptance practices with respect to ECD organs. Programs modifying their organ acceptance practices may be doing so without accounting for the fact that the SRTR models include risk adjustments for the outcomes associated with ECD kidneys, adjusting both for ECD designation and for each component of the ECD definition. As a result, some programs may decrease ECD utilization but not improve or even worsen their ratio of observed to expected outcomes. These programs may also perceive

an incentive to transplant lower risk patients, fearing that transplanting higher risk patients could make their performance appear substandard.

Given these considerations, it was hypothesized that observed trends associated with transplantation of ECD kidneys would be different for facilities that have been flagged for failing to meet outcomes COPs, compared with those programs with better relative survival outcomes. We therefore report trends in ECD organ utilization over the past ten years according to whether programs were flagged in any of the first three SRTR PSRs released after the CoPs went into effect (during the period from 2007 to 2008; Period 1), and again by whether or not they were flagged in any of the four PSRs released during 2009 and 2010 (Period 2). We also plot observed and expected kidney graft survival and the ratio of observed to expected graft failures by donor type. The donor types considered are: (1) donors after brain death who meet the ECD definition; (2) donors after circulatory death (DCD) who do not meet the ECD definition; (3) standard criteria donors (SCD) defined as donors after brain death, not meeting the ECD definition; and (4) living donors.

Changes in Transplant Recipient and Donor Characteristics

Potential impacts of the CoPs on transplantation practices might also be observed as shifts in recipient characteristics, such as age, prior transplant, body mass index (BMI), and diabetes status, should programs become averse to transplanting patients at higher risk of poor outcomes. Similarly, donor characteristics might shift in response to the implementation of the CoPs.

Changes to Waiting List Selection Criteria

Programs may, in response to the increased focus on transplant outcomes over the past few years, elect not to list candidates felt to be at high risk for poor outcomes, leave such candidates wait-listed but designated as inactive (Status 7), or remove such candidates from the waiting list completely. Such practices may have the unintended impact of disadvantaging specific populations of potential transplant recipients. For example, the composition of wait-listed candidates may see a shift with respect to risk factors such as age, BMI, previous transplant, socio-economic status or functional status. Finally, programs may differ in the extent to which they encourage kidney candidates to nominate willingness to accept ECD organs, or simply not accept available organs particularly when these organs are judged by the program to be marginal.

STUDY DESIGN

Cohort Selection and Study Period

Implementation of the Medicare CoPs officially began in July 2007; however, announcements regarding the forthcoming CMS regulations were released as early as 2005. Furthermore, the introduction of the CoPs did not occur in isolation. The OPTN Membership and Professional Standards Committee (MPSC) adopted the same methodology a few years earlier and some programs had already undergone MPSC reviews and site visits. Due to a number of factors including MPSC review, anticipation of the regulations and media attention (e.g. Weber and Ornstein June 2006 Los Angeles Times), some kidney transplant programs may have begun taking steps to improve their performance in terms of observed to expected outcomes well before the CoPs went into effect, whereas others may not have become aware of particularly poor outcomes until they were flagged by MPSC or through the CoPs later. In the absence of qualitative data detailing each program's reaction to the CoPs, we categorized programs more broadly based on their flagging status during two specific periods of interest to measure changes in outcomes that coincide in time with increased attention on outcomes as described above. In investigating program activities before, during and after the implementation of the CoPs, we summarized outcomes over the 10-year period from 2001 to 2010 among the 221 adult kidney transplant programs that were active during 2007. We considered explicit sequences of outcomes for the period 2007 to 2010 and categorized programs according to their compliance with the Medicare outcomes CoPs during this period. These summaries provide some insight into whether changes occurred contemporaneously with the timing of the regulations.

For the purposes of this report, study periods were defined using the PSR reporting intervals of July 2007, January 2008 and July 2008 (Period 1), and January 2009, July 2009, January 2010 and July 2010 (Period 2). Programs were then classified according to whether or not they were flagged in either of these two periods. Of note, nine programs were closed/inactive during all of 2009 and 2010 and therefore did not perform transplants throughout this period. These groupings are summarized in Table 1.

Table 1: Program classification for the 221 kidney transplant programs active during 2007.

Flagged for Non-conformance		Total number of Programs	Closed/Inactive 2009 and 2010
Period 1: PSRs released Jul '07, Jan '08 or Jul '08	**Period 2:** PSRs released Jan '09, Jul '09, Jan '10 or Jul '10		
Yes	Yes	31	1
Yes	No	17	3
No	No	159	5
No	Yes	14	0
Total		221	9

Of the 48 programs flagged during Period 1, 31 were flagged again during the Period 2, 17 were not flagged in Period 2. Four programs from among those flagged in Period 1 were closed or inactive for all of 2009 and 2010. One of these closed/inactive programs is included in the 31 programs flagged in both periods, and the remaining three closed/inactive programs come from the 17 programs flagged in Period 1 only. In the material that follows, results are shown for the following groups:

- All programs combined (N=221)
- Programs flagged in Period 1 but not in Period 2 (N=17)
- Programs flagged in both Period 1 and Period 2 (N=31)
- Programs not flagged in either Period 1 or Period 2 (N=159)

The 14 programs that were flagged in Period 2 but not in Period 1 are not examined separately. The present report is primarily concerned with how programs responded to citation under the outcomes CoPs and, since data on practices and outcomes are not currently available after 2010, it is not possible to characterize trends among programs flagged in 2009 or 2010 only.

With the data available, we were able to describe observable differences among these defined groups of programs over the past decade, whereas providing reasons for changes in program behavior or other details about these programs was not within the scope of this report. However, qualitative program-level data could be analyzed in a future study to provide greater insight into these particulars.

Assessing Differences in Transplant Practices and Outcomes

One area of interest is whether organ acceptance practice changed. Assessing this directly is challenging as the study was limited by a lack of detailed organ acceptance data for kidneys, particularly those from marginal donors such as ECD and DCD, as well as inherent differences in reported OPO conversion rates reflecting the fact that the measurement of the denominator (eligible deaths) changed during this time (2007). As an alternative, we analyzed yearly trends in the proportion of candidates that were indicated as being willing to accept ECD organs within each program, only among patients newly added to the waiting list that year. In addition, focusing on certain characteristics of these newly-listed patients provided insight into how

programs managed their risk over time with respect to factors such as age, BMI and socio-economic status.

With implementation of the CoPs occurring as recently as 2007, follow-up time for analysis of actual survival outcomes post-CoP implementation was somewhat short, thereby limiting the extent of post-implementation analyses possible. The PSR cohorts that determine flagging are overlapping and time-lagged in such a way that analyzing trends after 2007 using these reports alone seemed inadequate. Furthermore, expected outcomes based on donor and recipient risk factors are recalculated based upon each six-month PSR cohort of transplants, making it difficult to directly compare donor and recipient risk profiles across time periods. For these reasons, we chose to apply the same model estimates of donor and recipient risk to the transplants performed by each program over the ten-year period. The way in which programs managed their risk over time could then be compared by aggregating the effects of known kidney transplant risk factors (i.e., calculating "risk scores") for the time periods before, during and after flagging.

Data Sources

The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) collated and analyzed data from the CMS ESRD and Medicare claims database and the Scientific Registry of Transplant Recipients (SRTR) database, enhanced by the Social Security Death Master File (SSDMF) and Census Data on Income (SES) by ZIP code, County and State (for details, see Data Sources section of the Appendix).

Analytical Methods

Graft Survival

The methodology for computing observed and expected graft survival statistics is explained at length on the SRTR website at http://www.srtr.org/csr/current/programs-report.aspx. Some of the key elements of this methodology are included from the SRTR website below.

Graft survival (observed graft survival) is reported at the 1-year reporting time point for purposes of this report. Transplants that occur during the last 6 months of the cohort (January to June, 2010) have only 6 months of follow-up available; as a result, there is actually only six months follow-up data reported. The Kaplan-Meier method for computing survival uses all data available for each patient and assumes that the failure rate for those patients with incomplete follow-up would be the same as the rate for those with complete data while also accounting for their six month follow-up status. All available follow-up data for each graft were used in the calculation of the statistics reported here using standard censored data methods of survival analysis. Additional data from the SSDMF and CMS have been incorporated into the graft survival rates.

A graft is counted as failed when follow-up information indicates that one of the following has occurred: graft failure (including indication from return to dialysis), retransplant, or death; the time to graft failure is the time to first of these three events. OPTN follow-up forms are used to identify graft failure and retransplant dates. Additionally, CMS Medicare Claims data and Standard Information Management System (SIMS) data reported by ESRD Networks are used to identify patients returning to dialysis.

Expected Graft Survival

The expected graft survival at a given program and at a given time since transplant is the fraction of grafts that would be expected to be functioning at that time based on national experience, given the patient mix at this program. A program's estimated graft survival can be compared to the expected graft survival at each time point of interest. If the actual graft survival is greater than the expected graft survival, then the graft survival outcomes are better at this program than would be expected based on the national transplant experience for similar grafts and patients. Conversely, if the actual graft survival is less than the expected graft survival, then the graft survival is worse at this program than would be expected based on the national transplant experience for similar grafts and patients.

The national experience was analyzed using data for all grafts at all facilities in the United States. A Cox proportional hazards regression model for time to graft failure was fitted to the national data, which yielded the probability of graft survival at each time point based upon the characteristics of each patient. The expected survival for a given program is the average of these computed probabilities for patient characteristics at that program. The characteristics accounted for in these calculations are reported below and are similar to those that have been used in previous reports. The expected graft survival was adjusted for the patient characteristics as listed in the Risk-Adjustment Models on the SRTR website.

Ratio of Observed to Expected Graft Failures

For statistical comparisons, it is appropriate to compare the number of graft failures observed during follow-up to the number of graft failures that would be expected during follow-up based on national data and adjusting for patient mix. The ratio of observed to expected graft failures compares the entire survival curve up to the reporting time point to the curve expected for patients with the same characteristics based on the national experience, rather than just the survival at the reporting time point. A ratio greater than 1.00 indicates that there were more graft failures at the program than would have been expected based on the national experience, while a ratio less than 1.00 indicates that there were fewer graft failures at the program than would have been expected based on the national experience. For example, a ratio of 1.20 indicates that the graft failure rate at the program was, on average, 20% higher than the risk adjusted national rate. A ratio equal to 1.00 indicates that the graft failure rate at the program was, on average, the same as the risk adjusted national graft failure rate.

Donor and Recipient Risk Profiles

A one-year graft survival model was constructed using the July 2007 SRTR PSR cohort. The effects on graft survival of select recipient-related factors (age ≥65, previous transplant, BMI ≥30, diabetes) and donor related factors (age ≥65, BMI ≥30, diabetes, hypertension, creatinine >1.5, black race, DCD, death from cardiovascular event or stroke) were modeled using this 2007 PSR cohort of transplants. The survival model effects (betas) for each of these donor and recipient factors were then applied to the individual adult deceased-donor kidney transplants from 2001 to 2010. This was done by multiplying the characteristics of the recipients and donors by their respective effects and summing the linear combination. The exponential of the sum yielded a relative risk score which was then averaged by year (calculated relative to the average in 2007). Risk scores were calculated and analyzed separately for donor and recipient and as an overall combined risk score.

Average Income by Zip Code

Average income associated with the zip code of patient residence was obtained using the ZIP code data file released in January 2011 (see Data Sources section of the Appendix). Income averages available from the last census update (January 2002) were applied to patients for the entire decade of study (2001-2010) so that any differences in average income over time could be attributed to changes in patient mix, independent of economic trends. It should be noted, however, that this approach would not recognize substantial or unusual changes in the income in a given zip code over the ten year study.

LIMITATIONS

Evaluating the evidence for changes in transplant practices corresponding with the 2007 implementation of the CoPs is complicated by the long consultation phase which commenced in 2005, prior to implementation of these regulations. It is probable that some transplant programs were motivated by the announcement of the forthcoming CMS regulations to take steps to improve their performance, and that they undertook practices changes related to the CoPs long before the CoPs went into effect. Therefore trends are described broadly for the era surrounding the implementation of the CoPs, and not limited to those trends evident in the period immediately following July 2007. Another important limitation of the present analysis is that it is not possible to distinguish changes in program behavior and outcomes possibly attributable to the CoPs from those changes in behavior and outcomes that may be the result of other initiatives and policies taking place in the same era. The introduction of the Medicare CoPs occurred at a time when several initiatives and policy revisions were being undertaken to improve access to organ transplantation, and these have exerted their own influence on transplant volumes and outcomes, and on practices with respect to wait-listing, organ allocation and recipient selection. In particular, the Organ Donation Breakthrough Collaborative, launched in 2003, was associated with an increase in the number of organs donated from 2004 until the Collaborative was concluded in 2006. The subsequent Organ Transplantation Breakthrough Collaborative, launched in 2005, gave special focus to improved utilization of ECD and DCD organs. Secondly, the Organ Procurement and Transplantation Network (OPTN) introduced a mandatory national electronic offer system called DonorNet 2007® to expedite organ placement and give transplant programs better access to information about the deceased donor.

Additionally, HRSA and the OPTN provided ongoing review of outcomes data through the OPTN Membership and Professional Services Committee activity prior to the implementation of the CoPs, and transplant outcomes had come under media scrutiny. A further limitation of this analysis is that it is not possible to describe the exact nature or motivation behind any implied changes in individual program practices. While the present analysis is limited to an assessment of kidney transplant programs, as this involves the greatest number of transplant patients and is performed at nearly all transplant centers, possible associations with the implementation of the CoPs or citation by CMS for non-conformance with outcomes measures may be evaluated for other types of organ transplant programs in a future study. Finally, this report is not a specific validation of the measures utilized for flagging, rather it seeks to explore whether flagging as practice to-date is associated with any evidence of practice changes.

RESULTS

The analyses reported below evaluate possible effects of the implementation of the CoPs on activities, practices and outcomes, overall and according to program flagging status under the seven PSRs released between July 2007 and July 2010.

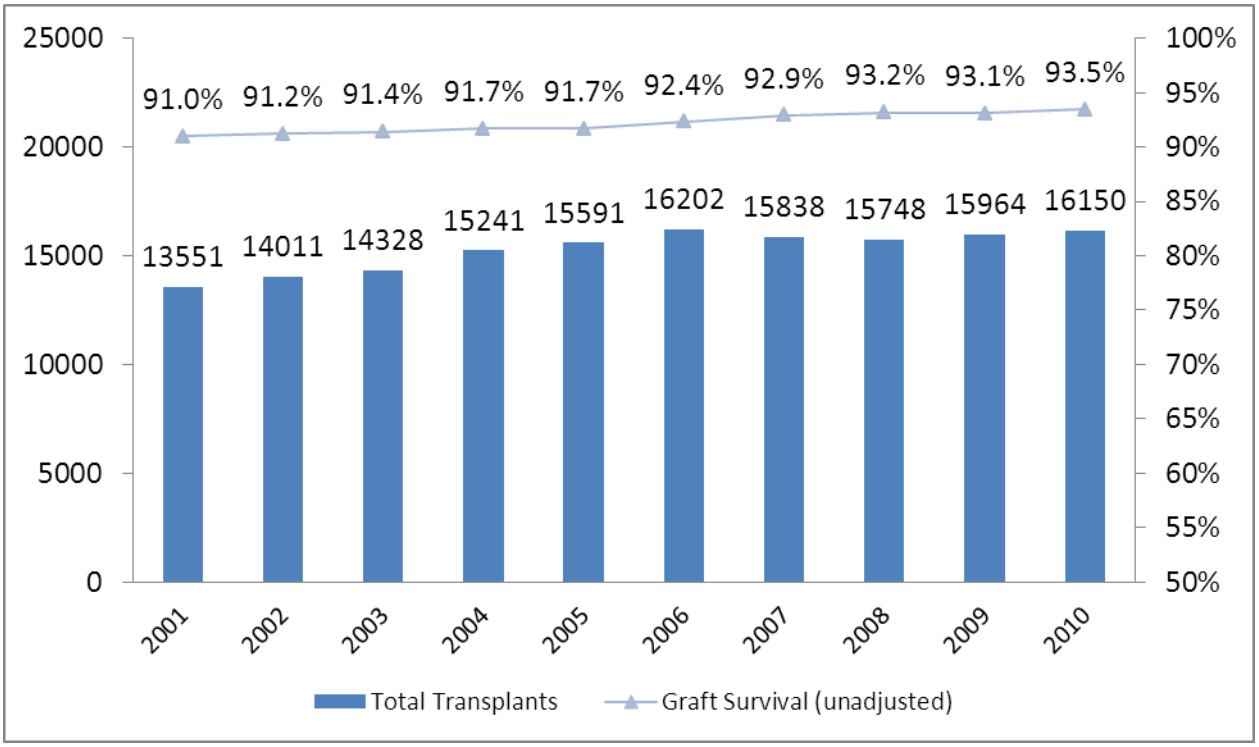
Trends in Transplant Volumes, Donor Utilization and Graft Outcomes

Overall Trends in Kidney Transplantation, 2001 to 2010

From 2001 to 2006, the total number of transplants grew 16%. Since the 2007 implementation of the Medicare CoPs for organ transplant programs, the total number of kidney transplants performed per annum fell slightly from a 2006 high but remained relatively stable between 2007 and 2010. Over the same period, unadjusted 1-year graft survival increased from 92.4% to 93.5% (Figure 1), which translates to an increasing number of functioning grafts even though the number of total transplants has leveled off in recent years. The peak in kidney transplant numbers observed in 2006 and the fall thereafter may reflect the impact of the Organ Donation Breakthrough Collaborative on organ availability over the period from 2003 to 2006. However, the change in the trend of growing transplant volume also occurs near the implementation of the CoPs and it is possible that some programs may have been influenced to maintain steady-state transplant volumes while focusing on outcomes.

Kidney transplant volumes increased for the duration of the Organ Donation Breakthrough Collaborative, which ran from April 2003 to October 2006. In 2006, the number of kidneys transplanted from SCDs was 16% higher than in 2003, an absolute increase of 1028 transplants (see Appendix Table 2). ECD kidney transplants were increased by 25% in 2006 compared with 2003 (representing 357 additional transplants in the 2006 calendar year). DCD (non-ECD) kidney transplants showed the largest proportionate increase, from 325 transplants in 2003 to 857 in 2006 (164%). It should be noted that, whereas the volume of SCD transplants fell following the conclusion of the Organ Donation Breakthrough Collaborative in 2006, DCD kidney transplants have steadily increased in number. Kidney transplants from ECDs increased in 2007 and 2008, and fell slightly in 2009 and 2010. These trends are shown in Figure 2. A decline in SCD transplants can be seen from 2007 onwards, while transplants from DCDs account for an increasing proportion of total kidney transplant activity over the period from 2007 to 2010. Organ acceptance rates increased gradually over the same period (see Figure 6), which may suggest that the trends in SCD and ECD kidney transplant rates after 2007 were to some extent the result of reduced organ availability coinciding with the completion of the Organ Donation Breakthrough Collaborative.

Figure 1: Total Kidney Transplants and Graft Survival. Total annual number of kidney transplants and unadjusted graft survival*, 2001-2010.



*Actual graft survival for the cohort of transplants within each year.

Figure 2: Kidney Transplants by Donor Type. Total annual number of kidney transplants by donor type, 2001-2010.

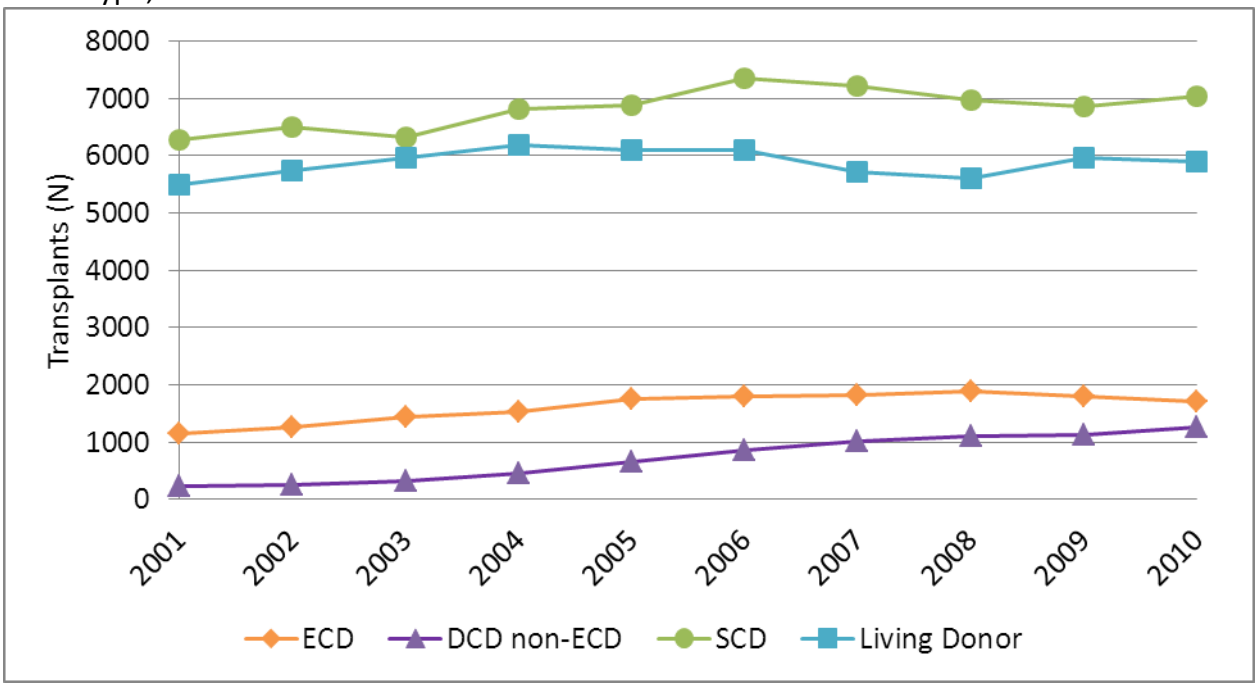


Figure 3 shows trends in kidney donor type over the decade stratified by flagging status as a percentage of the total transplants in each year. The group that was flagged in both periods (i.e. flagged in any of the first three SRTR PSRs released after the CoPs went into effect – Jul '07, Jan '08, Jul '08 - or any of the four PSRs released in Jan '09, Jul '09, Jan '10 and Jul '10) saw the percentage of ECD kidney transplants performed decline in each year from 2004 to 2010. The group that was flagged in Period 1 only (i.e. in any of the SRTR PSRs released in Jul '07, Jan '08, Jul '08, but not subsequent PSRs), saw a sharp decline in the percentage of ECD kidney transplants performed between 2005 and 2006, with a subsequent increase that brought this group in line with the non-flagged group by 2007. The actual number of ECD transplants decreases along with the number of SCD transplants for programs in both flagged groups (see Appendix Table 2).

