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organ transplantation

By Keith Rigg

Organs for transplantation may come from deceased or living donors, and the treatment both saves and enhances life. However, there is a lack of donor organs and the waiting list is increasing. This shortfall adds to the clinical, legal and ethical challenges. This *File* considers the diagnosis of death, presumed consent or 'opting-out', and payment for organs, and recommends we should all consider what we wish to happen to our organs and tissues after our death.

Organ transplantation has developed from a highly innovative procedure to routine clinical practice. Successful kidney transplantation started in the 1950s followed by heart, liver and pancreas transplants in the 1960s, and lung and small bowel transplants in the 1980s. Outcomes have steadily improved due to better surgical techniques and more effective immunosuppressive treatments. One-year graft survival is currently 94% for live donor kidneys, 88% for deceased donor kidneys, 86% for livers, 84% for hearts and 77% for lungs.[1] Longer term outcomes are similarly improving.

However, demand far exceeds the organs available. In the UK in the financial year 2007-8 there were 2,385 organs transplanted from 809 deceased donors with a further 839 live donor transplants, but there were 7,655 patients on the active waiting list.[2] This list grows at 8% per year, but 1,000 die each year while waiting or become too ill for a transplant.[3] While this shortfall persists, options will be considered to increase the number of available organs.

Some suggestions about organisation are uncontroversial, such as Organ Donation Taskforce recommendations which aim to increase donor numbers by 50% over the next five years.[3] Presumed consent and regulated payment for live donors raise more ethical questions. This *File* will focus on these, but not on potential technologies such as xenotransplantation (from animals to humans) and stem cell use.

What is the legal framework?

Organ donation and transplantation are covered by the Human Tissue Act 2004 in England, Wales and Northern Ireland;[4] and by the Human Tissue (Scotland) Act 2006.[5] Consent, or authorisation in Scotland, is the fundamental principle of both Acts and is required before organs can be removed from the deceased, stored, and used. Consent is also required from live patients offering organs, but is covered by common law.

The Human Tissue Authority was established in 2005 as the regulatory body for England, Wales and Northern Ireland and one of its statutory functions is to produce Codes of Practice.[6]

What does the Bible say?

The key ethical areas are the diagnosis of death, and the donation and allocation of organs. Although the Bible appears quiet on some specifics, a number of biblical principles can be applied.[7] In the Old Testament we see God as the creator and sustainer of life who is concerned with justice and the welfare of his people. Mankind's moral responsibility regarding these attributes is found in the Ten Commandments, where the last six in particular are summed up as 'Love your neighbour as yourself'.[8] In the New Testament Jesus reiterates the importance of loving God and loving our neighbour in his summary of the Commandments.[9]

Other principles include seeking to be obedient to God; treating others with respect since all are equal in God's sight; serving and self-sacrifice;[10] our bodies belonging to God; and our having a different body at our resurrection[11] so that we will not need our organs in heaven. CMF has written extensively about the biblical principles which should govern attitudes to our bodies and to use of them after death.[12]

Ethical issues around deceased donor transplantation

Diagnosis of death

There is currently no legal definition of death, although 'an irreversible loss of the capacity for consciousness combined with irreversible loss of the capacity to breathe spontaneously and hence to maintain a spontaneous heartbeat' is generally accepted. A patient who has had no heart beat or spontaneous respiration for 24 hours, for example, is clearly dead to all concerned, yet tissues such as skin and cornea can still be taken and used.

A patient with irreversible damage to the brain stem, where the nerve centres controlling breathing and heartbeat are situated, will rapidly develop respiratory and circulatory arrest, although both functions can be artificially maintained on a ventilator for a variable period of days. It was for such patients on intensive care units that the criteria to diagnose brain stem death were developed.[13] These criteria are needed irrespective of whether organ donation is being considered: it is always important to separate the treatment of the 'patient' from the treatment of the potential 'donor'.

