

SAVING MORE LIVES: BRINGING IRELAND'S ORGAN DONOR CONSENT INTO THE



MODERN AGE

Department of Health Consultation on the Human Tissue Bill 2017

22 September 2017



## Executive Summary

The Irish Donor Network (IDN) welcomes the introduction of opt-out consent as part of the forthcoming Human Tissue Bill (2017). The IDN represents seven patient groups concerned with organ donation and transplantation in Ireland. We contend that a soft opt-out system of consent as opposed to the opt-in policy, currently in operation in Ireland, will be better because:

- 1. It will save more lives:** The number of people awaiting organ transplants in Ireland is more than double the operations carried out. 587 people are currently waiting for potentially life changing organ transplants in Ireland in 2017. If more organs become available, more life-saving transplants can be undertaken.
- 2. It will bridge the gap between intention and the actual gift of organ donation:** The introduction of a 'soft' opt-out organ donor consent system in Ireland will bridge the gap between people's intentions and their behaviour. 85% of people in Ireland are willing to donate organs but only one third of us carry an organ donor card and many of us do not inform our next of kin of our intentions to donate or otherwise. This results in fewer organs than possible being donated.
- 3. It will improve organ donor rates in Ireland:** Ireland is in only 15th place out of the 28 European Union countries when it comes to organ donation, despite our very high support for organ donation. International evidence has confirmed the positive impact of opt-out consent on deceased organ donor rates. Over a three year period, after making the change to an opt-out system, Belgium saw its rate of organ donation increase by 100%. The recent experience in Wales with soft opt-out has also been very positive. The countries with the best rates of organ donation in Europe have some form of soft opt-out system combined with sufficient infrastructure.
- 4. It will modernise our organ donor system:** Organ donor cards and similar ad hoc initiatives such as phone apps or use of the driver license have had their day. They were useful and worthy in the past, but how many of us have lost and not replaced our donor cards? How many of us have not informed our next of kin of our organ donation intentions? The introduction of an online register for opting out of organ donation will bring Ireland into the modern age.
- 5. Organ donation will continue to be a 'gift of life'.** The new system will continue to embrace the concept of organ donation being a 'gift of life'. The only difference is that potentially more organs will be donated and as a result more families will benefit from the gift of life. Next of kin will continue to be consulted so no family will be forced to donate the organs of a loved one.
- 6. Ireland has sufficient resources to make soft opt-out succeed.** We will always need more resources for our health system, but in this case it should be noted that in Budget 2014 an additional €2.92m was granted specifically for the introduction of soft opt-out.



7. **'Let us get on with it'**. This proposed policy has been included in the last two programme for governments with no significant advances until the recent decision to implement the Human Tissue Bill (2017). Meanwhile, people continue to die waiting for a life-saving organ transplant in Ireland. Sufficient resources are in place, though more could always be provided (for example the opening of additional pre and post-transplant rooms) but this is not a reason to further delay this vital legislation.



## Who We Are?

The IDN is comprised of patient groups with a direct interest and concern in organ donation and transplant issues in Ireland. The role of the IDN is to bring groups together to encourage and help facilitate organ donation and contribute to the shaping of health policy and public awareness on donation and transplantation issues.

We have been involved in organ donor awareness for many years. We have made many submissions on soft opt-out over the past five years. Further, we successfully supported the transposition of the EU Directive on organ donor safety and quality in 2013 and we also successfully lobbied with others for the additional resources needed for transplant and donor co-ordinators in 2014 (€2.92m). The Associations and groups that make up our membership are listed below:

