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Review Article

Briefly about Organ Donation

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Abstract:

Organ donation is a sign of altruism and nobility, by which one person expresses his desire and intention to donate any part of the body after death for transplantation in order to help the seriously ill. Today, organ transplantation or transplantation is an accepted and successful way of treating patients in the world who, for whatever reason, have had an irreversible failure of the function of an individual organ necessary for life. In recent decades, in this way, organs whose function has ceased can be replaced by another, from another person - donor.

Keywords: donor; organs; ODR

Introduction

The organ donation and transplantation sector in the UK has a comprehensive legal and regulatory framework, with some important differences between the UK countries [1]. With the first successful deceased donor transplants performed in the UK and the emerging concept of brain death from 1959, there needed to be some clarity about the legality of the process. The Human Tissue Act (HTAct) 1961 and the HTAct (Northern Ireland) 1962 went some way to address this and subsequently there was a steady growth in deceased and living donor transplants.

The Human Organ Transplants Act 1989 was enacted speedily following an inquiry into the trafficking of Turkish peasants to be paid living donors for transplantation. This legislation was aimed primarily at prohibiting commercial dealings in organs for transplantation and restricting transplantation between persons not genetically related. As the complexity of organ donation and transplantation increased, there was a need for further legislative change, which was brought under the umbrella of the HTAct 2004. The main driver for this had, however, come out of the Bristol and Liverpool inquiries, where organs and tissues had often been removed, stored, or used without consent. The HTAct 2004 and the Human Tissue (Scotland) Act 2006 cover the removal, storage, and use of all organs and tissues. Organs can be donated in both life (living) and after death (cadaveric) [2]. After death and in appropriate circumstances a donor may be able to donate all major organs, corneas and tissue. A live donor can normally donate one kidney, a segment of liver or a piece of lung. There are two types of cadaveric donor, heart-beating and non-heartbeating. In the former the person's death is diagnosed following brain stem death tests and in the latter when their heartbeat has irreversibly ceased. Heart-beating donors are treated on a ventilator and as a result their circulation is maintained and they can be considered for multiorgan donation. Non-heart-beating donors can be considered for kidney and liver donation but the early perfusion of these organs is necessary to preserve them for transplantation. Although the Human Tissue Act only requires that reasonable enquiries be made of relatives to establish that the deceased had not expressed an objection to organ donation, it has become standard practice to seek the consent of relatives for donation. In gaining consent transplant co-ordinators take a detailed clinical history to guard against the transfer of transmissible disease between donor and recipient.

EU Directive

The EU Directive 2010/53/EU on the standards of quality and safety of human organs intended for transplantation was transposed into UK law by The Quality and Safety of Organs Intended for Transplantation Regulations 2012, which was implemented on 27 August 2012. [1]. The Directive was put in place to ensure there were common quality and safety standards for the procurement, transport, and use of organs at an EU level. The first objective of the Directive is the safety and quality of organs through common standards, which also facilitates organ exchange between member states. It also contributes indirectly to combating organ trafficking through the establishment of competent authorities, the authorization of transplantation centres, and the establishment of conditions of procurement and systems of traceability. At a later stage the Commission Implementing Directive 2012/25/EU, which sets out the rules for the transmission of information when organs are exchanged between member states, was transposed into UK law by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. The HTA is the competent

authority for the implementation of the Directive across the UK in conjunction with the relevant HTA Codes of Practice. All organizations undertaking procurement and transplantation activities require a licence, which is issued by the HTA in the UK. Particular emphasis is placed in the Directive on requirements to be met in relation to the management of risk involving living donors [3]. Human rights concerns have been raised about this form of donation and its use is constructed narrowly in other international legal instruments.98 Diverse approaches are taken to this form of organ donation as between Member States, with the United Kingdom having a much higher rate than Spain, for example. In the Recital, it is acknowledged that living donors face particular 'physical, physiological and social' risks as a result of undergoing non-therapeutic medical treatment to remove a healthy organ for transplant into another. In the substantive part of the Directive, Member States are required to take all necessary measures to ensure the highest possible protection of living donors in order to ensure the quality and safety of their organs for transplantation. Emphasis is placed on the need to engage in careful selection of living donors by reference to their health and medical history, which should be undertaken by suitably qualified and competent professionals. Records are also required to be kept in relation to organ donation by living donors, who should be monitored post-donation with respect to any risks and/or adverse reactions. While the Organ Donation Directive sets out a principled approach to guide organ donation and transplantation in the context of achieving a high level of quality and safety in the field, it is accompanied by a central focus on increasing organ procurement as a way of addressing the problems created by chronic organ shortage within the EU. Much of the policy discussions and consultation that took place prior to the adoption of the Organ Donation Directive focused on this issue, as well as how best to embed it within the proposed risk regulation regime.

