
UC DAVIS LAW REVIEW

VOL. 58, NO. 1



NOVEMBER 2024

Inequitable Organ Allocation

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Seventeen people die every day in the United States waiting for an organ transplant, and over 100,000 people are currently on waitlists to receive a donated organ. Given these stark numbers, the allocation policies governing who receives donated organs are both critically important and hotly debated. Congress passed the National Organ Transplant Act in 1984 with the goal of eliminating markets for organs and the promise of equitable access to transplants without regard to geography or socioeconomic status. Despite these laudable goals, recent developments in organ allocation policy have led to multiple lawsuits, congressional inquiries, and an exposé in the Washington Post.

Organ allocation policies developed over the past decade have increasingly mandated broader organ sharing across the country so that organs are less likely to be transplanted into nearby recipients. Analyzing a series of public and restricted-use datasets that include information on all organ donations, transplants, and waitlist registrations, I find consistent empirical evidence that organ allocation policy fails to achieve its goals. First, the metrics used to

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rank patients by medical urgency have been manipulated, particularly for heart and liver transplant candidates. Next, I find that socioeconomic inequities persist within organ allocation, with the income needed to receive an organ transplant increasing year-over-year (after adjusting for inflation).

Finally, I find that organ allocation policy has systematically ignored large swaths of the population and thereby impeded access to organ transplants. To estimate the degree to which allocation policy has ignored individuals in need of transplants, I develop a new population-based metric of need for organ transplants — transplant amenable deaths. These deaths include all those that could have potentially been avoided by the timely receipt of a transplant. Analyzing these deaths, I find evidence that parts of the country with the greatest need for transplants are routinely required to export their organs to other wealthier and more urban parts of the country with less need for transplants.

Transplant amenable deaths also offer an avenue of reform and the chance to achieve equitable access to organ transplants: I propose that new organ allocation policies be cabined by their impact on transplant amenable deaths so that these deaths are evenly spread across the country. Doing so can ensure organs go to areas where they are most needed while also allowing the most urgent patients to receive organs first. Such a distribution would also mitigate socioeconomic disparities.

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INTRODUCTION

In healthcare, geography matters. Geography matters both practically and legally. Across the United States, many individuals reside in primary care deserts, maternity care deserts, and mental healthcare deserts.¹ Rural residents have seen their access to care decline over the last decade as many rural hospitals have closed.² Similarly, state laws impact individuals’ access to health insurance and healthcare providers.³ The

¹ MARCH OF DIMES, NOWHERE TO GO: MATERNITY CARE DESERTS ACROSS THE U.S. 6 (2022), https://www.marchofdimes.org/sites/default/files/2022-10/2022_Maternity_Care_Report.pdf [<https://perma.cc/3XU4-4PF5>]; *Mental Health Care Health Professional Shortage Areas (HPSAs)*, KFF (Apr. 1, 2024), <https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/?currentTimeframe=o&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> [<https://perma.cc/8CJE-QPDW>]; *Primary Care Health Professional Shortage Areas (HPSAs)*, KFF (Apr. 1, 2024), <https://www.kff.org/other/state-indicator/primary-care-health-professional-shortage-areas-hpsas/?currentTimeframe=o&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> [<https://perma.cc/EQ38-MDMW>].

² AM. HOSP. ASS’N, RURAL HOSPITAL CLOSURES THREATEN ACCESS: SOLUTIONS TO PRESERVE CARE IN LOCAL COMMUNITIES 3 (2022), <https://www.aha.org/system/files/media/file/2022/09/rural-hospital-closures-threaten-access-report.pdf> [<https://perma.cc/6BZ9-VL93>].

³ See Benjamin J. McMichael, *Supply-side Health Policy: The Impact of Scope-of-practice Laws on Mortality*, 222 J. PUB. ECON. 1, 8 (2023) [hereinafter McMichael, *Supply-side Health Policy*]; Sarah Miller, Norman Johnson & Laura R. Wherry, *Medicaid and*

one healthcare context in which geography is not supposed to matter, however, is organ transplantation.⁴ Congress passed the National Organ Transplant Act (“NOTA”) in 1984, effectively federalizing the allocation and transplantation of human organs in the United States.⁵ Fifteen years later, the Department of Health and Human Services (“HHS”) passed what has come to be known as the “Final Rule,” implementing many of the goals of the NOTA and establishing the principle that donated organs should be “[d]istribut[ed] . . . over as broad a geographic area as feasible”⁶

In the years following the implementation of the Final Rule, practical considerations meant that geography still played a role in organ allocation and transplantation.⁷ Medical and technological limits prevented the transportation of organs over long distances, so many organs continued to be transplanted into individuals at relatively nearby transplant centers.⁸ As technology improved, however, donated organs could travel longer distances to patients in need.⁹ With these medical and technological limits relaxing over time, the entity responsible for developing rules around organ allocation under federal law — the Organ Procurement and Transplantation Network (“OPTN”) — has systematically implemented new policies de-emphasizing geography so that donated organs can travel further distances if sicker patients are farther away.¹⁰ Thus, the era of primarily local organ transplantations has largely given way to an era of organ sharing across the country.

In theory, such a “sickest first” policy seems both quite reasonable and consistent with medical ethics. Anyone who has visited a hospital emergency department is likely familiar with this type of system. If a

Mortality: New Evidence from Linked Survey and Administrative Data, 136 Q. J. ECON. 1783, 1823 (2021).

⁴ 42 C.F.R. § 121.8(b)(3) (2024).

⁵ 42 U.S.C. § 273.

⁶ 42 C.F.R. § 121.8(b)(3) (2024).

⁷ See Clyde F. Barker & James F. Markmann, *Historical Overview of Transplantation*, 3 COLD SPRING HARBOR PERSP. MED. 1, 12 (2013).

⁸ See Lei Jing, Leeann Yao, Michael Zhao, Li-ping Peng & Mingyao Liu, *Organ Preservation: From the Past to the Future*, 39 ACTA PHARMACOLOGICA SINICA 845, 845-46 (2018).

⁹ See *id.*

¹⁰ See *infra* Part II.C (discussing these various policies).

sicker patient arrives at the emergency department later than a healthier patient, the sicker patient will nevertheless receive treatment first.¹¹ Applying this logic to the allocation of life-saving organs, current allocation policies prioritize the sickest patients on organ waitlists. Such an approach would seemingly lead to the best use of those organs. However, critics have noted that transplant clinicians can manipulate measures of urgency, artificially boosting some patients on waitlists at the expense of others.¹² Additionally, current metrics used to evaluate whether allocation policy is working to ensure the sickest patients receive organs only include individuals who have accessed an organ waitlist.¹³ The current system ignores individuals who could benefit from an organ transplant (and may be sicker than waitlisted patients) but cannot access a transplant waitlist.¹⁴ Thus, the current approach may perpetuate existing socioeconomic, racial, and geographic inequities by failing to account for patients who cannot access the transplant system due to these inequities.

The divide over which patients matter when formulating and evaluating organ allocation policy, combined with other concerns over how to measure which patients are sickest when determining priority for scarce organs, has sparked an intense debate.¹⁵ This debate has only become more heated as recent policy changes have changed the flow of organs across the country.¹⁶ These changes in flow have resulted in parts of the country — principally the South and Midwest — exporting more

¹¹ Radiation Emergency Medical Management, *START Adult Triage Algorithm*, U.S. DEP'T OF HEALTH & HUM. SERVS., <https://remm.hhs.gov/startadult.htm> (last updated June 24, 2024) [<https://perma.cc/5VK6-A4V9>].

¹² See, e.g., Benjamin J. McMichael, *Stealing Organs?*, 97 IND. L.J. 135, 178-81 (2022) [hereinafter McMichael, *Stealing Organs?*] (providing evidence of manipulation in the organ allocation system).

¹³ See NAT'L RSCH. COUNCIL, *REALIZING THE PROMISE OF EQUITY IN THE ORGAN TRANSPLANTATION SYSTEM* 4 (Kenneth W. Kizer, Rebecca A. English & Meredith Hackmann eds., The National Academies Press 2022) [hereinafter NAT'L ACADEMIES].

¹⁴ See *infra* Part III.C.

¹⁵ See generally Lara C. Pullen, *Lawsuits Drive Transplant Community Debate Over Liver Allocation*, 19 AM. J. TRANSPLANTATION 1251 (2019) (discussing perspectives from both sides of the debate about formulating and evaluating organ allocation).

¹⁶ See generally *id.* (discussing the impact of different policies on the allocation of transplant organs).

organs recovered locally to the Northeast and California.¹⁷ New rules requiring these exports have sparked multiple federal lawsuits in the past few years,¹⁸ captured the attention of congressional leaders on both sides of the aisle,¹⁹ and led to what one author has described as a new “civil war” over donated organs.²⁰ Indeed, the causes and casualties of this war have been the subject of a *Washington Post* exposé.²¹

The federal government has acknowledged the intense debate over organ allocation and transplantation.²² It has also demonstrated a clear willingness to amend the framework governing organ allocation policy by implementing reforms to the entity governing organ allocation policy and the organizations responsible for recovering organs from donors.²³ Additionally, a recent report by the National Academies of Science,

¹⁷ See *infra* Part III.B.

¹⁸ See, e.g., *Adventist Health Sys./SunBelt, Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 17 F.4th 793 (8th Cir. 2021) (addressing issues around kidney allocation); *Callahan v. U.S. Dep’t of Health & Hum. Servs.*, through Alex M. Azar II, 939 F.3d 1251 (11th Cir. 2019) (addressing issues around liver allocation).

¹⁹ See Pullen, *supra* note 15, at 1256; Letter from Charles E. Grassley, Chairman, Senate Fin. Comm., to Alex Azar, Secretary, U.S. Dep’t of Health & Hum. Servs. (Jan. 24, 2019) <https://www.finance.senate.gov/imo/media/doc/CEG%20Liver%20Letter%20Signed%20FINAL.pdf> [<https://perma.cc/D23Q-5XSD>].

²⁰ Casey Ross, *U.S. States Are Waging a Civil War over Donated Livers. Will a New Proposal Finally Resolve It?*, STAT (Oct. 2, 2017), <https://www.statnews.com/2017/10/02/donor-livers-organ-transplant/> [<https://perma.cc/SX4Z-AAHN>].

²¹ Malena Carollo & Ben Tanen, *New Liver Transplant Rules Yield Winners, Losers as Wasted Organs Reach Record High*, WASH. POST (Mar. 21, 2023, 2:00 PM), <https://www.washingtonpost.com/business/2023/03/21/liver-transplants-acuity-circle-policy/> [hereinafter Carollo & Tanen, *Winners & Losers*].

²² See, e.g., *The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System: Hearing Before the Subcomm. on Health Care*, 118th Cong. (2023), <https://www.finance.senate.gov/hearings/the-cost-of-inaction-and-the-urgent-need-to-reform-the-us-transplant-system> [<https://perma.cc/ANX8-VBV4>] (detailing congressional investigations into the failures of the organ procurement, allocation, and transplantation systems).

²³ Congress passed a new law governing the organizations responsible for organ allocation policy in September 2023. *Securing the U.S. Organ Procurement and Transplantation Network Act*, Pub. L. No. 118-14, 137 Stat. 69 (2023). Recent regulations have reworked how organ procurement organizations are evaluated. Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 Fed. Reg. 77898 (Dec. 2, 2020) (to be codified at 42 C.F.R. pt. 486).

Engineering, and Medicine recognized the inequities in the organ transplantation system and the continuing issue of access to organ transplants.²⁴ However, neither the recent federal reforms, nor the report of the National Academies, confronted the fundamental issues of waitlist manipulation, attempted to measure the extent of inequities present in the system, or addressed the role of geography in allocation policies that mandate the flow of organs from one part of the country to the other.²⁵

This Article addresses those neglected issues head on. To do so, it offers a data-driven evaluation of the current approach to organ allocation policy and an examination of the implications of that approach for waitlist manipulation, socioeconomic inequities, and access to transplants. I rely on two principal sources of data to complete my analysis. First, restricted-use data from the Scientific Registry of Transplant Recipients (“SRTR”) includes information on every organ donation, waitlist registration, and transplantation from 2011 to 2022.²⁶ I also obtained permission to examine individuals’ zip codes, which provide better information on socioeconomic inequities than are available in the standard data. Second, I rely on mortality data from the National Vital Statistics System to investigate the implications of current policy for individuals in need of life-saving organ transplants across the country. By examining highly detailed data on individual causes of death, I construct a new measure of medical urgency among the population: transplant amenable deaths. Examining this measure, which does *not* rely on data from the organ transplantation system itself,

²⁴ NAT’L ACADEMIES, *supra* note 13, 85-116.

²⁵ See Securing the U.S. Organ Procurement and Transplantation Network Act, 137 Stat. 69 (failing to address the role of geography within allocation policy); Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 Fed. Reg. at 77898 (Feb. 1, 2021) (to be codified at 42 C.F.R. pt. 486); NAT’L ACADEMIES, *supra* note 13, 85-116.

²⁶ This study used data from the Scientific Registry of Transplant Recipients (“SRTR”). The SRTR data system includes data on all donors, wait-listed candidates, and transplant recipients in the US, submitted by the members of the Organ Procurement and Transplantation Network (“OPTN”). The Health Resources and Services Administration (“HRSA”), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors.

allows my analysis to look beyond the narrow confines of the transplant system to evaluate the role of allocation policy in meeting the needs of the entire population.

After outlining the details of the organ allocation, transplantation, and regulation in the United States, this Article examines the justifications of broader national organ sharing. In doing so, it adopts the analytical approach that led to these policies and considers only individuals on organ waitlists. One staunch proponent of this approach and broader national organ sharing generally is Alexandra Glazier, the CEO of a New England organ procurement organization. She has argued that “[b]y definition allocation and distribution policy is about determining where a defined pool of a resource goes.”²⁷ Explaining further, she noted that “the allocation and distribution policies are designed to rank order patients to receive actual organs that become available.”²⁸

Glazier articulated this argument in more depth when communicating with Brian M. Shepard, the then CEO of the organization responsible for developing and implementing allocation policy, about recent changes in the allocation policies governing livers.²⁹ Comparing two

²⁷ Alexandra K. Glazier, *The Lung Lawsuit: A Case Study in Organ Allocation Policy and Administrative Law*, 14 J. HEALTH & BIOMEDICAL L. 139, 143 (2018).

²⁸ *Id.*

²⁹ These conversations were revealed following the Eleventh Circuit’s affirmation of the district court’s order to unseal emails written and received by Glazier. *Callahan v. United Network for Organ Sharing*, 17 F.4th 1356, 1359 (11th Cir. 2021) (“The appellants here, preferring to avoid the release of embarrassing internal communications that were attached to briefing in the district court, seek to persuade us that we should weaken our rule [that judicial records are open to the public]. They urge us to evaluate the functional purpose of the documents at issue rather than their categorical status as judicial records. Our precedents, however, permit no such shift. The documents here are plainly judicial records and the appellants have not shown good cause to keep them sealed. We affirm.”). The relevant emails contain an internal numbering system, and for ease of readability and transparency, I will cite these emails as “*Callahan* Emails at [the relevant internal page number].” A complete list of all emails released pursuant to the court’s order are on file with the author. These emails have been the subject of various pieces of investigative journalism. *See, e.g.,* Malena Carollo, *In Emails, Contractor Tries to Orchestrate New Federal Transplant Policy*, THE MARKUP (Jan. 8, 2024, 1:02 PM), <https://themarkup.org/organ-failure/2024/01/08/in-emails-contractor-tries-to-orchestrate-new-federal-transplant-policy> [<https://perma.cc/D3JY->

states that have different levels of healthcare access, Glazier argued that “[t]he fact that Massachusetts does better than South Carolina in preventing preventable deaths and providing health care insurance coverage and access may be true but is unrelated to allocation policy.”³⁰ Taking this argument a step further, Glazier concluded that “[t]he fact that some states do better than others in preventing preventable deaths and providing health care insurance coverage and access means you’re a dumb fuck for living there,” but it does not mean “that people who live in [Massachusetts] should die waiting for livers.”³¹ In other words, organ allocation policy should facilitate the flow of donated livers from South Carolina to Massachusetts as long as Massachusetts patients *on the waitlist* are sicker. This is true even if South Carolinians overall have a much greater need for liver transplants than Bay Staters. Glazier stated this directly in arguing that it is “inappropriate to use organ allocation to rectify social injustices outside of [the] distribution of organs to those waiting.”³²

Though these arguments specifically disclaim any attempt to “rectify social injustices,” they have largely won the day.³³ HHS effectively endorsed many of the changes in allocation policy championed by Glazier.³⁴ In the same conversation, Glazier pointed out that “[t]he final rule . . . defines that allocation policy ‘shall be based on sound medical judgment’ and ‘shall not be based on the candidates place of residence

A7VU] [hereinafter *Carollo, In Emails*] (article addresses the emails that show how one company capitalized on the lung lawsuit to lay the groundwork for policy changes).

³⁰ *Callahan Emails* at 0018419, *Callahan v. U.S. Dep’t of Health and Hum. Servs.*, through Alex M. Azar II, 434 F.Supp.3d 1319 (N.D. Ga. 2020).

³¹ *Id.* at 0018418.

³² *Id.* at 0018441. Glazier noted at a different point that “[w]e can all agree that as nation we need to improve access to care for disadvantaged populations.” *Id.*

³³ Glazier also noted at one point that it is “total B[ull] S[hit] — and inappropriate to use organ allocation to rectify social injustices outside of [the] distribution of organs to those waiting” in response to a statement by Shephard that “[o]nly people who have means can get a transplant.” *Id.* at 0018441. She did note in the same conversation, however, that “[w]e can all agree that as a nation we need to improve access to care for disadvantaged populations.” *Id.*

³⁴ Letter from George Sigounas, Administrator, Health Res. & Servs. Admin., to Sue Dunn, President, Organ Procurement & Transplantation Network (July 31, 2018), https://optn.transplant.hrsa.gov/media/fjofsysl/hrsa_to_optn_organ_allocation_20180731.pdf [https://perma.cc/P7WV-CW4M].

or place of listing.”³⁵ Under this rule, she explained that “[o]rgan allocation must be based on medical criteria and be as fair as possible for those listed as candidates for transplantation. That is what the federal law mandates.”³⁶ While no federal court has ever endorsed this specific interpretation of the Final Rule’s geographic mandates, court decisions and agency actions have generally supported policies designed to facilitate greater national organ sharing based on the relative sickness of patients on the waitlist.³⁷ These decisions have also relied on evidence that shows meaningful disparities in access to donated organs across the country.³⁸ Returning to Glazier’s example, the data demonstrates that Massachusetts patients are, in fact, measurably sicker than South Carolina patients under the current approach to measuring sickness and medical urgency.³⁹ The analysis reported below similarly demonstrates that different parts of the country have better access to donated organs. This type of evidence has driven organ allocation policy over the past decade.⁴⁰

Next, having detailed the evidence that led to the current state of organ allocation policy, this Article turns to the implications of that policy. The analysis begins by examining whether current measures accurately reflect medical urgency, because these are the measures that justify the movement of organs across the country under the current system.⁴¹ The evidence suggests that transplant clinicians routinely

³⁵ Callahan Emails, *supra* note 29, at 0018418 (quoting 42 C.F.R. 121.8(1) & (8)).

³⁶ *Id.*

³⁷ The organization responsible for organ allocation policy supports the continued movement toward national organ sharing. The interim CEO of that organization, Maureen McBride, recently commented in a written statement: “I’m proud that UNOS distribution policies are today saving the lives of the sickest Americans no matter where they live, and we are now leading more improvement to further increase efficiency, accuracy and transparency across the system.” See Carollo & Tanen, *Winners & Losers*, *supra* note 21.

³⁸ Pullen, *supra* note 15, at 1255.

³⁹ See *infra* Part II.A.

⁴⁰ See Pullen, *supra* note 15, at 1255.

⁴¹ Seth Karp — director of the Vanderbilt University Medical Center transplant center — “worr[ies] that [the metrics to measure need and relative sickness for liver transplants] do not accurately reflect risk of death on the waitlist and that the fact that [these metrics] are baked into the allocation policy means that certain [parts of the country] will be disadvantaged.” *Id.*; see also McMichael, *Stealing Organs?*, *supra* note 12,

manipulate the measures for both heart and liver transplant candidates.⁴² The evidence for this comes from two policy changes in the last decade that provided transplant clinicians with clear ways to manipulate their patients' apparent medical urgency.⁴³ Almost immediately following the implementation of new allocation policies for livers and hearts, the relevant measures of medical urgency spiked in ways that are best explained by manipulation within the transplant system.⁴⁴

Looking beyond problems inherent to the current rules governing organ allocation, this Article next examines socioeconomic inequities within the organ allocation system.⁴⁵ Raising concerns about socioeconomic inequities, one transplant center director recently stated that policymakers have “reform[ed] . . . organ allocation policy so that it rewards the wealthy areas and wealthy states by providing resources from poor areas of the country”⁴⁶ In general, I find consistent evidence

at 192 (“The results of the empirical analysis reported in this Article evince a troubling trend: the systematic occurrence of manipulation within the liver allocation system.”).

⁴² See Thomas M. Cascino, Josef Stehlik, Wida S. Cherikh, Yulin Cheng, Tessa M.F. Watt, Alexander A. Brescia, Michael P. Thompson, Jeffrey S. McCullough, Min Zhang, Supriya Shore, Jessica R. Golbus, Francis D. Pagani, Donald S. Likosky & Keith D. Aaronson, *A Challenge to Equity in Transplantation: Increased Center-Level Variation in Short-Term Mechanical Circulatory Support Use in the Context of the Updated U.S. Heart Transplant Allocation Policy*, 41 J. HEART & LUNG TRANSPLANTATION 95, 100-01 (2022); McMichael, *Stealing Organs?*, *supra* note 12, at 139-42, 180.

⁴³ See Cascino et al., *supra* note 42; McMichael, *Stealing Organs?*, *supra* note 12, at 139-42, 180.

⁴⁴ See sources cited *supra* note 43.

⁴⁵ I focus on socioeconomic status and not other forms of inequity (such as racial discrimination) for two reasons. First, other work has investigated and continues to investigate racial inequity, and there is little reason to duplicate that work. Second, the Final Rule itself requires the development of “[p]olicies that reduce inequities resulting from socioeconomic status, including, but not limited to . . . [r]eform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities.” 42 C.F.R. § 121.4(a)(3)(iv). Thus, socioeconomic inequity can serve as *prima facie* evidence of the failure of allocation policies under the legal framework governing those policies.

⁴⁶ Malena Carollo & Ben Tanen, *Poorer States Suffer Under New Organ Donation Rules, As Livers Go to Waste*, THE MARKUP (Mar. 21, 2023, 2:00 PM), <https://themarkup.org/organ-failure/2023/03/21/poorer-states-suffer-under-new-organ-donation-rules-as-livers-go-to-waste> [https://perma.cc/Q49C-Y3FQ] [hereinafter Carollo & Tanen, *Poorer States*

that organ allocation policy over the last ten years has tolerated persistent socioeconomic inequities and that policies mandating broader organ sharing risk exacerbating these inequities. The average income of transplant recipients has increased markedly over the last several years, with shared organs routinely going to patients with higher incomes in comparison to organs recovered locally.⁴⁷ Additionally, an examination of incomes associated with organ donors and transplant recipients reveals that organ donors earn, on average, between \$5,000 and \$15,000 less than transplant recipients.⁴⁸ I also find greater disparities between donor and recipient incomes when an organ is used non-locally, such that greater national sharing risks widening already troubling gaps. This evidence suggests that organ allocation has exacerbated socioeconomic inequities.⁴⁹

Next, beyond the role of allocation policy in creating socioeconomic inequities within the allocation system itself, I consider the role of organ allocation across the entire population. Specifically, I consider the individuals that Glazier and other proponents of broader sharing pointedly wish to ignore.⁵⁰ To do so, I develop transplant amenable deaths as a population-based measure of medical urgency. My analysis of this measure suggests that organs are routinely harvested from donors who live in areas with more transplant amenable deaths per capita than the number of patients who receive those donated organs.

Suffer]. Timothy Schmitt — head of the transplant unit at the University of Kansas Health System — referred to policy changes facilitating greater national organ sharing as “the most backward plan that was ever created.” Carollo & Tanen, *Winners & Losers*, *supra* note 21.

⁴⁷ See *infra* Part III.B.

⁴⁸ See *id.*

⁴⁹ See 42 C.F.R. § 121.4(a)(3).

⁵⁰ Examining the entire population is necessary to understand the comprehensive effects of organ allocation policy. See Pullen, *supra* note 15, at 1251–54 (“Those who oppose the new allocation policy feel that HRSA was wrong to define the allocation problem in terms of patients on the waitlist and believes that allocation should encompass access to transplant centers, an access that may be threatened in less populated states if centers are forced to close due to a lack of organs to transplant. They take a broader view that encompasses the cumulative impact of organ allocation. In 2018, HRSA directed OPTN not to consider this cumulative impact, although that could change in 2019 in response to the February letter from Jones Day on behalf of 10 transplant centers.”).

In other words, organs tend to move from areas of higher transplant amenable deaths to areas of lower transplant amenable deaths. This movement is not consistent with a policy designed to increase access to transplants among populations with the greatest need for those transplants. Going further, I examine the relationship between imports and exports of organs and transplant amenable deaths per capita. In general, areas with more transplant amenable deaths are more likely to export organs than areas with fewer transplant amenable deaths — exactly the opposite pattern one would expect of policies designed to increase access to transplants.

The evidence developed here does not support the current approach to organ allocation policy. Problems with individual measures of medical urgency can be addressed without wholesale changes to allocation policy, and prior work has suggested some potential improvements.⁵¹ However, the other problems identified here — the exacerbation of socioeconomic status and disadvantaging individuals who cannot access a transplant waitlist — run much deeper and require more comprehensive reforms. Based on this evidence, I propose a new policy framework for organ allocation. Specifically, transplant amenable deaths should serve as guardrails for all future policy development, and I explore various policy options to install these regulatory guardrails. I offer multiple options instead of advocating for a single approach because one article cannot be the basis for reforming all of organ allocation policy. Other researchers should weigh in on various aspects of this proposal, and offering several different approaches to installing guardrails on allocation policy developments sets the table for continued conversation. This Article serves as an invitation for that conversation. In general, the goal should be to avoid moving organs from areas of high need to areas of low need based on transplant amenable deaths and avoid systematically transferring organs from low income to high income areas. Individual patient need should, of course, continue to factor into the allocation process based on improved

⁵¹ See, e.g., Dimitris Bertsimas, Jerry Kung, Nikolaos Trichakis, Yuchen Wang, Ryutaro Hirose & Parsia A. Vagefi, *Development and Validation of an Optimized Prediction of Mortality for Candidates Awaiting Liver Transplantation*, 19 AM. J. TRANSPLANTATION 1109, 1109-10 (2019) (developing a new model of medical urgency for liver transplant candidates using machine learning techniques).

measures of individual medical urgency. However, constraining movement of organs based on the impact of the overall system is necessary to ensure that the inequities infecting the current approach do not continue.

The remainder of this Article proceeds in four parts. Part I provides a brief background on organ allocation and transplantation and the complicated legal framework that grew up to govern them. It also details the data that the remainder of the Article analyzes. Part II uses that data to illustrate and examine the current legal framework governing organ allocation and transplantation, including justifications for the current approach. Part III explores the implications of the current system. It demonstrates that recent trends in organ allocation policy have enabled manipulation of medical urgency metrics and disadvantaged those of lower socioeconomic status and rural populations. It also develops the concept of transplant amenable deaths and demonstrates the problems associated with ignoring individuals unable to access an organ waitlist under current allocation policy. Part IV explores policies to remedy the failures of organ allocation policy identified in Part III. A brief conclusion follows.

I. ORGAN ALLOCATION IN THE UNITED STATES

For many diseases, organ transplantation represents the best (and, sometimes, only) treatment.⁵² Though medically complex, organ transplantation has developed from an experimental last-ditch option into a relatively routine treatment that surgeons perform thousands of times each year.⁵³ Unlike other surgeries, however, which can be performed as often as a surgeon is available, the number of available organs limits the number of transplant surgeries.⁵⁴ Given the life-and-death nature of organ allocation decisions, it is not surprising that the

⁵² See Roxana Moscalu, Anne Marie Smith & Harbans L. Sharma, *Diseases That Can be Cured Only by Organ Donations*, 2 ARCHIVE CLINICAL CASES 182, 182-97 (2015).

⁵³ See DAVID HAMILTON, A HISTORY OF ORGAN TRANSPLANTATION: ANCIENT LEGENDS TO MODERN PRACTICE 249-252 (2012).

