ORGAN DONATION

The issues discussed in this report have been selected because of their relevance to taking a decision regarding the use of 'living wills', or as better known in the US, 'Advance Directives', in relation to the donation of organs for transplantation.

Advance directives: More than just living wills

In an online article with the above title, the Mayo Clinic Staff explain the differences between these terms. So I am first reproducing the relevant points of this article.

'Advance directives are written instructions regarding your medical care preferences. Your family and doctors will consult your advance directives if you're unable to make your own health care decisions. Having written instructions can help reduce confusion or disagreement. Anyone age 18 or older may prepare advance directives.

Advance directives include:

Living will. This written, legal document spells out the types of medical treatments and life-sustaining measures you do and don't want, such as mechanical breathing (respiration and ventilation), tube feeding or resuscitation. In some states, living wills may be called health care declarations or health care directives.

Medical power of attorney (POA). The medical POA is a legal document that designates an individual — referred to as your health care agent or proxy — to make medical decisions for you in the event that you're unable to do so. A medical POA is sometimes called a durable power of attorney for health care. However, it is different from a power of attorney authorizing someone to make financial transactions for you.

Do not resuscitate (DNR) order. This is a request to not have cardiopulmonary resuscitation (CPR) if your heart stops or if you stop breathing. Advance directives do not have to include a DNR order, and you don't have to have an advance directive to have a DNR order. Your doctor can put a DNR order in your medical chart' ¹.

We were unable to obtain critical literature regarding the use of a living will in relation to organ donation and transplantation. Of significance is the fact that in the Report commissioned by the US Department of Health and Human Services, from the Rand Corporation, there is no mention of the use of Advance Directives for the procurement of organs.²

INTRODUCTION: STATISTICS

Normally organs are harvested from:

- (1) either living donors, in the case of regenerative tissue, e.g. bone marrow or in the case of one of a pair of organs, e.g. a kidney; or
- (2) cadaver donors.

Waiting list

Évery day in Europe, ten people die waiting for an organ transplant.³ In September 2009, the DOI reported 'According to the Commission, 12 persons a day are dying in Europe as they wait for organ transplants'.⁴

In Malta, there are no exact statistics documenting the number of patients awaiting a transplant. Two bodies have an interest in collecting this data, the Renal Transplant Unit and the Transplant Support Group (Malta).⁵

However the DOI in September 2009, reported that 'At the moment, there are 95 people waiting for an organ transplant'.⁶

Number of transplanted organs (cadaver / live)

The number of transplanted organs is published by the Department of Health on its website.⁷

	Organs Harvested in Malta 1999-2008											
Transplanted in	Kidney	Kidney Cornea Heart Liver Lung Pancreas Total										
Malta - all	104	139	6	0	0	0	249					
Males	66	77	6									
Females	38	62	0									
Abroad - all	10	0	10	37	2	2	61					

	Total num	Total number of donors by type and gender* 1999-2008							
	Live	Cadaver	Total						
Male	10	67	77						
Female	12	24	36						
Total	22	91	113						
*3 others in 1	1993 with incom	plete data							

	Donors by Age										
	<15	15-24	25-34	35-44	45-54	55-64	65-74	>75	Total		
Male	2	12	10	11	15	19	7	1	77		
Female	4	1	3	6	10	11	1	0	36		
Total	6	13	13	17	25	30	8	1	113		

	All Recipients by Age										
	<15	15-24	25-34	35-44	45-54	55-64	65-74	>75	Total		
Male	6	17	17	30	23	35	11	10	149		
Female	3	8	16	17	14	17	15	10	100		
Total	9	25	33	47	37	52	26	20	249		

	Kidney Recipients by Age										
	<15	15-24	25-34	35-44	45-54	55-64	65-74	>75	Total		
Male	0	3	8	12	18	20	5		66		
Female	0	3	8	5	12	8	2		38		
Total	0	6	16	17	30	28	7		104		

	Cornea Recipients by Age									
	<15	15-24	25-34	35-44	45-54	55-64	65-74	>75	Total	
Male	0	11	10	11	6	13	9	17	77	
Female	0	5	5	7	6	14	6	19	62	
Total	0	16	15	18	12	27	15	36	139	

The discrepancy between the number of donors (113) and organs (310) harvested is explained by multiple donations from cadaver donors.

