



**Irish Medical Organisation
Submission to the Department of Health
and Children on
Consent for Organ Donation after Death
for Transplantation**

March 2009

Submission on Consent for Organ Donation from the Irish Medical Organisation

The Irish Medical Organisation is pleased to make a submission on consent models for organ donation to the Department of Health and Children as part of consultation activities for the preparation of legislation.

The IMO acknowledges that this is an issue about choice, and that individual choice needs to be respected and accounted for. Information is paramount to making a choice, and should form the foundation of whatever model of consent is adopted.

1. Is there a requirement to change the current consent system in Ireland?

There is definitely a requirement to change the current consent system in Ireland. Currently, there is no formal registry of consent, and no legislation surrounding a consent system in Ireland.

While Donor Cards acknowledge the person's intention to donate, it is accepted procedure in Ireland to consult with the family of a potential donor to see if they have any objections to the procedure. It is only possible to ascertain if the individual would like to donate if they have a Donor Card present on them, or if they have expressed their wishes directly to their family. The formal process outlined by The National Organ Procurement Service, who currently coordinates organ transplants in Ireland, advises:

If you wish to become an organ donor after your death you should inform your next of kin of your intentions. Your next of kin would always be asked for consent in order for donation to proceed. Consent is never presumed, even if a donor card has been signed¹.

This clearly demonstrates that the current system needs to be replaced with appropriate measures to ensure individual choice is recognised, and that the best possible information is provided to the public to encourage family discussion in order for families to facilitate the wishes of individuals.

The Eurobarometer in 2007 showed that that 57% of Irish people would donate an organ from a deceased close family member, and that 40% of Irish people have discussed human organ donation or transplantation with their family.² This not only identifies the positive attitude towards organ donation in Ireland, particularly when it comes to those of family members, but also highlights the need for people to discuss these issues within their own families.

¹ The National Organ Procurement Service, Beaumont Hospital, http://www.beaumont.ie/depts/support/transplant/organ_procurement.html

² Eurobarometer European and Organ donation, 2007, http://ec.europa.eu/health/ph_threats/human_substance/documents/ebs272d_en.pdf

Considering the absence of any legislation surrounding this issue, the IMO certainly welcomes the opportunity for this process to begin, and believes that this is an opportunity to 'get it right' the first time. The lack of legislation has created uncertainty and a lack of understanding about organ donation in Ireland, with the consequence falling on those listed as waiting to receive donor organs. The current application of Donor Cards and the lack of a central registry in Ireland, containing the names of those who wish to consent or object to the donation of their organs, is a failure of our health system.

2. Do you have any ethical or moral issues with any of the consent models described?

No, the IMO does not have any ethical or moral issues with any of the consent models described, however at this time we stress the importance of information available in public sphere to ensure that be it an opt-in, opt-out or mandated method, more public awareness about organ donation needs to be generated.

Additionally, legislation should support whatever method is in place. Legislation needs to be the backbone of this model, to provide a legitimate framework for operation.

3. There are many variations on each consent model. Which one do you favour, and why?

The IMO would like to formally advocate the Hard Mandated Choice model, or Option C2.

Family consent is a major barrier to organ procurement.³ Most organ donors die young and unexpectedly, leaving their family devastated and in a state of shock. The need to consider organ donation places additional stress on the family at a difficult time and most families are unaware of the wishes of their relative. Also the need to request family consent places stress on health care workers, who fear further compounding the family's pain.

While the hard mandated choice model has been criticised as insensitive to families, it removes the burden of decision away from the family at an emotional time and places it on the individual when he or she is in a position to make an informed decision.

The IMO believes that sensitivity towards the family is vital in any system chosen. The families must be informed of their relative's decision, if they are not already aware, and reassured of the effectiveness and usefulness of organ donation if that is the relative's choice.

