The Effectiveness of an Opt-out Policy for Organ Donation

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INTRODUCTION

On the 15th March 2019, the Organ Donation Bill was granted royal assent, giving it formal confirmation as an Act of Parliament.[1] The Bill, also known as 'Max and Keira's law' In honour of the girl donating a heart and the boy receiving it, called for a change to the current approach to consent required from deceased organ donors.[1, 2] Currently England employs an 'opt-in system,' meaning one must express their wish to be an organ donor by joining the registry. As of spring 2020, England will operate a 'soft' opt-out system, meaning one has to register to opt-out, in order not to be considered an organ donor.[2] This approach is described as 'soft' because next of kin consent will remain an integral part of decision making.[3] The new system aims to increase organ donation rates and reduce the number of patients on the waiting list.[1]

The introduction of 'soft' opt-out legislation in England has been considered for many years. The UK Organ Donation Taskforce (UKODT) published a report in November 2008, unanimously voting against this approach.[4, 5] Although the committee described an opt-out approach as ethically sound, members remained sceptical about the effectiveness of this system in terms of increasing organ donation rates. The UKODT set out recommendations in their report "Organs for transplant," which were responsible for a greater than 50% increase in donation rates from 2008 to 2013.[6] These recommendations focussed on donor identification, coordination and retrieval of organs.[4, 6]

Despite this, there remains a pronounced difference between the number of donors and the number of patients requiring a transplant. Recent UK statistics revealed 6077 patients on the transplant waiting list.[7] Of those patients, 400 died while awaiting an organ.[7] The total number of deceased donors was 1600.[7] Overall, there has been a 7% increase in transplant waiting list numbers from the years 2001 to 2013.[8]

A recent survey revealed that 80% of adults in the UK would consider donating their organs, however the most recent NHS transplant activity report reported that only 38% of the population are registered organ donors.[7,9] This gap highlights a general public apathy towards organ donation. Theoretically, a soft opt-out system which makes donation the default position may combat this overall lack of motivation shown by society; hence the appeal of the opt-out approach has remained. Those in favour often cite the apparent success of this approach in a number of European countries. In 2014, the deceased organ donation rates were as follows; 26.9 per million in Belgium, 27.3 per million in Portugal, 35.1 per million in Croatia and 35.7 per million in Spain. These results are frequently compared to those from the UK; which had a deceased organ donation rate of 20.6 per million.[10] The first country to adopt a soft opt-out approach in the UK was Wales, following the Human Transplantation (Wales) Act in 2013 and as of December 2015 this system became a part of everyday clinical practice.[11]

Despite these promising statistics, this approach is met with criticisms. Firstly, for an opt-out approach to be effective, an assumption can be made that those not on the Organ Donation Registry cannot be used for organs. In the UK however, only 46% of the 1600 deceased organ donors in the 2018/2019 year were enlisted in the Organ Donation Registry.[7]

Furthermore, the change to a 'soft' opt-out approach does not remove the necessity of next of kin consent; therefore, the family still has the authority to override the decision made by the deceased. In consideration of this limitation of the scheme, one can question whether this policy change will actually have any effect at a daily clinical practice level.

Table 1: Next of kin consent rates reported in the NHS Blood and Transplant 2018/19 Activity Report.[7]

	Next of kin consent rate
Patient decision known/ODR status known	93.0%
Patient decision not known/ODR status not known	51.2%
When SN-OD involved	70.9%
When SN-OD not involved	29.8%

ODR: organ donation register; SN-OD: specialist nurse-organ donation.

Table 1 highlights next of kin consent rates in the 2018/19 activity report.[7] Consent rates remain low when a specialist organ donation nurse is not present when the family are approached and when the organ donation register status of the patient is not known; hence there is an argument that legislative change will not increase consent rates. Instead, further training is required for intensive care unit (ICU) staff with regards to approaching families and discussing end of life care. Indeed, the decision to not opt-out is less explicitly an obvious decision compared to the decision to opt-in; therefore, it can be more open to interpretation.

