OPO Best Practices

EXECUTIVE SUMMARY

Each year, more than 28,000 viable organs never get the opportunity to be transplanted to patients who desperately need them. And out of the organs that are obtained from deceased donors, about a fifth of kidneys and pancreases are never transplanted. Central to this problem is the extreme performance variability and lack of basic accountability of Organ Procurement Organizations (OPOs) who are responsible for obtaining transplantable organs within their regions across the U.S. Communities of color are disproportionately harmed by system failures. Despite very clear issues, no OPO has ever lost its certification status for poor performance, which is costing lives and taxpayer dollars. Yet there is new commitment from the federal government to address and correct solvable problems in the system. This document offers strategic and actionable insights to build on this momentum and improve organ recovery outcomes in the short and long term.

The 58 OPOs across the country are tasked with managing and coordinating an organ recovery process that broadly consists of three phases:

- **Phase 1: Procurement** - Coordinating with donor hospitals to procure organs from deceased donor patients who meet clinical criteria for donation.
- **Phase 2: Match & Recovery** - Matching the procured organ(s) with a patient on the waiting list to receive that organ, and overseeing surgical recovery of the organ(s).
- **Phase 3: Transport & Transplant** - Transporting the recovered organ to the transplant center in sufficient time so that it can be transplanted successfully.

We identified many issues specific to OPO practices that impede organ recovery efforts at every phase of the process, including:

- Unmade referrals of a potential donor

- OPOs not responding to a donor referral in time for the organ to be used successfully
- OPOs failing to obtain family authorization
- OPOs not being able to find a suitable recipient while the organ is still transplantable
- OPOs not safely transporting an organ to its destination in sufficient time

There are some clinical reasons that cause these drop off points and others. But unfortunately, there are far too many that are attributable to ineffective OPO practices, processes, communication, and technology.

> "We don't have an adequate way of expressing the harm of a non-approached donor. There are significant harms — the donor's decision to donate may not be honored, the family may not get closure or comfort, patients on the waiting list die, and costs increase to the national health care system. And yet OPOs are able to keep these harms invisible."

— Researcher

Many of these challenges have root causes that we believe can be addressed. In particular, there are critical opportunities related to:

- **Accountability** - Holding OPOs (who are government contractors) to more rigorous standards around organ recovery, transportation and logistics, and urgency around donor matching.
- **Staffing & Training** - Addressing understaffing and poor training to improve coordination and communication among key stakeholders in the system.
- **Data & Technology** - Improving data and technology throughout the process so that it can be leveraged more efficiently to support organ recovery.

A more detailed list of recommended actions can be found towards the end of the document.

The U.S. Department of Health and Human Services (HHS) has a critical window of opportunity to fix the organ transplant system, as catalyzed by the Executive Order on Advancing American Kidney Health that seeks to improve patient access to organ transplants, and a proposed rule change that holds OPOs accountable. These changes — once finalized and implemented — have the power to recover thousands of life-saving organs and save billions of taxpayer dollars.

INTRODUCTION

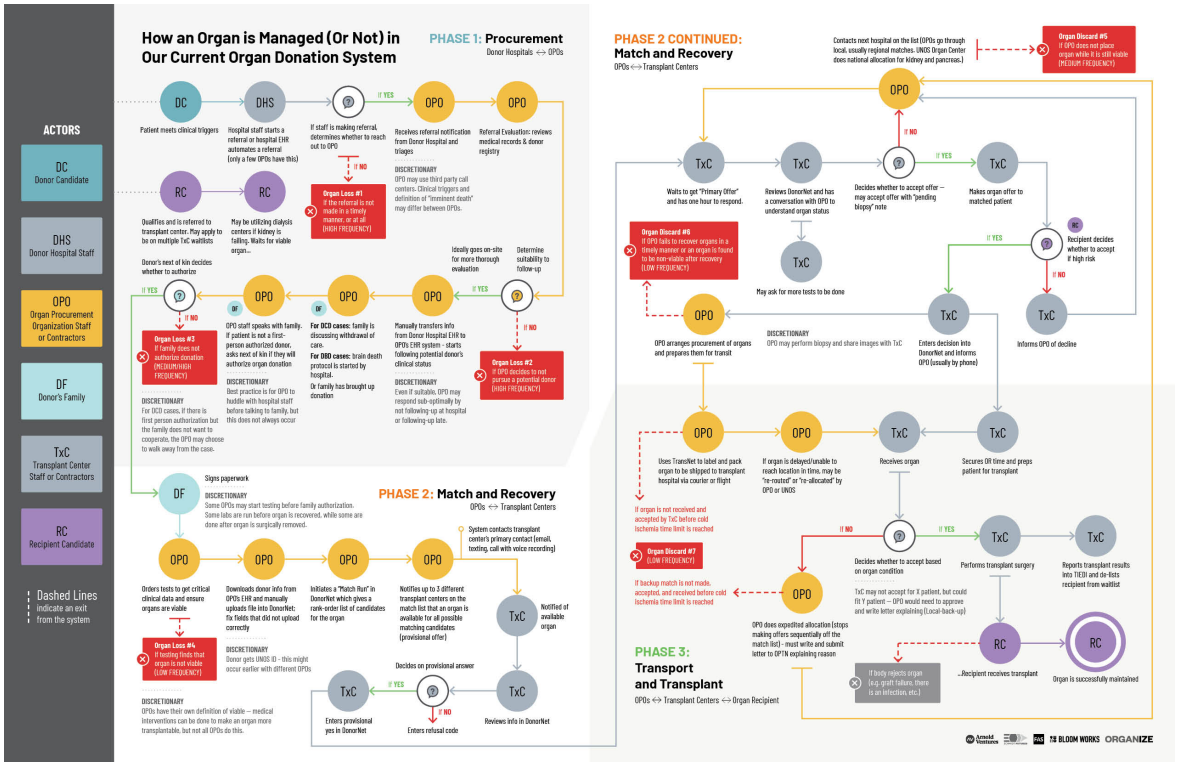
Problem: Currently, 58 Organ Procurement Organizations (OPOs) are designated across the US. They are each responsible for obtaining transplantable organs within their own territory of hospitals in their donation service area (DSA), without competition from any other organizations, which essentially renders each OPO as a monopoly for organ procurement for their DSA.[1] Without strong performance guardrails, performance of OPOs across the nation has been variable — by as much as 470% in organ recovery.[2] Despite this, no OPO has ever lost its government contract for poor performance. Research has shown that 28,000[3] organs each year go unrecovered by OPOs and a December 2019 Notice of Public Rulemaking from the Department of Health and Human Services (HHS) flagged a majority of the nation's OPOs as failing basic proposed outcome metrics.[4]

Opportunity: With the proposed rule change on outcome measures,[5] OPOs may be further motivated to improve their practices in order to avoid decertification. Potential competitive pressures from higher performing OPOs could help motivate OPOs to increase organ procurement and placement. Given the recent Executive Order on Advancing American Kidney Health,[6] Centers for Medicare & Medicaid Services (CMS) may also decide in the future to further refine other conditions of coverage to call for the adoption of practices that increase organ recovery and transplantation.

Discovery Sprint**:** Based on interviews with OPO, donor hospital, and transplant center staff, as well as researchers and other leaders[7] in the organ transplant system, this report offers insight into the issues impeding organ recovery and the practices that could address these issues. Given that there have been limited studies that examine the effects of specific OPO practices, the findings in this report are reinforced with data when possible, though are largely case studies.

Organ Recovery Process

Figure 4



[Download the "How an Organ is Managed (Or Not) in the Current Organ Donation System" PDF]

As mentioned above, OPOs have the responsibility of procuring organs from deceased patients and placing them with transplant centers. To carry out this responsibility, OPO staff must coordinate with donor hospitals[8] to procure organs from deceased donor patients who meet clinical criteria, and with transplant centers[9] to match those organs with recipients on the organ waiting list.

Phase 1: Procurement

1. Hospitals notify OPOs of "imminent deaths" based on clinical triggers. It is then the responsibility of the OPO to assess that patient's donation potential.
2. If the OPO decides this is an eligible donor, they will start to follow the case — ideally having an integrated plan of action with the donor hospital staff.[10]

3. Once brain death protocol is started, or in the case of donation after circulatory death (DCD),[11] that the family has begun discussing withdrawal of care,[12] the OPO will talk with the next of kin about organ donation — either to notify them if the patient was a registered donor, or to ask for organ donation authorization if the patient was not registered.

4. If donation is authorized, the OPO and hospital staff will do testing to gather more data and ensure the organs are viable and safe to transplant.

Phase 2: Match & Recovery

1. Once the organs are deemed transplantable, the OPO enters the donor's clinical data into the organ offer technology to run a "match list." This provides the OPO with an ordered list of the patients in line to receive that organ.
2. OPOs must work quickly to run down the match list to find an accepting transplant center and recipient.[13]
3. The surgical recovery of the organs is scheduled and usually takes place at the donor hospital.[14] For some organs, surgeons from the transplant centers will travel to the donor hospital to perform the surgical removal of the organs and take the organs back with them. For other organs, local surgeons will perform the surgery[15] and the organs must be shipped to the transplant center.

Phase 3: Transport & Transplant

1. Once organs are surgically removed, the OPO prepares them for transit, and arranges transportation.[16] The transportation of the organ to the transplant center is time-sensitive since the organ degrades with increased cold-ischemia time (time outside the body).[17]
2. Once the transplant center has the organ, surgeons transplant it into the recipient candidate.

NOTES

1. Government officials have noted that because of this given monopoly and lack of market pressure, OPOs should be held to stricter standards and more transparency. ↩
2. CMS NPRM: "We found a wide range of donation rates (1.65 to 6.45 donors/100 inpatient deaths) and organ transplantation rates (4.47 to 21.14 transplants/100 inpatient deaths). We did not find a correlation between the performance of OPOs and the number of deaths (reflecting experience with larger volumes of potential donors) or the number of patients on the waiting list (reflecting the demand for organs) in the DSA." ↩
3. "Reforming Organ Donation in America ,"*Bridgespan*, 2019. ↩

4. "OPOs Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization,"*Centers for Medicare & Medicaid Services*, 2019. ↩

5. New CMS proposed rule redefines donors as someone who actually had organ(s) transplanted, not just procured; and redefines donor potential as inpatient deaths among patients 75 years old or younger from any cause of death that would not prevent donation using CDC data. ↩

6. "Executive Order on Advancing American Kidney Health," *whitehouse.gov*, 2019. ↩

7. Throughout, we refer to interviewees by their titles and not names because many asked to remain anonymous for fear of retribution from OPOs and/or UNOS. ↩

8. Donor hospitals are any hospital that has both a ventilator and an operating room. All donor hospitals have only one OPO that they work with, while an OPO has multiple donor hospitals they work with in their DSA. ↩

9. Transplant centers are where patients needing a transplant are placed on a waitlist. "A transplant program is defined as a component within a transplant hospital that provides transplantation of a particular type of organ to include; heart, lung, liver, kidney, pancreas or intestine." CMS.gov ↩

10. Medical interventions to keep organs viable can begin before family authorization. ↩

11. Donation can occur after brain death (DBD) or after circulatory death (DCD). ↩

12. "For potential brain dead donors, the data indicates that best practices are to introduce the possibility of brain death as early as possible, specifically once the injury or the condition indicates it is not survivable. This is likely when the brain death protocol is started or when the family or health care providers begin discussing withdrawal of mechanical supports. For patients who are potentially eligible for DCD, it is when the family initiates a discussion of withdrawal of supports." - Researcher ↩

13. Because the organ offer technology contains only limited fields to view, the transplant surgeons and their intake teams usually have many questions for the OPO. ↩

14. Some OPOs transfer donors to a donor recovery center, a "purpose built facility for donor workup and management as well as for the organ procurement procedure." A Novel Organ Donor Facility: A Decade of Experience With Liver Donors ↩

15. Organ Recovery OR Room Set-up by an OPO - "Procedure: Organ Recovery Single or Multi-Organ,"*Iowa Donor Network*, 2015. ↩

16. § 486.346 Condition: Organ preparation and transport. "The OPO must develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival without compromise to the quality of the organ." ↩

17. Each type of organ has a cold-ischemia time (CIT) limit of when the organ can be out of the body and still successfully transplanted into the recipient. This can range from heart and lungs, which have 4-6 hours CIT, to kidneys which have 24-36 hours CIT. ↩

ORGAN DROP-OFF POINTS & POTENTIAL FIXES

Along the organ recovery process there are several drop-off[1] points where organs that had the potential to be transplanted are not.[2] These drop-off points are sometimes due to clinical reasons, but more often than not, are because of ineffective practices, processes, communication, and technology.

