

## **Impact of CMS Final Rule on Organ Procurement Organization Metrics and Procedural Trends in the Procurement of Pancreata for Research**

Jonathan Miller, PhD<sup>1,2</sup> (Jonathan.Miller@cdrg.org; ORCID 0000-0002-9562-7337)

Nicholas L. Wood, PhD<sup>1,2</sup> (Nick.Wood@cdrg.org; ORCID 0000-0003-0768-3759)

Grace R. Lyden, PhD<sup>1,2</sup> (Grace.Lyden@cdrg.org; ORCID 0000-0003-1408-851X)

David Zaun, MS<sup>1</sup> (David.Zaun@cdrg.org; ORCID 0000-0003-3787-2470)

Sean Van Slyck, MPA<sup>3</sup> (sean.vanslyck@dcids.org)

Roslyn B. Mannon, MD<sup>4</sup> (Roslyn.mannon@uncm.edu; ORCID 0000-0003-1776-3680)

Jon J. Snyder, PhD, MS<sup>1,2,5</sup> (Jon.Snyder@cdrg.org; ORCID 0000-0001-7974-8940)

<sup>1</sup>Scientific Registry of Transplant Recipients, Hennepin Healthcare Research Institute, Minneapolis, Minnesota, USA

<sup>2</sup>Department of Medicine, Hennepin Healthcare, University of Minnesota, Minneapolis, Minnesota, USA

<sup>3</sup>Sierra Donor Services, West Sacramento, California, USA

<sup>4</sup>Department of Internal Medicine, University of Nebraska Medical Center, Omaha, Nebraska, USA

<sup>5</sup>Department of Epidemiology and Community Health, University of Minnesota, Minneapolis, Minnesota, USA

**Correspondence:** Jonathan Miller, PhD

Scientific Registry of Transplant Recipients

Hennepin Healthcare Research Institute

701 Park Avenue, Suite S4.100

Minneapolis, MN 55415

Email: jonathan.miller@cdrg.org

**Running title:** CMS Final Rule, OPO Metrics, and Pancreas Procurement Trends

### **Conflicts of Interest and Source of Funding**

RBM is a co-chair of the SRTR Review Committee and reports grant funding from VericiDX; honoraria from Olaris Inc, VericiDx, and Chinook Therapeutics; and personal fees from CSL Behring/Vitaerris as member of the IMAGINE Trial Steering Committee, and from the American Journal of Transplantation as deputy editor of the journal, outside the submitted work. SVS is executive director of Sierra Donor Services OPO, co-chair of the SRTR Review Committee, and a member of the OPTN Membership and Professional Standards Committee. JJS is a statistical editor of the American Journal of Transplantation, secretary of the board of Donate Life America, treasurer of the Organ Donation and Transplantation Alliance, and a member of the Clinical Policy Board at LifeSource. The other authors of this manuscript have no conflicts of interest to disclose.

This work was conducted under the auspices of the Hennepin Healthcare Research Institute (HHRI), contractor for the Scientific Registry of Transplant Recipients (SRTR), under contract no. 75R60220C00011 (US Department of Health and Human Services, Health Resources and Services Administration, Health Systems Bureau, Division of Transplantation). The US Government (and others acting on its behalf) retains a paid-up, nonexclusive, irrevocable, worldwide license for all works produced under the SRTR contract, and to reproduce them, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. The data reported here have been supplied by HHRI as the contractor for SRTR. The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy of or interpretation by SRTR or the US Government.

## **Abbreviations**

CMS - Centers for Medicare & Medicaid Services

DSA – donation service area

OPO – organ procurement organization

OPTN – Organ Procurement and Transplantation Network

SRTR – Scientific Registry of Transplant Recipients

**Abstract:**

**Objective:** Pancreata recovered for research are included as a success (or positive) in the Centers for Medicare & Medicaid Services' (CMS's) donation and organ transplantation rate metrics for recertification of organ procurement organizations (OPOs).