- **Alpha One (Antitrypsin) Foundation:** The Alpha One Foundation was founded in 2001 to raise awareness, increase diagnosis, promote research and improve the treatment of Antitrypsin Deficiency (Alpha-1). [www.alpha1.ie](http://www.alpha1.ie)
- **Cystic Fibrosis Ireland (CFI):** CFI was founded in 1963 to support people and families living with Cystic Fibrosis (CF). Many people with CF will need a double lung transplant because of the damage caused to lungs by CF. [www.cfiireland.ie](http://www.cfiireland.ie)
- **Chronic Obstructive Pulmonary Disease Support Ireland (COPDSI):** COPDSI provides support for people with COPD in Ireland. [www.copd.ie](http://www.copd.ie)
- **Cystinosis Ireland:** Cystinosis is a rare, degenerative, inherited disease which frequently requires the need for kidney and sometimes other organ transplants. [www.cystinosis.ie](http://www.cystinosis.ie)
- **The Irish Heart and Lung Transplant Association (IHLTA):** The IHLTA is a voluntary organisation which includes heart, lung(s), heart and lung transplant recipients, family and supporters. [www.ihlta.com](http://www.ihlta.com)
- **The Irish Lung Fibrosis Association (ILFA):** The ILFA was set up in 2002 to support patients and families living with Idiopathic pulmonary fibrosis (IPF). [www.ilfa.ie](http://www.ilfa.ie)
- **The Pulmonary Hypertension Association Ireland:** PHA Ireland was established in 2005 to raise the profile of Pulmonary Hypertension (PH) and to support patients who are diagnosed and living with this disease in Ireland. Persons with PH may require lifesaving lung and liver transplants.

## Reason for Submission

The IDN has prepared this submission to confirm its support for Government's introduction of soft opt-out consent to organ donation as part of the Human Tissue Bill (2017). We welcome this proposed change subject to detailed examination of the forthcoming published legislation. We contend that a soft 'opt-out' system of consent as opposed to the 'opt-in' policy, currently in operation in Ireland, will make more organs available for donation by creating more potential donors.

This is because under an opt-out system, unlike under an opt-in system, individuals are presumed to want to donate their organs unless they opt out, usually through an online registry. For those who decide not to opt out, the important protection whereby



their next of kin will continue to be consulted before organs are donated will remain. With adequate public support and the right implementation, the introduction of soft opt-out will be a success, which will neither undermine personal autonomy nor the concept of organ donation as a gift.

### **Bridging the Gap Between Intention and the Actual Gift of Organ Donation**

In Ireland, an opt-in consent system for organ donation is currently in operation. It requires donors to explicitly consent to leaving their organs for donation. This is achieved through carrying an organ donor card. Alternatively, individuals can note their intention to donate on the organ donor e-card smartphone app or on their driver's license. Willing donors are asked to inform their family of their decision, as it is next of kin whose consent is currently required to authorize the donation of the deceased's organs. If no next of kin is available, or if they are indecisive, no consent is provided and organ donation does not proceed.

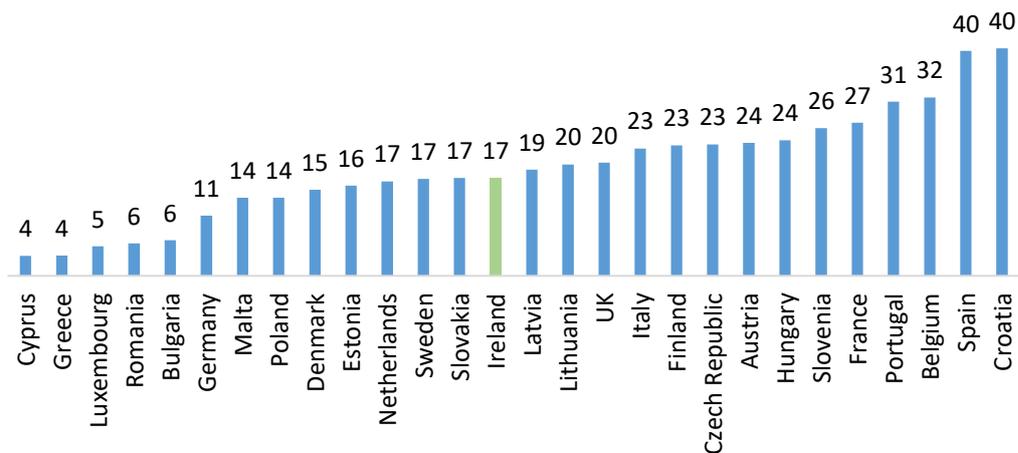
#### **The IDN notes the following problems with the present system:**