In the end, a multi-pronged approach was taken in the Directive. First, Member States are required to adopt and implement a set of 'operating procedures' which should establish a quality and safety framework covering key aspects of the organ donation and transplantation process. Although this approach allows Member States a large degree of flexibility, the Directive nevertheless makes clear that the framework should include procedures covering identity verification of donors; consent requirements for organ donation; the completion of both organ and donor characterization; the traceability of organs; and the reporting of serious adverse events and reactions in the transplantation process. There are requirements for facilitating information exchange and networking as between national competent authorities, as well as between regional and EU organ exchange organizations, with a view to strengthening cooperation in the wake of implementation of the Directive and learning from best practice in the field.

ODR

In the UK the current model for consent for organ donation is to opt in, where an individual makes a decision in life that they would like their organs to be used for transplantation after their death[1]. In other countries an opt-out model is in place, where everyone is assumed to agree to donate their organs after death unless they made an informed choice to opt out of donation during their lifetime. In reality, a soft opt-out model is used, whereby the family is consulted to see if they were aware of any unregistered objection and, if not, donation would proceed unless the family objected. From 1 December 2015, Wales introduced a soft opt-out system where two types of consent are recognized in law: deemed consent for those people who have not registered to opt out of donating an organ and express consent for those who have registered to say they wish to be a donor. England and Scotland are both currently developing opt-out legislation. The HTAct makes it clear that, where adults make a decision in life to, or not to, consent to organ donation taking place after their death, then that consent is sufficient for the activity to be lawful. In summary, the wishes of the deceased, in life, should take precedence. The commonest means by which an individual expresses their decision to consent to organ donation in the UK is through the Organ Donor Register (ODR), although individuals may also express their wishes by letting their family know. In practice it is preferable for an individual to do both. If individuals become potential deceased organ donors, specialist nurses in organ donation are able to search the ODR to see if they are registered, and, if so, will ask the family to support the decision. The conversation is facilitated when the individual's decision in life to consent for organ donation does not come as a surprise to their family. If a potential deceased organ donor had not expressed a wish in life, views will be sought from a nominated representative or a person in a qualifying relationship. Section 4 of the HTAct introduces the rarely used concept of a nominated representative whereby adults may appoint one or more people to represent them after death and to provide a consent decision on their behalf. Otherwise consent would be sought from a person in a qualifying relationship. In the UK, excluding Scotland, adults are defined as 18 years or over, whilst in Scotland it is 16 years or over. Where a child is a potential deceased organ donor, the provisions for consent depend on both the age of the child and whether they were competent to make a decision in life. In Scotland, if the child was aged over 12 and had clearly expressed a wish for organ donation in life, then authorization is not required from a person with parental responsibility. In the rest of the UK, if the child was deemed competent, the person with parental responsibility would still have their views and wishes taken into consideration. Throughout the UK, where the child was not deemed competent or had made no decision, the person with parental responsibility would give consent/authorization. Where there is no one with parental responsibility or, outside Scotland, in a qualifying relationship, then organ donation cannot proceed as consent cannot be given.

Removal of Organs

The removal of organs or tissues from the deceased for research purposes is clearly defined under the HTAct [1]. Consent is always required, but whether the place of removal needs to be an HTA licensed premise depends on the primary purpose for which the organ or tissue was removed. Removal for the primary purpose of transplantation does not require a licensed premise, but is required if the primary purpose is research. If the organ is removed for the primary purpose of transplantation, and then found to be unsuitable for transplantation, it can be used for research provided consent for research had been obtained, irrespective of whether the operating theatre was licensed for removal. However, if an organ is removed for the primary purpose of research even though other organs are removed from the same donor for transplantation, it must be done in an operating theatre that is licensed. The situation is different in Scotland, where the removal of organs for transplantation research

