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Chapter 1

MEDICO-LEGAL ASPECTS OF ORGAN DONATION

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ABSTRACT

This chapter deals with medico-legal issues that must be addressed on a national, European, and international level to guarantee the organisation of a viable Organ Transplant Service, which besides offering professional high quality medical services ensures that the rights of both donors and recipients are upheld. The discussion focuses on the two main pillars of human organ transplantation, *availability* and *access*, whether the organs are procured from living or dead donors. The pivotal factor in *availability* of organs is the *voluntary consent* of the donor. In relation to consent for cadaver organs, there is a critical look at the legally accepted *definitions of death* that have evolved primarily in relation to establishing death in patients on life support systems. Analysis of the opt-in or opt-out system is accompanied by a look at the role of donor cards, proxy consent and advance directives. The success of limiting coercion in obtaining consent is examined by analysing the criminalisation of *organ trafficking*, regulation of medical tourism and promotion of altruistic donation. Finally, there is consideration of the *rights of donors* to confidentiality, to compensation and to good quality of life post donation.

In discussing *access*, the role of the state is more important in terms of measures to set up a service with the right *infrastructure*, including donor registries, adequate budgeting for medical transplant services, licensing of facilities, training programmes for personnel and accreditation systems. Adequate *data protection* of health records, including donor registries, is essential, particularly when we are enhancing access by promoting *cross-border* transplant services. Harmonisation of legislation is crucial in cross-border services. Last but not least the role of *education* is outlined. This is the key to ensuring availability and access, through public awareness, promotion of patient support groups and improved communication between healthcare professionals and patients, on a national and international level.

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INTRODUCTION

Organ transplantation hinges on the essential element of donation, from donor to recipient, so discussion in relation to medico-legal issues must primarily focus on the donor-recipient relationship.

There must be a clear delineation of the rights and duties of both parties, in the context of the role of the state in ensuring optimum health for its citizens by providing an equitable transplantation service coupled with the assurance of safety, and long term health cover, for both donors and recipients.

Therefore this chapter addresses medico-legal issues with regard to ensuring equitable availability and access without compromising those rights.

The shortage of organs is now felt even more acutely due to the ever increasing demand for organs from an ageing population, accompanied by a decrease in availability, both of living and deceased organ donors, in part due to the ageing of the pool of potential living donors. Another factor is the reduction in suitable deceased donors following improvements in medical care, coupled with an international effort to reduce traumatic deaths, particularly those following road traffic accidents, which primarily have in past years provided the highest rate of deceased organ donations.

This has led countries to work towards global co-operation in organ sharing. In the European Union, EU, a task force set up to examine these issues, produced a ten point Action Plan On Organ Donation and Transplantation (2009-2015) for co-operation between member states aimed at maximising donation. In the US, the United Network for Organ Sharing (UNOS), a private organization, has the federal contract to run the Organ Procurement and Transplantation Network, OPTN, in line with the *National Organ Transplant Act* of 1984.

Donor Organs

Advances in biotechnology and medicine, including sophisticated medical equipment used in harvesting and banking organs, and the development of new drugs to combat rejection have increased the types of organs that can now be transplanted.

However the main organ remains the kidney, plus or minus pancreatic tissue, both from living and deceased donors. The kidney was the first living organ to be successfully transplanted in a human, in Boston in 1954, from one male to his identical twin (Public Broadcasting Service: *A Science Odyssey*). The first successful deceased organ transplant operation was also that of a kidney, in Belgium in 1963, followed by a liver transplant in 1967 in the USA, a heart transplant in 1967 in South Africa and heart/lungs in 1981 in the USA (Eurotransplant 2012)..

Living donors are only able to donate one of a pair of organs or part of an organ with regenerative potential, thus initially limiting donation to a kidney, but they can now donate portions of pancreas and liver. Tissues, such as bone and tendons, and of course blood, can also be donated.

Living donor organs have a longer post transplant life) since the organs are in a better physiologic state than deceased donor organs. Therefore there has been a drive to encourage and promote living organ donation.

Living donations are primarily directed to a specific recipient, to relatives who are genetically related, to family members who are not genetically related or to recipients who are in a close relationship with the donor. Directed live donation is now acceptable beyond these confines through programmes of extended matching, as a paired donation or in even more complex patterns of pooled donation, involving more than two donor-recipient pairs. A live donor can also donate to an unknown recipient on the official waiting list, and this may be in combination with pooled donation, thus starting a so called donor chain. Complex patterns of donation are approved by an independent ethics body, such procedure being first recommended by the Council of Europe's *Additional Protocol to the Convention on Human Rights and Biomedicine, on transplantation of organs and tissues of human origin* (2002) in response to the divergent views as to possible recipients of living donation.

Since a live donor is not available for all recipients, deceased or cadaver donors remain the more common type of organs to be transplanted, with the primary organ donated still being the kidney (Global Observatory on Donation and Transplantation, 2011; OPTN, 2012). Cornea donation is also high but this organ is considered as a tissue donation under the US *National Organ Transplant Act 1984*, section 301, mainly due to the possibility of relatively late donation after death and the longevity of banking.

In recent years, pancreatic islet cell donation has increased, paralleling the increase in diabetic patients worldwide, particularly affecting third world countries as they move to a Western lifestyle. The rise in heart/lung operations has been rather slow. Surgeons can now transplant portions of the gastrointestinal tract and even parts of the body, such as face and limbs, with increasing successful outcomes. With improvements in medical management of organ harvesting and donor and recipient healthcare, it is now possible to transplant organs that are not a perfect match or that satisfy so called 'expanded criteria' whether in terms of disease status, age or less than optimal immunological typing. Moreover cross-border health care programmes and fast transport services, are facilitating an increase in the number of cadaver multiple donations and enabling matching of a donor to the best possible recipient, even if living far away from the donor. Some programmes are designed between countries to enable recipients to move to a more specialized centre for surgery to a neighbouring country, which also provides the donated organ. Such examples in Europe include Spain and Portugal, and Malta and Italy (European Commission, 2012).

AVAILABILITY

Organ donation is by definition an altruistic action and in fact there is an overwhelming worldwide consensus on this issue, which is central to ensuring respect for human dignity, the right to physical integrity and safeguarding self-determination through the exercise of free and informed consent. This is a general principle embodied in all international instruments relating to organ donation and transplantation, in particular those produced by the World Health Organisation, WHO, (2010), the EU *Directive 2010/45/EU* (2010) and the Council of Europe's *Additional Protocol* (2002), as well as in all national specific legislation such as in the US (1984), Canada (British Columbia 1996), Australia (Victoria 1982) and UK (England 2004, Scotland 2006) legislation. However it is by no means a uniform worldwide practice, even in our times; unfortunately there are countries that use less than ethical, or even

criminal, means for organ procurement. These issues will be further explored in terms of limiting discriminatory practices to safeguard donor rights.

Consent

The main legal issue that underpins all donation for both living and deceased donors is informed consent while for the latter there is the added problem of a legal definition of death. Special arrangements in the case of living donors create specific legal problems relating to consent, such as in dealing with children as donors.

