Law Reform on Conditional Consent: Whose Choice is it Anyway?

Several years ago, after being stunned by what was uncovered during the Bristol Inquiry, Parliament enacted the Human Tissue Act 2004. The Act served to emphasize the need to secure valid consent in order to properly regulate the transplantation and storage of human organs and other materials. Nonetheless, areas for debate remain with regards to the ethics and apparent inconsistencies in consensual freedoms accorded to living donors as compared with postmortem situations and the families of dead donors.

The Human Tissue Authority applies a long-standing and rigid approach, so that the allocation of organs is to those with tissue compatibility and considered to be most in need. These organs can be accepted only on an “undirected” or “unconditional” basis. Organs that are given on condition run the risk of being refused or, alternatively, having their conditions ignored. This is in contrast to the initiative shown by states across the USA which allow for direct deceased donations.

The strict criteria imposed on donations given by dead and pre-mortem donors within the UK are not the result of legislation but the result of long standing practices dating as far back as 1961. Despite the lack of statutory backing for these practices a panel investigating conditional consent found that organs obtained in this manner were deemed to be legally binding.

Coran and Douglas have described the ethics underpinning the collection of deceased donors’ organs as impartial justice, in that it is based upon the desire to keep deceased donations equal and fair. This idea of fairness has been challenged by the outcome in the Laura Ashworth case, which saw the death of a mother arising on account of a technicality which was imposed in order to protect this so called “fairness”. Following

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1 Hereinafter referred to as ‘the Act’.  
3 Human Tissue Authority statement on directed donation of organs after death. Issue date 14 April 2008.  
4 Uniform Anatomical Gift Act 2006, s11 (a)  

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the Ashworth Affair, it now seems apparent that there may be flaws in the current system whereby pre-mortem organs and those of the deceased are obtained and transplanted.

This paper specifically considers the area of conditional consent to donation and offers pragmatic proposals for reform. These proposals take into account protection conferred by the Human Rights Act 1998⁷ and core bioethical principles such as autonomy and justice in order to produce a reform that is workable and administratively sound.

**Consent and Autonomy in contemporary law**

Autonomy and rights to self-determined choice are protected by Article 8 of the European Convention on Human Rights and is enforceable in the UK through the HRA. According to Dame Butler-Sloss “Article 8 protects the right to personal autonomy, otherwise described as the right to physical and bodily integrity.”⁸ Long before the enactment of the HRA the premise that one needed to respect the autonomy of another’s body by obtaining valid consent was already a tenet of English law as recognised by Lord Goff in Re F.⁹

Despite the sacrosanct need for respect to be shown for another’s body and its constituent parts, there are no recognized property rights attached to the human body or its parts. In English law this rule was established in Williams v Williams¹⁰, following which a body of case law has developed. In the absence of bodily property rights, the autonomy of the individual is protected by common law and by the Act. The Act requires consent to proceed anatomical examinations, determination of the cause of death, obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person), public display, research in connection with disorders or the functioning of the human body and transplantations.¹¹ For the purposes of the Act consent means “appropriate consent”¹² and it applies to

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⁷ Hereinafter referred to as the HRA.
⁸ NHS Trust “A” v Mrs M; NHS Trust “B” v Mrs H [2002] 2 AII ER 449
⁹ (a mental patient: sterilisation) [1990]
¹⁰ (1882) 20 CRD 659
¹¹ Human Tissue Act Part 1 Schedule 1
¹² Human Tissue Act 2004 s.1
relevant material collected from the living or the dead. Living individuals must give consent through writing and those who lack capacity, such as minors, appropriate consent will be that of the person with parental responsibility.

For deceased donations, when seeking appropriate consent practitioners look for any indication of consent that had been given by the individual whilst that person was alive and will include, i.e., a signature on the donor register. If no indication exists, or if there has been a considerable time between consent and death, section 7 provides a statutory hierarchy of potential nominated representatives who may give consent on behalf of the deceased.

**The Inadequacy of Pre-mortem Autonomy**

The primary argument here is concerning the free will and autonomy of pre-mortem donors and nominated representatives of the deceased. Once consent has been obtained, the Act fails to provide for any requirements that may need to be considered prior to donation on the part of donors or their nominated representatives. These factors include religion, ethical or cultural demands.

This is in contrast to that of the living donor. The premise behind living donations is free will, autonomy and informed consent. Persons with capacity can exercise their free and self-determined choice as to whom will benefit from their gift. They may donate to specific individuals in whom they have a special interest, for example, an individual may choose to donate following media publication of a child’s desperate plight. More controversially, a potential living donor may choose to donate on the basis of personal prejudices in respect of race, culture or religion.

