



Irish Medical Organisation
Submission to the Department of Health and Children on
The Introduction of an Opt-Out System of Consent for Organ Donation

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Submission on the Introduction of an Opt-Out System of Consent for Organ Donation from the Irish Medical Organisation

The Irish Medical Organisation is pleased to make a submission on the introduction of an opt-out system of consent for organ donation to the Department of Health and Children as part of consultation activities for the preparation of legislation.

The IMO acknowledges that the government intends to change the system of consent to one of opt-out consent. The IMO had formally advocated for the Hard Mandated Choice model as it, amongst other benefits, removes the burden of decision away from the family at an emotional time and places it on the individual when he or she is in a position to make an informed decision. However, the IMO accepts that the government has chosen to go with the opt-out model and, as such, we accept the invitation to submit our views on the practical aspects of introducing a system of opt-out consent for organ donation.

1. What are the major ethical or moral issues associated with the introduction of an opt-out model of consent?

The IMO does not have any major ethical or moral concerns with the introduction of an opt-out model of consent. However, at this time, we stress the importance of information being made available in the public sphere to ensure that more public awareness about organ donation is generated.

Additionally, legislation of an opt-out model of consent should be clear and transparent. Legislation needs to be the backbone of this model, to provide a legitimate framework for operation. It is also advisable that a regular review process be put in place to ensure that there is accountability for the procurement and use of all organs.

Furthermore, it is important that the donor's next of kin be kept up-to-date with the process. It is helpful to the family's grieving process to know that their loss has resulted in a benefit for another individual.

Regardless of the model of consent the IMO acknowledges that this is an issue about choice and that information is paramount to enable citizens to make informed decisions and that individual choice needs to be respected and accounted for.

2. What are the practical and operational issues to be examined in implementing this model?

Any model that requires a register of consent or objection will have practical issues surrounding its implementation. Often the turnaround times for organ donation and transplantation are quite short, therefore information regarding the potential donor and their consent status need to be collected in the most practical and time efficient manner as possible. The capturing of information on a large scale and maintaining confidentiality and information security is of the utmost importance. The practicality of administration may also need to be addressed.

Issues surrounding non-residents of Ireland also need to be accounted for. We believe it should be automatic that non-residents of Ireland should be excluded from organ donation. However, it is

important that the new legislation considers the issue of non-residents to ensure transplant coordinators and transplant teams have clear direction on this particular issue.

Another issue with any consent model is that the impact of donor policies in Europe found no obvious correlation between consent systems and donor efficiency.¹ Indeed, factors other than the consent system seem to be responsible for increased rates of organ donation particularly:

- Measures undertaken in hospitals to optimise donor procurement;
- Public awareness about the relevant aspects of organ donation.

As such, other factors to be considered in implementing this model include:

- Appropriate resources to design, implement and maintain central registry for Transplant Coordinators
 - The design of a central and secure database is a central component of the opt-out consent model. Proper funding should be allocated to its development and ongoing maintenance to allow Transplant Coordinators access to identify the preferences of prospective donors. Legislation should be in place to ensure the integrity of the database.
- A Sustained media campaign to generate public awareness
 - An ongoing media campaign in order to raise public awareness must saturate all areas of society, informing them of the facts and processes of organ donation, along with assurances that their family will be consulted and how to register their objection. Additionally, organ donation awareness should also be introduced into the educational environment, to ensure that adolescents reaching maturity are aware of the process, and to enable them to make an informed choice when they are older.
- Transplant Coordinators – improved function and increased number
 - Currently there are only five Transplant Coordinators in Ireland. Transplant Coordinators should be independent of the transplant team. In each of the donating hospitals there should be a designated person to take responsibility for the role of Transplant Coordinator. Their role should be that of liaising directly with the potential donor and their family, to talk through the donation process and provide any necessary assistance to the donation process.
- Increased funding towards training and equipment for transplant operations
 - Further resources should also be directed towards training and equipment in order to adequately perform transplants throughout designated centres in Ireland. Investigation into cost effective and suitable organ transportation methods should be conducted, with resource allocation supporting the best option.

3. Under a new statutory system, how should people opt out?

A person must register a formal objection during their lifetime if they do not want to become an organ donor after death. If a person wishes to become an organ donor after death, they do not need to take any action during their lifetime.

4. Should specific vulnerable groups be excluded from deeming their consent e.g. incapacitated adults?

¹ Coppen, Friele, Grevers, Blok and Van der Zee, "The Impact of Donor Policies in Europe: A Steady Increase, but not Everywhere", *BMC Health Services Research*, 2008 8:235 doi:10.1186/1472-6963-8-235

Legislation should allow for a process involving their legal guardians to facilitate children and incapacitated adults to make that decision. An age of consent should also be covered in legislation.

5. How should groups with religious or cultural objections be accommodated?

An individual must express their objection formally against organ donation through the national register.

6. Can an opt-out system of consent operate in the absence of a national register to record the wishes of those who wish to opt-out?

No. A secure, central register is essential for recording if individuals are opting out. It should be run independently from those carrying out transplant operations to ensure its integrity. It is not feasible to expect every individual's family to know their situation in relation to opting-out. As such, a national register is essential.

7. If a register is required who should hold this information?

The information should be recorded in a national database that is a secure record only to be accessed by transplant co-ordinators, and not medical staff that are part of a transplant team. Its security and protection is paramount to ensure individual choice and the inability to manipulate records from people outside the transplant coordination process. Information provided to people administering the database should be absolutely confidential. The easiest way to ensure identification would be by photo-identification or by an individual's PPS number. Consumer friendly processes should be applied to ensure that individuals are not intimidated by the procedure of registering their preference.

8. Should an opt-out system only cover the procurement of organs or should it also cover tissues that may be removed along with an organ e.g. heart valves?

The opt-out system should cover tissues that may be removed along with an organ. However, this ought to be made clear through legislation and through a public education and information programme. An individual must be able to opt-out and register objections should he/she wish. The deceased person's family must be consulted prior to removing any tissue. The Human Tissue Bill should set out a detailed consent framework in relation to donation of organs and tissues by living people for transplantation and research.

9. Should a person be able to register an objection to donating specific organs?

Yes a person should be able to register an objection to donating specific organs. The IMO is of the belief that a national register should have the capacity to accommodate the specific wishes of an individual.

10. Pending the development of a national system for individual health identifiers in this country, how can the record of those who have opted- out be best accessed in an accurate and timely fashion?

As a temporary solution, the IMO recommends the use of PPS Numbers to identify the record of those individuals who have chosen to opt-out. However, the IMO strongly recommends introducing a national system for individual health identifiers as soon as practicable.

11. If organs procured under the opt-out system are found to be unsuitable for transplantation, should these organs be eligible for use in research (which generally requires an explicit consent)?

Organs deemed unsuitable for transplantation should only be eligible for use in research if explicit consent has been acquired. As organs used for research are a separate issue to organs used for transplantation, separate explicit consent is essential.

12. What information is essential to include in a public awareness campaign about the opt-out system of organ donation?

It is important to acknowledge how vital a sustained public awareness campaign would be. An ongoing media campaign in order to raise public awareness must saturate all areas of society, informing them of the facts and processes of organ donation, along with assurances that their family will be consulted and how to register their objection. Additionally, organ donation awareness should also be introduced into the educational environment, to ensure that adolescents reaching maturity are aware of the process, and to enable them to make an informed choice when they are older.