⁵⁴ See 6 *Quick Facts About Organ Donation*, PENN MED., <https://www.pennmedicine.org/updates/blogs/transplant-update/2023/april/6-quick-facts-about-organ-donation> (last visited July 13, 2024) [<https://perma.cc/X9G7-TCNZ>] (detailing how many people die for lack of a transplantable organ in different contexts).

legal complexity of the framework governing organ allocation rivals the medical complexity of organ transplantation. Before delving into the specific legal issues that have ignited one of the most heated debates in healthcare law and policy, this Part details the development of organ transplantation and the current state of organ allocation policy in the United States. At the outset of navigating this legal labyrinth, it is worth repeating Eleventh Circuit’s words of caution: “Fair warning: This gets complicated.”⁵⁵

A. Organ Transplantation

The first transplant in the United States took place in 1954 at Brigham Hospital in Boston.⁵⁶ Over the next several decades, clinical techniques continued to develop,⁵⁷ but it was not until the 1980s that organ transplantation became a widely viable treatment.⁵⁸ The introduction of immunosuppressant drugs revolutionized organ transplantation by allowing the medical suppression of graft versus host disease and organ rejection.⁵⁹ While immunosuppressive drugs made many more transplants possible,⁶⁰ transplant clinicians must still carefully match donated organs to potential candidates based on various medical factors to mitigate the possibility of organ rejection.⁶¹ The combination of drugs

⁵⁵ Callahan v. United States Dep’t of Health & Human Servs., through Alex M. Azar II, 939 F.3d 1251, 1254 (11th Cir. 2019).

⁵⁶ HAMILTON, *supra* note 53, at 249-252.

⁵⁷ See Christoph Frohn, Lutz Fricke, Jan-Christoph Puchta & Holger Kirchner, *The Effect of HLA-C Matching on Acute Renal Transplant Rejection*, 16 NEPHROLOGY DIALYSIS TRANSPLANTATION 355, 355 (2001) (“The transplantation of kidney allografts has become a standard therapy for end-stage renal disease. The acute rejection of the graft by the host’s immune system remains an unsolved problem in this context.”).

⁵⁸ See Barker & Markmann, *supra* note 7, at 13-14.

⁵⁹ See *id.*

⁶⁰ See, e.g., Michael D. Duncan & David S. Wilkes, *Transplant-related Immunosuppression: A Review of Immunosuppression and Pulmonary Infections*, 2 PROC. AM. THORACIC SOC’Y 449, 449-55 (2005) (discussing various immunosuppressive therapies and some of the developments in these therapies since the 1980s).

⁶¹ The clinical science behind the compatibility of the donated organ and transplant candidate is well beyond the scope of this Article. For a non-medical discussion of organ matching and compatibility, see *Matching and Compatibility*, UC DAVIS HEALTH, <https://health.ucdavis.edu/transplant/livingkidneydonation/matching-and-compatibility.html> (last visited Jan. 21, 2024) [<https://perma.cc/R4PY-MDRJ>].

and careful clinical matching has transformed organ transplantation into a relatively routine clinical option for patients.

The development of immunosuppressive therapies and matching techniques arguably led to the current legal debate over organ allocation. “With the development of organ transplantation from an experimental procedure into a live-saving routine intervention, the scarcity of donor organs has become a defining issue at the heart of transplant medicine necessitating tragic choices on a daily basis.”⁶² These tragic choices are operationalized through organ allocation policy. In an attempt to avoid some of these tragic choices and increase the number of organ transplants performed, organ transplant centers in the 1960s began to develop informal connections to share organs among themselves.⁶³ If a transplant center gained access to a donated organ that was medically incompatible with its available transplant candidates, it would share that organ with a transplant center that had a medically compatible candidate.⁶⁴

These informal organ-sharing networks continued to develop alongside medical advances in organ transplantation and became increasingly important to both transplant centers and their patients.⁶⁵ Transplant centers gained access to additional organs, even if that meant sharing some of the organs recovered in their respective areas.⁶⁶ They also performed more (financially lucrative) transplants.⁶⁷ Patients gained greater access to life-saving transplants, and fewer donated organs were wasted because no medically compatible candidate was

⁶² Katrin S. Umgelter, Moritz Tobiasch, Aida Anetsberger, Manfred Blobner, Stefan Thorban & Andreas Umgelter, *Donor Organ Distribution According to Urgency of Need or Outcome Maximization in Liver Transplantation. A Questionnaire Survey Patients and Medical Staff*, 28 *TRANSPLANT INT’L* 448, 448 (2015).

⁶³ See J. Michael Dennis, *A Review of Centralized Rule-Making in American Transplantation*, 6 *TRANSPLANTATION REVS.* 130, 130-32 (1992) (discussing early informal networks that facilitated sharing organs among transplant programs).

⁶⁴ See *id.*

⁶⁵ See Richard J. Howard, Danielle L. Cornell & Larry Cochran, *History of Deceased Organ Donation, Transplantation, and Organ Procurement Organizations*, 22 *PROGRESS TRANSPLANTATION* 6, 10-11 (2012) (reviewing the early history of organ sharing through informal networks).

⁶⁶ See *id.*

⁶⁷ See *id.*

available.⁶⁸ The federal government recognized the importance of these networks, and in 1969, the Public Health Service began funding seven existing organ-sharing networks among transplant centers.⁶⁹

One network funded by the Public Health Service centered in Richmond, Virginia — the South-Eastern Regional Organ Procurement Network — eventually grew to include eighteen transplant centers.⁷⁰ Given its size and access to organs, this network began accepting requests from non-member transplant centers to list their patients on the network's matching system.⁷¹ The United Network for Organ Sharing (UNOS), which continues to play important roles in organ sharing and allocation policy today, emerged from this early informal network.⁷² UNOS began operating the first twenty-four-hour matching system in the mid-1970s, and by 1983, UNOS was the only system operating that could match donated organs to transplant candidates across the country.⁷³ Given UNOS's success and the increasingly national nature of organ sharing among transplant centers, Congress began to consider federal involvement in the distribution of donated organs.⁷⁴ The NOTA, which fundamentally changed the legal landscape around organ transplantation and allocation, was enacted in 1984.⁷⁵ That Act remains in effect today, and the next Section engages with the legal

⁶⁸ See *id.*

⁶⁹ DAVID L. WEIMER, *MEDICAL GOVERNANCE: VALUES, EXPERTISE, AND INTERESTS IN ORGAN TRANSPLANTATION* 44-45 (2010).

⁷⁰ *Id.* at 45; Richard A. Rettig, *The Politics of Organ Transplantation: A Parable of Our Time*, 14 J. HEALTH POL., POL'Y & L. 191, 193-204 (1989).

⁷¹ WEIMER, *supra* note 69, at 45; Rettig, *supra* note 70, at 196.

⁷² Howard et al., *supra* note 65, at 11; Rettig, *supra* note 70, at 207.

⁷³ WEIMER, *supra* note 69, at 75; see Howard et al., *supra* note 65, at 11; Rettig, *supra* note 70, at 210; see also Dennis, *supra* note 63, at 130 ("By 1983 almost all transplant programs paid a fee . . . to access the UNOS program for the placement and receipt of shared kidneys.").

⁷⁴ James F. Blumstein, *Government's Role in Organ Transplantation Policy*, 14 J. HEALTH POL., POL'Y & L. 5, 12-13 (1989); see Dennis, *supra* note 63, at 131 ("As the transplant community began to reconsider the need for a national network, the federal government took an interest in the rules for distributing organs."); Rettig, *supra* note 70, at 204-07 (describing early federal involvement in organ transplantation).

⁷⁵ WEIMER, *supra* note 69, at 46; Dennis, *supra* note 63, at 131; Rettig, *supra* note 70, at 204-05.

framework established by the NOTA and the increasingly contentious legal debate around organ allocation.

B. Organ Recovery, Donation, Allocation, and the Laws that Govern Them

The NOTA replaced informal organ-sharing networks with a federal legal framework for the allocation of donated organs for transplant.⁷⁶ The NOTA also banned the sale of human organs, leaving the federalized allocation scheme as the only legal means by which patients could obtain a cadaveric organ.⁷⁷ This non-market allocation system generated intense debate almost from its inception, and that debate has become even more heated over the last few years with the implementation of new rules.⁷⁸ Before engaging with those rules, however, this Part details the general framework created by the NOTA and subsequent regulations. The first key fact about the NOTA is that, though it includes “Transplant” in its name, it functions primarily to govern organ allocation, not transplant surgeries.⁷⁹ The next key fact about the NOTA is that the Act itself includes very little in the way of day-to-day allocation policies and rules.⁸⁰ Instead, it provides the framework in which those day-to-day rules are created and enforced.⁸¹

To create a framework for organ allocation, the NOTA established and defined the roles of various organizations that make organ allocation and transplantation possible.⁸² Consistent with the Eleventh Circuit’s admonition concerning the complexity of the organ allocation system,⁸³

⁷⁶ 42 U.S.C. § 273 *et seq.* A comprehensive discussion of the history of the NOTA is well beyond the scope of this Article. For that discussion, see generally Blumstein, *supra* note 74, at 5-39, and Rettig, *supra* note 70, at 191-227.

⁷⁷ 42 U.S.C. § 274e. Cadaveric organs refer to all organs recovered from deceased individuals.

⁷⁸ See Henry B. Hansmann, *The Economics and Ethics of Markets for Human Organs*, in *ORGAN TRANSPLANTATION POLICY: ISSUES AND PROSPECTS* 60-63 (James F. Blumstein & Frank A. Sloan eds., 1989).

⁷⁹ WEIMER, *supra* note 69, at 75 (“Indeed, it was only with [the passage of the NOTA] that the regime moved . . . to allocation.”).

⁸⁰ See 42 U.S.C. §§ 273-74(g).

⁸¹ See *id.*

⁸² *Id.*

⁸³ Callahan v. United States Dep’t of Health & Human Servs., through Alex M. Azar II, 939 F.3d 1251, 1254 (11th Cir. 2019) (stating “[f]air warning: This gets complicated”).

Table 1 provides an overview of the alphabet soup of various organizations, entities, and rules relevant to that system. The remainder of this section then explains how these various pieces fit together in the current organ allocation system.

TABLE 1: THE LEGAL FRAMEWORK AROUND ORGAN ALLOCATION

Acronym	Name	Summary
NOTA	National Organ Transplant Act	A federal law passed in 1984 that provides the framework for organ allocation and transplantation in the United States.
OPTN	Organ Procurement and Transplantation Network	The legal entity created by the NOTA to match donated organs to medically appropriate transplant candidates. The OPTN also develops the rules and policies that govern organ allocation. Membership rules ensure that transplant experts retain a voice in organ allocation policy. These rules also divide the country into 11 regions.
UNOS	United Network for Organ Sharing	The private, nonprofit entity that operates the OPTN.
OPO	Organ Procurement Organization	A nonprofit organization responsible for locating, procuring, and transporting organs for transplant. Each OPO has exclusive authority over a geographic area designated by the federal government.
DSA	Donation Service Area	The exclusive geographic area in which an OPO operates.

The OPTN forms the heart of the U.S. organ allocation system. The OPTN exists to match organs procured by OPOs to medically appropriate transplant candidates and to formulate policies that determine how to allocate donated organs.⁸⁴ The NOTA requires HHS to contract with an appropriate organization to operate the OPTN.⁸⁵ Since the passage of the NOTA, only UNOS has held the contract to

⁸⁴ 42 U.S.C. § 274(b)(2)(A) (“The Organ Procurement and Transplantation Network shall . . . establish . . . a national list of individuals who need organs, and . . . a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list . . .”).

⁸⁵ *Id.* § 274(a). The OPTN must “be a private nonprofit entity.” *Id.* § 274(b)(1)(A).

operate the OPTN.⁸⁶ Whenever an organ is recovered from an organ donor, the UNOS computer system executes a “match run.”⁸⁷ This match run creates a list of individuals who are medically compatible with a given organ.⁸⁸ “Blood type and other medical factors weigh into the allocation of every donated organ, but each organ type has its own individual distribution policy, which reflect factors that are unique to each organ type.”⁸⁹ These distribution (allocation) policies and factors ultimately rank-order transplant candidates, and the higher a candidate appears on this rank-ordered list, the greater that candidate’s need for a particular organ based on the allocation policies in place.⁹⁰

In addition to conducting match runs, the OPTN plays a substantial role in formulating the allocation policies that ultimately determine who receives life-saving organs. Indeed, “[s]ince it began operations in 1986, the OPTN has exercised de facto authority over the content of rules governing the procurement and allocation of cadaveric organs.”⁹¹ The use of a private body to develop such important rules — OPTN rules determine who lives and who dies on a daily basis — is unusual in the federal regulatory realm.⁹² The OPTN, which is overseen by HHS,⁹³ relies on various rulemaking bodies in setting organ allocation policy.⁹⁴ These bodies include transplant physicians, clinicians, and

⁸⁶ Greg Segal, Jennifer Erickson, Donna Cryer & Bryan Sivak, *Monopoly Be Gone: A New Chapter in U.S. Organ Procurement and Transplantation*, MEDPAGE TODAY (Apr. 4, 2023), <https://www.medpagetoday.com/opinion/second-opinions/103855> [<https://perma.cc/Q5W8-7C3A>].

⁸⁷ *How We Match Organs*, UNOS, <https://unos.org/transplant/how-we-match-organs/> (last visited Jan. 15, 2024) [<https://perma.cc/93VT-PTWA>].

⁸⁸ *See id.*

⁸⁹ *Id.*; *see also* 42 C.F.R. § 121.8 (directing that the OPTN’s allocation policies “[s]hall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate”).

⁹⁰ *How We Match Organs*, *supra* note 87.

⁹¹ WEIMER, *supra* note 69, at 73.

⁹² *See* 42 C.F.R. § 121.4.

⁹³ *See Callahan v. United States Dep’t of Health & Hum. Servs.*, through Alex M. Azar II, 939 F.3d 1251, 1254–57 (11th Cir. 2019) (discussing HHS oversight of the OPTN).

⁹⁴ *See How We Develop Policy*, UNOS, <https://unos.org/policy/how-we-develop-policy/> (last visited July 13, 2024) [<https://perma.cc/VRD2-ER4X>].

administrators from around the country.⁹⁵ More specifically, the NOTA provides membership rules that divide the country into regions to guarantee that transplant centers and transplant professionals from across the country play a role in the development of organ allocation policy.⁹⁶

In formulating organ allocation policies, the OPTN follows a process that resembles federal agency rulemaking. The OPTN must “[p]rovide opportunity for the OPTN membership and other interested parties to comment on proposed policies and shall take into account the comments received in developing and adopting policies for implementation by the OPTN.”⁹⁷ Though the OPTN lacks the enforcement authority of a federal agency, it possesses the authority to enforce its rules and policies by regulating membership in the OPTN.⁹⁸ OPTN membership is a prerequisite for participating in the U.S. organ allocation and transplantation system, so the threat of losing this membership provides clear incentives for complying with OPTN rules and policies.⁹⁹ In creating new rules and policies, the OPTN is subject to limited oversight by HHS and must create its rules and policies consistent with federal regulations.¹⁰⁰ Specifically, the Final Rule provides substantive guidance that governs OPTN rules.¹⁰¹ The interpretation of the Final Rule, particularly its provisions relating to the role of geography in organ allocation policies, has become central to the ongoing debate over those policies. The next section engages in detail with this debate and the interpretation of the Final Rule more generally. Before engaging with the allocation debate, however, it is

⁹⁵ *Liver Policy Updates*, UNOS, <https://unos.org/policy/liver/policy-updates/> (last visited July 13, 2024) [<https://perma.cc/5R7J-HRQ2>].

⁹⁶ See *Regions*, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, <https://optn.transplant.hrsa.gov/members/regions/> (last visited Jan. 16, 2024) [<https://perma.cc/49M3-NSLS>] (describing the role of regions within the OPTN).

⁹⁷ 42 C.F.R. § 121.4(b)(1).

⁹⁸ A federal law passed several years after the NOTA requires hospitals with transplant programs to be members of the OPTN and to “abide[] by the rules and requirements of” the OPTN. 42 U.S.C. § 1320b-8(a)(1)(B).

⁹⁹ *Id.*

¹⁰⁰ See *Callahan v. United States Dep’t of Health & Hum. Servs.*, through Alex M. Azar II, 939 F.3d 1251, 1254 (11th Cir. 2019).

¹⁰¹ 42 C.F.R. § 121.8.

helpful to understand the process of organ allocation, and how OPOs feature prominently in that process.

The NOTA tasks OPOs with the recovery of donated organs.¹⁰² OPOs “provide the cornerstone of the U.S. organ procurement system”¹⁰³ by working with transplant centers and hospitals within specific geographic areas to recover, preserve, and transport organs for transplantation.¹⁰⁴ Each OPO manages organ procurement in an exclusive geographic area of responsibility, referred to as DSAs, and HHS assigns DSAs to individual OPOs.¹⁰⁵ In the context of organ transplantation, “[t]he term ‘local’ . . . means an Organ Procurement Organization’s . . . designated service area.”¹⁰⁶

Currently, fifty-six different OPOs operate across the United States to recover organs donated for transplantation, though fifty-eight OPOs operated until 2020.¹⁰⁷ Because these fifty-eight OPOs operated during the time period analyzed in this Article, I will generally focus on fifty-eight separate OPOs and the fifty-eight DSAs they served. Within their individual DSAs, OPOs interact with local hospitals to identify potential organ donors.¹⁰⁸ Individuals (or their next of kin in some situations)

¹⁰² 42 U.S.C. § 273(a). The NOTA also requires that OPOs be nonprofit entities, and they are incorporated under state law. *Id.* § 273(b)(1)(B).

¹⁰³ DAVID L. KASERMAN & A. H. BARNETT, *THE U.S. ORGAN PROCUREMENT SYSTEM: A PRESCRIPTION FOR REFORM* 13 (2002).

¹⁰⁴ See *id.* at 13-14 (discussing the functions OPOs serve); Meredith M. Havekost, Note, *The Waiting Game: How States Can Solve the Organ-Donation Crisis*, 72 VAND. L. REV. 691, 694-95 (2019) (describing the roles OPOs play).

¹⁰⁵ See 42 U.S.C. § 273(b)(1)(E). Historically, these geographic areas overlapped, but OPOs now generally have exclusive authority within their assigned DSA.

¹⁰⁶ Glazier, *supra* note 27, at 140.

¹⁰⁷ See *Infinite Legacy Established After OPO Merger*, UNOS (Jan. 3, 2023), <https://unos.org/news/infinite-legacy-established-after-opo-merger/> [<https://perma.cc/54HQ-LHUD>]; *LifeChoice Donor Services and New England Organ Bank to Merge Jan. 1*, UNOS (Dec. 23, 2020), <https://unos.org/news/lifechoice-donor-services-and-new-england-organ-bank-to-merge-jan-1/> [<https://perma.cc/NHA5-PDBD>].

¹⁰⁸ *How UNOS, OPOs and Transplant Programs Work Together to Save Lives*, UNOS, <https://unos.org/about/national-organ-transplant-system/> (last visited July 23, 2024) [<https://perma.cc/M9AL-MVGC>].

must consent to donate their organs in the first instance.¹⁰⁹ Federal regulations require hospitals to notify their assigned OPO of patients who have died or will soon die so that the OPO can begin the organ harvesting process.¹¹⁰ This process can only commence after “the donor is declared medically and legally brain dead.”¹¹¹ Once an OPO has harvested an organ, it enters the match run system administered by UNOS described above.¹¹² That system determines to whom the organ will be allocated, and the OPO that recovered the organ must abide by that allocation decision.

Because OPOs are bound by the allocation decision made by the OPTN and the rules governing allocation at any given time, the debate over allocation policy has not generally focused directly on OPOs.¹¹³ However, the regulatory debates over OPOs and the OPTN, both of which have borne fruit with recent regulatory overhauls, are interconnected with the debate over the Final Rule, the role of geography, and broader national organ sharing. Accordingly, the next Section details the relationships between these various regulatory dust ups. Understanding the parallel debates over OPOs and the OPTN not only provides greater context for the unresolved debate over geography and allocation policy, but also provides a blueprint for potential regulatory solutions to the problems underlying the latter debates.

C. Parallel Regulatory Battles

The laws governing organ recovery, allocation, and transplantation are complex, but three key battlegrounds have emerged over the last several years. This Article focuses on the battle over geography, but two important and related debates provide relevant context and offer insight

¹⁰⁹ *How to Sign Up*, HEALTH RES. & SERVS. ADMIN., <https://www.organdonor.gov/sign-up/how> (last visited July 23, 2024) [<https://perma.cc/RVE3-GLAU>] (describing the process of becoming an organ donor).

¹¹⁰ 42 C.F.R. § 482.45 (2024) (detailing the procedures hospitals must follow when working with OPOs to identify potential donors).

¹¹¹ Havekost, *supra* note 104, at 695.

¹¹² *How We Match Organs*, *supra* note 87.

¹¹³ See Alex Chan & Alvin E. Roth, *Regulation of Organ Transplantation and Procurement: A Market Design Lab Experiment*, 132 J. POL. ECON. 1, 8-10 (forthcoming 2024), <https://doi.org/10.1086/730546>.

into that battle. First, advocates, clinicians, researchers, and policymakers have highlighted the flaws in the regulatory structure of the OPTN.¹¹⁴ Because this organization formulates the rules that govern the day-to-day allocation of donated organs, its form and function are critical to the transplantation system. Recently, the OPTN has come under fire for mismanagement of the organ allocation and transplantation system and concentrating power over such an important aspect of the healthcare system in a single organization.¹¹⁵ A report from the National Academies of Sciences, Engineering, and Medicine recommended a variety of improvements to the OPTN as part of its 2022 report.¹¹⁶ Other reports have offered similar criticisms of the current model and other options for reform.¹¹⁷

While the battle over the form and function of the OPTN has likely not yet concluded, Congress passed the Securing the U.S. Organ Procurement and Transplantation Network Act in September 2023, “which allows for the award of multiple grants, contracts, or cooperative agreements to operate the Organ Procurement and Transplantation Network.”¹¹⁸ This Act represents an important step forward on a critical issue plaguing the organ transplantation system. While it does not directly address the issue of geography, it demonstrates the willingness of the federal government to reform the current system.

A second key battle within the organ allocation debate also saw significant movement recently.¹¹⁹ Advocates, policymakers, and researchers have criticized the oversight of the OPOs responsible for

¹¹⁴ See Lenny Bernstein, *Troubled U.S. Organ Transplant System Targeted for Overhaul*, WASH. POST, <https://www.washingtonpost.com/health/2023/03/22/transplant-system-overhaul-unos/> (last updated Mar. 22, 2023, 6:29 PM) [<https://perma.cc/Y6BY-9A9J>].

¹¹⁵ *Id.*; Chris Tachibana, *Ending UNOS's Monopoly Over the U.S. Organ Transplant System*, PENN LEONARD DAVIS INST. OF HEALTH ECON. (May 30, 2023), <https://ldi.upenn.edu/our-work/research-updates/ending-unos-monopoly-over-the-u-s-organ-transplant-system/> [<https://perma.cc/SBN5-2KYS>].

¹¹⁶ NAT'L ACADEMIES, *supra* note 13, at 35-60.

¹¹⁷ See, e.g., Tachibana, *supra* note 115 (outlining problems with the current transplant system and detailing potential steps towards improvement).

¹¹⁸ Press Release, White House, Bill Signed: H.R. 2544 (Sept. 22, 2023), <https://www.whitehouse.gov/briefing-room/legislation/2023/09/22/bill-signed-h-r-2544> [<https://perma.cc/73DA-ND2E>].

¹¹⁹ See Pullen, *supra* note 15, at 1251-54.

recovering organs from donors across the country.¹²⁰ The federal government has historically relied on a form of self-regulation to police OPOs following the passage of the NOTA.¹²¹ To evaluate OPO performance, the federal government received reports from individual OPOs that included the number of “eligible deaths” occurring within the OPOs’ assigned DSAs and the number of organs the OPOs recovered each year.¹²² It used these two numbers to determine the rate of successful organ recoveries, which is the most important measure of OPOs’ success. However, because the number of “eligible deaths” was self-reported by OPOs, it did not necessarily provide a reliable metric for the number of deaths for which organ recovery was possible.¹²³

In conjunction with the problems of self-reported metrics, the federal government was unwilling to cut ties with poor-performing OPOs and replace them with new OPOs. The Federation of American Scientists has argued that “[m]any of the problems and inefficiencies of the organ waiting list are solvable, but the federal government has never . . . pulled a contract from one of its [OPOs] due to failure to perform, despite government reports showing as few as one in five potential organ donors are recovered.”¹²⁴

¹²⁰ See David S. Goldberg, Teresa Shafer & Laura Siminoff, *Important Facts About Organ Donation and OPO Performance*, 102 *TRANSPLANTATION* e249, e249-50 (2018) [hereinafter Goldberg et al., *Important Facts*]; David Goldberg, Brianna Doby, Laura Siminoff, Malay Shah & Raymond Lynch, *Rejecting Bias: The Case Against Race Adjustment for OPO Performance in Communities of Color*, 20 *AM. J. TRANSPLANTATION* 2337, 2337-42 (2020); Wali Johnson, Kathryn Kraft, Pranit Chotai, Raymond Lynch, Robert S. Dittus, David Goldberg, Fei Ye, Brianna Doby, Douglas E. Schaubel, Malay B. Shah & Seth J. Karp, *Variability in Organ Procurement Organization Performance by Individual Hospital in the United States*, 158 *JAMA SURGERY* 404, 404-09 (2023); see, e.g., Allan B. Massie & John Paul Roberts, *Geographic Disparity in Liver Allocation: Time to Act or Have Others Act for Us*, 102 *TRANSPLANTATION* 189, 189-90 (2018).

¹²¹ See Johnson et al., *supra* note 120; Raymond J. Lynch, Brianna L. Doby, David S. Goldberg, Kevin J. Lee, Arielle Cimen & Seth J. Karp, *Procurement Characteristics of High- and Low- Performing OPOs as Seen in OPTN/SRTR Data*, 22 *AM. J. TRANSPLANTATION* 455, 455-60 (2022).

¹²² Lynch et al., *supra* note 121, at 456-57.

¹²³ *Id.*

¹²⁴ *Organs Initiative*, FED. OF AM. SCIENTISTS, <https://fas.org/issues/organs-initiative/> (last visited Jan. 20, 2024) [<https://perma.cc/54RZ-XA7Y>]. Other groups connected to the Federation have similarly argued that “[t]hough nearly 95% of Americans support organ donation, massive systemic inefficiencies prevent the United States’ organ-

New federal regulations that became effective in 2021 have targeted the problems associated with under-performing OPOs.¹²⁵ These regulations replace OPO-reported “eligible deaths” with a more objective measure of the number of deaths which could result in an organ donation. Specifically, the new regulations require the use of “cause, age, and location consistent” (“CALC”) deaths.¹²⁶ As explained by transplant clinicians, CALC deaths are “those deaths occurring among persons aged [seventy-five] or younger from donation-consistent causes in the inpatient setting.”¹²⁷ These deaths are calculated based on death certificates recorded by individual states instead of death statistics reported by OPOs, providing the federal government with a more reliable metric of the number of deaths that may yield donated organs.¹²⁸ Thus, the new regulations implement more robust measures against which to judge OPO performance.¹²⁹ Additionally, the regulations also provide for the termination of contracts with OPOs which fail to meet certain benchmarks.¹³⁰ Though the new rules governing OPOs are not perfect,¹³¹ they demonstrate the

donation system from recovering organs.” DONNA CRYER, JENNIFER ERICKSON, CRYSTAL GADEGBEKEU, GREG SEGAL & ABE SUTTON, ADDRESSING THE ORGAN-DONATION CRISIS 2-3 (2020), <https://uploads.dayoneproject.org/2020/04/03165641/Addressing-the-Organ-Donation-Crisis.pdf> [<https://perma.cc/J4RR-MYVC>].

¹²⁵ Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 Fed. Reg. 77898, 77898 (Feb. 1, 2021) (to be codified at 42 C.F.R. pt. 486).

¹²⁶ *Id.*

¹²⁷ Lynch et al., *supra* note 121, at 456. Donation-consistent causes of death include “ischemic cardiac disease, stroke, and external causes.” *Id.* (“CALC deaths are those deaths occurring in persons aged 75 or younger in the inpatient acute care setting, from donation-consistent mechanism of death (ICD-10 codes I20–I25, I60–I69, and V01–Y89, corresponding to ischemic cardiac disease, stroke, and external causes).”).

¹²⁸ *Id.*

¹²⁹ Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 Fed. Reg. at 77898.

¹³⁰ *See id.*

¹³¹ *See* Alexandra Glazier, *New Regulations for Organ Procurement Organizations Pose Concerns*, BILL OF HEALTH (Jan. 7, 2021), <https://blog.petrieflom.law.harvard.edu/2021/01/07/regulation-organ-procurement-organizations-concerns> [<https://perma.cc/6TKW-D366>] (detailing concerns about the new regulations governing OPOs).

possibility of meaningful reform on the issues impacting the organ transplantation system.

While the reforms to the OPTN and OPOs represent important achievements, they do very little to address the debate over organ allocation. Unless the new regulations governing OPOs result in sufficiently more organ recoveries to allow every transplant candidate to receive an organ, they will not address the more fundamental debate over who should receive donated organs. Additionally, the best available evidence suggests that organ shortages will continue.¹³² With continued shortages, arguments over geography and organ allocation policy will likely intensify in the coming years.

The debate over organ allocation policy and the role of geography is multi-faceted, but two general points of view have emerged. On one side, advocates of broader organ sharing argue that this sharing is necessary to ensure that the most medically urgent patients receive organs first.¹³³ Without this sharing, they contend, geography will create arbitrary barriers to patients receiving necessary medical care.¹³⁴ On the other side, advocates of more locally focused allocation policy argue that measures of sickness used to justify broader sharing fail to represent which patients have the greatest need and are subject to manipulation by transplant centers.¹³⁵ They also argue that broader organ sharing exacerbates inequities in the healthcare system by denying access to transplants to more rural and impoverished areas of the country.¹³⁶

Both sides can find support for their arguments in the Final Rule.¹³⁷ Though the Final Rule does not govern day-to-day organ allocation policies, those policies must comply with the Final Rule under the NOTA.¹³⁸ Advocates of broader national organ sharing generally

¹³² Goldberg et al., *supra* note 120, at e249-50; Johnson et al., *supra* note 120, at 404-09.