**Methods:** Given these metrics directly incentivize recovery of pancreata for research, this study tracks trends in recovery of pancreata for research across the implementation of the CMS metrics.

**Results:** In the 26 months prior to the December 2, 2020, publication of the CMS metrics, research pancreata as a percent of organs transplanted, including research pancreata, was 1.7% nationally, including as much as 10.8% of organs transplanted within any OPO. In the 26 months after the CMS metrics were published, research pancreata increased to 5.1% of organs counted as transplants nationally, including as much as 20.3% within any OPO. If research pancreata were excluded from the CMS metrics, 6 OPOs would change their CMS evaluation status for recertification purposes: 2 would move up a tier and 4 would move down a tier.

**Conclusions:** Procurement of research pancreata has increased since the publication of the CMS performance metrics, OPOs vary in their recovery of pancreata for research, and recovery of pancreata for research can affect recertification of OPOs.

**Keywords:** Organ procurement organization; Research pancreas procurement; Certification metrics

## 1 Introduction

On December 2, 2020, the Centers for Medicare & Medicaid Services (CMS) issued a Final Rule with new metrics for recertifying organ procurement organizations (OPOs).<sup>1</sup> Under this Final Rule, which became effective on August 1, 2022, OPOs will be recertified based on their donation and organ transplantation rates. The denominator for these rates is potential donors, defined as total inpatient deaths in their donation service area among patients aged 75 years or younger with a primary cause of death consistent with organ donation. The numerator for the donation rate is the number of donors from whom at least 1 organ was transplanted or who had their pancreas submitted for research or islet transplantation. In the setting where only the pancreas was sent to research yet no organs were transplanted, this will be counted as a donor, per the CMS definition. The numerator for the age-adjusted organ transplantation rate is the number of organs transplanted from potential donors identified for the donation rate. Pancreata sent for research or islet transplantation would also count as an organ transplant for purpose of the organ transplantation rate, specifically, “Only bona fide research conducted by a qualified researcher using a pancreas from an organ donor would be counted.”<sup>1</sup> OPOs are then classified into 1 of 3 performance tiers based on each performance metric, as follows:

- Tier 1: The OPO’s current year performance metric is not significantly below the prior year’s 75th percentile of the respective metric.
- Tier 2: The OPO’s current year performance metric is not significantly below the prior year’s median of the respective metric.
- Tier 3: The OPO’s current-year performance metric is significantly below the prior year’s median of the respective metric.

The final tier is taken as the lower (worse) of the tiers estimated for each individual performance metric and would open the OPO for competition (tier 2) or decertification (tier 3).

This study describes trends in the procurement of pancreata recovered for research before and after publication of the CMS Final Rule. Additionally, this study estimates how research pancreata affected the CMS recertification evaluations.

## **2 Materials and Methods**

### **2.1 Population**

This study used data from the Scientific Registry of Transplant Recipients (SRTR) current as of January 31, 2023. The SRTR system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network (OPTN), and has been described elsewhere.<sup>2</sup> The Health Resources and Services Administration (HRSA), US Department of Health and Human Services, provides oversight to the activities of the OPTN and SRTR contractors. Data for estimation of donor potential were obtained from the Multiple Cause of Death (all counties) data made available from the National Vital Statistics System, National Center for Health Statistics, Centers for Disease Control and Prevention, US Department of Health and Human Services, and CMS.<sup>3</sup>

This study included all organs recovered for transplant and transplanted or pancreata recovered for the purpose of research or islets from January 1, 2009, to February 1, 2023, including organs recovered during the COVID-19 pandemic. Pancreata recovered for the purpose of research was defined as having a final disposition reason of “recovered for transplant: submitted for research,” “recovered for research,” and “recovered for pancreas islet cells”; these disposition reasons would not otherwise be included in the disposition code “transplanted.” For simplicity, hereafter we refer to both pancreata recovered for research and pancreata recovered for islets research (not including islets that are otherwise included in the “transplanted” disposition code) as “research pancreata.”