However this data may be incomplete for corneas. There is no information available from the ophthalmic surgeons. The number of live donors has remained small.

Rate of refusal (relatives)

There is no published information identifying the rate of refusal of a request for organ donation.

ORGAN TRANSPLANTS

Definition of Organs for donation

Many organs are now harvested for donation, including kidney, cornea, heart, liver, lung, pancreas, intestine, bone, skin, heart valves, tendons, ligaments, and saphenous veins. However in Malta, only kidney, cornea and heart transplants are carried out. These and other organs may be sent abroad through the arrangement in place with Italy.

Who can be a donor?

Currently in Malta, the majority of donations are cadaver donations. Anyone can be a donor, provided they are healthy. However even those 'who have or have had some forms of cancer can be eye donors. They could be an organ and tissue donor if they have been cancer-free for at least five years'⁸.

Naturally prior to the actual donation, stringent tests are carried out on the donor to ensure a healthy organ is being donated.

Age is not a barrier to donation, as noted in the supplied tables. However organ size varies with age and it may be necessary to match young donors to young recipients.

'Organ removal from a living donor may be carried out for the benefit of a recipient with whom the donor has a close personal relationship as defined by law, or, in the absence of such relationship, only under the conditions defined by law and with the approval of an appropriate independent body'9

We have recently started to see an increase in live renal donation in many countries but in Malta this is still slow on catching up to the 1 in 3 levels as in the UK.

Viability (life support)

Organs are suitable if they are viable, so apart from corneal donation, which can occur up to 24 hours after death, and even from deaths at home, most cadaver donors are obtained from deaths in ICUs where the patient is declared brain dead and the organs are kept perfused till harvesting.

CONSENT: OPTING IN / OPTING OUT

The Additional Protocol on Transplantation of Organs and Tissues of Human Origin (Oviedo), Article 2 states that 'for the purposes of this Protocol:

- '- the term transplantation covers the complete process of removal of an organ or tissue from one person and implantation of that organ or tissue into another person, including all procedures for preparation, preservation and storage;
- subject to the provisions of Article 20, the term 'removal' refers to removal for the purpose of implantation' 10.

The opt-in system

There are two main practices of legislation on organ retrieval. The **opt-in system** is practiced in countries like England, Malta, Canada. Organs can be retrieved from the dead body only if permission from the family of the deceased is given. Even the presence of a donor card signed by the deceased does not give the doctors a right to remove organs from the body. In Scotland, they recommend that the deceased's wishes take precedence over the wishes of the relatives.

With an opt-in system, donors are often asked to register with the appropriate authority and obtain an organ donor card following adequate information, enabling informed consent.

In the USA there is a system similar to the opting-in system with the provision that it is mandatory for medics to ask the family of the injured person whether they are willing to donate the organs before a life-support machine is switched off (Hamilton, 2003). This is known as the 'required request' policy. It states that it is illegal as well as irresponsible to

disconnect a ventilator from an individual who is declared dead following brain stem testing without first making proper enquiry as to the possibility of that individual's tissues and organs being used for the purposes of transplantation (Revised Uniform Anatomical Gift Act, UAGA, 1987). As a result of this policy, less opportunities of organ donation are missed.

Subsequent revision of the UAGA led to a new 'first person consent' law (donor rights law), effective as from January 2006, in over 40 states. This makes donation legal, obviating the need to ask for the relatives' decision, once the donor has enrolled into a registry. The potential donor enrolls in the registry of the Secretary of State Organ / Tissue Donor Program. This is accessed by Procurement co-ordinators who contact the potential applicant, (over 18 years old), provide information and obtain a medical history. The family members are asked if they want feedback as to what happens after donation. So after death, the family of the donor are contacted for the medical history at that time and also again to be asked if they want feedback regarding the donation.

'Federal regulations require hospitals to notify their regional organ procurement organization to evaluate patient deaths or imminent deaths for potential donation'¹¹. The organization assesses whether the deceased is medically eligible to be a donor. The coordinators would discuss issues with the family. If the patient is a registered donor, support is provided to the family. If the patient is not registered, then the co-ordinators have to, according to state and federal regulations, offer the families of the patient, the possibility to donate, receiving full information about their options. The co-ordinator together with the hospital staff, will discuss these options with the family and ask consent for donation.

