ORGAN DONATION

A LEAP TOWARDS REGULATION: THE PRESENT AND THE FUTURE

A POSITION PAPER BY ELSA MALTA’S SOCIAL POLICY ORGANISING COMMITTEE
Opportunities Ahead in Social Policy

ELSA Malta would like to thank…

Yet again our Legal & Social Policy Organizing Committee has amalgamated months of hard work, co-operation, planning & research to produce our position paper entitled ‘Organ Donation: a leap towards regulation - the present and future.’, and we can finally say that we are now also on the map when it comes to taking a particular stand on relevant issues.

ELSA Malta remains committed to be pro-active on several important issues that have a social impact. We will be there voicing our opinion, proposing legislation and discussing ideas. This position paper is a clear example. We believe that it is surely our duty, as a law student organisation to be relevant in today’s society and keep up to date with new proposed legislation.

Many people are behind such a project, and without them this would surely not have been possible. Our thanks goes to:

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On behalf of the ELSA Malta Social Policy Office, we hope that you enjoy reading our paper, take the time to evaluate our suggestions, and lastly to follow us and support us in our aim - to always be #pro-active!

Thank you.
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Maltese Law

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Conventions

Additional Protocol on Transplantation of Organs and Tissues of Human Origin

Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin ET Series 186

Additional Protocol to the Biomedicine Convention concerning the Transplantation of Organs and Tissues of Human Origin

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)

American Law

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White Papers


Position Papers

INTRODUCTION

In 50 years, organ transplantation has become a successful worldwide practice which has extended, and greatly enhanced the quality of thousands of lives. However, there are large differences between countries which have access to suitable transplantation which result in varieties in the levels of safety, quality, as well as efficacy in donation, and transplantation of human cells, tissues and organs.

The procurement of organs for transplantation involves the removal of organs from the bodies of deceased persons or the attainment of organs from living donors. This removal must follow specific legal requirements, *inter alia*, the definition of death and of consent. Organ transplantation is often the only treatment for irreversible organ failure, such as liver and heart failure. It is interesting to note that kidney transplantation is globally by far the most frequently carried out transplantation.

In 2011, 112,631 transplants were reported globally; a figure which illustrates an increase of 11.6% in transplants since 2008, indicating a rise in the number of donors. Despite these statistics, it is still difficult to quantify the different between the demand and availability. However, it can be noted that the gap is increasing.¹

There are various issues revolving around the organ donation system which give rise to diverse social implications. One of the main points which may arise is the fact that people coming from different strata of society often view the process of organ donation from varying perspectives. In addition, underprivileged people in less developed countries may be forced into organ trade activities in order to earn money.

Misconceptions about organ donation linked with religious beliefs as well as the lack of universal laws governing the organ donation process in different countries are often a challenge to combat medical tourism for organ transplantation. Misconceptions and lack of knowledge are prevalent at both an individual and a social level. The lack of awareness vis-à-vis organ donation as well as inadequate legislation, hinder people from a proactive approach towards organ donation.

Long waiting lists often transpire alongside organ transplantation mainly due to organ shortage. This results in a significant number of deaths among those waiting for an organ, and amongst those not considered for transplantation because of organ scarcity. In 2012, in the EU alone, 61,000 patients were waiting for an organ transplant. 80% of these were waiting for a kidney, 10% for a liver and several other thousands for other organs such as the heart, lungs or pancreas. In the same year, 3,780 people died whilst on the waiting list.²

Organ trafficking is an ever-increasing challenge, especially in countries like China and India. Indeed, the rise of organised criminal activity within such countries facilitates organ trafficking.

Despite efforts to boost altruistic organ donation and resolutions to curb transplant tourism, the black market continues to grow. At the same time, the worldwide escalation in the number of patients who require the transplants coupled with a shortage in the supply of transplants continues to fuel this trade. Healthcare providers and workers such as the physicians and transplant surgeons have the responsibility to ensure to the best of their ability that the organs they transplant must be obtained by upholding the highest standards of ethics and abiding by the law. Hence, the medical profession must be well-informed and motivated to contribute to this end. Moreover, enforcing changes in transplant practices requires more than academic and professional sanctions; governments of all countries must also be willing to adopt and enforce bans on organ purchases and transplant tourism.

The principal objective of this position paper is to give an overview of the current situation regarding organ donation in Malta. The aim of this paper is to delve in detail the different facets of this subject-matter, focusing on current position in Malta, the comparative aspect - organ donation in other countries, while also discussing the White Paper and the proposed situation in Malta. The negative issues surrounding organ donation are also addressed in this position paper. It is also important that organ donation is tackled from the religious point of view. Our aim as authors, on behalf of ELSA Malta, is to analyse these facets in light of the present situation in Malta, and to voice our position based on our research.

Religious beliefs are pivotal in the ambit of organ transplantation because these often determine one's acceptance or otherwise of such a medical intervention. For the purpose of this position paper, which is aimed to give a holistic local overview on this subject-matter, where religion is concerned, this paper is solely focusing on the views adopted and opinions held by the Roman Catholic Apostolic Religion, which is the religion of Malta in terms of Article 2(1) of the Constitution of Malta.
KEY CONCEPTS

Informed Consent

Explicit consent entails that the donor giving consent is doing so by following the proper registration required by the country he is residing.

Presumed consent on the other hand, requires no direct consent from the donor or the next-of-kin, but comprises the assumption that the donation would have been permitted by the potential donor, if permission was pursued.

Explicit consent is known as the opting-in system while presumed consent is the opt-out system. The difference between both systems is that, in an opt-in system, people need to sign up to an organ donation registry in order to donate their organs after death. In an opt-out, organ donation will be executed automatically unless there is the specific request made a priori the death of that potential donor, that he or she does not wish to donate his or her organs.

Definition of “organ”

In biological terms, organ refers to a group of tissues combined together which account for the human body’s functionality. An organ can refer to the brain, heart, liver, kidneys, eyes or skin.

On a national level, the White Paper on organ donation does not define the term “organ”. International instruments however have sought to standardize this term. To begin with, the EU Organ Directive which aimed at harmonizing the term at EU level, defines “organ” as a ‘differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy’.3 It thereby includes any component of the body, or part of it, that is able to maintain its distinctive function and its original purpose after donation.

Tissues and organs are not terms which are used interchangeably but they refer to different chemical and biological components in the human being. This also emerges from the definition of organ in the EU Organ Directive, as an organ is said to be ‘formed by different tissues’. Tissues connote a bundle of cells, other substances and materials. The Directive defines “tissue” as meaning each constituent part of the homo sapiens formed by cells.

Amongst the criticism of the definition given by the EU Organ Directive is that it fails to specify the respective ‘organs’ but relies on the above-mentioned generic definition.

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This contrasts with the provisions of the US National Organ Transplant Act which list the organs that the Act applies to in order to avoid confusion.\(^4\)

‘It is the mental life that matters\(^5\) - Brain Death

The concept of ‘brain death’ has evolved independently of the discovery of organ transplant donation but it is rather a necessary ancillary of modern medical advancements and intensive care, in particular, the artificial methodology of ventilation or life support systems which keeps a patient alive even when his or her brain ceases to operate.

Nowadays, the concept of brain death has been universally accepted. In the medical sphere brain death is usually associated with the collapse of organs’ function usually due to extensive brain damage. Brain death has been defined as the ‘irreversible loss of all functions of the brain, including the brainstem’\(^6,7\). The European Consensus Document defines brain death as the ‘complete and irreversible cessation of all cerebral and brain stem functions which, from the scientific, ethical and legal point of view is accepted as equivalent to the death of the individual’\(^8\).

Locally, a person may be taken off life support system without the ‘brain death’ criteria, if his condition is seen extraordinary that is his health condition is in a vegetative state. It is important in this regard that the doctor taking care of the dying person and the patient waiting to receive the organ are different.

In Malta, the White Paper proposes that Malta follows the Harvard Criteria of brain death (1968) to shape its position on the definition of brain death for the purposes of organ donation. According to these principles, for a person to be considered as brain dead, such a person must be: unreceptive and unresponsive; there must be no signs of movement or breathing; no reflexes; the patient must present with a flat

\(^4\) National Organ Transplant Act US, Title III Sec. 301 (c)(1), The term “human organ” means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin and any other human organ specified by the Secretary of Health and Human Services by regulation.


\(^6\) Brainstem is the posterior part of the brain that is made of the medulla, pons and the mid-brain. It adjoining the spinal cord, and has been described as being the part of the brain which is most resistant to anoxia, that is, lack of oxygen in the brain. Inter alia, the brain stem has regulatory and sensory functions including controlling breathing, consciousness, heart rate, sleeping and nervous system.


electroencephalogram; the body temperature must be lower than 32 °C and there must be no signs of Central Nervous System (CNS) depressants.

**Definition of organ shortage**

Organ shortage has been described as the disparity between the demand for organs and the supply available to meet those demands. In the past years the demand has increased rapidly owing to higher organ failures, *inter alia*, the liver, heart and kidney and higher successful organ transplantation. These demands however are not balanced by the available supply.

Organ shortage is mainly attributed to low donors. Sometimes matching criteria might also pose significant challenges to meet all patients’ needs as not every organ is suitable for every person. Organ shortage has also led to another issue, that is, selection. Only patients that have high percentage likelihood for a successful transplantation become eligible for transplantation. Another reason for organ shortage might be attributable to lack of cooperation between hospitals and the extensive fees associated with brain death diagnosis. Moreover, it has been argued that some medico-ethical issues might also contribute to the problem of organ shortage as several doctors still find it difficult to stop treating a patient and instead see such patient as an eligible organ donor.

‘Organ Donation: the gift of a lifetime’ - Organ Donation

Organ donation can be described in simple terminology as the giving of viable organs and tissues from one person to another by means of a surgical operation. Hence, it involves removing a damaged or dysfunctional organ and replacing it with a good one. Not all the organs in the human body can be donated and successfully transplanted. Moreover, not all transplantations have the same risks and success rates. Some transplantations may be less invasive than others such as skin and corneal transplants whilst others require specialised clinical procedures. All in all, however, the European Consensus Document highlights that around the world, patients with successful organ transplantation exceed a million, amongst which 70% lead a normal life in a timeframe of five years from the transplant procedure.

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9 Electroencephalogram is a neurological procedure that is used to monitor and record the electrical activity of a patient’s brain, which in a brain dead patient is absent.
10 These include, *inter alia*, tranquillisers and sedatives.
13 Friedrich Breyer and Hartmut Kliemt, ‘The Shortage of Human Organs, Causes, Consequences and Remedies’ (2007) 29 Analyse & Kritik 188.
15 European Directorate for the Quality of Medicine and Healthcare (n 8) 3.
Live organ donation and post-mortem organ donation

Live organ donation

LOD means that a living healthy person freely accepts to donate an organ to another person who needs it because it is dysfunctional or damaged.