## 2.2 Statistical Methods

Research pancreata recovered as a percentage of all organs recovered and transplanted (including research pancreata in this denominator) in the previous year was calculated for each day from January 1, 2010, to February 1, 2023. For example, the data point for March 12, 2012, would be the research pancreata as a percentage of all organs recovered and transplanted from March 13, 2011, to March 12, 2012, with each day moving the calculation window forward by 1 day. The rolling percent of all organs recovered and transplanted was calculated in the same way for kidneys, livers, hearts, and lungs recovered. Research-pancreas-only donors, defined as donors with a pancreas recovered for research but no other organs transplanted, as a percent of all donors with at least 1 organ transplanted (including research-pancreas-only donors in this denominator) in the previous year, was also calculated for each day from January 1, 2010, to February 1, 2023.

Research pancreata as a percentage of all organs recovered and transplanted, and research-pancreas-only donors as a percent of all donors with at least 1 organ transplanted, from December 2, 2020, to February 1, 2023, a period of 791 days, were calculated nationally and for each OPO that was operating at any time between October 3, 2018, and February 1, 2023 ( $n = 58$ ), and compared with the percentage for the 791 days prior to December 2, 2020 (October 3, 2018, to December 1, 2020). National changes in percentages of research pancreata and research-pancreas-only donors from before to after the publication of the CMS Final Rule were tested for statistical significance with  $\chi^2$  tests.

Tier rankings of OPOs were estimated for calendar year 2021 (corresponding to the 2023 CMS performance report) for the 57 OPOs operating in 2021 (reflecting 1 OPO merge) following the method described in the CMS Final Rule<sup>4</sup> both with research pancreata included in the numerator and with research pancreata excluded from the numerator. Tier boundaries were determined based on the 2020 percentiles (median and 75th) of the metrics, which were also calculated from the 57 OPOs both with and without research pancreata.

### 3 Results

The rolling percent of research pancreata out of all organs recovered and transplanted nationally rose dramatically following the December 2, 2020, publication of the CMS OPO Final Rule, from 1.53% on December 2, 2020, to 7.05% on February 1, 2023. Similarly, the rolling percent of research-pancreas-only donors as a percent of all donors with at least 1 organ transplanted rose from 0.21% on December 2, 2020, to 2.84% on February 1, 2023 (Figure 1). While, hearts, kidneys, livers, and lungs have historically represented greater percentages of all organs recovered and transplanted, ranging from about 8% for lungs to about 50% for kidneys, these percentages for hearts, kidneys, livers, and lungs decreased or remained stable following December 2, 2020 (See Figure, Supplemental Digital Content 1, for rolling percents of non-pancreas organs transplanted).

In the 791 days prior to the CMS Final Rule, the percentage of research pancreata as a proportion of all organs recovered and transplanted was 1.7% nationally and ranged from 0% to 10.77% by OPO, while in the 791 days following the CMS Final Rule the percentage of research pancreata was 5.1% nationally—a statistically significant increase ( $P < .001$ )—and ranged from 0% to 20.33% by OPO. There were 36 of 58 OPOs (62%) whose percent of research pancreata increased from the period prior to the Final Rule to the period after it, including 5 OPOs whose percent of research pancreata was more than 10 percentage points higher. By contrast, there were 19 OPOs (33%) whose percent of research pancreata decreased, although only 5 of those had a decrease greater than 1 percentage point and the largest decrease was 3.38 percentage points (Figure 2). There was a similar change in the percent of research-pancreas-only donors. In the 791 days before the CMS Final Rule, 0.22% of the donors were research-pancreas-only donors, and the maximum percent for an OPO was 4.90%; in the 791 days after the CMS Final Rule, 1.83% of donors were research-pancreas-only donors—a statistically significant increase ( $P < .001$ )—and the maximum percent for an OPO was 9.01% (Figure 2).