'This revision also preserves the right of other persons to make an anatomical gift of a decedent's organs if the decedent had not made a gift during life. And, it strengthens the right of an individual not to donate the individual's organs by signing a refusal that also bars others from making a gift of the individual's organs after the individual's death'¹². However what if the unconscious patient with a donor card also has a living will that states he does not want to remain on a ventilator? The Act is in favour of donation rather than safeguarding the living will ¹³. However not every doctor was happy with this and so states were asked to ensure that family members were 'consulted in such situations to try to determine what the donor would have wanted'¹⁴. But Caplan said "I think a person's instructions for end-of-life care should always take precedence over 'make me an organ donor'.

The Uniform Anatomical Gift Act, 2006, also establishes standards for donor registries, allows computerized registries of people for donors and accepts electronic signatures, but it makes no similar provision for those who do not want to be donors. It enables procurement organizations to gain access to donor registries, medical records, and records of the state motor vehicle department. There is introduction of regulations relating to cooperation and coordination between procurement organizations and coroners or medical examiners.

The opt-out system

On the other hand, with the **opt-out system**, which is practiced in countries like Spain, Austria and Belgium, the law allows, indeed requires in some countries, doctors to take organs from the dead body if they can be used for transplantation purposes without the permission of the family. In other words, there is 'presumed consent'. The only restriction is that, in cases where the deceased had indicated when alive, his or her wish not to donate organs, doctors must respect these wishes.

However, in some countries, like Italy, Sweden and Spain, the relatives are still allowed to object to organ donation. The Belgian Law on the **Procurement and Transplantation of Organs 1986**, states that 'donation cannot proceed if there is objection from a first degree relative or a spouse living with the donor, unless that objection is contrary to the deceased patient's stated wishes'. But in reality, although the relatives 'are not asked to consent to donation', they are told of the projected harvesting of organs and they 'may register an objection'.¹⁵.

'One's opinion on whether the legislator has a right to introduce 'presumed consent' depends on various factors, two major ones being: (i) how one looks upon organ donation and (ii) how one looks upon one's own body'.¹⁶

In a study looking at Informed Consent forms for renal transplant in the UK, the form could not be found in 10% of the medical notes. The authors make a case for giving patients an information sheet when they are first considered for transplantation. Once the patients agree to go ahead with the procedure, and they are put on a waiting list, the medical file should have a checklist with all complications that need to be discussed with the patient. Then the particular medical doctor could sign against the item discussed, so that when the time for transplant arrives, the transplant surgeon knows what is yet to be discussed with the patient before obtaining the final operation consent form. They also argue in favour of the transplant surgeon rather than the renal physician obtaining the operation consent.¹⁷

The BMA has argued for the introduction of 'a system of **presumed consent**, with **safeguards**, for adults, which allows doctors the discretion not to proceed if the potential donor's wishes are not known and it is clear that the donation would cause major distress to a first degree relative or long-term partner' 18.

The value of a presumed consent system, is apparently a higher rate of donations. However Antwerp, Belgium, which retained an opt-in system and enhanced their education policy maintained the same transplant rate when compared to Leuven, Belgium, where the rates rose from 15 to 40 donors per year over a 3-year period' 1920. In practice there have been too many other issues involved, to be able to definitely establish a causal link, but despite this, the BMA still believes that, 'as one part of a broader strategy, a shift to presumed consent is likely to have a positive effect on donation rates' 21.

In Spain the law requires the family to confirm, in writing, that the donor had not objected. However, the system operates more along the lines of informed, than presumed, consent and the permission of relatives is routinely sought for donation. In fact the recent success of increased donations in Spain has been attributed to the new mechanism for transplant co-ordination rather than the introduction of a version of presumed consent²².

ABUSE of SYSTEM

Organ donation has always been considered as a gift. The principle of voluntary unpaid donation of tissues and cells was recognised for the first time in Spain in 1979 and in Luxembourg, Belgium and Finland in the early 1980s. ²³ the same report states that 'donors cannot be remunerated but may receive compensation strictly limited to making good the expenses and inconvenience related to the donation' but Malta does not allow compensation. 'Most Member States also take measures to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis'. Malta has no specific regulation restricting or prohibiting the advertising of the need for, or availability of human tissues and cells, with a view to offering or seeking financial gain or comparable advantages.

