Joint Submission on Organ Donor Consent from:

Alpha One Foundation  
Cystic Fibrosis Ireland  
Irish Heart and Lung Transplant Association  
Irish Lung Fibrosis Association

September 2013

The need for a ‘Soft Opt-out Plus’ approach to the proposed change in organ donor consent Ireland.

4 patient groups have come together to make this submission. These are the Alpha One Foundation, Cystic Fibrosis Ireland, Irish Heart and Lung Association and the Irish Lung Fibrosis Association. We support the change to a soft opt approach plus the essential transplant and donor infrastructure that is needed to maximize the impact of soft opt out on donor and transplant rates in Ireland.

About 30,000 transplant operations were carried out in Europe in 2012 as advances in medical treatment keep people alive who previously would have died at a much earlier age. However the figures are also stark. Only 10 per cent of people who need a new organ in Europe will eventually get one. There were 61,500 people on the waiting lists in Europe and 5,500 were estimated to have died in 2011.¹

It has been estimated that there may be as many as 650 people in Ireland waiting for a kidney, liver, lung, heart or pancreas transplant. A significant proportion of these will die on the waiting list.

There is a challenge for health services across the EU, including Ireland, to ensure that organ donor and transplant systems are working at optimum levels while maintaining the highest possible standards.

Transplantation, taking account of the risks and possible adverse events that are always associated with such surgery, can extend and significantly improve the quality of life. Transplantation can also be justified from an economic as well as an ethical/medical perspective as those waiting for a transplant are often in need of expensive on going in-patient and out-patient care.

This paper supports a change to a soft-opt out system of donor consent, but emphasises that this change needs to be part of a package of measures to address existing gaps and weaknesses in organ donation and transplant infrastructure in Ireland. In short this paper advocates a ‘soft opt out plus’ approach

http://ec.europa.eu/health/blood_tissues_organs/docs/ev_20121009_facts_figures.pdfs
‘Hard’ and ‘Soft’ Opt-Out

In recent years the concept of ‘hard’ and ‘soft’ opt-out has entered into the discussion on organ donation consent. In this context, ‘hard’ and ‘soft’ indicates how much weight is placed on the views of Next-of-Kin (NOK).

‘Hard’ equals no consideration of NOK agreement to organ donation and ‘soft’ equals significant consideration of NOK views. There are very few countries that operate a ‘hard’ opt-out approach. Even those countries such as Austria, that profess to have a hard opt-out system in practice operates a soft-opt out system.

Soft opt-out is the position advocated by the Irish Government in their recent consultative document on organ donor consent and this is to be welcomed.

Present Position in Ireland and Proposed Change

The Irish Government is committed to introducing an opt-out approach as part of the forthcoming (and long delayed) Human Tissue Bill.

The Programme for Government published in 2011 states:

‘We will legislate to change the organ donation to an opt-out system for organ transplantation, rather than an opt-in system, so as to improve the availability of organs for patients in desperate need’.²

The approach of the government was further detailed in the present consultative process which proposes to include opt-out organ donation in the forthcoming Human Tissue Bill.

‘Currently in Ireland, when a potential organ donor is identified, the deceased 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, including where the deceased person had an organ donor card or had indicated their wish to become an organ donor on their driving licence.

The Government now intends 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 system³

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² The Government for National Recovery 2011-2016, p58
³ [http://www.dohc.ie/consultations/open/SystemConsent_OrganDonation/]
The present rate of organ donation in Ireland?

In recent years, Ireland has maintained a fairly average but fluctuating rate of organ donation by international standards. In 2011 for example, there were 93 deceased organ donors in Ireland, representing a deceased organ donor rate of 20.67 per million of population (pmp). As a result, Ireland was in 10th place, out of a total of 31 European countries covered by the Council of Europe organ donor table.

However it should be noted that in the same year (2011) four countries, Spain, Croatia, Belgium and Malta had a deceased organ donor rate of around 30 per million population or more, a figure that should become a benchmark to which Ireland could aspire. These are all countries with both a soft opt-out system and good transplant and organ donation infrastructure.

It is also important to highlight that in 2010 there was a significant dip in the deceased organ rate in Ireland which resulted in Ireland dropping to the bottom third of the organ table for the first time. Further, a 2008 HSE audit showed that up to 21% of potential organ donors in Irish hospitals were being missed.

In short, the rate of organ donation in Ireland could be significantly higher than at present compared with other countries and there could also be greater year to year consistency in the rate of organ donation.

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What are the factors that increase organ donation and transplantation?

Many countries, including Spain, Austria, Croatia, Singapore, Portugal, the Czech Republic and Belgium have opted for a change in organ donor consent to the soft opt-out approach.

This change to opt-out organ donation was widely recognised as a key factor that has increased organ donor and transplant rates in these countries in recent years.

However, it is also widely acknowledged in much recent analysis that the effectiveness of opt-out is interdependent with the standard of donor and transplant infrastructure in those countries.

Developments in the UK

The move to a soft opt-out position is under consideration in parts of the UK.