The traditional consent has been based on the willingness of the donor to gift his organ to a relative or, as stated in the Council of Europe's *Additional Protocol* (2002), article 10, to a person 'with whom the donor has a close personal relationship as defined by law'. However even in the Protocol a window is left open for non-related donors when it is stated, again in article 10, that in special cases, 'in the absence of such relationship, only under the conditions defined by law and with the approval of an appropriate independent body' donation can be accepted if approved by an ethics committee. There was strong debate at the drafting of the Protocol as initially the views were that living donation should be restricted but by 2004, the Council recommended (CM/AS(2004)Rec1611final) further 'distinctions on the basis of close personal relationships rather than blood relationships'. As already noted, this extended donation has now increased and is covered by local legislation. The rationale for ethical approval is to protect the donor and recipient from emotional attachments or expectations, which may lead to various degrees of persecution of recipients or to the undue burden of a sense of gratitude or responsibility suffered by the recipient towards the donor.

Informed Consent

The *Charter of Fundamental Rights of the European Union* in the first chapter on Dignity establishes the right to the integrity of the person, in article 3(2)(a), which 'in the fields of medicine and biology' requires due respect to the 'free and informed consent of the person concerned, according to the procedures laid down by law'. This is based on the basic ethical principle of guaranteeing individual autonomy.

Article 10 of the Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (1997), generally known as the *Convention on Human Rights and Biomedicine*, states that 'everyone has the right to respect for private life in relation to information about his or her health' emphasising the right to informed consent. Hand in hand with the right to consent goes the right to refuse a procedure or to withdraw consent (article 13). This option must be mentioned to the potential donor at the initial consultation with regard to enrolment and an explanation given as to their legal rights and the possible implications of withdrawing consent for both donor and potential recipient. This is of particular importance with intended directed donation, where a relation or trusted individual withdraws consent at a late stage, with resulting devastating psychological effects on the recipient.

Though consent to living organ donation may initially appear no different from consent to a surgical operation, it must be appreciated that this is totally different as primarily it is not for the benefit of the donor. The emphasis must be on informed consent, such that the donor appreciates the quality of life to himself or herself after the loss of the kidney, both from a medical aspect but also from possible limits to social life. However there is definitely a psychological impact due to the emotional and ethical issues involved, and donors should be offered counselling pre and post donation. It is not the remit of this chapter to discuss the ethics of possible coercion in non-related donation, but counselling becomes more imperative here. Specifically, the Council of Europe stresses the requirement for 'free, informed and specific consent' either 'in written form or before an official body' (article 13).

Competency

From a legal aspect consent depends on the competence of the potential donor to agree to the donation. This implies that the donor can understand the issues involved and can take a decision based on an assessment of benefits and risks. This is no different from any other consent for medical or civil matters. Special attention should be given to communicate information in a language that the donor understands, and is also able to ask questions to clarify any doubts.

Adult incompetent donors are usually excluded from being donors. While article 6(3) of the Council of Europe's *Convention on Human Rights and Biomedicine* (1997) provides for 'protection of persons not able to consent' by ensuring their interests are covered by an official representative, the *Additional Protocol* (2002) provides for a donation only in the case of donation to close relatives, or if 'the donation has the potential to be life-saving for the recipient' (article 14) or if there is no other compatible donor available. In practice, in such situations, legislation in most countries does allow guardians, or nominated representatives, to consent instead.

Minors can also be considered as incompetent but the cut off point for donating organs varies. In the Dutch *Organ Donation Act 1989*, 'adults and minors aged twelve years or more who are capable of reasonably assessing their interests in such matters may consent to the removal of their organs or certain specified organs after their death, or may record their objection to such removal'. Children in the UK are only exceptionally allowed to be living donors, with the approval of the Human Tissue Authority once consent to the procedure of organ removal is authorised by a Court, in accordance with the *Children's Act 1989*. 'Where a child is deemed competent to consent to that decision, the necessary consent will be their own' (Human Tissue Authority, UK, Code of practice 2, 2009). However there is a grey area legally for 16-18 year olds, since the *Children's Act* only covers those below sixteen, while they are still considered as minors under the *Human Tissue Act*. In the *Human Tissue Act (Scotland) 2006* there are different provisions for children aged 16 years and above. In particular they are only allowed to donate organs as part of domino procedures, which involve medical treatment for the child. This also applies to incompetent adults.

Germany amended its legislation (*German Transplantation Act, 1997*) and as from 1st August 2012 allows 16 year olds to consent for organ donation; so the law provides for individuals with health insurance, aged 16 years and over, to be asked regularly if they consent to being organ donors.

The difficulty is in balancing the rights of the donor with those of the recipient. It is even more difficult to accept that it is in a child's best interest to be a living organ donor. However there have been minors who offered to donate, and were considered competent to give consent, for the benefit of a sibling. More contentious is the issue of obtaining consent from parents for donation of organs from one child to a sibling, not to mention the decision to have another child just to be a donor for one of the children, although these classically involve bone marrow transplantation from a neonate to a sibling with leukaemia. The Court may need to be invoked to take a decision.

Although not all countries have enacted legislation to cover consent for medical procedures, in guidelines for professional medical practice, specifically in relation to transplant legislation, consent is always addressed.

Opt-in System

Organs or tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained. The removal shall not be carried out if the deceased person had objected to it (Council of Europe, *Additional Protocol*, 2002, article 17).

States recognise two systems of obtaining consent. In the 'opt in' system, individuals may be pro-active and register their willingness to donate after death by explicit consent in life, but more often such consent is specifically obtained from the relatives on the death of the potential donor. In the 'opt out' system, one has to definitely register an objection to the state, during life.

Valid explicit consent can be provided by carrying an organ donor card, by official registration in a state approved register or other system and by an Advance Directive.

Donor Cards

Donor cards are easy to obtain but in most countries they have no legal status and can be overridden by the relatives' wishes, doctors opting to ask relatives prior to harvesting organs.

The Eurobarometer study of 2006 revealed that although 81% of Europeans supported donor cards only 12% actually had a card and in fact there were significant differences between countries, with Holland having the highest rate with four out of ten citizens carrying a donor card while in Eastern Europeans and Baltic states only 1% carried a donor card. Having a donor card helps relatives to make a decision as to whether to consent to the harvesting of organs, because they are comforted from an assurance that they have carried out the wishes of their loved one.

Registry

The decision to donate carries more weight if it can be officially documented, for example on a driving licence, which has the added bonus of being accessible at a time when the patient may be unconscious and when there is limited time to ascertain the views of the individual. This is an accepted practice in many US and EU states, in Canada, Australia and New Zealand.

More definite consent is exercised by enrolment in an official national register, particularly if this is regulated by law and not by NGOs. Care needs to be taken however to

make sure that recipients are not on multiple waiting lists of different registries from the same or different countries. Co-operation between neighbouring organisations is therefore crucial. The EU has always aimed at such co-ordination, particularly in view of mobility of citizens and with the reality of cross-border organ exchange becoming more uniformly established. There has been a progression from the European Transplant Network, Eurotransplant, to a network of National Organisations and in the near future, in line with the new EU *Directive 2010/45/EU* to co-ordination of national Competent Authorities.

In the US, one can submit a Letter of Intent for organ donation, which is registered in the same way as an Advance Directive. The US Living Will Registry website informs applicants that ‘Your family will ultimately decide whether or not to donate your organs. Being able to read your wishes about organ donation will make their decision-making much easier, and discussing your wishes with your family now is the best way to help them make this decision’.

Registries require an administrative back up to ensure the register is kept up to date. Confirmation on a periodic basis, ideally annually, allows also for the possibility of opting out of the original decision. The information on the register is available to healthcare facilities that can access the system electronically. The US *Revised Uniform Anatomical Gift Act, UAGA, 2006*, (originally enacted in 1987) establishes standards for donor registries, allows computerised registries of donors and accepts electronic signatures, but it makes no similar provision for individuals who opt out of being donors. It enables procurement organizations to gain access to donor registries, medical records, and records of the state motor vehicle department.

