

*Unpublished and in draft with a presentation time of 15-20 minutes*

**With the forthcoming introduction of deemed consent in Wales in December 2015, is presumed (deemed) consent the future for organ donation in England?**

The questions I wish to address in the very short time allocated to me are

1. Will the introduction of presumed consent increase the number of organ donors.
2. If presumed consent is to be adopted in England, then can it be ethically justified?

**Why change the status quo?**

In England, we have a system of contracting into organ donation where, should you wish to donate organs on death; we simply, in one form or another, sign the organ donation register.

Over 21 million people have joined the NHS organ donation register and although this may sound an adequately large number, only about 1% of those registered as organ donors will die in circumstances where organs can be donated and as we will see later, family refusal to permit the deceased's wishes to be carried out account for over 40% of lost but suitable organs.

Just to give you a flavour of the number of organ transplantation that are carried out, since 1/04/2015 although 171 people donated their organs on death and 432 people have received transplants, there are still 6980 people waiting for transplants and 3 people die every day as there are insufficient available organs to meet the demand. Some patients are also removed from the organ donation waiting list as they become too ill to receive any available organs. Opinion polls published on the NHS BT website show that 90% of the population are in favour of organ donation and transplantation and we need to do all we can to realise popular support.

I maintain that, rather than retain a system where there are insufficient available organs to meet the demand, a system of presumed consent should be introduced. The Human Transplantation (Wales) Act 2013 has taken the brave and audacious move to change the current 'opt-in' organ donation system in Wales to a 'soft opt-out' system, also known as 'deemed consent'. A soft opt-out system is one where consent to the removal and use of organs and tissues for transplantation is deemed as having been given unless the deceased objected during their lifetime, and where the next of kin will be involved in the decision making process.

In doing so, Wales has disregarded the report of the Organ Donation Taskforce in 2008 'The potential impact of an opt out system for organ donation in the UK' which concluded that *'such a system has the potential to undermine the concept of donation as a gift, to erode trust in the NHS professionals and the Government and impact negatively on organ donation numbers'*.

#### Will the introduction of presumed consent increase the number of organ donors?

Abadie and Gay conducted one of the most respected and relied upon data analysis on the impact of presumed consent on deceased donor rates. Published in 2006, they constructed a dataset on organ donation rates for 22 countries over a 10 year period and after taking into account other determinants for cadaveric organ donation concluded that presumed consent has a positive and a sizeable effect on organ donation rates. Presumed consent countries have roughly 25-30% higher donation rates on average than those in informed consent countries.

#### International models

Spain is known to have a highly successful organ transplant programme and has the highest donor rate from deceased donors in the world at 33.8 per million population (pmp) in 2006. The comparable figure for the UK was 12.9 pmp in 2006. Presumed consent was introduced in Spain in 1979 but Spain's high deceased organ donor rates is not simply because of the introduction of presumed consent but also because of a highly sophisticated infrastructure. Whilst you may now question the true relevance of presumed consent on deceased organ donor rates, it is worth considering the effect of presumed consent in Belgium which provides convincing evidence of the positive effect of presumed consent. Introduced in Belgium in 1986, Antwerp refused to adopt presumed consent and retain contracting in. In contrast, Leuven, embraced the introduction of presumed consent and saw an increase of up to 40 donors per year over a 3 year period. Within Belgium as a whole, organ donation rose by 55% within a 5 year period.

Presumed consent is unlikely to account entirely for the variation of organ donation between countries as one needs to take into account the infrastructure of the organ donation system with the related investment in public health care, public attitudes and public awareness but it does appear that even where these other factors are taken into account, presumed consent still accounts for increased organ donation rates per population.

## Relatives' refusal of Organ Donation post mortem and the subsequent effect.

In *The role of families in organ donation: International evidence review 2012*, a document produced by the Welsh Government, the statistics for the family refusal rate for organ donation post mortem go to the root of the issue as to why the UK has a low organ donation rate and family refusal rates are the biggest single obstacle to organ donation in the UK.

