# Lost in Transplantation: Evaluating the Efficiency of Organ Procurement in the United States

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# Lost in Transplantation: Evaluating the Efficiency of Organ Procurement in the United States

# Abstract

In this paper, we provide a broad analysis of the performance of organ procurement organizations (OPOs) in the United States and investigate factors affecting the number and quality of procured organs. Using comprehensive data from 51 OPOs' annual cost reports from 2015 to 2020, we find wide variability in the number of procured organs and the percentage of non-viable organs across the different OPOs, and we empirically explain the drivers behind the geographic disparities. We find that the variability is partly explained by the geographic area an OPO covers, the percentage of the population registered as organ donors, the total number of OPO employees, the number of organ-donating hospitals and transplant centers per OPO, and the cause of death (especially drug-induced and motor-vehicle-accident-related). Our findings can help practitioners and policymakers improve the organ procurement process using concrete data and statistical tools.

# 1. Introduction

The global organ transplantation market is a growing market whose annual value is estimated at USD 12.4 billion.<sup>1</sup> The United States has the world's largest organ transplant program, with 41,354 organs transplanted in 2021.<sup>2</sup> The key players in the US organ transplantation system are the 57 US organ procurement organizations (OPOs) that comprise the Organ Procurement Transplantation Network (OPTN).<sup>3</sup> Regulated by the Centers for Medicare & Medicaid Services (CMS) under the National Organ Transplant Act of 1984, OPOs are not-for-profit entities that operate under federal contract to cover a specific geographic area. Within each area, an OPO is exclusively responsible for identifying eligible donors, recovering organs from deceased donors, obtaining consent for organ donation from next of kin, and transporting organs to transplant center hospitals (Hardart et al., 2017).

Although the US organ transplant program appears solid and the number of transplants increases substantially every year, there is a persistent shortage of organs available for transplantation. Over 107,000 Americans are on the US organ transplant wait list; an average of 150 people are added daily; and approximately 7,500 people on the wait list die annually.<sup>4</sup> In the U.S. Congress, the House Oversight Committee<sup>5</sup> and the Senate Finance Committee<sup>6</sup> each recently investigated the OPOs' performance, finances, and conflicts of interest and found the US procurement transplantation system to be vastly inefficient. In addition, a recent investigation by the CMS ranked more than half of all OPOs as failing or underperforming. Moreover, the CMS investigation estimated that up to 28,000 organs available from deceased donors go unprocured each year. This loss comes in addition to a high percentage of procured organs that, for multiple reasons, eventually become nonviable for patients on the waiting list.<sup>7</sup>

<sup>&</sup>lt;sup>1</sup> Grand view research market analysis report (2022). Available at <u>Transplantation Market Size & Share Report, 2022-</u> 2030 (grandviewresearch.com).

<sup>&</sup>lt;sup>2</sup> United Network for Organ Sharing (UNOS) report, 1/11/2022. Available at <u>All-time records again set in 2021 for</u> organ transplants, organ donation from deceased donors - UNOS.

<sup>&</sup>lt;sup>3</sup> Prior to Dec 31, 2020, there were 58 OPOs. As of January 1, 2021, two OPOs – LifeChoice Sonor Service and New England Donor Bank – had merged, bringing the total number to 57.

<sup>&</sup>lt;sup>4</sup> United Network for Organ Sharing (UNOS) data report, 2022. Available at <u>National data - OPTN (hrsa.gov)</u>. Accessed June 1, 2022.

<sup>&</sup>lt;sup>5</sup> <u>Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ</u> <u>Transplant Industry | House Committee on Oversight and Reform.</u>

<sup>&</sup>lt;sup>6</sup> Chairman's News | Newsroom | The United States Senate Committee on Finance

<sup>&</sup>lt;sup>7</sup> "Reforming Organ Donation in America." Bridgespan.org, The Bridgespan Group.

In this paper, we delve into the US procurement market using comprehensive data from 51 OPOs' annual cost reports (Form CMS 216-94) from 2015 to 2020—obtained under the Freedom of Information Act (FOIA)—in addition to data sources such as the American Hospital Directory, the Centers for Medicare & Medicaid Services, and the Centers for Disease Control and Prevention. We start by providing a comprehensive overview of the US procurement market. Next, using explanatory variables related to the OPO's assigned geographic area, OPO structure, and cause of death, we investigate i) factors affecting the number of organs procured by OPOs and ii) factors affecting the percentage of *viable* organs among all organs procured by OPOs. Finally, we assess whether the new CMS three-tier classification system can partially solve the issues we discuss. Our ultimate goals are to investigate the factors affecting the number or quality of procured organs and to help practitioners and policymakers improve the organ procurement process using concrete data and statistical tools.

First, we find wide variability in the number of procured organs and the percentage of nonviable organs across the different OPOs. The number of procured organs per year per OPO ranges from 115 to 2,158, while the percentage of non-viable organs spans 9%-25%. Examining the variation in the total number of procured organs, we demonstrate that when an OPO covers a larger geographic area, it procures fewer organs per 100,000 people. This finding suggests that OPOs are more effective in densely populated geographic areas (i.e., urban areas). Hence, opening less dense areas to more competition, increasing the number of OPO employees in less dense areas, or changing the incentive scheme based on population density could increase the number of organs procured per 100,000 people. We also provide evidence that incentivizing people to register as organ donors, adding OPO employees, and developing efficient systems for coordinating with organ-donating hospitals could increase the number of procured organs. We also find a significant positive correlation between drug-induced and motor-vehicle-accident-related death and the number of procured organs. To the best of our knowledge, our study represents the first research to analyze cause of death for the general population—i.e., all potential donors—in relation to organ procurement. The latter results support the claim that OPOs' increased organ procurement in recent years may be attributable to the drug epidemic and to the increase in motor vehicle deaths. Hence, the number of procured organs may decline if the US makes progress in these areas in the coming years. This possibility underscores the importance of improving the US procurement transplantation system.