There are two types of LODs; direct organ donation and indirect or altruistic organ donation. Direct organ donation refers to a donation where the recipient names a donor usually a family member or a friend that are willing to donate an organ. This is the most common type of LOD. Indirect organ donation refers to a donation where the organ is not intended for the benefit of a specific person but is rather an altruistic deed for the benefit of an unknown person who is genetically compatible.

LOD has a number of advantages inter alia higher chances of matching. This could also spare a lot of time and uncertainty for the patient, as it would bypass waiting lists whilst also increase the successful rate of the transplantation by enhanced pre-operation preparations including the administration of anti-rejection drugs.\(^{16}\)

Nonetheless, setting aside the benefits of LOD, the Convention on Human Rights and Biomedicine as well as the World Health Organization lay down an important principle that LOD is only acceptable for therapeutic reasons and if there is no other alternative available such as a PMOD.

Post-mortem organ donation

PMOD means that organs are procured from a deceased person after being diagnosed as brain dead. The donor must also have his or her organs in a good condition, that is, the organs must not have any type of infection, must be healthy and must function properly.\(^{17}\)

Cadaveric organ donations come with some constraints, for instance, organs have to be immediately stored and thereafter transplanted as their viability ranges from 48 hours to 72 hours depending on the organ involved.\(^{18}\) Moreover, other limits include those related to relatives’ consent and sometimes even religious restrictions. These


\(^{18}\) The kidney’s viability is approximately 48 hours to 72 hours whilst liver viability is around 24 to 48 hours.
Factors coupled with lack of education and grieving significantly limit PMOD. Studies show that the attitudes in favour or against PMOD amongst the public and even health care professionals depend on their occupation, understanding of the term brain death and organ donation contemplation within their family. Moreover, it was also shown that there are considerable concerns amongst the public about any possible mishandling of the cadaver.

**Opt-in and opt-out method of obtaining consent**

The two main methods of determining consent are, the opt-in method, which suggest that those who give explicit consent are donors, and the opt-out method, where any person who has not refused to be considered as a donor is in fact deemed to be one. The opt-out method is not always deemed to be that effective in circumstances where family members are required to give their consent or refusal by vetoing it.

**Financial incentives for live and post-mortem organ donations**

There have been several suggestions as to how one can increase organ donation to balance the organ demand. These include inter alia education, presumed consent for donation and monetary compensation. Indeed, it has been suggested that financial incentives would increase the rate of donations hence reduce organ shortage, and patients’ burdensome waiting time. However, it has been argued that monetary compensation to donors or relatives would also increase the overall financial costs of organ transplantation for governments or health insurance companies, as these agents would have to make good for all the costs involved. Apart from the major criticism that this practice is immoral, financial compensation especially for LOD could also lead to a dangerous situation where people are forced into donating their organs for money, in particular the poor. People could also rush into donating organs without effectively taking into consideration the health risks involved. Moreover, the Bioethics Consultative Committee, argues to the effect that any such practice is not therapeutic vis-à-vis the donor. The altruistic nature of LOD could ultimately be destroyed. To add to this, another ancillary problem is the difficulty that the legislator would encounter to regulate paid organ donations. Some pros of financial incentives have also been put highlighted, inter alia: that this reflects the concept of individual autonomy, it

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21 Becker and Elias (n 17) 9.
23 ibid 105.
enhances ‘societal good’ and altruism when intended to save lives, and could also facilitate ascertaining voluntariness.\textsuperscript{24}

\textsuperscript{24} ibid 105.
AN EXAMINATION OF MALTA'S POSITION AND PROCEDURE

Position in Malta prior to the transposition of the EU Organ Directive

Before the Directive was transposed into our laws, there was no legislation catering for organ donation in Malta. The Criminal Code, since 2002, punishes the trafficking of persons - adults and minors 25 for the purpose of exploitation in the removal of organs. 26 Otherwise, there was a 'legal vacuum' in legislation. In 2006 Malta adopted the Human Blood and Transplants Act, dealing with the regulation of human materials - blood, tissues and cells. However, despite the term 'transplants' in the title of the act, and a definition of 'organ', 27 organ transplantation is not dealt with in this Act. 28

Position in Malta after the transposition of the Directive

The lacuna in Maltese Medical Law was filled up by Directive 2010/45/EU 29 (later corrected to Directive 2010/53/EU). 30 This has resulted in the Maltese healthcare system to adopt 'a minimum harmonisation quality and safety legal framework pertaining to organs, enhanced donor and recipient protection' and this is most evident in LOD because the creation of the obligatory registry was imposed in order to collect data, and in turn, this allows Malta to expand in cross-border organ exchange. 31 Cross-border organ exchange is to be considered in light of Implementing Directive 2012/25/EU 32 and the transposed Legal Notice 141 of 2014, 33 aimed at aiding communication in such organ exchanges between Member States. The HBTA regulates both the Directive and the Implementing Directive.

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26 Criminal Code 1854, Chapter 9 of the Laws of Malta, s 248C, 248D.
28 Aquilina (n 25).
Salient provisions of the Directive

The Directive is to 'ensure standards of quality and safety for human organs intended for transplantation to the human body'.\(^{34}\) The framework to be established by the Directive caters for all the stages involved - donation, transplantation and disposal. Transplantation is dealt with in considerable detail, allowing both LOD and PMOD, as well as multiple donations to more than one recipient. The framework regulates the adoption and implementation of operating procedures, mainly, the donor identity verification and procurements organisations. The latter have to be in place to take care of organ procurement which in turn acts as a deterrent to the illegal trafficking of organs. MS are obliged to provide information to the Commission on the authority of the procurement organisations.

MS are to compile a register of living donors in adherence to data protection legislation. MS are to set up the required authorities to enforce the provisions laid down by such law.\(^{35}\) Organ exchange with third countries\(^{36}\) and European organ exchange organisations\(^{37}\) are also dealt with by the Directive.

The Directive leans towards the idea of not allowing payment but encouraging voluntary organ donation. The Directive includes an exception, in that the living donors are permitted to receive financial compensation for the expenses and loss of income due to the organ donation. One is to note that reimbursement is recognised by the Organ Donation Taskforce because it eliminates disincentives to organ donation management.\(^{38}\) The MS have the liberty to fix the thresholds accordingly. Hence, if a donor travels to another MS he will be able to request reimbursement for the accommodation fees. Additionally, once the donor agrees to undergo surgical operations then it would be likely that such donor would have to take unpaid leave. In such a case, the donor would also be able to receive financial compensation in relation to the loss of income.\(^{39}\)

Although cleverly and professionally written, the Directive contains some lacunae, such as xenotransplantation, and the definition of death.\(^{40}\) These two ethical issues ought to be addressed at EU level. The transplantation of animal organs in humans is unregulated by the Directive and also in Malta. Xenotransplantation is a multi-faceted concept which raises a multitude of issues, including, inter alia, donor allocation in a society where many die while on the waiting list for an organ; animal rights of the

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\(^{34}\) Aquilina (n 25) 6.
\(^{35}\) L.N. 141 of 2014 (n 33) s 17.
\(^{36}\) ibid s 20.
\(^{37}\) ibid s 21.
\(^{39}\) Falzon (n 31) 73.
\(^{40}\) Aquilina (n 25) 8.
animals to be used as donors; whether children and infants are to be recipients of xenografts; and potential impacts on recipients of animal organs. \(^{41}\) Malta should regulate such issue, as other MS like Germany and Spain do. The definition of death is also matter that needs to be addressed.

The Directive also fails to delve into bio-tourism, and consequently, Maltese law does not prohibit such a practice. Such a niche of tourism is to be regulated, so as to be prohibited, or carefully legislated upon or allowed in our country.

Bio-engineering is another area that remains unregulated by law, whether foreign or local, although at EU level, the European Economic and Social Committee acknowledged that such technology may be useful in the creation of artificial organs.\(^{42}\) Moreover, one has to consider 3D printing and stem cell research as potential avenues to organ shortage solutions in the long term, which are yet to be regulated on as well.

**Legislation in Malta**

**Organ Transplants (Quality And Safety) Regulations - Legal Notice 345 Of 2012**

These regulations were adopted into Maltese law on 12 October 2012 with the scope of transposing the European Parliament and Council Directive 2010/53/EU of 7 July 2012.\(^{43}\)

The health and safety of the recipient and the donor are safeguarded and the regulations provide for the requirement of guidelines for consent procedures;\(^{44}\) organ characterisation - with data to be collected according to the schedule\(^{45}\) and organ transport.\(^{46}\) Furthermore, qualified medical professionals are to supervise and guide the process from donation to transplantation.\(^{47}\) The protection of living donors is safeguarded by procurement organisations and transplantation centres to guarantee the safety of organs. Living donors are selected on a basis of health and medical history.\(^{48}\)

Appropriate operating procedures to ensure information on organ and donor characterisation reaching the transplantation centre in due time are to be taken, and


\(^{42}\) Opinion of the European Economic and Social Committee on Promoting the European single market combining biomedical engineering with the medical and care services industry (2015/C 291/07) C 291/45.

\(^{43}\) Organ Transplants (Quality and Safety) Regulations, S.L. 483.06, Regulation 1(2).

\(^{44}\) ibid Regulation 14.

\(^{45}\) ibid Regulation 7.

\(^{46}\) ibid Regulation 8.

\(^{47}\) ibid Regulation 12.

