

ORGAN QUALITY AS A COMPLICATING FACTOR IN PROPOSED SYSTEMS OF INDUCEMENTS FOR ORGAN DONATION

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I

INTRODUCTION

All potentially transplantable organs are not created equally. Even among organs currently used for transplantation, there exists a wide spectrum of quality. Donor risk factors can account for as much as a twenty-percent absolute difference in post-transplant survival.¹ Thus, in some cases, actual receipt of a transplant matters less than the quality of organ received.

Organ quality might complicate inducements for organ donation in several ways. First, organ quality can diminish the impact of inducements on net increase in organs transplanted, and furthermore, can increase the cost of inducements. Second, whether directed toward organ-procurement organizations or potential living or deceased donors, inducements risk increasing the supply of organs at the expense of quality. Finally, the heterogeneous quality of organs can complicate market systems.

These issues are most relevant to deceased-donor organs, and can be less problematic in the setting of living donation. Furthermore, there are a number of potential regulatory mechanisms that could mitigate concerns related to organ quality.

II

WHAT IS ORGAN QUALITY?

For the potential recipient of a solid organ transplant, whether from the deceased or living, two types of donor-specific risks exist: (1) risk of disease transmission, such as infection or malignancy, and (2) risk of graft failure. Of the two, the latter risk is both more common and more harmful. Among *potential* donors, the prevalence of transmissible diseases is approximately ten percent,² and, since donor-screening methods are fairly effective, disease

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1. See S. Feng et al., *Characteristics Associated with Liver Graft Failure: The Concept of a Donor Risk Index*, 6 AM. J. TRANSPLANTATION 783, 786–89 (2006).

2. See K. Ellingson et al., *Estimated Risk of Human Immunodeficiency Virus and Hepatitis C Virus Infection Among Potential Organ Donors from 17 Organ Procurement Organizations in the United States*, 11 AM. J. TRANSPLANTATION 1201, 1206 (2011); M. A. Nalesnik et al., *Donor-*

transmission occurs in just under one percent of transplantation cases, causing nine deaths in 2007.^{2,3} By contrast, risk factors for graft failure are present in more than two-thirds of *actual* donors, and are even more common in the overall population of potential donors.⁴ These risk factors include donor age, type and cause of death, and medical comorbidities, all of which not only affect pre-transplant organ function, but also make the organ more susceptible to ischemic injury during procurement and storage.⁵ Among deceased-donor organs currently used for transplantation, donor-specific risk factors account for an absolute difference of twenty percent in risk of graft failure for the recipient.⁶ For example, an average-risk recipient of a liver transplant will have a twenty-percent risk of graft failure with a high-quality organ, and a forty-percent risk of graft failure with a low-quality organ.⁷ Because re-transplantation is often not possible, in many cases graft failure means death for the recipient. Thus, even conservative estimates implicate donor risk factors for graft failure as causing more than 1000 deaths each year.⁸ For these reasons, studies show that, when faced with an offer of a below-average-quality organ, some patients are actually better off declining that offer in order to wait for a better one.⁹

III

HOW DOES ORGAN QUALITY AFFECT ORGAN UTILIZATION?

In 2011, only 3.5% of Americans who died while hospitalized became organ donors.¹⁰ Poor organ quality prevented many prospective donations—organs from most deceased people are not usable.¹¹ For example, two of the most important risk factors for graft failure are donor age and type of death. Donor age over seventy years increases the risk of graft failure by 20–60% depending upon the type of organ and other factors, whereas donation after circulatory death (DCD) increases the risk by 50–70% compared to donation after brain

Transmitted Malignancies in Organ Transplantation: Assessment of Clinical Risk, 11 AM. J. TRANSPLANTATION 1140 (2011).

3. M. G. Ison et al., *Donor-Derived Disease Transmission Events in the United States: Data Reviewed by the OPTN/UNOS Disease Transmission Advisory Committee*, 9 AM. J. TRANSPLANTATION 1929, 1929 (2009).

