Position Paper
on the
Government’s Consultation Document on the
Proposal for Legislation on Organ
and Tissue Donation

MAY 2015
Organ and tissue donation is a societal issue that demands the positive engagement of all stakeholders in civil society for its successful implementation and for achieving its goal of allowing “more lives to be saved and improve the quality of others”\textsuperscript{1} The publication of a \textit{White Paper} and the launching of a public consultation, before legislating on the matter, can actually motivate individuals, associations and institutions to look at the current practice and see what is at stake and what is the reasonable way forward to improve it. The Government’s initiative is a major step forward especially as it sets to regulate a practice that has been carried out in Malta for many years. The objective of the whole exercise is certainly good, since an adequate supply of tissues and especially organs will make a big difference to people who need them to stay alive or to improve the quality of their life.

This position paper, which has been prepared at the request of the Maltese Episcopal Conference by a group that includes experts in the field of clinical medicine, psychology, philosophy and theology, is a response to the Government’s call to all stakeholders in society to participate in the development and formulation of a healthcare policy on organ and tissue donation. The Church, as one of the stakeholders in the Maltese society, wants to participate in the consultation process since this issue has social, cultural, ethical and religious dimensions. Moreover, empirical studies have shown that both faith and cultural attitudes were important influencing factors for individuals when deciding to become organ donors.

1. The Current Policy

1.1 The procurement of tissues and organs for transplantation has been going on for a considerable number of years in Malta and abroad. One envisages that the proposed legislation would enlarge the pool of tissues and organs for transplantation. However, as the \textit{White Paper} notes, legislation that considers only efficiency has its own limitations. The system that it will be creating requires an operational mechanism that is more complex in practice than the current one. Its success depends also and, perhaps to a large extent, on how the practice that it will be establishing will fit into the Maltese social and cultural, and religious context. However, before we can gauge the necessity of any reform, the status of our current system warrants consideration.

1.2 It is very important to point out that the current procurement rate compares very well with that in the other EU Member States. In fact, in 2013, Malta placed second in organ donation according to a study, published by the Netherlands Institute for health services research in 2013, on the uptake and intake of the EU Action Plan on

\textsuperscript{1} Proposal for Legislation on Organ and Tissue Donation. A Maltese Governments White Paper, p. 3.
organ donation and transplantation (2009-2015). This study notes that “with a deceased donation rate per million population higher than 20 million, Malta’s deceased donation rate per million population is amongst the highest included in this study.”² The results are similar with respect to living kidney donation: “With a living kidney donation rate per million population higher than 10 million in 2011, Malta’s kidney living donation rate per million population is among the higher of the countries included in this study.”³

1.3 The following statistical information gives a more specific picture of the situation. In Malta, a total of 151 cadaveric transplants were carried out in the 15 year period between 1999 and 2013 giving a cadaveric transplant yearly rate of 25, extrapolated to rates per million population (pmp), which is not too far from the results obtained by Spain, which heads the table in cadaveric renal transplants.

Live donor transplants in Malta account for 20% of all transplants (as opposed to only 3% in Spain). Combining deceased and living kidney transplants in Malta gives a figure of 32 pmp. This means that the present system is functioning well, so that we should not try to overhaul it but to improve it.

The point is certainly not to minimize the importance and urgency of a comprehensive legislative framework for the current practice of organ and tissue procurement. Yet, it is certainly indicative that there is something very positive and effective in the current practice, which can well provide a sound basis for further development.

Do we need to change a system that is already giving good results without raising serious ethical, cultural and religious issues? Would it be more reasonable to embark on a national action plan to consolidate a system that in actual fact is already widely accepted by so many stakeholders and the public in general? Do we need a change in our system when doctors at the Intensive Therapy Unit in MDH state that the number of refusals is close to nil when relatives are requested to consent for post-mortem organ donation? So why should one oblige people to do what they are ready to do voluntarily? Will a change in the current system damage or promote the relationship of trust between clinicians caring for patients at the end of life and their families? Why changing a system that has worked for over 30 years thanks to the dedicated service of our doctors and nurses?

2. Organ Donation as an Act of Giving

2.1 In the first sentence of the foreword to the White Paper, the Hon. Parliamentary Secretary for Health, Dr. Chris Fearne, rightly refers to organ donation as the “greatest gift of all” – and this is the way that organ donation should always be perceived – i.e. a voluntary gift for the benefit of individuals who are most deserving of it. A necessary dimension of a gift is that it must be given; it is an act of uncompelled generosity. One cannot receive a gift from the other if the other has not consented to the giving. Without that consent, the practice becomes taking and

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² Actor study, Nivel 2013, p.88.
³ Ibid.
getting rather than giving and receiving organs. The notion of altruism and of giving organs and tissues is important to preserving human dignity and integrity.