Next, we show that approximately 15% of organs are unviable. This means that, on average, each OPO discards approximately 120 organs every year. When we explore the variation in the number of viable organs, we find that the size of an OPO's geographic area has a negative impact on the number of viable organs per 100,000 people. One explanation for this, based on our conversation with industry experts, is that organ coordinators usually are stationed in close proximity to an OPO headquarters in an urban area. When OPOs cover large rural areas, a higher percentage of organs become nonviable because the ischemic time (the time in which organs are viable for transplantation) is exceeded as organs are located, recovered, and transported. Thus, limiting an OPO's geographic area—especially its less population-dense areas—and having more employees who are physically located in less population-dense areas, could increase organ quality.<sup>8</sup> OPO performance could also be improved by implementing more education, for both OPO and donating-hospital employees, regarding organ donation procedures, and by streamlining coordination systems. In addition, we show that increasing the number of transplant centers from an average of 4.5 per OPO could help OPOs locate recipients during the ischemic time and reduce the rate of organ discard. When we examine the impact of cause of death on organ quality, we find that the number of donors who die due to drug intoxication or motor vehicle accidents is positively associated with both the total number of viable organs and the percentage of total viable organs out of all the organs. These results support our claim that the increased number of transplant procedures in the US is significantly attributable to the drug epidemic and the increase in motor vehicle deaths, rather than to improved OPO efficiency.

Finally, we examine a new Department of Health and Human Service (HHS) rule that i) classifies OPOs into three performance-based tiers, ii) opens the OPOs' designated service areas to more competition, and iii) allows the federal contracts of underperforming OPOs to be revoked. Our findings suggest that implementing the new three tiers rule (CFR 42-486) will increase both the quantity and the quality of procured organs, saving thousands of lives every year.

Our paper contributes to recent management and healthcare literature that focuses on theoretical modeling of the organ transplantation system (Kong et al. 2010; Dai and Tayur 2020; Dai et al. 2020; Kskinocak and Savva 2020) and identification of the drivers behind geographic

<sup>&</sup>lt;sup>8</sup> Simply increasing the total number of full-time OPO employees and the number of organ-donating hospitals may increase the number of total organs procured, but it could reduce the quality of those organs.

disparities in that system. We also contribute to recent empirical research on the organ transplantation system. For example, Wang et al. (2022) study the impact of direct flights on the total number of transplanted kidneys, and Held et al. (2021) examine disparities in kidney cost. In contrast to these papers, our research focuses not only on kidneys but also the four other most frequently transplanted solid organs (liver, heart, lungs, and pancreas); these five organs together represent over 98% of the solid organs market (Held et al. 2021). Our study also attempts to identify possible drivers for the number of organs procured and the quality of those organs, taking into account the OPOs' geographic areas and organizational structures and the causes of death in those areas. In addition, to the best of our knowledge, our paper is the first to use a comprehensive database of OPOs and to provide a thorough overview of the US procurement market. By using concrete and comprehensive data powered by statistical tools, we can help practitioners and policymakers improve the organ procurement process.

The remainder of the paper proceeds as follows. In Section 2, we discuss the sample selection process and descriptive statistics. In Section 3, we present the empirical results. We draw our conclusions in Section 4.

## 2. Sample Selection and Descriptive Statistics

## **2.1. Sample Selection**

Our sample comprises 51 independent OPOs and includes data from 2015 to 2020. We manually collected all financial and operational information related to procurement activities from federally mandated reports (Form CMS 216-94) obtained under a FOIA request. Data from seven hospital-based OPOs were not available under the FOIA request. The federally mandated reports include information about the OPOs' revenue, expenses, operations, and total organs retrieved. For each OPO, we supplement this data with specific geographic information on the number of hospitals (American Hospital Directory and Scientific Registry of Transplant Recipients), information on mortality and population (Centers for Disease Control and Prevention), donor-specific data (Organ Procurement and Transplantation Network), Medicaid data (Medicaid.com), the wage index (Centers for Medicare & Medicaid Services), and donor registration data (National Donate Life Registry). The comprehensive database we develop using these sources allows us to avoid using OPOs' self-reported "death metric," which has been shown to have numerous

limitations and has been widely criticized by researchers and policymakers (Goldberg et al., 2015, 2017; Siminoff et al., 2018). A total of 276 OPO-year observations are included in the final sample.

#### 2.2. Descriptive Statistics

Table 1 presents a statistical summary of all variables used in this study. Panel A of Table 1 presents the descriptive statistics (mean, median, standard deviation, 25%, and 75%) for the total number of organs as well as the number of viable organs procured by each OPO every year.

As seen in Panel A, the average (median) number of the most commonly transplanted solid organs that each OPO procures in a year is 764.1 (688).<sup>9</sup> The average (median) number of organs procured per 100,000 people is 9.9 (8.9). Approximately 85% of the organs procured (642.3 organs) are viable; hence, each OPO wastes, on average, 122 organs each year. Figures 1A and 1B illustrate the wide variability, across OPOs, in the number of procured organs and the percentage of non-viable organs, respectively. The number of procured organs ranges from 115 to 2,158, while the percentage of non-viable organs spans 9%–25%. Figures 1A and 1B do not indicate that a relationship exists between the number of procured organs and the percentage of viable organs.

The most commonly procured organs are the kidney (which makes up more than 50% of the market), liver, heart, lungs, and pancreas. On average, the kidney accounts for 393.4 procured organs per OPO, followed by the liver (190.4), heart (76.7), lungs (69.6), and pancreas (33.8). The heart has the highest viability percentage at approximately (96%), while the pancreas has the lowest (67%). Only about two-thirds of procured pancreas organs are transplanted.