¹³³ Glazier, *supra* note 27, at 143-44.

¹³⁴ See, e.g., Carollo & Tanen, *Winners & Losers*, *supra* note 21 (detailing these arguments); see also Glazier, *supra* note 27, at 140-45 (detailing more formal arguments).

¹³⁵ Pullen, *supra* note 15, at 1255.

¹³⁶ *Id.*

¹³⁷ *Id.* at 1253 (“[T]he transplantation community is split between those who are focused on section 121.8 of the Final Rule, which details expectations for organ allocation policy and considers the waitlist the most important factor, and those who are focused on section 121.4, with its inclusion of equity in relation to socioeconomic factors.”).

¹³⁸ 42 U.S.C. § 274(b)(2)(A).

emphasize Section 121.8 of the Final Rule, which provides in part that organ allocation policies “[s]hall not be based on the candidate’s place of residence or place of listing.”¹³⁹ That section further lists as an “[a]llocation performance goal . . . [d]istributing organs over as broad a geographic area as feasible . . . and in order of decreasing medical urgency.”¹⁴⁰ In contrast, advocates of locally focused allocation often point to section 121.4 of the Final Rule, which requires the development of “[p]olicies that reduce inequities resulting from socioeconomic status.”¹⁴¹ It further directs the “[r]eform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities.”¹⁴² They argue that broader national organ sharing results in poorer areas of the country sending more of the organs they recover to richer areas of the country.¹⁴³

While their conflicting interpretations of the Final Rule certainly contribute to their disagreement, reducing the positions of each side in the organ allocation debate to a simple disagreement over the interpretation of a regulation would oversimplify the issues.¹⁴⁴ Indeed, both sides recognize that a regulation favoring one side or the other will not end the debate. With Congressional leaders signaling a strong interest in organ allocation policy,¹⁴⁵ both local and national advocates

¹³⁹ 42 C.F.R. § 121.8(a)(8); *cf.* 42 C.F.R. § 121.2 (stating that the term “[t]ransplant candidate means an individual who has been identified as medically suited to benefit from an organ transplant and has been placed on the waiting list by the individual’s transplant program”).

¹⁴⁰ 42 C.F.R. § 121.8(b)(3).

¹⁴¹ *Id.* § 121.4(a)(3).

¹⁴² *Id.* § 121.4(a)(3)(iv).

¹⁴³ Carollo & Tanen, *Winners & Losers*, *supra* note 21.

¹⁴⁴ *See, e.g.*, Callahan v. United States Dep’t of Health & Hum. Servs., through Alex M. Azar II, 434 F. Supp. 3d 1319, 1327 (N.D. Ga. 2020) (acknowledging in the context of a lawsuit over liver allocation policy that “[t]he issues at stake have causes, ramifications, and potential legislative remedies that extend beyond the contours of this case”).

¹⁴⁵ *See, e.g.*, Letter from Charles E. Grassley to Alex Azar, *supra* note 19 (“We are writing to voice concern about a national policy change that could lead to prolonged waiting periods for many Americans seeking liver transplants.”); *see also* Letter from Charles E. Grassley to Alex Azar, *supra* note 19 (expressing concern that the move toward more national sharing “ignored the impact of socio-economic factors and local organ procurement efforts that help ensure successful liver transplants”); *Organ*

have offered extensive policy arguments in case Congress decides to repeal or amend the NOTA and abrogate the Finale Rule.¹⁴⁶

The next Section engages with the arguments and evidence proffered by those in favor of broader national organ sharing and does not limit itself to the narrow confines of the Final Rule. In doing so, it does not seek to simply recite the static evidence that is provided in the existing literature. Instead, it synthesizes existing arguments and evidence using the most recently available data to demonstrate why the last ten years of allocation policy development have largely favored broader organ sharing. Before developing that data-driven explanation and evaluation, the next Section details the relevant data.

D. Examining Organ Allocation Policy: The Data

To examine a complete picture of the organ transplantation system, I analyze a series of datasets that provide different information between 2011 and 2021.¹⁴⁷ First, I rely on the Scientific Registry of Transplant Recipients (“SRTR”) for information on all aspects of the organ transplantation system.¹⁴⁸ Gathering data from OPOs, the OPTN, and other sources, the SRTR has created a comprehensive series of datasets on donors, transplant candidates, waitlist registrations, transplant surgeries, and post-transplant care.¹⁴⁹ With respect to donors, the SRTR datasets include information on every organ donor’s demographics,

Transplants: Changes in Allocation Policies for Donated Livers and Lungs, U.S. GOV’T ACCOUNTABILITY OFF. (Nov. 4, 2020), <https://www.gao.gov/assets/gao-21-70.pdf> [<https://perma.cc/J2T3-SCV8>].

¹⁴⁶ See *supra* note 145 and accompanying text.

¹⁴⁷ This study was determined to be exempt from review by the Institutional Review Board.

¹⁴⁸ *Data That Drives Development*, SCI. REGISTRY OF TRANSPLANT RECIPIENTS, <https://www.srtr.org/about-the-data/the-srtr-database/> (last visited Feb. 25, 2021) [<https://perma.cc/J693-HSC4>]. This study used data from the Scientific Registry of Transplant Recipients (“SRTR”). The SRTR data system includes data on all donor, wait-listed candidates, and transplant recipients in the US, submitted by the members of the Organ Procurement and Transplantation Network (“OPTN”). The Health Resources and Services Administration (“HRSA”), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors.

¹⁴⁹ *Id.*

medical history, location of donation, which organs were harvested, and the OPO that harvested the organs.¹⁵⁰

For transplant candidates, the SRTR datasets include detailed medical histories, the transplant center that listed the candidate for a transplant, the DSA in which the transplant center is located, and the date of transplant.¹⁵¹ By combining information across donors and transplant recipients, I can directly examine the role of geography in organ allocation policy. Specifically, I can identify whether a transplanted organ was recovered locally (i.e., the organ was recovered in the same DSA where the patient received their transplant) or was shared non-locally (i.e., the organ was recovered in a different DSA from where the patient received transplant).¹⁵² Using this information, I can identify flows of organs from within and across DSAs, and this ability is key to examining the role of allocation policy in helping or hurting organ transplantation in different parts of the country.

While the SRTR datasets include nearly comprehensive information on organ donors, transplant recipients, and transplant surgeries, they do not include information on the number of people who have elected to become organ donors.¹⁵³ To obtain that information, I rely on a dataset compiled by Donate Life America.¹⁵⁴ This dataset provides information on the number of individuals registered as organ donors in each state between 2010 and 2020.¹⁵⁵ Referred to as “designations,”

¹⁵⁰ See *id.* The data reported here have been supplied by the Hennepin Healthcare Research Institute (“HHRI”) as the contractor for the Scientific Registry of Transplant Recipients (“SRTR”). The interpretation and reporting of these data are the responsibility of the author and in no way should be seen as an official policy of or interpretation by the SRTR or the U.S. Government.

¹⁵¹ See *id.*

¹⁵² For the purposes of determining whether a patient used a local organ, I assign a patient to the DSA associated with the transplant center where the transplant occurred.

¹⁵³ See *SAF Data Dictionary*, SCI. REGISTRY OF TRANSPLANT RECIPIENTS, <https://www.srtr.org/requesting-srtr-data/saf-data-dictionary/> (last visited Sept. 17, 2024) [<https://perma.cc/3GB8-AUS3>].

¹⁵⁴ *Organ, Eye, and Tissue Donation Statistics*, DONATE LIFE AMERICA, <https://www.donatelife.net/statistics/> (last visited Jan. 20, 2024) [<https://perma.cc/W974-Y6LB>].

¹⁵⁵ See *id.*

these organ donor registrations represent a key component of the organ allocation and transplantation system.¹⁵⁶

Next, to further understand organ donations and recoveries, I gather information on the number of deaths that could potentially result in organ donation, consistent with the definition of such deaths in recently promulgated regulations. Specifically, I start with data on every death that occurred in the United States between 2011 and 2021. Data on these deaths comes from the United States' National Vital Statistics System, which is maintained by the National Center for Health Statistics ("NCHS") and the Centers for Disease Control and Prevention ("CDC"). I received permission from the NCHS to analyze the restricted-use mortality files which provide detailed information on all deaths at the county level.¹⁵⁷ Included in the dataset are the decedent's year of death, state and county of death, and cause of death as indexed by the International Classification of Diseases (Tenth Revision) ("ICD-10") codes. The ICD-10 codes represent a standardized method for classifying causes of death and provide a comprehensive scheme to isolate specific causes of death.

Using the ICD-10 codes available in the mortality data, I follow the CALC methodology as defined in recent federal regulations to identify all deaths consistent with organ donation in each county and in each month across the entire United States between 2011 and 2021.¹⁵⁸ Specifically, I identify deaths of individuals aged seventy-five or younger who died in a hospital inpatient setting.¹⁵⁹ Among these individuals, I count the number of decedents whose underlying cause of death is coded as "donation consistent" based on the CALC methodology's list of donation consistent ICD-10 codes.¹⁶⁰ Even though the federal

¹⁵⁶ *See id.*

¹⁵⁷ Documentation to this effect is on file with the author.

¹⁵⁸ Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 Fed. Reg. 77898, 77908 (Feb. 1, 2021) (to be codified at 42 C.F.R. pt. 486).

¹⁵⁹ Lynch et al., *supra* note 121, at 455 ("CALC deaths are those deaths occurring in persons aged 75 or younger in the inpatient acute care setting, from donation-consistent mechanism of death.").

¹⁶⁰ *Id.* at 456 (including the following: "ICD-10 codes I20–I25, I60–I69, and V01–Y89, corresponding to ischemic cardiac disease, stroke, and external causes").

regulations only govern OPO performance after 2021, calculating the rate of CALC deaths over time provides a comprehensive picture of the number of organs available over time. And because this methodology does so without relying on any information self-reported by OPOs, it provides an objective number of deaths consistent with donation.

Next, I use the same information from the mortality data to construct a new measure of transplant amenable deaths. In the interest of clarity, I detail the construction of this novel metric below in closer proximity to the analysis of transplant amenable deaths.¹⁶¹

Finally, I gather demographic data on the United States population at the county and zip-code levels from the American Community Survey.¹⁶² These data allow me to calculate various relevant outcomes on a per capita basis throughout my analysis and identify rural counties through the rural-urban commuting area codes associated with individual zip codes. I use per capita income over time to calculate the relative affluence of different parts of the country that benefit from or are harmed by new organ allocation policies.

Throughout the analysis, I combine all the datasets described above in various ways and at different levels of aggregation. For much of the analysis, I aggregate the data to the DSA level. Because much of the debate over organ allocation policy focuses on the non-local sharing of organs, the DSA-level represents the most natural level at which to examine the data.¹⁶³ I also consider the national, county, state, and zip-code levels for different parts of the analysis. Collectively, the datasets

¹⁶¹ See *infra* Part III.C.

¹⁶² *American Community Survey*, U.S. CENSUS BUREAU, <https://www.census.gov/programs-surveys/acs> (last visited Jan. 20, 2024) [<https://perma.cc/WKA6-KHHV>].

¹⁶³ For the NCHS death data and population data, aggregating to the DSA level is straightforward since DSAs are simply collections of individual counties. Roughly forty counties belong to more than one DSA. When aggregating data to the DSA level, these counties are aggregated to all DSAs to which they belong. When reporting information graphically at the county level, these counties are only reported as belonging to a single DSA. Reporting information in this way does not alter any conclusions about the data and is done only to improve readability. For the SRTR transplant data, I assign individuals and outcomes to DSAs based on the DSA in which the relevant transplant center was located. For the organ designation data, which is only available at the state level, I apportion designations across all counties in each state in proportion to the county population. I then aggregate this county-level information to the DSA level.

I gather and combine offer unprecedented insight into the organ allocation debate.

To provide an overview of the transplant landscape, Figure 1 reports the number of transplants per capita in 2021 — the most recent complete year of data. Darker shades indicate more transplants per capita. Yellow¹⁶⁴ indicates that data are not available either because the relevant DSA includes no transplant centers that perform the relevant type of organ transplantation or because there are not enough transplants to ensure the confidentiality of patients. I maintain this reporting procedure throughout the Article. In the latter case, those patients are included in aggregate analyses but are not reported at the DSA level to protect their privacy. In general, Figure 1 clearly demonstrates wide geographic variation in transplants per capita. The following two Parts engage with the ongoing debate over the reasons underlying and the implications of this geographic variation.

¹⁶⁴ The figures contained in the print version of this Article have been formatted in grayscale. Nonetheless, the language in this Article referencing the colors contained in the figures remains unchanged. For a more accurate understanding of the data being presented and discussed, please view the online version of this Article at lawreview.law.ucdavis.edu.

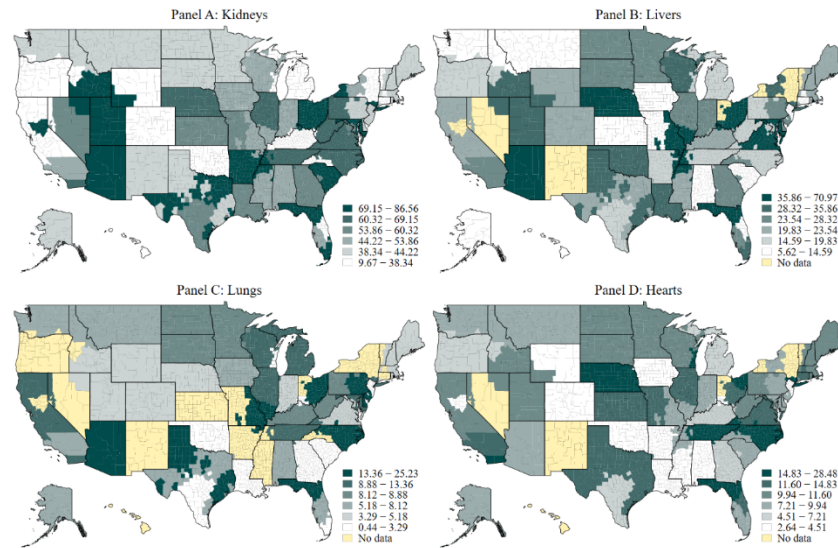
FIGURE 1: TRANSPLANTS PER CAPITA

Fig. 1: Transplants per 1,000,000 individuals are reported for all DSAs in 2021. Each panel reports transplants per capita for the organ listed in the panel title.

II. NATIONAL ORGAN ALLOCATION AND THE FINAL RULE

Advocates of broader national organ sharing tend to focus on the role of organ allocation policy in moving organs from one part of the country to the other in terms of the benefits accruing to patients currently waitlisted for organs.¹⁶⁵ They do not generally consider the impacts of these policies on individuals not waitlisted for an organ transplant or on the organ allocation and transplantation system overall.¹⁶⁶ In general, advocates of broader national organ sharing have won most of the legal battles over organ allocation policy.¹⁶⁷ Federal regulations and judicial

¹⁶⁵ Glazier, *supra* note 27, at 143 (“The founding principle under the federally established framework is that donated organs are a national resource and should be allocated based on a system that is focused on the patients.”).

¹⁶⁶ See Callahan Emails, *supra* note 29, at 0018441 (arguing that it is “[inappropriate to] use organ allocation to rectify social injustices outside of [the] distribution of organs to those waiting”).

¹⁶⁷ See *Adventist Health Sys./SunBelt, Inc. v. United States Dep’t of Health & Hum. Servs.*, 17 F.4th 793 (8th Cir. 2021); *Callahan v. United States Dep’t of Health & Hum.*

interpretations of those regulations have largely supported those broader sharing efforts. Thus, while this Part articulates the arguments in favor of broader national organ sharing, it also illustrates the current approach to organ allocation policy.

A. *Medical Ethics, the Final Rule, and Disparities in Need*

Those in favor of broader national organ sharing rely heavily on the argument that ethics requires the organ transplant system to prioritize the sickest patients regardless of where those patients reside.¹⁶⁸ If the sickest patient is not local and saving that patient means an organ must travel a long distance, the ethical response is to transport the organ to wherever the most medically urgent patient is located. In support of this ethical argument, advocates point to the Final Rule which provides that “allocation policies . . . [s]hall not be based on the candidate’s place of residence or place of listing”¹⁶⁹ and requires “[d]istributing organs over as broad a geographic area as feasible.”¹⁷⁰ Succinctly summarizing these arguments, one group stated flatly that “geographic disparities violate the Code of Federal Regulations as well as . . . ethical principles of organ allocation.”¹⁷¹

From this ethical and legal starting point, national sharing advocates have pointed out for years that geographic inequities exist in the transplant system.¹⁷² One ethicist explained in the context of liver allocation that “people on liver transplant waiting lists in some major metropolitan areas across the United States are 30 percent less likely than similarly ill people in other communities to receive deceased donor

Servs., through *Alex M. Azar II*, 939 F.3d 1251 (11th Cir. 2019) (siding with national organ advocates).

¹⁶⁸ S.E. Gentry, A.B. Massie, S.W. Cheek, K.L. Lentine, E.H. Chow, C.E. Wickliffe, N. Dzebashvili, P.R. Salvalaggio, M.A. Schnitzler, D.A. Axelrod & D.L. Segev, *Addressing Geographic Disparities in Liver Transplantation Through Redistricting*, 13 AM. J. TRANSPLANTATION 2052, 2052 (2013); Bruce C. Vladeck, Sander Florman & Jonathan Cooper, *Rationing Livers: The Persistence of Geographic Inequity in Organ Allocation*, 14 AM. MED. ASS’N J. ETHICS 245, 245 (2012).

¹⁶⁹ 42 C.F.R. § 121.8(a)(8).

¹⁷⁰ *Id.* § 121.8(b)(3).

¹⁷¹ Gentry et al., *supra* note 168, at 2052.

¹⁷² See, e.g., *id.* (arguing that inequities persist in the organ transplant system due to geography).

transplants.”¹⁷³ He further opined that “[r]easonable people could well differ on the precise criteria for allocating such a scarce, life-saving resource as donated livers, but it is hard to make a case that the patient’s place of residence should be a criterion.”¹⁷⁴ Stating a similar concern more bluntly, Sandy Feng commented that “[p]eople are dying. It’s just not fair.”¹⁷⁵ And to alleviate these concerns, John R. Lake — director of solid organ transplantation at the University of Minnesota Medical Center — argued that “a policy that prioritizes transplanting the sickest patients will save lives.”¹⁷⁶

An important aspect of national advocates’ arguments with respect to geographic disparities in medical urgency for transplants concerns which individuals matter when assessing those disparities. When arguing in favor of de-emphasizing geography, national advocates focus only on individuals who have been able to access the organ transplant system and join a waitlist.¹⁷⁷ As highlighted by Alexandra Glazier’s statements above, national advocates generally disclaim any consideration of the effect of organ allocation policy on access to transplantation for individuals not able to access a waitlist.¹⁷⁸

Consistent with their arguments and their focus solely on waitlisted individuals, advocates of greater national organ sharing emphasize evidence that waitlisted patients are not equally sick in all areas of the country.¹⁷⁹ Measures of sickness and medical urgency vary from organ to organ, but one measure common to all is deaths on waitlists. Beginning with this measure, Figure 2 reports the number of deaths per 10,000 patient days on a waitlist for kidneys (Panel A), livers (Panel B), lungs (Panel C), and hearts (Panel D) in 2021. In Figure 2, darker shades indicate a higher rate of deaths among waitlisted patients. Figure 2

¹⁷³ Vladeck et al., *supra* note 168, at 245.

¹⁷⁴ *Id.*

¹⁷⁵ Pullen, *supra* note 15, at 1253.

¹⁷⁶ *Id.*

¹⁷⁷ See, e.g., Glazier, *supra* note 27 (“By definition allocation and distribution policy is about determining where a defined pool of a resource goes. It is a zero-sum game. This does not mean efforts should not be focused on increasing the organ pool, but whatever size the pool is, the allocation and distribution policies are designed to rank order patients to receive actual organs that become available.”).

¹⁷⁸ See *supra* Introduction.

¹⁷⁹ Vladeck et al., *supra* note 168, at 246.

clearly demonstrates wide variation in waitlist death rates across the country. In some donation service areas, this rate is less than 1 per 10,000 patient days, while in other areas, the rate tops 15 per 10,000 patient days for some organs.

FIGURE 2: DEATHS PER DAY ON WAITLISTS

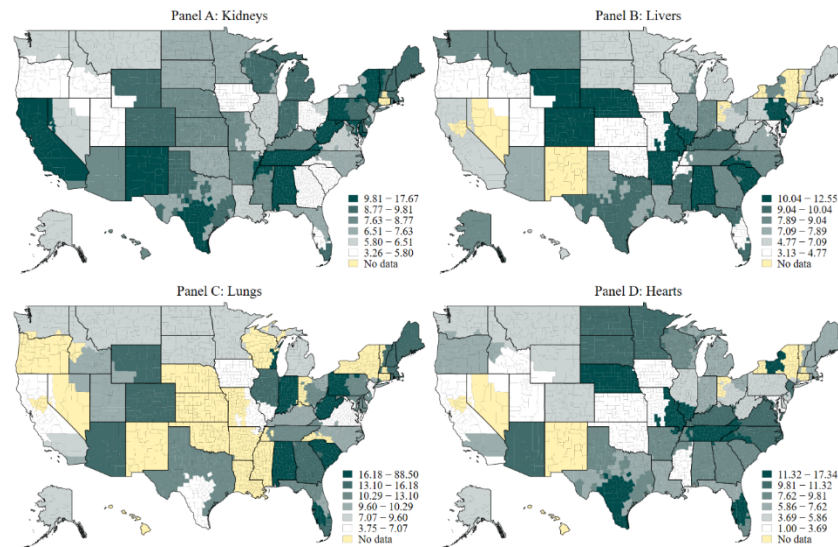


Fig. 2: Waitlist deaths per 10,000 patient waitlist days are reported for all DSAs in 2021. Each panel reports deaths per day for the organ listed in the panel title.

The evidence reported in Figure 2 supports national advocates' position that, without a wider distribution of donated organs, relatively sicker patients must wait while relatively healthier patients receive transplants. Interestingly, the evidence in Figure 2 clearly demonstrates geographic disparities in waitlist deaths, but the pattern of deaths does not necessarily suggest that the Northeast and California — the most vigorous advocates of broader national sharing — should receive a substantially larger share of donated organs.¹⁸⁰

Of course, the waitlist death rate is not the only measure of which areas of the country need more organs, and allocation policy relies on

¹⁸⁰ See *infra* Part IV.A (discussing the role of transplant centers in the Northeast and California).

different measures of medical urgency for different organs.¹⁸¹ Liver allocation policy, for example, relies on the allocation Median End-Stage Liver Disease (“MELD”) score.¹⁸² The MELD score varies from 6 to 40, with higher numbers indicating sicker (and more medically urgent) patients.¹⁸³ Lung allocation policy relies on the Lung Allocation Score (“LAS”), which ranges from 0 to 100.¹⁸⁴ Again, higher scores indicate sicker patients.¹⁸⁵ Heart allocation policy does not include a scoring system, but patients are placed into six statuses depending on their medical urgency, with lower numbers indicating greater urgency.¹⁸⁶ Kidney allocation policy lacks a comparable scoring system and relies more heavily on waiting time than the policies governing other organs.¹⁸⁷

¹⁸¹ Not all agree on that these metrics accurately capture a patient’s medical urgency, but I focus on these measures here because they are the legally relevant measures. Bertsimas et al., *supra* note 51, at 1109; Scott W. Biggins & Sandy Feng, *In a MELD-Based Economy, How Can We Fight Off Inflation?*, 13 LIVER TRANSPLANTATION 2, 2 (2007).

¹⁸² *Understanding the MELD Score*, PENN MED. (Oct. 10, 2021), <https://www.pennmedicine.org/updates/blogs/transplant-update/2021/october/understanding-the-meld-score#:~:text=The%20MELD%20score%20ranges%20from,worsening%20of%20your%20liver%20disease> [https://perma.cc/TA67-ZQVE].

¹⁸³ *Id.* The allocation MELD score can be the patient’s laboratory MELD score, which is based on a specific formula that takes four blood test values as inputs. This laboratory MELD score may be increased with exception points if a clinician files an appeal for a candidate and a review board determines that a particular candidate requires a higher MELD score based on that candidate’s clinical status that is not accurately captured by the laboratory MELD score. *Id.*

¹⁸⁴ *The Lung Allocation Score*, PULMONARY HYPERTENSION ASS’N, <https://phassociation.org/patients/treatments/transplant/information-for-ph-patients/before-lung-transplant/the-lung-allocation-score/> (last visited Jan. 20, 2024) [https://perma.cc/893X-NDUD].

¹⁸⁵ *Id.*

¹⁸⁶ Technically, seven statuses exist, but one of the seven includes only inactive patients. *Heart Transplant Waiting List*, PENN MED., <https://www.pennmedicine.org/for-patients-and-visitors/find-a-program-or-service/transplant-institute/heart-transplant/heart-waiting-list> (last visited Jan. 19, 2024) [https://perma.cc/5K6S-VG99].

¹⁸⁷ Taylor A. Melanson, Laura C. Plantinga, Mohua Basu, Stephen O. Pastan, Sumit Mohan, Jason M. Hockenberry, David Howard & Rachel E. Patzer, *New Kidney Allocation System Associated with Increased Rates of Transplants Among Black and Hispanic Patients*, 36 HEALTH AFFAIRS 1078, 1078 (2017) (“The primary factor for determining a patient’s priority level on the kidney transplant waitlist is how long they have been waiting for a transplant.”).

Figure 3 reports measures of medical urgency using the scoring system specific to each organ. The measures reported in Figure 3 represent the average final measure of all individuals receiving a transplant in each donation service area in 2021.¹⁸⁸ The evidence reported in Figure 3 supports the concern that patients are not equally sick across the country, which generally supports the need for organ sharing across the country.

FIGURE 3: MEASURES OF MEDICAL URGENCY

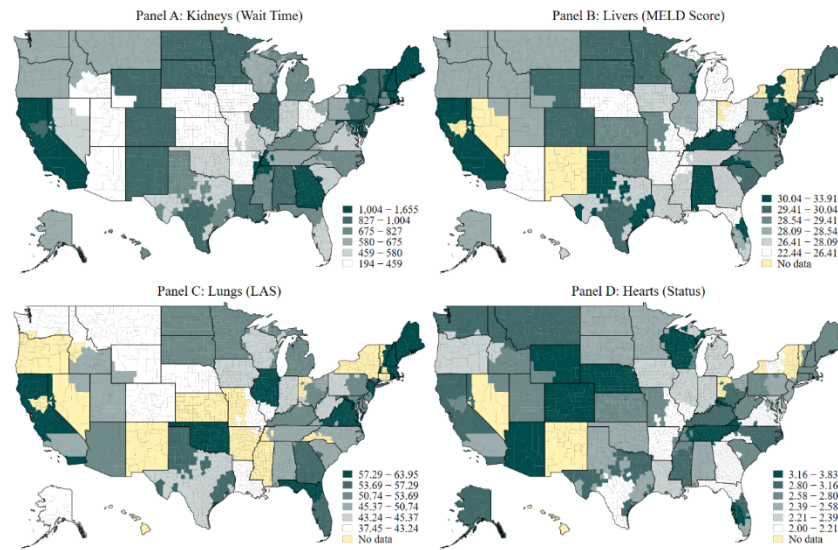


Fig. 3: Organ-specific metrics of medical urgency are reported for all DSAs in 2021. Panel A reports mean wait time at transplant for kidney transplant recipients. Panel B reports mean MELD scores for liver transplant recipients. Panel C reports mean LAS for lung transplant recipients. Panel D reports mean status for heart transplant recipients.

While the evidence reported in Figures 2 and 3 demonstrates geographic disparities in medical urgency, they do not convey the full scope of geographic disparities. The next Section details gaps in access

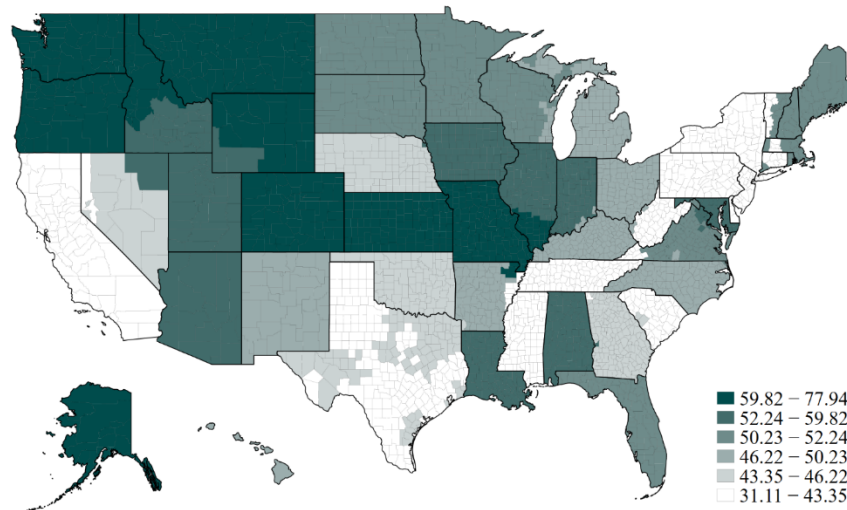
¹⁸⁸ Reporting measures at the time of transplant is standard practice in the medical literature, and I adopt that practice in Figure 3. *Id.*; Dimitris Bertsimas, Theodore Papalexopoulos, Nikolaos Trichakis, Yuchen Wang, Ryutaro Hirose & Parsia A. Vagefi, *Balancing Efficiency and Fairness in Liver Transplant Access: Tradeoff Curves for the Assessment of Organ Distribution Policies*, 104 TRANSPLANTATION 981, 982-86 (2020).

to donated organs, which play an important role in advocates' arguments for greater national organ sharing.