only requires the necessary authorization. Using human bodies or parts of bodies from the deceased for anatomical examination, education, and training are also scheduled purposes under the HTAct, and consent is required for the removal, storage, and use in England, Wales, and Northern Ireland. This does not apply to human cadavers imported into England, Wales, and Northern Ireland, and this includes material that is fresh, frozen, plastinated, dried, embalmed, or preserved in some way. Imported human material is covered by a separate Code of Practice, and it is expected that appropriate consent will have been obtained in the country of origin and that the material is used in accordance with that purpose. The storage of this material is, however, a licensable activity under the HTAct. The code specifies that institutions wishing to import material 'should be able to demonstrate that the purposes for which they wish to import such material cannot be adequately met by comparable material available from sources within those countries, or is for a particular purpose which justifies the import'. Three points need to be understood about the mechanics of transplantation [4]. First, the organ must be suitable for transplant- that means it should be 'healthy enough' and retain a reasonable 'shelf life'. That does not mean that the donor must have enjoyed perfect health but controversy has arisen over what we might call risky transplants. Reports of a coroner's inquest in Wales raised a nice question of consent and the condition of donor organs. Two patients died as a result of the kidneys they received having been infected by a parasitic worm. The organs came from a homeless alcoholic and had been rejected by other transplant teams. The families of the dead recipients argued that while their relative might have been prepared to take a risk to receive an organ they should have received much more information about the risk of the kidney on offer. Most deaths occur in the elderly: age alone is no barrier to donation. Organs are now taken from an increasingly older range of cadaver donors, but those who die of progressive organ failure, common in the very old, are unsuitable donors. Second, the organ must remain viable - in good condition. Either the transplant must take place a very short time after its removal from the donor, or means must be found to preserve it while it is transported to the potential recipient. Finally, there should be a tissue match between donor and recipient. Improvements in drugs used to prevent rejection of 'alien' organs have made it possible to use a wider range of donors with less emphasis on the perfect tissue match but a live transplant from a close relative is still an optimal choice. A healthy sibling may be able to provide a matched organ that can be transplanted within minutes of its removal from the donor.

Patient's Condition

The potential donor is examined by two independent consultants, not directly involved in the patient's management [5]. They must satisfy themselves that there is no potentially reversible cause (e.g. drugs) for the patient's condition, that all the most basic reflexes, e.g. cough, gag, corneal and vestibular, have been lost, and that no spontaneous breathing occurs when the ventilator is disconnected. These tests must be carried out at least twice over a period of several hours. Electroencephalography (EEG testing) is of doubtful value, as many cases have been reported where a heavily sedated patient showed no signs of electrical activity, but electrical activity returned as the drugs were metabolised. It is no longer included in the criteria used in the UK. After the first set of tests have proved positive for brainstem death, it is appropriate to begin making plans for organ or tissue donation as soon as possible. Tests of liver, kidney and lung function are performed, and the necessary consent is sought from the next-of-kin. The next-of-kin should be approached sympathetically and given time to adjust to the situation. Many are helped to a decision by the knowledge that someone else is to be helped. Their written consent should be fully informed, and only obtained after detailed discussions and explanations of the procedure have taken place. If multiple organ 'harvesting' is being considered, the hospital administrators should be advised. They can then keep the media at bay and protect the family's privacy. Under no circumstances should the name of the donor or the recipient be made public by the hospital; if the relatives wish to do so, that is their affair. The patient's medical condition is reviewed by the OPO (organ procurement organizations) coordinator to determine if the patient is a medically suitable candidate for organ/tissue donation [6]. The donor registry is accessed in the state where the donor resided to determine if their donation preferences have been recorded. If the patient has indicated their wish to be a donor, the next of kin or health-care proxy is informed of their decision, and a medical/social history is obtained in order to facilitate the donation. If the decedent's wishes are unknown, the coordinator will then discuss the possible donation options. In the case of pediatric donation, appropriate authorization is obtained from the patient's next of kin who is usually the mother and/or father. The family is given sufficient time and support to understand the value of organ/tissue donation and to answer any questions or concerns they may have. The ME/C (Medical Examiner or Coroner) is notified according to local protocols to discuss the circumstances of the case in order to obtain clearance and provide any additional information or testing as requested. After securing appropriate authorization, the organ/tissue donation process is set in motion and the OPO assumes responsibility for the management of the donor after the declaration of brain death. (Donation after cardiac death, or DCD, is another avenue for donation after the decision to discontinue treatment has been made by the family.) Donor management requires a high level of clinical expertise to ensure that all suitable organs remain viable for transplantation. The donor's hemodynamic stability is of utmost importance to the organ recovery process and is maintained through mechanical ventilation. The goal of donor management is to maximize the function of each organ prior to surgical recovery. Physical assessment and laboratory and diagnostic testing are performed to determine appropriate interventions to maximize the organs suitable for transplant. Blood and tissue samples are sent for tissue typing and infectious disease testing. The donor information is then entered into the UNOS (United Network for Organ Sharing) computer to determine the appropriate allocation of the donated organs. The OPO coordinator accesses the list of potential recipients and begins the process of contacting the corresponding transplant centers for organ placement. The surgical recovery process often requires the logistic support and cooperation of multiple surgical teams from different transplant centers. ME/Cs are encouraged to attend the organ recovery procedure to address any concerns regarding the preservation/collection of forensic evidence. The organs are recovered, flushed, and preserved in protective solutions ready for transport to the recipient transplant center. OPOs provide support and follow-up regarding the outcome of the donation process to the donor family, hospital, and ME/C staff. Donor family follow-up begins immediately after the donation and continues for a period of time up to a year after the donation through telephone contact, grief