Panel B of Table 1 reports the descriptive statistics (mean and standard deviation) of the dependent and independent variables and the correlation coefficients between variable pairs. The average OPO covers a geographic area of 66,152 square miles. The average annual number of deaths in each geographic area (*Total\_Death*) is 93,193, of which 52,334 are people 75 years of age and older. The average number of registered donors per OPO (*Total\_Reg\_Donors*) is approximately 4.5 million, and the number of Medicaid enrollees (*Total\_Medicaid*) is 2.6 million. The average number of full-time employees per OPO (*Full\_Time\_Emp*) is 142, and each OPO works with approximately 36 donating hospitals. On average, an OPO has 4.5 Medicare-approved transplant centers within its service area. Panel B also provides information on cause of

<sup>&</sup>lt;sup>9</sup> The most commonly transplanted solid organs—the kidney, liver, heart and pancreas—account for approximately 98% of the solid organ market (Held et., 2021).

death. In each geographic region, on average, 2,357 people die annually from drug-related causes, 1,227 die from alcohol-related causes, 1,502 die from self-harm, and 1,382 die in car accidents. The correlation analyses demonstrate that most of the correlations are considerably less than the 0.8 threshold that would suggest multicollinearity (Gujarati, 2019).

#### **3.** Empirical Results

#### **3.1. Total Organs Procured**

The CMS investigation estimated that up to 28,000 available organs from deceased donors go unprocured each year, and Figure 1A reveals wide variability in the number of procured organs between different OPOs. Cannon et al. (2019) examine patterns of geographic variability in mortality and find no evidence that geographic patterns play a role in OPO performance. This finding prompts us to examine the variation in total organs recovered from deceased donors across different OPOs.

Table 2 presents the results of the analysis of the total organs procured (viable and nonviable) by each OPO. In Models 1–3, the dependent variable is the log of the number of organs procured by an OPO each year (Total Organs). Models 4-6 examine the total number of organs procured per 100,000 people (Total Organs per 100K). In Models 1 and 4, we include explanatory variables related to the assigned geographic area (Land Area, Total Death, Above 75 Death, Total Reg Donors, Total Medicaid, and Wage Index). In Models 2 and 5, we also include attributes related to OPO structure (Full Time Emp, Donating Hospitals, and *Transplant Hospitals*). Finally, Models 3 and 6 control for the total number of deaths in the service according of death (Total Drug Death, Total Alcohol Death, area to cause Total Self Harm Death, and Total Car Death). The log of the explanatory variables is used for all the tests.

First, we consider the relationship between organ procurement and an OPO's assigned geographic area. In Model 3, the estimated coefficient on *Land\_Area* is 0.208 and significantly positive, demonstrating that an OPO procures more organs, on average, when its geographic coverage area is larger. On the other hand, in Model 6, the coefficient on *Land\_Area* is -0.001 and significantly negative, indicating that an OPO procures fewer organs per 100,000 people when its coverage area is larger. These results suggest that OPOs are more efficient when they oversee smaller or more densely populated geographic areas (urban zones). Table 2 also indicates that the

number of organs procured by an OPO (both in total and per 100,000 people) is positively associated with the total number of deaths in the given year (*Total\_Death*) and negatively associated with the number of people enrolled in Medicaid (*Total\_Medicaid*). Model 6 provides evidence that the number of organs procured per 100,000 people increases when the number of deaths among people aged 75 and over falls (*Above\_75\_Death*) and when the number of registered donors rises (*Total\_Reg\_Donors*). Although *Above\_75\_Death* and *Total\_Reg\_Donors* are significantly correlated with *Total\_Organs\_per\_100K*, they are not correlated with *Total\_Organs*. In total, these results suggest that limiting the each OPO's geographic coverage area (especially its less population-dense areas), opening an OPO's less dense areas to more competition, increasing the number of OPO employees in less dense areas, and incentivizing people to register as organ donors could all increase the relative number of organs procured per 100,000 people. On the other hand, these results might also suggest that the OPOs' incentives are not properly aligned with maximizing the total number of procured organs, and that OPOs, in their donor-registration efforts, disproportionally target individuals in urban areas.

Next, we examine the relationship between organ procurement and OPO attributes. The results from Model 3 indicate that the number of full-time employees at an OPO (*Full\_Time\_Emp*) and the number of organ-donating hospitals in the area (*Donating\_Hospitals*) are positively associated with the number of organs the OPO procures (both in total and per 100,000 people). The estimated coefficient of *Full\_Time\_Emp* is 0.001 with a p-value of 0.001, and the coefficient of *Donating\_Hospitals* is 1.877 with a p-value of 0.001. The results on employees suggest that increasing the number of full-time OPO workers (especially in more rural areas) and providing them with more professional education could improve OPO performance. The results on hospitals imply that, to improve performance, OPOs should develop efficient and timely coordinating systems with as many organ-donating hospitals as possible (and ignore Section 371(b)(3)(A) of the Public Health Service Act, which does not require them to have agreements with all of the organ-donating hospitals in their areas).

Finally, we examine the relationship between organ procurement and cause of death for the general population (entire potential donors). Model 6 shows a negative association between alcohol-related deaths (*Total\_Alcohol\_Death*) and *Total\_Organs\_per\_100K*. More importantly, however, we find that drug-induced deaths (*Total\_Drug\_Death*) and motor-vehicle-accident-

related deaths (*Total\_Car\_Death*) are significantly and positively correlated the number of procured organs (both in total and per 100,000 people). Given that, between 2015 and 2020 in the US, the national mortality rate for drug overdoses increased by approximately 75% (from 52,404 deaths to 91,799) and the national mortality rate for motor-vehicle-related deaths rose by approximately 10% (from 35,485 to 38,824), our results provide evidence that the recent increase in organ procurement by OPOs is significantly attributable to drug- and motor-vehicle-related deaths. Hence, the number of procured organs may decline if the US makes progress against the drug epidemic or in promoting highway safety. This possibility highlights the importance of improving to the US procurement transplantation system.

