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RESEARCH ARTICLE

Patient Selection and Volume in the Era Surrounding Implementation of Medicare Conditions of Participation for Transplant Programs

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Objective. To evaluate evidence of practice changes affecting kidney transplant program volumes, and donor, recipient and candidate selection in the era surrounding the introduction of Centers for Medicare and Medicaid Services (CMS) conditions of participation (CoPs) for organ transplant programs.

Data. Scientific Registry of Transplant Recipients; CMS ESRD and Medicare claims databases.

Design. Retrospective analysis of national registry data.

Methods. A Cox proportional hazards model of 1-year graft survival was used to derive risks associated with deceased-donor kidney transplants performed from 2001 to 2010.

Findings. Among programs with ongoing noncompliance with the CoPs, kidney transplant volumes declined by 38 percent (n = 766) from 2006 to 2011, including a 55 percent drop in expanded criteria donor transplants. Volume increased by 6 percent (n = 638) among programs remaining in compliance. Aggregate risk of 1-year graft failure increased over time due to increasing recipient age and obesity, and longer ESRD duration.

Conclusions. Although trends in aggregate risk of 1-year kidney graft loss do not indicate that the introduction of the CoPs has systematically reduced opportunities for marginal candidates or that there has been a systematic shift away from utilization of higher risk deceased donor kidneys, total volume and expanded criteria donor utilization decreased overall among programs with ongoing noncompliance.

Key Words. Medicare, Medicaid, kidney transplantation, regulation, quality improvement

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The Centers for Medicare and Medicaid Services (CMS) is the largest single payer of transplant services in the United States, and it approves transplant programs that receive Medicare reimbursement. In March 2007, CMS published as a final rule in the Federal Register conditions of participation (CoPs) for organ transplant programs. These CoPS establish requirements for the approval and re-approval of transplant centers; programs not attaining specified 1-year post-transplant patient and graft survival rates risk loss of Medicare approval for reimbursement (Centers for Medicare and Medicaid Services 2007). Transplant programs are required to report candidate and recipient information to the Organ Procurement and Transplantation Network (OPTN). These data are analyzed by the Scientific Registry of Transplant Recipients (SRTR) and subsequently published at http://www.srtr.org in bi-annual program-specific reports (PSRs). PSR outcomes are generated based on rolling 2½-year cohorts of patients and include 1-year observed and expected outcomes; that is, the number of events expected for that program based on national averages and adjusted for the casemix of the program. The specific tolerance limits set by CMS are as follows: 1-year observed patient deaths or graft failures exceeding expected values by 50 percent, an absolute difference in the number of observed (actual) versus expected adverse events (patient deaths or graft failures) in excess of 3, and a statistically significant difference between observed and expected events (one-sided t-test; $p < .05$) (Hamilton 2008). PSRs are monitored by CMS, private insurers, and the public for outcomes that might indicate potential quality or safety issues.

The implication of risk adjustment methodology for the fair appraisal of program performance is a subject of ongoing debate (Abecassis et al. 2009; Howard, Cornell, and Schold 2009; Axelrod 2013). Although the SRTR case

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mix adjustment is comprehensive for donor-and recipient-related factors, it is not possible, and indeed not the intent of the SRTR and regulators, to exhaustively account for all determinants of patient and graft outcomes when evaluating program outcomes. A related concern is that the focus on outcomes as a requirement for CMS approval, combined with a lack of confidence in the adequacy of SRTR risk adjustment, may have prompted some programs to modify their organ and candidate selection criteria based on the perception that more conservative practices in the acceptance of donor organs and selection of recipients may allow them to avoid citation (Weinhandl et al. 2009; Schold, Arrington, and Levine 2010). In aggregate, such practices would likely have the unintended consequences of disadvantaging higher risk transplant candidates and potentially reducing overall transplant volumes.

We evaluated the evidence for practice changes affecting kidney transplant volumes, wait-listing decisions, organ acceptance, and recipient selection in the era surrounding the introduction of the CoPs. We examined trends in kidney transplantation only because this involves the greatest number of recipients and is performed at nearly all transplant centers. Furthermore, one of the most important trends in organ transplantation over the past decade has been the utilization of expanded criteria donor (ECD) kidneys (Port et al. 2002), and we explore evidence of changing utilization of ECD kidneys in the years subsequent to the implementation of the CoPs. In the absence of qualitative data detailing each program's reaction to the CoPs, we focused on practices subsequent to the first SRTR outcomes flag recorded after the CoPs came into effect. We hypothesized that those programs with SRTR-reported outcomes exceeding case mix–adjusted tolerance limits on one or more occasions would be the most likely to exhibit risk-averse practices affecting volumes and selection with respect to candidates, recipients, and donors.

METHODS

Data and Sources

Data were from the SRTR database (candidate, recipient, and donor characteristics; program transplant outcomes; and derived compliance with CoPs/flagging history), and CMS ESRD and Medicare claims databases (ESRD patient demographics, clinical characteristics at initiation of maintenance hemodialysis or preemptive kidney transplantation; Medicare claims, including those for dialysis and hospitalization; and death dates). These data were enhanced by cross-referencing the Social Security Death Master File for additional ascertainment of dates of death not reported by transplant programs, and by inclusion of Census Data on Income by ZIP code (http://www.melissadata.com/products/zip-data.htm). The same average income, as available from the last census update (January 2002), was used for each patient in each year of the period under study, so that any trends with respect to average income over time could be attributed to changes in patient mix, independent of economic trends. All programs with an adult kidney PSR for July 2007 that performed at least one adult kidney transplant in 2007 were included in the present analysis ($N = 221$). Combined kidney-pancreas transplants were excluded from the analysis (other multiorgan kidney transplants were included).

Definitions

Kidney transplant programs were grouped according to their SRTR-reported performance with respect to graft outcomes subsequent to the implementation of the CoPs. Four groups of programs were identified based on outcomes reported in PSRs released between July 2007 and July 2012:

Never flagged: programs that were not flagged for outcomes in any of the PSRs over the period from July 2007 to July 2012; $n = 142$.