Advance Directives

An even more specific legal acknowledgement of the wishes of a potential donor, and a certain way of ensuring these wishes are respected after death, is an Advance Directive.

An Advance Directive is a legal instrument, introduced primarily in the US, although it is also being utilised in Europe and Australia, to address the wishes of the individual regarding their future healthcare should they be in a state of unconsciousness or with dementia, unable to take decisions at the time. Such a scenario is of course more plausible today as advances in healthcare have ensured long term survival through maintenance on life support systems.

An Advance Directive may include a) a Living Will dealing specifically with issues relating to healthcare; or b) a medical Power of Attorney, or a durable power of attorney for healthcare, which nominates a representative or proxy to take decisions instead of the patient, in relation to life-sustaining measures (this is separate from a proxy for financial transactions); or c) a Do Not Resuscitate, DNR, order, which indicates that the individual agrees to refuse cardiopulmonary resuscitation.

The US *Patient Self-Determination Act, 1991* makes it mandatory to inform patients on admission, or registration, to hospital or nursing homes, about their rights under state laws governing Advance Directives, including ‘(1) the right to participate in and direct their own health care decisions; (2) the right to accept or refuse medical or surgical treatment; (3) the right to prepare an Advance Directive; and (4) information on the provider’s policies that govern the utilization of these rights. The act prohibits institutions from discriminating against a patient who does not have an Advance Directive’ (Wilkinson, Wenger and Shugarman, 2007). The Act also obliges health institutions to provide education on Advance Directives.

However in the Report commissioned by the US Department of Health and Human Services, from the Rand Corporation, there is no mention of the use of Advance Directives for the procurement of organs (Wilkinson et al., 2007). It has been legally argued that an Advance Directive is only effective during life and so cannot regulate what happens after death. In fact, in traditional forms used in the UK and Australia, there is no mention of organ donation on the forms. However in the US, in line with the *Revised UAGA* and local state law, one may register as an organ donor via an Advance Directive, even on line, without obtaining legal advice, although legal advice is recommended. Not all Advance Directives include a section on views regarding organ donation but the applicant may indicate their wish to be a donor in the comments section of the form. Such a decision is often then automatically registered on the individual's driving licence.

Opt-Out System

In the 'opt out' system or presumed consent system everyone is considered as a potential donor unless they actually opt out of being donors, in which instance their wishes must be respected. The legal issues here relate to the right to health, the right to autonomy and taking your own decisions, as well as the right to privacy, that is, taking a decision without involvement from the state. On the other hand putting the onus on the individual to register lack of consent may cause discrimination to the individual. The German National Ethics Council (2007) has argued that if you refuse to be a potential donor than you should forfeit the right to be considered as a recipient, should you become ill and require a donation.

The UK had seriously considered such a move following the recommendation of the British Medical Association in 2000, but the UK Organ Donation Taskforce, set up in 2008 concluded that the time was as yet inopportune, arguing mostly against the system from the point of view of increased expense. Ironically, its report outlined findings that showed a definite association of an increase in donated organs with a presumed consent system; in the case of deceased donations, this amounted to up to six donations more, per million of the population (Bird and Harris, 2010).

On 2nd July 2013, the Welsh Assembly in the UK voted in favour of the Human Transplantation (Wales) Bill, which will introduce an 'opt out' consent system in Wales in 2015, for individuals over 18 years, who have been residents in Wales for at least one year. The Bill provides for objection by relatives or long term friends.

Opt-in vs. Opt-Out System

A presumed consent system appears to provide the possibility for more donations, since the pool of potential donors is much larger than that in the explicit consent system, where the percentage of the population actually enrolling in a register remains low. However the review by Coppen, Friele, Gevers, Blok and van der Zee (2008) of consent systems in ten European countries showed that a presumed consent system does not necessarily translate into a definite increase in donations. The study covered 1995-2005 and included Austria, Belgium, France, Italy, Spain, Sweden, United Kingdom with presumed consent and Germany, the Netherlands and Switzerland with explicit consent. In 2006, the *Human Tissue Act* introduced formal

explicit consent in the UK, when previously organs could be harvested if it was established that the deceased had not objected to transplantation. The researchers actually compared the number of deceased who were potentially suitable organ donors to the number of actually transplanted organs, or for France and Sweden to the number of organs harvested, rather than looking at changes in stark figures of national donation rates.

Previous studies by Gevers, Janssen and Friele (2004) on European systems had found no significant differences in organ donation between the 'opt in' and 'opt out' systems. The answer may be in the role of relatives, whose involvement reduces the potential increase expected. The usual practice is for the medical authorities to obtain consent for harvesting organs, from the relatives of the potential donor, whether this is a legal requirement or not and in fact, even where the local legislation allows for presumed consent, at least in Europe, all doctors take into account the relatives' wishes. The European Commission's study group, ALLIANCE-O (2004-2007), came to the same conclusion that in day-to-day practice, the two concepts do not differ significantly. A significant difference does only exist when the next of kin of a potential donor is not identified.

The family is faced with the complex issues of accepting bereavement while agreeing to donation. For some, this is a straightforward logical procedure, as they see that their loved one's wishes are respected, or that the death had not been in vain. On the other hand, it may mean that the relative sees the donor as remaining alive in the recipient, with ensuing psychological effects for both the relative, and if confidentiality as to donor identity cannot be maintained, possibly also for the recipient.

The Eurobarometer Report (2007) established that 23% did not know whether to donate a deceased relative's organs as opposed to 18% that were unsure about donating their own organs, thus it appears to be more difficult to decide about donating a relative's organs. The refusal rate for agreeing to donation of organs from a deceased relative was 23% as opposed to 26% refusal to donate your own organs after death. The study also showed a positive correlation of willingness to donate, whether your own or a relative's organs, with the level of education, the work position, which also reflected education, and with age. Thus senior citizens and those looking after the home were less likely to give a definite answer in favour of donation.

Success in obtaining consent reflects also on the communication skills of the health carers, as much as it does on the wishes of the deceased being known to the relatives. They are much more likely to agree to donation if they know their relative's wishes, which is why discussion with family members about being an organ donor needs to be promoted. Again in the Eurobarometer study, 41% of European citizens had discussed organ donation with their family compared to 58% who had never raised the subject. Significant differences between EU countries exist with 75% of Dutch citizens and 66% of Swedish citizens having discussed organ donation as compared to only 24% in Austria and 28% in Portugal.

In a study by Coppen, Friele, Gevers and van der Zee (2010) involving a questionnaire sent to the Dutch Health Care Consumer Panel in 2004 and 2007, respondents were more likely to consent to donation from a deceased relative if they knew the relative had explicitly wished this and two thirds of respondents (response rate 98% and 80% respectively for 2004 and 2007) wanted to be consulted, whatever the consent system was.

In fact there are variations in the application of the presumed consent system with some countries rigidly adhering to the law and in others like Italy, Sweden and Spain, the relatives are still allowed to object to organ donation. The Belgian Law on the *Procurement and*

Transplantation of Organs 1986, in article 10(1) dealing with deceased donors, states that ‘Organs and tissue intended for transplantation’ ...‘may be removed from [anyone who is registered in the municipal register or has been registered as an alien for more than six months] unless it has been established that opposition to such removal has been expressed.’ Article 10(4) emphasises that:

The physician may not proceed with removal:

- if opposition has been expressed in the manner established by the King;
- if opposition is expressed by the donor in another way and provided the physician is duly informed;
- if a surviving relative informs him of opposition. This opposition cannot be in contradiction of an explicit last will made by the donor.

