

Submission by the Society for the Protection of Unborn Children (SPUC) to the Health and Social Care Committee of the National Assembly of Wales regarding the *Human Transplantation (Wales) Bill*

The intent of this Bill to increase organ donation rates is laudable, and this is demonstrated in Wales which has amongst the highest organ donation rates in Europe.¹ Organ donation is generally viewed in a positive light in the community and its representation as a ‘gift of life’, when carried out in an ethically sound manner, is well established. This perspective is particularly the case for the major faiths, and the Catholic Church for example has described organ donation as contributing to an “authentic culture of life”.²

There are two key principles that underlie an ethically sound approach to organ donation. The first is that a donation is a gift that should be voluntary and free from any coercion. The second is that the human dignity of both donor and recipient must be paramount. Both donor and recipient should be provided with the best medical care available prior to and during transplantation, and where death occurs, the deceased must be treated with dignity. Does this Bill uphold these principles, and what other issues does it raise?

Consent

Informed consent is now firmly established as one of the key principles that underlies modern medical practice. Informed consent ensures that individuals have sovereignty over their body and are able to have a say in how they are to be treated. This extends beyond death inasmuch as respect for the deceased person also means respect for their wishes about how their body is to be treated after death.

This Bill treats the notion of consent in an incongruous way to the extent that what is commonly understood by consent is at risk of being corrupted.

An opt out system is often referred to as a presumed consent system, the idea being that where someone’s wishes are not known we might presume upon some grounds what they might actually have wanted. The Bill goes one step further by using the phrase ‘deemed consent’. The meaning conveyed by this terminology is that the State is simply able to call lack of consent, consent. That is to say, it renders the notion of true consent meaningless by confounding it with its opposite.

*The idea that the absence of an objection represents informed consent is plainly nonsense and consent that is not informed is valueless.*³

On several occasions the Bill’s Explanatory Memorandum perpetuates the incongruity.

¹ <http://www.bbc.co.uk/news/uk-wales-politics-16797510> and <http://www.walesonline.co.uk/news/wales-news/2012/08/23/organ-transplants-in-wales-increase-18-as-uk-donations-hit-record-highs-91466-31684837/#.UPcQd8JBYyN.email>

² Address by Pope John Paul II to the 18th International Congress of the Transplantation Society 2000. See http://www.vatican.va/holy_father/john_paul_ii/speeches/2000/jul-sep/documents/hf_jp-ii_spe_20000829_transplants_en.html

³ Rafael Matesanz & John W Fabre, Too many presumptions: Advocates of a presumed consent system of organ donation are ignoring the weakness of the evidence. *The Guardian* 17 November 2008. See <http://www.guardian.co.uk/commentisfree/2008/nov/17/organ-donation-health/print>

*When it comes to giving consent to organ donation, it is for the deceased to decide whether to opt in, opt out or have their consent deemed.*⁴

But how can the deceased be said to have decided whether to have their consent deemed when the driver behind deemed consent does not know what the deceased would have wanted?

Furthermore, by setting into law an incongruity, this Bill risks corrupting the notion of informed consent so that its operation in other contexts might also become confounded. For example, might the concept of deemed consent be applied to organs and tissues for research or commercial purposes in the future? What about Involuntary euthanasia as practised in Holland and Belgium, where the patient is unable to resist, the doctor or nurse may feel 'empowered' to administer a fatal dose on the grounds that the patient can be presumed to have given consent because she did not leave a living will to forbid it.⁵

Moreover, the principle of free and informed consent is the cornerstone of opposition to the commercialization of organ 'donation', and more particularly the deplorable business of trafficking in human organs. Erosion of this principle in one context such as promoted by this Bill, will lead to its erosion in these other contexts where exploitation occurs, making them more difficult to control.

Implementation of an opt out system is based upon the hope that the donation rate will increase. Whether it will is addressed below, but despite the Explanatory Memorandum attempting to suggest that deemed consent is a choice someone makes, in reality it is more than likely that some who do not wish to become organ donors will end up having their organs removed. At the very least, deemed consent means we simply do not know, but given the fact that a significant number in the community do not want to donate their organs, any increase in donation rate will likely come from these people. Evidence from previous consultations show that voluntary organ donors often strongly resent their donation being taken for granted and turned into a compulsory 'donation'.⁶

Wellesley describes it as follows:

Despite only 29% of the population being on the NHS organ donor register, when families are asked if they will offer their deceased relative's organs for donation, 59% agree. This figure is remarkably similar to the 62% of adults who say they would be happy to donate their organs. There doesn't appear to be a significant gap between the proportion of people who actually donate and those who say they are willing to do so.

