The Effect of Augmenting OPTN Data With External Death Data on Calculating Patient Survival Rates After Organ Transplantation

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Background. Although the Organ Procurement and Transplantation Network (OPTN) database contains a rich set of data on United States transplant recipients, follow-up data may be incomplete. It was of interest to determine if augmenting OPTN data with external death data altered patient survival estimates. **Methods.** Solitary kidney, liver, heart, and lung transplants performed between January 1, 2011, and January 31, 2013, were queried from the OPTN database. Unadjusted Kaplan-Meier 3-year patient survival rates were computed using 4 nonmutually exclusive augmented datasets: OPTN only, OPTN + verified external deaths, OPTN + verified + unverified external deaths (OPTN + all), and an additional source extending recipient survival time if no death was found in OPTN + all (OPTN + all [Assumed Alive]). Pairwise comparisons were made using unadjusted Cox Proportional Hazards analyses applying Bonferroni adjustments. **Results.** Although differences in patient survival rates across data sources were small (≤ 1 percentage point), OPTN only data often yielded slightly higher patient survival rates than sources including external death data. No significant differences were found, including comparing OPTN + verified (hazard ratio [HR], 1.05; 95% confidence interval [95% CI], 1.00-1.10; $P = 0.0356$), OPTN + all (HR, 1.06; 95% CI, 1.01-1.11; $P = 0.0243$), and OPTN + all (Assumed Alive) (HR, 1.00; 95% CI, 0.96-1.05; $P = 0.8587$) versus OPTN only, or OPTN + verified (HR, 1.05; 95% CI, 1.00-1.10; $P = 0.0511$), and OPTN + all (HR, 1.05; 95% CI, 1.00-1.10; $P = 0.0353$) versus OPTN + all (Assumed Alive). **Conclusions.** Patient survival rates varied minimally with augmented data sources, although using external death data without extending the survival time of recipients not identified in these sources results in a biased estimate. It remains important for transplant centers to maintain contact with transplant recipients and obtain necessary follow-up information, because this information can improve the transplantation process for future recipients.

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Since 1986, deceased donor organ allocation and distribution in the United States has been continually evolving under the direction of the Organ Procurement and Transplantation Network (OPTN) based on a variety of factors, including a large pool of clinical expertise as well as timely and structured data collection. All transplant centers in the

United States are required to be members of the OPTN, which mandates submission of complete and accurate data on donors, waitlist candidates, and transplant recipients. These data are necessary to monitor and evaluate policies related to organ allocation and distribution for efficacy and for adherence to the Final Rule¹ and are submitted to the United Network for Organ Sharing, who currently operates the OPTN contract under the Health Resources and Services Administration of the US Department of Health and Human Services.

Although the OPTN database is relatively complete in terms of donor, waitlist candidate, and transplant recipient information, there are some limitations regarding follow-up data.² As part of the data submission process for the OPTN, transplant centers are required to report transplant data to the OPTN within 60 days of transplant. Data regarding outcomes (including recipient death^{3,4}) at 6 months posttransplant and at each transplant anniversary thereafter, until recipient death or graft failure, are required to be reported within 30 days of the transplant anniversary. In other words, if graft failure occurs but the recipient is still alive, follow-up terminates with the report of the graft failure. In addition, transplant centers are currently required by policy to submit the appropriate follow-up form within 14 days of notification of transplant recipient death or graft failure if it occurs outside of the annual follow-up anniversary.

Recipient follow-up forms are submitted to the OPTN through UNet^{SM}, a Web-based utility that was deployed on October 25, 1999. Even with these reporting requirements,

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data may be incomplete for some recipients. It is important to emphasize that although policy requires submission of annual follow-up data for recipients, no requirement exists for submission at exactly 365 days. Despite the allowable 60-day data submission lag for transplant data and 30-day data submission lag for follow-up data for transplant centers to remain compliant, delays in reporting may occur. For example, recipients that become lost to follow-up may actually be deceased, which may not be known by the transplanting center, and will thus be incomplete in the OPTN database.

