Commentary

The Ethics of Organ Transplantation: Shortages and Strategies

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Introduction

One of the most significant advances in critical care medicine during the last 40 years is the development of organ transplantation. Successful transplantations give patients with otherwise untreatable degenerative diseases a new lease on life, or enable them to lead a more fulfilling or productive existence. In cases such as renal failure, transplantation offers patients a better clinical outcome than other treatment options such as dialysis; being more cost-effective, it may also free up much needed resources for other healthcare areas.[1]

However, these benefits have not been maximised due to the persistent shortage of organs available for transplants. Even so, more and more patients are being considered for transplantation because of advances in technologies and immunosuppression, the relaxation of eligibility criteria for waiting list consideration, and the rising incidence of organ diseases and failures in ageing populations. Repeat and multiple organ transplants have also increased. As in many other countries, demand in Singapore has far outpaced supply. At the end of 2007, the number of people on the national waiting list for kidney transplantation was 563 but a total of only 46 transplants were performed.[2] The waiting time can apparently go up to 9 years.[3] Such circumstances invite an "ethics of triage" in which decisions about allocation become decisions about who will die and who will live.

The trope of an "organ crisis" thus appears frequently in the bioethics literature and in media around the world. This has been resisted by some commentators for obscuring the reality of gradual but definite strides in medical progress, and more importantly, for prompting the implementation of initiatives to increase the number of organs procured from both deceased and living persons with less than desired forethought to potential ethical problems or pitfalls.[4] The purpose of this paper is to highlight and comment on the ethical issues and dilemmas raised by some of the strategies implemented or proposed to address the inadequate supply of organs for transplantation, namely the use of (a) an opt-out (or presumed consent) system; (b) donation after controlled cardiac death; (c) extended criteria for deceased donors; and (d) financial inducement in live kidney donation. The aim is to inform and stimulate discussion and debate on moving forward with ethically responsible (or at least acceptable) organ procurement practices in the Singapore context.

Presumed Consent

Gift giving or voluntary donation to benefit another person – as an expression of altruism and social solidarity – has been the ethical cornerstone of the medico-social practice of organ procurement and transplantation. Traditionally, the practice has been institutionalised as an opt-in system, which depends on having the expressed consent of a donor and/or obtaining the consent of the person's family after death. However, due to the poor donation rate in countries using the opt-in system, some countries such as Spain, Israel and Singapore have enacted laws to establish an "opt-out" or "presumed consent" system, which assumes the presence of consent where there is no clear indication that it has been retracted.[5]

The main ethical issue with presumed consent – a subject of heated debate currently in the USA and the UK – is whether the practice, in putting the onus on individuals to indicate their unwillingness to participate, demonstrates sufficient respect for persons and their right of self-determination in accordance with the ethos of modern medicine and society.[6-8] In relation to this, critics point out the possibility of "false positives": instances where the individual did not know about the law and therefore had not objected, or instances where the individual did have objections but for some reasons did not register dissent.[1] Advocates of presumed consent counter that the goal of saving or improving the quality of many more lives outweighs the theoretical consideration of autonomy violations, which should be few, if not rare, in actual occurrences given that surveys typically show a high degree of public support for deceased organ donation.[8,9] More importantly, the spirit of voluntariness and respect for self-determination can be maintained by extensive publicity pre- and post-implementation to ensure that the public is

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aware and informed, and by the provision of simple and convenient procedures for anyone to opt out. The line between voluntariness and conscription in which the interests of the individual are made subservient to the needs of the state need not be crossed in presuming consent for organ donation after death.

Another ethical concern is the proper role of the family. In opt-in systems, it takes time to discuss or negotiate donation with bereaved families. Sometimes, families refuse consent when they do not know the wishes of the dead in advance. The legal presumption of consent based on respect for personal autonomy seems to imply that the donation decision should no longer involve the donor's family.[9] Indeed, having the legal power to bypass or minimise family involvement may simplify the procurement process (which involves a series of technically demanding yet time-constrained procedures) with the prospect of injecting more efficiency and reducing wastage of organs in the system. In practice however, such "streamlining" is not followed through in most presumed consent systems.[10] In the Spanish model of presumed consent – which produces the highest deceased organ donation rate in the world – transplant coordinators always approach families to understand the wishes of the deceased about donation, or to seek permission for donation if the wishes of the deceased are unknown. The final decision of families on donation is always respected.[7,9,11] Besides preventing grief from turning into distress (which can be considered as a form of harm) in allowing family members to make sense and meaning of their kin's death through involvement in the donation decision, such practices are ethically justified on the grounds that respect for persons typically translates in common understanding – given that persons are relational, familial beings – as respect for families. How to balance this respect with obligations to those awaiting transplants is a dilemma.

