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Deemed consent: Assessing the new opt-out approach to organ procurement in Wales

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Deemed consent: Assessing the new opt-out approach to organ procurement in Wales

In December 2015, Wales became the first country in the United Kingdom to move away from an opt-in system in organ procurement. The new legislation introduces the concept of deemed consent whereby a person who neither opt in nor opt out, is deemed to have consented to donation. The data released by the NHS in July 2017 provides an excellent opportunity to assess this legislation in light of concerns that it would decrease procurement rates for living and deceased donation, as well as sparking an increase in family refusals. None of these concerns have come to pass, with Wales experiencing more registered donors, fewer family refusals and more living donations. Though, as the number of actual donors have dropped slightly from a high level, the situation must be monitored closely in the years to come.

Keywords: Donation/Procurement of Organs/Tissues; Family; Ethics; Informed Consent; Living Wills/Advance Directives

Introduction

When the Welsh Assembly passed the Human Transplantation (Wales) Act in July 2013, [1] Wales became the first part of the United Kingdom to abandon the opt-in model in organ procurement. Broadly speaking, an opt-in procurement system considers as organ donors only those who have registered or declared their wish to donate.[2] In contrast, opt-out procurement systems consider people as donors if they do not register an objection. In a similar vein, the Welsh legislation introduces the concept of deemed consent, where competent adults who have neither registered their consent, nor their objection to donation, are deemed to have no objection to donation.[1] This legislative change puts Wales in the company of several European countries with similar systems. Both Scotland and Ireland are currently considering similar policies.[3,4] The Welsh legislation came into effect in December 2015, and improvements in procurement rates have been widely reported in media outlets.[5–7] In light of the NHS Activity Report released in July 2017,[8] this article provides a systematic assessment of its effects. Where appropriate, the findings of the official evaluation of the Welsh law, published November 2017, is included.[9] The assessment is conducted in three steps. First, the new Welsh procurement practice is described in detail. The presentation draws on legislative texts, official descriptions and the official *Code of Practice* issued for Specialist Nurses for Organ Donation, and others working with transplantation in Wales. Second, important concerns raised in the context of the Welsh legislation are presented. These highlight concerns that the new Welsh legislation would result in fewer living and deceased donors, and that it

would spark an increase in family refusals. Third, the effects of the Welsh legislation is assessed employing newly released data from the NHS Organ Donation and Transplantation Activity Report.[8] The comparative logic employed is to compare how key indicators develop in Wales before and after the change of legislation, and then compare this finding to the development in the United Kingdom as a whole. This is done by comparing key parameters from the 2016/17 Activity report with that from 2014/15. In doing so, the parameters from the last activity report under the previous legislation is compared with the first report covering a whole financial year under the new legislation.ⁱ The comparative logic beyond this is a difference in differences design, where the effect in Wales is measured against the change in the parts of the United Kingdom that did not change the organ procurement system.ⁱⁱ With this approach, we expect to be able to gain valuable knowledge regarding the effect of deemed consent in Wales. This knowledge can then be added to our broader knowledge regarding the effect of opt-out systems. Such knowledge comes both from experimental surveys and comparisons between countries and they tend to show that opt-out systems yield higher donation rates.[10–13]ⁱⁱⁱ In the end of the final section, the limits of the findings are discussed.

The Human Transplantation (Wales) Act 2013

In relation to donation of solid organs for transplantation, the Human Transplantation (Wales) Act 2013 has three different categories. The first two are familiar categories in organ procurement: Those who have registered that they consent to donation, and those

ⁱ The 2015/2016 report is not included in this comparison because it covers eight months under the previous legislation and only four under the new.

ⁱⁱ When comparing Wales with the United Kingdom as a whole, the comparison introduces a slight systematic underestimation of the difference because Wales is part of the United Kingdom and automatically pulls the average slightly towards Wales. The available data does not allow for a different comparison, and as the Welsh population constitutes only 5% of the UK inhabitants, the effect is not large enough to really be a problem.