A further criticism of the soft opt-out approach is the use of the apparent success in other countries to argue for its introduction. Success of organ donation in Spain is often misguidedly described as being a direct result of the implementation of its 1979 policy change.[12, 13] In addition to this, despite statistics from Wales seeming to yield positive results, it is still too early to infer long term outcomes due to legislative changes.[14]

Ethically, there is the notion that a soft-opt out approach to consent goes against the principle of informed consent and that it undermines the 'altruistic' nature of organ donation.[15] With this in mind, some have argued that opt-out legislation will alienate the public; with this in turn leading to reduced donation rates.[15]

Studies on opt-out legislation have reported promising results in terms of its effectiveness at improving donor rates. Despite this, there remains doubt in terms of how much of this success can be attributed to legislative change. This is due to the fact that these changes tend to be accompanied by more generalised improvements in infrastructure surrounding organ donation. Additionally, studies on this topic are generally limited in their design and there is currently no prospective randomised controlled trial evidence.

This review aims to explore the effectiveness of a soft opt-out approach. Special attention has been paid to literature on organ donation in Spain and Wales. Spain was chosen because the country is currently the world leader in terms of organ donation rates and it implemented a soft opt-out policy to consent for organ donation in 1979. Wales was chosen as it is the most applicable to England. Wales provides a unique opportunity to assess the effect of an opt-out approach in a UK based population.[16]

DISCUSSION

To date there have been three literature reviews evaluating opt-out legislation.[17-19]

Research been limited to two types of studies.[20] 'Before and after' studies measure donation rates in one country pre- and post-legislation change. Cross country studies compare those with opt-in vs opt-out approaches to consent for deceased donors with the aim of investigating the effect of legislation on donation rates. Cross country studies are limited by the heterogeneity in confounding factors between countries. Therefore, the best available evidence is gained from before and after studies.[20]

Rithalia *et al.*[17] identified five 'before and after' studies, which provided results for three countries. Overall, the results from these studies are positive, indicating an increase in the number of donors per million of the population (pmp) following the implementation of opt-out legislation. The major limiting factor is that these five studies only reported results for three countries. No further 'before and after' studies were identified by the subsequent reviews from Palmer and Ahmad *et al.*[18, 19]

The cross country studies included in all three reviews report similar increases in deceased donor rates in opt-out countries compared to countries which operate an opt-in approach to consent for deceased organ donation.

Superficially at least, these results support the notion that opt-out legislation is associated with an increase in organ donation rates. However, there are other possible explanations. For instance, concurrent changes alongside legislation are likely to have played a role for the increased organ donation rates seen; furthermore, these confounding factors are difficult to measure and control.

Rithalia *et al.*[17] concluded that opt-out approaches alone "are unlikely to explaining the varying organ donation rates". The authors state that a "combination of legislation, availability of donors, transplantation system organisation and infrastructure, wealth and investment in healthcare, as well as underlying public attitudes" all play a role, "although the relative importance of each is not clear".

Table 2: Summary of the literature review evidence available.

	Rithalia *et al.*	**Palmer**	**Ahmad *et al.***
Year	2009	2012	2019
Literature search time period	Inception – 2008	Inception – 2012	2006 – 2016
Number of studies included	9	5	6
Types of study	4 CCS 5 BAS	CCS	CCS
Surveys	n/a	3	n/a
Results	CCS 2.7-6.14 donors per million increase associated with opt-out legislation (2 studies) 20-30% increase in DDR associated with opt-out legislation (2 studies) BAS Austria: from 4.6 to 27.2 donors pmp (5 year time period) Belgium 10.9-41.3 donors pmp (3 year period) Singapore 4.7-31.3 donors pmp (3 year period)	17 – 34 countries. 13-20% increase in DDR associated with opt out-legislation	22 – 48 countries 21-76% increase in DDR associated with opt-out legislation

CCS: cross country studies; BAS: Before and after studies; PMP; per million of the population; DDR: deceased donation rates.

Palmer produced an updated evidence review in 2012.[18] This review included two new cross country comparisons. As a part of this evidence review, Palmer included two surveys conducted in Wales, one commissioned by the Welsh government and one commissioned by British Broadcasting Corporation (BBC) Wales. These surveys identified that 49% and 63% of participants were in favour of an opt-out approach respectively. These findings must be interpreted with caution because the surveys were conducted before legislative change. It is not possible to hypothesise what the current public opinion is from the results of these surveys, although at the time the findings were encouraging. Overall, Palmer concluded an association between opt-out legislation and increased organ donation rates, with the caveat that "there can be no guarantees that legislative change will result in increased organ donation rates".

Ahmad *et al.*[19] identified six studies that fit the inclusion criteria of cross country comparison including the UK, the USA and Spain. These strict inclusion criteria are a major limiting factor of the overall results described in this review.

Although the research so far has shown positive findings, there is still great potential for further progress. A key aim of future studies should be to reduce the effect of confounding factors in order to isolate policy change as the variable affecting organ donor rates.