While Figure 3 shows the utilization among all the programs combined for each flagging group, Appendix Figure 15 shows the range of changes at the program-level for the flagging groups over time. As discussed in more detail below, Figures 4 and 5 summarize this information in a slightly different way. Appendix Figure 15 displays the change in ECD utilization at the program-level with positive numbers indicating an increase in ECD utilization compared to 2006. Each panel of Appendix Figure 15 corresponds to one of the lines in panel 1 of Figure 3. For each group, the line through the middle of the box is the median change and the diamond is the mean change. The top and bottom of the box show the 25^{th} and 75^{th} percentiles (the middle half of facilities have changes in the range shown by the box) and the whiskers show the minimum and maximum values that are within 1.5 times the interquartile range.

For the group of programs flagged in Period 1 only (2^{nd} panel of Appendix Figure 15 and blue line in ECD panel of Figure 3), the ECD utilization increases in 2007 and 2008 and then decreases again. Appendix Figure 15 shows that approximately half of the facilities in this group have lower ECD utilization and half have higher ECD utilization in 2007 and 2008 compared to 2006 (the median line is at approximately 0 change). However, the boxes extend much farther above the zero line than below indicating that the half of programs with decreases in ECD utilization had relatively small decreases while those with increases had larger increases.

Figure 4 shows the program-level change in ECD utilization, focusing on the absolute change in percent ECD utilization between 2006 and 2010 showing the range of differences amongst programs in each of the flagging groups (i.e. the last box from each panel of Appendix Figure 15). Figure 5 summarizes this information in a slightly different way, categorizing programs as having decreased utilization more than 2 percentage points, stayed the same within 2 percentage points, or increased utilization by more than 2 percentage points. As discussed above, the facilities flagged in Period 1 only tended to increase their ECD utilization between 2006 and 2010 while those flagged in both periods tended to decrease ECD utilization. Among programs not flagged, the distribution of increases and decreases was similar.

Figure 3: Utilization by Donor Type. Trends in utilization of different kidney donor types as a proportion of all kidney transplants performed within each year, by flagging status.

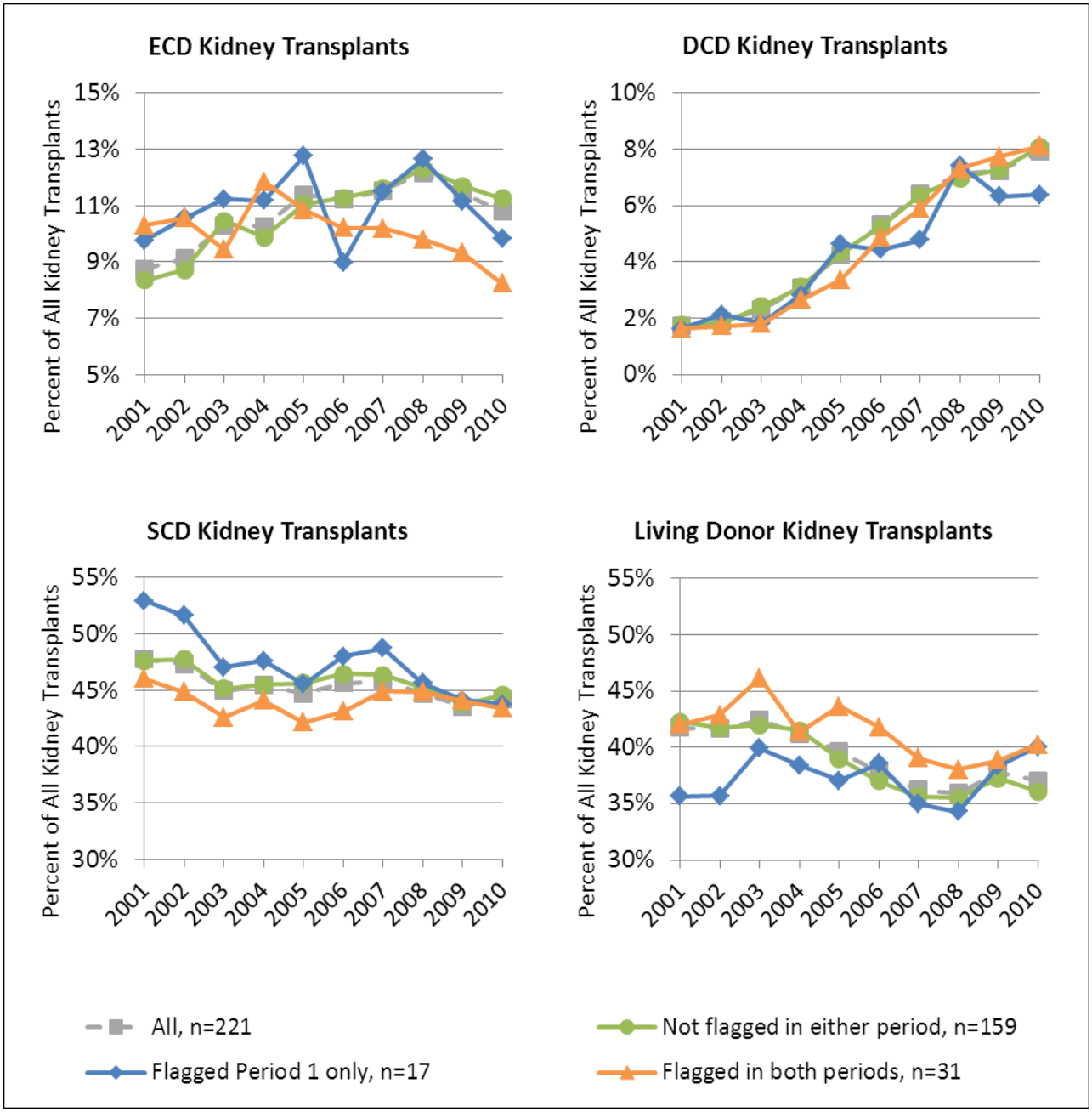


Figure 4: Percent change in ECD Use. Program change in percent ECD transplants in 2010 vs. 2006.

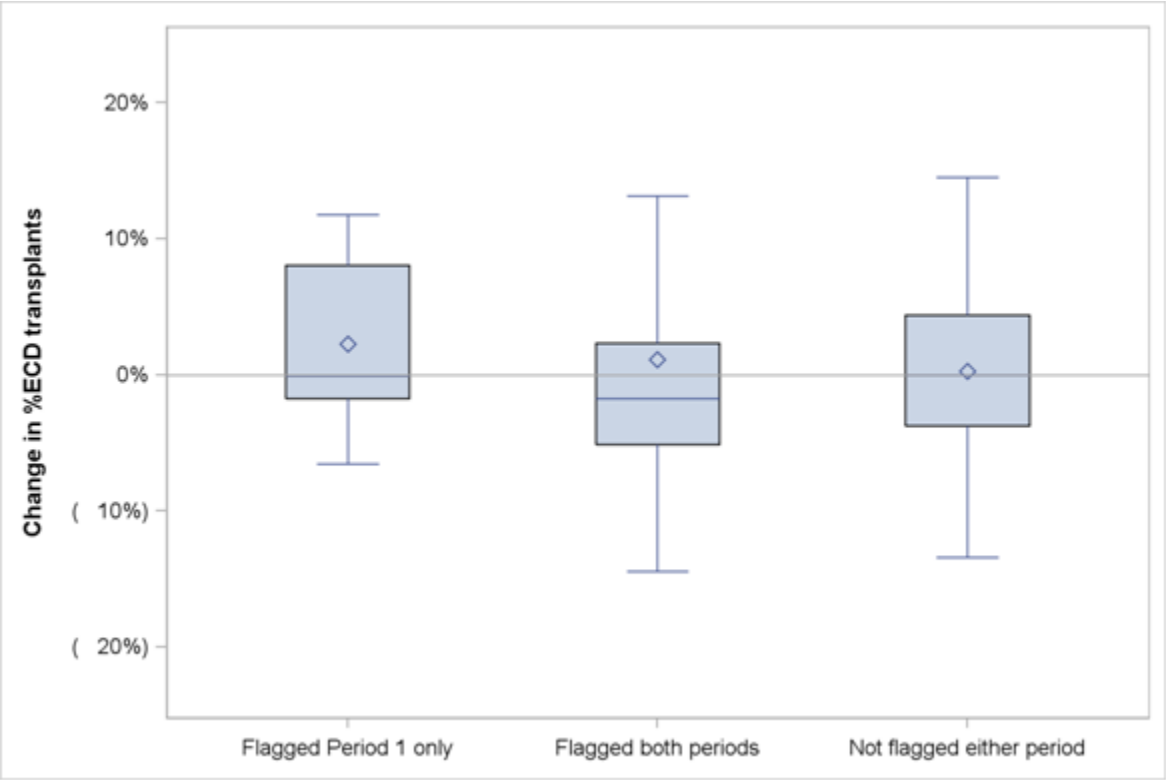
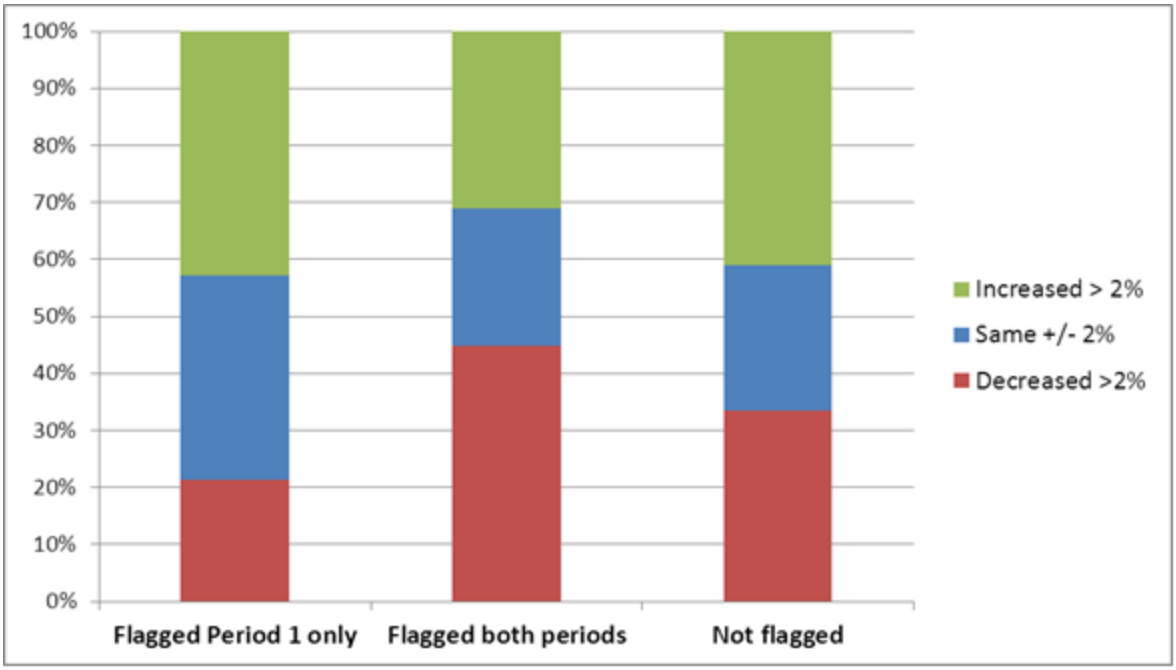


Figure 5: Change in ECD Use. Program change in the utilization of ECD kidney transplants, 2010 vs. 2006.



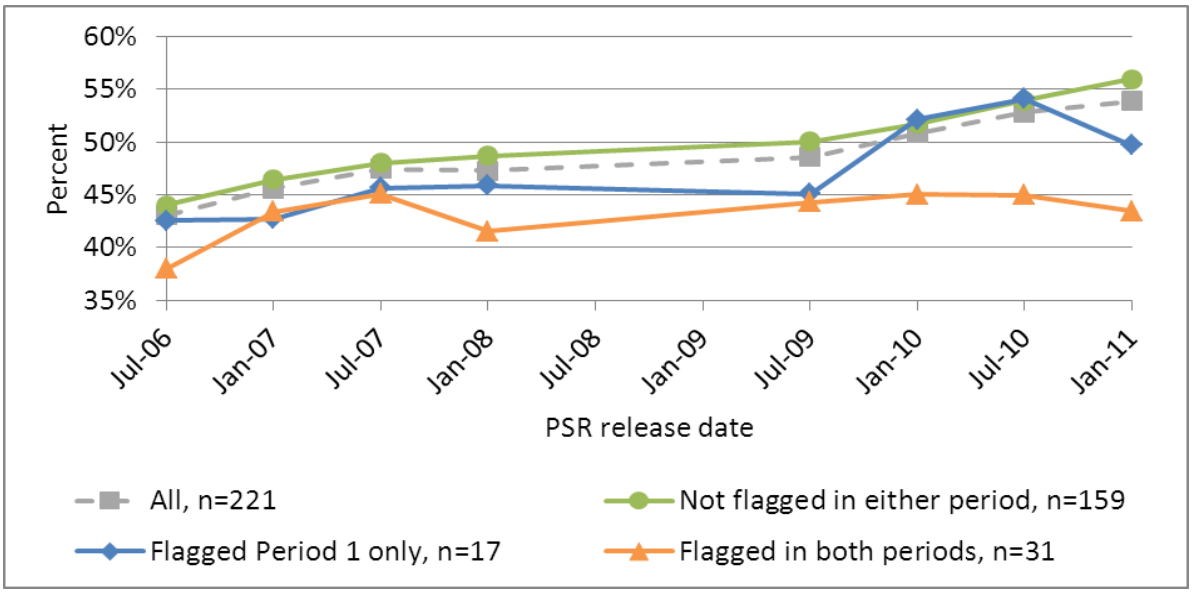
Organ Acceptance

Figure 6 shows the average percentages of kidneys offered for transplantation that programs accepted, within each flagging group. The plotted percentages are the average acceptance rates of 'good'[4] organs within each calendar year associated with the PSR release date. For almost every time point from July 2006 to January 2011, programs that were not flagged in either period had a higher average acceptance rate compared with the other flagging groups. This is consistent with previous reports that high acceptance rates are not associated with poorer post-transplant patient survival, rather programs with higher acceptance rates have higher rates of transplantation of patients on their waiting list while also maintaining patient outcomes[5]. It may be that programs that were not flagged in either period not only achieved better transplant outcomes, but were also the best prepared in terms of organization and/or resources to accept organs when they were offered. Programs that were flagged in Period 1 only, however, did lift their average kidney acceptance rate in 2009. This could suggest confidence in their ability to achieve acceptable post-transplant outcomes. Interestingly, programs that were flagged in both periods did not, on average, decrease acceptance over the period subsequent to the introduction to the Medicare CoPs, which provides some evidence that flagging did not have the effect of causing 'good' organs to be turned down by these programs.

[4] Good organs are kidneys that, in general, would be accepted on behalf of a wide range of candidates, by a large fraction of programs. Exclusions include organs that were not transplanted, organs from ECDs or DCDs, Organs that were not accepted either within 50 offers or by one of the first three centers offered the organ, organs with long cold ischemia time, organs refused due to positive cross-match etc. Acceptance rates are adjusted for donor-related and other factors (age, race, gender, height, HBV/HVC status, blood type, COD, creatinine, hypertension, local vs. regional or national donor, number of patients on the wait-list on January 1 at the transplant program).

[5] Wolfe RA, LaPorte FB, Rodgers AM, Roys EC, Fant G, Leichtman AB. Developing organ offer and acceptance measures: When 'good' organs are turned down. Am J Transplant 2007; 7 (Part 2): 1404-1411.

Figure 6: Organ Acceptance. Average kidney acceptance rates by flagging status group, 2006 to 2011.



Trends in Kidney Graft Survival, 2006 to 2010

Both actual and expected kidney graft survival rates have increased steadily over the period from January 2006 to July 2010 (see Appendix Figure 16). This is a uniform trend across flagging groups and donor types, although programs that were flagged in Period 1 only saw particular improvement in the survival of ECD kidney transplants and living donor kidney transplants after 2007/2008. The group that was flagged in both periods saw later improvement in the actual survival of kidney grafts from all donor types, with survival improving after January 2009.

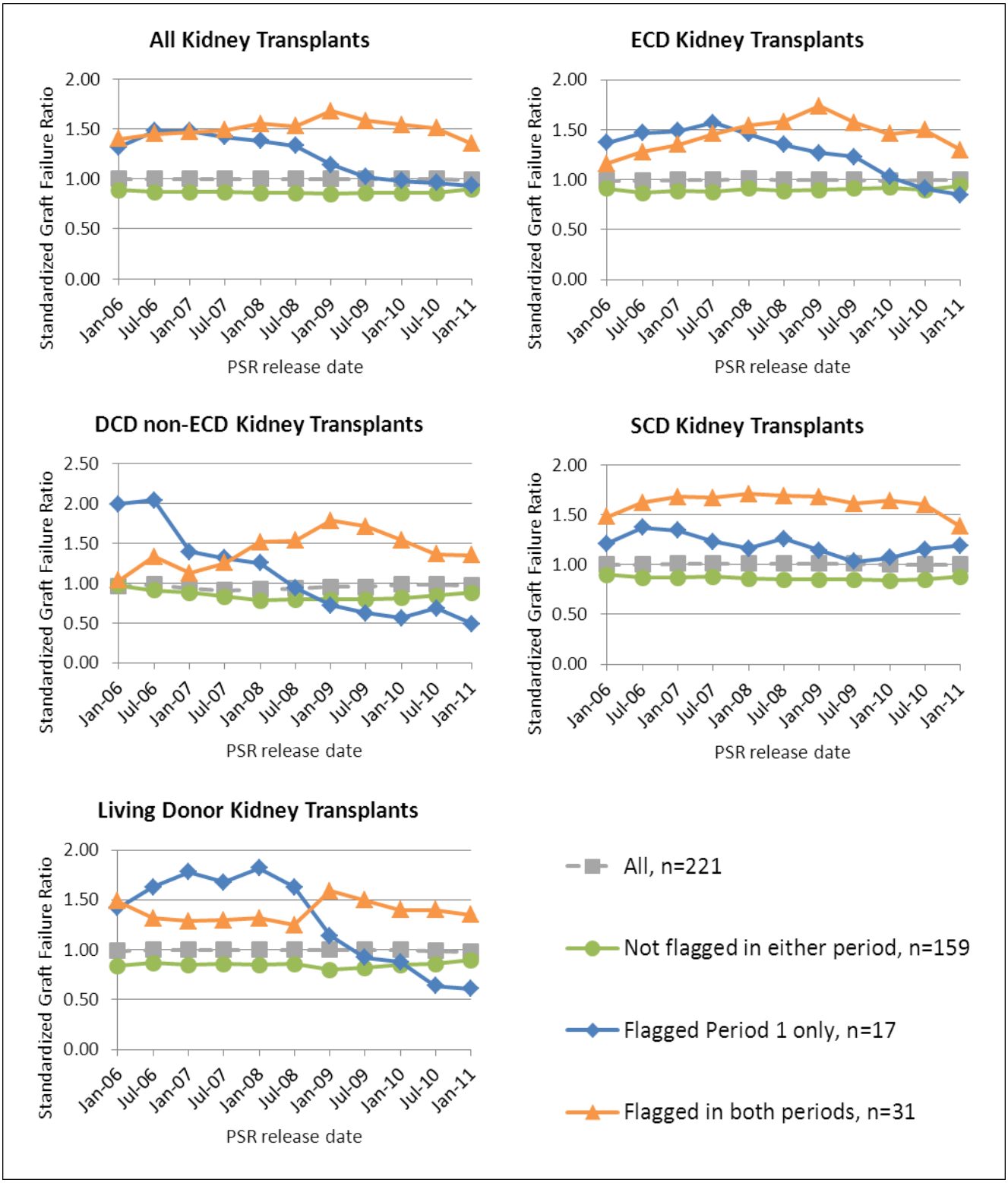
Figure 7 shows standardized graft failure ratios at one year post-transplant, by donor type and flagging status. The group flagged in both periods would of course be expected to have higher graft failure rates overall, but Figure 7 shows that they achieved poorer than expected graft survival outcomes for all donor types over the entire period from Jan 2006 to Jan 2011. While one-year standardized graft failure ratio for ECD kidney transplants actually increased until 2009 for the group that was flagged in both periods, after this point the group saw a strong improvement in graft survival. Similarly, the group flagged in Period 1 only showed a steady reduction in the standardized graft failure ratio for ECD kidney transplants after July 2007. This suggests that some practice changes/program improvements occurred following flagging in Period 1 or Period 2 to improve the outcomes of ECD transplants.

Most notably, this group that was flagged in Period 1 only also saw very sharp improvements in standardized graft failure ratios for transplants from DCD and living donors. It can be concluded from the donor type specific graphs that the overall improvement in graft outcomes for these 17 programs is driven primarily by reductions in graft failure from living donor kidney transplants (which comprise approximately 40% of transplants at these programs, similar to the figure of 37% of kidney transplants overall), followed by DCD and ECD transplants (which

comprise 6% and 9% of kidney transplants performed by the group that was flagged in Period 1, respectively).

Those programs that were not flagged in either Period were doing the highest average number of transplants in 2007, whereas programs that were flagged in Period 1 or both periods were doing fewer (see Appendix Figure 14). This suggests that there is some positive correlation between good outcomes and transplant volume. It is also interesting that the group flagged in Period 1 only and the group flagged in both periods both have standardized graft failure ratios below the 1.5 threshold for flagging (which is in fact based on patient survival, not graft failure alone) for all donor types by January 2011 (Figure 7). This indicates that these programs as a group have improved, and in fact, of the 48 kidney programs flagged in Period 1 only (n=17) or in both Period 1 and 2 (n=31), two-thirds (33) are no longer flagged in January 2011. It should be noted that being flagged in Period 1 or Period 2 does not mean that a program was flagged in all three PSRs in 2007/2008 or all four PSRs in 2009/2010 respectively, and therefore the averaged standardized graft failure ratios may be less than the 1.5, even in the flagged groups.

Figure 7: **Graft Failure.** Standardized kidney graft failure ratio in the first year post-transplant, by donor type and flagging status, 2006 to 2010.



