HEALTH AND MEDICINE DIVISION

REALIZING THE PROMISE OF EQUITY IN THE ORGAN TRANSPLANTATION SYSTEM

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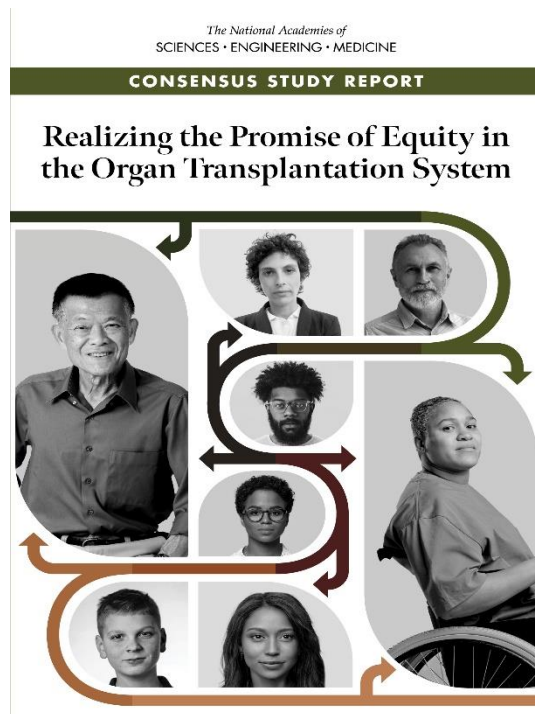
CONSENSUS STUDY REPORT

Realizing the Promise of Equity in the Organ Transplantation System

Public Release Webinar
February 25, 2022

PRESENTATION PREVIEW

1. Highlight some characteristics of the U.S. organ transplant system

2. Present some details about the study

3. Review the study's key conclusions and recommendations

U.S. ORGAN TRANSPLANT SYSTEM

➤ **A highly complex and continually evolving system composed of numerous parts, including >250 transplant hospitals, 57 OPOs, ~5,000 donor hospitals, government regulators, many thousands of healthcare professionals, numerous advocacy organizations, and hundreds of thousands of patients and potential donors**

➤ **>1million kidney transplants since 1954**

➤ **41,354 organ transplants were done in 2021 (up from 12,623 in 1988), including 24,669 kidney, 9,236 liver, and 3,817 heart transplants***

➤ **13,861 deceased organ donors in 2021***

➤ **>110,000 persons wait listed for a transplant (2021)***

➤ **90% Americans support organ donation**

Common Perception	Reality
People who died while waiting for an organ were "too far down the list" to get offers.	People who die waiting have gotten offers—and usually quite a lot of them. (And many patients needing an organ never get waitlisted)
Because donated organs are scarce, they get snapped up quickly on match runs.	Organs are typically offered many times before being accepted; they are not usually snapped up.
Scarcity of organs is the principal limiting factor in getting a transplant.	While there are not enough donated organs to meet the need, many organs donated for transplantation are not used.
Variations in OPO performance are the main reason some patients get transplants sooner.	While OPO performance varies, transplant center performance also significantly varies, even within the same donor service area; this variation impacts when patients get transplanted.
Kidneys that are not used are "marginal".	Good kidneys are also not used.
Patients are routinely consulted about organ offers.	Patients are consulted about the organ their center decides to accept for them; patients are not informed about organs that were declined on their behalf.
Patients have to wait a long time before getting a kidney transplant.	Donated kidney offers often come to patients' centers very soon after wait-listing.

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ABOUT THE STUDY

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➢ Directed to be done by Congress (Consolidated Appropriations Act, 2020*)

➢ Sponsored by National Institutes of Health (NIAID)

➢ Focused only on deceased organ donation

➢ Considered all organs but particular focus on kidneys (85% of waiting list is for a kidney)

➢ Not asked to explore issues related to tissue procurement and use

➢ Analyzed evidence from a systems perspective and guided by the principle of putting the patient at the center of system improvement

➢ Focused on problems and making improvements

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Committee on a Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution

