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Mean Fomhair 2013

Houses of the Oireachtas

Joint Committee on Health and Children

Report on Organ Donation

September 2013

31/HHCN/013

Foreword by the Chairman of the Joint Committee on Health and Children, Jerry Buttimer TD.

The Joint Committee on Health and Children warmly welcomes the Government's consultative process regarding its proposal to change the current practice of expressed consent or "*opt-in consent*" to one of "*opt-out consent*" in relation to organ donation in Ireland.

In June 2012, more than 1,700 Irish adults were receiving haemodialysis, yet throughout all of 2012, just 163 renal transplants were carried out in the Republic of Ireland. To meet the needs of those receiving haemodialysis our health system should be performing in the region of 300 kidney transplants each year. This low rate of organ donation is reflected in Ireland ranking 23rd in European league tables for organ donation.

Our current practice of using the "opt-in" system (or expressed consent) is used by only a small minority of countries in the EU. Countries that have changed to "*opt-out"* systems have seen significant increases in their rates of organ donation. Over a three year period after making the change to opt-out systems, Belgium saw its rate of organ donation increase by 100%, while over the same period, Singapore saw an increase of a massive 700%.

Changing to a *soft opt-out system* has the potential to change public attitudes toward organ donation, and more importantly to vastly increase our rate of organ donation. It is vital that in such a new system, the family of the next of kin would always be consulted. This will ensure that the principle that donation is a gift is maintained.

The Joint Committee is strongly of the view that any transition to a *soft opt-out system* must be supported by increased investment in essential infrastructure, transplant surgeons and trained support staff. Each kidney transplant has the potential to save €680,000 over a 15 year period. A short term investment in our organ donation infrastructure has the potential to deliver real long term savings for our h
health system, not to mention the long term benefits to the lives of organ recipients.

The Joint Committee welcomes the current public consultation on the proposals to change how Ireland operates its systems of organ donation. This underpins the ethos that everyone should have the right to participate in decisions affecting their health and to have their concerns heard. Individuals should be empowered to exercise control over their own health and to participate in the decision making process around health law and policy. Any transition to a new *soft opt-out* system should also be accompanied by a significant public awareness campaign prior to such changes taking effect.

The Joint Committee recommends that any transition to a *soft opt-out* system will only apply to organs available for donation to other patients and not to reproductive organs, or other organs and tissues for research purposes.

All persons over 16 years and with legally recognised mental capacity should have the ability to dissent from “presumed consent”. For children under 16 years of age and those lacking the legal capacity to consent, the next of kin should retain full control over consent, and the *opt-in* requirement should remain in these cases.

The Joint Committee recommends the establishment of a National Register on Withholding Consent to Organ Donation. This should be automatically accessible to organ procurement services and managed by the health departments.

In April of this year, the Joint Committee held two public hearings examining organ donation in Ireland, in which we heard the views of a wide range of stakeholders, including organ donors, organ recipients, practicing clinicians and surgeons, support organisations, the National Organ Procurement Service, the Irish Medicines Board and the Department of Health.

These hearings greatly enhanced the Joint Committee's understanding of the position pertaining to organ donation in Ireland and reaffirmed our view that the transition to a *soft opt-out* system is a necessary one.

I would like to thank all the witnesses who attended our hearings, and made submissions, for their very informative contributions to this important issue. The oral presentations made at the hearings, along with the transcripts of those hearings are appended hereunder as the basis of the Joint Committee's submission to the public consultation process.

I would like to thank all the members of the Joint Committee for their contributions and co-operation on this important body of work, and in particular, those of the opposition party spokespeople on Health. I would also like to thank the Oireachtas Library and Research Service, the Clerk to the Committee and the staff of the Committee Secretariat for their assistance in the production of this report.

Jerry Buttimer

Jerry Buttimer, T.D.,

Chairman,

Joint Committee on Health and Children
26th September 2013.

Members of Joint Committee on Health and Children

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Senator Imelda Henry **(Fine Gael)**	**Senator Marc MacSharry** **(Fianna Fáil)**	**Senator Jillian Van Turnhout** **(Independent)**

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Prof. Peter Conlon
Dr. Colman O'Loughlin
Dr James O'Rourke
Dr Ruairi Dwyer
Dr. Liam Plant
Mr. JP McDowell
Department of Health
Professor Jim Egan
Irish Medicines Board

SECTION 2 ORAL PRESENTATIONS

My name is Mark Murphy. I am the CEO of the Irish Kidney Association. I will commence by giving you a brief outline of the history and evolution of the IKA and treatment of Kidney Failure in Ireland.

Dialysis as a treatment is 70 years old. It came to Ireland in 1958 and kidney transplantation started in January 1964.

In 1978 the Irish Kidney Association was founded by three groups of kidney patients coming together from Dublin, Cork and Galway, where haemodialysis was available. The catalyst was the need to start an Awareness Campaign to the public highlighting the need for kidney donation after death. The first Kidney Donor Cards were then produced by the IKA for the first awareness campaigns – 10 years after the UK Health System had produced theirs.

As time moved on many more haemodialysis centres were built some funded by the IKA and some built by the IKA.

The IKA grew as the success of dialysis and transplantation grew. A new drug was discovered, Cyclosporine which is very effective in stopping the body from rejecting a new strange donated organ. This permitted far superior longevity in successful kidney transplantation and liver, heart, lung and pancreas organ transplants also became possible and are now along with Kidney transplantation, normal surgery and expected by society.

Currently in Ireland out of 3,900 patients with failed kidneys 53% or 2,100 are transplanted and 47% or 1,800 are on dialysis. Including all other organ transplants, there are just under 3,000 people in Ireland enjoying extended life because of organ donation resulting in transplantation.

Anyone who says that Irish organ donation and transplantation system is not working is simply wrong and misinformed.

What is true, and why we are here today talking to you is that Ireland is the only country in Europe that never legislated for the Organ Donation and Transplantation Process. We did transpose the EU Directive on Quality & Safety of Organ Donation & Transplantation last August into a Department of Health Statutory Instrument.

The Houses of the Oireachtas has never willingly debated organ donation and transplantation except for the Senator Quinn's private members bill number 43 of 2008.

The discussion today surrounds the consent we seek from the public for deceased organ donation. For the last 49 years the consent has been Informed Consent by the Next-of-kin of the deceased. If no Next-of-kin are available, if they cannot make up their mind in time, if there is a dispute within the family, all these situations are described as "No consent" and organ donation does not proceed. If consent is refused obviously organ donation does not proceed, but that decision is also grouped together with the other situations and called "No consent" in all the records available to us.

This dilemma of no consent has frustrated people across the globe and particularly in Europe where organ transplantation is advanced and as many as 10 people a day now die because of the lack of donated organs.

Some jurisdictions created a law of Presumed Consent. The Spanish were the first to do so in 1979 and many countries choose to follow. In the course of the next 10 years the Spanish realised that creating this consent law made no significant difference to the donation rates and there was a wide variance in hospitals organ donation rates. In the country they realised that the shortage of organ donations was not because of the public's lack of willingness, it was much more to do with the clinical practice and process and individuals skills of healthcare staff with donating familie.

In 1989 the Spanish created an organisation called Organización Nacional de Trasplantes, (O.N.T) They trained and placed Organ Donor Coordinators into their hospitals nationally and organised the organ donation process.

Spain, as a result, has topped and leads the Worlds organ donation rates ever since. They average 35 donors per million of population (PMP) other countries again followed Spain's example and many are achieving over 30 donors per million of population as a consequence.

The Architect and head of O.N.T. Dr. Rafael Matesanz repeatedly states that changing laws on consent does not change organ donation rates. You must change clinical practice inside your hospitals to increase the rates. The practice in Spain is "Informed Consent" and is internationally recognised as being so regardless of what the law on the statute books suggests which is presumed consent.

Again the rest of Europe found out the exact same and presumed consent hard or soft versions are not now practiced anywhere in Europe – they all use informed consent.

What is worth considering is that in our strongly held view – re-naming our consent system, which would suggest presumed consent is simply going to confuse and divide the public. The Irish people like to be asked, not told, to do something.

Some people have no Next-of-kin, some are estranged from their families entirely, some are separated and not legally so, awaiting divorce etc some relatives will not be found in time. How is consent achievable for these people?

Should a decision posted on a register be acceptable for organ donation to proceed in these circumstances?

Could we go a little further and suggest that the recorded wishes of the deceased should be paramount.

We do advocate for a National Organ Donor Registry to be used to show the Next-of-kin the proof of decision by the deceased. Should we take the decision in the registry as consent – if Next-of-kin are not available? Food for thought.

That might require written consent rather than an online registry. If so, why not consider written consent by the person as consent after their death – in the circumstances I have described – unavailable next of kin.

The NHSBT news press release of last week announced that the UK had increased organ donation by 50% in 5 years. They did not alter their consent – they changed clinical practice – as we are suggesting we should do.

In summary:

Creating a consent law that is different in name but in practice will be operated exactly as best practice dictates – which is informed consent – is fool hardy and will only lead to confusion for the public – unnecessarily.

We have to introduce the Spanish Organ Donor Coordinator Model and the infrastructure surrounding organ donation to make real changes. We can increase our rates just like the UK have done and save and extend the lives of 50% more people as a consequence.

The least important issue in the packages of changes you will learn about in these presentations today, is the consent issue. The infrastructure proposed will change everything for the better.

Ironically, the Spanish, Croatians and other European countries have proven that this infrastructural investment returns net savings in costs for other treatments, that far out way the initial investment.

At worst, it will be cost neutral on our health system and we will improve and extend many more lives.

Submission to the Joint Oireachtas Committee on Health
From the Irish Donor Network
Chairperson: Philip Watt (also CEO of Cystic Fibrosis Ireland)
Position of the IDN on the proposed change in organ donation and related issues

The Irish Donor Network (IDN) is comprised of patient groups which have a direct interest and concern on organ donation and transplant issues in Ireland. The role of the Irish Donor Network (IDN) is to bring patient groups together to:

- Encourage and help facilitate organ donation
- Contribute to the shaping of health policy on donation and transplantation
- Raise public awareness on donation and transplantation

There is a division of opinion among patient groups in the IDN in respect of this submission. Those patient groups in the IDN that favour the policy position set out is this submission are:

- The Alpha One Foundation
- Cystic Fibrosis Ireland (CFI)- *formerly the Cystic Fibrosis Association of Ireland*
- Irish Heart and Lung Transplant Association (IHLTA)
- Irish Lung Fibrosis Association (ILFA)

The patient group in the IDN that does not support the policy position set out in the paper is:

- The Irish Kidney Association

Background and Key Terms

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’.[1]

Ireland presently has an opt-in position. If you wish to become an organ donor after your death, potential donors are advised to inform their next of kin of their intentions and to carry an organ donor card. In Ireland next of kin are *always* asked for consent in order for a donation to proceed. In Ireland, consent is never presumed, even if a donor card has been signed.[2]

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

We understand that the government will be proposing a ‘soft’ opt out approach, which means that next of kin (NOK) must continue to give their consent to the organ donation of a family member who is a potential organ donor. Under no circumstances would the IDN support a ‘hard opt-out’ approach whereby NOK would not be consulted.

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[1] The Government for National Recovery 2011-2016, p58

[2] National Organ Procurement Service, Beaumont Hospital (accessed November 2012) http://www.beaumont.ie/index.jsp?p=105&n=454

The IDN would further contend that, from reviewing the existing international evidence, that those few countries that profess to operate a hard opt out system, that in fact that this is not actually applied in practice and NOK continue to be consulted (for example in Austria).

The IDN acknowledges the excellent standard and dedication of our transplant coordinators, surgeons and teams and the procurement team in Beaumont Hospital. We would contend without their dedication and skill, and the support of patient groups especially in promoting organ donation, the transplantation and donation rates would be considerably less than at present.

The Position of the Irish Donor Network

The position of the groups represented on the Irish Donor Network (with the exception of the Irish Kidney Association) is that:

1. **We support the change to 'soft opt out', but only if it is part of package of measures (detailed below) to improve organ donation and transplantation in Ireland**. It would be wrong for the Irish Government to present the movement to an opt out system as a panacea for improving donor and transplant rates in Ireland without addressing the existing gaps and weaknesses in the present donor and transplant system.

2. **The Irish government must develop a meaningful consultative awareness and public awareness process** in advance of a change to 'soft opt out' whereby key stakeholders and the general public can be fully informed of the proposed change and have an opportunity to express their views both for and against.

Package of Essential Measures

The package of essential measures that would need to accompany a change in the 'donor law' should include the following (in summary).

1. **Appointment of a Network of Donor Coordinators** would be assigned to major ICU hospitals in Ireland. These medical and nursing personnel will underpin the organ donation process by protecting the interests and welfare of those families who chose to donate organs in difficult circumstances.
2. **The National Organ Donation and Transplantation Office (NODTO)** The Office would be given sufficient resources and status to undertake its functions. The level of existing resources at present is completely inadequate
3. **A national on-line organ donor registry would be established.** This would provide potential donors the opportunity to indicate if they wish to opt out of all or some forms of organ donation. For example a person may want to donate one or more organs but not others.
4. **Specific measures to improve the rate of lung and heart transplantation in Ireland.** These measures include the replacement of the cardio thoracic surgeon in the Mater hospital who retired in 2010 (Mr Freddie Wood) and adequate inpatient isolation rooms for surgery preparation and recovery.
5. The **National Organ Procurement Office** (NOPO) would be established on an independent from any one hospital basis to accommodate the standards required by

both the EU tissue directive and the EU directive 2010/53/EC.

6. Greater support must be provided by the government towards annual **public awareness campaigns for organ donation** irrespective of the change to opt out. Such campaigns must be undertaken in partnership with the patient groups.

Submission from Phyllis Cunningham on behalf of the Organ Procurement Office

Thank you for giving me the opportunity to give my viewpoint as someone who for the last 26 years has been deeply involved in all aspects of organ donation and transplantation.

My name is Phyllis Cunningham. I am a qualified nurse and started my career in Jervis St. Hospital. My current role is, Senior Transplant Coordinator and I manage the Organ Procurement Service, currently based in Beaumont Hospital. I manage a team of five Transplant Co-ordinators and liaise with 40 Intensive Care Units around Ireland. I also work closely with Transplant units in hospitals in UK and N. Ireland. I set up the Organ Transplant Service in Beaumont Hospital in 1986 and have continued to work in the area. Every day, I witness first hand the life saving and life changing outcome of organ transplantation.

I have experienced the development of all the transplant services in Ireland and see the increasing demand for more organs for transplant. In 1999, for instance, there was an average of 100 patients on the waiting list for renal transplant and 145 transplants took place. Today, there are 600 people on the waiting list and at best we expect to achieve 180 renal transplant by the end of the year.

I am humbled by the wonderful families I meet who make the very unselfish and thoughtful decision to donate their loved ones organs at a very difficult and traumatic time. I have experienced the comfort and consolation families have derived from Organ Donation and I passionately feel that every family should be offered the opportunity to consider donation in circumstances where it would be possible.

If I could share with you my most recent experience.I was involved in a case with the two parents whose six year old boy died suddenly in extraordinary tragic circumstances. For confidentiality, medical and legal reasons I cannot discuss the circumstances. But what I would like to highlight is that these parents, who have many questions that will require open and honest answers, regarding the lead up to their son’s tragic death, at a very difficult time, spontaneously donated their son’s organs for transplantation and the recipient was another child (in a life saving situation).This wholly unselfish gesture of the donor family ensured that the recipient family would not have to go through what they just had just experienced - the loss of their child.

I welcome legislation to support an increase in organ donation. However, I have concerns about the term Presumed Consent. I feel this term has negative connotations as it loses sight of the fact that the donor family is front and central to the whole process and so the ultimate choice must rest with the Family.

In practice, it should be presumed that all families would like to be asked about organ

donation and in keeping with their loved ones wishes they will make the right decision for them.
The ultimate decision will be with the family of the deceased. I believe, the best approach would be to incorporate into the legislation an Opt out system which would involve the family.

And most important, In conjunction with any legislation there needs to be ongoing public awareness and education about the need for and benefits of organ transplantation... Knowing the wishes of your loved regarding Organ Donation is easier for a family than having to make a decision on their behalf at very difficult and traumatic time.

Legislation and education alone are not enough - More Resources are required to deal with the potential increase in the service and a robust Infrastructure needs to be put in place to ensure discussion with the families about organ donation is done in the Right way at the Right time by the Right person.

Organ donation truly is the most precious gift, given unconditionally and wholeheartedly with such goodwill to the organ recipient.

Organ donation not only benefits transplantation but it is a key element to support families in their grieving process. It is very important that we can maintain a positive and sensitive approach at a most traumatic time for a grieving family.

Transplantation in Ireland

My name is David Hickey. I am the Director of the National Kidney and Pancreas Transplant Programme, this national programme also has responsibility for Organ Procurement.
I have been committed to this programme for thirty years, personally performing over 1,500 transplants and 500 organ procurements, so I am in the unique position to comment on the global picture pertaining to all transplantation, but in particular my own area, kidney and pancreas transplantation and organ procurement.

The National Transplant Programme started in Jervis St in 1964 and this year will complete it 4000th transplant. Every initiative and advance in this area has been through the hard work of a few committed individuals, there has never been a national approach to the problem. For example in the move to Beaumont in 1987, they forgot that a transplant programme needed to be catered for. We ended up with an ad hoc arrangement which has continued to the present day.

I am here today to talk about legislating for organ procurement, however, I cannot let the opportunity pass without commenting on the overall picture in kidney and pancreas transplantation currently in Ireland, as any increase in organ procurement is going to have a significant knock on effect in a currently under performing service.

There are essentially four issues that I need to bring to your attention.

1. Lack of Organ Donors
2. Poor infrastructure in which are transplant patients are housed
3. Shortage of Transplant Surgeons
4. Ideal situation that we should be striving for

Increasing Organ Donation, Investment & Legislation

Obviously, the more donors we have, the more organs are available for our patients in end organ failure – liver, kidney, pancreas, heart and lung. However, as my area of expertise is kidney and pancreas transplantation and its procurement, I am going to confine my specific comments to this area.

There is a global shortage of organs for transplantation, particularly kidneys, as renal failure is increasing at an alarming rate, it is accepted that it will bankrupt most health services in the next 20 years if not addressed in a radical fashion now. Without a significant increase in both deceased organ and living donors, we are going to be at a situation in the very near future where dialysis is going to be rationed ie. Nobody over 55 being dialysed leading to as already happens in the developing world, reliance on commercial illegal (backstreet) transplantation.

Over the past ten years, there has been an explosion in the number of patients coming onto the transplant waiting list. This has not been matched by an increase in our deceased donor transplants. In fact we have reached a plateau with this, which without significant infrastructural change, will not be improved.

We have essentially been stuck at 21 donors pmp for the past 20 years, and whilst this was in the top 5 in Europe for a long time, we have now fallen significantly in the league table, as other countries have grasped this nettle and invested in the infrastructure that has resulted in their organ procurement rates being significantly higher, e.g. Spain, Austria, Belgium, Croatia etc.

We urgently need to move towards a transplant situation where we are performing 300 transplants per year in Ireland. This is going to come from an increased living related programme, but significantly from increased procurement of deceased donor organs. This can only be done by an actual investment in this area. No publicity campaign, no wringing of the hands, no sad stories in the papers, can achieve this. More money needs to be invested in Organ Procurement. More donors mean more transplants and we currently cannot deal with what we have. Sixty five patients (live donors) have been fully worked up at great personal and public expense and cannot be given a date for transplant. The wait for a living donor transplant is longer than waiting on the deceased donor list. The maximum waiting time for this procedure once worked up should be 3 months (Norway)
There are two problems with this,

1. The Donor & Recipient will have to be re-evaluated after 2yrs.
2. The recipient may have actually received a deceased donor Transplant, depriving another patient (without a living donor) of a transplant.

The other area that will certainly help increase donation rates has been Joe Brolly's initiative re the so called 'presumed consent' or 'opt out' option. Much has been said about the unfortunate wording of presumed consent, and I believe that this has to be removed from the lexicology. The presumption should be that the medical and nursing staff bring the topic to the awareness of the potential donor family to allow them the opportunity to think about this process and decide whether it is suitable for them. It must also be remembered that this is a service to the donor family and immense **consolation** can be derived from donating. Conversely there is also immense **desolation** derived from not being afforded the opportunity.

Whilst it is understood that the family will always be asked and their wishes will always be respected, this legislation will normalise the concept of organ donation. The fact that organ donation has been brought to this forum for discussion in itself will generate a lot of positive awareness about the current situation and will help significantly promote our enterprise. However, it has to be accepted, that the countries that have seen significant increase in organ donation and this increase has been attributed to the adoption of presumed consent, in reality has been the result of massive investment in both physical and personnel infrastructure, e.g. the Spanish Model of which you are well aware and of which I can answer questions afterwards.

Infrastructure

Hospitals are a place where we experience some of our saddest and happiest moments in our lives. It is generally accepted in modern architecture that they should be amongst the most inspiring public buildings in civilised society.

The current situation in the National Kidney Transplant Centre, unfortunately falls far short of this and cannot be improved without a radical rethink of how organ transplant services should be delivered for a country of 4.6 million people.
I believe a good model to look at would be Norway, a country similar in population, where all transplants are housed in a National Transplant Institute situated in the University of Oslo. This country performs twice as many kidneys and six times as many lung transplants as Ireland. In Norway all transplants are performed in a single national transplant centre attached to the Oslo University Hospital, localising all transplant expertise under the one roof as opposed to a triplication of support services as applies in Ireland.
This is what we need to strive for.

Transplant Surgeons

No Transplant Surgeons, No Transplants

There is a worldwide shortage of trained and capable transplant surgeons. This is because of the lifestyle, unfriendly nature of the work which involves much night work and weekend work. This crisis is a bigger threat to the management of end organ failure than the lack of donors
If the European Working Time Directive was strictly adhered to in transplantation, we would probably need twenty transplant surgeons to run our currently service. Presently, we have four wholetime equivalents, i.e. funding for four transplant surgeons in our service. The minimum UK requirement as of 1997 is 2 kidney transplant surgeons per million of population (pmp). The unattractive nature of transplant surgery has to be addressed, has to be incentivised and there has to be added compensation for people who take on this difficult lifestyle.

The Future

The future is now. It has to be accepted that we should follow the lines of most serious international programmes and have all intra-abdominal and heart/lung transplant patients under the one roof. This should be part of a University Hospital.
The details of what a transplant centre should look like are well established but essentially, everyone should have an acuity adaptable single room with plenty of space, good lighting, proper air conditioning and low sound. Contemporary hospital design is essential for transplantation. Six patients to a room, men and women mixed, one bathroom is no longer acceptable, if it ever was.

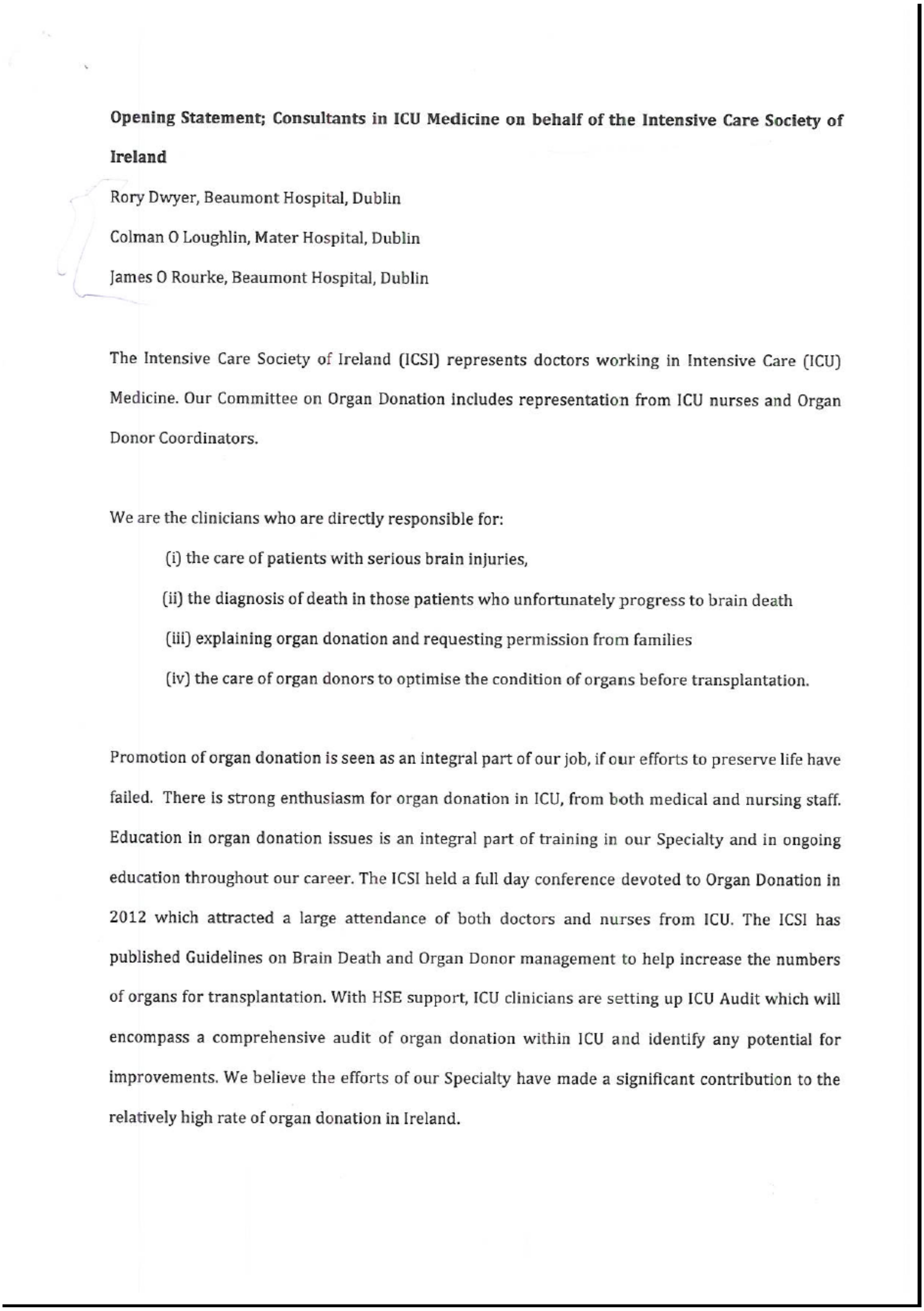
The concept that transplant patients would be happy to be transplanted on the side of the street, whilst probably true, should not be the mantra adopted.

Solution

A model, somewhat similar to Norway, needs to be established. This can be done in any of the three hospitals, incorporating Organ Procurement, liver, kidney, pancreas, heart and lung transplantation. Bone marrow should also consider being part of this centre. This could probably be done very quickly as there are possibilities of empty space in both Vincent's and the Mater. This would be an incredible advantage to the most important person involved in transplantation**, the patient,** who has been moved further and further from the centre of all discussions over the last 20 years.

This New National Centre should have separate budget and governance, be independent of the CEO of any hospital it is located in and answerable only to the NODTO, Department of Health and the HSE.

This is essential.



Opening Statement; Consultants in ICU Medicine on behalf of the Intensive Care Society of Ireland

Rory Dwyer, Beaumont Hospital, Dublin

Colman O Loughlin, Mater Hospital, Dublin

James O Rourke, Beaumont Hospital, Dublin

The Intensive Care Society of Ireland (ICSI) represents doctors working in Intensive Care (ICU) Medicine. Our Committee on Organ Donation includes representation from ICU nurses and Organ Donor Coordinators.

We are the clinicians who are directly responsible for:

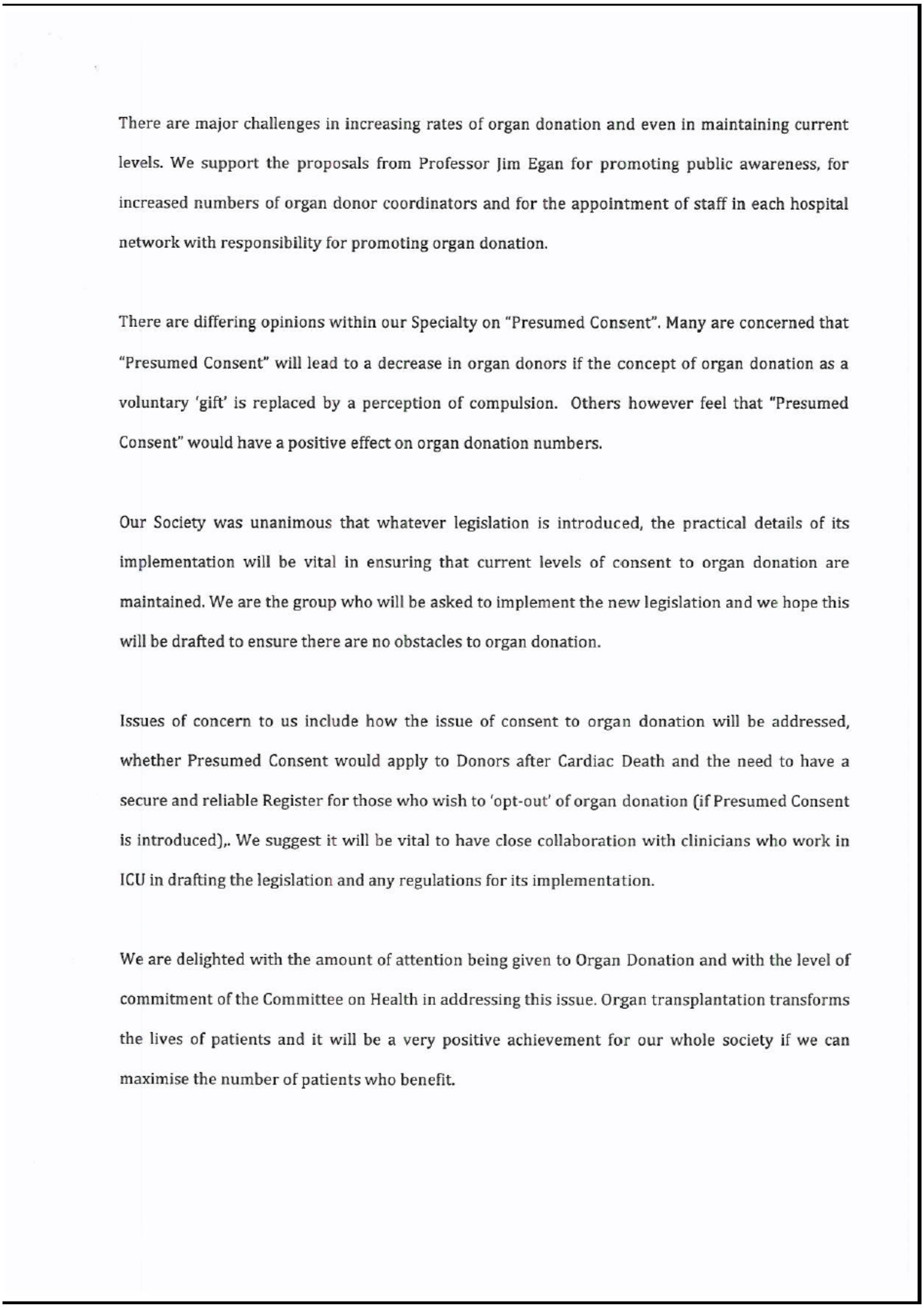
(i) the care of patients with serious brain injuries,

(ii) the diagnosis of death in those patients who unfortunately progress to brain death

(iii) explaining organ donation and requesting permission from families

(iv) the care of organ donors to optimise the condition of organs before transplantation.

Promotion of organ donation is seen as an integral part of our job, if our efforts to preserve life have failed. There is strong enthusiasm for organ donation in ICU, from both medical and nursing staff. Education in organ donation issues is an integral part of training in our Specialty and in ongoing education throughout our career. The ICSI held a full day conference devoted to Organ Donation in 2012 which attracted a large attendance of both doctors and nurses from ICU. The ICSI has published Guidelines on Brain Death and Organ Donor management to help increase the numbers of organs for transplantation. With HSE support, ICU clinicians are setting up ICU Audit which will encompass a comprehensive audit of organ donation within ICU and identify any potential for improvements. We believe the efforts of our Specialty have made a significant contribution to the relatively high rate of organ donation in Ireland.



There are major challenges in increasing rates of organ donation and even in maintaining current levels. We support the proposals from Professor Jim Egan for promoting public awareness, for increased numbers of organ donor coordinators and for the appointment of staff in each hospital network with responsibility for promoting organ donation.

There are differing opinions within our Specialty on "Presumed Consent". Many are concerned that "Presumed Consent" will lead to a decrease in organ donors if the concept of organ donation as a voluntary 'gift' is replaced by a perception of compulsion. Others however feel that "Presumed Consent" would have a positive effect on organ donation numbers.

Our Society was unanimous that whatever legislation is introduced, the practical details of its implementation will be vital in ensuring that current levels of consent to organ donation are maintained. We are the group who will be asked to implement the new legislation and we hope this will be drafted to ensure there are no obstacles to organ donation.

Issues of concern to us include how the issue of consent to organ donation will be addressed, whether Presumed Consent would apply to Donors after Cardiac Death and the need to have a secure and reliable Register for those who wish to 'opt-out' of organ donation (if Presumed Consent is introduced),. We suggest it will be vital to have close collaboration with clinicians who work in ICU in drafting the legislation and any regulations for its implementation.

We are delighted with the amount of attention being given to Organ Donation and with the level of commitment of the Committee on Health in addressing this issue. Organ transplantation transforms the lives of patients and it will be a very positive achievement for our whole society if we can maximise the number of patients who benefit.

Joint Committee on Health and Children
Organ Donation Meeting 25th April 2013

Opening Statement by Professor Jim Egan
Director of the National Organ Donation and Transplantation office
Health Service Executive

Organ Donation and Transplantation in the Republic of Ireland

I thank the committee for the invitation to attend this meeting on this important topic and to make an opening statement.

I will begin by giving you a little background on myself.

I am Prof Jim Egan and I am the HSE's Director of the National Organ Donation and Transplantation office appointed by the Royal College of Surgeons and Royal College of Physicians in April 2011. I am a fellow of the joint faculty of Intensive Care Medicine. I am the Irish Representative of the European Committee on Organ Transplantation of the Council of Europe. Former Chairman of The European Respiratory Society Transplantation Group, current Co Chair of the American and International Society of Heart and Lung Transplantation Societies committee for the management of chronic rejection

There are three distinct transplant programmes in this country. These clinical units are unique, in that, although located in three University teaching hospitals in Dublin they deliver services to the entire nation. They are located and compete for resources in acute hospitals, which also deliver regional and acute local services.

The National Renal and Pancreas transplant programme is based at Beaumont Hospital, Dublin. The National Liver transplant program is located in St Vincent's University Hospital. Both the Heart transplant program and the Lung transplant program is based in the Mater Misericordiae University Hospital. **At present there are 685 patients and families awaiting transplantation.**

Organ donation in Ireland is based on a "opt in" donation system. There is an average of 80 donations per annum. However in 2010 there were 58 donations. Coordination of organ donation is provided by the renal transplant service at Beaumont Hospital. This is unusual in an international context and has arisen based on historical needs, to compensate for the absence of formal structures

Recognising the substantial health care benefits of organ transplantation, the **EU Commission Action plan on Organ Donation and Transplantation (2009-2015)** emphasizes a requirement of all European States to identify potential organ donors and support their conversion to actual organ donors.

"soft opt out" / Presumed Consent

The goal of "soft opt out" is to allow organ donation to be the society norm. It does not devalue organ donation as an extraordinary gift of one family to another. However "soft opt out" consent legislation in isolation does not enhance organ donation, it is part of a package which includes donation infrastructure. Donation infrastructure protects the interest of the donor and families, ensuring a compassionate and professional approach.

Specific data supports presumed consent. A review of presumed consent published in the British Medical Journal indicates that presumed consent is associated with a 25% increase in organ donation rates or an additional 2-6 donors per million of the population.

