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**Abstract:**

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Oversimplification and Misplaced Blame will Not Solve the Complex Kidney Underutilization Problem

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The Washington Post article, “70 deaths, many wasted organs are blamed on transplant system errors,”¹ and Senate Hearings of August 3, 2022,² both gave the misleading impression that the organ discard problem is primarily attributable to transportation-related mistakes, other human or system errors, and outdated computer technology that slows down the organ allocation process. As in all medical fields,³ transplantation is not immune to avoidable mishaps, which have indeed led directly to organs being rendered unusable.⁴ And the process of allocating less-than-ideal organs can indeed be painfully slow: so slow, in fact, that viable organs sometimes go unused due to the combined risk of elevated cold ischemia time (a common offer refusal reason)⁵ and whatever factors led to the organ being deemed less-than-ideal in the first place.⁶ ⁷

But the predominant drivers of a nearly 25% kidney discard rate are not mishaps or poor technology. Rather, the US transplant system suffers from an organ offer refusal problem: far too many offers of imperfect but transplant-quality kidneys are refused on behalf of (or directly by) patients, prolonging the time it takes to find a clinically suitable ‘home’ (patient) at a transplant center willing to take on the risk. In fact, the mean match run sequence number among accepted kidneys was recently estimated at 665, indicating it is not atypical for hundreds – even thousands – of offers to be refused prior to finally securing an acceptance.⁸ Once a kidney has a firm acceptance, the discard rate is only about 5%,⁸ ⁹ indicating that approximately 80% of the discard problem is attributable to inability to find an acceptor; a minority of discards occur post-acceptance, after an unexpected incident such as a positive crossmatch, transportation delay, etc. The most common kidney discard reason reported by
Organ Procurement Organizations (OPO) is, in fact, “no recipient located – list exhausted,”
suggesting the OPO attempted in vain to find an acceptor among all possible candidates.

In an era of organ scarcity, where even the lowest quality kidneys have been shown to
confer a survival (and likely quality of life) benefit over dialysis for many patients, how can it
be that transplant decision-making seems to reflect an era of plenty?

Three fundamental realities

Recent critics of the US transplant system seemingly fail to appreciate three fundamental
realities of kidney transplantation relevant to the organ utilization challenge:

(1) Not all donated kidneys are created alike

(2) The kidney allocation system is still largely tethered to the “first-come, first-served”
    fairness principle

(3) Major changes to organ allocation policy do not come easy

Critical comments about the U.S. kidney discard rate seem to imply that the pool of
available kidneys resembles a homogenous, fungible commodity, glossing over the fact that
vast clinical differences exist among kidneys offered for transplant. Evaluating a deceased
donor organ offer in many ways parallels shopping for a used car. A 20-year old Civic with
175,000 miles on it might be perfectly adequate for “point A to B” travel for a few years, but
clearly isn’t in the same league as a near-mint Lexus with under 10,000 miles and coming off a
short-term lease. Analogously, deceased donor kidneys vary substantially along a quality
spectrum that portends highly differential expected graft longevity, depending on donor age,
medical history, etc. The decision to accept any particular kidney for any specific patient involves consideration of two key risks – graft failure and disease transmission – along with tremendous uncertainty in how things will turn out for any given case, and may very well be the most complex decision in all of medicine.

A third, critical dimension driving the complexity of the kidney acceptance decision is the very real possibility that another, “better” kidney soon will be offered to the patient. If so, the right decision may indeed be to decline. And despite being substantially overhauled in 2014, the “first-come, first-served” principle – a hallmark of fairness in the US – is still largely entrenched into the kidney allocation system. While arguably “fair,” the byproduct is that the transplant candidates that tend to be the first ones offered less-than-ideal kidneys are also among the first to receive offers for much higher quality kidneys, due to having accrued substantial qualified waiting (or dialysis) time. This aspect of the system induces a disincentive to accept imperfect kidneys for the candidates at the top of the match run. These early refusals slow down the placement process, leading to a cascade of further refusals as the cold ischemia clock keeps ticking, and the combination of the organ being ‘too old’ and ‘too cold’ requires a boldness that not even the most risk-tolerant transplant program is willing to take.

Ways to improve the system

There is certainly room for improvement in the operational parameters and DonorNet system features that govern the mechanics of the organ offering process, most notably in the manner and timing in which offers are distributed and responded to. For example, the inefficient use of the ‘provisional yes’ response has been a long-recognized pain point in the
organ placement process. Encouragingly, the entire paradigm for sending and responding to offers is now being reexamined by UNOS, with guidance from the OPTN Operations & Safety Committee. And UNOS has recently implemented or begun piloting a number of sophisticated and potentially impactful DonorNet system enhancements: allowing users to see the complete donor record and respond to offers on a mobile device; allowing programs to avoid receiving unwanted offers by establishing multicriteria donor filters; and displaying novel predictive analytics (e.g., “time to next offer”) to combat decision complexity.

Still, the impact of operational and system features designed to foster faster progression down the match list has limited potential to address the discard problem if the allocation system still results in first-offered candidates having a built-in disincentive to accept less-than-ideal kidneys. One of UNOS’s stated aspirational goals is that no matter where on the quality spectrum an organ lies, the first person offered the organ should be the right one to accept it, in terms of medical suitability, fairness, and the decision-calculus surrounding the risks and benefits of accepting vs. waiting for another. But the current system, built on a foundation emphasizing equity – not placement efficiency or maximizing organ utilization – is antithetical to that aspired reality.