DROP-OFF POINT #1: *WHEN "IMMINENT DEATH" REFERRAL IS NOT MADE IN A TIMELY MANNER, OR AT ALL*

Frequency/Size of Drop-off: **HIGH**[3]

While the exact number has not been captured, researchers and OPO experts we spoke to estimate that there is a large number of referrals that are never made. A referral for a potential donor is a crucial step[4] because it kicks off the whole organ recovery process.[5] There is a significant opportunity for OPOs to work more effectively with donor hospitals and ensure all viable patients are referred. A missed referral means a missed approach, which means a missed opportunity to save up to eight lives (as every donor may have up to 8 transplantable organs).

CAUSES

Lack of mandated standardization

While there are recommended clinical criteria for donation in the OPTN policies,[6] OPOs ultimately have the discretion to define clinical triggers,[7] as well as the terms "imminent death" and "timely referral" as part of their donor hospital agreements.[8] This means that the clinical triggers do not have to be evidence-based and can be determined by a non-clinical person. Under current evaluation standards, OPOs are not incentivized to pursue

every organ (more on this later). The resulting variations in clinical triggers make it harder for staff, such as travel nurses, who may move between hospitals to keep track of when to refer a potential donor.

> "Inherited handshake deals led to a lot of the [different] discretionary practices…there's a floor, but there's no ceiling of the best clinical triggers that are implemented nationally, they're all over the place."

— Researcher

Poor training and working relationships with donor hospitals

In addition to varying clinical triggers, if OPOs do a poor job in educating hospital staff on organ donation and not maintaining a strong working relationship, hospital staff may be less likely to make timely referrals to OPOs. They may be busy/distracted or are not aware of the steps to refer. It is not only whether or not the hospital staff know the clinical triggers, but whether it is top of mind for them and whether they have the bandwidth to call it in, when they are focused on many other important tasks.

We heard from an OPO leader that, *"Many OPOs have instructed hospitals to NOT call on [to refer] certain patients thus eliminating organ donors before they even get to the OPO."* OPOs do this to tamper with the numbers they have to report as referrals in order to avoid documentation of cases where healthcare providers (HCPs) or the OPO anticipate that it will be an unlikely donation. Research has shown that implicit bias and preconceptions of who is likely to donate disproportionately affect minorities and people of color (see Inequity in Organ Donation). "Past studies comparing the experiences of African American (AA) and Caucasian families who have made decisions about donating a family member's organs found that donor-eligible AA patients were less likely to be referred to an OPO by hospital staff."[9]

OPOs are supposed to find these missed referrals in their death record reviews, but we heard, *"There's no incentive to find those missed referrals. If they [the hospital] missed*

making a referral, they [the OPO] have to report it. There are incentives in the chain to cover up everybody else in the chain." - OPO COO. One example of this, shared with us by a researcher, is that an OPO said they were getting 100% of referrals based on the OPO's death record audits, but when the OPO adopted an electronic automated referral system, the number of referrals went up. Because of this, an OPO leader emphasized that the referral potential for a donor hospital should not be assumed based on previous history of referral.

POTENTIAL FIXES

Standardize clinical triggers nationally

Clinical triggers for a donor referral should be evidence-based and determined by medical experts. A researcher told us that if they had access to better OPO data (that currently lives in OPO tech systems[10] but never gets reported to the OPTN[11]), they could determine what are the best clinical triggers based on historical data. This would clear the path for a set of nationally mandated clinical triggers that all OPOs and donor hospitals would use for referrals.

Leverage technology to make referrals less dependent on busy staff

Hospital staff are extremely busy and have multiple concurrent responsibilities. While it would still be important for OPOs to coordinate with hospital staff once onsite, making the initial referral less dependent on staff will lessen the chances for human error and alleviate the burden on hospital staff.

- There are two tech systems currently being used to a very limited degree that attempt to do this. One version "pings" hospital staff when a patient meets clinical criteria, still requiring the nurse to call the OPO. The other is a fully-automated system that activates a referral to the OPO via a third party system, such as iTransplant.
- These e-referral systems have shown increases in referrals[12], but are slow to integrate and do not work with all hospital electronic medical record (EMR) systems. They are also currently only used as bespoke solutions between a single hospital and an OPO, which will only add further unnecessary complexity to the system if such technologies continue to be adopted ad hoc.

- A technical solution needs to happen at a national level rather than piecemeal.[13] Having a national standard for clinical triggers will also make a national e-referral

system simpler to implement. The ONC should set interoperability standards and requirements between OPOs, Donor Hospitals, and OPTNs in order to enable the introduction of new technologies into the organ donation space that currently is highly fragmented with a significant amount of information blocking put in place by incumbents.[14] Having a standardized national system for automated referrals could also be useful for gathering data on average response time and help to evaluate OPOs on how well they are responding to referrals, which could inform potential OPO conditions for coverage requirements.

Better education for donor hospital staff

More frequent and consistent donor hospital education is needed, not only for timely referrals but also for all the ways that OPOs and hospital staff need to coordinate. One OPO reported doing their hospital education annually, which is not nearly enough given the staff turnover and travel nurses who might be utilized. Donor hospital education is not standardized and varies greatly between OPOs.[15] The hospital training may only be as good as how well the OPO staff are trained themselves, which is highly variable and non-standardized. When done by the Hospital Development Coordinator, who is non-clinical, trainings should be accompanied by a clinical OPO person, such as the clinical coordinator. In addition to advising on *when* a potential donor should be referred, OPOs should also provide education on clinical donor management,[16] so that donors do not expire and organs do not fail before OPO staff is able to follow-up on the referral. *"It [donor hospital training] is a hit or miss. OPO staff are also undertrained and under-knowledged…the content of the education could be improved." - OPO COO*

Donor hospital agreements set some expectations and protocols, but it is unclear who actually sees this agreement. We spoke with hospital frontline staff who said they were unaware of such an agreement and did not know what it contained. The expectations and agreements in these protocols should be a part of the donor hospital education by OPOs. As told to us by frontline staff,[17] hospitals may need further protocols and agreements, such as what labs and procedures can be completed before a doctor declares brain death[18] or before the next of kin has fully consented to donation.

Institute feedback loop

OPOs and donor hospitals working relationships often suffer.[19] To identify — and, ideally, remediate — these issues before the damage becomes irreparable, there should be a standardized and regular feedback loop[20] between OPOs and donor hospital staff who make referrals or were involved with a potential donor. This comes directly from an ICU nurse who told us, *"We need a feedback loop for performance. Right now they do their thing, we do our thing. There's no meshing. No feedback."* The first goal of this feedback

loop is awareness – OPOs should have no excuses for being unaware of problems between OPO and hospital staff. The second goal is for these problems to be addressed effectively. To that end, this feedback data should be shared with CMS to ensure that actions are being taken.

Currently donor hospitals and transplant centers[21] can file a formal complaint to CMS to open up an investigation into an OPO.[22] However, most hospitals do not file a complaint even when there are issues, because they do not think CMS will do anything about it. This is learned behavior, as CMS has never once successfully decertified an OPO for underperformance, in large part due to the lack of reliable metric data[23] to enable enforcement of regulations.[24] It is a lot of work for the hospital to file, with low expectations on return, which makes it an ineffective feedback mechanism. Some hospital staff we spoke to were not even aware that this mechanism existed. Similarly, donor hospitals and transplant centers can file a formal complaint to the OPTN, however such complaints are heard by the OPO subcommittee[25] which is run by OPOs, presenting a clear conflict of interest.

Some OPOs may already be surveying their donor hospitals, but that information is kept internal and there is no meaningful pressure or accountability for the OPO to act on that information. CMS could tell OPOs that they need to survey hospitals (with standardized questions)[26] and share that information back to CMS and the OPTN.

NOTES

1. Clinically, these drop-off points are referred to as either "organ loss" if the organ was never procured or "organ discard" if the organ was procured but never transplanted. ↩
2. "Breakdown in the Organ Donation Process and Its Effect on Organ Availability," *Journal of Transplantation*, 2015. "An eligible decedent is four times more likely to become an organ donor when there is no process breakdown" ↩
3. From interviews and published research, we estimated the frequency of each drop-off point relative to each other and to the total organs that are never procured or placed. This is not a more exact number because of the lack of transparent data and huge variance between OPOs. ↩
4. "The critical pathway for deceased donation," *Transplant International*, 2011. "Identification and referral of the potential deceased organ donor is one of the most critical steps in the realization of donation after death. Referral should occur when the clinical prognosis is established and the patient is either dead by neurologic

criteria, the clinical condition reveals death to be imminent, or further treatment would be futile." ↩

5. These typically come from donor hospital staff, or in very limited instances, through an electronic automated system. ↩
6. "OPTN Policies," Organ Procurement and Transplantation Network, 2019. ↩
7. Clinical triggers to refer include a ventilated patient with a severe neurologic injury and one of the following: A patient whom a physician is evaluating for brain death, or a patient with a Glasgow Coma Score (GCS) of five or less, or a plan to discuss withdrawal of life-sustaining therapies. There is a set of recommended clinical triggers, but OPOs ultimately determine the final triggers for each of their donor hospitals. ↩
8. §486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks. "An OPO must have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after cardiac death (if the OPO has a protocol for donation after cardiac death) and the requirements for hospitals at § 482.45 or § 485.643. The agreement must specify the meaning of the terms "timely referral" and "imminent death." ↩
9. "A Comparison of the Content and Quality of Organ Donation Discussions with African American Families Who Authorize and Refuse Donation," *Journal of Racial and Ethnic Health Disparities*, 2020. ↩
10. OPOs currently use closed tech systems that are not readily accessible to outside parties, even for scientific academic research. ↩
11. What is the OPTN?," *optn.transplant.hrsa.gov*. "The Organ Procurement and Transplantation Network (OPTN) is a national transplant network established by federal law (the National Organ Transplant Act of 1984) and federal regulation (the OPTN Final Rule). Currently, every transplant hospital, organ procurement organization and transplant histocompatibility laboratory in the U.S. is an OPTN member." ↩
12. One OPO using the fully-automated referral system estimated a 5%-10% increase in referrals. ↩
13. An electronic referral should make it easy for an Intensive Care Unit clinician to click a single button in the electronic medical record when a patient is at end of life, to both notify the OPTN database directly and copy its local OPO that a potential donor should be evaluated by the OPO. It is important to stress the need for good user experience

design to reduce, not add, burden on referral from the hospital staff. Electronic referral would have the added benefit of reducing time and transcription errors in organ procurement for the OPO. Staff from OPOs would also benefit from this feature, so they do not have to use tertiary systems, where manual data entry leads to the opportunity to lose or mistype data. ↩

14. "Across the community there is a consensus that this process would greatly benefit from automation between the Donor Hospital EMRs and OPO systems — if not directly into the OPTN tech system." (Link to tech doc) ↩

15. While there have been efforts to provide standard recommendations for training, these are adopted inconsistently. See Appendix E in this paper for a matrix of different donor hospital training programs: Roles and Training in the Donation Process: A Resource Guide ↩

16. "Roles and Training in the Donation Process: A Resource Guide," *HHS/HRSA*, 2000. "Donor management techniques (e.g., medications, respiratory care, fluid resuscitation) to optimize oxygenation of organs, maintain hemodynamic stability, and sustain fluid and electrolyte balance must be initiated to ensure the integrity of the organs and tissues for transplantation." ↩