Single flag (July 2007 to July 2009): programs that were flagged for outcomes in only one of the first five PSRs released after the CoPs came into effect (July 2007, January 2008, July 2008, January 2009, or July 2009); $n = 16$.

Multiple flags (July 2007 to July 2009), returned to compliance: programs that were flagged for outcomes in two or more of the first five PSRs released after the CoPs came into effect but were not flagged in any subsequent PSRs released between July 2009 and July 2012; $n = 14$.

Ongoing noncompliance (July 2007 to July 2012): programs that were flagged for outcomes in two or more of the first five PSRs released after the CoPs came into effect, and also received one or more additional flags between July 2009 and July 2012; $n = 26$.

These groups emphasize outcomes during the first 2 years following the implementation of the CoPs in order to maximize the follow-up period over which to observe practice changes. Programs that received their first outcomes flag after July 2009 were excluded from the main analyses, given the shorter follow-up period over which to observe any changes in practice subsequent to flagging ($n = 23$). Programs that closed at any point after July 2007 were included in the analysis, contributing data up to and including the year they closed (in years subsequent to closure, transplant volume is set to zero; $n = 13$). Programs that voluntarily withdrew from Medicare between July 2007 and July 2012 ($n = 5$) were included in the analysis prior to and subsequent to their withdrawal. The reasoning for this approach was that volume loss as a result of any program closure, or subsequent to withdrawal from Medicare, is a natural consequence of the regulatory process and relevant to the wider question of whether shifts in program practices have occurred since the introduction of the CoPs.

Analysis of Donor, Recipient, and Transplant Risk

Risks of 1-year graft failure associated with donor, recipient, and transplant characteristics were estimated for all deceased donor kidney transplants performed among recipients ≥18 years of age during the period under study. The donor-related risk burden was assessed according to all covariates in the OPTN Donor Profile Index: age, black race, creatinine >1.5, hypertension, diabetes, stroke, height, weight, HCV status, DCD status, and cause of death (Organ Procurement and Transplant Network (OPTN) 2012);. Recipient-related risk was estimated according to all recipient-related covariates in the SRTR (PSR) risk adjustment model (January 2012), which included previous solid organ transplant, age, gender, race, BMI, recipient diagnosis of diabetes, recipient diagnosis of hypertension, recipient diagnosis of other vascular disease, HCV status, peak PRA, preemptive transplantation, year of ESRD treatment, and insurance status (Scientific Registry of Transplant Recipients (SRTR) 2012). The overall burden of risk associated with transplantation was assessed according to all covariates in the SRTR risk adjustment model, including the donor and recipient factors listed above plus cold ischemia time, pulsatile perfusion, organ shared outside DSA, and HLA mismatch (Scientific Registry of Transplant Recipients (SRTR) 2012).

Risks of 1-year graft failure were estimated by applying to each individual adult deceased-donor kidney transplant performed between 2001 and 2011, and to each newly wait-listed adult candidate, the survival model effects (betas) associated with donor, recipient, and transplant characteristics. This was done by multiplying the characteristics of the donors, recipients, and transplants by their respective effects (betas) and summing the linear combination. The covariate betas calculated by SRTR for the January 2012 wave of PSRs were applied (Scientific Registry of Transplant Recipients [SRTR] 2012) and are based on outcomes of deceased donor kidney transplants performed between July 2008 and January 2010. Average program risks attributable to donor/recipient/transplant factors within each calendar year were calculated as the total program risk for that year, divided by the total number of transplants performed by the program in that year. Change over time in risk was calculated as the average program risk in each year divided by the average national risk attributable to donor/recipient/transplant factors in 2007. Average risks of 1-year graft failure within program groups (i.e., never flagged, single flag etc.) were calculated with weighting for program size (i.e., each group was treated as one large program), to better reflect the scale of any systematic shift away from high-risk donors or recipients. To evaluate the statistical significance of shifts in aggregate risk over time, linear trend tests were conducted. Individual (patient-level) risks were regressed against year within each program performance group, and the beta coefficient for year tested for a linear association with risk.

Finally, a sensitivity analysis was conducted, calculating unweighted risks of 1-year graft failure for each program group to determine whether weighting had a qualitative effect on the results. All analyses were performed in SAS Version 9.2. *p*-values for the difference between groups with respect to prevalence of individual donor, recipient, and transplant characteristics were calculated by Pearson's chi-squared test for equivalent proportions.