4. Feng, *supra* note 1, at 784–86.

5. See Feng, *supra* note 1, at 784–85; Panduranga S. Rao et al., *A Comprehensive Risk Quantification Score for Deceased Donor Kidneys: The Kidney Donor Risk Index*, 88 TRANSPLANTATION 231, 231, 233 (2009).

6. See Feng, *supra* note 1, at 787; Rao, *supra* note 5, at 231.

7. Feng, *supra* note 1, at 787.

8. Feng, *supra* note 1, at 787–88.

9. See, e.g., D. E. Schaubel et al., *The Survival Benefit of Deceased Donor Liver Transplantation as a Function of Candidate Disease Severity and Donor Quality*, 8 AM. J. TRANSPLANTATION 419, 423–25 (2008).

10. UNITED STATES ORGAN TRANSPLANTATION, OPTN & SRTR ANNUAL DATA REPORT 2011 (2012) [hereinafter OPTN & SRTR ANNUAL DATA REPORT 2011], at 181, available at http://srrtr.transplant.hrsa.gov/annual_reports/2011/pdf/2011_SRTR_ADR.pdf.

11. *Id.*

death (DBD).¹² Thus, although individuals with one or both of these characteristics account for 95% of deaths, they contribute less than 5% of donor organs.¹³ This is not because the individuals or their families decline donation. Rather, transplant centers are not willing to use their organs, and in most cases their families are not even approached for consent. Furthermore, among individuals who do become donors, meaning that they donate at least one organ, not all of their organs are procured, and 10% of those procured are discarded—again, for reasons of organ quality.¹⁴ In 2011, 79% of eligible deaths consented for donation.¹⁵ Therefore, as shown in the following table that uses 2011 data, organ quality has a much larger impact on supply than does consent rate.¹⁶

Table

Total deaths in the United States	2,513,171
Age <70 and brain death	9023
Met above criteria and consented for donation	7128

The Organ Procurement and Transplantation Network (OPTN) has developed a series of metrics for quantifying donation activity—donation rate, organs recovered per donor, organs transplanted per donor, discard rate—each of which is influenced by donor risk factors for graft failure.¹⁷ Similarly, in the case of disease transmission, donors with behavioral risk factors for recently acquired infection are given the status “Centers for Disease Control high risk:” Organs from these donors are used less frequently than organs without this label.¹⁸

IV

HOW COULD ORGAN QUALITY COMPLICATE INDUCEMENTS FOR DONATION?

Within the context of inducements, the relationship between organ quality and organ utilization has four implications, which vary somewhat depending on the type of donation—deceased versus living—as well as the target of the inducement—the patient, family, or health care provider. The majority of the

12. SCIENTIFIC REGISTRY OF TRANSPLANT, RECIPIENTS RISK MODEL DOCUMENTATION (2014), available at http://www.srtr.org/csr/current/Centers/201402_1401/modtabs/Risk/LIADC2G.pdf.

13. OPTN & SRTR ANNUAL DATA REPORT 2011, *supra* note 10, at 181.

14. OPTN & SRTR, ANNUAL DATA REPORT: DECEASED ORGAN DONATION (2011), available at http://srtr.transplant.hrsa.gov/annual_reports/2011/pdf/07_dod_12.pdf.

15. *Id.*

16. *Id.*

17. OPTN & SRTR ANNUAL DATA REPORT 2011, *supra* note 10, at 181.

18. K. I. Duan et al., *Centers for Disease Control ‘High-Risk’ Donors and Kidney Utilization*, 10 AM. J. TRANSPLANTATION 416, 416, 418 (2010).

organ-quality concerns are most relevant to deceased-organ donation, however.

First, the winnowing effect of organ quality could dilute the beneficial impact of the inducements on the volume of organs actually used for transplantation. This issue would be most relevant to deceased donation: As described above, the majority of deaths do not result in donation for reasons of organ quality. If inducements were to yield more people being willing to donate, but their organs were not to be used, then the ultimate goal of increasing transplantation would not be achieved.