Secondly, European league tables of organ donation rates are consistently dominated by those countries who have presumed consent in partnership with formal organ donation infrastructures. Including Spain Portugal, Croatia. The "Spanish model" is the international gold standard for organ donation and transplantation.

Infrastructure
In order to comply with both national and international needs, three structures in the Irish Health service require development:

1. **Intensive Care 'key donation personnel'** would be assigned across the health service in line with International practice and the EU Commission action plan. These medical and nursing personnel will underpin the organ donation process by protecting the interests and welfare of those families who chose to donate organs in difficult circumstances.

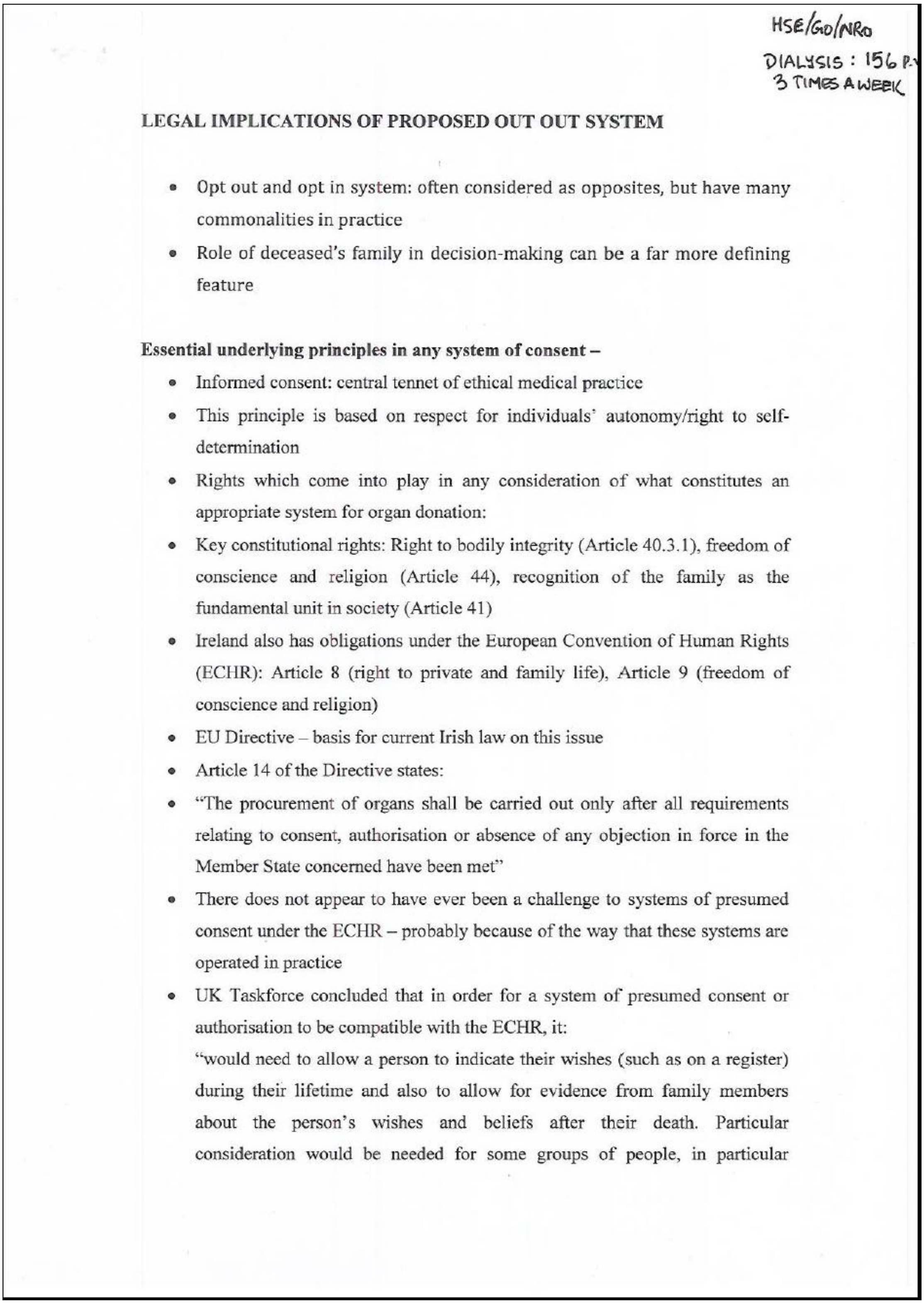
2. The **National Organ Procurement Office (NOPO)** would be independent of recipient coordination to comply with the standards required by both the EU tissue directive and the EU directive 2010/53/EC. This is also in keeping with both the 2011 HSE commissioned independent International Review of Transplant services and Irish Medicines Board recommendations, who regulate this area.

3. The recently established HSE **National Organ Donation and Transplantation Office (NODTO)** would be positioned to establish a financial and governance framework to protect the interest of both donors and recipients in a challenging fiscal environment.

The deployment of these structures will;

- Bring Ireland in line with the International practice norms
- Mitigate the risks of a fall in organ donation rates in a changing society
- Remove 530 patients from dialysis over 10 years
- Save an additional 21 lives of patients with end stage liver disease per annum
- Save an additional 35 lives of patients end stage lung disease per annum (15 patients with Cystic Fibrosis patients, 20 patients with lung fibrosis)
- Save an additional 19 lives of patients with end stage heart disease per annum
- Provide a platform to co-operate with services for Northern Ireland
- Save an estimated 61 million Euro over 10 years

Thank you



HSE/GO/NRO

DIALYSIS : 156 P.
3 TIMES A WEEK

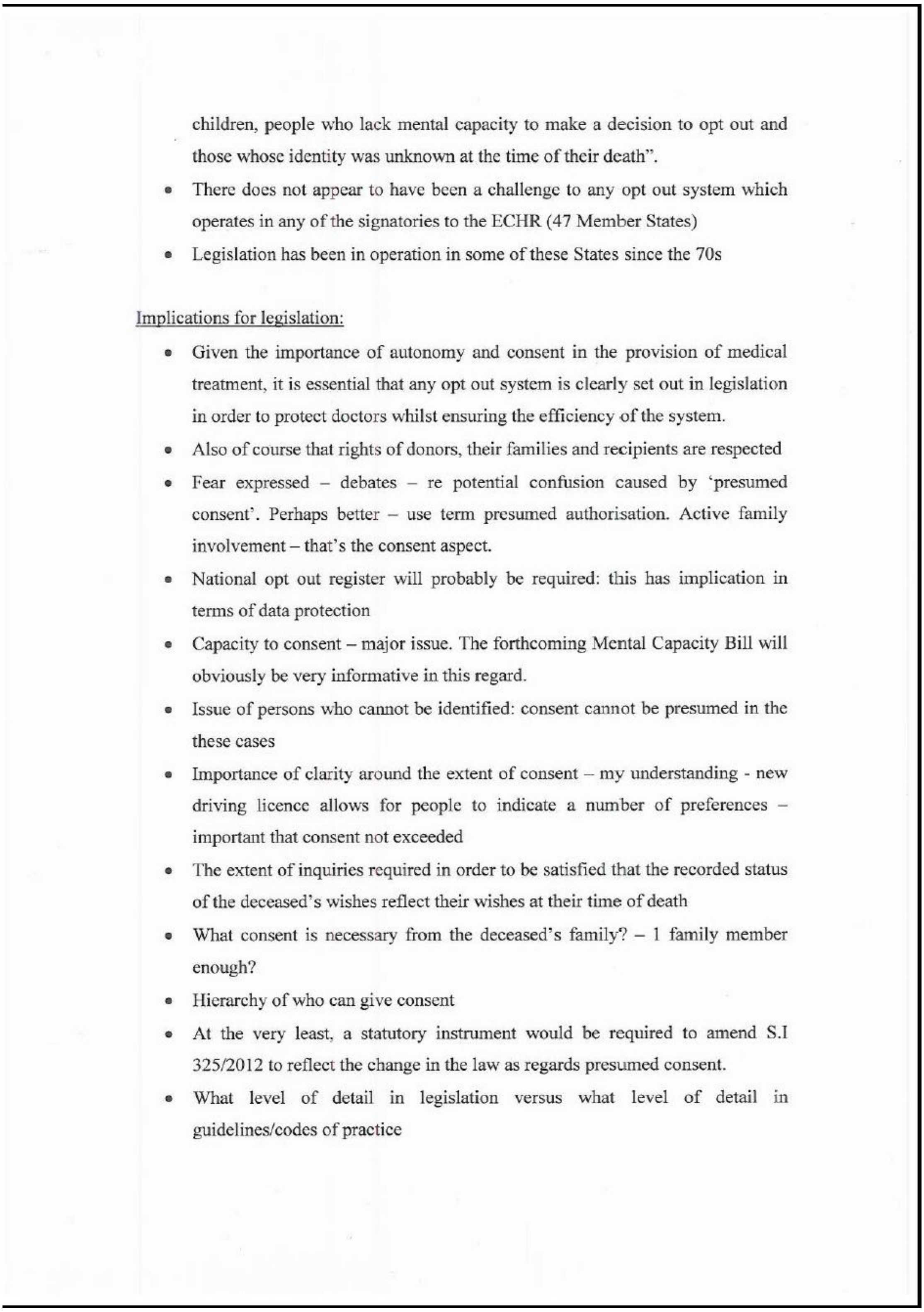
LEGAL IMPLICATIONS OF PROPOSED OUT OUT SYSTEM

- Opt out and opt in system: often considered as opposites, but have many commonalities in practice
- Role of deceased's family in decision-making can be a far more defining feature

Essential underlying principles in any system of consent –

- Informed consent: central tennet of ethical medical practice
- This principle is based on respect for individuals' autonomy/right to self-determination
- Rights which come into play in any consideration of what constitutes an appropriate system for organ donation:
- Key constitutional rights: Right to bodily integrity (Article 40.3.1), freedom of conscience and religion (Article 44), recognition of the family as the fundamental unit in society (Article 41)
- Ireland also has obligations under the European Convention of Human Rights (ECHR): Article 8 (right to private and family life), Article 9 (freedom of conscience and religion)
- EU Directive – basis for current Irish law on this issue
- Article 14 of the Directive states:
- "The procurement of organs shall be carried out only after all requirements relating to consent, authorisation or absence of any objection in force in the Member State concerned have been met"
- There does not appear to have ever been a challenge to systems of presumed consent under the ECHR – probably because of the way that these systems are operated in practice
- UK Taskforce concluded that in order for a system of presumed consent or authorisation to be compatible with the ECHR, it:

  "would need to allow a person to indicate their wishes (such as on a register) during their lifetime and also to allow for evidence from family members about the person's wishes and beliefs after their death. Particular consideration would be needed for some groups of people, in particular

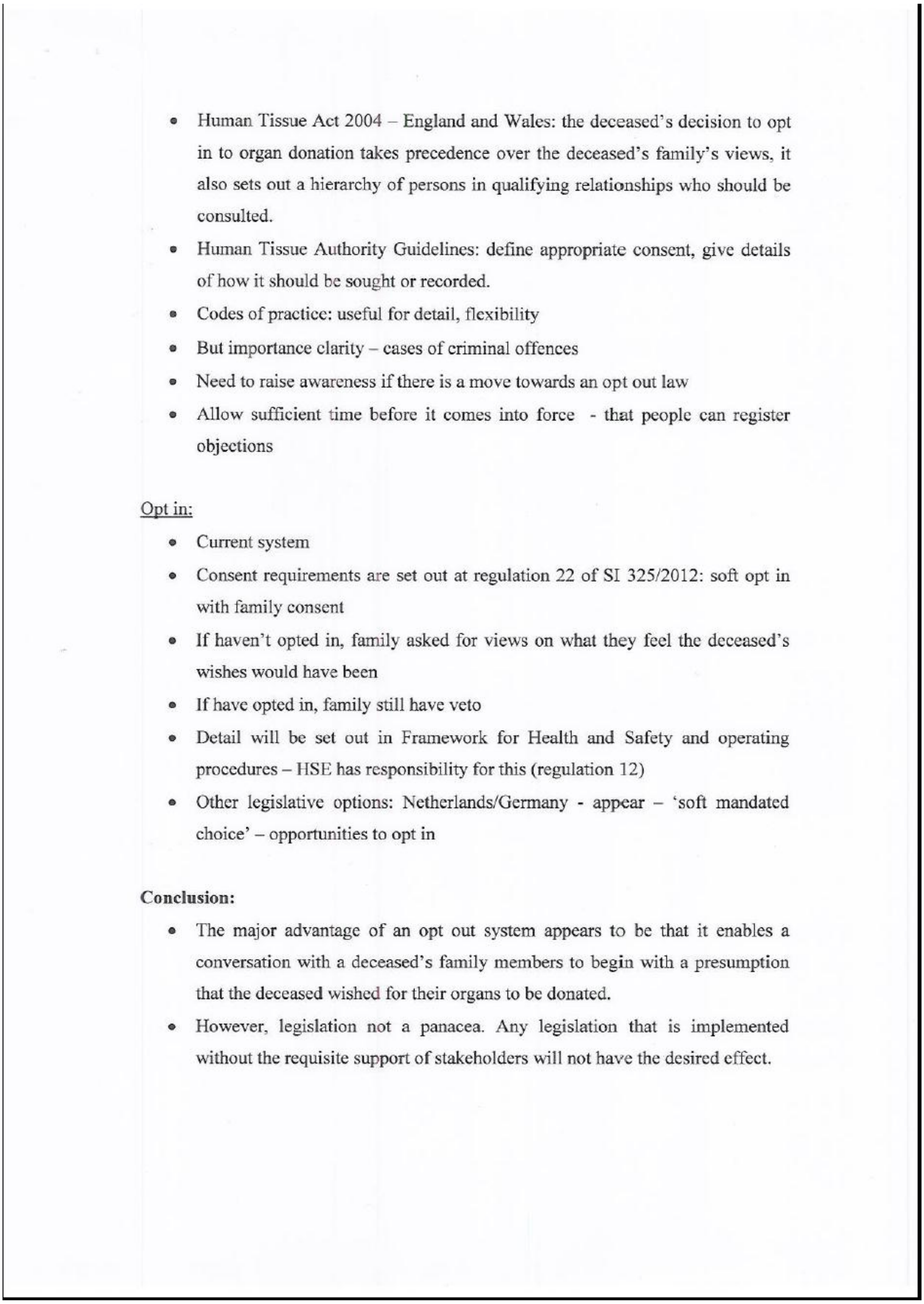


children, people who lack mental capacity to make a decision to opt out and those whose identity was unknown at the time of their death".

- There does not appear to have been a challenge to any opt out system which operates in any of the signatories to the ECHR (47 Member States)
- Legislation has been in operation in some of these States since the 70s

Implications for legislation:

- Given the importance of autonomy and consent in the provision of medical treatment, it is essential that any opt out system is clearly set out in legislation in order to protect doctors whilst ensuring the efficiency of the system.
- Also of course that rights of donors, their families and recipients are respected
- Fear expressed – debates – re potential confusion caused by 'presumed consent'. Perhaps better – use term presumed authorisation. Active family involvement – that's the consent aspect.
- National opt out register will probably be required: this has implication in terms of data protection
- Capacity to consent – major issue. The forthcoming Mental Capacity Bill will obviously be very informative in this regard.
- Issue of persons who cannot be identified: consent cannot be presumed in the these cases
- Importance of clarity around the extent of consent – my understanding - new driving licence allows for people to indicate a number of preferences – important that consent not exceeded
- The extent of inquiries required in order to be satisfied that the recorded status of the deceased's wishes reflect their wishes at their time of death
- What consent is necessary from the deceased's family? – 1 family member enough?
- Hierarchy of who can give consent
- At the very least, a statutory instrument would be required to amend S.I 325/2012 to reflect the change in the law as regards presumed consent.
- What level of detail in legislation versus what level of detail in guidelines/codes of practice



- Human Tissue Act 2004 – England and Wales: the deceased's decision to opt in to organ donation takes precedence over the deceased's family's views, it also sets out a hierarchy of persons in qualifying relationships who should be consulted.
- Human Tissue Authority Guidelines: define appropriate consent, give details of how it should be sought or recorded.
- Codes of practice: useful for detail, flexibility
- But importance clarity – cases of criminal offences
- Need to raise awareness if there is a move towards an opt out law
- Allow sufficient time before it comes into force - that people can register objections

Opt in:

- Current system
- Consent requirements are set out at regulation 22 of SI 325/2012: soft opt in with family consent
- If haven't opted in, family asked for views on what they feel the deceased's wishes would have been
- If have opted in, family still have veto
- Detail will be set out in Framework for Health and Safety and operating procedures – HSE has responsibility for this (regulation 12)
- Other legislative options: Netherlands/Germany - appear – 'soft mandated choice' – opportunities to opt in

Conclusion:

- The major advantage of an opt out system appears to be that it enables a conversation with a deceased's family members to begin with a presumption that the deceased wished for their organs to be donated.
- However, legislation not a panacea. Any legislation that is implemented without the requisite support of stakeholders will not have the desired effect.

Good Morning.

Thank you for asking me to attend today. My name is Liam Plant. I work as a Consultant Renal Physician at Cork University Hospital. Between 2003 and 2009 I acted as Chair of the National Strategic Review of Renal Services. Since March 2009 I have been the National Clinical Director of the HSE National Renal Office (NRO). The National Renal Office is responsible for planning, co-coordinating and managing the strategic framework of Renal Services across the country. Prior to 2001 I worked as a Consultant Renal Physician at the Royal Infirmary of Edinburgh.

In common with all countries, the number of our fellow citizens afflicted by permanent kidney failure (technically described as End-Stage Kidney Disease (ESKD)) continues to grow. The NRO conducts an Annual Census of this on the 31st of December each year. On 31/12/12 just under 4,000 of our fellow citizens had ESKD, 81 of these being aged under 18 years. Of the 3,876 adults with ESKD, 1560 (40%) received treatment by Haemodialysis at a number of Haemodialysis Units dispersed around the country. 237 (6%) were treated by one of the forms of Home Dialysis in their own homes. Thankfully, and a testament to the existing success of the Renal Transplant Programme in Ireland, 2079 (54%) already have a functioning Kidney Transplant. 62% of children with ESKD currently have a Kidney Transplant.

Whereas all types of renal replacement therapies are successful treatments for ESKD, prolonging survival, improving functional status and allowing patients to carry on with their lives, there is no doubt that Kidney Transplantation is the best of these options. It is the policy of the NRO that strategic planning should seek to maximize the numbers of patients who can avail of this. Whereas not all patients may be suitable as recipients of a kidney transplant, many more than have currently received one are so. This is reflected in the waiting list for kidney transplantation.

As well as being a considerable physical, social and psychological burden on patients with ESKD treated by any of the forms of dialysis therapies, the costs to the State of providing these therapies are very substantial. In 2011, the ESRI noted (Activity in Acute Public Hospitals Annual Report 2010) that the highest ranked procedure for Day Patients in Public Hospitals was Haemodialysis, accounting for over one-fifth of all such cases. In 2012 almost 250,000 such procedures were delivered. Irish patients travelling to-and-from their Haemodialysis Units travelled over 13.5 million km in 2012. Despite reductions in the costs of such treatments in recent years, the sheer number of procedures continues to generate very substantial revenue charges.

In the 5 years since 2007, the number of adults with ESKD has increased by 24%, an absolute increase of 743 patients. Of this increase, 63% has been accounted for by an increase in the numbers of those with a functioning Kidney Transplant (466), with the remaining increase due to an increase in those treated by Dialysis (277).

There is, therefore, little doubt but that an increase in access to organs suitable for transplantation would improve the survival, rehabilitation and quality of life of many more patients with ESKD than at present. Furthermore, the potential future costs of

Dialysis therapies foregone as a consequence of an increase in the transplantation rate would benefit the Renal Programme, the Health Service as a whole and the Irish taxpayer.

The principal question that needs to be addressed is: how is this best achieved? A variety of potential solutions have been advanced by a variety of individuals, organizations and health care systems. I am happy to offer my own observations on those elements that I think are likely to increase transplantation, whilst preserving the confidence of the wider citizenry in the organization of this activity. Undoubtedly, increasing the resources available to support Living Donor transplantation is a key element. But what of Deceased Donor transplantation?

As has been highlighted in a UK Health Technology Assessment (Health Technology Assessment 2009; 13:26), a number of elements contribute to the variation in rates of organ donation between countries. These include:

1. The national wealth and the investment made in Health Care Services.
2. The legislative framework that underpins donation (particularly as this applies to questions of ‘presumed’ or ‘informed’ consent).
3. The availability of potential donors
4. Public attitudes to, knowledge of, and education about organ donation and transplantation.
5. The organization and infrastructure provided to deliver organ donation and transplantation services.

Much commentary has focused on Item 2 and it is of great importance. However, I would strongly associate myself with the views expressed by others that in the absence of a robust organization and infrastructure to support this endeavor, any legislative framework is unlikely to achieve its maximum potential in increasing donation. Similarly, robust engagement with the public to minimize anxiety, misunderstanding and fear regarding any potential legislative changes must also be of the highest importance.

Thank you.

Statement to the Joint Committee on Health and Children on Consent for Organ Donation

April 25th 2013

Mary Jackson, Principal Officer
Cancer, Blood and Organs Unit, Department of Health

I wish to thank the Chairman for the opportunity to address you today on this important subject. I am joined by my colleagues who are also involved in shaping organ donation and transplantation policy. Dr Siobhán O'Sullivan is Chief Bioethics Officer to the Department of Health. Siobhán is also a member of the Council of Europe Committee on Bioethics and of the HSE's National Consent Advisory Group. Dr Patrick Costello is Blood, Tissues and Organs Manager in the Irish Medicines Board, which is the competent authority authorising organ donation and transplantation under Ireland's EU Regulations.

EU Directive on quality and safety of organs intended for transplantation

A priority for our health system is to ensure that every link in the donation and transplantation chain is safe. EU Directive 2010/53/EC, which was transposed into Irish law by SI No 325 of 27 August 2012 has set criteria for quality and safety. The Irish Medicines Board is working with Professor Egan in the HSE's National Organ Donation and Transplantation Office to ensure that organ procurement and the activities in Ireland's three transplantation centres at Beaumont, the Mater and St Vincents Hospitals meet these criteria.

EU Action Plan on Organ Donation 2009-2015.

In addition to mandatory standards for quality and safety, the EU has set out a 10 point Action Plan on Organ Donation and Transplantation, which aims to strengthen cooperation between Member States in order to increase organ availability and enhance the efficiency and accessibility of transplantation systems, while at the same time improving quality and safety. The actions, to be implemented by Member States are to:

1. Promote the role of transplant donor coordinators in every hospital where there is potential for organ donation.
2. Promote quality improvement programmes in every hospital where there is a potential for organ donation.
3. Exchange best practice on living donation programmes among EU Member States: Support registers of living donors.
4. Improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation.
5. Facilitate the identification of organ donors across Europe and cross-border donation in Europe.
6. Enhance the organisational models of organ donation and transplantation in the EU Member States.
7. Promote EU wide agreements on aspects of transplantation medicine.
8. Facilitate the interchange of organs between national authorities.
9. Evaluate post-transplantation results.
10. Promote a common accreditation system for organ donation/procurement and transplantation programmes.

Ireland is prioritising areas for attention from this list, which will positively impact on organ donor rates.

Programme for Government Commitment on measures to increase the number of organs available for transplantation

Another major initiative is the Programme for Government commitment to legislate to change to an opt-out system for organ donation, rather than an opt-in system, which is currently the case in order to improve the availability of organs for patients in need of transplantation. This commitment, which will require legislation, has divided members of the clinical community and also the voluntary sector. However, as we have seen in other jurisdictions, it is not the legislative base, but the infrastructure and donation and transplantation systems in place, and how potential donors and their families are encouraged to donate, that make the difference in increasing the number of donations.

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.

We must change the cultural attitude towards organ donation and make organ donation the norm in Ireland. The present system of consent will change to one of "presumed" or "deemed" consent, which means that the consent of an individual to organ donation is deemed or presumed to have been given unless they objected during their lifetime. If a person does not wish to become an organ donor after death, they will need to register an objection during their lifetime - a process known as opting out.

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 asked to provide as much information as possible on the person's medical and social history. The Minister has stressed that there would be no instance whereby organ donation would proceed against the wishes of the deceased's family. The system to be introduced is therefore a "soft opt-out" system.

The Department is currently drafting the Heads of 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 Bill will also legislate for consent for the use of organs and tissues removed from a living person for transplantation and research.

The logistics of establishing a system of presumed consent are complex. Many factors other than the introduction of a system of presumed consent affect organ donation rates. The availability of donors, transplantation infrastructure, public attitude, and investment in healthcare all play a role. 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.

A secure IT system must be established and maintained. The Welsh Government, which is planning to introduce an opt-out system, envisaged that this would cost over €5m over the first 10 years for a population that is two thirds that of the Ireland.

In the absence of a personal unique health identifier, the identification of individuals and the maintenance of a national registry of potential donors is problematic.

An opt-out system would require an extensive and well-resourced communications strategy.
Measures would have to be put in place and sustained to protect the rights of vulnerable groups and marginalised members of society. For example, how would a homeless person, or a person who lacks capacity register their wish to opt-out?

Department of Health's consultation process

The Department will commence a consultation process on presumed consent in the next few weeks and will be inviting interested parties to submit their views on the practical aspects of introducing a system of presumed consent for organ donation. We will pose a range of questions, allow around 6 weeks for consultation, distil the information received and then have a focused workshop on the findings of this consultation. The workshop will involve clinicians, Irish Donor Network representatives and other relevant parties to give direction to the next steps and the shape of the legislation and what is needed in the health system to implement a soft opt-out system. We would also be pleased to have a representative of this Committee in attendance on the day.

Links with the Irish Donor Network

The health system must put people and patients at the centre of anything we do. The Irish Donor Network gave an important input to discussions on the detail of the implementation of Irish regulations on quality and safety for donation and transplantation. Its member organisations - Alpha One, Cystic Fibrosis Association, Irish Kidney Association, Irish Heart Lung Association and the Irish Lung Fibrosis Association - will continue to be partners in relation to the development of policy and actions. Indeed, the Network met the Minister in February to provide its members' views to him, especially on the issue of consent to transplantation. The Network also pointed to service areas where improvements could be made to enhance donation and transplantation potential.

Conclusion

In conclusion, I wish to thank the Committee for giving me the opportunity to present the Department's position today. Two clear messages came from the presentations from organisations and individuals to the Committee last week. Firstly, like other countries throughout Europe, Ireland has waiting lists for transplantation and secondly, legislation alone will not solve the problem, but we must work together to increase Irish organ donation and transplantation rates. A framework to ensure quality and safety is being developed and in parallel with this we must make organ donation the default position for most people and maximise the number of organs available for transplantation and ensure that our hospital system is resourced to provide as many people as possible with the gift of life through organ transplantation.

PRESENTATION TO OIREACHTAS HEALTH COMMITTEE ON TOPIC OF ORGAN TRANSPLANTATION IN IRELAND

Professor Peter J Conlon FRCPI, Clinical Director of Transplantation Urology and Nephrology, Beaumont Hospital.

Ladies and gentlemen thank you for inviting me to speak to you about the topic of organ transplantation in Ireland. My name is Professor Peter J Conlon. I am clinical director of one of the largest kidney transplant centres in the British Isles and have more than 20 years of experience in kidney transplantation. The views expressed here are shared by the vast majority of my colleagues in the care of dialysis and transplant patients in Ireland.

Patients with kidney failure have a number of therapeutic options. It is true to say that most patients in the world with kidney failure die without any significant treatment, as the treatment although effective is expensive and requires a sophisticated medical system to deliver it. Patients with kidney failure who have the good fortune to live in Ireland have access to a number of treatment options including home peritoneal dialysis, home haemodialysis, in-centre haemodialysis; deceased donor kidney transplantation or live donor transplantation.

The Benefits of Kidney Transplantation

Kidney transplantation is without question the best treatment for almost all patients with kidney failure. Kidney transplantation provides the best quality of life for patients with kidney failure, more than doubles their life expectancy compared to remaining on dialysis and in the process each kidney transplant saves the state in excess of 750 thousand euros over the life time of the transplant. Many patients receiving a live donor kidney transplant can reasonably expect their transplant to function for in excess of 40 years which mostly means for the rest of their life. There are many impediments to delivering more kidney transplants but the major impediment at present is the availability of suitable donors and the infrastructure to deliver these transplants.

Ireland has had a successful kidney transplant programme for almost 50 years but nothing like as successful as it needs to be or could be.

I believe that Ireland should be aspiring to achieve kidney transplantation success similar to Norway. For comparison purposes I will compare the two countries in terms of their approach to Kidney transplantation. Ireland has a population of 4.6 million, Norway has a population of 4.8 million both very similar. Ireland has performed an average of 150 kidney transplants per year over the last 10 years; Norway has performed between 270 and 300 transplants annually. As a result of this difference in kidney transplant activity Norway has a stable population of 370 patients on maintenance dialysis while Ireland has in excess of 1800 patients on dialysis. Ireland could with appropriate investment within a few years be achieving transplantation results similar to Norway with enormous benefits to patients with kidney failure in Ireland and in the process save in excess of 300 million euros over 10 years.

Organ Procurement

The most scarce resource in transplantation is organ donors. Kidney transplantation is almost unique amongst organs that can be transplanted in that live donors are a major source of organs for successful transplantation. Let me however first discuss deceased kidney donation.

Organ procurement in Ireland which is essential for all the disciplines of transplantation including Heart, Lung and liver is run on a shoe string.
All organ procurement is run out of an office in Beaumont hospital staffed by 5 very committed and professional transplant coordinators. These coordinators also have many other duties besides organ procurement. There is practically no infrastructure for organ procurement outside Beaumont Hospital in the regional hospitals. The transplant coordinators at Beaumont Hospital have developed a network of "link nurses" in each ICU who on their spare time assist in educating their colleagues on organ procurement. This is no way to run a Lifesaving Transplantation service

These issues have become all the more urgent in that the recently implemented EU directive on organ donation mandates the separation of organ procurement and transplantation and also mandates much more rigorous traceability and organ quality criteria.
There is in my view an urgent requirement to establish a formal National Organ Procurement Agency which would provide a national resource to every ICU and emergency room in the country an expertise in organ procurement.
Ireland has as I said 5 Transplant coordinators, Northern Ireland with a population less than half of ours has 27 and in the UK they have more than 200. When the UK recently implemented an investment in organ procurement they achieved a 50% increase in organ donation.
Implementing a resource to properly manage organ donation is in my view far more important than implementing a presumed consent law and likely to result in a far more dramatic increase in organ donation.

Living Kidney Donor Transplantation

Living donor kidney transplantation is also an important process in treating kidney failure and in fact delivers far better long term results than deceased kidney transplantation. I am pleased to inform you that the department of health and children and the HSE has recently committed funding to deliver the first phase of a very significant expansion in live kidney donation and has agreed in principle to fund a plan that hopes over the next 3 years to deliver 100 living kidney donation operations annually. This plan has been stimied at every corner and has not yet been implemented and quite frankly I am unsure when it will be implemented, despite the urgent need. There are currently in excess of 100 kidney donor/recipient pairs awaiting living kidney donation in Ireland.

There are however a number of very important other issues that need to be urgently addressed if Ireland is to realise the full potential of living kidney donation and in this regard the implementation of the Human Tissue bill will be necessary to deliver on these targets.

Coverage of Out of pocket expenses for living kidney donors

Each living kidney donor saves the state in excess of 750,000 euros in health care costs. Currently however a living donor pays all expenses related to travel (to and from the hospital), extra child care etc. Typically a living donor will require several weeks off work from major surgery, and thus will not be available for work. It will typically cost each living kidney donor between 5 and 7 thousand euros by way of lost income and out of pocket expenses. It is common practice in most developed countries for health authorities to cover out of pocket expenses for living kidney donors. In the UK the state will cover up to £ 5,000 in out of pocket expenses. The EU directive requires the minister of health and children to implement such a system. I would urge him to implement this without further delay.

It is unfair that not alone does a living kidney donor give up one of his kidneys but also that it should cost him personally so much money in lost income and out of pocket expenses.

Altruistic Kidney Donation

I am aware of at least two Irish individuals who wanted to become altruistic kidney donor (This is where an individual recognising that there are many people in Ireland need a kidney transplant offers one of his or her kidneys for transplantation to somebody they do not know) and because there was no legislation permitting this in Ireland they went to UK to give one of their kidneys to the UK system. This was a loss for ever to Irish patients with kidney failure. Altruistic kidney donation (because of the unique ethical dilemmas it raises) needs the Human Tissue act before we can begin this important additional source of organs for transplantation.

Paired Kidney Exchange

Patients with a Blood group or tissue type incompatible donor can now frequently find a compatible donor by way of Paired Kidney Exchange .We have recently developed a relationship with UK Blood and Transplant for the sharing of living human kidneys with the UK as part of the implementation of a paired kidney exchange system for Ireland. This will allow large numbers of Irish and Uk patients to receive a live donor transplant that would not otherwise be possible. In order to implement paired kidney exchange scheme with the Uk we will require the Irish Government or one of its agencies to enter into a service level agreement with the UK transplant Authority

Kidney Donors living Abroad

We have significant numbers of patients living in Ireland receiving kidney treatment here that have a relative abroad who would like to come to Ireland and donate a kidney to their loved one. There is currently not a clear cut mechanism or policy from the department of health allowing these donors to come to Ireland and receive their care in Irish hospital and health care institutions in order to facilitate organ donation in Ireland.

Public Information Campaigns about Organ Donation.

I also believe that much like the Road safety Authority transformed the Irish public's view of road safety by their hard hitting public awareness campaigns similar resources should be put into promoting organ donation awareness amongst the general public.

Recruitment and Retention of Transplant Professionals

Transplant surgery commonly occurs in the early hours of the morning and is consequently arduous. If a transplant programme is to be successful the system needs to ensure that there is an ongoing supply of these highly skilled professionals particularly transplant surgeons , which typically takes 15 years to train. Failure to implement Working time directive and bans on recruitment has put this essential resources in peril.

Concluding Remarks

As somebody who every day in my work witness the fantastic life saving and changing benefits that organ transplantation brings to the Irish population I would support any proposal that would ethically allow for the expansion of this technology in Ireland. I believe that bringing in a presumed consent law would have very little impact in expanding organ transplantation and should not be at the top of our priority list but rather the reorganisation of organ procurement services to ensure that every potential organ donor be they living or deceased is identified and facilitated to donate and result in successful transplantation. There is also an urgent need to implement planned expansion of transplantation infrastructure at Beaumont Hospital to ensure that all live and deceased kidney transplants can be performed to a high standard and without delay

I thank you for your time.

Statement to the Joint Committee on Health and Children on Consent for Organ Donation

April 25th 2013

Dr. Siobhán O'Sullivan, Chief Bioethics Officer

I would like to thank the committee for the opportunity to address some of the ethical questions arising in the context of consent for organ donation and more specifically, the pertinent ethical issues to be considered when introducing a presumed or opt-out consent model. As Chief Bioethics Officer in the Department of Health, my role is to support the Department in achieving its mandate and strategic objectives through the provision of bioethical analysis and advice.

The success of any organ procurement system is contingent upon its capacity to fulfil three interconnected objectives: the first is good outcomes in terms of quantity and quality of organs, the second is the maintenance of public trust in the transplantation system and the third is respect for ethical principles. As the need for organs increases, transplantation systems have explored a number of innovative strategies to increase donation rates, many of which have proved ethically challenging. Strategies include expanding the criteria for declaring death, living donation, donation after circulatory death, anonymous donation, directed donation, opt-out policies and economic incentives. These strategies are not necessarily unacceptable, they are just morally debatable. While the ultimate goal is to save lives and improve the quality of life of transplant recipients, this goal needs to be achieved through means that do not violate socially accepted ethical norms.