In Malta, Article 248C of the *Criminal Code* makes it illegal to indulge in traffic involving persons for exploitation in the removal of organs, for instance, for transplantation. Furthermore article 248A(2) makes it illegal to obtain organs by means of:

- (a) 'violence or threats, including abduction;
- (b) deceit or fraud;
- (c) misuse of authority, influence or pressure;
- (d) the giving or receiving of payments or benefits to achieve the consent of the person having control over another person.'

However the immediacy for those on a waiting list has led to recipients seeking to obtain organs through payment. Malta Today reported in 2009 that one could obtain a liver transplant from an official Hospital Trust for $\[\in \]$ 75,000. 'The money is shared between the transplant surgeon, who may get around $\[\in \]$ 20,000, and the hospital trust. The money does not pay for the organ itself, but for hospital accommodation and pre- and post-operative care.'

INFORMATION / AWARENESS

The Bioethics Convention states: 'An intervention in the health field may only be carried out after the person concerned has given free and **informed consent** to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks'²⁵.

The Additional Protocol on Transplantation of Organs and Tissues of Human Origin states: 'Parties shall provide information for health professionals and for the public in general on the need for organs and tissues. They shall also provide information on the conditions relating to removal and implantation of organs and tissues, including matters relating to consent or authorization, in particular with regard to removal from deceased persons' 26.

'The fact that respondents have already discussed this subject with their family has a strong influence on their willingness to donate one of their organs'²⁷. The fact that respondents have already discussed the question of organ donations and transplantations with their family is the most discriminating factor on this question, more so from the respondent's socio-demographic category.

'The respondent's level of education and his or her occupation are fairly discriminating criteria for these questions: the higher the respondent's level of education and socio-professional level, the more he or she has a positive view of organ donations. However, the most discriminating criterion is undoubtedly the fact of having already discussed this subject with family members. This has an extremely positive impact on the results'. Therefore it is likely that 'communication campaigns will have very positive consequences – in the short or medium term – on the population's acceptance of organ donations'²⁸.

In fact, the value of campaigns has been shown in Malta, ten years after the campaign in 1995. 'The results of the four surveys on attitudes towards organ donation indicate that the national campaign succeeded in increasing the number of organ card donors and in creating more positive attitudes towards organ donation. It is significant that this increase was sustained over a decade following the campaign, probably with the help of other campaigns like Life-cycle'. Also after the campaign doctors 'involved in organ procurement and organ transplantation 'found it easier to approach families of possible donors' after the campaign as 'the topic of organ donation was very often in the media' and were expecting the doctors to bring the subject up'²⁹.

Changing the attitudes of people towards organ donation through public communication campaigns helps to increase the number of people who are willing to donate their organs after their death³⁰,³¹.

Counselling prior to becoming donor / living will patient

The Additional Protocol on Transplantation states: 'The recipient and, where appropriate, the person or body providing authorization for the implantation shall beforehand be given appropriate information as to the purpose and nature of the implantation, its consequences and risks, as well as on the alternatives to the intervention'³².

The Eurobarometer³³ reported that some 41% of European citizens have already raised the question of organ donations or transplantations during discussions with their family compared to 58% who have never broached this subject. An analysis by country of the results therefore reveal fairly considerable differences between the EU15 and MS10

countries. However, there are also significant differences between the EU15 countries: 75% of Dutch citizens and 66% of Swedish citizens have already discussed organ donations with their family, compared with only 24% of citizens in Austria and 28% in Portugal.

Malta stands out as the only new Member State to record as score above the European average (44% versus 42% for the EU25).

PUBLIC ATTITUDES

General attitudes to transplantation

Eurobarometer³⁴ reports that some 56% of Europeans are ready to donate one of their organs to an organ donation service immediately after their death. Just over one in four is against the idea (26%), while almost one in five felt unable to express an opinion on this question (18%).

An analysis of the results by country reveals some fairly significant differences. Citizens in Northern European countries are more likely to envisage donating an organ. Except for Malta, which stands out once again (75% of citizens in Malta would be willing to donate one of their organs compared with 10% who are against the idea), support among citizens for the idea of donating one of their organs after their death is strongest in Northern Europe: Sweden (81%), Finland (73%), Belgium (71%), the Netherlands and Denmark (69% in both countries).

Sweden (74%), Finland (73%), the Netherlands (66%) and Belgium (65%) are the countries with the highest levels of acceptance for the idea of donating an organ from a deceased close family member with Malta (71%) once again standing out among the above countries from the centre and North of Europe.

