Public Consultation

Introduction of an Opt-Out System of Consent for Organ Donation

Overview

This consultation document relates to new proposals on organ donation by deceased people.

Organ transplantation adds years of life as well as quality of life to organ recipients. Ironically, however, its success, has led to organ shortages in Ireland and throughout Europe, and so heightens the need for more donations and transplant procedures to be undertaken.

In 2012, there were a total of 78 deceased donors which resulted in 244 organs being retrieved. This equates to a donor rate of 17.03 per million population (pmp). In comparison, Spain had a rate of 35.3 pmp (in 2011) while the UK had a rate of 17.4 in 2012. There are approximately 650 people on the organ transplant waiting lists.

Given the scarcity of organs available in Ireland for transplantation, it is important that as a society we do all that we can to increase the number of organs available for transplantation. A critical part of this is to build on the current positive attitude towards organ donation. In this context, the Programme for Government commits to introducing an opt-out system of organ donation, with a view to improving the availability of organs for patients in need of transplantation.

Currently in Ireland, when a potential organ donor is identified, the person's family is asked for their consent to allow organ donation to take place. This is known as “express” consent or an “opt-in” process to becoming an organ donor. In other words, the choice and the decision to become an organ donor rests with the family of the deceased.

The Government now intend to change this system of consent to one of opt-out consent. What this will mean in practice is that the health professionals involved will not have to actively seek the deceased's family's express consent for organ donation. Instead, consent will be deemed unless the person has, while alive, registered his/her wish not to become an organ donor after death. This is known as “opting-out”. However, it is proposed that, even though consent is deemed, the family will in practice always be consulted prior to removing any organ and if the family objects to the organ donation, the donation will not proceed. This is what is known as a “soft” opt-out system.
**Context**

The Department is currently preparing legislative proposals for a Human Tissue Bill which will legislate for the giving of consent for the removal, retention, storage, use and disposal of organs and tissues from deceased persons in the context of post-mortems, transplantation, research or anatomical examination. The Human Tissue Bill will also set out a detailed consent framework in relation to donation of organs and tissues by living people for transplantation and research.

A public consultation took place in 2009 seeking views on the question of which system of consent for organ donation Ireland should adopt in regard to organ donation by deceased people. The views of interested parties were sought on three systems – opt-in (the current system), opt-out and mandated choice/required request.

While the Government at the time decided to proceed with the Human Tissue Bill on the basis of maintaining the current system of consent i.e. opt-in, the Programme for Government commits to introducing an opt-out system of consent.

Countries which operate an opt-out system generally have higher organ donation rates. Ireland is among a minority of EU Member States, including the United Kingdom, the Netherlands and Germany that don’t operate an opt-out system.

The Department is aware that changing the system of consent is just one aspect in a package of measures that will be required to increase organ donation rates. In this regard, the Department, in conjunction with the HSE’s National Organ Donation and Transplantation Office, is considering what practices and organisational changes, along with a change to the consent system, could further improve donation rates in this country.

**What Will Opt-Out Mean in Practice?**

If a person does not wish to become an organ donor after death, they will need to register a formal objection during their lifetime - a process known as opting out. If, on the other hand, a person wishes to become an organ donor after death, they do not need to take any action during their lifetime.

The deceased’s family or next of kin will still have an important role to play in the process of organ donation. While the next of kin will not be required to give their consent to the donation itself, they will be consulted and asked to provide as much information as possible on the person’s medical and social history. As stated earlier, it is intended that, in practice, there would be no instance whereby organ donation would proceed against the wishes of the next of kin of the deceased. It is also intended that safeguards will be included in the legislation to protect vulnerable groups in society.

The system to be introduced could therefore be described as one of “soft opt-out”.
Who Will Be Affected by this Policy Change?
Following enactment of the legislation, all those over the age of 18 who live and die in Ireland will be considered as potential organ donors unless they opt out in their lifetime. A person will need to be “ordinarily resident” in Ireland for 12 months or more for the new opt-out consent law to apply to them. After this period, people will be deemed to have given their consent to donation, unless they had already stated they did not wish to be a donor.

Who Will Not Be Affected by this Policy Change?
Not every person who dies in Ireland will be deemed to have consented to organ donation. The proposed opt-out arrangements will not apply to children (i.e. people under the age of 18) or to people living in Ireland at the time of their death but who are not ordinarily resident in this country. The Human Tissue Bill will set out separate consent provisions for such people. In addition, operational arrangements may be needed to support some groups in making a decision.

We Would Like Your Views
The Department wishes to invite interested parties to submit their views on the practical aspects of introducing a system of opt-out consent for organ donation.

The Department would be interested to hear your general views but would particularly like your views on the following questions:

1. What in your view are the major ethical or moral issues associated with the introduction of an opt-out model of consent?
2. What are the practical and operational issues to be examined in implementing this model?
3. Under a new statutory system, how should people opt out?
4. Should specific vulnerable groups be excluded from deeming their consent e.g. incapacitated adults?
5. How should groups with religious or cultural objections be accommodated?
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?
7. If a register is required who should hold this information?
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?
9. Should a person be able to register an objection to donating specific organs?

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?

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)?

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

How to Respond

Written responses by individuals, groups or organisations are welcome and should be sent by e-mail to: optout@health.gov.ie or posted to: Opt-Out Consent Consultation, Department of Health, R. 309, Hawkins House, Hawkins Street, Dublin 2.

Latest date for receipt of responses is Friday, September 20th 2013.

For further information please contact the Blood and Organs Policy Unit at the Department of Health at (01) 6354732 or (01) 6354196.

How Your Response Will Be Used

The Department will publish a summary of the submissions received as part of this consultation on its website. It is likely that this summary will contain a list of those who have made submissions and may include direct quotes from some submissions. In such cases it is intended to attribute these quotes to the person or group who made the submission.

If you do not want your submission to be referred to in the circumstances described above, please let the Department know at the time of your submission.

All submissions received will be subject to the Freedom of Information Acts 1997 and 2003 and may be released in response to a Freedom of Information request.

Department of Health
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