\(^{48}\) ibid Regulation 15.
there should be the transmission of information on organ and donor characterisation
to the other MS of organ exchange cases.\textsuperscript{49}

A registry like the one that the Transplant Support Group Malta maintains through the
registration of donor cards is now legally required in order to register live donors and
events affecting their health.\textsuperscript{50} Such a registry is indispensable as in EU MS because
this is the most important source of information on donor status. Organ traceability is
to be ensured to safeguard the health of donors and recipients while a donor and
recipient identification system to identify donations and recipients is to be maintained,
while data is to be retained according to the framework and it is to be stored for thirty
years.\textsuperscript{51}

When it comes to organ exchange, the necessary information to ensure the traceability
of organs is to be transmitted by the procurement organisations and transplant centres
according to Article 29 of Directive 2010/53/EU.\textsuperscript{52} The Authority is to authorise and
supervise organ exchange with third countries, therefore it may authorise the
conclusion of agreements with counterparts in third countries.\textsuperscript{53}

The regulations provide that there is to be a system put in place in order to report and
transmit information on serious adverse effects and reactions that occur during and
after transplantation and the procurement organisations and transplantation centres
are to investigate and register such events while having operating procedures for the
adequate management of these events.\textsuperscript{54}

The principles to govern organ donation are found in Regulation 13. Firstly, organ
donation from deceased and living donors is to be voluntary and unpaid and secondly
compensation is to be strictly limited to make good for expenses and loss of income
related to donation. This principle of non-financial gain from the human body and its
parts is reiterated in Article 21 of the CHRB\textsuperscript{55} as well as in the Additional Protocol.\textsuperscript{56}
Moreover, it is vital to note that Article 3 (2)(c) of the EU Charter of Fundamental Rights
is against financial gain accruing from the human body or any of its parts.\textsuperscript{57} The
Maltese legal framework does not provide for the conferral of financial compensation.
However, there is significant consensus with respect to the possibility of allowing
financial compensation for expenses sustained and for the loss of income. Although
the compensation thresholds would have to be approved by the Superintendent of

\textsuperscript{49} ibid Regulation 7(5) and 7(6).
\textsuperscript{50} ibid Regulation 15.
\textsuperscript{51} ibid Regulation 10.
\textsuperscript{52} ibid Regulation 10(4).
\textsuperscript{53} ibid Regulation 18.
\textsuperscript{54} ibid Regulation 11.
\textsuperscript{55} Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the
\textsuperscript{56} Additional Protocol to the Convention on Human Rights and Biomedicine concerning
Transplantation of Organs and Tissues of Human Origin art 21(1).
\textsuperscript{57} Commission Staff Working Document, ‘Action Plan on Organ Donation and Transplantation (2009-
Public Health this acts as an incentive for donors, due to the fact that the individual ought not to worry about any expenses or loss of income.\textsuperscript{58} Thirdly, it shall be illegal to advertise the need for, or availability of, organs where such advertising is with a view to offering or seeking financial gain or comparable advantage. Fourthly, organ procurement is to be on a non-profit basis.\textsuperscript{59}

Procurement organisations and transplantation centres are to safeguard the fundamental right to protection of personal data in relation to organ donation as provided by the Data Protection Act. Punishment for unauthorised access of data and the misuse of the system or data to trace donors or recipients contrary to law is punishable as per Regulation 20.\textsuperscript{60} The regulation provides for penalties, with fines not exceeding €11,646. In case of an offence, the Authority sends notice in writing describing the offence and the required remedy, along with the applicable fine. If within twenty-one days of service of such notice, responsibility is accepted, the fine is paid and the law is respected, there would be no further proceedings. Otherwise, proceedings take place according to the Criminal Code provisions.\textsuperscript{61}

**Information Procedures For The Exchange, Between Member States, Of Human Organs Intended For Transplantation Regulations, 2014 - Legal Notice 141 Of 2014**

These regulations were made by virtue of Article 16 of the HBTA with the scope of transposing Commission Implementing Directive 2012/25/EU that ‘lays down information procedures for the exchange, between MS, of human organs intended for transplantation’.\textsuperscript{62} The regulations set out, ‘procedures for the transmission of information on organ and donor characterisation; procedures for the transmission of the necessary information to ensure the traceability of organs; [and] procedures for ensuring the reporting of serious adverse events and reactions.’\textsuperscript{63}

In case of organ exchange, the transplantation centre of origin is to send the collected information to 'characterise the procured organs and the donor' according to Regulation 7 of the Organ Transplants (Quality and Safety) Regulations, to the competent authorities.\textsuperscript{64} When Malta is the country of origin, the data to be transferred is regulated by Regulation 8.

\textsuperscript{58} The Parliamentary Secretary for Health, *Proposal for Legislation on Organ and Tissue Donation* (White Paper, 2015).
\textsuperscript{59} Organ Transplants (Quality and Safety) Regulations (n 43) Regulation 13.
\textsuperscript{60} ibid Regulation 16.
\textsuperscript{61} ibid Regulation 20.
\textsuperscript{62} L.N. 141 of 2014 (n 32) Regulation 1.
\textsuperscript{63} ibid Regulation 3.
\textsuperscript{64} Ibid Regulation 7.
Current position in Malta

The attitude of the Maltese society vis-à-vis organ donation is a positive one, because according to 2007 research, 75% of the citizens expressed their will to donate an organ after their death, while only 10% expressed their views against organ donation.65

The starting point in analysing the current position in Malta is by referring to the Directive, which does not regulate the method of consent, leaving MS to regulate the matter. This is evident through recital 21 of the Directive, providing: ‘This Directive is without prejudice to the broad diversity of the systems of consent already in place in the Member States.’66 With Malta moving towards amalgamating the opt-in and opt-out systems by making it possible for individuals who indicate throughout their lifetime their desire, or lack of, to donate organs, to be respected, leads to the question of whether incorporating the Netherlands’ method of obtaining consent would be effective in Malta.67

Voluntary unpaid donation of tissues and cells has been recognised as early as 1979 in Spain and in the start of the 1980’s in Luxembourg, Belgium and Finland. Since 2006 the principle was legally recognised by all the EU MS. Malta, together with Cyprus, was the last to introduce the principle into our legislation with the Tissue and Cells Directive transposition.68

For a person to become an organ donor, he can either, apply through the TSG website; contact the Renal Unit at Mater Dei Hospital, register through a doctor, or during an event organised by TSG or the Lifecycle group.69 People without a signed donor card are not automatically considered as organ donors, as the next-of-kin is to take the decision whether organ donation is to be made.70 Making one’s wish to donate organs known to relatives is influential on their willingness to donate such organs.71 Having specially trained people to approach relatives, such as transplant coordinators helps

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67 In the Netherlands, upon individuals reaching eighteen years of age, a donor form is received and one has the possibility to express his desire.
69 Organ and Tissue Donation White Paper (n 58) 11.
in identifying potential organ donors at an early stage and consequently approach the family of the individual and have timely contact with them, in order to maximise the chances of acquiescence. It is interesting to note that Germany has strict laws whereby when relatives are to decide whether organs are to be donated, this can only be done if they were in contact with the deceased during the last two years of his life. Were Malta to adopt such a law, the relatives’ decision is more likely to be akin to deceased's intentions.

In Illinois, the opportunity for an individual to register himself on the registry is widened, since while an ID card is being issued, people are given the opportunity to enter in the registry. Such a possibility in Malta, coupled with a continuous public awareness campaign will likely lead to a positive fluctuation in donor card holders.

Malta currently practises the opt-in system, and therefore organs can be obtained from donors only when the relatives of the deceased give their permission, even if the deceased had a signed donor card. The donor card enjoys no legal status and therefore if the family of a potential donor objects, the organs are not donated. Indeed, if relatives have a valid reason, no organ donation takes place. Sufficient reasons to uphold an objection to donate organs include the prospective donor changing his mind and having informed his family or else the prospective donor having converted to a religion that disapproves with organ donation.

Local organ transplantations are that of the heart, kidneys and corneas. Other organs are transported to the United Kingdom or Italy. The UK allows Maltese patients to receive liver transplantation there while Italy provides free compatibility tests in Malta. In 2011 the Malta reached an agreement with the Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione, enabling Maltese patients to benefit from lung transplants.

There is no age limit for organ donation but children under sixteen years of age require the consent of their parents or guardians. Factors that are taken into consideration when it comes to organ allocation include, inter alia, the blood type, the duration on the waiting list and the severity of the patient's conditions. A living donor can choose the kidney recipient but for PMOD there is no selection by the individual, as the organs are received according to severity, provided they are compatible. According to Article

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72 Anne-Marie Farrell, David Price and Muireann Quigley, 
73 Falzon (n 32) 58.
75 Bonnici (n 14).
77 Transplant Support Group Malta (n 70).
78 Bonnici (n 14).
10 of the Additional Protocol to the CHRB, LOD may be carried out benefitting a recipient who has a close personal relationship with the donor, but without such a relationship, the law is to be observed and an independent body is to approve such donation.\(^{79}\)

Individuals who have or have had cancer are able to be corneal donors, and those who have been in remission for more than five years may be donors. For a person’s organs to be harvested, the individual is to be declared brain-dead, normally at a hospital. Sometimes corneas can be obtained from donors dying at home.\(^{80}\)

Due to the Directive, organ recipients are not allowed to know the identity of the donor. This is required in order to reduce blackmailing opportunities. In practice, due to Malta’s size, it is normal for patients to discover the identity of their donor.\(^{81}\)

Spain is the leading country in organ donation. An efficient system is the result of various factors. One needs to take into consideration the number of doctors and nurses, the latter of which work with the transplant co-ordinator and ensure availability of ICU beds. The way the family is approached is to be taken into consideration as well. One might therefore argue that if Malta committed itself to improve on such issues, organ donation figures would improve.

**Transplant Support Group Malta**

Recipients of donated organs or tissues, whether locally or abroad, individuals on the waiting list, renal care patients, living donors, and widows/widowers of deceased donors are able to join the Transplant Support Group.

The TSG’s main aim is to promote organ donation by conducting continuous awareness campaigns in favour of becoming organ donors. This has been done despite having no legislation in place. Currently minors are excluded from being able to register for an organ donor card, although with the new law, sixteen year olds will be able to register. Around 2,000 individuals register for a donor card each year, thus since 2000, there have been approximately around 30,000 registered. Another role is to share the experience of particular individuals with potential donors and recipients. Moreover, it brings to the local authorities’ attention any shortcomings and ethical issues.\(^{82}\)

With the limited resources and manpower that the TSG has, a bi-lingual promo and registration brochure act as a means to answer frequently asked questions on organ donation and on registration.

\(^{80}\) Transplant Support Group Malta (n 70).
\(^{81}\) ibid.
\(^{82}\) Organ and Tissue Donation White Paper (n 58) 10.
The TSG’s opinion is that if an individual is not in possession of a donor card but the family still express their desire to donate the organs, then such a wish is to be respected and accepted. The group emphasises that relatives are to be consulted, so that the dignity of the donor is respected. The TSG favours organ donation legislation since this would legalise current practises. The group holds that the relationship between the recipients and the donors is to be retained, despite the Directive being against such practise due to confidentiality.

The TSG’s opinion regarding the opt-out system, where the State assumes that every person is a donor unless denial is signified in writing, is that it is not the ideal system for Malta, because even though one can make the argument that such a system provides a better supply of organs if introduced in Malta, due to the enormous demand for organs, because the Group considers that basing a system on an assumption might backfire. Therefore the TSG is against an opt-out system mainly because of their belief that organ donation is a positive gesture which is to be obtained through a conscious and informed decision. The TSG favours the opt-in system, based on expressed/informed consent, which Malta has used in the past years.