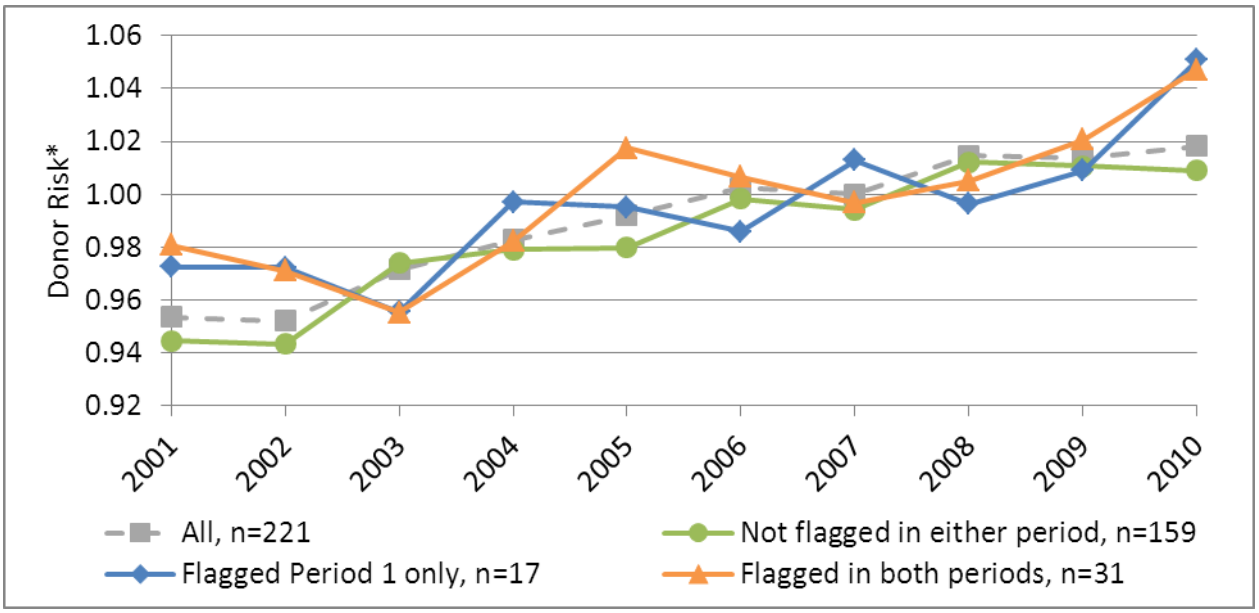
Donor and Recipient Risk Profiles, 2001 to 2010

Donor Risk Profiles

There are many factors that can increase the risk associated with using kidneys from a particular donor. Just as programs may have responded to the Medicare CoPs by decreasing their utilization of ECDs, they may also have made these decisions based on the components of the ECD definition or other donor risk factors. This section examines trends in the use of donors with various risk factors and a metric combining these risk factors into a single measure of donor risk.

In order to estimate the overall risk associated with a particular donor we fit a model predicting one-year graft loss based on known donor risk factors including donor age, diabetes status, creatinine, BMI, hypertension, race, DCD, and cause of death (see Appendix Table 3 for model details). We then took the average risk for donors in each year (relative to 2007) to determine whether donor risk factors have changed over time. Figure 8 shows the trend over time in this measure of overall donor risk. Between 2001 and 2010, the average donor risk increased approximately 6% ($p<0.0001$). This increase was fairly steady over the time period and the pattern was similar regardless of program flagging status. There is no indication, with respect to this measure of donor risk, that flagged programs on average changed their practice to accept less risky donors in reaction to the flagging.

Figure 8: Donor Risk Score. Program average risk of graft loss, relative to the average in 2007, one-year post-transplant due to donor-related factors*, for adult recipients of deceased donor kidneys.



*Donor related factors are age ≥65, BMI ≥30, diabetes, hypertension, creatinine >1.5, race, DCD, death from cardiovascular event or stroke. A value greater than 1 corresponds to greater risk, and a value less than 1 corresponds to lower risk, relative to the standard.

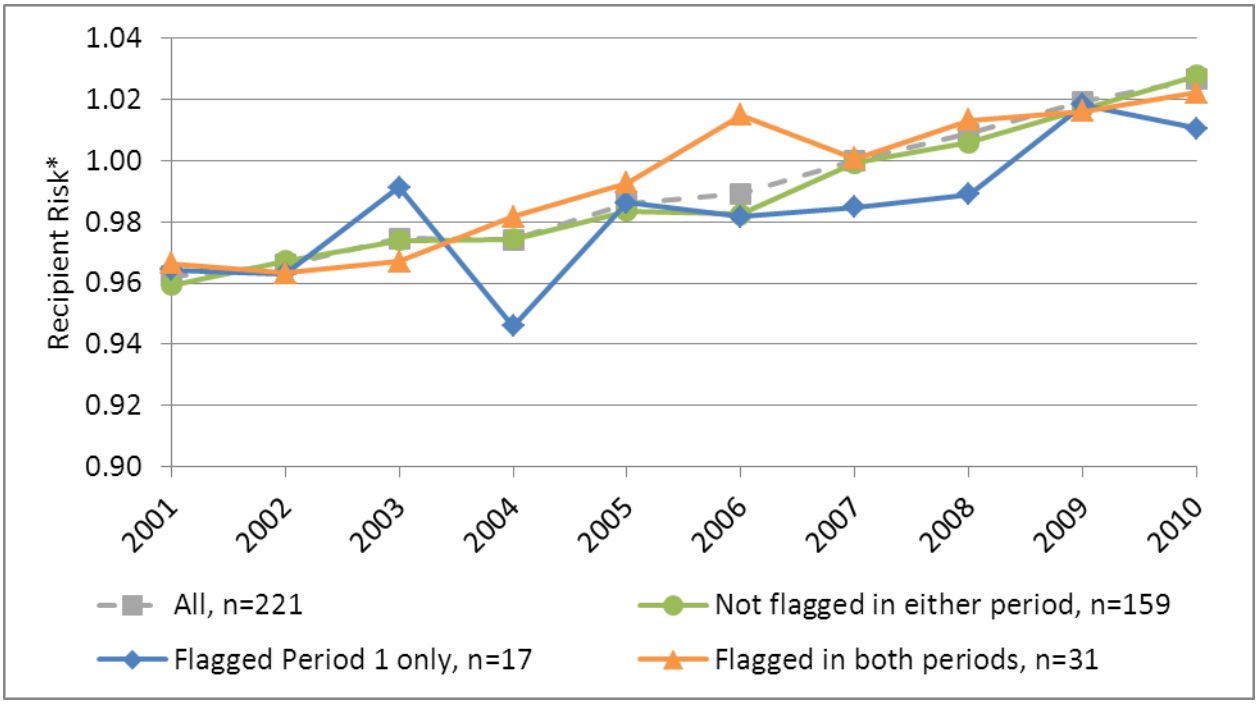
Looking separately at the components of the donor risk measure we see no difference between programs that were flagged and those not flagged in the percent of donors 65 or older, with diabetes, with creatinine >1.5, with BMI≥30, with hypertension, or who died of a cerebrovascular accident or stroke (see Appendix Figure 19 to Appendix Figure 24). The general trends over time are interesting, showing that utilization of donors with diabetes, with creatinine >1.5, BMI≥30, hypertension and organs from black donors has increased over the past 10 years while the use of donors who died of CVA or stroke has decreased. There has been no change overall in the use of donors 65 years or older.

Recipient Risk Profiles

Transplant programs that have fallen out of compliance with the CoPs or been in jeopardy of doing so may perceive an incentive to transplant lower risk patients, reflecting concern that transplanting higher risk patients could make their performance appear substandard. This section examines trends in recipients with various risk factors and a metric combining these risk factors into a single measure of recipient risk similar to the donor risk metric described in the previous section.

In order to estimate of the risk of graft loss due to kidney transplant recipient characteristics and the impact changes in these characteristics may have had on program outcomes, we fit a model predicting one-year graft loss including known recipient risk factors of recipient age, previous transplant, BMI, and diabetes (see Appendix Table 3 for model details). The average recipient risk was then calculated for each year using parameter estimates from the model. Figure 9 shows the trend over time in this measure of overall recipient risk which is very similar to the trend in overall donor risk. Between 2001 and 2010, the average recipient risk increased approximately 7% ($p<0.0001$). On average, this increase was fairly steady over the time period and the pattern was similar for programs flagged and not flagged. There is no indication, with respect to this measure of recipient risk that flagged programs as a group changed their practice to transplant less risky recipients in reaction to the flagging.

Figure 9: Recipient Risk Score. Average program risk, relative to the average in 2007, of graft loss in the first year post transplant due to recipient-related factors* for adult recipients of deceased donor kidney transplants (2001-2010), stratified by flagging status.



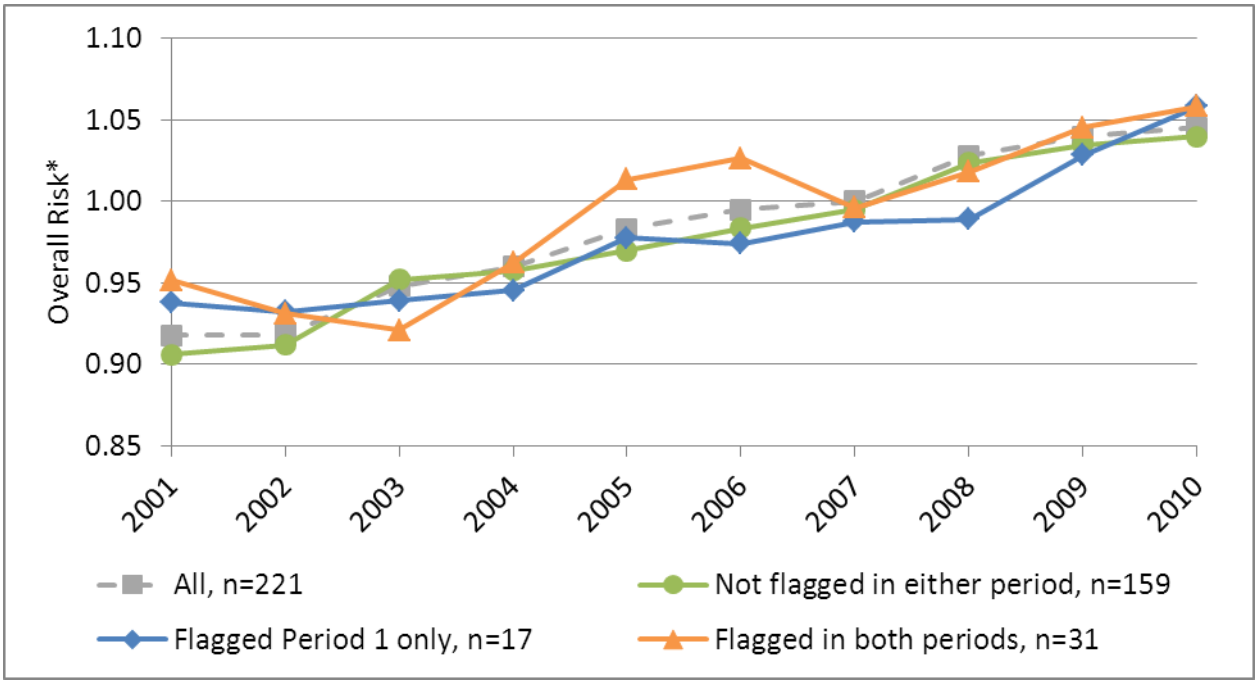
*Recipient-related factors are age ≥65, previous transplant of any organ type, BMI ≥30, diabetes. A value greater than 1 corresponds to greater risk, and a value less than 1 corresponds to lower risk relative to the standard used.

Looking separately at the components of the recipient risk measure we see that, like the donor population, the overall recipient population also has increasing rates of diabetes and obesity. There is no difference between programs that were flagged and those not flagged in the percent of recipients with a previous transplant, BMI ≥ 30, or diabetes (see Appendix Figure 26 to Appendix Figure 28). With respect to age distribution, the percentage of recipients 65 years and older increased steadily throughout the period from 2001 to 2010, but was consistently lowest in the group that was flagged in Period 1 only. All other groups clustered closely together in recipient age trends (see Appendix Figure 29). It is possible that, in addition to an increasing population burden of obesity and diabetes, another factor that could be influencing trends in recipient risk is an increase in organ availability resulting from the Organ Donation Breakthrough Collaborative. Greater organ availability would theoretically give greater access to transplantation to wait-listed patients with less-optimal risk profiles.

Overall Risk Profiles

Overall graft failure risk was determined by the combination of selected donor and recipient risk factors described in the previous two sections (see also Appendix Table 3). This was done to assess trends in overall risk based solely on a set of modifiable donor and recipient factors that programs may have attempted to alter once flagged. The overall risk therefore does not include donor-recipient interaction type factors such as HLA matching or cold ischemia time. Figure 10 shows the trend in the overall risk measure over the past decade, overall and separately for each of several flagging groups. This risk increased approximately 13% between 2001 and 2010 reflecting the 6% increase in donor risk and 7% increase in recipient risk over the decade.

Figure 10: Overall Risk Score. Program average overall risk of graft loss, relative to the average in 2007, in the first year post transplant due to the combination of recipient and donor-related factors for adult recipients of deceased donor kidney transplants (2001-2010), stratified by flagging status.*



*A value greater than 1 corresponds to greater risk, and a value less than 1 corresponds to lower risk relative to the standard used.

This increase in overall risk was fairly steady over the time period and the pattern was similar regardless of program flagging status. There is no indication, with respect to this measure of combined recipient and donor risk, that programs that were flagged changed their practice to perform overall less risky transplants. In addition to the risk associated with the donor and the recipient, it is important for programs to choose appropriate donors for each recipient. For

instance, in general a young non-diabetic patient should not be transplanted with an ECD organ. Although there are situations where this would be appropriate, it is relatively uncommon. In order to address this question, we looked at the donor–recipient risk combination for flagged and non-flagged programs over the decade. There were no meaningful differences in the use of high risk donors in high risk recipients (top 10 percent of risk scores for each) between flagged and non-flagged programs (p=0.96).

It is interesting to note that the improvements in graft survival seen over the decade have occurred in conjunction with overall increased donor and recipient risk. Based on the analyses provided here there is no indication that programs responded to flagging by selecting less risky donors or recipients, or that selected changes in donor or recipient risk profiles are responsible for improvements in observed graft survival since 2007.

Trends in Characteristics of Patients Newly Wait-listed for Kidney Transplantation

The following set of analyses attempts to identify whether program wait-list practices changed following the implementation of Medicare CoPs, or subsequent to citation by CMS for non-conformance under the outcomes CoPs.

This set of analyses are important to review because it is reasonable to believe that a program may elect not to list a candidate felt to be at high risk for poor outcomes, or alternatively, remove them, move them to inactive status, or simply not accept organs for them. Further, one may suspect that these practices might be adopted more frequently at programs with poorer than expected results. Such practices may have the unintended impact of disadvantaging specific populations of potential transplant recipients.

While the list of potential risk factors is large, we focus on patient specific factors well documented to impact post-transplant outcomes. By comparing the different program groupings over time we can consider any differences between the groups in the context of general trends that are reflected throughout all programs.

Patient Characteristics

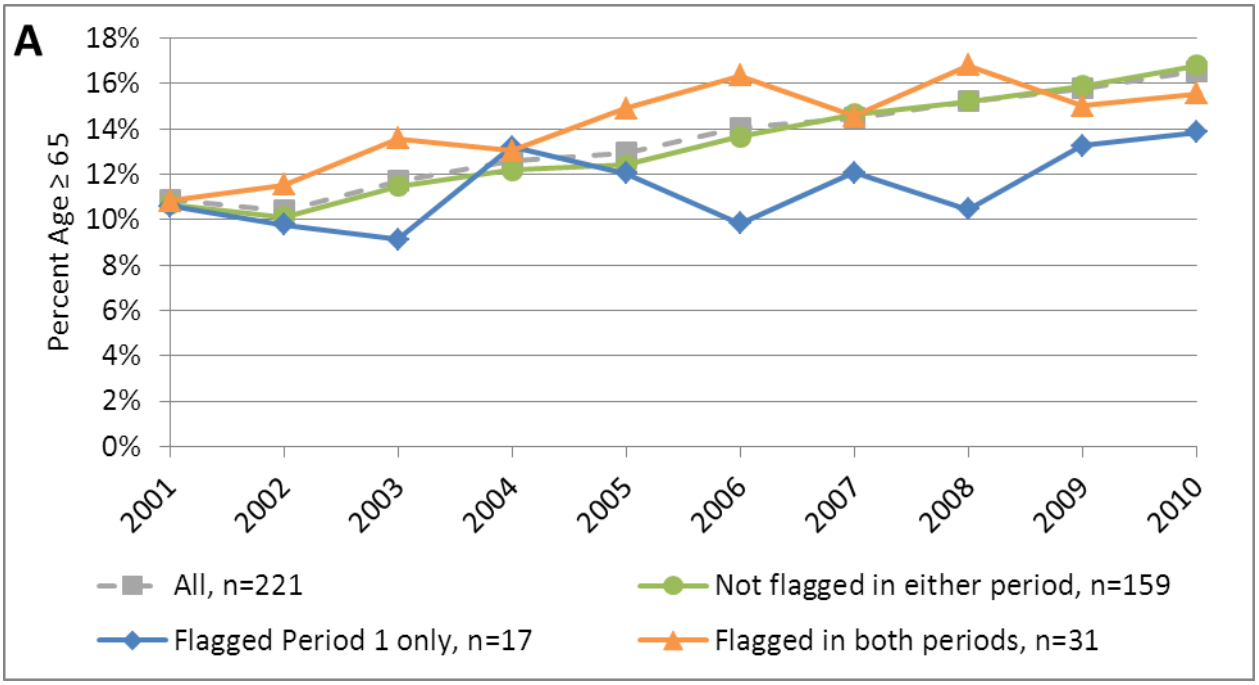
Figure 11 shows the age trends of adult patients newly wait-listed for kidney transplantation from 2001 to 2010. Across all programs there has been a steady increase in the program average percent of patients 65 and older, from 11% in 2001 to 17% in 2010. This overall trend has remained stable and does not appear to have changed following introduction of the CoPs. Most of the defined groups follow the overall trend closely over the entire time period with the exception of the programs that were flagged in Period 1 only. The average percent of newly wait-listed adult patients, 65 or older, for these 17 programs falls below all other groups in most time periods, most notably from 2006 to 2008. In 2006, 10% of adult patients newly wait-listed by these programs were 65 or older compared to 14% for all programs (p=0.01). The timing of this significant difference coincides roughly with the 2007 implementation of the

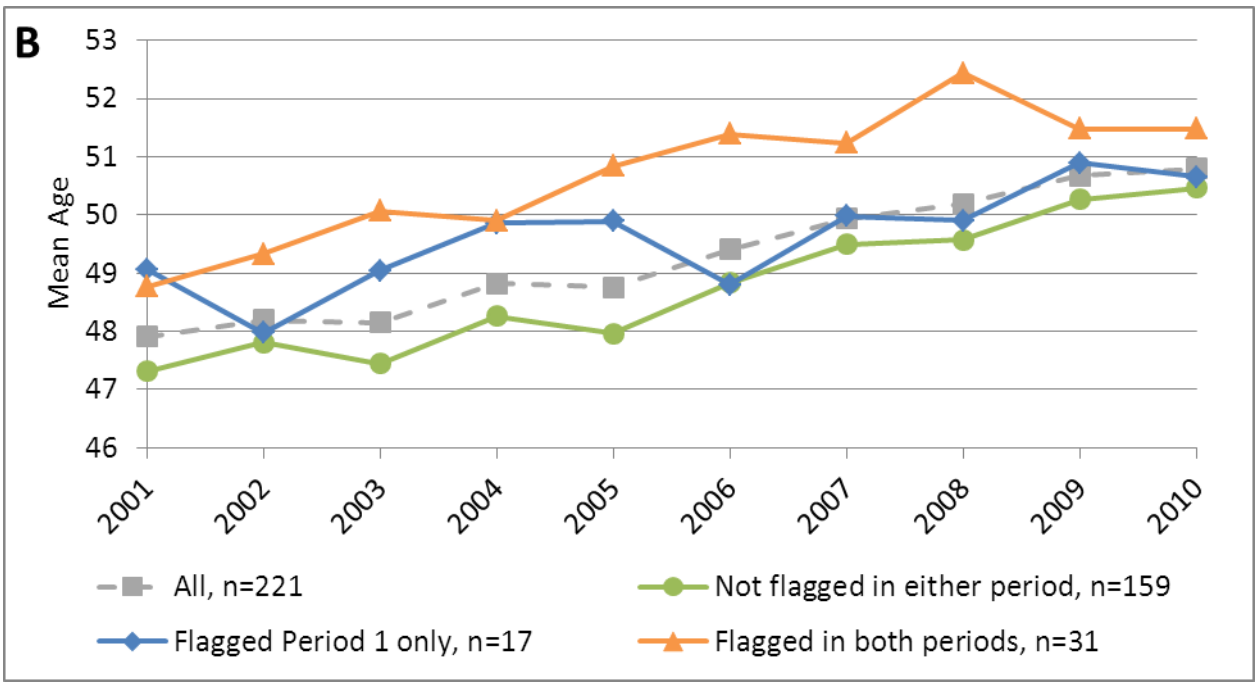
COPs. The anticipation of which may have been one factor if some of these programs did attempt to reduce recipient risk with respect to age.

Figure 11 also shows the mean age of adult patients over all programs, and in each flagging group. The mean age of adult patients wait-listed for kidney transplantation steadily increases, over all programs, from 48 in 2001 to 51 in 2010 ($p<0.0001$). From 2001 through 2010, the mean age of recipients for programs flagged in Period 1 only and programs that were flagged in both periods is consistently greater than the mean age of the programs not flagged in either period. The mean age of transplant recipients does not increase as steeply for the 17 programs flagged in Period 1 only compared with other flagging groups. This may suggest a possible change in wait-list practices in an attempt to transplant younger, and therefore less risky, patients on average.

In addition to age, we explored trends in obesity status and previous transplants among newly wait-listed adult patients (see Appendix Figure 30 and Appendix Figure 31 respectively). The average percent of newly wait-listed patients with a BMI of at least 30 has increased from about 30% in 2001 to about 40% in 2010, with no apparent difference in trends among the groups. The average percent of newly wait-listed patients that had a previous kidney transplant is just above 15% for most years, and fluctuates only slightly over time. There does not appear to be a difference in this trend for any of the groups.

Figure 11: Age Trends among New Listings. Age trends among adult patients newly wait-listed for kidney transplantation, (A) percent aged 65 and older, and (B) average program age.*





*Mean calculated within each program and then average within each flagging category (equal weighting on all programs).

Willingness to Accept an ECD Kidney

Willingness to accept an ECD organ is indicated by the listing program in cooperation with the transplant candidate on the Transplant Candidate Registration (TCR) form. This may seem to be a trait of the patient that is not subject to program control; however, the variation among programs suggests that patients may encounter some level of influence. That is, the possibility of obtaining an ECD organ may be framed in a positive ("you may obtain an organ more quickly"), or negative manner ("these organs are inferior").

Assuming that a program does have some influence over how likely a newly wait-listed candidate is to consent to accept an ECD organ, it was of interest to explore whether any of the defined groups differed in the way they designated candidates for ECD allocation, or changed at any time points corresponding to the implementation of the CoPs, or flagging under the CoPs.