Donor card

Donor cards are not legally binding in Malta but the Transplant Support Group (Malta) urges people to 'discuss organ donation with your family because if you don't have a signed donor card, the decision of your organ donation will be made by your legal next-of-kin at the time of death'³⁵. Also the Support Group emphasises that if relatives know the deceased's wishes, their decision is much easier.

When someone has just died, it is sometimes difficult to ascertain their wishes regarding the delicate subject of organ donation. Sometimes even the deceased person's family does not know his or her wishes in this regard, and is not in a position to take a decision, especially at a very difficult time following the sometimes brutal announcement of the death of a loved one. An organ donation card makes clear the deceased person's wishes and can therefore guide families which must give their consent for any donation.

More than four out of five Europeans are in favour of the use of organ donation cards. A socio-demographic analysis reveals a slight difference according to the respondent's

gender: women are slightly more likely than men to have an organ donation card (14% versus 10% of men). However, education is once again the most discriminating criterion: 8% of those who left school before the age of 16 have a card, compared with 18% of those who studied up to or beyond the age of 20.³⁶

'The level of information, often correlated to the respondent's level of education, seems therefore to play an important role in the use of organ donation cards, and more generally with regard to opinions on organ donations and transplantation: the most educated respondents' (or at least on societal issues), are the 'most in favour of organ donations and organ donation cards; moreover the number of them having an organ donation card is above the European average'. 37

The proportion of respondents who had a donor card increased slowly but steadily over the four surveys: 7%, 9%, 13% and 14%, with the differences between the first and the third and fourth surveys being both significant³⁸. By the time the Eurobarometer report was published, the possession of a donor card had risen to 15%³⁹.

An alternative to donor cards would be the use of the driving licence or the passport as the document on which the donor's wish is recorded for legal purposes. However this should only be acceptable provided the potential donor is in apposition to give informed consent and not just filling in a box on a form.

Reaction to living will?

We were unable to find literature relating people's reaction to the use of living wills for transplantation issues. We could not answer the question as to whether the living will has actually resulted in an increase in organ availability.

LIVING WILL and ORGAN TRANSPLANTATION

The US situation

In USA, the **Patient Self-Determination Act**, an amendment to the Omnibus Budget Reconciliation Act of 1990, which became effective in December 1991 makes it mandatory to inform patients on admission or registration to hospital or nursing homes, about their rights under state laws governing Advance Directives, including '(1) the right to participate in and direct their own health care decisions; (2) the right to accept or refuse medical or surgical treatment; (3) the right to prepare an AD; and (4) information on the provider's policies that govern the utilization of these rights. The act prohibits institutions from discriminating against a patient who does not have an AD⁴⁰. The Act also obliges health institutions to provide education on Advance Directives.

Advance Directives may not include a section on views regarding organ donation. The US Living Registry states that if there is no such section, 'you can write-in your wishes

as to whether or not you want to donate your organs in the "comments" section of your document, or you can submit a separate letter of intent for organ donation. Your family will ultimately decide whether or not to donate your organs. Being able to read your wishes about organ donation will make their decision-making much easier, and discussing your wishes with your family now is the best way to help them make this decision. So it appears that it does not carry the same legal protection as an Advance Directive, as yet, in the US.

The living will registry

The U.S. Living Will Registry states that once the will is registered, they will send the donor labels for the driver's license and insurance card, and a wallet card indicating registration is legally binding. They will send an update letter each year to the donor, to confirm that the donor's wishes have not changed, and to allow him to make any changes to the contact information. In this way, there will be no doubt as to whether the letter of intent still reflects current wishes⁴².

The U.S. Living Will Registry's automated secure Internet and telephone/fax systems make advance directives and organ donor information available to health care providers across the country quickly and easily.⁴³

The Living Wills Registry in (Canada) has become a 'facilitative instrument' in the field of potential tissue donation. However the website specifically states that the 'Organ Donation declaration will have no bearing on the implementation of the living will and the Power of Attorney for Personal Care' 44.

OTHER ISSUES:INFRASTRUCTURE

Registration for donors

There would be an urgent need to have a register, easily accessible to all interested parties involved in transplantation. A centralised registry seems to be the norm in Belgium, the US and Canada but in the UK, the BMA suggested the ability to opt out through the general practitioner.