B. Disparities in Organ Availability

The problem of disparities in medical urgency would not necessarily prove problematic if areas of the country with higher need had commensurate access to more donated organs. However, this is not generally the case. Indeed, the debate over the best way to regulate OPOs and their performance in recovering organs for transplantation illustrates the importance of disparities in access to organs.¹⁸⁹ Figure 4 reports disparities in the first step toward organ donation — “designations.” This term refers to the number of individuals who have agreed through at least one avenue to become organ donors upon their death. Figure 4 reports designations per 100 people across 58 DSAs in 2020 — the last year for which designation data is available. More individuals per capita in the Midwest and Pacific Northwest have agreed to donate their organs when they die than other parts of the country. Parts of the South and Southwest similarly agree to donate at higher levels. California, Texas, New England and the upper Mid-Atlantic have fewer organ donors per capita. And the variation in designations is not trivial. New York and New Jersey have the lowest levels with only about one-third of individuals having agreed to become organ donors, while Colorado has the highest number of organ donors per capita with over 8% of people agreeing to donate.

¹⁸⁹ See *supra* Part I.C.

FIGURE 4: DONOR DESIGNATIONS PER 100 INDIVIDUALS*Fig. 4: Donor Designations per 100 people reported for all DSAs in 2020.*

Next, Figure 5 demonstrates disparities in the number of organs recovered from donors. Consistent with the recent regulatory changes described above, Figure 5 reports the number of kidneys (Panel A), livers (Panel B), lungs (Panel C), and hearts (Panel D) per 100 CALC deaths.¹⁹⁰ Geographic patterns differ across organs, but the Midwestern and mountain states tend to perform better than the rest of the country in recovering organs. While focusing on organ recoveries per 100 CALC deaths is consistent with recent regulations, it can be somewhat deceptive because different parts of the country experience different numbers of CALC deaths. In general, the southern states experience more CALC deaths than the rest of the country.

¹⁹⁰ For a definition and discussion of CALC deaths, see *supra* Part I.C.

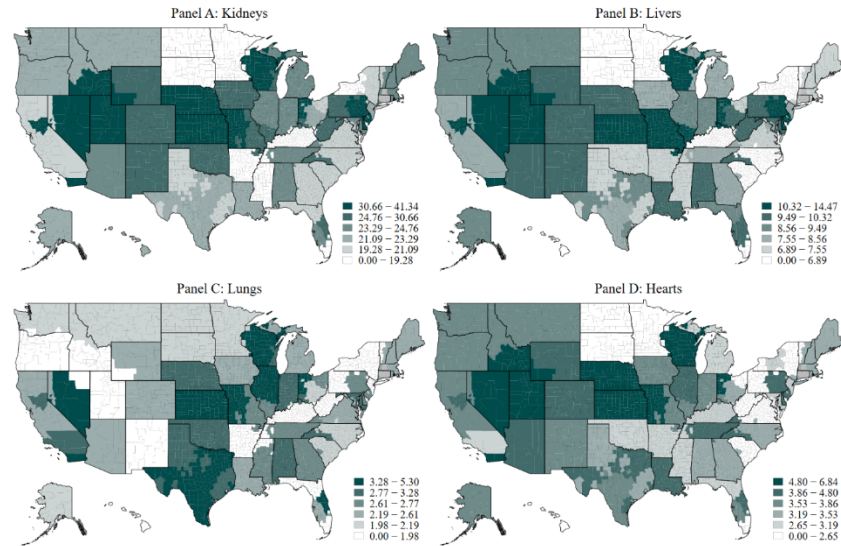
FIGURE 5: ORGAN RECOVERIES PER 100 CALC DEATHS

Fig. 5: Organ recoveries per 100 CALC deaths are reported for all DSAs in 2021. Each Panel reports recoveries per 100 CALC deaths for the organ listed in the title.

In general, the areas of the country with the most medically urgent patients do not align with the areas of the country with the greatest supplies of donated organs. Without any organ sharing, this will obviously result in some waitlisted patients who are relatively less sick receiving a transplant well before some waitlisted patients who are relatively sicker because they live in an area with better access to donated organs. Of course, some patients could gain access to waitlists in parts of the country where they do not reside. Steve Jobs, who resided in California at the time, was famously waitlisted at a Memphis hospital for a liver transplant because the DSA including Memphis had better access to organs.¹⁹¹ While no law prohibits patients from waitlisting at multiple hospitals, relatively few people do so because of the expense

¹⁹¹ Mallory Locklear, *Steve Jobs' Liver — And the Quest for a Better Organ Algorithm*, ARS TECHNICA (Mar. 15, 2017), <https://arstechnica.com/science/2017/03/live-death-math-and-efficiency-the-quest-to-solve-us-organ-transplants-woes/#:~:text=In%202009%2C%20Steve%20Jobs%20received,seem%20like%20an%20odd%20choice> [https://perma.cc/HRK6-5EF9].

involved. Similarly, hospitals may have policies discouraging multiple waitlisting.¹⁹²

Given the difficulty of moving patients around the country to receive transplants, organ allocation policy under the NOTA and Final Rule should, according to advocates of national organ sharing, move donated organs to the patients in greatest need. If, for example, the DSA covering Kansas recovers twice as many organs as the DSA covering New York City, but the waitlisted patients in New York City are, on average, four times sicker than those waitlisted in Kansas, then Kansas should send many of its recovered organs to New York City. The next Section discusses in detail policies developed to achieve this type of outcome across the country.

C. Organ Sharing to Equalize Availability

Prior to the passage of the NOTA, transplant centers voluntarily shared organs among themselves when a particular center did not have any suitable patients for a recovered organ.¹⁹³ In the NOTA era, however, such sharing has become mandatory. In the years since the NOTA, and particularly since the Final Rule, organ allocation rules have gradually but clearly moved toward requiring greater organ sharing.¹⁹⁴ The continued pace towards more organ sharing is generally consistent with the policy preferences of those in favor of national organ sharing. Though no single policy has resulted in true national organ sharing (i.e., the locations of the donor and recipient are ignored completely), the constellation of policies implemented over the last two decades has resulted in much more organ sharing.

A complete review of all individual policies passed and implemented by the OPTN over the last two decades would fill several volumes and is, therefore, well beyond the scope of this Article. However, several individual policies have moved the allocation system more quickly towards national organ allocation than other, less impactful policies.

¹⁹² *Multiple Listing*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, <https://optn.transplant.hrsa.gov/patients/about-transplantation/multiple-listing/> (last visited July 2, 2024) [<https://perma.cc/KM8R-7WAU>].

¹⁹³ See *supra* Part I.A.

¹⁹⁴ See *infra* Table 2.

For ease of exposition, I will refer to these as “major” allocation policies, and Table 2 provides a brief overview of these policies.

TABLE 2: MAJOR ALLOCATION POLICIES

Date Implemented	Organ	Policy Name	Brief Description
12-4-2014	Kidney	Kidney Allocation Scheme	“A key feature of the new KAS is preferential allocation of best quality organs to wait-list candidates with the longest predictive survival in a concept called longevity matching. Highly sensitized recipients would get extra points and enjoy widespread sharing of organs in order to increase accessibility to transplant.” ¹⁹⁵
3-15-2021	Kidney	DSA Elimination	“The OPTN has eliminated DSA and region from the allocation systems of all other organ types, and replaced them with a distance-based approach. In the new system for kidney and pancreas allocation, the first unit of distribution is no longer DSA and instead becomes a 250 nautical mile circle around the donor hospital.” ¹⁹⁶
6-18-2013	Liver	Share 35	“Under Share 35, deceased donor livers are offered first to all candidates in the Region with MELD of 35 or higher, regardless of DSA, before being offered to other local candidates and then regional candidates.” ¹⁹⁷

¹⁹⁵ Bhavna Chopra & Kalathil K. Sureshkumar, *Changing Organ Allocation Policy for Kidney Transplantation in the United States*, 5 *WORLD J. TRANSPLANTATION* 38, 38 (2015).

¹⁹⁶ *March 15 Policy Implementation: Removal of DSA From Kidney and Pancreas Allocation*, UNOS (Mar. 1, 2021), <https://unos.org/news/mar-15-policy-implementation-remove-dsa-kidney-pancreas-allocation/#:~:text=The%20OPTN%20has%20eliminated%20DSA,circle%20around%20the%20donor%20hospital> [https://perma.cc/YPK3-G3ER].

¹⁹⁷ A.B. Massie, E.K.H. Chow, C.E. Wickliffe, X. Luo, S.E. Gentry, D.C. Mulligan & D.L. Segev, *Early Changes in Liver Distribution Following Implementation of Share 35*, 15 *AM. J. TRANSPLANTATION* 659, 659 (2015).

2-4-2020	Liver	DSA Elimination	“This policy changes allocation of livers to remove references to DSA and region and incorporate distance from the donor hospital [(specifically 150 nautical miles (nm), 250 nm and 500 nm)].” ¹⁹⁸
11-24-2017	Lung	DSA Elimination	“In an urgent response to a lawsuit filed by a patient demanding broader geographic access to lungs in November 2017, the second major change in lung allocation occurred when the primary allocation unit for donor lungs expanded from the local donation service area (DSA) to a 250-nautical mile radius around the donor hospital.” ¹⁹⁹
10-18-2018	Heart	Six Tiers	“[T]he existing 3-tier system was converted to a 6-tier system to provide more granular separation of wait listed patients by clinical condition and urgency of transplant.” ²⁰⁰
1-9-2020	Heart	DSA Elimination	“[S]everal OPTN policy updates were implemented to eliminate the use of donation service areas, or DSAs, from heart transplantation and replace them with a 250 nautical mile circle.” ²⁰¹

One common theme across all four organs is the elimination of the DSA as a relevant geographic unit. These changes have occurred relatively recently and functionally eliminated the preferences local patients formerly received. Focusing on liver allocation before the

¹⁹⁸ OPTN, OPTN POLICY NOTICE: LIVER AND INTESTINE DISTRIBUTION USING DISTANCE FROM DONOR HOSPITAL 1 (2019), https://optn.transplant.hrsa.gov/media/2788/liver_policynotice_201901.pdf [<https://perma.cc/SB7H-R8D4>].

¹⁹⁹ Luke J. Benvenuto & Selim M. Arcasoy, *The New Allocation Era and Policy*, 13 J. THORACIC DISEASE 6504, 6504 (2021).

²⁰⁰ Arman Kilic, Michael A. Mathier, Gavin W. Hickey, Ibrahim Sultan, Victor O. Morell, Suresh R. Mulukutla, Mary E. Keebler, *Evolving Trends in Adult Heart Transplant with the 2018 Heart Allocation Policy Change*, 6 JAMA CARDIOLOGY 159, 160 (2020).

²⁰¹ DSA Removed from Thoracic Allocation System Jan. 9, 2020, UNOS (Jan. 9, 2020), <https://unos.org/news/policy-changes/dsa-to-be-removed-from-thoracic-allocation-system-jan-9-2020/> [<https://perma.cc/37DS-X683>].

elimination of DSAs as a geographic unit as an example,²⁰² donated livers were first offered to clinically appropriate transplant candidates in descending order of MELD score within the DSA where the liver was recovered. If no suitable candidate was found, the liver would be offered to clinically appropriate candidates in descending order of MELD score within the OPTN region where the liver was recovered. If no suitable candidate was found within this region, the liver would be offered to all clinically appropriate candidates nationally in descending order of MELD score.²⁰³

When the OPTN eliminated DSAs as a geographic unit of distribution for different organs, it generally replaced them with a concentric circle approach. Instead of offering organs in descending order of medical urgency within a DSA, it generally began offering them in descending order of medical urgency within concentric circles of the hospital where the organ was recovered.²⁰⁴ For example, the new liver allocation policy “prioritizes candidates in similar groupings of medical urgency within 150, 250 and 500 nautical miles from the donor hospital.”²⁰⁵ While this type of policy maintains some local preferences, it eliminates set geographic units.²⁰⁶ In doing so, it moves further towards a truly

²⁰² This example simplifies the process of finding a suitable liver transplant candidate. While it is essentially accurate, it omits several details. For example, prior to the elimination of DSAs as a geographic unit, livers would be offered first to all candidates in the OPTN region where the liver was recovered who had a MELD score of 35 or higher — this was the change implemented by the Share 35 policy. If no suitable candidate was found, the liver would then be offered within the DSA, then within the region, then nationally as described. A full description of the process prior to the elimination of DSAs can be found in McMichael, *Stealing Organs?*, *supra* note 12, at 152-54.

²⁰³ *Id.*

²⁰⁴ Emmanouil Giorgakis, Tommy Ivanics, David Wallace, Allison Wells, Julius Balogh, Hailey Hardgrave, Derek Krinock, Garrett Klutts, Lyle Burdine, Andrew Singer & Amit Mathur, *Acuity Circles Allocation Policy Impact on Waitlist Mortality and Donation After Circulatory Death Liver Transplantation: A Nationwide Retrospective Analysis*, 6 HEALTH SCI. REPS. 1006, 1006 (2023).

²⁰⁵ *System Notice: Liver and Intestinal Organ Distribution Based on Acuity Circles Implemented Feb. 4*, UNOS (Feb. 4, 2020), <https://unos.org/news/system-implementation-notice-liver-and-intestinal-organ-distribution-based-on-acuity-circles-implemented-feb-4/> [<https://perma.cc/2EDZ-DNXG>]. Again, this is a simplification for the purposes of exposition.

²⁰⁶ This type of concentric circle policy differs in the details across the four organs considered here.

national organ allocation policy. It is worth noting that the OPTN has recently implemented new policies that would qualify as “major” and move even further toward national organ sharing and that the OPTN continues to consider new policies for implementation in the future.²⁰⁷ Because these policy changes have occurred so recently, however, it is not yet possible to examine their impacts.

Examining the impact of recent allocation policies on organ sharing, Figure 6 reports the percentage of organ transplants using locally sourced organs over time. The effect of the major allocation policies is obvious in the substantial declines in the percentage of locally sourced organs. Before the implementation of the kidney allocation scheme, a little more than 75% of kidney transplants used local organs. After, the number fell to approximately 60%. It fell even further after DSAs were eliminated as a unit of allocation to less than 40%. In Panel B, the percentage of liver transplants relying on local organs oscillated around 70% before falling below 60% following the implementation of the Share 35 policy. As with kidneys, the percentage of liver transplants using local organs fell below 40% following the elimination of DSAs.

²⁰⁷ For example, in March 2023, the OPTN implemented a new lung allocation policy based on what it calls continuous distribution. This policy eliminates the LAS and replaces it with a new scoring system designed to reduce clinical factors, candidate urgency, and distance between donor and recipient into a single score. *New Lung Allocation Policy in Effect*, OPTN (Mar. 20, 2023), <https://optn.transplant.hrsa.gov/news/new-lung-allocation-policy-in-effect/> [<https://perma.cc/36DJ-TD8Y>].

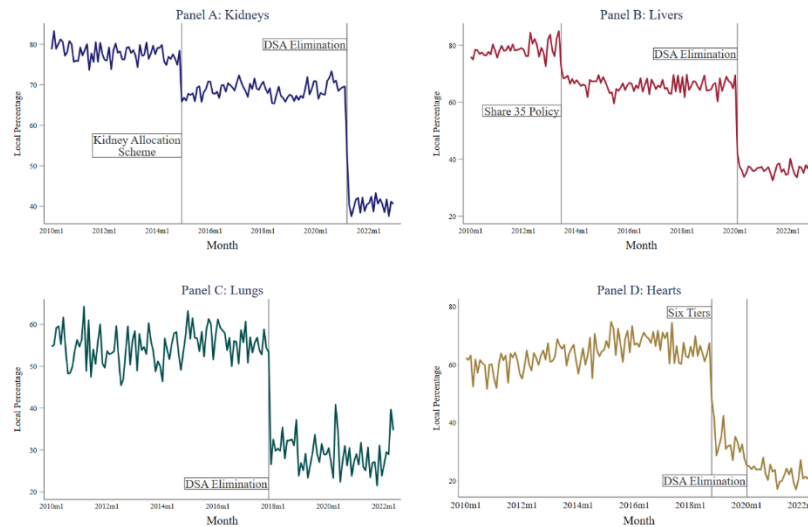
FIGURE 6: ORGAN SHARING AND THE MAJOR ALLOCATION POLICIES

Fig. 6: The percentage of transplants using local organs are reported for each month between January 2010 and December 2021. Each Panel reports local percentages for the organ listed in the title. Labeled vertical lines indicate relevant changes in organ allocation policy (as described in Table 2).

Turning to lungs in Panel C, between 50% and 60% of transplants used locally sourced organs before falling to below 30% when DSAs were eliminated as a unit of allocation. For hearts, the implementation of the six tiers system dropped the local percentage from above 60% to between 30% and 40%. This number fell even further to around 20% once DSAs were eliminated in heart allocation. In general, Figure 6 demonstrates the success of the major allocation policies in achieving greater organ sharing. Those opposed to greater national organ sharing have tried to stop the implementation of various policies, but as the next Section explains, they have largely been unsuccessful.

D. Legal Victories on Geography

Advocates of national organ sharing often state categorically that federal law requires the broadest possible sharing of organs.²⁰⁸ These

²⁰⁸ See, e.g., Benvenuto & Arcasoy, *supra* note 199, at 6504;

statements are neither entirely accurate nor entirely inaccurate. No federal court has been properly presented the question of how to interpret the Final Rule and its geographic mandate *de novo*. Instead, courts in various cases have deferred to policy changes (that implicitly relied on this interpretation of the Final Rule) directed by HHS and implemented by the OPTN under an arbitrary and capricious standard of review.²⁰⁹ This evolution of decisions has resulted in progressively broader organ sharing as courts have refused to overturn individual policies requiring more sharing. This series of legal victories has proven instrumental in effecting the policy changes detailed in Table 2 above. The current regulatory landscape is largely a product of a back-and-forth between HHS (and the OPTN) and federal courts that have been asked to intervene in organ allocation policies on multiple occasions.

The first lawsuit filed in a string of victories for national advocates concerned a lung transplant candidate in the Southern District of New York in 2017.²¹⁰ At the time the lawsuit was filed, lung allocation policy still included local preferences, and the plaintiff had not been matched with donated lungs under that policy.²¹¹ The plaintiff sought “to require the Acting Secretary of [HHS] to allocate available donor lungs based on medical priority instead of the current antiquated and arbitrary system that gives priority based on a candidate’s place of residence.”²¹² The

The [Lung Allocation Score] has been successful in prioritizing the sickest candidates and reducing waitlist mortality in line with the Final Rule mandates. However, the LAS model did not address geographic variability in donor lung supply and demand, leading to disparities in waiting list survival based on a patient’s listing location, which was inconsistent with the Final Rule.

Id.; Gentry et al., *supra* note 168, at 2052 (“Geographic disparities violate the Code of Federal Regulations.”).

²⁰⁹ See *Adventist Health Sys./SunBelt, Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 17 F.4th 793 (8th Cir. 2021); *Callahan v. U.S. Dep’t of Health & Hum. Servs.*, through Alex M. Azar II, 939 F.3d 1251 (11th Cir. 2019).

²¹⁰ See Glazier, *supra* note 27, at 140-44 (discussing the lawsuit and its background).

²¹¹ *Id.*

²¹² Verified Complaint for a Temporary Restraining Order and Preliminary and Permanent Injunctive Relief at 1, *Holman v. U.S. Dep’t of Health & Hum. Servs. through Hargan*, No. 1:17-CV-09041, (S.D.N.Y. Nov. 19, 2017).

district court did not grant injunctive relief to the plaintiff immediately but ordered HHS to review current lung allocation policy.²¹³

The plaintiff appealed immediately to the Second Circuit, which ordered HHS to produce a report in three days.²¹⁴ HHS ordered the OPTN to evaluate its current lung allocation policy in short order, and the OPTN decided to replace the current policy with one that prioritized patients within a 250 nautical mile radius of a donor.²¹⁵ HHS accepted this policy, and it eventually became permanent as detailed in Table 2 above. While the case clearly resulted in a movement away from locally focused allocation policy toward nationally focused allocation policy, the relevant policy change stemmed from HHS's response to a court ordered report, not a judgment as to the requirements of the Final Rule.

Despite the fact that the court did not enjoin the existing policy or order the development of a new policy change directly, advocates of national organ allocation policy quickly realized how effective lawsuits could be. One advocate explained, “[i]t took the field ten years to make a significant change to kidney allocation and the community had been debating liver allocation for over five years. With a single lawsuit and a HHS directive, lung allocation was changed in a week.”²¹⁶ More lawsuits followed.²¹⁷

In 2018, a group of six patients from California, New York, and Massachusetts filed a complaint against HHS in the Southern District of New York. In it, they sought to require HHS and the OPTN “to implement within six months a new liver allocation policy not based on

²¹³ *Id.*; Letter from George Sigounas, Administrator, Health Res. and Servs. Admin., to Yolanda Becker, President, Organ Procurement & Transplantation Network (Nov. 21, 2017), https://optn.transplant.hrsa.gov/media/2397/hrsa_letter_to_optn_20171121.pdf (last visited July 3, 2023) [<https://perma.cc/RHH6-TA6B>].

²¹⁴ Glazier, *supra* note 27, at 145.

²¹⁵ LIZ ROBBINS CALLAHAN & KIMBERLY UCCELLINI, BROADER SHARING OF ADULT DONOR LUNGS 1-4 (2017), https://optn.transplant.hrsa.gov/media/2314/broader_sharing_lungs_20171124.pdf [<https://perma.cc/9RE2-7QBN>]; *Policy Modification to Lung Distribution Sequence*, OPTN (Nov. 22, 2017), <https://optn.transplant.hrsa.gov/news/policy-modification-to-lung-distribution-sequence/> [<https://perma.cc/DN3N-9EAU>].

²¹⁶ Glazier, *supra* note 27, at 146.

²¹⁷ See *Adventist Health Sys./SunBelt, Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 17 F.4th 793 (8th Cir. 2021); *Callahan v. U.S. Dep’t of Health & Hum. Servs.*, through Alex M. Azar II, 939 F.3d 1251 (11th Cir. 2019) (siding with national organ advocates).

arbitrary Donation Service Areas (“DSAs”) or Region Areas, but rather as a zone-based liver distribution policy.”²¹⁸ HHS again directed the OPTN to develop a new allocation policy for livers.²¹⁹ The OPTN responded by developing what became known as the Acuity Circles Policy for liver allocation.²²⁰ As with other policies based on concentric circles, DSAs were eliminated and livers would be allocated to patients with the highest medical urgency within wider and wider circles around the location of the donor.²²¹

Though it lacked the force of a court order, HHS’s directive that the OPTN develop a new liver allocation policy that both eliminated DSAs and focused only on patients waitlisted for livers generated substantial pushback among those in favor of locally focused allocation policies. These advocates, led by four liver transplant candidates and multiple transplant centers across the South and Midwest, filed their own lawsuit in the Northern District of Georgia seeking to prevent the implementation of the new liver allocation policy.²²² The district court initially denied plaintiffs a temporary restraining order the day before the new liver allocation policy was to take effect.²²³ Plaintiffs

²¹⁸ Pullen, *supra* note 15, at 1251.

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *Id.* at 1253. In directing the OPTN to create a new allocation policy, HHS specifically instructed that DSAs should not be used, though it did not categorically forbid the use of geographic units. Letter from George Sigounas to Sue Dunn, *supra* note 34, at 1, 3 (“HRSA finds that geographic constraints may be appropriate if they can be justified in light of the regulatory requirements, but that DSAs and Regions have not and cannot be justified under such requirements.”); *see also id.* at 3 (“If some form of geographic limitation is incorporated, the OPTN Board should provide its written rationale, together with supporting evidence, explaining how any such limitation is justified and required by 42 CFR 121.8(a)(8), including concerning the size and shape of any geographic units selected.”). HHS further directed the OPTN to “consider the effects of any proposed policies on their ‘cumulative effect on socioeconomic inequities,’ as well as other factors described in NOTA and the OPTN final rule.” *Id.* at 4. However, it included instructions to consider “effect of the policy socioeconomic inequities on all transplant candidates on the national OPTN liver waiting list.” *Id.* at 3.

²²² *See Callahan v. U.S. Dep’t of Health & Hum. Servs.*, through Alex M. Azar II, 939 F.3d 1251, 1257 (11th Cir. 2019); *Callahan v. U.S. Dep’t of Health & Hum. Servs.*, through Alex M. Azar II, No. 1:19-CV-1783-AT, 2019 WL 3539815, at *1 (N.D. Ga. May 14, 2019), *aff’d in part and remanded sub nom. Callahan*, 939 F.3d 1251.

²²³ *Id.*

immediately appealed to the Eleventh Circuit, and the district court instructed the OPTN to return to the previously applicable liver allocation policy pending appeal.²²⁴ The OPTN only did so after the district court threatened contempt.²²⁵

The issue before the Eleventh Circuit concerned a narrow aspect of administrative law, and the case essentially distills down to what HHS is required to do when aggrieved parties file a comment concerning organ allocation policy. In connection with the New York dispute described above, HHS decided to intervene²²⁶ and required the implementation of a new liver allocation policy — the acuity circles policy.²²⁷ When parties aggrieved by the new acuity circles policy filed a similar comment with HHS, it refused to intervene and allowed the acuity circles policy to continue in effect.²²⁸ Rejecting plaintiffs' claims to the contrary, the court held that HHS was not required to "(1) refer[] . . . the new liver-allocation policy to an entity called the Advisory Committee on Organ Transplantation [or] (2) publi[sh] . . . the new policy in the Federal Register for public comment."²²⁹ In other words, federal law grants HHS the discretion to determine when to require the development of new allocation policies by the OPTN in response to

²²⁴ Blake Farmer, *As Thousands Wait for Transplants, Medical Centers Fight to Keep Livers Close to Home*, NPR (May 14, 2019), <https://www.npr.org/sections/health-shots/2019/05/14/723371270/new-liver-donation-system-takes-effect-despite-ongoing-lawsuit> [<https://perma.cc/FCM6-CCFJ>].

²²⁵ *Id.*

²²⁶ *Callahan*, 939 F.3d at 1256 ("Of course, the Secretary [of HHS] had initiated the process by directing [the OPTN] to adopt a new, DSA-less allocation policy.").

²²⁷ *Id.* at 1255 ("In May 2018, however, a group of patients awaiting liver transplants filed a comment with the Secretary pursuant to 42 C.F.R. § 121.4(d)4 criticizing any continued use of DSAs in liver-allocation determinations. Two months later, in July 2018, the Secretary instructed United Network's Board to scrap the December 2017 policy and adopt a new one that eliminated the use of Regions and DSAs altogether.").

²²⁸ *Id.* at 1256 ("The new policy's detractors, however, brought HHS into the mix. Just as critics of the December 2017 policy had done, a group of hospitals that opposed the new policy filed a comment with the Secretary asking him to suspend the new policy's implementation until something better could be developed. This time, though, the policy survived the challenge. Acting on the Secretary's behalf, the Administrator of HHS's Health Resources and Services Administration responded to the comment, announcing that no further action was warranted and that the new policy would take effect as scheduled.").

²²⁹ *Id.* at 1254.

critical comments. The candidates and transplant centers from the South and Midwest were simply on the losing side of HHS's discretion while the earlier New York, Massachusetts, and California transplant candidates were on the winning side.²³⁰

The next lawsuit involved the allocation policy governing kidneys and was filed in the Southern District of Iowa.²³¹ Many of the same Southern and Midwestern transplant centers involved in the liver case were involved in this case. The plaintiffs sought a preliminary injunction against a new kidney allocation policy that eliminated the use of DSAs.²³² The court determined under a deferential standard of review that the plaintiffs "failed to demonstrate they are likely to succeed on the merits of their claim that adoption of the Fixed Circle Policy (the new kidney allocation policy) was arbitrary and capricious agency action."²³³ The new kidney allocation policy the Eighth Circuit refused to halt remains in effect today, as reported in Table 2 above.

²³⁰ On remand, district court rejected plaintiffs' remaining claims. As with earlier litigation, the court did not issue a substantive interpretation of the Final Rule or its geographic mandates with respect to organ allocation policies. *Callahan v. U.S. Dep't of Health & Hum. Servs.*, through *Alex M. Azar II*, 434 F. Supp. 3d 1319, 1327 (N.D. Ga. 2020) ("The Court's role in this case is not to determine which policy is best, but whether the policymakers in question acted at very least within legal requirements — that their adoption of the new liver allocation policy was not arbitrary or capricious or in violation of Plaintiffs' procedural due process rights. The Court holds today that Defendants met this basic threshold legal standard. The Court also recognizes, however, the profound issues and institutional disruption created by Defendants' handling of this policy change.").

