SENATOR FOR A DAY PROGRAM

SENATE BILL

NO. 7

Session of 2020

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REFERRED TO SENATE HEALTH AND HUMAN SERVICES COMMITTEE

Opt-Out Organ Donation

Upon birth, all Pennsylvanian citizens shall be registered as organ donors. An individual may be removed as an organ donor after notifying the Department of Health. The Department of Health shall create forms and procedures to administer and facilitate this process.

This bill shall take effect immediately.

Editorials

Organ donation:

opting in or opting out?

Both Jeremy Corbyn and Theresa May have recently expressed their support for a change to the law in England to introduce an opting-out system for organ donation, and the Department of Health is consulting on the issue. This is based on the assumption that it would make a significant impact on the shortage of organs for transplantation and thus save hundreds of lives each year. It is a popular assumption, because the intention is so obviously well meaning. Sadly, though, it is an assumption that offers false hope.

> *"The need for more organs for transplantation is pressing, but there seems to be little merit in pursuing a change in the law ..."*

WOULD A CHANGE IN THE LAW INCREASE DECEASED DONATION?

There is no good evidence from anywhere in the world that a change in the law leads to a sustained increase in donation. Indeed, there are countries where in fact donation has decreased, and Brazil offers perhaps the best example of this. The few publications that suggest a possible benefit have important methodological flaws that make it very difficult to isolate the impact of the law.[1] The evidence was reviewed in great detail as part of the second Organ Donation Taskforce report in 2008,[2] and little has changed since then. So what is the basis for the assumption? There are at least two important misunderstandings in the case that are often made. First, there is the superficially attractive observation of the Spanish donation experience. Spain has opting-out legislation and for many years has had the highest donation rate in the world. But the Spanish authorities have stated repeatedly that their 'success' does not stem from the law.[3] Opting out was introduced in Spain in 1979, with no apparent effect. Ten years later, in 1989, a national transplant organisation was established with a wide-ranging brief to transform the donation system, based primarily on the employment of medically qualified donor coordinators in every hospital. The effects were immediate, and Spain has led the way since then. The Spanish model has been introduced successfully in other regions and countries, including northern Italy, Croatia, and Portugal. There were no changes in the law, but there were dramatic increases in organ donation as a result of nationally led changes in clinical practice in intensive care units (ICUs). Moreover, Spain does not in fact operate an opting-out system — there is no register for people to either opt in or opt out. As in England, consent for donation is explicit and comes either from the patient in life or through their family.

There is one other important factor relevant to the Spanish success: different countries have different numbers of potential donors. Very few patients die in circumstances that allow organ donation to proceed (about one in a 100 in the UK). For clinical and practical reasons the patient must die from the 'right' diseases (that is, be free of transmissible agents such as cancer and significant infections), in the 'right' place (that is, in hospital and probably in an ICU), and in the 'right' way (that is, death must be, at least to some extent, expected and predictable). Most donors have suffered a catastrophic brain injury from intracerebral bleeding, trauma, or hypoxia, and have been treated in intensive care. For many years Spain has had between two and three times as many ICU beds per capita compared with the UK. Different resources and approaches to end-of-life care result in different numbers of potential donors — and therefore of actual donors.

Second, a common misunderstanding is that under current opt-in legislation 'in order to be a donor you have to have opted in, by joining the NHS Organ Donor Register (ODR)'. Because only 36% of the population have signed up there is a false belief that the other 64% will never be donors, because they haven't opted in. In fact, in the UK last year the families of almost all brain dead potential donors were approached about donation,[4] regardless of whether the patient was registered on the ODR. Certainly registration is to be encouraged as it makes it so much easier for the family to know their relative's wishes, but it is absolutely not a requirement. Over 90% of families now agree to donation when the patient was registered but about 70% agree even when the patient was not registered. The suggestion that opting out would somehow add the 'missing' 64% of the population to the donor pool is quite wrong — in practice, they are there already.