In Spain, the system operates more along lines of informed, than presumed, consent and permission of relatives is routinely sought and the law requires the family to confirm, in writing, that the donor had not objected to donation. However the huge success that Spain has had in achieving and maintaining the best European rates for organ procurement is attributed more to the organizational aspect of a co-ordinated efficient service than to consent legislation.

In the US, the *Revised UAGA 2006* provides a combination of opt in and opt out systems, enhancing the rights of donors and making both donation and refusal legal. The Act enhances the rights of individuals in expressing their decisions as to their choice regarding organ donation. So it obviates the need to ask relatives for consent once the donor is enrolled in a registry, although relatives may be contacted for medical history and to see if they want feedback regarding the outcome of donation. For those who chose to opt out, the law provides for specifically barring other persons from making a gift of the individual’s organs after the individual’s death.

UAGA 2006 makes it illegal and irresponsible to disconnect a ventilator from a person declared brain dead without first making proper enquiry as to the possibility of harvesting tissues and organs, the policy being not to waste opportunities for organ donation. Therefore it also ‘preserves the right of other persons to make an anatomical gift of a decedent’s organs if the decedent had not made a gift during life’, such persons being of course relatives or designated proxies. Federal law requires that hospitals have an agreement with an organ procurement organization, such that patient deaths or imminent deaths are reported for assessment as to potential donation. If the procurement organisation establishes that a deceased person who is medically suitable to be a donor is not registered as a donor, the transplant co-ordinators must, in line with legislation, contact the family and request consent for organ donation. The Act also provides for an individual to delegate a healthcare agent or proxy, to take the decision as to donation or not.

Coercion to Consent

The removal of organs without proper consent ‘constitutes a serious violation of human dignity and physical integrity’ (EU *Directive 2011/36/EU*). The issue of adequate

communication and explanation to ensure informed consent has already been addressed. Here the focus is on limiting coercion to obtain consent.

Organ Trafficking

The worst possible scenario for this is organ trafficking, often accompanied by other crimes. In 1990, the *UN Convention on the Rights of the Child* became the first international legal instrument to urge states to prevent ‘the abduction of, the sale of or traffic in children for any purpose or in any form’, (article 35), which later became more explicitly referred to in the *UN Optional Protocol to the Convention on the sale of children, child prostitution and child pornography* (2002) with specific mention in article 3.1.(a)(i)b of the ‘transfer of organs of the child for profit’ as one of the offences to be considered as a criminal act in the state parties. The *2000 UN Trafficking Protocol* included removal of organs as a form of exploitation in its definition of trafficking, in article 3(a), which definition is also employed in the *Council of Europe Convention on action against trafficking in human beings* (2005). Trafficking in persons includes ‘recruitment, transportation, transfer, harbouring or receipt of persons’ and the use of ‘the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation’, including the removal of organs. Practically the same definition is found in article 2.1 and article 2.3 of the *EU Directive 2011/36/EU on preventing and combating trafficking in human beings and protecting its victims. .)*

In 2004, the World Health Organisation asked member states ‘to take measures to protect the poorest and vulnerable groups from transplant tourism and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs’ (WHA Resolution 57.18, 2004). Recently this resolve was re-iterated at the *Declaration of Istanbul on organ trafficking and transplant tourism, 2008* developed through The Transplantation Society and the International Society of Nephrology.

EU Directive 2011/36/EU, article 8, provides for victim protection, emphasising that victims of trafficking should not be prosecuted ‘for their involvement in criminal activities which they have been compelled to commit as a direct consequence of being subjected to’ any threats. Article 12.4 states that they should ‘receive specific treatment aimed at preventing secondary victimisation’ and further trauma during the criminal proceedings; this may also encourage victims to come forward and report abuses.

Figures with regard to trafficking are not easy to obtain but it is likely that abduction for forced removal of an organ through criminal action, when the donor cannot resist, is rare. There is sporadic documented evidence of criminal organisations that kidnap people, particularly children, with a view to stealing their organs, but many of the reports are thought to be unfounded (Caplan, Dominguez-Gil, Matesanz and Prior, 2009; Pearson, 2004). More likely is the removal of organs, mainly a kidney by deceit, such as removal of a kidney while in hospital for some other operation or enticing persons to a job in another country and then exerting pressure for the sale of a kidney (Pearson, 2004).

However poverty remains the main driving force, as concluded in a study by Shimazono (2007), published in the *WHO Bulletin*, which estimates that in 2005, 5% of all recipients had travelled overseas for an organ transplant. The study identified India, Pakistan and the

Philippines as organ exporters while the organ importing countries were listed as ‘Australia, Canada, Israel, Japan, Oman, Saudi Arabia and the USA’ according to Organs Watch, a research unit set up at Berkeley, University of California. Organs Watch, quoted by Pearson (2004), also claims that there is significant organ trafficking in Argentina, Brazil, Cuba, India, Iran, Israel/West Bank, Moldova/Romania, Philippines, Russia, Turkey, USA and South Africa. The UN estimates 5-10% of all kidney transplants are the result of trafficking (Caplan et al. 2009). This is facilitated by a shortage of organs in a country linked with poor regulatory frameworks in another and backed by organized criminal syndicates that act as intermediaries and brokers offering various packages, nowadays openly on the internet.

Poor individuals are enticed to sell a kidney through sheer necessity, lured by the promise of substantial monies, which then either never materialize or are considerably less and in most cases the payment to the donor is completely mismatched with the payment to the recipient. Some ethicists, such as Savulescu (2003) do argue in favour of the right of a person to choose to sell an organ as an answer to poverty, which is considered as a greater evil. However such a practice cheapens the value of the body, which becomes a commodity, while it also encourages a clandestine market which primarily favours the more well to do prospective recipients.

Other forms of deception include the lack of provision of adequate health care; in fact donors caught in the illegal trade are often victims of poor health, since the surgery may be less than safe or adequate and there is no post transplant care. The recipients may also be at risk since the donor may not reveal all health information and adequate safety of organs and medical management cannot be ensured; however the chance to obtain a living organ by fast track may be enough enticement for such potential recipients.

The position in Europe appears to be changing. In the questionnaire sent by the Council of Europe to EU members in 2002, six states were aware of recipients travelling to other countries to obtain organs, identifying Turkey and India as places for transplant tourism; Turkey and some eastern European states did acknowledge cases of illegal removal of organs in their own country as well as the receipt of illegal organs (Council of Europe, 2004, 2nd June). There are now recent claims that the illegal organ trafficking is increasing in Europe due to the financial crisis with people in Greece, Italy, Spain and the Balkans attempting to sell organs, including a kidney, bone marrow, lungs or corneas (Bioedge, June 2012).

A group of people who are more likely to be exposed to coercion to being organ donors are ‘prisoners or persons deprived of their liberty’, from whom ‘any donations must be subject to guaranteed absence of pressure, to be checked by the appropriate bodies independent of the prison authorities’ (Council of Europe, 2004, 21st June). It has long been alleged that China utilised organs from executed prisoners, with an apparently unwritten agreement between the medical and legal authorities for this to occur, putting into question the professional ethics as well as the human rights issues. In fact the World Medical Association, WMA, had condemned such practices at the 173rd WMA Council Session in 2006. There were also questions as to how many foreigners actually were recipients of such organs, although in 2007 the State Council of China legislated in favour of prohibiting commercial transplantation (Caplan et al., 2009). It is therefore heartening to finally have the state run agency, Xinhua, report that China’s vice minister of Health has pledged ‘to abolish organ donations from prisoners’ and to set up a regulated organ procurement and transplantation system (Bioedge, March 2012).