Kenneth W. Kizer (*Chair*), Atlas Research

Itai Ashlagi, Stanford University

Charles Bearden, Clinical Consulting Associates

*Yolanda Becker, formerly University of Chicago

Alexander M. Capron, University of Southern California

Bernice Coleman, Cedars-Sinai Smidt Heart Institute

Leigh Anne Dageforde, Massachusetts General Hospital

Sue Dunn, formerly of Donor Alliance

Robert D. Gibbons, University of Chicago

Elisa J. Gordon, Northwestern University, Feinberg School of Medicine

Renee Landers, Suffolk University Law School

Mario Macis, Johns Hopkins University Carey Business School

Jewel Mullen, University of Texas at Austin, Dell Medical School

Neil R. Powe, University of California San Francisco Medicine Service

Dorry L. Segev, New York University (*as of February 1, 2022*)

Dennis Wagner, Yes And Leadership, LLC

James B. Young, Cleveland Clinic Lerner College of Medicine

*Dr. Becker resigned from the committee as of September 15, 2021

ABOUT THE STUDY: Statement of Task

➢ Examine the economic, ethical, policy, regulatory, and operational issues relevant to organ allocation policy decisions involving deceased donor organs.

➢ Make recommendations to:

  ✓ Maximize public and professional trust in the organ donation, procurement, allocation, and distribution process.

  ✓ Better align the performance metrics of various stakeholders within the Organ Procurement and Transplantation Network (OPTN) – donor service areas, organ procurement organizations, and transplant centers – to maximize donor referrals, evaluations, procurement and organ placement/allocation while minimizing organ discard rates.

ABOUT THE STUDY: Study Process

- ➢ Data driven - reviewed scientific literature and publicly available data
- ➢ Commissioned 7 papers – e.g., use of standardized performance measures and quality improvement; algorithms used in kidney and liver allocation, survival benefit, others
- ➢ Gathered public input
  - ✓ 4 virtual public meetings (Dec 2020; Feb, Apr and Jul 2021)
  - ✓ Received written comments from stakeholders
- ➢ Reviewed and deliberated on evidence (between Nov 2020-Feb 2022)
  - ✓ 17 closed session full committee meetings (virtual)
  - ✓ Many smaller subgroup meetings (virtual)/calls

KEY CONCLUSIONS AND RECOMMENDATIONS:
3 Groupings

I. **Need to improve equity**

II. **Need to use more donated organs**

III. **Need to improve the system and system performance**

KEY CONCLUSIONS: Improving Equity

➢ The current U.S. organ transplantation system is demonstrably inequitable.

➢ Certain groups of patients (e.g., persons of color, lower socioeconomic status, female gender; older patients; individuals with disabilities or inheritable diseases such as cystic fibrosis) receive organ transplants at a disproportionately lower rate and after longer waiting times than other patients with comparable medical need.

KEY CONCLUSIONS: Improving Equity

- ➢ Oversight of the organ transplantation system does not begin until individuals with end-stage organ failure are wait-listed for a transplant; there is no oversight when individuals are diagnosed with end-stage organ failure.

- ➢ For many persons who would benefit from organ transplantation, access to referral for transplant evaluation and eventual placement on the waiting list is limited. Many of the inequities in the system arise from lack of access to transplantation evaluation.

- ➢ Black patients have a 37 percent lower chance of being referred for a kidney transplant prior to beginning maintenance dialysis (preemptive kidney transplantation).

- ➢ Patients who are white, have greater health literacy, and have private health insurance have greater access to preemptive kidney transplantation.

KEY RECOMMENDATIONS: Improving Equity

➢ **Recommendation 3: Under the direction and oversight of the Congress, HHS should be held accountable for achieving equity in the organ transplantation system in the next 5 years.**

- ✓ **Within 1 to 2 years, HHS should publish a strategy with specific proposed requirements, regulations, payment structures, and other changes that will lead to the elimination of disparities.**

- ✓ **HHS should extend its regulatory oversight of the organ transplantation system beginning, at least, at the time a patient reaches end-stage organ failure and extending beyond 1-year post-transplant.**

- ✓ **HHS should develop, implement, and evaluate rigorous approaches for transplant teams to communicate routinely with wait-listed candidates about organs offered to them to facilitate shared decision making about whether to accept a proffered organ.**

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KEY RECOMMENDATIONS: Improving Equity in the Near-Term (next 1-2 years)

➢ **Recommendation 4:** The OPTN should accelerate finalizing continuous distribution allocation frameworks for all organs.*

  ✓ The OPTN should implement for all organs by the end of 2024, should include an organ-specific upper bound on the weight of "distance to donor hospital" in the continuous distribution equation.