17. "*We're used to doing procedures after brain death, but before brain death, we're in this weird position to get asked to do some procedures, or order some labs. It's not a very clear cut protocol of when, how, and why. I had an experience where they [OPO staff] were asking us to repeat a bunch of things [tests] that had already been done and asking us to do excessive amounts of blood work on someone, and the family hadn't actually decided that they were willing to go through this process [organ donation] yet. It does become this scenario of what we are supposed to be doing. What's required, versus what's more negotiable with a clinical reason behind it*." -ICU nurse ↩

18. "Variability of Brain Death Policies in the United States," *JAMA Neurology*, 2016. "Hospital policies in the United States for the determination of brain death are still widely variable and not fully congruent with contemporary practice parameters." ↩

19. "Our results suggest that these relationships need maintenance and/or repair. Just over half (56.4%) of the HCPs interviewed found OPO staff to be helpful or supportive, and only 8% considered them part of the hospital team. While legal and regulatory statutes mandate the involvement of OPO staff during consent for donation and subsequent maintenance of donor-eligible patients, nearly two-thirds of respondents considered OPO staff "outsiders" while some characterized them as 'bullies' or 'vultures'." Interim Results of a National Test of the Rapid Assessment of Hospital Procurement Barriers in Donation (RAPiD) ↩

20. While most hospitals have some version of a "donor council," experts we spoke to confirmed that they are broken and ineffectual. ↩

21. "Our team at the transplant center is well aware that if you make a complaint about an OPO, you're likely to get investigated yourself. The name of the game is retribution, not transparency or correction. UNOS's MPSC [Membership and Professional Standards Committee] is made up of people who work in the field, and OPOs hold serious grudges. And absolutely no one is looking out for the donor families or potential donor families." - Researcher ↩

22. Whistleblowers can file complaints at HHS Office of the Inspector General: File a Complaint ↩

23. "Despite low performance, organ collection group gets new federal contract," *Washington Post*, 2019. ↩

24. "Executive Order on Advancing American Kidney Health," *White House*, 2010. The Executive Order specifically called on HHS to make the new regs "enforceable": "Within 90 days of the date of this order, the Secretary shall propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and **enforceable objective metrics** for evaluating an OPO's performance." ↩

25. "Membership and Professional Standards Committee," *OPTN*, 2020. ↩

26. When an OPO leader was asked who they would want to take this survey and what information they would want, they said they would want the medical team nurses, techs, anyone who was working on the unit where the donor was. They would want to ask about how the OPO staff interacted with the hospital staff, how knowledgeable the OPO staff seemed, whether they learned anything from the OPO staff, and what was the quality of the engagement (friendly, non-intimidating, etc). ↩

DROP-OFF POINT #2: *WHEN AN OPO DECIDES TO NOT PURSUE A POTENTIAL DONATION*

Frequency/Size of Drop-off: **HIGH**

When a referral does come in from donor hospital staff, it is evaluated and triaged to determine whether it is a case that should be followed by the OPO. In 2018, 1.07 million

referrals were reported, ultimately resulting in 10,721 deceased donors and 29,676 transplants.[1] While not all referrals are clinically able to become donors, the OPTN itself estimated in a 2015 study that OPOs are recovering "potentially only one-fifth of the true [donor] potential" suggesting that "significant donation potential exists that is not currently being realized."[2] Researchers estimate that this is a very large drop-off point for that lost donation potential, though the exact number is unknown because of inaccurate OPO self-reporting and lack of transparent data.

"I believe a root problem is the OPTN's lack of focus on organ procurement issues. They are almost exclusively focused on ranking transplant candidates…OPOs are harassed by the OPTN for not allocating organs in proper sequence but there is no accountability for not recovering a suitable organ"

— OPO CEO

CAUSES

Third-party call center deficiencies

Referral notifications go to whichever communication center is handling the referral. The person receiving the referrals takes in basic potential donor information and triages the case. Many OPOs are utilizing paid third-party call centers as the first point of contact for referrals from donor hospitals. One OPO leader noted, *"Many OPOs subcontract the phone receiving system with non or barely qualified phone operators"* while a researcher also told us, *"There's definitely a big overlap between low performers and use of a third party communication center.."* Third party phone operators follow a set protocol[3] given by the OPO, but may not do as good of a job in making discernments and decisions requiring critical analysis as trained OPO staff.

This initial triaging is a critical step in donation. As told to us by an organ research expert, *"If you asked me where do we lose the 28,000 organs, I would say most of them are lost here, at the first set of triage. A tremendous amount of drop-off happens at this moment."*

Ruling out for non-medical reasons

Even after the first set of triage when the OPO has decided to follow the case, they may still not get to the point of approaching the family for consent. A researcher noted that OPO coordinators[4] often use a rule criteria indicating "donor patient never became brain dead" as the reason why they stopped pursuing a potential donation, but often that is because the brain death test was never conducted. As noted in a 2018 study, "The failure to formally pronounce brain death may be due to a decision to withdraw supportive care prior to discussing donation with the family or staff belief that the family is unlikely to agree to donation. This critical flaw in the definition of eligible deaths[5] fails to accurately reflect the potential donor pool within the population."[6] As one OPO coordinator told us, *"It's better for our data if MD never declares brain death"* because then the OPO does not have to count the case as an eligible donor that did not result in donation.[7]

Rather than the clinical justifications OPOs provide, researchers and OPO experts noted the actual reasons for not pursuing a potential donor to be:

- Donor's family wanted to turn off the ventilator and no one offered them the opportunity for donation
- OPO coordinator was taking too long to get to the hospital
- Hospital or OPO staff thought that the family was unlikely to donate
- OPO coordinator did not think it was a good donation prospect because the patient was marginal[8] and only had one potential organ for donation[9]
- OPO coordinator may turn away from a referral because it is deemed as a highly emotional case
- Person responding to a referral may have "recency bias" if the last few cases did not end well and may project this bias onto the current case

"Where OPOs 'determine' eligibility is a huge gap in the system. Many OPOs rule out patients that could be ruled in. Lack of training/knowledge, preconceived notions, pure laziness." - OPO COO

"[OPO] Coordinators try to talk their Administrator on Call out of doing a lot of donors because they know if they move forward then they will have to work the case for the next X number of hours." - OPO CEO

Similar to how preconceptions disproportionately affected families of color (see Inequity in Organ Donation) in regards to the initial referrals, these rule outs have resulted in health care providers (HCP) "affording black families fewer opportunities than white families to consider the donation decision with HCP or OPO staff. Black families were more likely than white families to have not spoken with an OPO representative."[10]

As another study noted, "The odds that a family of a White patient was approached for donation were nearly twice those for a family of an African American."[11]

When an organ is perceived to have some irregularities, OPO coordinators might do a "test match run" and decide the case is not worth pursuing because there are not a lot of recipients in the match list, so it may be harder to place the organ. The current technology fails to log these test match runs, which means that there is no record of the many viable referrals that never become donors.

Inadequate staffing for onsite follow-up

Even if the OPO determines that the potential donor is suitable to follow-up, the OPO may respond sub-optimally. For example, they may not show up in person (calling by phone instead) or they may follow up late, because they are not properly staffed to cover all referrals. As described by an OPO coordinator, *"This becomes detrimental especially when we're looking at donation after circulatory death. We're constantly finding ourselves behind the eight ball…By the time these families decide to withdraw care, they're done, they're emotionally and physically exhausted. And now we're asking them to wait 2.5 hours for us to get there to talk to them."*

Currently, there is no accountability for OPO coordinators to show up every time and in a timely manner, even if they have an agreement with the hospital on when they should show up (usually within an hour). OPOs often staff for the minimum need, rather than for the largest potential need. For example, we heard of an OPO that regularly only had two family care coordinators on call at a time, for a donation service area of 40+ hospitals. An ICU physician told us, *"My most recent interaction, we called them [the OPO] and said we're going to talk to the family, we think they're going to transition. We called them a day in advance, called them again in the morning, called them again in the afternoon, and they didn't show up until the evening. They'd been given more than 24 hours notice."*[12]

When inadequate staffing results in OPO coordinators not showing up onsite in a timely manner, this becomes harmful to the potential donation. *"This is another massive gap in the system and where many, many donors are lost. Coordinators don't go onsite and the management of the patient falls to the hospital/physician who is trained to provide care through death, but not after death. Being, and staying onsite is critical." - OPO COO*

An important note is that understaffing of frontline coordinators does not result from OPO resource constraint, but rather from resource misallocation. For example, audits and investigative journalism[13] [14] have found OPOs misspending taxpayer dollars on items such as retreats to 5-star hotels, private planes, and Rose Bowl tickets, as well as overly generous compensation packages for executives.[15]

POTENTIAL FIXES

Improved technology and data on what happens to referrals

Better technology could standardize how referrals are tracked to make that information more transparent for all cases, including when third-party call centers are used. Currently that data lives in OPO systems like iTransplant and are only selectively shared with CMS or OPTN auditors during infrequent audits. As part of an "OPTN tech stack" for the organ transplant technology ecosystem (see Technology Recommendations), a function could be to track all referrals from end-to-end with indicators for which organs are viable for transplant and whether test match runs were done. This information would be housed in a central data warehouse under the OPTN technical system caretaker[16] and be available to SRTR[17] and CMS for auditing. This information should also have validation points for who is reporting the data and how it is being collected for full transparency, and should be publicly available to researchers for analysis. A mandate to automatically track end-to-end data on every referral will help track trends, determine best practices, and prevent inaccurate OPO reporting.

Limit discretionary rule outs

There should be a checks and balance system for referral rule outs. Rule outs should be medically based and only be done by a clinical person, ideally a medical director or administrator on call (AOC) with qualified training. Additionally, when conducted, test match runs should clearly indicate one of two results: either "yes" there are matches, or "no," there are no matches. If there is even one potential match, the case should not be closed out because of anticipated difficulty in placing the organ.

Pursue expanded criteria donors

Along those lines, OPOs should increase their attempts to procure marginal donors (formerly known as expanded criteria donors, or ECD).[18] Studies have shown that "kidney transplantation from ECD is associated with similar rates of recipient and graft survival compared to those obtained in kidney transplantation from standard criteria donors"[19] and accepting such a kidney[20] may significantly decrease waitlist time, which results in a longer and higher quality of life when compared to remaining on dialysis.[21] The OPTN Deceased Donor Potential Study also pointed out that, "some of the unrealized potential may also be unrecognized under current practice, with organ donation not pursued due to misperceptions of the suitability for donation and concerns about impact of pursuit on performance metrics."[22] Introducing more marginal organs into the offer pool can

help normalize them to more conservative transplant programs as viable options. Often OPOs do not because they think the organ will be difficult to place, but as one researcher told us, *"OPOs don't understand that what they offer to the system affects the appetite of the transplant centers. First two years, they might have a higher discard rate, but you're shifting the appetite."*

Improve accountability for existing staff

While many OPOs need to hire more staff to respond to 100% of referrals, they also need to hold existing staff to better management and stronger accountability standards. An OPO CEO who dramatically increased the OPO's organ donation rate said, *"Hiring new staff wasn't necessary at first; accountability was the issue. Things needed to be made clear on expectations ."* Expectations include that coordinators should respond to a referral within an hour (or whatever time is set in their donor hospital agreement). Showing up, even if the case ends up not being a potential donor, is a chance for coordinators to show their face to hospital staff and do donor hospital education.