The way to control illegal trade in organs is by robust regulation of medical practice, transplant procedures and facilities and procurement institutions; it is here that EU *Directives 2010/45/EU and 2011/36/EU* and domestic legislation play an important part. Most developed countries have stringent laws and guidelines to regulate the healthcare professions and medical practice, and any unprofessional or unethical behaviour warrants disciplinary action, including the withdrawal of a licence to practice. The World Health Organisation (2010) guidelines for healthcare workers in relation to organ procurement and transplantation were endorsed at the 63rd World Health Assembly.

A national framework with payment for organs has apparently been legalized in Iran, since 1998. Donors are granted a one year medical insurance, the price is fixed by the Government and there is an annual fee by the recipient to the living donor. National organs cannot be used for foreigners (Caplan et al., 2009). Iran claims to have no waiting list, but there is still discrimination in accessibility in relation to ethnicity.

Definition of Death

The Council of Europe *Additional Protocol* (2002) is specific, stating that harvesting of organs from the deceased must not occur ‘unless that person has been certified dead in accordance with the law’ (article 16). In the US this fundamental principle is commonly referred to as the ‘dead donor rule’.

Most countries have legislation for registration of deaths following Death Certification by a medical practitioner but not all countries have established a definition of death, preferring to leave this to the medical profession. This state of affairs was undisputed right through the mid 20th century but with the advances of life support systems, it has been possible to maintain unconscious individuals alive through the use of artificial ventilation. This has put pressure on legislators to define death in such individuals and so allow healthcare professionals to terminate artificial support without the claim of medical negligence being incurred.

Pellegrino, chairman of the President’s Council on Bioethics, issued a personal statement in the white paper, *Controversies in the determination of death*, of 2008. He states that the ‘definitions’ of death:

fall into two categories: the philosophical and the empirical. The first seek a conceptual understanding of the essential differences between life and death. The second seek to determine the clinical signs, tests, or criteria which separate life and death most accurately. Ideally, a full definition would link the concept of life (or death) with its clinical manifestations as closely as possible. So far, this linkage has been the subject of controversy because of its pivotal role in ethically justifying the removal of vital organs from donors in transplantation protocols.

Gómez-Lobo, also in a personal statement, in the same report, affirmed that ‘the definition of death as ‘the irreversible cessation of life’ is a definition by exclusion’.

In this chapter we are only interested in the empirical definition of death and how it affects the legal acceptance of death. However the President’s report was instrumental in confirming the ethics of the legally established ‘dead donor rule’ prior to transplantation, which had been undermined by some bioethicists arguing that since criteria for diagnosing

death were not perfect, consent remained the only necessary ethical issue. Indeed Veatch (2008) argues that donors or relatives could choose the criteria that suit them best for defining death.

From time immemorial death has always been diagnosed following cessation of cardiac and respiratory functions, easily diagnosed by absence of heart sounds and breath sounds respectively. However this is no longer possible with a patient on a ventilator, which is aimed to ensure a supply of oxygen to maintain a circulation with perfusion of all organs, which therefore continue to function, irrespective of the function of the brain. In fact such a medical intervention is primarily used for patients with brain damage. It is in these patients that the concept of brain death was developed.

The study of neuroanatomy and neurophysiology has enabled mapping of neural pathways and delineation of brain function, such that we can distinguish the '*higher brain*' composed of (a) the cerebral hemispheres, responsible for action that is based on conscious awareness, including perception, emotion, thought, and language, and the cerebellum, which co-ordinates movement and (b) the '*lower brain*', composed of the brainstem, which houses the vital respiratory centre and also the reticular activating system, which is the regulatory switch for consciousness, whether the cerebral hemispheres are functioning or not.

In the US the definition of death has always favoured *whole-brain death*, which is commonly just referred to as *brain death*, that is the death of the entire brain including the cerebral hemispheres, cerebellum and brainstem, which is based on the idea of the brain as the motor that integrates all bodily functions, a view pronounced by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical Behavioral Research in 1981. The Commission noted that 'the neurological standard for death requires an irreversible loss of all brain functions, not complete anatomical destruction of the tissue. Members of the President's Council on Bioethics in the White Paper of 2008, took the explanation even further stating that:

the patient with total brain failure is no longer able to carry out the fundamental work of a living organism. Such a patient has lost—and lost irreversibly—a fundamental openness to the surrounding environment as well as the capacity and drive to act on this environment on his or her own behalf.

In fact all US states have incorporated the whole-brain standard, as part of the definition of death, together with the cardiopulmonary standard, which now reads in the *Uniform Determination of Death Act, 1981* as: '(1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem'.

Veatch (1989), basing his arguments on the philosophy of personhood has even contended for limiting definition of death to death of the higher brain, rather than the whole brain. Another reason put forward for adopting the 'higher brain standard' is that patients diagnosed as brain dead may still have some somatic integrative functions or even minor brain function, such as some localized electroencephalographic activity. However a diagnosis limited to death only of the higher brain means that patients with persistent vegetative state, who have a functioning brainstem but no higher brain functions would be diagnosed as dead.

In the UK, the Royal College of Physicians in 1995 developed a definition of death as 'the irreversible loss of the capacity for consciousness, combined with irreversible loss of the

capacity to breathe' and equated 'brainstem death' to death of the individual. In the UK there is no statutory definition of death, although this definition has been recognized in court cases. The term 'brainstem death' was formally adopted in 1995 by the Royal College of Physicians although the concept had been first laid out by Pallis in 1982. However criteria for testing brain stem function had been in use since 1976, as established by the Conference of Medical Royal Colleges, when they were first indicated as tests for assessing prognosis of severely comatose individuals with brain damage. The tests would identify those in whom there was no possibility of recovery and so the ventilator could be switched off and the patients declared dead.

The definition of brain death is established following rigorous testing of brain function. The first set of criteria was laid out in 1968 by the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death and have evolved with just minor changes. It has been argued by Capron (2001) that this committee started the confusion in terminology by using the word 'death' to 'describe the loss of function in an organ -the brain'. This idea was again stressed by Pellegrino, in a personal statement, in the President's Council White Paper (2008) when he argued that equating death with total loss of mental capacity is essentially identifying 'death of the organism with death of one organ - the brain'.

The criteria for establishing brain death rely on the concept of irreversible brain damage. Before tests are carried out, the patient must be comatose with diagnosed structural brain damage and there must be exclusion of hypothermia, drugs and metabolic diseases as a cause of coma. The tests must show absence of spontaneous breathing, absence of motor responses and of brainstem reflexes. They are also performed by more than one doctor and repeated once after a time interval. Such a protocol is considered for diagnosing brainstem death but for whole brain death, other tests need to be carried out. These include an electroencephalogram, EEG, to demonstrate loss of cortical function, and radionuclide scanning or intracranial 4-vessel cerebral angiography or ultrasonography, to ascertain loss of cerebral blood flow.