Figure 12 shows the average percent of newly wait-listed adult patients that indicated a willingness to accept an ECD organ, for all programs and each of the defined flagging groups from 2001 to 2010. From 2001 to 2002 all of the groups increased their average percent ECD designation and track closely with one another. Beginning in 2003 there appears to be a difference in behavior between some of the groups. The programs flagged in Period 1 only and the programs flagged in both periods had the highest percentage of newly listed patients designating willingness to accept an ECD kidney between 2003 and 2005. For example, an average of 52% of newly wait-listed patients consented to an ECD organ in 2003 at programs flagged in Period 1 only, compared to an average of 43% at programs that were not flagged in either period ($p=0.045$). The percent of patients willing to accept an ECD kidney remained high for the group flagged in both periods throughout the interval from 2006 to 2010, but declined after 2004 in the group flagged in Period 1 only, falling as low as 36% in 2008.

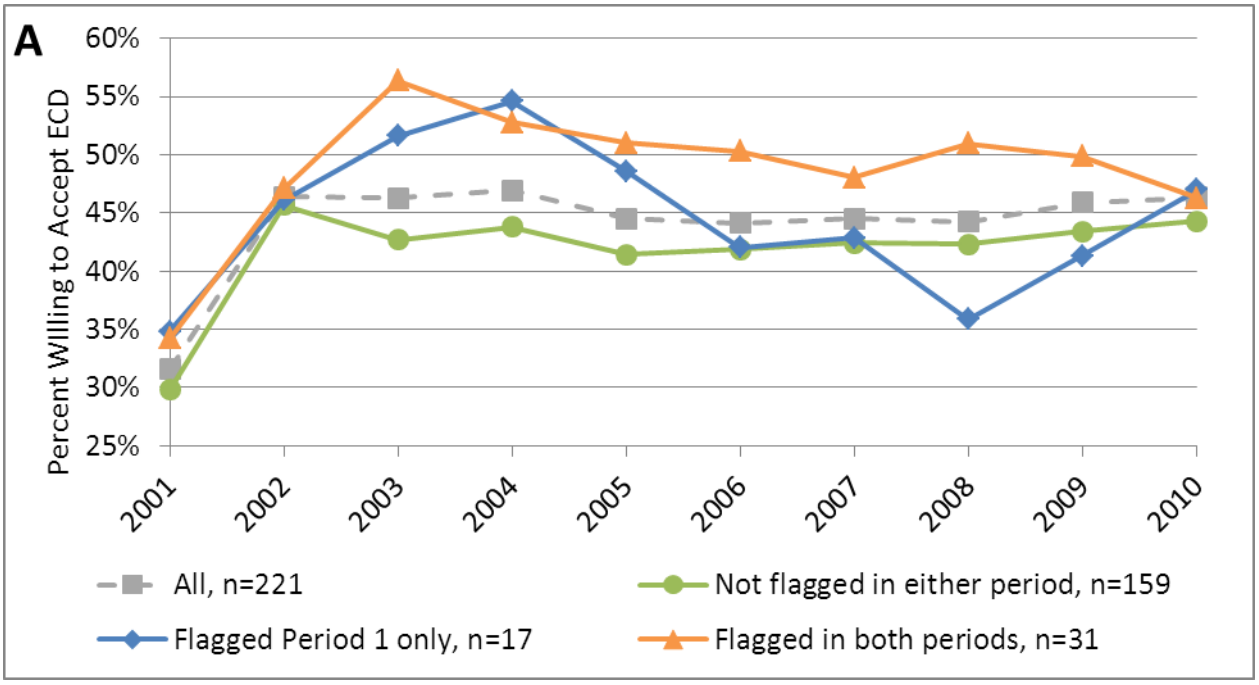
This Figure possibly suggests that the programs of the two flagged groups were more aggressive in influencing patients to consent to accept an ECD organ between 2003 and 2005. This tendency may have diminished with anticipation of the CoPs. Because flagging is determined by transplants 1 to 3 ½ year prior, which in turn are influenced by patients wait-listed in the years prior to transplantation, influencing more patients in 2003 and 2004 to accept ECD organs may have been a program trait associated with taking on a higher burden of risk.

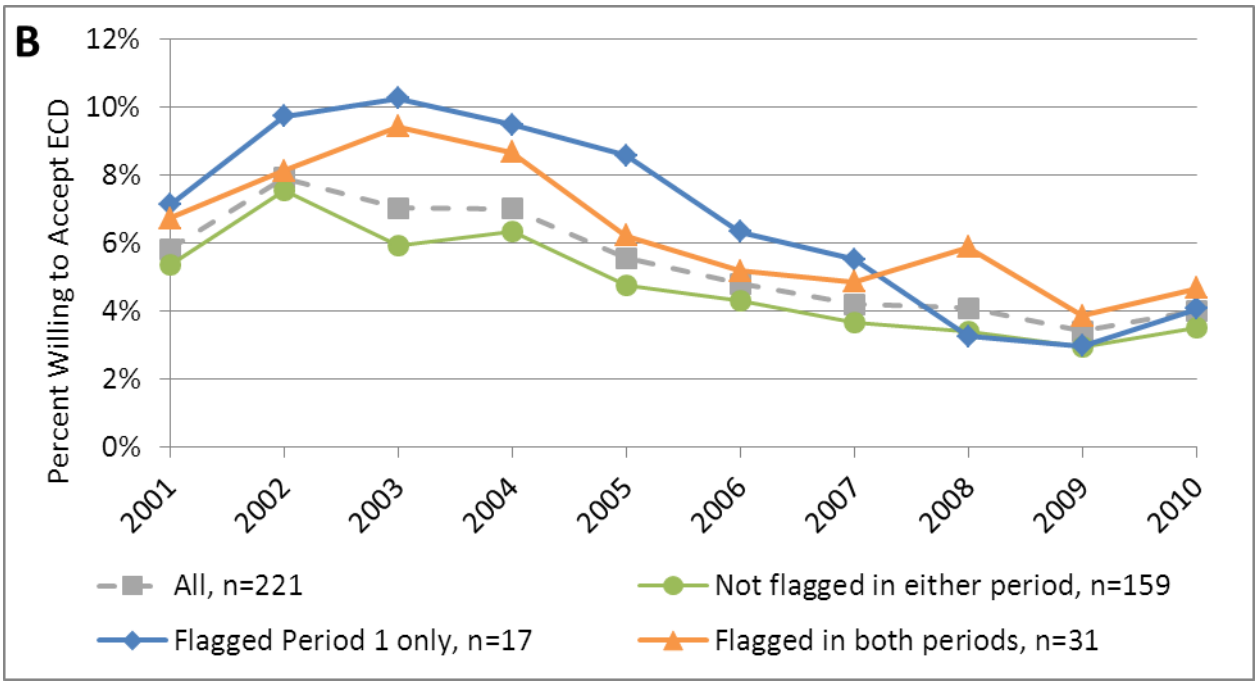
The 17 programs flagged in Period 1 only were initially among the programs with the highest average percent of newly wait-listed patients the program indicated were willing to accept an ECD organ, but later dropped below the overall average percent. Just as the initial aggressiveness may have been associated with a higher burden of risk, the reduction of this average percent may have been associated with increased attention paid to risky behavior in attempt to correct it. If the reduction most evident in 2008 was part of a conscious change, it may be associated with some changes in practice that helped these programs improve their outcomes and avoid further flagging.

Willingness to Receive an ECD Organ by Healthier Patients

Figure 12 also shows the percent of newly wait-listed healthy, lower-risk candidates that the program indicated were willing to accept an ECD organ. A healthy, low-risk patient is meant to be someone who may be able to wait longer than others for a transplant and is defined for this analysis as someone younger than 40 years of age, and non-diabetic. If a program is overly-aggressive in its influence over whether a patient lists as willing to accept and ECD organ, the assumption is that it may be possible to see patients you would not normally expect opting for an ECD organ. Figure 12 shows that an average of 7% of these low-risk patients across all programs consented to an ECD organ in 2003. In the group flagged in Period 1 only, this percentage was 10%; in the group that was not flagged in either period this figure was 6% ($p=0.009$). This difference diminishes over the remaining years and by 2010 there is no distinguishable difference between the groups.

Figure 12: ECD Willingness among New Listings. Willingness of newly listed adult patients awaiting kidney transplantation to accept an ECD kidney: (A) among all candidates, and (B) among non-diabetic candidates under age 40.





Socio-economic status and access to transplantation

Socio-economic status may be a factor in whether a patient is put forward for kidney transplantation or not, due to a belief that education level, income and/or other socio-economic factors may impact a patient's means to comply with follow-up care (e.g. less wealthy patients in rural areas with low income may have barriers to finding transportation to the program). Therefore we wanted to see if there were any changes in wait-listing practices associated with socio-economic factors for any of the groups. We explored income and education as our measures of socio-economic status. Specifically, we looked at income (represented in 2002 dollars for all years) by zip code of candidate residence and education level indicated for each newly wait-listed patient.

Figure 13: Wait-list Income. Average resident income of patient zip code.

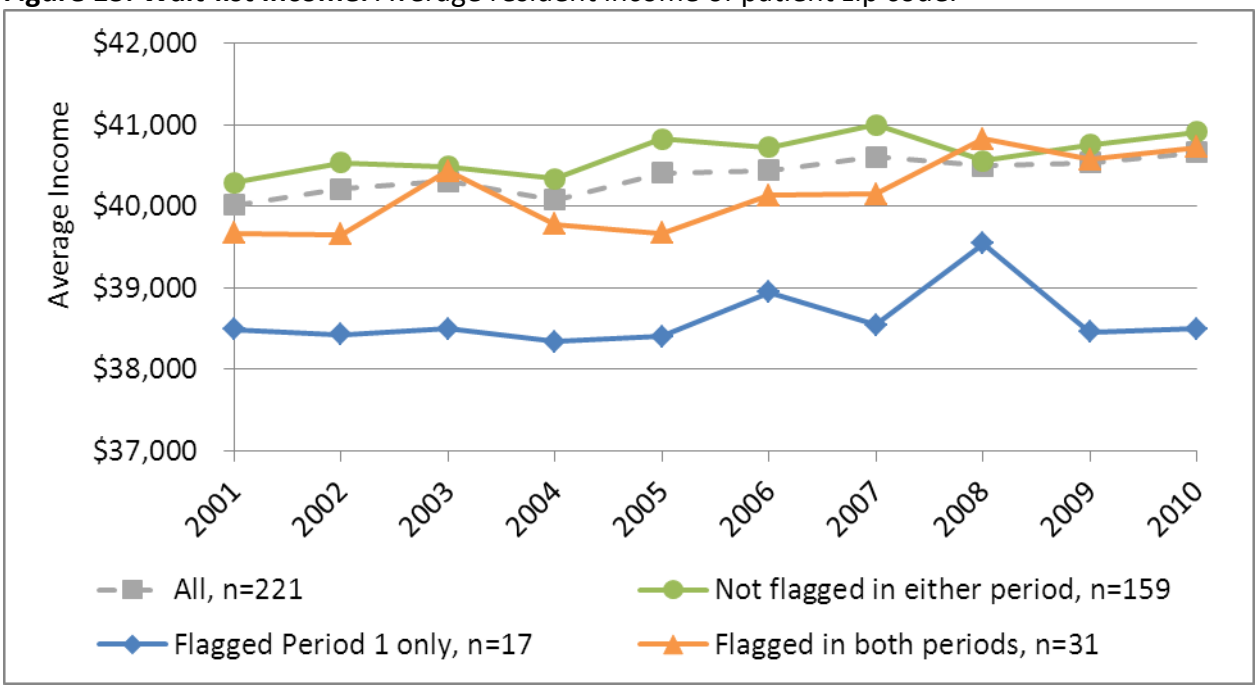


Figure 13 shows the trend in average income over time for each of the groups. Specifically, we took the average resident income in the zip code of each newly wait-listed patient, calculated the average for each program, and averaged over the programs in each group. The trend is fairly stable and the groups remain in the same relative position from 2001 to 2010. The programs that were not flagged in either period had the highest average income; surprisingly, however, the programs flagged in Period 1 only consistently had the lowest. In addition to program average income, we calculated the percent of newly wait-listed patients at each program living in a zip code where the average income is less than $30,000 or greater than $50,000. The percent of patients in each program was then averaged over the groups. Appendix Figure 33 shows the average percent of newly listed patients from a zip code where the average income is less than $30,000 and greater than $50,000, respectively. The relationships between

the groups are generally consistent with Figure 13, with programs that were not flagged in either period having the smallest percent of candidates from zip codes with average incomes below $30,000 and the largest percent from zip codes with average incomes above $50,000. Although programs that were flagged in both period appeared to have decreased their percentage of lower income (<$30,000) patients newly added to the wait-list substantially, from 18% in 2005 to 13% in 2008, this difference was not statistically significant (p=0.34).

Appendix Figure 34 displays the percent of newly listed patients with a high school diploma or less education and the percent of candidates with less than a high school diploma. All of the groups show similar levels of education, and similar trends over time.

SUMMARY

The following table provides a summary of findings from analyses outlined in the Executive Summary at the beginning of the report and then discussed in subsequent sections of the report. Additionally, more detail can be found in figures and tables included in the Appendix following this summary table.

SUMMARY TABLE OF FINDINGS

Parameter	Description of main trends for each flagging group		
	Overall* (n=221)	**Flagged in Period 1 only (n=17)**	**Flagged in both periods (n=31)**
Utilization of donor types			
Number of ECD transplants (Figure 3-5, Figures 14-15, Table 2)	Increased from 1151 to 1898 between 2001 and 2008, but dropped to 1719 in 2010 (representing 9%, 12% and 11% of all kidney Tx in 2001, 2008 and 2010 respectively).	Increased slowly between 2001 (n=90, 10% of all Tx) and 2005 (n=124, 13% of all Tx), then fluctuated from 2006 onwards with an overall decline (2010: n=86, 10% of all Tx).	Fluctuated somewhat between 2001 and 2006, ranging from 9% (n=200) to 12% (n=263) of all Tx. ECD Tx declined steadily between 2007 (n=194, 10% of all TX) and 2010 (n=138, 8% of all Tx).
Number of DCD transplants (Figure 3, Figure 14, Table 2)	Increased steadily over the 10-yr period from 2001 (n=227, 2% of all Tx) to 2010 (n=1260, 8% of all Tx).	Increased steadily over the 10-yr period from 2001 (n=15, 2% of all Tx) to 2010 (n=56, 6% of all Tx).	Increased steadily over the 10-yr period from 2001 (n=33, 2% of all Tx) to 2010 (n=136, 8% of all Tx).
Number of SCD transplants (Figure 3, Figure 14, Table 2)	Increased between 2001 (n=6282) and 2006 (n=7350), but declined after 2007. The proportion of kidney Tx made up of SCD Tx gradually declined over the 10-yr period.	Gradual decline over the 10-yr period from 2001 (n=488, 53% of all Tx) to 2010 (n=383, 44% of all Tx).	Fluctuated somewhat between 2001 (n=933) and 2006 (n=975, 43% of all Tx), then declined in number between 2007 (n=855) and 2010 (n=727, 43% of all Tx). The proportion of kidney Tx made up of SCD Tx remained fairly constant.
Number of living donor transplants (Figure 3, Figure 14, Table 2)	Steady over the 10-yr period, but declining as a proportion of all kidney Tx (37% in 2010).	Fairly constant over the 10-yr period, although numbers fell in 2007 (n=307 vs. 348 in 2006) and 2008 (n=309).	Fluctuated somewhat between 2001 (n=852) and 2006 (n=946, 42% of all Tx), then declined in number between 2007 (n=744) and 2010 (n=674, 40% of all Tx). The proportion of kidney Tx made up of living donor Tx remained fairly constant.

Parameter	Description of main trends for each flagging group		
	Overall* (n=221)	**Flagged in Period 1 only (n=17)**	**Flagged in both periods (n=31)**
Standardized one-year graft failure ratio			
All kidney transplants (Figure 7, Figure 16)	One-yr graft survival increased steadily between Jan ’06 and Jan ‘11. The ratio of observed to expected one-year graft survival was ~1.00 throughout.	Actual graft survival was below expected from Jan ’06 to Jul ‘10, but showed steady improvement after Jul ’07. By Jan ’11, the standardized graft failure ratio had fallen below 1.00 for this group.	Actual graft survival was below expected for the entire period from Jan ’06 to Jan’11. The standardized graft failure ratio worsened until Jan ’09, after which improvement in one-year survival could be seen.
SCD transplants (Figure 7, Figure 16)	As above	Actual graft survival was below expected from Jan ’06 to Jan ‘11, with an overall trend towards improvement.	Actual graft survival was below expected for the entire period from Jan ’06 to Jan’11. One-year graft survival improved slightly from Jan ’09 onwards.
Living donor transplants (Figure 7, Figure 16)	As above	Strong improvement in actual graft survival was seen after Jan ’08, and by Jul ’09 the standardized graft failure ratio was below 1.00 and showing further improvement.	Actual graft survival was below expected for the entire period from Jan ’06 to Jan’11. There was little improvement in the standardized graft failure ratio.
ECD kidney transplants(Figure 7, Figure 16)	As above	Actual survival of ECD transplants started to improve after Jul ’07, showing steady gains and exceeding expected survival after Jan ’10.	Actual graft survival was below expected for the entire period from Jan ’06 to Jan’11. The standardized graft failure ratio worsened until Jan ’09, after which improvement in one-year survival could be seen.

Parameter	Description of main trends for each flagging group		
	Overall* (n=221)	**Flagged in Period 1 only (n=17)**	**Flagged in both periods (n=31)**
DCD transplants (Figure 7, Figure 16)	One-year graft survival increased steadily from Jul '07. Actual graft survival exceeded expected graft survival throughout the period between Jul '07 to Jan '11	Actual survival of DCD transplants improved steadily after July '06, exceeding expected survival by Jul '08. Standardized graft failure ratios declined steadily from Jan '07 onwards	As above
Kidney acceptance rate (Figure 6)	Increased steadily between Jul '06 and Jan '11	Increased between Jan and Jul '07, then plateaued between Jul '07 and Jul '09, then increased again between Jul '09 and Jan '11.	Was lower compared with all other groups and, after a short increase between Jul '06 and Jul '07, remained fairly steady.
Donor Risk (Figure 8, Figure 19 – Figure 25)	Avg risk increases by 6% over 10-yr period ($p<0.0001$). Steady slight increase in the percentage of donors with diabetes, hypertension, BMI 30+, creatinine >1.5 mg/dL and in donors of black race. There was no change in the percentage of donors aged 65+. The percentage of donors with COD of stroke/CV showed a steady slight decline.	Dropped slighted between '04 and '07, otherwise similar to overall donor risk. The percentage of donors with diabetes spikes at 9.5% in 2007 but otherwise follows overall. Conversely, the percent of donors with creatinine >1.5 mg/dL drops between 04' and '05 but otherwise follows overall. Black race was slightly more prevalent among donors in this group.	Decreased between '05 and '07 and then climbed from '07 to '10. The percentage of donors aged 65+ dropped from 4.2% in 2007 to 1.5% in 2010. The percent of donors who were diabetic was higher than overall in '05 to '06, with a drop in '07 and a steady increase in diabetic donors thereafter. This group had a higher percentage of donors with creatinine >1.5 mg/dL

Parameter	Description of main trends for each flagging group		
	Overall* (n=221)	**Flagged in Period 1 only (n=17)**	**Flagged in both periods (n=31)**
Recipient Risk (Figure 9, Figure 26 - Figure 29)	Avg risk increases by 7% over 10-yr period. Steady slight increase in the percentage of recipients with age 65+, BMI 30+ and diabetes, but no change in the percentage of recipients with a previous Tx.	Increased over the 10-yr period but risk scores below overall for ’04 to ’08. The percentage of recipients age 65+ was lower than for other groups between ’04 and ’08, and the percentage with a BMI 30+ fell between ’07 and ’08. There was no change in the percentage of recipients with diabetes.	Avg risk somewhat higher than overall between ’04 and ’06, but subsequently brought into line with overall recipient risk. Steady slight increase in the percentage of recipients with age 65+ and BMI 30+. No change in the percentage of recipients with a previous kidney Tx or diabetes.
Overall transplant risk (Figure 10)	Avg risk increases by 13% over 10-yr period ($p<0.0001$).	Increases steadily over 10-yr period.	Consistently higher risk than overall for ’04 to ‘07, then follows overall trend.
Characteristics of newly wait-listed patients (Figure 11, Figure 30, Figure 31)	The percentage aged 65+ and with BMI 30+ increase steadily over the 10-yr period. The percentage with a previous kidney Tx decreased slightly over this period.	The percentage aged 65+ was lower than overall from ’04 onwards. The percentage with BMI 30+ increased steadily and the percentage with a previous Tx decreased slightly over the 10-yr period, in line with the overall observations.	The percentage aged 65+ increased steadily, at or above the overall rate, over the 10 yr period. The percentage with BMI 30+ also increased steadily, while the percentage with a previous Tx decreased slightly over the 10-yr period, in line with the overall observations.
Willingness to accept an ECD kidney (Figure 12)	Unchanged overall; drops steadily among "inappropriate" candidates over 10-yr period	Drops dramatically (from 55% to 42%) between ‘04 and ‘06, then remains below or at overall rate	Drops between ‘05 and ‘07 (and steadily among "inappropriate" candidates); consistently higher than overall.

Parameter	Description of main trends for each flagging group		
	Overall* (n=221)	**Flagged in Period 1 only (n=17)**	**Flagged in both periods (n=31)**
Candidate socio-economic status (Figure 13, Figure 33, Figure 34)	No change.	Relatively unchanged, but consistently lower income levels than overall.	Decrease in low income (<30K) patients added to waitlist over time (slight increase in average income), although non-significant. Education level unchanged.

*Overall trends are driven largely by the 159 programs that were not flagged in either period, therefore mirror trends for this group.

APPENDIX

The appendix includes additional figures and tables related to those in the main report. Although they are not all referred to in the report, they are provided here for the interested reader for completeness.

CONTENTS

Supplementary Figures

Figure 14: Kidney Transplants by Donor Type. Trends in utilization of different kidney donor types as the absolute number of all kidney transplants performed within each year, by flagging status.