2.2 Since the first successful transplant procedure in the early fifties, the Catholic Church has explicitly supported both living organ donation and the procurement of organs from the dead. Pope Francis describes the act of organ donation as “a testimony of love for our neighbour” when he met with the Transplantation Committee for the Council of Europe which gathered in Rome in October 2014. From a Catholic moral perspective, organ donation is justified by the principles of charity and solidarity. The donor fulfils the Lord’s great challenge to his disciples: “This is my commandment, that you love one another as I have loved you. Greater love has no man than this, that a man lay down his life for his friends” (John 15:12–13).

Organ donation is an act of self-gift of the human person. As Pope John Paul II noted in an address to an international congress on transplants, “Every organ transplant has its source in a decision of great ethical value: 'the decision to offer without reward a part of one’s own body for the health and well-being of another person.' Here precisely lies the nobility of the gesture, a gesture which is a genuine act of love.”

The stipulation that an organ donor must explicitly and freely consent to the donation, prior to organ procurement, is a necessary ethical requirement for two reasons. First, informed consent affirms and protects the intrinsic dignity and inviolability of the human person who is a steward, not the master, of his/her own body. Secondly, informed consent respects the essential formality of the donated organ as a gift that one person gives to another. Accordingly, neither the individual nor anyone else, certainly not society, may treat the human body, or any of its organs, as property that can be taken and distributed at will. The donation of our organs is not something that can be presumed, for then it would no longer be a donation. The language of donation should be used honestly and is only applicable where there is a relationship of giving.

2.3 The White Paper presents different options, basically an opt-in system, where persons give their explicit consent, and an opt-out system where those who do not signify their refusal to donate their organs are understood to be in favour.

The system that safeguards the dimension of gift in the act of organ donation is the opt-in system. For this reason we are in favour of an opt-in system, where the donors explicitly signify their wish to donate their organs. On the other hand, the opt-out system precludes the person’s possibility to freely express his/her decision to donate his/her tissues and organs, thus undermining the dimension of gift that requires the explicit and free informed consent of the human person. One of the objectives highlighted by the White Paper is to create a framework that is “in alignment with the Maltese culture of generosity and altruism”, and such culture can be sustained if the legislation offers Maltese citizens the possibility to express their decision on organ donation.

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4 JOHN PAUL II, Address to the 18th International Congress of the Transplantation Society (29 August 2000), 3.

5 White Paper, p. 3.
In an opt-out system the State assumes the power over the body of the dead person (in the absence of explicit refusal). The corpse remains symbolically related to the deceased person and thus cannot be simply used as an organ depository unless the person has expressed such a wish before his/her death. In those cases when no preference has been expressed by the deceased person, the decision should be taken by relatives, not by the State. In an opt-out system there is the risk that what should be considered as a “donation” loses its significance as an act of giving and can also be interpreted as lacking in the respect (pietas) that the living ought to give to the deceased.

Moreover, an opt-in system is more likely to be accepted by the general population as it leaves the decision in the hands of the individual “making the gift”. Transplant recipients are more likely to accept an organ if they know that it has been positively given – presumed consent renders it an action by default. Family members should be consulted; the family is a valuable source of information about a deceased’s previous health condition and this reduces potential medical risks in removing organs without full discussion with the family. The presence of a definite (as opposed to a presumed) consent makes it easier for the family to understand and comply with the expressed wishes of the deceased.

2.4 Studies show that, in general, countries adopting opt-out systems have a higher total number of kidneys donated. The latest study is “An international comparison of deceased and living organ donation/transplant rates in opt-in and opt-out systems: a panel study” by Lee Shepherd, Ronan E O. Carroll, Eamon Ferguson. The donation/transplantation in relation of the opt-in and opt-out systems varies from one country to another. For example Austria and Denmark both adopt opt-out systems yet their deceased kidney donor rates per million population are 18.8 and 11.5 respectively, as opposed to Spain which also operates an opt-out system with a transplant rate of 35 pmp. Countries like Germany and the United States operate an opt-in system with transplant rates of 15.3 pmp and 25.9 pmp respectively.