Patient survival rates are often used by OPTN committees to provide evidence for revising organ allocation policies. In addition, transplant centers or regions may wish to assess their own performance against benchmarks, whereas the general public may request data for informed decision-making when pursuing the option of organ transplantation. Additionally, many researchers access this database to assess or predict patient outcomes.² It is important to have accurate data to support all of these critical goals.

To enhance completeness of death ascertainment, the OPTN database is supplemented with deaths reported from various external data sources. One example of an external source is the Social Security Administration Death Master File (SSDMF) database, which includes “death reports from various sources, including family members, funeral homes, hospitals, and financial institutions”.⁵ It is noteworthy to mention that as of November 1, 2011, there was a change to the SSDMF database such that they no longer include protected state death records,⁵ or entries in the SSDMF database that were based on information directly from the states (ie from state death certificates). This change resulted in the most (more than 4 million) records being removed from the SSDMF database, and approximately 1 million fewer records added to the database annually.⁵

External death data sources include both verified and unverified death dates, which are defined in the next section. In addition, transplant recipients can be assumed to be alive, that is, have their patient survival time extended, if there is no death date in any of the data sources (OPTN and external death data). Given the ability of the OPTN to supplement data submitted to the OPTN from transplant centers with external data sources, it was of interest to determine if augmenting OPTN data with different external death data altered commonly referenced patient survival rate estimates.

This article is organized as follows. First, we describe the 4 nonmutually exclusive augmented datasets considered in calculating patient survival rates. A comprehensive comparison of patient survival/death rates across the data sources follows. In particular, patient survival/death rates are compared across data sources by transplanted organ type. Additionally, we investigated if certain recipients were more or less likely to have their patient survival time extended. The article concludes with a discussion.

MATERIALS AND METHODS

OPTN Data

Solitary kidney, liver, heart, and lung transplants performed in the United States between November 1, 2011, and January 31, 2013, were identified in the OPTN database, which includes data on all donors, waitlist candidates, and transplant recipients in the United States. Submission forms

and requirements have been described previously and elsewhere.^{2,6,7} The OPTN data are as of April 1, 2016, and are subject to change based on future data submission or correction. Given the standard 60-day transplant data submission lag described above, this includes all 3-year posttransplant follow-ups through January 31, 2016. This cohort was chosen for 2 reasons: (1) The limited public availability of deaths from the SSDMF beginning in November 1, 2011,⁵ and (2) to allow all recipients an opportunity to have a 3-year posttransplant follow-up while leaving time for the data submission window.

External Data Sources

With the inclusion of external sources of death data, 4 data sources were used for calculating patient survival time, which are inherently nonmutually exclusive. These data sources are nested in that all begin with OPTN only data, but may be augmented with external data. In the order specified and subsequently described below, each data source encompasses the previous data source and adds additional information. In order of least to most information, the 4 data sources are: (1) OPTN data (OPTN only), (2) OPTN data plus external verified sources (OPTN + verified), (3) OPTN data plus external verified sources plus external unverified sources (OPTN + all), and (4) OPTN + all and assuming recipients without a death date are alive by extending their patient survival time (OPTN + all [Assumed Alive]).

In order for an external death to be included in OPTN + verified, OPTN + all, or OPTN + all (Assumed Alive), the algorithm first searches the OPTN database for death dates reported anywhere in the OPTN system, and then extends to external sources. Deaths are classified as either verified or unverified based on a data source hierarchy. A death date from an external data source was considered verified if it was found via the following, including, but not limited to, and in no particular order: the public SSDMF file, an obituary match, a transplant center, or family member contact.

If a death date is found but not verified, it is considered unverified. The OPTN is unable to release where unverified death dates are found. However, any death found in any external source that was disputed by a patient or member is not considered an unverified death as the patient is handled in the analysis as still being alive. Although unverified deaths cannot be released in an identifiable manner, they may be used in aggregate analyses performed by OPTN and Scientific Registry of Transplant Recipient contractors.