Gift giving or voluntary donation to benefit another person, as an expression of altruism and social solidarity has been the ethical cornerstone of organ procurement and transplantation. Traditionally, the practice has been institutionalised as an opt-in system, which depends on having the express or explicit consent of the person and/or obtaining the consent of the person's family after death. The presumed consent model has been adopted by a number of countries in an effort to boost donor numbers. Ethicists have pointed out, the term presumed consent is something of a misnomer as consent is an active rather than a passive process, and thus the term opt-out represents a more appropriate use of terminology to describe this model.

The principal ethical objection raised in relation to the opt-out model is the loss of autonomy and right to self-determination of potential donors. Opponents also argue that the fact that someone has not registered an objection to donation, does not mean that s/he agrees to be a donor. It may simply reflect that they had not read the necessary materials, did not know the relevant facts, or were otherwise unable to participate in the debate over organ donation. This could lead to removal of organs from those who did not wish to donate. Commentators have argued that this situation is morally unacceptable because it violates the principle of respect for autonomy that underlies our concept of informed consent. Fears have also been expressed that an opt-out system could undermine solidarity and altruism as important motives for organ donation. It has been argued that the state (acting through health professionals and the health care system) would be intervening to 'take' organs rather than facilitating their being 'given' and there is at least a risk that some degree of trust in the system could be lost, potentially decreasing the availability of organs for donation.

Proponents of the opt-out model counter that if the change of policy from opt-in to opt-out were to be broadcast widely, there would be no diminution of the exercise of self determination and therefore personal autonomy would not be affected. Furthermore, it has been argued that an opt-out system enhances autonomy as public surveys have shown a high willingness on of the part of the public to donate their organs and by failing to remove people’s organs, one is thus acting contrary to their (unexpressed) wishes. Supporters of an opt-out model also employ a utilitarian argument as support for implementing such a policy. Such a model provides the greatest good for the greatest number of people by harming no one and benefiting many. This thesis hinges on the fact that the dead or least their surviving interest cannot be harmed and that any curtailment of individual freedom is legitimate in the interest of the common good, that is the survival of other citizens. Another argument proffered in support of a policy change to an opt-out system is that it would facilitate a change in attitudes so that donation would be increasingly seen as 'natural' or 'normal', hence increasing the likelihood that families would conclude that donation would be in line with their deceased relative's wishes.

I respectfully suggest that there are a number of ethically relevant considerations in introducing an opt-out system in Ireland. In advance of any change in the system, the population should be informed of and receive the relevant information on the changes to the current arrangements concerning organ removal. There should be provision of simple and convenient procedures for anyone to opt-out and it should be possible for individuals to revise their wishes at any time. It must be ensured that – as a result of poor language or reading skills, educational level, or socioeconomic/health status – no-one’s understanding is limited to such an extent that their silence is construed as consent to organ donation. The issue of vulnerable groups requires special attention in this context.

Under a presumed consent system, hospitals would need to have reliable and continuous access to the *latest* recorded wishes of potential organ donors. It would need to be defined who is responsible for the documentation, who is allowed to enter records (data control) and who would have access to the information recorded (data protection, data security). It would also need to be ensured that records are valid (data currency) and correctly assigned (identity security). Not least, the state would also have a responsibility to prevent social stigmatization of individuals who opt out and might thus be regarded as “lacking in solidarity”.

Finally, it is important to emphasise that deceased donation is a complex area, affected not only by law, administration and infrastructure but also ideology and values.

SECTION 3 TRANSCRIPTS OF MEETINGS

Thursday, 18 April 2013

The Joint Committee met at 09:30

MEMBERS PRESENT:

Deputy Catherine Byrne,
Deputy Ciara Conway,
Deputy Regina Doherty,
Deputy Peter Fitzpatrick,
Deputy Seamus Healy,
Deputy Billy Kelleher,
Deputy Sandra McLellan,
Deputy Caoimhghín Ó Caoláin,
Deputy Mary Mitchell O'Connor,
Senator Colm Burke,
Senator Marc MacSharry,
Senator Jillian van Turnhout.

In attendance: Deputies Paudie Coffey and Patrick O'Donovan, and Senators Paul Bradford and Mark Daly.

DEPUTY JERRY BUTTIMER IN THE CHAIR.

The joint committee met in private session until 10 a.m.

Organ Donation: Discussion

Chairman:

I welcome everybody to the meeting, in which we will discuss organ donation. It is the first of two meetings on the issue. Briefing papers from the Department of Health and a research paper from the Oireachtas Library and Research Service have been circulated to members.

I wish to express my gratitude to the service for its excellent work.

This morning we will hear personal and advocacy perspectives on organ donation, particularly from those with a personal experience of donation and advocacy groups representing those affected by organ donation. I welcome each witness here today and apologise for the earlier hold up; we had some private business to attend to. I thank the witnesses for coming this morning and making time to join our discussion on the first of two meetings.

Before we commence, I asked members and those in Visitors Gallery to ensure their mobile phones are completely turned off as they interfere with the broadcasting equipment, even when switched to silent, which is unfair to the staff and affects the transmission of our proceedings.

By virtue of section 17(2)(*l*) of the Defamation Act 2009, witnesses are protected by absolute privilege in respect of the evidence they give to the committee. If they are directed by it to cease giving evidence on a particular matter and continue to so do, they are entitled thereafter only to qualified privilege in respect of their evidence. They are directed that only evidence connected with the subject matter of these proceedings is to be given and asked to respect the parliamentary practice to the effect that, where possible, they should not criticise or make charges against a person or persons or an entity by name or in such a way as to make him, her or it identifiable. The submissions made to the committee and opening statements will be published on its website after the meeting. Members are reminded of the long-standing parliamentary practice to the effect that they should not comment on, criticise or make charges against a person outside the Houses or an official by name or in such a way as to make him or her identifiable.

We will have the presentations by the advocacy groups first followed by questions and answers. I will take questions and answers in groups of three. I welcome Ms Phyllis Cunningham, senior transplant coordinator from the National Organ Procurement Service and invite her to make her opening remarks.

Ms Phyllis Cunningham:

I thank the committee for giving me the opportunity to give my viewpoint as someone who for the last 26 years has been deeply involved in all aspects of organ donation and transplantation. My name is Phyllis Cunningham, I am a qualified nurse and I started my career in Jervis St. Hospital. My current role is senior transplant coordinator and I manage the National Organ Procurement Service, currently based in Beaumont Hospital. I manage a team of five transplant coordinators and liaise with 40 intensive care units around Ireland. I also work closely with transplant units in hospitals in Britain and Northern Ireland. I set up the organ transplant service in Beaumont Hospital in 1986 and have continued to work in the area.

Every day I witness at first hand the life saving and life changing outcome of organ transplantation. I have experienced the development of all the transplant services in Ireland and see the increasing demand for more organs for transplant. In 1999, for instance, there was an average of 100 patients on the waiting list for renal transplant and 145 transplants took place. Today, there are 600 people on the waiting list and at best we expect to achieve 180 renal transplants by the end of the year.

I am humbled by the wonderful families I meet who make the very unselfish and thoughtful decision to donate their loved ones organs at a very difficult and traumatic time. I have experienced the comfort and consolation families have derived from organ donation and I passionately feel that every family should be offered the opportunity to consider donation in circumstances where it would be possible.

I would like to share with the committee my most recent experience. I was involved in a case with two parents whose six year old boy died suddenly in extraordinarily tragic circumstances. For confidentiality, medical and legal reasons, I cannot discuss the circumstances. I would like to highlight, however, that these parents, who have many questions that will require open and honest answers regarding the lead up to their son's tragic death, at a very difficult time spontaneously donated their son's organs for transplantation and the recipient was another child in a life saving situation. This wholly unselfish gesture of the donor family ensured that the recipient family would not have to go through what they just had just experienced: the loss of their child.

I welcome legislation to support an increase in organ donation but I have concerns about the term "presumed consent". I feel this term has negative connotations as it loses sight of the fact that the donor family is central to the whole process and so the ultimate choice must rest with the family. In practice, it should be presumed that all families would like to be asked about organ donation and in keeping with their loved ones wishes they will make the right decision for them. The ultimate decision will be with the family of the deceased. I believe the best approach would be to incorporate into the legislation an opt-out system which would involve the family.

Most importantly, in conjunction with any legislation there needs to be ongoing public awareness and education about the need for and benefits of organ transplantation. Knowing the wishes of your loved regarding organ donation is easier for a family than having to make a decision on their behalf at very difficult and traumatic time.

Legislation and education alone are not enough. More resources are required to deal with the potential increase in the service and a robust infrastructure must be put in place to ensure discussion with the families about organ donation is done in the right way at the right time by the right person.

Organ donation truly is the most precious gift, given unconditionally and wholeheartedly with such goodwill to the organ recipient. Organ donation not only benefits transplantation but it is a key element to support families in their grieving process. It is very important that we can maintain a positive and sensitive approach at a most traumatic time for a grieving family.

I will share an example of the gratitude felt by recipients by reading an excerpt from a letter written by a 16 year old to his donor family on the anniversary of his transplant. He said:

> I know this time of year is very hard for you but I hope it helps to know that I think of you every day and how grateful I am for the wonderful gift you gave me. Everything I do, everything I achieve, I do it for you. Most especially, I bring your loved one with me and I will try never to let you down. Once again, thank you for changing my life, from a kidney recipient.

In reply, the family wrote back, "Our lives will never be the same because of the loss of our loved one but your letter is beautiful remembrance. Take care and best wishes for the future".

Chairman:

Our next witnesses, Mr. Joe Brolly and Mr. Shane Finnegan, are sharing time.

Mr. Joe Brolly:

I thank the committee and the Chairman for inviting us here today. I am a part-timer but the celebrity surrounding this failed transplant has captured people's imaginations.

We have worked closely with the main stakeholders, North and South, and our question was "How can we help?". It quickly became clear to us that the way to help was to work towards the putting in place in the South of proper infrastructure for organ donation and to move towards the system operated by the leading European donor rate countries.

It has been a huge adventure for me and I see beside me, and I cannot say how ecstatic I am to see her, Ms Noreen O'Halloran, whom I met at an event for the Mercy Hospital in Cork earlier this year. At that stage, she was so ill I thought things might not work out for her. I sent her a text about six weeks to say I was thinking of her and she texted back to say not to worry because she was on her way to the hospital for a transplant. Five weeks ago she received a kidney from the family of a deceased donor in very difficult circumstances, as they always are. The transformation is extraordinary. This is the amazing Noreen O'Halloran today, and she is a full supporter of the Government's proposed legislation for soft opt-out. She has her own website for patients, which she will talk about. The fact she is here today is a symbol that there is nothing to fear from this because family consent is at the heart of the proposal.

If members would be good enough to look at the document that has been circulated, from the *makelifeyourlegacy.com* website, "Opt for Life!", we hope that a one-stop shop can be worked out with people like Professor Jim Egan and Dave Hickey, and with Phyllis Cunningham, who is the doyenne, the mother of organ donation in this society, who works tirelessly often with little help and few resources, along with her team in Beaumont Hospital. The point of our involvement is to ensure the organ donation system is fit for purpose. There is no reason we should be lagging behind the main European countries.

This is very easily solved and it makes perfect economic sense.

Briefly, I want to tell the committee about the position in Northern Ireland. One of the documents that I have circulated to the committee is from the Department of Health and Social Services with whom we have been working closely in the North. Over five years, in the North, by putting in place the infrastructure that Professor Egan recommended in his paper which is one of the appendices in the document the committee has, we have achieved an 81% increase. That is coming from a very low base in Northern Ireland five years ago of approximately 13 or 14 donors per million of the population - we are now at 22 per million.

One of the appendices in the document is drafted by Dr. Paul Glover, who is the national director in the North for organ donation and transplantation. The five main parties, all of the patient associations in the North and all of the main stake holders are unanimously in favour of a move to soft opt-out for the following reason. Even with a good infrastructure, we have reached a ceiling in the North and we realise now that the way to move to the next level is to move to soft opt-out.

Briefly, I will explain the proposal. I appreciate that most of the members are in tune with what is going on. The reason I started this is that after I came out of the transplant and I went on the radio talking about how people must become donors, I received a call from one of the McNicholl girls, a mountainy woman from Dungiven which is close to me. She said I was wasting my time and that we should do what is done in Belgium, where everybody is a donor unless they do not want to be and one's family still has the final say. She told me that everybody is a donor in Belgium and it is merely a normal part of the dying process.

This proposal, what the Minister is proposing, will make organ donation the norm in society. If one thinks of it logically for a moment, the question at present is, "Should I decide to become a donor?" Apathy is a big problem in that regard - we only have 27% or 28% of the people involved. Under the new system, the question will be, "Is there a reason that I should not be a donor?" That will more properly accord with the overwhelming view in society that organ donation is good. Who does not want to save seven lives after he or she is dead?

I do not want to go through all the nitty-gritty, but the committee will see the basics of the proposals and all the statistics set out. A phrase is often used about this - I have been using social media and I am aware that Ms O'Halloran used it too. The question that keeps comes back from people is, "Why have we not done this already? It is a no-brainer."

I commend the proposal to the committee. The committee will spend time reading the document. We have a limited amount of time here and I will pass over to my good friend.

Chairman:

I welcome Mr. Shane Finnegan to the meeting.

Mr. Shane Finnegan:

I thank Mr. Brolly. I also thank and congratulate the Chairman for acting so promptly and with such an open mind on this issue when Mr. Brolly and I first met him a couple of months ago. I also commend the Chairman and the committee for hosting these hearings, today and next weeks.

I struggled when I first sat down to consider what I could add to this process. I am an organ donation campaigner with all the facts, but the many other eminent representatives one will see here, today and on 25 April, can relay that information to the committee. Then I thought there is something that I can bring to this table that some others cannot, that is, what this process is like through the eyes of the patient. I will tell the committee what this debate and the issue of organ donation looks like through my eyes.

First and foremost, I see a wildly fluctuating system where in any given year someone like me may have a slim chance of a transplant. In another year, such as 2010 when organ donation dropped by 28%, I would have no chance. I see the top ten European countries for organ donation have adopted the opt-out system and being representative of patients dependent on the Irish health service, I validly ask the question, "Is that a coincidence?"

I also see in 2012 that Ireland, a giving country full of compassionate people, has an organ donation rate of 20 per million population compared to 35 per million in countries such as Spain and Croatia. As a proud Irish person, I see this outlook on organ donation as not being reflective of the Irish people. Contrary to all the good work of the talented professionals who work in this field, I see that this is the result of a confined and restricted system.

I can say with some conviction that Irish people are compassionate as regards organ donation because Mr. Brolly and myself had independent research conducted by Amárach on the soft opt-out system. The question we asked the Irish public was, "Would you support a system of organ donation where all of us were donors unless we have opted out during our lifetime, with the next of kin always having the final say?" In a survey of over 1,000 persons and without any education on this issue, 71% said "Yes", 11% were indifferent and 18% said "No". The committee is the first to hear this research. Mr. Brolly and I will be issuing this to the media later today. With a good education process that would accompany legislative change, Mr. Brolly and I firmly believe these figures on public support would rise. As a patient, I see us pushing an open door.

Finally, I will give one last statistic which for me, as a long-term renal patient, is the most concerning of all. In 2000, there were only 150 patients awaiting kidney transplants. Today, that figure is closer to 650, a 413% rise. People are living longer. Type 2 diabetes sufferers are on the increase and the current waiting list will not dissipate any time soon unless we make this very subtle change.

With dialysis patients each costing the health service €70,000 a year, there are long-term savings to be made by changing. One cannot put a cost on a human life. That is for others. Fr. Alex Reid once stated that if by his actions he could save one life, then it will have been worth it. How often do the committee members, as legislators, have the opportunity to go back to their constituents and say they are actively saving multiple lives? I do not think anyone before the committee today, or on 25 April, would question that.

After 20 years knocking around renal units, transport wards, dialysis units and operating theatres, I have not seen or heard of a system that can impart change and make the difference the way this opt-out system could. Call me naive. I see no plan B.

I would ask the committee not to have somebody like me sitting in front of it in ten years' time when the situation is undoubtedly worse. They should give us hope, show leadership of which I see an abundance in this room and start helping us drive the change.

Chairman:

I would point out to Mr. Brolly that the Minister and the Government have not yet published legislation.

Mr. Joe Brolly:

I appreciate that.

Chairman:

Hopefully, as part of our deliberations, we will feed into that process.

Mr. Joe Brolly:

I understand.

Chairman:

I welcome Ms Christine Quinn from Castlebar, County Mayo, and thank her for attending. I am aware that the Taoiseach has been in contact with her as well because he asked us this morning to send his best wishes to her.

Ms Christine Quinn:

I am here today to speak to the committee thanks to the selfless generosity of a donor family.

Briefly, I will tell the committee my story, which began in January 2007 when I got sick. Up until then, I was in perfect health. Later that year I was diagnosed with a rare and incurable lung condition. Over the next few years my condition deteriorated until, in August 2011, matters reached a critical stage. I could no longer work and I was hospitalised. I was dependent on oxygen to keep me breathing. My life was very grim and there was no end in sight.

Professor Jim Egan, with his wonderful team at the Mater Misericordiae University Hospital, was my life-saver. They cared for me and never let me give up hope. With their help and support, and tremendous kindness, I was given the chance to have a second shot at life. Professor Egan agreed, at this stage, that a transplant was my only means of survival. I was ecstatic, but at the same time I was very nervous wondering would I survive. I was one of the very lucky ones. I was put on that transplant list.

At this stage, I had what everyone else would say was everything but, in reality, I had nothing. I had a good job. I had plenty of money. I had my own house, plenty of friends and my own car, but that was nothing because I had not got my health. None of it was any good to me.

I could barely walk and I could not breathe. I depended on my family and friends to do absolutely everything for me.

Oxygen kept me alive and in September 2011, just two weeks after being put on the list, I got the call that saved my life. I was given the ultimate gift of a lung transplant and thankfully I have never looked back. I am now back at work and am able to do the things in life I love and best of all I can go for a walk and breathe fresh air, something I could not do. I can now do the simple things in life that we all take so much for granted.

People should not be fooled - it was by no means an easy journey and there were days when I wondered if it was worth it all. As members look at me today they see living proof that organ transplantation works. I will be forever grateful to the wonderful family that allowed their loved one to be my donor. There are huge waiting lists for recipients and a great shortage of donors. Advances in medical science result in more successes in transplantation, which should encourage more people to be organ donors.

Chairman:

I thank Ms Quinn for coming this morning and sharing her story.

Our next group of speakers Ms Noreen O'Halloran, Mr. Michael Kiely and Ms Annette Betson are also sharing time. I ask Ms O'Halloran to lead off.

Ms Noreen O'Halloran:

I thank the Chairman and members of the committee for the invitation to attend this morning's meeting, which affords us an opportunity to set out our proposals, which we feel would improve the current organ donation system in Ireland. Mr. Michael Kiely and Ms Annette Betson and I are very pleased to be here and have listened with great interest to the many invited guests. We also hope our personal experience of organ failure will assist the members of the committee and give them a greater understanding of how organ failure affects the lives of patients and their families.

I will give a brief introduction. Mr. Kiely suffers from end-stage kidney failure and after being on hospital haemodialysis, his sister, Ms Betson, decided to become a living donor to him. As a result in January 2012, Ms Betson successfully donated one of her kidneys to Mr. Kiely. I was diagnosed with polycystic kidney disease at the age of 18 and started peritoneal dialysis or home dialysis in September 2011. I am happy to report that five weeks ago I received a kidney transplant from a deceased donor through Beaumont Hospital. My form of kidney failure is hereditary and unfortunately has affected four generations of my family. My father, Mr. Tom O'Halloran, has suffered with this illness for 30 years and is currently awaiting his third kidney transplant. So far he has been waiting for six years. It would be more common for a parent to be proud of his or her child, but I can say wholeheartedly that I am so proud of my father as a result of what he has been through. While I would always have loved to have given my dad a kidney, since that is not possible being here is the only way I can help him.

It is because of what we have been through or in my case what I still see my father going through that Mr. Kiely, Ms Betson and I would like see an improvement in the current organ donation system. In that respect we have two proposals we feel could greatly improve the current system of organ donation. Our first proposal is the employment of more co-ordinators in all acute hospitals. We feel that the role of the co-ordinator is extremely important, particularly in identifying potential donors and also in comforting families who have decided to donate their loved ones' organs. At present Beaumont Hospital has six co-ordinators with none in any of the other acute hospitals. As a result we believe potential donors are being missed. Having two co-ordinators in each acute hospital would go a long way towards ensuring that organs are not being overlooked and result in more transplants thereby saving more lives.

Our second proposal is the establishment of a national organ donor register, which we believe would encourage more people to sign up indicating their willingness to be a donor. In this age of technology, this seems the most effective way to obtain donors. The UK operates a similar register and after running a campaign at the start of the year to highlight organ donation, an additional 147,000 people registered. While I appreciate that it has a greater population, as this form seems to work there, why should Ireland not establish a similar register?

The newly introduced driving licence format gives an opportunity to tick part 4 in question 20 agreeing to become an organ donor whereby code 115 will appear on the licence. The Government is already in effect collecting this information therefore making it easier to establish a register. For people without access to a computer we feel that organ donor cards could still be used but perhaps a prepaid envelope should be included with the card allowing them to send their details for entry into the organ donor register. It would be imperative for all acute hospitals to be able to access this database should an issue with organ donation arise.

Over the past nine years there has been a significant increase of 785 patients needing dialysis. There are various reasons, including obesity, diabetes, and high blood pressure. The end result is that the number of patients needing dialysis is increasing annually. As of 31 December 2012, some 1,828 people were on dialysis at a cost to the State of €118.9 million. This can be compared with the cost of transplant per patient at €96,000. I should say I got these figures from the HSE. If we were to increase kidney transplants by 100 each year to reach a target of 250 per annum, the cost to the State would be €24 million, thereby reducing the burden of dialysis on the State to €94.9 million. It should be noted that post-transplant the cost of maintaining a patient on drugs and hospital visits is approximately €10,000. An estimate is that each transplant results in a saving to the health service of in excess of €830,000 per patient over the lifetime of the graft, which is approximately 15 years. An increase in transplant activity of 100 transplants therefore results in savings of €83 million over the lives of those 100 patients when compared with maintaining them on dialysis.

Since I received my kidney transplant and after consulting various renal consultants and clinical nurses, I have been informed that the rate of rejection of a kidney transplant is now minimal. This is due to the exceptional cross-matching in Beaumont Hospital and advances in immunosuppressants. Therefore the medical staff rarely see rejection anymore. While I say that the average life of a kidney transplant is between ten and 15 years, as a kidney recipient, I am certainly aiming for many more than 15 years. Hence the saving of €830,000 I mentioned earlier could possibly be greater.

The kidney transplant programme in Ireland is at a critical juncture where, in order to further develop the programme for both living and deceased donors further investment in infrastructure is needed. The investment would result in a doubling of the life expectancy in patients with renal failure and a saving to the health service of in excess of €240 million over the next ten years. Expansion of kidney transplantation to 250 transplants annually would result in the following benefits over the next ten years: a reduction of more than 1,000 in the number of patients maintained on dialysis; a reduction in dialysis treatments of 1.4 million; a reduction of 2.8 million patient journeys to dialysis treatment centres; and a doubling of the life expectancy patients would have if they continued on dialysis. All those figures have been supplied by the HSE.

Having been on two forms of dialysis over 17 months - I know Mr. Kiely will agree with me on this, I cannot overemphasise how my life has been transformed in just five weeks. I have never felt better. A weight has been lifted from my shoulders and my life is my own again.

The following needs to be done in order for Ireland to reach its full potential of donors. We need to train more co-ordinators in all acute hospitals. We appreciate there would initial costs to such a project, but as highlighted by the figures I quoted earlier, the cost would be greatly outweighed by the benefit of getting patients off dialysis and improving their quality of life. We need to establish a national organ donor register that is accessible by all acute hospitals.

The information could be collected on this register or on the new driving licence application form. Promoting living donors could be achieved by trying to reduce the time it takes for cross-matching and work-ups. People could be encouraged to donate through incentives. In some parts of the United States tax incentives are offered to those who offer a kidney to a loved one. In the past week, Australia announced it would pay three weeks wages to anyone who agreed to become a living donor to a loved one to a maximum of AU$3,600. Perhaps Ireland could consider a similar or different incentive to encourage living donors.

Public awareness is extremely important. We feel most people not affected by organ donation do not fully understand its implications or how they can help. Recently, and unbelievably, I was asked by a man in his mid-30s what was dialysis. This is why educating and informing is so important. Real-life stories are the best at achieving this. For my part, six months ago I decided to establish a website, *kidneyfailuremystory.com*, with a view to raising awareness of dialysis and documenting how it has affected my life. In a way I wanted to give hope to other patients who had just started dialysis. At times the isolation can be immense. To date, in less than six months, more than 19,000 people have viewed the site. If only a fraction of these 19,000 people decide to carry a donor card as a result I will have been successful in raising awareness. At no stage has anyone ever disagreed with soft opt-out. Everyone has been in favour of it.

Mr. Kiely, Ms Betson and I hope committee members have found our presentation informative, and that they appreciate our concerns regarding organ donation. While we do not expect miracles we would like to see an improvement of the current system, a change for a better, and a more positive future for all patients awaiting any form of transplant, whether heart, lungs, liver, pancreas or kidney. Who knows when any of us or our families may be affected by organ failure. It should be noted one is three times more likely in life to need a transplant than to have ones organs donated. Since the numbers awaiting transplants are growing yearly we cannot emphasise enough the real need for an immediate improvement. For this reason we are in favour of soft opt-out and for change sooner rather than later. I thank the committee.

Chairman:

I thank Ms O'Halloran, Mr. Kiely and Ms Betson. This afternoon they will speak in the audio-visual room at a meeting organised by Deputy Patrick O'Donovan. I hope other Members of the Oireachtas who are not here this morning will be able to attend. I thank the witnesses for appearing before the committee.

Our next set of speakers from the Irish Kidney Association are Mr. Martin Doody, chairperson, and Mr. Mark Murphy. I apologise on behalf of Deputy Ó Caoláin, who must speak in the Dáil on the Order of Business on behalf of Sinn Féin. I also apologise on behalf of Senator Marc MacSharry, who must also leave to attend the Order of Business in the Seanad on behalf of Fianna Fáil. Deputy Ó Caoláin asked me to express his support for the witnesses this morning.

Mr. Mark Murphy:

I am the CEO of the Irish Kidney Association, IKA. I will commence by giving the committee a brief outline of the history and evolution of the Irish Kidney Association and treatment of kidney failure in Ireland. Dialysis as a treatment is 70 years old. It came to Ireland in 1958 and kidney transplantation started in January 1964. In 1978 the Irish Kidney Association was founded by three groups of kidney patients coming together from Dublin, Cork and Galway, where haemodialysis was available. The catalyst was the need to start a public awareness campaign highlighting the need for kidney donation after death. The first kidney donor cards were produced by the IKA for the first awareness campaigns, which were ten years after the UK health system had produced its cards.

As time moved on many more haemodialysis centres were opened, some funded and others built by the IKA. The IKA grew along with the success of dialysis and transplantation. A new drug, cyclosporine, was discovered, which is very effective in stopping the body from rejecting a strange new donated organ. This permitted far superior kidney transplantation and liver, heart, lung and pancreas organ transplants also became possible. Along with kidney transplantation they are now considered normal surgery and expected by society. At present in Ireland, out of 3,900 patients with failed kidneys 53%, or 2,100, are transplanted and 47%, or 1,800, are on dialysis. Including all other organ transplants, just under 3,000 people in Ireland enjoy extended life because of organ donation resulting in transplantation.

Anyone who says the Irish organ donation and transplantation system is not working is wrong and misinformed. What is true, and the reason we are before the committee today, is that Ireland is the only country in Europe which has never legislated for the organ donation and transplantation process. What we have done is transpose last August the EU directive on the quality and safety of organ donation and transplantation into a Department of Health statutory instrument. The Houses of the Oireachtas have never willingly debated organ donation and transplantation, except for Senator Quinn’s Private Members' Bill, No. 43 of 2008.

The discussion today surrounds the consent we seek from the public for deceased organ donation. For the past 49 years this has been informed consent by the next-of-kin of the deceased. Situations such as where no next-of-kin are available, next-of-kin not being able to make up their minds in time, or a dispute within a family are described as “no consent” and organ donation does not proceed. Obviously organ donation does not proceed if consent is refused, but this decision is grouped together with the other situations I described and labelled “no consent” in all the records available to us. This dilemma of "no consent" has frustrated people across the globe, particularly in Europe where organ transplantation is advanced but as many as ten people a day die because of the lack of donated organs.

Some jurisdictions created a law of presumed consent. The Spanish were the first to do so in 1979 and many countries chose to follow. In the course of the following ten years, the Spanish realised creating this consent law made no significant difference to the donation rates and there was a wide variance in hospitals' organ donation rates. Spain realised the shortage of organ donations was not because of the public’s lack of willingness; it was much more to do with the clinical practice and process and the individual skills of health care staff in dealing with donating families. In 1989 the Spanish created an organisation, Organización Nacional de Trasplantes, ONT, which trained and placed organ donor co-ordinators in hospitals and organised the organ donation process. As a result, Spain has led the world's organ donation rates ever since. It averages 35 donors per million of population. Other countries which followed Spain’s example are achieving more than 30 donors per million of population as a consequence.

The architect, and head, of ONT, Dr. Rafael Matesanz, repeatedly states that changing laws on consent does not change organ donation rates. One must change clinical practice inside hospitals to increase the rates. The practice in Spain is informed consent, and is internationally recognised as being so regardless of what the law on the statute books suggests, which is presumed consent. The rest of Europe found the exact same, and hard or soft presumed consent is not practised anywhere in Europe, where all countries use informed consent.

In our strongly held view it is worth considering the point that renaming our consent system to suggest presumed consent, will simply confuse and divide the public. The Irish people like to be asked, and not told, to do something. Some people have no next-of-kin, some are entirely estranged from their families, some are separated, and not legally so, awaiting divorce, and some relatives will not be found in time.

How is consent achievable for these people? Should a decision posted on a register be acceptable for organ donation to proceed in these circumstances? Could we go a little further and suggest that the recorded wishes of the deceased should be paramount? We advocate, as do others, for a national organ donor registry to be used to show the next of kin the proof of decision by the deceased in his or her lifetime. Should we take the decision in the registry as consent if next of kin are not available? That is food for thought. That might require written consent rather than an online registry. If so, why not consider written consent by the person as consent after their death in the circumstances I have described where next of kin are unavailable? NHS Blood and Transplant issued a press release last week announcing that the UK had increased organ donation by 50% in five years. They did not alter their consent system. They changed clinical practice, as we are suggesting we should do.

Creating a consent law that is different in name but in practice will be operated exactly as best practice dictates - which is informed consent - is foolhardy and will only lead to unnecessary confusion for the public. We must introduce the Spanish organ donor co-ordinator model and the infrastructure surrounding organ donation to make real changes. We can increase our rates just as the UK has done and save and extend the lives of 50% more people as a consequence. The least important issue in the packages of changes the committee will learn about in these presentations today is the consent issue. The infrastructure proposed will change everything for the better. Ironically, the Spanish, Croatians and other European countries have proven that this infrastructural investment returns net savings in costs for other treatments that far outweigh the initial investment. At worst, it will be cost-neutral on our health system and we will improve and extend many more lives.

Chairman:

I thank Mr. Murphy for his presentation and for coming here this morning. Our next speaker is Mr. Brendan Gilligan who is the chairperson of the Irish Heart and Lung Transplant Association.

Mr. Brendan Gilligan:

I am a heart transplant recipient of 11 years. The first heart transplant took place in the Mater Hospital in September 1985. Until the end of December 2012, there have been 296 heart transplants in Ireland. The Irish Heart and Lung Transplant Association is a non-Government funded patient group. We welcome the opportunity to put forward our view on the proposed changes in organ donation from opt-in to op-out and the problems this would create if is changed without specific measures being put in place beforehand.

Ireland is a very giving and altruistic society and our current donation rates, while not the highest in Europe, are still about 20 per million of population which ranks us just above mid-table in the list of European countries. However, we can and should do better. There is no evidence that presumed consent soft opt-out by itself will improve donor rates and to consider it without having the necessary infrastructure in place to support it would harm the gift of life ethic, which is so important to the idea of organ donation.

Therefore, before considering a change from opt-in to opt-out, let us look at the infrastructure that needs to be in place. First, we need specialised donor co-ordinators in all our major hospitals. As alluded to by Mr. Murphy, the NHS Blood and Transplant recently released details of a 50% increase in donation figures over the past number of years. One of the major factors in achieving that was the employment of a network of 250 specialist nurse co-ordinators throughout the UK system. Second, we need a national donor registry. The Government needs to give sufficient resources to publicity campaigns across the country to inform people of the meaning of presumed consent and to promote donor awareness. We also need proper funding for our national organ donation transplant office to allow it to function to its full potential. The importance of the infrastructure cannot be underestimated and will require additional resources to ensure that presumed consent soft opt-out is introduced properly.

It would be wrong for committee members and their colleagues to legislate for a change to opt-out thinking that it will improve organ donation and transplantation without first addressing the weaknesses and gaps that exist in our current system. We support the premise of presumed consent soft opt-out but only if the aforementioned infrastructure is set in place beforehand. We owe it to the public and the many people awaiting a life-saving organ transplant to ensure that this is introduced with the necessary measures in place.

Chairman:

I thank Mr. Gilligan for his presentation. I should also have welcomed Mr. Martin Doody, chairperson of the Irish Kidney Association. I know he will be taking part in the question and answer session later on. Our final speaker in this segment of the meeting is Mr. Philip Watts, chief executive officer of Cystic Fibrosis Ireland and the Irish Donor Network. I welcome him and thank him for his patience.

Mr. Philip Watts:

The Irish Donor Network, IDN, is a network that brings together all the patient groups with a direct interest in and concern about organ donation and transplantation in Ireland. Our role is to encourage and facilitate organ donation and shape policy in respect of transplantation and donation. Much of our work has been done behind the scenes over the years. We have contributed much in terms of a positive atmosphere towards organ donation in Ireland. At the outset, it is important to say there is a division of opinion among us in respect of the question of soft opt-out. Most of the groups in our network are in favour of moving to that process but we respectively and gently disagree with our colleagues from the Irish Kidney Association. There is a significant amount on which we do agree but we disagree on this issue. The other groups who are in favour of moving to a soft opt-out position include: the Alpha One Foundation, which is represented here in the public Gallery by Ms Catherine O'Connor; Cystic Fibrosis Ireland, which I represent; the Irish Heart and Lung Transplant Association, which is represented by Mr. Gilligan; and the Irish Lung Fibrosis Association, which is also represented in the public Gallery today.

We are in favour of moving to a soft op-out position and we understand this position will be presented by the Government. All the Government has said on this issue to date is three lines in the programme for Government 2011-2016 so there is an onus on the Minister to set out in more detail what exactly it means by shifting to an opt-out position and to explain what a soft opt-out position is. That needs to be done sooner rather than later. Under no circumstances would the groups we represent in this submission support a hard opt-out approach whereby next of kin would not be consulted. Next of kin should always be consulted in respect of organ donation. This is the major change between now and 2009 when this issue was considered before and the Government was suggesting a hard opt-out position. We agree with the Irish Kidney Association that those countries that profess to operate a hard opt-out system whereby next of kin are not consulted, for example, Austria, do not actually apply it in practice. The IDN acknowledges the excellent individuals involved in transplantation and co-ordination, such as Ms Phyllis Cunningham with whom we have worked for many years and who is representative of the excellent standard of transplant co-ordinators, surgeons and teams and the procurement team. We contend that without their dedication and skill, often working far beyond what they are called to do, transplantation and donation rates would fall considerably.

We support a move to soft opt-out but we agree with Mr. Gilligan's argument that it must be accompanied by package of essential measures. The last thing we want to do is move towards a soft opt-out position and then see no difference in the organ donation and transplantation rates in a year's time.