Indeed, Spain has the highest rates of transplants, a trend that has been noted since the early 1990s; yet an opt-out system has been in operation since 1979 and it is generally acknowledged that the higher transplant rates have not been due to presumed consent per se, but due to improvements in the transplant co-ordination network, effective investment in transplants logistics, staffing and administrative coordination and improving the quality of information on organ donation available to the public.

The study quoted above, however, also shows that the rate of live transplants diminishes significantly in countries adopting an opt-out system – for example, the proportion of live to cadaveric donations is about 1 in 3 in UK, US and Israel (all adopting an opt-in system); in Spain only 3% were from living donors in 2006. Some

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figures for live organ donation 2011 were as follows: Opt out countries – Austria 6 pmp, Finland 2.4, Italy 3.5, Spain 6.6; opt-in countries Germany 9.7, UK 16.5.7

3. Ethical Issues

3.1 One fundamental ethical issue related to the introduction of an opting-out system is the argument of whether or not persons have a right over their body and whether it is their property. Those who believe that we own our bodies and that this right is transferred to the next of kin upon one’s death, argue that the State has no right to remove organs from a dead person without having the family’s consent or a living will stating that the person wants to donate his/her organs. There are others however who believe that ownership of organs rests with the State, and that it is right and just for the state to delegate its authority to the hospital and transplant team so that these can authorize the removal of organs from dead persons and give them to patients in need of a transplant. Patients, they argue, should not depend on the generosity of others. This line of thinking in favour of the opt-in or opt-out systems based on the paradigm of ownership is inadequate since the body is not something that we own but is the mode in which we are present to each other and communicate with each other.

3.2 Tissue and organ donations from living persons may be justified solely for therapeutic reasons, taking into account various clinical factors: “urgency, the probability of successful transplant surgery given the patient’s condition, the prospect that the organ will thrive, and, as a final consideration, the order of priority of the request”.8 What the Oviedo Convention states in this regard is relevant in this context: “Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.”9

The new law on organ donation should clearly prohibit the transplantation of those organs that ensure personal and procreative identity, namely, the brain and the gonads.10 Gonadal transplant is unethical if it is used to treat a problem of infertility for two reasons: (1) it is not aimed to save a person’s life; (2) it causes a disturbance in the recipient’s personal identity.

3.3 An important ethical issue related to organ donation is the issue of financial remuneration. The White Paper’s condemnation of underground markets

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7 EU Publication: 7th Journalistic Workshop on Organ Donation and Transplantation; 7 October 2013.
10 “The brain and the gonads may not be transplanted because they ensure personal and procreative identity respectively. These are organs which embody the characteristic uniqueness of the person which medicine is bound to protect.” PONTIFICAL COUNCIL FOR PASTORAL ASSISTANCE AND HEALTH CARE WORKERS, Charter for Health Care Workers (1995) 88.
surrounding organ trafficking and its proposals to counter it are praiseworthy. The *Oviedo Convention* in article 21 on the prohibition of financial gain states clearly that “the human body and its parts shall not ... give rise to financial gain”. Moreover, the Additional Protocol to the *Oviedo Convention* concerning Transplantation of Organs and Tissues of Human Origin reiterates in article 21 that the commercialization of the human body is against the human dignity and integrity of the human person. Furthermore, the same article states that advertising the need for or availability of organs or tissues, with a view to offering or seeking financial gain or comparable advantage, should be prohibited. The same principle applies in the case of living organ donors although it may be permissible for such donors to receive reimbursement of expenses such as loss of earnings which are reasonably attributable to the donation.

3.4 The ethical principles framed by the *Live Organ Transplant Advisory Committee* (LOTAC) – to which the White Paper refers – should form part of the criteria of live organ transplants. The principles are the following:

a) The donor is willing to donate the organ (principle of autonomy);
b) The donor is well informed by his specialist and consents freely (principle of free and informed consent);
c) The donor is not being subjected to coercion or duress (principle of non-coercion);
d) The donation is free and is not subject to a financial or material consideration (principles of dignity, integrity and non-commercialisation);
e) The risk to the donor’s health is acceptable (principle of non-maleficence);
f) The recipient will benefit from the procedure (principle of beneficence).