³ Spital A. *Mandated Choice for Organ Donation: Time to Give it a Try*, Annals of Internal Medicine July 1996 Vol 125 Issue 1 pp66-69

Under a Hard Mandated Choice system organ donation would become a civic responsibility, like voting or jury duty. It would be a focal point of society, something that people would have to decide on.

It is important to acknowledge how vital a sustained public awareness campaign would be in regards to implementing a hard mandated choice system. After the initial campaign, continuing public awareness would need to be generated through places like schools, GPs, and other avenues where information about organ donation and the seriousness of the issue can be conveyed and appropriately absorbed. It should permeate through to all generations, and information should be readily accessible.

4. Do you feel strongly in favour of your preferred option on principle or is your support based on the potential effectiveness of the preferred option in increasing organ donation rates?

Research into the impact of donor policies in Europe found no obvious correlation between consent systems and donor efficiency rates (conversion of potential donors into actual donors).⁴

Factors other than the consent system seem to be responsible for increased rates of organ donation particularly:

- Measures undertaken in hospitals to optimise donor procurement;
- Public awareness about the relevant aspects of organ donation.

Our support for the hard-mandated choice option is based on the potential effectiveness of increasing organ donation rates as it places the legal onus on the individual to make an informed decision on organ donation.

5. Do you foresee any practical problems with implementing any of the models?

Some practical problems regarding the different consent models include:

- Any model that requires a register of consent or objection will have practical issues surrounding its implementation. Often the turn around times for organ donation and transplantation are quite short, therefore information regarding the potential donor and their consent status need to be collected in the most practical and time efficient manner as possible. The capturing of information on a large scale and maintaining confidentiality and information security is of the utmost importance. The practicality of administration may also need to be addressed.

⁴ Copen R, Friele R, Gevers S, Blok G and Van der Zee J; The impact of donor policies in Europe: a steady increase, but not everywhere. BMC Health Services Research 2008 8:235 doi:10.1186/1472-6963-8-235

- Issues surrounding non-residents of Ireland need to be accounted for. We believe it should be automatic that non-residents of Ireland should be excluded from organ donation.
- A1 – Hard Opt Out. We believe there would have to be very strong legislation in place to ensure the legal protection of doctors performing the organ extraction against the wishes of a family or an individual who has not formally registered their wishes.
- C3 – Required Request. While this option does not advocate necessarily a formal register, this requires people to make immediate decisions in hospital. If there is insufficient time or the individual feels under pressure to make a decision in hospital, this could be quite traumatic and unethical.

6. Under a new statutory system:

a) how would people opt-in or opt-out?

A secure, central register is essential for recording if individuals are opting in or opting out. It should be run independently from those carrying out transplant operations to ensure its integrity. Whether these preferences are recorded at the time of obtaining a drivers licence or passport, there should be avenues available to change preferences at all times.

b) how would children and vulnerable groups be treated?

Legislation should allow for their legal guardians to make that decision. An age of consent should also be covered in legislation.

c) how would non-residents be treated?

As they are non-residents, they should not fall under the legislation. If their relatives are present, their consent could be sought, however the IMO advises that this is an area that needs legislative consideration to ensure transplant co-ordinators and transplant teams have clear direction on this particular issue.

d) how would people whose first language is neither Irish nor English be catered for, or people who are illiterate?

Like any other service, information should be made available to them in their language. If they are in a situation where timeframes are critical, an interpretive service should be available 24 hours a day to enable clear communication between the physicians, transplant co-ordinators, the potential donor and their relatives.

e) how would groups with religious or cultural objections be accommodated?

A hard mandated choice model obliges an individual to register their objection formally against organ donation.

f) should people be able to withhold consent for some organs or tissues, but consent to donation of others.

This could present a very large logistical problem. However it could also be accommodated in the hard mandated choice model as a complete objection or a partial objection. A partial objection could have the capacity to record what organs the individual consents to, and what organs they object too.

g) how should the information on consent be recorded, and in what form?