⁴ Welsh Government, *Explanatory Memorandum Incorporating the Regulatory Impact Assessment and Explanatory Notes*, 3 Dec 2012, p18 at 42.

⁵ Stateline Centraal Bureau voor de Statistiek, Deaths by Medical end-of-life decision; age, cause of death. Updated on 11 July 2012.

<http://statline.cbs.nl/StatWeb/publication/?VW=T&DM=SLen&PA=81655ENG&LA=en>;

Bregje D Onwuteaka-Philipsen et al, Trends in end-of-life practices before and after the enactment of the euthanasia law in the Netherlands from 1990 to 2010: a repeated cross-sectional survey, *The Lancet*, July 2012; http://press.thelancet.com/netherlands_euthanasia.pdf; Els Inghelbrecht et al, The role of nurses in physician-assisted deaths in Belgium, *Canadian Medical Association Journal*, 6/15/10 vol. 182 no. 9 <http://www.cmaj.ca/content/182/9/905.full.pdf+html>

⁶ <http://wales.gov.uk/consultations/healthsocialcare/organ/?lang=en&status=closed> See responses 41, 54, 88, 91, 116 & 32 others in White Paper Consultation Nov. '11 -Jan.'12

If an opt out system is able to achieve donation rates higher than 62% then it must be taking organs from unwilling donors.⁷

He goes on to say:

Given that consent rates are already 59%, we do not need a radical overhaul of the system; we need ways of encouraging people to want to donate.⁸

One of the problems with the current system is that there remains uncertainty about consent to organ donation. That is, some who may be candidates for organ donation have not joined the organ donor register, and next of kin end up deciding on their behalf, or if there are no surrogate decision makers, the uncertainty means donation does not proceed. However, an opt out system does nothing for uncertainty and in fact there is the potential for it to be exacerbated if poor communication means people remain unclear about how the system works, or if there is a backlash through loss of trust in the authorities.

Deemed consent also corrupts the notion of donation itself. When someone gives freely of something so precious that allows another to live, it involves a certain respect for persons to honour that free choice. Just as commercialization of organ 'donation' would diminish human dignity by placing a monetary value upon body parts, that is, effectively objectification, deeming consent diminishes human dignity by taking body parts from someone without knowing anything about their deeply held core beliefs relating to treatment of their body after death. For some religious groups this is particularly pertinent.

Considerable effort has gone into establishing the conceptual and cultural framework surrounding organ donation as a free gift. Implementing an opt out system risks gradually undermining that effort. While this does not *appear* to have happened in countries like Spain, its highly coordinated transplant system is almost certainly responsible for the high rates, and the opt out aspect of the system may be doing nothing directly or may hinder even better rates. Matesanz describes the presumed consent law as irrelevant to their high donation rate.⁹

Organ donation as a freely given gift is also important for recipients. Might they not want to be assured that the organ they have received was genuinely *donated* by someone? Concern about how organs are obtained is likely to be an important question of conscience for recipients and potential recipients alike.

State Overreach and Trust

The question of trust or maintaining good faith regarding organ donation relates to both the health professions and to the State.

Trust has already been damaged by the Alder Hey scandals about tissue and organ retention without consent, and while it is not known to what extent these practices may have influenced organ donation rates, there is at least reason to suspect they might have done so. The Human Tissue Act 2004 was enacted to restore trust by embedding the concept of informed consent. There have been two periods when there was a significant drop in the donation rate: when Panorama identified a significant chance of organ

⁷ Hugo Wellesley, A nudge in the right direction for organ donation – but is it enough? *British Medical Journal* 343:778-9, 15 Oct 2011.

⁸ *Ibid.*

⁹ Matesanz & Fabre, *Op. Cit.*, 2008

donors being left untreated in A&E¹⁰ and the Alder Hey scandal.¹¹ Currently, those who don't wish to become donors cite reasons related to trust.

*... concern about “the level of respect given to a deceased person’s body” and “whether doctors make every possible effort to help patients identified as potential donors” are two of the most commonly cited reasons for not wanting to register as a donor.*¹²

With an opt out system, the State, through the health system and professions, might be seen as ‘taking’ organs without explicit consent. Some will view this as State overreach, and there is then a risk that this could exacerbate the somewhat damaged trust that already exists in this sensitive area about the use of organs and tissues at the time of death.