The register would need to be electronic to be easily accessible and kept up to date. So Data Protection issues have to be covered well. The BMA recommends that checking the register should be mandatory before any organs are removed and, if the individual had not registered an objection, this information should be passed on to the relatives. If a member of the close family volunteers information about an unregistered objection, the donation should not proceed⁴⁵

The Information Society Directorate General is supporting the creation of a European online registry on organs, cells and tissues through the EUROCET project. https://www.eurodonor.org/eurocet/

Transplant co-ordinators

The literature emphasises that success stories increasing the availability of donor organs depend strongly on an improvement of the available infrastructure. One important feature in countries with success stories, like Spain, has been investment in this area, particularly in relation to the setting up of Transplant co-ordinators, with specific training and formal job descriptions. The co-ordinators liaise with families and so higher rates of donation have been attributed to their work, as has happened in Spain.

The UK Transplant Co-ordinators' Association has called for a national body to be established with responsibility for developing national standards for continuing education and training and to ensure consistency in the quality of service delivery across the country⁴⁶. The Royal College of Surgeons, UK recommended that all transplant co-ordinators should be employed, recruited and trained by the proposed National Transplant Service and have a common career structure, salary scales, job description and standards of practice⁴⁷.

THE MALTA SITUATION

Malta is one of the few European countries that does not have a Transplant Authority and this should be a priority if we are to review the organizational structure and produce an efficient system, suited to Malta's needs.

The **Transplant Support Group (Malta)** is in favour of legislation regulating organ donation, so as to legalise its long standing practices. Therefore the group supports, in fact advocates for An Official Donor Register, with mandatory update. They recommend that the Register should be accessible to authorised personnel, including ITU doctors and the Transplant Co-ordinator. These should be trained how to approach and deal with the family of the potential donor, particularly regarding seeking informed consent for harvesting organs.

The group is therefore against an opt-out system, principally because of their strong belief that a donation should be altruistic without any pressure and after having reached a conscious decision following adequate information. The latter information may be lacking if the state has a 'presumed consent' policy. They do insist that the potential donor should inform the family about such a decision.

The group would also like to retain the current practice of a close relationship of recipients with donors, a practice that the EU guidelines reject in view of loss of confidentiality, as laid out in the ⁴⁸. It was realized that in Malta, it is impossible to

maintain confidentiality as to the identity of cadaver donors. Moreover since the recipients were meeting with the donor's relatives, 'without any support and guidelines', the transplant co-ordinator is now acting as the middleman, arranging a meeting if both sides are wiling to meet, through the Transplant Support Group⁴⁹.

13

¹ http://www.mayoclinic.com/health/living-wills/HA00014 Mayo Clinic Staff.

Wilkinson A, Wenger N, Shugarman LR. (June 2007). Literature Review on Advance Directives, commissioned by U.S. Department of Health and Human Services from the RAND Corporation.

³ 28th March 2008, http://www.euronews.net/2008/03/28/every day-in-europe-ten-people-die-waiting-for-an-organ-transplant/.

⁴ 22nd September 2009, DOI, http://www.doi.gov.mt/en/commentaries/2009/09/tim21.asp.

⁵ Transplant Support Group, Malta, http://www.transplantsupport.com.mt/about.htm.

⁶ 22nd September 2009, DOI, http://www.doi.gov.mt/en/commentaries/2009/09/tim21.asp.

⁷ http://www.sahha.gov.mt/pages.aspx?page=47, data provided by Mr. Anthony Bugeja, Transplant Coordinator, Mater Dei Hospital and Mr. Mark Debono, Staff Nurse, Mater Dei Hospital.

⁸ Transplant Support Group (Malta), http://www.transplantsupport.com.mt/faq.htm

⁹ Additional Protocol on Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24.1.2002, Article 10.

¹⁰ Additional Protocol on Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24.1.2002, Article 2.

¹¹ http://www.donatelifeillinois.org/donatelife/how_donation_works.htm

¹² Uniform Anatomical Gift Act, 2006 with latest amendments, 2009, Prefatory Note http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=1&tabid=63

¹³ Stein R. (Wednesday, April 4, 2007). States Revising Organ-Donation Law, Critics Fear Measure May Not Go Far Enough to Protect Donors, Washington Post Staff Writer,

http://www.washingtonpost.com/wp-dyn/content/article/2007/04/03/AR2007040302062.html ¹⁴ ibid

¹⁵ Organ Donation in the twenty first century. Time for a consolidated approach. (June 2000) http://www.bma.org.uk/images/OrganDonation_tcm41-147010.pdf

Lauri MA. (2006). Metaphors of organ donation, social representations of the body and the opt-out system, British Journal of Health Psychology, (2009), 14, 647–666.

