

Presentation to the Joint Oireachtas Committee on Health

16 October 2019

From: The Irish Donor Network

In favour of the Human Tissue Bill and Soft-Opt Out Organ Donation, but also calling for the necessary resources for implementing the legislation.

1. Introduction

Organ donation is a precious gift that saves lives. In large part due to a shortage of organs, people continue to die in Ireland unnecessarily while on the waiting list for the organs they desperately need in order to preserve and enhance their lives and health.

One organ donor can potentially save 7 lives. There are also benefits to their families, Irish society in general, the Irish health system and the wider economy in promoting transplantation. That is why the Irish Donor network (IDN) is committed to encouraging transplantation and to increase the numbers of donors and of lives saved.

In this context the IDN warmly welcomes the introduction by Minister Simon Harris T.D. and the Irish Government of the Human Tissue Bill, 2019, and in particular the provisions to provide for an Opt-Out system of consent for organ donation and for an associated register. We note that this change is also widely supported by most political parties in Ireland, the medical community, by the vast majority of relevant patient groups and the general public.

However, we also wish to make clear in this submission that the ambition to make more organs available for transplant may be blunted/not reach full potential if it is not accompanied by the necessary supporting resources and infrastructure including in particular:

- More organ retrieval surgeons
- More donor nurse specialists in major ICU hospitals
- Improved hospital infrastructure and staffing levels in the 3 transplant centres (Mater; Beaumont and St Vincents' Hospitals), including pre and post-operative rooms and sufficient access time to operating theatres.

- Sufficient resources for a national public awareness programme to explain the change to soft opt out and for an easily understood and accessible on line opt out registry
- Some modest resources to patient groups to support the public awareness programme that will accompany the Human Tissue Bill.

2. The Irish Donor Network

Just a brief word about ourselves: The IDN is comprised of the following patient groups:

- Alpha One Foundation (A1)
- Chronic Obstructive Pulmonary Disease Support Ireland (COPD)
- Children's Liver Disease Ireland (CLDI)
- Disease Support Ireland (COPD)
- Cystic Fibrosis Ireland (CFI)
- Cystinosis Ireland (CI)
- The Irish Heart and Lung Transplant Association (IHLTA)
- The Irish Lung Fibrosis Association (ILFA)

Soft opt out is also supported by the Irish Heart Foundation; the Irish Thoracic Society and the Irish Hospice Foundation and many other key stakeholders concerned with organ donation and transplantation in Ireland.

3. Why IDN supports the Human Tissue Bill and Soft Opt-Out

The IDN strongly supports the introduction of a 'Soft Opt-Out' system for organ donation, which basically means an opt-out system with inherent safeguards. The IDN has been campaigning for such a system for many years

Under the proposed new system, the donor's next of kin would still be consulted, but the deceased donors' consent would be presumed unless there is evidence that they do not wish to donate. An alternative approach is the 'Hard Opt-Out' system that would seek to deny any say on organ donation from the potential donor's next of kin. This approach was tried in some countries (Austria for example) and did not work and such a Hard Opt-out approach would not work in Ireland in our view. In short, we welcome the overall approach adopted in the Human Tissue Bill.

While it is always challenging to make direct comparisons with other countries, the decision to bring in Soft Opt-Out in Ireland follows the success of Soft Opt-Out in many other EU countries including in particular Austria, Spain and Belgium.¹

There has also been a strong momentum growing in the UK to introduce Soft Opt-Out in recent years. In England, the Organ Donation (Deemed Consent) Bill has passed through the UK Parliament, with implementation due to start in April 2020. This will replace the present on line Opt in *and* Opt out system which has failed to deliver and which should not be considered for Ireland. Under the existing system, only 38 per cent of the UK population has registered their wish to opt in on the existing online organ donor register, which is why most UK health bodies concerned with transplant are now seeking to replace this approach.

In short, IDN does not want to import an opt in and opt out system into Ireland, because this system has clearly demonstrated failure in England.

Donor cards, apps, codes on drivers licenses are worthy additions to any public awareness programme, including those going forward and have served an important public awareness purpose in the past in Ireland. However, they are not a substitute for a comprehensive organ donor consent legislative process and a system based on evidence.

In Scotland, a new Bill was enacted in July 2019. In Wales, such a system has now been in place since December 2015. In 2017 there were 39 organs transplanted in Wales using its deemed consent system out of 160 organ transplants. Only 6% of people opted out of the system. Authoritative research published in BMJ concluded that the change in Wales had a positive impact on donation but stressed the importance of supporting initiatives and investment to ensure continued progress.