There are two types of deceased donors: the heart-beating or donation-after-

brain-stem-death (DBD) donor and the non-heart-beating or donation-after-cardiac-death (DCD) donor. The DBD donor will typically be on a critical care unit with severe brain injury and, when a clinical diagnosis of brain stem death is confirmed and providing consent is obtained, organs for transplantation may be removed.

There are different categories of DCD donors, but essentially a diagnosis of cardiac death will be made with cessation of heart beat and respiration, after treatment has been withdrawn because it is now medically futile. If consent has previously been obtained, and after a stand-off period to ensure there is no spontaneous return of cardiac function, then organs may be removed.

Brain stem death

Many philosophers, ethicists, theologians and clinicians have debated when is the exact point of death? There is no agreed view. What has been accepted is that death is a process. Likewise it is accepted that irreversible destruction of the brain stem has a dire prognosis with no prospect of recovery. Therefore the majority view is that brain stem death can be considered as the patient being dead, even while respiratory and circulatory functions are artificially maintained by a ventilator. This position is supported within law and by the Code of Practice for the diagnosis of brain stem death,[14] which is currently being revised.

However, there is an opposing minority view that brainstem death doesn't equate with death, until the heart has stopped beating and respiration has ceased. It is therefore only after the removal of organs that the patient can be considered truly dead. The criteria for brain stem death are therefore prognostic rather than diagnostic, and cessation of brain stem function is part of the process of dying rather than the point of death.[15,16] The 1980 BBC *Panorama* – 'Transplants: are the donors really dead?' – espoused this view, but it has been repeated regularly over the years. It is likely there will always be opposing views, but what is important is that the public have confidence in the professionals and are helped to understand what is meant by brain stem death.[17]

Cardiac death

Within the last decade there has been an increase in the number of DCD donors as a result of the decrease in DBD donors. The procedure is outlined above and although the majority have no ethical or legal concerns, there is an opposing view. The main issue relates to the stand-off period between the time of the heart stopping and perfusion of the organs prior to removal. For most tissues any period greater than 10 minutes is likely to mean injury caused by the circulation ceasing that will be detrimental to usage, while shorter periods may cause concerns about the certainty of death. Spontaneous auto-resuscitation or the 'Lazarus' phenomenon[18] is rare, but may occur up to 10 minutes after the heart stops.

Around the world stand-off times of 2, 5 or 10 minutes are used. In the UK 10 minutes is standard practice, although there are some intensive care specialists who feel this is not long enough. One recommendation of the Organ Donation Taskforce is to resolve outstanding legal, ethical and professional issues[3] and this area requires clarification.

Presumed consent

UK legislation is based on 'opting-in', where individuals express their wish to donate their organs. The 2004 Act[4] and its supporting Code of Practice[6] state that where an adult, while competent, has given consent for donation after death (eg through the organ donor register) then that consent is sufficient for the activity to be lawful. Where the wishes of an individual are not known, the views of a nominated representative or a person in a qualifying relationship will be sought. Although it is legal to remove organs from an individual who had expressed in life a wish to donate, this would not be enforced where a family member had strong objections.

Although surveys show that 90% of the UK population favour organ donation, only 25% are on the register.[19] Currently 40% of families of potential organ donors on intensive care units will not give consent for donation.[20] Some would therefore argue that 'opting-in' does not work so other legislative frameworks should be considered. These include:

- '*Opt-out*' or *presumed consent* where consent for organ donation is presumed unless the individual has expressed their objection in life. This may be the 'hard' option where relatives' views are not taken into consideration, and the 'soft' option where they are
- *Required request*, which is law in some USA states, where it is a requirement to ask about donation with families of potential donors
- *Required response* or *mandated choice* where all adults are required to make a choice about whether they wish to donate their organs or not

In either of its two forms, presumed consent is the legislative framework in much of mainland Europe and is currently on the political agenda in the UK. The British Medical Association[21] and others have lobbied for it throughout this decade. It was extensively debated when the Human Tissue Bill was going through Parliament in 2004, but was not supported.