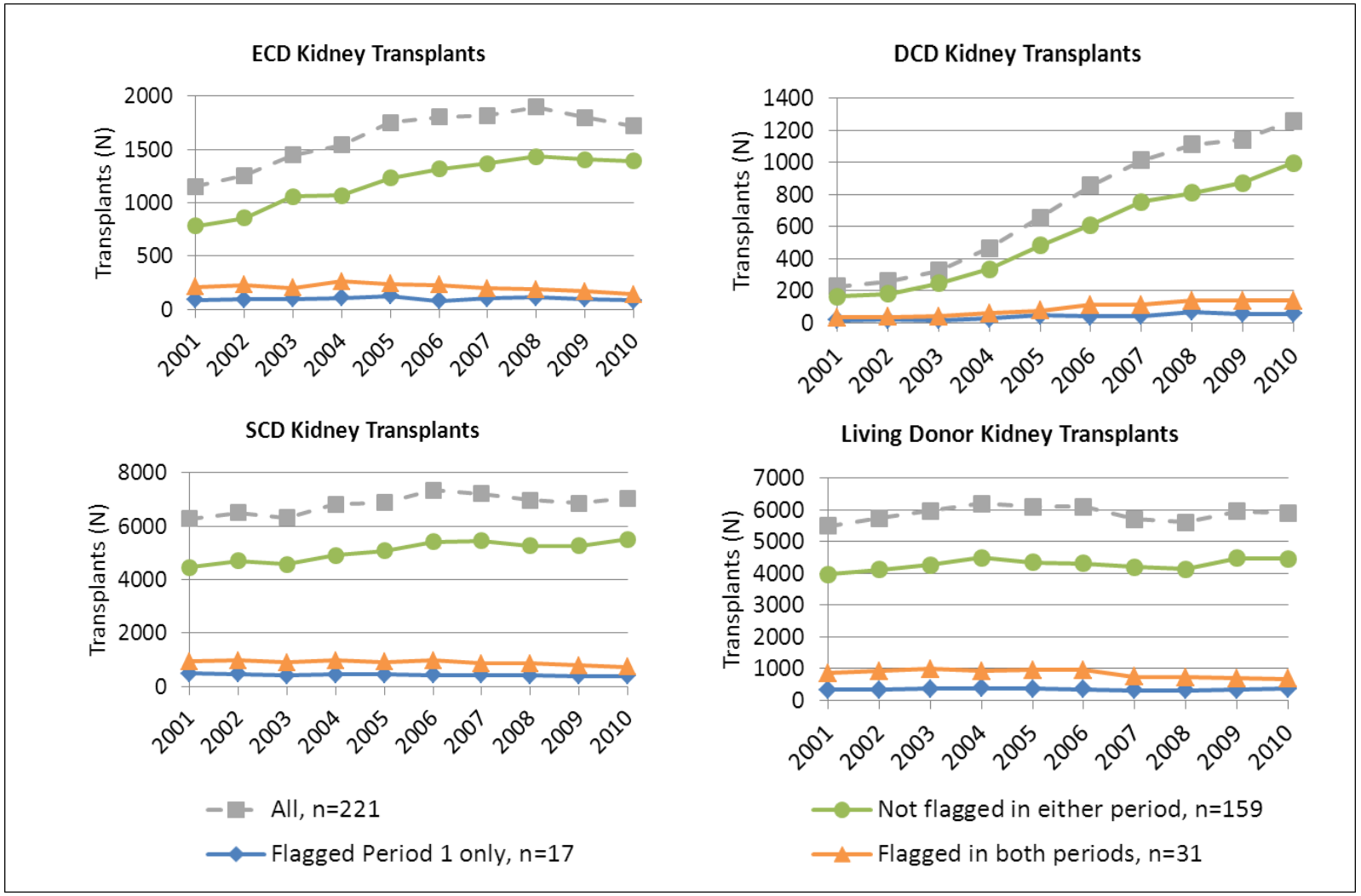


Figure 15: ECD Utilization Change. Program change in the utilization of ECD kidney transplants (vs. 2006).

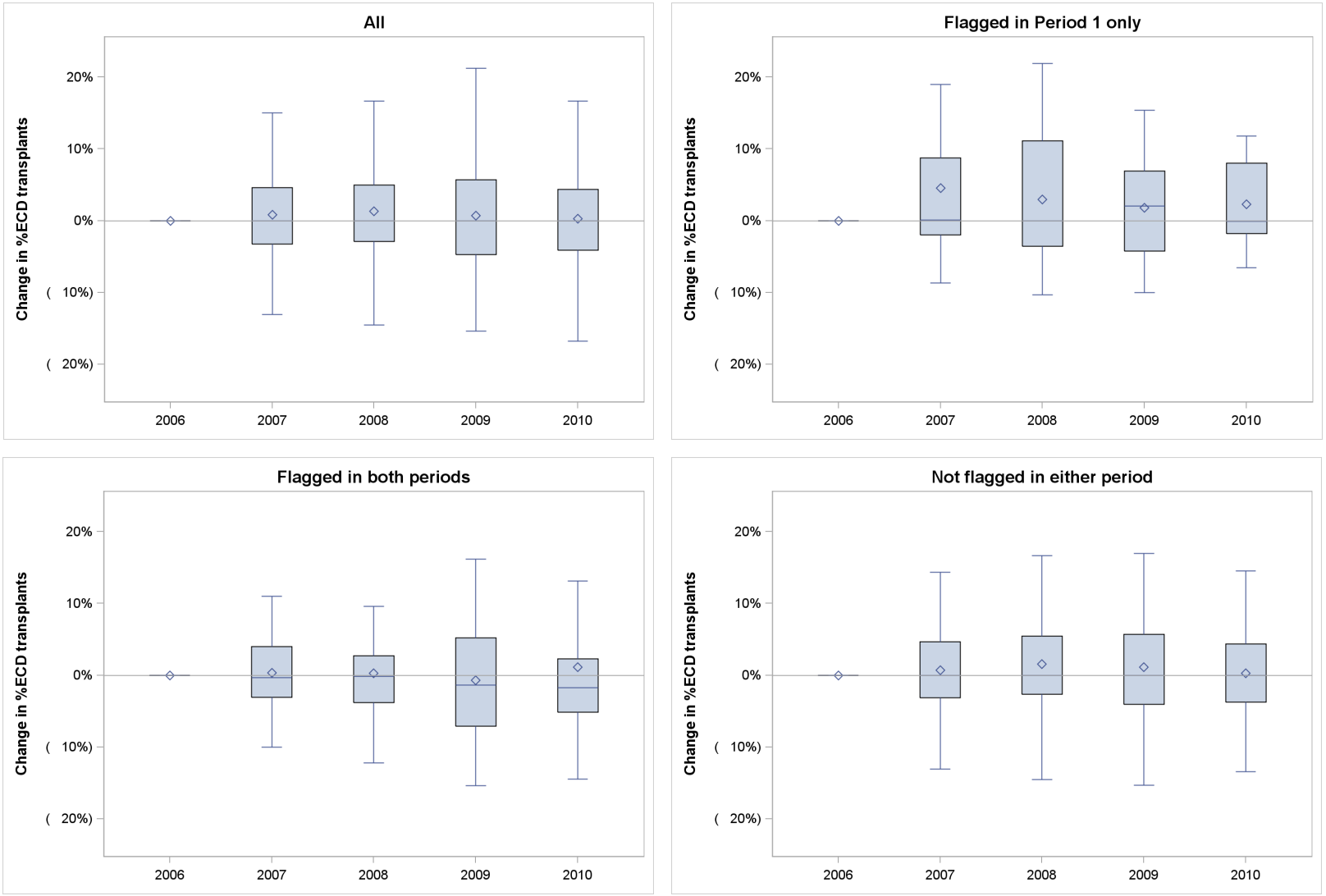


Figure 16: Graft Survival. Actual and expected one-year kidney graft survival across donor types by flagging status

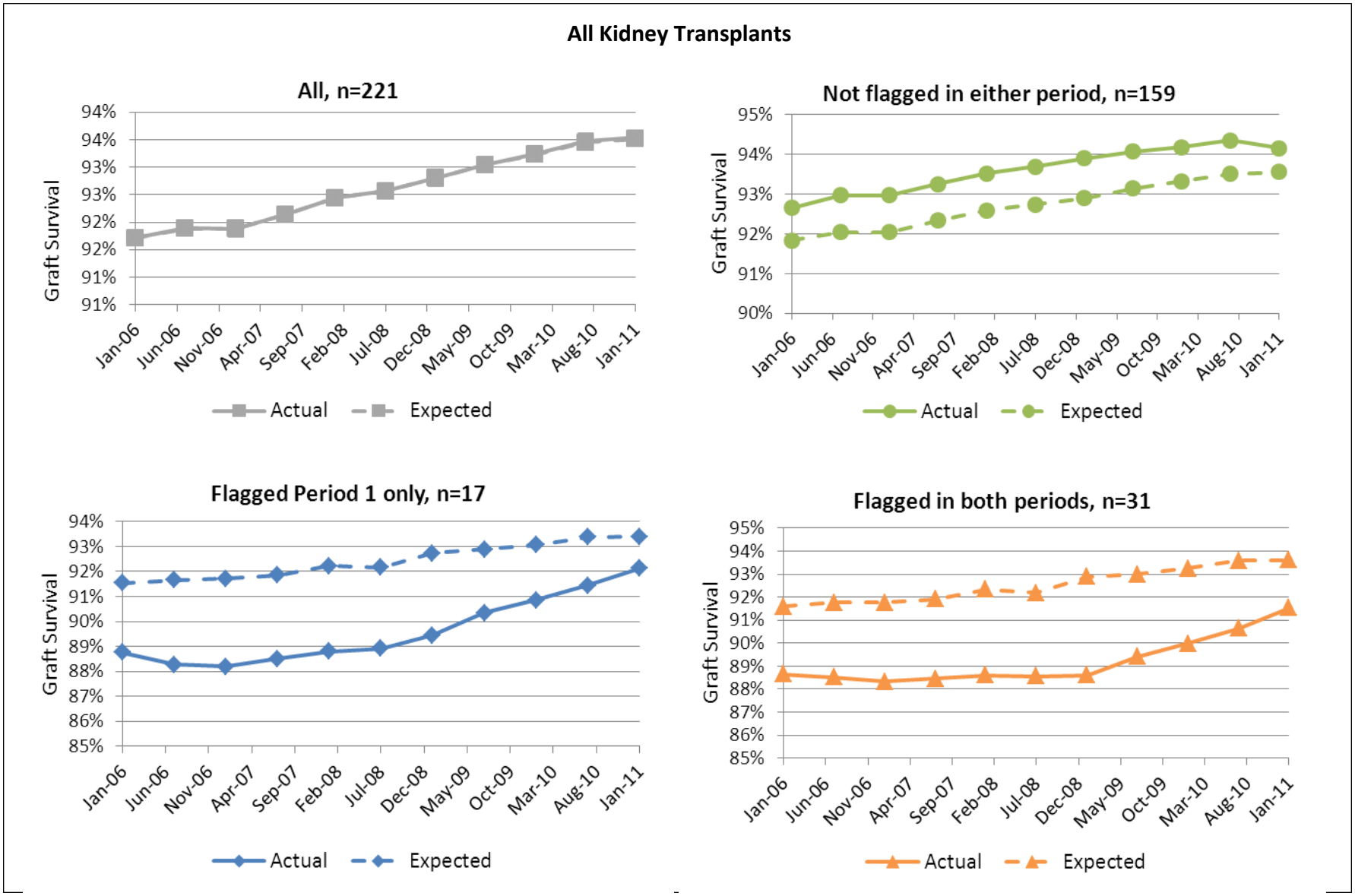


Figure 16: Graft Survival. Actual and expected one-year kidney graft survival across donor types by flagging status (continued)

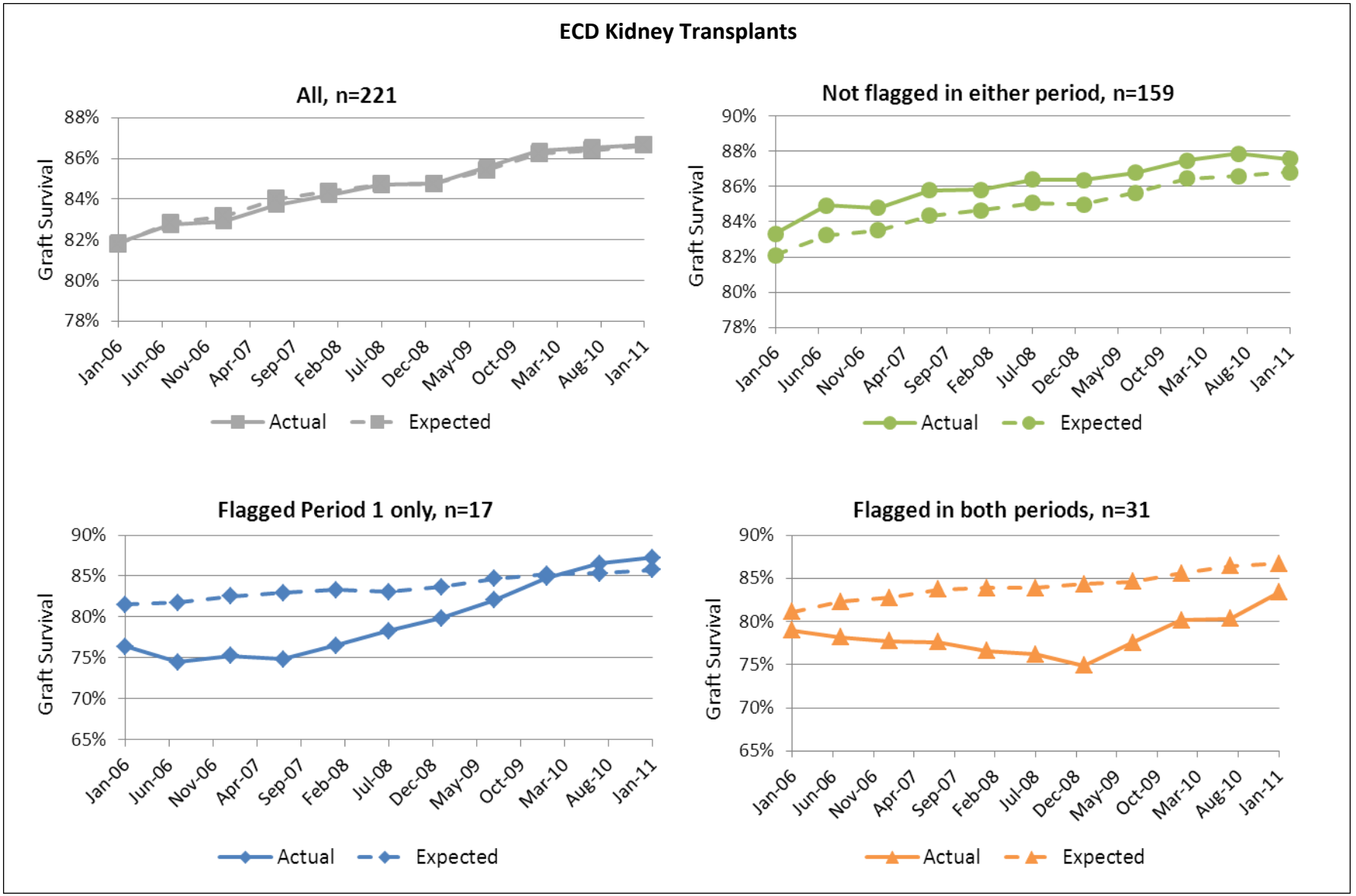


Figure 16: Graft Survival. Actual and expected one-year kidney graft survival across donor types by flagging status (continued)

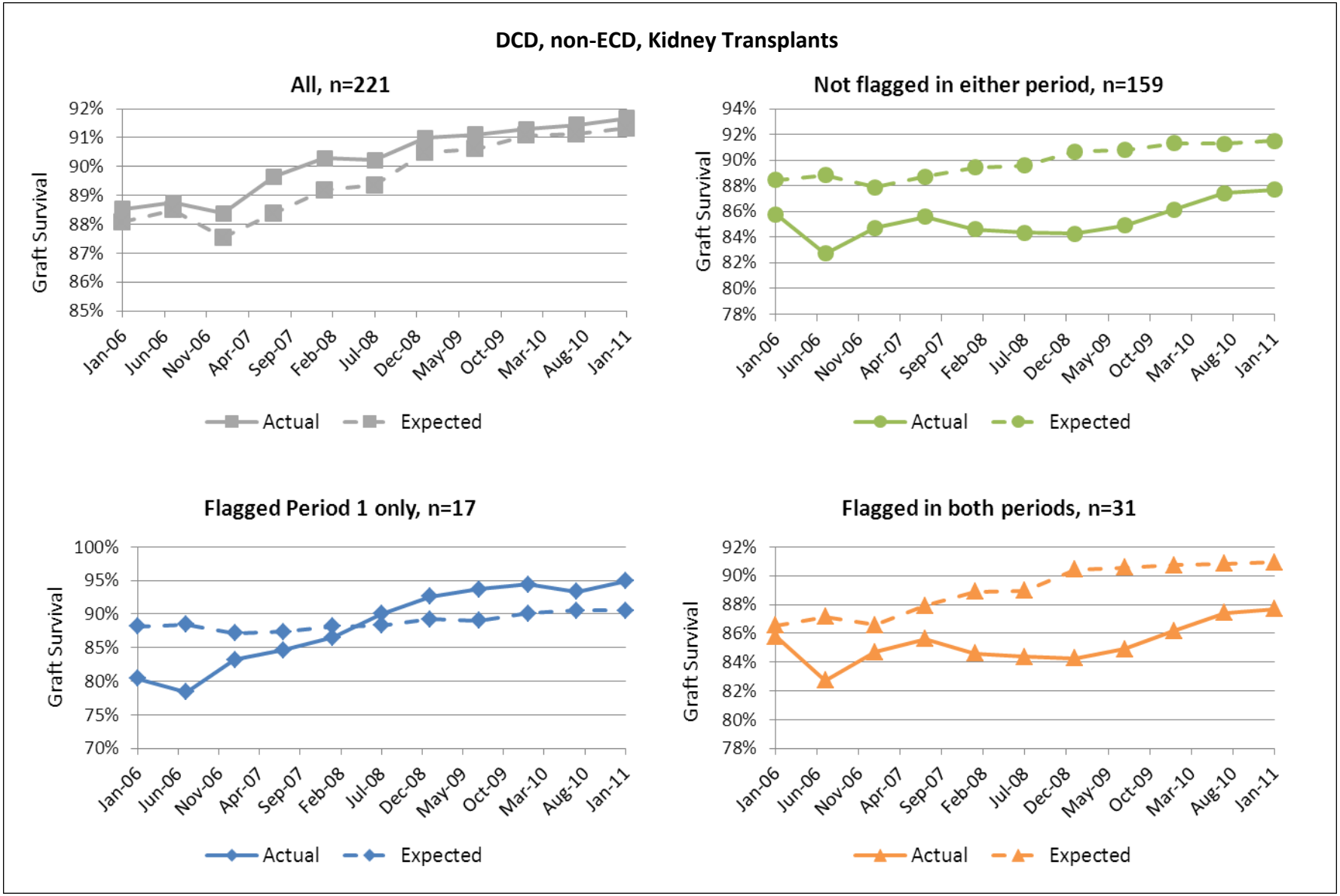


Figure 16: Graft Survival. Actual and expected one-year kidney graft survival across donor types by flagging status (continued)

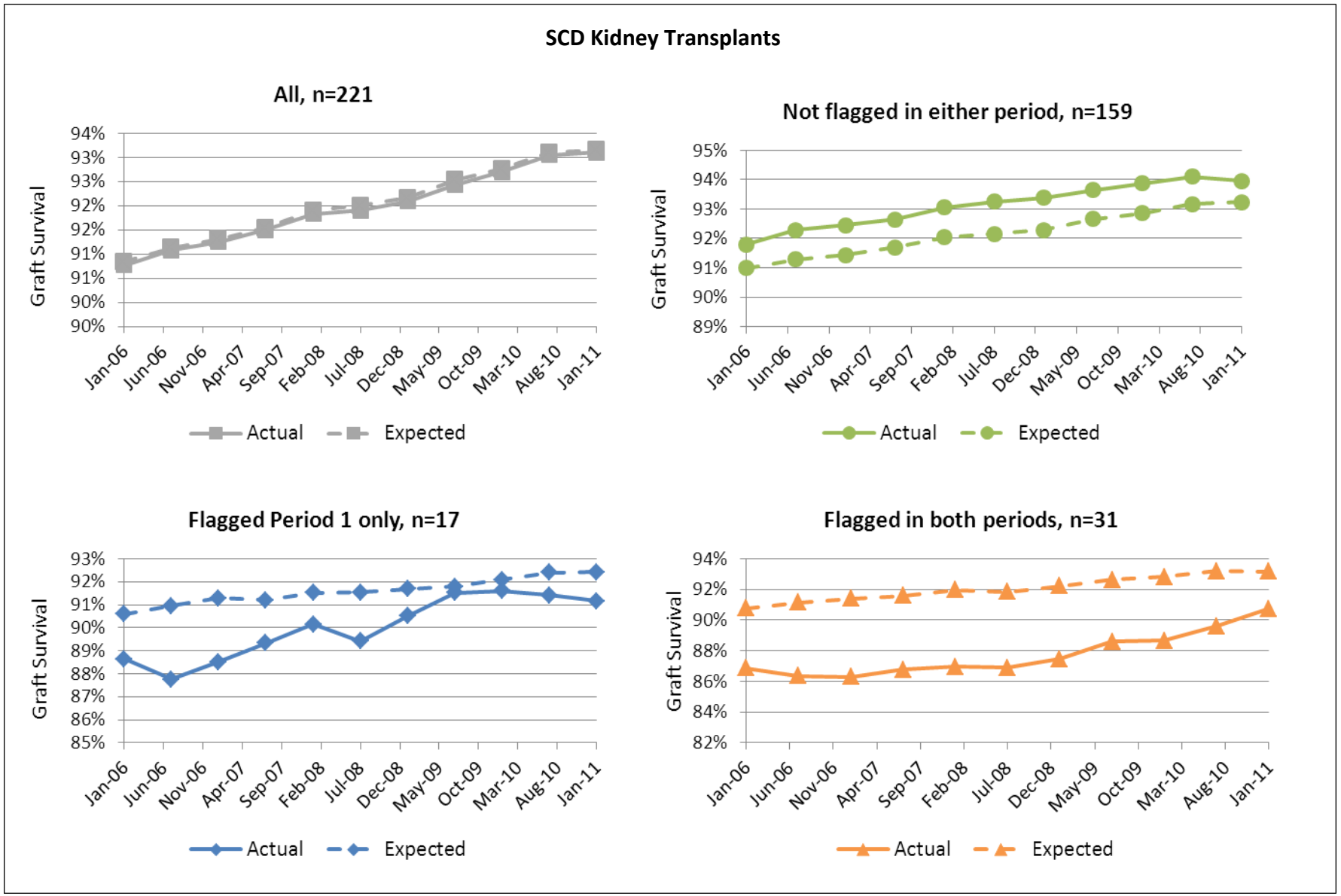


Figure 16: Graft Survival. Actual and expected one-year kidney graft survival across donor types by flagging status (continued)