The infrastructure for transplantation and organ donation must be improved. The committee has heard a number of people, including patient representatives, state that a key issue is the appointment of a network of donor co-ordinators who would be assigned to major hospitals with ICU units. Basically, they would be medical and nursing personnel who would ensure the smooth operation of the organ and transplant process, including protecting the interest and welfare of families who choose to donate organs in very difficult circumstances.

We have, believe it or not, a national organ donation and transplant office. It does fantastic work and is led by Professor Jim Egan but he has no resources. He carries out the work in addition to his day job as co-ordinator of the lung transplant programme at the Mater Hospital with virtually no secretarial support. If we are serious about co-ordinating organ donation and transplantation, adequate resources must be given to the office.

I have heard staff at the Department of Health say that they will not develop a national organ donor registry. How can people opt-out if there is no registry? One simply needs to design a website that will allow people to indicate their preference. We must also list a menu of organs to donate because some people may be happy to donate their kidneys but not lungs. It is important to give them a choice.

From a lung transplant perspective, and I know that Ms Catherine O'Connor and Mr. Brendan Gilligan would agree, we need to take specific measures to improve the rate of heart and lung transplantation in Ireland. Top priority should be a replacement for the very fine surgeon, Professor Freddie Wood, at the Mater Hospital. There is also an inadequate number of rooms for surgery, preparation and recovery at the hospital and we need seven rooms for a transplant programme. A soft opt-out system will make a difference based on other experience but not without these specific measures that I have outlined. I agree with the soft opt-out but only as part of a package of measures. A soft opt-out cannot be introduced on the cheap.

Chairman:

I thank Mr. Watts for his presentation. I welcome a delegation to the Visitors Gallery that consists of Ms Nicola Cassidy, Irish Lung Fibrosis Association, ILFA, Ms Lorna Murphy, ILFA and transplant nurse at the Mater Hospital, Ms Catherine O'Connor and Ms Mary O'Connor, Irish Donor Network, and Ms Patricia May. I call on Deputy Kelleher to commence for Fianna Fáil.

Deputy Billy Kelleher:

I welcome everybody here. I found the presentations informative and inspiring. To be truthful, when I have read about a living donor I wondered how I would respond if my brother looked me in the eye and said "Bill, it's life or death for me". I admire the people who have donated. Many of us would probably find it hard to make such a judgment call.

With regard to the broader issue, I support the soft opt-out option. Some people may know Dr. Patrick Hennessy from Cork who advocated donating and received a kidney. I know him very well and have visited him a number of times. Ireland has a low donation rate of only 20 organ donations per 1 million of population. I do not have an intimate knowledge of the infrastructure that is required. I have wondered whether the low rate is due to a cultural or religious factors. Is there a reason we do not proactively donate organs? Ireland is an altruistic nation in many ways. Is there a reason Ireland does not rank high in the table of countries that donate organs? Is it simply that we do not have the proper infrastructure? Do we not have enough donor co-ordinators in the trauma units and accident and emergency units in hospitals? Are there other reasons?

Very often legislation does not necessarily change the public's mind but it obliges Governments to do things about the legislation that they have enacted which means putting in place infrastructure in hospitals to encourage and allow organ donation. We must remember that two patients are involved in the process, the one that donates and the one that receives. I hope that organ donor co-ordinators in hospitals will have a strong understanding of donation and be trained in how to deal sensitively with people. Co-ordinators will have to deal with people whose loved one has or is going to have his or her life support machine turned off and his or her family will have strong emotions.

A family sent me information that their young child had been involved in a car accident but had subsequently died. Afterwards the parents regretted that they had not made the decision to donate his organs. They were very emotional. At the time their only focus was on their son and they never looked beyond that but sometime later they regretted not donating his organs. Whatever decision is reached on legislation and the presumed consent or soft opt-out, we must ensure that in all cases the family is consulted. It does not matter whether it is a hard or soft opt-out, in every case the family must be consulted and the infrastructure must be put in place.

I listened to wonderful comments on organ donation made by Mr. Joe Brolly, Mr. Shane Finnegan, Ms Noreen O'Halloran and others. Very often the committee talks about policy and administration but on this occasion it should promote the concept of organ donation. Aside from dealing with the appropriate legislation, we should advocate strongly and give people a platform to express ways to develop organ donation. We are talking about life and death here but organ donation needs proper administration. There have been advances in technology, medical technologies and immuno-suppressants. We should also examine North-South relations and the possibility of a strong island-based transplant system just like what we are doing for rare communicable diseases. We should work closely with the UK in that context. I know that there is strong co-operation between various hospitals. We should also set up an infrastructure that will allow us to improve our ranking in the league of organ donation. We need a strong international co-ordinating body and the EU is working on same. Mr. Joe Brolly and others have saved lives and are inspiring, I am emotional even talking about it. I am squeamish at the best of times and I do not like going to hospitals.

Mr. Joe Brolly:

Then the Deputy had better not donate a kidney.

Deputy Billy Kelleher:

When my wife was having our children in the labour ward I was down the corridor. I opted out of my family responsibilities at that time.

Chairman:

I thought there were metrosexuals in Fianna Fáil.

Deputy Billy Kelleher:

It is incredible that people generously donate their organs and I am not just saying that because the donors are present. I read a newspaper article published in *The Irish Examiner* about a family in Kilcully, White's Cross, County Cork. I do know what I would do if asked to donate. I thank everybody for coming here.

People hold varying views on organ donation but they must not damage the approach that the committee and delegations wish to reach. We must ensure that the matter does not become divisive in the broader context of encouraging more people to give life.

Chairman:

I call Deputy Sandra McLellan and welcome her on her first outing as the Sinn Féin lead spokesperson. She is a new member of the committee and has made a good contribution since joining.

Deputy Sandra McLellan:

I thank the Chairman and I welcome the delegations.

The presentations have been very informative and quite emotional for those who have had recent transplants. Deputy Ó Caoláin was due to be the lead Sinn Féin speaker today, but he had to go to the Dáil for Leaders' Questions. He was anxious to hear the witnesses' contributions this morning and he understands how compelling their cases are.

I support the opt-out position. Family discussion on the issue is key to any successful scheme. It is important that people who are in favour of donating their organs tell their next of kin so that if there is a tragic accident it reduces the burden on the family to make the decision to donate the organ. I would also like to see specialist transplant co-ordinators trained in grief counselling based in every hospital trauma unit. When this model was introduced in Spain it led to a large increase in the number of families consenting to donate the organs of a loved one. It is important that we consider introducing a system to maximise the number of organs available.

I accept it is important to have a national organ-donor register. Ongoing public awareness and education are very important to promote donor awareness. What types of campaign do the witnesses plan to hold? Do they plan to go into schools? Sometimes there is a problem with lack of awareness. If schoolchildren grow up with it, it becomes second nature for the next generation. I found the witnesses' arguments based on their real live experience very compelling.

Senator Jillian van Turnhout:

I echo what the previous speaker said and I thank the witnesses very much. I am quite new to this issue of organ donation. I lived in Belgium for approximately three years at the beginning of the 1990s, shortly after its system was introduced, and it was quite a hot topic there. I agreed with it at the time and I still instinctively agree. However, I wish to tease out some issues. I understand that 24 of the 27 EU member states have some sort of presumed consent or opt-out system in place. We need to consider those who are not in favour of the presumed consent model. After Belgium introduced the system in 1986 there was a significant awareness-raising campaign and perhaps the rise in organ donations could be attributed to the awareness-raising campaign rather than the legislative changes. People might argue that the US has one of the best rates of organ donation but it does not have presumed consent. Ms O'Halloran mentioned the tax incentives in one of the states. The US have what I believe is called a presumptive approach, whereby families are approached on the presumption that they will agree. With the exception of the representatives of the Irish Kidney Association, all the witnesses have mentioned presumed consent. There has been coherence on the package of measures that needs to be introduced. If the measures were all introduced, why would we need presumed consent? What difference would it make?

I found the presentations very informative and I am absolutely convinced that we need legislation. I had not realised we had an absence of primary legislation and that we only have the statutory instrument to introduce the European directive. Why would we choose presumed consent rather than a presumptive approach? Irish people do not like being told they have to do something and it is a very emotive time for families of potential donors. I want to ensure we get this right.

Chairman:

I will call the other members, after which we will go back to the witnesses.

Senator Colm Burke:

I wish to thank all the witnesses and commend them on their very comprehensive presentations. I recently spoke a medical consultant who was involved in a team looking after a patient. They spent five hours in the operating theatre trying to get someone through a very difficult situation and they thought they had done a great job. They found that in the theatre next door there was a team of doctors down from Dublin doing organ harvesting involving a girl who had unfortunately had a tragic accident and whose family decided to donate the organs. They were extremely impressed by the co-ordination that was going on. That family's decision to donate organs resulted in the transplant of a liver, a pancreas and kidneys. After spending three or four hours on organ harvesting, they advised the consultant, to whom I spoke, that they were flying back to Dublin, with all the recipients already on the way to Dublin. They were then scheduled to continue on after midnight to complete the transplants. That indicates the commitment of the medical and nursing teams involved in transplant area. We should acknowledge the great work they do. When we look at the health service we are very good at identifying the deficiencies. However, it is also very important that we give recognition to the work being done there.

Earlier this morning I raised an issue I have with the HSE. Does a specific person in the HSE have responsibility for this area or does each hospital act independently? When discussing co-ordinators in hospitals, the first question is whether one person should be answerable in the HSE and work from there. I agree with the witnesses. In the case I was discussing, the consultants in the hospital advised the parents that the person would not come through. The family had no one else to fall back on for assistance. Appointing co-ordinators is important, but is one person in the HSE responsible? Is there a mechanism for co-ordination between the HSE and the voluntary hospitals?

The European cross-border health care directive was passed in February 2011 and has to be implemented now. Is there now far more co-ordination between health services in Europe and particularly between the UK and Ireland in this area? Up to now each country has been working individually. With more specialisation, could we develop a more comprehensive service through more co-ordination between member states?

The key issue the witnesses have identified is that of co-ordinators within the hospitals. With regard to the possibility of a change in the area of consent, coming from a legal background I know the difficulties that can arise in dealing with the administration of estates. It is always a difficult time for families. I am certainly in favour of a change in the law in this area, and presumed consent, which is a better option at this stage, is something towards which we should be working. It also requires a major public information process. We achieved this in the area of road safety. This is one area that should be given priority from the point of view of national co-ordination and a national campaign.

Deputy Ciara Conway:

I wish to thank witnesses for their contributions. In particular I single out those who shared very personal stories on their journeys involving organ donation, which is the nub of the issue. What would happen if it was my sister, brother or daughter? I have experience of it in that two years ago my uncle was a recipient of a kidney from another family member. I have seen the life-changing impact not just on him but on all of us in terms of our appreciation of him and how selfless the donor was.

Deputy Kelleher asked what choice we would make if we were faced with it. I commend those who spoke because it is not easy, and I thank them very much. There has been much talk in recent years about organ donation, particularly during the campaigns mounted in awareness weeks. In recent months the conversation has changed with regard to the soft opt out model, which is something we need to think about and something which I support. In my preparation for today I discussed this issue at home with family members and friends. An issue of which I became aware, and perhaps somebody might be able to shine a bit of light on it, is that gay people are not allowed to be organ donors. Given the amount of testing and tissue matching carried out in the Mater Hospital why can my friend, who happens to be gay, not carry a donor card? If this is not true it needs to be stated because I was confronted with it in the run-up to today's meeting. On the back of the very insightful weekend we had on marriage equality and the steps society is taking-----

Chairman:

As a gay person I have an e-donor card.

Deputy Ciara Conway:

I know but-----

Chairman:

It would be interesting to find out.

Deputy Ciara Conway:

I am stating this is the information out there and now is the time we need to speak about these matters and set the record straight.

Chairman:

We will certainly follow up on this. I have been carrying a donor card for a long time.

Senator Jillian van Turnhout:

I think it is wrong.

Deputy Ciara Conway:

I know from a series of parliamentary questions that gay people are not allowed to donate blood.

Chairman:

That is correct.

Deputy Mary Mitchell O'Connor:

I thank all of the witnesses for their presentations and say well done to Mr. Brolly for being a living donor. I was struck by Ms Quinn stating it was the ultimate gift she received. Ms O'Halloran stated her life is now her own. This goes back to what Deputy Conway stated, that we must measure it in our own lives. I have two boys and if they needed a donor I would want them to be able to receive a kidney transplant. As a mother I would think twice about donating their organs but if we introduce this it will change the ethos and it will be up for discussion in the family home. One is three times more likely to need an organ than to donate one.

Perhaps I misunderstood, but Mr. Murphy, the chief executive officer of the Irish Kidney Association, stated the status quo is okay. If I were on dialysis I do not know whether I would be that happy. He stated 1,800 people are on dialysis and 3,000 people are enjoying new organs. I am aware of a UCD student from Waterford who has great difficulty. He goes into hospital three days a week and if he wants to go home to his family at weekends, like any student, it must be organised with Waterford Regional Hospital. It is a huge issue if he wants to go on holidays. He is a young student and wants a life ahead of him. I find it hard that the CEO of the Irish Kidney Association stated the status quo is fine. I will give him plenty of time to answer. He stated we need a co-ordinated network in the hospitals, but my understanding is those who want the soft opt out option also want this. What is important is that the family has a say. Mr. Murphy gave examples of people who live alone or are separated, but having this conversation now will give Irish people time before they are ill or on their deathbed for this decision to be made. We are discussing a new ethos whereby people will discuss the soft opt out.

Deputy Regina Doherty:

I thank the witnesses for appearing before the committee. I apologise for being late for the meeting but I had another appointment. I have huge admiration for people such as Mr. Brolly - and the example he has set is second to none - who give of themselves to those in desperate need. I am in favour of what is collectively sought, which is the soft opt out option. Prior to the meeting today I did a quick run around of my husband's brothers and sisters and my own to see how many of us had organ donor cards, how many of us did not and the reasons for this. Just under 40% of our family members have organ donor cards, which is good, and I am one of them. I cannot take the credit for going out and getting my organ donor card. The only reason I have it is that my husband brought home the form years ago. With regard to the members of our family who do not have an organ donor card, it is not because they do not want to carry one it is just that they have not got around to organising it. Life is busy. Taking this as a small yardstick, the vast majority of people in Ireland do not have exceptional reasons for not carrying an organ donor card, they just have not got around to it. Presumed consent is very worthwhile and it is incumbent on all of us to get behind it and ensure it happens and that we will not be speaking about it again in a number of years.

As this is not owned by anybody in the Department of Health or the HSE, I could not find a definitive answer on how much the ICT infrastructure would cost if we were to put it in place, how much the network co-ordinators in each hospital would cost and how we could fit it into the budgets. If it is not being measured it is certainly not being considered for future budgets. Do any of the witnesses' organisations have these figures so we can take them back and begin real substantive talks about how we can ensure it is included in budgets in the coming years?

Deputy Paudie Coffey:

I am not a member of the committee but I have been listening with interest to all of the contributions. I thank the Chairman and the committee for the work they are doing on organ donation. I come from a donor family, and this is the first time I have spoken about it on public record. Almost 24 years ago I tragically lost a sister, my nearest sibling, to a brain haemorrhage. At the time we as a family spoke about organ donation. It is something which appears at a very tragic moment in a family's life and we did not have much time to think about it. We decided she would donate and I must say, almost 24 years later, it is one of the most fulfilling things we did as a family and is something of which we are very proud. She donated two kidneys to two different individuals, one a young man the same age as her and another man who was quite a bit older. Both men are now close friends of the family and visit us and we speak openly about it. We gave them a whole new life. I am very much in favour of any proposal which would encourage donation in any way. I have listened carefully to the arguments on presumed consent and we should consider it. If people wish to opt out then let them do so. Organ donation is a valuable gift which we can all give.

Mr. Mark Murphy:

I have a number of questions to answer and other questions would be better answered by Ms Cunningham. I will go directly to Deputy Mitchell O'Connor. I wish to clarify an issue as she stated I was complacent as such. I am very clear the consent issue is the least important issue. What needs to change is the infrastructure. The reason I state the consent issue is the least important is because it is merely renaming what already exists.

No one is suggesting that the practice in which the manner consent is conducted in a hospital should change. Why change the name of it for the public? The family is always contacted. If consent is not achievable, should we consider other ways? Renaming what is already the practice, that is, informed consent, might not be clever. I do not know how it will affect the public other than to divide the public. A poll was done, which we had nothing to do with, and of 5,000 people, 46% did not want presumed consent, 47% wanted presumed consent and 7% did not have an opinion. The 5,000 were clearly divided.

As far as I am concerned, 90% of the public are willing organ donors. Let us not use the term "presumed consent". Everyone is trying to get away from it, but one cannot. If one says "soft informed consent", the term "presumed consent" pops out. The public hears the presumption of consent. It does not understand soft in, soft out. "Presumed consent" is the phrase that creates emotion and division in the public and I do not want to have anything to do with it, if members do not mind me saying. Soft opt-outs do not work. Immediately, it gets converted into meaning presumed consent, as it did by all members. That is what I-----

Deputy Sandra McLellan:

No, we did not.

Chairman:

In that context, can the language we use help?

Mr. Mark Murphy:

The committee would be trying to change the English language.

Chairman:

No. I have an open mind in this regard. Were Mr. Murphy to take his hypothesis to its natural conclusion, the *status quo* would be maintained because of a confusion in terminology and an unwillingness to embrace the need for everyone to buy into this approach. Am I wrong?

Mr. Mark Murphy:

The trick is in donor co-ordination.

Chairman:

Yes.

Mr. Mark Murphy:

It is not in what the Chairman calls consent.

Ms Phyllis Cunningham:

I would not like to call it a trick, but a great deal is involved. Everything is important. We need public awareness. It is important that families have been able to discuss and decide on this matter in normal times. Making that decision is difficult and those people are wonderful. Co-ordination is important, but so are other factors. Families have declined to make donations - we do not like to use the word "refused" - because they did not know what their loved ones wanted. People regret that they were unable to make this decision.

Many people want to donate. I have been involved in this field for a long time. When I discussed the matter with the members of my family, they wanted to be donors, but they never got cards. It is not an issue one wishes to raise with one's children, but if people do not want to donate and if they can record that-----

Chairman:

Outside of the emotion in the immediate aftermath of a death, have we a body of evidence to suggest why families decline?

Ms Phyllis Cunningham:

No. We need to determine whether donors are being lost. We need an ongoing audit to determine the areas we need to improve or develop. We have set up a new national organ donation and transplant office with the HSE. Professor Jim Egan is its clinical leader.

Chairman:

He will attend our meeting next week.

Ms Phyllis Cunningham:

Many of us are involved in that office. A submission is being made to the Department covering a range of topics, including an increase in staffing and public awareness. The latter is key. As with the Road Safety Authority, RSA, we need to invest money in national campaigns to promote organ donation and inform people of the benefits. Gays are not excluded as organ donors.

Chairman:

That was my information. I have an e-donor card or app.

Mr. Brendan Gilligan:

The Chairman's app of state. I concur with Ms Cunningham's remarks. The key is public awareness. The Government will need to invest resources if it is serious about what it is about to do legislatively. Attempting to change the wording without the proper measures being in place first will cause problems. We must be sure that they are in place.

Mr. Martin Doody:

I have had two kidney transplants and a pancreas transplant and would not be addressing the committee today without the altruism of my donor family and the skill of the wonderful people at Beaumont Hospital. I would not like anyone to believe that I was in favour of the *status quo*, as I am not. As Ms Cunningham, Mr. Gilligan and Mr. Murphy have stated, we need to change the public perception. If we had a fully financed public awareness campaign, the Irish people would respond.

The register is a must. If people are asked to put their names on a register, they will. Being able to show a donor's family that he or she took the time to put his or her name on the register instead of it simply being the case that he or she did not opt out is a strong endorsement. This is where our resources should focus, not on changing the name.

Chairman:

I call Mr. Watts. After him, Mr. Brolly, Ms Quinn, Ms O'Halloran, Mr. Kiely and Ms Betson will be next.

Mr. Philip Watts:

In the past year in the UK, there has been a fantastic increase in organ donation and transplant rates. The British Medical Association, BMA, released a press release two days ago to the effect that this improvement was due to the infrastructural changes. It believes that the rates would be even better if the UK moved to a soft out situation. It is a crucial part of a package.

I agree with Deputy Kelleher, in that the tone of the debate is important. We respect the Irish Kidney Association's right to differ, but the debate's tone is crucial in terms of keeping the public on board.

The costings issue is vital. In these straitened economic times and given the strain on our health system, measures must be costed, for example, donor co-ordinators and websites. However, if these are not put in place, there is a danger that this move could be botched. The Minister must accept the message that he cannot introduce a soft opt-out without the rest of the package of measures.

I thank the two patient representatives and Mr. Brolly. What he did personally was exceptional, but his campaign has brought this issue into the public domain. It has been important.

Mr. Joe Brolly:

I cannot believe that Senator van Turnhout is called "van Turnhout". It is the perfect name for a politician. One could not make it up.

Chairman:

Love bombing does not work on the committee. She is perfect.

Senator Jillian van Turnhout:

The Chairman is a gentleman.

(Interruptions).

Chairman:

We are good neighbours. There is always chocolate in her office, by the way.

Mr. Joe Brolly:

We in the North have done a great deal of work. I had privileged access to the First and Deputy First Ministers as well as the health Minister. We worked with all of the parties. I say "we", but I am a part-timer. There is unanimity in the North on the soft opt-out. All of the stakeholders, patient groups and clinical leads are in favour of it. I will revert to this issue.

All of the parties agreed that it was important that no misinformation be peddled and that the message be given clearly to the public, namely, the proposed system is based on a family's written and informed consent.

Regarding the US rates, America runs a market model. Everything is about money. We are a neighbourly society. Society must decide how it wants to approach the issue of organ donation.

In that regard, there has been a subtle but very effective change throughout Europe. It is not a coincidence that all of the leading countries operate this model. The York Group, which conducted the research for the UK's organ donation task force, and its document, Make Life your Legacy, has been circulated to members - which I assure them they can trust - and all other recognised studies incorporated into the UK donation task force report and, in turn, into the government programme, concluded that when all other variables are taken into account soft opt-out has a significant beneficial affect on organ donation rates.

My second point is an important one. I have circulated members with the Department of Health's circular to us and the comments by the head of the UK donation task force, Ms Elizabeth Buggins. The new organ donation infrastructure in the United Kingdom, including Northern Ireland, has been in place now for five years. Scotland is now considering moving to soft opt-out because the rates there have remained relatively static. Wales is in the process of finalising its public consultation on the issue. There is unanimity in Northern Ireland on this. There is a reason for this. After five years, the level has increased from an atrocious 13 to 14 donors per million to an acceptable 20 to 21 per million. This has given us stability but nothing more. After five years of flat out publicity to which a huge amount of resources was devoted - members will see in the documents circulated what has been devoted to this area - only 28% of people are on the organ donor register. The rate of family refusal in Belgium hovers between 2% and 5%. The rate of refusal in Spain is the same. The reason there is not a strong living donor programme in Spain is they do not need it.

Chairman:

How is that verified? Is that information contained in the body of evidence?

Mr. Joe Brolly:

It is evident from the Spanish rates in terms of organ donation. I have worked with Mr. Nizam Mamode, head of transplant services at Guy's Hospital. He has a very close working relationship with Dr. Rafael. The document I have circulated was vetted by Mr. Mamode. This is not my document. While I put it together and my name is at the end of it, many other people contributed to it.

In spite of the advances in England, while last year organ donation increased to approximately 20 per million of population there were 125 refusals by families, which equates to approximately 800 potentially life saving transplants of people on the organ donor register. Within the constraints of the opt-in system the debate now beginning in England, with which we disagree because we believe that donation is a sacred and family gift because donation also affects the family of the deceased person, is on why a family should be allowed to override the consent of a person who signed up to the organ donor register. We believe that is a dangerous route to go down because death is a communal thing in the end. In an effort to move this on, the head of the organ donation task force in the UK has stated that she believes that family consent should be over-borne by a person's name being on the register. The answer to the problem of family refusal is soft opt-out. The reason for this is set out not only in the international research but in the British Medical Association's recent report, which is set out in the document circulated and which I will not bore members by reading.

I agree with Deputy Regina Doherty's comments. People with whom I usually discussed football are now raising this issue with me. When the question becomes, "Is there a reason we should not be organ donors?" the cultural shift is affected. As stated in the British Medical Association's report, organ donation then becomes the default position, which with public support changes cultural expectations in society and represents a more positive view of organ donation. I do not believe there is any particular magic to that: it is just logic. Appendix I, which was drafted by Dr. Paul Glover, who is the counterpart of Professor Jim Egan in the North, states that organ donation rates in the North have increased by 54% since the implementation of all of the changes. However, attainment of the maximum donor potential has not been fully realised despite the creation of this infrastructure, which contains aspects of the Spanish model. In a nutshell, this does not pose any threat: it is a good message. People will be content once family consent is at the heart of what is proposed.

On the issue raised earlier - I cannot recall which Member asked the question - about doctors asking questions, this does not arise where specialised nurses exist. We have 14 specialised nurses in the North, who are embedded in the intensive care units. Their first job is to ask the questions. It is not the job of doctors to do so. As Ms Cunningham will agree it would not be the job of someone like Dave Hickey, who at 2 a.m. is driving to Sligo hospital to help procure organs, to do so. There are embedded people in the system whose job it is to spend time with the families and ask the questions in a sensitive way. In those circumstances, the three-pronged approach of soft opt-out, proper infrastructure and good public awareness is the way to go, as is the case in the leading donor rate countries. There is no reason we ought not to follow that.

Chairman:

Would Mr. Finnegan like to comment?

Mr. Shane Finnegan:

I would like members to take the following away from today's meeting. Everybody is aware of the advances in terms of organ donation in the UK during the past five years. It has been very positive. Why then is Wales, Northern Ireland and Scotland moving to a system of soft opt-out? The answer is because they can see another 50% increase in organ donation as a result. That is the bottom line.

Chairman:

Would Ms Quinn like to comment?

Ms Christine Quinn:

On awareness, I got sick suddenly and knew nothing about organ donation prior to my transplant. I never had a problem with it but was never asked about it. Key to all of this is awareness and the availability of proper information regarding the procedure. Following my transplant, I went back to work in June. I work in a large organisation. I have discussed organ donation with my work colleagues and my family. I have yet to meet any person who can give a reason people should not donate organs.

Chairman:

Ms Betson.

Ms Annette Betson:

As a living donor, I would like to see more resources for Beaumont Hospital and more public awareness, in particular among school-going children. We have done this in our local area and it has worked really well. The feedback from it has been fantastic. It is all about information and awareness. I thank the doctors, nurses and staff generally at Beaumont Hospital who are doing great work.

Chairman:

Mr. Kiely.

Mr. Michael Kiely:

People often assume that organ donation primarily follows a road accident, the number of which nationally is high.

In reality, very little comes from that source. Donation occurs mostly from when people get head trauma, bleeding in the brain and such conditions. People are kept alive to be brought to hospital, and there should be more resources put into sustaining people on ventilators. These are the examples of where organs are available and why we need co-ordinators. The doctors travelling with emergency cases should sustain life until patients get to a trauma centre so they can be looked after properly.

Ms Noreen O'Halloran:

Deputy Kelleher asked why we have so few donors and I reiterate what Ms Quinn said, namely, it is simply about a lack of education and information. Like everything, unless the issue is at a person's doorstep or there is experience of the matter, people will not be educated enough. For example, after I received my transplant I was asked if I would still need dialysis. I was often asked if I could miss dialysis and as I noted in the presentation, somebody recently asked me what dialysis is. People do not understand the issue and the education just is not there. If people had more information, they would be more likely to keep a donor card.

Mr. Mark Murphy:

I have the statistics for Europe and Ireland for the last number of years. The Spanish living transplant programme is greater than ours and growing far more rapidly. The Spanish have over 12,000 people on dialysis and complacency is not as much of a problem because the demand is so great and dialysis is so expensive. One sees that although it is not as consistent as we would like, over the past six years Ireland has been in the top ten in Europe with regard to the deceased donation process, although not for the living donation process, where we are lower. We are not awful and we are far from it. We can improve greatly and we have a willing population. For the past 24 years, awareness campaigns have been under the remit of the Minister for Health's allocation from the national lottery. We receive a quarter of what we used to get per annum. The lottery is not tax-based revenue and we have never got such money from the Exchequer.

If we compare it to 22 transplanting hospitals in the UK, Beaumont Hospital, for its size, does a great proportion of procedures. It is the only kidney transplanting hospital in Ireland, which is right, as it has great practice. Nevertheless, it is a very small hospital to do what it does in comparison to the hospitals in the UK. Infrastructure in intensive care units is a problem and the audit is absolutely necessary. Although we are not bad, we could be far better. I am not complacent and do not want to be accused of that. Those who know me realise that I am not complacent about this. We are in the top ten countries.

Deputy Catherine Byrne:

I apologise for not being here before but the wind took the front off my office last night. At least I do not have to blame vandals. I did not get much of a chance to read the submission but I know about organ donation. Some 20 years ago a family member passed away after being involved in a tragic hit-and-run. At 20 years old, that person had a donor card and so the organs were donated in Beaumont Hospital. Families may be reluctant when standing around the bed to make such a choice and people hold on to any flicker of life. Although I have attended many family funerals and seen many people passing away, it was most difficult to walk out of a room which had somebody being supported by a machine, knowing that 20 minutes later that person would not be in the world. There is a benefit as we attended, through the Irish Kidney Association, a mass every year that commemorates people who have given organs. As a family, it gave us some comfort to know that people had received a gift of life in the process. That family member would have been 40 last week as he died two weeks before his 20th birthday.

There is a reluctance by family members to carry through on organ donation if they feel there is any glimmer of hope.

Chairman:

The Deputy should be aware that there is a vote on going in the Seanad.

Deputy Catherine Byrne:

The process must involve education. This question may have been asked but is there any reluctance to authorise donations because of religious beliefs? What kind of work is done in colleges and workplaces to promote organ donation? Families who have gone through the process of giving consent should be given appropriate medical information, especially if people must give permission to switch off the machine. Somebody has mentioned that nurses are the first port of call and I remember that clearly. We were brought into a room and although I do not know if the nurse was trained in such matters, there was a sense of compassion in what she was doing which helped in the long run.

Deputy Mary Mitchell O'Connor:

I am trying to get my head around this issue. I read Mr. Murphy's submission, which indicated that anybody who indicates that the high organ donation and transplant system is not working is simply wrong and misinformed. He also spoke about an organ donor registry. Why would people register if they do not carry a card? Why is Mr. Murphy so convinced that if people do not have a card, they will still go on the organ donor registry?

We do not always carry the cards. My children signed them years ago but I do not know where they are. I may change my handbag every week and I may not know where my driving licence or card are.

Deputy Paudie Coffey:

Every week or every day?

Chairman:

I thought the Deputy changed it every hour.

Deputy Mary Mitchell O'Connor:

I am aware that there are journalists present so I did not want to say I changed it every day. How will the system work as I find it a little confusing?

Mr. Mark Murphy:

That is the point about a registry. The donor card may have been the only card in a wallet 35 years ago and now we are swamped with them. Its day is coming to an end and we need a registry so people do not have to carry the card. There are phone apps and there are ways to get people on a registry so they will not have to renew a donor card every time a purse is lost. The card may always remain as a symbol but we need an electronic process. It is demanded by the public.

Chairman:

I remind people that this is the first of a number of meetings we are having regarding organ donation. There is an iPhone app for organ donation if members wish to consider it. This morning is about raising awareness rather than having a divergence of views, and we must try to continue the excellent work being done by advocacy groups and the excellent witnesses this morning. It is important we come from our meeting today and next week championing the idea and issue of organ donation, irrespective of Government decisions. We must broaden the public perception and encourage people to become organ donors.

I thank everybody for attending the meeting this morning. The human interest stories have been fantastic and have raised the profile of this issue. I particularly thank the witnesses and wish them continued health and success. I thank Shane and Joe for being, perhaps, the celebrity advocates. I also thank the members of the committee for their heartfelt contributions. I remind members of the Select Committee on Health and Children that there is a meeting of the select committee next Tuesday at 5 p.m. The joint committee will meet again tomorrow at 9.30 a.m. for our quarterly meeting with the Minister for Children and Youth Affairs, Deputy Frances Fitzgerald.

The joint committee adjourned at 11.50 a.m. until 9.30 a.m. on Friday, 19 April 2013.

Thursday, 25 April 2013

The Joint Committee met at 09:30
MEMBERS PRESENT:

Deputy Catherine Byrne,
Deputy Robert Dowds,
Deputy Seamus Healy,
Deputy Billy Kelleher,
Deputy Mattie McGrath,
Deputy Sandra McLellan,
Deputy Eamonn Maloney,
Deputy Denis Naughten,
Deputy Caoimhghín Ó Caoláin,
Deputy Mary Mitchell O'Connor,
Senator Colm Burke,
Senator John Crown,
Senator Jillian van Turnhout.

In attendance: Deputy Tom Fleming and Senators Mark Daly and Feargal Quinn.

DEPUTY JERRY BUTTIMER IN THE CHAIR.

The joint committee met in private session until 9.55 a.m.

Organ Donation: Discussion (Resumed)

Chairman:

We have received apologies from Deputies Catherine Byrne, Regina Doherty and Peter Fitzpatrick.

I remind witnesses, members and those in the public Gallery that their mobile telephones should be turned off rather than in the silent position because they interfere with the broadcasting equipment and it is unfair to members of staff. This morning we are holding the second of three hearings to examine the issue of organ donation in Ireland. I thank all our witnesses for being here and apologise for the short delay in starting due to some private business of the committee.

Members have already received the briefing from the Department of Health and an excellent research paper from the Oireachtas Library and Research Service. I thank the Oireachtas Library and Research Service for the sterling work that it provides to members of the committee and of the Houses. This morning we will hear the medical perspective on the subject from medical professionals working at the coal face of organ donation, and from hospitals around the country. We will also hear from the legal community.

I welcome all the witnesses, Professor David Hickey, Professor Peter Conlon, Dr. James O'Rourke, Dr. Colman O'Loughlin, Dr. Ruairí Dwyer and Dr. Liam Plant. We will be joined shortly by Mr. J.P. McDowell. I thank the witnesses for being here this morning.

Before I commence I remind witnesses about the rules on privilege. Witnesses are protected by absolute privilege in respect of their evidence to the committee. However, if a witness is directed by the committee to cease giving evidence in regard to a particular matter and continues to do so, the witness is entitled thereafter only to a qualified privilege in respect of his evidence. Witnesses are directed that only evidence connected with the subject matter of these proceedings is to be given and are asked to respect the parliamentary practice to the effect that, where possible, they should not criticise or make charges against any person, persons or entity by name or in such a way as to make him, her or it identifiable. Members are reminded of the long-standing parliamentary practice to the effect that they should not comment on, criticise or make charges against a person outside the Houses or an official either by name or in such a way as to make him or her identifiable.

With that I call on Professor David Hickey to make the opening remarks.

Dr. David Hickey:

I thank the committee for inviting me. I also thank them for giving me a "professorship". I will bring this back to Professor Conlon and maybe we can-----

Chairman:

I hope Dr. Hickey gets the remuneration.

Dr. David Hickey:

It is nice. I do appreciate it.

I am the director of the national kidney and pancreas transplant programme. This programme is also responsible for organ procurement which is the main topic of discussion today. I have been committed to this programme for 30 years, having personally performed over 1,500 kidney and pancreas transplants and 300 organ procurements. I feel I am in a position to comment at least on my own area which is organ procurement, kidney and pancreas transplant.

The programme started in Jervis Street in 1964 and this year we will complete our 4,000th transplant. This puts the national kidney transplant programme in the top 20 in the world in terms of numbers done. We started only six years after the first successful transplant was done in Boston. We have been at this a long time and I have seen many things happen. Every initiative and advance in this area has been made through the hard work of a few committed individuals. There has never been a national approach to the concept and problems associated with organ donation and kidney transplantation. For example, when we moved to Beaumont in 1987 they forgot that there was a transplant programme moving from Jervis Street and we had to re-jig the urology ward. Essentially that *ad hoc* concept is how transplantation has been dealt with since.