➢ **Recommendation 5: The OPTN should eliminate pre-dialysis waiting time credit from the kidney allocation system**

  ✓ The OPTN should discontinue the use of pre-dialysis waiting time credit, or "points", in the kidney allocation system. Points should only accumulate when a patient begins regularly administered dialysis. NB: This is not recommending that access to deceased donor kidney transplantation be limited only to those who have started dialysis; just that pre-dialysis waiting time points should end.

*Since deceased donor organs are a national resource, the fairest way to allocate them to patients on the waiting list is on a national, continuous basis, in accordance with the OPTN Final Rule 2000 as most recently revised by HHS. The committee recognizes that some members of the transplant community feel strongly that deceased donor organs procured in a particular geographic area should be retained for allocation to wait-listed patients in that area.

KEY RECOMMENDATIONS: Improving Equity in the Near- and Longer-Term (next 1-5 years)

➢ **Recommendation 7: HHS should resolve areas of inequity in organ allocation algorithms**

  ➢ The OPTN should update prediction models (e.g., KDPI, EPTS, and MELD) using the most recent data at least every 5 years.

  ➢ Modify MELD or establish a new prioritization scheme that includes a modifier based on body size or muscle mass.

  ➢ HHS should immediately implement the recommendations of the NKF/ASN task force to use the revised equation, which eliminates race, in calculating kidney function (eGFR), and require laboratories to use the revised equation for high-risk individuals that incorporates a blood test for cystatin C along with serum creatinine and that laboratories are capable of conducting validated cystatin C tests.

  ➢ HHS should resolve the use of race in KDPI and other clinical algorithm within 12 months.

KEY CONCLUSIONS: Use More Donated Organs

➢ Too many donated organs are not transplanted each year.
  ✓ >20 percent of kidneys, 10 percent of livers, 6.5 percent of lungs, and almost 1 percent of hearts go unused.
  ✓ Organs procured but not used in 2019:4,460 kidneys, 345 pancreata, 874 livers, 5 intestines, 31 hearts, 338 lungs

➢ It is too easy for transplant centers to decline usable organs, and accountability for transplant center decision making is lacking.

➢ Non-use of organs is higher on weekends

➢ The demand for organs consistently exceeds supply, and the continued underuse of available, usable, donated organs requires priority action.

KEY CONCLUSIONS: Use More Donated Organs

➢ **Organ non-use has been trending upward since 2000 despite organ quality remaining stable.**

➢ **Donors and their families generously and selflessly make the gifts of donation possible. The non-utilization of organs that are suitable for transplantation does not honor those gifts.**
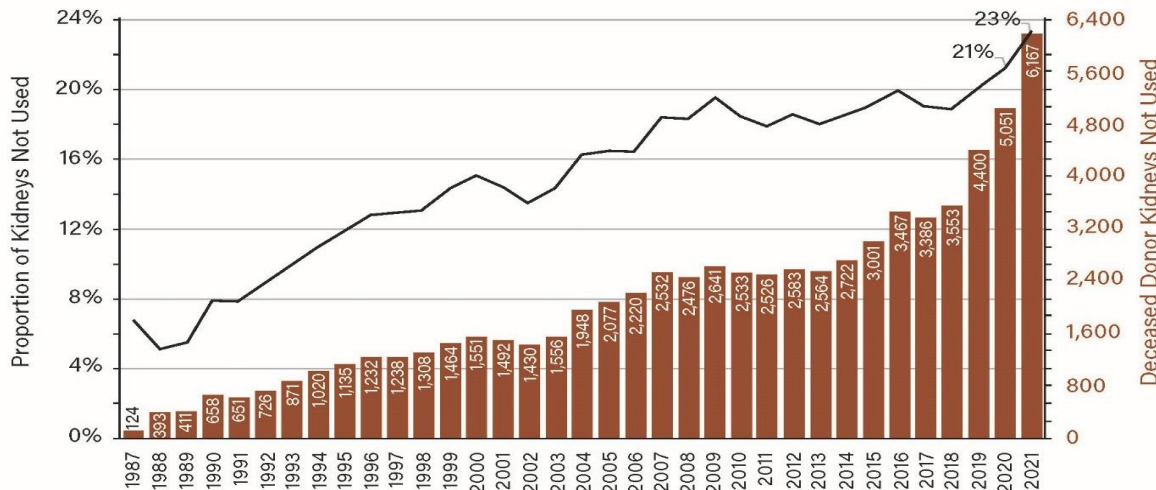

Figure 6-5: Proportion and number of nonused deceased donor kidneys (1987-2021).