Second, organ quality could affect the cost-effectiveness of an inducement system. This issue would be relevant for both deceased and living donation. Consider, for example, a system that covers funeral expenses if a family were to agree to donate their loved one's organ. Would the payment occur regardless of whether the organs were actually to be used? If so, there would be many more payments than actual donations. If payment were contingent upon organ utilization, however, this could lead to dissatisfaction and perceptions of discrimination among families.

Third, inducements could increase the supply of organs at the expense of quality. This issue would be relevant for deceased donation and, to a lesser extent, living donation. Additional lower-quality organs might be used for transplantation, resulting in poor patient outcomes, or the inducements could even alter procurement patterns in such a way as to decrease the quality of existing organs. The transmission of infectious diseases through reliance on lower-quality organs and the increased utilization of cardiac death donors (who might have progressed to brain death and are therefore more likely to donate lower-quality organs) are two examples of poor patient outcomes or altered procurement patterns that could occur with an increased supply of lower-quality organs.

A. Example 1: Transmission of infectious diseases

Although uncommon, the risk of transmitting infectious diseases such as HIV and viral hepatitis via transplantation causes great concern to recipients, transplant centers, and the general public. The most recent known transmission from a deceased donor, in 2007, was the source of numerous news articles and several lawsuits.¹⁹ Each donor is extensively tested, but these tests can be falsely negative if the donor has recently acquired the infection. The “window” period for failing to detect recent infections ranges from one week to three months depending on the virus and type of test performed.²⁰ The more sensitive the test, the higher the risk of false positives, and of wasting perfectly good organs. Thus, the risk of disease transmission always exists.

Because the diagnostic tests are not perfect, current practice relies heavily

19. See S. D. Halpern et al., *Informing Candidates for Solid-Organ Transplantation About Donor Risk Factors*, 358 NEW ENG. J. MED. 2832, 2832 (2008).

20. L. M. Kucirka et al., *Risk of Window Period Hepatitis-C Infection in High Infectious Risk Donors: Systematic Review and Meta-Analysis*, 11 AM. J. TRANSPLANTATION 1188, 1189 (2011).

on screening potential donors for behavioral risk factors. Donor families—or in the case of living donation, the donors themselves—are queried about recent drug use, sexual activity, and other risk factors for transmissible diseases. This screening presumes that donors and their families answer honestly. A recent case of HIV transmission from a living donor highlighted the fragility of this presumption.²¹ In that case, the donor failed to disclose his high-risk behavior and acquired HIV between evaluation and donation, thereby transmitting the infection to the recipient.²² It is easy to envision how financial inducements for donation could lead potential donors (or their families) to prevaricate, thus increasing the screening process's inability to detect the likelihood of a window-period transmission.

B. Example 2: The case of DCD organs

Inducements might be aimed not only at donors and their families, but also at health care providers; in the latter case, recent history provides an example of how these inducements can have unintended consequences. Recall from part III that organs obtained through DCD can increase the risk of graft failure during transplantation by fifty to seventy percent in comparison to organs obtained through DBD. DCD is classified as controlled when cardiopulmonary arrest occurs in the setting of planned withdrawal of care (Maastricht type 3), and uncontrolled when cardiopulmonary arrest occurs unexpectedly (Maastricht types 1, 2 and 4).²³ For logistical reasons and due to ethical concerns about donation in the uncontrolled setting, most DCD occurs in a planned fashion in the intensive care unit (ICU).²⁴ The past two decades have seen significant advances in surgical techniques for DCD transplantation and improved consensus among the transplant community regarding ethical protocols, such as strict separation between the ICU and transplant teams.²⁵ As such, DCD has begun to be viewed as an increasingly viable alternative for expanding the donor pool—despite their lower quality.

The Organ Donation Breakthrough Collaborative, a program sponsored by the Department of Health and Human Services, set as one of its goals an increase in rates of DCD transplantation.²⁶ As a result, DCD was added to the metrics by which Organ Procurement Organizations are judged. Possibly due to these efforts, as well as due to increased comfort and familiarity among the

21. See generally Ctrs. for Disease Control & Prevention, *HIV Transmitted from a Living Organ Donor—New York City, 2009*, 60 MORBIDITY MORTALITY WKLY. REP. 298, 298–301 (2011).