The main subject of the discussion today is organ procurement. While we need more organ donors I want to emphasise the impact of that on a service that is already stretched beyond its limits in which we are already failing our patients. The numbers waiting are increasing but the numbers being transplanted are not. I will talk about the lack of organ donors, the poor infrastructure in which transplant patients are housed, the shortage of transplant surgeons which is reaching crisis and what I think the ideal for the country should be.

The more donors we have the more organs are available for our patients with end organ failure - liver, kidney, pancreas, heart and lung. There is a global shortage of organs for transplantation, particularly kidneys. It is generally accepted around the world, particularly the western world where this is taken very seriously, that renal failure management is going to bankrupt health services in the next 20 years. I do not know the figures here but in the United States already something like 15% of the health care budget goes on less than 1% of the renal failure patients. With diabetes and end-stage renal failure increasing this will get worse. We need to address this because if we do not we will be talking about rationing dialysis in the not too distant future. That means that there will be no dialysis for people like me or anyone over 60. If one is under a certain age there will be no dialysis. If perhaps one is mentally retarded, or if one is not a valuable member of society, there will be no dialysis and so on. This is a slippery slope and it happens in countries that cannot sustain themselves with transplantation, such as India, Pakistan and Israel, where people go abroad and buy kidneys because there is no alternative apart from dying. While one can have ethical concerns about that, if one has to choose between dying and buying a kidney most people eventually will buy the kidney. That is a slippery slope that is at the end of failure to address this problem while we can still do something.

We have reached a plateau in transplantation in Ireland. We have approximately 18-20 donors per 1 million of the population which up to ten years ago was one of the best rates in Europe. Seeing the coming storm, most European countries have adopted a process of investing in organ donation. It has been done under the concept of presumed consent, the soft opt-out.

The legislation had certain achievements, including bringing transplantation into mainstream discussion at government level in these countries. Most people involved in transplantation travel and know the real advantage is the huge investment in infrastructure at local donating hospital level.

I am sure everyone here knows that presumed consent does not mean a thing. Nobody anywhere in the world takes organs from a child or a person's loved one without seeking the permission of the family. This just does not happen. One can call it what one likes. The presumed consent concept should mean it is presumed anyone looking after a patient who has died offers the family the opportunity to donate. This is an immense consolation to the family. It is a service to a family who has lost a loved one and is not just an organ procurement agency looking to do more business. It offers immense consolation down the line that a young person's family knows that at least, out of a hopeless situation, five people had their lives saved and significantly improved. The other side of the coin is that occasionally we receive letters from families who were not offered this consolation and not asked about organ donation. It is usually out of a perceived kindness as medical personnel wonder how can they possibly bring up this topic at such a time. It is a very delicate area which needs to be examined. The kernel of the problem is that people do not ask because they feel, and justifiably so, that as they have been looking after someone for a while they cannot possibly turn around and ask. I support the concept of soft opt-out presumed consent, but only if it brings organ donation into the main arena and introduces a presumption that everyone wants to do it, and the infrastructure must go in at ground level, which has been the message throughout Europe.

We must address the issue of infrastructure. Hospitals are generally accepted as the location of some of the saddest and happiest moments of our lives. Internationally it is recognised that when it comes to architecture, hospitals should be among the most inspiring public buildings. Every one of us has horror stories and happy stories from hospitals and can empathise with this. The situation in most hospitals is unacceptable for 2013 living. We should examine having something similar to the situation in Norway, a country of 4.6 million people. It has one transplant centre which does six times as many lungs and twice as many kidneys as we do. We must look at this.

The next problem in transplantation is transplant surgeons. No transplant surgeons means no transplant. This is a bigger crisis than the lack of donors for the continuation of transplantation in Ireland. Transplantation surgery cannot recruit young people into training. Anyone we do train goes to the United States the minute he or she can tie a knot because of the opportunities there. It involves night work and weekend work and is not what we call a lifestyle-friendly medical career, which is what many graduates seek nowadays. I will give an example of the impact. Transplant surgeons have the second highest divorce rate among surgeons in the world. Neurosurgeons have a higher rate, mainly because they are neurosurgeons. With transplant surgeons it is because of the lifestyle - they are never there.

Chairman:

I note all of the witnesses are men.

Deputy Robert Dowds:

How do they compare to politicians?

Dr. David Hickey:

It is almost as hard as political life.

We should have all organ transplantation and procurement under one roof, as is done in Norway and most of the big European centres. Triplicating services is not a great idea. Consider the expertise that liver can bring to kidney and heart and lung can bring to pancreas. I do not have any idea where such a centre should be, but the issue should be addressed. It is a very cost-effective way of treating people and we should consider it seriously.

We should examine the model in Norway. We should develop a national centre for organ transplantation, and perhaps bone marrow could be included in that, because the personnel involved have a great deal of expertise in infections and immunosuppression. The new national centre should be located in a university hospital, independent of that hospital's board and CEO and answering only to the national organ donation and transplant office of the HSE and the Department of Health. This is essential if we are to stem the tide which is beginning to overflow us. To give an example of how serious the situation is, we have 65 patients who have been fully worked up with their donors for living donor transplantation. These are people who have taken time off work and gone to significant expense to donate a kidney to a loved one. However, we cannot give these people dates for their transplants. At the rate we are transplanting, they will have to wait two and a half to three years to get their living donor transplant. This means that in two years they will have to be re-evaluated and some of the organs concerned will have deteriorated and will no longer be transplantable. A person may have had a blood transfusion and become immunologically incompatible. We risk losing them. The other problem is that these patients are also on the deceased donor list. People who already have a living donor allocated end up getting a deceased donor and taking a kidney off someone else.

I thank the committee for the opportunity to bring our problems to the fore. I have no doubt that in two years' time we will be cutting the ribbon on a brand-new national organ transplant centre which will be a world leader in its field.

Professor Peter Conlon:

I thank the committee for inviting me to speak about organ transplantation in Ireland. I am the clinical director of one of the largest kidney transplant centres in the British Isles and have more than 20 years of experience in kidney transplantation. The views I express are shared by the vast majority of my colleagues in the care of dialysis and transplant patients in Ireland.

Patients with kidney failure have a number of therapeutic options. It is true to say that most patients in the world with kidney failure die without any significant treatment, as the treatment, although effective, is extremely expensive and requires a very sophisticated medical system to deliver it. Patients with kidney failure who have the good fortune to live in Ireland have access to a number of treatment options including peritoneal dialysis, home haemodialysis, in-centre haemodialysis, deceased donor kidney transplantation or live donor transplantation.

Kidney transplantation is without question the best treatment for almost all patients with kidney failure. It provides the best quality of life for patients with kidney failure, more than doubles their life expectancy compared to remaining on dialysis and, in the process, saves the State more than €750,000 over the lifetime of the recipient for each kidney transplant performed. Many patients receiving a live donor kidney transplant can reasonably expect their transplanted organs to function for more than 40 years, which mostly means for the rest of their lives. There are many impediments to delivering more kidney transplants, but the major impediment at present is the availability of suitable donors and the infrastructure to deliver these transplants.

As Professor Hickey described, Ireland has had a successful kidney transplant programme for almost 50 years, but it is nothing like as successful as it could or should be. Ireland should be aspiring to achieve kidney transplantation success similar to that of Norway. Professor Hickey has already described some of the Norwegian experiences. I will compare the two countries in terms of their approach to kidney transplantation. Ireland has a population of 4.6 million, and Norway has a similar population of 4.8 million. Ireland has performed an average of 150 kidney transplants per year over the past ten years, while Norway has performed between 270 and 300 transplants annually. As a result of this difference in kidney transplant activity, Norway has a stable population of 370 patients on maintenance dialysis while Ireland has more than 1,800 patients on dialysis. Ireland could, with appropriate investment, within a few years achieve transplantation results similar to Norway, with enormous benefits to patients with kidney failure in Ireland, and in the process save the State more than €300 million.

The scarcest resource in transplantation is organ donors. Kidney transplantation is almost unique among organ transplantation in that living donors are a major source of organs for successful transplantation. I will first discuss deceased kidney donation.

Organ procurement in Ireland, which is essential for all the disciplines of transplantation - including heart, lung and liver - is run on a shoestring. All organ procurement is run out of an office in Beaumont Hospital staffed by five very committed and professional transplant co-ordinators. These individuals also have many other duties besides organ procurement. There is practically no infrastructure for organ procurement outside Beaumont Hospital in the regional hospitals. The transplant co-ordinators at Beaumont Hospital have developed a network of link nurses in each intensive care unit, ICU, who - in their spare time - assist in educating their colleagues on organ procurement. This is no way to run a transplantation service.

These issues have become all the more urgent in view of the fact that the recently implemented EU directive on organ donation mandates the separation of organ procurement and transplantation and also insists on much more rigorous traceability and organ quality criteria. There is an urgent requirement to establish a formal national organ procurement agency, which would provide a national resource to every ICU and emergency room in the country, namely, expertise in organ procurement. As already stated, Ireland has five transplant co-ordinators. Northern Ireland, with a population less than half the size of the Republic's, has 27 and in the UK there are more than 200. When the UK recently implemented an investment in organ procurement, there was a 50% increase in organ donations. Implementing resources to properly manage organ donation is far more important than implementing a presumed consent law and is likely to result in a far more dramatic increase in organ donation.

Living donor kidney transplantation is also an important process in treating kidney failure and delivers far better long-term results than deceased kidney transplantation. I am pleased to inform members that the Department of Health and the HSE have recently committed funding to deliver the first phase of a very significant expansion in live kidney donation and have agreed, in principle, to fund a plan which, it is hoped, will deliver during the next three years 100 living kidney donation operations annually. This plan has been stymied at every turn and has not yet been implemented. I am unsure when it will be implemented, despite the urgent need that exists. There are currently almost 100 kidney donor-recipient pairs awaiting living kidney donation in Ireland.

There are, however, a number of very important other issues that need to be urgently addressed if Ireland is to realise the full potential of living kidney donation. In this regard, the implementation of the human tissue Bill will be necessary to deliver on the relevant targets. The first of the issues to which I refer relates to coverage of the out-of-pocket expenses of living kidney donors. Each living kidney donor saves the State more than €750,000 euros in health care costs. Currently, however, a living donor pays all expenses relating to travel to and from the hospital, extra child care costs, etc. Typically, a living donor will require several weeks off work following such major surgery and thus will not be available for work. It typically costs each living kidney donor between €5,000 and €7,000 in lost income and out-of-pocket expenses. It is common practice in most developed countries for health authorities to cover out-of-pocket expenses for living kidney donors. In the UK, the state covers up to £5,000 in such expenses. The EU directive requires the Minister for Health to implement such a system. I urge him to implement it without further delay. It is unfair that not only does a living kidney donor gives up one of his kidneys but that it also costs him so much money in lost income.

I am aware of at least two Irish individuals who wanted to become altruistic kidney donors. Such donors are people who recognise that there is a major need in respect of those with kidney failure and offer to donate one of their own kidneys to individuals they do not know. As a result of the lack of legislation permitting such donation in this country, it is not yet possible. The two altruistic donors to whom I refer donated their kidneys to people in the UK because it was not possible to donate in Ireland. This means that two kidneys were lost to Irish patients forever. Human tissue legislation would be necessary in order to legalise altruistic kidney donations here.

Patients with a donor who is incompatible due to a blood group or tissue type mismatch can now frequently find a compatible donor by way of a paired kidney exchange programme. We have recently developed a relationship with NHS Blood and Transplant in the UK for the sharing of living human kidneys as part of the implementation of a paired kidney exchange system. This will allow large numbers of Irish and UK patients to receive live donor transplants that would not otherwise be possible. In order to implement the paired kidney exchange scheme with the UK, the Government or one of its agencies will be required to enter into a service level agreement with the UK transplant authority.

A significant number of patients living in Ireland and receiving kidney treatment here have relatives abroad who would like to come to Ireland and donate a kidney to their loved ones. There is currently no clear-cut mechanism or policy from the Department of Health to allow these donors to come to Ireland and receive care in Irish hospital and health care institutions in order to facilitate organ donation here.

The Road Safety Authority, by way of its hard-hitting public awareness campaigns, has transformed people's view of road safety. I am of the view that a level of resources similar to that employed in respect of road safety campaigns should be invested in promoting organ donation awareness among the general public.

Transplant surgery commonly occurs in the early hours of the morning and is consequently arduous. If a transplant programme is to be successful, the system needs to ensure there is an ongoing supply of these highly skilled professionals. I refer, in particular, to transplant surgeons, whose training typically takes 15 years to complete. Failure to implement the working time directive and bans on recruitment have put this essential resource in peril.

As somebody who each day witnesses the fantastic life-saving and life-changing benefits that organ transplantation brings to the Irish population, I would support any proposal that would ethically allow for the expansion of this technology in this country. I am of the opinion that introducing a presumed consent law would have very little impact in expanding organ transplantation and should not be at the top of our priority list. Rather, we must focus on the reorganisation of organ procurement services to ensure that every potential organ donor, whether living or deceased, is identified and facilitated in order that successful transplantations can take place. There is also an urgent need to implement the planned expansion of transplantation infrastructure at Beaumont Hospital to ensure that all live and deceased kidney transplants can be performed to a high standard and without delay.

Chairman:

Copies of the opening statement of Dr. Ruairí Dwyer, Dr. Colman O'Loughlin and Dr. James O'Rourke have been circulated to members.

Dr. Ruairí Dwyer:

I am Ruairí Dwyer and I am a consultant in the ICU in Beaumont Hospital. I have been involved with identifying and obtaining consent for transplantation there. In that context, I work in close collaboration with the organ procurement service run by Ms Phyllis Cunningham, who came before the committee last week. I am chairman of the committee on organ donation of the Intensive Care Society of Ireland, ICSI. The ICSI represents doctors who work in intensive care medicine. Our committee and organisation include representatives of nurses who work in ICUs and organ donor co-ordinators. We emphasise the importance of links with ICU nursing in respect of this issue. As intensive care consultants, we are the clinicians who are directly responsible for the care of all patients with serious brain injuries and the diagnosis of death in those patients who unfortunately progress to brain death. We are involved in explaining organ donation and in requesting permission from families for such donations. We are also involved in the care of organ donors in order to optimise the number of organs suitable for transplantation.

Promotion of organ donation is seen as being an integral part of our job if our efforts to preserve life have failed. There is strong enthusiasm in ICUs on the part of both medical and nursing staff. Education in organ donation issues is an integral part of the training relating to our specialty. This education remains ongoing throughout our careers. The ICSI held a day-long conference devoted to organ donation in 2012. This attracted a large attendance of both medical and nursing staff who work in intensive care. The ICSI has published guidelines on the diagnosis of brain death and on organ donor management in order to help increase the number of organs available for transplantation. With support from the HSE, intensive care clinicians are establishing an audit programme which will encompass a comprehensive audit of organ donation within ICU and which will identify any potential for improvements in this area.

We believe that our specialty has made a significant contribution to the relatively high rate of organ donation in Ireland. However, we see major challenges in increasing the rates of organ donation and even in maintaining current rates of organ donation. I work in the neurosurgical centre in Beaumont Hospital. When I started 20 years ago we had a brain death diagnosed probably once a week but now we have such a diagnosis once or twice a month. That is the pool we are recruiting from for organ donors.

We strongly support the proposals from Professor Egan, which have been mentioned by the two previous speakers, for promoting public awareness, for increased numbers of organ donor co-ordinators and for the appointment of staff in each hospital network with responsibility for promoting organ donation. There are differing opinions within our specialty on presumed consent. Many are concerned that presumed consent could lead to a decrease in organ donation if the concept of organ donation as a voluntary gift is replaced by a perception of compulsion. Others, however, feel that presumed consent would have a positive effect on organ donation numbers. On balance, that is my position. I will return to that at the end of the statement.

Our society was unanimous that whatever legislation is introduced, the practical details of its implementation will be vital in ensuring that current levels of consent to organ donation are maintained. We are the group who will be asked to implement any new legislation and we hope it will be drafted to ensure there are no accidental obstacles to organ donation in it. Issues of concern to us include how the issue of consent to organ donation will be addressed in practical terms. We must examine what will happen if no relatives are available to provide consent and whether presumed consent would apply to donors after cardiac death, which are a different group to donors after brain death. There is need to have a secure register for those who wish to opt out of organ donation before death, if presumed consent was introduced. We suggest it would be vital to have close collaboration with the clinicians on the ground who work in ICU in drafting any legislation or regulations for its implementation.

We are delighted with the amount of attention being given to organ donation and with the level of commitment of this committee in addressing the issue. Organ transplantation transforms the lives of patients and it will be a very positive achievement for society as a whole if we can maximise the number of patients who benefit from it.

To return to the issue of presumed consent, we canvassed opinion within intensive care medicine. A fairly significant majority was opposed on the basis that it could have the opposite effect to what is intended. That is something on which my colleagues will elaborate. On balance, I feel it would have a positive effect in terms of changing the terms on which we approach patients for organ donation, in making organ donation the norm rather than the opt-in position. Most importantly, when one looks at the evidence that is available from countries that have introduced presumed consent, it seems to be associated with a small but significant increase in organ donation, provided it is linked with improvements in resources, in particular improvements in staff who are aligned with organ donor co-ordination services.

Dr. Colman O'Loughlin:

I will be brief. What I want to do is drill down a little into what Dr. Dwyer has mentioned. I also represent the Intensive Care Society of Ireland, which in turn represents the consultants working in intensive care medicine throughout the country. The committee has a copy of our position statement on presumed consent addressed to the Minister. Our position is that we favour staying as we are with an opt-in situation. That was not a unanimous position. It was a majority decision. Dr. Dwyer explained that many people had different views.

Chairman:

We received a letter from the Intensive Care Society of Ireland signed by Dr. O’Brien.

Dr. Colman O'Loughlin:

What I will do is drill down a little deeper into what we do as intensivists and why the views of the Intensive Care Society of Ireland on organ donation should carry a lot of weight. The majority of organs donated in this country are donated from brain-dead donors. The care of those patients occurs in intensive care units. Brain death occurs in intensive care after a significant brain injury where a person is on a life-support machine. The staff involved include the intensive care specialist, the nursing team and our trainees. It is our job to care for those patients. Our primary duty of care is to the patients and, by extension, to their families. Sometimes a brain injury progresses onto brain death. That is a clinical diagnosis that we must make at the bedside. We do two sets of brain stem tests. They are identical tests done by two separate groups of people separated by a brief period of time. Our job is to do the tests, the first, to determine brain death, and the second to confirm that at a later stage.

It is between the two sets of brain stem tests that we approach the family of the patient and bring up the issue of organ donation. How we do that is very important. It will be obvious to everyone that this is a period of extreme trauma for the family. There will be overwhelming grief, a lot of confusion, anger and a huge amount of tension among family members because these types of events happen, by and large, to young people and they happen very suddenly. One has to imagine what it is like to deal with these scenarios, the patients and their families. When we engage with them on the issue of organ donation it is very important that we do it delicately with a lot of compassion and empathy. How we say it and how we bring it up is extremely important. We are advocates for the patients and, thereby, their families. We do not have any say in who is on a waiting list for organ transplantation. We have no idea of what is happening on that end. We are on one end only. In these circumstances, we do not ask them to be organ donors or we do not ask them not to be organ donors, we give them the opportunity to consider organ donation. We do not necessarily ask for an answer straight away.

What we normally do is go back and do the second set of brain stem tests to confirm brain death. Time of death will be at the conclusion of the second set of brain stem tests. At this stage we will go back to the family and re-engage with them and ask for their opinion on the topic of organ donation. We will have families come back to us and say “Yes”, that for many years they have talked about it and it is something that they as a family and their deceased relative really supported for many years, and that they would like to consent to the process of organ donation. To that family I say, “Thank you for considering this. You have done the right thing for you, your family and your deceased relative.” Alternatively, the family might come and say they are not sure, that they have talked about it and they have never been easy with the concept, that they are not comfortable with it and not really keen to consent to organ donation. To that family I say, “Thank you for considering it. You have done the right thing for you, your family, and the deceased relative.”

What I am trying to say is that there is no right answer, there is no wrong answer. There is only the answer that is given to me by the family. I have to accept it. I have to remain and continue to remain neutral in the process. My duty of care is to the patient in the bed and his or her family and to no one else. I have to be really neutral. One might ask why I do not lobby for transplantation. I do not for the same reason that I cannot lobby against it. I have to be neutral. I can raise the question. Dr. Hickey explained the matter eloquently. My job is to ensure that in every single incident that brain death occurs in this country, the question is asked to the family to give them the option. Not to give the option is a dereliction of care from a societal point of view. I cannot sway their opinion either way but I have to give people the option. The role of the Intensive Care Society of Ireland in that is to make sure that this happens; to educate our colleagues and to provide resources and training for them so that they are aware of how brain death occurs, that they test for it properly and that they are given the proper skills to deal with the families, help them to come to terms with what is happening and to phrase the issue of organ donation in a neutral, empathic manner.

That is really what I want to say and I want to set the scene as to why and how this happens every single day, separate from the transplantation issue. I have reservations about presumed consent, largely because, as echoed by our transplant colleagues, I do not think it will make a huge difference. I go back to what I said about how we interact with a family and where I could bring presumed consent into the conversation. I am not going to change my style of conversation with the family, regardless of what comes out of this process because that is what is practised throughout the world and that is the recognised way of trying to deal with this delicate scenario with traumatised families.

Consequently, I do not see it as a huge issue but as being way down the list.

I will not go through all of the resource allocations required as that issue has been eloquently discussed this morning. However, from the perspective of consent, it is not the big issue. It is not the big ticket and I do not think changing this will make any difference. What really will make a difference is increasing resources and infrastructure.

Chairman:

I thank Dr. O'Loughlin and invite Dr. O'Rourke to make his statement.

Dr. James O'Rourke:

I promise to be brief. I thank the joint committee for its invitation to speak today.

Mr. Hickey has devoted his whole life to transplantation and if anyone deserves to be a professor, it is him for sure and I mean that sincerely. He has alluded to the entire spectrum of organ donation, from the time an organ comes from the donor patient to when it is transplanted into the recipient patient, where it goes and the circumstances involved, as well as the resources and funding available at each stage. My colleague, Dr. Dwyer, and I work together in the intensive care unit of Beaumont Hospital. Both of us care for patients with neurocritical injuries - traumatic brain injuries or intracranial haemorrhages. In his presentation Dr. Dwyer alludes to the fact that when we started 20 years ago, we used to carry out brainstem tests perhaps once a week. Certainly, the demographic of patients we see is testimony to the success of the Road Safety Authority. As members are aware, in 1998 approximately 400 people were killed on the roads, whereas in 2012, approximately 160 people died. Organ donation rates mirror exactly road fatality rates. Clearly, the number of people killed will also reflect the number who experience catastrophic injuries, which is testimony to the success of the Road Safety Authority and its laudable work in recent years.

Essentially, the pool of potential organ donors has decreased. As to what should be done about this, my colleagues have suggested and I strongly concur that we must never miss an opportunity where there is the potential for organ donation. However, we lack infrastructure that could facilitate this process. I will speak a little about that issue. The other aspect is that we must look a little more widely in the field. My own area of specialist interest is donation after determination of death by cardiovascular criteria, also known as donation after cardiac death, DCD, or non-heart beating donation. This is an area in which I am very interested and which in a way mirrors donation after brainstem death, DBD. They are similar in a way, in pertaining to deceased donation.

I will read briefly from my statement. On the proposed changes to the current opt-in system of legislation, I support fully the position taken by the Intensive Care Society of Ireland in stating the majority of its members oppose changes to current legislation. This opinion has not changed since the previous submission made in 2009. Members will be aware that in that public consultation document the opinion of 23 of 30 learned organisations canvassed on the topic was against a presumed consent model. This is my personal opinion and we are all on the same page, in that no one will argue that to receive an organ transplant is a life-saving procedure. For my part, as an intensive care clinician, I am very committed and believe it to be the gift of life. However, nothing can ever be presumed in a gift and nothing should be taken for granted. We rely on public trust and confidence in the medical profession and it would only require a single case to go wrong or blown up in the newspapers for such trust to be damaged. Were the public to be led to believe doctors are now entitled to take organs, unless they have signed up to an opt-out register of some kind, this could be counter-productive overall. In my submission I state further that in 2010 Ireland ranked ninth out of 27 countries in our rates of organ donations, at 17 per million of population. That is not bad if one thinks that among the European Union of 27 member states Ireland ranks ninth. While that is okay, we run a long way behind Spain where there is a rate of 30 organ donors per million of population.

The rest of my submission relates to the subject about which Mr. Hickey and Professor Conlon have spoken, with a little bit drawn from my own area of intensive care, essentially on resourcing the donor transplant co-ordinators and providing more level 3 clinical intensive care beds. I am very proud to work in Beaumont Hospital which is a great institution. When I qualified there in 1995, we had 20 intensive care beds, whereas today we have 17. The population has not become smaller and one must now be pretty sick to get into the intensive care unit in Beaumont Hospital. As a result, while we would like to give everyone the opportunity and facilitate organ donation, where possible, one's bed is not cold in Beaumont Hospital before someone else is in it. That is a fact. The resourcing of intensive care beds is an important component of organ donation. Families should be given the opportunity, where possible, to enable their loved ones to become organ donors. However, as often happens in the triage of patients, in a case in which one patient has been critically injured and will not survive and someone else is arriving in casualty who is gasping for breath, one will always take the patient gasping for breath because he or she has a chance of living. However, resourcing intensive care units and providing high level intensive care beds should be a key priority. Beyond this, from my perspective, I can only echo what Mr. Hickey and Professor Conlon said.

While I accept that the medical literature shows a positive slant where presumed consent has been introduced, this is somewhat clouded by turning the camera on organ donation for a short period of time and increasing public awareness. The increased organ donor numbers seen where presumed consent was introduced may be a reflection of this, that is, a reflection of increased infrastructural investment in the area.

The new driving licences are great, as they are little cards that allow for a code 15 regarding organ donation to be included. Personally, it should be more like the American model and more explicit. It should be a mandated request on documentation for passports or driving licences. I am also in favour of requiring a request in order that each patient or each family can be given the opportunity to donate organs, if there is potential for organ donation.

Chairman:

I thank Dr. O'Rourke. The next speaker is Dr. Liam Plant who is the national clinical director of the HSE's national renal office, as well as being a consultant physician in Cork University Hospital.

Dr. Liam Plant:

I will read from my statement. However, in the absence of parochialism since the Chairman has put the Cork man last, some of the remarks have already been made by my colleagues.

Chairman:

Our position in the hierarchy is well known.

Dr. Liam Plant:

I might add two points of information on numbers which might inform the joint committee which I thank for its invitation. I work as a consultant renal physician at Cork University Hospital. Between 2003 and 2009, I acted as chair of the national strategic review of renal services.

Since March 2009, I have been the national clinical director of the HSE national renal office. The national renal office is responsible for planning, co-ordinating and managing the strategic framework of renal services across the country. Prior to 2001, I worked as a consultant renal physician at the Royal Infirmary of Edinburgh and was involved in the organisation, co-ordination and delivery of renal and transplant services in that country.

As has already been said, in common with all countries, the number of our fellow citizens affected by permanent kidney failure, a term which, as the committee will have heard, is technically described, perhaps rather unpleasantly, as end-stage kidney diseases, ESKD - it merely means that one's kidneys are permanently failed and one either needs dialysis or a transplant - continues to grow. The national renal office conducts an annual census of this on 31 December each year. On 31 December 2012 - this is in part answer to a question the Chairman posed to the Minister on 5 March last - just under 4,000 of our fellow citizens had end-stage kidney disease, 81 being children under the age of 18. Of the 3,876 adults with end-stage kidney disease, 1,560 or 40% of the total received treatment by haemodialysis at a number or haemodialysis units dispersed around the country. Some 237 or 6% of the total were treated by one of the forms of home haemodialysis or home dialysis - there are different forms - in their own homes. Thankfully, and I would echo what has been stated already that this is a testament to the existing success of the renal transplant programme in Ireland, 2,079 or 54% of the total already have a functioning kidney transplant, and 62% of children with end-stage kidney disease currently have a kidney transplant.

It is important to stress that whereas all types of renal replacement therapy are successful treatments for end-stage kidney disease, prolonging survival, improving functional status and allowing patients to carry on with their lives, there is no doubt that kidney transplantation is the best of these options. I will not reiterate what has been said on this already. It is the policy of the national renal office that strategic planning should seek to maximise the number of patients who can avail of this and whereas not all patients may be suitable as recipients of a kidney transplant, many more than have currently received one are so and this is reflected in the waiting list for transplantation.

As well as being a considerable physical, social and psychological burden on patients with end-stage kidney disease treated by any of the forms of dialysis therapy, the costs to the State of providing these therapies are very substantial. In 2011, the ESRI noted - the reference is given as "Activity in Acute Public Hospitals, Annual Report 2010" - that the single highest-ranked procedure for day patient attendances at acute public hospitals was haemodialysis and that accounted for one fifth of all day-case attendances. In 2012, we delivered just under 250,000 haemodialysis procedures in Ireland. Another metric which many may find compelling is that last year, with a careful mapping exercise, we identified that Irish patients who travel to and from dialysis - one must remember they go 156 times a year - travelled 13.5 million km in 2012, and the State provides a degree of subsidy to this.

Despite reductions in the unit costs of these treatments over the past few years, they continue to generate very substantial revenue charges. Professor Hickey referred to those numbers. The best estimate that our office could make on the cost of this would be as follows. We believe that the attributable costs for dialysis, excluding support for transplant and certain drugs, comes to approximately €91 million for haemodialysis and approximately €7 million for home therapies. If a patient is transplanted, he or she will also be on transplant drugs which would cost roughly the same as the other drugs they are on. Effectively, just under €100 million is the cost of the dialysis therapies for 1,800 of our fellow citizens.

In the five years since 2007, the number of adults with ESKD has increased by 24%. That is an absolute increase of 743 patients. Of this increase, 63% has been accounted for by an increase in the number of those with a functioning transplant - that number being 466 - with the remaining increase due to an increase in those treated by dialysis - 277.

The second point of information is that we are very comfortable in modelling the likely future growth in end-stage kidney disease. Based upon what has happened previously and what we would anticipate in the future - one must remember that the growth in the number of persons at the end of every year with end-stage kidney disease is the sum of new patients who start for the first time minus those patients who, regrettably, pass away and how they are distributed depends upon dialysis - we would project that every year we will have between 114 and 178 additional end-stage kidney disease patients in the Republic of Ireland. If I take the mid-point of that which is 150, and if there is no additional transplantation, that means that every year we will have to open a new haemodialysis unit the size of Cork University Hospital dialysis unit, which is the second largest in the State. If transplantation rates go up, that proportion that will go up will obviously diminish.

There is, therefore, echoing what others stated, little doubt but that an increase in access to organs suitable for transplantation would improve the survival, rehabilitation and quality of life of many more patients with ESKD than at present. Furthermore, the potential future costs of dialysis therapies that would be forgone - these would not be savings we would now make but future costs we would avoid - would benefit the renal programme, the health services as a whole and the Irish taxpayer.

The principal question that needs to be addressed and is being addressed by this committee is "how is this best achieved?". A variety of potential solutions have been advanced by a variety of individuals, organisations and healthcare systems. I am happy to offer my own observations on those elements that I think are likely to increase transplantation while at the same time, as has been mentioned, preserving the confidence of the wider citizenry in the organisation of this activity.

Undoubtedly, increasing the resources available to support living-donor transplantation is a key element, but what of deceased-donor transplantation? As has been highlighted in a 2009 United Kingdom health technology assessment, a number of elements contribute to the variation rates of organ donation between countries. These include: the national wealth and investment made in health care services; the legislative framework that underpins donation, particularly as this applies to questions of presumed or informed consent; the availability of potential donors - comment has been made about variations, thankfully, in road traffic deaths and other issues; public attitudes to, knowledge of and education about organ donation and transplantation; and, critically, the organisation and infrastructure provided to deliver organ donation and transplantation. Much of the commentary has focused on legislative framework which is of extreme importance. However, I would strongly associate myself with the views expressed by others that in the absence of a robust organisation and infrastructure to support this endeavour, any legislative framework is unlikely to achieve its maximum potential in increasing donation. Similarly, robust engagement with the public to minimise anxiety, misunderstanding and fear regarding any potential legislative change must also be of the highest importance.

Chairman:

I thank Dr. Plant. The final speaker in this session is Mr. J. P. McDowell, partner in McDowell Purcell Solicitors, giving a legal perspective. I thank him for coming in at short notice. We appreciate his flexibility in being here this morning.

Mr. J. P. McDowell:

I belatedly made some notes. I am not quite sure whether anyone is anxious to circulate them but I have them here if anyone wants to reflect on them.

Chairman:

I thank Mr. McDowell.

Mr. J. P. McDowell:

I apologise for not circulating them in advance.

I listened carefully to the medical practitioners who have given evidence to the committee and I am grateful for the opportunity to address the committee. Listening to the evidence that has been given, it seems that the concern and focus of the medical community at the very least is possibly not around the issue of opt-in or opt-out and presumed consent, but more around the issue of what legislation can bring in terms of infrastructure and resources.

When preparing for this, I was struck by what the CEO of the Spanish transplant authority stated recently about the early years of opt-in in Spain. He made the point that in the first ten years of the presumed consent or opt-out structure in Spain during the period leading up to 1979, the opt-out structure introduced by legislation there did not increase rates of donation significantly.

He was making the point that increased rates of donation represented the introduction of expert liaison personnel or transplant coordinators throughout the intensive care units around the hospital network, and that the opt-out or presumed consent system, in itself, was not necessarily contributing to increased rates of donation. That possibly touches on some of the issues highlighted by the medical practitioners who have already given evidence. Regulation 22, within the recent statutory instrument, is the current legal background. That follows the directive. The directive itself does not compel member states to introduce one system or another but it compels them to address the issue of consent. That is exactly what this member state has done. It has issued a statutory instrument in which the issue of consent has been addressed. Consent is required from the next of kin of the deceased at present.

As I understand it, there is a framework to be introduced by the HSE. We are awaiting its publication. This committee is now interested in considering whether presumed consent is ethically and legally robust and whether it is potentially challengeable. Throughout the 30 years in which presumed consent has been introduced in various member states, there has been no challenge to it or an opt-out system. I refer to a challenge on the basis of the convention. The committee may be aware that the European convention provides for a number of rights that might provide the basis of a challenge to a presumed consent system. One is Article 8, which establishes the right to a private and family life, and another is Article 9, which pertains to the freedom of conscience and religion. We also have constitutional rights, which would have to be observed in any legislative structure. We have Article 40.3.1°, the right to bodily integrity, Article 44, the right to freedom of conscience and religion, and Article 41, which recognises the family as a fundamental unit. These rights are all relevant in this territory.

I am not quite certain from a legal perspective whether there is a significant difference between an opt-in system and an opt-out system in terms of whether the underpinning legislation is legally fragile or robust. The key would seem to be the extent to which the consent of the family members of the deceased is being sought. The further one drifts away from that principle, be it through an opt-out or opt-in arrangement, the more fragile the structure becomes, not only for reasons associated with the convention or the Constitution but also for reasons that underpin medical practice. The whole concept of medical practice is based on one of the central tenets of informed consent. Thus, if one moves to an opt-in or opt-out system that takes the rights, needs and decisions of the family away and establishes a right to veto its decisions or views, for example, it begins to sit uncomfortably with the tenet of consent that underpins medical practice.

At its centre, this debate is about consent. I am not quite sure whether presumed consent is necessarily going to increase the figures on donation. Some of the evidence would suggest that it may do so marginally but perhaps it will not do so at all. One of the key concerns must be about the issue of medical practitioners and protecting them. A key aspect of any legislation introduced should be to set out the consent process clearly. In the United Kingdom, for example, the Human Tissue Act goes through a system of defining qualifying relationships in terms of next of kin and it stipulates people who must be consulted. Underneath that, it introduces codes of practice that provide another layer of detail on what is required. That would probably be envisaged in the legislation that may be introduced.