Spain

Spain introduced legislation in 1979 implementing the soft opt-out system of consent for organ donation, yet for the first ten years following this organ donation rates and familial refusal rates remained the same.[21] Improvements were seen from 1989, coinciding with major infrastructural changes.[13] Separate provincial organ donation programmes were united under the management of the Spanish National Transplant Organisation.[12] Certain unique characteristics of the Spanish system have also been attributed to its impressive organ donation rates; these include the introduction of transplant co-ordinators at each hospital, a high number of intensive care beds, regular organ transplant training courses that over 11,000 healthcare professionals have participated in and a positive relationship between the national transplant organisation, the public and the media.[12]

Attributing the apparent success of Spain to its 1979 opt-out legislation is a misconception observed in the literature.[16, 22] In 2010, an article in the British Medical Journal (BMJ) was published, co-authored by the director of the Spanish Organ donation organisation. This article provides a number of arguments emphasising the lack of importance of the 1979 legislation change on current organ donation practice in Spain.[12] Firstly, the change to an opt-out system is described as a "dormant law," with the authors making the point that Spain makes no effort to raise awareness of it. In addition, Spain does not even have an opt-out register available for its citizens to specify their wishes. A third point of note made by the authors is that in current Spanish clinical practice written consent of the family is needed.

Wales

With regards to the legislation change in Wales, it is hoped that citizens will either opt-out or opt-in on the organ donation register and to discuss this decision with family.[14] If nothing is done, it is assumed that the person consents to the retrieval of their organs.

Currently, there has been one published observational study assessing the effect of the policy change in Wales. Noyes *et al.*[14] collected routine data on all potential organ donors 18 months after the 1st December 2015 and three years prior to this date. The results reported 205 deceased donors in Wales, 18 months after the change in legislation. Of these donors, 182 had a known decision, meaning that they expressed a decision in their life, or had their consent deemed. The remaining 23 had to have familial consent as they either lacked capacity or were a child. There was a statistically significant rise in the overall consent rate from 45.8% in 2014/15 to 61%. In this same time period the authors identified that the consent rate in the rest of the UK had also risen in a statistically significant manner. It is therefore not possible to conclude that legislative changes in wales resulted in the increased rates seen.

Familial overrides occurred in 16.4% (12/73) of opt-in decisions and in 39.1% (18/46) of deemed consents.[14] The authors have speculated that this increase in familial overrides could be explained by the option of deemed consent made possible by the soft opt-out legislation. This provided families with an opportunity to reject something that was only recently made available. This data only provides short term results with a small overall sample and longer term information is required in order to gain a fuller understanding of the situation. Qualitative studies exploring the decision making processes by families is necessary to understand the effect of legislation on the next of kin. Overall the authors concluded that the "introduction of the soft opt-out reversed a decline and subsequently improved consent rates for deceased donation in Wales; in addition "family member overrides" were a primary issue that prevented successful donation.[14]

CONCLUSION

The main goal of this paper was to evaluate the effectiveness of opt-out legislation. The major concerns associated with a switch to an opt-out policy are that it may not affect practice at a daily clinical level and it may go as far as decreasing consent rates. The best available evidence has provided promising findings, indicating an association between opt-out policy and increased donor rates. The generalisability of results is subject to the major limitation that confounding factors exist and most likely play a role in improved organ donation programmes internationally. With this in mind, it is difficult to quantify the actual effect of legislative change on organ donation.

The secondary goal of this paper was to investigate the effect of the opt-out policy on organ donation in Spain and Wales. There is still a lack of long term data on organ donation in Wales, but short term findings have indicated an overall increase in consent rates. It is difficult to hypothesise as to why there was an increase in family refusal rates seen. With such a small sample size, statistical analysis was precluded. Long term collection of data will provide more information on this trend.

Spain holds the esteemed position as the world's leader in organ donation and because of this an understanding of the country's current organ donation practices is required. Taken together, the literature on the Spanish organ donation system provides strong evidence for infrastructural changes as an important cause of the improved rates seen. The implication is that legislative change is not an independent method of improving organ donation. Legislative change should be accompanied by non-legislative change including re-organising systems in hospital, education and public awareness campaigns.

This article has consolidated previous information from past research. It is recommended that further research is undertaken in the following ways: prospective study designs; accounting for confounding variables, with qualitative research to supplement the evidence gained from quantitative study methods.

Conflict of Interest

The author states that there is no conflict of interest related to this article.

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