3.5 The allocation of organs raises the ethical issue of distributive justice. Clear guidelines need to be drawn up with regard to eligibility and relative need of patients on renal replacement therapy who are waiting for a transplant. The distribution of organs should be based on the medical assessment of relative need, urgency and outcome, and how long a person has been on the waiting list. It is important to identify factors that should not be taken into account, such as:

a) race, nationality, religious belief, gender, marital status, sexual orientation, social status, disability or age (except where conditions associated with the patient’s age or gender directly determine the likelihood of a poorer outcome);
b) willingness of family members to be donors (after death);
c) need for a transplant arising from the patient’s past behaviour;
d) capacity to pay; or

3.6 In general one considers the use of an organ from a live donor only if the following conditions are met:

a) surgery to remove the organ is not dangerous,
b) donor’s life can continue normally after the donation,
c) donor will not need prolonged and chronic medical care,
d) success rate in the recipient is quite high.
4. Concerns

4.1 The current procurement system draws much of its power and success from the altruism that people show for each other. People in general are disposed to help each other by offering an organ or a tissue after their death and, sometimes even during their life, to somebody who needs it to remain alive or to improve the quality of one’s life. It seems, however, that the White Paper is rather prejudiced against a system that is exclusively based on altruism. “Exclusive reliance on the present altruistic tissue and organ procurement processes in many countries and also in Malta”, it says, “is not only rife with problems, but also improvident.”

Rightly enough, the White Paper is far from saying that an opt-out system is preferable, because it is more efficient in procuring organs for transplantation. Efficiency is at best only one aspect that needs to be considered in the ethical evaluation of a particular action or practice. There are other aspects that have to be taken into account. Very often, these present themselves in the form of what are called concerns that people may have about a certain course of action.

The White Paper mentions two concerns which people often have about an opt-out system. One is that individuals would lose rights over their bodies and the other is that the power to remove organs for transplantation would be in the hands of the state. The two are inter-related. If one argues on the basis of the right over one’s body, the power that the state acquires over your and my body as a result of an opt-out system will surely be a source of concern. The assumption behind this kind of argument is that the rights over our bodies are a species of property rights. The image implied is that my body is something that I own. So when I am giving an organ, I am disposing of part of my body. The ownership image does not bring out fully the significance of what people are doing when they are giving a tissue or an organ. On the contrary it is hiding, if not altogether distorting, the nature of organ donation as a gift that people are making to each other. Introducing the concept of opting-out might create fear in many people. Different people have different representations of organ donation and these have to be taken into consideration when changing practices.

4.2 A delicate ethical issue related to organ donation ex mortuo is about the criteria that should be observed in order to ascertain that the body from which organs are to be procured is actually a dead human body. The Additional Protocol to the Oviedo Convention concerning Transplantation of Organs and Tissues of Human Origin states in article 16 that “organs or tissues shall not be removed from the body of a deceased person unless that person has been dead in accordance with the law”. The White Paper refers to the fact that “in Malta the Harvard principle of Brain Death is very often adopted” mentioning the principle’s six criteria.

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Brain death, to be understood as the death of the whole brain (brain and brain stem), is by far (according to medical and scientific knowledge to date), the most adequate principle to determine the death of a human person since the complete and irreversible loss of all the functions of the brain and brain stem mark the end of the person’s life as a living organism.

Consequently, the need to procure organs should not make room for other principles such as the cortical death principle (that states that it is sufficient that the upper brain functions cease in order to declare that a person is dead) that in fact can only indicate the loss of some functions but not the death of the human organism. It is also the case that several of the countries, including Spain, that have comparatively higher donation rates also have stricter practices in relation to diagnosing death by the neurological criterion. Most countries with higher donation rates also require ancillary testing showing absence of blood flow to the brain, and do not rely on the clinical criteria for brain stem function alone. It may well be that there is greater public confidence in the diagnosis of death by health professionals in those countries, and that this has led to greater acceptance of organ donation. Moreover, a sufficient waiting time should be respected in order to determine the irreversible loss of the functions of the whole brain. Such waiting time – not specified in the White Paper – should be determined by science and law and be ethically reasonable.

Organ procurement may take place from heart-beating cadavers – presuming that all criteria for death determination as mentioned above are respected. In this case, the heart continues to beat due to its intrinsic capacity because of artificial respiration. Such procedure allows maintaining the functioning of the organs (and their viability) for transplantation.

Some counties, in order to increase organ donation, have started the practice of retrieving organs from non-hearth beating bodies. In this context, an ethical debate arises as to when to withdraw artificial respiratory support. The problems regarding such practice are: the lack of sufficient time to ascertain the irreversibility of all functions; the refusal to resuscitate a person whose organs could positively respond thus prolonging his/her life (even if for a short time); and the pressure to hasten the determination of death in order to procure healthy organs. These contentious issues need further study.