Additionally, a recipient was Assumed Alive if no death was reported on an OPTN transplant recipient follow-up form, and no death date was identified using any of the data sources (in other words, no death recorded in OPTN + all). In these cases, patient survival time is calculated as the time from transplant to the more recent of (1) the standard 60 day data submission lag of the analysis data set, less 30 days, to account for reporting lag (for this analysis, recipients are Assumed Alive as of December 31, 2015); or (2) the last reported patient status to the OPTN. For the former, additional days were added to these recipients' survival time. This data source is referred to as OPTN + all (Assumed Alive) and includes all information from OPTN + all plus the allowable extension of patient survival time. For example, a patient transplanted on August 22, 2012, who was known to be alive as of September 25, 2012, and has no record of death in OPTN + all will have an OPTN only, OPTN + verified,

and an OPTN + all patient survival time of 34 days, but will have an OPTN + all (Assumed Alive) patient survival time of 1226 days (ie, days from August 22, 2012, to December 31, 2015).

In instances where 2 or more differing death dates for a single recipient are found in external data sources, there is an a priori hierarchy in place to determine which death date to use for that recipient. Death dates in the OPTN database are considered to be the primary date. If a death date was found in an external death data source and is later reported to the OPTN, the date reported to the OPTN is used.

Statistical Analysis

All analyses were performed via SAS Enterprise Guide version 5.1 [SAS Institute, Cary, NC].

The data were analyzed overall, as well as stratified by transplanted organ (kidney, liver, heart, or lung). Unadjusted Kaplan-Meier patient survival rates and 95% confidence intervals (CI) were calculated across data sources.

To determine whether patient survival rate estimates differed by data source, Cox proportional hazards models were used overall and separately for each organ stratification, clustering on patient ID, to adjust the standard error (because the same patients are used in each data source). Hazard ratios (HR) and 95% CIs were used to describe the effect sizes; an HR equal to 1 suggests that there was no difference in the probability of patient death that was dependent on data source. Because we are making 6 pairwise comparisons (overall and by stratified organ), post hoc comparisons were made using the Bonferroni correction; *P* values from the Cox proportional hazard models were considered statistically significant at a Bonferroni adjusted alpha level of 0.0017 (0.05/30).

A comparison of recipient and transplant characteristics between recipients who had days added to their patient survival time versus those that did not was performed. Characteristics included time added (in days), transplant organ (categorized as heart, kidney, liver, or lung), recipient age group (pediatric [0-17 years] or adult [18+ years]), donor type (deceased or living), recipient sex, recipient ethnicity (categorized as white, Black, Hispanic, Asian, or other/unknown), recipient blood type (categorized as A, B, AB, or O), recipient citizenship (US citizen or other/unknown), recipient primary source of payment (categorized as private, public: Medicare, Medicare FFS, Choice, public: Medicaid, public: other (CHIP, VA, other), or other/unknown), if the recipient was receiving their first or a repeat transplant (of the same organ type), and most recent OPTN

patient status (categorized as alive, deceased, lost to follow-up, or retransplanted).

Continuous variables were summarized using medians and interquartile ranges and compared using Wilcoxon rank-sum tests. Categorical variables were summarized using counts and percentages and compared using Pearson χ^2 tests. A multivariable logistic analysis was performed to determine which characteristics were most important in predicting if a recipient had days added to their patient survival time, in the presence of all other factors. A recipient was not considered to be in the extended patient survival time group if they had 7 or less days added to their patient survival time. Adjusted odds ratios (AOR) and 95% CIs were used to describe the effect sizes; an AOR equal to 1 suggests that there was no difference in the probability of extending patient survival time that was associated with the corresponding characteristic, controlling for other characteristics. A significance level of 5% was assumed for all tests comparing recipients who did and did not have their patient survival time extended.