²³¹ See *Adventist Health Sys./Sunbelt, Inc. v. U.S. Dep't of Health & Hum. Servs.*, No. 3:20-CV-00101-SMR-SBJ, 2021 WL 973455, at *1 (S.D. Iowa Mar. 12, 2021); see also *Adventist Health Sys./SunBelt, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 17 F.4th 793, 806-07 (8th Cir. 2021).

²³² *Adventist Health Sys./SunBelt, Inc.*, 17 F.4th at 796 ("In December 2019, OPTN adopted a new policy that significantly changes the method for allocating donated kidneys to kidney transplant patients. In December 2020, days before the new policy's scheduled implementation, plaintiffs — adversely affected hospital systems and a patient on the kidney waitlist (collectively, the 'Hospitals') — sued to enjoin the new policy as unlawful under the Transplant Act and the Administrative Procedure Act . . .").

²³³ *Id.* at 805.

In general, advocates of nationally focused organ allocation have enjoyed significant legal success over the last decade.²³⁴ While they have not yet secured a binding legal interpretation of the Final Rule that it, in fact, requires national organ allocation, they have nevertheless secured a series of policy victories that have moved towards national allocation. As illustrated here, national advocates typically begin by securing an intervention by HHS and a subsequent directive that the OPTN modify the allocation policy for a given organ. Opponents of these new policies developed under HHS instructions are then unable to enjoin the implementation of the policies in the court system. Their failure stems from the insulated nature of agency decisions,²³⁵ the nature of HHS's discretion in determining when to intervene in organ allocation policy,²³⁶ and the OPTN's status a private entity that is not subject to the same requirements as federal agencies.²³⁷

The unique nature of the federal law governing organ allocation policies means that changes in allocation policy are reviewed asymmetrically depending on whether HHS decides to become involved and, if so, how it becomes involved. Given these issues, local advocates' best hope is the establishment of a new legal framework. Congress has certainly indicated a willingness to become involved in issues surrounding organ transplantation, so the primary question is whether Congress *should* become involved (or if the current system should

²³⁴ See, e.g., *id.* at 796 (affirming the District Court's opinion that the implementation of HHS's policy was procedurally correct); *Callahan*, 939 F.3d at 1251-53 (affirming the District Court's finding that the HHS can allocate liver donations as they see fit).

²³⁵ *Adventist Health Sys./SunBelt, Inc.*, 17 F.4th at 803-04; *Callahan*, 434 F. Supp. 3d at 1337-38.

²³⁶ *Callahan*, 939 F.3d at 1254.

²³⁷ *Callahan*, 434 F. Supp. at 1352 ("In sum, Congress at least purported to give the OPTN policies real regulatory authority, HHS attempted to rein in this authority, and whether OPTN policies are truly voluntary is debatable. It's a close case, especially in the context of organ allocation policies that in practice are the product of the OPTN's national policymaking, review, and implementation, even at the organ waitlist level. But in light of the structural evidence indicating Congress's intent in passing NOTA that the OPTN be a nonprofit entity separate from the government and HHS's longstanding interpretation of Section 1138 of the Social Security Act, the Court holds that the OPTN is not an agency for the purpose of the Administrative Procedure Act.").

remain in place).²³⁸ The next Part provides important new information on that question by investigating whether the current system is achieving the goals it set out to achieve and whether the pursuit of those goals has created more problems than solutions.

III. A DATA-DRIVEN VIEW OF THE IMPLICATIONS OF NATIONAL ORGAN ALLOCATION

Advocates of broader national organ sharing remain laser focused on the provision in the Final Rule mandating organ allocation policies “[s]hall not be based on the candidate’s place of residence or place of listing.”²³⁹ While policies that have stemmed from this focus arguably address some issues, these policies are not without disadvantages. This Part examines three issues that may undermine the continued push toward greater national organ sharing. First, it considers the basis for organ sharing generally — metrics used to determine medical urgency. Absent local preferences for organ allocation, these metrics become much more important since they determine who lives and who dies in many cases. Because they form the primary evidence base for increased organ sharing, the question of whether they accurately represent medical need is critically important. Beyond providing important insight into the features of the current system, the efficacy of medical urgency metrics is relevant to the more general mandate of the Final Rule that organs be used efficiently and not wasted.²⁴⁰ If these metrics are inaccurate or unreliable, the claim that organs are used efficiently within the current system is hard to justify.

Next, I examine the implications of broader national sharing for patients of different socioeconomic statuses. In doing so, I consider important questions of whether the organ allocation system prioritizes relatively richer patients over relatively poorer patients. I am also able to answer the question of whether lower income individuals tend to

²³⁸ Congress recently passed a law to change how the OPTN is regulated. *See* Securing the U.S. Organ Procurement and Transplantation Network Act, Pub. L. No. 118-14, 137 Stat. 69 (2023).

²³⁹ 42 C.F.R. § 121.8(a)(8).

²⁴⁰ The Final Rule directs that allocation policies “[s]hall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement.” *Id.* § 121.8(a)(5).

provide organs to higher income individuals. While using the poor as organ donors for the rich is an oft-used plot in fiction, it may be highly problematic as an outcome of real-life organ allocation policies.²⁴¹ This outcome may also violate the Final Rule by exacerbating socioeconomic inequities.²⁴²

Finally, this Part examines the implications of organ allocation policies beyond the narrow confines of organ waitlists. Though advocates of broader sharing vehemently argue that off-waitlist individuals are irrelevant to organ allocation policy under the Final Rule, I focus on these otherwise invisible individuals to develop a more comprehensive picture of allocation policies. To return to the emergency department analogy, I agree with national advocates that individuals in the emergency room should be ranked in order of medical urgency. I disagree, however, that they are the only patients that matter. Healthcare policy should (and does) consider how to better serve individuals who cannot make it to the emergency department. A patient who dies on the curb because of the lack of care that could have been provided in the emergency department should matter just as much to healthcare policy as a patient who dies in the emergency department itself.

A. *Bad Metrics?*

With the de-emphasis of local preferences, decisions of how to allocate individual organs rely more heavily on the metrics used to rank patients by medical urgency. The National Academies' 2022 report emphasized that the organ transplant system relies on too many, inconsistent metrics for evaluation.²⁴³ Beyond that general issue, recent work has highlighted the failures of current allocation metrics to

²⁴¹ For example, in the film *Moneyball*, the manager of the underfunded Oakland Athletics complains of being organ donors for the rich when the much wealthier New York Yankees sign his best players to new contracts. *MONEYBALL* (Columbia Pictures 2011).

²⁴² See 42 C.F.R. § 121.4(a)(3)(i)–(iv). Specifically, this violates the prohibition on exacerbating socioeconomic inequities by providing richer individuals a benefit at the expense of poorer individuals. *Id.* § 121.4(a)(3)(iv).

²⁴³ NAT'L ACADEMIES, *supra* note 13, at 200–02.

accurately capture medical urgency.²⁴⁴ This presents a significant problem for the continued push toward greater national organ sharing because arguments in favor of this push rely heavily on the fact that more medically urgent patients must wait for organs in some parts of the country while less medically urgent patients obtain organs faster in other parts of the country. Importantly, operationalizing this argument to move toward broader organ sharing turns on the ability to accurately measure medical urgency. As described above, liver candidates receive a MELD score, lung candidates receive an LAS, and heart candidates are placed into six tiers to quantify their medical urgency.²⁴⁵ The highest statuses are reserved for those most likely to die in the shortest amount of time, and everyone else receives a score or status that, in theory, is correlated with their mortality risk.²⁴⁶

While these different measures represent a patient's medical urgency in theory, they are not perfect. For example, they only capture certain clinical information and may omit other risk factors for death that can obscure a patient's actual medical urgency. In the context of livers, for example, Jayme Locke, the director of transplantation at the University of Alabama at Birmingham explained that "[t]here's this assumption that if your MELD score is 29 and you live in rural Appalachia, you're just as sick as someone who lives in downtown Manhattan."²⁴⁷ This assumption is flawed however, as Lock continued that the patient from Appalachia "may have the same medical score, but they come with far more co-morbidities and are much sicker."²⁴⁸ Even without these confounding factors, which the MELD score was never designed to

²⁴⁴ See, e.g., William F. Parker, Nicole E. Dussault, Renea Jablonski, Edward R. Garrity & Matthew M. Churpek, *Assessing the Accuracy of the Lung Allocation Score*, 41 J. HEART & LUNG TRANSPLANTATION 217, 217 (2022) [hereinafter Parker et al., *Assessing Accuracy*] ("The waitlist and the post-transplant models that constitute the LAS are inaccurate, limiting the ability of the system to rank candidates on the waitlist in the correct order.").

²⁴⁵ See *supra* Part II.A.

²⁴⁶ *Id.*

²⁴⁷ Carollo & Tanen, *Winners & Losers*, *supra* note 21.

²⁴⁸ *Id.*

account for, evidence suggests that the MELD score's predictive accuracy has declined.²⁴⁹

Similarly, a recent study focused on lungs found that “[t]he waitlist and the post-transplant models that constitute the LAS are inaccurate, limiting the ability of the system to rank candidates on the waitlist in the correct order.”²⁵⁰ The six tiers used to rank heart transplant candidates also suffer from problems. One study found that this “system has only moderate ability to rank-order candidates by medical urgency.”²⁵¹ Researchers have begun developing new models and metrics to better quantify medical urgency. For example, one group developed a machine-learning approach to replace the MELD score for liver candidates,²⁵² and other groups have worked toward better metrics for hearts and lungs.²⁵³ These attempts may mitigate some of the problems

²⁴⁹ See Elizabeth L. Godfrey, Tahir H. Malik, Jennifer C. Lai, Ayse L. Mindikoglu, N. Thao N. Galván, Ronald T. Cotton, Christine A. O'Mahony, John A. Goss & Abbas Rana, *The Decreasing Predictive Power of MELD in an Era of Changing Etiology of Liver Disease*, 19 AM. J. TRANSPLANTATION 3299, 3299 (2019) (“While MELD still predicts mortality, its accuracy has decreased; changing etiology of disease may contribute.”).

²⁵⁰ Parker et al., *Assessing Accuracy*, *supra* note 244, at 217; see also Jarrod E. Dalton, Carli J. Lehr, Paul R. Gunsalus, Lyla Mourany & Maryam Valapour, *Miscalibration of Lung Allocation Models Leads to Inaccurate Waitlist Mortality Predictions*, 23 AM. J. TRANSPLANTATION 72, 72 (2023) (“The waitlist model underpredicts risk for 78% of US transplant candidates with an unequal distribution of miscalibration across subgroups leading to inaccurate ranking of transplant candidates.”).

²⁵¹ Kenley M. Pelzer, Kevin C. Zhang, Kevin A. Lazenby, Nikhil Narang, Matthew M. Churpek, Allen S. Anderson & William F. Parker, *The Accuracy of Initial U.S. Heart Transplant Candidate Rankings*, 11 JACC: HEART FAILURE 504, 504 (2023).

²⁵² Bertsimas et al., *supra* note 51, at 1109 (“These data demonstrate the potential of machine learning technology to help guide clinical practice, and potentially guide national policy.”); see also Zeng-Lei He, Jun-Bin Zhou, Zhi-Kun Liu, Si-Yi Dong, Yun-Tao Zhang, Tian Shen, Shu-Sen Zheng & Xiao Xu, *Application of Machine Learning Models for Predicting Acute Kidney Injury Following Donation After Cardiac Death Liver Transplantation*, 20 HEPATOBIILIARY & PANCREATIC DISEASES INT’L 222, 224-30 (2021) (discussing machine learning models in the context of preventing specific injuries during transplantation).

²⁵³ Pelzer et al., *supra* note 251, at 504 (“Predictive models that incorporate physiologic measurements can more effectively rank-order heart transplant candidates by urgency.”); Darren E. Stewart, Dallas W. Wood, James B. Alcorn, Erika D. Lease, Michael Hayes, Brett Hauber & Rebecca E. Goff, *A Revealed Preference Analysis To Develop Composite Scores Approximating Lung Allocation Policy in the U.S.*, 21 BMC MED. INFORMATICS & DECISION MAKING 1, 1 (2021) (“Revealed preference analysis of lung

with existing urgency metrics, but it is highly unlikely any scoring system will ever have enough information about every individual patient to classify their medical urgency perfectly accurately.

Even if such a metric becomes available, existing evidence suggests that medical urgency metrics are manipulated to make patients appear sicker than they are. For example, one study focused on livers and MELD scores found “that transplant professionals have routinely manipulated the waitlist priority of their patients” and that “this manipulation occurs more often in areas of the country that argue most vehemently in favor of national allocation policies.”²⁵⁴ Additionally, the study found that transplant centers facing more competition for donated livers engaged in more manipulation than centers facing less competition.²⁵⁵ A 2018 study of heart allocation policy found similar results. In particular, “[c]ompetition for transplantable donor hearts is associated with the potential overtreatment of hemodynamically stable candidates.”²⁵⁶ This “[o]vertreatment may compromise the fair and efficient allocation of scarce deceased donor hearts.”²⁵⁷ A later study by many of the same authors found evidence that, following the introduction of the six tiers heart allocation policy, transplant centers over-treated patients to increase their apparent medical urgency and their likelihood of receiving a heart.²⁵⁸ This led “to significantly more high-priority status listings than anticipated” and meant that “the new allocation system may not function as intended.”²⁵⁹

allocation match runs produced composite scores that capture the essence of current policy while removing rigid boundaries of the current classification-based system.”).

²⁵⁴ McMichael, *Stealing Organs?*, *supra* note 12, at 135.

²⁵⁵ *Id.* at 141 (“Additionally, the scores of patients at transplant centers facing more competition for livers were more likely to spike above the threshold than the scores of patients at transplant centers facing less competition.”).

²⁵⁶ William F. Parker, Allen S. Anderson, Donald Hedeker, Elbert S. Huang, Edward R. Garrity, Mark Siegler & Matthew M. Churpek, *Geographic Variation in the Treatment of U.S. Adult Heart Transplant Candidates*, 71 J. AM. COLL. CARDIOLOGY 1715, 1715 (2018) [hereinafter Parker et al., *Geographic Variation*].

²⁵⁷ *Id.*

²⁵⁸ See William F. Parker, Kevin Chung, Allen S. Anderson, Mark Siegler, Elbert S. Huang & Matthew M. Churpek, *Practice Changes at U.S. Transplant Centers After the New Adult Heart Allocation Policy*, 75 J. AM. COLL. CARDIOLOGY 2906, 2906 (2020) [hereinafter Parker et al., *Practice Changes*].

²⁵⁹ *Id.*

A full investigation of manipulation in the organ allocation system is beyond the scope of this Article, but Figure 7 reports evidence consistent with what prior studies have found. Panel A reports the proportion of individuals waitlisted for a liver transplant who (1) have a laboratory MELD score under 35 *and* (2) have an exception-based MELD score of 35 or over. The first vertical line marks the implementation of the Share 35 policy. This policy is relevant because it allowed patients with a MELD score of thirty-five or higher to access livers from outside their DSA. Thus, exceeding this threshold became an obvious goal. In Panel A, a spike is clearly visible in the proportion of transplant candidates who fail to qualify for livers drawn from a wider geography based only on their laboratory MELD scores — which are based on objective blood tests — but qualify based on their exception-based MELD scores — which are based on potentially manipulable applications and appeals processes. It is nearly impossible to explain this sudden spike coinciding with the Share 35 policy without manipulation. Additionally, the second vertical line indicates a change in the rules governing exception points that made it more difficult to game the system with exception points awarded for hepatocellular carcinoma (“HCC” — a type of liver cancer). This small, but important rule change reduced the ability of candidates and transplant professionals to game the system, and Figure 7 clearly shows a dip in individuals qualifying for broader access to livers based on exception points alone following this change.²⁶⁰

²⁶⁰ See Bertsimas et al., *supra* note 51, at 1114 (“The use of MELD exception points within the current scoring system has represented an arbitrary, yet advantageous, solution for certain subpopulations of candidates, most notably those candidates with HCC The latter ‘HCC advantage’ has been addressed through first serial downgrades in the amount of MELD exception points granted, and subsequently, more recently, with both a delayed initiation of MELD exception points (6-month delay), as well as a cap on the extent of points an individual can achieve (MELD 34 cap).”).

FIGURE 7: LIVER AND HEART WAITLIST CHANGES FOLLOWING THE INTRODUCTION OF NEW POLICIES

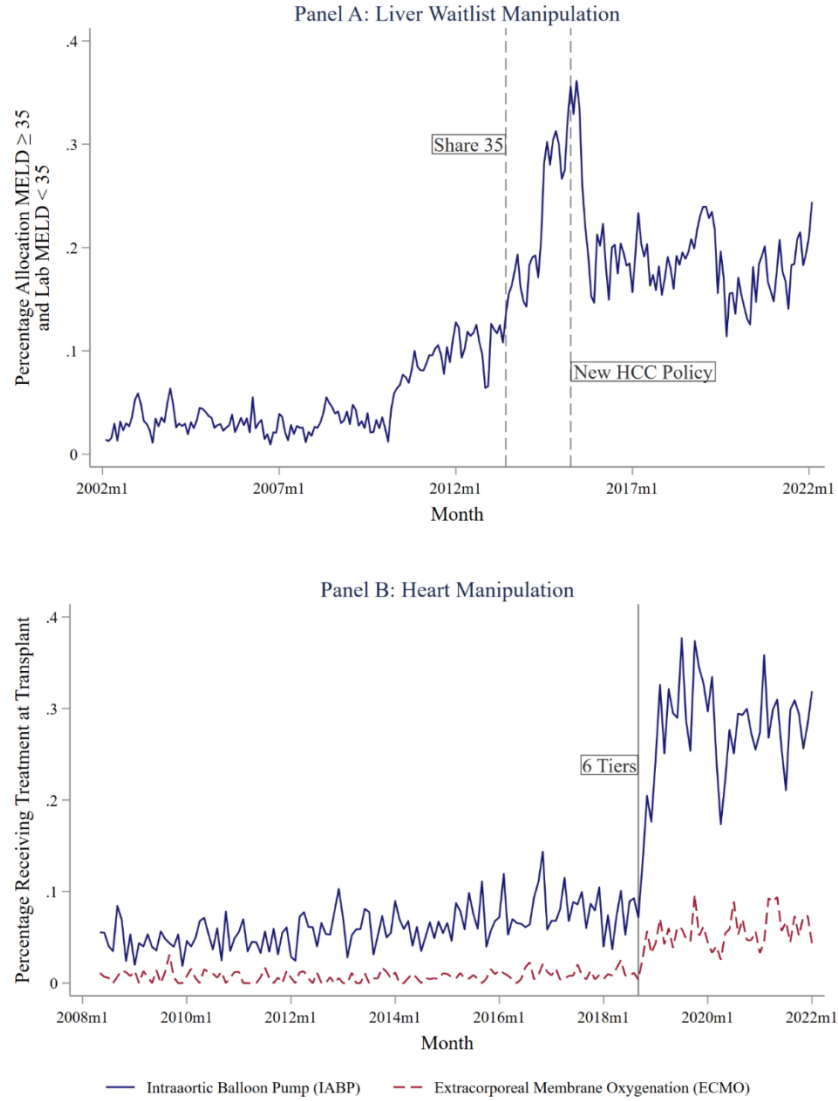


Fig. 7: Panel A reports percentage of individuals on liver waitlists who had an allocation MELD score of 35 or higher and a laboratory MELD score of 34 or lower over time. Labeled vertical lines indicate relevant changes in liver allocation policy. Panel B reports the percentage of heart transplant recipients who had received an intra-aortic balloon pump and extracorporeal membrane oxygenation over time.

Panel B in Figure 7 reports the percentage of heart transplant recipients who had previously received an intra-aortic balloon pump (“IABP”) or extra-corporeal membrane oxygenation (“ECMO”). After the implementation of the six tiers policy for heart allocation, receiving either of these medical interventions could increase a candidate’s status on the waitlist, even if these interventions were not medically necessary. As illustrated in Panel B, the proportion of transplant recipients who had undergone these medical interventions spiked immediately following the implementation of the six tiers allocation policy. Panel B does not, itself, prove the existence of manipulation — one would expect that the policy itself would increase the share of recipients who had received these interventions because they were awarded higher status. Nevertheless, Panel B is illustrative of and consistent with prior work which has demonstrated the existence of manipulation in heart allocation.²⁶¹

While Figure 7 does not illustrate manipulation of the lung and kidney allocation systems, that does not imply that such manipulation does not occur. In fact, a 2018 report from the OPTN listed the various ways that transplant professionals could manipulate the apparent sickness of their patients, including the two ways illustrated in Figure 7.²⁶² At the time, the report noted that no studies had found evidence of manipulation, but that has changed substantially in the last five years.²⁶³ Additionally, the report highlighted “numerous well-publicized reports and editorials highlighting alleged or potential purposeful manipulation of the allocation system.”²⁶⁴ The clear evidence of manipulation recently developed in academic literature and other anecdotal evidence of similar behavior undermines arguments that geographic disparities in

²⁶¹ Parker et al., *Geographic Variation*, *supra* note 256, at 1715; Parker et al., *Practice Changes*, *supra* note 258, at 2906.

²⁶² OPTN & UNOS, MANIPULATION OF THE ORGAN ALLOCATION SYSTEM WAITLIST PRIORITY THROUGH THE ESCALATION OF MEDICAL THERAPIES 1-8 (2018), https://optn.transplant.hrsa.gov/media/2500/ethics_whitepaper_201806.pdf [<https://perma.cc/Y4EZ-8AK4>].

²⁶³ *See id.* at 3.

²⁶⁴ *Id.*

medical urgency metrics justify greater organ sharing.²⁶⁵ Even if these studies are wrong, however, and no manipulation of urgency measures occurs, that does not imply that current metrics accurately capture medical urgency.

Focusing on livers, which have a clear measure of medical urgency based only on blood tests, transplant physicians and others have criticized the MELD score for failing to account for other factors that may affect individuals' need for a transplant. And these factors disproportionately affect those in poorer and more rural areas.²⁶⁶ Timothy Schmitt explained that patients with diabetes or hypertension — both of which are more common in poorer and more rural states — are more likely to die than patients without these conditions even if they have the exact same MELD score.²⁶⁷ If organ allocation policies acknowledged and sought to address these types of geographic and socioeconomic disparities, those policies would likely seek to funnel organs from richer, more urban areas towards poorer, more rural areas. However, as the next Section details, this does not occur.

B. Allocation Based on Affluence and Urban Status?

Despite their weaknesses, the various measures of medical urgency described in the last Section have formed the foundation for changes in organ allocation policy. These changes have also altered how donated organs flow from one part of the country to another. To examine these flows of organs, it is helpful to consider the net “imports” and “exports” of individual organs. To calculate net imports and exports for each DSA in each year, I count the number of organs recovered within a given DSA's boundaries but transplanted into a candidate in a different DSA. I separately count the number of organs transplanted within the DSA

²⁶⁵ See Cascino et al., *supra* note 42, at 101-02; McMichael, *Stealing Organs?*, *supra* note 12, at 195-96; Jason Snyder, *Gaming the Liver Transplant Market*, 26 J.L. ECON. & ORG. 546, 547-48 (2010).

²⁶⁶ Carollo & Tanen, *Winners & Losers*, *supra* note 21 (“Even when patients make it onto the waitlist, some factors that affect the poor are not counted. The numerical score from six to 40 used to measure the severity of a patient's liver disease, called a MELD score, does not take into account other medical conditions a patient may have, such as hypertension or diabetes, which are more prevalent in rural states.”).

²⁶⁷ *Id.*

that were recovered from donors in other DSAs. Combining these two numbers yields the net imports/exports of each DSA. Figure 8 reports the net imports and exports of all DSAs. Shades of red indicate that a DSA is a net importer of organs (i.e., receives more organs from other DSAs than it sends to other DSAs). Shades of blue indicate that a DSA is a net exporter of organs (i.e., sends more organs to other DSAs than it receives from other DSAs).²⁶⁸

FIGURE 8: NET IMPORTS AND EXPORTS OF ORGANS

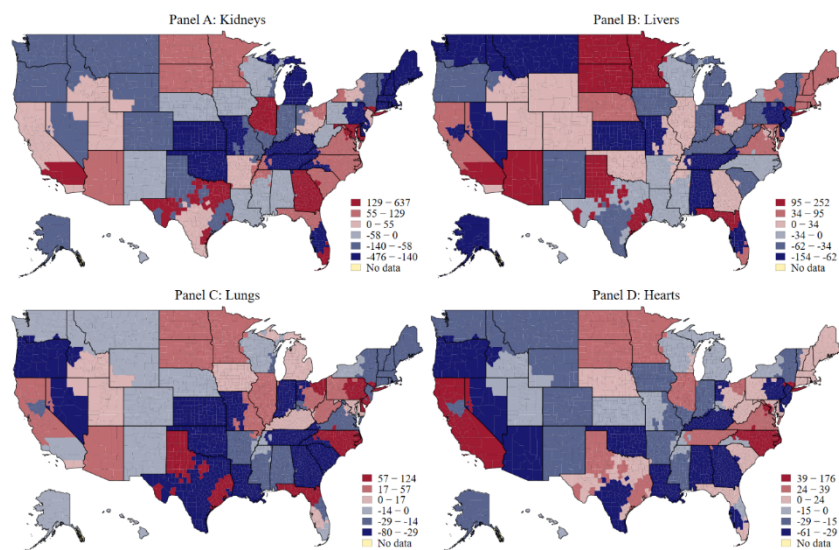


Fig. 8: Net organ imports (red) and exports (blue) are reported for each DSA. Each Panel reports net imports/exports for the organ listed in the title.

The import-export patterns visible in Figure 8 are not what one would expect of allocation policies focused on equity. Consider two very different DSAs — the one containing New York City and the one containing most of Alabama. Between the two, New Yorkers have much

²⁶⁸ Net imports and exports differ meaningfully from the percentage of transplants using local organs described above. Where local organ percentages capture the proportion of transplant relying on imported organs, the net imports and exports reported in Figure 9 capture the overall flow of organs between DSAs. Even a DSA using a relatively small percentage of local organs may be a net exporter as long as its exports exceed its imports. Thus, examining net imports and exports provides deeper insight into which DSAs ultimately draw in more organs than they send out.

better access to healthcare, have higher incomes, and are less likely to live in rural areas than Alabamians.²⁶⁹ However, across all four organs, the DSA containing most of Alabama is a net exporter — and is in the highest exporter category for two organs — while the DSA containing most of New York is in the highest importer category for all four organs. Comparing the DSA containing Kansas and the DSA containing the less rural and more affluent Los Angeles yields a similar story. The former is always an exporter while the latter is, except for lungs, an importer.

While these simple comparisons illustrate the failure of organ allocation policy to address the role of socioeconomic status, a broader analysis is necessary to demonstrate such a failure on a system-wide basis. Organ transplant data — even the restricted-use data examined here — does not include information on socioeconomic status of donors, transplant candidates, or transplant recipients.²⁷⁰ This unfortunate fact makes examining the role of socioeconomic status in allocation policy difficult, but not impossible. I take two general approaches to examining socioeconomic status. The restricted-use data I examine includes the zip codes of organ donors and transplant recipients. Using these zip codes, I assign donors and candidates to one of the following three categories: rural, suburban, and urban. To do so, I use rural-urban commuting area codes available from the United States Department of Agriculture.²⁷¹ Next, I examine the socioeconomic status of donors and recipients based on their zip codes. Using data from the American Community Survey, I match each individual to the median income of their associated zip code. Doing so allows me to examine the average socioeconomic status of donors relative to recipients. All incomes are reported in 2022 dollars to account for inflation and facilitate comparison across years.

²⁶⁹ DAVID C. RADLEY, JESSE C. BAUMGARTNER, SARA R. COLLINS & LAURIE C. ZEPHYRIN, 2023 SCORECARD ON STATE HEALTH SYSTEM PERFORMANCE (2023), <https://www.commonwealthfund.org/publications/scorecard/2023/jun/2023-scorecard-state-health-system-performance> [<https://perma.cc/9F4S-XHQQ>].

²⁷⁰ OPTN, DATA COLLECTION TO ASSESS SOCIOECONOMIC STATUS & ACCESS TO TRANSPLANT 4 (2020), https://optn.transplant.hrsa.gov/media/3507/2020_springpc_mac_sesdatacollection.pdf [<https://perma.cc/66EV-6QA5>].

²⁷¹ Rural-urban commuting area codes associated with urban areas include 1–3. Rural-urban commuting area codes associated with suburban areas include 4–5. Rural-urban commuting codes of 6 and above are associated with rural areas.

Figure 9 reports the number of donors and recipients falling into different rural categories in 2021. Urban residents are the primary donors and transplant recipients, but across all organs, a small rural-urban disparity is evident. Rural and suburban areas generally have more organ donors than they do transplant recipients. Urban areas, on the other hand, have more recipients than they have donors.