KEY RECOMMENDATIONS: Use More Donated Organs

Recommendation 10: Increase transparency and accountability for organ offer declines and prioritize patient engagement in decisions regarding organ offers

✓ HHS should update the OPTN contract to require increased transparency around organ offer declines and require transplant center accountability for patient engagement and partnership between transplant center professionals and patients in deciding whether to accept or reject an offered organ.
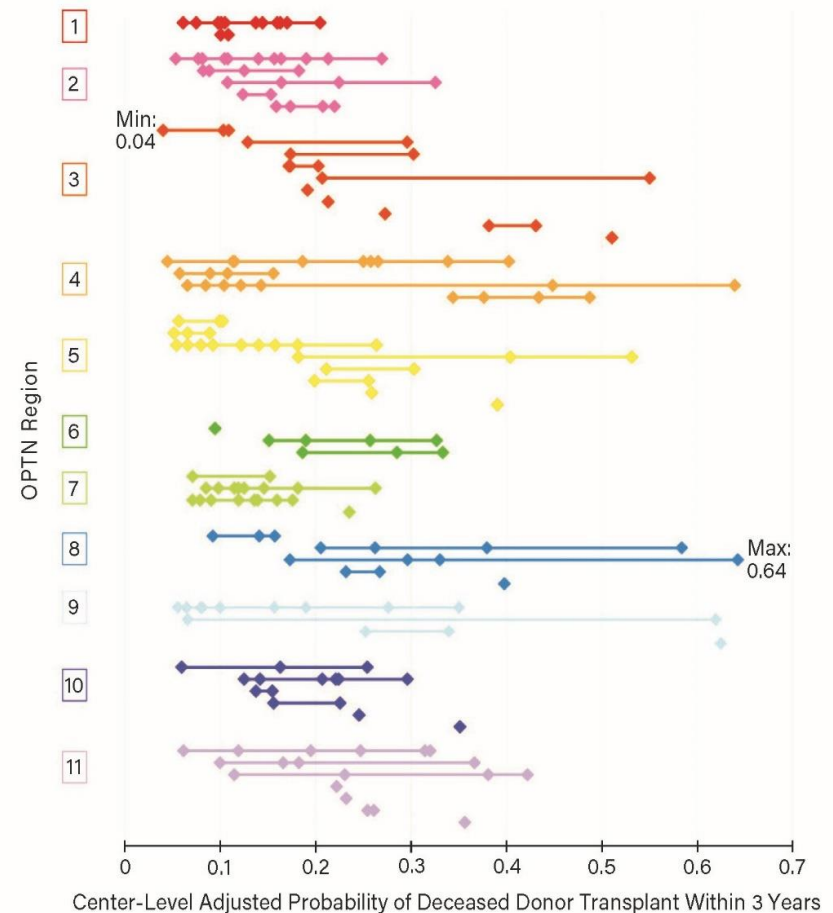

Figure 6-10: Range in adjusted center-level probability of deceased donor kidney transplant within 3 years of wait listing in 2015 showing significant variation within and across DSAs.

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KEY RECOMMENDATIONS: Use More Donated Organs
Near term implementation (1-2 years)

➢ **Recommendation 14: Align reimbursement and programs with desired behaviors and outcomes**

  ✓ CMS should align payment and other policies to meet the national performance goals for the organ transplantation system (see Recommendation 1). Within two years, CMS should:

   ▪ Expand quality improvement initiatives aimed at reducing kidney nonuse rates

   ▪ Expand current work in the end-stage renal disease program to refer more eligible patients for transplant and help them receive transplants

   ▪ Increase the existing dialysis withholding payment, as needed, to fund ESRD quality improvement activities (Congressional action required)

   ▪ Increase reimbursement, as needed, for referral for transplant evaluation for all organ types, and in the case of kidney transplant, even before dialysis begins

   ▪ CMS and other payors should consider new opportunities to increase the use of organs by increasing payment, as needed, for kidney transplants that require a higher level of care.