Better OPO coordinator staffing and support

OPOs should be staffing for their highest potential in a DSA, rather than the current or minimum volume. While this can be difficult because an OPO may get five potential donors in a day, and then zero donors the next week, they need to stay overstaffed to ensure that no potential organs are lost from inadequate staffing. Historical data on past referrals and national averages can be used to determine the potential at which the OPO should be staffed[23]. *"OPOs were literally saying, we have 30 coordinators, they need 80, but they can't conceptually understand that. So they go to 39 and go, wow we increased by 30%" - OPO COO*

To be able to staff adequately, OPOs need a qualified pool of candidates.[24] *"The easy answer is, well let's go get more coordinators. It's not that easy, because most people, even those in the medical field, don't know that this industry exists." - OPO COO*. OPOs and other related organizations can help expand the hiring pool by publicizing in analogous fields to attract new talent and raise awareness of OPO coordinator positions as potential career paths. As one study noted, "Given that one of the most difficult aspects of a coordinator's work is juggling the unusual hours of the job and the on-call lifestyle, prior experience in a critical care environment is perhaps the single most important background characteristic that an OPO director should look for in hiring. This could include work in an intensive care unit, an emergency department, or as a paramedic."[25]

To maintain adequate staffing, OPOs need to not only hire enough staff, but also to retain them. Studies have found OPO staff yearly attrition rates to range from 17% to

28%, with average job tenure of less than three years.[26] A study surveying coordinators representing 52 out of 58 OPOs reported a wide range in annual compensation, ranging from under $45,000 to over $100,000. This study also noted that there are other strategies for retaining coordinators beyond salary. For example, they could include benefits such as reduced number of days each month that employees are on-call and a separate pay when on-call, regardless of actually being called into service.[27]

Research suggests that "lack of any formalized training to perform their job functions likely contributes to the high rates of staff burnout and turnover"[28] and 75% of coordinators surveyed "expressed a desire for more training and education opportunities."[29] OPO coordinators should be trained in trauma-informed care for approaching difficult cases and be provided with healthy strategies for managing stress to prevent burn out. Long hours can also affect an OPO coordinator's ability to make critical decisions. We heard from a consultant who has worked with many OPOs that some coordinators who stay on longer will *"develop maladaptive behaviors to cope with that level of stress, trauma, and lack of rest."* and that *"We tend to hollow out the workforce and then complain when we have these really deplorable conditions."*

Additionally, OPOs should staff coordinators remotely outside of the main office and in the hospitals to optimize response time. Ideal are in-house coordinators at major hospitals. "The presence of an in-house coordinator (IHC) program significantly improves conversion rates for organ donation as well as organ yield."[30] [31]

NOTES

1. "OPTN/SRTR 2018 Annual Data Report: Deceased Organ Donation," *American Journal of Transplantation*, 2020. ↩
2. "OPTN Deceased Donor Potential Study ,"*UNOS*, 2015. ↩
3. The first set of triage options are typically: hard yes, hard no, escalation (to AOC, then medical director), or wait and see (becomes re-referral). ↩
4. OPOs vary in how they define the role of "OPO coordinator." We use it throughout this document to encompass the roles of OPO clinical coordinators, organ procurement coordinators, and family care/family support coordinators. ↩
5. "Patterns of geographic variability in mortality and eligible deaths between organ procurement organizations," American Journal of Transplantation, 2019. "Eligible death is an OPO-reported metric rather than a product of formal epidemiological analysis, however, and may be confounded with OPO performance…The eligible death

ratio demonstrated greater variability, with a 4.5-fold difference between the OPOs with the highest and lowest rates." ↩

6. "How Inaccurate Metrics Hide the True Potential for Organ Donation in the United States," *Progress in Transplantation*, 2018. ↩

7. "Whether it's [a referral is] imminent, eligible, or neither can change throughout the process, depending on when you close a referral out. That's how OPOs have a way to manipulate that metric. So, if there is a 74-year old that hasn't been declared brain dead, but we think the patient is brain dead, and the physician says they're not going to do brain death testing unless the family is interested in donation. Well, that patient is not eligible until that brain death testing occurs. So, you can have a conversation about donation and the family says they're not interested. Then the brain death testing never occurs to make the patient eligible, so they get dispositioned as a neither. If testing does occur, you get put in a position where you have to get authorization or your conversion rate is damaged." - OPO CEO ↩

8. "Kidneys from marginal donors: views of patients on informed consent," *Nephrology Dialysis Transplantation*, 2002. "The concept of marginal donors includes older organ donors, donors with complicating diseases, non-heartbeating donors and sometimes infants. There is no standard definition." ↩

9. In a letter from AOPO to OMB: "OPOs "game" the process of meeting the [metrics] by only targeting "high-yield" organ candidates." And "the OPO is incentivized (for fear of being decertified) to not pursue, or even evaluate the potential for donation of these types of donors [with only 1 or 2 organs available]. This practice results in fewer organs being transplanted, and more lives lost." Meeting Record, obamawhitehouse.archives.gov ↩

10. "Comparison of black and white families' experiences and perceptions regarding organ donation requests," *Critical Care Medicine*, 2003. ↩

11. "The influence of race on approaching families for organ donation and their decision to donate." American Journal of Public health, 1999. ↩

12. Internal OPO documents have noted similar cases: An ICU physician is documented as "He states it was very difficult to get in touch with the OPO. He stated he then called to let the OPO know that declaration was occurring and he was told that the OPO did not have any staff to send." ↩

13. "Taxpayers help pay for organ donor groups' parties, Rose Parade expenses," *Trib Live*, 2013 ↩

14. "Review of OneLegacy's Reported Fiscal Year 2006 Organ Acquisition Overhead Costs and Administrative and General Costs," *HHS/Office of Inspector General*, 2010. ↩

15. "Gift of life worth millions to donation organizations,"*Trib Live*, 2013 ↩

16. "The current "transplant tech ecosystem" contains many disparate systems that each handle their own data. A better solution would be to build a Data Warehouse as a Single Source of Truth (SSoT) with the OPTN technical system caretaker." (link to tech doc) ↩

17. "The Scientific Registry of Transplant Recipients: SRTR," srtr.transplant.hrsa.gov. "Scientific Registry of Transplant Recipients (SRTR) supports the ongoing evaluation of solid organ transplantation in the United States. SRTR designs and carries out data analyses and maintains two websites to disseminate organ transplant information." ↩

18. "Expanded Criteria Donors," *UC Davis Transplant Center*. "Expanded criteria donor (ECD) is any donor over the age of 60, or a donor over the age of 50 with two of the following: a history of high blood pressure, a creatinine (blood test that shows kidney function) greater than or equal to 1.5, or death resulting from a stroke." ↩

19. "Outcome of Kidney Transplantation from Expanded Criteria Deceased Donors," *American Society of Nephrology*, 2017. ↩

20. "Many donor kidneys that are discarded may be suitable for transplantation," Transplantation, 2017. ↩

21. "Expanded Criteria Donors," *UC Davis Transplant Center*. ↩

22. "OPTN Deceased Donor Potential Study," *UNOS*, 2015. ↩

23. One high performing OPO we spoke to said there is no exact equation for coordinators to donors ratio, since the condition of the potential donor and the time available to approach a family can be highly variable. They suggested that OPOs could come up with an acquity score calculation that determines how much staffing resources might be needed for each case. ↩

24. "Given that one of the most difficult aspects of a coordinator's work is juggling the unusual hours of the job and the on-call lifestyle, prior experience in a critical care environment is perhaps the single most important background characteristic that an OPO director should look for in hiring." Improving the Recruitment and Retention of Organ Procurement Coordinators: A Survey Study ↩

25. "Improving the Recruitment and Retention of Organ Procurement Coordinators: A Survey Study," *The American Society of Transplantation*, 2009. ↩

26. *ibid* ↩

27. *ibid* ↩

28. "Communicating Effectively About Organ Donation," *Transplantation Direct*, 2015. ↩

29. "Improving the Recruitment and Retention of Organ Procurement Coordinators: A Survey Study," *The American Society of Transplantation*, 2009. ↩

30. "In-House Coordinator Programs Improve Conversion Rates for Organ Donation," *The Journal of Trauma: Injury, Infection, and Critical Care*, 2011. ↩

31. "Spain model: World leaders in organ donation," *The Journal of the American Medical Association*, 1999. Spain, which leads the world in organ donation, has a national integrated system where organ donation is the responsibility of the hospital. ↩

DROP-OFF POINT #3: *WHEN AN OPO DOES NOT OBTAIN FAMILY AUTHORIZATION*

Frequency/Size of Drop-off: **MEDIUM/HIGH**

Family authorization rates can vary widely from OPO to OPO, with even the national authorization rate average ranging based on different analysis and sources. A 2015 study of 2008-2013 data found authorization rates ranging from 63.5% to 89.5%[1] while other studies estimated between 65%[2] to 75%[3] on average nationwide. Accuracy of these authorization rates is questionable, however, because OPOs self-report their rates. As an OPO CEO noted, *"If an OPO is reporting a 90% authorization rate, I would be worried about how often they are actually approaching."*

Regardless, this is one of the most fixable drop-off points because 80% of families report that they would have donated if they had been approached correctly.[4] When we have seen OPOs dramatically improve their organ transplant rate with new leadership, the new leadership's focus always included improving family authorization rates.

CAUSES

Poor timing/poor interaction

Problematic OPO approaches to family, such as approaching at the wrong time or having a poor quality of interaction may lead to families declining authorization.[5] The likelihood of wrong time and poor interaction is exacerbated if OPO staff is not coordinating with hospital staff. Studies have shown that "initial receptivity to organ donation may reflect the family's experience with the hospital healthcare team prior to the donation request…These results reveal the association between the donation decision and the coordination between HCPs and OPO staff."[6]

Best practices for approaching families as documented in several sources[7] are not always followed. For example, the OPO coordinator may not come in-person, may not be sensitive to cultural or religious issues, may not educate family about misconceptions, may not cover critical topics in their discussion with the family, or may not spend adequate time with the family. "Previous studies found] that when referred, African American (AA) families report less complete discussions about the possibility of organ donation and are often not told of the need for transplantable organs within the AA community."[8]Additionally, because it is an overwhelming time for many families, some may need to be approached multiple times, thus some coordinators may give up too early on obtaining authorization.

Poor training and support for requestors

Currently there is no central source of truth or training for coordinators requesting authorization from a donor's next of kin. We have heard of only one masters program in the country (at University of Toledo[9]) that provides accredited training on how to become an organ donation coordinator.[10] There are smaller programs from different OPOs[11] and associations, and a certificate[12] that is not required to be hired as a coordinator. One OPO leader told us, *"There's no real specialized training. There's one Masters program in Toledo. So, they self-train…right now [OPO coordinator training] is disjointed, it's sporadic. There's no good training program in the country that I would endorse."* While a former OPO coordinator said, *"Training keeps getting worse and worse… there's no standard training, it's very subjective. There's the CPTC [certification program][13] but you don't even need to do it to be a coordinator. They're setting people [OPO staff] free before they're really ready."* Other studies have also spoken to this need, "Standardized training for organ donation request staff is needed to ensure the highest quality communication during requests, optimize rates of family authorization to donation in all regions, and increase the supply of organs available for transplantation."[14]

Poor coordination with hospital staff

When OPO staff does not coordinate with hospital staff, it can be detrimental to family authorization rates and to the long term working relationship between the OPO and the hospital. One study reported that "the majority of HCPs continue to view OPO staff as outsiders rather than part of the healthcare team. A multidisciplinary request protocol involving both HCPs and OPO staff in family donation conversations has proven effective in increasing rates of organ donation."[15]

When the coordination does not happen, OPOs remain as "outsiders" and can adversely affect the end of life care planning that the hospital staff already has in play, resulting in a poor interaction with the donor family. We heard from hospital staff, *"We have a terrible*

relationship with the OPO - they don't come in until the end... Steamrolling in talking to the family when they think it's the right time. Often it's after we've already set up a game plan... they jump in and take over...we don't even know who they are." This has further ramifications, as we heard from one donor hospital physician, *"A lot of my coworkers are not donors because of how terrible the process is at our hospital...the Palliative Care Director is not a donor because of the number of times [the OPO] really ruined end of life care."*

Not utilizing data

Lack of benchmarking data can lead to lack of motivation to improve, because OPO staff could be unaware of how they compare to other OPOs, including being unaware that they may have significant room to improve. One OPO leader who increased organ recovery at their OPO by nearly 30% in their first year as CEO used data to benchmark where their OPO was and shared with their staff that they were in the fourth quartile for authorization and conversion of donors. The staff at that OPO said they did not know they were that bad. There needed to be awareness of the problem before it could be addressed. Similarly, when data are not used to understand the demographics of an OPO's DSA, it is a missed opportunity for the OPO to staff and train coordinators better to approach donor families of those demographics.