Arguably, such respect for the self-determined choice of the living is a necessary precondition. The lives of living donors will inevitably be affected by the decision to donate which might have implications for the remainder of their lives. Thus, it is understandable that any decision should be properly made with sufficient information, but also made in accordance with personal values and ideologies.

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On the other hand, the free will given to living donors may potentially permit abuse such as unlawful commercial dealings and exploitation.

This compares with deceased donation practices whereby neither the nominated representative, nor the prior requests of the donor, may influence the choice of recipient. Coran and Douglas have dubbed organs donated by pre-mortem donors and their representatives as organs for allocation as opposed to organs for donation.13 Irrespective of the reasons behind such unequal treatment, given the possible bereavement and trauma caused by the donor’s death, it seems likely that it could provide great comfort for a family to have an influence in how an organ (or tissue) is used.

Conditional consent

The chasm between the consensual liberties afforded to the living and compared with those of the dead is the result of long-standing practices, although these distinctions became apparent only relatively recently. In 1998 the relatives of an individual placed a condition that the organs of their deceased family member could only be used if they went to a white person. Coincidentally the individuals at the top of the liver and kidney transplant waiting lists were white. As it was felt that the conditions in this instance could be adhered to, the organs were accepted and successfully transplanted into waiting recipients. Considerable publicity was to follow. Frank Dobson, the Health Secretary at the time stated "I was appalled when I learned today the initial details of this case. As soon as I heard, I asked my permanent secretary to carry out an urgent investigation to find out what happened and to ensure it never happens again."14

The panel set up by the Department of Health concluded that since the organs were gifted to those in accordance with the waiting list no one had been prejudicially disadvantaged. The panel also found that it was inappropriate for the organ to have been accepted in the first place and it was suggested that organs ought to

13 Supra [6]
be refused if a condition had been attached. These findings prompted the General Medical Council to issue guidelines effectively prohibiting the acceptance of conditional organs.

The rationale behind this prohibition is clear, given the potential for controversial conditions in that an outright ban would safeguard the future allocation system. What seems to be taken for granted is that despite the apparent outrageousness of the condition, the lives of three individuals had been saved. In balancing between life and morality presumably greatest weight should be given to life, as the will to live is subjective whilst the preservation of society’s moral integrity represents a communal desire.

Not all conditions are as controversial as that above. Wilkinson puts forward an example of a condition being attached to a kidney in that in the event of death, the prospective donor’s kidney should be given to a sibling. Wilkinson argues that it is perfectly acceptable for a person to have a special interest in their loved ones and having a special interest in donating to a child is no more wrong as donating to a children’s charity. Wilkinson’s argument was actively demonstrated by the 2008 Ashworth affair.

In 2008 a 21 year old, Laura Ashworth, requested a controversial direct donation to her mother Rachel Leake who was receiving dialysis for end stage renal failure. At the time of Ashworth’s death, the formal process for a living donation between the two had not taken place. As Ashworth was registered on the donor register, her organs were taken and transplanted into two strangers, following her death. The matter was referred to the Human Tissue Authority which issued a statement confirming the decision. Considerable critic followed, in many ways Ashworth served to illustrate many of the arguments advanced about the inconsistency between living and pre-mortem donors. Rachel Leake who unfortunately died as the result of this technicality was the catalyst for the policy document “Requested Allocation of a Deceased Donor Organ”.

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15 TM Wilkinson, What's not Wrong with Conditional Organ Donation? [2003], 29 JME 163-164
16 Ibid [15]
17 Supra [3]
18 Hereinafter referred to as RADDO : REQUESTED ALLOCATION OF A DECEASED DONOR ORGAN, March 2010
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The policy document still enforces unconditional donation but allows discretionary exemptions in specific circumstances such as the death of a potential living donor or where the organ might benefit a family member or friend. The policy also calls for it to be clearly communicated that deceased donations are unconditional, and allows greater decision-making powers to the NHS Blood and Transplant.\(^{19}\)

**The Case for Reform**

The RADDO policy creates a more informed system with added flexibility when dealing with complex situations, although inconsistencies persist between the donor groups. RADDO still endorses unconditional consent but provides the NHSBT with discretionary powers in specific circumstances, where consent has been given unconditionally donors can now put forward preferred recipients. These recipients must either be relatives or close friends.\(^{20}\) The preferred recipient will not be a priority but only a factor to be considered, priority still is given to the waiting list.\(^{21}\) Given that the relevant statute does not require anything more than appropriate consent, referrals to the NHSBT are simply at the hospitals discretion theoretically leaving to chance the possibility for more controversial actions with restricted legal ramifications.

RADDO makes the case that “conditions offend against the fundamental principle that organs are donated voluntarily and freely and should go to patients according to the agreed criteria.”\(^ {22}\) Pattinson stated “the notion of “appropriate consent” implies voluntary and free consent but why are organs directed to a specified individual any less voluntary or free?”\(^ {23}\) Also, If this is the case hypothetically almost all direct living donations are in breach of the Act.