The whole brain standard has spread throughout the world while the brainstem standard is only accepted in the UK and some countries with a past British connection, e.g. India, although Canada and Australia have also embraced the whole brain standard. Wijdicks (2002) has argued for standardization of the criteria required for diagnosis; based on a study comparing the methods employed in diagnosing brain death in 80 countries, he revealed that even in countries with the same legal definition, practices varied. Only 88% had guidelines and they all provided for absence of respiration, motor responses and brainstem reflexes. Only 59% of all countries recommended the apnoea test. The confirmatory tests were in fact only compulsory in 40% of the guidelines. Wijdicks, Varelas, Gronseth and Greer in 2010 reviewed the 1995 guidelines of the American Academy of Neurology on the diagnosis of brain death. They concluded that there was not enough evidence to establish if the new tests could determine the loss of function of the entire brain.

The use of neurological criteria has never been uniformly accepted as a means of declaring death. Controversy is still present from religious groups, notably the Jewish faith as Torah law accepts death only with the absence of cardiac and respiratory function. Section 5 of The State of New Jersey *Declaration of Death Act*, prohibits medical diagnosis of death by neurological criteria for patients who have religious objections.

It is therefore almost ironic that we are now seeing a return to using the cardiopulmonary standard of diagnosing death, that is, death due to the irreversible loss of the circulation with

the advent of organ donation following cardiac death or the so called non-heart beating donor, or controlled donation after cardiac death. This type of donation was introduced at the University of Pittsburgh, US in 1992. Donations, with informed consent, are being accepted from patients dying following irreversible cardiac and circulatory arrest, without such patients having previously been on life support systems. However death must occur in a medical environment such that an established minimal time elapses before harvesting of organs. Organ harvesting occurs within a short time of the declaration of death and it has the advantage of providing organs in a better state of circulation than those from the dead donor.

Donation after cardiac death is increasing at a faster rate than that from brain dead individuals, at least in the UK, as reported by the NHS Blood and Transplant Health Authority in 2012. The cardiopulmonary standard is easier to comprehend by the lay person but unfortunately the practice of the procedure is not always dignified, if not bordering on the unethical. These patients are fulfilling the legal requirements for death but in an effort to obtain organs, there is an intense vigil to restart the perfusion process just after five minutes of the diagnosis to fulfill the requirement for a minimum warm ischaemia time, to ensure the viability of the organs. Adding to the contentious ethical issues is that in an effort not to lose precious seconds, there is preparation of the potential donor by medication and insertion of vascular cannulas and other medical equipment in the agonal patient, to be ready to switch on perfusion within five minutes of death. This is an undignified way to die.

The issues of donation from anencephalic neonates is being addressed here because it depends on the definition of death. Anencephalic infants are born with a neural tube defect resulting in failure of closure of the skull. They usually have limited cerebral cortex and cerebellum but the brain stem is present, and so they can breathe spontaneously, have newborn reflexes and variable autonomic function but they lack consciousness. Such children may live for just a few seconds but many survive without life support for hours or days. These neonates are not aware of their existence,

However Shewmon (1989) thinks that the brainstem in anencephalics can actually exhibit function usually attributable to the cortex, due to neuroplasticity.

Organs would only be beneficial to infants of a similar age. This makes a match difficult to obtain, and organ shortage is a real issue unless there is adequate co-operation between centres. In children, using medical criteria to define brain stem death is difficult. Guidelines for brain death in infants were formulated in 1987 by a Task Force composed of representatives from the American Academy of Pediatrics, the American Academy of Neurology, the Child Neurology Society, the American Neurological Association, the American Bar Association, and the National Institute of Neurological Diseases and Communicative Disorders and Stroke. These are similar to adult guidelines but protocols depend on age, e.g. for children between 7 days and 2 months of age, 2 sets of examinations and an EEG separated by 48 hours are recommended. However the criteria did not apply to infants below 7 days as there was insufficient data available. In anencephalics, there are greater problems because they can maintain an irregular function of the brain stem for up to 3 weeks (Parisi, Squiteri, Carottie, Dicarilo and Gagliardi, 1999). Also EEG and cerebral blood flow may be inappropriate tests as there are no cerebral hemispheres.

Ashwal and Serna-Fonseca (2006) recommend using the 1987 criteria for neonates, but emphasise that cranial nerve function is difficult to assess in term and preterm neonates and moreover these reflexes are still not fully developed. Sekar (2007) also suggests that the guidelines could be applied to neonates.

There is the added problem of deciding on viability of organs, to avoid unnecessarily endangering the safety of recipients. There is concern as to the viability of organs from anencephalics who were not on a life support system at the time of death because of gradual deterioration of already poor cardiorespiratory function, giving rise to ischaemia. If the infants are maintained on a life support system from birth, the organs are not ischaemic but, according to the Canadian Paediatric Society, 2005, 'while organ function may be maintained with life support, as brainstem function deteriorates, multisystem organ failure develops before sudden death.' In fact the Society does not recommend organ donation from anencephalics. This statement was reaffirmed in 2009 and 2013.

Donor Rights

Integrity

The *Charter of Fundamental Rights of the European Union* (2010) highlights the integrity of the person in article 3(1): 'Everyone has the right to respect for his or her physical and mental integrity'.

The Council of Europe's *Convention for the Protection of Human Rights and Fundamental Freedoms* (2010) provides protection of human rights and fundamental freedoms for all individuals, including the right to life and protection of health interests. Article 5, the 'Right to liberty and security' provides for the right to security of the person. Being a donor and giving away an organ can be arguably construed as violating this right unless this is a definite act of will, that is, it is accomplished with full consent in keeping with ensuring one's autonomy.

Article 1 of the Council of Europe's *Convention on Human Rights and Biomedicine* (1997) provides for protection of 'the dignity and identity of all human beings'; 'respect for their integrity and other rights and fundamental freedoms' in medical matters'. One can argue from a psychological standpoint that losing an organ damages the individual's identity.

Confidentiality

Consent is likely to be given only if the donor is convinced of the legality of the process and that his/her rights are being protected. The EU *Directive 2010/45/EU* considers confidentiality important. In the preamble, paragraph 22, it is stated that 'As a general principle, the identity of the recipient(s) should not be disclosed to the donor or the donor's family or vice versa'. A close relationship between donor and recipient has, albeit only known of anecdotally, led to the recipient being almost stalked by relatives of the deceased. On the other hand patient associations have in general been in favour of a relationship being forged between donors and recipients and have acted as a go-between for bringing about meetings between the parties. It is also worth noting that confidentiality is extremely difficult to ensure in small states where the media is easily the first to disseminate information about victims of major trauma accidents.

The protection of personal data and confidentiality is emphasised with respect to both donors' and recipients' personal data, in the context of traceability, registries, records of procurement organisations and transplantation centres as well as data processing, all in line with *Directive 95/46/EC on the protection of individuals with regard to the processing of*

personal data and on the free movement of such data. Confidentiality in relation to data is also repeated in article 23(1) of the *Additional Protocol on Transplantation* (2002).

Health

According to the *Charter of Fundamental Rights of the European Union* (2010), article 35, 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices'. Living donors also have a right to expect adequate health care after the donation. The Council of Europe's *Additional Protocol on Transplantation* (2002), article 7, states that 'appropriate medical follow-up shall be offered to living donors and recipients after transplantation'.

Early problems include post-operative complications but these are minimal. Living donor surgery has a 0.03% mortality in the US (National Kidney Registry, 2012). Living donors have the same lifespan and end stage kidney disease as the age / sex / ethnicity matched population (Ibrahim, Foley, Tan, Rogers, Bailey, Guo, Gross and Matas, 2009). Where health services depend primarily on insurance, the donor from a low socioeconomic class is disadvantaged with regard to post donation healthcare.