Nevertheless, to maintain public support for presumed consent and belief in it as a voluntary system, it is important (especially in countries with strong communitarian ideals like Singapore in which the family is held as the unit of society) that the family continues to play a part in the donation decision. To this end, the prompt involvement of transplant coordinators is critical, which will require the close monitoring of intensive care units and emergency departments to identify potential donors; the systematic monitoring of the condition of probable donors, their location and family background; and the discussion of early coordination and sharing of information with organ retrieval teams. Contact with the family should, however, be made only after the patient/potential donor has been certified as brain dead (This is statutorily required under Singapore's presumed consent law – the Human Organ Transplant Act (HOTA), which aims at preventing any real or perceived conflict of interest and misunderstanding towards the clinicians and the hospitals. Good communication practices for transplant coordinators that correlate strongly with getting family permission include spending time with the family to build a relationship of care and psychosocial support, not mentioning the legal requirement of donation but the potential of donation to help or save others and discussing issues of concern that the family has, such as the effect of donation on funeral arrangements, in particular, the disfigurement of the body.[12] It may also be useful as part of the publicity campaign, and in line with social solidarity, to encourage people who subscribe to organ donation at death to discuss their prior wishes with family members.

Presumed consent legislation has not necessarily improved the rate of organ donation from the deceased – some of the lowest donation rates in the world belong to countries with presumed consent.[13,14] Some writers suggest that correlations between presumed consent systems and increased donation rates arise for reasons other than the existence of "a different kind of choice for donors",[9] the use of the force of the law to ensure procurement compliance,[7] or the availability of certain incentives and disincentives.[9] More likely, the correlation comes about because the legalisation of presumed consent signals, for most countries who enacted such a law, a strong commitment to establish and continually improve the system's infrastructure, organisation, public promotion and practices, which involve the negotiation of relationships between persons, families, clinicians, transplant coordinators, state agencies and other relevant actors towards the endeavour of contributing and distributing organs at death for the benefit of others.[7,9]

Donation after Controlled Cardiac Death

An ethical principle that has been the guide for organ transplantation since its inception is the "dead donor rule", which states that vital organs should be procured from persons only after they are determined as dead. The dead donor rule preserves society's commitment to respect persons and human life, and helps maintain public trust by alleviating the concern that the utilitarian imperative to save as many lives as possible through transplantation will lead to substandard or unacceptable end-of-life care. Adherence to the dead donor rule results in norms that govern the process of determining death, such as the norm of strict separation between the medical team certifying death and the medical team effecting the procurement of organs. This prevents any conflict between the interests of patients and the interests of organ recipients.

The dead donor rule as a categorical requirement of transplantation ethics is, however, being challenged by the emergence of controlled cardiac death as an increasingly accepted strategy to expand the pool of donors, defined here as donation after controlled cardiac death (DCCD).

Singapore's HOTA, which was introduced in 1987, was amended in 2004 to extend eligibility from death due to accidents to all causes of death.[15] Under the Interpretation Act, death can be determined on the basis of neurological criteria or brain death, or on the basis of cardiopulmonary criteria or cardiac death. Taken in conjunction, these pieces of legislation imply at least the *possibility* of DCCD becoming a more common local practice in view of the organ shortage.