\(^{19}\) Hereinafter referred to as NHSBT.

\(^{20}\) REQUESTED ALLOCATION OF A DECEASED DONOR ORGAN, March 2010

\(^{21}\) Ibid [20]

\(^{22}\) Ibid [20]

\(^{23}\) Shaun D Pattinson, Directed donation and ownership of human organs, September 2011, p398
RADDO’s interests appears to be based on the “greatest need principle” consequently inferring that the needs of other override that of the donor or the representative. Giving that the UK operates an opt-in system, it is unacceptable for the interests of others to trump the interests of the individual.

It is therefore time for the law to revisit the situation rather than to conserve an outdated and unfair system.

The proposal
My proposal calls for the legalization of conditional consent subject to specific safeguards.

This would bring the current deceased and pre-mortem donor system closer to that of the living with minimal consequences for cadaveric donations. A reform of this magnitude would need robust checks and balances in order to improve the current, and arguably inequitable, situation within the UK.

Both arguments for and against conditional consent are not right or wrong, thus any proposal put forward to remedy the injustice should endeavor to encompass both sides of the argument.

One of the key arguments put forward against conditional consent is the desire to keep donations indiscriminate and fair. The actions of the family of the racist back in 1998 clearly defiled public integrity, consequently strengthening the argument for the prohibition on conditions, but what Ashworth has taught us is that not all conditions are bad ones. What is being suggested is that the motive behind conditions be brought into consideration. To restrict the influx of radically motivated conditions law makers should consider imposing a duty for all pre-mortem and deceased conditions to be compatible with the Equality Act 2010. The Equality Act would serve in rooting out conditions which are contrary to public integrity.

The Ashworth affair highlighted the inadequacies between the respect given to the wishes of living donors compared to pre-mortem and the families of deceased donors. In many ways this respect for the autonomy of the living has benefited the current system as direct living donations are on the rise, but in a fair and unambiguous system consistency is paramount. Pattinson pointed out that the only practical gain in direct

24 Ibid [23]
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donation is “the satisfaction of believing that they could assist someone they care for or even love.”25 This practical benefit arguably should be extended to pre-mortem donors and the families of deceased donors. Given the trauma of death it would be equitable for any reform to unequivocally allow for direct deceased donations between relatives and close friends. This change in law should bring the UK on par with the US and if the rise in direct living donations is anything to go by, theoretically this should lead to a rise in deceased donations.

The set up of the NHSBT by RADDO to consider conditions in certain circumstances was a good idea, but its fundamental flaw is that its discretionary powers were limited to certain circumstances. Also, as hospitals were not legally bound to report to the NHSBT, the NHSBT are effectively a toothless animal. Perhaps what should be done is the NHSBT should oversee all conditional donations. The system should work as a hierarchy system with doctors making the initial decisions in regard to conditions, followed by a right to appeal to the NHSBT and then to the courts.

Giving the NHSBT greater powers allows for a doctrine of precedent to be created through the appeal mechanism, this will assist doctors in separating good conditions from others more controversial.

Lawmakers should consider making it mandatory for individuals who in receipt of a conditional organ to be made aware that there is a condition attached to the organ and of the nature of the condition. This suggestion simply illustrates long standing practice of informed consent and patients rights to refuse treatment.

25 Supra [23]
Conclusion

The nature of organ donations is changing. What may begin as minor inconsistencies may develop into catastrophes over time. My proposals seeks to remedy the situation by addressing the core of the injustice, which is the reluctance to except conditional organs. The proposals allow for the nature and motives behind a condition to be considered, instead of the current approach of simply disregarding all conditions.

These proposals incorporate a number of legal principles, with the aim to create consistency between living and deceased donations. There are concerns that given the number of statutes embodied in this proposal, authorities responsible for deciding upon a condition may find it difficult to apply. Furthermore, given obvious time constraints, authorities responsible for decisions may find themselves under significant pressure. They may be issues in regards to the proposed hierarchy structure of appeal. It is questionable whether doctors may be able to adjust to the role of allowing or disallowing conditions. Doctors may be more inclined to except organs regardless of conditions, as ultimately doctors are required to act in the best interest of patients.

The role of doctors is forever evolving, as doctors are consistently faced with ethical dilemmas. Given the proposed appeal system, sufficient safeguards are arguably in place to support doctors making difficult decisions. This is again re-enforced by past precedents and procedures which will be introduced through associated statutes and principles incorporated in the proposal.

In conclusion, the true potential of this proposal rests in the hands of the authorities who would be responsible for its application. What the proposal does is to reverse the assumption that all conditions are adverse, allowing them all to be considered on an objective basis.

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