ⁱⁱⁱ A Welsh review of the available literature found that ‘opt-out systems for organ donation are associated with increased organ donation rates and increased reported willingness to donate’.[14]

who have registered that they do not. The novel addition is the third category, where some are *deemed to have consented*. This means that a person at the age of 18 or above, who while alive, had the capacity to understand the concept of consent, who have lived in Wales for 12 months, and who have not registered any opinion regarding organ donation, is deemed to have consented unless a) the person has appointed someone to deal with the issue of consent, or b) a relative or long-standing friend provides credible evidence that the deceased did not wish to donate.[1]

While the introduction of deemed consent differs from the legislation in the rest of the United Kingdom, we can only understand this difference by examining the role of the family.^{iv} This pertains to the weight given to family objections when the deceased is a registered donor, and to the role of the family in situations where the deceased has not registered an opinion regarding donation. Across these situations, the family consent rate in the United Kingdom is currently 62,7% [8], and this falls short of the official target of reaching 80% in 2020.[15] The question of family refusals is often emphasized by the NHS.[16,17] Furthermore, it is a key component in the NHS strategy document from 2013, *Taking Organ Transplantation to 2020*.^v[15]

Let us first look at the group of potential donors who have consented to donation. In Wales, as well as in the rest of the United Kingdom, it is lawful to remove organs from registered donors despite family objections.[1,29] The NHS states that in cases of a registered donor where the family objects, specialists will discuss the matter with the family, encourage them to accept the decision and clarify that the family does not have a legal right to override the decision.[30,31] However, family objections will often result in

^{iv} While there are differences between for example England and Scotland, these differences are quite small.

^v The ethics of this practice, often referred to as a family veto, has also been the subject of considerable discussion.[18–26,2,27,28]

the organs not being removed. The national guideline for SN-OD, specialist nurses in relation to organ donations, states that "[a]lthough the relatives have no legal right to veto the patient's decision, cases need to be considered sensitively"[32] and furthermore submits that in both Wales and the rest of the United Kingdom, it is "not unlawful not to proceed".[32] Thus, for those who consent to donation, the rights of the family and the actual practices are quite similar in Wales and the rest of the United Kingdom. Family refusals are lawful, and firm family objections may result in the organs not being removed for transplantation.[16,33] If the family does not object, organ removal for transplantation will proceed.

The most prominent difference between Wales and the rest of the United Kingdom is the introduction of deemed consent. How are the role and rights of the family in deemed consent cases compared to cases in the rest of the United Kingdom where people have not registered their wishes regarding donation? In such cases, the practice in the rest of the United Kingdom is such that the family will be asked what they think the deceased would have wanted in terms of donation.[30,34] The practice in Wales regarding deemed consent is different. Those who are deemed to have consented under the already listed criteria do in effect have the same status as those who have registered their consent in terms of what role is assigned to the family. The status can, at least in principle, only be revoked if someone produces credible evidence that the deceased did in fact oppose consent.[1,35] The official FAQ produced by NHS Wales notes that families are needed to supply medical background information, and that the family and close friends "can also inform medical staff if the deceased objected to organ donation but had not registered an opt-out decision. If this happens then donation will not go ahead. However this objection would have to be based on the views of the deceased."[36] Consequently, the official policy

is that only evidence based objections that are based on the views of the deceased will suffice. In practice however, this does not mean that family refusals cannot happen in other situations. The official guideline, which is developed specifically for SN-OD working in Wales, states that there is "no requirement that organ donation goes ahead when consent can be deemed, but rather it would be lawful for such organ donation to take place".[35] Thus, in line with the practices for registered donors, also in cases when consent is deemed, donation will not proceed if the family firmly objects.[37] Official statistics suggest that such overruling by the family happens.[8]

For those who register as donors and their family there is no real difference between the system employed in Wales and the system which is in force in the rest of the United Kingdom. The same holds, as a matter of fact, for those who register that they do not wish to donate. Formally, the real difference pertains to those who do not declare or register anything regarding donation. In Wales their consent is deemed, while in the rest of the United Kingdom, their families are consulted. However, given that we know family objections are allowed to overrule deemed consent, the difference between the two systems decreases. Two important differences remain though. First, the legal status of those who do not make a decision regarding donation is different in Wales, and second, the official standard of evidence required to change that status is higher in Wales. While official guidelines and statistics provide us with reasons to believe that firm family objections are allowed to block the removal of organs in cases where consent would otherwise have been deemed in Wales, the different starting point of the conversation in terms of the legal status of the body and the level of evidence required, may very well make a real difference.