Some might argue that since the next of kin and other surrogates can decide on behalf of a person why shouldn't the State be permitted to do likewise? But the State is not in the type of relationship to the individual to be able to consent on his or her behalf. It does not have the personal knowledge or interest necessary to act in that role. As such, an opt out system represents an unacceptable level of interference by an impersonal State in personal life.

An opt out system therefore has the potential to further alienate those who already mistrust the authorities. A perusal of feedback from the public about opt out plans reveals significant numbers of people who currently are registered to donate, but who would deliberately opt out in protest about state interference if a presumed consent system were introduced.¹³

Additionally, there are other concerns about practices within organ transplantation that are controversial and have the potential to lead to mistrust. These primarily surround determination of death criteria.¹⁴ As David W Evans MD, FRCP has noted:

“the basis upon which a mortally sick patient is declared “deceased” – for the purpose of

¹⁰http://journals.lww.com/transplantjournal/Citation/1996/12150/The_Panorama_Effect_on_Altruistic_Organ_Donation.37.aspx

¹¹ <http://news.bbc.co.uk/1/hi/health/1475676.stm> Eye transplants hit by Alder Hey

¹² Hugo Wellesley, A nudge in the right direction for organ donation – but is it enough? *British Medical Journal* 343:778-9, 15 Oct 2011.

¹³ This issue has been raised by others [for example, Simon Bramhall, Presumed consent for organ donation: a case against. *Ann R Coll Surg Engl* 93(4):270-272, May 2011]. See also public forums, for example: <http://www.guardian.co.uk/society/2012/jul/27/nhs-organ-donor-optout-transplants#start-of-comments>

¹⁴ In a recent paper in the *New England Journal of Medicine*, [Boucek MM *et al.*, Pediatric Heart Transplantation after Declaration of Cardiocirculatory Death. *NEJM* 359:709-714, 2008] heart transplant surgeons described how they modified the definition of death for three brain-damaged infants whose hearts were removed for transplantation into three other infants with severe heart problems. The controversy surrounds the likelihood that the children were not in fact dead. The journal invited two bioethicists, Robert Truog and Franklin Miller, to write a commentary [The Dead Donor Rule and Organ Transplantation. RD Truog & FG. Miller, *NEJM* 359:674-675, 2008], which is when the controversy really began to deepen. The essential line taken by Truog and Miller is that it really doesn't matter whether the patient is dead or not. Instead what really counts is whether informed consent has been given. In their assertion that it is “perfectly ethical” to remove organs from patients who are *not really* or *convincingly* dead, they give voice to the utilitarian ethic, which is that the outcome – organs that save people's lives - is really so good that traditionally unethical means can be justified.

acquiring his or her organs for transplantation without legal difficulties – is very different from the basis upon which death is ordinarily diagnosed and certified and that highly relevant fact is not fully and generally understood.”

The proposals ignore the facts concerning this area of scientific dispute, yet this is a question with enormous ethical implications. Most organ donors are unaware that their hearts may be beating when their organs are taken, and that they may be pink, warm, able to heal wounds, fight infections, respond to stimuli, etc. They are also unaware of common practices of paralyzing and (sometimes) anaesthetizing supposedly brain dead donors before their organs are taken. Simply signing a donor card does not in any way indicate that the prospective consenting donor understands what will be involved, and those who are merely ‘presumed to consent’ are likely to know even less.

It is extraordinary that the issue of determination of death, which must govern consideration of so many other issues in organ donation, is so often ignored, in spite of the US President’s Council findings (see appendix) and the growing scholarly literature on the question. That the public are not made aware of the controversy, even in a consultation on organ donation, is deeply regrettable. Notions of informed consent, let alone presumed consent, are meaningless unless the facts of the matter are openly discussed and considered.

As the public detects the erosion of important values in the quest for more organs they will begin to wonder whether too much has been traded. There is already enough risk of generating mistrust from these controversial practices without introducing more. The question of whether so-called ‘brain-death’ or ‘brain stem death’ is actual death.

Justice

There is another reason, based upon justice and equity, why an opt out system is likely to be problematic. Those who are marginalized, poor, disabled, or disenfranchised for whatever reason, and without families or other advocates to stand up for them, are likely to be the ones who either never hear about how the scheme works or suffer some dysfunction such that they never get to the point of making a decision or acting upon it.

It is these vulnerable groups who should be the very ones the State is supposed to care for and whose rights it should defend. An opt out system, by unintentionally disproportionately targeting such individuals for deemed consent, represents an abrogation of the State’s role to impartially protect all members of the community.