POTENTIAL FIXES

Better training for requestors

There needs to be standardized training of OPO coordinators on best practices for approaching donor families for authorization.[16] [17] Research indicates that the factor most likely to predict whether a family will donate is whether the OPO coordinator showed sensitivity and compassion to the family and did not pressure them to donate.[18] Research also shows the critical need for initial training for staff involved in these conversations, even as there are no national standards that mandate these trainings.[19] Such training could focus on already-established best approach practices, including:

- Separating requests for organ donation from declaration of death[20]
- Effectively communicating[21] [22] with the family - including initiating the request in an empathic manner, acknowledging the loss of the patient, covering key topics,[23] developing a supportive trust-based relationship, and providing closure to the family.
- Timing is also crucial to making effective requests. When families perceive that the request was made at the appropriate time, they are more likely to consent.

In addition to best approach practices, requestors should undergo explicit and implicit bias training, as research has shown that implicit bias is a factor in donor family approaches. "There is also evidence of implicit bias, i.e., the extra-conscious beliefs or attitudes toward individuals by virtue of some 'irrelevant characteristic,' that permeate discussions of organ donation with African American families about the opportunity for donation while in hospital."[24] [25]

Spend more time with donor families

A clear strategy to increase family authorization is to enable OPO coordinators to spend enough time with donor families - particularly ensuring that families of color receive the same compassionate time and treatment. Research shows that family decision makers "from regions with the highest authorization rates reported the longest discussions about donation with their respective OPO requesters"[26] and that "Families who had two-thirds more contact with OPO staff were 3 times as likely to donate irrespective of other factors."[27]

Hiring appropriate OPO staff

Previous drop off points discussed the need for OPOs to hire the appropriate *number* of OPO staff, but they also need to hire the *right people* in their staffing. As one OPO leader told us, "*Demographics is important. You have to make sure you're talking the right language and talking to the right people…We consciously did an org chart review and we matched it to our demographics and by zip code, by hospitals, by interactions.*" Studies have shown that OPO staff is overwhelmingly white and female, which does not accurately represent all the potential donor families the staff is approaching.[28] "At least one study[29] has shown family authorization rates for organ donation are higher for African Americans when the OPO staff discussing donation are also African American, but the majority of OPO staff continue to be Caucasian…These results [of lower AA authorization rates] emphasize the critical need for culturally appropriate communication skills to be deployed with African American families throughout the organ donation conversation."[30]

Not only race and sex, but language is also a factor to consider for staffing.[31] Staff should also reflect language demographics of the DSA, given that "avoiding translators during the approach process may improve donation rates."[32] We heard of one example of an OPO that had a large Spanish-speaking population in the DSA, yet 9 out of 10 staff members could not speak Spanish.

One OPO leader told us that not only do OPOs need more diversity in their frontline staff, but also in their leadership. To get to this, diverse staff needs to be developed to take on

more leadership roles. *"Leadership and clinical teams at OPOs tend to be overwhelmingly, shockingly White. Black folks donate when the OPO provides optimal care for Black families. And serving communities of color isn't hiring a single token representative to work in PR or community outreach…it's growing representation in all ranks of leadership for the communities of color your OPO serves." -Researcher*

Coordination with hospital staff on approach

Regular coordination between the OPO and hospital staff helps ensure communication and better integration of the ethos of saving as many lives as possible through organ donation. Hospital staff can assist with preparing families for the approach, and may even help with the authorization[33] if they are involved in the OPO's planning. One donor hospital physician noted that at a previous hospital she worked at that had a good relationship with their OPO, the OPO staff would always come to the hospital staff first to ask, "when would be a good time and who should we approach?" This would enable the physician to say, "I think they'd be a great candidate, I don't know where the family's at but I plan on talking to them in a little bit. If you're here, I can allow you to come in towards the end of the meeting, etc."

"Physicians are trying to keep their patient alive, so sometimes a death is perceived as a failure…How can we make this tragic negative turn into something more positive…have a bit of a silver lining. When we remind them of that, it becomes less of the old mentality that oh, the grim reaper is here, the vultures are here. It's, these are our partners/trusted colleagues who we know won't talk with the family until the time is appropriate. Establishing those relationships are absolutely key."

- OPO Coordinator

The responsibility for building relationships and educating donor hospitals often falls exclusively to a "Hospital Development Coordinator," however, the responsibility should extend to all OPO staff who come onsite at a hospital. A donor family approach should not be the first time the hospital staff meets an OPO coordinator. As an OPO leader told us, high performing OPOs know that *"Organ donation should NOT be transactional. OPOs can't show up only when there's a donor. OPOs have to have a relationship [with the donor hospital] BEFORE there's a donor." (paraphrased)*

Strong leadership and use of data

Changes in OPO leadership have often resulted in dramatic increases in organ donation rates. "After the Washington OPO hired a new CEO in 2010 and the Oklahoma OPO hired a new CEO in 2012, donors doubled. In 2017, the South Carolina OPO hired a new CEO and saw a 40% increase in donors, and San Francisco, California, increased donors by nearly 30% within 1 year after a new CEO was hired. These numbers far outpace the corresponding overall national increase in donors from the opioid epidemic."[34]

These leaders have increased donors by focusing on shifting culture within the organizations, using data to better understand community demographics, and aligning all efforts towards procuring and placing organs. One OPO leader said, *"I looked at every area of our organization and how it's functioning. We were not aligned with our mission: every donor, every time. There were processes and procedures in place that blocked our mission to save every life possible. "*

One example of building culture to improve organ recovery we heard was, *"The family authorization piece is the number one thing we focused on. We had a system where we would actually notify all the staff that we had a family authorization pending…So even if you're in accounting, you know that someone's down in the hospital talking to a family. We wanted this to be in their DNA. This is what we do. This is the moment. The person talking to family knows that everyone's supporting them at the home office and we're all in this together…We saw our family authorizations go through the roof."*

NOTES

1. "Increasing the Number of Organ Transplants in the United States by Optimizing Donor Authorization Rates," *American Journal of Transplantation*, 2015. ↩
2. "Communicating Effectively About Organ Donation," *Transplantation Direct*, 2015. ↩
3. "Ethics of deceased organ donor recovery," *OPTN*, 2016. ↩

4. According to a well-published researcher who analyzed organ donation opinion polls and behavioral data. ↩

5. "You can flatly approach someone, and they will flatly say no. Or you can empower and inspire them. It's a science, you have to study, you have to be prepared, you have to know your audience. It's all about the approach. All of our approaches, as much as possible, should be planned. That's why I have authorization coaches who can help identify things that could thwart the 'yes.' Buddhist people have different things that they want done, but will still donate. Muslim families will donate, but they need certain things done within 24 hours. This is our job to know these things. The things that I'm doing are not rocket science. I'm just being sensitive to people's needs. It's being inclusive. People say 'whoa, what are you doing to get those results?' And I laugh and I say, it's just responding to people's needs. It's hard work, but it's completely doable. I don't want people to think I'm doing something no one else can do. I'm not. It's just customer service. But a lot of OPOs wouldn't do that. They would bring up all kinds of excuses." - OPO CEO ↩

6. "A Comparison of the Content and Quality of Organ Donation Discussions with African American Families Who Authorize and Refuse Donation," *Journal of Racial and Ethnic Health Disparities*, 2020. ↩

7. "Regional Differences in Communication Process and Outcomes of Requests for Solid Organ Donation," American Journal of Transplantation, 2017; "Communicating Effectively About Organ Donation," *Transplantation Direct*, 2015; "Education Corner ," *The Alliance*; "Factors Influencing Families' Consent for Donation of Solid Organs for Transplantation," *The Journal of the American Medical Association*, 2001; Fast Facts And Concepts #79: Discussing Organ Donation With Families ," *Palliative Care Network of Wisconsin*, 2015; and more ↩

8. "Comparison of black and white families' experiences and perceptions regarding organ donation requests," *Critical Care Medicine*, 2003. ↩

9. "Human Donation Science Master's Programs," *University of Toledo*. ↩

10. "University of Toledo program trains organ donation coordinators," *The Blade*, 2018. ↩

11. Gift of Life Institute (Philadelphia OPO) ↩

12. "How to Become an Organ Procurement Coordinator," *RegisteredNursing.org*. ↩

13. "Certification Examinations," *American Board for Transplant Certification*. ↩

14. "Regional Differences in Communication Process and Outcomes of Requests for Solid Organ Donation," American Journal of Transplantation, 2017. ↩

15. "Interim Results of a National Test of the Rapid Assessment of Hospital Procurement Barriers in Donation (RAPiD)," *American Journal of Transplantation*, 2012. ↩

16. "Consent to organ donation: a review," *Progress in Transplantation*, 2013. ↩

17. "Communicating Effectively About Organ Donation: A Randomized Trial of a Behavioral Communication Intervention to Improve Discussions About Donation," *Transplantation Direct*, 2015. ↩

18. "Regional Differences in Communication Process and Outcomes of Requests for Solid Organ Donation," *American Journal of Transplantation*, 2017. ↩

19. *ibid* ↩

20. A researcher noted, "The best way to do this, however, is to start the discussion early, before the formal declaration of death is made. The OPO or hospital staff will often tell the family that the patient is dead, and then 2 minutes later ask about donation. They think this is separating the request from the declaration of death. The better way to do it is to not see the 'request' as a single event but as a conversation that starts when there's a real possibility that the patient will not survive and is or will probably become brain dead." ↩

21. "Consent to organ donation: a review," *Progress in Transplantation*, 2013. "Effective communication during requests involves 5 key tasks: (1) initiating the request in an empathic manner with the appropriate introductions, role clarifications, and an acknowledgment of the loss of the patient; (2) soliciting family and patient information by using clear, open-ended questions while avoiding interruptions; (3) soliciting the family's perspectives and beliefs about organ donation and the patient's donation wishes; (4) developing and maintaining a supportive, trust-based relationship with the family that includes addressing concerns and questions with sensitivity and providing information underscoring the benefits of donation; and (5) providing closure by summarizing the family's position regarding donation, outlining the next steps in the process, and expressing gratitude for the family's time and consideration of donation." ↩

22. "A Comparison of the Content and Quality of Organ Donation Discussions with African American Families Who Authorize and Refuse Donation," *Journal of Racial and Ethnic Health Disparities*, 2020. "This included the OPO requester using higher levels of relational and effective communication skills such as listening carefully to the FDMs, taking their concerns seriously, being responsive to these concerns, giving FDMs enough time to discuss important issues, checking in with and summarizing their understanding about donation, encouraging FDMs to continue talking, responding to strong emotion with sensitivity and empathy, and offering additional services or assistance. This is consistent with prior studies showing a positive relationship between high quality communication skills and donation behaviors in other populations." ↩

23. "Factors Influencing Families' Consent for Donation of Solid Organs for Transplantation," *The Journal of the American Medical Association*, 2001. Key topics to assuage potential concerns include: "Topics correlated with consent to organ donation were the costs of donation, the impact of donation on funeral arrangements, disfigurement of the body, and assurances that the family had a choice about which organs to donate." (There are no donation costs for the family, but this is often a concern.) ↩

24. "A Comparison of the Content and Quality of Organ Donation Discussions with African American Families Who Authorize and Refuse Donation," *Journal of Racial and Ethnic Health Disparities*, 2020. ↩

25. "I always hear that Black American's don't donate, that's not true. I was born here as a Black American. We have to keep in mind what Black Americans have gone through the decades. You need experts and people who look like me to talk to these families. There's a lot of things that might lead to distrust or being offensive." - OPO leader ↩

26. "Regional Differences in Communication Process and Outcomes of Requests for Solid Organ Donation," *American Journal of Transplantation*, 2017. ↩

27. "Factors Influencing Families' Consent for Donation of Solid Organs for Transplantation," *The Journal of the American Medical Association*, 2001. ↩

28. "Communicating Effectively About Organ Donation: A Randomized Trial of a Behavioral Communication Intervention to Improve Discussions About Donation," *Transplantation Direct*, 2015. ↩

29. "The impact of race on organ donation authorization discussed in the context of liver transplantation," *Transactions of the American Clinical and Climatological Association*, 2012. ↩

30. "A Comparison of the Content and Quality of Organ Donation Discussions with African American Families Who Authorize and Refuse Donation," *Journal of Racial and Ethnic Health Disparities*, 2020. ↩

31. "Improving organ donation rates by modifying the family approach process," The Journal of Trauma and Acute Care Surgery, 2014. "Variables such as race and sex of OPO representative and time of day should be considered before approaching a family for organ donation. Avoiding translators during the approach process may improve donation rates." ↩

32. "Improving organ donation rates by modifying the family approach process," The Journal of Trauma and Acute Care Surgery, 2014. ↩

33. OPOs have the discretion to confer some hospital staff as "designated requestor" as they deem appropriate. ↩

34. "Fixing Organ Donation: What Gets Measured, Gets Fixed," *Jama Surgery*, 2020. ↩

DROP-OFF POINT #4: *WHEN AN OPO FINDS AFTER TESTING THAT ORGAN IS NOT VIABLE*

Frequency/Size of Drop-off: **LOW**

Researchers and OPO staff we talked to estimated that this is a low drop-off point[1] relative to other drop-off points. The important note here is that there is a lot of discretion afforded to OPOs at this point, which is problematic in the broader context of a lack of transparency, accountability, or regulatory pressure to improve. OPOs can each have their own definition of viability (suitability and transplantability) when they start this testing.