Based on CMS-calculated metrics as defined in the Methods section, we identified 6 OPOs that would change tier rankings if research pancreata were excluded from the numerators of the metrics. Four of the 6 would move down a tier, including 1 that would move to the lowest tier and be subject to decertification. Of these 4 OPOs, 3 had research pancreata as more than 9% of their organs transplanted (Table 1). Two OPOs would move up a tier, and avoid certain decertification, if research pancreata were excluded, moving from tier 3 to tier 2. These OPOs had 1% or less of their organs transplanted as research pancreata. Thus, the inclusion of research pancreata had significant impacts on certification metrics in 10.5% of OPOs.

#### **4 Discussion**

While pancreas represents a smaller percent of organs recovered and transplanted, likely due to the smaller number of pancreas candidates on the waiting list and lower volumes of pancreas transplants compared with other organs in a year,<sup>5</sup> there has been a steady and notable rise in the recovery of pancreata for research or islet research as a percent of all organs recovered and transplanted since the December 2, 2020, CMS OPO Final Rule. The maximum percent of research pancreata by OPO has risen from 10.8% before the CMS Final Rule to 20.3% after it. Thus, the inclusion of research pancreata in the numerator of the CMS metrics resulted in a dramatic increase in the number of pancreata acquired for research. However, this metric had mixed benefits to OPOs in terms of performance assessment.

The increase in the procurement of research pancreata was not foreseen in the CMS Final Rule, which projected that, “In 2016 to 2018 the number of such pancreas research projects have been between 500 and 600 a year (579 in 2018). This is 1.73 percent of the number of transplants in 2018, and we project a similar fraction in our estimates for future years.”<sup>1</sup> This study shows that this projection has not held, and some OPOs have responded to the incentive to procure research pancreata, unsurprisingly, by dramatically increasing the procurement of research pancreata.

A concurrent study, which confirms the trend of increasing research pancreata procurement, used the CMS public reports and subtracted research pancreata from the OPO numerators to determine which OPOs benefit from including research pancreata in the numerator.<sup>6</sup> This study held the CMS 75% and 50% thresholds fixed as reported in the public report.<sup>7</sup> In contrast, our study fully recalculates the metrics using CMS's method,<sup>4</sup> which allows the tier thresholds to vary as would be the case in practice if research pancreata were included in the numerator. Using this approach, we have been able to show that there is not only a set of OPOs that benefit from inclusion of research pancreata in the numerator, but also a set of OPOs that are detrimentally affected by including research pancreata in the numerator as the shift in the tier thresholds pushes them into a lower tier and risk of decertification.

Transplant centers performing pancreas research or islet transplant are geographically distributed in the US such that not all OPOs have centers performing pancreas research in their donation service area (DSA).<sup>8</sup> The lack of this access for some OPOs may contribute to disparities in procurement of research pancreata. While OPOs may build relationships with centers outside of their DSA to allow procurement of research pancreata, we are not aware of any data available on the disposition of research pancreata that allows analysis of how common it is for OPOs to allocate research pancreata outside of their DSA. Making more data available on the disposition of research pancreata would help in analysis to identify best practices for procurement and placement of research pancreata.

Historically, costs for procurement of pancreata for research have been paid by research grants or institutional funds at the transplant center performing the research.<sup>9</sup> However, we are not aware of ongoing data collection on costs and payments for research pancreas procurement. As the benefits to OPOs may have increased to procure research pancreata following the CMS Final Rule, making data available on costs and payment would allow analysis that could better inform discussions on cost sharing for research pancreas procurement.

The impact of research pancreata on the CMS tiers demonstrates a potential shortcoming of the new metrics. Whether this is an intended consequence of the metrics as designed, and how this feature of the metrics affects final OPO evaluations, should be considered by CMS and the community at large. We believe there should be transparency for the interested public about the effects these metrics are having on research pancreata, research-pancreas-only donors, and the OPO performance evaluations.