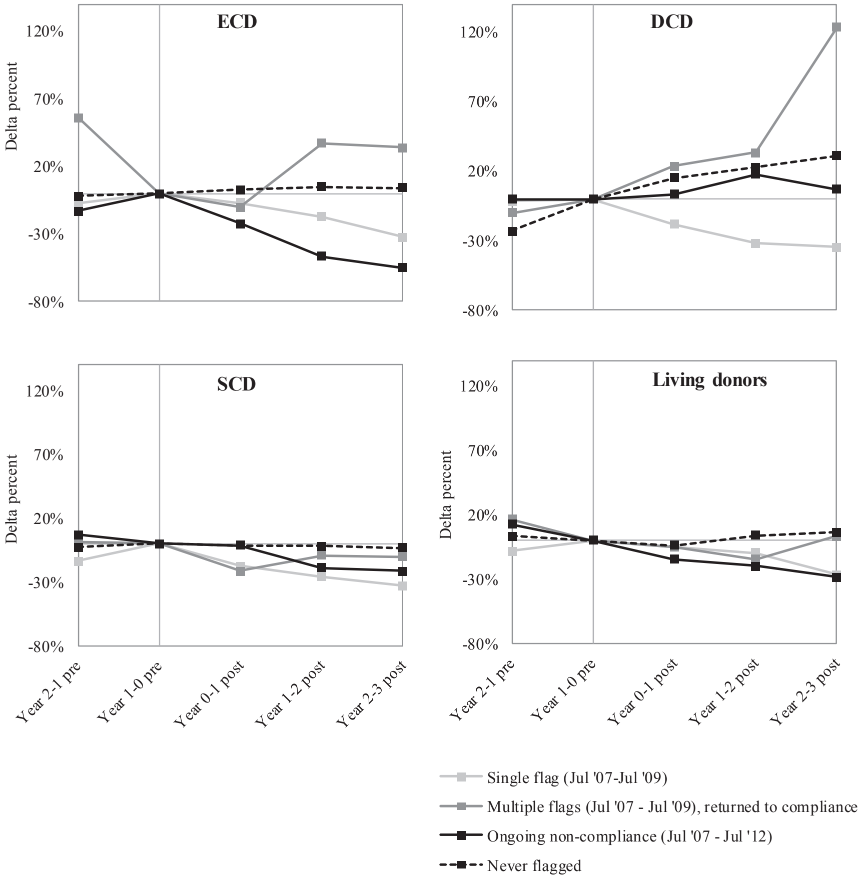
Results

The total number of kidney transplants performed by the 221 adults programs included in the present analysis fell from a high of 16,109 in 2006, to 15,764 in 2011 (Medicare CoPs for organ transplant programs were implemented in mid 2007). A reduction in volume from 2,013 transplants performed in 2006 to 1,247 transplants performed in 2011 was observed for the group of programs with ongoing noncompliance (average decline of 30 kidney transplants per program over this interval, or 38 percent of total volume). Smaller reductions in volumes were observed for the group of programs with a single flag (918 transplants in 2006 vs. 862 transplants in 2011, average 5-year decline of 3.5 transplants per program, or 6 percent), and for the group of programs that received multiple flags but returned to compliance (1,046 transplants in 2006 vs 1,032 transplants in 2011, average 5-year decline of 1 transplant per program, or 1 percent). In contrast, total kidney transplant volumes increased among programs that were never flagged, from 10,492 transplants in 2006 to 11,130 transplants in 2011 (average per program increase of 4.5 transplants, or 6 percent).

Compared to the number of transplants performed in the 12 months leading up to their first PSR flag after the CoPs came into effect, 2–3 years after this first flag the 16 programs with a single flag performed 33.3 percent fewer standard criteria donor (SCD) kidney transplants, 26.3 percent fewer living donor kidney transplants, 32.3 percent fewer ECD kidney transplants, and 34.7 percent fewer donors after circulatory death (DCD) kidney transplants (Figure 1). The 14 programs that received multiple flags but returned to compliance performed a total of 10.0 percent fewer SCD, 3.4 percent more living donor, 33.9 percent more ECD, and 123 percent more DCD transplants 2–3 years after their first flag. The 26 programs with ongoing noncompliance performed a total of 21.1 percent fewer SCD, 28.5 percent fewer living donor, 55.1 percent fewer ECD, and 6.8 percent more DCD transplants 2–3 years after their first flag. By comparison, the 142 programs that were never flagged for outcomes performed 3.3 percent fewer SCD, 6.2 percent more living donor, 4.2 percent more ECD, and 31.0 percent more DCD transplants over the same interval. The relative utilization of ECD kidneys (the proportion of all kidney transplants derived from ECDs) remained fairly consistent across all performance groups (Figure 2), only showing a consistent decline among programs with ongoing noncompliance. In this group of programs, ECD utilization fell from 12 percent at 0–1 years prior to first outcomes flag to 8 percent at 2–3 years after first flag.

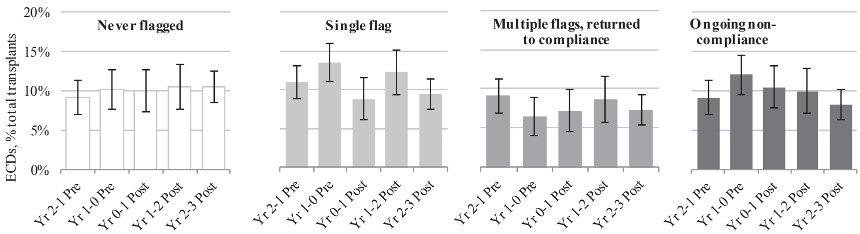
Table 1 shows the prevalence of individual donor, recipient, and transplant-related risk factors within each group of programs, at time points 2–1 years pre- versus 1–2 years post first outcomes flag (or July 2005/July 2006 vs July 2008/July 2009 for never-flagged programs). The proportion of donors with diabetes increased among all program groups, as did the proportion of donors with serum creatinine >1.5. For the group of programs that were never flagged, the proportion of donors that were aged older than 60 years or DCD also increased significantly. Among programs that received multiple flags between July 2007 and July 2009 but subsequently returned to compliance, the proportion of donors who were black, had hypertension, died of stroke, or were DCD all significantly increased. The proportion of DCDs also increased significantly among programs with ongoing noncompliance; however, the proportion of donors who were aged >60, black, had hypertension, died from stroke, or were ECD declined. Despite significant variation in the proportion of donors with diabetes or hypertension at 2–1 years pre first flag (July 2005/July 2006 for never-flagged programs), the prevalence of these risk factors was not statistically different across each flagging group by 1–2 years post first flag (or July 2008/July 2009).