In one sense, the issue of presumed consent may well provide a positive context or starting point for a conversation between a medical practitioner and the deceased's relatives in an intensive care unit. That may well be positive. However, from a legal perspective, I am not certain whether it is important that there be an opt-in or opt-out arrangement, but the key is to note that the further one drifts away from the issue of consent from relatives, the more potentially challengeable or fragile any legislative structure becomes.

That is a summary of my views on some of the legal implications flowing from an opt-in or opt-out system. There is further detail in the document that has been circulated. I will be happy to answer questions.

Chairman:

We appreciate Mr. McDowell's attendance this morning and his making the effort to be here.

Deputy Billy Kelleher:

I welcome all the presentations. We had the same discussion last week. While there may be varying views on how we approach this issue, it is important that organ donation be encouraged and facilitated, where possible. Many steps need to be taken.

Dr. Plant implied that we can profile the challenges that will be faced in the years ahead in the context of kidney failure and other conditions requiring transplantation. It is quite obvious that there will be difficulties associated with transplant surgeons. Perhaps talking about organ donation in isolation without promoting infrastructure and its development would mean the committee would be failing in its responsibility. Clearly, it is not just a case of organ donation; it is also a question of infrastructure and having personnel trained to approach families.

Does the doctor who was treating the patient who suffered from brain or cardiac death approach the family? Is that normally the case or is there a specialist nurse or staff member who has experience and training in approaching families with regard to organ donation? Does it happen on an *ad hoc* basis or are there structures and protocols in place? Does it depend on the consultant, surgeon or doctor?

I once encountered a family which lost a loved one and which was too traumatised in its grief to think of organ donation. The family has regretted it since. There are organs available every week that could be used but which are not used. We do not know why. We do not know whether there are cultural issues at play or whether we just do not profile, highlight and encourage organ donation enough. We do not know whether there is sufficient infrastructure in place. Much discussion needs to be held, not only on the legislative side. We must really promote the concept at Government level and throughout broader society.

When one sees the progress made in regard to the national paediatric centre, I have great confidence that action on the national transplant centre, on which I welcome the views, will happen very quickly.

As regards all-island based transplantation and harvesting, and on an east-west basis, is there a greater capacity for us? We are a small nation with limited resources so can we pool them on an all-island basis, in a structured way, including between Britain and Ireland? Surely there must be greater scope and potential to pool our resources in that area. In the coming years with the difficulties in which the State finds itself, I do not believe that the longer-term planning needed in the context of training transplant surgeons and other investments in infrastructure will happen as quickly as we would like. Therefore, there is the potential for co-operation in that area.

We are witnessing an international trade in organs, which is both illegal and unethical. It is disturbing and emanates from Latin America, Asia and parts of Africa. Clearly, the West is encouraging organ donation in whatever guise, be it soft consent, informed consent or opt-out. By encouraging people to donate organs it will surely assist in reducing the illegal trade. One would hope that is the case, although it may not be. As parliamentarians, we can do many things nationally and internationally in the European context.

I am intrigued how the system works at the coalface. For instance, in a hopeless case when all chances of survival are gone, who approaches the next of kin or is it done on an *ad hoc* basis?

Deputy Caoimhghín Ó Caoláin:

I joint with the Chairman and other colleagues in welcoming each of the contributors. Like so much in life and death, this is not a straightforward issue by any measure. Dr. O'Rourke talked about the one-page system. It must be acknowledged that, irrespective of the different views on presumption or signing up, everybody is sincerely working towards the objective of improved donor availability and the consequent access for those in need. It is a matter of trying to find the appropriate response.

I would like to ask a few additional questions. Both Dr. Hickey and Professor Conlon referred to the Norwegian model. As regards the number of transplant surgeons, I note that in the third page of his presentation, Dr. Hickey spoke of a current situation involving four whole-time equivalents. Is that the actual number currently *in situ* for the kidney service, or is it the picture across the board? He indicated that if we were to exercise the European Working-Time Directive we would need 20 transplant surgeons to run our current service. Will he clarify if that is particular to the kidney transplant area or does it cover all transplant issues that arise?

I am taken with Dr. Hickey's argument for a single centre of excellence and expertise that would cover all the various areas of need. I note that we currently have a triplication of such facilities in Ireland, which obviously does not allow for that professional engagement on a continuous basis and all the other advantages that would occur.

I thank the witnesses for what they have said. At the end of the day, even if the presumed approach were to be legislated for, could the current capacity cope even if there was a significant increase? Clearly, that remains a matter for debate among Dr. Hickey and his colleagues. From what I can ascertain from what he and others have said, they simply could not cope with a significant increase in availability.

Professor Conlon referred to establishing a national organ procurement agency. I know that there are representatives of the procurement end of this who have made important and useful contributions. I cannot fail to note that we have only five transplant co-ordinators here - a fact which, compared to the figures in Northern Ireland and Britain, jumps off the page at me.

Professor Conlon indicated that the proper management of organ donation would have a greater impact and a more dramatic increase in organ availability than even the presumed idea that is coming into play. I understand the concerns outlined by Dr. Dwyer and his colleagues that presumed consent could lead to a decrease in organ donation. I am not so sure that would be the case, however. It would be alarming if it were. In that respect, it would offer a break in the current enthusiasm for the presumed approach which was well described here last week by a range of people, including living donors and recipients who gave powerful testimony. One young woman, just five weeks after a kidney donation, looked in better health than any of us gathered here today. It was wonderful.

Dr. O'Loughlin referred to a number of measures that should be taken to have a more certain outcome than the presumed approach. Is Dr. Hickey's view on a single centre of excellence shared across the board? The Intensive Care Society of Ireland's correspondence to the Minister speaks of particular measures but I presume they are only in the context of the current trilocation of activity.

Dr. Plant strongly emphasised that the organisation and infrastructure provided to deliver organ donation and transplant services is a more certain requirement now and with more definite positive outcomes.

I thank each of the witnesses for their respective contributions. The well-intentioned, non-professional case that is being presented by people like Mr. Brolly and others who have taken up this issue, is gaining significant momentum. It will have the support of influential organisations and other interests in the coming week. I am aware that this matter will be addressed further then. The contributions we have heard are timely and welcome. I thank the witnesses for them. When the Chair allows it, perhaps they can respond to the questions I have posed.

Senator John Crown:

I welcome my fellow professional colleagues here today. Their illustrative, illuminating, educational, informative and humane presentations have gone to the heart of some of the most difficult interactions that doctors have with patients and their families. It is not all that long ago that I used to find myself occasionally having this conversation with relatives. It is one of the most difficult areas.

I would like to pay particular tribute to Professor Hickey who has been an extraordinarily wonderful role model for young Irish doctors in terms of his devotion to this cause over the years and for keeping it on the agenda where it should be.

The problems of transplantation are contributed to partly by the organ crisis. I am delighted that so many of our colleagues have correctly and forthrightly pointed out that one of the major problems is also resourcing. There is no doubt that this is a microcosm of the health service in general and its problems. Unfortunately, we have a system which is under-resourced, grotesquely understaffed and mismanaged by people who should not be managing it. The people who should be managing the service are being relegated to the status of clinical technicians by a group of people who should not be making the relevant decisions. The system is not underfunded, but it is severely malfunded and requires reform. Professor Hickey's apocalyptic scenario involving the rationing of dialysis should not be dismissed as a Cormac McCarthy-like future fiction. The inexplicably widely-loved NHS in the United Kingdom was doing this until comparatively recently. Certainly, in my professional memory, middle-aged patients were systematically denied dialysis in certain regions as it was felt the system could not support them.

I am 100% in favour of Professor Hickey's suggestion that we should have a solitary national transplant centre. While much of my criticism is aimed at bureaucracy, there is a certain amount to be laid at the door of doctors and medical-school politics. Norway has a slightly larger population than Ireland and has four medical schools. There is only one medical school in Oslo, while Dublin, with a smaller population, has six medical schools. We have one medical school per 750,000 inhabitants, whereas the European average is one per 1.5 million. The average in the United States of America is one school per 1.2 million people. One cannot have rational structures when one disperses one's resources across an irrational number of centres, which are kept alive for the benefit of powerful medical-political and academic forces with a vested interest in maintaining them. It is an issue we must discuss, albeit in another forum.

Professor Hickey, Dr. Conlon and Dr. Plant are perhaps best placed to assist me on the following. As a general rule of thumb, the number of specialists *per capita* in Ireland is approximately 80% of the number in the UK, while the UK has approximately one third of the number which is the norm in continental Europe. In turn, the number in continental Europe is substantially lower than in North America. Do the three witnesses know roughly what our figures are and how we compare? I suspect that by European standards we are grotesquely under-provided not only with transplant surgeons but with nephrologists, if only somewhat under-provided by UK standards. Is that a fair characterisation?

Senator Colm Burke:

I thank all the contributors for their excellent presentations this morning. I have learned a great deal from them. Has there been any discussion of providing one transplant unit for the country among the medical profession, the HSE and the Department of Health? The need for a long-term plan has been highlighted. I have a serious problem with the way the HSE is dealing with the general doctor issue at the moment. We seem to be going from year to year rather than planning for the long term. I wonder if those involved in this area have worked to set out a ten-year plan with clear targets and if that includes the creation of a single unit. We are dealing in many areas nationally with reconfiguration of the service. Has the creation of a single transplant unit been part of the discussion process on such reconfiguration?

If the problem of organ donors and the availability of space to carry out the work were resolved in the morning, what would the system's maximum transplant capacity be? Professor Hickey said we should aim to carry out 300 transplants per annum. If we resolved all the other issues, how long would it take to reach that target and how many additional consultants and beds would be required? What is the maximum number of transplants that could be carried out with the current capacity in the system if we had all the necessary organ donors and theatre and bed space? It is important to identify at this stage where we are at and what we can deal with.

Deputy Sandra McLellan:

I welcome the witnesses and thank them for their very interesting presentations, which follow on from those given last week. It was lovely last week to hear emotional stories from live donors and to see recipients and how they benefited.

I read some of the opening statements last night and was struck by how little I knew. I did not know that Ireland did not have a specific transplant centre and a faced a serious lack of transplant surgeons into the future. I learned that the programme is run from an office in Beaumont Hospital and has only five co-ordinators, who have other duties to attend to. I had thought we were much further along than that. We seem to be very behind the times. I was also struck by the huge size of the investment required in the system even if we had the donors. I was also struck that a living donor had to pay for his or her own expenses, which are of the order of €5,000 to €7,000. While that is a small amount of money given the return, many people will find they cannot afford those sums. We must be living in the Dark Ages to expect people to do that. I was further struck by the fact that we do not have legislation to cover the scenario in which a person wants to donate an organ and the donor must therefore travel abroad in order to donate.

Most of the questions I wished to raise have been dealt with by other speakers. I thank the witnesses for their contributions. They were a real eye-opener and very informative. I agree 100% that we must apply resources to making people more aware of the organ donor programme and to encouraging donations. As I said, I am a member of the health committee and the presentations have been a significant eye-opener.

Deputy Catherine Byrne:

I would love to say there was a pot of gold at the end of the rainbow into which we could dig to build facilities and assist people who want to be live donors. Unfortunately, there is not. I do not know what the last Administration was doing here, but they had a lot of money which was not invested in the right places. I am interested in the points raised about Northern Ireland and the United Kingdom and their investment in organ procurement. What do they actually do?

I address the next point to Dr. Colman O'Loughlin. I have sat in a room in which someone has asked my family the question to which he just referred. It is a very tough question. One's initial reaction is "No - not in a million years." When one gets a second opinion after a day or two, one lives in hope and considers that if there is anything that can be done for other people, it is the right thing to do. When we were asked the question, the issue was dealt with in the most compassionate way possible. As a member of a family which was involved in an organ donation decision 20 years ago, I believe that a little piece of our family member is still out there in some community or family where someone is living a full life. Someone used the phrase "a lifeline of hope". It is important that when people face that terrible time in their lives they have as much information as possible. It must be told to them with the greatest compassion and understanding that they are being asked to allow someone who has been in their life to pass on while someone else is given a new lease of life.

As much information as possible must be given compassionately to such families, and it must be explained to them that someone dear in their life could give someone else a new lease of life.

I found the briefing material interesting to read. At a meeting yesterday with the Minister for Children and Youth Affairs, Deputy Frances Fitzgerald, she informed us that we need €1.5 billion every month to keep the State afloat and pay people's wages. It is a sad reflection on all of us that when we had plenty, more was not done in helping agencies such as this. Coming from a donor family, we certainly appreciated the way we were dealt with and it helped heal some of the sadness involved. It gave us a different appreciation of the dilemma of making life-changing decisions when it comes to organ donation.

Senator Mark Daly:

I have been observing this debate for six years and have come to the conclusion it is a fundamental failure of the political process. No amount of money will make any difference to our organ donation system until we have the correct procedures and structures in place. I was in the Seanad when Senator Feargal Quinn introduced his presumed consent legislation, which was hotly debated. When one reads the headline, it might make sense. However, when one delves down into the matter, it is clear it does not work unless there are systems behind it and co-ordinators who would meet the families in question to ask them to consider donation. A process is needed, but we do not have one in place.

In the public consultation process on the matter in 2009, 23 out of 30 organisations involved stated that presumed consent is not the way to go. I believe we are now going to have another public consultation. There is nothing like having another report on what we already have been told. Having a report and pretending there is action does not deal with the problem.

In 2012, the EU directive on organ transplantation was implemented in Ireland. Many of the delegation were in Dublin Castle when we had what I can only describe as a box-ticking exercise. It involved officials from the HSE discussing a directive, a draft of which was not available to anybody in advance of the meeting, which meant we were all talking in generalities. After having made my contribution at this meeting, I found it amazing that the directive was not put before the Dáil, the Seanad or the health committee but was signed in on the last possible day, 28 August 2012, by the Minister. That was a failure of process. It was a significant opportunity missed.

Our first organ transplantation legislation in the State was itself a failure of process. Here we are now talking about presumed consent, which would not make a blind bit of difference if we brought the legislation in tomorrow morning because there would be nothing underneath it to support it. There would be no system to ensure people could talk to families about organ donation. We could have a required request system, which would be more effective. Again, however, unless one has the structures in place, it cannot work. It is a failure of our process that our first organ transplantation legislation in the State was introduced last year but no legislator had any input into it and the concerns of the delegation were not taken on board.

Senator John Crown:

Is it correct that under a regime of presumed consent, the doctors involved would not necessarily go over the firmly expressed opinions of the relatives if they said they would not allow donation? People may think this is a recipe for contention between medical staff and families involved, when it is not.

Dr. Liam Plant:

Senator Crown asked about staffing levels. I can provide him with the exact staffing level for nephrologists, which will likely reflect on the other specialties in question. The mean number of consultant whole-time equivalents per million of the population in the United Kingdom is 7.4. In the Republic of Ireland, it is 4.6. There is also a regional disparity, with about 6.3 per million in the HSE Dublin north east region but 5 in the HSE south region, 3.8 in the HSE west region and 3.6 in the HSE Dublin mid-Leinster region. The second metric, which is similar, is the mean number of consultant whole-time equivalents available per 100 end-stage kidney disease patients. In the UK it is 1.1, while in the Republic of Ireland it is 0.6. Again, there is regional variation. These data are accessible on our website at *hse.ie/nro*.

I profoundly agree with Deputy Catherine Byrne on the fact that there is no pot of gold at the end of the rainbow. However, we have revenue locked within the programme for treatment of end-stage kidney disease. There is €100 million for costs attributable to dialysis. If a proportion of those patients received a transplant, that revenue would no longer be required. With respect to Senator Crown, I do not believe we will have a situation in which we will not dialyse people. I cannot envisage that happening. However, if we do not increase access to transplantation, the numbers on dialysis will continue to increase.

We have reduced costs dramatically in the past three years, but no matter how cheap one makes it, a patient has to have this treatment 156 times a year. Senator Crown used the word “malfunded”. The taxpayer, through the HSE, is funding end-stage kidney disease treatment. It is a question of which way we want to do this. Unusually for a health care issue, in this case the treatment that is the highest quality and has the best outcome is the cheapest.

Dr. Ruairí Dwyer:

We hear anecdotes about families requesting that an organ donation not be made. We see that as a major failure on our part and it is something we go to great lengths to avoid. If it is any comfort, it seems to happen rarely. There was a formal audit of potential donors in 2008 which found that less than 5% of families asked that organs not be donated. Part of our routine with all patients is to ensure the family has been offered the opportunity to allow for organ donation. We are well aware of the long-term benefits to the patient who receives the organ donation. The organ donor co-ordinators support the whole process. Our job in intensive care is primarily looking after the living. We also see organ donation as an integral part of our job, but with the EU directive there is an incredible amount of paperwork in place or coming down the line in this area. If this can be dealt with by the co-ordinator rather than being added to our workload, it will facilitate the process of organ donation considerably.

It is perhaps not the business of this committee but the issue of the single transplant centre has been raised by a number of members. I may have a different perspective compared to others. There are synergies in having a transplantation centre as part of a general hospital that would be lost in having a single transplant centre. At a time when we are trying to merge obstetric hospitals with general hospitals, there might be negative effects in terms of access to specialists in many areas. In the case of kidney transplantations in Beaumont Hospital, there is access to endocrinologists and a large general intensive care unit that would not be available in a single centre.

I will pass on some of the other questions which will be answered by my colleagues.

Dr. Colman O'Loughlin:

I would like to address the question raised by Deputy Billy Kelleher about whether it is the treating doctor who raises the issue of organ donation with the family. It is the treating intensivist who does it. By necessity and largely because the process begins when a patient is admitted to an intensive care unit with a brain injury which progresses to brain death, we recognise this process quickly and in all of our interactions with our very sick patients - the sickest patients are in intensive care units - we focus on the family dynamics because they are extraordinarily overwhelming and very difficult for us, as well as for the families involved. From the outset, we pay particular attention to developing a bond with the families. We must explain the concept of brain death. As many learned individuals still struggle with the concept, trying to explain it to a family coming in cold is difficult. Their relative is warm and has a pulse, the screen monitor looks normal and yet he or she is dead. One then throws organ donation on top of this. We develop a bond and try to build trust, which is extraordinarily important and can make a significant difference. The corollary - lack of trust - can blow everything out of the water. We must, therefore, be very careful in that regard. It is necessary that the person involved with the patient is present when one brings up the issue of organ donation.

Should we have support? Yes, we should, but we do not have it. We have an organ procurement office in Beaumont Hospital run by a fantastic group of people who are also transplant co-ordinators. Having a procurement person who is also a transplant co-ordinator and on both sides of the fence would be horrendous in any other civilised country. That cannot continue and must stop. We must have a dedicated organ procurement office staffed separately from transplant co-ordinators. They are different jobs and should be staffed differently. Should they be in a position to come to the hospital when we have a potential organ donor? Yes, they should. I did most of my speciality training in Melbourne where there was a fantastic organisation called Life Gift Victoria which was run by the government rather than medics. It had people on call to arrive at a hospital within whatever timeframe was possible when they heard about a potential organ donor. They were present when one approached the families and would have received specialist training. I have received as much training as I can have in this area. I have 30 other patients in my intensive care unit at the same time, but these are the people who are dedicated to this cause and have fantastic skills. Therefore, we should have them.

To respond to some of Deputy Catherine Byrne's comments, this is a very difficult time. We are very encouraged when a family comes forward to us with its support for the organ donation process. We must bear in mind, however, that it is within the right of the family not to go down that route. We must be very careful not to guide it one way or another. We can bring up the issue. That is the best we can do with trust. I am very glad the Deputy had a positive experience with the medical specialists with whom she dealt. We focus on that relationship with the family, which is incredibly important. I do not have strong feelings on this issue because the family has the ultimate say as to whether to opt in or out. As Professor Hickey said, we would never overrule its decision. Generating trust with the family and developing that bond is very important for us.

Any external influence such as the presumption of consent or the idea that altruism is being removed from the process is potentially dangerous. I do not have any figures for the committee, as the research is very weak. Mr. Joe Brolly, whom we all should congratulate for raising the topic, continually describes the euphoria he felt in gifting his kidney. That is important - he gifted it and felt euphoric. There is a small chance that the concept of the presumption of consent might take away slightly from this; therefore, it is very difficult to bring that argument into the process.

Dr. James O'Rourke:

I echo what Dr. Dwyer and Dr. O'Loughlin said. I am strongly committed to organ donation and believe families get much solace in the long term. Deputy Catherine Byrne described her experience. I had one experience a number of years ago of a small child who died and there was almost a case of medical misadventure. I remember sitting with the parents in the room and not bringing up the issue of organ donation. In retrospect, I would do so today. I would not miss that opportunity again. There are very few opportunities where the potential for organ donation is missed because the issue is not raised by me and my colleagues in the intensive care unit.

Going back to the resource implications, most organ donation result from the intensive care unit. There are patients who never reach the intensive care unit owing to resource restrictions who could become organ donors but are not given that opportunity owing to limitations in the number of intensive care beds. I do not have anything more to offer.

Professor Peter Conlon:

Deputy Catherine Byrne commented that there was no pot of gold to fund the health care system. As each kidney donor will save about €700,000, one could consider a kidney donor to be a pot of gold. When one multiplies this figure, the economics of transplantation are enormous. I said up to €300 million could be saved over ten years by treating kidney failure predominantly by way of transplantation rather than by dialysis.

Senator Colm Burke spoke about whether we could cope with the level of transplantation. As we said, we cannot. We have 100 pairs of donors and recipients waiting to donate a kidney to each other. Therefore, it will take us three years to do it. With this in mind, we have put together a business plan to very rapidly try to expand capacity.

Chairman:

I apologise, as there is a vote in the Seanad.

Senator Colm Burke:

I just wanted to hear the answer. I will skip it if I have to.

Professor Peter Conlon:

Many of the elements of the plan are in place to be rolled out in the next six or 12 months to build an immediate short-term transplant unit at Beaumont Hospital, to commit to a larger unit in two or three years and appoint 30 staff. We have approval to appoint 30 staff. The consultant appointments committee is delaying the process. We have worked hard in recent years, but it will require the implementation of this plan and reaching the next second and third stages to have any hope of coping with the numbers of patients mentioned.

Dr. David Hickey:

I again thank the committee for giving us this opportunity. Everything has been more or less covered. All of the questions have been adequately covered.

I was very interested to hear about Deputy Catherine Byrne's personal experience. I think she would agree that if she had not been offered the opportunity, it would have been a source of sadness for her family. It is a service to the donating community.

The single unit will be located on a university hospital campus such as the one in Oslo in order that we would have our great anaesthetic colleagues beside us all the way. In respect of cost, it is a question of what is the priority. There is a hospital just down the road from here called the Mater hospital, with a plaque on it dated 1846, when construction of the hospital began. That was in the middle of the Famine and there was a set of priorities. It is still a leading hospital.

Professor Conlon has said it is cost-effective to do it, but how a society looks after this group of people who suffer a slow death over a period of years makes a statement about it. Money should be made available for this centre. It should be an attractive career for people who will want to spend their lives in it. The way to do this is to have a single centre that will be state-of-the-art and in which where there will be no triplication of services and in which all units will be brought together to develop a centre that will be worthy of this country and the community we serve

To reply to Senator John Crown's question, we are being distracted from looking after people by meetings with ambivalent paraprofessionals in the hospital setting. This centre needs to be governed, managed and funded by an organisation such as the national organ donor and transplantation office and answerable to this committee, the Government and, ultimately, the people. The patient has been pushed down the priority list in health care. It is all about budgets, targets and business speak. We need to get back to doing what we would want to be done to us if we were sick.

Dr. Liam Plant:

Given the expertise on offer at this meeting, we have focused on kidney transplants, in particular. However, it is important to acknowledge that dialysis can be provided for those who cannot have a kidney transplant, whereas our fellow citizens who have cystic fibrosis or are dealing with heart or liver failure are in more difficult circumstances. The absence of a transplant does not mean they will cost the State X euro in replacement therapy; it means a loss to their families or communities. We have not focused on this issue sufficiently. We should not forget the people in question. The Republic of Ireland has the highest frequency of cystic fibrosis in the world. This is another group of people who present a particular charge to the success of this project.

Deputy Billy Kelleher:

In the context of all-island and east-west co-operation, there are bilateral agreements between hospitals and consultants may have personal relationships with their counterparts in Britain and Northern Ireland, but surely when we develop a national transplant centre, we should pool resources on an all-island basis. I acknowledge that the Mater hospital was built during the Famine of the 1840s and that we should have a statement of intent, but the greater good can suffer, even in the context of the national children's hospital. I am not denying all of the good that has been done, but we should consider the bigger picture.

Deputy Caoimhghín Ó Caoláin:

I concur with Deputy Billy Kelleher. On my question about the current complement of those practising, Professor Hickey has indicated that it is in the order of 20 whole-time equivalents. What is the current complement across the board of kidney and all other relevant specialties and what figure does he believe it should be?

On the concpet of presumed consent, all of the views expressed indicate an acceptance that the next of kin or family should retain the right to give final approval. I presume the delegates would agree, but it is not something that we should be afraid to address. Donor card holders are making a very clear statement, but is it also the case that next of kin and family have the right to intervene and say "No"? An issue arises both in terms of the current situation and what might apply in terms of presumed consent, but it is very strong in the case of donor card holders. It is a matter that should be addressed because if it was my wish as a donor card holder, I would be strongly of the view that my family has no right to object.

Dr. David Hickey:

As far as I am aware, the concept of presumed consent is not practised anywhere in Europe. It is in the books, but it never happens that a family is sidestepped in this situation. If one person in the family is uncomfortable, the story is over because we do not want to cause more trouble and strife. The donor card is a useful vehicle for those who are looking after someone who has just died to bring up the topic. If the family is not interested in engaging, that is the end of it. While one could argue legally in favour of going down that road, people who have struggled to save somebody for three or four days understand the situation very well. The donor card is useful and the concept of presumed consent may offer a similar vehicle in making organ donation the norm rather than the exception. In a not insignificant number of intensive care unit cases, the topic is raised by the family. That is great for everyone who is looking after the patient because it is not necessary to initiate the request.

In terms of numbers, we have four full-time equivalents. All of our transplant surgeons also perform significant urology procedures. Some perform more significant procedures than others, but they have a second job, which is often very busy. These four full-time equivalents are involved in transplants and organ procurements, as well as looking after the national children's transplant unit, which used to be in Beaumont hospital but has been moved to Temple Street Hospital. Two of us are double jobbing in that regard. As Dr. Plant noted, we have half of the necessary numbers when compared with the United Kingdom and these are not blue ribbon numbers. We are way behind what we need. If a transplant surgeon is confined to working 48 hours per week and he or she happens to be on duty over a weekend in which a couple of donors become available, that is the week gone. Twenty might be an exaggeration, but it would not be a great exaggeration.

Dr. Liam Plant:

Deputy Billy Kelleher's question resonates with my own experience of moving from Scotland to Ireland. I asked my colleagues why we were not participating with others in other parts of these islands. If one is operating in a wider geographic catchment, typically there is movement of donor organs within an area. This means the time between organ removal and placement becomes extended in what is called a longer cold aschemia time. The cold aschemia time in the Republic of Ireland is considerably shorter than it is in the United Kingdom. There is an inexorable logic, whereby four or five areas joined together, with a common rule of sharing, will produce an imbalance of trade after a period of time because smaller areas will disproportionately provide more organs for larger areas. The other issue is the nature of the background donor population. Our ethnic background and age structure are different from those in the United Kingdom. Kidney donors on this island tend to be younger, the cold aschemia time tends to be shorter and such an imbalance of trade is relatively minor. When I first returned here, I was strongly of the view that we should share, but my experience and observations over time have led me to believe we are just about big enough.

Dr. David Hickey:

It is an important question. We had a sharing arrangement with the United Kingdom between 1989 and 2001. Everything Dr. Plant described came to fruition. There was a negative balance of trade every year and, because of transportation, even for the best matched imported kidneys, we had no knowledge about who had removed them, how they had been managed in ICU or the quality of the ICU concerned.

We had no control over that. The best-matched imported kidneys did worse than the worst-matched local kidneys and we pulled out of that arrangement. Generally speaking, again, with 60 million_in the UK, the smaller centres do not get the rewards. They become demoralised, their efforts deteriorate and organ procurement declines as a result. That has been the situation in the US where big centres have cannibalised small centres, and everybody is a loser when that happens. We must maintain our own integrity here. There are situations where a bigger pool like the UK is important, such as the paired organ exchange which Professor Conlon is running. We are involved with the North for pancreas transplantation. There are 27 co-ordinators there. Maybe they could spare some for us. Involvement with the North may be a possibility. Professor Conlon would know better than I do. I do not know. In terms of the deceased donation rates here, we should look after our own people first and export what we cannot use.

Mr. J. P. McDowell:

Deputy Ó Caoláin sought clarity on whether someone who has a signed organ donation card still requires the consent of the family after his or her death. The law, as introduced by the BSI last year, provides that the family's consent is legally required. So even when one has a kidney donor card that suggests that one is happy for one's kidneys to be used in the event of one's death, the law states that the consent of the family is required.

Dr. Colman O'Loughlin:

It is comforting to us, as the intensivists who interact with the families, that there is legal protection. It would never be the case that we would do it anyway. The donor card has always been a guide, an important guide. Most families would be aware that the person carried an organ donor card, and by and large they would be supportive if they were aware. There are occasions when the patient has had a donor card and the family has not agreed and we go with the family on every single occasion. It has never happened in Europe but there was a case in Singapore where there was a physical fight in the intensive care unit on this issue and I do not want to get into that in any shape or form in my practice, but it can happen.

Dr. Ruairi Dwyer:

I return to Deputy Ó Caoláin's earlier question on whether there is a risk of decreased donations with presumed consent, and there is. That is why many of my colleagues are concerned about this. Brazil introduced presumed consent some 15 years ago and it was followed by a decrease in donations, so they reversed it. The experience in Europe has been different. Where European countries have introduced presumed consent, associated with a strong campaign to gain social support for this, there seems to have been an associated increase in donations. There is data from two centres in Belgium where one centre adopted presumed consent and the other did not. There was a major difference in organ donation rates over the following couple of years in the presumed consent centre.

Prof Peter Conlon:

To address the question of sharing organs among larger areas, many factors go into making up how well kidneys do five and ten years out. The results in Ireland are better than in the UK and much better than in the US. So smaller, in terms of not sharing kidneys over long distances, is often better than sending kidneys that are 24 hours on ice and have travelled half way up and down the country.

Chairman:

I thank everybody for their participation, in particular Dr. Hickey, Professor Conlon, Dr. O'Rourke, Dr. O'Loughlin, Dr. Dwyer, Dr. Plant and Mr. McDowell.

Sitting suspended at 11.55 a.m. and resumed at noon.

Chairman:

We will resume the second part of the meeting. I remind members, witnesses and guests in the Public Gallery to turn off their mobile phones for the duration of the meeting. This is the third and final hearing on organ donations in Ireland. We will examine the policy perspective with officials from the Department of Health, the HSE and the Irish Medicines Board, IMB. I welcome Ms Mary Jackson, Professor Jim Egan, Dr. Siobhán O'Sullivan and Dr. Patrick Costello.

Before I commence I remind witnesses about the rules on privilege. Witnesses are protected by absolute privilege in respect of their evidence to the committee. However, if a witness is directed by the committee to cease giving evidence in regard to a particular matter and continues to do so, the witness is entitled thereafter only to a qualified privilege in respect of his evidence. Witnesses are directed that only evidence connected with the subject matter of these proceedings is to be given and are asked to respect the parliamentary practice that, where possible, they should not criticise or make charges against any person, persons or entity by name or in such a way as to make him, her or it identifiable. Members are reminded of the long-standing parliamentary practice to the effect that they should not comment on, criticise or make charges against a person outside the House or an official either by name or in such a way as to make him or her identifiable.

I offer apologies on behalf of Deputies Kelleher, O'Caoláin and Mitchell O'Connor and Senator Colm Burke who have to attend other meetings. Sometimes on the graveyard shift in committees, members have other commitments they cannot get out of. Nevertheless, I thank the officials for attending. This is an important issue and I call on Ms Mary Jackson to make the opening remarks.

Ms Mary Jackson:

I thank the Chairman for the opportunity to address the committee on this important issue. I am joined by my colleagues who are also involved in shaping organ donation and transplantation policy. Dr. Siobhán O'Sullivan is chief bioethics officer to the Department of Health and she is also a member of the Council of Europe committee on bioethics and of the HSE's national consent advisory group. Dr. Patrick Costello is blood, tissues and organs manager for the IMB, which is the competent authority authorising organ donation and transplantation under Ireland's EU regulations.

A priority for our health system is to ensure that every link in the donation and transplantation chain is safe. EU Directive 2010/53/EC, which was transposed into Irish law by SI No. 325 of 27 August 2012 has set criteria for quality and safety and enshrined them in law. The IMB is working with Professor Egan in the HSE's national organ donation and transplantation office to ensure organ procurement and the activities in Ireland's three transplantation centres at Beaumont Hospital, the Mater Hospital and St. Vincent's Hospital meet these criteria.

In addition to mandatory standards for quality and safety, the EU has set out a ten-point action plan on organ donation and transplantation, which aims to strengthen co-operation between member states to increase organ availability and enhance the efficiency and accessibility of transplantation systems, while, at the same time, improving quality and safety. The actions, to be implemented by member states are to promote the role of transplant donor co-ordinators in every hospital where there is potential for organ donation; promote quality improvement programmes in every hospital where there is a potential for organ donation; exchange best practice on living donation programmes among member states: improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation; facilitate the identification of organ donors across Europe and cross-border donation in Europe; enhance the organisational models of organ donation and transplantation in member states; promote EU wide agreements on aspects of transplantation medicine; facilitate the interchange of organs between national authorities; evaluate post-transplantation results; and promote a common accreditation system for organ donation, procurement and transplantation programmes. Ireland is prioritising areas for attention from this list, which will positively impact on organ donor rates.

Another major initiative is the programme for Government commitment to legislate to change to an opt-out system for organ donation about which we have heard a great deal during these hearings. This commitment will require legislation and has divided members of the clinical community and the voluntary sector. However, as we have seen in other jurisdictions, it is not the legislative base, but the infrastructure and donation and transplantation systems in place, and how potential donors and their families are encouraged to donate, that make the difference in increasing the number of donations. Ireland is among a minority of EU member states, including the United Kingdom, the Netherlands and Germany that do not operate an opt-out system.

We must change the cultural attitude towards organ donation and make organ donation the norm in Ireland. The present system of consent will change to one of "presumed" or "deemed" consent, which means that the consent of an individual to organ donation is deemed or presumed to have been given unless they objected during their lifetime. If a person does not wish to become an organ donor after death, they will need to register an objection during their lifetime - a process known as opting out. The deceased's family or next of kin will still have an important role to play in the process of organ donation, as we heard strongly from the presentations earlier. While the next of kin will not be required to give their consent to the donation itself, they will be asked to provide as much information as possible on the person's medical and social history. The Minister has stressed that there would be no instance whereby organ donation would proceed against the wishes of the deceased's family. The system to be introduced is, therefore, a "soft opt-out" system.

The Department is drafting the heads of 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 Bill will also legislate for consent for the use of organs and tissues removed from a living person for transplantation and research. The logistics of establishing a system of presumed consent are complex. Many factors, other than the introduction of a system of presumed consent, affect organ donation rates. The availability of donors, transplantation infrastructure, public attitude, and investment in health care all play a role. 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, will further improve donation rates in this country. A secure information technology system must be established and maintained. The Welsh Government, which is planning to introduce an opt-out system, envisaged that this would cost more than €5 million for ten years for a population that is two thirds that of the Ireland.