#### **3.2.** Viable and Non-Viable Organs

Table 2 demonstrates that approximately 15% of organs are unviable, which means that each OPO, on average, discards approximately 120 organs every year. The leading reasons for organ discard, according to Mohan et al. (2018), are findings during biopsy, poor organ function, and inability to locate a recipient during the ischemic time. Even when an organ is nonviable, the CMS reimburses OPOs for all related costs (as it does for viable kidneys) (Chapter 33 in Form CMS-216-94). Furthermore, Held et al. (2021) show that OPOs that retrieve more nonviable kidneys experience higher costs and reimbursements per kidney. Therefore, OPOs appear to have a financial incentive to improve the total number of procured organs but not the efficiency of the organ recovery process. Based on these points, our second research question explores variation in the number of viable organs procured and suggests ways to increase the supply of viable organs.

Table 3 reports our estimation results analyzing the viable organs procured by each OPO. In Models 1–3, the dependent variable is the log of the number of viable organs procured by an OPO each year (*Total\_Viable\_Organs*). Models 4–6 examine the total number of viable organs per 100,000 people (*Total\_Viable\_Organs\_100K*), and Models 7–9 test the percentage of viable organs (*Perc\_Viable\_Organs*). Similar to Table 2, we include, in Models 1–9, explanatory variables related to the assigned geographic area, OPO structure, and cause of death.

We begin with variables related to the assigned geographic area. Table 3 Model 3 documents a positive association between *Total\_Viable\_Organs* and *Land\_Area*, indicating that OPOs that cover a larger geographic area procure more viable organs in total. However, Model 6 reveals a significantly negative coefficient between *Land\_Area* and *Total\_Viable\_Organs\_100K*, and

Model 9 reveals a marginally negative coefficient between Land\_Area and Perc\_Viable\_Organs. These results suggest that limiting the each OPO's geographic coverage area, especially the less densely populated areas, will increase not only the number of viable organs procured per 100,000 people but also organ quality (i.e., the percentage of viable organs). Table 3 also shows that organ quality (Perc\_Viable\_Organs) is significantly positively associated with the total number of deaths (Total\_Death) and the average number of registered donors (Total\_Reg\_Donors) and negatively associated with the number of deaths in adults aged 75 years and older (Above\_75). Total\_Medicaid has a significant negative relationship with the total number of viable organs but not with the percentage of viable organs. These results suggest that limiting an OPO's geographic area (especially its less population dense areas), opening the less dense areas to more competition, and increasing the number of employees in less dense areas could improve the OPOs' effectiveness in terms of both the number and percentage of viable organs procured.

Regarding OPO structure, both *Full\_Time\_Emp* and *Donating\_Hospitals* are positively correlated with the total number of viable organs but negatively correlated with the percentage of viable organs. These results suggest that increasing the number of full-time OPO employees, providing more professional education to these employees, and raising the number of organ-donating hospitals per OPO can increase the total number of viable organs, but may also reduce average organ quality. Thus, OPO performance and the number of successful transplants might be improved through i) more professional education, for both OPO and donating-hospital employees, regarding organ donation procedures, and ii) better systems for coordinating with organ-donating hospitals. In addition, we find a significant correlation between the number of Medicare-approved transplant centers (*Transplant\_Hospitals*) and all measures of OPO effectiveness. This is not surprising, given that these centers can facilitate locating a recipient during the ischemic time and reduce the rate of organ discard. Currently, each OPO, on average, works with only 4.5 Medicare-approved transplant centers. Augmenting this number is likely to improve OPO performance.

Finally, when we assess the impact of cause of death on the number and percentage of viable organs, we include the variables *Actual\_Drug\_Death*, *Actual\_Alcohol\_Death*, *Actual\_Self\_Harm\_Death*, and *Actual\_Car\_Death* to represent the number of total drug-, alcohol-, suicide-, and motor-vehicle-related deaths among donors in a specific donation service area.

These variables, unlike those in the Sections 3.1 and 3.2, were calculated from the sample of actual organ donors rather than from the general population. Models 3, 6, and 9 in Table 3 support that an increased number of donors who died due to drug intoxication or a motor vehicle accident is positively associated with both the total number of viable organs and the percentage of viable organs out of all procured organs. The results in Models 6 and 9 also marginally support the argument that organs procured from donors with an alcohol-related cause of death are of lower quality: on average, the number and percentage of viable organs in these cases are lower than for organs procured following deaths from other causes. The results related to actual causes of death provide additional support for our claim that the increase in transplant procedures in the US in recent years is attributable to the drug epidemic and rising motor vehicle deaths, not to an increase in OPO efficiency.

# **3.3.** Type of Organs

This section explores whether the market for procured organs behaves differently depending on the organ type. Prior research has largely examined the kidney organ market (e.g., Held et al., 2021) and ignored other major organs. Table 1 identifies the most commonly procured organ as the kidney (which accounts for over 50% of the market), followed by the liver, heart, lungs, and pancreas. In light of this, we compare the amount and quality of OPO-procured kidneys to the amount and quality of other OPO-procured organs. Table 4 presents the results. Models 1-3 examine the variation in the kidney market, while models 4–6 analyze the other procured organs. The dependent variables Total Organs Per 100K in Models 1 3. are and Total Viable Organs 100K in Models 2 and 4, and Perc Viable Organs in Models 3 and 6.

The variable *Land\_Area* has a significantly positive correlation with the total number of procured kidneys (coefficient 0.001) but a significantly negative correlation with the other procured organs. And while *Land\_Area* does not seem to impact the viability level of kidneys (measured by total viable kidneys per 100,000 people and by the percentage of viable kidneys), it has a significantly negative impact on the viability of other organs (measured by total viable organs per 100,000 people and by the percentage of viable organs per 100,000 people and by the percentage of viable organs. The differences in the viability results could be attributable to differences in the organs' ischemic time. Because the kidney's ischemic time is the longest of the major organs, the kidney remains viable longer, which is a benefit when

longer travel is required.<sup>10</sup> Table 4 also indicates a significant difference between the impacts of *Total\_Death* and *Above\_75\_Death* on *Perc\_Viabl\_Organs*. These variables have no significant impact on the percentage of viable kidneys, but have a significant positive impact on the viability percentages of other organs. In contrast, *Full\_Time\_Emp* reduces the percentage of viable kidneys but has no impact on other organs. When we assess the impact of cause of death on OPO effectiveness using different organ types, we find that drug overdose deaths have a strong positive impact on both the total number of procured kidneys and the total number of other procured organs. In addition, drug overdose deaths have a significant positive impact on the viability percentage of viable kidneys). Alcohol-related deaths produce a nearly opposite effect: a negative impact on the viability of other organs and no impact on kidney viability. Finally, Table 4 also provides evidence that the total number of procured kidneys.