FIGURE 9: ORGAN DONORS AND TRANSPLANT RECIPIENTS BY RURAL STATUS

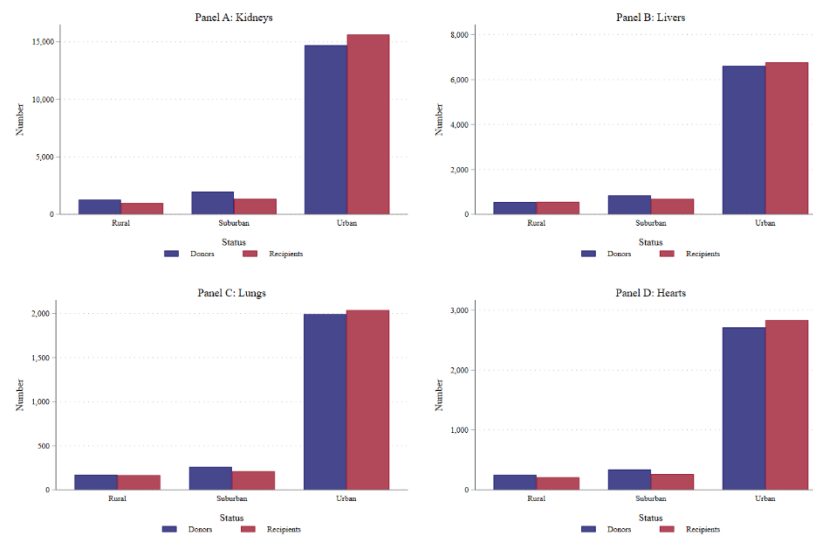


Fig. 9: Each panel reports the number of organ donors (blue) and transplant recipients (red) who lived in rural, suburban, and urban counties in 2021.

Figure 10 explores socioeconomic inequities in the organ allocation system. In general, the income of transplant recipients has trended upward over time (i.e., richer people are more likely to receive transplants over time). Since all income numbers are adjusted to 2022 dollars, the increase represents a meaningful upward shift in the income of transplant recipients. Importantly, the incomes of individuals receiving a shared organ are higher than those receiving a local organ across all years and organs, suggesting that broader organ sharing may further exacerbate socioeconomic inequities.

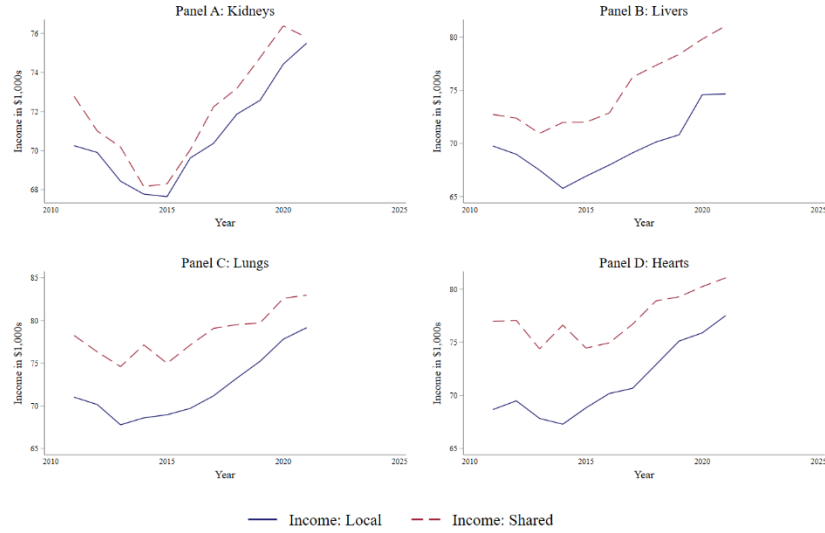
FIGURE 10: INCOME OF TRANSPLANT RECIPIENTS

Fig. 10: Each panel reports the average income of transplant recipients who received a local (solid blue line) or shared (dashed red line). All income amounts are reported in thousands of 2022 dollars.

Exploring socioeconomic inequities across organ donors and transplant recipients, Figure 11 reports the average income difference between recipients and donors across local and shared organs. Positive numbers indicate the recipient had a higher income than the donor, and negative numbers the opposite. The solid blue line represents the average recipient-donor income difference for local organs, and the red dashed line represents the average income difference for shared organs. Apart from local organs for kidneys, the recipient-donor income difference is universally positive, indicating that recipients routinely have higher incomes than donors.

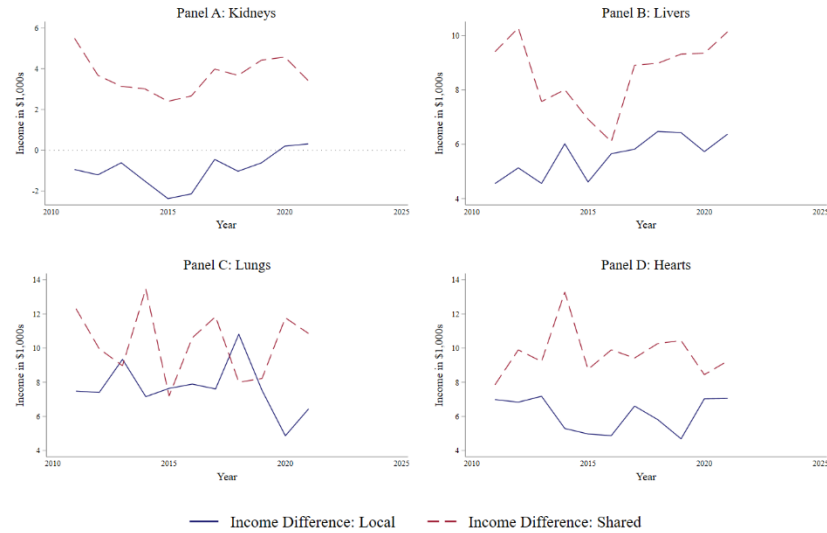
FIGURE 11: INCOME DIFFERENCES BETWEEN DONORS AND RECIPIENTS

Fig. 11: Each panel reports the average difference in income between organ donors and transplant recipients. The solid blue line reports this difference for local organs, and the dashed red line represents this difference for shared organs. Positive differences indicate that recipients had higher incomes than donors. Negative differences indicate that recipients had lower incomes than donors. All income amounts are reported in thousands of 2022 dollars.

Except for lungs in some years, the income difference favoring recipients over donors is more pronounced among shared organs than local organs. This pattern is unsurprising since locally transplanted organs are more likely to involve similarly situated individuals. Shared organs, on the other hand, appear more likely to travel from lower income areas to higher income areas, consistent with the exacerbation of socioeconomic inequities. In other words, poorer parts of the country are subsidizing the organ transplantation needs of richer parts of the country. If certain years involved lower income areas of the country providing more organs to higher income areas while other years involved the opposite, this would not necessarily indicate a problem. However, the fact that lower income areas consistently supply more organs to higher income areas raises serious concerns about whether allocation policies have remained faithful to the Final Rule's directive

that “allocation policies [be reformed] based on assessment of their cumulative effect on socioeconomic inequities”²⁷²

While explaining the various, interlocking mechanisms that systematically create the socioeconomic inequities observable in the previous two figures is beyond the scope of this Article, it is worth exploring one obvious explanation. Lower income individuals lack adequate access to healthcare.²⁷³ Becoming a transplant candidate requires not only access to healthcare generally, including primary care providers and at least one layer of specialty care providers, but also access to high-level transplant care. As Figure 12 demonstrates, this care is not uniformly accessible across the country. In general, the Southeastern and lower Midwestern parts of the country lack the same level of access as other areas. These areas also tend to have lower per capita income. Even in areas with higher access to transplant physicians, lower income individuals almost certainly have a harder time accessing the healthcare system and navigating it successfully to transplant care (which is often considered quaternary care, or the most advanced care available).²⁷⁴

²⁷² 42 C.F.R. § 121.4(a)(3)(iv) (2014).

²⁷³ Malerie Lazar & Lisa Davenport, *Barriers to Health Care Access for Low Income Families: A Review of Literature*, 35 J. CMTY. HEALTH NURSING 28, 28-37 (2018).

²⁷⁴ See *id.* at 30-31.

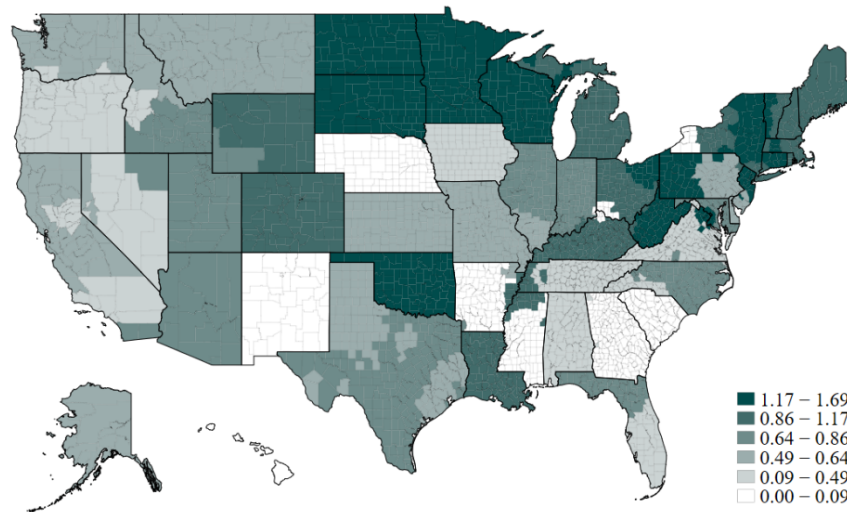
FIGURE 12: TRANSPLANT PHYSICIANS PER CAPITA

Fig. 12: The number of transplant physicians per 1,000,000 residents in 2019 are reported for all DSAs.

A recent article explained that, to access a transplant waitlist, a patient “need[s] insurance or other means to pay for their treatment” and they must “be able to pay for regular appointments” once they access a waitlist in the first place.²⁷⁵ Patients must then pay for “weeks of recovery at the hospital afterward and thousands of dollars a month in anti-rejection medication for the rest of their lives.”²⁷⁶ Even after accounting for the care itself, patients “must show up for regular appointments, which often require[s] access to a car and sometimes a friend or family member to drive.”²⁷⁷ Lower income individuals, especially those in more rural areas which require even more driving time to reach a transplant center in urban areas, are at a significant disadvantage when seeking transplant care.

In contrast to the difficulty of becoming a transplant candidate (and eventually a transplant recipient), becoming an organ donor is relatively easy. Once an individual signs up at a local department of motor vehicles office or consents via other means, that person only needs to die in a

²⁷⁵ Carollo & Tanen, *Winners & Losers*, *supra* note 21.

²⁷⁶ *Id.*

²⁷⁷ *Id.*

way consistent with organ donation.²⁷⁸ As detailed above,²⁷⁹ an entire infrastructure exists to identify organ donors and recover their organs, with every county in the United States belonging to at least one DSA and served by its associated OPO. Beyond the lack of income barriers to donation, which makes it easier for lower income individuals to become donors, lower income individuals tend to die at higher rates than higher income individuals, increasing the chances that they will donate their organs.²⁸⁰ These factors unsurprisingly lead to lower income donors more regularly saving the lives of higher income transplant recipients.²⁸¹

Collectively, the evidence detailed in this Section supports the concern that allocation policies have done little to address socioeconomic inequities. The evidence also supports the conclusion that those policies have resulted in a regressive organ allocation system that systematically moves organs from lower income to higher income areas of the country. Perhaps most troublingly, the evidence suggests that one of the key outcomes Congress hoped to avoid by passing the NOTA has occurred. One of the NOTA's most famous provisions bans the sale of organs, prohibiting the existence of any market for organs.²⁸² Indeed, the NOTA was passed in response to a proposal by a Virginia entrepreneur to buy and sell human organs in 1983.²⁸³ "At the time [of the NOTA's passage], Congress was exceptionally concerned about the

²⁷⁸ See *Sign up to Be an Organ Donor*, HRSA, <https://www.organdonor.gov/sign-up> (last updated July 8, 2024) [<https://perma.cc/C3QR-BBDM>].

²⁷⁹ See *supra* Part I.C.

²⁸⁰ David Brady, Ulrich Kohler & Hui Zheng, *Novel Estimates of Mortality Associated with Poverty in the US*, 183 JAMA INTERNAL MED. 618, 619 (2023) (finding greater mortality hazards with poverty).

²⁸¹ It is possible to argue that higher income individuals should have greater access to organ transplants because they are more valuable to society. However, that is not the argument that has been used to justify greater national organ sharing, and it runs counter to the various ethical principles underlying the current system. If proponents of broader sharing are prepared to justify that sharing along these lines, future work can engage with those arguments. For the time being, however, I will not directly address this issue.

²⁸² 42 U.S.C. § 274e.

²⁸³ See Susan Hankin Denise, Note, *Regulating the Sale of Human Organs*, 71 VA. L. REV. 1015, 1021-23 (1985) (discussing the proposed market in organs).

rise of an organ market.”²⁸⁴ Congress had multiple concerns about organ markets, but one was that organ transplantation would only be available to the wealthiest patients.²⁸⁵ Ironically, the regulatory system set up to avoid that outcome has largely resulted in exactly that outcome, as richer areas of the country draw in organs from poorer areas. Even more ironically, because this outcome occurred via regulation instead of markets, the richer areas need not compensate the poorer areas directly for the organs they import — the proverbial having one’s cake and eating it too.

Though neither the OPTN nor any government agency has ever said so explicitly, the evidence developed in this Section largely suggests they agree with national sharing advocate Alexandra Glazier that it is “inappropriate to use organ allocation to rectify social injustices outside of [the] distribution of organs to those waiting.”²⁸⁶ There is little indication that allocation policy accounts in any meaningful way for socioeconomic status or rural status. Instead, the evidence is consistent with allocation policy using socioeconomic and rural status as leverage to require the export of more organs to richer, more urban areas — though the evidence does not directly support that as a causal claim.

Because socioeconomic status tends to correlate with geography and access to healthcare, socioeconomic inequities may easily translate into geographic inequities. The next Section explores this issue in detail. Instead of only considering the transplant system, however, it examines geographic inequities across the entire population.

C. Ignoring “Invisible” Patients

Much of the evidence used to justify broader national organ sharing comes from transplant waitlists.²⁸⁷ That evidence, however, necessarily excludes anyone who lacks sufficient access to the healthcare system to

²⁸⁴ Gwen Mayes, *Buying and Selling Organs for Transplantation in the United States*, MEDSCAPE (Dec. 9, 2003), https://www.medscape.org/viewarticle/465200_2 [<https://perma.cc/XFE6-GGK7>].

²⁸⁵ See *id.*

²⁸⁶ Callahan Emails, *supra* note 29, at 0018441. Glazier noted at a different point that “[w]e can all agree that as a nation we need to improve access to care for disadvantaged populations.” *Id.* at 0018419.

²⁸⁷ See Giorgakis et al., *supra* note 204.

be placed on a waitlist by a transplant center.²⁸⁸ A recent joint report from the National Academies of Sciences, Engineering, and Medicine acknowledged the importance of accessing a transplant waitlist. “Getting onto the waiting list — being listed — is metaphorically the gateway that must open for one to have access to receiving a transplant of a deceased donor organ.”²⁸⁹ Highlighting inequities, the report continued “[f]or many persons who would benefit from organ transplantation — and particularly racial and ethnic minorities, individuals of lower socioeconomic status, those who live in rural areas, or undocumented immigrants or individuals with an intellectual disability — this gate may be especially hard to open.”²⁹⁰ Moreover, “[i]t is well established that inequities arise in access to referrals, evaluation, and the waiting list for organ transplant.”²⁹¹

Unsurprisingly, “[t]he committee [responsible for drafting the report] conclude[d] that the current organ transplantation system is demonstrably inequitable.”²⁹² The failure to consider patients who have not yet accessed an organ waitlist was one reason for this conclusion.²⁹³ Because the OPTN’s “purview” only extends to the beginning of the waiting list, transplant rates across populations are not commensurate with their medical needs.²⁹⁴

The report drafters are correct that the OPTN’s “purview” to monitor and regulate the transplant system begins with a patient’s appearance on a waitlist. However, the Final Rule clearly contemplates access to transplant as a relevant factor to consider when formulating allocation

²⁸⁸ See *id.*

²⁸⁹ NAT’L ACADEMIES, *supra* note 13, at 4.

²⁹⁰ *Id.*

²⁹¹ *Id.*

²⁹² *Id.* at 5.

²⁹³ *Id.* at 4 (“The purview of the OPTN begins when an individual patient is added to the waiting list for a deceased donor organ. The committee finds that this gap in oversight presents a significant challenge to ensuring fairness and equity in the organ transplantation system and that federal oversight should expand to begin when an individual is diagnosed with end-stage organ failure and include the steps involved in identifying patients as needing a transplant before patients are added to the waiting list.”).

²⁹⁴ *Id.*

policy.²⁹⁵ In directing that policies “be designed . . . to promote patient access to transplantation,” the Final Rule directs policymakers to consider individuals who do not currently have access to transplantation.²⁹⁶ Advocates of broader organ sharing have interpreted this to mean that when developing allocation policies, only patients on the waitlist who have not yet received a transplant are relevant.²⁹⁷ The evidence suggests HHS may agree with this interpretation.²⁹⁸ However, it is not at all clear that individuals who have not been able to access a transplant waitlist are, or should be, invisible to allocation policy. Thus, even under the current legal regime, the OPTN is not necessarily required to ignore patients not yet on waitlists when formulating allocation policy. While the OPTN is not required to ignore non-waitlisted patients, its decision to do so may systematically disadvantage entire groups of people across the country. By ignoring non-waitlisted individuals, the OPTN risks providing organs to less medically urgent individuals over more medically urgent individuals in violation of its mandate.

Understanding the impact of OPTN policies on non-waitlisted patients is critically important, but evaluating these impacts is exceedingly difficult because data on non-waitlisted patients simply does not exist. Unlike the detailed SRTR dataset, which provides information on every organ donor, waitlisted patient, and transplant recipient, no such dataset exists for individuals who have been unable to access a waitlist. To address this absence of data, I develop a new measure of “transplant amenable deaths.”

By transplant amenable deaths, I mean deaths that could have been avoided by the receipt of a transplant. This concept stems from work in the health economics and health services research literatures on healthcare amenable deaths.²⁹⁹ In that literature, researchers evaluated

²⁹⁵ 42 C.F.R. §§ 121.4(a)(3), 121.8(a)(5).

²⁹⁶ *Id.* § 121.8(a)(5).

²⁹⁷ Glazier, *supra* note 27, at 141-43.

²⁹⁸ NAT'L ACADEMIES, *supra* note 13 at 85-116.

²⁹⁹ See, e.g., McMichael, *Supply-side Health Policy*, *supra* note 3 (examining the effect on health-care amenable death through the increased use of nurse practitioners and physician assistants); Miller et al., *supra* note 3, at 1795 (outlining an empirical strategy reviewing expansion vs. non-expansion Medicare states and annual mortality); Ellen

underlying causes of death as recorded on individual death certificates and determined which ones could have been avoided with timely access to healthcare. While no work has previously employed the concept of transplant amenable deaths,³⁰⁰ I constructed this measure of mortality by modifying the approach used for healthcare amenable deaths. Specifically, I started with data on every death that occurred in the United States between 2011 and 2021. Data on these deaths come from the United States' National Vital Statistics System, as described above.³⁰¹

Using the ICD-10 codes available in the mortality data, I isolated specific codes that identify deaths that may have been avoided had the decedent received a transplant. To identify these codes, I reviewed the diagnoses available in the SRTR dataset for transplant candidates and recipients to identify the conditions that a transplant could treat. I then matched those diagnoses with ICD-10 codes to generate a list of ICD-10 codes for transplant amenable deaths.³⁰² I subsequently counted the

Nolte & Martin McKee, *Variations in Amenable Mortality — Trends in 16 High-Income Nations*, 103 HEALTH POL'Y 47, 47-52 (2011) (identifying “amenable mortality” as premature death which should not occur given “timely and effective health care”); Benjamin D. Sommers, *State Medicaid Expansions and Mortality, Revisited: A Cost-Benefit Analysis*, 3 AM. J. HEALTH ECON. 392 (2017) (exploring causes of death and presenting a cost-benefit analysis).

³⁰⁰ Prior studies have examined something conceptually similar to my definition of transplant amenable deaths. In the context of kidney transplantation, one study examined all end-stage kidney disease deaths. Katherine Ross-Driscoll, David Axelrod, Raymond Lynch & Rachel E. Patzer, *Using Geographic Catchment Areas to Measure Population-based Access to Kidney Transplant in the United States*, 104 TRANSPLANTATION e342, e342-50 (2020) [hereinafter Ross-Driscoll et al., *Kidneys*]. Similarly, another study focused on access to liver transplantation analyzed all end-stage liver disease deaths. Katherine Ross-Driscoll, Jonathan Gunasti, Arrey-Takor Ayuk-Arrey, Joel T. Adler, David Axelrod, Lisa McElroy, Rachel E. Patzer & Raymond Lynch, *Identifying and Understanding Variation in Population-based Access to Liver Transplantation in the United States*, 23 AM. J. TRANSPLANTATION 1401, 1401-1410 (2023) [hereinafter Ross-Driscoll et al., *Livers*]. While I pursue similar goals as this prior work, my definition of transplant amenable deaths covers all four major solid organs and is more narrowly tailored to capture deaths that could have been avoided with a transplant.

³⁰¹ *Supra* Part I.D.

³⁰² I confirmed with very helpful SRTR staff that the diagnosis codes available in the SRTR dataset were not available as ICD-10 codes. Therefore, I compared individual descriptions of diagnoses in the SRTR dataset with descriptions of ICD-10 codes to

number of deaths that include one of these transplant amenable causes as the underlying cause of death. Because individual diagnoses are specific to different types of organ transplants, I developed measures of transplant amenable deaths separately for kidney, liver, lung, and heart transplants.³⁰³ To be clear, this process will not lead to perfect counts of actual transplant amenable deaths in the sense that a transplant would certainly have saved a particular decedent's life. Determining whether a transplant will save someone's life requires a thorough medical examination, and even then, physicians may disagree over whether a transplant may save a particular person's life. It is not possible to recreate such a medical examination using only ICD-10 codes and therefore not possible to isolate every single person who would have survived but for the failure to receive a transplant.

Even with these limitations in mind, however, gathering data on deaths that potentially could have been avoided with a transplant provides critically important context to the organ allocation policy

identify the ICD-10 codes most consistent with the diagnoses of individuals waitlisted for and receiving transplants. In this way, I identified the set of deaths that may be avoided by receipt of a transplant.

³⁰³ Individual ICD-10 codes accounting for underlying cause of death begin with a letter followed by four digits in the mortality data (ICD-10 codes can be more specific, but the mortality data only includes five digits in total). The following lists provide definitions for all four types of transplant amenable deaths. An asterisk indicates that all codes beginning with the preceding digits are included in the relevant measure of transplant amenable deaths. Kidney transplant amenable deaths include the following. Diabetes with kidney complications: E102* E112* E132*; Hypertensive kidney disease: I12* I13*; Glomerular diseases: N00* N01* N02* N03* N04* N05*; Kidney failure: N17* N18* N19* N26*; Congenital malformations of kidney: Q60* Q61* Q63*. Liver transplant amenable deaths include the following. Liver disease: K70* K71* K72* K73* K74* K75* K76* K77*; Hepatitis: B15* B16* B17* B18* B19*; Malignant neoplasm: of liver C22*; Diseases of biliary tract: K83*; Malformations of bile ducts and liver: Q442 Q446 Q447. Lung transplant amenable deaths include the following. Sarcoidosis: D860* D862*; Cystic fibrosis: E840* E849*; Primary pulmonary hypertension: I270*; Emphysema: J43*; Chronic obstructive pulmonary disease: J44*; Interstitial pulmonary disease: J841* J848* J849*; Respiratory failure: J96*; Scleroderma with lung involvement: M348*. Heart transplant amenable deaths include the following. Viral diseases of the heart: B332*; Amyloidosis, heart: E854*; Hypertensive heart disease: I11* I13*; Chronic ischemic heart disease: I25*; Cardiomyopathy: I42*; Ventricular tachycardia: I472*; Ventricular fibrillation: I4901*; Heart failure: I50*; Peripartum cardiomyopathy: O903*; Congenital malformations: Q20* Q21* Q23* Q24*.

debate. Without some way to measure the impact of organ allocation policy on individuals who, through no fault of their own, cannot access waitlists, such individuals would remain invisible to organ allocation policy. By counting transplant amenable deaths, I can calculate the number of people in different parts of the country who needed a transplant before their death and thereby measure the relative need for donated organs across the country among *all* individuals.

Importantly, federal regulators have already demonstrated, by adopting the number of CALC deaths described above as an official measure for OPOs, a willingness to accept imperfect metrics derived from death certificates. It is certainly not the case that every CALC death could yield transplantable organs for many different reasons (many of which are not recordable on death certificates).³⁰⁴ Nevertheless, the importance of having a valid metric to judge OPO performance justifies the use of CALC deaths as an official metric. Similarly, the fact that not every death coded as transplant amenable could have been avoided with a transplant does not invalidate the use of transplant amenable deaths to examine organ allocation policy. Additionally, as with CALC deaths, the fact that transplant amenable deaths are counted using death certificates and not outcome measures reported by individuals associated with the transplant system means this measure is not manipulable in the same way as the measures of medical urgency discussed above. Thus, transplant amenable deaths represent the best, if not perfect, outcome by which to examine the impact of organ allocation policies on individuals who have not been waitlisted for a transplant.

Figure 13 reports the rate of transplant amenable deaths per 100,000 individuals for each organ. In general, the South, the lower Midwest, and Appalachia experience higher rates of transplant amenable deaths than the rest of the country. Interestingly, the panels in Figure 13 are nearly the mirror image of the number of transplant physicians per capita presented in Figure 12. More importantly for organ allocation policy, however, is the fact that the areas of the country that experience the

³⁰⁴ For example, if someone dies with a CALC death definition, their liver may not be transplantable if they independently suffered from liver disease.

most transplant amenable deaths are also the areas of the country that tend to export more organs.

FIGURE 13: TRANSPLANT AMENABLE DEATHS PER 100,000 RESIDENTS

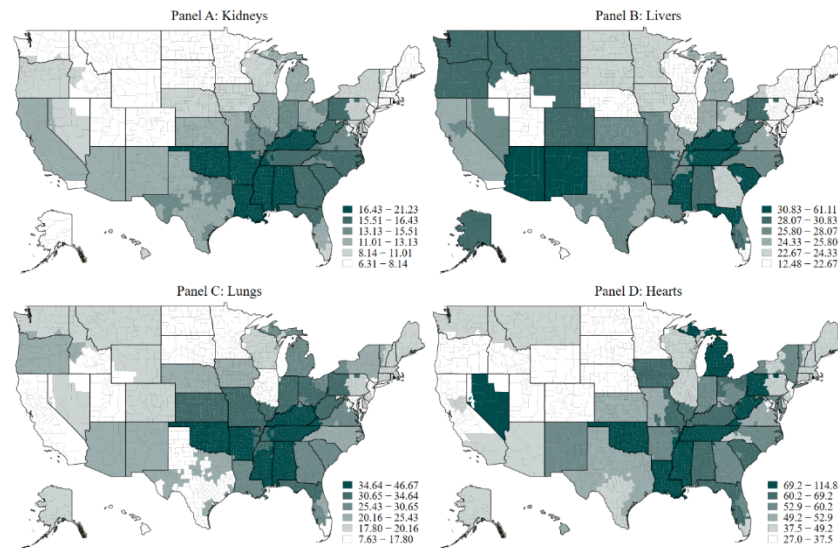


Fig. 13: Each panel reports the number of transplant amenable deaths per 100,000 residents in 2021. Transplant amenable deaths are defined separately for each organ.

To further explore the relationship between transplant amenable deaths and the net imports and exports of organs, Figure 14 plots transplant amenable deaths per capita against net imports/exports. Each shape represents a single DSA, and the shapes are scaled based on the population of the relevant DSA. To distinguish between different parts of the country, blue squares represent DSAs in the South, yellow triangles represent Midwestern DSAs, red diamonds represent DSAs in the Northeast and California, and green circles represent all other DSAs. The sloped lines represent the relationship between transplant amenable deaths per capita and net imports/exports. A negatively sloped line indicates that, as transplant amenable deaths per capita increases, exports increase. These lines are based on simple linear regressions that include all DSAs, weighted by population. The difference in marker shapes and colors in Figure 14 are purely for informational purposes only, and all DSAs are included in the linear regression.