RESULTS

The analysis included 32 205 solitary solid organ kidney, liver, heart, or lung transplants performed at 249 transplant centers in the United States between November 1, 2011, and January 31, 2013, most (62%) of which were kidneys (Table 1). The number of unique patients and cumulative deaths within 3 years posttransplant identified through each data source is also shown in Table 1.

Note that Table 1 does not show the percentage of deaths identified in each data source, because a recipient with a death found in the OPTN database (the majority of death dates for the recipients) was not searched for in external data sources. Rather, only 192 additional deaths were found for the cohort in external sources after searching the OPTN database; 179 of these were verified deaths and 13 were unverified. Because most transplants within the OPTN are kidney transplants, the inclusion of external death data mostly supplements kidney transplants, adding 149 (78%) of the 192 deaths (142 using OPTN + verified and an additional 7 using OPTN + all). Heart and lung had the least amount of additional deaths, both verified and unverified, included from external data sources at 8 and 12 respectively.

Unadjusted Kaplan-Meier Analysis

Three-year patient survival rates are shown in Figure 1 by data source used to calculate patient survival time overall and stratified by transplanted organ.

TABLE 1.
Number of transplants, patients, and deaths by data source, overall and by transplanted organ for solitary kidney, liver, heart, or lung transplants performed between November 1, 2011, and January 31, 2013

Organ	No. Transplants	%	No. Unique Patients	No. cumulative deaths ^a by data source		
				OPTN Only	OPTN + Verified	OPTN + All
Kidney	20 024	62.2	19 999	1100	1242	1249
Liver	7169	22.33	7020	1087	1106	1110
Heart	2827	8.8	2821	422	429	430
Lung	2185	6.8	2171	621	632	633
Overall	32 205	100.0	32 007	3230	3409	3422

^aDeath within 3 years posttransplant.

FIGURE 1. Kaplan-Meier 3-year posttransplant patient survival by transplanted organ for solitary kidney, liver, heart, and lung transplants performed between November 1, 2011, and January 31, 2013.

Overall, at 3 years posttransplant, there were no substantial differences in patient survival rates across data sources. Within each transplanted organ strata, patient survival rates varied up to 0.8 percentage points across the data sources. Regardless of data source, kidney recipients had the highest patient survival rate, whereas lung recipients had the lowest patient survival rate.

For kidney and heart recipients, OPTN only data had the highest patient survival rates, followed by OPTN + all (Assumed Alive) data, while for liver and lung recipients, OPTN + all (Assumed Alive) data had marginally higher patient survival rates than OPTN only data. However, in either scenario, the 2 were very similar. Across all organs, OPTN + verified and OPTN + all data had slightly lower patient survival rates than OPTN only and OPTN + all (Assumed Alive), but were almost identical to one another. Heart recipients saw the least variability in patient survival rates across the 4 data sources with only a 0.3 percentage point spread between OPTN only and OPTN + all, which respectively yielded the largest to smallest patient survival rates.

Unadjusted Cox Proportional Hazard Cluster Analysis

Cox proportional hazard regression models were used to assess the relationship between data source and patient death within 3 years posttransplant; results can be seen in Figure 2.

Overall, recipients in OPTN + verified (HR, 1.05; 95% CI, 1.00-1.10; $P = 0.0356$) and OPTN + all (HR, 1.06; 95% CI, 1.01-1.11; $P = 0.0356$) had a 5% to 6% higher probability of patient death versus OPTN only data, though this difference was not statistically significant after applying the Bonferroni adjustment. The same results were seen when comparing OPTN + verified (HR, 1.05; 95% CI, 1.00-1.10; $P = 0.0511$) and OPTN + all (HR, 1.05; 95% CI, 1.00-1.10; $P = 0.0353$) versus OPTN + all (Assumed Alive). There was also no difference between OPTN + all (Assumed Alive) versus OPTN only (HR, 1.00; 95% CI, 0.96-1.05; $P = 0.8587$) or OPTN + verified versus OPTN + all (HR, 1.00; 95% CI, 0.95-1.04; $P = 0.8790$).