DCCD typically involves patients whose life-support is disconnected and whose medical care is orchestrated for donation after an end-of-life decision (usually by the family) is made on the basis of prognosis (for example, non-survivable neurological injuries for which treatment is futile) independent of the prospects of organ donation. The recommended protocol is to wait at least 2 to at most 5 minutes after the onset of asystole to ensure that cessation of circulatory and respiratory functions is *irreversible*.[16] The rationale for the recommended duration is based on limited available data which suggests that autoresuscitation does not occur after 65 seconds; it does not mean that the patient cannot be revived by cardiopulmonary resuscitation within or after that period.[16]

Given this, the understanding of "irreversibility" in death determination for DCCD – commonly taken as "impossible to reverse" – is problematic, for it is now taken to mean "non-reversal by choice."[17] Moreover, the certification of death of the donor based on irreversible cessation of heart-beat and circulation appears difficult to sustain if the heart of the donor is restarted in the recipient. A recent journal article reported on the success of a research protocol at Denver's Children's Hospital for the donation of infant hearts after cardiac death, in which the asystole duration was shortened to 75 seconds.[18] The reduced duration was justified on the grounds of preventing organ damage from warm ischaemia so that the heart transplantations could proceed. The determination of death was therefore altered or manipulated for the purposes of transplantation, a charge levelled at the notion of brain death (that continues to this day) when it was proposed as the appropriate interpretation of the dead donor rule.

Regardless of how research protocols on death determination test the limits of socially acceptable DCCD, any adopted protocol (even within the recommended duration) for a DCCD programme will reflect an ethical judgement. A shorter duration reflects judgement in favour of an improvement in quality and quantity of organs procured over an increased certainty of death. A longer duration reflects the reverse. The intertwined nature of death determination and transplantation objectives in DCCD lends support to the argument that consent and non-maleficence (in patient prognosis) – as safeguards for patient interests – should be elevated in importance over the dead donor rule in assessing whether a procurement decision and procedure is ethically acceptable.[17,19] This may result in a significant liberalisation of human organ sources beyond the deceased and living to include those in liminal states, such as people who are not brain dead but are imminently dying or have lost their higher brain functions.[20]

The other controversial aspect of DCCD concerns the practice of administering medications and interventions (for example, vasodilators and anticoagulants like heparin) before, or just as, life-support is withdrawn *solely* for the purpose of preserving the viability of organs rather than for ensuring the best interests of the donor.[16,21] Supporters of such a practice justify these interventions by pointing to the minimal harm or low risks to the patient-donors, and the increased benefits to organ recipients.[21] In addition to this justification, consent – which could be in the form of an advance directive or the consent of the legal designate or family – is used (once again) to mitigate the import of any ethical objection to this procurement practice.

Research shows that outcomes for graft and recipient survival for kidneys and pancreas transplanted from controlled (and uncontrolled) cardiac death donors are similar to those transplanted from brain dead donors.[22] Outcomes for livers transplanted from controlled cardiac death donors are comparably worse and many transplant surgeons therefore do not advise such livers being transplanted in very sick patients with acute liver failure;[23] outcomes for hearts and lungs transplanted after controlled cardiac death (compared with brain death donors) may emerge as the practice of DCCD grows.[24,25]

Extended Donor Criteria

Increasingly, organs from deceased donors with clinical risk factors (such as hypertension and advanced age) – known as extended criteria donor organs – are offered to those on the waiting list to shorten their waiting time. Such transplanted organs are associated with poorer clinical outcomes compared with those procured from donors who meet standard criteria. A trend is also emerging in which organs from deceased donors with high behavioural or circumstantial risk factors for disease transmission are added to the supply line. Transmission of HIV (which has a window period before detection) and hard-to-detect viruses to recipients through such sources have been reported.[26,27] The extent to which donor criteria should be liberalised to increase the deceased donor pool poses a dilemma given the real possibility of tainting the supply of deceased organs.

In view of differences in organ quality, uncertain and evolving risks and outcomes, and the promotion of autonomy, a potential recipient should be informed of the

foreseeable risks and benefits of receiving a non-standard deceased organ, and be allowed to accept or decline the organ at the time of offer and/or prior to waiting list placement. In other words, patients should be allowed to choose organ "quality" over availability or vice-versa in accordance with their values and preferences and risk aversion. The ethical downside is that such a policy may result in an inequity of outcomes between patients who accept all sources of deceased organs and patients who do not[28] (This raises the question of whether and on what ethical basis any incentive, in the form of financial support for subsequent medical treatment and/or priority for retransplantation, should be given to those who opt to be transplanted with organs with clinical risk factors). How respect for autonomy and maintenance of inequity will be balanced policy-wise will depend on the extent which the supply of transplanted organs is regarded as a "singular public good… distributed to maximise public health" or "a market of … available goods from which eligible recipients might select in order to maximise their own well-being".[28]

The latter would become the sole or main characterisation of the organ supply with the establishment of a legal market in living non-related organs, which offers the prospects of a regular source of organs with better short- and long-term outcomes than deceased organs.