## **3.4. OPO Ratings**

In early 2021, HHS revised the CFR 42-486 rule regarding OPO outcome measure requirements.<sup>11</sup> The new HHS rule is designed to open the designated service area to more competition and permits revoking the federal contract for designated service areas for OPOs that are classified as underperforming (Tier 2) or failing (Tier 3). HHS projects that comply with the rule are expected to save 7,000 lives per year, and projections suggest that Medicare will save USD 1 billion annually in forgone dialysis costs for transplanted organs.

The OPO rating is based on 2020 data from the website opodata.org. The data includes 22 (43%) Tier 1 OPOs, 11 (22%) Tier 2 OPOs, and 18 (35%) Tier 3 OPOs. Table 5 presents the associations between OPO ratings and tier classification. Columns 1, 2, and 3 examine the association between OPO ranking and *Total\_Organs\_Per\_100K*, *Total\_Viable\_Organs\_100K*, and *Perc\_Viable\_Organs*, respectively. The coefficient on *Tier\_3\_Indicator* in Column 1 of Table 5 is -0.462, suggesting that Tier 3 OPOs procure significantly fewer organs than Tier 1 and 2 OPOs. However, we find no significant association between *Total\_Organs\_Per\_100K* and *Tier\_1\_Indicator*, indicating that the total number of organs procured by Tier 1 OPOs is insignificantly different from that of Tier 2 OPOs. Columns 2 and 3 examine the correlation

<sup>&</sup>lt;sup>10</sup> Organ Preservation: Practice Essentials, Pathophysiology of Organ Preservation, Preservation Solutions and Their Pharmacology (medscape.com)

<sup>&</sup>lt;sup>11</sup> <u>CMS-3380-F\_11-20-20\_updated@430.docx</u>

between OPO tier and procured organ viability. We find a significant positive correlation between *Tier\_1\_Indicator* and measures of viability and a significant negative correlation between *Tier\_3\_Indicator* and measures of viability. These results suggest that, relative to Tier 3 OPOs, Tier 1 OPOs procure higher quality organs or are more efficient in locating recipients or transferring organs during the ischemic time. The results of the association between geographic area, OPO structure, and cause of death and the quality measure are qualitatively similar to our results in prior sections. Our findings propose that invoking the new CFR 42-486 rule—i.e., opening designated service areas to more competition and revoking federal contracts for designated service areas of underperforming OPOs—will increase both the quantity and the quality of organs and can save thousands of lives every year.

## 4. Conclusion

The United States has the world's largest organ transplant system. The key players in the system are 57 OPOs, each of which is exclusively responsible for identifying eligible donors, recovering organs from deceased donors, obtaining consent for organ donation from next of kin, and transporting organs to transplant center hospitals within a specific geographic area. Despite the efforts of these OPOs, there is a persistent shortage of organs available for transplantation, and a CMS investigation estimated that i) up to 28,000 available organs from deceased donors go unprocured each year and ii) a high percentage of procured organs become nonviable.

We provide the first broad analysis of performance of organ procurement organizations (OPOs) in the United States. Using comprehensive data from 51 OPOs' annual cost reports from 2015 to 2020, we empirically investigate the factors affecting the number and quality of procured organs. The paper offers data-based and statistically sound recommendations to help practitioners and policymakers improve the organ procurement process. For example, we indicate that OPOs are more effective in dense geographic areas (i.e., urban areas), so developing efficient coordinating systems with as many organ-donating hospitals as possible and increasing the number of transplant centers could improve the organ procurement process. Our paper also raises the concern that if the increased number of OPO-procured organs in recent years is significantly attributable to drug- and automobile-related deaths, then progress in these areas may lead to future declines in procured organs. Finally, our results indicate that the revised HHS rule on the outcome

measure requirements for OPOs is a step towards improving the organ procurement market; however, improving the organ procurement market will require HHS to open the designated service area to more competition or to revoke federal contracts for designated service areas for OPOs classified as underperforming or failing.

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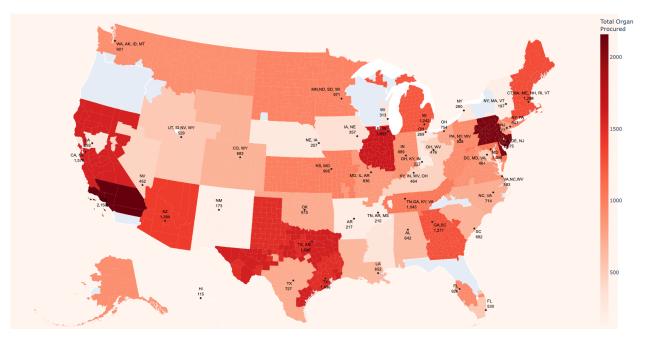
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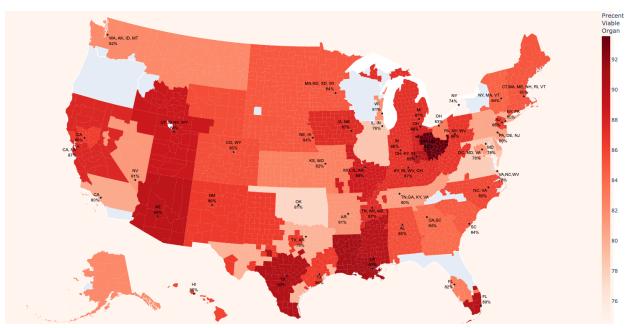
# Figure 1

