

# Organ donation in Malta – what’s new?

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Malta transposed Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (European Parliament and Council, 2010) on 12<sup>th</sup> October 2012 through Legal Notice 345 of 2012, entitled Organ Transplants (Quality and Safety) Regulations, 2012, Subsidiary Legislation to the Human Blood and Transplants Act (Cap483), enacted in 2006.

This long awaited legislation provides a firm legal backing for transplantation services that are structured such as to ensure health and safety to both donor and recipient. The regulations apply to practices and procedures along the entire pathway from donation to transplantation of solid organs, and even beyond, to the collection of post transplant medical data.

Malta has a good track record of safe working practices in transplant services. These have been offered since the early 1980’s, initially limited to corneal transplants, but soon followed by the first kidney transplant in 1983. Heart transplants are performed once a year, with the first being in 1996. (Transplant Support Group, Malta, 2013) Patients requiring liver transplants are referred to the UK while recently, in 2011, an agreement was reached with Palermo, Sicily for a lung transplant service. (ACCORD, 2012)

## **NEW LEGISLATION**

### **Transplant Authority**

The main impact of the legislation is to set up a formally recognized structural framework, with procurement organisations and transplantation centres being accountable to a transplant Authority (Organ Transplants (Quality and Safety) Regulations, 2012, Regulation 3), which is to ensure that international standards are maintained.

The lack of a specific organizational structure may not have been so obvious locally since there is only one transplant centre, but success stories increasing the availability of donor organs, led by Spain, (Matesanz, 2013) have strongly relied on restructuring of the

organizational set up with co-ordination between the public, as potential donors, and the formal service providers.

Legislation provides for a Licensing Authority, to be represented by the Superintendent of Public Health, (Organ Transplants (Quality and Safety) Regulations, 2012, Regulation 3) who may delegate functions to other bodies. The Authority is empowered to license procurement organisations and transplantation centres and has a remit to ensure that appropriate operating procedures are in place, through regular adequate control measures, including site inspections. The Authority promotes safety through regulation of the use of facilities, equipment, instruments, materials and medical devices, in concordance with national and international standards of practice.

### **Safety of Organs**

The main emphasis is on the health and safety of both recipient and donor. The Organ Transplants (Quality and Safety) Regulations (2012) lay down a requirement for guidelines concerning procedures related to donor consent (Regulation 14), organ characterisation (Regulation 7), and adequate organ transport (Regulation 8), and in fact the Directive and the local legislation lay down the minimum data set required for organ characterisation (Regulation 7 and Schedule). All medical activities, from donation to transplantation, must be under the guidance and advice of suitably qualified medical professionals (Regulation 12). Regulation 4.3 empowers procurement organisations and transplantation centres to ensure appropriate qualifications and competency, and further requires training programmes to be set up and provided.

A formal mechanism needs to be set up to enable reporting of serious adverse events and reactions, occurring during or after transplantation, to the Authority. Procurement organisations and transplant centres must investigate and register the adverse events and are required to have operating procedures for the adequate management of such events (Regulations 11(1) and 11(2)).

Traceability becomes an important element in the follow up of the patients involved. Regulation 10 requires adequate identification data on the donor and recipient to be kept by the procurement agencies and transplant centres for a minimum of thirty years after donation. Data is confidential and collection and storage must comply with the Data Protection Act, Cap 440 (2001). Data may be kept as an electronic record and must be made available to all parties in an organ exchange system involving more than one state. (Organ Transplants (Quality and Safety) Regulations, 2012, Regulation 7(6)).

### Living Donor Registry

So far Malta has had an informal Registry through donor cards registered with the Transplant Support Group. It is now a legal requirement to have an official registry of live donors and to record events that affect the donor's health, even after transplant (Organ Transplants (Quality and Safety) Regulations, 2012, Regulations 15(3) and 15(4)). Such a registry must be coupled with the identification system of recipients, necessary for organ traceability. (Regulation 10(1)b). Details of the set up of such a registry are still to be formulated. One foresees an electronic register, which is easily accessible to all interested parties and which can be easily kept up to date.

### Compensation

The Organ Transplants (Quality and Safety) Regulations (2012) state in Regulation 13(1) that donation must be 'voluntary and unpaid'. The principle that the 'human body and its parts shall not, as such, give rise to financial gain' was formally established in article 21 of the Convention on Human Rights and Biomedicine (Council of Europe, 1997) and repeated in article 21(1) in the Additional Protocol (Council of Europe, 2002), where it also rules out 'comparable advantage' but 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'. Regulation 13(2) also allows compensation for loss of income and expenses related to the donation but guidelines have to be set up by the Authority for such compensation; these may be either in the form of monies or comparable benefits. Any adverts related to organ donation that include financial gain or comparable advantage are also prohibited by law (Regulation 13(3)).