Financial Inducement: Incentives or Reimbursements in Live Kidney Donation?

To bridge the gap between supply and demand, transplant programmes around the world, including those in Singapore, are implementing and studying various strategies to encourage living donation of kidneys, given that perioperative mortality and morbidity associated with kidney nephrectomy are very low for donors.[29] These strategies include the use of financial incentives or of reimbursement of expenses that otherwise serve as disincentives. A key ethical concern with the use of financial incentives or rewards is that it may promote transplant commercialism, defined by the Declaration of Istanbul on Transplant Tourism and Organ Trafficking (convened by the Transplantation Society and International Society of Nephrology) as "a practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain", which leads to or supports the continuation or proliferation of organ trafficking and transplant tourism.[30] According to the Declaration, transplant commercialism, organ trafficking and transplant tourism are unethical practices that need to be stopped collectively by regional and global efforts as they erode the legacy of organ transplantation as a "shining symbol of human solidarity" and a "celebration of the gift of health by one individual to another."[31] In line with this stance, the Declaration opposes financial schemes that can enrich live donors or provide them with valuable consideration with regard to their present socio-economic conditions. However, it does not oppose schemes that remove socio-economic disincentives that limit the altruistic pursuit of living organ donation (Such disincentives, which include financial ramifications of time missed from work and concerns about childcare, job security, or future health insurance coverage, may account for why living-related donation rates are not higher than they should be in many countries[32]). The Declaration, in line with the World Health Organization (WHO) Guiding Principles on Human Cell, Tissue and Organ Transplantation,[33] therefore permits reimbursement for actual, documentable costs (such as lost income, provision of disability, life and health insurance related to the donation, medical expenses incurred for post-discharge care etc) of donating a live organ, which will not constitute as payment as long as the reimbursement leaves donors neither better nor worse off medically and financially postoperatively.

Proposals for a Regulated Market

Beyond reimbursement schemes, some advocates for living kidney donation propose the legalisation of a regulated market, which would entail the rejection of the ethical framework of the Declaration of Istanbul and the WHO Guiding Principles, as an alternative way to address the kidney shortage.[34-36] Such a market requires the establishment of a national agency to oversee all transactions (thus eliminating middlemen and direct transactions) in order to control the extent and fairness of the financial rewards, which should be more substantial than reimbursements and/or compensation in order to induce those (emotionally, legally and genetically) unrelated to potential recipients to join and expand the donor pool. Most proposals also provide for a single agency to screen and manage the donor pool, and match the transplants on clinical criteria.

One ethical justification put forward for establishing such a legalised market is to eliminate (or at least undercut) the on-going exploitation of donors (typically the poor in developing countries) in the black market,[3,34] which has resulted in poor socio-economic outcomes and post-surgery care for donors in most transactions and poor clinical outcomes for recipients in some transactions. By providing proper pre- and post-surgery care and increasing the benefits of donation through reasonable or fair financial rewards that are much higher than in the black market, it is argued that a regulated market will enable a favourable benefit-risk ratio for donors. In addition, informed and voluntary consent on the probable risks, benefits and consequences of live kidney donation would be ensured as a safeguard against autonomy violations and exploitation of the vulnerable. Leveraging informed consent and fair financial rewards, a legally regulated market in kidneys

would be intended to overcome the ethical opposition directed at black markets or at unregulated legal markets.

On the other hand, there are also important ethical concerns and considerations relating to the establishment of a regulated market for living kidney donations.