The only experience of opting out in the UK comes from Wales, where legislation for what is called 'deemed consent' was introduced in December 2015. Although this still allows a role for the patient's family, this is limited to providing information about the patient's wishes, and the family's attitude to donation should not be relevant. The numbers are small and it is premature to draw conclusions but in the first full year after the new law was introduced donor numbers were almost unchanged, while in the first 6 months of the second year they have fallen (on an annualised basis) by 14% (compared with a rise of 9% in England in the same time period).[5]

IS OPTING OUT A 'BETTER' FORM OF CONSENT?

There are also ethical and practical concerns about a change to the law. Opting-out laws cover a spectrum but are usually described as either 'hard' or 'soft'. Under a hard system organs will be removed after death if the individual has not opted out, and the family have no role. It is this system that leads to the frequently heard objection that the state is taking over the person's body after death, and there are major ethical concerns. Consent is an active process that cannot be 'presumed' simply because no objection is known. It is not clear that such a system would be acceptable to intensive care clinicians, who play such a vital role in the care of potential donors. Under a soft system there is a presumption in favour of donation but the family have the final say. Ethically this is far less troublesome. However, it is not always apparent that the media and the public are aware of the differences between a hard and a soft system, and the widespread objection to the former may have an adverse effect on the possible acceptability of the latter, and so have an adverse impact on donation.

ARE THERE ANY ALTERNATIVES?

So if opting out is not the solution, what is? For nearly 20 years the UK had a poor record in organ donation, and the

numbers were falling from the start of this century. In 2008 the Organ Donation Taskforce report was published[6] with a series of recommendations that have all been implemented. They have transformed the donation system and overall donor numbers have increased by over 70% since then, and continue to do so — at least in England.[7] Key to this transformation has been tremendous work by intensive care clinicians and the specialist nurses who work with them, combined with central support from a national donation organisation, NHS Blood and Transplant. Fundamental to this has been the move to recognise donation as being in the best interests of an individual who had wished to be a donor rather than seeing potential organ donors simply as a source of organs for someone else — autonomy rather than utilitarianism, if you like. These results are spectacular but everyone concerned knows that there is much more that can and should be done — and they are working hard to do it.

These results speak for themselves and more of the same would seem to be an excellent policy. GPs and practice nurses can play a valuable role by including organ donation in any discussions about a patient's end-of-life wishes and by promoting the Organ Donor Register alongside other public health issues ('stop smoking, lose weight, and join the Organ Donor Register'). The need for more organs for transplantation is pressing, but there seems to be little merit in pursuing a change in the law that appears to revert to the utilitarian approach that is now discredited and is unproven, controversial, expensive, ethically questionable, and possibly risky.

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The Case for Mandatory Organ Donation

SCOTT CARNEY - 05.08.07

Curbing the illegal trade in human organs just might mean scrapping the way we think about the rights of brain-dead organ donors.
Organ brokers have already proven that they are savvy enough to skirt legal roadblocks, and their businesses will continue as the supply of available donor organs remains small and the profits high.

Increasing the supply of cadaver organs is an obvious solution, but volunteer programs have not produced enough organs to make a difference. Now some leading ethicists and doctors are re-examining the principle of informed consent in government organ-donor programs, arguing that harvesting from cadavers should be a routine procedure just like autopsies in murder investigations.

"Routine recovery would be much simpler and cheaper to implement than proposals designed to stimulate consent because there would be no need for donor registries, no need to train requestors, no need for stringent government regulation, no need to consider paying for organs, and no need for permanent public education campaigns," wrote Aaron Spital, a clinical professor at Mount Sinai School of Medicine, and James Stacey Taylor, an assistant professor of philosophy at the College of New Jersey, in a controversial article published this year by the American Society of Nephrology.

This approach faces obvious and enormous obstacles, challenging as it does widely and deeply held beliefs about the sanctity of the body, even in death. But it could be the only solution that works.