### Confidentiality

An issue which is addressed in the law but will prove difficult to enforce in Malta is confidentiality. Procurement organisations are barred from revealing the identity of the recipient to the donor or the family and vice versa (Organ Transplants (Quality and Safety) Regulations, 2012, Regulation 16).

It has been the practice locally for the Transplant Support Group to facilitate meetings between donor and recipient, if they so wish. This will therefore not be possible if the organisation is also involved in procurement. It may however prove impractical to ensure anonymity of donations in the local scenario.

### Organ Exchange

The Authority may oversee agreements with European member states or third parties for the purpose of organ exchange (Organ Transplants (Quality and Safety) Regulations, 2012, Regulation 3(2)j). There is a willingness, and a necessity, to ensure this happens on an international scale to maximize use of donations. Malta already has experience in this field because there has been a reciprocal arrangement with Italy for some years and in fact over the past 10 years Malta has donated more than 50 livers to Italy. (ACCORD, 2012)

## FURTHER ISSUES TO BE ADDRESSED

### Consent

The EU Directive 2010/45/EU asks for proper informed consent from donors but leaves the decision as to the model of consent to the state (Directive, Article 14). The local legislation (Organ Transplants (Quality and Safety) Regulations, 2012, Regulation 14) requires the Authority to lay down the standards expected in obtaining consent, including the information to be imparted. Guidelines should be forthcoming in future, so presumably a decision has to be taken whether to have an 'opt in' informed consent or an 'opt out' presumed consent system and who can consent or object on behalf of the donor. Who legally 'owns' deceased donor organs, and therefore can take decisions as to their use, is not clear.

Malta has always practiced an 'opt in' system, with cadaver organs being retrieved only if permission is obtained from the family. Research into the attitude of the Maltese towards an 'opt out' system have been unfavourable (Lauri, 2006, p.27). 'Opt in' systems may be strengthened with introduction of Advance Directives specifically for organ donation. This may be coupled with introducing donor cards as legal evidence of registering as

an organ donor. At present donor cards have no legal status in Malta but they do provide relatives with an indication of the beliefs and wishes of the deceased.

### Criteria for Allocation

The law does not discuss criteria for organ allocation, which according to WHO (2010) should be guided by clinical criteria and ethical norms. However 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 'extended or expanded criteria' whether in terms of disease status, age or less than optimal immunological typing (Stratta, 2004). Thus older kidneys may be used for older recipients and Hepatitis B or C positive organs may be donated to positive recipients. Guidelines about such criteria should be issued.

### Definition of Death

Malta has no official legal definition of death although brain stem death is legally accepted for the purpose of certification of death. Till now most deceased donors have been patients declared brain stem dead following brain injury. This in itself is a controversial issue with brain stem death being accepted in only a few countries, as in Malta, which follows the UK practice. Most countries accept whole brain death, requiring evidence of loss of higher brain function prior to making the diagnosis and certification of death.

So far, locally, there has not been a move to follow the emerging practice of trying to maximise the number of deceased organ donations, by using organs, with informed consent, from the so called non-heart beating donor. These are patients dying following cardiac death with irreversible cardiac and circulatory arrest, without previously having been on life support systems. This practice is marked with ethical problems since in such cases the death has to be anticipated and almost witnessed by healthcareers such that harvesting of organs can start within five minutes of death.

### The Way Forward

Malta has already committed itself to the issues laid down in the law, before it was even enacted, when it joined as a project partner in ACCORD, 'Achieving Comprehensive Coordination in Organ Donation throughout the European Union', a Joint Action DG SANCO Consortium of 23 associated partners and 9 collaborating partners, under the leadership of the Spanish National Transplant Organization, ONT. The project is running from May 2012 to November 2015 and is concentrating on three

main aims: live donor registries, cooperation between intensive care and donor transplant coordinators and joint projects between countries to share experiences and support learning from each other to improve performance on specific issues mentioned in the EU Directive.

The Maltese have a positive attitude to organ donation. In the Special Eurobarometer 2007 study, 75% of citizens in Malta were willing to donate one of their organs after death as compared with 10% who were against the idea (Eurobarometer, 2007, p.7). Seventy-one per cent of Maltese were in favour of donating an organ from a deceased close family member (Eurobarometer, 2007, p.12). Discussion of organ donation with the family and making one's views known to the family has a strong influence on willingness to donate relatives' organs. (Lauri, 2006, p.28) Therefore we should continue to promote awareness about organ donation through national campaigns.

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