First, while the financial scheme seeks to address exploitation by creating a favourable benefit-risk ratio for donors, it does not address exploitation when considered from a social justice point of view, since it will induce only (or mainly) the poorest to bear the burdens of living kidney donation. Inducement is an aspect of everyday life and choice but becomes unethical when it becomes "undue", that is, an attractive offer that leads persons to do something they would normally object to doing based on serious risks to fundamental interests such as life and health.[37] It can be argued that such an ethical objection does not prevent us from inducing the poor to take on occupations such as high-rise window cleaning which also pose risks to fundamental interests. However the comparison of occupational risks with risks of nephrectomy cannot be equivalent, as occupational risks are calculated over the long run whereas the risks of nephrectomy – low as they may be – are based on risks of the operation itself.[38] In addition, one must also factor in the social, psychological and medical risks that continue to exist long after the surgery, some of which are lifelong. As such, consent for living kidney donation involving financial incentives or rewards cannot but be seriously compromised as a proper autonomous choice, regardless of proper disclosure of risks and consequences.[38]

It might be possible to decrease the exploitative aspects of inducements to donate by ensuring proper medical coverage for the future risks to donors. For example, one might guarantee access to dialysis and priority for transplantation should renal failure occur. However, long-term access to organ vendors (as opposed to unpaid organ donors) has proven to be problematic,[39] something that can perhaps be attributed to stigma associated with organ selling. Access is bound to be even more difficult when organ vendors come from a country different from that of the organ recipient. Solidarity with other countries may also be affected insofar as such medical care is provided to just some of the donor's country's citizens, and because of the possibility of an adverse effect on the recruitment of donors to meet domestic needs for organs. The ethics of transplantation must therefore be considered holistically from a regional/global rather than just a national perspective.

Second, the elimination of the black market through the establishment of the legal market is unlikely so long as the black market is not also tackled by other measures, such as the setting up of a regional/global cooperative framework that imposes sanctions on medical professionals who engage in transplant commercialism. Unless real sanctions are imposed on clinicians and other intermediaries who take part in the international organ trade, the black market will continue to target those with a lack of information or those who are more concerned with financial benefits than safeguards for their health and life. Additionally, the black market might transform itself into a "gray" market offering "high quality" products, which aims to provide recipients with kidneys from donors with the least clinical, behavioural and circumstantial risk factors. If a market were allowed to thrive on the basis of patient and donor autonomy alone, we can conceivably reach a point when clinicians would be allowed to transplant 2 kidneys from 2 different donors to, or conduct many repeat transplants for one recipient. It would be difficult to justify legal sanctions or limits on such practices once the boundary for legalised material incentives is breached.

Third, the legal market – like the black market – may induce living non-related donors to withhold important clinical, behavioural and circumstantial information that may result in the transmission of donor diseases to the kidney transplant recipient.

Fourth, the establishment of a legal market in living non-related donations may undercut the establishment of a deceased organ donation programme that continues to provide kidneys to either those who cannot afford the package of financial benefits for the donor but who do not qualify for financial help from voluntary welfare organisations, or those with religious or other personal objections to inducing others to donate a body part while alive. Such undercutting may arise not because of a decrease in altruistic motives among the population, but because of the diversion of resources away from developing and improving the infrastructure, logistics and organisation of the deceased kidney donation programme, which as noted earlier is perhaps the most critical factor to ensuring its success. Moreover, under an environment in which a living non-related source is legalised, it would be difficult to establish a procurement system for deceased kidneys that could effectively negotiate the opposition of or refusal by families.

Fifth, the growth and development of a living related donation programme – which (as shown in countries like Norway[40]) is a viable way to help address the organ shortage – may also be undercut. It would be much harder to persuade those related to the recipient to donate a kidney if there is a readily available source from the market, with no worries about imposing risks on family members.

Conclusion

The ethics of organ transplantation raises common but profound issues and dilemmas in medical ethics: our responsibility to the sick and dying and its limits; informed

consent as a safeguard for patients' interests and its proper scope based on conceptions of persons and autonomy; end-of-life decisions and notions of death; the value of bodily life and integrity; the effect of technology on medical professionalism and values; and social equity in the allocation of basic health goods. As policy makers and healthcare professionals in Singapore fashion strategies and systems to meet the national organ shortage, the choices they make will have profound ethical implications for the public at large, for the medical profession and for the worldwide environment within which organs for transplantation are obtained.

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