Concerns regarding deemed consent

Although a large majority of the Welsh Assembly passed the new legislation on organ

procurement,[1] it was a controversial decision.[38] This section presents prominent concerns regarding deemed consent. These will then later be employed in assessing the new legislation. As the overarching purpose of the new legislation is to increase the number of organs available for transplants, it is unsurprising that quite a few of the concerns question the expected benefits of the legislation. The first concern is *fewer living donors*. [39,40] While it is not particularly clear how this decrease in living donations would be brought about, the thought could be that higher donation rates for deceased donors removes a sense of urgency and thus diminishes the number of people feeling that they should make a living donation.^{vi} As kidneys from living donors provide better results for their recipients this would be bad. In what follows, living donors refer to every form of living donation registered. This means that the numbers reported are the sum of direct donation to friends and family, non-directed (altruistic) donations to those on the waiting list, paired/pooled exchanges and altruistic donor chains.[7]^{vii} The second concern is *fewer deceased donors through opt-out*. The thought is that a controversial change in the procurement system may spark a public reaction, leading people to opt-out in great numbers. The experiences from Chile[44] and Brazil[39] are sometimes provided as examples of negative reactions to the introduction of opt-out legislation. The third concern is *fewer deceased donors through family refusals*. Here the concern is similar to the previous one; a rise in family refusal rates is the main driver behind the fall in available organs. The concerns that introducing deemed consent will result in fewer living and/or fewer deceased donors through various mechanisms are of an empirical nature. While

^{vi} It is sometimes suggested that new sources of donors may replace rather than supplement other sources. In a different context, a fall in living donors was observed in Hongkong when it became possible to travel to China to buy organs. [41] In Iran, payment for donated kidneys has reduced the share of related donors, and people prefer not to ask their family members to donate.[42,43]

^{vii} Paired/pooled exchanges refers to situations where the relative of person A donates to person B in exchange for the relative of person A donating to person B. Altruistic donor chains describe longer chains of exchanges.

there were also concerns related to whether deemed consent shows proper respect for donor autonomy [38,40], these discussions are bracketed in order to properly discuss the concerns related to the number of registered donors, of organs procured, and of family refusals.

An empirical assessment of deemed consent

This section employs newly released data to assess the effects of the changed Welsh legislation. While there has been frequent media reports on the success of the new legislation[5–7], others have suggested that these reports presented premature conclusions given the sparse available data at the time.[45] With the publication of the NHS Organ Donation and Transplantation Activity Report of 2016/2017 in July 2017, the legislation can be assessed on firmer ground. To assess the critiques presented in the previous section, the following parameters are selected: Donor registration, donation rates for living and deceased donors and finally, family refusal rates. The development of key indicators are compared from the 2014/1015 to the 2016/2017 Activity Report. Here the numbers from Wales are contrasted to those from the United Kingdom as a whole. Donor numbers rather than number of organs transplanted are reported because the number of transplants also varies with utilization rates. Following the standard in the literature, numbers are reported in per million people (pmp) to control for variation in population size. Where applicable the findings in the official evaluation are also noted. This report includes 7 quartiles of data, but does not consider every measure considered here. .

Let us consider the developments in living donation. Across the United Kingdom, kidneys are the most frequently donated organ through living donation while the rest are liver lobes.[8,46] The majority of living donations are directed to a family member

or friend.[8] For all kinds of living donation, the living donor rate increased in Wales from 13,3 to 14,8 pmp, while it dropped from 17,0 to 16,0 pmp across the United Kingdom.[8,46] Thus, as Wales improved against the background of a drop in the United Kingdom, the concern about a fall in living donors have so far proven unfounded.