The information should be recorded in a national database that is a secure record only to be accessed by transplant co-ordinators, and not medical staff that are part of a transplant team. Its security and protection is paramount to ensure individual choice and the inability to manipulate records from people outside the transplant coordination process.

Information provided to people administering the database should be absolutely confidential. The easiest way to ensure identification would be by photo-identification or by an individual's PPS number. Consumer friendly processes should be applied to ensure that individuals are not intimidated by the procedure of registering their preference.

h) how would transplant staff access the consent status of potential donor when time is of the essence?

24 hour Transplant Co-ordinators are already in existence in Ireland. Their numbers would be increased and their role would expand to allow access to the electronic register to determine if the prospective donor is suitable or not. Co-ordinators should be independent of the medical team, and reviews should be conducted to confirm that they are following correct procedure. This register and its administration should be built into legislation to ensure the protection of those within the register, and those who administer it are accountable.

i) what would be the impact on resources of the preferred consent model?

If a hard mandated choice model was adopted in Ireland, there would have to be significant funding improvements to build the best possible operational framework for this model to succeed.

Appropriate resources to design, implement and maintain central registry for Transplant Coordinators

The design of a central and secure database is a central component of the hard mandated choice model. Proper funding should be allocated to its development and ongoing maintenance to allow Transplant Coordinators access to identify the preferences of prospective donors. Legislation should be in place to ensure the integrity of the database.

Sustained media campaign to generate public awareness

An ongoing media campaign in order to raise public awareness must saturate all areas of society, informing them of the facts and processes of organ donation, along with assurances that their family will be consulted and how to register their objection. Additionally, organ donation awareness should also be introduced into the educational environment, to ensure that adolescents reaching maturity are aware of the process, and to enable them to make an informed choice when they are older.

Transplant Coordinators – improved function and increased number

Currently there are only three Transplant Coordinators in Ireland. Transplant Coordinators should be independent of the transplant team, and one should be permanently based in each of the donating hospitals in Ireland. Their role should be that of liaising directly with the potential donor and their family, to talk through the donation process and provide any necessary assistance to the donation process.

Increased funding towards training and equipment for transplant operations

Resource allocation should also be directed towards training and equipment in order to adequately perform transplants throughout designated centres in Ireland. Investigation into cost effective and suitable organ transportation methods should be conducted, with resource allocation supporting the best option.

7. What would be the advantages and disadvantages of a change to an opt-out system? How might the disadvantages be overcome?

Advantage – increases the pool of organ donors

Presumed consent, like all models, works through supportive mechanisms designed to increase donation rates. Implementing presumed consent alone without this support will not increase donation rates⁵. Components that influence organ donation include legislation, the infrastructure surrounding organ donation, investment in the system and public awareness⁶.

Disadvantage – the cost of change

One of the biggest disadvantages would be the ongoing communication with the public about this issue, to ensure that everyone is properly informed in regards to an opt-out system. Sustained and targeted communication strategies directed at all levels of the community are required, and reinforcement through medical practitioners along with the education system needs to be invested in to ensure people have the necessary information.

Disadvantage – the ‘fear’ of presumed consent.

Moving from a non-legislated and a system that has required ultimately the approval of a family member, to a presumed consent model would require a strategy that would deal with such a significant change in practice. Changing public attitudes and managing public fears about a change in process will need to be dealt with appropriately.

⁵ Coppen R, Friele R, Gevers S, Blok G and Van der Zee J; The impact of donor policies in Europe: a steady increase, but not everywhere. BMC Health Services Research 2008 8:235 doi:10.1186/1472-6963-8-235

⁶ Rithalia A, McDaid C, Suekarran S, Myers L and Sowden A; Impact of presumed consent for organ donation on donation rates: a systematic review. BMJ 2009:338:a3162 doi:10.1136/bmj.a3162

8. What is the potential for increasing donation levels while retaining the current opt-in system? What improvements are needed to the current system to make it more effective?