### **Acknowledgments**

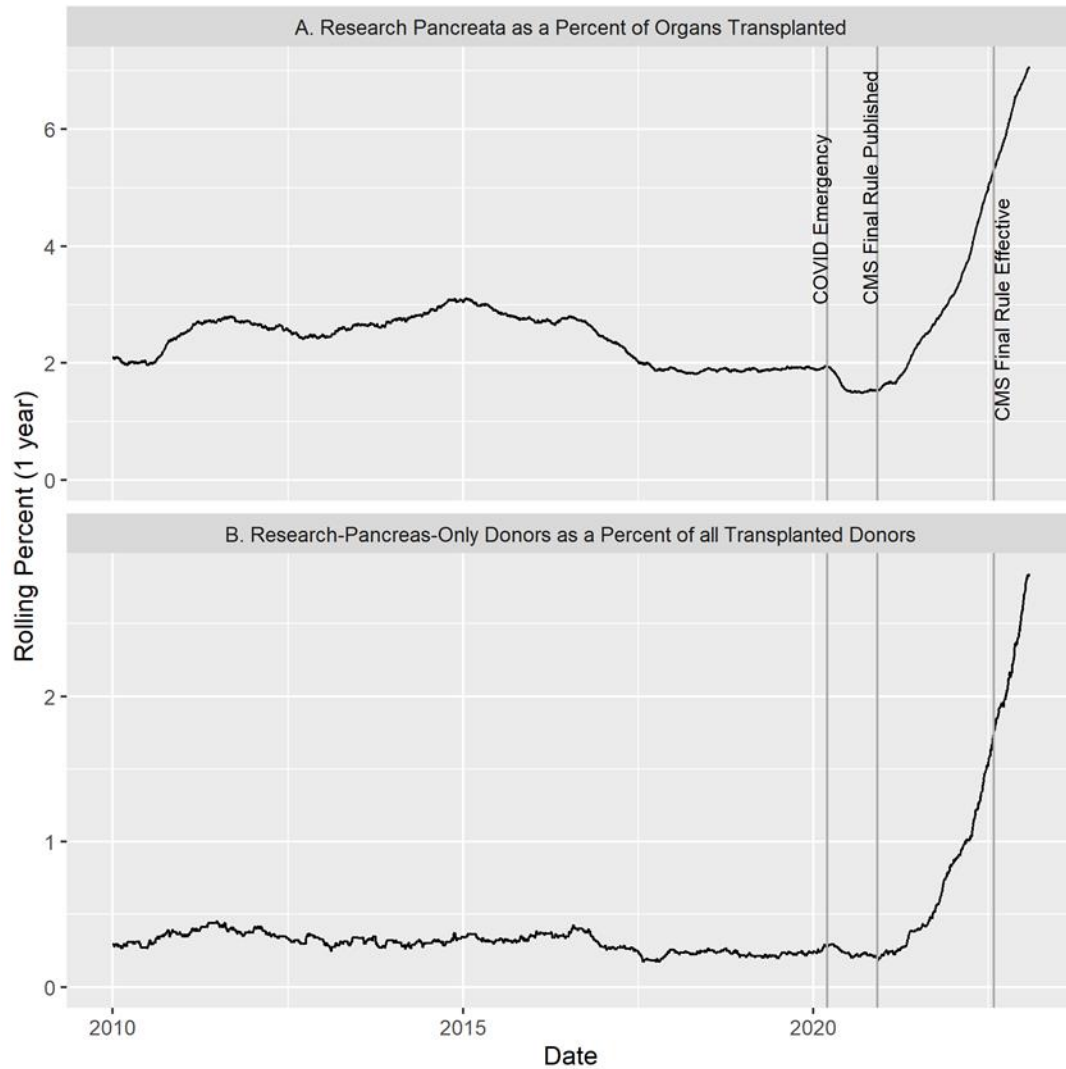
The authors thank SRTR colleague Anna Gillette for manuscript editing.

### **Data availability statement**

The data that support the findings of this study are available from the corresponding author upon reasonable request.