programs, and annual services of remembrance. Donor families have expressed that the act of organ/tissue donation was the only comfort gained in an otherwise tragic situation.

Living Donors

Some argue ethically and morally that all intra-familial donations should be prohibited simply because of the coercive forces operating within the family unit which, hypothetically, could justify the need for requiring an incompetent healthy sibling to make a forced organ donation to a competent, unhealthy brother or sister [7]. If such a scenario were in fact to be written, no destructive harm to the particular family unit would occur. Indeed, just the opposite would happen—for the unit would be preserved and strengthened by such a donation. At a minimum, the factors that constitute a valid consent should be defined with as much precision as possible—recognizing as such that there is an enormous factual difference between a family member authorizing tissue removal from the body of a deceased relative and, on the other hand, from a living relative. There are other ethical and social considerations raised regarding organ transplants from living donors. One simply finds such actions to be inherently immoral. This idea builds on the belief in the general ethical principle that life should always be preserved and, further, that one should never seek his own destruction nor endanger in any way his own life except as an expression of love for another. Commerce in human body parts— it is maintained—also acts to restrict free will and individual autonomy. This, in turn, is buttressed by the view that, in harming oneself by deliberately undergoing tissue removal, one may well indeed harm society by later becoming sick or enfeebled and thus a burden upon it. Abstract moral principles and concerns of this nature must give way to the realities and the needs of contemporary society and not stand as roadblocks to the maintenance of actual life. The counter-utilitarian argument to these moral-ethical concerns states that any absolute prohibition on the use of organs from minors or incompetents is unjustified—this, in light of the simple fact that donations from such classes restore health and renew life to others and are done without jeopardizing or ending the lives of the donors. Where the risks from the donation to the minor, incompetent or incarcerated prisoner are minimal, or even if substantial yet much less than the harm that would occur to an individual donee deprived of the benefits of sustained living, organ transplantations should be undertaken. The first principal of medical ethics, primum non nocere ("first do no harm"), charges the medical profession with considering the potential harm of any medical intervention [8]. However, living donation, as a procedure not undertaken to benefit the individual undergoing surgery, is associated with inherent harm to the donor, when interpreted in a broad sense of the word. Risks include blood loss, pain, temporary loss of wages, reduction in organ function, visible physical changes such has scarring, and loss of the whole self. The medical evaluation of live donors necessarily takes a more narrow interpretation of harm to mean undue risk, those that are modifiable or preventable that may be associated with substantial new morbidity, both perioperative and long term—occurrences such as inadequate remaining organ function, major cardiovascular events, infection, or even death. Some have advocated the complete separation of the donor evaluation from all recipient considerations as necessary to preserve an unbiased assessment of the donor; however, the medical selection of live donors must consider organ recipient issues such as transmission of infection or malignancy, the provision of adequate organ function, and the risk of recurrent disease. When an independent living donor team is not possible, the living donor advocate can serve only the living donor and is not involved in the evaluation of the transplant candidate.

Conclusion

Today, organs (kidneys, liver, pancreas, heart, lungs) can be transplanted, as well as tissues (skin, parts of bones, heart valves, blood vessels, corneas, etc.). Transplantation benefits patients with complete kidney failure, treated with hemodialysis or peritoneal dialysis three times a week to save lives, patients with terminal heart, liver or lung failure whose life expectancy does not exceed a few weeks or months, patients with diabetes who it cannot control, blind people, as well as patients who need to have some tissue replaced.

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