Empirical research carried out by Rosenblum et al illustrates that out of 32 countries; the UK had the 8th highest family refusal rate (43%). Although one cannot categorically conclude that there is a clear relationship between the high rate of relatives' refusal and our current system of opt in, it appears to be more than a coincidence that out of the 13 countries that fared the worst for family refusal, all except 3 informed rather than presumed consent. Of the other 19 countries that had the best rates of family refusal (Czech topping the list at about 5%), only one country, Ireland has presumed consent. To put this into context, where the deceased had expressed a desire to donate organ on his or her death, his wishes were effectively overruled in 43% of cases. This is an extraordinary statistic bearing in mind that 71% claim that it would annoy them to think that their own or others wishes may not be respected (source Optimisa 2013 taking organ transplantation 2020 – changing public behaviour. Only 50% of the public have ever discussion organ donation and only 37% have ever discussed it with close family and friends).

The HT (Wales) Act which introduces a soft opt out system of organ donation in Wales, will not allow relatives to override either the recorded wishes or the deemed wishes of the deceased. However, the explanatory memorandum states '*it is important to stress that the next of kin will be treated with sensitivity and their feelings will be carefully considered.*' Therefore, even where the deceased had specifically expressed a wish during his lifetime to donate his organs on death, it will still be possible for the relatives to refuse, although in countries where there is presumed consent, this is always more unlikely.

Soft opt out does not ride rough shod over the relatives wishes as the importance of respecting where possible, the relatives' refusal is fundamental. After all, presumed consent can also back fire. Where there is an element of distrust between the medical professional and the potential donors, unless issues are considered sympathetically, there is the potential for the population to opt out en-masse. For example, in Brazil, presumed consent was repealed only one year after it was introduced in a climate of mistrust and concerns about body snatching.

Although relatives may find it difficult to agree to removal of their loved ones organs in our current opt in system (as statistics show), perhaps lest they feel morally responsible for desecrating a body, the advantage of a presumed consent system means that relatives are relieved of the emotional burden of making that decision and are merely required to confirm the deceased's wishes.

A survey of the Welsh adult population in 2012, prior to the introduction of the HT (Wales) Bill showed that 62% of respondents had not discussed their organ donation wishes with their family. This confirms that there is a need to be greater awareness within families about deemed consent in Wales and the role of the family remains critical to the new deemed consent legislation. Regardless of any legislation, the familial discussions remain at the heart of the potential success and need to be very carefully considered as if they are overlooked, the objective of the introduction of presumed consent could be reversed.

### Ethical issues

Organ donation has always been considered to be an altruistic act and it is argued that the sense of altruism will be lost if we move towards presumed consent. However, the objective of organ donation is to save lives and the idea that people want to feel good about themselves should perhaps not take centre stage. However, if presumed consent were to be introduced, together with the associated publicity it would generate, more people may consider donating organs, thereby generating the altruistic feeling.

The HT (Wales) Act provides that a person can opt in or opt out. It is only where the person does nothing that consent will be deemed. Opponents argue that the default position of presumed consent allows the State to interfere or use out bodies without consent which runs contrary to the principle of individual autonomy that is now the bedrock of medical practice.

It would therefore be the case where someone hasn't made their refusal known and had not opted in, it would be acceptable to remove organs for which a person has no further use and which can save the lives of others. If this argument is valid, then what we are assuming is that the majority of people actually want to do the 'right' thing, that we believe that it is in the interests of society that the social policy should be that it is preferable to remove organs from those who have no need of them, to provide those who are in need of them.

It is indeed possible that organs may be removed from those who have not either opted in or opted out and be taken under the principle of presumed consent. However, is it worse for organs to be removed from an unfortunate few where there is no consent or to retain a

system where relatives are able and do, in 43% of situations, overrule a person's consent and autonomous decision in their lifetime to donate their organs?

In conclusion, we should wait and see how deemed consent fairs in Wales but I believe that presumed consent is the way forward (together with an improved infrastructure) to ensure that organs which would otherwise go to waste and be eaten by the worms can go to save the lives of others. It may be a utilitarian and communitarian approach but the empirical evidence supports the introduction and the ethical arguments should not outweigh the lifesaving or life enhancing benefit to others. Where the cost to the individual is very low, I maintain there is a moral duty to help others.