¹⁷ Edwards AG, Weale AR, Morgan JD. (2005). Informed consent in renal transplantation, Postgrad Med J 2005;81:188–190. doi: 10.1136/pgmj.2004.024760.

¹⁸ Organ Donation in the twenty first century. Time for a consolidated approach. (June 2000).

¹⁹ Michielsen P. Effect of transplantation laws on organ procurement. In Touraine JL et al (eds), *Organ Shortage: The Solutions*. Netherlands: Kluwer Academic Publishers, 1995: 33-39.

²⁰ Kennedy I, Sells RA, Daar AS, Guttmann RD, Hoffenberg R, Lock M, Radcliffe-Richards J, Tilney N, for the International Forum for Transplant Ethics. (1998). The case for A presumed consent in organ donation. *The Lancet* 1998; 351:1650-1652.

²¹ Organ Donation in the twenty first century. Time for a consolidated approach. (June 2000).

²² Matesanz R, Miranda B. (1996). Organ donation for Transplantation. The Spanish model. Spain: Groupo Aula Medica.

²³ Report from the Commission to the Council and the European Parliament, on the promotion by Member States of voluntary unpaid donation of tissues and cells, Brussels, 2006.

Organ transplant sale to Malta angers UK patients, Malta Today, 7th January 2009, http://www.maltatoday.com.mt/2009/01/07/t12.html.

²⁵ Council of Europe, 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, Oviedo, 04.04.1997, article 5, General Rule.

²⁶ Additional Protocol on Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24.1.2002, article 8, Information for health professionals and the public.

²⁷ Europeans and Organ Donation, Special Eurobarometer, May 2007.

²⁸ ibid

³⁴ ibid

³⁶ Europeans and Organ Donation, Special Eurobarometer, May 2007.

 37 ibid

³⁹ Europeans and Organ Donation, Special Eurobarometer, May 2007.

⁴⁰ Wilkinson A., Wenger N., Shugarman LR. (June 2007). Literature Review on Advance Directives, commissioned by U.S. Department of Health and Human Services from the RAND Corporation.

⁴¹ Organ Donation Information and Registration, US Living Will Registry,

http://www.uslivingwillregistry.com/organdonation.shtm.

⁴² Organ Donation Information and Registration, US Living Will Registry, http://www.uslivingwillregistry.com/organdonation.shtm.

43 ibid

44 http://www.sentex.net/~lwr/detail.html#ORGAN

⁴⁵ Organ Donation in the twenty first century. Time for a consolidated approach. (June 2000).

⁴⁶ UK Transplant Co-ordinators Association (UKTCA), *The National Organ Procurement Service. The way forward for organ procurement.* UKTCA, October 1999.

⁴⁷ Organ Donation in the 21st Century: time for a consolidated approach, BMA, 2003.

²⁹ Lauri MA. (2006). Attitudes towards organ donation in Malta in the last decade, Malta Medical Journal Volume 18 Issue 04.

³⁰ Kopfman JE., Smith SW. (1996). Understanding the audiences of a health communication campaign: A discriminant analysis of potential organ donors based on intent to donate. Journal of Applied Communication Research, 24, 22–49.

³¹ Lauri M A. (2006). Attitudes towards organ donation in the last decade. Malta Medical Journal, 18(4), 27–31.

³² Additional Protocol on Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24.1.2002, article 5, Information for the recipient.

³³ Europeans and Organ Donation, Special Eurobarometer, May 2007.

³⁵ Transplant Support Group (Malta), http://www.transplantsupport.com.mt/faq.htm

³⁸ Lauri M.A. (2006). Attitudes towards organ donation in the last decade. Malta Medical Journal, 18(4), 27–31.

⁴⁸ Additional Protocol on Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24.1.2002, Article 23.

⁴⁹ 1st September 2009, Organ donors don't have final word, http://www.timesofmalta.com/articles/view/20090901/local/organ-donors-dont-have-final-word