Since then, as the shortage of organs has increased, the Chief Medical Officer in his 2006 report[22] proposed amending legislation to create an opt-out system, with proper safeguards and good public information. The Prime Minister subsequently added his support[23] and the Organ Donation Task Force was asked to 'examine the potential impact on organ donation of introducing an "opt-out" or presumed consent system across the UK, having regard to the views of the public and stakeholders on the clinical, ethical, legal and societal issues, and to publish its findings'.[24] They are due to report in summer 2008. Surveys have shown an increasing proportion of the population in favour of presumed consent, the latest in October 2007 showing 64% in favour.[21]

Supporting arguments

- Presumed consent more accurately reflects the wishes of the population. 90% support organ donation and presumed consent makes donation

the default position. Similarly it potentially makes it easier for families to reach a decision, and changes the professionals' approach to families at the difficult time around death. UK supporters advocate the 'soft' option so families would still have a role in decision making.

- More organs will be made available for transplantation, although it is difficult to prove that introducing presumed consent results in this, as there are many confounding factors. Some studies have shown that, accounting for other factors, presumed consent countries have a 25-30% higher donation rate than informed consent countries,[25] although other studies have not shown this.
- Safeguards would be in place to exclude children and other vulnerable individuals without the capacity to consent.

Opposing arguments

- Presumed consent equals no consent, unless there is an extensive public information programme (which would need to capture the entire adult population including those on the margins of society). Only this would ensure that those who do not opt out have made a positive choice, rather than doing so by default.
- Legislation recently changed because of concern about events at Alder Hey and Bristol, and consent is now the golden thread running through the Human Tissue Act. Donation for transplantation is one of the scheduled purposes where consent is required. It would send a conflicting message to change legislation so soon and now say consent for transplantation can be treated differently from other procedures.
- 'Donation' may become 'taking' organs rather than 'giving' them and lead to a perception that the state is deciding what happens to an individual's organs rather than the individual (or the relatives, under a 'soft' system) making the decision.
- Presumed consent alone will not solve the organ shortage.

CMF recognises why an opting-out system may seem attractive, but supports organ donation as an altruistic free gift in the context of fully informed consent.[26] The Church of England recognises 'that an opt-in or opt-out system is not a question on which Christians hold a single set of views. The opt-in system reflects our concern to celebrate and support gracious gifts, freely given. The opt-out approach stresses Christian concern for human solidarity and living sacrificially for others.'[27]

Further informed public debate is required and the Organ Donation Task Force findings may help clarify the direction of travel. There is a balance to be found between respecting the wishes of donors and their families, recognising the need of potential organ recipients, and acknowledging the influence of societal, cultural and theological values.

Allocation of organs

The underlying ethical principles are straightforward in that organs should be allocated irrespective of age, gender, race, religion or social standing. Scripture supports this, as we have seen. However, the reality is more complex because organs are a scarce resource and not every individual who needs an organ will receive one.

UK Transplant run the organ-specific national allocation schemes with an overarching principle of ensuring patients are treated equally. Donated organs should be allocated in a fair and unbiased way, based on the patient's need and the importance of achieving the closest possible match between donor and recipient.[28] Some patients have a greater clinical need, while others have been waiting longer; donation rates are greater in some ethnic groups, while the need for transplantation is greater in other groups. Utilitarian principles therefore compete against deontological (duty-based) ones.[29] Resource allocation has been discussed in greater detail in a previous *CMF File*.[30]

Ethical issues around living donor transplantation

The first successful living donor kidney transplant was performed by Joseph Murray in Boston in 1954 between identical twins. Throughout the early years living donor transplantation continued at low levels, but within the last decade UK numbers have increased significantly year on year. Living donor kidney transplants currently account for 36% of transplants, and the rate is generally higher in those countries with lower deceased donation rates.