KEY RECOMMENDATIONS: Use More Donated Organs Near term implementation (1-2 years)

➢ **Recommendation 9: The OPTN should make it easier for transplant centers to say "yes" to organ offers**

  ✓ Require the use of more refined filters for transplant centers to indicate their preferences for which kidneys will be accepted, if offered;

  ✓ Implement expedited placement policies, at first offer, for difficult-to-place kidneys;

  ✓ Gradually increase the number of simultaneous offers of a given organ;

  ✓ Require hospitals with transplant centers to ensure organ procurement operations and transplants can occur seven days a week;

  ✓ Develop evidence-based standards for organ quality assessment to be used by all OPOs (carefully consider the value of biopsies) and develop clear guidelines for transplant centers to request any additional organ quality testing beyond the standardized requirements.

KEY CONCLUSIONS: Improve System Performance

➢ **The performance of the U.S. organ transplantation system, and its component parts, is highly variable and often inexplicable, with little understanding or justification for areas of variation that are acceptable or unacceptable.**

  ✓ **Creating standardized, consensus-based metrics to compare performance of donor hospitals, OPOs, and transplant centers needs to be a priority for HHS and the OPTN.**

  ✓ **There is a need to reduce variations in the performance of donor hospitals, OPOs, and transplant centers in order to increase equity, efficiency, usefulness, reliability, predictability, and trustworthiness of the transplant system.**

  ✓ **Federal agencies overseeing the transplantation system will need to collaborate on data collection, even for the parts of the system they don't oversee, to ensure relevant, accurate, and timely data are available about the transplantation system.**

KEY CONCLUSIONS: Improve System Performance

- ➢ Wait-listed patients at transplant centers with low offer acceptance rates have only a 4 percent chance of getting a transplant within 3 years. Conversely, a patient waiting at a transplant center with a high offer acceptance rate has a 65 percent chance of getting a transplant within 3 years.

- ➢ Nonuse of organs is higher on Fridays, Saturdays, and Sundays. This weekend effect can be mitigated through appropriate planning and surgical scheduling management.

- ➢ Donor care units are an innovation in organ procurement and provide an opportunity to bring consistency and high-quality care to donor organ procurement and the donor family care experience.

- ➢ Transplant professionals are working hard to do the right thing, but the system needs to be improved to produce different outcomes.

KEY RECOMMENDATIONS: Improve System Performance

➢ Recommendation 1: HHS should develop national performance goals for the U.S. organ transplantation system to drive national progress using the proven capabilities of the highest performing (top 5-10%) donor hospitals, OPOs, and transplant centers. HHS should establish the following national goals:

- ✓ Improve donation among minority populations and disadvantaged populations, and increase transplantation rates among minority and disadvantaged populations, based on the proven practices of donor hospitals, OPOs, and transplant centers which have the highest rates in these areas.

- ✓ All transplant centers should reduce donated kidney nonuse rates to 5 percent or less (building on current CMS kidney transplant collaborative goal).

- ✓ Increase the number of organs procured from medically complex donors, including increasing DCDD donor to at least 45 percent of all deceased donors, with no reductions in the number of organs procured from donors from neurological determination of death.

- ✓ Increase the number of transplants to at least 50,000 by 2026.