Similarly, for kidney transplant recipients, there were no statistically significant differences across any data sources after applying the Bonferroni adjustment. Although there were no statistically significant differences, OPTN + verified (HR, 1.13; 95% CI, 1.04-1.22; $P = 0.0044$) and OPTN + all (HR, 1.13; 95% CI, 1.04-1.23; $P = 0.0044$) had a 13% higher hazard of patient death versus OPTN only data. Similar results were seen when comparing OPTN + verified (HR, 1.07; 95% CI, 0.99-1.16; $P = 0.0805$) and OPTN + all (HR, 1.08; 95% CI, 1.00-1.17; $P = 0.0597$) versus OPTN + all (Assumed Alive), although the magnitude was about half at only 7% to 8%. OPTN + all (Assumed Alive) yielded a 5% higher hazard of patient death versus OPTN only data (HR, 1.05; 95%

FIGURE 2. Hazard ratio plot for probability of patient death within 3 years posttransplant by transplanted organ for solitary kidney, liver, heart, and lung transplants performed between November 1, 2011, and January 31, 2013.

CI, 0.97-1.14; $P = 0.2472$), and there was no difference in OPTN + verified versus OPTN + all (HR, 0.99; 95% CI, 0.92-1.08; $P = 0.8945$).

Likewise, within liver, heart, and lung alone transplant recipients, there were no statistical differences in patient survival rates for any data source comparisons, with all hazard ratios ranging between 0.99 and 1.03.

Characteristics of Recipients With and Without Extended Survival Time (Assumed Alive)

A comparison of recipient and transplant characteristics, using the OPTN + all (Assumed Alive) data source, for recipients that had time added (more than 7 days) versus those that did not have time added (7 or less days) to their patient survival time can be seen in Table 2 (univariable) and Figure 3 (multivariable). Approximately 74% of recipients had more than 7 days added to their patient survival time. Among those with extended patient survival time, the median number of days added was 175 (interquartile range, 79-275), and 88% had less than 1 year added. Of recipients that were alive as of their last patient status in the OPTN database, 89% had less than 1 year added to their patient survival time,

while only 10% of those lost to follow-up had less than 1 year added to their patient survival time.

In univariable analysis, all comparisons were statistically significant between those with and without extended patient survival time with the exception of recipient blood type, primary source of payment, and repeat transplant, although these differences may not be clinically meaningful. A multivariable logistic regression analysis was also used to estimate the association of these characteristics with the extension of patient survival time; results can be seen in Figure 3 (data not shown if <5 recipients). It was found that liver, heart, and lung recipients are significantly less likely to have their patient survival time extended compared to kidney recipients (liver: AOR, 0.88; 95% CI, 0.80-0.97; heart: AOR, 0.74; 95% CI, 0.65-0.83; lung: AOR, 0.70; 95% CI, 0.60-0.81), and recipients who, as of their most recent follow-up, are considered lost to follow-up in the OPTN system are significantly more likely to have their patient survival time extended compared with those who are considered to be alive in the OPTN system (AOR, 1.92; 95% CI, 1.38-2.67). Non-US citizens (AOR, 1.17; 95% CI, 0.98-1.39) and recipients with other/unknown primary form of payment (AOR,

TABLE 2.

Comparison of solitary kidney, liver, heart, or lung transplants performed between November 1, 2011, and January 31, 2013 by extension of patient survival time