The many reasons for this include the increasing shortage of deceased donor organs, better outcomes for live donor transplants, and the increasing use (with improved outcomes) of minimally invasive surgery for the donor operation. The live donor procedure in the properly evaluated patient is generally safe with morbidity (serious complications) in 2-4% and a mortality of 0.003% (3 patients per 100,000 will die). Previously, live donor kidney transplantation was considered an area of ethical debate, in that an individual was having with a low risk an operation they didn't themselves need. However, there is now general acceptance of this provided the donor is able to give informed consent with no coercion.

Should autonomy be overridden?

Living donation with other organs, such as liver lobes and lung lobes, is now becoming more frequent. These procedures have higher rates of morbidity and mortality and, for example, adult to adult liver lobe donation has a mortality of 1 in 200 with a 10-20% risk of major per-operative complications. Is there a level of risk where personal autonomy should be overridden? Potential donors may be willing to take a greater risk than their recipients or clinicians would be willing to take. There is a balance to be struck between personal autonomy and responsibilities or moral accountability.[31]

There is an argument for applying a scriptural precedent: 'Greater love has no-one than this, that he lay down his life for his friends',[10] but this should be considered as demonstrating the broad principles of service and self-sacrifice, rather than as a specific command!

Unregulated organ sales

Around the world there have been many examples of unregulated organ sales, including well publicised ones from Pakistan and India. Until recently organs from executed prisoners were regularly used for transplantation in China. There are people desperate enough to donate an organ for money; individuals who are desperate enough for an organ and are willing to pay for it; and those middlemen who are happy to broker the deal and take a large profit for themselves.

Clinical outcomes are poorer for both donor and recipient, and from a Christian perspective this is ethically unacceptable. The World Health Assembly acknowledges the risk of exploitation of live kidney donors and passed a resolution in 2004 urging member states to 'protect the poorest and vulnerable groups from transplant tourism and the sale of tissue and organs'.[32] Despite that, these practices do continue.

Regulated organ sales

One solution proposed to stop organ trafficking is to introduce regulated organ sales. This system has been in place in Iran since the late 1980s and appears to have had a significant impact upon waiting lists.[33] Increasingly, ethicists, economists and a minority of transplant clinicians on both sides of the Atlantic have been advocating this as the way forward.[34]

Advocates argue that introducing monetary incentives would reduce or even abolish waiting lists for kidney transplants; would stop unregulated organ sales as there would no longer be a market; and would also allow individuals the opportunity to express their own personal autonomy.

Opponents argue that regulated organ sales result in a commodification of body parts and take away the 'gift' principle which has been the mainstay of organ donation in the UK; that the poor are exploited since the wealthy are unlikely to donate for payment; and that, paradoxically, deceased and living donor organ donation rates may decrease as 'altruistic' motives compete with financial motives.

At present this debate is theoretical because selling organs is illegal under the Human Tissue Act 2004.[4] Christian ethical values as stated clearly by CMF[26] and the Church of England[27] oppose the selling of organs because of the arguments stated above.

'Transplant tourism'

The phenomenon of the wealthy going abroad to buy organs has highlighted not only the shortage for transplantation, but also global inequalities in healthcare and economics. Reports suggest that donors don't always receive acceptable levels of care, or reimbursement. Potential recipients are advised not to travel abroad for transplantation from a paid donor, but healthcare professionals still have a duty to care for them on their return to the UK, if that is the choice they have made.

It is easy to criticise those who make the difficult choice to go down this route, but they may see it as their only chance to get a transplant. The Christian response must involve campaigning for relief of global poverty and healthcare inequalities. A previous *CMF File* tackled globalisation and health in more detail.[35]

Conclusion

Perhaps our natural reaction is to think organ donation and transplantation don't concern me unless I know family or friends who are affected. However, CMF encourages you to get involved on two levels:

- Consider what you would like to happen to your organs and tissues after you die, and tell your family and friends. The Christian church can set an example in this area.[26] If you do wish to donate your organs and tissues after your death, then get your details onto the organ donor register now (*www.uktransplant.org.uk*).
- These significant ethical issues such as presumed consent, definition of death, and payment for organs affect many and need consideration from a Christian perspective. Use this *File* to be better informed to join in the public debate.

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