OPO Variability in Percent of DCDD donors
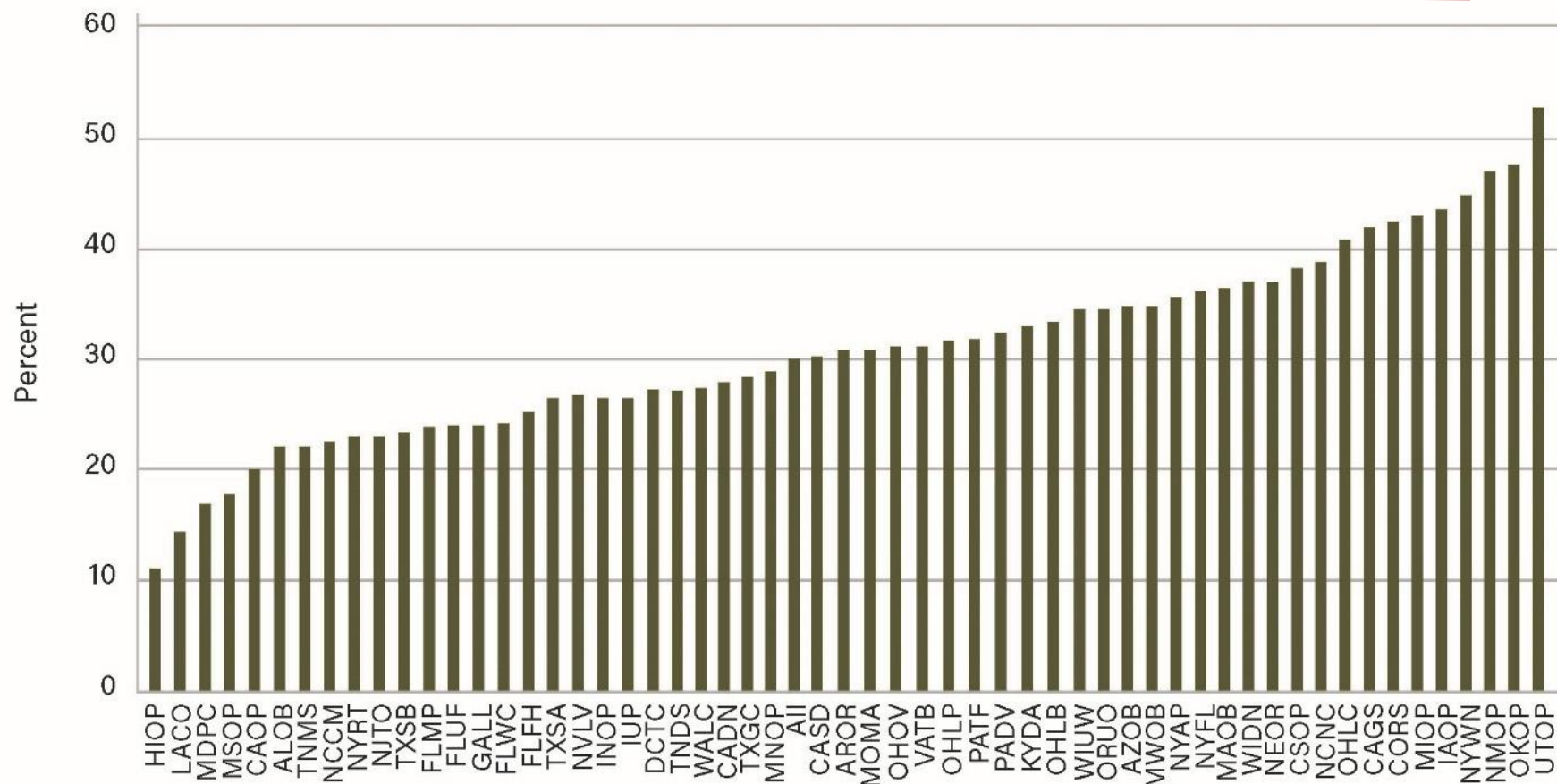
FIGURE 6-3 Variability in percent of donation after determination of circulatory death (DCDD) donors by OPO.
NOTE: All donation services donors *n* = 13,817. National average for all donation services areas in 2021 = 30 percent. DSA identifiers are identified by OPTN codes: the first two letters are the state where the OPO is headquartered, and the second two letters are related to what was submitted to CMS upon the original application.