4.3 The White Paper suggests as a possible option in a opt-in system that “children over 12 years of age who are considered legally competent to register themselves can be given the opportunity to register as organ donors, but only after extensive education to empower educators, parents and guardians to discuss the issue is provided.”

The White Paper does not offer any reasonable grounds to explain the choice of 12 years as an age threshold for minors to be able to register themselves, except the fact that this possible in Scotland. One must point out, however, that in Scotland, children as young as 12 are prosecutable in court, can be given a custodial sentence, may choose legal representation and can apply for legal aid or assistance.
if they have sufficient understanding.\textsuperscript{15} This is not the case in Malta. Indeed, locally, the age of criminal responsibility has been increased in 2014 from 12 to 14 years of age.\textsuperscript{16} This was a step in the right direction which must be followed in other areas. Moreover, if the law on organ donation were to presume that children above the age of 12 were of sufficient understanding to give permission for organ donation, would this not open the possibility of presuming sufficient understanding and competence to decide also for other issues, such as the right to vote, to work (and possibly stop attending school), to live and travel by themselves, and so on? Moreover, even though the White Paper seems to have donation of organs \textit{ex mortuo} in mind, there is no clear distinction between minors as donors \textit{ex mortuo} and minors as donors \textit{ex vivo}, thus making it possible that at the age of 12 a minor would be capable to decide whether to be a living donor. This, in fact, seems to be another lacuna of the White Paper, since one may argue that the possibility of when minors could be considered for donation \textit{ex vivo} are not spelled out. For example, in which cases are minors allowed to be organ donors \textit{ex vivo} (e.g. kidneys)? Is this possible only between siblings or may minors be allowed to donate organs to their parents? Is the minor’s refusal in such cases binding? Will such decisions be left to the discretion of an ethical committee, or to a judicial ruling which respects the best interests of the child? Furthermore, if the law will presume a sufficient understanding for 12 year olds to register for organ donation, will 12 year olds be similarly presumed to have a sufficient understanding to decide to donate blood, for example?

Our concern is that the proposal that twelve-year-olds should be considered legally competent to become an organ or tissue donor is contradicted by psychological studies and the same Maltese law which considers a minor at that age not yet mature enough to make decisions by himself/herself or be held fully responsible for his/her actions. Thus, the age threshold for organ donation and tissue in the case of minors needs more thought and reflection.

In fact, the suggested age seems to contradict various studies which show – as the American Academy of Paediatrics observes – that

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\[\ldots\text{] the ability to understand the risks and benefits of donation and to make an informed decision improves with the developmental maturity of the minor. There exist some data to suggest, at least in hypothetical cases, that older adolescents make decisions as well as their adult counterparts, but there is not a specific age at which these capacities uniformly exist. Case-by-case review by the transplant team and an independent advocacy team is necessary. Additional consultations by a psychiatrist and/or an ethics committee are recommended for younger minors.}\textsuperscript{17}
\end{quote}

\textsuperscript{15} \url{http://www.organdonationscotland.org/am-i-eligible}.

\textsuperscript{16} \url{http://www.timesofmalta.com/articles/view/20140122/local/age-of-criminal-responsibility-being-raised.503555}.

\textsuperscript{17} Laine FRIEDMAN ROSS et al., “Minors as Living Solid-Organ Donors”, in \textit{Pediatrics} 122/2 (1 August 2008), 454-461, 459.
Thus, considering that in Malta a 16-year-old Maltese citizen is being given the right to vote in the local elections, and can work, it would be more logical if minors under the age of 16 would be considered unable to give a free and informed permission to register to become an organ donor. Younger children may become organ donors *ex mortuo* with the permission of their parents under a soft opt in system.

Therefore, a twelve-year-old’s decision to donate his/her organs or tissue should involve the explicit consent of the parents or legal guardian, not excluding – as the *Oviedo Convention* states – that, “the opinion of the minors shall be taken into consideration as an increasingly determining factor in proportion to his age and degree of maturity”. Consequently, article 20 of the *Oviedo Convention* on the protection of persons not able to consent to organ removal should apply:

a) No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5.

b) Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:

(i) there is no compatible donor available who has the capacity to consent;

(ii) the recipient is a brother or sister of the donor;

(iii) the donation must have the potential to be life-saving for the recipient;

(iv) the authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the competent body;

(v) the potential donor concerned does not object.