In the absence of a personal unique health identifier, the identification of individuals and the maintenance of a national registry of potential donors is problematic. An opt-out system would require an extensive and well resourced communications strategy. Measures would have to be put in place and sustained to protect the rights of vulnerable groups and the marginalised members of our society. For example, how would a homeless person, or a person who lacks capacity register his or her wish to opt out? The Department will commence a consultation process on presumed consent in the next few weeks and will invite interested parties to submit their views on the practical aspects of introducing this system. We will pose a range of questions, allow approximately six weeks for consultation, distil the information received and then have a focused workshop on the findings of this consultation.

The workshop will involve clinicians, the HSE, Irish Donor Network representatives and other relevant parties to give direction to the next steps, the shape of the legislation and what is needed in the health system to implement a soft opt-out system. We would also be pleased to have representatives of this committee in attendance on the day.

The health system must put people and patients at the centre of everything we do. The Irish Donor Network gave an important input to discussions on the detail of the implementation of Irish regulations on quality and safety in donation and transplantation. Its member organisations - the Alpha One Foundation, Cystic Fibrosis Ireland, the Irish Kidney Association, the Irish Heart and Lung Transplant Association and the Irish Lung Fibrosis Association - will continue to be partners in the development of policy and actions. Indeed, representatives of the network met the Minister in February to provide its members’ views to him, especially on the issue of consent to transplantation. The network also pointed to service areas where improvements could be made to enhance donation and transplantation potential.

I thank the committee for giving me the opportunity to present the Department’s position today. Two clear messages came from the presentations given by the representatives of organisations and individuals who appeared before the committee. First, like other countries throughout Europe, Ireland has waiting lists for transplantation. Second, legislation alone will not solve the problem, but we must work together to increase Irish organ donation and transplantation rates.

A framework to ensure quality and safety is being developed and enhanced. In parallel with this, we must make organ donation the default position for most people and maximise the number of organs available for transplantation. We must ensure that our hospital system is resourced to provide as many people as possible with the gift of life through organ transplantation.

Chairman:

I thank Ms Jackson for her presentation.

Dr. Siobhán O'Sullivan:

I thank the committee for the opportunity to address some of the ethical questions arising in the context of consent for organ donation and, more specifically, the pertinent ethical issues to be considered when introducing a presumed or opt-out consent model. As chief bioethics officer in the Department of Health, my role is to support the Department in achieving its mandate and strategic objectives through the provision of bioethical analysis and advice.

The success of any organ procurement system is contingent upon its capacity to fulfil three interconnected objectives: good outcomes in terms of quantity and quality of organs; the maintenance of public trust in the transplantation system; and respect for ethical principles. As the need for organs increases worldwide as well as here in Ireland, transplantation systems have explored a number of innovative strategies to increase donation rates, many of which have proved ethically challenging. Strategies include expanding the criteria for declaring death, living donation, donation after circulatory death, anonymous donation, directed donation, opt-out policies and even the introduction of economic incentives for donors. These strategies are not necessarily unacceptable, but they are morally debatable. While the ultimate goal is to save lives and improve the quality of life for transplant recipients, this goal needs to be achieved through means that do not violate socially accepted ethical norms.

Gift giving or voluntary donation to benefit another person as an expression of altruism and social solidarity has been the ethical cornerstone of organ procurement and transplantation in this country. Traditionally, the practice has been institutionalised as an opt-in system, which depends on having the express or explicit consent of the person or obtaining the consent of the person’s family after death. The presumed consent model has been adopted by a number of countries in Europe and globally in an effort to boost donor numbers. Ethicists have pointed out that the term "presumed consent" is something of a misnomer, as consent is an active rather than a passive process, and thus we prefer the term "opt-out", which we believe is a more appropriate use of terminology to describe the model.

The principal ethical objection to the opt-out model is the loss of autonomy and the right to self-determination of potential donors. Opponents also argue that the fact that someone did not register an objection to donation does not necessarily mean that he or she agreed to be a donor. It may simply mean that he or she had not read the necessary materials, did not know the relevant facts, or was otherwise unable to participate in the debate over organ donation. This could lead to the removal of organs from those who did not wish to donate - so-called false positives, if one likes. Commentators have argued that this situation is morally unacceptable because it violates the principle of respect for autonomy that underlies our concept of informed consent. Fears have also been expressed that an opt-out system could undermine solidarity and altruism as important motives for organ donation. It has been argued that the State, acting through health professionals and the transplantation system, would be intervening to take organs rather than facilitating their donation. There is at least a risk that some degree of trust in the system could be lost, potentially decreasing the availability of organs for transplant.

Proponents of the opt-out model counter that if a change of policy from opt-in to opt-out were to be broadcast widely, there would be no diminution of the exercise of self-determination and therefore personal autonomy would not be affected. Furthermore, it has been argued that an opt-out system enhances autonomy, as public surveys have shown a high willingness on the part of the public to donate their organs; thus, by failing to remove people’s organs, one is acting contrary to their wishes, even if they may be unexpressed wishes.

Supporters of an opt-out model also employ what we in ethics would call a utilitarian argument. This basically means that one provides the greatest good for the greatest number of people by harming no one and benefiting many. This particular thesis hinges on the fact that the dead or least their surviving interest cannot be harmed and that any curtailment of individual freedom is legitimate in the interest of the common good - that is, the survival of other citizens.

Another argument proffered in support of a policy change to an opt-out system is that it would facilitate a change in attitude - members heard that earlier this morning - so that donation would be increasingly seen as natural or normal, hence increasing the likelihood that families would conclude that donation was in line with their deceased relative's wishes.

I respectfully suggest that there are a number of ethically relevant considerations in introducing an opt-out system in Ireland. I am sure some of these will be considered as part of the pubic consultation process. In advance of any change in the system, the population should be informed of and receive relevant information on changes to the current arrangements concerning organ removal. This is to allow them to exercise their right to self-determination and opt out of the system if they so wish. There should be a simple and convenient procedure for anyone to opt out and it should be possible for individuals to revise their wishes at any time. We are all aware that our values can change over a lifetime depending on our personal experiences, and therefore that kind of facility is essential. It must be ensured that poor language or reading skills, a low level of educational attainment or poor socioeconomic or health status do not result in anyone’s understanding being limited to such an extent that his or her silence could be construed as consent to organ donation. The issue of how we might deal with vulnerable groups requires special attention.

Under a presumed-consent system, hospitals would need to have reliable and continuous access to the latest recorded wishes of potential organ donors. It would require a definition of who is responsible for the documentation, who is allowed to enter records, who has access to the information recorded and when. Some countries - for example, Sweden - do not allow access to the register until brain death has been diagnosed. This is to ensure the population does not get the idea that the system is effectively keeping an eye out for potential donors. Other countries actually allow checking of the register before the second set of brain-death testing takes place. These are all important things to take into consideration. We need to have regard to who would have access to the information and how that information is managed. There are also the more mundane, but nevertheless important, issues of data protection and data security that need to be taken into account. We would need to ensure that records are valid and correctly assigned, because it is important to be able to correctly identify the individual and his or her wishes.

Not least, the State has a responsibility to prevent the social stigmatisation of individuals who might opt out for their own reasons and who may not wish to be part of the process and thus may be regarded by the rest of society as lacking in solidarity. We must do some work in this regard. It is important to emphasise that deceased donation is a complex area, affected not only by law, administration and infrastructure but also by ideology and values. That is why I am especially grateful to have had this opportunity to address the committee on issues which are slightly off-kilter but centrally important.

Professor Jim Egan:

I thank the committee for the opportunity to speak today on this important topic for many families in the country. I was appointed as the HSE’s director of the national organ donation and transplantation office via the Royal College of Surgeons and Royal College of Physicians in April 2011. I am a fellow of the joint faculty of intensive care medicine. I am the Irish representative on the Council of Europe committee on organ transplantation. I am a former chairman of the European Respiratory Society transplantation group, and am the co-chair of the International Society of Heart and Lung Transplantation committee for the management of chronic rejection.

I am privileged to be involved in the care of patients and families who are awaiting organ transplantation. I have had the benefit and fortune to work with wonderful surgeons such as David Hickey, Oscar Traynor at St. Vincent's University Hospital and Jim McCarthy at the Mater hospital. These are highly skilled individuals who execute this form of treatment. I am continually humbled by the generosity of Irish society and the Irish families who donate in the most difficult of circumstances - truly Olympian events which affect other people's lives - and save lives on a regular basis.

The three distinct transplant programmes in this country are unique in that, although located in university teaching hospitals in Dublin, they must provide a service for the entire nation while competing for resources with other regional and acute local services in those hospitals. At present, 685 patients and their families are awaiting transplantation in Ireland. Organ donation in Ireland is based on an opt-in system, and thankfully it is rare for somebody to die in circumstances which allow organ donation. Of 3,000 deaths in intensive care units per annum, approximately 80 to 100 cases are patients in these circumstances. In 2010 only 58 donations were made. The procurement and co-ordination of organ donation is provided by the renal transplant service because of the absence of standard formal structures. This gap has been filled very successfully in a voluntary capacity based on historical needs over many years.

Internationally, many stakeholders emphasise the benefits of organ transplantation. The European Commission Action Plan on Organ Donation and Transplantation (2009-2015) emphasizes the substantial health care benefits of organ transplantation and states that all European states need to identify potential organ donors and support their conversion to actual organ donors. The goal of soft opt-out is to allow organ donation to be the society norm. It does not devalue organ donation as an extraordinary gift from one family to another. However, soft opt-out legislation alone does not enhance organ donation. It is part of a package that includes donation infrastructure. Donation infrastructure protects the interests of families and donors, ensuring a compassionate and professional approach at the time of donation.

Earlier, we heard subjective views on specific data, but there is specific data which supports presumed consent. A review of presumed consent published in *BMJ*, formerly known as the *British Medical Journal*, indicates that it is associated with a 25% increase in organ donation rates, or an additional two to six donors per million of population. This is further emphasised in the UK health technology assessment report mentioned by Dr. Plant earlier today. European league tables of organ donation rates are consistently dominated by those countries which have presumed consent in partnership with formal organ donation infrastructures, including Spain, Portugal and Croatia. Generally speaking, we quote the Spanish model as the international standard for organ donation and transplantation, but Norway is also an excellent role model.

To comply with society's expectations and national and international needs, three structures must be deployed in the Irish health service, and we are actively working on these. Intensive care key donation personnel would be assigned throughout the health service in line with international practice and the European Commission action plan. These medical and nursing personnel will underpin the organ donation process by protecting the interests and welfare of those families who choose to donate organs in the most difficult of circumstances. The second element of infrastructure development is the national organ procurement office, which would be developed to be independent of recipient co-ordination to comply with the standards required by the EU tissue directive and the EU organ directive. It would also be in keeping with the 2011 HSE-commissioned independent international review of transplant services we completed and the recommendations of the Irish Medicines Board, which regulates this area. The third element is the recently established HSE national organ donation and transplantation office, which would be positioned to establish a financial and governance framework to protect the interests of donors and recipients in the current challenging fiscal environment.

Deploying these three structures would will bring Ireland in line with international practice norms, mitigate the risks of a fall in organ donation rates in a changing society - a very significant risk based on the experience in 2010 - potentially remove up to 530 patients from dialysis over the next ten years, and save up to 750 additional lives of patients with advanced liver, lung and heart disease over the next ten years. These structures would also provide a platform for co-operation with services in Northern Ireland. In a very measured fashion, deploying these structures would save up to €60 million over the next ten years.

It is our goal to have one of the very best organ donation and transplantation systems in Europe and we are deeply committed to this. I thank committee members for their attention and I am happy to take any questions in due course.

Dr. Patrick Costello:

I am the blood, tissue and organ manager at the Irish Medicines Board, which is one of two competent authorities appointed for implementation of the 2010 directive which sets the standard for the quality and safety of human organs intended for transplantation. This was transposed through SI 325/2012. The other competent authority is the HSE, which established the national organ donation and transplantation office as its representative and as a competent authority for implementing the legislation.

The legislation is relatively limited and divides the two organisations' roles. The Irish Medicines Board, IMB, is responsible for the inspection and authorisation of procurement organisations and transplantation centres. It is also responsible for reviewing adverse events or reactions that are attributable to the quality and safety of a transplanted organ. The HSE has a wider role in implementing the legislation. It must develop the framework for the quality and safety of organs. This includes issuing guidance to health care establishments and professionals on best practice in transplantation. It has a role in the establishment of a donor and recipient registry and in the control of organ exchanges between Ireland and other member states. It also plays a critical role in respect of reviewing and learning from adverse events and reactions.

The IMB has been appointed to its role because we have a history of regulating health care facilities, in that we were responsible for implementing the blood and tissue legislation. There is an overlap between tissues and organs. In theory, multi-organ donors could become multi-tissue donors as well. Two of our organ centres are also tissue establishments. We are committed to working with the HSE, the Department of Health and our clinical colleagues, from whom the committee has heard, in the implementation of this legislation.

Deputy Sandra McLellan:

I apologise for Deputy Ó Caoláin's absence. He must shortly leave for a meeting of the joint executive of the North-South Interparliamentary Association in Stormont. He wishes that he could have been present.

I thank our guests for their presentations. We also received presentations last week. Our guests are more than welcome, as this is an important issue. We support an opt out. It is important that donor card holders discuss their intentions with family members so that there is a lesser onus on those members to make a decision. Resources need to be invested in organ donation awareness campaigns, as we must promote donor awareness and encourage people to donate. We should roll out campaigns in schools. The younger that people become interested, the more it becomes a part of normal life.

Organ donation is one issue, but capacity, resources and infrastructure comprise another. A major investment is required to move us into line with best international practice. When reading the statements, I was struck by the fact that Ireland did not have a specific transplant centre or enough transplant surgeons. This important area is being run out of an office by five co-ordinators in Beaumont Hospital in Dublin who have other duties.

The Deputy First Minister, Mr. Martin McGuinness, MLA, recently indicated that he would introduce legislation through the Northern Ireland Executive to provide for presumed consent.

Deputy Catherine Byrne:

I thank the delegates. With any medical matter, public trust is a priority. Our first action when we go to hospital for any procedure, large or small, is to sign a consent form. We trust that the medical professionals caring for us will make the right decisions. I was struck by the query about what happens to homeless people and who acts as their voice. Will the delegates elaborate more broadly? We should not remove people's ability to make decisions on what happens to their bodies after they have been incapacitated. Their families should have a role in providing consent when the time comes for their relatives to pass.

All of the presentations at our recent meetings have been interesting. Some of the delegates may have been sitting in the Gallery when I referred to my personal experience of a family member who was an organ donor. It gives the gift of life to others. If those of us who must make this difficult decision keep in mind the fact that someone else is living because our loved ones have passed on, it gives some comfort. The person we lost is forever young in our minds, having only passed away at 20 years of age.

Chairman:

I compliment Senator Quinn on his work on this issue in the previous Seanad. He is welcome.

Senator Feargal Quinn:

I thank the Chairman. I welcome and am delighted to see the team in attendance. When I introduced my Bill in 2009, few voices questioned the safety of or belief in presumed consent. There were many additions to the effect that, as Professor Egan explained well, presumed consent would only work if the infrastructure was in place. We also took on board a great deal of information about Spain.

We have heard little opposition to presumed consent, although there has been a question regarding finance. Savings of €60 million over a ten-year period were mentioned. Perhaps someone might touch on this matter. Such savings would address people's doubts in this regard.

I am frustrated by the length of time needed to get anything done in either House. We adjourned our debate and the then Minister for Health and Children, Ms Mary Harney, stated that she wished to take public opinion, but nothing has happened since. There are few voices against presumed consent, but such a system must be tied in with other factors. The only voice that was loudly not in favour of presumed consent was the Irish Kidney Association. What are its concerns?

Chairman:

It presented to us last Thursday.

Senator Feargal Quinn:

Yes. I apologise for being unable to attend. I do not understand its concerns or why it does not approve of presumed consent. It seems that everyone else is in favour. I urge that we reintroduce my legislation or a Government Bill. With the committee, I visited the Minister for Health, Deputy Reilly, from whom there was no strong opposition. He seemed to be in favour of presumed consent as well, assuming precautions were taken. We can push on that open door. I hope that we do.

Chairman:

Is Senator Crown satisfied?

Senator John Crown:

Yes.

Ms Mary Jackson:

I take Deputy Byrne's point. The thrust in legislating for the opt-out or soft opt-out system is not meant to undermine trust or change our wonderful system, given the doctors' descriptions of what happens. Patients and their families must be put at the centre of everything. We want to consult on how best to implement a soft opt-out system so that we can get it right and take everyone's concerns into consideration.

Members of the Irish Kidney Association are present in the Gallery. I took Mr. Murphy's main point to be that we should not concentrate on the cold words of legislation alone, but on the practical elements, for example, proper infrastructure and people who can do the job of getting consent and maximising organ donation well.

Given the cost of implementation, Ireland faces a particular problem in setting up a register of donors, be it a register of opt-ins or opt-outs. Experience in the UK shows a low number of registrations, approximately 28%. Nor do we have a unique health identifier, which is another problem for legislation. If there are five Mary Jacksons living in my locality, how do I know who is who on the register? The practical, logistical and cost implications cannot be overlooked when putting a system in place.

Chairman:

Thank you, Ms Jackson.

Professor Jim Egan:

On the point raised by Deputy Catherine Byrne, unequivocally it will never happen that organs will be harvested without permission. The key terminology is "soft". This is a soft opt-out proposal which means the wishes of the family will remain to the front and at the centre of the whole process.

On Senator Feargal Quinn's comments, it is accepted internationally that there are substantial financial benefits to be accrued from transplantation. We have seen business cases proposed in the United Kingdom which underpin its substantial investment of almost £60 million in organ donation and transplantation. The United Kingdom sees this as a cost effective and cost neutral process. This is about preventing people from spending time on dialysis and saving money through the use of appropriate measures.

On Deputy Sandra McLellan's point on Northern Ireland, given that the population of the Republic of Ireland is 4.5 million and that the population of Northern Ireland is 1.8 million, it is eminently sensible that there be synergy from the point of view of the cost effectiveness of our working with our colleagues in Northern Ireland. We need to be on a sensible platform in that regard. As we have heard, they are way ahead from an infrastructural perspective. We need to get to a comparable position. We could then seek to work closely with them.

Dr. Siobhán O'Sullivan:

Deputy Catherine Byrne raised the issue of vulnerable categories. I, too, have concerns about what is proposed in the case of homeless persons and incapacitated adults. For example, some countries operating opt-out systems allow for children, whereas here parents act as advocates for children. We need to look carefully at this issue. The difficulty is that while in a soft opt-out, there may be a family that can act as an advocate for the deceased, there will always be marginalised groups in society which will not have that support. This needs to be recognised. There is a need for the inclusion of safeguards in relation to advocates acting on behalf of such persons. It is an issue that requires serious consideration and I thank the Deputy for rasing it.

On the question of autonomy, it has often be said the soft opt-out system allows greater autonomy because the person's wish - once a person has not objected, it is taken that he or she is happy to be a donor - cannot be overridden by the family and is, therefore, a much better system. However, any opt-out system operating in Europe involves the family. This is for practical reasons as much as anything else because one needs to ask the family practical questions about lifestyle and so on. Most countries operate soft opt-out systems, with Austria being the only country that operates a system in which the family is not involved. There are a huge number of variances in the systems operating across Europe in terms of family involvement. In Norway the family is very important and central to the process, with communication being the key. This is largely because Norway does not operate an opt-out register. As such, talking to the family is one of the only ways to establish whether the deceased person wanted to donate. In Belgium the family must be involved, but nobody is clear on what "involved" means. In other countries authorisation from the family is required. There are a large number of opt-out models which state how a family must be involved. This comes back to my final point, namely, that we must be aware of the ethical norms operating and values. In Ireland the family generally is involved. We need to be aware of how that is going to work and take this into account in our deliberations on how this might translate into legislation.

Chairman:

Thank you, Dr. O'Sullivan. Are there further questions?

Ms Mary Jackson:

I would like to add one further point. I am not sure if it was said in the course of the discussion thus far, but an example of the commitment of the system to working to improve the position is the €3.5 million allocated to the living kidney donor programme in the HSE's service plan for 2013. At a time of very constrained resources, this is an important commitment. We know that transplantation is better for a patient and adds value to the system.

Chairman:

I thank the delegates for attending. This is the third of our series of meetings on the issue of organ donation. It is important that we continue to advocate and promulgate organ donation. The joint committee will meet in private session next week to consider how to progress and assist in the formulation of policy as outlined in the programme for Government. The briefings received today and in our previous two meetings will form a major part of our analysis, on which we will report back to the Department and the Minister.

The joint committee adjourned at 12.50 p.m. *sine die*.

SECTION 4 LIBRARY & RESEARCH PAPER FOR COMMITTEE

Oireachtas Library
& Research Service
Seirbhís Leabharlainne & Taighde an Oireachtais
Houses of the Oireachtas
Tithe an Oireachtais

Organ Donation Policy in Ireland and other Countries

Background research paper for the

Joint Committee on Health and Children

What does this research paper for the Committee examine?

This paper reviews the current position in relation to Organ Donation Policy in Ireland as well as the changes proposed in the Programme for Government and elsewhere. In addition the paper looks at the position of stakeholder organisations in response to these changes before looking at approaches taken in the UK, USA, Canada, Australia, New Zealand and Spain.

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Executive summary

The context to the drafting of this Briefing Paper

This document aims to facilitate discussion in the context of progressing the Committee's work programme. The document is intended to be impartial and is based on research from secondary sources. While every effort has been made to ensure that the document is error free, the L&RS cannot give an absolute guarantee as to the accuracy, definitiveness, or timeliness of any information contained within it.

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Executive Summary

Ireland currently has an opt-in (sometimes called informed consent) approach to organ donation. In the case of Ireland this means that while a person may, while living, express an interest in donating his or her organs their relatives are not bound to abide by these wishes and the consent of the family is always required.

The Programme for Government envisages the introduction of an opt-out system of organ donation, with a view to improving the availability of organs for patients in need of transplantation. This would mean 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 presumed unless the person has, while alive, registered his/her wish not to become an organ donor after death.

In 2009, the Department of Health and Children announced the commencement of a public consultation on proposals for a Human Tissue Bill. Stakeholder organisations were asked what type of organ donation system they favoured and most organisations chose the opt-in system.

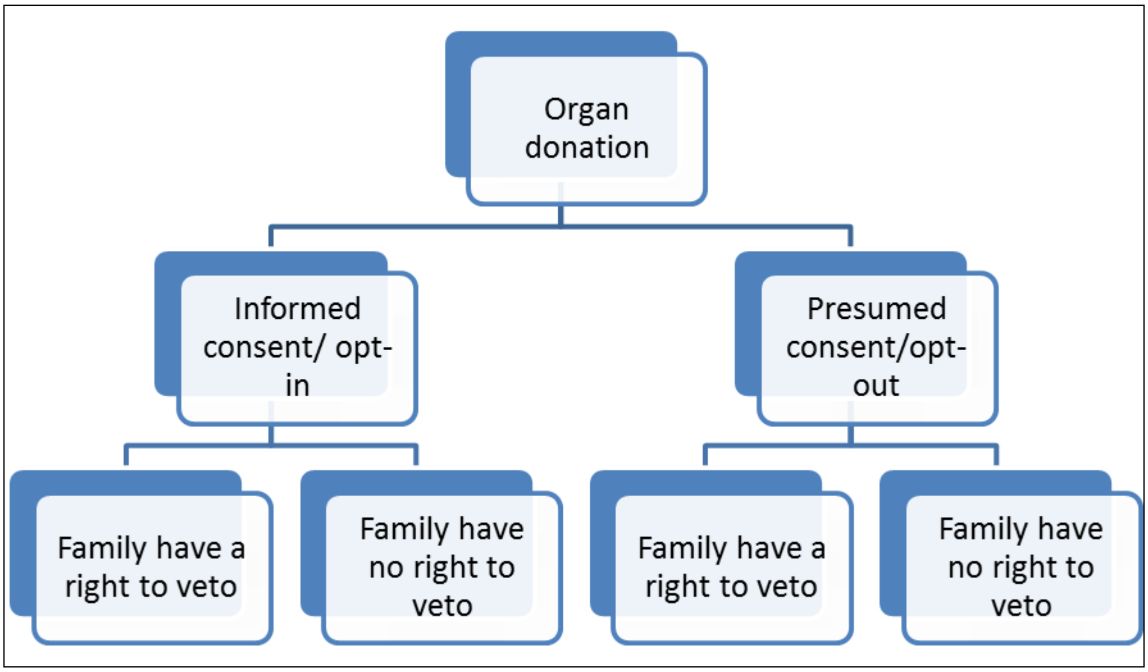
While studies have found that countries with an opt-out system tend to have higher donation rates, it is difficult to demonstrate a direct causal link between opt-out systems and donation rates, because it is difficult to exclude other factors that might have had an impact. For example: legislation, availability of donors, infrastructure, wealth and investment in health care, as well as underlying public attitudes may all play a role. Critics of presumed consent state that it interferes with an individual's right to autonomy and warn that there may be a public backlash against organ donation as a result.

Introduction

The major systems of organ donation

Most of the major organ donation systems can be categorised as 'opt-in/informed consent' or 'opt-out/presumed consent'. An important factor in both systems is whether family members can object to donation.

Figure 1: Major systems of organ donation



Source: Previous L&RS on-demand research paper

Opt-Out System

The opt-out or presumed consent system of organ donation works on the basis that people are presumed to be willing donors unless they express otherwise to a relevant authority while living.

The system of presumed consent is operated in a number of European countries and it has been suggested that, in general, countries with the opt-out system have a better ratio of donors versus people on transplant waiting lists than countries with the more conventional opt-in system. Critics of presumed consent state that it interferes with an individual's right to autonomy and warn that there may be a public backlash against organ donation as a result. They state that individuals may be more likely to donate if they feel free to exercise a choice rather than, as they see it, being compelled to do so by the law. A practical issue also exists, as despite operating an opt-out system most countries will still respect the wishes of the next-of-kin.

Opt-In System

The opt-in or informed consent system of organ donation is a voluntary one and has been described as a system which respects an individual's right to autonomy. It is also an altruistic system i.e. people donate their organs for the sake of others without expecting anything in return. However, there still remains a discrepancy between the public's expression of willingness to donate and actual donation rates. Another criticism, which has been made regarding the opt-in system, is that relatives can override the previously expressed wishes of the deceased.

Current position in Ireland

Ireland currently has an opt-in system; in the case of Ireland a person may, while living, express an interest in donating his or her organs (by carrying an organ donor card, for example) but relatives are not bound to abide by these wishes and their consent is always required.

In Ireland all organ donations are coordinated through the Irish Procurement Office in Beaumont Hospital in Dublin.[3] If no suitable recipient for an organ is found in Ireland then the Beaumont Hospital will contact the UK centres and offer the organ to recipients in the UK. There is a specific liver exchange programme in operation with the UK and last year the Beaumont Hospital received 8 livers from the UK and gave 22 livers to the UK via the NHSBT.[4] Presently Ireland does not take kidneys, hearts or lungs from the UK but does give these to the UK if there are no local recipients available.[5]

Patients in Northern Ireland can join Ireland's transplant register, but they cannot be on both registers at the same time. A protocol is in place for Northern Ireland to

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[3] Beaumont Hospital, Dublin, Facts about Organ Donation in Ireland, www.beaumont.ie/index.jsp?p=454&n=457

[4] NHS Blood and Transplant (NHSBT) manages the national voluntary donation system for blood, tissues, organs and stem cells in the United Kingdom.

[5] Personal Communication between RAISE,NIA and Transplant Co-ordinator, Beaumont Hospital, Dublin, 18th January 2013.

utilise the Republic's organ retrieval teams if one is not available from the UK. This has been required on two occasions in the past due to bad weather.[6]

Organ Donation Statistics

Ireland has one of the highest rates of organ donation in the world.[7] In 2012 there were a total of 78 donors which equates to a donor rate of 17.03 per million population (pmp).[8]

Table 1: Organ donation statistics 2003-2012

	03	04	05	06	07	08	09	10	11	12
Total Deceased Donors	86	89	76	91	88	81	90	58	93	78
Total Transplants*	187	206	205	234	223	224	261	174	275	239
Donor Rate (pmp)								13.68 %	20.3 %	17.03 %
*Living donors included in the total transplants figure			2	4	5	10	18	23	27	32

Proposed changes to Organ Donation Policy in Ireland [9]

Human Tissue Bill

The Heads of a Human Tissue Bill which will meet the key recommendation of the Madden Report[10] that no hospital post-mortem may be carried out and no tissue retained without consent/authorisation are at an advanced stage of drafting.

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[6] NI Assembly, Plenary Debate, 21st February 2012, http://www.niassembly.gov.uk/Assembly-Business/Official-Report/Reports-11-12/21-February-2012/#a8

[7] http://www.beaumont.ie/index.jsp?p=454&n=457

[8] Statistics provided, on request, to the L&RS by the Cancer, Blood and Organs Policy Unit of theDepartment of Health April 2013

[9] This section incorporates information provided by the Department of Health to the L&RS on the 12th of April 2013.

[10] Report of Dr Deirdre Madden on *Post Mortem Practice and Procedures* (2006) available online at: http://www.dohc.ie/publications/madden.html

The Human Tissue Bill 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 legislate for consent for the use of organs and tissues removed from a living person for transplantation and research.

Consent for Organ Donation – opt out system

The Programme for Government (2011) envisages the introduction of an opt-out system of organ donation, with a view to improving the availability of organs for patients in need of transplantation. This will require detailed consideration and further consultation and the Department is developing proposals for Government on this matter.

What this system of 'presumed' consent would mean in practice is that the health professionals involved would not have to actively seek the deceased's family's express consent for organ donation. Instead, consent will be presumed unless the person has, while alive, registered his/her wish not to become an organ donor after death. This is known as 'opting-out'. In such circumstances, even though consent is presumed, in practice, the family will always be consulted prior to organ donation 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.

The Department of Health plans to undertake a public consultation on the practicalities of introducing a system of presumed consent. It is proposed that the consultation will comprise a written consultation open to all members of the public and a meeting of key stakeholders.

Some of the most significant practical issues to be addressed include:

- difficulties in ensuring the identification of every individual in the absence of a national individual health identifier (IHI).[11]
- considerable financial investment would be required. Up-front funding would be required to establish and maintain a robust and secure national ICT

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[11] An IHI is a unique, non-transferable lifetime number assigned to all individuals accessing health and social care in Ireland. Its purpose is to accurately identify the individual, enabling health and social care to be delivered to the right patient, in the right place and at the right time. For further information see: http://www.hiqa.ie/healthcare/informing-decision-making/unique-identifiers

system to record a person's wish to opt-out. Funding would also be required for an on-going advertising campaign to advise the population of their right to opt-out.

European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations

These Regulations, which transpose EU Directive 2010/53/EU came into effect, in Ireland, on 27 August 2012. The Irish Medicines Board (IMB) is the competent authority under the Regulations for the authorisation of donation and transplantation in accordance with the requirements of the Regulations. The Health Service Exexcutive (HSE) is the competent authority for quality and safety aspects of the Regulations.

The Directive provides a clear legal framework for organ donation and transplantation in the European Union. It provides for the authorisation of procurement and transplantation centres and activities, for traceability systems, as well as for the reporting of serious adverse events and reactions. Moreover, the Directive sets requirements for the safe transportation of organs and for the characterisation of every donor and organ.

The Department of Health is working with the HSE and the IMB to ensure that hospitals meet the requirements in the Regulations. The HSE's National Organ Donation and Transplantation Office (NODTO) is overseeing the development of guidance documents, which will set out the appropriate processes and procedures to comply with quality and safety standards for all aspects of donation and transplantation. It is also assisting hospitals through its National Transplant Advisory Group, to comply with the Regulations.

EU Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation Between Member States

Along with the Directive, the EU Action Plan on Organ Donation and Transplantation addresses three key challenges to save lives:

1. improving the quality and safety of organs across Europe;
2. increasing organ availability; and
3. making transplant systems more efficient and accessible.

This Action Plan aims to reinforce cooperation between Member States through the identification and development of common objectives and guidelines, jointly agreed indicators and benchmarks, regular reporting and identification and sharing of best practices.

Organ Donation and code on new driving licences

Following discussions with the Department of Health, the new Driving Licence Application Form contains a question asking applicants to "*Tick here if you would like a code on your licence indicating your wish to become an organ donor*". The guidance notes for completion of the Driving Licence Application Form explain that "*If you wish to donate your organs you can record this on your licence. The licence will contain a code that will make medical professionals aware of your intention. However, in keeping with the current legal position, your next of kin will be consulted in the event of any decision of this nature.*"

Since the introduction of the new type of driving licence on January 19th, the code that will appear on new driving licences issued to people who indicate they wish to become an organ donor is 115. The Department has written to the National Organ Donation and Transplantation Office and the Regional Directors of Operations in the HSE asking them to alert relevant hospital staff to this initiative and to the code which will appear on new driving licences of people who wish to donate.

Public Services Card

The Department of Health has also been in discussion with the Department of Social Protection (DSP) with a view to including this code on the Public Services Card.[12]

Other Initiatives

The Department is planning to develop a number of policies in the area of organ donation and transplantation including:-

- A policy in relation to voluntary unpaid donations of organs;
- A policy in relation to the reimbursement of living donors; and
- A policy in relation to non-EU/EEA residents and transplantation.

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[12] A new Public Services Card is being introduced which is initially replacing the Social Services Card used to collect social welfare payments and the Free Travel Pass. The card was first introduced in 2012. It is currently being rolled out to people getting certain social welfare payments and to new applicants for other social welfare payments. Not all social welfare clients will get a Public Services Card immediately.

Stakeholder perspective

In 2009, the then Minister for Health and Children, announced the commencement of a public consultation on proposals for a Human Tissue Bill. As part of the preparation of the Human Tissue Bill, the Department undertook a separate consultation process on the issue of the type of consent to be provided for organ donation. Stakeholders were presented with three options:

1. Opt-out (presumed consent- the person is presumed to have consented to donate his or her organs after death unless he or she has specified otherwiseor
2. Opt-in (explicit consent) - the person can decide in advance to consent to donate his or her organs or to nominate someone to make the decision on his/her behalf after death. Where the deceased has not made a decision, his or her family may do so;or
3. Mandated choice /required consent - people would be required by law to specify whether or not they wish to donate their organs after death.

This section looks at the responses received by the Department as part of the consultation.[13] The responses from 30 organisations/representatives are displayed in Table 2.

Of the 30 submissions received from organisations or representative bodies, 1 favoured the opt-out system, 23 favoured the opt-in system, and 3 favoured forms of mandated choice or required request.

Of the 23 submissions that favoured the opt-in system, 15 favoured combining it with versions of required request and/or mandated choice, and 9 favoured combining it with a form of mandatory reporting.