*Inevitably, the socially disadvantaged and poorly literate will be less aware of their rights, less likely to care about them in advance and less likely to have confident advocates in the face of medical authority at the time of their deaths.*¹⁵

Will it Work?

Whether opt out systems *per se* increase organ donation rates remains controversial, and more research is needed to ascertain any potential effect one way or the other.

¹⁵ Matesanz & Fabre, *Op. Cit.*, 2008

To the readers of this submission the following conclusion from the UK's Organ Donation Taskforce in 2008 will probably be familiar:

*"...after examining the evidence, the Taskforce reached a clear consensus in recommending that an opt out system should not be introduced in the UK at the present time. The Taskforce concluded that such a system has the potential to undermine the concept of donation as a gift, to erode trust in NHS professionals and the Government, and negatively impact on organ donation numbers. It would distract attention away from essential improvements to systems and infrastructure and from the urgent need to improve public awareness and understanding of organ donation. Furthermore, it would be challenging and costly to implement successfully. Most compelling of all, we found no convincing evidence that it would deliver significant increases in the number of donated organs."*¹⁶

Spain is often cited as an example of the success brought about by opt out systems. However, notably Spain changed its legislation to an opt out system 10 years prior to any change in the donation rate. What made the difference was a highly coordinated transplant system with a focus on intensivists in all major hospitals. According to the Clinical Director of the *Organizacion Nacioanl de Trasplantes* in Madrid, Rafael Matesanz, the evidence for a positive impact of presumed consent is very thin.

*... it [an opt out system] contributes little or nothing to the improvement of organ donation rates and, on the debit side, diverts precious resources to imaginary rather than effective solutions.*¹⁷

A systematic review of the impact of presumed consent on organ donation rates concluded that an opt out system alone could not account for increased donation rates and whilst there was an association between presumed consent and increased rates, no evidence for causality exists.¹⁸

A more recent review of kidney donation rates similarly found that countries with presumed consent had higher rates of deceased donation, but notably, kidney donations from live donors were lower.¹⁹ Again, no causal relationship between presumed consent and increased donation rates could be shown.

What then are those things which are likely to make the most difference?

They include factors that influence the numbers of potential donors, such as motor and other accident rates, population age distribution, and the way that death is determined. Also critical are how coordinated the transplant system is, community wealth and investment in health care, and most importantly, the attitudes of the public to organ donation and their level of awareness. And central to public attitude is trust, which will be affected by the degree of ethical probity.

¹⁶ The potential impact of an opt out system for organ donation in the UK. An independent report from the *Organ Donation Taskforce*. Nov 2008, p 23.

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090303.pdf

¹⁷ Matesanz & Fabre, *Op. Cit.*, 2008

¹⁸ Rithalia A, McDaid C, Suekarran S, Myers L & Sowden A, Impact of presumed consent for organ donation on donation rates: a systematic review. *British Medical Journal* 338, a3162, 2009

¹⁹ Horvat LD, Cuerden MS, Kim J, Korval JJ, Young A & Gard Amit X, Informing the Debate: Rates of Kidney Transplantation in Nations with Presumed Consent. *Annals of Internal Medicine* 153:641, 2010

Impact on Next of Kin

An important element of this particular opt out approach is that it is described as ‘soft’, meaning that the next of kin have a say in what is to happen. The explanatory memorandum makes it clear that this soft approach will not lead to exclusion of families at a time of significant distress. However, the Explanatory Memorandum also perpetuates the myth that deemed consent means honouring the wishes of the deceased, and this is what really counts, not what relatives might want.

... it is, as a matter of law, the wishes of the deceased which are relevant.²⁰

And,

Where relations do not produce any information about the wishes of the deceased, then they will be in a position of knowing the deceased had not opted out, and had made no further wishes known. In these cases, the default position is that the deceased was in favour of donation and, as a matter of law, the deceased’s consent is deemed.²¹

In the end, the Bill makes it clear that the next of kin have no power of veto. Even so, the Memorandum states that clinical teams will not “add to the distress of families by insisting on donation”. Which means that, despite the lack of power of veto, effectively families have the final say if they wish, just as they currently do.

What then will this Bill have really changed?

Perhaps in reality what will have changed is that there may now develop a degree of coercive influence over families to agree to donation even though they may be distressed by doing so. Some may comply because the “information” they are able to provide is not, in the eyes of clinical authority, strong enough. To them however, there may be real reasons which are difficult to articulate, especially given the intensity of grieving at such a time.

Dealing with relatives about organ donation at the time of the death of a loved one is hard enough and the approach has always been one of gently encouraging donation.