Regarding deceased donors there are two measures to consider. The first is the extent to which the new legislation affected the activity in the donor register, while the second considers changes in actual donation rates. Regarding registered donors, the number of registered organ donors rose from 339,759 to 377,839 pmp in Wales, while in the United Kingdom as a whole the increase was from 327,853 to 361,784 pmp.[8,46]^{viii} With an increase of 38,08 pmp in Wales, compared to the increase of 33,93 in the United Kingdom as a whole, the registration rate in Wales rose more than it did across the United Kingdom, and it rose from a higher starting point. However people did opt-out in Wales. As of April 2017, 5,6% has opted out.[8] Measured in pmp, this corresponds to a 2017 rate of 56,389 pmp in Wales. This number is so high that it actually affects the United Kingdom number. The absolute numbers are 174,806 opt-outs in Wales, and 29,709 in the rest of the United Kingdom.[8] Thus, regarding registered donors, people in Wales registered their willingness to donate at a higher rate than in the United Kingdom as a whole. However, people also chose to opt-out at a higher rate, and the increase in opt-outs (in Wales) are larger than the increase in people who opted in. This however cannot be interpreted in support of the concern that the introduction of deemed consent would lead to a fall in donors. The fact that more people register that they wish to opt-out is to be expected because this communication of position matters more under an opt-out system

^{viii} Note that two nominally different categories are compared. The 2014/2015 numbers are all-registered, while the 2015/2016 are all who registered opt-in. This is necessary as only the new report differentiates between opt-in/opt out registrations. However, given that very few registered to opt-out earlier, doing so is unproblematic.

than under an opt-in one. What should be noted however is that by 2017 37,7% of the adult population are registered donors, 5,6% have opted out and the remaining majority remains in a position where their consent will (most likely) be deemed. Therefore, the numbers from the organ donor register do not support the concern of reduced overall donation rates through opt-out or decreased opt-in systems.

When we consider the number of donors, the picture becomes more complicated. Let us take a look at the actual donor rates for deceased donors. Here Wales dropped from 23,1 to 21,9 pmp, while across the United Kingdom the rate increased from 19,9 pmp to 21,6 pmp.[8,46] These numbers are best understood against the development of the number of eligible donors; i.e. donors who could medically speaking become donors. Observing the development in actual donors alongside the development in eligible donors, gives us an idea as to whether the development in the former is caused by fluctuations in the number of people who are suitable donors from a medical point of view. The eligible donor rate in Wales dropped from 106,8 to 98,4 pmp.[8,46] In the United Kingdom as a whole, it fell from 87,6 to 86,9 pmp.[8,46] Despite Wales experiencing a very large fall on 8,4 pmp in the number of eligible donors, the actual donation rate drops only by 1,2 pmp. In the United Kingdom as a whole, the eligible donation rate drops only slightly by 0,7 pmp, and this transforms into an increase of 1,7 pmp in the actual donation rate. Given that the Welsh numbers remain above those of the United Kingdom as a whole and the ration of actual donors to eligible donors increased in Wales, at least the concern of a large drop in donation rates can be rejected. However, the expected increase cannot be identified in the numbers and this must be followed closely in the years to come. Over various measures, this is also the finding in the official evaluation.[9] This also includes a comparison between Wales and data from North East England.[9]

Let us consider next the rate of family refusals. Two important measures must be assessed: The overall family refusal rate, and the family refusal rate for those who have not declared anything. These distinctions are important because of the already highlighted differences in the legal framework, and because it is known that families are more likely to agree to donation when a patient's decision is known to them.[17]

How does the introduction of deemed consent affect the share of family refusals in cases where the deceased had not made a decision regarding donation? As already explained, the consent of eligible donors are deemed in Wales, if their wishes are not known. According to the 2016/2017 Activity report, Wales has a family consent rate in these cases of 60,6%,[8] whereas the level in the rest of the United Kingdom is 46,7%.[8] While there are unfortunately no country-specific numbers for this indicator in the earlier reports, the difference indicates that the changed Welsh legislation matters. While the number of cases with deemed consent are only 33, the 13 cases of deemed consent in the 2015-2016 financial year were encouragingly at a similar rate.[47] Thus, it seems that the changed status of those who have not declared their wishes regarding donation affects the family refusal rate in a positive way.