	Extended patient survival time ^a ? (N = 32205)		P
	No (N = 8361) N (%)	Yes (N = 23844) N (%)	
Time added, d	—		
Median (IQR)	—	175.0 (79.0 - 275.0)	
Organ			<0.0001
Heart	904 (10.8)	1923 (8.1)	
Kidney	4080 (48.8)	15944 (66.9)	
Liver	2333 (27.9)	4836 (20.3)	
Lung	1044 (12.5)	1141 (4.8)	
Recipient age group			<0.0001
Pediatric	434 (5.2)	1562 (6.6)	
Adult	7927 (94.8)	22282 (93.4)	
Donor type			<0.0001
Deceased	7007 (83.8)	17 774 (74.5)	
Living	1354 (16.2)	6070 (25.5)	
Recipient sex			0.0212
Female	3028 (36.2)	8973 (37.6)	
Male	5333 (63.8)	14 871 (62.4)	
Recipient ethnicity			<0.0001
White	5248 (62.8)	13 726 (57.6)	
Black	1553 (18.6)	4980 (20.9)	
Hispanic	1033 (12.4)	3496 (14.7)	
Asian	403 (4.8)	1289 (5.4)	
Other/unknown	124 (1.5)	353 (1.5)	
Recipient blood type			0.8204
A	3160 (37.8)	8943 (37.5)	
B	413 (4.9)	1204 (5.0)	
AB	1138 (13.6)	3180 (13.3)	
O	3650 (43.7)	10 517 (44.1)	
Recipient citizenship			<0.0001
US citizen	8065 (96.5)	22 599 (94.8)	
Other/unknown	296 (3.5)	1245 (5.2)	
Recipient primary source of payment			0.0777
Private	3504 (41.9)	10 129 (42.5)	
Public: Medicare, Medicare FFS, Choice	3868 (46.3)	11 057 (46.4)	
Public: Medicaid	718 (8.6)	1923 (8.1)	
Public: Other (CHIP, VA, Other)	228 (2.7)	570 (2.4)	
Other/unknown	43 (0.5)	165 (0.7)	
Previous transplant?			0.5923
No	7598 (90.9)	21 621 (90.7)	
Yes	763 (9.1)	2223 (9.3)	
Most recent OPTN patient status			<0.0001
Alive	4225 (50.5)	23 409 (98.2)	
Deceased	3586 (42.9)	0 (0.0)	
Lost to follow-up	39 (0.5)	435 (1.8)	
Retransplanted	511 (6.1)	0 (0.0)	

^a Recipients considered to have extended patient survival time had more than 7 days added.
IQR, interquartile range.

1.97; 95% CI, 1.13-3.43) were marginally more likely to have their patient survival time extended versus US citizens and recipients with private insurance, respectively. There were no other significant differences.

DISCUSSION

The OPTN database contains records on over 900 000 patients with approximately 30 000 data elements relating to

donor, waiting list, and transplant data. As the current OPTN contractor, United Network for Organ Sharing is responsible for collecting and maintaining the database. Over time, it is thought that the database has improved with regard to complete and accurate data, for reasons including, but not limited to, increased outreach, data submission requirements in policy, and the movement from paper to electronic data submission. Moreover, OPTN data are augmented with

FIGURE 3. AOR plot of extension of patient survival time and various recipient characteristics for solitary kidney, liver, heart, or lung transplants performed between November 1, 2011, and January 31, 2013.

additional external sources of data to enrich the OPTN database and allow for more accurate estimates of patient survival, a practice that has been in place since 2004.

Although the OPTN database contains a plethora of information, there are subsets of the recipient population who may not have complete information with regard to posttransplant survival. With access to external data sources, the OPTN data can be enriched with external death dates to allow for more accurate analysis, which in turn can improve transplant policy development, among other things. It was the intent of this study to determine if augmenting OPTN data with external death data altered patient survival estimates.

Because using the OPTN database alone captures fewer deaths than data that includes external deaths, it was anticipated that patient survival estimates using OPTN only might be higher than all other data sources. Additionally, because OPTN + all (Assumed Alive) extends patient survival times, patient survival rates calculated using this data source were thought to be slightly higher than that of OPTN + verified and OPTN + all.

Several conclusions can be drawn from this study. First, the analyses demonstrated that the inclusion of these external death data for OPTN + verified and OPTN + all yielded survival rates that are slightly lower than OPTN only and OPTN + all (Assumed Alive), but still very comparable. Additionally, OPTN only and OPTN + all (Assumed Alive) tended to yield

similar patient survival rates to one another, whereas OPTN + verified and OPTN + all also tended to yield similar rates to one another as well. However, differences between any source comparisons were very small. Furthermore, adding additional death dates without extending survival days for those without a death date tends to slightly bias patient survival rates downward versus OPTN only data, although these differences were not found to be statistically significant. Longer follow-up is needed to assess if the impact of augmenting OPTN data with external death data changes as the time from transplant increases.