# Average Organ Procurement in the US



# (A) Maps of Total Organs by Service Area

(B) Maps of Percentage Viable Organs by Service Area



		Descriptive St	austics		
Panel A: Procured Organs					
	Mean	Median	SD	25%	75%
Total Organs	764.1	688	499.6	319	1017.5
Total Organs 100K	9.9	8.9	6.5	5	14.1
Total Viable Organs	642.3	589	410.7	284.5	836.5
Perc Viable Organs	84.7	85.1	4.8	81.3	87.8
Total Kidney	393.4	348.5	261.4	184.5	518
Total Kidney 100K	5.1	4.9	3.4	2.4	7.1
Total_Viable_Kidney	320.7	294.5	208.5	153	405
Perc Viable Kidney	82.1	82.5	5.4	78.9	86.2
Total Liver	190.4	172	126.9	79.5	254
Total Liver 100K	2.4	2.1	1.6	1.2	3.6
Total_Viable_Liver	167.4	148.5	109.2	69.5	220
Perc Viable Liver	88.7	89.1	6.7	83.7	93.9
Total Heart	76.7	67	53.1	34	104.5
Total Heart 100K	1	0.8	0.7	0.4	1.3
Total_Viable_Heart	74.7	66	50.1	35	100.5
Perc Viable Heart	96.2	97.2	4.6	94.4	100
Total Lung	69.6	57.5	55.2	23	97.5
Total Lung 100	0.9	0.7	0.7	0.3	1.2
Total_Viable_Lung	58.7	45.5	48.3	20	81
Perc Viable Lung	84.7	85.7	12.5	77.6	95.1
Total Pancreas	33.8	28	25.41	14	47
Total Pancreas 100	0.4	0.3	0.3	0.1	0.6
Total_Viable_Pancreas	21.5	18	15.5	10	30
Perc_Viable_Pancreas	67.3	68.3	19.2	53.5	80

Table 1Descriptive Statistics

Panel B: Descriptive Statistics

I allel D. Dese		41151105																		
	Mean	SD	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)
1)Total_Organs	764.1	499.6	1.00																	
2)Total_Organs_per_100K	9.9	8.9	0.32	1.00																
3)Total_Viable_Organs	642.3	410.7	0.99	0.32	1.00															
4)Total_Viable_Organs_100K	8.4	5.5	0.30	0.99	0.31	1.00														
5)Perc_Viable_Organs	84.7	4.8	-0.20	-0.11	-0.13	-0.03	1.00													
6)Land_Area	66,152	71,336	0.11	0.24	0.11	0.24	-0.02	1.00												
7)Total_Death	93,193	71,665	0.38	-0.57	0.39	-0.58	0.01	-0.16	1.00											
8)Above_75	52,334	39,811	0.36	-0.57	0.36	-0.58	-0.03	-0.19	0.99	1.00										
9)Total_Reg_Donors	4,591,465	3,608,712	0.42	-0.51	0.42	-0.52	0.03	-0.04	0.94	0.92	1.00									
10)Total_Medicaid	2,666,126	3,010,352	0.31	-0.49	0.31	-0.49	-0.04	-0.10	0.87	0.89	0.87	1.00								
11)Wage_Index	0.86	0.16	0.19	-0.14	0.19	-0.14	0.07	0.22	0.36	0.36	0.44	0.57	1.00							
12)Full_Time_Emp	142.1	163	0.28	0.03	0.27	0.01	-0.23	-0.03	0.09	0.07	0.13	0.06	0.04	1.00						
13)Donating_Hospitals	36.4	22.2	0.87	0.12	0.86	0.10	-0.16	0.09	0.43	0.41	0.47	0.39	0.26	0.22	1.00					
14)Transplant_Hospitals	4.5	3.3	0.74	0.20	0.73	0.19	-0.14	0.09	0.26	0.25	0.25	0.15	0.17	0.20	0.79	1.00				
15)Total_Drug_Death	2,357	1,765	0.30	-0.53	0.31	-0.54	0.03	-0.24	0.88	0.90	0.77	0.75	0.29	0.03	0.34	0.21	1.00			
16)Total_Alcohol_Death	1,227	1,206	0.34	-0.46	0.35	-0.47	0.00	-0.04	0.91	0.91	0.92	0.94	0.56	0.07	0.39	0.14	0.77	1.00		
17)Total_Self_Harm_Death	1,502	1,131	0.41	-0.52	0.41	-0.52	0.03	-0.08	0.95	0.93	0.96	0.83	0.32	0.09	0.43	0.22	0.79	0.91	1.00	
18) Total_Car_Death	1,382	1,213	0.38	-0.49	0.38	-0.50	0.05	-0.12	0.92	0.88	0.93	0.79	0.27	0.06	0.41	0.16	0.71	0.89	0.97	1.00

This table describes our sample. Panel A reports descriptive statistics for the procured organs. Panel B reports the variable of interest and control variables' descriptive statistics and correlation matrix. See the Appendix for variable definitions.