The groups involved in the IDN have been involved in supporting organ donation for many years The IDN believes that, as part of a broader strategy, including improvements in organ donation and transplantation infrastructure, resourcing and organisation, a shift to an opt-out system will have a positive impact on donation rates. While there are challenges in drawing direct comparisons from the experiences of other countries, comparative research

¹ Shaw et al (2017) Family over rules? An ethical analysis of allowing families to overrule donation intentions. *Transplantation* 2017; 101; 482-487.

has found that an opt-out system is one of a number of factors that are positively associated with higher donation rates.

Independent research evidence by the University of York, which undertook a systematic review of the published data, showed a positive association between opt-out legislation or practice and higher rates of donation.²

- Four methodologically sound studies comparing donation rates in countries with and without opt-out found that opt-out law or practice was associated with increased donation rates. In three of the studies the increases were statistically significant.
- Five methodologically sound studies comparing donation rates in a single country before and after the introduction of an opt-out law all found a consistent increase in organ donation rates following the introduction of legislation.
- More recent evidence reviews, for the Welsh and Scottish Governments, have reached similar conclusions.³

Research undertaken in Ireland shows that 80 per cent and more, support organ donation but only about a third of us tend to carry a donor card. The IDN supports the principle behind an opt-out system, that if people don't object to their organs being used after death, they should be used to save lives. Under an opt-out system, individuals have the same choice as in an opt-in system—to donate or not to donate—so individual autonomy and choice are protected and respected under this proposed new system.

It is simply the way people's views are expressed that would change. All organ donation is a gift and should be recognised as such, irrespective of the model of consent in place. Families are often comforted by knowing something good has come from their loss.

The expectation of IDN is that, under an opt-out system, organ donation would become the default position which, over time, changes expectations in society and becomes the societal norm. Thus, there would be a shift where donation is natural and expected thing to do.

² British Medical Journal. Extensive list of research and opinions on presumed consent and organ donation

³ Rithalia, A., [McDaid, C.](#), [Suekarran, S.](#), [Norman, G.](#), Myers, L. & [Sowden, A.](#), Various publications over the past decade

4. Living Kidney Sharing Scheme

This allows for a kidney donation from a stranger or a relative or a friend. The sharing scheme is presently available and working well in Northern Ireland with 89 donors that were not relatives in recent years. IDN supports the emergence of a Living Kidney Sharing Scheme in the Republic of Ireland to be facilitated through the Human Tissue Bill.

5. Public Awareness Programme Needed

Even where there is widespread support for a new measure, public awareness about any such important proposed changes is crucial. IDN welcomes government commitment to a national public awareness campaign. IDN contends that this campaign should be a well-resourced, high-profile, consistent and persistent publicity campaign to enable a more informed public debate.

The success of an opt-out system relies upon people knowing about their options and being able, easily and quickly, to opt-out if that is their wish. This is not about forcing people into donation. It is about making it as easy as possible for an individual's willingness to donate organs after their death to be acted upon. Additionally, publicity will increase awareness about transplantation and its benefits, increase the understanding and social acceptability of organ donation, and promote discussion within families and between friends, so that there is greater awareness of individuals' wishes. The key factor should be what the deceased person wanted in relation to donation. The family's role should be to provide information to contribute to the decision, rather than to give consent themselves but if they have strong objections this should also be respected.

The success of an opt out system in Ireland is also dependent on investment in transplantation infrastructure and human resources, building on previous investment and In particular:

- More retrieval surgeons in the major ICU hospitals in Ireland
- Nurse specialist Organ Donor Coordinators in the major ICU hospitals in Ireland

- Adequate resourcing of pre and posttransplant rooms in the 3 transplant hospitals in Ireland – The Mater (MMUH); St Vincent’s (SVUH) and Beaumont Hospital
- Adequate resourcing to patient groups supporting the change to Soft Opt Out.

Conclusion

People continue to die waiting for a transplant in Ireland. The submission from the 8 patient groups of the IDN contends that the momentum in Ireland for change is growing, as it is with our nearest neighbours in the UK, However as with all major changes, the introduction of Soft Opt-Out needs to be accompanied by a persistent, continuing and adequately resourced public awareness programme, an online opt out registry and a significant additional investment in transplant infrastructure and key specialised staff. Patient groups in particular the IDN has played a key role in supporting this change. A Living Kidney Sharing Scheme should also be facilitated by the Human Tissue Bill. Some modest resources to help raise public awareness before and after the Human Tissue Bill is enacted, would also be welcome.

IDN wishes to acknowledge the work of senior officials in the ODTI, HSE and the Department of Health, Including Ministers’ Simon Harris TD and Finian McGrath TD in preparing the Human Tissue Bill. We urge that this legislation is enacted as soon as possible.