Table 2: The following table summarises the option favoured by the 30 organisations/ representative bodies that made a submission to the consultation.[14]

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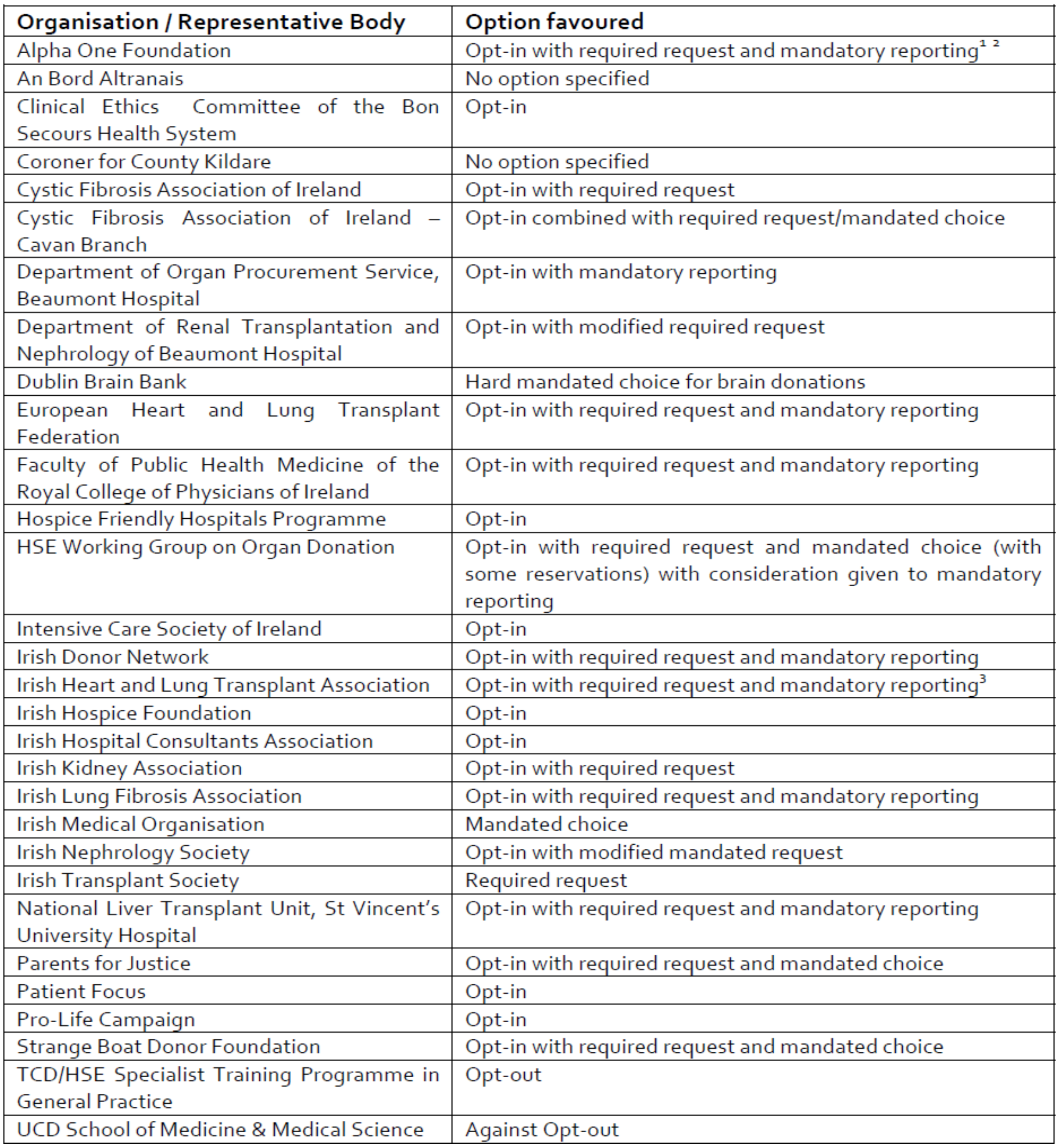
[13] http://www.dohc.ie/issues/human_tissue_bill/consent_submissions_overview.pdf?direct=1



Organisation / Representative Body	Option favoured
Alpha One Foundation	Opt-in with required request and mandatory reporting[1] [2]
An Bord Altranais	No option specified
Clinical Ethics Committee of the Bon Secours Health System	Opt-in
Coroner for County Kildare	No option specified
Cystic Fibrosis Association of Ireland	Opt-in with required request
Cystic Fibrosis Association of Ireland – Cavan Branch	Opt-in combined with required request/mandated choice
Department of Organ Procurement Service, Beaumont Hospital	Opt-in with mandatory reporting
Department of Renal Transplantation and Nephrology of Beaumont Hospital	Opt-in with modified required request
Dublin Brain Bank	Hard mandated choice for brain donations
European Heart and Lung Transplant Federation	Opt-in with required request and mandatory reporting
Faculty of Public Health Medicine of the Royal College of Physicians of Ireland	Opt-in with required request and mandatory reporting
Hospice Friendly Hospitals Programme	Opt-in
HSE Working Group on Organ Donation	Opt-in with required request and mandated choice (with some reservations) with consideration given to mandatory reporting
Intensive Care Society of Ireland	Opt-in
Irish Donor Network	Opt-in with required request and mandatory reporting
Irish Heart and Lung Transplant Association	Opt-in with required request and mandatory reporting[3]
Irish Hospice Foundation	Opt-in
Irish Hospital Consultants Association	Opt-in
Irish Kidney Association	Opt-in with required request
Irish Lung Fibrosis Association	Opt-in with required request and mandatory reporting
Irish Medical Organisation	Mandated choice
Irish Nephrology Society	Opt-in with modified mandated request
Irish Transplant Society	Required request
National Liver Transplant Unit, St Vincent's University Hospital	Opt-in with required request and mandatory reporting
Parents for Justice	Opt-in with required request and mandated choice
Patient Focus	Opt-in
Pro-Life Campaign	Opt-in
Strange Boat Donor Foundation	Opt-in with required request and mandated choice
TCD/HSE Specialist Training Programme in General Practice	Opt-out
UCD School of Medicine & Medical Science	Against Opt-out

The Department of Health (2009) noted in *Report on Public Consultation on Consent for Organ Donation* that:

> "While the vast majority of individual submissions favoured the introduction of a system of opt-out consent for organ donation, only one organisation / representative group supported this option. The vast majority of organisations / representative groups favoured the maintenance of the current opt-in system of consent but with enhancements such as the establishment of a transplant authority that would be responsible for coordinating the whole area of organ transplantation and the expansion of the role of donor coordinator."

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[14] Ibid.

International perspective

The United Kingdom, the United States of America, Canada, New Zealand and Australia all use an opt-in system. A number of jurisdictions (the UK, Tasmania, Queensland, New South Wales, Victoria and Western Australia (i.e. States within Australia) for example) have recently examined the option of introducing an opt-out system but have rejected the option.

This section now looks at a selection of countries in greater detail:

United Kingdom

The UK currently has an opt-in system but investigated the introduction of an opt-out system in depth in 2006.[15] The work was carried out by the Organ Donation Taskforce (the Taskforce) which came to the following conclusion:

> "The Taskforce's members came to this review of presumed consent with an open mind, with many sympathetic to the view that presumed consent seems an obvious step forward. However, the more the Taskforce examined the evidence, the less obvious the benefit, and the more multifaceted and multidimensional the issue of increasing donor numbers was revealed to be.
>
> It became clear that what appears to be a simple idea to increase numbers may not in fact generate additional donors in sufficient numbers to justify the significant investment needed to put a new system in place. Moreover, there are risks in going down the opt-out route which could impact negatively on organ donation. The Taskforce reached a clear consensus in their recommendation that an opt-out system should not be introduced in the United Kingdom at the present time."

Despite rejecting the introduction of presumed consent, the UK Taskforce made a series of recommendations beginning with the establishment of a United Kingdom-wide organ donation organisation. The other recommendations focused on the following areas:

- legal and ethical issues;
- the role of the national health system;
- organisation of co-ordination and retrieval;
- training; and
- public recognition and public promotion of donation.

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[15] The potential impact of an opt- out system for organ donation in the UK: an independent report from the Organ Donation Taskforce http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_090312 This link has a huge amount of information in relation to organ donation.

Since the review in 2006 a more coordinated approach to organ donation has been taken in the UK and organ donation rates in the United Kingdom have increased from 12.9 donors per million of population (dpmp) to 16.4 dpmp in 2010.

While it was felt by the Taskforce that an opt-out system could be generally compatible with the European Convention of Human Rights that particular consideration would be needed for some groups of people, in particular children, people who lack the mental capacity to make a decision to opt out and those whose identity was unknown at the time of their death.

United States of America

Every US State operates an opt- in system. All States base their human tissue and organ donation law on the 1968 *Uniform Anatomical Gift Act*[16] the 1987 *Uniform Anatomical Gift Act* [17]or the 2006 Unifor*m Anatomical Gift Act (2006 UAGA).*[18] The 2006 UAGA removes elements of presumed consent that were present in earlier versions of the legislation. Under the 1987 UAGA some retrieval of corneas, tissues and organs was permitted without the actual consent of the dead person or by a family member where a body was under the custody of a coroner or medical examiner.

Canada

All Canadian provinces have an opt-in system. Organ and tissue donation and transplantation come under provincial jurisdiction. In each province the provincial statute dealing with organ and tissue donation is based on a uniform statute created by the Uniform Law Conference of Canada. The most recent version of this statute is the *Uniform Human Tissue Donation Act* 1990.[19] Under the *Uniform Act* post-mortem consent can either be by way of the donor while living or by way of a proxy for the deceased in the absence of donor consent.

In order for the donor to consent to post-mortem removal of his or her organs for transplantation purposes, the donor must be at least 16 years of age and must

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[16] http://www.uniformlaws.org/LegislativeFactSheet.aspx?title=Anatomical%20Gift%20(1968)

[17] http://www.uniformlaws.org/Act.aspx?title=Anatomical%20Gift%20Act%20(1987)

[18] http://www.uniformlaws.org/Act.aspx?title=Anatomical%20Gift%20Act%20(2006)

[19] http://www.ulcc.ca/en/uniform-acts-en-gb-1/440-human-tissue-donation-act/284-human-tissue-donation-act-1990-draft

understand ‘the nature and consequences of transplanting tissue from his or her body after death.’

It is an informed consent organ donation regime, because the donor must understand the consequences of this decision.

Some provinces have variations of this consent process in their legislation. There have been periodic attempts to change to an opt-out system but they have not been successful.

A citizen’s panel in Ontario[20] in 2007 rejected presumed consent, saying it took the giant leap from not hearing about organ donation at all to “everyone is now an organ donor.” A number of panel members argued it was a violation of civil rights and said this negative option approach was not acceptable in Ontario. The major concern focused on doubts that the government would properly inform everyone, especially new Canadians, those whose mother tongue is neither English nor French, and those with mental disabilities. The citizen’s panel concluded that presumed consent was “too passive a method to be a clear statement of an individual’s intent.’ The Ontario government decided not to change its organ donation system.

Australia

Each State and territory in Australia operates an opt-in organ donation system. The National Clinical Task Force on Organ and Tissue Donation’s final report[21] in 2008 explicitly recommends against introducing a presumed consent (opt-out) system in any State or territory in Australia. The report found that:

> “One of the main problems that hampers moves to increase organ donation rates in Australia is the fragmented organ donation and transplantation sector. In contrast with the United States and several other comparable countries, Australia does not operate a national donor coordination network or single coordinating agency. The system is state and territory based, with a large number of stakeholders working at various levels and differences in procedures, processes and legislation between jurisdictions.”

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[20] 2010 Annual Report of the Office of the Auditor General of Ontario www.auditor.on.ca/en/reports_en/en10/310en10.pdf

[21] National Clinical Task Force on Organ and Tissue Donation final report: think nationally, act locally http://www.health.gov.au/internet/main/publishing.nsf/Content/734953F7721631D3CA257458000F330E/$File/Volume%201.pdf

Consent to donate organ, eyes and tissue

- In the States of New South Wales and Queensland, organ, eye and tissue donation may proceed where the deceased has given written consent to the removal of tissue;
- In Victoria, organ, eye and tissue donation may proceed where the deceased has ‘expressed the wish for, or consented to removal of tissue’ in writing, or orally during their last illness; and
- In South Australia, Western Australia, Tasmania, the Australian Capital Territory and the Northern Territory, organ, eye and tissue donation may proceed where the deceased has “expressed the wish for, or consented to” the removal of tissue, with the nature of that expression not specified.

In Australia it is interesting to note that there are very different donation rates among the States despite having virtually identical organ donor systems. For example, in 2009 South Australia reported 20 donors per million of the population, while Western Australia recorded the lowest donation rate of 9 per million of the population. The South Australia Health Minister has attributed it to:

> "Greater public awareness and the highly effective organ donation coordination system we've pioneered in South Australia has resulted in a rate that is among the best in the world…..
>
> South Australia is one of the few states to assist private hospitals with the costs of organ donation and we've also recruited and trained a network of senior clinicians and specialist nurses to work in major public hospitals at the forefront of the national campaign to raise donor rates.’[22]"

New Zealand (NZ)

The most recent legislation in NZ affecting organ donation is the *Human Tissue Act 2008.*[23] The Act confirms that NZ operates an opt-in system of organ donation. The Act makes informed consent the fundamental principle underpinning the lawful collection and use of human tissue.

It replaces the use of 'lack of objection' in the Human Tissue Act 1964 with 'informed consent' which is consistent with the Code of Health and Disability Services Consumers’ Rights. It specifies who may give consent or raise an objection for the collection and use of human tissue (including for a purpose not covered by the original consent).

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[22] http://news.smh.com.au/breaking-news-national/sa-leader-in-organ-donor-rates-20100523-w3ip.html
[23] http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html

Under the Act, the primary consent or objection will be that of the deceased, if formally recorded before he or she died, or of someone nominated by the person to make the decision on his or her behalf. If there is no nominee consent or objection may be given collectively by the deceased's immediate family, or by a specified member of the immediate family.

The existence of informed consent is sufficient for organ or tissue donation to be lawful. However, in practice, there can be a number of reasons why donation should not proceed - organs and tissue may be unsuitable for donation, the family may be aware that the person changed their mind since recording their consent, or the immediate family may be distressed by a decision to proceed with donation. The Act allows for collection and use not to proceed in these circumstances.

Spain

As Spain consistently has the highest donation rate in the world at around 34-35 donors per million population, it is useful to look at the Spanish model. Modifications of the 'Spanish model' have been introduced in the USA and in Italy. The information for Spain is directly extracted from *Building on Progress: Where next for organ donation policy in the UK?* British Medical Association, (Chapter 6).

In Spain opt-out legislation was introduced in 1979 and permits organs to be taken for transplantation with the consent of the family or in the absence of any known objection by the deceased. There is no opt-out register and families must report known objections to the transplant co-ordinator. Donation rates increased slightly after the introduction of this legislation but did not increase significantly until 1989 when the *Organizacion Nacional de Trasplantes* (ONT) was established. It is now generally accepted that although the legislation had some impact the major success is due to the organisational model. The ONT undertook a programme of 'professionlisation' of organ donation through a network of professionals working at national, regional and local level. By 1999 there were 139 transplant co-ordinating teams - one in each hospital where there is the potential for organ donation.

Some of the practices used in Spain have come in for criticism, for example:

- the role of the transplant co-ordinator has been interpreted at times as trying to 'persuade' the family to agree to donation;

- transplant co-ordinators are paid variable amounts based on the hours worked so they are paid more when there are donors. This has the potential to be interpreted as incentive payments for donations achieved; and
- the transplant co-ordinator may also have clinical responsibility for the patient's treatment in intensive care – this could be perceived as a conflict of interest.

Increasing the number of donors – possible options

This section sets out a number of possible options to achieve an increase in the number of donors, of which opt-out systems are one. The information is largely taken, as referenced, from the 2012 British Medical Association (BMA) publication *Building on Progress: Where next for organ donation policy in the UK?*

Expanding the Pool of Potential Donors

Expanding controlled Donation after Circulatory Death (DCD) programmes to emergency departments (EDs) – attention has recently focused on EDs where patients are admitted who are not expected to survive their injuries and donation after circulatory death may be possible. At present treatment is often withdrawn in the ED and organ donation not considered;[24]

Expanding the type of organs used from DCD donors – the majority of organs transplanted from donors following DCD are kidneys, although some pancreases, livers and lungs have also been transplanted. The possibility of heart donation from DCD donors has also been raised. However, the fact that an individual is declared dead following cessation of cardio-respiratory function but the heart is subsequently restarted in another person is a difficult concept, one that would require careful explanation to relatives and more research is needed before introduction into clinical practice ;[25]

Expanding living donation – the majority of living donors donate a kidney but it is also possible to donate part of the liver or lung lobes (not currently UK practice). It is now widely accepted that the risk to kidney donors is within acceptable levels but with

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[24] *Building on Progress: Where next for organ donation policy in the UK?* British Medical Association, February 2012, p.36, http://bma.org.uk/-/media/Files/PDFs/Working%20for%20change/Shaping%20healthcare/organdonation_buildingonprogressfebruary2012.pdf

[25] Building on Progress: Where next for organ donation policy in the UK? British Medical Association, February 2012, p.38,

liver and lung donation the risks are significantly higher and this would be a key factor in uptake of such living donation. Many people are not aware that they could donate a kidney to a stranger;[26]

Use of 'higher risk' donor organs – the NHSBT has developed a list of absolute contraindications for donation and advised that all potential donors who have none of these should be referred for donation even if the likelihood of organs being accepted appears low. Risk factors include age of donor, cause of death , body mass index, risk of transmissible disease being passed on (previous use of intravenous drugs, high risk sexual behaviour, previous history of malignancy); and[27]

Elective ventilation – this involves starting ventilation when the patient is close to death, with the specific intent of facilitating organ donation. This is not current UK practice, although the BMA argues that where an individual had expressed a wish to donate organs after death, some steps to facilitate that could be in an individual's best interests or benefit. The UK Donation Ethic Committee has called for further debate on this issue.[28]

Recent reviews of organ donation policies.

Western Australia recently reviewed its organ donation legislation[29] and looked at donation rates from countries with presumed and informed consent systems.

Figure 2: Type of consent, by Number of Donors (dpmp) in 2002 Worldwide[30]

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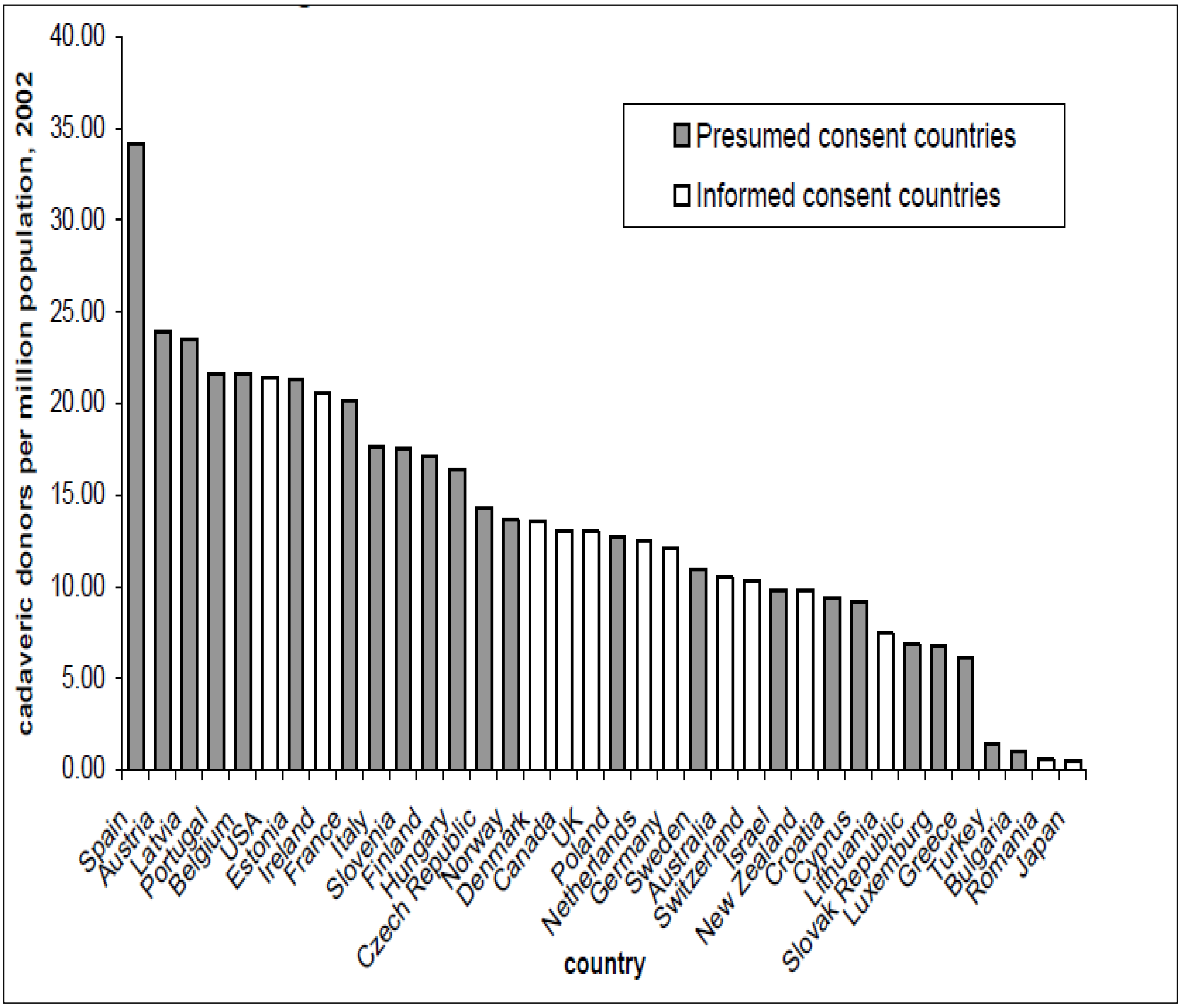
[26] Building on Progress: Where next for organ donation policy in the UK? British Medical Association, February 2012, p.39,

[27] Building on Progress: Where next for organ donation policy in the UK? British Medical Association, February 2012, p.39,

[28] Building on Progress: Where next for organ donation policy in the UK? British Medical Association, February 2012, p.40,

[29] www.parliament.wa.gov.au/publications/tabledpapers.nsf/.../3336.pdf Adopting an opt-out registration system for *organ* donation- Parliament of Western Australia

[30] Abadie, A. and S. Gay, *The impact of presumed consent legislation on cadaveric organ donation: A cross-country study.* Journal of Health Economics, 2006



A paper for the parliament of Western Australia comments on these figures by saying that:

- It is clear that in 2002 most countries with opt-out legislation have higher organ donation rates than most countries with opting in legislation.
- However exceptions exist in both directions and there has been significant movement since 2002 in the performance of countries that do not appear to be dependent on the system of consent.
- The USA and Ireland have the same organ donation rate as Belgium despite an opting in system. These two countries have newly reinforced organ donation agencies and strong cultural vision of community generosity.
- Countries with opt-out legislation can do less well than Australia but may not have comparable standards of healthcare (e.g. Croatia, Cyprus and Turkey).

A UK review of consent systems and organ donations[31] found that:

> "Austria is the only European country where presumed consent is strictly enforced. Organ donation rates in Austria are not significantly higher than other countries, including Ireland where consent is not presumed. Conversely, Spain has the highest rate of organ donation in the world. The 'presumed consent' model in Spain is not strictly enforced and invariably, family members are consulted. The high rate of organ donation in Spain cannot conclusively be attributed to the presumption of consent."

The authors concluded that:

> "Presumed consent alone is unlikely to explain the variation in organ donation rates between different countries. A combination of legislation, availability of donors, transplantation system organisation and infrastructure, wealth and investment in health care, as well as underlying public attitudes to and awareness of organ donation and transplantation, may all play a role, although the relative importance of each is not clear."

The British Medical Association (BMA) publication *Building on Progress: Where next for organ donation policy in the UK?* accepts that it is not easy to demonstrate a direct causal link between opt-out and donation rates, because it is difficult to exclude other factors that might have had an impact. However, after reviewing the evidence the BMA concludes that there is a positive association between the two, "*that is to say that those counties that have an opt-out system tend to have higher donation rates although it cannot be said for certain what causes them*".[32]

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[31] A systematic review of presumed consent systems for deceased organ donation[31] (Rithalia A, McDaid C, Suekarran S, Norman G, Myers L, Sowden A. (Centre for Reviews and Dissemination, University of York, UK))

[32] Building on Progress: Where next for organ donation policy in the UK? British Medical Association, February 2012, p.48,

SECTION 5 SUBMISSION FROM FIANNA FÁIL

> The Recent Oireachtas Library and Research Service note on 'Organ Donation Policy in Ireland and other Countries' is an excellent study in the topic of Organ Donation and the issue of consent.
> In its executive summary it stated that "countries with an opt -out system tend to have a higher donation rates, it is difficult to demonstrate a direct causal line between opt-out systems and donation rates, because it is difficult to exclude other factors that might have had an impact".
>
> A review of consent by the UK was consistent with those of the L&RS note "The high rate of organ donation in spain cannot conclusively be attributed to the presumption of consent"
> These "other factors" alluded to in the L&RS note, which have increased organ donation rates in Spain, the EU's most successful country on organ donation, are explained in an excellent interview in the Sunday Business Post by the head of the Spanish Transplant Authority Dr Rafael Matesanz.
>
> One single national transplant authority.
> Organ donor coordinators.
>
> In his Sunday Business post interview he 'expressed concern at the Irish Governments failure to create and resource a national transplant authority'.
>
> Minister Reilly missed an opportunity to transform our transplant system and instead of appointing one national authority last year to give leadership on organ donation and transplantation Minister Reilly divided the responsibilities between the HSE and the IMB.
>
> Dr Rafael Matesanz also agreed that "the most important thing" Ireland could do to improve its transplant rate was to have dedicated personell in major intensive care units to ask families and take charge of the entire process of organ donation
>
> There are currently over 650 people, 1 in 10 of whom will die, awaiting heart, lung, liver, kidney and pancreas organ transplants in Ireland. This does not include this who are taken off the transplant list as they are deemed too sick to receive one. Dialysis cost the state 1.2 billion over 10 years. If the 500 people who are currently awaiting a kidney transplant were to receive a donation the resulting saving to the tax payer would be 325,000,000.
>
> The correct new system could increase the number of successful transplants, reduce waiting times by years and improve people's lives.
>
> We note the previous consultation process on the consent issue by the department of health in 2009, 30 submissions were received form organisations and representatives bodies.
> 1 favoured opt-out system (TCD/HSE Specialist Training Programme in General Practise)
> 23 favoured the opt-in system
> 3 favoured forms of mandated choice or required request.
>
> We are in favour of any progressive move in relation to consent and presumed, as a Senate nominee of the Irish Kidney Association I believe that the government should follow the findings of the last consultative process and the advice of the head of the Spanish Transplant Authority Dr Rafael Matesanz. We should have on National Organ Donation Authority and we should appoint organ donor coordinators in hospitals.

SECTION 6 SUBMISSION FROM SINN FÉIN

Submission on Organ Donation to
Oireachtas Health & Children Committee
by
Deputy Caoimhghín Ó Caoláin
Sinn Féin Health & Children Spokesperson

We need to address the question of organ donation and transplant in its entirety. There is a severe shortage of organs for transplant. There is also a severe deficit in the infrastructure for delivering transplants, in terms of personnel, physical structures and funding. All of these shortfalls need to be addressed in a comprehensive manner.

Speaking at the Oireachtas Health & Children Committee in April 2013, David Hickey, Director of the National Kidney and Pancreas Transplant Programme, identified the three big gaps in the current system. These are lack of organ donors, poor infrastructure in which our transplant patients are housed and a shortage of Transplant Surgeons. And he said these gaps must be filled by means of increased organ donation, investment and legislation.

Current Sinn Féin policy supports the ‘presumed consent’ or opt-out rather than opt-in system of organ donation. That reflects our desire to meet the need for greatly increased donations and transplants. That desire is shared by all, whatever their views on the best model of consent for organ donation.

Having said that, debate on organ donation, including at the Health & Children Committee and in the Dáil, has increased knowledge of the issue and there is a new general awareness of the complexity of the opt-in, opt-out scenarios. Clearly, it is far from a black and white choice between opt-in and opt-out.

Underlying our position are a number of key principles which we believe should underpin the delivery of health services.

- We believe that everyone has the right to enjoy the benefits of scientific progress and its application without discrimination.

- We believe that it is necessary to use regulatory policy to protect the public good including the safeguarding of public health and safety.
- Everyone has the right to participate in decisions affecting their health and to have their concerns heard. This means that individuals must be empowered to exercise control over their own health and to participate in the decision-making process around health law and policy.
- And, very importantly, people should not be subjected to medical or scientific intervention without their informed consent.

We recall the pain inflicted and injustice done to families in the cases where the organs of children were removed without parental knowledge much less consent.

On this basis, we believe that a complete and comprehensive public consultation should take place on the issue of organ donation.

We have called on the Irish Government, British Government and Assembly Executive to ensure that:

- The principle of presumed consent, if adopted, would operate only with regard to organs available for donation to other patients and would not extend to reproductive organs, other tissues and organs for research.
- Presumed consent would operate based on the idea that ‘everybody carries a donor card’.
- All persons who have the ability under the current ‘Opt-In’ policy to provide consent shall have the ability to dissent from ‘presumed consent’, i.e. those who are over-16 and with legally recognised mental capacity.
- For children under 16 and those adults lacking legal capacity to consent, the next-of-kin should retain full control over consent, and the Opt-In requirement should remain in place.
- It should be the responsibility of the relevant health bodies to comprehensively inform the public of a presumed consent policy, if

adopted, and an information booklet fully outlining the rights of potential donors and their families should be sent to every household and educational institution. This should include the ability to consent/dissent; how to officially register and 'opt-out' of donating; the legal position regarding children; how organ donation works; how the new process will work in practice; safeguards that will be put in place to protect the public.

- An all-Ireland National Register on Withholding Consent to Organ Donation should be established. This would be automatically accessible to the organ procurement service/s and managed by the health department/s.

This State currently operates under an Opt-In Scheme. There is no legal restriction on the age you can choose to donate organs in the event of your death but you must carry an organ donor card should you wish to donate, or otherwise register your willingness (to 'opt-in') with a voluntary organisation such as the Irish Kidney Association. There is no legislation governing organ donations and the law regarding consent and who can provide it is therefore unclear.

There is currently no legal definition in this State of what constitutes 'informed consent'. In some cases where there is no registered opt-in the medical team may request the next of kin to donate the organs of a deceased person but there is no law governing this practice. Generally, the consent of the next of kin is accepted as valid and a refusal by the next of kin is not contested. Those over the age of 16 may consent to medical treatment and organ donation on their own behalf. Where a person is under this age a medical professional can take consent from the next-of-kin. All organ donations are coordinated by the National Organ Procurement Service, Beaumont Hospital, Dublin under the authority of the Department of Health and Children.

An Opt-In system also operates in the 6 Counties. All organ transplantation within the North is governed by the British Human Tissue Act (2004). Transplant NI is accountable to the 6 Counties Minister for Health in the Assembly and to the British Parliament through the English Department of Health.

Research published in 2009 in the British Medical Journal found that donation rates **do** increase after the introduction of presumed consent systems. The same research showed that legislation, availability of donors, organisation and infrastructure of transplantation services, investment in health care and public attitudes to and awareness of organ donation **all** play a role.

This latter is an extremely important point. It is far from a one-dimensional issue. Changing the donor consent system is not by any means a panacea. It may form a key part – but still only a part – of a more comprehensive approach. It was put well by the leading transplant surgeon in the country, David Hickey, at the Health & Children Committee last week. He is worth quoting at some length: He said:

> *The other area that will certainly help increase donation rates has been Joe Brolly's initiative re the so called 'presumed consent' or 'opt out' option. Much has been said about the unfortunate wording of presumed consent, and I believe that this has to be removed from the lexicology. The presumption should be that the medical and nursing staff bring the topic to the awareness of the potential donor family to allow them the opportunity to think about this process and decide whether it is suitable for them. It must also be remembered that this is a service to the donor family and immense* ***consolation*** *can be derived from donating. Conversely there is also immense* ***desolation*** *derived from not being afforded the opportunity…. However, it has to be accepted, that the countries that have seen significant increase in organ donation and this increase has been attributed to the adoption of presumed consent, in reality has been the result of massive investment in both physical and personnel infrastructure.*

Another clinician, Liam Plant, stated:

> *In the absence of a robust organization and infrastructure to support this endeavour, any legislative framework is unlikely to achieve its maximum potential in increasing donation. Similarly, robust engagement with the public to minimize anxiety, misunderstanding and fear regarding any potential legislative changes must also be of the highest importance.*

We must address all aspects of this issue, **most especially the need for greater resources to be devoted to organ transplant by Government**. This would result in significant long-term savings for the State but, far more importantly, it would save and enhance more lives.

Meán Fómhair 2013

SECTION 7 SUBMISSION FROM SENATOR JOHN CROWN

Suggested recommendations to be included in the Joint Committee on Health and Children's Organ Donation Report

We should

1. Have a donor registrar, with a soft opt-out
2. Have a single national organ transplant program, individually funded on one site
3. Have a single unit located on site responsible for increasing organ transplantation numbers
4. Have an organ transplant network organised regionally
    a. Similar to the Spanish Model, to encourage organ donation
    b. Also responsible for virtual clinics / remote clinics, linked with local clinicians, to facilitate local patient care

Senator John Crown
September 2013

SECTION 8 TERMS OF REFERENCE

a. Functions of the Committee – derived from Standing Orders [DSO 82A; SSO 70A]

(1) The Select Committee shall consider and report to the Dáil on—

(a) such aspects of the expenditure, administration and policy of the relevant Government Department or Departments and associated public bodies as the Committee may select, and

(b) European Union matters within the remit of the relevant Department or Departments.

(2) The Select Committee may be joined with a Select Committee appointed by Seanad Éireann to form a Joint Committee for the purposes of the functions set out below, other than at paragraph (3), and to report thereon to both Houses of the Oireachtas.

(3) Without prejudice to the generality of paragraph (1), the Select Committee shall consider, in respect of the relevant Department or Departments, such—

(a) Bills,

(b) proposals contained in any motion, including any motion within the meaning of Standing Order 164,

(c) Estimates for Public Services, and

(d) other matters

as shall be referred to the Select Committee by the Dáil, and

(e) Annual Output Statements, and

(f) such Value for Money and Policy Reviews as the Select Committee may select.

(4) The Joint Committee may consider the following matters in respect of the relevant Department or Departments and associated public bodies, and report thereon to both Houses of the Oireachtas:

(a) matters of policy for which the Minister is officially responsible,

(b) public affairs administered by the Department,

(c) policy issues arising from Value for Money and Policy Reviews conducted or commissioned by the Department,

(d) Government policy in respect of bodies under the aegis of the Department,

(e) policy issues concerning bodies which are partly or wholly funded by the State or which are established or appointed by a member of the Government or the Oireachtas,

(f) the general scheme or draft heads of any Bill published by the Minister,

(*g*) statutory instruments, including those laid or laid in draft before either House or both Houses and those made under the European Communities Acts 1972 to 2009,

(*h*) strategy statements laid before either or both Houses of the Oireachtas pursuant to the Public Service Management Act 1997,

(*i*) annual reports or annual reports and accounts, required by law, and laid before either or both Houses of the Oireachtas, of the Department or bodies referred to in paragraph (4)(*d*) and (*e*) and the overall operational results, statements of strategy and corporate plans of such bodies, and

(*j*) such other matters as may be referred to it by the Dáil and/or Seanad from time to time.

(5) Without prejudice to the generality of paragraph (1), the Joint Committee shall consider, in respect of the relevant Department or Departments—

(a) EU draft legislative acts standing referred to the Select Committee under Standing Order 105, including the compliance of such acts with the principle of subsidiarity,

(b) other proposals for EU legislation and related policy issues, including programmes and guidelines prepared by the European Commission as a basis of possible legislative action,

(c) non-legislative documents published by any EU institution in relation to EU policy matters, and

(d) matters listed for consideration on the agenda for meetings of the relevant EU Council of Ministers and the outcome of such meetings.

(6) A sub-Committee stands established in respect of each Department within the remit of the Select Committee to consider the matters outlined in paragraph (3), and the following arrangements apply to such sub-Committees:

(*a*) the matters outlined in paragraph (3) which require referral to the Select Committee by the Dáil may be referred directly to such sub-Committees, and (*b*) each such sub-Committee has the powers defined in Standing Order 83(1) and (2) and may report directly to the Dáil, including by way of Message under Standing Order 87.

(7) The Chairman of the Joint Committee, who shall be a member of Dáil Éireann, shall also be the Chairman of the Select Committee and of any sub-Committee or Committees standing established in respect of the Select Committee.

(8) The following may attend meetings of the Select or Joint Committee, for the purposes of the functions set out in paragraph (5) and may take part in proceedings without having a right to vote or to move motions and amendments:

(*a*) Members of the European Parliament elected from constituencies in Ireland, including Northern Ireland,

(*b*) Members of the Irish delegation to the Parliamentary Assembly of the Council of Europe, and

(*c*) at the invitation of the Committee, other Members of the European Parliament.