Figure 1: Percentage Change in Aggregate Transplant Volume, by Organ Type, Relative to Year Prior to First Outcomes Flag (Time Zero, Indicated by the Vertical Line); for Programs That Were Never Flagged, Percentage Change Is Calculated Relative to Kidney Transplant Volume in the Twelve Months from July 2006 to July 2007



With respect to recipient-related factors, the prevalence of age >60, ESRD >2 years, and BMI ≥30 kg/m^2 increased over time across all flagging groups. Among programs that were never flagged, the proportion of recipients who were black, had a diagnosis of hypertensive nephropathy, or a PRA ≥80 also increased significantly (July 2005/July 2006 vs. July 2008/July 2009). Similar shifts in recipient characteristics were observed for the group of

Figure 2: Average Program Utilization of ECD Kidneys, as a Percent of All Kidney Transplants in That Time Interval (Unweighted); Error Bars Show the Standard Error around the Mean Values



programs that received multiple flags but returned to compliance. At time points both pre- and post-first flag, the group of programs with ongoing non-compliance transplanted the highest proportion of recipients who had a primary diagnosis of diabetic or hypertensive nephropathy, or an ESRD duration of ≥2 years, and the lowest proportion of recipients with private insurance as their private insurance type. At 2–1 years prior to first flag (July 2005/July 2006 for never-flagged programs), there was significant variation between flagging groups in the prevalence of recipients who were aged >60, black, recipients of a previous transplant, had a primary diagnosis of diabetic nephropathy or hypertensive nephropathy, an ESRD duration ≥2 years, BMI ≥30 kg/m^2, and in the proportion of recipients with private insurance as their primary insurance type. By 1–2 years post-first flag (or July 2008/July 2009), disparities between groups in the prevalence of older recipients and the proportion who had received a previous transplant were no longer significant. With respect to transplant-related risk factors, there was significant heterogeneity in the prevalence of organs shared outside the OPO, but, in general, the proportion of organs that were shared declined over time across flagging groups. The proportion of pumped kidneys and non-zero HLA mismatch transplants increased over time in all groups.

Table 2 shows trends in the prevalence of selected clinical and demographic characteristics for candidates newly wait-listed for kidney transplantation, prior to and subsequent to first outcomes flag (or July 2005/July 2006 vs. July 2008/July 2009 for never-flagged programs). The prevalence of BMI ≥30 kg/m^2 was the only candidate-related characteristic that increased over time in all groups. Among programs that were never flagged, the prevalence of age >60, diabetic and hypertensive nephropathy, PRA ≥80, preemptive listings, and average zipcode income <$30,000 increased, whereas the

Table 1: Change in the Prevalence of Donor, Recipient, and Transplant Characteristics by Program Category, Prior to and Following the First Outcomes Flag

	Prevalence (%)								Comparisons across Groups (p-value)	
	Never Flagged		Single Flag (July '07–July '09)		Multiple Flags (July '07–July '09), Returned to Compliance		Ongoing Non-Compliance			
	July '05–July '06	July '08–July '09	2–1 years pre	1–2 years post	2–1 years pre	1–2 years post	2–1 years pre	1–2 years post	2–1 years pre†	1–2 years post‡
N	10,336	10,740	910	815	1,052	873	1,960	1,476		
Donor characteristics										
Age >60	6.2	7.2**	7.7	6.6	6.5	7.2	6.8	5.7	.28	.20
Black	12.4	12.1	14.2	13.9	13.0	16.3*	14.7	13.7	.024	.001
Hypertension	17.3	17.8	19.2	18.9	13.4	17.3*	17.6	15.2	.004	.071
Diabetes	3.8	4.8**	5.2	6.5	2.8	4.0	4.2	5.2	.044	.083
Cause of death: stroke	24.2	23.3	21.9	20.4	17.6	24.2***	23.4	21.2	<.001	.072
Serum creatinine >1.5	8.8	9.3	11.2	14.9*	6.6	8.6	9.7	11.0	.002	<.001
DCD	5.0	7.5***	8.5	6.6	3.0	5.4*	6.6	10.0***	<.001	<.001
ECD	11.5	11.8	13.0	12.9	8.8	9.3	10.9	8.9	.018	.001
Recipient factors										
Age >60	23.0	26.9***	27.5	29.8	19.3	26.0***	24.0	27.6*	<.001	.27
Black	22.9	24.5*	24.1	25.6	23.8	31.6***	29.4	27.5	<.001	<.001
Any previous transplant	13.8	13.3	15.4	16.4	16.9	14.1	15.1	14.1	.019	.080
Diagnosis: Diabetic nephropathy	24.1	24.5	26.0	25.8	18.8	20.2	27.5	29.0	<.001	<.001

Continued

Table 1. *Continued*

	Prevalence (%)									
	Never Flagged		*Single Flag (July '07–July '09)*		*Multiple Flags (July '07–July '09), Returned to Compliance*		*Ongoing Non-Compliance*		*Comparisons across Groups (p-value)*	
	July '05–July '06	*July '08–July '09*	*2–1 years pre*	*1–2 years post*	*2–1 years pre*	*1–2 years post*	*2–1 years pre*	*1–2 years post*	*2–1 years pre*†	*1–2 years post*‡
Diagnosis: Hypertensive nephropathy	22.4	24.0*	24.0	23.3	21.6	26.7*	32.8	32.3	<.001	<.001
PRA ≥80	9.4	11.7***	10.2	10.1	9.2	13.1*	9.7	10.6	.84	.16
ESRD >2 years	53.4	55.6**	49.0	53.0	48.4	51.4	56.7	58.4	<.001	.005
BMI ≥30 kg/m^2	24.7	29.5***	28.1	35.5**	27.0	30.7	30.8	34.6*	<.001	<.001
Insurance type: Primary private	41.2	41.0	40.2	42.2	45.3	44.6	32.2	30.2	<.001	<.001
Transplant factors										
Shared outside OPO	56.5	53.2***	66.3	66.5	63.9	59.8	52.7	47.8**	<.001	<.001
Pumped kidneys	13.4	19.4***	13.4	16.6	8.1	14.6***	19.0	27.6***	<.001	<.001
Nonzero HLA mismatch	88.3	89.6**	89.8	93.3*	88.4	90.8	86.8	92.5***	.12	<.001
Cold ischemia time >12 hours	42.8	43.5	50.1	47.0	35.6	37.5	41.3	43.8	<.001	.001

Notes. Chi-squared p-value for the difference, within each program category, in proportions at time periods pre/post time time zero: $*p < .05$; $**p < .005$; $***p < .001$.

†Chi-squared p-value for the difference across all groups (3 d.f.) in the proportion of donors/recipients/transplants with the respective characteristic at 2–1 years pre-first outcomes flag (or 2005–2006 for programs that were never flagged).