CAUSES

Primarily clinical reasons

Organs can be deemed non-viable for a number of clinical reasons. One interviewee provided an example of how this can look:, *"We had one of those last week, the patient was going into multi-organ system failure, secondary to septic shock. We took a run at the case to see if we could turn anything around using current practices. We spent 24 hours managing, I ended up going onsite the next day ... but the patient's liver was still failing... unfortunately it didn't become realistic to continue moving forward."*

Poor clinical donor management

Sometimes the condition of the organ is related to clinical donor management.[2] Transition of care for deceased donor management can be messy and confusing if the OPO and hospital staff do not have a clear protocol. Previous research has stated, "a collaborative effort between the nurse and the procurement coordinator will help maintain the stability of the donor's condition and contribute to timely completion of diagnostic studies."[3]

POTENTIAL FIXES

Measures to make organs more transplantable

There are measures that can be taken to make an organ more suitable for transplantation, but not all OPOs carry out these efforts consistently. For example, an organ can be perfused to improve functionality to take a non-transplantable organ and make it transplantable. *"Donor management needs to be standardized and outcomes evaluated. Most OPOs do not participate in the donor management goals workgroup.*[4] *Most OPOs blow it off." - OPO CEO.*

Clinical donor management training

In addition to education for hospital staff, key OPO roles such as the medical directors and administrators on call should undergo standardized deceased donor management training. As we heard from a former OPO coordinator, *"Medical directors don't have training on donor management. They sometimes treat them like they're a live patient. It is totally different."*

NOTES

1. "I would say less than 5%, a lot of those big factors we're going to catch in the beginning." - OPO Coordinator ↩
2. "Roles and Training in the Donation Process: A Resource Guide," *HHS/HRSA*, 2000. Clinically managing the donor body to keep organs viable. "A study by Hauptman and O'Connor (1997) noted that without aggressive support, cardiac arrest occurs in 20 percent of potential donors within 6 hours after the declaration of brain death and in 50 percent of donors within 24 hours." ↩
3. *ibid* ↩
4. "The Impact of Meeting Donor Management Goals on the Number of Organs Transplanted per Expanded Criteria Donor," JAMA Surgery, 2014. ↩

DROP-OFF POINT #5: *WHEN AN OPO DOES NOT PLACE AN ORGAN WHILE IT IS STILL VIABLE*

Frequency/Size of Drop-off: **MEDIUM**

OPOs use the UNOS organ offer technology to generate a match list between the organ and recipient candidates on the waitlist. OPOs are responsible for going down this list to manage organs offers[1] until the offer is accepted. Ideally every organ from a donor would have an accepted match before it is surgically removed, but that is often not the case.[2] When that happens, OPOs are running against the clock because of how long the organ is outside the body. As one OPO leader told us, *"Organ placement can take forever – many times it is the commitment of the coordinator doing the allocation that drives whether the organ gets placed. Many OPOs 'try' locally/regionally – going through the list but if it 'gets too hard' they give up and the organ is lost."*

How often this happens varies depending on organ type and OPO practices. As reported to the OPTN in 2018, 19% of kidneys, 21% of pancreases, 8% of livers, 3% of intestines, 1% of hearts, and 7% of lungs were recovered for transplant but not transplanted.[3] OPO experts we spoke to said they believe not placing the organ in time is the largest point of organ discard for the remaining drop off points.[4]

CAUSES

Bad organ offer technology

DonorNet interface is difficult to use and presents information in a way that can discourage organ acceptance by disregarding behavioral biases and placing a large cognitive burden on transplant surgeons.[5] As a result 84% of all kidney offers are declined by transplant centers on first offer because of organ or donor quality concerns, patient-related factors, logistical limitations, or other concerns.[6] Additionally, the waitlist is not updated properly, resulting in 17% of transplanted kidneys getting offered to at least 1 deceased patient.[7] This is not only bad technology practice, but it also wastes time and contributes to discards[8]. A researcher has framed this as, *"The offer has never made it to a patient who CAN accept it. What tends to happen is that sick people*

get offers for organs that they can't tolerate because they're too sick already. They'll have too many complications. There IS a patient for that organ, but an offer never makes it to a patient who can accept the organ."

Ineffective use of time working through the match list

Several decision loops occur during the placement process. After doing the match run to get a match list, an OPO can notify up to 3 transplant programs (for an unlimited number of corresponding waitlist recipient candidates) on the list that there is a potential match. For each recipient candidate, transplant centers have an hour to acknowledge the provisional offer, then an hour to evaluate the offer and put in their provisional yes or refusal code. We have heard that transplant centers will often say yes to the provisional offer, even if they have not fully evaluated the offer and use this as a way to "hold" their place in line. This provisional offer is meant to save time by removing recipients who are not interested, but because it is not used properly, it wastes time when the primary offer comes around because only then will some transplant centers start the evaluation process.

The primary offer is given to one recipient on the list at a time, and transplant centers have one hour to respond. The offer does not automatically close after an hour, however, so transplant centers may take more than the allotted hour to respond, which eats up time and contributes to discards if they ultimately refuse the organ.

Additionally, transplant centers may ask for more tests to be done before responding to an offer. While OPTN policy does list some labs that must occur before offers are made, because of the wide range of potential donor conditions, there are some tests that are not mandated, yet are often still needed by transplant centers to make an offer decision, such as a cardiac catheterization or chest computed tomography (CT) scan. Some OPOs are less proactive about performing these tests before the match run as a perceived cost saving measure, which can waste valuable time.

UNOS Organ Center inadequacies

UNOS Organ Center is responsible for kidneys that need to be placed nationally, and pancreata that need to be placed regionally or nationally. We heard from multiple people in the OPO industry about how slow, inefficient, and unaccountable the UNOS Organ Center can be.

One former OPO coordinator told us, *"When I was placing organs, I would have 3 phone calls out at once, not wasting a minute…The UNOS [Organ Center] people don't have that urgency. They sit at their desk, they make their call, they go to the next one. They don't*

have 5 calls out, they don't call ahead to an aggressive transplant center…The good OPOs, they are on it, they don't waste a minute and they'll do some of UNOS' work for them. UNOS [Organ Center] people are non-clinical people with no emotional tie to the case."

Another OPO expert highlighted, *"The UNOS Organ Center is so bad at this [placing organs]. I'm fighting with them on the phone, tell them you made a mistake, call the transplant center back, while I have a doctor yelling in my other ear. It is horrendous.* ***There is no external check on the quality of UNOS' own internal allocation system****…Any miscommunication or loss of communication can add enough cold-ischemic time [for the organ to become non-viable].* ***We have no visibility into how often this happens because only UNOS can report that to UNOS****."*

POTENTIAL FIXES

Better organ offer technology

The following changes in the organ offer technology could help increase transplant center acceptance:

- Provide assisted clinical decision making[9] [10] by showing users the probability of how long it might take for their patient to get a better organ offer,[11] or the value of this accepting the kidney over their patient staying on dialysis.

- Stop showing how many other transplant centers have rejected the offer in order to mitigate for risk-aversion.
- Automatically sync data between the waitlist, death registry, and other sources for death data to ensure offers are not made to deceased patients.
- Update the provisional and primary offer notification system to modern standards[12] to ensure transplant centers can see the most pertinent information as soon as possible. These are functions that can be built into the "OPTN Tech Stack" as part of the Organ Transplant Technology Ecosystem *(link to tech doc).*

More comprehensive testing done earlier

OPOs should be proactive in getting all reasonable tests done to discover any major issues before offers are made. To avoid time wasted on the back and forth, standards for which donor patient criteria should mandate which tests should be set by a nationally respected, third party entity. One OPO CEO said he believed that OPOs should take the approach of, *"Let's proactively get all these tests done and put all the info out there, then make our offers."*

Virtual crossmatching

A reliance by some OPOs on physical (rather than virtual) crossmatching means that an OPO will sometimes draw several vials of blood from a donor in front of their family before the family has even authorized donation. Moving to virtual crossmatching[13] means that one vial of blood can be drawn after donor authorization with the family, and that blood can be virtually matched with all patients on the waitlist, which greatly increases the transplant center's ability to quickly accept an organ offer.[14]

More persistent matching/placement

As one OPO leader told us, *"Our philosophy has always been that there is a home for every organ...and we HAVE to place EVERY organ. Not all OPOs share this philosophy."* This is an approach that all OPOs should have for every case. In order to do this, OPOs need to get to know and establish good relationships with all their transplant centers, so that they are aware of who is more likely to accept what types of organs. One leading OPO said, "We sent an Advanced Practice Registered Nurse to every transplant center in our new allocation area," which speaks to the persistence and resources some OPOs will put into establishing relationships with their transplant centers.

Since the organ offer match run technology is inefficient, OPOs with high placement metrics have surgeons available they can call to expedite an organ at risk of discard. Additionally, the UNOS Organ Center should be held accountable for their organ placement by a third-party that is not the OPTN, since UNOS runs the OPTN. Their metrics and outcome performance data should be made publicly available along with all other OPOs' data.

> "You are effectively incentivized to discard [the organ] or not pursue. Working hard to place the organ with a transplant center that will take it is not rewarded. The frustrating thing is you can spend hours justifying expedited placement, whereas just walking away is not questioned."
>
> - OPO CEO

NOTES

1. For kidneys and pancreases, OPOs are responsible for local and regional matches, for national matches it goes to the UNOS Organ Center. ↩
2. A donor could provide up to 8 organs that need to be matched to potentially 8 different recipients at 8 different transplant centers. This can become a massive coordination effort in both timing and geography. ↩
3. "OPTN/SRTR 2018 Annual Data Report: Deceased Organ Donation," *American Journal of Transplantation*, 2020. ↩
4. "Why So Many Kidneys Are Discarded: An Analysis of 36,700 Discards," *KidneyNews.org*, 2018. This analysis found that between 2000 and 2015, 14.6% of kidney discards were because of "inability to locate a recipient." ↩
5. "Increasing Kidney Transplant," *Core77*, 2020. ↩
6. "Association Between Declined Deceased Donor Kidney Offers and Candidate Outcomes," *JAMA Network Open*, 2019. ↩
7. "Kidney transplant offers to deceased candidates," *American Journal of Transplantation*, 2018. ↩
8. "Many donor kidneys that are discarded may be suitable for transplantation," *American Society of Nephrology*, 2017. ↩
9. "Increasing Kidney Transplant," *Core77*, 2020. ↩
10. "If I receive a kidney offer, part of my decision-making will be contingent on how long it will take for the kidney to arrive to my center. Often times, I am looking at flight plans and google maps to figure it out myself." - Transplant Surgeon ↩
11. "Many who die waiting for a kidney had multiple offers, study finds," *Science Daily*, 2019. "In some cases, a decline may have been the right decision, but our data suggest that many others probably would have been better served if their transplant center had accepted one of the offers...Of the 280,041 patients who received at least one offer, 30% (approximately 85,000 people) either died on the waitlist or were removed from the waitlist before receiving a kidney." ↩
12. "Digital Services Playbook," U.S. Digital Service ↩
13. "A Virtual Crossmatch-based Strategy Facilitates Sharing of Deceased Donor Kidneys for Highly Sensitized Recipients," *Transplantation*, 2020. ↩
14. To aid in virtual crossmatching, transplant centers need to also keep results of their patients ready for virtual crossmatching. One OPO aids this effort by keeping virtual crossmatch results for all patients in their local coverage area. The system of virtual

crossmatching should ideally be integrated into the organ matching technology so that a donor and candidates labs can be shown compared at the time of offer. ↩

DROP-OFF POINT #6: *WHEN AN OPO FAILS TO RECOVER ORGANS IN A TIMELY MANNER OR AN ORGAN IS FOUND TO BE NON-VIABLE AFTER RECOVERY*

Frequency/Size of Drop-off: **LOW**

Between when an organ offer is accepted and when the organ is transplanted into a recipient candidate, there are still potential failure points that could result in the organ not being transplanted. While these drop-off points do not occur frequently, they could often be avoided altogether.