4.4 Another concern is the harvesting of organs from anencephalic newborns. Since small size organs are lacking and anencephalic newborns are sometimes considered as organ donors, it is important that the law on transplants states, in line with a biologically appropriate definition of human life, that the anencephalic newborn is a human person whose dignity needs to be respected and thus cannot be retained as a mere depository of human organs. It is ethically unacceptable to intubate and put on ventilation, or resuscitate an anencephalic newborn for the sole purpose of organ transplantation – these are cases that constitute therapeutic obstinacy and

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19 *Oviedo Convention*, Art. 20.

20 “The most obvious evidence of their personhood is their birth. These infants are not embryos or fetuses, but living, breathing infants who are born in the same way as other infants. While some doubt exists that infants with anencephaly exhibit the characteristics of a person, it is documented that “these infants like other infants, sleep, eat, breathe, smile, and cry.” Additionally, most infants with anencephaly have all the characteristics of biological life including a functioning brain stem; they are just missing a large portion of their brain. They also have the same genetic structure as humans and despite their inability to meet the other required criterion set out by experts, it has never been established that anencephalic infants lack the protection of personhood. By meeting many of the required characteristics of personhood, anencephalic infants are entitled to all the rights and privileges that any other person possesses. As a result, their organs cannot be used for organ donation prior to a declaration of death under the current standard or a change in their current recognition as persons.” Samantha J. Gilman, “The use of anencephalic infants as an organ source: an on-going question”, in *Elon Law Review* 4/71 (2012), 71-92, 78.
exploitation of a human being. The anencephalic infant should be given ordinary care until his/her death occurs naturally. Despite that no ethical difficulty exists to procure organs from anencephalic foetuses or newborns after death, the ethical problem persists because to date it is very difficult to use the accepted criteria of determination of death that apply for adults and children to anencephalic persons.²¹ Consequently, it is suggested that the White Paper prohibits that anencephalic persons be considered for organ donation.

5. Recommendations

The concept of organ donation, being a voluntary gift, must be retained and protected. Indeed, potential donors should feel that they are initiating the act rather than being forced by legislation to donate on the ground of a presumed consent. The new legislation should strengthen the opt-in system.

The system should allow the family of the deceased to continue to play an active role in the procurement process so that the donation would not simply be as an act of generosity on the part of an individual but as a generous gesture on the part of one’s family as well. In those instances where an individual has registered as a donor, the family should be consulted as a sign of respect for the next-of-kin and possibly to gather the information that family members may have with regard to the health of a potential donor. In the case of somebody dying without having registered to be a donor, his or her organs may be removed only with the consent of his or her family.

The opt-out system is complex, gives rise to several difficulties and is very costly to implement. These resources could be better utilized if directed towards the continuing improvement of the opt-in system.

The following recommendations spell out the measures that need to be taken (a) to promote the opt-in system, (b) to manage it more effectively and (c) to ensure an on-going review:

5.1 Promotion

The opt-in system may be promoted in several ways. The following may be mentioned:

(i) Legislating to give legal validity to the donor card, while providing the necessary tools that can help relatives to cooperate in the deceased person’s act of gift;
(ii) Educating the public about the various aspects of organ donation;
(iii) An on-going educational campaign to encourage donors to inform relatives about their decision so that the latter may be able to accept the donors’ wish;
(iv) Offering better training to doctors and nurses to deal with potential donors and their families;
(v) Initiating an ethical debate on non-heart beating organ donation among healthcare professionals and the general public;
(vi) Having a law that is fair and seen to be fair by the public;

(vii) Distributing donated organs in a fair and open manner to remove any shadow of doubt regarding the way in which the system is operating;
(viii) Doctors should be encouraged to consider that it is their duty to request organ donation when such candidates exist.

5.2 Management

The following are some of the measures that can be taken to develop a sound management base for an opt-in system:

(i) Integrating the present system, which operates on an entirely voluntary basis, in the public health system. This could be done by creating an official register of donors that is continuously updated. The register should be easily accessible to doctors at the Intensive Therapy Unit at MDH for easy identification of potential donors;
(ii) Simplifying the opt-in system and providing more easily accessible information about the ways in which people can register;
(iii) Increasing the accessibility for every adult Maltese citizen to become an organ donor (for example, by asking the individual whether he/she wants to become an organ donor when registering for a driving licence or an identity card);
(iv) Strengthening the transplant donor coordinator currently existing;
(v) Ensuring that the Kidney Allocation Policy (including the one currently in use) is transparent, user-friendly and easily accessible to all stakeholders (patients, healthcare professionals and the general public).

5.3 On-going Review

Efforts should be made to make the best use of the donated organs. Continuous scientific development necessitates an on-going review of the allocation criteria for the best use of these scarce resources.

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