TSG hold that there are two issues which are to be considers: the legality of the donor card and the honouring the deceased donor's wishes by his next-of-kin. Firstly, the Group holds that awarding legal status to the donor card would translate in more registrations. As regards next-of-kin, the two valid reasons for them overriding the original desire to donate organs are the revocation of such desire made known to the next-of-kin and limited instances of conversion to another religion that forbids transplantation of organs.

Live Organ Transplant Advisory Committee

The Committee has the important task of interviewing both the donor and recipient to ascertain that a number of ethical principles are respected. To start off, the Committee is to assess that the donor, through the principle of autonomy, is willing to donate the organ. In addition, the donor must be well informed by his specialists and gives consent to the procedure. This highlights the principle of free and informed consent. Moreover, the donor must not be subject to any coercion or duress and the donation should be free and not subject to any financial or material consideration. In this manner, the principle of non-coercion and the principles of dignity, integrity and non-commercialisation are observed. The risk of the donor's health should be acceptable and the recipient is to benefit from the procedure.

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83 Bonnici (n 14).
84 Additional Protocol on Transplantation of Organs and Tissues of Human Origin art 23.
85 Bioethics Consultative Committee Opinion Report (n 74) 12.
Whenever the donor is seeking to proceed with live organ donation, the donor must sign a form stating that no payment, coercion, duress or inducement has been or is being offered or made. The form is to be signed by the donor in the presence of the clinician. On the other hand, the recipient is also required to sign a similar form attesting that no payment of money or of money's worth has been made or will be made by the recipient or by any other person to the prospective donor or to any other person. This important formal procedure emanates from the Committee's views that transplantation is a selfless gift without expectation of remuneration. Through this formality, the Committee strongly emphasises altruism, in reinforcing the philosophy of voluntary and unpaid donation, and solidarity between the donor and the recipient.

In 2012, an interesting situation arose when Sarah Borg posted an advertisement demanding potential kidney donors to consider giving their organ specifically to Mr. Bartolo against a payment of €5,000, which according to Ms. Borg would cover medical and other expenses. However the Live Organ Transplant Advisory Committee decided the advert promoted by Ms. Borg goes against the principle of "distributive justice" adopted when people, anonymously, offer and donate their organs to patients. In this case, the Committee argued that the donors can donate their organs by contacting the hospital to start the process of donation where the kidney would go to whoever needs it most.

In the respective case, the Committee held that it is against any form of financial inducement and also against advertising, either with or without any financial inducement, for living organ donation to a directed recipient, as opposed to undirected donation to the transplantation system, for use by any patient who is in greatest need for it.

Organ donation procedure in Malta

The procedure for an organ to be transplanted begins with the availability of an organ. Two medical officers certify a person brain-dead, separately and at different times, and carry out separate tests. Before there is the actual donation, intensive tests are conducted on the donor in order to ensure that the organ is healthy. When a patient is certified as brain-dead, the process of organ removal commences, provided that the relatives of the patients acquiesce. When there is such availability, a sample from this organ is tested for compatibility in a Rome clinic and tissue typing and blood grouping are established. The Live Donor Transplant Advisory Committee evaluates

87 Bonnici (n 14).
88 Bioethics Consultative Committee Opinion Report (n 74) 4.
89 Bonnici (n 14).
90 Ibid.
each organ donation case separately and then proceeds to recommend the best action.\textsuperscript{91}

Patients on the waiting list in Malta are contacted in order to undergo a similar test. Since the recipient is chosen according to compatibility it may be the case that patients receive organs before others. The test is almost certain if an organ is a good match. Therefore repercussions from transplantations are rare and when this occurs, normally this is due to some undiagnosed medical condition of the recipient. Life support machines decelerate the organs' deterioration process but the transplantation is to occur within 24 hours of the donor's death in order for the organ to remain healthy.\textsuperscript{92}

The financing for the organ donation is provided for by the local healthcare authorities, and therefore no medical costs are borne.\textsuperscript{93}


\textsuperscript{92} ibid.

\textsuperscript{93} Netherlands Institute for Health Services Research, Study on the set-up of organ donation and transplantation in the EU Member States, uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015) (NIVEL 2013) 88.
A CORRELATIVE ANALYSIS OF ORGAN DONATION AND TRANSPLANTATION IN THE EUROPEAN UNION, UNITED STATES OF AMERICA AND ISRAEL

The chief factors considered by countries in the realm of organ donation worldwide

Countries have enacted laws with a set of factors in mind,\(^94\) to permit a potential donor to give consent or even refuse the donation of their organs with some permitting to leave this decision in the hands of relatives.

The legal basis of the EU in the field of public health and its mechanisms

The EU is well-renowned for its division of competences between the Union and the MS, as illustrated in the Lisbon Treaty, showing that there mainly three competences which the EU encompasses, i.e. exclusive, shared and supporting competence.

Article 4 (2)(k) of Treaty on the Functioning of the European Union, states that in relation to the 'common safety concerns in public health matters' the EU enjoys shared competence.\(^95\) This is because national governments would be more aware of the needs present in such sector and public health matters differ greatly from one MS to another since each MS enjoys different cultural and moral values, together with different legal and administrative frameworks.

This retention of a discretionary national element is imperative in the public health field and the EU is not authorised to 'affect national legislation on the donation or medical use of organs and blood.'\(^96\) However, the EU is not totally excluded, rather it adopts a facilitating and coordinating role in the adoption of effective health policies through 'shared competence' with the MS.

The two mechanisms in relation to organ donation used by the Community are an Action Plan, which focuses on the cooperation between MS to increase organ donation by exchanging ideas and providing fair access to transplantation, and Legal Instruments, primarily composed of the aforementioned Directive.

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\(^94\) The risk of transmission of disease; the limited supply of organs and; organ trafficking, are three factors paramount and undeniably unforgettable in the execution of this procedure. Jurisdictions hence strive to ensure the quality and safety of organs, the availability of organs and fight against organ trafficking.

\(^95\) Shared Competences (Article 4 of the TFEU): the EU and Member States are authorized to adopt binding acts in these fields. However, Member States may exercise their competence only in so far as the EU has not exercised, or has decided not to exercise, its own competence.

\(^96\) Ibid art 168 (7).
It is imperative to identify the systems which are most potent at EU level for the promotion of the best practice and aiding countries comprising less-developed systems in improving their practices.

**Consent systems for post mortem organ donation in Europe**

The Additional Protocol to the CHRB\(^97\) states that, ‘organs and tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained’ and ‘the removal shall not be carried out if the deceased person has objected to it’\(^98\). EU states keep national registries of donors and non-donors\(^99\) hence make it easier for professionals to have direct, readily available, facile access when confronted with a person who might be a potential donor.

In this position paper, we are going to look at different European Countries, particularly, Belgium, France, Spain, the Netherlands and the UK to examine their legislation in force with regards to organ donation and how the systems operate, hence a description of the salient features of the adopted system in each country is provided.

**Belgium**

The Removal and Transplantation of Organs, enacted in 1986 stipulates that organs may be removed post mortem unless the deceased person has made an objection, (filed in the national registry or expressed in some other way during his lifetime), or unless partners or the next-of-kin object. Objections of relatives cannot take place when the donor gave his explicit consent recorded in the national registry. In the absence of a recorded wish, relatives are normally informed that the deceased is considered to be a donor, however there is no imposition by law to do so. Should partners or relatives hold any objections, relatives have to take initiatives to voice out their objections.\(^100\)

**France**

The country’s rules on organ donation have been re-written and any deceased adult will be considered to have given their approval for organs to be used, unless they have made any objections which would have had to be placed in a national registry. Relatives of the deceased will be informed that the adult's organs are going to be used in organ donation.\(^101\)

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\(^97\) Additional Protocol to the Biomedicine Convention concerning the Transplantation of Organs and Tissues of Human Origin.

\(^98\) ibid art 17.

\(^99\) Such registries have not replaced personal documents such as donor cards, yet the EU has noted that they have become the most imperative source of information on donor status.


\(^101\) ibid.
Germany

Germany comprises an explicit consent system, allowing organ donation solely when there has been the expressed consent of the donor as stated in the Transplantation Act of 1997. This explicit consent of the donor is given by filling in an official document known as the 'Organspendeausweis', where one can state his consent or objection, or even entrust the decision to a particular person. A national registry is found in Germany and in the absence of the Organspendeausweis, the relatives, highlighted by the law, are asked about whether they know of any statements which the deceased might have made during his lifetime about the matter. If not the responsible physician inquires for the consent of relatives which must have had contact with the deceased during the last two years before his death; consent which has to be based on the presumed will of the deceased.102

The Netherlands

The specific legislation in this context is the 1998 Organ Donation Act. When a Dutch citizen reaches 18 years of age, he/she will receive a donor form with the following options: consent to organ removal or to removal of specific organs; refusal; leave the decision to relatives or to specific person. The form has to be sent back and the potential donor's decision is placed in a national registry. There is however no exclusion of giving consent through a personal document. In the absence of any decision, relatives designated by the law can give vicarious consent.103

Spain

Spain was one of the pioneers in countries with legislation on the subject particularly with the 1979 Act on removal and transplantation of organs, and later followed by several orders and decrees. In the 1979 Act, there is in place a strict opting out system, that is, that the removal of organs for therapeutical purposes is allowed when the deceased has not raised an objection. In order to establish whether an objection has been made or not, an inspection of the medical file, a search of personal belongings and consultation with relatives is carried out; and organ donation is carried out.104

United Kingdom

The Human Tissue Act of 1961 allows a person to give consent for removal and use of body parts after their death for several purposes, including therapeutically ones. The will of the person is central in the UK to the extent that the person or institution in possession of the deceased's body – which will often be a hospital if the potential donor died there - has to allow the use of body parts in accordance with his/ her will until the body is in fact claimed by the family or coroner. In case of an unknown will

102 ibid.
103 ibid.
the hospital may permit the use of the body parts as long as it is established that the deceased person did not have any objections against that use. In this case, there also has to be the verification as to whether the deceased person's partner or other relatives have objections and they must decide in conformity with the presumed will of the deceased. According to the letter of the law, the UK comprises an opting out system yet in practice due to the fact that relatives are always asked to decide, the system in force is often regarded as an opting in system even though strictly speaking it is not.105

**Conclusion on the European perspective with regard to organ donation in Europe**

In conclusion, the opting-in system is more closely intertwined with the notion that a man has full sovereignty over his body and self-determination, while although the opting out system denies no personal freedom it keeps in mind solidarity with those in need of organs as its focal point. Despite the different ways which member states cater for PMOD, uniform agreement between MS shows that the will of the individual (consent/refusal) has to always be respected and prevail over the will of the next-of-kin.