CAUSES

Failure to secure OR and surgeon in time

OPOs may have difficulty securing an operating room and/or surgeon, so it takes them a long time to get in to recover the organs. This could come up against (real or perceived) family time constraints, especially for DCD deaths. A Washington Post investigation reported that a potential donor's mother "said she was 'devastated' when the OPO told her they couldn't find a match for her daughter's organs. She was stunned to learn later about the dispute over a surgeon…"If they needed more time to find one, we would have agreed to give them more time. They didn't ask."[1] Donor families are sometimes given unrealistic expectations by the OPO coordinator of how long the process might take and start to get anxious about wanting the process to draw to a close.

Mistrust for remote recovery

The recovery[2] of the organs from a donor needs to be sequenced and may need to accommodate several different surgeons in one operating room.[3] Currently, transplant center surgeons will often fly in to personally recover the organ that they will be

transplanting. There is a lack of trust for the local team to do the recovery, less so because of surgical error, but because of the decision making that is needed to make the final determination of whether the organ is transplantable. Once the organ is surgically removed from the body, it can reveal certain information that cannot be determined by labs beforehand.

POTENTIAL FIXES

Hospital agreements and setting family expectations

As discussed in earlier drop off points, OPOs need to establish good working relationships with their donor hospitals and transplant centers, which can help facilitate easier access to operating room times and surgeons. OPOs could even set up operating room time and surgeon agreements into their contracts if this issue persists. OPO coordinators need to set more realistic expectations with donor families about the variability of how long the matching and recovery might take (e.g. that it may take 3 days, rather than one day).

Local recovery teams

Some OPOs have their own recovery teams — trained surgeons or other certified clinicians who are on staff. Other OPOs rely on their local transplant surgeons to do the recovery. Surgeons who do not recover their own organs often ask who is doing the recovery, and OPOs should have back-up surgeons available whenever possible in case the accepting team is not available.

Certain technology like Google Glass can give transplant surgeons good visuals into the organ so that they can make their own call on whether it's transplantable, regardless of whether they were the ones doing the recovery. Imaging is an important aspect of the decision making. As one OPO coordinator told us, *"COVID is forcing them [transplant surgeons] to trust other procurement surgeons,"* which could open up possibilities for this to become normalized in the future.

NOTES

1. "Lives Lost, Organs Wasted," Washington Post, 2018. ↩

2. "Organ Recovery Procedures," *Iowa Donor Network*. Sometimes the term "procurement" is used interchangeably to mean surgical removal of organs. We will be using the term "recovery" in this paper to avoid confusion with our use of the term "procuring" to mean securing and getting authorization for donation. ↩
3. "LifeGift Organ & Tissue Donation Resource Manual," *Lifesource*, 2008. ↩

DROP-OFF POINT #7: *WHEN AN OPO FAILS TO TRANSPORT AN ORGAN TO ITS DESTINATION IN A TIMELY MANNER, OR IF ON ARRIVAL THE ORGAN IS UNSUITABLE FOR THE INTENDED RECIPIENT*

Frequency/Size of Drop-off: **LOW**

Analysis by Kaiser Health News (KHN) and Reveal from the Center for Investigative Reporting found that, even from the small subset of kidneys placed by the UNOS Organ Center, "between 2014 and 2019, nearly 170 organs could not be transplanted and almost 370 endured 'near misses,' with delays of two hours or more, after transportation problems."[1] For organs handled by the UNOS Organ Center, KHN reported 7% of those shipments encountered transportation problems - meaning this failure happens several times each month. One OPO coordinator we spoke to estimated this drop-off point to be about 10%. We don't know how often organ damage from transportation issues occurs across all OPOs because of lack of transparent data, but it should be a never-event and can be mitigated.

"The real issue, in a time when we can track our tube of toothpaste from Amazon in real-time, is where organs are. Giving the organ to an unreliable courier at 2:30am and feeling confident that it's going to be safe, protected, and taken directly to the destination...that's the real issue." - OPO COO

CAUSES

Lack of standardization, communication, and data

There are mandates on labeling, packaging, and who witnesses necessary signatures, but there is complete discretion for what methods OPOs can use to transport organs. Thus, every OPO manages transportation of organs differently and ad hoc. As one logistics expert framed it, *"It's people on the fly, making their own determinations, they're not making decisions based on data."* Because everyone is doing things differently, there's no central source of data to analyze what are the best routing and transportation practices.

Antiquated tracking systems are being used, as KHN reports, "Surgeons themselves often go to hospitals to collect and transport hearts, which survive only four to six hours out of the body. But kidneys and pancreases — which have longer shelf lives — often travel commercial, as cargo. As such, they can end up missing connecting flights or being delayed like lost luggage. Worse still, they are typically tracked with a primitive system of phone calls and paper manifests, with no GPS[2] or other electronic tracking required.[3]

The condition of the organ is not monitored during transport, which can also contribute to discard if its condition becomes less transplantable. Poor communication between the local recovery/procurement surgeon and transplant surgeon, as facilitated by the OPO, may also result in the transplant surgeon having different expectations of the organ and rejecting it when it arrives because of the differing condition.

Poor logistics and routing

"Logistics is not a core competency of OPOs, even though one of their core responsibilities is getting organs to transplant centers," a logistics expert told us. This is evident in the inconsistent quality of transportation reported (e.g. organ box arrived with tire marks[4]). There are multiple handoffs, which when handled ineffectively, result in wasted time.

Cold-ischemic time (CIT) is a major issue in organ transport. Research has indicated that "each additional hour of travel may shorten the life the organ can provide to the transplanted patient."[5] A study found that "each additional hour of CIT was associated with a significant 1.3% increased risk of graft failure and 1.8% increased risk of death."[6] Therefore OPOs should be doing everything possible to reduce cold time. Oftentimes, OPOs will default to booking a flight, when having the organ driven to its destination would be faster and more efficient than waiting for the next available flight[7]. As a former OPO coordinator noted, *"There's going down a checklist - and there's critical thinking to reduce cold time."*

POTENTIAL FIXES

Capture data to improve routing and transparency

One of the conditions of coverage that OPOs must uphold in order to stay certified is to transport organs in a manner that "ensures their arrival without compromise to the quality of the organ."[8] CMS should hold OPOs accountable for every organ shipment under their purview — including recently documented failures.[9] UNOS needs to be held accountable likewise for organ transport failures handled by the UNOS Organ Center. Additionally, OPOs should capture and make available the data on transport method, time, cost, and organ condition for each organ shipment in order to make route and transport method optimizations. Tracking organ vitals and transport conditions (such as temperature and vibrations) can provide data on how travel conditions affect organ condition. Once enough data has been gathered and shared, CMS can implement standardized regulations on what is acceptable for transport.

Utilize modern technology and better communication

"Modern logistics is almost entirely now a technological problem which has been solved by numerous industries," notes our team's technologist, "Particularly in the area of transportation, there is high interest and private funding focused on improving the logistical challenge of transporting organs."[10] HHS could tap these logistics industry experts by creating a federal contract for organ logistics and separate out all of the OPTN's current transportation responsibilities. . Additionally, all OPOs should utilize organ life-extending technology currently used by some OPO peers, such as TransMedic[11] and shipping kidneys on a pump to keep organs in optimal condition.

In terms of communication between surgeons, it should always be a practice for OPOs, when possible, to have a conference call between the procuring surgeon and transplant surgeon before any organ recoveries to ensure everyone is on the same page on expectation.

NOTES

1. "How Lifesaving Organs For Transplant Go Missing In Transit," *Kaiser Health News*, 2020. ↩

2. Note that GPS is not necessarily the solution, given that a Reveal investigation reported that an organ was left in an airport because Delta had trouble locating a GPS device, and so Delta staff did not send the organ on the connecting flight, resulting in a "near miss." ↩

3. While better tracking would not solve the issue of delayed cargo transportation, it can increase accountability, transparency, and inform better decision making on which transportation method to use. ↩

4. "Lost in transplantation," *Reveal from the Center for Investigating Reporting*, 2020. ↩

5. "Tackling the Growing Problem of Transporting Organs," *American Journal of Transplantation*, 2019. ↩

6. "With Donor Kidneys, Every Hour of Cold Ischemia Time Matters," Renal and Urology News, 2015. ↩

7. "Tackling the Growing Problem of Transporting Organs," *American Journal of Transplantation*, 2019. "Organ donation tends to occur in the evening or early morning, which potentially delays movement of the recovered organ until the airport opens and a flight is available." ↩

8. "§ 486.346 Condition: Organ preparation and transport," *Code of Federal Regulations*. "The OPO must develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival without compromise to the quality of the organ." ↩

9. "Lost in transplantation," *Reveal from the Center for Investigating Reporting*, 2020. ↩

10. Technology Recommendations ↩

11. Transmedics.com ↩

CMS RECOMMENDATIONS

In order to achieve the ambitious goals of the Executive Order on Advancing American Kidney Health,[1] which seeks to help 17,000 more patients access life-saving deceased donor kidney transplants each year, as well as 11,000 patients receive heart, liver, lung, and pancreas transplants, CMS in collaboration with HRSA can take many actions within their oversight of OPOs, transplant centers, donor hospitals, and the OPTN.

OPOs

Below are recommended changes to current OPO conditions of coverage, not in exact language but in essence of what should be changed or added to recover more organs, as outlined above.

§ 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.[2] CMS can clarify:

- Hospital agreement should include protocols for both donation after brain death (DBD) and donation after cardiac death (DCD) cases.
- Increase designated requestor training for hospital staff to at least quarterly

§ 486.324 Condition: Administration and governing body.[3] CMS can clarify:

- All OPOs should recover organs from donors after cardiac death and have policies in place for their protocol on how to do so.

§ 486.326 Condition: Human resources. CMS can clarify:

- OPO should have staffing measures in place for when interacting with potential donors' next of kin for donation authorization. To the extent possible, preference should be for staff to reflect the demographics (in terms of race and language) of the community in the OPO's DSA. Additionally, staff should undergo cultural sensitivity training for the demographics represented in their regions.[4]
- Specifically for standards on qualifications,[5] individuals involved in donor assessment, procurement, and placement should have clinical experience or documented clinical training.
- For standards on staffing,[6] rule out of medical suitability for organ donation must be done by individuals with a clinical background; and OPOs must have a sufficient number of qualified staff to respond to 100% of potential donor referrals within an hour, including by going onsite in all cases to the extent possible.
- For standards on education, training, and performance evaluation,[7] individuals involved in donor assessment, procurement, and placement must undergo annual continued education clinical training. Individuals directly involved in, or who supervise, clinical donor management must undergo or have documented training on deceased donor management protocols and best practices. Individuals involved in speaking with next of kin for donation authorization should undergo training on donor family communication best practices, implicit bias, racial-equity, and trauma-informed care.