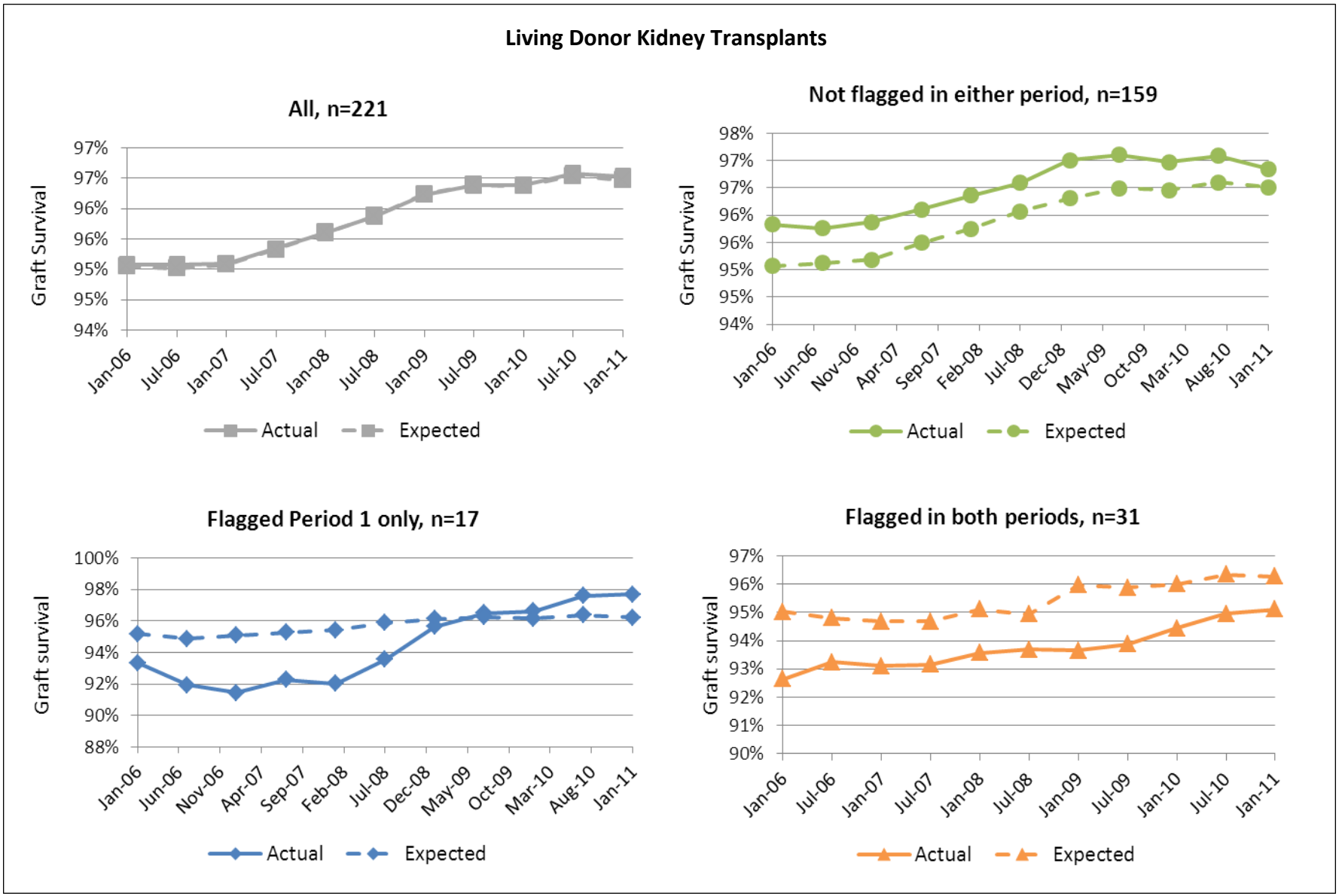
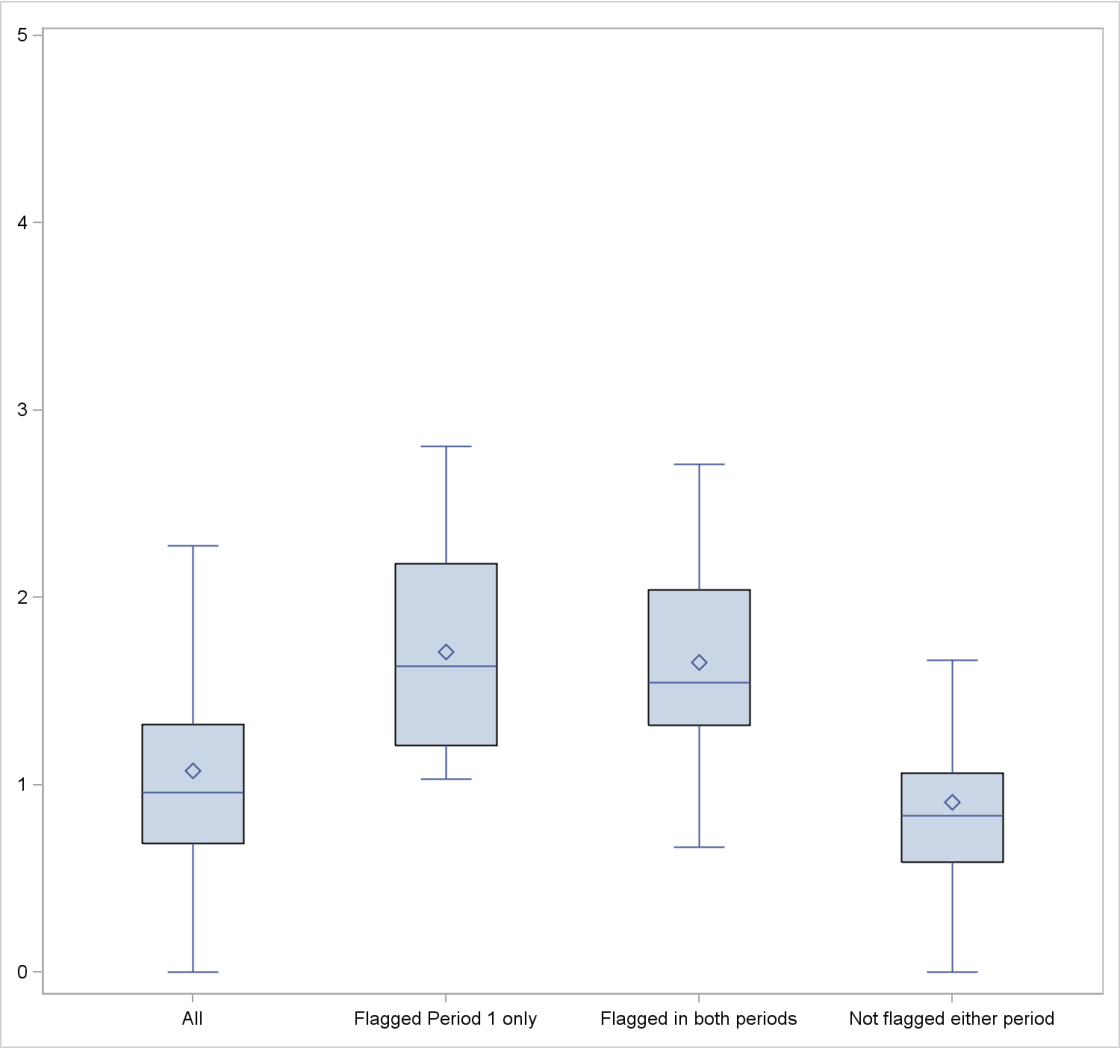
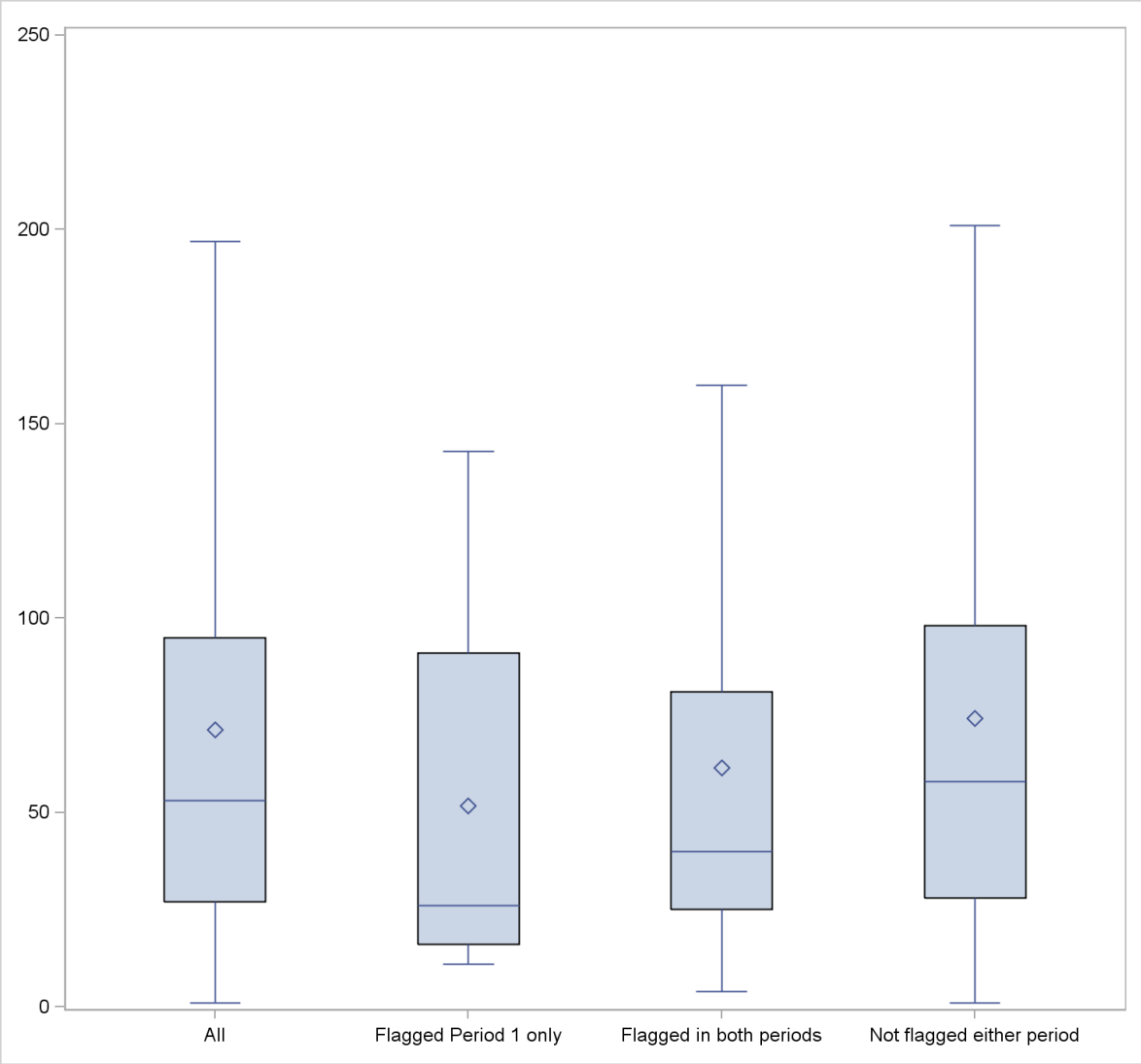


Figure 17: Program **Graft Survival.** Distribution of individual program standardized graft failure ratios for 1-year graft failure in 2007, by flagging group.



Percentile	All, n=221	Flagged Period 1 only, n=17	Flagged in both periods, n=31	Not flagged in either period, n=159
5	0.00	1.03	0.91	0.00
25	0.69	1.21	1.32	0.59
50	0.96	1.63	1.54	0.83
75	1.32	2.18	2.04	1.06
95	2.28	2.81	2.68	1.56

Figure 18: Program Kidney Transplant Volume. Distribution of kidney transplant numbers by flagging group, for the 2007 calendar year.



Percentile	All, n=221	Flagged Period 1 only, n=17	Flagged in both periods, n=31	Not flagged in either period, n=159
5	3	11	14	1
25	27	16	25	28
50	53	26	40	58
75	95	91	81	98
95	201	143	175	210

Figure 19: Donor Creatinine. Donor Risk score components: percentage of donors with creatinine > 1.5 mg/dL.

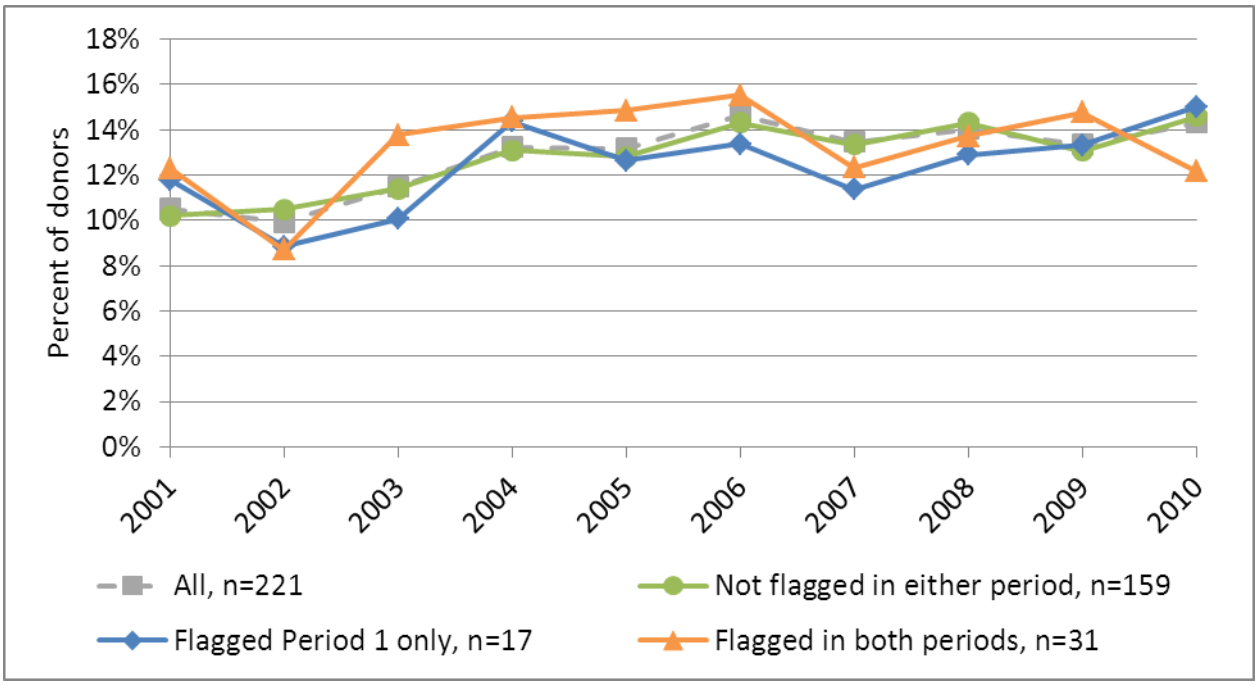


Figure 20: Donor Age. Donor risk score components: percentage of donors aged ≥65 years.

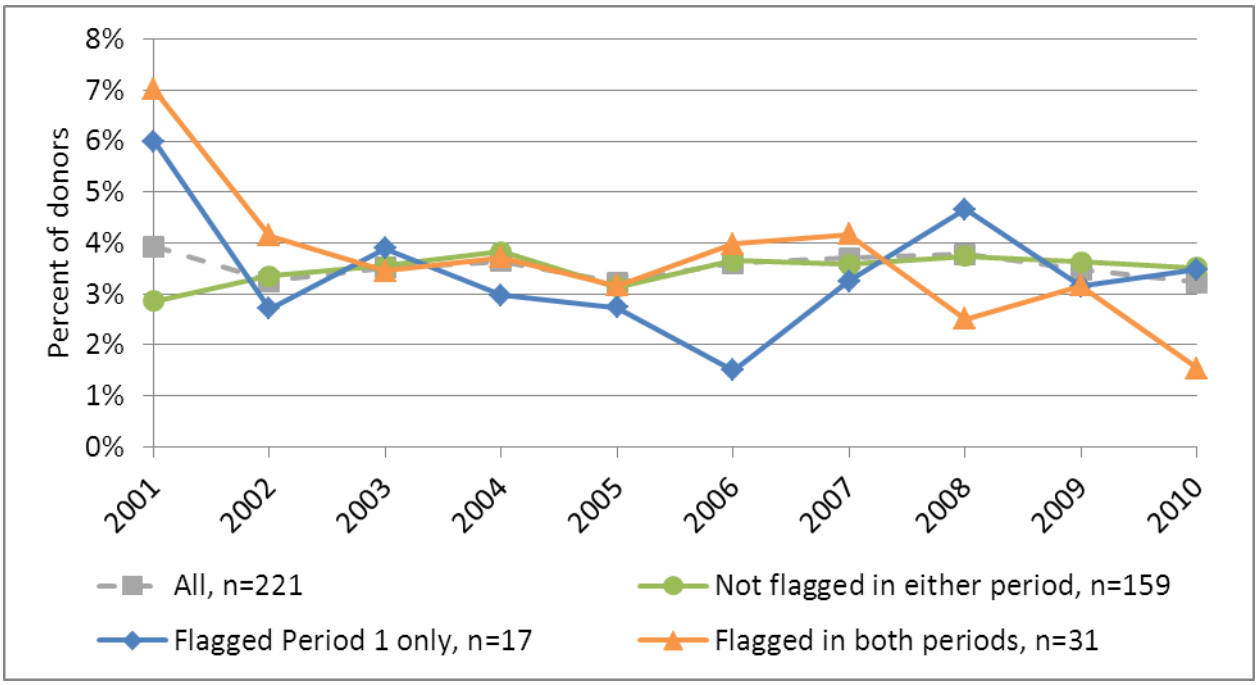


Figure 21: **Donor Diabetes.** Donor Risk score components: percentage of donors with diabetes.

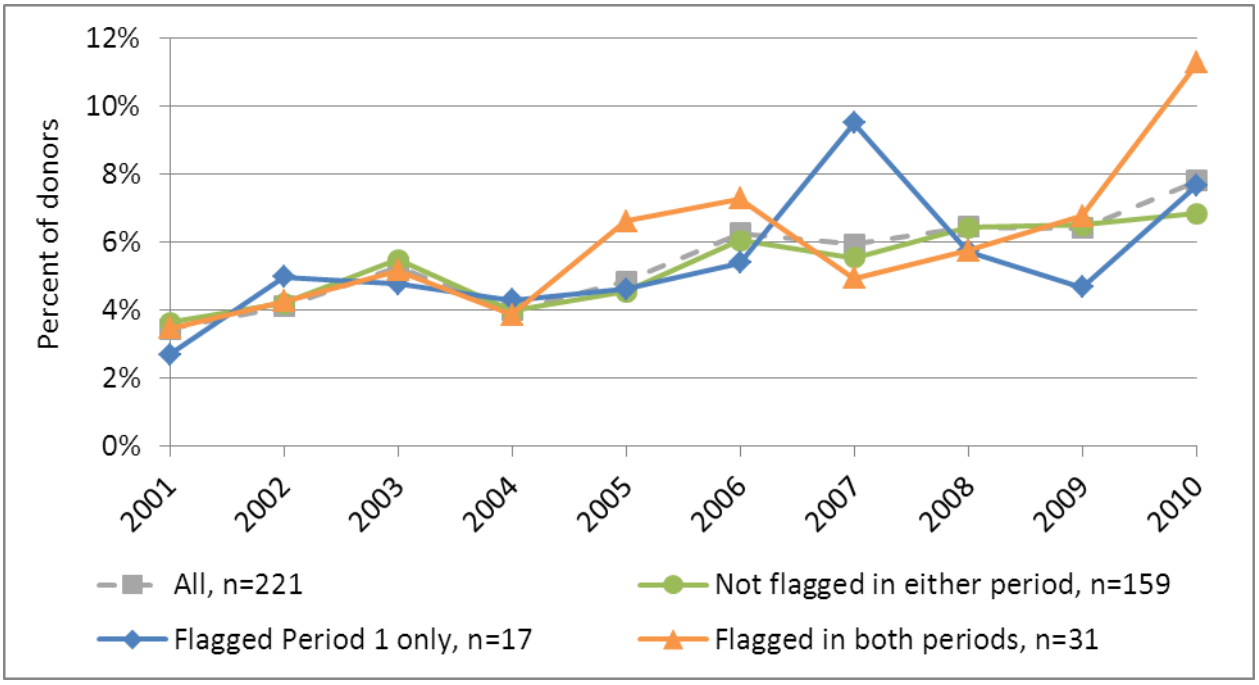


Figure 22: Donor BMI. Donor risk score components: percentage of donors with BMI ≥ 30 kg/m^2.

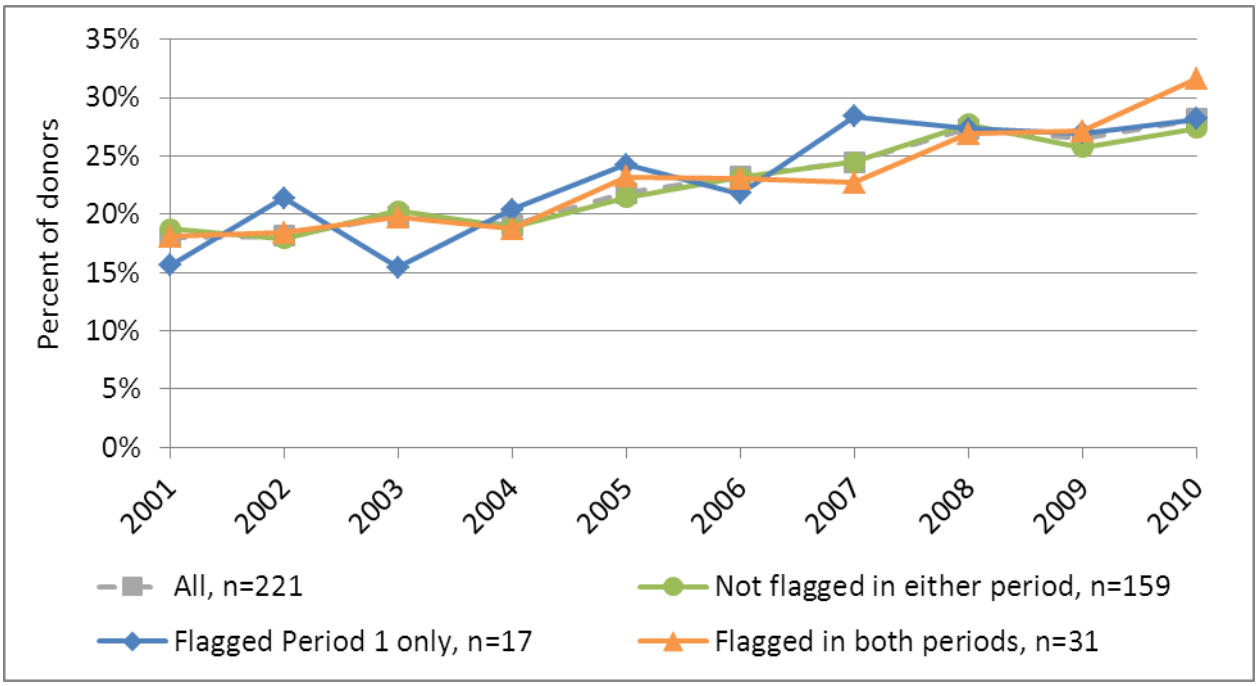


Figure 23: Donor Hypertension. Donor risk score components: percentage of donors with a history of hypertension.

