

## REVIEW

# The principles of gift law and the regulation of organ donation

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**Summary**

The principles of gift law establish a consistent international legal understanding of consent to donation under a range of regulatory systems. Gift law as the primary legal principle is important to both the foundation of systems that prevent organ sales and the consideration of strategies to increase organ donation for transplantation.

**Introduction**

The regulation of consent to organ donation provides the cornerstone to any system of transplantation by establishing the legal and ethical infrastructure from which the rights and duties of donors, transplant professionals and recipients can be understood. The approach to the consent for organ donation internationally mainly adheres to a system of either “opt in” – necessitating the consent of family or the individual or “opt out” in which the consent may be presumed unless the individual took an affirmative step to refuse donation. Uniform principles of gift law provide a useful legal paradigm to frame the regulation of consent to donation both under systems of explicit “opt in” consent and “opt out” presumed consent. Global strategies to increase organ donation may effectively utilize regulation of consent under gift law principles.

**The principles of gift law**

Gift law has its origins in the legal doctrine of property. To “give” is understood to mean “the act by which the owner of a thing voluntarily transfers the title and possession of the same from himself to another person without consideration” [1]. Gifts of any type must fulfill three basic elements to be legally recognized: (i) there must be donative intent; (ii) the gift must be physically transferred or delivered; and (iii) the gift must be accepted [2]. Once all three criteria are met, the gift is complete and enforceable under the law.

Organ donation is anatomical gifting – the uncompensated transfer of organs from the donor transplanted into the recipient. Anatomical gifts are “conditional” upon the death of the donor. Accordingly, once consent exists and after the donor has died, the gifted organs may be surgically recovered, transferred and accepted for transplantation.

Each of the three elements of gift law supports the central international tenants of organ donation and provides a coherent and well-established legal context regardless of whether the system is one of explicit or presumed consent. The legal understanding of organ donation as a gift furthers the principles set forth in the Declaration of Istanbul by establishing the legal foundation to systems that prevent organ sales [3].

### Donative intent

Gift law principles firmly root voluntariness as the central construct in organ donation. Under legally established principles, gifts cannot be made absent intent. Donative intent means simply that the donor has formed an affirmative objective to donate. In the context of organ donation, donative intent requires that the donor (or donor's family by proxy) voluntarily makes the anatomical gift. As an exercise of autonomy, donative intent is a powerful element of gift law, providing ethical support to uphold the individual's organ donation decision even in the face of family objection.

The legal requirement of donative intent can be established through a "document of gift" which is the documentation of consent to the donation. By documenting consent to donation, the donor expresses an intent to make an anatomical gift after death. Under an explicit consent system, an individual may document consent to deceased organ donation by signing a donor card or by registering as a donor during the driver's license renewal process or through an internet-based donor registry.

### *Donative intent in opt-out systems*

The gift law requirement of donative intent provides some challenge to systems that regulate organ donation under presumed consent models. It is harder to conclude that donative intent is evidenced by the absence of a documented choice to opt-out. Nonetheless, many have argued that the presumed consent remains a voluntary system of donation given that there is a readily available mechanism to exercise the right to refuse donation. In this manner, presumed consent models still follow gift law principles but do not satisfy the element of donative intent as clearly as systems of explicit consent.

It is more difficult under a presumed consent system to support an autonomy concept of the donor's intent to make an anatomical gift. This may in part account for the difficulty some presumed consent countries have moving forward over family objections. Comparatively, explicit consent models are squarely predicated on the concept of donative intent which provides stronger ethical support to follow the donor's decision even if the family objects.

### *Donative intent versus informed consent in deceased donation*

Notably, the regulation of deceased donation under a gift law construct does not incorporate an informed consent standard as that term is commonly understood. Although surprising to some, given that informed consent is a pinnacle legal doctrine of health care, the law clearly views deceased donation as anatomical gifting and not as a healthcare decision for the donor. The informed consent doctrine fundamentally requires the consenting party make a decision regarding a proposed healthcare treatment or procedure through a facilitated understanding of the attendant risks and benefits. There are, however, neither risks nor benefits to a deceased donor from donation.