FIGURE 14: RELATIONSHIP BETWEEN TRANSPLANT AMENABLE DEATHS AND NET IMPORTS/EXPORTS

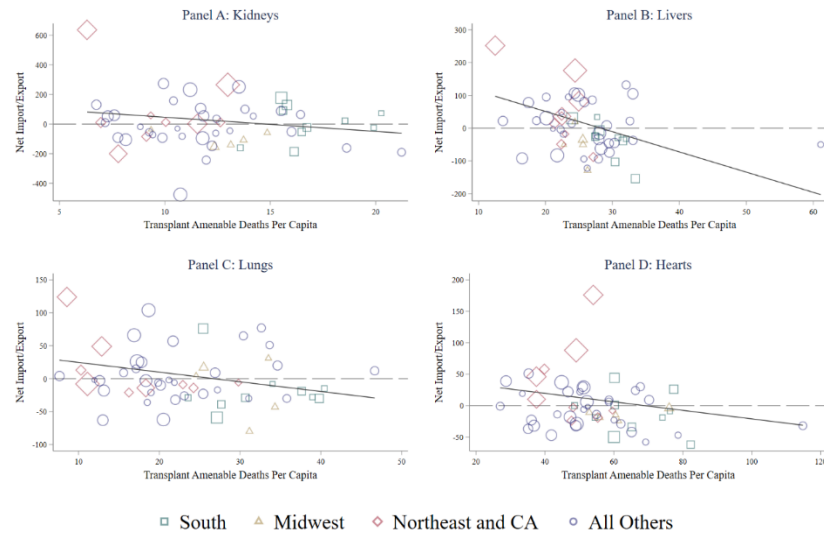


Fig. 14: Each panel reports a weighted scatterplot demonstrating the relationship between net imports/exports and transplant amenable deaths per 100,000 residents. Each point represents a DSA in 2021 and is weighted by the DSA's population. Linear regression lines are fitted based on these weighted points.

In general, Figure 14 reports troubling evidence. Across all four organs, a higher rate of transplant amenable deaths is associated with more exports of organs. To further explore the relationship between net imports/exports and transplant amenable deaths, Table 3 reports a series of regression models that include all years between 2011 and 2021. The dependent variable in each regression represents net imports/exports, and the independent variable represents transplant amenable deaths per capita. The reported coefficients represent the association between these two variables. Across all four organs, the estimated association is negative, suggesting that an increase in transplant amenable deaths per capita is associated with an increase in organ exports (because organ exports are represented by negative numbers in the net import and export analysis). An increase of one kidney transplant amenable death per capita is associated with almost four more organs being exported. An increase of one liver transplant amenable death per capita is associated with over two more liver

exports. An increase of one heart or lung transplant amenable death per capita is associated with less than one more organ export, and the association for lungs is not statistically significant.

TABLE 3: RELATIONSHIP BETWEEN NET IMPORTS/EXPORTS AND TRANSPLANT AMENABLE DEATHS

		(1)	(2)	(3)	(4)
		Kidneys	Livers	Lungs	Hearts
Transplant	Amenable	-3.852	-2.569**	-0.225	-0.411**
Deaths		(2.717)	(1.129)	(0.431)	(0.159)
Observations		626	626	624	618
R-squared		0.019	0.063	0.003	0.036

*Tbl. 3: Each column reports the results of a simple linear regression with net imports/exports as the dependent variable and transplant amenable deaths per 100,000 residents as the independent variable. The unit of observation is the DSA-year. Standard errors clustered at the DSA level are reported in parentheses. * Statistically significant at the 10% level; ** Statistically significant at the 5% level; *** Statistically significant at the 1% level.*

In general, these results suggest that the more people die in ways that could have been avoided with a transplant, the more organs that part of the country exports to other areas. To quote one transplant center director, this looks like “the most backward plan that was ever created.”³⁰⁵ While the results reported in Figure 14 and Table 3 do not establish that organ allocation policy causes areas with higher death rates to export more organs in a statistical or econometric sense, the legal and policy context certainly suggests that organ allocation policy is the problem.

Unlike other policy contexts where a state or federal law seeks to change some behavior or outcome in a larger context — for example, tort law aims to deter unreasonable conduct, and environmental regulations aims to prohibit polluting — organ allocation policy operates within a closed system created entirely by the federal government. The fact that Congress federalized the organ allocation

³⁰⁵ Carollo & Tanen, *Winners & Losers*, *supra* note 21.

system and prohibited individuals from seeking transplants outside this system fundamentally means that any failures of that system are attributable only to that system. In other words, the evidence in Figure 14 and Table 3 does not mathematically establish that the current approach to organ allocation policy caused a perverse relationship between imports/exports and transplant amenable deaths, but the legal and policy context leave only the current system to blame.

Overall, my examination of transplant amenable deaths presents a troubling picture of the organ allocation system. That system essentially forces areas of the country who need organs most, as measured by people who could be saved by transplants, to export those organs to other parts of the country. This may seem counterintuitive because the organ allocation system includes specific measures of medical urgency in the criteria it uses to determine who receives which organ. But when large swaths of the population who both cannot access the transplant system and are likely to be the sickest patients (two factors likely correlated with lower socioeconomic status) are excluded from policy development, perverse outcomes can occur. And that is exactly what appears to have happened in the case of American organ allocation policy.

D. The Evidence in Context

The evidence developed above substantially undermines the evidence base in favor of broader national organ sharing. It suggests that the allocation metrics, which become increasingly important as local preferences are eroded, may be inaccurate or actively manipulated. The evidence further demonstrates the persistence of socioeconomic inequities. One factor that may explain this continuing inequity is the fact that not all patients have the same access to the organ transplantation system. If patients of lower socioeconomic status (as well as other disadvantaged groups) lack adequate access to the healthcare system or the smaller transplant system within the larger system, they will have difficulty receiving transplants. Conversely, the system is well set up to harvest their organs, and lower socioeconomic status as well as other factors often lead to death earlier and more

often.³⁰⁶ The final category derived from evidence of transplant amenable deaths is consistent with this explanation, as it suggests that the decision to only consider on-waitlist individuals when formulating organ allocation policy has deepened inequity in access to organ transplants. If lower socioeconomic status individuals are more likely to die in general, they will also die of transplant amenable causes more often.

To illustrate this relationship, Table 4 reports a series of regression results from models with transplant amenable deaths per capita as the dependent variable and median income as the independent variable. The models include all counties in the United States between 2011 and 2021, with data on median income at the county level coming from the American Community Survey.³⁰⁷ The reported coefficients represent the relationship between these two variables. In general, the estimated coefficients are negative and statistically significant, implying that an increase in median income is associated with a decrease in transplant amenable deaths per capita. The magnitudes of the associations are larger for lungs and hearts than kidneys and livers, which suggests that the same increase in median income averts more heart and lung transplant amenable deaths than kidneys or livers.

³⁰⁶ See Brady et al., *supra* note 280, at 618.

³⁰⁷ American Community Survey (ACS), U.S. CENSUS BUREAU, <https://www.census.gov/programs-surveys/acs> (last visited July 9, 2024) [<https://perma.cc/LN2H-C665>].

TABLE 4: RELATIONSHIP BETWEEN TRANSPLANT AMENABLE DEATHS AND MEDIAN INCOME

	(1) Kidneys	(2) Livers	(3) Lungs	(4) Hearts
Median Income	-0.019*** (0.001)	-0.028*** (0.001)	-0.059*** (0.002)	-0.055*** (0.002)
Observations	341,912	341,912	341,912	341,912
R-squared	0.007	0.006	0.023	0.011

Tbl. 4: Each column reports the results of a simple linear regression transplant amenable deaths per 100,000 residents as the dependent variable and median income as the independent variable. The unit of observation is the county-year. Standard errors clustered at the county level are reported in parentheses. * Statistically significant at the 10% level; ** Statistically significant at the 5% level; *** Statistically significant at the 1% level.

The results in Table 4 demonstrate that the sets of results from the previous Section are intimately connected. Poorer individuals die more often of transplant amenable deaths. As previously detailed, they are also systematically excluded from the transplant system and tend to live in the South, Midwest, and Appalachia to a greater extent than other parts of the country. Unsurprisingly, this makes poorer individuals a robust source of organs with little ability to access transplants. This collection of evidence highlights the frustrating nature of claims that organ allocation policy should work to equalize the demand and supply of organs across the country.³⁰⁸ That is a desirable goal in general, but when large segments of demand are knowingly suppressed in the areas of greatest supply, it is disingenuous to argue that this type of equalization will yield an efficient outcome (to say nothing of fairness). It simply funnels organs from where they are needed more (in areas of suppressed demand and high supply) to where they are needed less (in

³⁰⁸ See CHAD SOUTHWARD & MATTHEW PRENTICE, GEOGRAPHIC ORGAN DISTRIBUTION PRINCIPLES AND MODELS RECOMMENDATIONS REPORT 4 (2018), https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf [<https://perma.cc/L5TE-MZY3>] (“Geographic distribution may be constrained in order to reduce inherent differences in the ratio of donor supply and demand across the country.”).

areas of nearly complete demand and low supply). Indeed, the analysis of transplant amenable deaths reported above demonstrates that this is exactly what occurs under the current approach to organ allocation policy. When all individuals are considered via transplant amenable deaths, it becomes clear that organ allocation policy has resulted in outcomes antithetical to its stated goals by decreasing access to transplants, using organs less efficiently, and exacerbating socioeconomic inequities. The next Part explores the implications of these perverse outcomes, considers potential explanations for them, and most importantly, examines policy options to reverse course.

IV. RETHINKING ALLOCATION POLICY

Based on the troubling evidence reported in the preceding Parts, this Part accomplishes three objectives. First, it explores explanations for how organ allocation policy has developed the way it has. Second, it considers the implications for the future of the transplant system if organ allocation policy continues down its current path. Third, it considers potential solutions to the problems identified above. The goal of this Part is neither to definitively explain why organ allocation policy has failed or develop a definitive solution that will immediately resolve these failures. Instead, the goal is to consider different explanations as they may provide insight into solutions, and then offer potential regulatory fixes that can start a conversation among legal and health policy scholars. Such a conversation will be necessary to generate comprehensive and long-lasting reforms that will eliminate the problems identified here.

A. *What Explains the Failure of Existing Policy*

Multiple reasons may explain the failures of organ allocation policy detailed above. Perhaps the most obvious explanation is simple misfeasance. A series of bad policy decisions compounding over time led to the development of organ allocation policy that fails to achieve the goals it was designed to meet. For example, the decision to exclude off-waitlist individuals when formulating specific allocation policies may stem from the difficulty of collecting data on these individuals and not an intent to exclude them. Similarly, developing measures of medical

urgency is difficult, and those in charge of doing so may have simply developed the best measures they could given existing clinical and technological constraints. Over time, these series of bad, but not necessarily malicious, decisions have simply coalesced to undermine the ability of organ allocation policy to achieve its goals.

While this series-of-unfortunate-events explanation is certainly plausible, recent investigative journalism has uncovered evidence that a more systematic push to advantage certain areas of the country over others has motivated the development of organ allocation policy.³⁰⁹ Combining those investigations with the evidence here can better elucidate why organ allocation policy has failed to achieve its goals. In general, the evidence detailed above is consistent with the systematic push by interested parties to create privileged access to organs in the Northeast and California. Before delving into that consistency, it is important to note that the evidence developed in this Article cannot, by itself, establish with certainty that the behaviors identified in recent investigations caused the failure of allocation policy to achieve its goals. And not all the evidence is perfectly consistent with the explanation offered by recent investigations.³¹⁰ On the whole, however, the evidence from my analysis is consistent with the less-than-good-faith behaviors recent investigations have targeted as the cause of organ allocation policy's failures.

Multiple journalists contributed to recent investigations of the organ allocation policy development process.³¹¹ However, four articles written by Malena Carollo, Ben Tanen, Hospeh Menn, and Lenny Bernstein and published in the *Washington Post* and *The Markup* are particularly helpful in uncovering problematic details in the policy process.³¹² While the

³⁰⁹ Malena Carollo & Ben Tanen, *How a Group of Health Executives Transformed the Liver Transplant System*, THE MARKUP (Mar. 21, 2023, 6:45 PM), <https://themarkup.org/organ-failure/2023/03/21/how-a-group-of-health-executives-transformed-the-liver-transplant-system> [https://perma.cc/CY7T-WJ7Z] [hereinafter Carollo & Tanen, *Liver Transplant System*].

³¹⁰ Some states in the south and midwest benefitted from recent changes in organ allocation policy (Oklahoma for example).

³¹¹ See, e.g., Pullen, *supra* note 15 (providing a critical overview of organ allocation policies and describing the debate surrounding new policy changes).

³¹² In the interest of disclosure, one of these reporters interviewed me, and one of my research assistants exchanged emails with a different reporter.

underlying debate stretches back much further, an important tipping point toward greater national organ sharing occurred in 2015 with the formation of the lobbying group Coalition for Organ Distribution Equity (“CODE”).³¹³ The Greater New York Hospital Association joined with the OPO that collects organs in New York City and the OPO that collects organs in Los Angeles to form CODE.³¹⁴ Eventually, over “a dozen organizations” consisting primarily of hospitals “across New York, California, and Massachusetts” joined CODE to consolidate their lobbying efforts (and dollars).³¹⁵ The group retained a lobbying firm with the goal of reforming the organ allocation system, spending over \$250,000 on lobbying efforts before 2017.³¹⁶

While CODE worked in the background to change allocation policy in favor of the Northeast and California, the 2017 lawsuit over lungs offered another avenue of reform. As detailed above, a New York patient who was dissatisfied with her ability to obtain donated lungs sued HHS, asking the court to require the broader sharing of lungs across the country. HHS ordered the OPTN to reevaluate its existing policy once the court became involved, but the OPTN’s approach “was more an overhaul than a reexamination.”³¹⁷ Indeed, “[w]ithin four days of the [court] order, UNOS’s executive committee voted unanimously to change the lung distribution system [to increase organ sharing] — against its own lung committee’s initial recommendation.”³¹⁸

³¹³ Carollo & Tanen, *Liver Transplant System*, supra note 309; *New Coalition Aims to Reduce Geographic Disparities in Organ Allocation*, HEALIO (May 21, 2015), <https://www.healio.com/news/nephrology/20180227/new-coalition-aims-to-reduce-geographic-disparities> (last visited Jan. 21, 2024) [<https://perma.cc/K6N4-V4BN>]. To be clear, this was not the only group formed with the goal of modifying the organ allocation system. Transplant centers in Georgia, Kansas, Iowa, and Texas formed Keep Transplants Fair to pursue their own goals with respect to organ allocation policy. Jordan Michael Smith, *The Gross Inequality of Organ Transplants in America*, NEW REPUBLIC (Nov. 8, 2017), <https://newrepublic.com/article/145682/gross-inequality-organ-transplants-america> [<https://perma.cc/VF4X-6SE5>].

³¹⁴ Carollo & Tanen, *Liver Transplant System*, supra note 309.

³¹⁵ *Id.*

³¹⁶ Smith, supra note 313.

³¹⁷ Carollo & Tanen, *Liver Transplant System*, supra note 309.

³¹⁸ *Id.*

Following the lung lawsuit, Brian Shepard, who was in charge of the OPTN via his position as CEO of UNOS at the time, worked with Alexandra Glazier to create a new “ad hoc geography committee” to examine broader organ sharing for other organs.³¹⁹ They did so to leverage the momentum created by the lung lawsuit to instantiate broader sharing among other organs.³²⁰ That committee included Glazier and was chaired by Kevin O’Connor who had worked with Glazier for six years.³²¹ The committee produced a ten-page report outlining new principles and recommendations for broader organ sharing. The first principle was that “[d]eceased donor organs are a national resource to be distributed as broadly as feasible.”³²² The report does not mention socioeconomic status or its role under the Final Rule. It does, however, strongly emphasize the geography provisions in the Final Rule.³²³

At roughly the same time the committee began its work, the attorney who handled the lung lawsuit in New York sent a letter to HHS requesting that livers, like lungs, be shared more broadly.³²⁴ Shortly after the letter was sent, the OPTN approved a new liver allocation policy, but this policy did not go far enough for advocates of national sharing.³²⁵ The attorney sent another letter and threatened suit if liver allocation policy were not further modified to mandate greater sharing.³²⁶ When that change did not occur, six plaintiffs filed suit.³²⁷ “Three of the six plaintiffs said they were directly recruited by the CODE-member hospitals where they were being treated.”³²⁸ The Greater New York Hospital Association paid at least \$200,000 towards this lawsuit after

³¹⁹ *Id.*

³²⁰ *Id.*

³²¹ *Id.*

³²² SOUTHWARD & PRENTICE, *supra* note 308, at 3.

³²³ *Id.*

³²⁴ Carollo & Tanen, *Liver Transplant System*, *supra* note 309.

³²⁵ *Id.*

³²⁶ *Id.*

³²⁷ *Id.*

³²⁸ *Id.*

its “board of governors . . . ‘authorized’ the association to ‘support and coordinate a lawsuit challenging the current liver allocation system.’”³²⁹

In the lead up to the lawsuit over liver policy, CODE continued its lobbying efforts and circulated a memorandum to members of Congress about its lawsuit, encouraging them to support broader sharing for livers. A New York representative then introduced a bill to achieve this. The bill had twenty-seven co-sponsors, and twenty-six of those co-sponsors hailed from New York, California, and Massachusetts.³³⁰ The representative who introduced the bill had a strong relationship with the Greater New York Hospital Association, and the Association donated nearly \$60,000 to the 2018 campaigns of New York co-sponsors of the bill.³³¹

Ultimately the efforts of CODE and others in the Northeast and California were successful, as the OPTN fast tracked the development of a new liver allocation policy — the elimination of DSAs as a unit of allocation. While HHS only asked the OPTN to justify its current approach, the OPTN completely revamped the policies governing livers. While new policies typically spend five years in development, the new liver policy spent only six months. And the OPTN even rejected the committee’s recommended policy in favor of the one that involved even greater organ sharing.³³² While transplant centers in the South and Midwest attempted to stop the policy by objecting to HHS and filing suit in the Northern District of Georgia, the asymmetric review process for allocation policies employed by HHS meant that they were unsuccessful.

While the information uncovered by recent investigations only pertains to liver allocation policy, it certainly suggests that the failures of organ allocation detailed above result not from oversight or negligence but active manipulation by organizations in certain parts of the country. And the evidence developed above is consistent with this type of manipulation. Ostensibly, allocation policy is supposed to avoid exacerbating socioeconomic inequities, increase access to transplants, and use organs efficiently. There is little indication that the current

³²⁹ *Id.*

³³⁰ Fairness in Liver Allocation Act of 2018, H.R. 6517, 115th Congress. (2018).

³³¹ Carollo & Tanen, *Liver Transplant System*, supra note 309.

³³² The committee expressed concern that the acuity circles’ version of broader sharing could increase the number of discarded livers and decrease efficiency. *Id.*

approach accomplishes any of these goals. The pattern of manipulation described in recent reports could easily explain the obvious failures of organ allocation policy seen in the results above.

Additionally, those investigations included additional examinations of specific policies focused on livers. Focusing on the change in liver transplants following the elimination of DSAs as a unit of allocation, the investigations “found sharp declines in life-saving [liver transplant] surgeries in Puerto Rico and seven states, all but one Southern or Midwestern: Alabama, Louisiana, Kansas, North Carolina, South Dakota, Iowa, and Pennsylvania.”³³³ Conversely, “New York and California, whose transplant industry officials lobbied for the new policy, logged their highest numbers of liver transplants in more than a decade in 2021 — 603 and 959, respectively.”³³⁴ Putting a finer point on it, one article stated that “[i]n Alabama, . . . where twice as many people die of liver disease per capita than in New York, adult liver transplants fell 44 percent under the new rules, to 72.”³³⁵ Further consistent with the evidence detailed above, all seven of the states that saw sharp reductions in transplants have below average income.³³⁶ While states outside of the Northeast and California also benefited from the new liver allocation policy,³³⁷ it is difficult to explain the failure of organ allocation policy to achieve its stated goals while simultaneously enriching specific parts of the country without active manipulation.

The efforts of investigative journalists have, so far, been limited to liver allocation policy, but my results support extending their conclusions to other organs. My results across all organs are consistent with the pattern of changes in the specific liver allocation policies under investigation. Across all organs, donors in poorer parts of the country are more likely to export their organs to transplant recipients in richer parts of the country. And I find consistent evidence that the needs of the South, Midwest, Appalachia, and other less wealthy parts of the country

³³³ Carollo & Tanen, *Poorer States Suffer*, *supra* note 46.

³³⁴ *Id.*

³³⁵ *Id.*

³³⁶ *See id.*

³³⁷ “Some states that did not appear to be part of the lobbying process also increased transplant volume under the policy, notably Oklahoma and Utah.” Carollo & Tanen, *Poorer States Suffer*, *supra* note 46.

suffer most under the current approach to organ allocation policy across all organs. I also find that the Northeast and California are the greatest beneficiaries of current policy. Indeed, higher numbers of transplant amenable deaths predict more exports, not imports, of organs. My results, standing alone, do not prove manipulation of the organ allocation system. But they are certainly consistent with manipulation and fit very neatly with the problematic behavior uncovered by recent investigative journalism.

In addition to being consistent with recent reports and extending the conclusions of those reports to all four organs, my analysis of transplant amenable deaths offers additional insight into why the uncovered manipulation of organ allocation policy leads to such poor outcomes. By ignoring large swaths of the population that are more likely to lack the means necessary to access transplant care, allocation policy has ensured that the wealthy matter more when determining who has access to transplants. In other words, the efforts of several policy insiders have been effective at ensuring the very individuals who could upset the balance in favor of richer areas of the country are systematically excluded from consideration in policy development. This has occurred while organ recovery policy detailed above simultaneously ensures that poorer (and therefore more likely to die) individuals continue to serve as a source of donated organs. The next Section examines the implications of continuing down the current path of organ allocation policy.

B. Implications for the Future of Organ Transplantation

The consistent evidence of the failure of organ allocation policy reported above is, standing alone, sufficient to raise concerns about the future of the organ transplantation system. Combined with the investigative reporting discussed in the previous Section, however, it brings into question the long-term viability of the transplantation system if nothing changes. Fundamentally, the organ allocation and transplantation system relies on donors to function. Without markets for organs, only donations within the federalized system can provide the means necessary for lifesaving surgeries, and donations rely on individuals agreeing to donate their organs upon death. Those donations

may decrease if the people asked to make them lose confidence in the fairness of the organ allocation process.

For example, Germany experienced a scandal involving manipulation of the liver allocation system in 2012.³³⁸ In the wake of the scandal, “[d]onation rates declined by 20 to 40 percent and resulted in a significant decline in the number of overall organ transplants performed.”³³⁹ The scandal significantly undermined public confidence in the liver transplant system, and “public outrage would inevitably impact on donation.”³⁴⁰ Even before the scandal, “[t]here was already disquiet among some members of the public that organs donated in one country such as the UK could be given to recipients in other EU countries via the Eurotransplant network,”³⁴¹ just as many individuals in the United States prefer that organs are transplanted in the same local area where they are recovered.³⁴²

Indeed, the United States may be on a path toward falling donation rates as decreased perceived fairness of organ allocation compounds existing misgivings about broader national organ sharing. In their 2022 report, the National Academies recognized that “some people believe that sending organs donated at a hospital to recipients in distant cities is unfair to patients awaiting an organ at a transplant center located in the same city as the donor hospital.”³⁴³ And a recent study found that potential donors value having their organs allocated to patients

³³⁸ Julia Rehsmann, *A Revealing Scandal: The German Transplant Scandal Between Structural Failures, Moralizing Rules, and Ambivalent Manipulations*, 11 J. LIVER TRANSPLANTATION 1, 1 (2023).

³³⁹ UNOS, MANIPULATION OF THE ORGAN ALLOCATION SYSTEM WAITLIST PRIORITY THROUGH THE ESCALATION OF MEDICAL THERAPIES 4 (2018), https://optn.transplant.hrsa.gov/media/2500/ethics_whitepaper_201806.pdf [<https://perma.cc/GR6N-HXBD>]; see also David Shaw, *Lessons from the German Organ Scandal*, 14 J. INTENSIVE CARE SOC’Y 200, 201-02 (2013) (reviewing the scandal).

³⁴⁰ Shaw, *supra* note 339, at 200.

³⁴¹ *Id.*

³⁴² Heather W. O’Dell, Benjamin J. McMichael, Suzie Lee, Jay L. Karp, R. Lawrence VanHorn & Seth J. Karp, *Public Attitudes Toward Contemporary Issues in Liver Allocation*, 19 AM. J. TRANSPLANTATION 1212, 1214 (2019).

³⁴³ NAT’L ACADEMIES, *supra* note 24, at 77.

nearby.³⁴⁴ If potential donors see a system that fails to allocate organs consistent with their preferences or a system that is manipulated to benefit of some at the expense of others, the United States may well see a reduction in the number of donors similar to what occurred in Germany.

For example, potential donors may look at the actions of transplant centers in the Northeast and California and see a classic free-riding problem. New Yorkers tend to be some of the least generous people when it comes to organ donation, as seen above. Instead of working to increase donation rates in their own backyard through public outreach or education, transplant centers (and the OPOs that serve them) in New York and other areas of low donation rates seek to effect rule changes that mandate more organ imports from other parts of the country. These other areas tend to have more generous populations or have successfully encouraged more organ donations. This type of behavior may not sit well with potential donors who see a series of insiders gaming the system to their advantage. It may eventually affect the willingness of people to agree to donation.

Beyond the willingness of individuals to become organ donors, the free-riding problem and the dysfunction of organ allocation policy may generally lead to an unraveling of the legal foundation of the organ transplantation system. While Congress federalized organ donation with the NOTA, the transplantation system continues to rely heavily on state laws and state infrastructure. For example, the Uniform Anatomical Gift Act, adopted in some form by all fifty states, governs important aspects of organ donation.³⁴⁵ It prescribes processes for becoming a donor and allows a surviving relative to make a donation decision for an individual who did not make one before death. It also limits the liability of individual healthcare providers who recover organs

³⁴⁴ O'Dell et al., *supra* note 342, at 1214 (“Respondents were 11% less likely to choose an otherwise identical individual to receive a liver who ‘lives in another state’ relative to someone who ‘lives in your state’ (P < .001).”).

³⁴⁵ A review of the different versions of this uniform act is beyond the scope of this article, but the Uniform Law Commission provides a helpful summary. *Anatomical Gift Act*, UNIFORM L. COMM’N, <https://www.uniformlaws.org/committees/community-home?CommunityKey=015e18ad-4806-4dff-b011-8e1ebcod1dof> (last visited July 22, 2024) [<https://perma.cc/D2WN-EQGM>].

following permission to do so by a relative.³⁴⁶ In addition to the legal framework, states contribute infrastructure such as the ability to become an organ donor when an individual applies for a driver's license.

These state commitments are not a given, and the Kansas legislature recently considered intervening in what it perceived to be an unfair system. Specifically, the Kansas legislature introduced a bill that would have permitted organ donors to limit their consent to donate only to in-state patients.³⁴⁷ Limiting consent in this way would allow individuals to effectively ban the exportation of their donated organs from the state, thereby ensuring a greater portion of organs were used in local transplantations. Ultimately, the bill did not pass, but it demonstrates the potential fragility of the state legal system that underlies the federal organ allocation and transplantation system.³⁴⁸ It also highlights the importance of accounting for public opinion in the allocation system, as the public is ultimately the source of all donated organs.

Policymakers have apparently recognized the urgency in the need to reform the organ transplantation system to avoid a collapse of that system along the lines of what happened in Germany. As described above, federal policymakers overhauled the regulatory framework governing OPOs in 2021, and Congress reformed the OPTN with the Securing the U.S. Organ Procurement and Transplantation Network Act in 2023. While these represent important steps toward fixing the organ transplantation system, neither addresses the failures detailed in this Article. To do so, the next Section offers several options to reform the framework around organ allocation policy.

C. A New Metric and a New Regulatory Framework

Given the problems identified above, the precarious state into which they may push the organ transplant system, and the failure of the existing entities responsible for organ allocation policy, Congress should strongly consider building on its recent successes by modifying the legal framework around organ allocation policy. Commenting on the

³⁴⁶ *Id.*

³⁴⁷ S.B. 194, 2019 Leg., Reg. Sess. (Kan. 2019).

³⁴⁸ SB 194: *Bill History*, KAN. LEGISLATURE https://www.kslegislature.org/li_2020/b2019_20/measures/sb194/ (last visited July 7, 2024) [perma.cc/93TV-TACP].

machinations described above, Senator Chuck Grassley stated “UNOS’s scheme to circumvent the law betrayed vulnerable patients, and, shockingly, HHS was complicit in the plan.”³⁴⁹ He further warned: “Make no mistake: any future attempts to bypass laws governing the organ donation system, including the recent bipartisan reforms I spearheaded, will not be tolerated.”³⁵⁰ Senator Elizabeth Warren referred to the organ allocation system as a “dangerous mess.”³⁵¹ Based on these comments and the evidence developed above, new congressional action would be the best path forward. Simply changing the existing regulatory structure under HHS would likely prove insufficient since HHS has demonstrated an inability to address problems in the past. Congress has clearly demonstrated a willingness to reform the organ transplant system over the past few years, so new action is almost certainly politically feasible.

Whatever the eventual legislation looks like, the path to meaningful reform will be a long and complicated one. This Article does not pretend to navigate that path from beginning to end. Instead, it seeks to identify the initial, but most important, steps. First, the myopic focus on the argument that geography should not matter is simply “applesauce”³⁵² and should be wholeheartedly abandoned. Geography clearly matters for people who need a transplant. The rhetorical strategy of arguing that geography should not matter has become a pretext for arguing that only individuals who can access healthcare and the transplantation system matter for allocation policy. Not only is this argument the source of many of the problems identified above, it is also disingenuous. If geography does not matter for individuals who have already accessed an organ waitlist, then organ allocation policy will exacerbate socioeconomic inequities and deprive thousands of access to transplants, just as seen in the results above. By ensuring that geography

³⁴⁹ Carollo, *In Emails*, *supra* note 29.

³⁵⁰ *Id.*

³⁵¹ Carollo & Tanen, *Poorer States Suffer*, *supra* note 46.