	A	nalyzing 1 ot	ai Organs r	rocured		
		Total_Organs	7	Total	_Organs_per_	_100K
	(1)	(2)	(3)	(4)	(5)	(6)
Land_Area	0.279***	0.187***	0.208***	-0.001***	-0.001**	-0.001**
_	(0.034)	(0.026)	(0.033)	(0.000)	(0.000)	(0.000)
Total Death	1.927***	3.795***	2.849***	0.013*	0.014***	0.009 <sup>**</sup>
—	(0.632)	(0.733)	(0.862)	(0.007)	(0.004)	(0.004)
Above 75 Death	0.073	-0.083	-0.117	-0.016	-0.022***	-0.019***
	(0.529)	(0.628)	(0.665)	(0.010)	(0.007)	(0.006)
Total Reg Donors	0.278*	-0.114	-0.205	0.001**	0.001*	0.001*
_ 0_	(0.158)	(0.116)	(0.138)	(0.000)	(0.000)	(0.000)
Total Medicaid	-0.656***	-0.610***	-0.534***	-0.001***	-0.001***	-0.001***
—	(0.150)	(0.108)	(0.120)	(0.000)	(0.000)	(0.000)
Wage Indx	0.475	0.124	-0.086	3.533	2.039	1.814
0 =	(0.363)	(0.268)	(0.277)	(3.742)	(2.341)	(2.092)
Full Time Emp		0.001***	0.001***		0.182*	0.229***
		(0.000)	(0.000)		(0.094)	(0.084)
Donating Hospitals		1.759***	1.877***		11.934***	12.285***
0_ 1		(0.204)	(0.219)		(1.436)	(1.332)
Transplant Hospitals		1.573	1.557		7.871	8.944
· _ ·		(1.122)	(1.222)		(9.125)	(9.073)
Total Drug Death			0.388***			1.586***
			(0.099)			(0.308)
Total Alcohol Death			-0.121			-0.963***
			(0.123)			(0.264)
Total Self Harm Death			-0.064			0.351
			(0.214)			(0.394)
Total_Car_Death			0.696***			1.387***
			(0.179)			(0.338)
Intercept	-2.262**	-5.169***	0.161	0.225	5.670	5.001
	(0.927)	(0.697)	(1.560)	(5.603)	(3.501)	(3.185)
Year Fixed Effect	Yes	Yes	Yes	Yes	Yes	Yes
Adjusted R <sup>2</sup>	0.443	0.722	0.744	0.333	0.759	0.812
# Observations	276	276	276	276	276	276

 Table 2

 Analyzing Total Organs Procured

This table presents estimation results for the total organ procured regression. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively. See the Appendix for variable definitions.

		Analyzing Viable Organs Procured							
	Tota	al_Viable_Or	gans	Total_	Viable_Organ	100K IS_100K	Per	c_Viable_Org	gans
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Land_Area	0.286***	0.173***	0.213***	-0.001***	-0.001***	-0.001***	-0.002	-0.002	-0.006*
	(0.033)	(0.025)	(0.030)	(0.000)	(0.000)	(0.000)	(0.003)	(0.003)	(0.003)
Total_Death	1.251*	3.873***	0.406	0.011*	0.012***	0.007**	0.174***	$0.160^{**}$	0.152
	(0.662)	(0.538)	(0.893)	(0.005)	(0.004)	(0.003)	(0.058)	(0.062)	(0.108)
Above_75	-0.066	-2.448***	-0.385	-0.004	-0.021***	-0.017***	-0.104**	-0.093*	-0.115
	(0.515)	(0.438)	(0.644)	(0.008)	(0.005)	(0.005)	(0.045)	(0.051)	(0.088)
Total Reg Donors	0.357**	0.287**	0.313**	0.001**	0.001**	0.001**	$0.028^{*}$	0.049***	0.034**
	(0.168)	(0.122)	(0.136)	(0.000)	(0.000)	(0.000)	(0.014)	(0.014)	(0.016)
Total Medicaid	-0.663***	-0.626***	-0.537***	-0.002***	-0.001***	-0.001***	-0.008	-0.019	-0.008
—	(0.146)	(0.104)	(0.113)	(0.000)	(0.000)	(0.000)	(0.013)	(0.012)	(0.013)
Wage Indx	0.650*	0.349	-0.163	2.839	2.181	1.879	0.069**	0.086**	0.058
0 _	(0.376)	(0.289)	(0.294)	(3.134)	(1.925)	(1.696)	(0.033)	(0.033)	(0.036)
Full Time Emp		0.001***	0.001***		0.046	0.078		-0.001***	-0.001***
		(0.000)	(0.000)		(0.079)	(0.070)		(0.000)	(0.000)
Donating Hospitals		1.556***	1.711***		8.826***	8.794***		-0.083***	-0.078***
		(0.202)	(0.211)		(1.215)	(1.120)		(0.023)	(0.025)
Transplant Hospitals		3.474***	2.841***		41.266***	26.154***		0.357***	0.343***
		(2.95)	(0.954)		(7.681)	(6.344)		(0.127)	(0.124)
Actual Drug Death			0.534***			1.112***			0.038***
_ 0_			(0.104)			(0.251)			(0.012)
Actual Alcohol Death			-0.180			-0.662***			-0.025*
			(-0.115)			(0.215)			(0.013)
Actual Self Harm Death			-0.323			0.404			-0.016
_ *			(0.213)			(0.319)			(0.025)
Actual Car Death			0.975***			1.264***			0.069***
			(0.179)			(0.274)			(0.021)
Intercept	-1.767	-7.059***	-2.289	0.043	3.738	2.733	0.982***	1.175***	1.469***
*	(1.165)	(0.926)	(1.562)	(2.693)	(2.889)	(2.588)	(0.103)	(0.108)	(0.189)
Year Fixed Effect	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Adjusted R <sup>2</sup>	0.462	0.742	0.775	0.336	0.772	0.827	0.084	0.242	0.284
# Observations	276	276	276	276	276	276	276	276	276

Table 3Analyzing Viable Organs Procured

This table presents estimation results for the viable organs procured regression. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively. See the Appendix for variable definitions.