22. See *id.*

23. Peter L. Abt et al., *Donation After Cardiac Death in the US: History and Use*, 203 J. AM. COLL. SURGEONS 208, 208 (2006).

24. See *id.* at 209.

25. See generally D. J. Reich et al., *ASTS Recommended Practice Guidelines for Controlled Donation After Cardiac Death Organ Procurement and Transplantation*, 9 AM. J. TRANSPLANTATION 2004 (2009).

26. Teresa J. Shafer et al., *Organ Donation Breakthrough Collaborative: Increasing Organ Donation Through System Redesign*, CRITICAL CARE NURSE, Apr. 2006, at 33, 34.

transplant and intensive-care communities, DCD increased from 1.1% of donors in 1995 to 11.2% in 2010.²⁷ However, this increase is associated with a proportional decline in the numbers of DBD, and a decrease in the number of organs transplanted per donor.²⁸ These trends lead many experts to fear that the push for DCD is causing life support to be withdrawn among individuals who would have progressed to brain death given more time.²⁹ In other words, potential donors via DBD are being converted to donors via DCD. Thus, in this case, inducements aimed at health care providers might lead to an increased total number of donors but a decrease in the pool of good-quality donors.

To clarify, aside from the unique situation of DCD organs, it is unlikely that inducements aimed at donors or families would adversely impact the pool of *good-quality* organs—rather, inducements are likely to expand the pool of *total* organs by a disproportionate increase in the pool of lower-quality organs. The only possible way that inducements might decrease the number of good-quality organs would be via a negative incentive for charitable donors. That is, financial incentives might partially erase the motivation for certain individuals to donate as a gift or sacrifice, and these individuals might also tend to have the highest-quality organs. However, there is no evidence that such a situation would likely occur.

Finally, the variation in organ quality and the resulting heterogeneity in value among organs might complicate the development of organ markets, whether for living or deceased donation. Any type of inducement for donation would create an organ market—a system where parties engage in exchange. This could take the form of financial or nonfinancial reimbursement to donors or their families for the act of donation, or it could take the form of organ exchanges, such as paired donation or donor chains. However, such systems would be complicated by the fact that organs are not commodities—in the sense that they are not interchangeable with one another—and thus might have differential value. For example, paired donation occurs when one living person wants to donate a kidney to his or her intended recipient (pair A), but their blood types are not compatible.³⁰ In order to overcome this problem, another aspiring donor and recipient are identified (pair B) with the same problem. Donor A donates to recipient B, while donor B donates to recipient A. Donor chains are simply an extension of this concept—donor A donates to recipient B, donor B donates to recipient C, and donor C donates to recipient A.³¹ This might seem an ideal solution to a biological problem until one considers the

27. Eric S. Orman et al., *Declining Liver Utilization for Transplantation in the United States and the Impact of Donation After Cardiac Death*, 19 LIVER TRANSPLANTATION 59, 61 (2013).

28. *See id.*

29. *Id.* at 66.

30. For additional discussion of paired-kidney exchanges, see Philip J. Cook & Kimberly D. Krawiec, *A Primer on Kidney Transplantation: Anatomy of the Shortage*, 77 LAW & CONTEMP. PROBS., no. 3, 2014 at 1.

31. *See* Michael A. Rees et al., *A Nonsimultaneous, Extended, Altruistic-Donor Chain*, 360 NEW ENG. J. MED. 1096, 1096–97 (2009).

issue of organ quality. If donor A were young and healthy, and donor C were old and unhealthy, organ quality would be discordant between the two pairs. Such an arrangement would not be fair or satisfactory to pair A, because donor A's kidney might last on average ten years longer than the kidney from donor C would. Many programs have rules in place to prevent recipients in kidney-pair donation pools from receiving a lower-quality organ than they would have gotten from their paired donor.

Extending this concept to the setting of financial inducements for donation leads to many questions and complications. For example, would the amount of the inducement need to be adjusted for the quality of the organ, and if so, who would set these prices—the regulatory body or the free market? Ultimately, inducements might be set at fixed amounts to cover only the financial costs of the donors, but even then, would donors be liable for failure to disclose risk factors for poor organ quality? Clearly, organ markets would be much simpler to design if all organs were interchangeable.