This Bill risks shifting practice towards more persuasion and perhaps even coercion.

The Bill should be consistent with the expressed concern for the welfare of the next of kin and permit them to have power of veto. Questions can be raised about whether such safeguards for the family will be implemented and respected, and for how long.

Other Issues

CONSCIENTIOUS OBJECTION

The Bill makes no provision for conscientious objection. This is an important oversight given that considerable objections have been expressed on moral grounds to presumed consent systems. Health professionals ought to be assured by specific reference in this Bill to their right to conscientiously object to practices they may wish to absent themselves from with an adequate explanation on moral, cultural or religious grounds.

²⁰ Welsh Government, *Explanatory Memorandum Incorporating the Regulatory Impact Assessment and Explanatory Notes*, 3 Dec 2012, p19 at 44

²¹ *Ibid.*

WHAT TISSUE, WHAT ORGAN, WHAT PURPOSE?

The Bill permits at 3(2)(b) “removing from the body of a deceased person, for use for that purpose, any relevant material of which the body consists or which it contains.” Relevant material includes anything which “consists of or includes human cells” but excludes embryos, gametes, hair and nails.

Little attention has been given to the different significance of organs and other body parts that can or may be transplanted in the near future. A presumed consent system that effectively transfers ownership of the body to the State could mean that *any* organ or tissue can be used for transplant. There are some important nuances here that relate to identifiability of the deceased as well as to reproductive continuity. In recent surgical operations, faces and whole limbs have been transplanted. Other transplant techniques may permit gonadal tissue to be transplanted, leading to the potential for children to be born whose biological parents are deceased. The purpose for which transplants could be used may also raise ethical questions. For example, genitalia from deceased people may be able to be transplanted in sex change operations, or tissues may be used for cosmetic surgery. While a discussion about the ethics of these matters should take place sooner rather than later, as far as the issue of consent is concerned, ethically more contentious transplantation would become more rather than less problematic under a presumed consent system.

Furthermore, greater interest in foetal tissues for transplant, coupled with no right of veto for next of kin under this Bill, could risk significant distress for women at a very traumatic time. The point is, an opt out system represents a shift away from the rights of the deceased, and also from the rights of the next of kin. If a culture develops within the health system that ‘presumes consent’, there is a real risk of a corrosive effect upon people’s ability to have a genuine say in the face of medical authority.

EFFECTIVENESS OF A COMMUNICATIONS STRATEGY

Whenever opt out systems are promoted, advocates always emphasise how effective communication will be to ensure that everyone has clearly had the opportunity to decide to opt out. This is naïve. Besides the fact that the interest in doing so is a recognition that to deny someone that opportunity is a denial of a basic right, in reality communication is never that good and as stated before, the disadvantaged are by far less likely to hear or effectively process such a message. For example, it will be very challenging to ensure effective information for non-English or non-Welsh speaking visitors, people who do not have access to the internet, people who have audio or visual impairments.

If this Bill does pass, what is the likelihood of communications strategies effectively addressing key aspects of organ donation including detail about determination of death and that there remain significant unresolved ethical issues and strong differences of opinion about the process and also about what is being proposed by some in the field? It is also important that people are aware of what can and will be transplanted. If *informed* consent is really the gold standard, then the Government must treat it as such.

There can also be genuine concern that because the Welsh Government appears committed to a presumed consent system, the communications strategy will reflect that position and communicate any putative benefit at the expense of the risks, both ethical and practical.

Given that the Government is committed to the expense of a programme of public education, would it not make more sense, especially given the poor likelihood of success of an opt out system, to implement an education programme directed at enhancing people's free choices to participate in organ donation. The approximately 40% of the population not prepared to donate represents fertile ground for changing people's minds.

Conclusion

The context in which organ donation occurs is clearly an ethically sensitive one for a range of reasons. The living grieve the loss of a loved one in very unique and personal ways, and while some find some comfort in knowing the death contributed to good for others, some also struggle with uncertainty about whether they made the right decision and honoured the deceased wishes or not. The whole business rests on a fine balance of trust, sensitivity, respect, transparency and genuine care.

It is too great a risk to implement a system which will damage these goods, and an opt out system is such a system.

Other nations have had significant success without presumed consent, and some with it have lower rates than Wales²². It is no panacea, and what will be lost in the longer term is not worth any potential short term gain.

Wales should look to the US and Spain's systems of coordination to enhance its donation rates, and set aside deemed consent thereby ensuring it preserves carefully considered and long standing ethical norms.

²² For example, Sweden and Israel.