**Figure 1.** Rolling percent of research pancreata across all organ procurement organizations.

Panel A represents rolling percent of all organs transplanted or recovered for pancreas research, while panel B shows donors in which the only organ obtained was the research pancreas as a percent of all donors from whom an organ was transplanted or recovered for pancreas research. CMS, Centers for Medicare & Medicaid Services.



**Figure 2.** Comparison of OPO acquisition of research pancreata before and after CMS Final Rule update. In panel A, research pancreata as a percent of all organs transplanted or recovered for pancreas research in the 791 days before the CMS Final Rule update (x-axis) and in the 791 days after the CMS Final Rule update (y-axis). A program falling on the diagonal line would have the same percent before the update to after the update. In panel B, research-pancreas-only donors as a percent of all donors with an organ transplanted or recovered for pancreas research in the 791 days before the CMS Final Rule update (x-axis) and in the 791 days after the CMS Final Rule update (y-axis). CMS, Centers for Medicare & Medicaid Services; OPO, organ procurement organization.

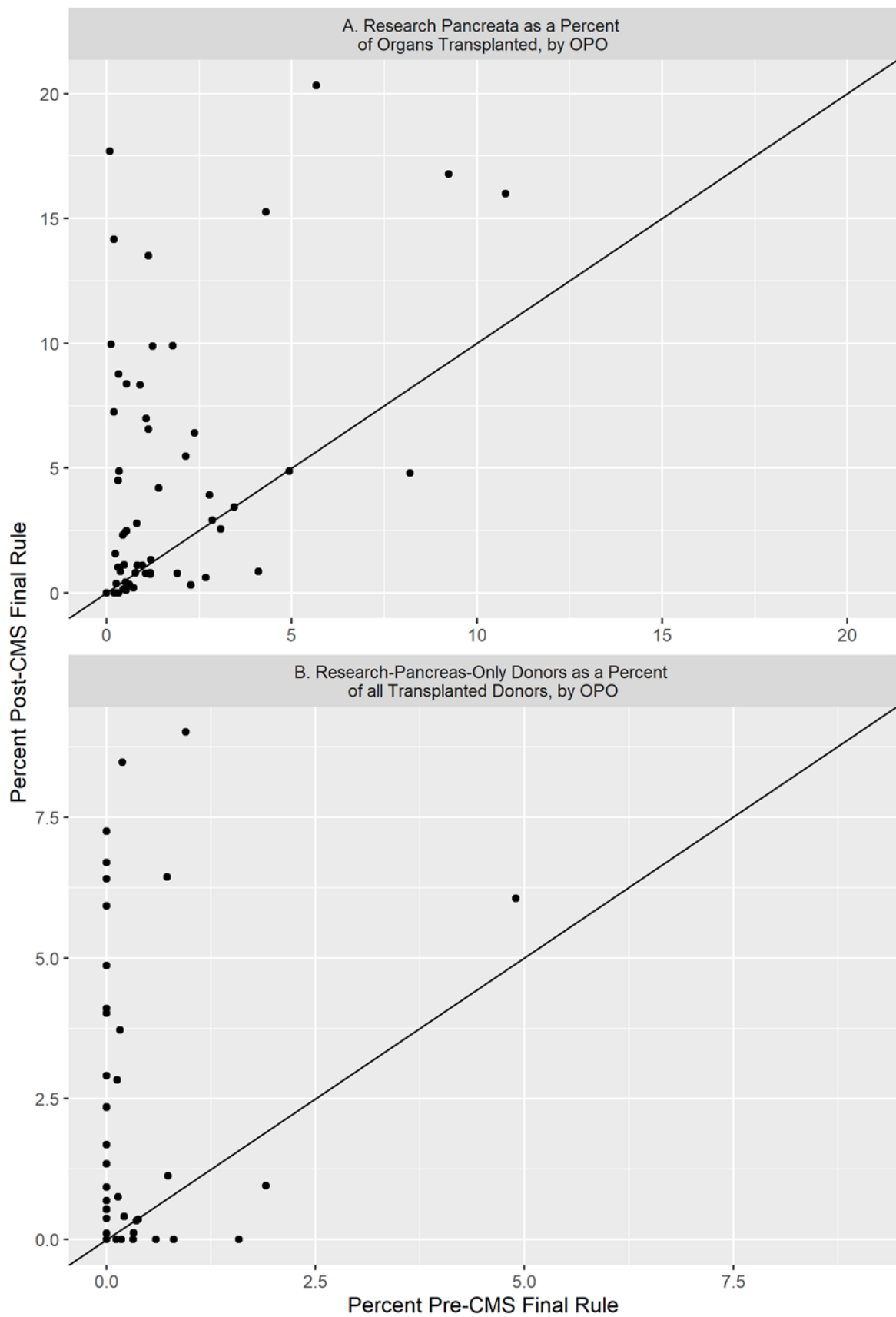


Table 1: OPOs that change 2021 tier when research pancreata are excluded

OPO	Calculated 2021 Tier	Calculated 2021 Tier without Research Pancreata	Pre Final Rule: Percent Research Pancreata	Post Final Rule: Percent Research Pancreata	Pre-Post Difference in Percent Research Pancreata
OPO1	3	2	0.31	1.04	0.72
OPO2	1	2	5.66	20.33	14.67
OPO3	1	2	0.12	9.97	9.85
OPO4	1	2	2.78	3.92	1.14
OPO5	2	3	1.14	13.51	12.38
OPO6	3	2	2.68	0.61	-2.06