So how do we go from here – a system with built-in disincentives to accept offers – to there – a system that is still equitable but also “tuned for acceptance”? Kidney allocation policy should be modified in two key ways: (1) by changing the way waiting/dialysis time is used to prioritize patients, and (2) codifying expedited placement pathways to aid OPOs in finding homes for hard-to-place kidneys.
In some European countries’ implementation of the Senior Program, in which older-donor kidneys are preferentially offered to older candidates, senior patients are required to choose one list – the older (age 65+) donor kidney list, or the all other kidney list – from which to receive offers: they cannot remain on both. The choice is clear – wait longer for a higher quality organ, or get transplanted more quickly with a shorter-longevity kidney. The Extended Criteria Donor (ECD) and high Kidney Donor Profile Index (KDPI) programs were implemented in the U.S. such that candidates who choose to receive these offers also remain on the list for ideal quality organs, weakening any incentive to accept the former given the very real possibility of receiving the latter.

Reducing patients’ options by segmenting the allocation system and forcing a choice between a shorter wait for a shorter longevity kidney, or vice versa, is not the only (nor necessarily best) way to tune the decision-making calculus toward acceptance. Altering how waiting time is used to prioritize patients across the donor quality (e.g., KDPI) spectrum, according to a paradigm coined as “dealing from the bottom of the deck”, may be a more effective approach to consider as the OPTN migrates to the continuous distribution framework. If a patient just added to the list with little or no waiting time priority for the best kidneys was given first dibs on a higher KDPI kidney, the incentive equation may change in a way that fosters securing offer acceptance earlier in the placement process.

Given the drastic differences in kidney utilization practices among kidney programs, the OPTN is implementing a new monitoring framework designed to exert upward pressure on and reduce variability in offer acceptance rates. Since the longstanding, hyper-focus on early post-transplant success rates has contributed to risk aversion, “balancing the scorecard” in way
that calls out overly selective acceptance practices may help nudge the system toward transplanting more organs. However, since significant program-to-program variation is likely to persist, codifying into kidney allocation policy a center-targeted expedited placement pathway may have even greater potential to reduce avoidable discards.40, 41

Currently, to salvage an organ at high risk of discard, OPOs are permitted to deviate from the prescribed patient order and expedite placement to centers with a track record of accepting similar organs, bypassing higher-priority candidates at other centers. However, this practice is not standardized and varies widely, and thus is likely suboptimal in terms of utilization and may be inequitable in terms of organ distribution.42 Codifying an expedited placement system, as recommended by a National Kidney Foundation panel,43 into KAS would include a pre-determined, evidence-driven set of triggers that identify scenarios with an unusually high probability of discard under the standard (sequential) allocation approach.44 Determining the right parameters for an effective expedited placement allocation system may not be easy45, 46 but could make a significant impact if well-engineered.

Practical challenges to realizing change

But are such ideas -- prioritizing just-listed patients ahead those with years on dialysis, and bypassing more medically or ethically justified patients to expedite placement to patients at another center – fair, equitable, and legally permissible? Though these strategies would only be applied to a subset of donated organs, would such bold changes be perceived by patients and the broader transplant community as “unfair,” potentially risking the foundation of trust that holds up the entire system? The OPTN Final Rule requires allocation policies be
equitable. But a viable kidney that is discarded benefits no one. The transplant community may need to sacrifice some degree of geographic equity – where patients listed at the most aggressive programs will receive transplants faster than patients listed elsewhere – in order to have a meaningful impact on utility, recognizing that more transplants indirectly benefits all patients in need, as a rising tide lifts all boats.\textsuperscript{47}

The organ allocation policy development process in the U.S. is intentionally deliberative, involving numerous stakeholders, committee evidence gathering, formal public comment periods, and ultimately Board of Directors’ approval and implementation. The OPTN aims to achieve broad consensus in developing and implementing new, often highly complex policies as expeditiously as possible, a colossal and underappreciated balancing act made all the more challenging due to vested interests resistant to change.\textsuperscript{48} Achieving an acceptable balance between equity, utility, and efficiency has taken years\textsuperscript{49,50} – a reality that should be recognized by critics who may assume existence of an ‘easy button’ for quickly improving such a complex system.

\textit{Concluding thoughts}

Individuals and institutions responsible for preventable errors should be held accountable to drive down the rate of mishaps. The logistics of organ transportation, for example, remains an area ripe for process improvement and technological innovation.\textsuperscript{51-53} The OPTN Operations & Safety and Disease Advisory committees should continue to embrace their mission and study transplant errors,\textsuperscript{4} disseminate process improvement successes to the community,\textsuperscript{54,55} and propose new policies as needed.\textsuperscript{56-58} Donor-derived disease transmissions
attributable to the limitations of testing (i.e., “window period” infections) should be distinguished from avoidable transmissions caused by testing or communication errors.\textsuperscript{55, 59} The risk of contracting a donor-derived infection should be recognized to be extremely low (approximately 0.18%),\textsuperscript{60} far lower than risks associated with remaining on dialysis.\textsuperscript{61, 62} And OPOs should be held accountable to high standards through better metrics and tangible consequences of underperformance, to ensure that significant opportunities for donation and transplantation are not being missed.\textsuperscript{63-65}

Though the juxtaposition of “wasted organs” and “system errors” makes for a good headline, despite the system's flaws, the number of kidney transplants has increased 37% over the past 6 years, from 18,597 in 2015 to a record 25,490 in 2021. The transplant community and its critics should recognize that the roots of the unacceptably high, 20-25% discard rate in the U.S. run deeper than the soundbites might suggest. Only once the true nature of the kidney discard problem (decision-making complexity) and the challenges in overcoming it (revising an allocation system still largely anchored in the deeply ingrained American ethic: “no cutting in line!”) are fully appreciated, will the transplant community be in a position to thoughtfully develop and enact truly impactful solutions. The OPTN should not migrate kidney policy to the continuous distribution framework without incorporating bold policy changes that squarely address the kidney discard problem.
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