Compensation

The principle of voluntary unpaid donation of tissues and cells was recognised for the first time in Spain in 1979 and in Luxembourg, Belgium and Finland in the early 1980s (European Commission, 2006). The same report states that donors cannot be remunerated but may receive compensation strictly limited to making good the expenses and inconvenience related to the donation. The principle that the body or body parts should not be a source of financial gain was formally established in article 21 in the *Convention on Human Rights and Biomedicine* (1997) and repeated in article 21(1) in the *Additional Protocol* (2002), which does allow 'compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations; payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation' and 'compensation in case of undue damage resulting from the removal of organs or tissues from living persons'. This would include remuneration for travel, time off work and healthcare costs. There could be a system of compensation by the recipient's insurer to make up for the savings in terms of healthcare for the recipient. Living donors may also have to travel abroad to be with their relative recipient if the transplant operation is not possible in their country of origin; they should also qualify for compensation.

Advertising for an organ with an offer of money is illegal in most countries and is mentioned in the Council of Europe's *Additional Protocol* (2002) in article 21(2): 'Advertising the need for, or availability of, organs or tissues, with a view to offering or seeking financial gain or comparable advantage, shall be prohibited'. This view was to emerge again in article 13.3 in the EU *Directive, 2010/45/EU*. However advertising for organs on the internet is now a reality for pooled donation schemes, which are meant to be voluntary non compensated schemes. Such schemes are now officially organized either on a national basis or by charities.

ACCESS

The *Charter of Fundamental Rights of the European Union* (2010), article 35 emphasises that: ‘Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.’

Allocation

Protocols

One of the main tenets of Human Rights law is protection of individuals from discrimination. Most countries have legal provisions to respect patient rights in the field of organ donation and transplantation, in particular with regard to ensuring justice in the allocation of organs and resources. WHO (2010) in its Guiding Principles on human cell, tissue and organ transplantation states that ‘The allocation of organs, cells and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations. Allocation rules, defined by appropriately constituted committees, should be equitable, externally justified, and transparent’. Yet it is extremely difficult to get a standard response to the question of how recipients are prioritized to allocate donor organs from deceased donors. The issue of course does not arise with a living donor as there is a one to one approach or at least in the chain system there is the best match possible approach.

The decision has always been, rightly so, left in the hands of the medical practitioners, yet there is no uniform harmonised standard by WHO. In the US, the Organ Procurement and Transplantation Network, OPTN, is empowered through the *National Organ Transplant Act* to produce allocation guidelines and these are available on their website. All major guidelines address the health status of the recipient and put this at the top of their list, based on an assessment of urgency in relation to chance of cure. Recipients may be assessed in terms of QALYs, Quality-Adjusted Life Years, where one year of perfect health amounts to one (1) QALY. There are of course objective ways of assessing QALYs and these depend on potential income lost. Is that right for assessing whether to receive an organ or not? This would put a rich recipient ahead on the list, way above the patient from a lower socioeconomic group. On the other hand the social class may have adverse influence on the possibility of success of the transplant because the potential recipient is envisioned as one who may not be able to keep up with the healthcare required, if the state is not in a position to assist with funds; this further disadvantages the poorer recipients. Patients on dialysis actually cost more in terms of healthcare than transplant recipients, so it may be beneficial for the state to invest in funding transplantation rather than treatment for end stage renal disease. As WHO (2010) states: ‘no recipient should be excluded solely for financial reasons’.

Medical issues limiting donation relate principally to medical assessment of suitability of an organ for donation. The first criterion is naturally for the organ to be healthy and free of transmissible infective diseases. Tests for immunity, blood grouping and HLA typing (six antigen matching) are used, especially for kidneys. There are no contentious issues here as naturally one needs to ensure safety to recipients. Legislation across Europe is now in the

process of standardisation as the EU *Directive 2010/45/EU* is being transposed into domestic legislation.

UNOS, the United Network for Organ Sharing in the US, has been the national US operator of OPTN, since 1986. OPTN has a policy laying down minimum standards for screening donors, easily accessible on its website. In all protocols donors need to be free of infectious diseases that are transmitted by blood, primarily hepatitis B and C and HIV. In the US, there is current scientific evidence advocating infected individuals to agree to be donors to infected recipients, in a move to increase the pool of donors (UCSF, 2012). Studies show that the grafts have been accepted without significant problems (Morales, Campistol, Dominguez-Gil, Andrés, Esforzado, Oppenheimer, Castellano, Fuertes, Bruguera and Praga, 2010). The main advantage for the recipient is the enhanced quality of life; taking people off dialysis early gives them a better quality of life than waiting on the transplant list (Tonelli, Weibe, Knoll, Bello, Jadhav, Klarenbach and Gill, 2011). However the practice has as yet not been uniformly incorporated in medical guidelines.

One factor that is not nowadays a barrier, is age, provided the individual's health is good. Most recognized criteria delineate an age cut off point for organs, based on the well established fact that increasing age of the donor organ, particularly well established for kidneys, is associated with shorter post transplant survival than for kidneys donated from younger donors. However there is no reason why older recipients cannot be matched to older donor kidneys, which satisfy the 'expanded criteria' for donors. Of course concomitant disease increases the morbidity, so a transplant would not be considered. However corneas can be donated in patients with systemic cancer.

On the other hand age is a limiting factor in relation to matching the size of the donor organ to the recipient. The size of the organ is important for transplants from children to children. For child to adult donation, traditionally kidneys donated from young children were both given to the same recipient but now a single kidney has been successfully transplanted. Kidneys have been donated even from a deceased infant as young as 9 months and transplanted into adults (Zhang, Paramesh, Florman, Yau, Balamuthusamy, Krane and Slakey, 2009).

Living Donors for Non-Related Recipients

The issue of whether donations from living non-related donors should be uniformly available is slowly gaining acceptance and it must be seriously considered as a real choice to increase donations. The main objections are ethical but with robust legislation to ensure infrastructure and confidentiality to preserve the donor's rights, there should be no major objection. In fact there are now chain systems run by NGOs as well as by some US states that foster this type of donation built on the deceased donor donation best match. With improvements in computerized data systems, it has become increasingly easy to identify, locate and prepare recipients for transplant without running risks of losing viability and wastage of organs. Now, organs can be sent to any country in the world with a minimum delay and in conditions that can preserve viability. This is the concept used in chains but here the match is the important bottom line.

Health of the Recipient

The main issue is always to ensure that having undergone the emotional and psychological trauma of receiving an organ, there is only the most minimal likelihood that

rejection occurs. The EU has been at the forefront of ensuring transplant safety and has directives dealing with this issue for blood (*Directive 2002/98/EC*), tissues and cells (*Directive 2004/23/EC*) and solid organs (*Directive 2010/45/EU*). These directives all ask for testing of the donors prior to making them eligible to be donors. This includes testing for infectious diseases, that may be absolute contraindications to being a donor, such as HIV, hepatitis B and C, although even now this practice is changing as infected individuals may be donors to infected recipients.

With a view to ensuring that health authorities have complied, there is emphasis on the traceability of the organ (*Directive 2010/45/EU*, article 10) such that any adverse events can be linked to the possibility of a problem in the donor. In rare instances this may be a genetic problem.

Matching is of course crucial for kidneys; the better the match the more likely is the success of this transplant but the heart does not need to be matched. HLA typing is often farmed out to laboratories that may not be part of the hospitals offering the transplant services and it falls to the competent Transplant Authority to ensure the laboratories are in line with the local legislation regulating laboratories, including relevant ISO accreditation and professionalism in laboratory scientists.