OPO, organ procurement organization

## References

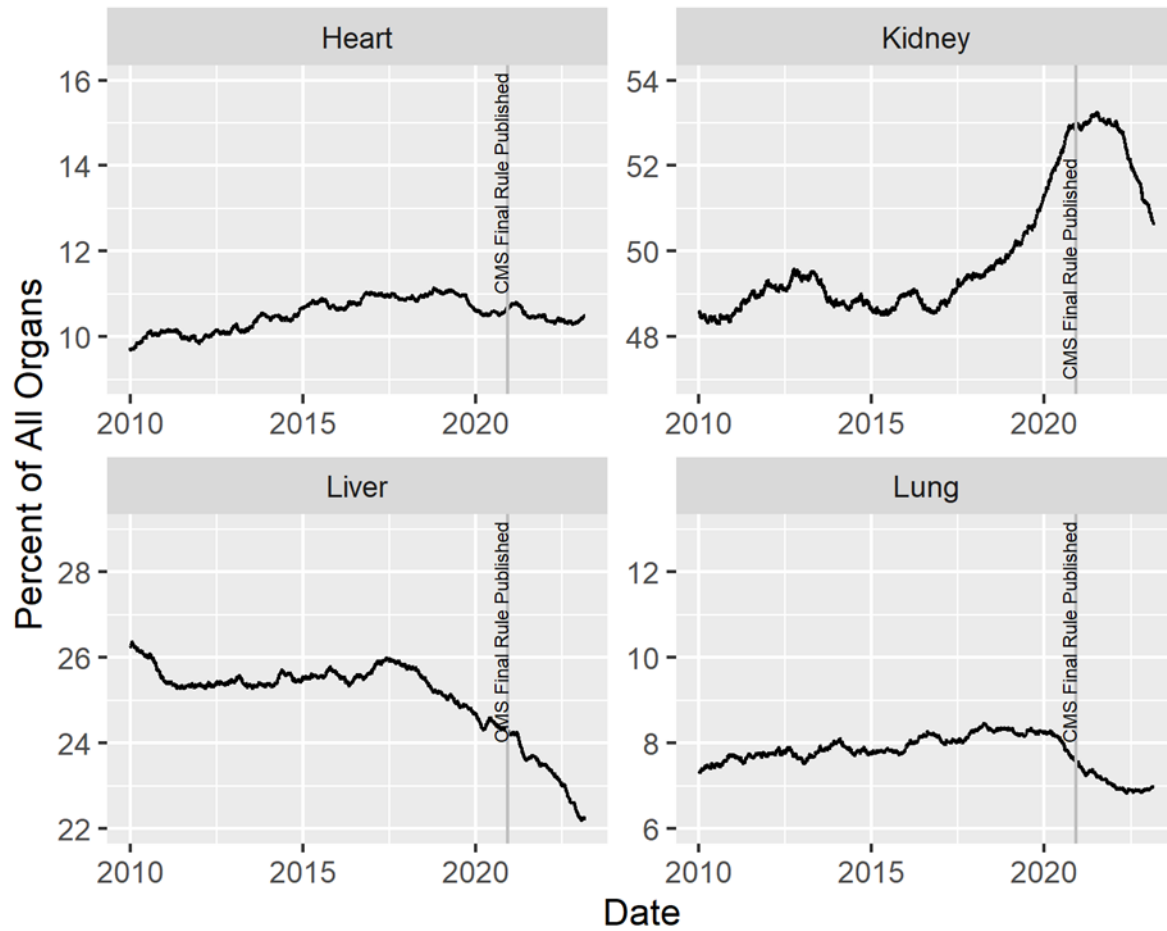
1. Department of Health and Human Services. Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations. *Fed Regist 42 CFR, Part 486*. 2020;85:77898-77949.
2. Leppke S, Leighton T, Zaun D, et al. Scientific Registry of Transplant Recipients: Collecting, analyzing, and reporting data on transplantation in the United States. *Transplant Rev*. 2013;27(2):50-56. doi:10.1016/j.trre.2013.01.002
3. Centers for Disease Control and Prevention. Restricted-Use Vital Statistics Data. Published 2023. Accessed April 4, 2023. <https://www.cdc.gov/nchs/nvss/nvss-restricted-data.htm>
4. CMS Quality Certification and Oversight Reports. OPO Public Performance Report User Guide. Accessed November 4, 2023. [https://qcor.cms.gov/documents/OPO\\_Public\\_Performance\\_Report-User\\_Guide\\_for\\_the\\_2026\\_Certification\\_Period.pdf](https://qcor.cms.gov/documents/OPO_Public_Performance_Report-User_Guide_for_the_2026_Certification_Period.pdf)
5. Schladt DP, Israni AK. OPTN/SRTR 2021 Annual Data Report: Introduction. *Am J Transplant*. 2023;23(2S1):S12-S20. doi:10.1016/j.ajt.2023.02.003