**Organ donation in the United States of America**

In 1984, U.S. Congress passed the National Organ Transplant Act (P.L. 98-507), to address the nation’s critical organ donation shortage and improve organ matching and placement process.106

The abovementioned act establishes the Organ Procurement and Transplantation Network which helps maintain a national registry in order to carry out organ matching. The act also maintains that the network should be operated by a private, non-profit organisation under federal contract.107

Further studies were carried out in 1986, which led to the U.S. Department of Health and Human Services, which requested proposals for the operation of the OPTN.108

The OPTN Strategic Plan highlights the major initiatives of the OPTN over a 3 year period and it was approved by the OPTN/UNOS Board of Directors in June 2015.109

The OPTN Strategic Plan promotes:

- an increase in the number of transplants

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105 S Gevers, A Janssen, R Friele (n 100) 177.
107 ibid.
108 ibid.
109 ibid.
• to provide equity in access to transplants
• to improve waitlisted patients, living donors and transplant recipient outcomes
• to promote living donor and transplant recipient safety
• to promote the efficient management of the OPTN.\textsuperscript{110}

\textbf{Mandated choice}

The USA have also considered the mandated choice, where citizens are duty bound by law to decide in advance of any illness or death, whether or not they wish to be donors. This choice must be indicated during the performance state-related tasks, such as, the renewal of a licence, benefit claims and filing of tax documentation.\textsuperscript{111} The state would have a record of the intention of each and every individual, accessible at the time of death. This would therefore give an individual autonomy to decide on the eventuality of organ donation, and perhaps making the process more straightforward by releasing family members from their obligation to take such strenuous decision on behalf of their relative at the time of death. However, to be ethically correct, this practice requires eloquent exchange and peruse of information, on the basis of informed consent.\textsuperscript{112}

\textbf{Organ donation in Israel}

Organ Donation and allocation is regulated by the Organ Transplant Act2008\textsuperscript{113}. Prior this act Israel faced lack of availability of organs for transplantation\textsuperscript{114}. This act allows a priority point system, where priority points are allotted to individuals who sign donor cards, make a non-directed/ non-specified organ donation during their lifetime, have a relative deemed to be of first degree signing a donor card or by giving one's consent to the procurement of organs post death. Points are split into a hierarchy, that is points of: Maximum\textsuperscript{115}, Regular\textsuperscript{116} or Second\textsuperscript{117} priority. Preferential status is given to an individual willing to donate an organ, as Israel aims at convincing “free riders”\textsuperscript{118} to change their perspective to that, an individual who is willing to receive an organ must be willing to donate one too. Such a system may be criticised on the fact that it fails to give points to living donors who have made their donation to a loved one and because

\textsuperscript{110} ibid.
\textsuperscript{111} P Chouhan and H Draper, ‘Modified Mandated Choice for Organ Procurement’ (2003) 29 Journal of Medical Ethics 157, 162.
\textsuperscript{112} Ronald M. Davis, ‘Meeting the Demand for Donor Organs in the US. It’s Time for Bold Public Policy, such as Mandated Choice and Presumed Consent’ (1999) 27 British Medical Journal 1382, 1382.
\textsuperscript{113} Came into effect in Israel in January 2010.
\textsuperscript{114} In fact Israel had one of the lowest organ donation rates among developed countries.
\textsuperscript{115} Maximum priority - granted to the candidates who give consent for organ donation from a deceased first-degree relative or those who have donated either a kidney, liver lobe or a lung lobe during their lifetime to a non-specified recipient.
\textsuperscript{116} Granted to those candidates who are in possession of a donor card, thus they have consented to the donation of their organs after their death.
\textsuperscript{117} Granted to candidates who have a first-degree relative in possession of a donor card, even though they do not have one themselves.
\textsuperscript{118} People who are willing to receive an organ but reluctant to provide one.
of the fact that it is mostly deemed as strategic behaviour to increase donations. Nonetheless, although in its 'infant years' the system has been well-received and there have been an increase in numbers of people who have signed donor cards, transplants and providing necessary motivation to individuals willing to accept an organ but not in donating one.\(^{119}\)

\(^{119}\) Organ Donation (State of Israel Ministry of Health)  
<http://www.health.gov.il/English/Topics/organ_transplant/Pages/organs_donors.aspx>  
accessed on 23 February 2015.
AN ANALYSIS OF THE MALTESE PROPOSAL FOR LEGISLATION ON ORGAN AND TISSUE DONATION

Opt-out system versus opt-in system


The soft opt-out system refers to a system where the removal and use of organs from deceased persons is permissible unless they have opted out from such option during their lifetime. Nonetheless, this system would still allow relatives of the deceased to be involved in the decision making process of the donation. Similarly, the hard opt-out system also refers to the presumed consent of organ donation after the death of a person which means that the relatives would not have a say. In such systems, the removal and use of organs would not be permissible if the person has registered an objection through a formal mechanism during the person's lifetime and thus, the assumption is that everyone living in Malta is willing to donate the organs after one's death.

The White Paper makes reference to a number of important definitions which deal with the issue of organ donation. These include the definitions of PMOD, LOD and brain death, where the latter is defined by the White Paper on the basis of the criteria adopted by Harvard Principle. The mentioned definitions have been described above.

The proposals on organ donation seek to establish a legislative framework which ensures equitable approach with respect to race, faith and human rights as well as disability, age, sexual orientation, marriage and civil partnership, or gender and gender reassignment.

The White Paper embarks upon a position where it lists out the elements of an opt-in system, but also proposes positive arguments to an opt-out system where the presumed consent principle is carefully set out. The opt-out system as proposed in the White Paper will apply to people who are 18 years or over, and who are residents of the Maltese islands. Maltese people will be given the opportunity to make an objection to the donation of their organs and tissues in the event of their death.

The proposed system, as listed out in the White Paper, will apply to people who have lived in the Maltese Islands for a ‘sufficient time in order to gain knowledge and understanding of the system’. Nonetheless, the issue remains with regard to the true definition of the term ‘resident of the Maltese Islands’, especially with regard to

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120 Organ and Tissue Donation White Paper (n 58) 6.
121 ibid 7.
122 ibid 25.
the period of time which a person need to have spent to be considered as a resident of Malta.

In view of the operational aspect of the system, the opt-out system would require the maintenance of accurate records, constant updating, and information available to every person on how to make an objection to some or all organs being donated.\textsuperscript{123} In order for an individual to make a valid objection, there must be:

- Access to and availability of information about the opt-out donation system;
- All methods put in place to enable an individual to make a confidential objection to donation in an easy and accessible manner;
- An ability on the part of the individual to understand the information available and how to reach a decision;
- An efficient system by which an objection can be made and is recorded;
- The possibility for an individual to register his/her intentions to donate all organs and tissues or to select specific organs or tissues.\textsuperscript{124}

The White Paper further proposes two sub-options. Firstly, that after death families could be involved in the decision-making process around the donation (soft opt-out option). Secondly, it also proposes that the deceased's recorded decision not to donate organs as taken during his lifetime would be respected without the involvement of any third parties after his/her death (hard opt-out option).

The White Paper has the aim of ‘shifting the burden of the decision of whether or not the organs of the deceased should be donated from the grieving relatives onto the deceased himself/herself’.\textsuperscript{125} In this regard, the Paper suggests that a hard opt-out system would shift such burden from the grieving relatives on to the deceased himself/herself.

The opt-out system being proposed has to be integrated in a flexible manner to accommodate changes so as to ensure that the individual's choices are respected and followed should death occur. Such changes include situations where individuals may change their mind, where people move to or from the Maltese Islands and where young people reach 18 years of age.

**Required request**

The White Paper recommends a mechanism referred as required request which seeks to increase the supply of cadaveric organ donations while ensuring the voluntary nature of such an act. The Required Request consists of a law which mandates hospital staff to bring up the issue of organ donation with the relatives of a deceased patient.

\textsuperscript{123} ibid 26.
\textsuperscript{124} ibid.
\textsuperscript{125} ibid 3.
The Paper defines the term **Required Request** as;

that it shall be illegal, as well as irresponsible and immoral to disconnect a ventilator from an individual who is declared dead following brain stem testing without first making proper enquiries to the possibility of that individual’s tissues and organs being used for the purposes of transplantation.\(^{126}\)

**Living will**

Another mechanism which the White Paper proposes is the **living will** which is a legal document which allows an individual to list out and specify the conditions of the medical treatment which that individual would like to receive in the event the individual becomes too sick or injured to communicate such wishes.\(^{127}\) This mechanism has the main aim of safeguarding the wishes of those individuals who have opted in as donors, especially those who have opted for a donor card.

**Compensation to cover expenses or loss of income by donor**

A controversial issue which crops up from time to time concerns payment, incentives, rewards or compensation for live organ donations. The legal situation in Malta is against any remuneration and advertising for a living organ donation to a directed recipient. The proposed Paper suggests the introduction of financial compensation for expenses or loss of income due to post-op recovery to the live donor but this is to be in line with guidelines issued by the Superintendent of Public Health.

**Underground markets surrounding organ trafficking**

The indefinite delays on the transplantation waiting lists and the scarce supply of organs, has led to development of international underground markets where a number of terminally ill people who can afford to pay are reverting to the possibility of buying organs through such markets. On the other hand, a growing number of vulnerable people are willing to supply their own organs against payments. The Maltese Government is constantly striving to prevent such need for Maltese patients to resort to such illegal measures.\(^{128}\)

In order to combat this offence, the challenge is to implement an organ procurement policy that results in greater supply of organs to its greatest potential. The present situation in Malta is based upon the altruistic donation of organs which over the years have led to the problem of shortage of organs. The Maltese Government is working towards establishing as a criminal offence the illegal removal of human organs from living or deceased donors if the consent is not obtained from the donor or the relatives of the donor prior to the removal of the organs, or if a financial transaction to purchase

\(^{126}\) ibid 29.
\(^{127}\) ibid.
\(^{128}\) ibid 22.
illegal organ donation takes is effected either in favour of the living donor himself or to a third party in the case of cadaveric donation.