In an attempt to ensure safety within the EU, *Directive 2010/45/EU* requires adverse event reporting (article 4(g), article 11 and article 17(d)) and post transplant results (article 17(e)), including adverse reactions of drugs used to prevent rejection and pharmacovigilance. However data is not easily available from all countries, although mechanisms for reporting exist, such as the NOTIFY Library of Adverse Events and Reactions, co-ordinated by the WHO and the Italian National Transplant Centre, with the collaboration of the EU funded project SOHO V&S, Vigilance and Surveillance of Substances of Human Origin. More emphasis must be placed on organisational structures to ensure data collection. Member states in Europe must have a Competent Authority to organise the transplant system and this must report to the Commission every three years to confirm compliance with the EU *Directive 2010/45/EU*, article 17 and article 22. UNOS, is the responsible body in the States.

Data Protection

The duty of a state to keep records must be in compliance with Data Protection laws, for sensitive health data. In the EU, the *Data Protection Directive 95/46/EC*, has been transposed into national legislation for member states. In the US, similar provisions are available through the *Privacy Act, 1974* and the *Electronic Communications Privacy Act*. The Council of Europe's *Convention on Human Rights and Biomedicine* (1997) states in article 10 that: 'Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed'.

The *Charter of Fundamental Rights of the European Union* (2010), article 8 states:

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.

Directive 2010/45/EU lays down the minimum data that must be collected to ensure the quality and safety of organs, including a register of donors, demographic details and medical history of the donors and recipients. Article 16 emphasises the need for protection of all personal data collected. Data has to be kept secure over the years to allow traceability of organs (article 10) should a safety issue arise. Data has to be up to date to avoid the stress of contacting relatives or donors themselves who have opted out of being organ donors or who have changed their wish to donate through an Advance Directive. States must ensure that the stored data is easily available to the authorised personnel who are providing the transplant service, that is the competent authority or its delegate. For an efficient service, access to donor registries, including the list of those who have opted out, must be available to procurement organisations and transplant centres, so that donor – recipient matches are made possible in the shortest available time. Proper maintenance of data also ensures that there is no accidental contact with relatives of deceased individuals who have opted out, mistakenly to ask for consent and thus causing undue emotional stress on the relatives. Electronic data has made storage and retrieval much easier but has also led to the need for more electronic security measures.

Organisational Structures

In the 10 point policy of the EU (2008), it was recognized that to increase organ donation there is a need to employ certain strategies. Experience from countries with an actual increase in the number of donations and successful operations, has shown that the success story devolves around a sound administrative set up. Spain has actually been on record to explain her progress in this field. Initially thought to be due to presumed consent, it became obvious that with a soft presumed consent policy and no register for opting out, this was not the full explanation. It soon became evident that the dedicated medical transplant co-ordinators were responsible for the success. As the personnel liaising with families, they were in a key role to explain the organ donation process; naturally they had to be properly trained.

In the EU, *Directive 2010/45/EU*, article 17, provides for a competent Transplant Authority, to be a regulatory body, which can delegate its powers to another body on a national level. The Authority must oversee the whole sequence from donation to transplant and beyond to post transplant surveillance of the health of both parties. The administrative duties include the responsibility for identifying an organizational structure adequate for the country. The Authority is to authorise, maybe through licensing, the functions of procurement organisations that retrieve and transport the donor organs, and to oversee the function of transplant centres, directly involved in the surgery.

The Transplant Authority's role extends to ensuring that all hospitals are adequately licensed for the service they provide. They have to inspect premises on a regular basis. Such licence usually includes accreditation of premises and adequate resources, and mandates employment of fully trained professional healthcarers, whether doctors or paramedics. It must be in a position to recommend adequate training for personnel, including training for the administrators of the system.

One important aspect is the funding of the service. It is to the benefit of all if these services are centrally funded on a national basis out of the health budget. *Revised UAGA* in US also establishes standards for donor registries, allows computerized registries of donors

and accepts electronic signatures, but it makes no similar provision for those who do not want to be donors. It enables procurement organizations to gain access to donor registries, medical records, and records of the state motor vehicle department. There is introduction of regulations relating to cooperation and co-ordination between procurement organizations and coroners or medical examiners.

Mobility

Competent Transplant Authorities that maintain robust organizational structures are in a unique position to promote and facilitate transplant medicine and research as they form relations with counterparts in neighbouring and distant countries in an effort to maximise resources and knowledge through the set up of international organ exchange systems. On a national level, countries do have specific arrangements with neighbouring states for cross-border movement and healthcare but it would be beneficial to all if this were on a European basis. Though it is mainly organs that are transported, where more practical, as in heart and lung transplants, it is the recipient who travels.

The EU *Directive 2011/24/EU* on cross-border healthcare specifically states in article 1(3)(b) that it does not apply to ‘allocation of, and access to, organs for the purpose of organ transplants’. However for organ procurement there is a specific transplant policy, involving cross border co-operation, as outlined in the EU Action Plan on Organ Donation and Transplantation (2009-2015). Of course if a country is not in a position to offer specialised services, it has the human rights duty to allow its citizens to travel abroad and to pay for the healthcare services accessed in the other state. The Directive does allow organ exchange with third party countries (article 20) and European organ exchange organisations (article 21), under the supervision of the competent Transplant Authority.

Education

EU directives always insist on dissemination of the law but this is only a small step towards increasing knowledge and awareness about organ donation. Much work has to be done by the competent Transplant Authority to educate the public if we are to see an increase in the availability of organs. Successful programmes have invested in involving the public via media programmes and patient support groups. The latter are always proactive in meeting with relatives of both donors and recipients, offering counselling and advice and long term support. However counselling should be provided as part of the hospital based transplant services, or else farmed out to the procurement agencies, who are ultimately responsible for ensuring that informed consent is obtained.

Increased deceased donation depends on the communication skills of the person requesting organ donation from relatives. So training in this field is mandatory for all doctors who will be in such units but also for transplant co-ordinators who have to train others how to approach potential donors and their relatives. With regard to professionals, it is recognized that there are full time specialists in some countries, who are primarily involved in just transplant work but in many countries the services are offered, when the need arises, by professionals with a specialised interest. This emphasises the need for professional

qualifications of personnel but also continual in house training for the specialists. The competent Transplant Authority should ensure that there is funding for these activities.

Accreditation schemes for laboratories should be in place in all laboratories, whose services are used to carry out tests on donor samples. All hospital facilities must be run according to accepted standards and guidelines. Last, but not least, research on transplant medicine has to continue on a national level, as well as throughout networks, such as Eurotransplant, the European Transplant Network.

CONCLUSION

Legislation is obviously necessary to ensure health and safety in the procurement and use of organs, to ensure equity in access to transplant services and to keep a check on abuse of the system. Its role in increasing availability of organs is in establishing proper guidelines for the medical professional responsible for obtaining consent, or for declaring death and in regulating professionals and institutions. It is however only one step; the way forward involves more international harmonisation and standardisation to ensure efficient use of resources in an attempt to provide early access to suitable organs for all those on a waiting list.

We are seeing a change in the type of organs available, with living donation being increasingly available for non-directed transplantation and deceased donor organs obtained from non-heart beating cadavers. It is now possible to engineer simple biological tissues, such as trachea or urinary bladder, from one's own stem cells, and though building complex solid organs will probably not be available for some years yet, the research may provide alternative pathways for repairing organs.

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