The BMA (British Medical Association) has supported a change in legislation to opt-out with safeguards (soft opt-out) since 1999. This policy has been reaffirmed on many occasions since. The main reasons for the BMA’s support can be summarised as follows:

- ‘We believe that, as one part of a broader strategy, a shift to an opt-out system will have a positive effect on donation rates.
- Studies show that a large majority of people would be willing to donate but only 29% of the population are on the NHS Organ Donor Register or carry a donor card. While this level of apathy exists despite people’s good intentions, people will continue to die while waiting for donor organs.
- The BMA supports the principle behind an opt-out system – that if people do not object to their organs being used after death, they should be used to save lives.
- Under an opt-out system individuals have exactly the same choice as in an opt-in system – to donate or not to donate.
- The decision not to opt-out of donation is as much of a gift as a decision to opt-in.
- An opt-out system gives added protection to those who do not wish to donate and makes it more likely that those who are willing to donate will be able to do so.
- Organ donation becomes the default position which, with public support, changes cultural expectations in society. This represents a more positive view of organ donation which is to be encouraged.
- Overall an opt-out system is better for recipients (because more organs will be available) better for donors (because it is more likely their wishes will be respected) and better for relatives (because it is more likely that the individual’s own wishes will be known).’
In July 2013 the Welsh Assembly was the first administrative area in the UK to move to an opt-out system.

Welsh Assembly Members voted in favour of the bill by 43 votes to 8, with two abstentions. The Welsh government said it hoped the new law would increase donors by a quarter.

The position in Ireland

An external review on transplant services in Ireland commissioned by the National Organ Donation and Transplantation Office (NODTO) in 2011 identified systemic issues that need to be addressed in Ireland.

They provided 10 recommendations including the need for an enhanced procurement organisation, the placement of key donation personnel (Donor Coordinators) in Intensive Care Units throughout the country and the provision of adequate resources for the NODTO.

There are differences between organ transplant programmes in Ireland.

For example if we look at the 2011 Council of Europe figures again, Ireland was 8th out of 30 countries in the European league table for kidney transplantation, 12th out of 28 countries for liver transplantation and we were 12th out of 22 for pancreas transplantation.

By contrast Ireland was in 24th place in respect of heart transplantation and 15th out of 20 countries in respect of lung transplantation.

With the appointment of a dedicated lung transplant surgeon in the Mater in late 2011, there has been a significant increase in overall lung transplantation in 2012 and 2013 figures indicate further improvements in the rate of transplantation with 6 IPF transplants already performed up to mid-July.

The National Organ Donation and Transplantation Office has indicated that the following targets are achievable for Ireland if the infrastructure is improved and soft opt-out is introduced:

- Increase deceased organ donation rates from 18pmp to 24pmp
- Increase living renal transplant rate to 30% of deceased donation
- Increase heart donation conversion rates from 13% to 25%
- Increase lung donation conversion rates from 16% to 35%
- Establish a deceased cardiac donation (DCD) programme

In short, there needs to be improvements across all organ donor and transplant infrastructure in Ireland but with a particular additional focus in respect the heart and lung transplant programmes.

This must build on the recent progress brought about by the appointment of the first dedicated lung transplant surgeon in the Mater Hospital in late 2011. This appointment was strongly supported and lobbied for by patient groups.

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More needs to be achieved; the appointment of a cardio-thoracic surgeon to replace the eminent surgeon, Mr Freddie Wood, has been promised by the HSE but still not delivered.

The recently opened new ward block in the Mater Hospital, including dedicated post-transplant rooms, and the 12 new operating theatres are to be welcomed. However 3 of these operating theatres are not in service because of a lack of anesthetists.

Additional resources for the Kidney transplant programme are needed. The recent investment by government in the living donor programme is to be welcomed but further resources are needed. Those who are donating to the living donor programme should have their out-of-pocket expenses met by the Government, consistent with the recent EU Directive on Quality and Safety of Human Organs used in Transplantation.

Towards Soft Opt-Out Plus

This submission supports the change to a soft opt-out system of organ donor consent plus a range of measures to improve transplant and donor infrastructure including in particular:-

- The appointment of a network of organ donor coordinators in our major ICU hospitals.
- To give adequate resources for the National Organ Donation and Transplant Office, led by Professor Jim Egan
- To bring in further measures to improve the kidney, lung, heart, pancreas and liver transplant programmes in Ireland.

Response to Specific Questions in DOHC Consultative Document

The DOHC consultative paper asks a number of specific questions that are responded to in this section of our submission

1. The major ethical issue would be to ensure that the necessary infrastructure is in place to support soft opt-out. Without these measures the impact of soft opt-out could be severely blunted.
2. The major practical and operational issues have been set out in this document including assignment of donor coordinators to major ICU hospitals; adequate public awareness programmes involving both the State and the patient groups and adequate resources for NODTO.
3. Normal protocols should apply to vulnerable groups such as those with an impaired ability to make a choice to opt out.
4. Sensitivity to cultural practices related to death is an important issue that should be taken into account through consultation with the potential donor’s family or through the ability to opt-out.

From January 2013 to date 31st July 2013:
There have been 53 Deceased Donors to date
Renal Transplants - 109 (of which 89 were deceased donations and 20 were live donations)
Pancreas - 7
Liver - 34
Heart - 7
Lung - 18 (of which 10 were double and 8 single)

From 1st January 2012 to 31st December 2012
There were a total of 78 Deceased Donors
Renal Transplants- 163 (of which 131 were deceased donations, 32 were live donations)
Pancreas - 1
Liver - 50
Heart - 10
Lung - 14 of which 4 were double and 10 single.

From 1st January 2011 to 31st December 2011
There were a total of 93 Deceased Donors
Renal Transplants – 192 (of which 165 were deceased donations, 27 were live donations)
Pancreas – 8
Liver – 61
Heart – 6
Lung – 8 of which 1 was double and 7 single.