It was expected that many recipients would need days added to their patient survival time in order to get current given the likely difference between their transplant anniversary and the Assumed Alive cutoff date used in this analysis. This is evident by observing that many recipients had days added to their patient survival time, but the vast majority had their patient survival time extended by less than 1 year's worth of time.

When comparing recipients (in univariable analyses) who had extended patient survival time in the Assumed Alive scenario to those who did not, there were many statistically significant differences, although few appeared clinically relevant and were likely due to large sample sizes. Results of a subsequent multivariable analysis showed that both kidney and lost to follow-up recipients were significantly more likely

have their patient survival time extended than other organ recipients or recipients who are alive in the OPTN database as of their most recent follow-up. OPTN + all (Assumed Alive) was structured around the fact that if a recipient did not have a death attached, that recipient should be assumed to still be alive as of a specified date, so it was expected that lost to follow-up recipients would have days added to their survival time. The prevalence of kidney recipients having days added to their patient survival time could be due to several factors. The majority of transplant recipients are kidney, so it is possible that the large sample compared to liver, heart, or lung recipients naturally captures more of these patients. Moreover, a kidney recipient could theoretically seek care at a primary care office or a dialysis facility (in the case of graft failure) rather than a transplant center posttransplant, while recipients of other organs often require more specialized follow-up care provided at the transplant center.

It is noteworthy to mention the difference in the cumulative number of deaths captured by OPTN only and OPTN + all in Table 1 does not represent data error, but rather represents missing, unknown, or unreported data to the OPTN from the transplant centers. Because the inclusion of external death data may provide a more holistic view of posttransplant patient survival, when researchers request data from the OPTN via Standard Transplant Analysis and Research files, they now have access to OPTN + verified data as opposed to OPTN only data and SSDMF death dates [as of the December 2014 release]. The OPTN and Scientific Registry of Transplant Recipient contractors are permitted to use unverified deaths in aggregate analysis, but these deaths may not be released in an identifiable manner, and thus are not included in the Standard Transplant Analysis and Research files or otherwise made available to the public.

The strengths of this study include (1) the use of the OPTN dataset, the largest transplant database in the United States; (2) the use of a cohort after the SSDMF removal of state records for consistency; (3) stratification by organ to analyze potential organ differences as well as the effect for both large and small sample sizes; (4) allowing all recipients in the study cohort to reach their 3-year posttransplant follow-up anniversary while leaving time for the form submission deadline; (5) the use of statistical modeling to make comparisons across the data sources that do and do not include external death data; and (6) the comparison between patients who had extended patient survival time under the Assumed Alive assumption versus those that do not.

There are also several limitations to this study. First and foremost, we are unable to release all of the external data sources to obtain death dates, and therefore cannot provide the number/percentage of deaths verified by source. Additionally, we are unable to release the sources used to obtain unverified death dates. Also, this analysis was based on transplants as opposed to recipients. A patient receiving multiple transplants and then becoming deceased could, in some cases, be counted as multiple deaths in the analysis, potentially biasing the patient survival rates downward.

In summary, the results across all data sources do not differ substantially for the aggregate analyses, so the choice of data source is not critical. Despite this, a more accurate and complete database is always preferable. Using only OPTN data is a reasonable source of ascertainment of patient survival, although it does yield slightly higher patient survival estimates. Bias may occur when augmenting OPTN data with external data sources but not extending the patient survival time for recipients with no death date, although the difference was not statistically significant. Therefore, it is recommended to use the Assumed Alive assumption if adding in external sources of death data to mitigate this bias. It remains important for transplant centers to maintain contact with transplant recipients and obtain the necessary follow-up information as this information can help improve the transplantation process for future recipients.

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