‡Chi-squared p-value for the difference across all groups (3 d.f.) in the proportion of donors/recipients/transplants with the respective characteristic at 1–2 years post first outcomes flag (or 2008–2009 for programs that were never flagged).

Table 2: Change in the Prevalence of Clinical and Demographic Characteristics among Newly Wait-listed Transplant Candidates, Prior to and Following First Citation for Outcomes

	Prevalence (%)									
	Never Flagged		*Single Flag (July '07–July '09)*		*Multiple Flags (July '07–July '09), Returned to Compliance*		*Ongoing Non-Compliance*		*Comparisons across Groups (p-value)*	
	July '05–July '06	*July '08–July '09*	*2–1 years pre*	*1–2 years post*	*2–1 years pre*	*1–2 years post*	*2–1 years pre*	*1–2 years post*	*2–1 years pre†*	*1–2 years post‡*
N	19,572	22,051	704	762	1,396	1,715	3,192	2,741		
Candidate factors										
Age >60	23.6	27.4***	27.3	29.1	22.7	22.0	26.9	25.9	<.001	<.001
Black	27.8	27.3	31.1	28.8	28.4	40.8***	32.5	31.9	<.001	<.001
Any previous transplant	15.5	14.4**	18.9	16.6	18.8	16.2	16.9	16.8	<.001	<.001
Diagnosis: Diabetic nephropathy	29.2	31.7***	25.0	29.9**	20.7	23.0	32.2	30.4	<.001	<.001
Diagnosis: Hypertensive nephropathy	21.7	23.7***	23.6	25.5	24.9	24.7	27.7	29.2	<.001	<.001
PRA ≥80	6.5	7.0*	6.9	1.8***	6.9	8.4	6.2	4.2***	.754	<.001
ESRD >2 years	32.9	32.4	33.3	32.0	35.9	39.0	37.3	36.5	<.001	<.001
Preemptive listings	20.3	22.7***	22.1	27.2***	21.1	20.8	17.8	20.0*	.001	<.001
BMI ≥30 kg/m^2	33.9	38.0***	35.6	41.8***	31.3	42.3***	35.6	39.2**	.018	<.001
Insurance type: Primary private	44.5	45.3	41.4	43.3	46.4	44.1	40.6	37.8*	<.001	<.001

Continued

Table 2. *Continued*

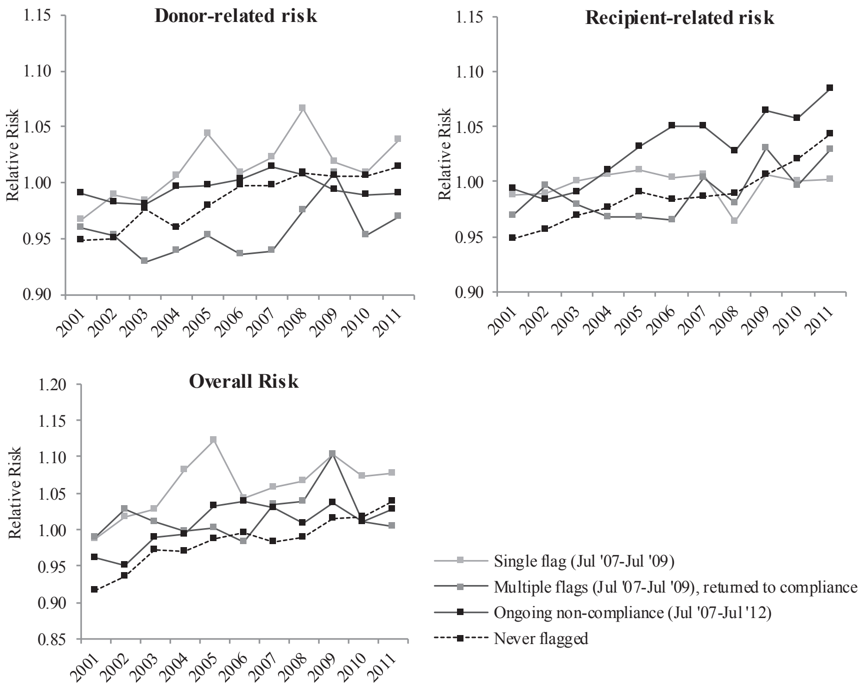
	Prevalence (%)								Comparisons across Groups (p-value)	
	Never Flagged		Single Flag (July '07–July '09)		Multiple Flags (July '07–July '09), Returned to Compliance		Ongoing Non-Compliance			
	July '05–July '06	July '08–July '09	2–1 years pre	1–2 years post	2–1 years pre	1–2 years post	2–1 years pre	1–2 years post	2–1 years pre†	1–2 years post‡
Average ZIP income <$30,000§	12.1	13.1**	14.5	15.2	12.4	9.0*	14.8	15.3	<.001	<.001
Less than high school diploma	6.7	6.7	4.5	5.4	5.6	4.7	6.1	7.2	.002	.001
Distance to transplant center (avg miles)¶	83.1	87.2	54.6	69.4**	92.1	85.5	43.3	41.4	<.001	<.001

Notes. Chi-squared p-value for difference in proportions at pre/post time periods: $*p < .05$; $**p < .005$; $***p < .001$.
†Chi-squared p-value for the difference across all groups (3 d.f.) in the proportion of donors/recipients/transplants with the respective characteristic at 2–1 years pre-first outcomes flag (or 2005–2006 for programs that were never flagged).
‡Chi-squared p-value for the difference across all groups (3 d.f.) in the proportion of donors/recipients/transplants with the respective characteristic at 1–2 years post first outcomes flag (or 2008–2009 for programs that were never flagged).
§Average income for each group was calculated based on the average resident income in the zip code of each newly wait-listed patient.
¶p-values for differences in distance to transplant center at different time points calculated according to a two-sided t-test of equal variances.