		Analyzing	Viable Organs b	ased on Organ T	уре				
		Kidneys	0	All Other Organs					
	Total_Organs Per 100	Total_Viable Organs 100K	Perc_Viable Organs	Total_Organs Per 100	Total_Viable Organs 100K	Perc_Viable Organs			
	$\overline{(1)}$	(2)	(3)	$(\overline{4})$	(5)	(6)			
Land Area	0.001***	0.000	0.005	-0.002***	-0.001***	-0.003***			
—	(0.000)	(0.000)	(0.004)	(0.000)	(0.000)	(0.001)			
Total Death	$0.004^{**}$	$0.004^{**}$	0.028	0.005**	0.006**	0.159**			
—	(0.002)	(0.002)	(0.065)	(0.002)	(0.004)	(0.061)			
Above 75 Death	-0.007**	-0.007**	-0.026	-0.012***	-0.025***	-0.152***			
	(0.003)	(0.003)	(0.064)	(0.003)	(0.007)	(0.049)			
Total Reg Donors	-0.001***	-0.000***	0.049***	0.001	0.001**	0.019			
_ 0_	(0.000)	(0.000)	(0.017)	(0.000)	(0.000)	(0.013)			
Total_Medicaid	-0.001***	-0.001***	-0.003	0.000	-0.001***	-0.011			
	(-0.000)	(0.000)	(0.015)	(0.000)	(0.000)	(0.015)			
Wage Indx	1.447	1.192	0.097**	0.367	1.827	0.032			
	(1.106)	(0.880)	(0.042)	(1.103)	(1.599)	(0.030)			
Full Time Emp	0.152***	0.098***	-0.001***	$0.077^{*}$	0.064	0.000			
	(0.044)	(0.035)	(0.000)	(0.044)	(0.059)	(0.000)			
Donating Hospitals	6.915***	5.097***	-0.075***	5.370***	9.482***	-0.066***			
	(0.704)	(0.556)	(0.027)	(0.702)	(1.532)	(0.023)			
Transplant Hospitals	7.748	14.223***	0.336**	7.605	32.129***	0.350***			
<u>-</u> F	(4.799)	(3.693)	(0.159)	(5.783)	(8.283)	(0.128)			
Total Drug Death	0.748***	(0.090)	(0.10))	0.837***	(0.200)	(01120)			
	(0.163)			(0.162)					
Actual Drug Death	()	0.538***	-0.000		0.938***	$0.040^{***}$			
		(0.206)	(0.000)		(0.317)	(0.011)			
Total Alcohol Death	-0.536***	(0.200)	(((((((((((((((((((((((((((((((((((((((	-0.426***	(00000))	(010-1)			
	(0.139)			(0.139)					
Actual Alcohol Death	(0.125))	-0.346***	0.000	(0.10))	-0.592*	-0.028**			
		(0.106)	(0.000)		(0.340)	(0.011)			
Total Self Harm Death	0.289	(0.100)	(0.000)	0.061	(0.2.0)	()			
	(0.208)			(0.207)					
Actual Self Harm Death	(0.200)	-0.464	-0.001	(0.207)	-0.381	-0.019			
		(0.513)	(0.001)		(0.329)	(0.023)			

 Table 4

Total Car Death	0.564			0.822***		
	(0.179)			(0.178)		
Actual Car Death		1.501**	$0.192^{***}$		1.138***	0.054***
		(0.637)	(0.064)		(0.143)	(0.017)
Intercept	1.557	1.336	0.612***	3.444	2.343	1.821***
	(1.684)	(1.358)	(0.174)	(1.679)	(2.244)	(0.212)
Year Fixed Effect	Yes	Yes	Yes	Yes	Yes	Yes
Adjusted R <sup>2</sup>	0.804	0.805	0.224	0.788	0.835	0.300
# Observations	276	276	276	276	276	276

This table presents estimation results for the viable organs procured regression. Columns 1 through 3 present the results only for the kidneys, and Columns 4 through 6 present the results for the rest of the organs. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively. See the Appendix for variable definitions.

	I	Analyzing OPO Ti	ier System		
	Total_Organs	Total_Viable	Perc_Viable		
	Per_100K	Organs_100K	Organs		
	(1)	(2)	(3)		
Tier 1 Indicator	0.613	0.561*	0.013**		
	(0.486)	(0.293)	(0.005)		
Tier 3 Indicator	-0.462**	-0.571**	-0.021**		
	(0.202)	(0.269)	(0.007)		
Land Area	0.001**	0.000	0.003		
	(0.000)	(0.000)	(0.002)		
Total Death	0.009**	0.003*	0.022		
Total_Doali	(0.004)	(0.002)	(0.058)		
Above 75 Death	-0.019***	-0.008**	-0.030		
Above_/5_Death					
Total Pag Donorg	(0.006) -0.001*	$(0.004) \\ -0.000^*$	$(0.058) \\ 0.044^{***}$		
Total_Reg_Donors					
	(0.000)	(0.000)	(0.013)		
Total_Medicaid	-0.001****	-0.001**	-0.003		
	(-0.000)	(0.000)	(0.011)		
Wage_Indx	1.678	1.217	0.095**		
	(1.106)	(0.846)	(0.044)		
Full_Time_Emp	0.122***	0.103***	-0.001***		
	(0.038)	(0.031)	(0.000)		
Donating_Hospitals	8.320***	4.853***	-0.071***		
	(1.217)	(0.534)	(0.023)		
Transplant_Hospitals	6.956	15.017***	0.362**		
	(4.970)	(3.820)	(0.173)		
Total Drug Death	0.721***				
_ 0_	(0.155)				
Actual Drug Death		0.522**	-0.000		
		(0.217)	(0.000)		
Total Alcohol Death	-0.551***	(**==*)	(*****)		
	(0.147)				
Actual Alcohol Death	(0.117)	-0.340***	0.000		
Actual_Alcohol_Death		(0.111)	(0.000)		
Total Self Harm Death	0.238	(0.111)	(0.000)		
Total_Sell_Hallin_Death					
	(0.214)	0.472	0.001		
Actual_Self_Harm_Death		-0.473	0.001		
	0.501	(0.494)	(0.000)		
Total_Car_Death	0.531				
	(0.162)	**	. ***		
Actual_Car_Death		1.531**	0.210***		
		(0.650)	(0.069)		
Intercept	1.534	1.419	0.591***		
	(1.629)	(1.388)	(0.180)		
Year Fixed Effect	Yes	Yes	Yes		
Adjusted R <sup>2</sup>	0.819	0.809	0.229		
# Observations	276	276	276		

Table 5

 # Observations
 276
 276

 This table presents estimation results for the total and viable organs procured regression based on the OPOs' tier classification. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively. See the Appendix for variable definitions.