§ 486.328 Condition: Reporting of data.[8] CMS can clarify additions related to:

- Timeliness of OPO staff follow-up on eligible donors, and whether follow-up was onsite;
- Data on demographics of donor families/next of kin who were approached for authorization (including at a minimum race/ethnicity, age, whether they were HIV-positive, and whether they were an extended criteria/marginal donor); and
- Data on staff demographics (gender, race, languages spoken) and background (clinical/non-clinical).

§ 486.330 Condition: Information management.[9] CMS can clarify:

- Addition to referral information requiring the OPO to create a record for every referral using CMS provided data protocol:[10] The record must include, at a minimum: date, time, and origin of referral; who at the OPO received the referral; how it was triaged; how long it took OPO staff to follow-up and whether it was onsite or not. CMS and OPOs should be analyzing this data as part of their QAPIs.

§ 486.342 Condition: Requesting consent.[11] CMS can clarify that the OPO should also ask about and clearly document any family time constraints, as well as provide the following information to the donor family:

- Costs associated with donation (there should be none)
- Timeframes for the donation decision and donation process, including any potential delays to funeral arrangements
- The donor's eligibility to donate and ability for the family to decide which organs to donate
- The need for organs and the potential to help others, especially within that donor's demographic community if applicable
- The treatment of the donor's body during organ recovery
- If applicable, an explanation of a brain death diagnosis

§ 486.344 Condition: Evaluation and management of potential donors and organ placement and recovery. CMS can clarify:

- Within potential donor protocol management,[12] the OPO must implement a system that ensures that a qualified physician or other qualified individual with a clinical background is available to assist in the medical management of a potential donor when the surgeon on call is unavailable.
- Within testing,[13] utilize virtual crossmatching as the primary method for donor and recipient matching to the extent possible. Ensure that the potential donor's

blood is typed using two separate blood samples and have a protocol in place for donors who have undergone transfusion.[14]

- Within the collaboration with transplant program standards,[15] the OPO should also have a protocol in place for donors who have undergone blood transfusion.
- For donation after cardiac death,[16] all OPOs should recover organs from donors after cardiac death and allow for the mention/socialization of donation after cardiac death prior to the family making the decision to stop/withdraw care.[17]
- Additionally, given that some hospitals express reticence to participate in DCD cases (either performing or receiving) as they increase their mortality rate thereby impacting their national benchmarking scores (a situation amplified if the DCD withdrawal occurs intraoperatively), CMS should ensure practices are in place so that such reporting does not count against hospitals performing DCDs, particularly as regards counting of deaths in the operating room.

§ 486.346 Condition: Organ preparation and transport. CMS can clarify:[18]

- The OPO must document how the organ is transported, track its condition during transport, and its final cold-ischemic time at arrival to the transplant center.

§ 486.348 Condition: Quality assessment and performance improvement (QAPI). CMS can clarify:[19]

- These actions should include participation in peer-reviewed academic research to the extent possible.[20]

Other: These are recommendations that do not fit into current OPO Conditions of Coverage**

- Monitor the Standard Acquisition Charge (SAC) fees that OPOs pass to transplant centers and which are reimbursed by CMS. With broader allocation boundaries, the cost of organs acquisition has increased, without oversight or cap.[21]
- The Office of the National Coordinator (ONC) for Health Information Technology should set interoperability standards and requirements between OPOs, Donor Hospitals, and OPTNs in order to enable the introduction of new technologies into the organ donation space that currently is highly fragmented with significant amounts of information blocking put in place by incumbents. This will enable workflows between hospitals and OPOs to move from phone/paper based exchanges into auditable and near real-time automated workflows, including more timely, electronic referrals of potential donors.

Donor Hospitals and Transplant Centers

- Experience surveys could be developed and administered as part of the upcoming ESRD Treatment Choices Learning Collaborative. Just as CMS monitors patient experience with HCAHPS, CMS could monitor and measure OPO performance based on input from clinical hospital teams involved in organ donation (on topics such as OPO staff interactions, staff knowledge, and quality of the engagement). These surveys could provide insight into how clinicians experience OPOs and illuminate opportunities for research.

OPTN (HRSA)

- Update organ offer technology to meet modern software standards and address baseline usability concerns, as described in drop-off point #1 above and in Driving Innovation in the Organ Transplant Technology "Ecosystem" *(link to tech doc)*.
- CMS currently requires OPOs to retain records of donors which creates duplicative systems in OPO databases. HRSA should instead require that this data be captured, managed, and centralized in an OPTN database as part of the Organ Transplant Technology "ecosystem" *(link to tech doc)*. If able to take effect, this would require changes to OPO Condition of Coverage § 486.330 as well.
- HRSA should make available to all transplant centers and OPOs the data dashboards of organ procurement and transplant information as a service of the OPTN. Transplant centers and OPOs should not have to pay additional money individually for this information.

NOTES

1. "Executive Order on Advancing American Kidney Health," *whitehouse.gov*, 2019. ↩
2. Current regulation language § 486.322 (a) Standard: Hospital agreements. An OPO must have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after cardiac death (if the OPO has a protocol for donation after cardiac death) and the requirements for hospitals at § 482.45 or § 485.643. The agreement must specify the meaning of the terms "timely referral" and "imminent death." (b) Standard: Designated requestor training for hospital staff. The OPO must offer to provide designated requestor training on at least an annual basis for hospital and critical access hospital staff. ↩

3. Current regulation language § 486.324(g) The OPO's policies must state whether the OPO recovers organs from donors after cardiac death. ↩
4. Current regulation language § 486.326 All OPOs must have a sufficient number of qualified staff, including a director, a medical director, organ procurement coordinators, and hospital development staff to obtain all usable organs from potential donors, and to ensure that required services are provided to families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research. ↩
5. Current regulation language § 486.326(a) Standard: Qualifications. (1) The OPO must ensure that all individuals who provide services and/or supervise services, including services furnished under contract or arrangement, are qualified to provide or supervise the services. ↩
6. Current regulation language § 486.326(b) Standard: Staffing. (1) The OPO must provide sufficient coverage, either by its own staff or under contract or arrangement, to assure both that hospital referral calls are screened for donor potential and that potential donors are evaluated for medical suitability for organ and/or tissue donation in a timely manner. (2) The OPO must have a sufficient number of qualified staff to provide information and support to potential organ donor families; request consent for donation; ensure optimal maintenance of the donor, efficient placement of organs, and adequate oversight of organ recovery; and conduct QAPI activities, such as death record reviews and hospital development. ↩
7. Current regulation language § 486.326(c) Standard: Education, training, and performance evaluation. The OPO must provide its staff with the education, training, and supervision necessary to furnish required services. Training must include but is not limited to performance expectations for staff, applicable organizational policies and procedures, and QAPI activities. OPOs must evaluate the performance of their staff and provide training, as needed, to improve individual and overall staff performance and effectiveness. ↩
8. Current regulation language § 486.328(a) An OPO must provide individually-identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Beneficiaries, and DHHS, as requested by the Secretary. The data may include, but are not limited to: (1) Number of hospital deaths; (2) Results of death record reviews; (3) Number and timeliness of referral calls from hospitals; (4) Number of eligible deaths; (5) Data related to non-recovery of organs; (6) Data about consents for donation; (7) Number of eligible donors; (8) Number of organs recovered, by type of organ; and (9) Number of organs transplanted, by type of organ. ↩
9. Current regulation language § 486.330 An OPO must establish and use an electronic information management system to maintain the required medical, social and

identifying information for every donor and transplant beneficiary and develop and follow procedures to ensure the confidentiality and security of the information.(a) Donor information. The OPO must maintain a record for every donor. The record must include, at a minimum, information identifying the donor (for example, name, address, date of birth, social security number or other unique identifier, such as Medicare health insurance claim number), organs and (when applicable) tissues recovered, date of the organ recovery, donor management data, all test results, current hospital history, past medical and social history, the pronouncement of death, and consent and next-of-kin information.(b) Disposition of organs. The OPO must maintain records showing the disposition of each organ recovered for the purpose of transplantation, including information identifying transplant beneficiaries.(c) Data retention. Donor and transplant beneficiary records must be maintained in a human readable and reproducible paper or electronic format for 7 years.(d) Format of records. The OPO must maintain data in a format that can readily be transferred to a successor OPO and in the event of a transfer must provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO. Records and data subject to this requirement include donor and transplant beneficiary records and procedural manuals and other materials used in conducting OPO operations. ↩

10. See recommendation below under OPTN (HRSA) about potentially incorporating all OPO data into a central database instead. ↩

11. Current regulation language § 486.342 (a) An OPO must have a written protocol to ensure that, in the absence of a donor document, the individual(s) responsible for making the donation decision are informed of their options to donate organs or tissues (when the OPO is making a request for tissues) or to decline to donate. **The OPO must provide to the individual(s) responsible for making the donation decision, at a minimum, the following: **(1) A list of the organs and/or tissues that may be recovered. (2) The most likely uses for the donated organs or tissues. (3) A description of the screening and recovery processes. (4) Information about the organizations that will recover, process, and distribute the tissue. (5) Information regarding access to and release of the donor's medical records. (6) An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body. ↩

12. Current regulation language § 486.344 (a) Potential donor protocol management. (2) The OPO must implement a system that ensures that a qualified physician or other qualified individual is available to assist in the medical management of a potential donor when the surgeon on call is unavailable. ↩

13. Current regulation language § 486.344 (c) *Testing.* The OPO must do the following: (2) Ensure that screening and testing of the potential donor (including point-of-care testing and blood typing) are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this

chapter. (3) Ensure that the potential donor's blood is typed using two separate blood samples. ↩

14. He died when he got the wrong lungs. It wasn't the only organ error in SC that day. ↩

15. Current regulation language § 486.344 (d) Standard: Collaboration with transplant programs. (2) The protocol must ensure that: (i) The OPO is responsible for two separate determinations of the donor's blood type; ↩

16. Current regulation language § 486.344 (f) Donation after cardiac death. If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following: ↩

17. Inclusion of this information provides more timely and complete options for the family about end of life decisions. Hospitals interpret the intent of this regulation to preclude a pre-withdrawal DCD discussion mention. Inadequate time to consider/pursue DCD is often cited as the reason for declination. ↩

18. Current regulation language § 486.346 (c) The OPO must develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival without compromise to the quality of the organ. The protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two individuals, one of whom must be an OPO employee, that information listed on the labels is correct. ↩

19. Current regulation language § 486.348 (a) Standard: Components of a QAPI program. The OPO's QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to OPO activities, such as hospital development, designated requestor training, donor management, timeliness of on-site response to hospital referrals, consent practices, organ recovery and placement, and organ packaging and transport. The OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained. ↩

20. Topics of high value include research to improve OPO practices in deceased donor evaluation, family authorization approach, deceased donor management, and organ recovery. (1) Priority should be given to evaluating and improving OPO practice among historically under-recovered and marginalized groups, such as racial/ethnic minority patients, rural patients, older patients, single organ donors, HIV-positive patients, and decedents evaluated for DCD donation. (2) Evaluation and improvement measures for organ donation must include a requirement for both ongoing scheduled review of actual performance in context with objectively determined donation potential. Local donation performance must be considered with regard to both trajectory compared to prior periods and relative performance compared to other areas of the country. (3) In addition to regular data-driven analysis of performance, further research is needed

to determine the role of specific practices and processes in both high- and low-performing areas. (4) These analyses should include data from hospital and OPO stakeholders of sufficient detail to identify root causes of missed opportunities and systemic patterns of resource allocation. (5) The architecture of OPO performance data must be designed to facilitate third party review of practice and process data. Academic institutions and researchers with an interest in transplant and quality improvement must be granted access to all mandated data, including data reported that could be used for performance assessment of federal transplant contractors including the OPTN and SRTR. ↩

21. "*Almost all are imports now. It's really become expensive*" said one intake coordinator for a transplant center. Another surgeon told us that organ transplant cost had increased by a million dollars due to additional "processing fees," and that "that additional million is going to the OPO's." ↩

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