The work of the Irish Donor Network has seen many Irish citizens apply for and carry a Donor Card, however a central registry accessible by Transplant Coordinators is still required to record this choice by the individual. Additionally, legislation would also be required to ensure that this system is protected within the law, and to provide the necessary framework for this model of consent fulfils its aim of protecting the choice of individuals. Innovative ways to encourage individuals to sign the organ donation registry would be required, as the messages would have to be a strong call-to-action.

Measures to increase family consent for organ donation need to be implemented. Research shows that how donation is broached and handled in hospitals is a critical factor in determining donor rates.⁷ Health care professionals dealing with families of potential donors must be trained in how to approach the subject appropriately.⁸ Families are more likely to agree to donation if they are prepared for the request. This involves spending time with families and assessing their beliefs regarding the patient's survival. Calling on the transplant coordinator to meet with families should be standard practice as incomplete or inaccurate information on the process may limit consent.

9. Will the identification and management of potential organ donors affect patient care and hospital practice under a system of presumed consent? Will presumed consent make things easier or more difficult for staff, potential donors and their families?

The IMO does not believe that a presumed consent model, or any model, will negatively affect patient care and hospital practice. Critical care staff's primary concern is the patient, not the recipients of transplants. However, increased awareness of the identification of potential donors will need to be generated in acute care staff. Under presumed consent, there are strict identifying guidelines just like there are under the current system.

Staff

The IMO believes that a presumed consent model will however impact negatively on the doctor-patient and doctor-family relationships particularly given the recent controversy over organ retention as highlighted in the Madden report. A presumed consent model shifts the onus from organ donation by the individual or their family to organ collection by the healthcare professional. Such a system

⁷ Organ Donation Taskforce UK. *The Potential Impact Of An Opt Out System For Organ Donation In The UK – An Independent Report From The Organ Donation Taskforce*. 2008 p17

⁸ Smirnoff L.A., Gordon N., Hewlitt J., Arnold R.M *Factors Influencing Families' Consent For Donation Of Solid Organs For Transplantation* JAMA 2001; 286 (1): 71-77

could be fraught with problems and would require strong legislation to protect medical staff.

Potential donors

Presumed consent would make it much easier for potential donors – they do not have to do anything except tell their next of kin that they wish for their organs to be donated. They do not have to sign anything, but they do have to ask their families to respect their wishes. This is the easiest form of providing consent in any of the models presented.

Families

Soft presumed consent still places the onus on the families to make a choice regarding organ donation at a stressful and emotional time. Hard presumed consent models can be even more distressing for families, as they would know that their wishes or unregistered wishes of their relatives may not be respected.

10. Are there any alternatives to the opt-in and opt-out models of consent? What would the advantages of such systems be?

Mandated Choice

A hard mandated choice system is the model advocated by the IMO. It requires everyone to register their preference regarding organ donation. As mentioned above it relieves the family of the burden of making a decision over organ donation.

A soft mandated choice system that does not require people to register their preference, but provides the option, may not be as effective as other options regarding consent. It would still be costly to administer, but would require a large communication campaign (again the same as other choice systems) and because there is no direct action required by individuals, the uptake of registering preferences may not be as significant.

Required request where a person's wishes MUST be determined before death would not be advocated, as often circumstances in Emergency Departments and ICU's are traumatic enough without having to broach the subject of organ donation. The IMO believes that the significant amount of distress and hurt that would be caused in this instance is too great to advocate this system.

11. What are the advantages and disadvantages of incorporating mandated choice with an opt-in system?

As mentioned above the advantage of incorporating a mandated choice with an opt-in system would be that organ donation would become a civic responsibility, like voting or jury duty. It would be a focal point of society, something that people would have to decide on.

The disadvantage of this system is that it may be costly to administer, and to follow up on. To ensure that everyone is captured in the system would require significant resources. Whether an opt-in, opt-out or mandated choice is implemented a central register to facilitate organ transplantation is required.