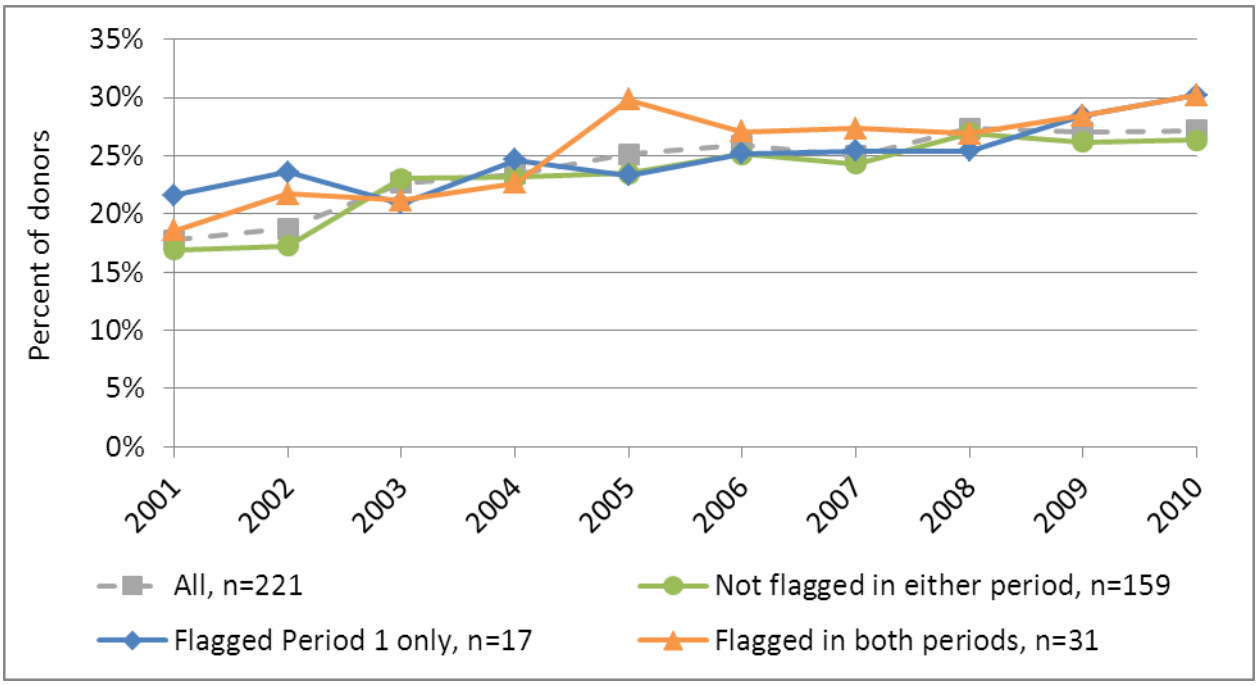


Figure 24: Donor COD. Donor risk score components: percentage of donors with COD CV/Stroke.

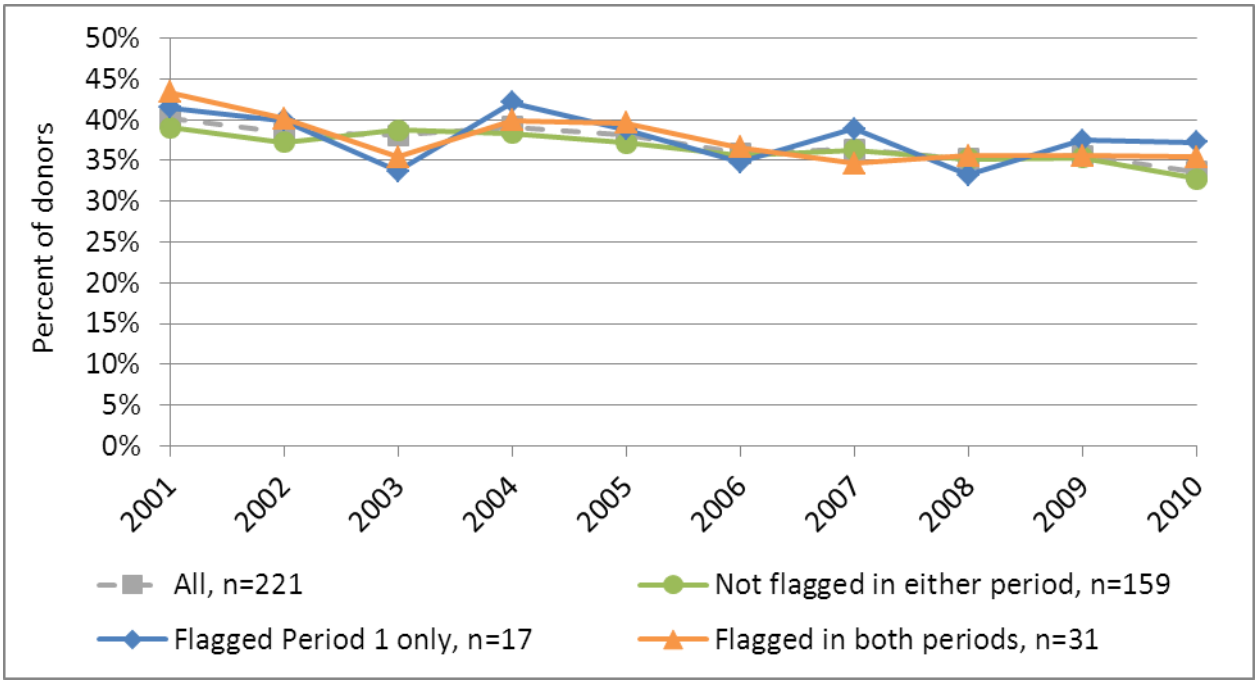


Figure 25: Donor Race. Donor risk score components: percentage of donor of black race.

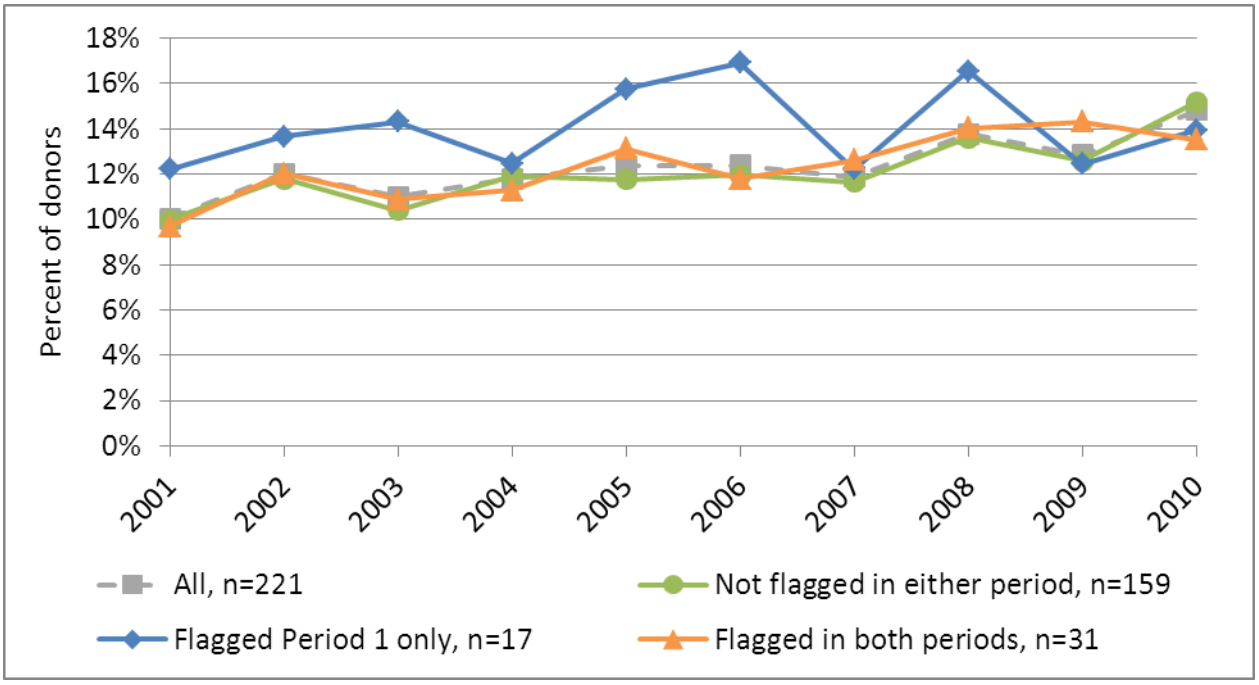


Figure 26: Recipient Previous Transplant. Recipient risk score components: percentage of recipients with a previous transplant of any organ type.

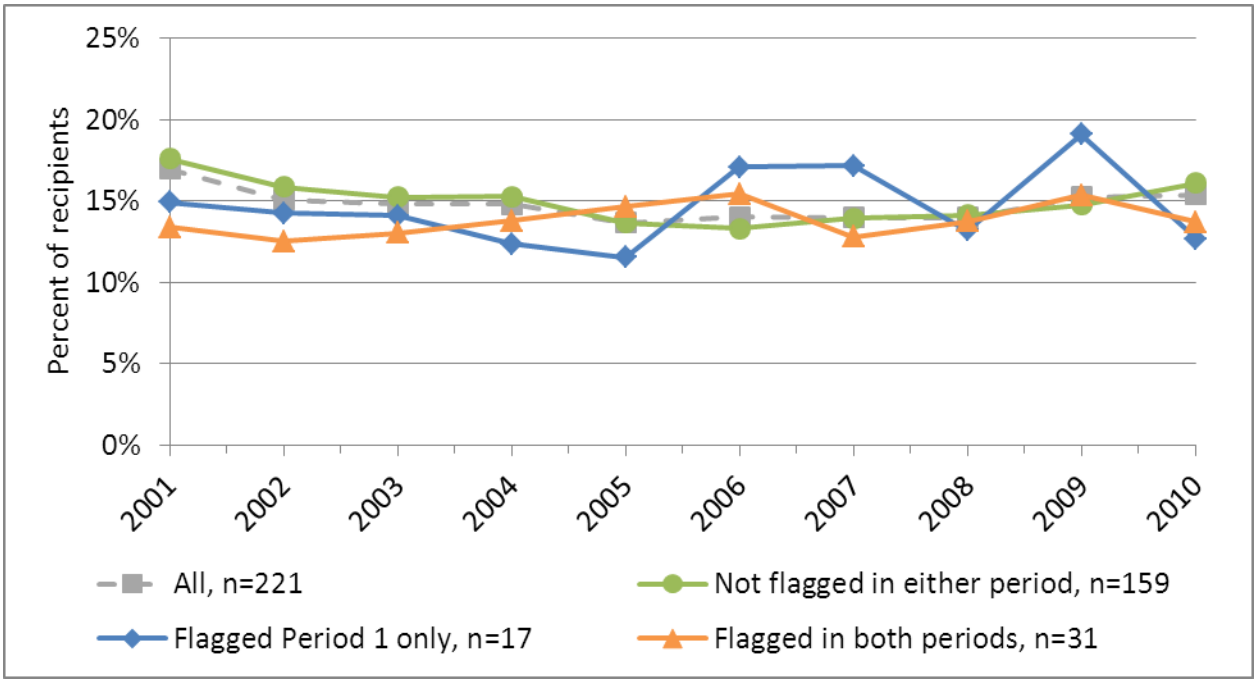


Figure 27: Recipient BMI. Recipient risk score components: percentage of recipients with BMI ≥ 30 kg/m^2.

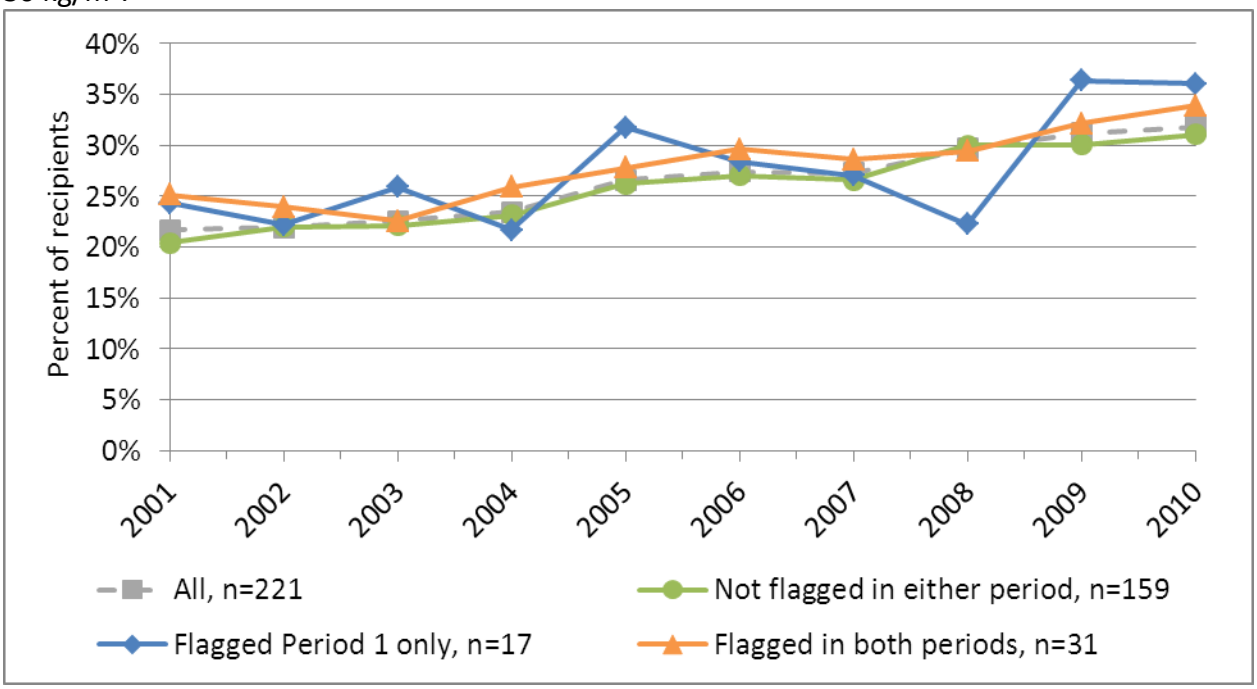


Figure 28: Recipient Diabetes. Recipient risk score components: percentage of recipients with diabetes.

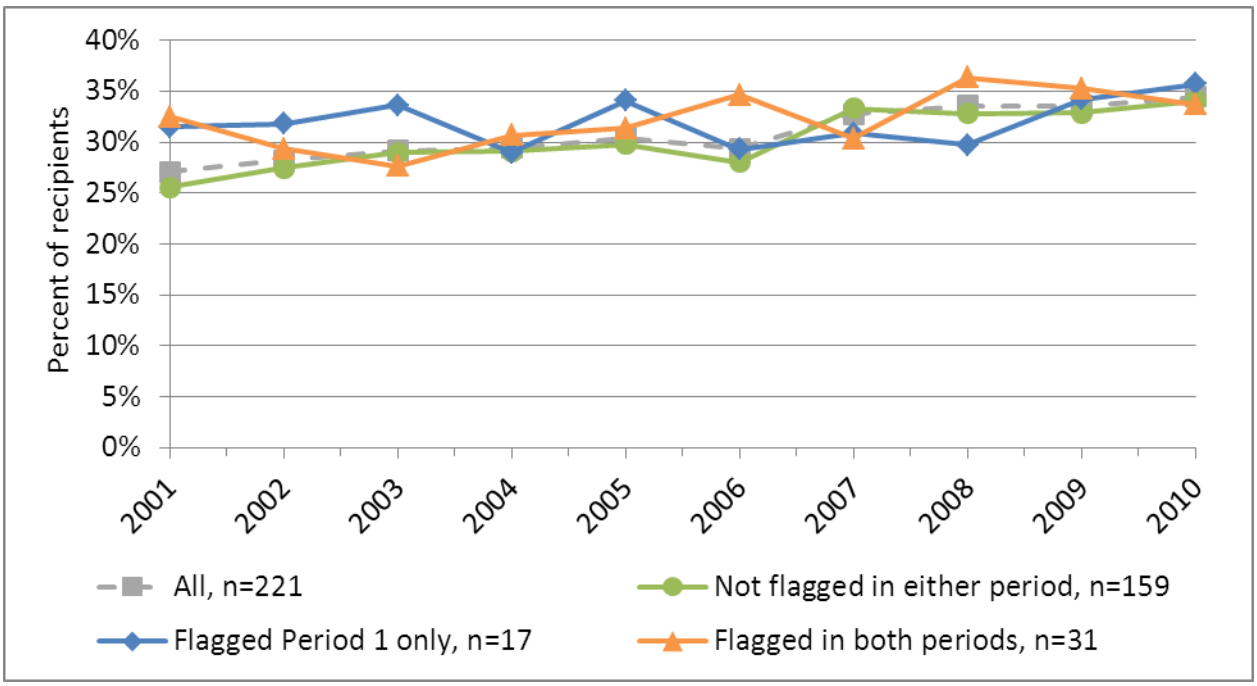


Figure 29: Recipient Age. Recipient risk score components: percentage of recipients 65 years and older.

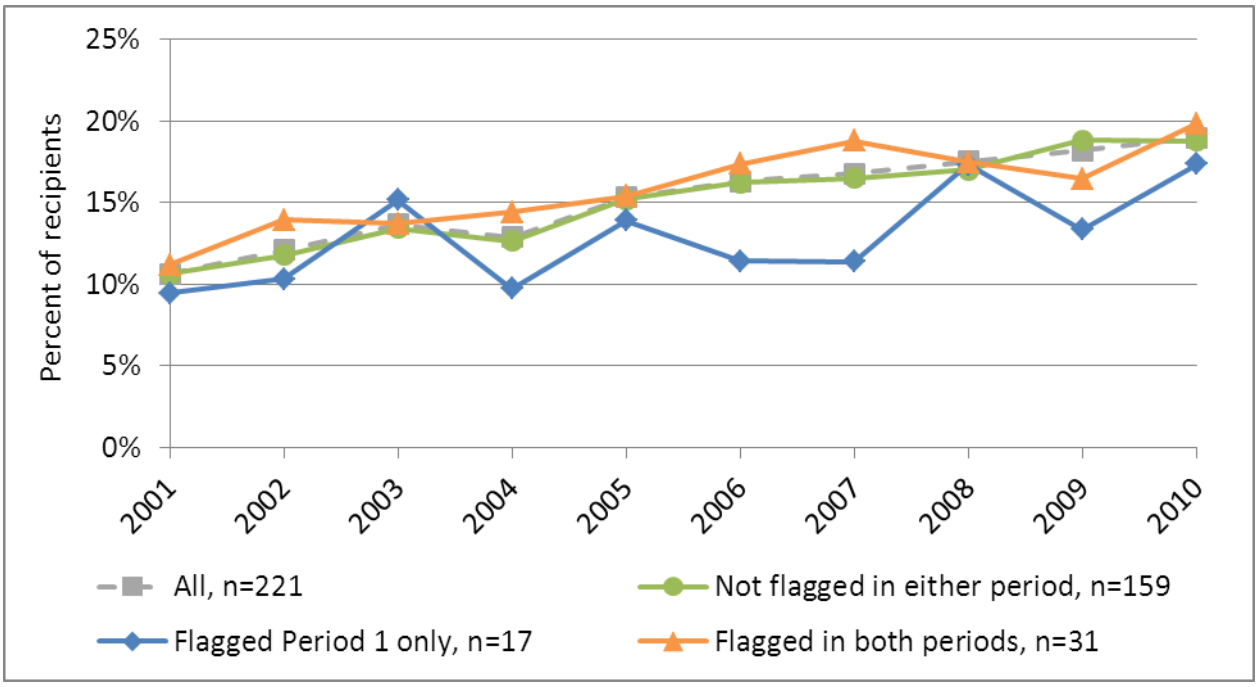


Figure 30: BMI among New Listings. Obesity trends among adult patients newly wait-listed for kidney transplantation.