The present and proposed position of organ donation associations in Malta

In addition to the TSG which was mentioned earlier in the paper, the Live Organ Transplant Advisory Committee, set up in 2003, is present within the Maltese framework to evaluate individual cases of live organ donation and recommend the best action and approach to be followed. The Committee is composed of specialists in the field and has the important function of interviewing both the donor and the recipient, making sure that the donor's consent is willingly, uncoerced and well-informed.129

With regard to these two main entities dealing with organ donation, the White Paper does not specifically provide any new proposals which would regulate their work. Nonetheless, the White Paper on Organ Donation mentions the policy addressing live donation in relation to the Committee, emphasising that the Committee should continue viewing transplantation as a selfless gift, voluntary and unpaid donation, without expectation of remuneration. The White Paper also mentions the principle of distributive justice which the Committee is to employ in ensuring that organs are distributed to each person according to their need.

Age of registration

In relation to cadaveric donations, the Proposals for Legislation on Organ and Tissue Donation propose legislative changes which allow children as young as 12 years to become organ donors, following education programmes to empower parents and guardians as well as educators to discuss the issue. At the present moment, Maltese law automatically excludes any person under 18 years of age to apply for an organ donor card since children under 18 years of age are considered to be minors under Article 158 of the Civil Code.130

The White Paper makes explicit reference to the English and Scottish legal system where children are allowed to be registered as organ donors, thereby being able to register for organ donation themselves. The White Paper proposes that even if the parents or guardians of the child under 12 years of age consents to the child's registration as an organ donor, an organ donation will not be possible.131 Moreover, the Proposals suggest that the only possibility where a child under 12 years of age can donate the organs is when the child dies and the parents or guardians explicitly consent to organ donation.

129 ibid 19.
130 Civil Code, Chapter 16 of the Laws of Malta, s 158.
131 ibid 31.
Another possible option proposed in the White Paper refers to an opt-in system which allows children over 12 years of age to register as organ donors after extensive education to parents, guardians and educators. With regards to a possible opt-out system, the White Paper proposes that children between 16 and 18 years of age could be included in the population of persons donating their organs but, like adults, they are given the facility to opt-out.

With respect to live donations, the present system allows only individuals who are over 18 years of age to donate organs while they are still alive. The White Paper seems to take the position that this issue should not be amended as due to their young age, children are considered to lack the capacity to understand the nature and consequences of the donation.

Parliamentary debate in the Social Affairs Committee

In the Parliamentary Debate, Rev. Prof. Emanuel Agius (Dean of the Faculty of Theology) argued that Malta, as a State seeking to legislate organ donation, should take into account the Oviedo Protocol (2002) and the European Union Directive 2010/45/EU, where the former deals mainly with the values which are to be embraced by such legislation, especially with the necessity of obtaining an informed consent, the prohibition of financial transactions, equitable access, confidentiality and traceability. On the other hand, the 2010 Directive is important as the only competence which the European Union has on health deals mainly with the safety and security of European Union citizens. The Directive deals with the safety and on the importance of the principle of altruism.

In his arguments, Rev. Prof. Agius argued that before implementing any form of legislation regulating organ donation, educative campaigns on such issues should be promoted. This would prove to be essential when dealing with non-heart-beating organ transplants, especially due to different reactions of medical professionals which may result in non-receptivity of such options by the public when medicals may object to the procedure.

In his opinion, Rev. Prof. Agius argues that the legislation should focus on guaranteeing the best possible care to the patient and also the involvement of relatives in taking such decisions. With regards to the issue of defining the term brain death, Rev. Prof. Agius held that the standard practice applied by Harvard University is the accepted practice in the field as it is accepted by the majority of European States.

In his contribution, Rev. Prof. Agius also deals with the issue of allocation of health resources which is also dealt with by the Oviedo Protocol and the mentioned European Union Directive. In his views, Rev. Prof. Agius provided that this should not be based on a first come first served basis or on the importance of the person but rather, on a

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132 Parliamentary Debate in the Social Affairs Committee, Discussion on the Drafting of Legislation on Organ Donation – Continuation (17 December 2014).
case by case basis. According to Agius, the objective criteria determining the allocation of the organs should be based on the medical condition of the recipient and the complications which might arise following the reception of such organ. Therefore, it would be the durability of that organ which would be given importance. It is only in extreme cases that, according to Rev. Prof. Agius, the age of the person plays a role in the allocation of resources. However, age is an element which should be avoided as it would give rise to other issues.

In his statement, Rev. Prof. Agius provided that he was in favour of an opt-out system. However, he relates the system with the issue of educating the public that even though they did not express their intention of donating their organs after their death, they are presumed to have been given consent. Rather than viewing the opt-out system as infringing the principle of expressed consent of a citizen, it should be seen as a form of exception to the principle as an act of altruism.

A possible way of educating the public may be by inserting an option in the identity cards or vehicle licenses stating whether the particular citizen wishes to donate his or her organs. This is a way of raising the awareness on informed consent of citizens in Malta in favour of organ donation.

In the Parliamentary Debate reference was made to the issue of who owns the cadaver, whether it is the State or not. It is in Austria that a law clarifies that the State is the owner of the cadaver. In England, the practice is that if a person does in a hospital, the cadaver would be owned by the hospital and thus, the hospital would decide about organ donation. In the view of both Rev. Prof. Agius and Dr. Brigitte Gafa’, in Malta, it is only when the deceased has a donor card that the relatives may be convinced to consent to organ donation. However, this does not have legal force in Malta. Dr. Gafa’ argued that if the donor cards were to be given legal force, it would become equivalent to having a clause in a testament clarifying the wishes of the deceased which would override the relatives' wishes.

In her arguments, Dr. Bridget Ellul dealt with various elements of organ donation such as the definition of brain death and brain stem death as well as cardiac death, the living will and the expanded criteria of organ donation to include HIV or hepatitis infected donors (to donate organs to infected recipients alike).

Prof. Maryanne Lauri also contributed to the Parliamentary Debate held on legislating organ donation. Prof. Lauri provided that there was a positive attitude towards organ donation. However, the attitude changed whenever the public was asked about the opt-out system due to the fear that the medical doctors would not do everything in their power to save their lives. Studies show that the majority of the Maltese public are against opting-out system but in favour of donor cards being recognised above the wishes of the family members.

Prof. Lauri argued in favour of retaining the present system of having a donor card, rather than adopting the opt-out system. However, Prof. Lauri argued that the donor
card should either be legally recognised or the wishes of the donor should be listed on a formal document such as the identity card of the driving licence.

In the Parliamentary Debate, Prof. Pierre Mallia, who chairs the Health Ethics Committee, started off his argument by pointing out that ideally, there should be enough donations to cure every person. However, organ donations should be voluntary. In this respect, the legislator must pay due attention to "cannibalistic" legislations where mechanisms are introduced to constantly increase the amount of organs at disposal. However, it is impossible to ever attaining enough organs to be at the disposal of recipients.

In his views, Prof. Mallia argued in favour of educative campaigns which should start at the moment in educating the general public on the available system of organ donation, rather than starting such campaigns when an opt-out system is introduced. Otherwise, this may highlight the "cannibalistic" element of aiming to attain as much organs as possible. Moreover, adopting such a system would result in preying on the ignorance and indifference to take action, that is, the people's lack of awareness.¹³³

The New Cannibalism is a phrase coined by anthropologist Nancy Scheper-Hughes in 1998 for an article written for The New Internationalist. Her argument was that the actual exploitation is an ethical failing, a human exploitation; a perception of the poor as organ sources which may be used to extend the lives of the wealthy.¹³⁴

NEGATIVE ISSUES ARISING FROM THE DONATION OF ORGANS

The transplantation of organs is not an easy task and the lack of organs available makes it even more difficult for those patients waiting to receive a transplant. In a number of countries, the responsiveness and the effort contributed towards organ donation programmes is often hindered by many factors which include but are not limited to legal and socio-cultural issues. It is safe to say that these issues do not only feature in underdeveloped countries but the scarcity of organs also exists in developed countries which do not have the adequate legal and medical structures to answer to this ever-increasing demand for organs. Generally, the use of live donors in the case of liver and kidney transplantations are acceptable in most countries. However, it is notable to point out that there is widespread consensus amongst most countries against the organ trading for transplantation from live donors.

As a result, an international organ trade emerged in order for patients to travel to other countries with the aim of obtaining organs. The trading of organs would usually revolve around the idea of profit-making which is often frowned upon by most countries. Since the trading of organs occurs through the black market, a number of health concerns were raised by key health organizations from all parts of the world. In 2004, a World Health Assembly passed a resolution which encouraged MS to undertake the necessary actions and procedures to safeguard the rights of those who are poor and defenceless from the illegal trade of organs.

In essence, organ trafficking may be assimilated to the trafficking of drugs, weapons and humans. Although many organisations have brought to the fore awareness with respect to organ trading, trafficking is still on the rise, especially due to profit-making which continuously draws criminals towards the black market. Furthermore, it is pertinent to point out that international media outlets have often dramatized newsworthy events relating to organ trafficking. At times they have gone overboard when reporting about kidnappings and the organ markets.\textsuperscript{135} Undeniably, the media has often given more attention to reports concerning kidnapping with the intention of stealing organs rather than concentrating on the bigger issue at hand which is the trafficking of organs, tissues and cells.

Nonetheless, even though reports have often been distorted, the international community is well aware of atrocities occurring through organ trafficking which result in the violation of human rights.\textsuperscript{136}


The organ trafficking black market

Organ trafficking is deemed to be one of the most ghastly crimes in today’s world. Unfortunately, a recent study disclosed that this illicit underground commerce is often supported by legitimate institutions. Around the globe there have been instances where trafficked organs ended up being circulated within health care systems which in turn made these trades look genuine. This means that both national and international authorities cannot keep track of such unlawful activities and it makes it much more difficult to combat organ trafficking.137

A differentiation must be made between human trafficking with the aim of removing organs and trafficking for organs, tissues and cells. With respect to the former category, the removal of organs consists in a forced transportation of a person to an illicit location where consequently organs are removed from that person. On the other hand, trafficking for OTC often occurs through compulsion and intimidation and eventually such organs would be sold on the black market.

Numerous countries have joined forces to devise legislative structures to tackle both human trafficking for the removal of organs and OTC trafficking. Nonetheless, not all countries have the same views with regards to this issue. In truth, although a good number of States have an outright prohibition on organ trafficking, some other States deal with this crime differently. Some countries prefer to target the source of the problem by addressing the lack of organ volunteers. Alternatively, some other countries would rather tackle this problem by focusing on the eradication of criminal organisations which are often called Organ Vendors.138

Organ Vendors operating within the underground black market may be categorised into three classes. The first class comprises individuals who are alive and who have no problem with selling their organs. Such organs would include, a part of their liver or lung, or a kidney. The second class includes those individuals who give their consent for their organs to be removed after they would have passed away, as long as they are certified as being suitable donors. The last class of vendors consists of deceased donors who have selected surrogates who will be given compensation for the acquired organs. Surrogates are often close family members or maybe even a charitable organisation. In a nutshell, the deceased’s organs would be bestowed upon the surrogate, with the ultimate aim of selling them.139

Treating human trafficking for organ removal as a threat to human rights

Human rights activists often hold that human trafficking for organ removal should not be approached as simply a problem of supply and demand of organs or just a criminal act. However, in order to combat this type of human trafficking it is important to invoke a strategy which has the protection of human rights as its' core value. The victim ought to be given a vital role when implementing projects to fight off this type of criminal activity.