proportion of candidates that had received a previous transplant declined. Among programs flagged in multiple PSRs from July 2007 at July 2009 that returned to compliance, the proportion of newly wait-listed candidates who were black significantly increased, but the proportion of candidates from low-income areas, with less than a high school diploma, and living further from the transplant center decreased. Among programs with ongoing noncompliance, the proportion of newly wait-listed candidates with private insurance as their primary insurance type and the percentage with PRA ≥80 percent significantly decreased, while the proportion of candidates listed preemptively increased. Nonsignificant increases in the prevalence of neighborhood income <$30,000 and lower educational attainment were also observed for the ongoing noncompliance group. The proportion of sensitized candidates (PRA ≥80) was similar across all flagging groups at 2–1 years pre-first flag (range: 6.2–6.9 percent); however, at 1–2 years post-first flag (or July 2008/July 2009) the proportion of candidates with PRA ≥80 ranged from 1.8 percent among programs receiving a single flag between July 2007 and July 2009, to 8.4 percent among programs flagged in multiple PSRs that returned to compliance ($p < .001$). At both 2–1 years pre and 1–2 years post-first flag, the group of programs with ongoing noncompliance had the highest proportion of candidates with diabetic and hypertensive nephropathy, the lowest proportion with private insurance as their primary insurance type, the lowest proportion of candidates preemptively listed for transplantation, the highest proportion from low-income neighborhoods, and the shortest distance from candidate ZIP-code to transplant center. In contrast, in both 2005/2006 and 2008/2009, the group of programs that were never flagged had the lowest proportion of newly wait-listed candidates that were black, had received a prior transplant, or had a primary diagnosis of hypertensive nephropathy.

Aggregate trends in risk of 1-year graft failure attributable to donor, recipient, and overall transplant characteristics by program group, for deceased donor kidney transplants performed over the interval from 2001 and 2011, are shown in Figure 3. Regression models testing for linear trends in relative risk of 1-year graft failure over time indicated that the weighted average risk associated with donor-related factors increased significantly over time among programs that were never flagged ($\beta = 0.007$, $p < .0001$), programs receiving a single flag ($\beta = 0.006$, $p < .0001$), and programs that were flagged in multiple PSRs but returned to compliance ($\beta = 0.003$, $p = .0008$). Average risk associated with recipient-related factors increased significantly over time among programs that were never flagged ($\beta = 0.008$, $p < .0001$), programs that were flagged in multiple PSRs but returned to compliance ($\beta = 0.005$, $p = .0005$),

Figure 3: Aggregate Risk of One-Year Graft Failure, Relative to the Overall Risk in 2007, Associated with Donor, Recipient and Overall Transplant Characteristics (Deceased Donor Kidney Transplants)



Aggregate Risk is the Average Risk within Each Group of Programs, Weighted for Program Size. The Average Sample Sizes (Average Annual Number of Transplants, 2001–2011) for Each Group of Programs Were 847 (Single Flag), 995 (Multiple Flags, Returned to Compliance), 1,702 (Ongoing Non-Compliance), and 10,078 (Never Flagged)

programs with ongoing noncompliance ($\beta = 0.0094$, $p < .0001$), but not programs with a single flag ($\beta = 0.0002$, $p = .9$). Programs with ongoing noncompliance showed a higher burden of risk due to recipient factors, compared with the other groups of programs, over the majority of this interval. The risk of 1-year graft failure associated with transplant characteristics overall increased among programs that were never flagged ($\beta = 0.009$, $p < .0001$), programs that were flagged on a single occasion ($\beta = 0.007$, $p = .0016$), and programs with ongoing noncompliance ($\beta = 0.007$, $p < .0001$). In almost all calendar years the overall transplant risk, relative to overall transplant risk in 2007, was lowest for the group of programs that were never flagged.

Sensitivity analyses estimating the unweighted aggregate risks of 1-year graft failure associated with donor, recipient, and overall transplant factors yielded similar qualitative trends toward increasing aggregate transplant risks. The main difference, compared with the weighted analyses, was that there was less differentiation between the program groups; no one group of programs showed a consistently higher or lower donor/recipient/transplant-associated risk than any other group of programs on unweighted analysis.

Discussion

There remains considerable debate in the transplant community as to the potential trade-offs associated with increased regulation of transplant programs in terms of organ utilization, transplant volumes, and access to transplantation for higher risk candidates. We found that, since the implementation of the Medicare CoPs in mid-2007, kidney transplant volumes in the United States have overall remained steady; however, declines in transplant volume, in particular ECD transplant volume, were observed for programs with ongoing noncompliance. Risk of 1-year graft failure associated with recipient-related factors, by comparison, showed a trend toward an increasing burden of risk over time, both among programs that were never flagged and among programs with ongoing noncompliance. This trend was driven largely by increases in the overall proportion of recipients aged >60 years or with a BMI ≥ 30 kg/m^2.

Interestingly, programs with ongoing noncompliance showed a consistently higher aggregate burden of risk due to recipient-related factors compared with programs with fewer or no outcomes flags. This was predominantly attributable to a higher prevalence of recipients with hypertensive nephropathy, diabetes, BMI ≥ 30 kg/m^2, and ESRD duration >2 years in this group of programs. By contrast, the group of programs that were never flagged had the lowest aggregate risk of 1-year graft failure due to overall transplant factors in almost all calendar years from 2001 to 2011. Previous studies have found that programs serving a high-risk patient population were more likely to be flagged by SRTR for poor outcomes (Schold et al. 2008). In addition, a recent analysis of the relationship between community health indicators and post-transplant outcomes found that the burden of poor physical and mental health, smoking, obesity, physical inactivity, preventable hospital stays, illiteracy, low income, and low birth weight was predictive of graft and patient survival among transplant recipients resident in that community (Schold et al. 2012). It may be the case that the health outcomes of the surrounding population influence outcomes seen in the PSRs, such that programs serving high-risk communities might be more susceptible to outcomes flagging. Conversely, the finding of consistently lower aggregate risk of 1-year graft failure among programs that were never flagged may suggest selection bias on the part of these programs. It should also be noted, however, that the higher burden of recipient-related risk among programs with ongoing noncompliance and the lower overall risk among programs that were never flagged were observed only in analyses weighted for program size; therefore, while these findings reflect the national experience overall, they will not be indicative of the experience of each individual transplant program.