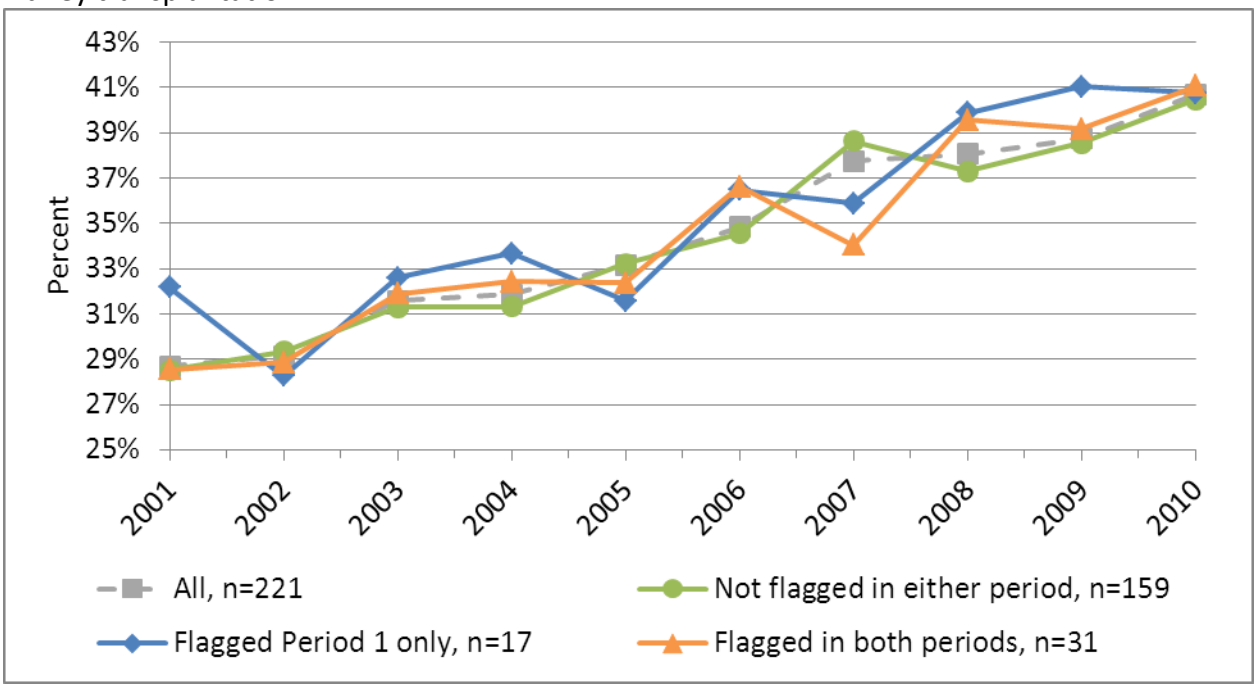
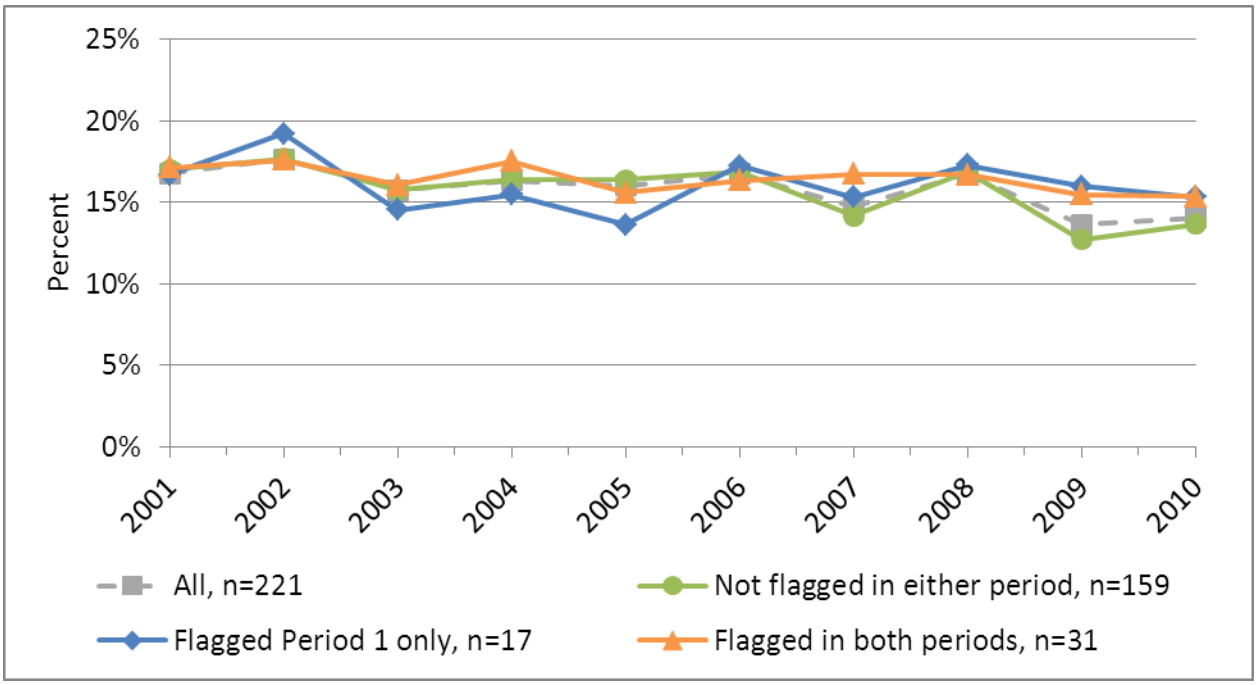


Figure 31: Previous Transplants among New Listings. Proportion of newly wait-listed patients to have received a previous kidney transplant.



**Percent of newly wait-listed patients to have received a previous kidney transplant is calculated within each program and then averaged within each flagging category, with equal weighting on all programs.

Figure 32: **New Listings and Inactive Status.** (A) Newly wait-listed patients, and (B) patients set to inactive status, as percent of the total wait-list within each calendar year.

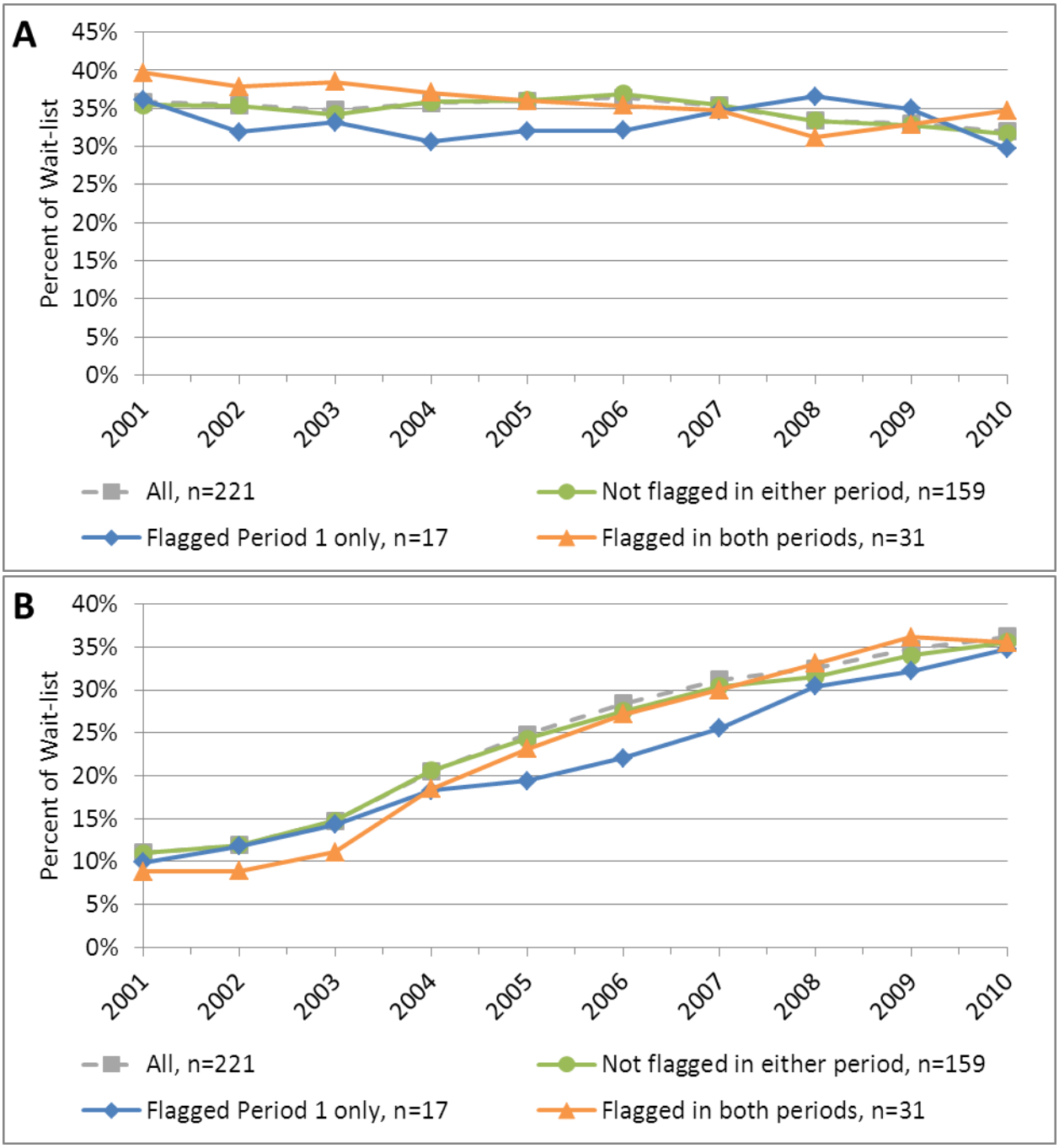
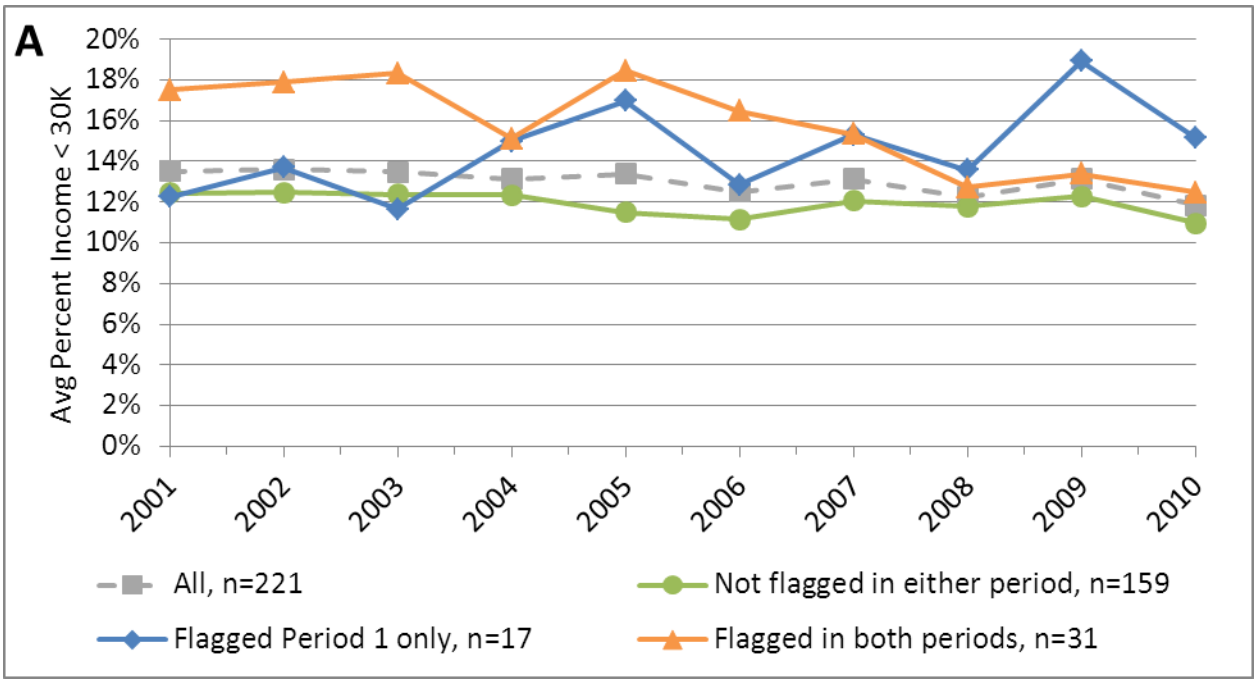


Figure 33: Income among New Listings. The average percent of newly wait-listed patients from a zip code where the average income is (A) less than $30,000 and (B) greater than $50,000.



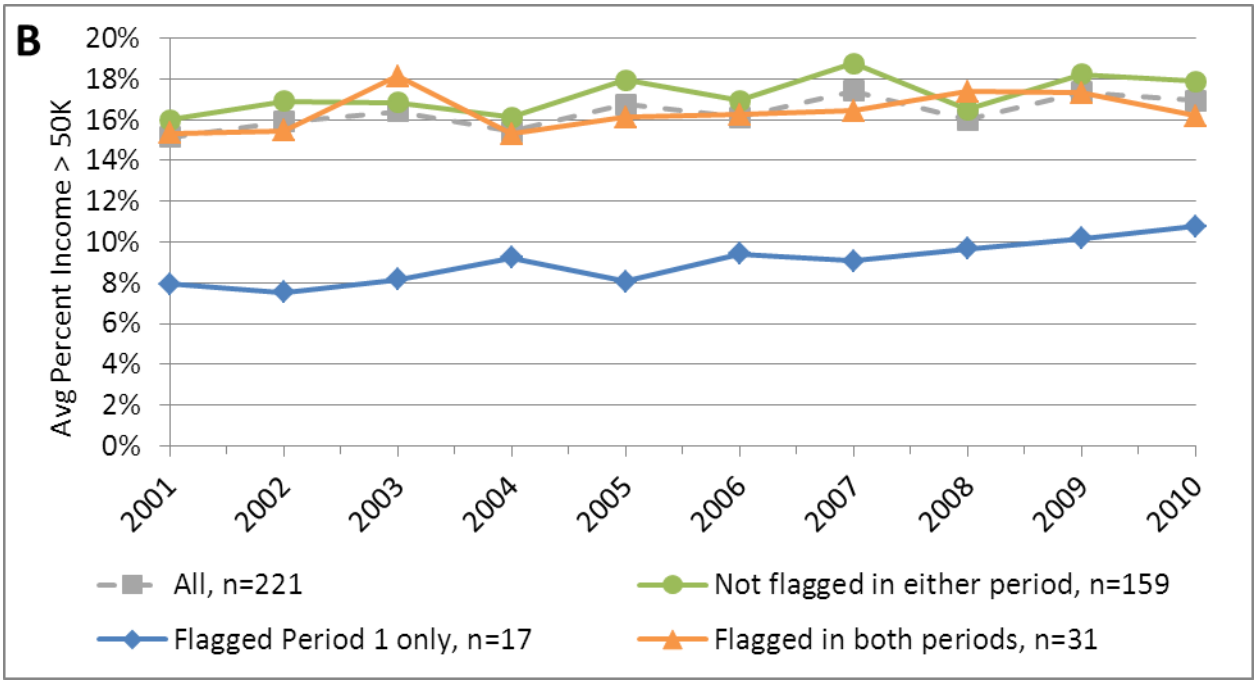
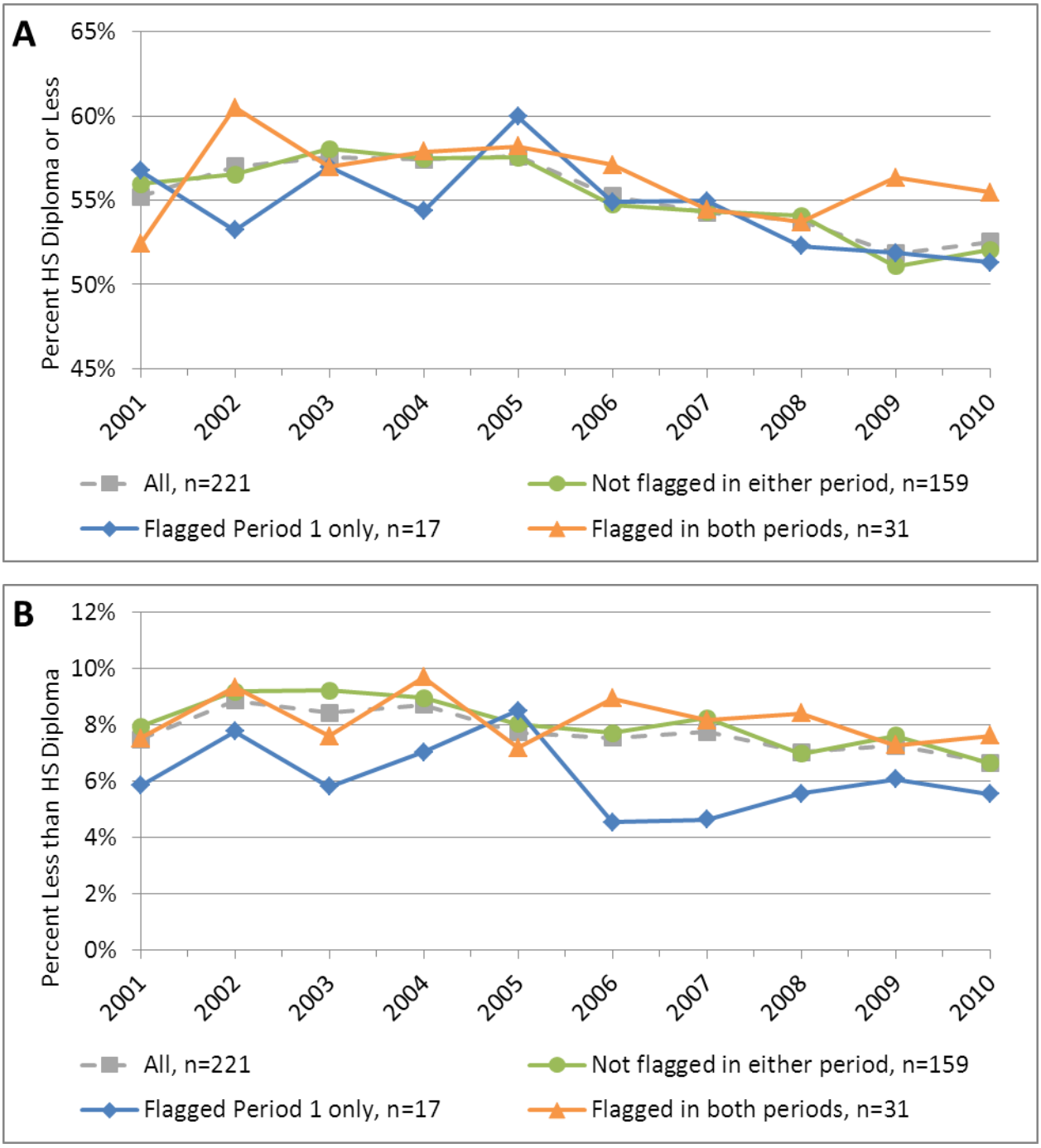


Figure 34: **Education among New Listings.** Education level of wait-listed patients: (A) percent of wait-listed patients with a high-school diploma or less, and (B) percent of wait-listed patients with less than a high school diploma.



Data Tables

Table 2: Trends in transplant volumes and utilization of high-risk donors, 2001-2010

	Transplants by donor type							
	Living		SCD		ECD		DCD, non-ECD	
Year	N	%	N	%	N	%	N	%
	All programs, n=221							
2001	5494	42%	6282	48%	1151	9%	227	2%
2002	5735	42%	6508	47%	1254	9%	260	2%
2003	5965	42%	6322	45%	1449	10%	325	2%
2004	6195	41%	6827	45%	1542	10%	465	3%
2005	6103	40%	6882	45%	1754	11%	655	4%
2006	6097	38%	7350	46%	1806	11%	857	5%
2007	5711	36%	7212	46%	1818	12%	1013	6%
2008	5611	36%	6973	45%	1898	12%	1114	7%
2009	5956	38%	6870	44%	1802	11%	1141	7%
2010	5901	37%	7044	44%	1719	11%	1260	8%
	Flagged Period 1 only, n=17							
2001	329	36%	488	53%	90	10%	15	2%
2002	318	36%	460	52%	94	11%	19	2%
2003	352	40%	415	47%	99	11%	16	2%
2004	368	38%	456	48%	107	11%	27	3%
2005	360	37%	442	46%	124	13%	45	5%
2006	348	39%	433	48%	81	9%	40	4%
2007	307	35%	428	49%	101	12%	42	5%
2008	309	34%	411	46%	114	13%	67	7%
2009	334	38%	384	44%	97	11%	55	6%
2010	351	40%	383	44%	86	10%	56	6%
	Flagged in both periods, n=31							
2001	852	42%	933	46%	209	10%	33	2%
2002	923	43%	965	45%	227	11%	37	2%
2003	979	46%	903	43%	200	9%	38	2%
2004	918	41%	978	44%	263	12%	59	3%
2005	957	44%	924	42%	238	11%	74	3%
2006	946	42%	975	43%	231	10%	110	5%
2007	744	39%	855	45%	194	10%	112	6%

2008	722	38%	852	45%	186	10%	139	7%
2009	692	39%	785	44%	166	9%	138	8%
2010	674	40%	727	43%	138	8%	136	8%
	Not flagged in either period, n=159							
2001	3965	42%	4464	48%	782	8%	165	2%
2002	4115	42%	4709	48%	859	9%	180	2%
2003	4258	42%	4579	45%	1061	10%	245	2%
2004	4487	42%	4919	46%	1068	10%	336	3%
2005	4344	39%	5083	46%	1233	11%	483	4%
2006	4316	37%	5417	46%	1315	11%	610	5%
2007	4207	36%	5463	46%	1367	12%	753	6%
2008	4142	36%	5269	45%	1436	12%	812	7%
2009	4473	37%	5260	44%	1405	12%	874	7%
2010	4459	36%	5511	45%	1392	11%	998	8%

Table 3: Parameter Estimates from the Recipient and Donor Risk Models

One-Year Graft Failure Risk Model	Parameter Estimate (Beta)	Risk Ratio	P-value
Recipient Factors			
Age 65+	0.40429	1.50	<.0001
Previous kidney transplant	0.41867	1.52	<.0001
BMI 30+	0.08898	1.09	0.0763
Diabetes	0.24855	1.28	<.0001
Donor Factors			
Age 65+	0.30596	1.36	0.0003
Diabetes	0.30913	1.36	0.0001
DCD	0.38229	1.47	<.0001
Hypertension	0.27082	1.31	<.0001
BMI 30+	-0.01846	0.98	0.723
Cause of death=stroke	0.34612	1.41	<.0001
Creatinine > 1.5	0.02648	1.03	0.6619
Black race	0.12406	1.13	0.0512

Data Sources

Database: **Consolidated Renal Operations in a Web-enabled Network (CROWN), including ESRD Network Standard Information Management System (SIMS) and Renal management Information System (REMIS), Institutional Claims, Physician/Supplier File, Enrollment Database**

Data Elements: ESRD patient demographics, characteristics at initiation; Medicare claims, including those for dialysis and hospitalization; death dates

Data Issues: REMIS and SIMS data updated quarterly. Current data processed through April 2011.

Database: **Scientific Registry of Transplant Recipients (SRTR)**

Data Elements: Transplant candidate and recipient characteristics including demographics, comorbidity and other severity measures associated with graft and patient survival; Donor characteristics such as Expanded Criteria Donor (ECD) factors and components for donor profile indexing (liver and kidney only); Program transplant outcomes and compliance with Medicare Conditions of Participation.

Data Issues: The SRTR database updates are processed monthly. Our current data extend through April 30, 2011. Acquisition and integration of organ acceptance data, though potentially useful, may not be feasible in the timeframe for this project. We will identify other surrogates for determining changes in organ utilization such as discard rate and organs per donor.

Database: **Social Security Death Master File (SSDMF)**

Data Elements: The SSDMF file updates are publicly available from the Social Security Administration (SSA), contains over 80 million records created from reports of death to the SSA, for beneficiaries and non-beneficiaries alike. This allows for additional ascertainment of dates of death not reported by transplant programs.

Data Issues: According to past SRTR studies (Levine, et al. 2005), significant fractions of all the deaths are reported by other available sources, as 19% of these deaths were reported by the SSDMF and 3% of the deaths were reported first by another transplantation program. In cases where discrepancies arise among different death dates reported, we will rely on what is reported by the program, first and foremost. The primary reason for this decision is that deaths are often reported to the SSDMF as occurring on either the first or last day of the month, or on the 15th of the month as an 'average'.

Database: **Census Data Appended by ZIP*Data**

Data Elements: Income (SES) by ZIP code, County and State

Data Issues: Data are updated twice per year. Latest update occurred in January 2011.