If a State opts to tackle human trafficking for organ removal from a human rights approach, then the appropriate norms and principles should be applied, and as a result the necessary attention would be given to the victims. The 2010 UN Commentary on Recommended Principles and Guidelines on Human Rights and Human Trafficking holds that if one is to view this issue from a human rights angle, then various factors ought to be taken into consideration, such as public policy, addressing the relevant laws and how they may affect individuals who have been subject to trafficking or individuals who are susceptible to being trafficked. Moreover, in International law it is generally accepted that States are duty-bound to offer suitable legal remedies for victims. As such, remedies must be effective enough to tackle the violations which the victims would have endured.

From the perspective of human trafficking for organ removal, the necessary legal tools should be provided, for instance, the provision of free legal aid and the right to judicial review. On the other hand, from a medical viewpoint the required aftercare should be provided as well as support from the designated local authorities. Hence, it is advisable for human rights' organisations to team up to provide the necessary care and support and to assess the current state of human rights in their respective States.

Organ trading – the aspects of purchasing and selling

It is often held that the sale and purchase of human organs for the purpose of transplantation goes against the honour and dignity of a person, and thus there should be an outright ban on such commercial transactions. Academics, including Scheper-Hughes, have supported this ban, while some academics emanating from States having adopted more liberal views and have recommended that this type of trade should be lifted be regulated by the State with the primary aim of reducing manipulation, medical risks and hazards emerging from illegal operations.

Other aspects should also be taken into consideration. For instance, most States encourage and support individuals who choose to volunteer and donate their organs.

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and tissues, and as such would oppose any sort of financial compensation since this particular method would hinder the voluntary aspect instilled into many societies. Additionally, access to essential medical care which depends on one’s financial status is not consistent with the principles of justice. Indeed, the advertising of organs is also prohibited in a number of States.

Nonetheless, although many human rights activists support the prohibition against the purchase and selling of human organs, the underground organ market continues to thrive in countries such as India, China, and the Philippines. India is one of the most perilous countries with respect to organ trading. Several weak and vulnerable individuals undergo dangerous surgical procedures to have their organs extracted and are insufficiently and unreasonably compensated. Even though around fifteen years ago organ trading was held to be illegal, the sale of organs is still on the increase, especially the kidneys which are mostly needed for diabetic patients.

Coincidentally, in order for a vendor to effectively operate within the organ black market or even for an individual to merely purchase an organ, they often resort to the media. Today, social media and the internet are the main portals through which announcements are made by those interested in purchasing an organ. In this respect, the WHO Guiding Principles prohibit advertising in connection with obtaining an organ in return for financial compensation. Comparatively, the EU Directive also gives its stance regarding advertising and clearly states that a prohibition on advertising subsists in relation to announcements made in order to obtain an organ subject to payment. The need to advertise stems from the high demand of organs and such advertising is prohibited when a financial gain is contemplated.

In essence, the Directive seems to allow the advertising of organs even though the purchaser and the seller might have struck a deal with respect to reimbursement for costs stemming from the donation per se. This sort of deal would be acceptable so long as it does not procure any sort of financial gain. From a rational point of view, such arrangements would definitely encourage individuals to donate, and through advertising one would be able to reach individuals other than just family members. Nonetheless, advertising hinders organ allocation rights. For instance, a few years ago in Malta an advertisement was published in order to announce the need for a kidney and as a result a number of individuals disclosed their interest to donate their kidney to this particular person, irrespective of whether there were other individuals on the waiting lists.

**Transplant tourism**

Organ trade may manifest in various ways, but the most popular way is through transplant tourism. Both organ trafficking and transplant tourism are frowned upon due

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144 Falzon (n 31).
to their negative criminal and health connotations and consequences. With respect to transplant tourism, the prospective recipients would normally travel to another country in order to receive a transplant. Although the term “transplant tourism” might sound unsympathetic and dodgy, it has been adopted, utilised and defined by various health organisations and networks, such as the United Network for Organ Sharing (UNOS). 145

In fact, “Transplant tourism” includes a combination of various commercial aspects and factors, not just the buying and selling of organs. Essentially, in order to expedite the procedures travelling logistics are often organised by specialised people within the organ trading chain and they are frequently supported by a marketing strategy, which often involves the setting up of internet websites which specifically attract transplant tourists.

Additionally, since the traders’ main aim is to make profit, more often than not the donor is rarely given suitable compensation. As an example, individuals who donate their kidneys normally receive less than one-third of the price that beneficiaries pay for the organ. Moreover, usually the donor after the removal of the organ would not be offered any treatment, care, or follow-up check-ups. If the donor neglects his health after the extraction, he might have to face the consequences which might affect his life and his working abilities. 146

The debate in relation to the correctness or otherwise of organ trading continues to persist globally, however it seems that there are many organisations, States, academics and individuals who are against organ trading. Outright evidence of this trend has manifested through the 2008 Istanbul Declaration. Undoubtedly, this illicit practice has been banned in a number of countries and there have been a number of legislative initiatives aimed at passing laws to eradicate this practice. As a result, prospective recipients are compelled to choose other methods of obtaining organs, often through legal and legitimate methods. 147

After a thorough analysis of the negative effects of organ trafficking and organ trading, it is also essential to delve into the undesirable aspects of “organ allocation”. It is no surprise that waiting lists are long, disheartening, and difficult to maintain. Before a patient is placed on a waiting list, he must undergo various check-ups and then the patient would be either designated as an active recipient or else as an inactive recipient. In essence, an individual with a prognosis of renal failure is often assigned to the waiting list as soon as renal dialysis starts to take place. As such, a patient who is selected as an active recipient would be able to receive an organ transplant as soon as an organ becomes available. On the other hand, an individual who is diagnosed

with a particular illness, disorder or infection which could negatively impact his post-operative wellness, a provisional inactive status is bestowed on that individual until he regains his former health.¹⁴⁸

**Transplant rejection**

Unfortunately, organ transplant operations do not always meet their desired ends. In fact, rejection is considered to be one of the main obstacles to successful transplantation. The recipient’s body might reject the transplant due to a negative response from his immune system. The immune system safeguards a person’s well-being from foreign substances which are deemed to be detrimental to one’s health. When an individual receives an organ, the immune system might identify that organ as being foreign. A rejection often occurs when the immune system senses antigens which are different from its own.

Normally medical practitioners try to match these antigens. Often tests are carried out on both the organ donor and the recipient. In this regard, such practice would often prevent the possibility of a transplant failure. Additionally, recipients are continuously encouraged to take their prescribed immunosuppressive medicines. These precautionary actions significantly reduce the risk of transplant failure and death.¹⁴⁹

¹⁴⁸ Organ and Tissue Donation White Paper (n 58).
RELIGIOUS VIEWS ON ORGAN DONATION

General overview
Uncertainty still revolves around the issue of compatibility of organ donation with the various religious beliefs present in society nowadays. Despite the diverse rationales behind each position adopted by different religions, the majority of them, do in fact support and often promote organ donation.

According to a 2009 study conducted by the European Commission, of those Europeans unwilling to donate their own or a loved one’s organs, only 7% are reluctant to do so for religious reasons. From the same study, it was also concluded that the country whose nationals are most likely to be hesitant to donate organs due to their religious beliefs, is Turkey.

The Roman Catholic Church

In light of the proposed organ donation legislation, in May 2015 the Church in Malta issued its position paper regarding the subject. At the outset, the religious entity recognised that at present, the organ donation process is already yielding positive results, that is, people donate their organs despite the fact that they are not legally bound to do so, and consequently expressed its thought that in its opinion it would not be wise to alter such a system.

On 29 August 2000, Pope John Paul II greeted the 18th International Congress of the Transplant Society outlining that the ‘Church has no other aim but the integral good of the human person.’

The Roman Catholic Church favours organ donation and encourages its people to donate their organs to those in need, especially the sick. Throughout the last decade, there have been various occasions where the Church has expressed its views regarding this matter.

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151 ibid.
153 ibid.
Pope John Paul II stated that ‘with the advent of organ transplantation, which began with blood transfusion, man has found a way to give of himself, of his blood and of his body, so that others may continue to live’.\(^{156}\)

In the Encyclical Letter Evangelium Vitae on The Value and Inviolability of Human Life it was held that ‘Christians should embrace this ‘challenge to their generosity and fraternal love’ so long as ethical principles are followed’.\(^{157}\)

So, as held in the Congregation for the Doctrine of Faith, Donum Vitae, this medical procedure should not be an unconditional one. One should not only consider what is technically possible or otherwise, but more importantly, one should ensure that human nature and integrity is respected in its fullness.\(^{158}\)

For this reason, the Catholic Church condemns trading of human organs as these cannot be considered as being ‘objects’ of sale.\(^{159}\) The decision to donate something of ourselves for the well-being of another, without remuneration, is one of great ethical value.\(^{160}\) This is the only legitimate context for organ donation, what makes it intrinsically noble.

A further point relates to the requirement of informed consent. Both the donor and the recipient should be adequately knowledgeable as to what the process entails, so that consequently, they would be capable of consenting or declining in a free and diligent manner.\(^{161}\) Consent of relatives comes into play when the donor would have failed to take a position on the matter.\(^{162}\)

The Catechism of the Catholic Church stipulates that ‘the transplant of organs is morally acceptable with the consent of the donor and without excessive risks to him or her’.\(^{163}\) Hence one could argue that the donor’s life is a priority.\(^{164}\) Certainty that the


\(^{159}\) 18th International Congress of the Transplantation Society (n 155).


\(^{161}\) 18th International Congress of the Transplantation Society (n 155).

\(^{162}\) ibid.


\(^{164}\) ibid.
A challenging question which follows is, at what point would a person be deemed dead with absolute certainty?

There is no scientific technique which directly determines the exact point of death of an individual. However, such happening is generally followed by certain biological signs, which do in fact confirm that the person has actually died. The Church merely compares scientific findings with the unity of the person as understood by Christian belief.