Roughly half a million people around the world suffer from kidney failure and many are willing to pay any price for a donor organ. They have two options: wait on impossibly long donation lists or pay someone for a live donor transplant.

The United Network for Organ Sharing, which runs the current system of cadaver donation in the United States, maintains lists of brain-dead patients around the country and actively tries to match up prospective donors. At present there are more than 90,000 people waiting for kidneys but only about 14,000 donors enter the system each year.

The shortage of donors isn't based on a shortage of brain-dead people in hospitals, but on the shortage of people whose organs – even after they have opted into a convoluted and difficult organ-donation program – never find their way to a viable patient. A 2005 Gallup poll revealed that more than half the population of the United States was willing to donate organs after death, but inefficiencies in the current system mean that even willing donors often end up not donating because families raise objections or there is a question about consent.

Fewer than two out of 10 families opt to donate organs of relatives after death. Hospitals often are unwilling to share organs from donors on their rolls and waste organs while waiting to set up their own in-house transplants. Often, perfectly good transplant organs get lost in a bureaucratic shuffle.

Routine organ donations would dramatically increase the supply of donor organs; with a little effort it would be possible to set up a system to transport donation-worthy organs anywhere in the world.

Once removed from a body, a kidney has a 72-hour window before it needs to be transplanted into a patient. If we use FedEx as our yardstick, with the right transportation infrastructure, that kidney can travel to any point on the globe in less than 24 hours – giving surgeons on either end of the transplant team two days to find a viable donor and perform the necessary surgery. And once regulations for transporting human organs cut though red tape, the cost of transportation would be less than a first-class plane ticket.

"Bold proposals like those posited by (Spital and Taylor) are necessary to fuel spirited debate and influence public policy. From an ethical view, much of what they have written can be supported and resonates well with some who contemplate such issues," wrote Ron Gimbel, assistant professor in the preventive medicine and biometrics department at the Uniformed Services University of the Health Sciences in Bethesda, Maryland, in an e-mail conversation with Wired News.

Setting up a mandatory system of organ donation would undoubtedly stir protests from around the country. Americans are used to the idea of having a choice over the state of our bodies after death and many people would be irked that the government would be meddling into some of the most sensitive and private moments of a family's life.

In fact, that concept is an illusion. In cases where the cause of death is ambiguous, the government routinely conducts autopsies where large pieces of the person's viscera are removed for scientific analysis – often later to be used in a criminal investigation.

In addition, as Spital and Taylor argue, the government reserves the right to draft young men against their will into war and risk their lives in combat operations.

Nancy Scheper-Hughes, a medical anthropologist at the University of California at Berkeley who has made her career writing about violence caused by poverty, stresses that the current system of organ donation breeds inequalities – but she is equally wary of a system that doesn't allow people to opt out of becoming organ donors after death.

"Why make everyone pay a body tax?" she asks. "We have 60 million people who are uninsured in this country; why should we force the people who we denied health care in their life to offer up their bodies after they die? The history of transplants has been replete with doctors who have put themselves above the law and (think) that they are ahead of the morality of the time and that society has to catch up with them," she said.

"This proposal doesn't seem to be any different," she added.

If mandatory donation is politically unfeasible now, the United States could consider an opt-out rather than the opt-in organ-donation policy, known as "presumed consent" and adopted in various guises in France, Spain, Australia, Belgium and Portugal. (At present, no country mandates that organs must be relinquished at death.)

These laws vary in their details but in general assume that someone would want to be an organ donor unless they explicitly make their objections known by registering in a national online database. Organ-donation rates in all of these countries outstrip the U.S. rates. Powerhouse transplant organizations in the Unites States like the American Kidney Fund have lobbied for this system since 2004, but have yet to make headway in national policy.

"Research shows that there would be a increase of between 16 percent to 50 percent in the availability of organs, and others have speculated that this would eliminate the shortage of organs in some categories," said Eric Johnson, professor of business at Columbia University and a proponent of presumed-consent policy.