KEY RECOMMENDATIONS: Improve System Performance

➤ **Recommendation 12: Create a dashboard of standardized metrics to track performance and evaluate results in the U.S. organ transplantation system.**

✓ **HHS should use a combination of currently collected data and new data elements specifically related to access to transplant to create a publicly available dashboard of standardized metrics to measure the performance of the organ transplantation system. The metrics should be meaningful to donor families, individuals with chronic disease or organ failure, transplant candidates, and individuals on the waiting list and their families.**

Referring Organizations & Transplant Centers

Novel measurements
- Access: Number of Patients Referred to the Center for Evaluation
- Access: Number of Referred Patients Who Were Evaluated
- Access: Number of Evaluated Patients Who Were Listed
- Number of Organs Offered to Patients That Were Declined
- Survival benefit

Exsisting measurements
- Number of Listed Patients Who Died Waiting
- Number of Listed Patients Who Were Transplanted
- 1 Year Graft Survival of Transplanted Patients
- 5 Year Graft Survival of Transplanted Patients

Donor Hospitals & OPOs

Novel measurements
- Number of Ventilated Deaths within 1 Hour of Extubation
- Number of Deaths Medically Suitable for Donation
- Number of Referred Deaths Responded to by OPO
- Number of Authorizations

Exsisting measurements
- Number of Total Deaths
- Number of Organs Transplanted
- Number of Deaths Referred by Hospitals to OPO

Figure 7-1: Recommended Measurement Elements for Referring Organizations, Transplant Centers, Donor Hospitals, and OPOs

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KEY RECOMMENDATIONS: Improve System Performance

➢ **Recommendation 11: Require the establishment and use of a donor care unit for each organ procurement organization.**

  ✓ To better serve donors and families, increase cost-effectiveness, and foster innovation in organ rehabilitation and donor intervention research, HHS should require each of the 57 OPOs to create, establish, and manage a donor care unit (DCU).

  ✓ CMS should adjust reimbursement, as needed, to ensure transplant centers are incentivized to transfer donors to an OPO DCU.

KEY RECOMMENDATIONS: Improve System Performance

➢ Recommendation 2: Improve the Organ Procurement and Transplantation Network (OPTN) policy-making process.

  ✓ HHS should hold the OPTN and HRSA accountable for developing a more expedient, and responsive policy-making process including increasing racial, ethnic, professional, and gender diversity on the boards and committees responsible for developing OPTN polices.

  ✓ HHS should consider requiring the OPTN to work with and receive support from an external organization, such as the National Quality Forum (NQF) or National Academy of Public Administration, with expertise in guiding federal programs through unique challenges in leadership and stakeholder collaboration.

  ✓ HHS should require the OPTN to consider the following elements of the policy-making process:

    ▪ Proven approaches by others, such as the NQF Measure Applications Partnership, for meeting aggressive timelines with intensive, consensus-based, multistakeholder policy development processes;

    ▪ Optimal board size and stakeholder balance;

    ▪ Continuous and concurrent versus sequential policy-making processes;

    ▪ Managing strategic priorities and ensuring priority items have sufficient momentum, institutional memory, and timelines;

    ▪ Alternative governance models; and

    ▪ Appropriate tools and processes for evaluating the effectiveness of the policy-making process.

KEY RECOMMENDATIONS: Improve System Performance

➢ Recommendation 8: Modernize the information technology infrastructure and data collection for deceased donor organ procurement, allocation, distribution, and transplantation.

✓ HHS should ensure that the OPTN uses a state-of-the-art information technology infrastructure that optimizes the use of new and evolving technologies to support the needs and future directions of the organ transplantation system.

✓ HHS should evaluate how well the current IT system meets the needs of the transplant system by collecting and analyzing data from IT end users (e.g., OPOs and transplant teams) and other stakeholders.

✓ Based on the evaluation of the current IT system, HHS should consider:

✓ separating the IT infrastructure components from the remainder of the OPTN contract and instituting a new competitive process for an IT services contractor. *OR*,

✓ Incorporating the identified improvements in the next OPTN contract bidding process in 2023. *OR*,

✓ Pursue an alternative approach that would achieve the same desired outcome.

Improve System Performance

2021

- Inequitable
- Patients unaware of organ declines

- >20% deceased donor kidneys not used
- Inexplicable wide variation in performance of OPOs, transplant centers, and donor hospitals
- Limited and controversial metrics on system performance

- Few OPOs have donor care units
- Legacy IT system

2026

- Equitable
- Pts aware of organ offers and declines through reporting and shared decision-making
- <5% deceased donor kidneys not used
- Reduced and explainable variation in performance of OPOs, transplant centers, and donor hospitals
- Dashboard of consensus metrics providing a complete picture of system performance
- All OPOs have donor care units
- State-of-the-Art, forward looking IT system

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QUESTIONS/COMMENTS