Although we found little evidence to suggest that transplant programs have in aggregate reduced their exposure to any of the factors accounted for in the SRTR risk-adjustment model, we did observe some evidence of reduced wait-listing of candidates living in low-income neighborhoods among programs receiving multiple flags that subsequently returned to compliance. The proportion of newly wait-listed candidates with less than a high school diploma, and the average distance to the transplant center also declined in this group. This is likely to be due at least in part to more conservative candidate selection criteria, based on the belief that socio-economic factors may affect the ability of the patient to comply with care post-transplant. In contrast, among programs with ongoing non-compliance the proportions of newly wait-listed candidates living in low-income neighborhoods or without a high school diploma both in fact increased. These trends likely reflect some degree of loss of referrals and changing payer center selection, as private payers have been using the SRTR PSRs to identify centers of excellence and to discourage or exclude beneficiaries from selecting programs with poor post-transplant outcomes. Indeed, programs with multiple flags or ongoing noncompliance experienced a decline in the proportion of newly listed candidates with private insurance as their primary insurance type over the interval pre-/post-first outcomes flag.

Our findings are consistent with a recent study of trends in kidney transplant volumes subsequent to the implementation of the CMS CoPs. Schold et al. found that programs with 1-year graft or patient survival significantly lower than expected at least once between January 2007 and July 2009 were more likely to show a reduction in SCD, ECD and living donor transplant volume over time, relative to other programs; however, other than modest reductions in ECD utilization, cold ischemia time, and private insurance (none of which were significant in our analysis), the authors did not find evidence that reductions in transplant volume among low-performing centers were explained by risk-averse practices (Schold et al. 2013). Indeed, in addition to the loss of privately insured patients, programs under CMS review may be advised or even mandated to undergo a period of inactivity while they regroup, and therefore temporary volume loss may in some cases be a deliberate, rather than unintended, consequence of the CoPs (Hamilton 2013).

Furthermore, it must be noted that the introduction of the Medicare CoPs occurred at a time when several initiatives and policy revisions had recently been undertaken to improve access to organ transplantation, potentially influencing transplant volumes and outcomes, and practices with respect to wait-listing, organ allocation, and recipient selection. The OPTN implemented a range of policies in 2002 intended to maximize the recovery and utilization of ECD kidneys and expedite placement (Metzger et al. 2003). The Organ Donation Breakthrough Collaborative, launched in 2003, was associated with an increase in the number of organs donated until the Collaborative was concluded in 2006 (Howard et al. 2007). The subsequent Organ Transplantation Breakthrough Collaborative, launched in 2005, gave special focus to improved utilization of ECD and DCD organs (Leichtman et al. 2008). Yet the number of deceased donors in the United States has not increased since the end of the Collaborative era, due to some extent to a 15 percent drop in the number of reported eligible deaths from 2006 to 2009 and a sustained high rate of organ discard (Wynn and Alexander 2011). Whether, or to what extent, these trends are driven by the increasing difficulty in placing high-risk organs is unclear but warrants further investigation. Several of the observed trends with respect to donor, recipient, and transplant characteristics over the era surrounding the introduction of the CoPs are also likely to be linked to medical and policy developments immediately prior to the introduction of the CoPs, such as increased application of pulsatile perfusion preservation (Abboud et al. 2011), changes to deceased donor kidney allocation policy eliminating priority based on HLA-B matching (Ashby et al. 2011), and the 2007 introduction of DonorNet (Massie et al. 2009; Gerber et al. 2010). It is therefore difficult to isolate evidence of risk-averse practices related to program performance subsequent to the introduction of the CoPs in the context of general shifts toward higher risk transplants as well as demographic and broader epidemiological trends (e.g., increasing rates of obesity).

The main limitation of our analysis is the inability, in the absence of qualitative data describing each programs reaction to the introduction of the CoPs, to describe the exact nature, motivation, or timing behind any implied changes in individual program practices. Implementation of the Medicare CoPs officially began in July 2007; however, announcements regarding the forthcoming CMS regulations were released as early as 2005, and the OPTN Membership and Professional Standards Committee (MPSC) had adopted similar methodology several years earlier, with some programs having already undergone MPSC reviews and site visits. Another limitation of our analysis is that it was not possible to interrogate all possible criteria by which programs might select organs and candidates if seeking to minimize their exposure to risk of adverse transplant outcomes. We evaluated trends for all components of the SRTR risk-adjustment model, which focuses on factors shown to have a high probability of being associated with patient or graft outcomes (Dickinson et al. 2008). However, programs may decide to select or exclude recipients on the basis of a wider set of comorbidities not included in risk adjustment models but shown to predict graft failure, such as cardiac disease, neurological disease, anemia or fluid, and electrolyte disorders (Weinhandl et al. 2009), or more subjective factors such as socio-economic disadvantage and associated expectations concerning patient adherence.

We observed a decline in transplant volumes, particularly ECD volumes, for the subgroup of adult kidney transplant programs that experienced ongoing noncompliance subsequent to the introduction of the Medicare CoPs. While we did not observe evidence of programs systematically reducing their exposure to risk factors accounted for in SRTR risk adjustment models, we did observe some evidence of greater selectivity with respect to socio-economic factors among programs with multiple flags that returned to compliance. A detailed qualitative evaluation of responses to the regulations at the program level would clarify these findings.

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References

Abboud, I., C. Antoine, F. Gaudez, F. Fieux, C. Lefaucheur, E. Pillebout, D. Viglietti, T. Serrato, J. Verine, M. Flamant, M. N. Peraldi, and D. Glotz. 2011. "Pulsatile Perfusion Preservation for Expanded-Criteria Donors Kidneys: Impact on Delayed Graft Function Rate." *International Journal of Artificial Organs* 34 (6): 513–8.

Abecassis, M. M., R. Burke, G. B. Klintmalm, A. J. Matas, R. M. Merion, D. Millman, K. Olthoff, and J. P. Roberts. 2009. "American Society of Transplant Surgeons Transplant Center Outcomes Requirements–A Threat to Innovation." *American Journal of Transplantation* 9 (6): 1279–86.