Furthermore, the legal duty to obtain informed consent is born out of the doctor-patient relationship [4]. The decision to be a deceased donor, however, may (and often does) occur completely outside of such a fiduciary relationship. This is true for both explicit and presumed consent models where consent for organ donation can be secured independent of medical treatment months, years or even decades before the donor's death.

As with any type of gift, a person may choose to inform themselves about the organ donation process or remain uninformed but the legal ability to make an anatomical gift remains. Outside of the gift law context, other postdeath decisions such as burial or cremation are similarly not legally required to meet an informed consent standard. In fact, there are some premortem patient directives that fall outside of informed consent as well. Individuals may sign advanced health care directives (including "do not resuscitate"), for example, without any legal requirement that these significant decisions meet an informed consent standard.

There is universal agreement that potential organ donors or donor families should be directed to information that may assist in the donation decision-making. It is the responsibility of donation professionals to provide access to such information and facilitate an understanding of organ donation if requested. Nonetheless, it is important to the integrity of existing donor registration systems internationally (whether opt-out or opt-in) that consent to organ donation is, in fact, within the legal constructs of anatomical gift law which does not incorporate an informed consent requirement.

Criticisms of consenting to donation through donor registries under opt-in models often focus on the lack of informed consent [5]. The process of registering as an organ donor is not, however, intended to meet legal informed consent standards. Rather, the act of registering as an organ donor fulfills the legal requirement of documenting the donor's intent to make an anatomical gift; to voluntarily transfer organs to another upon death. This is

legally sufficient under gift law principles. The desire for family consent in addition to the donor's own designation may be culturally important but it is not legally required under gift law principles. In fact, under gift law, the family, or any other third party does not have the right to over-ride a valid gift that was made by the donor prior to death.

A similar analysis can be made with presumed consent systems. Assuming consent to donation unless the individual opts-out through registration is not designed to incorporate informed consent standards. To the contrary, under a presumed consent model the anatomical gift is legally secured by an absence of affirmative steps to refuse. This should not, however, be confused with support for conscription – the idea that organs are to be donated by law with no opportunity to opt-out. Such a model would not meet the requirements of donative intent and therefore, is not supported by the tenants of gift law.

#### *Donative intent and donation after cardiac death*

In nations that allow for organ donation after cardiac death (DCD), concepts from both gift law and the informed consent doctrine must be considered. DCD is a form of deceased donation where the dead donor rule remains paramount even if clinical debate exists over appropriate time intervals before the declaration of death under DCD protocols. DCD, however, also requires coordination with end of life decisions to withdraw support separate and aside from the organ donation itself. The convergence of these events draws upon the legal constructs of both informed consent for withdrawal of support as well as donative intent to make an anatomical gift. For this reason, DCD necessitates attention to both legal principles.

The potential DCD donor may have already made an anatomical gift conditional upon death. However, there must be a decision to withdraw continued treatment and life support prior to death declaration and the subsequent surgical recovery of donated organs. The withdrawal of support requires informed consent from the patient's legal surrogate even if the patient had previously documented donative intent to make an organ donation. The anatomical gift does not include a withdrawal of care directive. The result is an interesting combination along the continuum of legal principles of consent for deceased donation and the informed consent principles underlying medical decisions.

#### **Transfer**

The second legal element of a gift requires the transfer of the gift from the donor to the recipient. In the context of

organ donation, this involves the recovery of the donated organ and the delivery of the organ to the recipient. The anatomical gift includes consent for the organ to be surgically removed and provided to a recipient for transplantation. Those involved in the recovery and transport process are custodians of the anatomical gift for benefit of the recipient. Gift law directs that the recovered organ be delivered to the recipient so that the final element – acceptance – may occur.

#### **Acceptance**

The final element of gift law requires that the gift be accepted before the legally binding transfer is deemed complete. The system of organ donation and transplantation incorporates this element by establishing the potential recipient's right to accept or reject an offered organ. The anatomical gift is made by the donor but transplantation occurs only after the recipient (or the recipient's surgeon) accepts the organ.

Gift law also resolves the legal status of an organ once recovered and transplanted. The sanction of the transplantation of the donated organ into the recipient must be understood as a legally binding transfer. Absent such a principle, possession of the transplanted organ could be separated from the right to keep it. This result would be particularly troublesome in the context of living donation [6].