6. Goldberg D, Chyou D, Wulf R, Wadsworth M. CMS Final Rule for Organ Donation: Unintended Consequences of the Pancreas Research Loophole. *medRxiv*. Published online 2023. doi:<https://doi.org/10.1101/2023.03.19.23287457>
7. CMS Quality Certification and Oversight Reports. OPO Public Performance Report - 2022. Published 2022. Accessed November 4, 2022. [https://qcor.cms.gov/documents/Public\\_2022\\_OPO\\_Report.xlsx](https://qcor.cms.gov/documents/Public_2022_OPO_Report.xlsx)
8. Collaborative Islet Transplant Registry. *Eleventh Allograft Report*. 11th ed. (CITR Coordinating Center, ed.). The Emmes Corporation; 2022. [www.CITRegistry.org](http://www.CITRegistry.org)
9. Markmann JF, Kaufman DB, Ricordi C, Schwab P, Stock PG. Charges for Pancreata



Recovered for Islet Transplantation. Published 2007.

<https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/charges-for-pancreata-recovered-for-islet-transplantation/>

Supplemental Digital Content 1. doc



**Supplemental Digital Content 1, Figure.** Rolling percent of hearts, kidneys, livers, and lungs transplanted as a percent of all organs transplanted or recovered for pancreas research. CMS, Centers for Medicare & Medicaid Services.