Another issue relates to the assignment of organs and the establishment of a priority waiting-list. This is necessary since resources are still quite limited, despite many efforts to promote this practice. Precedence is to be determined considering immunological and clinical factors, and decisions made should not be discriminatory or utilitarian in nature.

Given the shortage of organs to meet the medical need, the idea of xenotransplantation started kicking in. This involves organ transplantation obtained from animal species. Regarding this subject-matter, Pope Pius XII in his address to the Italian Association of Cornea Donors and to Clinical Oculists and Legal Medical Practitioners (1956), held that in order for this procedure to be legitimate, the psychological or genetic identity of the recipient must not be compromised and furthermore, that he or she is not subject to unreasonable risk.

What the Church is concerned about, and is full-out against, is human cloning with the intent to obtain organs. Such procedures are not morally acceptable if these will involve any kind of manipulation and/or destruction of human embryos, even though the goal per se is good. The Church pushes forward the idea of adult stem-cell usage as this would ensure respect to human life and integrity, even at its very initial stages.

In a world which is becoming increasingly multi-cultural, it is crucial that medical practitioners and society in general, be much more aware and knowledgeable about the various beliefs emerging from the various religions or ideologies concerning organ donation. This is indispensable because these greatly impact decision-making, the echo of the individual’s will which must be valued during the whole process.

A person who has the mental capacity to decide, has the right to choose whether to reject or accept a possible treatment. Ethicists opine that certain refusals are justified

165 18th International Congress of the Transplantation Society (n 155).
166 ibid.
167 ibid.
168 Celia Deane-Drummond, Brave New World? Theology, Ethics and the Human Genome (T & T Clark 2003).
169 18th International Congress of the Transplantation Society (n 155).
while others are not. In the 1950's, Pope Pius XII introduced the ordinary/extraordinary classification system of treatment\(^{170}\) which has shed some light regarding this matter.

**Ordinary and extraordinary treatment**

‘Ordinary’ treatment is a simple, inexpensive, routine mechanism which is available to those who require such, posing minimal risk of harm and is likely to be beneficial to the patient without causing much pain or distress.\(^{171}\) From a moral standpoint, refusal of ordinary treatment is incorrect since one has a general obligation to sustain his life.\(^{172}\) On the other hand, ‘extraordinary’ treatment, which is defined as ‘those means or measures which are not usually available, do not offer a reasonable hope of benefit and cause unbearable pain and suffering’,\(^{173}\) places no moral duty on the patient to accept such a treatment.

The Quinlan case showcased these principles in practice. Post-accident, a twenty-one year old girl was put on life-support machines. Her Roman Catholic parents wanted to switch off the machines and let their child die naturally. However, the doctors disagreed since the girl still did not satisfy the brain dead criteria. The court ruled in favour of the parents because the conditions established by a social institution can take precedence over scientific thought.\(^{174}\)

So, prima facie, the classification seems sufficient. However, there is an element of subjectivity since what is ‘extraordinary’ or ‘ordinary’ for one person or his relatives, might not be considered so by others.\(^{175}\)

**Conclusion**

The Church laid down a number of recommendations which encourage the opt-in system including; granting legal status to the donor card, adequately educating the public (especially the healthcare staff and donors’ relatives) regarding issues relating to organ donation, stirring ethical debate between medical experts and the public and establishing a just legal regime.\(^{176}\)

As a means to increase the aforementioned system’s effectiveness the Church outlined the following: laying down and constantly updating an official donor register to be available to the Intensive Therapy Unit staff, simplifying the system and create incentives rendering it more accessible to the public at large, consolidating the

\(^{172}\) ibid.
\(^{174}\) Mallia (n 170) 160.
\(^{175}\) ibid.
\(^{176}\) The Church in Malta (n 154) 12.
transplant donor coordinator and ascertain that any existing policy (such as the Kidney Allocation Policy) is transparent, clear and available to stakeholders.\textsuperscript{177}

Furthermore, continuous evaluation is key in order to ensure that the organ donation process reaches its maximum potential. Scientific evolution requires optimum screening of allocation criteria to avoid waste of such valuable and often scarce resources.\textsuperscript{178}

In the aforementioned position paper, the Church held that it favours the opt-in system because it ‘safeguards the dimension of gift’ since the individual expressly gives consent to donate his organs post-mortem.\textsuperscript{179} The Church stated that in order to promote a sense of generosity and altruism, the legislative framework should be flexible enough to render possible the free-decision of the individual. An interesting consideration put forward by the Church is that minors aged 12 are not in a position to freely give permission to become organ donors. At this juncture, the Church seems to favour the idea that since certain voting privileges are being granted to 16 year old citizens, it would be reasonable to follow such logic in the realm of organ donation as well.\textsuperscript{180}

\textsuperscript{177} ibid 13.  
\textsuperscript{178} ibid  
\textsuperscript{179} The Church in Malta (n 154) 4.  
\textsuperscript{180} ibid (n 154) 11.
ALTERNATIVES TO ORGAN DONATION - THE FUTURE

Progress within transplantation research has led to new techniques being developed which can alleviate and decrease the problem of the difference between the available organs and the actual demand for organs. Three evolving areas in this field are stem cell therapy, therapeutic cloning and xenotransplantation.

Stem cell therapy

The new developments in the area of induced pluripotent stem cells have led to the possibility of producing patient-specific stem cells. Although the human does not have the ability to grow its own organs, the latter may be developed via stem cells. Such cells may be developed from mature cells which may regenerate the particular tissue or organ necessitated by the recipient. It has been established by different studies that adult tissue-specific stem cells are characterised by ‘plasticity and differentiate or trans-differentiate to cells of various lineages’ which makes them more viable to be used for organ transplantation.¹⁸¹

The most widely-used therapy to obtain stem cells is bone marrow therapy, which involves the extraction and harvesting of bone marrow stem cells. Scientists have also discovered how to transform differentiated cells into their parent stem cells, which has widened the horizon in respect to medical therapy. While it is still in its initial phases, studies have confirmed the successful treatment of various conditions which are otherwise difficult to treat, including organ donation.¹⁸²

Despite this scientific breakthrough, some ethical issues arise from some of the techniques used, as they involve the destruction of the embryo in order to obtain these stem cells. These lead to questioning about the moral status of the embryo and discussions related to life and conception.

Therapeutic cloning

Organ cloning is another method of obtaining organs and tissues. There are three types of cloning including therapeutic cloning, which is the most promising in the field. Resorting to organ cloning instead of other methods of procuring organs, mainly organ donation, would eliminate the need for anti-suppressive drugs against organ rejection. However, there are still several issues which have to be addressed before organ


cloning is utilised, including the inefficiency of harvesting stem cells and consequently, creating organs from them.\textsuperscript{183}

**Xenotransplantation**

Xenotransplantation is the process whereby living animal cells, tissues or organs are extracted from one species and transplanted into another. The first attempt at such transplantation was in the early 1900's but it was unsuccessful. Animal subjects such as pigs, goats, lambs and monkeys have been used for research, but because of ethical issues and concerns about diseases, monkeys are no longer used. For several reasons, pigs are the preferred subjects nowadays. Early transplants failed and in 1944 it was discovered that the reason was transplant rejection, whereby the human body recognises the transplant and consequently attacks it, leading it to be rejected by the body and failing.\textsuperscript{184}

Immunosuppressive drugs were identified and used to prevent rejection in human-to-human organ donation. Research into whether immunosuppressive drugs can prevent rejection in xenotransplantation was carried out, but success rates were still low. Cell-based xenotransplantation is the potential treatment for disease, with research in pig cell transplants showing promising results in treating diseases such as diabetes and strokes. Nowadays research tends to focus into whether genetically modifying animals may prevent organ rejection or not.\textsuperscript{185}

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\textsuperscript{183} Organ Cloning (Organ Cloning) <www.cloneorgans.com> accessed 21 November 2015.
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ELSA MALTA’S POSITION ON ORGAN DONATION

Following extensive research on the various existing forms of organ donation systems around the world, and taking into account the present system in Malta, ELSA Malta believes that the best system to be adopted in Malta is one which introduces mechanisms to enforce the donor's wishes and to promote the altruistic element of organ donation through awareness campaigns. The latter is to include awareness to the public regarding the various aspects of organ donation as well as conducting campaigns to promote donors to inform their relatives as to their decision to donate their organs.

In this regard, ELSA Malta believes that a soft opt-out system with added mechanisms would be ideal since it allows the removal and use of organs unless the deceased opted out during his or her lifetime. Nonetheless, this system would still allow the deceased's next-of-kin to consent in situations where the deceased has not opted in or out. The proposed system should be equipped with a registry system listing the wishes of donors, give legal status to donor cards and introduce the option of donating one's organs in identification documents such as identity cards.

A hard opt-out system whereby everyone would automatically be placed on the donor register, unless they choose to opt out, may be culturally unacceptable by the Maltese. Therefore, the proposed system should be based on altruistic laws and the informed consent of the individuals. The availability of donors' organs is often a question of life and death for patients requiring a transplant. With the introduction of transplantation of organs within the medical field, one of the main limiting factors of this technique is the shortage of organs.

If Malta were to adopt a soft opt-in or a hard opt-in system, the situation would remain practically the same and transplantation of organs would still be limited due to the fact that donors must themselves register to be recognised as such. The only change which Malta would experience if the Maltese Parliament adopts a hard opt-in system would be that of giving more importance to the donor's wishes. Issues relating to organ donation are sensitive and delicate.

ELSA Malta believes that even though the subject of organ donation is a sensitive one, it merits discussion on a national basis so as to inform and educate each and every individual, being potential donors, about the benefits of organ donation and the possibility of opting out if an opt-out system is pursued.

Finally, ELSA Malta believes that any upcoming law is to be fair, and which can be seen to be fair by the public, while leading to a system where the distribution of organs is more transparent, thereby clarifying the modus operandi of the system.
'Ten years ago I contracted meningitis due to which I lost both my legs, parts of my fingers and the function of my kidneys. In October 2008 I started undergoing dialysis – a 4-hour procedure which has to be done at least three times a week at hospital, where you are basically hooked onto a machine which cleanses all your blood and does the work of the kidneys.

Luckily, I had four donors who were willing to donate their kidney to me. The prospective donors were my father, my husband, my uncle and my mother-in-law. They all underwent blood tests to check their compatibility with the result being that my father’s kidney was a near perfect match. In February 2009 my father and I underwent a kidney transplant. I have now been living with my father’s kidney for the past 7 years. Thanks to my father’s donation I can now lead a normal life. I will be forever grateful to my father for the gift of life.'

Amy Camilleri Zahra - organ receiver
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