V

THE SPECIAL CASE OF LIVING-KIDNEY DONATION

The medical risks of donating a kidney are relatively small—death rates are approximately one in 10,000—and the potential donor pool is large; therefore, inducements for living donors could have the most impact compared to deceased donation. Many of the organ-quality concerns would be less relevant in this situation because the majority of donors with substantial risk factors for graft failure, such as age and medical comorbidities, would be ruled out due to safety concerns. In other words, these risk factors for graft failure are also risk factors for complications from donation, and these patients would thus be excluded from donating by the medical team.

Furthermore, unless the sums involved were very large, it would be unlikely that inducements would motivate potential live donors to lie about their medical history. Unlike deceased donation, the live donor experiences significant inconvenience and discomfort because of transplantation and is at least partially motivated by the recipient's interests. And, even if a recipient receives a slightly-lower-than-average-quality organ from a live donor as a result of inducements, she is likely better off than waiting years for a deceased-donor organ. There are still regulatory concerns, such as constructing the inducement in a way that cannot be construed as "payment" in order to limit donor liability for poor recipient outcome. Nonetheless, the issue of organ quality is likely most problematic in the setting of deceased donation.

VI

REGULATORY MECHANISMS TO MITIGATE UNWANTED EFFECTS ON ORGAN QUALITY DUE TO INDUCEMENT

Regulatory mechanisms could mitigate potential problems related to inducements and organ quality. The most immediate consideration would be

the format and size of inducements. To the extent that inducements are provided in the form of reimbursement for costs of donation and are maintained at a modest sum, the financial incentives for donation that could otherwise increase the volume of poor-quality organs are diminished. Or, rather than payment up-front, if living donors are required to submit receipts for their costs, this could make donation appear to be less of a money-making proposition and thus decrease the risk of prevarication. This structure would also decrease program costs, because payments would be only partial if the donor were ruled out during evaluation, and might limit donor liability for a poor recipient outcome. A similar approach could be taken for funeral costs in the case of deceased donation.

A second mechanism to consider would be adjusting incentives for quality. For hospitals and organ-procurement organizations that stand to profit from organ donation, their reimbursement could be tied to the quality of the organ, using validated scoring systems.³² Likewise, donors or their families could be reimbursed on a sliding scale based upon organ quality. Linking quality to payment is not without precedent—compensation for egg donation can vary more than ten-fold, depending on characteristics of the donor.³³

A third, more radical approach would be to make inducements dependent upon the outcome of the recipient. Although potentially cumbersome to implement, this mechanism would significantly reduce any negative impact on organ quality and would also emphasize the ultimate goal: successful transplantation. Linking reimbursement to recipient outcome might also reduce the number of lawsuits against donors by recipients or their families. However, the uncertainty about receiving payment could be seen as a negative aspect for potential donors, particularly because they might correctly perceive that many factors determining outcome are beyond their control. This, plus the time delay required to ascertain outcome, could substantially dilute the magnitude of incentive for donation. For these reasons, tying reimbursement to quality metrics seems the more practical approach.

VI

CONCLUSION

In summary, both living- and deceased-donor organs vary substantially in quality, meaning that the recipient's risks of disease transmission and graft failure depend significantly on donor characteristics. This could complicate inducements for organ donation by diminishing the impact of inducements, by causing an increase in organ supply at the expense of quality, and by disrupting market arrangements. None of these risks is insurmountable, nor should any of them be used as an argument against inducements. Rather, system designs for

32. Feng, *supra* note 1, at 784–85, 787; Rao, *supra* note 5, at 231–33, 236.

33. Debora Spar, *The Egg Trade—Making Sense of the Market for Human Oocytes*, 356 *NEW ENG. J. MED.* 1289, 1289 (2007).

donations should take organ quality into consideration and include features to mitigate these risks, such as linking reimbursement to organ quality. Ultimately, it is important to keep in mind the primary goal, which is not the number of donors, but rather the number of successful transplants.