1. Prospective donors have to opt in to the system
2. Many people do not tell next of kin of their organ donor intentions
3. Many lose and do not renew their organ donor card
4. There is little evidence that the support for organ donation on the Irish driver's license is effective beyond raising general awareness
5. The pool of potential organ donors is significantly smaller in an opt-out system

While we recognise that organ procurement services have been enhanced and new regulations for quality and safety have been implemented in respect of organ donation and transplant services, we must also accept that under the current 'opt-in' system, used by only a handful of countries in the European Union, organs are being lost that could save lives.

As a result, Ireland lies only in mid-table when it comes to a comparison with rates of organ donation in other European Union countries. In 2015, Ireland was in 15th place for deceased organ donation out of the EU28 countries, with 17 deceased donors per million, compared with 40 deceased donors per million in Croatia and Spain, which have a soft 'opt-out' system (Figure 1).

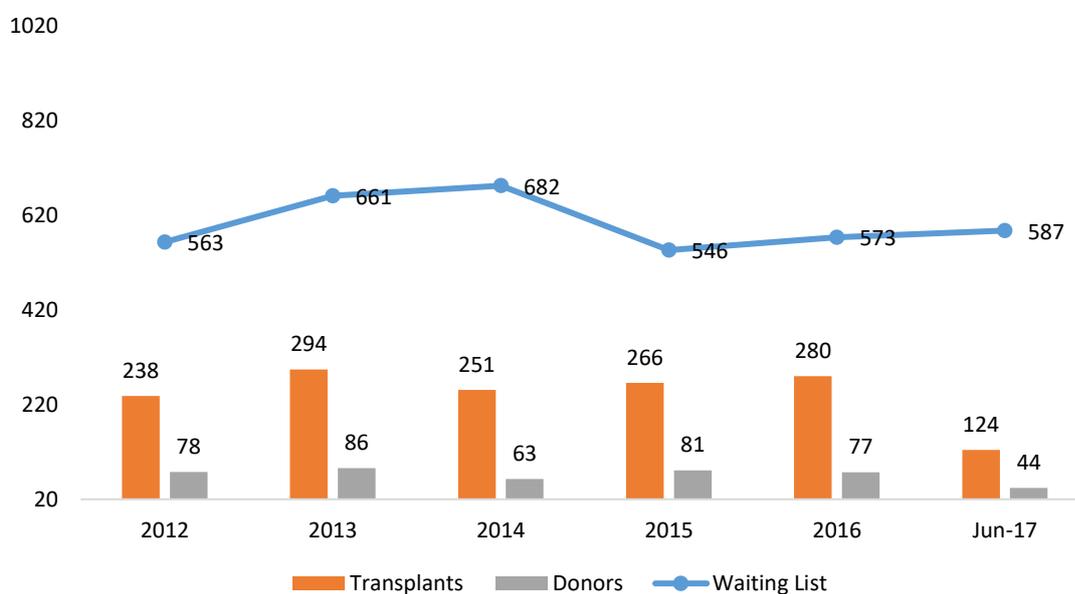
**Figure 1:** Deceased donors per million across EU28 (2015)



**Source:** 2016 Newsletter of the European Directorate for the Quality of Medicines (EDQM)

In 2016, 280 organ transplants were successfully undertaken but approximately 573 patients were still on the waiting list for lung, heart, liver, kidney, or pancreas transplants at the end of the year. This number has since increased to 587 so far in 2017 (Figure 2).