12. how would mandated choice work in practice? What would be the most effective methods of administering a mandated choice system to ensure that it would be:

- a) fair and
- b) achieve maximum coverage?

To ensure that mandated choice worked in practice, registering preference would have to tie in to another form of service, such as hospital admission (regardless of the condition), recording of preference by GPs or even when you get a drivers licence or another form of identification. The disadvantage of this system is that so many people would have to have access to the system in order to update individual details, that data security and confidentiality could be left exposed. Additionally, the amount of training given across the board would also be significant, to ensure that people who are recording the information are doing so correctly and can address specific concerns if people do have them. To ensure that the system is fair, people would have to have the ability to change their preference if they wish to do so.

13. What are the advantages and disadvantages of incorporating required request with an opt-in system?

The required request system is fundamentally flawed as it does not necessarily provide for a central register of consent. This would require staff requesting consent often in traumatic circumstances (A&E, ICU) from either the potential donor or the family. To confront them with this issue, possibly without prior discussion between the family and the potential donor having ever taken place, could create public perception issues between the medical profession and the public.

The advantage of incorporating required request with a hard opt-in system would be that individual choice would be respected, and that no family would be able to veto. This system would indicate that organs were being donated willingly by the donor, and that it was an active choice. The downside to this again is that it may be deemed insensitive to families' views at such a difficult time.

If it is a soft opt-in system with required request, the advantage to this would be that the individual has registered their consent to the donor process, and that the family would be consulted in regards to the donation process. Again measures would have to be implemented to increase family consent rates.

14. Will the identification and management of potential organ donors under required request system affect patient care and hospital practice? Will required request make things easier or more difficult for staff, potential donors and their families?

As stated in Question 9, we believe that with the appropriate training and procedures put in place, patient care and hospital practice will not be adversely affected.

The clear disadvantage of this system would be that asking for request in traumatic circumstances that are often associated with Accident and Emergency departments and ICUs may negatively impact on consent levels. The absence of a registry in this circumstance does not provide for people wishing to signify their wishes in advance.

15. If the current system is changed to one of presumed consent, should some groups be given the option of remaining outside the new system, if for example they have religious or cultural problems with the change? What practical problems would this present and how should be addressed?

The IMO believes that yes, some groups should be given the option to remain outside the new system. There are significant practical problems associated with this task, especially identifying the groups and ensuring that individuals within the groups are registered as not consenting to organ donation. Families would need to be directly involved in the organ donation process. They can object on the individual's behalf if they have not been captured within the process.

To address these groups, administrative support should be provided to ensure that staff maintaining the registry of opt-outs has contact points within the group to ensure that people within the group are registered as opting out. Specialised staff liaising with the group will be able to maintain the lines of communication between the group and the register and ensure that their views are accounted for formally and respected.

A presumed consent model obliges an individual to register their objection formally against organ donation.

16. Do you have any other proposals for improving donation consent rates?

The IMO firmly believes that no system of consent will be effective unless there is increased public debate surrounding organ donation. Introducing key messages into mainstream media is fundamental to the success of any increase in donation rates. To stimulate public discussion will also bring it into the homes of people who have not had to address this issue previously.

Generating public awareness is just one step, calling for action on the issue is another foundation block in improving consent rates. Supportive legislation that provides an operating framework for organ donation is one of the most important features of any consent system.

Appropriate resource allocation also needs to be addressed to enable functions within any consent system to be implemented effectively. Again increased funding is needed for training and equipment to perform transplant operations. The role of the transplant coordinator in providing accurate and complete information on the donation process is essential to relieving the distress to families around the issue of organ donation.

Therefore, the IMO believes that the only way forward is through clear legislation, public awareness and appropriate resource allocation to ensure that a comprehensive and practical framework provides the necessary avenues for successful delivery of this legislation.