³⁵² See *King v. Burwell*, 576 U.S. 473, 507 (2015) (Scalia, J., dissenting) (“Pure applesauce.”); *Zuni Pub. Sch. Dist. No. 89 v. Dep’t of Educ.*, 550 U.S. 81, 113 (2007) (Scalia, J., dissenting) (“The sheer applesauce of this statutory interpretation should be obvious.”).

does not matter for some (those on waitlists), organ allocation policy ensures that geography will make all the difference for others.

With this highly problematic set of arguments out of the way, the next step will be to determine the broad contours of the organ allocation system. In doing so, the goal is not to completely de-emphasize individuals currently on waitlists. Their medical needs should still factor into how organs are allocated across the country, even if new rules prevent the level of organ imports/exports that have become common in recent years. In general, reframing the laws around organ allocation will require making a series of decisions, such as determining the proper measure of medical urgency on waitlists, picking the right level of geography, determining the proper role for geography, and placing guardrails on organ allocation policy to prevent it from re-creating the same problems seen above. Some of these issues have received more attention from researchers and policymakers than others, and the remainder of this Section assumes the task of outlining different options for reform.

1. New Measures of Medical Urgency

While organ sharing should be reduced from current levels, it should not be eliminated completely. Ensuring that whatever form organ sharing takes in the future remains as equitable and efficient as possible will require new measures of medical urgency. Multiple researchers have highlighted issues with current measures of medical urgency as described above,³⁵³ and some research has begun to identify better approaches. Research led by Dimitris Bertsimas developed an “optimized prediction of mortality (OPOM) [which] utilize[s] machine-learning optimal classification tree models trained to predict a candidate’s 3-month waitlist mortality or removal utilizing” a dataset similar to the one analyzed above.³⁵⁴ That model “more accurately and objectively prioritizes candidates for liver transplantation based on disease severity, allowing for more equitable allocation of livers with a resultant significant number of additional lives saved every year.”³⁵⁵

³⁵³ See *supra* Part III.A.

³⁵⁴ Bertsimas et al., *supra* note 51, at 1109.

³⁵⁵ *Id.*

Future work may extend this type of machine-learning approach to other organs, resulting in the development of better calibrated metrics of medical urgency.³⁵⁶

As the development of new medical urgency metrics progresses, care should be taken to avoid manipulable metrics. Even a metric that works perfectly to predict medical urgency will not result in the efficient allocation of organs if it is manipulated to benefit certain patients. The National Academies' 2022 report recognized this need, urging the use of "simulations to model and account for predicted changes in behavior following a policy change."³⁵⁷ Current "simulators do not capture behavior change in response to new allocation policies" and use older data as the relevant baseline, rendering policies developed with these simulators susceptible to bias and potential manipulation.³⁵⁸ Updating simulation processes in conjunction with the development of new machine-learning techniques may avoid unintended and potentially perverse behavior changes that ultimately harm patients and undermine the organ allocation system. While accounting for behavior changes and attempting to avoid the possibility of manipulation would bolster measures of medical urgency and make them more reliable as a means to allocate organs, these changes not directly address the issue of geography.

2. Choosing the Right Geographic Unit for Allocation

The first question to answer when determining the proper role for geography is whether organ allocation policy will continue to use allocative units (i.e., defined geographic areas that play a meaningful role in how organs are allocated). Historically, DSAs have served this purpose, with individuals residing within the DSA where the organ was recovered receiving some degree of priority for that organ.³⁵⁹ Recent

³⁵⁶ See *supra* Part III.A.

³⁵⁷ NAT'L ACADEMIES, *supra* note 24, at 143; see also David S. Goldberg, Matthew Levine, Seth Karp, Richard Gilroy & L. Peter, *Share 35 Changes Center Level Liver Acceptance Practices*, 23 LIVER TRANSPLANTATION 604, 604-13 (2017) (discussing changes in the behavior of surgeons and patients following the implementation of the Share 35 policy for liver allocation).

³⁵⁸ NAT'L ACADEMIES, *supra* note 24, at 143.

³⁵⁹ See McMichael, *Stealing Organs?*, *supra* note 12, at 153-54.

changes have eliminated DSAs as allocative units in favor of drawing concentric circles around the location where the organ was recovered and giving individuals within that area some degree of preference in allocation. Future policies will likely involve moving even further down this path to “continuous distribution.”³⁶⁰

The move toward greater national organ sharing via the elimination of DSAs has not, based on the evidence developed here, done anything to mitigate socioeconomic inequities or increase access to transplantation. Indeed, shared organs seem to exacerbate socioeconomic inequities to a greater extent than local organs. Allowing organs to move across the country without regulatory guardrails around ensuring access to off-waitlist individuals risks further undermining access to transplant care. The next section addresses what guardrails should be in place. However, limiting organ allocation through considerations of off-waitlist individuals requires some unit of allocation, so this section addresses this important threshold issue.

Until recently, DSAs served as units of allocation, and they certainly have some attractive properties when used as such. For example, their use ensures the creation of a local unit of allocation that allows transplant centers to work with OPOs to improve donation rates. It may also address the concern of reciprocity since it places all individuals in the same situation when it comes to donation. If Person 1 agrees to donate and improve the availability of organs, Person 2 may see that and also agree to donate. Since everyone is in the same boat, they may agree to donate at higher rates. Relatedly, this approach reduces the ability to free ride on the efforts of others. If all individuals in a given area are responsible for increasing the availability of organs for their own potential use, their incentives align around donation instead of encouraging the system to import organs from elsewhere. Finally, using DSAs as an allocative unit simplifies administrative tasks because individual DSAs can be judged based on both the rate of organ recovery and a new metric designed to guard against inefficient and inappropriate organ imports/exports. By avoiding a new allocative unit, it will be easier to administer any new allocation rules and compare the effectiveness of those rules with the effectiveness of organ recovery rules without

³⁶⁰ NAT’L ACADEMIES, *supra* note 24, at 8-9.

converting to a different geographic unit. For these reasons, returning to DSAs as a unit of allocation may be the best option.

However, DSAs are not the only option and were not designed with organ allocation in mind. For example, the fact that DSAs may contain discontinuous collections of counties and have shapes that result in organs flying over individuals in need to reach other individuals lends itself to criticism.³⁶¹ These factors arguably contributed to some court decisions that led to the end of DSAs as a unit of allocation.³⁶² Additionally, not all DSAs include transplant centers that perform organ transplants for all organs. Using DSAs as an allocative unit would leave organs recovered in DSAs lacking the relevant type of transplant center in something of a limbo. They could not be transplanted into local patients since no local patients exist. Without local patients, the incentive alignment discussed above would likely not materialize. Given these issues, two other units of geography are worth considering: transplant referral regions (“TRRs”) and states.

First, recent research developed the concept of TRRs to measure access to transplants. TRRs “were designed to define communities served by a transplant center or group of centers,”³⁶³ and have been developed for both livers and kidneys.³⁶⁴ Researchers have used TRRs when analyzing access to transplants, and each TRR includes one or several nearby (within ten miles of one another) transplant centers that tend to draw in most of the surrounding population who receive transplant care.³⁶⁵ When developing TRRs, researchers consider both

³⁶¹ The Eleventh Circuit offered the following example: “Under the current, DSA-based policy, if a liver becomes available in Charleston, South Carolina, it would be offered to a moderately ill patient in Memphis, Tennessee (600 miles away) before a critically ill patient in Atlanta, Georgia (266 miles away) — and indeed, would have to be flown directly over Atlanta en route to Memphis.” *Callahan v. United States Dep’t of Health & Hum. Servs.*, through *Alex M. Azar II*, 939 F.3d 1251, 1255 (11th Cir. 2019).

³⁶² *Id.* at 1255 n.3.

³⁶³ Ross-Driscoll et al., *Livers*, *supra* note 300, at 1402; Ross-Driscoll et al., *Kidneys*, *supra* note 300; Tyler Schappe, Sarah Peskoe, Nrupen Bhavsar, L. Ebony Boulware, Jane Pendergast & Lisa M. McElroy, *Geospatial Analysis of Organ Transplant Referral Regions*, 5 JAMA NETWORK OPEN 1 (2022).

³⁶⁴ Ross-Driscoll et al., *Livers*, *supra* note 300, at 1402; Ross-Driscoll et al., *Kidneys*, *supra* note 300, at e342-e350.

³⁶⁵ Ross-Driscoll et al., *Kidneys*, *supra* note 300.

individuals who have access to the transplant system by using waitlist data and individuals who may need a transplant by using mortality data. While TRRs rely on all end-stage liver disease deaths or end-stage renal disease deaths instead of the more specific definition of transplant amenable deaths used here, they are well-suited to the regulatory task of ensuring that individuals in all parts of the country have access to transplants. They could also be updated to rely on transplant amenable deaths.

Replacing DSAs with TRRs as the unit of allocation may offer several benefits. Doing so avoids the problem of discontinuous geographic units and therefore addresses the concerns that courts have with using DSAs as units of allocation. Next, TRRs generally outnumber DSAs which would make allocation even more locally focused. A more locally focused regulatory system could better honor the general wish of donors that their organs be transplanted into nearby individuals.³⁶⁶ Additionally, since TRRs are tied to specific transplant centers which are, in turn, tied to specific OPOs, some of the benefits of aligning organ recovery with transplantations outlined above may be present with the use of TRRs as units of allocation. Finally, using TRRs directly addresses the problem that some DSAs lack access to transplant centers that perform all types of organ transplants. Because TRRs are centered on transplant centers that perform the relevant organ transplant, their use would avoid this problematic situation.

On the other hand, however, TRRs have some features that make them ill-suited to use as allocative units. For example, the small size of some TRRs and the related issue of the large number of TRRs may lead to inefficiencies. These issues may require combining certain TRRs into larger units. Next, because TRRs are defined for each organ, the same patient could reside in different TRRs for different organs. This fact may complicate the incentive alignment that would occur when using DSAs as the allocative unit, and it may mean individual transplant centers need to work with multiple groups when seeking to improve donation and transplantation rates. Additionally, TRRs are not necessarily fixed geographically. If patients near the border between two TRRs decide to switch where they receive care, the relevant TRRs would need to adjust

³⁶⁶ O'Dell et al., *supra* note 342, at 1214-16.

as well. If a new transplant center emerges, it would necessarily create a new TRR. Some of these issues could be addressed with regulatory definitions of TRRs, but, because TRRs were originally designed to measure transplant access and not accommodate allocation policy, they may not be the best choice as an allocative unit.

States, on the other hand, have geographic boundaries that are both clearly fixed and unchanging. Beyond their clear borders, states may serve well as allocative units because so many other federal programs (and obviously state programs) rely on states as the relevant units. Aligning organ allocation policy with existing regulatory frameworks may generate benefits that could not be realized with other units of allocation. States, for example, are responsible for passing many of the laws that organ allocation and transplantation rely on, including those determining when death occurs for the purpose of organ harvesting, who may practice medicine, how to fund many hospitals, etc. Having allocation policy aligned with individual states would allow transplant clinicians and OPO officials to work directly with states when advocating for particular policies that may improve allocation and transplantation beyond the federal requirements. In theory, using states as allocative units mitigates the risk that states attempt to keep organs within their boundaries through creative means (which almost happened in Kansas). With states integrated into the allocative process as individual units, they may be more willing to work within the existing system instead of attempting to undermine that system.

Next, many state boundaries align relatively closely with existing DSA boundaries, meaning that some of the efficiencies discussed above in terms of aligning organ recovery with organ allocation may be realized with states as allocative units. This may also help align state policies with the promotion of both organ donation and transplantation as states would more clearly see the benefits of these policies among their own populations. For example, it may encourage states like New York and New Jersey, which have some of the lowest rates of donor designations, to adopt policies to address this dearth of registered organ donors.³⁶⁷ Beyond policy alignment, prior work has identified explicit

³⁶⁷ *How Many People Are Organ Donors?*, DONOR ALLIANCE (Nov. 17, 2023), <https://www.donoralliance.org/newsroom/donation-essentials/how-many-people-are-organ-donors/> [<https://perma.cc/63VX-SKJJ>].

preferences among potential donors that organs remain within state boundaries.³⁶⁸ Thus, not only will using states as allocative units potentially encourage donation, it will also honor individual preferences and potentially result in more unity around improving donation and transplantation rates.

However, several potential issues militate against the use of states as allocative units. As with DSAs, not every state has a transplant center that performs all types of organ transplants. For the purposes of those organs, states may need to be grouped into larger regions. For example, New Mexico and Arizona could be grouped into one “state” for the purposes of lung donation, allocation, and transplantation. Smaller states such as Rhode Island, Vermont, and others could similarly join a larger regional allocative unit even if they have access to all four organ transplants within their borders.

In general, DSAs, TRRs, and states represent the most viable options for allocative units, though each option also involves some drawbacks. Regulators may devise alternative options, but choosing one of these three offers immediate benefits without the need to start from scratch. Once policymakers choose an allocative unit, they will need to determine the appropriate role for geography and set up regulatory guardrails to ensure that past mistakes do not recur under a new approach.

3. Installing Geographic Guardrails

Whatever allocative unit becomes central to a new organ allocation system, that system will require a regulatory framework to guard against the problems that have impacted the current system. Specifically, new guardrails should mitigate socioeconomic inequities and ensure broad access to transplants. While both these goals are important, it will be helpful to avoid trying to do too much at once when developing new rules. The more moving parts that are introduced simultaneously, the more likely the new system will fail to achieve its goals. With this in mind, I will focus primarily on increasing access to transplants and ensuring that all individuals who could benefit from a transplant, regardless of waitlist status, are considered in allocation policy. As

³⁶⁸ *Id.*

demonstrated above, there is a clear relationship between income and transplant amenable deaths across the country. I also found evidence of a strong (though perverse) association between transplant amenable deaths and net imports/exports of recovered organs. Given these relationships, any new legal framework designed to promote access to transplants in areas with relatively higher rates of transplant amenable deaths will almost certainly work to mitigate socioeconomic inequities as well. Accordingly, I focus on access to transplants, with the understanding that future work can re-evaluate the need for specific interventions targeting any socioeconomic inequities that remain. This both allows policy to be adaptable and avoids misguided attempts to fix everything at once, only to have new policies work at cross-cutting purposes.

Turning to the specifics of future guardrails, any set of rules designed to prevent inappropriate or inefficient imports and exports of organs should rely primarily on external data. Policymakers with authority over the transplantation system have already learned this lesson the hard way in the context of reforming the regulations governing OPOs. Historically, OPOs self-reported the data that regulators then used to judge the performance of each OPO. Unsurprisingly, this led to critical issues, necessitating the replacement of these internally derived metrics with externally validated CALC deaths. Following that reform, OPOs are judged based on the rate of organ recoveries, with CALC deaths providing the denominator. Organ allocation policy similarly requires an external metric to judge the appropriateness of organ imports and exports. Transplant amenable deaths are well suited to the role of an external metric.³⁶⁹ Mortality data from death certificates, from which transplant amenable deaths are derived, is not manipulable within the allocation system and therefore provides an important check on that

³⁶⁹ Future work may re-evaluate the specifics of the definition of transplant amenable deaths proposed in this Article. Prior work has used all end-stage liver or end-stage kidney disease deaths as a relevant metric. Ross-Driscoll et al., *Livers*, *supra* note 300; Ross-Driscoll et al., *Kidneys*, *supra* note 300. These, in conjunction with the analogs for lung and heart disease, may have better qualities as an external metric than my definition of transplant amenable deaths. For the purposes of this Article, I will assume that my definition of transplant amenable deaths is the chosen external metric with the understanding that future work may refine or alter this definition.

system along the same lines of CALC deaths in the organ recovery system.

With transplant amenable deaths determining the relative need for transplants across the country (similar to CALC deaths determining the availability of donated organs), the next issue is determining how to incorporate that metric into a new legal framework designed to promote access to transplants. Fundamentally, promoting equal access to transplants across the country means equalizing the relative supply and demand for transplants in each allocative unit. Prior work — even by those opposed to a role for geography — has recognized this fundamental goal.³⁷⁰ Transplant amenable deaths reliably capture demand for organ transplants (from all individuals, not just waitlisted individuals), and transplants themselves represent the supply. Given these metrics, a simple way to evaluate the equality across different regions is to consider the following proportion, which I will refer to as the “TXD proportion”:³⁷¹

$$\frac{\text{number of transplants}}{(\text{number of transplants}) + (\text{number of transplant amenable deaths})}$$

Essentially, this metric captures the proportion of individuals who were saved by a transplant. Assuming each transplant represents a life saved and each transplant amenable death represents a life lost for lack of a transplant, the denominator represents all individuals who would have died if no transplants occurred in the relevant geographic unit. The numerator represents all individuals who were saved by a transplant. This metric will vary from zero (if no transplants occur and everyone dies as a result) to one (if all individuals who need a transplant receive one). This metric is not the only way to consider supply and demand, but it captures those variables in a simple, compact, and easy-to-understand form.

Figure 15 reports the TXD proportion for all DSAs in 2021. In general, the South and Midwest have lower TXD proportions than the Northeast and West Coast, though some parts of the South and Midwest tend to have higher TXD proportions. Overall, Figure 15 provides an overview of where organs are most needed across the country based on both the

³⁷⁰ SOUTHWARD & PRENTICE, *supra* note 308, at 3.

³⁷¹ “TX” is a common abbreviation for “transplant,” and “D” stands for “death.”

number of transplants and the number of transplant amenable deaths. Using the population-based metric reported in Figure 15 can provide the basis for a new legal framework around organ allocation policy, and the remainder of this section explores ways to do so.

FIGURE 15: TXD PROPORTIONS

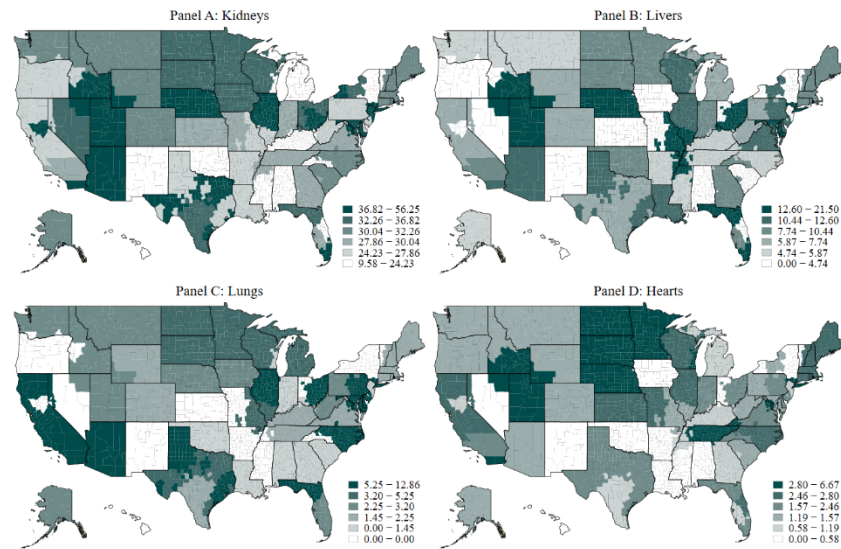


Fig. 15: TXD Proportions are reported for all DSAs in 2022. Each Panel reports the TXD proportions for the organ listed in the title. All TXD proportions are multiplied by 100 to facilitate readability.

When incorporating the TXD proportion into a specific framework to guard against inefficient organ imports/exports, the goal should be to equalize this proportion across the country. If that happens, then every allocative unit will experience the same percentage of individuals saved among all individuals who would have died absent a transplant. Importantly, achieving this type of equality does *not* require that no organ imports or exports occur. Unless organ recovery rates exactly match the needs of the relevant allocative unit — an unlikely occurrence — areas of the country recovering relatively more organs may need to export some of those organs to other parts of the country in order to equalize TXD proportions across units. However, justifying these types of exports will be easier and more transparent as neither the number of transplants, nor the number of transplant amenable deaths, is

manipulable in the same way as patient-specific metrics that are currently used to justify organ exports.

The next issue concerns exactly how to deploy the TXD proportion to achieve relative equality across the country. Perhaps the most obvious method is to ban the transfer of organs from allocative units with higher TXD proportions to units with lower TXD proportions. Effectively, this method prohibits transfers in the “wrong” direction. It ensures that the unit with the highest TXD proportion can import organs from any other unit and prohibits the unit with the lowest TXD proportion from importing any organs.

While this type of approach may achieve the goal of equality, it works as a blunt instrument and may cause any number of harms based on its inflexibility. For example, use of the TXD proportion in this way risks ignoring the fact that trade among units may save more lives since some patients are limited to accepting only certain organs based on legitimate clinical factors. If a patient who is limited in this way resides in a high TXD-proportion unit, that patient is more likely to die since the unit cannot import a relatively rare organ to save that patient (even if other units have no patients with the same limiting clinical factors). In other words, the blunt approach risks subverting medical judgement for the sake of rote equality. It also risks causing the exact harm that pushed policymakers away from local preferences in the first place. If a patient who is more medically urgent (using any reasonable measure of such) happens to reside in a unit with a higher TXD proportion than a patient who is less medically urgent, the more medically urgent will necessarily die under the blunt use of a guardrail incorporating the TXD proportion. While geography should play more of a role than it currently does, the blunt approach likely swings too far in this direction and eliminates far too much medical judgment in the organ allocation system.

To tune the use of the TXD proportion more finely, policymakers could consider allowing the import and export of organs among all allocative units but use TXD proportions to ensure that units import and export organs commensurate with their need. One way to implement this would be on a pairwise basis so that, for any two allocative units, the net imports/exports between them must have the same ratio as their TXD proportions. For example, if unit X has a TXD proportion of 0.5 and unit Y has a TXD proportion of 0.75, then the ratio

between the two is $2/3$. Thus, the ratio of imports and exports between the two units must be $2:3$ so that unit X imports three organs from unit Y for every two organs it exports to unit Y. This approach allows for much more discretion and the incorporation of medical judgment as between individual candidates than the blunt approach. By allowing clearly sicker patients to receive organs from allocative units which are worse off (as measured by TXD proportions), this approach preserves the role for medical urgency and medical decision-making.

However, keeping track of each pair of allocative units is cumbersome and ignores the reality that many different allocative units must work together within the system. A better approach may be to generalize this pairwise limit on imports and exports so that each unit's net imports and exports must have the same ratio as the ratio between that unit's TXD proportion and the national TXD proportion. For example, if unit X has a TXD proportion of 0.3 and the national TXD proportion is 0.6 , then unit X must import two organs for every organ it exports (since the ratio between its TXD proportion and the national proportion is $1:2$). As with the pairwise approach, this method incorporates medical decision-making and more flexibility than the blunt approach. Implementing it could lead to an equilibrium where all allocative units have roughly the same TXD proportion.

Moving beyond incorporating the TXD proportion as a hard limit on imports and exports, policymakers may resurrect the old "payback" system with TXD proportions policing specific paybacks. Prior to the modern approach to organ sharing, transplant centers would share organs they could not use with other transplant centers who had clinically appropriate patients waiting for an organ. These organs were shared with the understanding that the receiving transplant center would "pay back" the sharing transplant center with another organ in the future. This system was eventually abandoned, and it includes obvious drawbacks. For example, organ availability and recovery could determine winners and losers in the payback system, as opposed to more justifiable metrics like medical need among individual patients or the population generally.

Reviving "paybacks," policymakers could require allocative units receiving organs from units with lower TXD proportions to send payback organs in the future. For example, if units A and B have TXD

proportions of 0.25 and 0.5, respectively, then for every organ transferred from A to B, B would owe two organs as payback to A. As with the previous option, this pairwise approach could be extended nationally by comparing each geographic unit's TXD proportion with the national average and calculating paybacks by comparing these numbers. By incorporating paybacks, this option makes even more room for medical decision-making and discretion so that individuals who urgently need a particular organ can gain access to it via organ sharing. Under this system, the receiving unit would be expected to repay the sharing unit with an organ in the future.

Each of the options outlined above (except for the blunt approach) use relative TXD proportions as guardrails to limit organ sharing without creating inflexible rules that prohibit sharing a particular organ. By avoiding unbreakable rules, these options leave room for some amount of medical discretion and can incorporate (updated) measures of medical urgency to allow specific transplant candidates to access organs from a wider pool. For example, most organs have something akin to an emergency status (sometimes called status 1) that indicates the patient will die within seven days without a transplant.³⁷² If a patient with this type of medical status needs a shared organ and a unit with a lower TXD proportion has an organ available, it will make sense to share that organ with the medically urgent patient at the expense of individuals in the lower-TXD-proportion unit if they will survive much longer and can therefore wait for the next organ. The sharing unit will then receive more organs in the future to compensate for the loss of the organ to the medically urgent patient.

While this example illustrates the continued flexibility of the approaches outlined so far, it also highlights an important detail that must be resolved. At what point does the unit with the lower TXD proportion not share an organ with a more medically urgent patient in unit with a higher TXD proportion? Patients with one week to live may not be asked to forego an organ, but some patients who are marginally more medically urgent will be unable to receive organs before marginally less medically urgent patients in the interest of equalizing TXD proportions across the country. This could mean that a patient

³⁷² See *Heart Transplant Waiting List*, *supra* note 186.

with an estimated two months to live may not receive an organ while a patient in a geographic unit with a lower TXD proportion who has an estimated three months to live would receive an organ. Deciding where to draw this line between medical urgency levels that will justify organ sharing requires significantly more consideration, evaluation, and analysis. This Article does not attempt to answer that specific question definitively.

However, it is important to acknowledge that this type of decision will need to be made in order ensure broader access to transplants. In many cases, medical urgency alone will not suffice to allow some patients to “jump the line.” While this may seem at odds with current goals in organ allocation policy, acknowledging and addressing this difficult issue will be necessary to avoid ignoring large swaths of the population and undermining access to transplants for everyone (not just those sufficiently privileged to access a waitlist). Avoiding difficult questions like this has almost certainly contributed to the problems identified above.

Overall, policymakers have many different options available to reform organ allocation policy to promote better access to transplants and mitigate socioeconomic inequities. This Article seeks to lay out some basic options to start a conversation among researchers and policymakers but does not purport to evaluate all policy options. Even if one of the options detailed above is ultimately implemented, there remain important details to resolve. And this Article serves as a general invitation to discuss those details and other potential options among the scholarly and policy communities. While it does not purport to solve any issues definitively, it takes important first steps towards ensuring everyone, regardless of their status or privilege, matters when formulating organ allocation policy.

CONCLUSION

I sincerely hope that someone reading this Article one hundred years after its publication finds cause to reminisce about a past where genetically personalized, lab-grown organs were not available on demand. I hope they find it quaint that organs from one human were once necessary to save the life of another human. Until medical technology reaches such a point (or until enough organs are donated to

provide a transplant to every patient who needs one), however, organ allocation policy will continue to determine who lives and who dies. Given this reality, ensuring organ allocation operates efficiently and fairly must remain a priority of the healthcare system. Unfortunately, the empirical evidence developed in this Article does not support the conclusion that organ allocation policy achieves its stated goals of efficiently using organs, avoiding the exacerbation of socioeconomic inequities, or promoting access to transplants.

Over the past decade, organ allocation has moved toward greater national organ sharing. Advocates of such an approach can point to meaningful evidence that the supply of donated organs differs across the country and that individuals on organ waitlists have different levels of medical urgency. This evidence has largely carried the day at both the OPTN, the private body responsible for developing day-to-day organ allocation policies, and HHS, which is responsible for overseeing the OPTN and implementing higher level policy. Courts have typically accepted the move toward broader organ sharing under deferential standards of review, and the asymmetric nature of HHS's review process has generally meant that only those in favor of broader national organ sharing have been able to achieve their goals.

Against this backdrop of broader organ sharing, however, socioeconomic inequities have persisted. The inflation-adjusted income of individuals receiving a transplant has increased over the past decade, and the average gap between the income of organ donors and transplant recipients is around \$10,000. Part of the reason socioeconomic inequities have persisted stems from the way organ allocation policy is formulated and implemented. In developing new policies, policymakers knowingly ignore large swaths of the population who could benefit from an organ transplant but lack the ability to access an organ waitlist.

By focusing only on waitlisted individuals when deciding how to allocate donated organs, current organ allocation policy systematically excludes many individuals from lifesaving transplant surgeries. One way to address this important problem is to incorporate population-based measures of need for transplants into organ allocation policy. Instead of relying only on metrics of medical urgency (which may be inaccurate and actively manipulated based on the evidence reported here), I argue that allocation policy should consider information on everyone who

could benefit from a transplant. Specifically, the novel metric of transplant amenable deaths, developed in this Article, can measure need for transplants across the population. And as a metric based on data external to the transplant system, it is not manipulable within that system.

By incorporating transplant amenable deaths into a the TXD proportion, policymakers have a new tool to ensure that, while the medical urgency of individual waitlisted patients continues to matter, the needs of the overall population factor into the flow of donated organs across the country. Future research should continue to work out the details of exactly how to weigh population needs against individual needs in implementing specific allocation policy. These details may take time to get right, but the time has come to begin that process. Given the problems identified with the current approach to organ allocation policy in this Article and in other work, continuing along the current path is simply untenable. Congress and federal regulators have demonstrated a willingness to overhaul other parts of the organ transplantation system in the past several years. This Article serves as an invitation to continue down that path by overhauling organ allocation policy.