**Figure 2:** Deceased donors, transplant operations and 'active' transplant list (2012 - Jun 2017)



**Source:** Written answer 776. 26 July 2017. Health Minister's response to parliamentary question from Deputy Louise O'Reilly in relation to organ donation data.



We maintain that due to the serious shortage of organ donors and consequent long waiting lists for transplant operations in Ireland that we must change our current approach to organ donation to a soft opt-out model of consent.

According to public surveys, approximately 85% of the Irish population are willing to donate their organs, yet only one third of respondents carry a donor card<sup>1</sup>. The new soft opt-out system will remove the increasingly outdated system whereby capturing donors' intentions is reliant upon carrying an organ donor card or linked initiatives, including the use of a driver's license whereby you have to opt-in to indicate your wish to donate organs. Therefore, if this survey is representative of the public's opinion, the introduction of an opt-out system will increase the number of donors and would give added protection to those who do not wish to donate, as their details would be included in an opt-out register.

This new soft opt-out consent system will replace reliance on the worthy but ad hoc organ donor card system of past years. This opt-in system was useful in the past, but there is evidence that it is no longer fit for purpose as the intentions of many potential organ donors continue to remain unknown. The change will not be complex as it will just involve making the process of organ donation much more straightforward but it will require the Government to clearly set out the detail of the change through a series of public information initiatives.

**Conclusion: How a soft opt-out organ donation system would operate in practice?**

### **Hard Versus Soft Opt-Out**

The IDN recognises the additional €2.92 million for organ donation posts given in 2014. There are additional resources needed for the organ donation and transplant system in Ireland, including for example, the opening of pre and post-transplant rooms, but these should not be made an excuse for not introducing a soft opt-out system.

We agree with a soft opt out system whereby next of kin are always consulted in the event of forthcoming decision on organ donation and their wishes fully respected. This is in keeping with the present ethos of 'a gift of life' and represents an important and practical protection for the deceased and their family. Countries, such as Austria, that have gone down the route of adopting hard opt-out consent, where next of kin is not consulted, have discovered that this model is unworkable and have dropped the system.

The introduction of the "soft" opt-out system would also convey advantages because it facilitates the initiation of communication about organ donation with next of kin. This will result in more people being registered to donate their organs and ultimately in more lives being saved. With adequate public support and the right implementation, the introduction of soft 'opt-out' will be a success, which will neither undermine personal autonomy nor the concept of organ donation as a gift.

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<sup>1</sup>*Organ Donation and Transplant Ireland Annual Report 2015.*



## **Public Support and Awareness**

The experience of the introduction of soft opt-out in Wales offers key lessons for the introduction of soft 'opt-out' in Ireland. It highlights the importance of public awareness and its role in increasing overall family consent rates for organ donation, alongside the introduction of opt-out consent. The Welsh Government made significant efforts to inform the public of the exact nature of the new soft opt-out system in the two years prior to its introduction. During this period, the number of organ transplants increased each year, from 120 between the 1 December 2013 and 31 October 2014, to 160 between 1 December 2015 and 2016<sup>2</sup>.

According to the Human Tissue Bill (2017) consultation questionnaire document, the introduction of opt-out consent in Ireland will similarly be accompanied by a publicity campaign aiming to raise awareness of organ donation among individuals and to encourage discussion among families of their intentions in relation to organ donation. This should take the form of high profile, awareness-raising campaigns for at least 12 months before the introduction of the new system and on a regular basis after implementation.

Flanking measures to support soft opt-out should also include:

- The opening of pre and post-transplant rooms
- Resources to fund an ongoing public awareness campaign
- The development of a secure, regularly updated, national electronic registry for organ donation, which accounts for and facilitates the fact that some people may change their mind. .

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<sup>2</sup>UK first, Welsh organ donation system celebrates first anniversary

*The Irish Donor Network Support for 'Soft Opt Out' Organ Donation*