Ashby, V. B., F. K. Port, R. A. Wolfe, J. J. Wynn, W. W. Williams, J. P. Roberts, and A. B. Leichtman. 2011. "Transplanting Kidneys without Points for HLA-B Matching: Consequences of the Policy Change." *American Journal of Transplantation* 11 (8): 1712–8.

Axelrod, D. A. 2013. "Balancing Accountable Care with Risk Aversion: Transplantation as a Model." *American Journal of Transplantation* 13 (1): 7–8.

Centers for Medicare and Medicaid Services. 2007. "Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; Final Rule." 42 CFR Parts 405, 482, 488 and 498 Medicare Programs. Department of Health & Human Services. Federal Register.

Dickinson, D. M., C. J. Arrington, G. Fant, G. N. Levine, D. E. Schaubel, T. L. Pruett, M. S. Roberts, and R. A. Wolfe. 2008. "SRTR Program-Specific Reports on Outcomes: A Guide for the New Reader." *American Journal of Transplantation* 8 (4 Pt 2): 1012–26.

Gerber, D. A., C. J. Arrington, S. E. Taranto, T. Baker, and R. S. Sung. 2010. "DonorNet and the Potential Effects on Organ Utilization." *American Journal of Transplantation* 10 (4 Pt 2): 1081–9.

Hamilton, T. E. 2008. "Improving Organ Transplantation in the United States — a Regulatory Perspective." *American Journal of Transplantation* 8 (12): 2503–5.

———. 2013. "Regulatory Oversight in Transplantation: Are the Patients Really Better Off?" *Current Opinion in Organ Transplantation* 18 (2): 203–9.

Howard, R. J., D. L. Cornell, and J. D. Schold. 2009. "CMS Oversight, OPOs and Transplant Centers and the Law of Unintended Consequences." *Clinical Transplantation* 23 (6): 778–83.

Howard, D. H., L. A. Siminoff, V. McBride, and M. Lin. 2007. "Does Quality Improvement Work? Evaluation of the Organ Donation Breakthrough Collaborative." *Health Services Research* 42 (6, Part I): 2160–73.

Leichtman, A. B., D. Cohen, D. Keith, K. O'Connor, M. Goldstein, V. McBride, C. J. Gould, L. L. Christensen, and V. B. Ashby. 2008. "Kidney and Pancreas Transplantation in the United States, 1997-2006: The HRSA Breakthrough Collaboratives and the 58 DSA Challenge." *American Journal of Transplantation* 8 (4 Pt 2): 946–57.

Massie, A. B., S. L. Zeger, R. A. Montgomery, and D. L. Segev. 2009. "The Effects of DonorNet 2007 on Kidney Distribution Equity and Efficiency." *American Journal of Transplantation* 9 (7): 1550–7.

Metzger, R. A., F. L. Delmonico, S. Feng, F. K. Port, J. J. Wynn, and R. M. Merion. 2003. "Expanded Criteria Donors for Kidney Transplantation." *American Journal of Transplantation* 3 (Suppl 4): 114–25.

Organ Procurement and Transplant Network (OPTN). 2012. "A Guide to Calculating and Interpreting the Kidney Donor Profile Index (KDPI)" [accessed on December 7, 2012]. Available at http://optn.transplant.hrsa.gov/ContentDocuments/Guide_to_Calculating_Interpreting_KDPI.pdf

Port, F. K., J. L. Bragg-Gresham, R. A. Metzger, D. M. Dykstra, B. W. Gillespie, E. W. Young, F. L. Delmonico, J. J. Wynn, R. M. Merion, R. A. Wolfe, and P. J. Held. 2002. "Donor Characteristics Associated with Reduced Graft Survival: An Approach to Expanding the Pool of Kidney Donors." *Transplantation* 74 (9): 1281–6.

Schold, J. D., C. J. Arrington, and G. Levine. 2010. "Significant Alterations in Reported Clinical Practice Associated with Increased Oversight of Organ Transplant Center Performance." *Progress in Transplantation* 20 (3): 279–87.

Schold, J. D., T. R. Srinivas, R. J. Howard, I. R. Jamieson, and H. U. Meier-Kriesche. 2008. "The Association of Candidate Mortality Rates with Kidney Transplant Outcomes and Center Performance Evaluations." *Transplantation* 85 (1): 1–6.

Schold, J. D., L. D. Buccini, M. W. Kattan, D. A. Goldfarb, S. M. Flechner, T. R. Srinivas, E. D. Poggio, R. Fatica, L. K. Kayler, and A. R. Sehgal. 2012. "The Association of Community Health Indicators with Outcomes for Kidney Transplant Recipients in the United States." *Archives of Surgery* 147 (6): 520–6.

Schold, J. D., L. D. Buccini, T. R. Srinivas, R. T. Srinivas, E. D. Poggio, S. M. Flechner, C. Soria, D. L. Segev, J. Fung, and D. A. Goldfarb. 2013. "The Association of Center Performance Evaluations and Kidney Transplant Volume in the United States." *American Journal of Transplantation* 13 (1): 67–75.

Scientific Registry of Transplant Recipients (SRTR). 2012. "Risk Model Documentation" [accessed on December 7, 2012]. Available at http://www.srtr.org/csr/current/Centers/201206/modtabs/Risk/KIADC2G.pdf

Weinhandl, E. D., J. J. Snyder, A. K. Israni, and B. L. Kasiske. 2009. "Effect of Comorbidity Adjustment on CMS Criteria for Kidney Transplant Center Performance." *American Journal of Transplantation* 9 (3): 506–16.

Wynn, J. J., and C. E. Alexander. 2011. "Increasing Organ Donation and Transplantation: The U.S. Experience over the Past Decade." *Transplant International* 24 (4): 324–32.

Supporting Information

Additional supporting information may be found in the online version of this article:

Appendix SA1: Author Matrix.