Once removed, the donated organ is understood as a gift. Such a gift is legally enforceable after delivery to and acceptance by the transplant recipient. This analysis precludes an assertion of rights by the living donor or deceased donor's estate over a donated organ once the organ has been transplanted into the recipient. The gift status of a donated organ regardless of whether the donor was living or deceased provides the transplant recipient with consistent legal authority for continued possession of the transplanted organ.

#### **Gift law as a barrier to market systems**

Gift law also provides a coherent legal principle to a system of transplantation that prohibits the purchase or sale of organs given that, by definition, gifts involve an uncompensated transfer. A system that relies on gift law principles as the fundamental legal basis for consent to donation constructs a significant principled legal barrier to creating an open or regulated organ market system. The existing United States federal law prohibiting purchase and sale of organs is buttressed by 50 state laws regulating consent to donation through gift law principles [7].

Over-turning the federal ban would not eliminate the legal requirement in the United States that consent for

donation be accomplished through the voluntary and uncompensated transfer of organs because donation is based on gift law principles. Any regulation of consent to donation that is built on gift law principles precludes the possibility of exchanging organs for money as this would abrogate the fundamental tenant of gifts. In this manner, gift law supports the Declaration of Istanbul by providing an obstacle to transplant commercialism.

### Strategies for increasing donation while preserving gift law principles

The regulation of consent has importance beyond the mechanics of how an organ can be legally transferred from the donor to the recipient. The mechanism of consent regulation can impact the availability of organs for transplantation. It has been shown, for example, that countries with presumed consent models have higher rates of organ donation [8]. There are other ways in which the regulation of consent can leverage change while preserving gift law principles. The regulation of consent can also serve as a strategy to address the shortage of organs for transplantation by integrating allocation incentives. This type of approach was recently adopted in Israel [9]. The Israeli organ donation legislation will grant allocation priority to those who have signed up to be organ donors or whose first degree relatives have registered as donors or who have died and become donors. Such a strategy has the potential to achieve significantly increased donation rates within the existing gift law paradigm. Preserving gift law is important to ensure a continued and unifying international legal principle for the noncommercial regulation of consent to organ donation.

Concerns regarding this type of strategy have been voiced but are significantly less than those objections mounted in the debate over financial incentives as a method to increase organ donation. Providing some measure of potential future allocation priority to those who are donors is not the same – ethically or legally – as paying for an organ. Gift law principles permit the exchange of nonmonetary benefits conferred on a donor. This has been demonstrated in the U.S., for example, through ethical and legal support for kidney paired exchange programs and a priority granted for living donors if a transplant is later needed [10,11].

The ethical pillar of equity provides support for a system that ties the regulation of consent to organ donation to the regulation of access to transplantation. A nation that calls upon its population to be donors should provide fair access to organs if it expects that consent will be obtained. The reciprocal point also holds. Those that are eligible to receive transplants should be willing to donate.

Referred to as “reciprocal altruism,” there is a readily understood, simple, ethical parity to such a strategy [12]. It would seemingly reduce inequities while simultaneously broaden access by increasing available organs for transplant over time.

Equity also demands the fair distribution of benefits and burdens of an organ procurement and allocation program. Granting some priority to those who have registered as donors in the allocation of available deceased organs can accomplish this synergy. It is not a matter of absolute qualification nor is such a concept based on moral character that some are more deserving than others. Rather, it is the idea that transplantation is a community endeavor that requires community obligation because it can only be achieved through organ donation. Without organ donation there can be no transplantation. This is not to suggest that consent and allocation be tied to the point of over-riding critical factors such as medical need and utility. It is a concept for incentivizing participation in creating a community resource – organs for transplantation – for which everyone would have an opportunity to benefit.

### Conclusion

Gift law principles provide an international framework for the regulation of organ donation under either opt-in or opt-out systems. Organ donation understood as anatomical gifting solidifies voluntariness and the noncommercial transfer as central constructs consistent with the Declaration of Istanbul. Within the principles of gift law, there is opportunity to leverage the regulation of consent to increase organ donation and transplantation.

### Funding

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