The activity report includes a further indicator of interest. It is a summary measure which includes all potential donors and the extent to which their family will consent to donation.^{ix} For Wales this is calculated for by "including all expressed decisions, deemed consent and family consent." [47] From 2014/2015 to 2016-2017, the family consent rate in Wales increased from 48.5% to 64,0%.[8,46] This is a much larger increase than in the United Kingdom as a whole with a rise people from 57,8 to 62,7 [46,47]. The official evaluation finds a similar trend in assessing this parameter. In combination, these

^{ix} The official name is the "consent/authorisation rate" as the latter term is used in Scotland.

numbers seem sufficient to reject the idea that the introduction of the deemed consent category would spark a large increase in family refusals. In fact, the opposite effect can be detected. The reported findings are summarized in table 1.

Table 1. Key Indicators

	Wales 14/15	Wales 16/17	Wales: 14/15-16/17	UK 14/15	UK 16/17	UK 14/15- 16/17	Wales – UK
Living donors (pmp)	13,3	14,8	1,5	17	16	-1	2,5
Registered donors (pmp)	339,759	377,839	38,08	327,853	361,784	33,931	4,149
Opt-out registrations (pmp)	0	56389	56389	0	3130	3130	53259
Eligible donors (pmp)	106,8	98,4	-8,4	87,6	86,9	-0,7	-7,7
Actual donors (pmp)	23,1	21,9	-1,2	19,9	21,6	1,7	-2,9
Overall Consent rate (%)	48,5	64	15,5	57,8	62,7	4,9	10,6

In assessing the findings above, it is important to acknowledge the limitations of the conducted study. The most important limitation pertains to the relative short time which has passed since the new Welsh legislation came into effect. While we have reasons to expect some behavioral changes in the wake of a new legislation (and assess these), the above can only be an assessment of the initial effects of the legislation, not a final assessment. We should therefore assess key indicators in the years to come. Two other

limitations should be acknowledged. One is that the above relies on quantitative data. While these shed some light over the effects of the new legislation, they cannot provide a complete picture. Moving forward, qualitative studies should supplement these findings to increase our knowledge regarding important aspects, such as the content of remaining family objections. The official evaluation interestingly reports on qualitative data from the general public, which included participant's suggestions for how to encourage people to discuss organ donation with their family.[9] A final limitation pertains to the numerous factors which affect people's donation decisions and the overall number of transplants. As clarified in the assessment, the number of eligible donors vary from year to year, but other factors than legislation must also be considered. It is very plausible that proposing and passing a law which significantly changes the organ procurement system instigates a lot of attention. Thus, medical professionals working within the transplant sector and the general public are likely to pay extra attention to organ transplantation in ways which may affect procurement rates and donation decisions. The Human Transplantation (Wales) Act 2013 was accompanied by extra training and awareness programs for medical professionals and by public awareness campaigns[48–50]. With this in mind, the observed changes should not be attributed only to the change from opt-in to opt-out. It follows also from some of the initiatives which accompanied it, and some of the debates which it led to. The public awareness campaigns that were launched up until the change came into effect were quite successful.[9] To illustrate this, it should be highlighted that the share who declared that they would opt-out if opt-out policies were introduced were much higher in 2012, than the number of people who have actually opted opt.[51] In surveys, a growing share of the population indicated that they were aware of a proposed change topping around 80%, and of these 90% correctly identified the nature of the change as one of opt-out/presumed consent.[52] These numbers indicate a high level of awareness. In fact, in

the baseline survey from 2012, a quarter of the respondents replied that they did not know when asked to describe the then existing organ procurement system.[51] As there has recently been a drop, it is clear that there is a need for a continues effort.[9] This is also underscored by the finding in the official evaluation that the role of the family is difficult to get across to both the general public and NHS Staff.

We cannot clearly disaggregate the effects from campaigns and the effects from legislation. Partly because it is likely that campaigns would not have been as effective, had they not accompanied a proposed change in legislation. This is important to mention, however, because the above successes in terms of donor registration and improvements in family consent rates should not be understood as something which is automatically achieved by a legislative change.

Despite these limitations, the above study provides us with an important early assessment of organ donation in Wales in light of concerns raised when it was passed. The predictions pertaining to people opting out, not registering, and the change sparking an increase in family refusals were unfounded. On these parameters Wales outperforms the rest of the United Kingdom. However, as actual donation numbers have not increased further investigation into the reasons for this result is required. While the small drop in actual donors is unlikely to be related to the new legislation, it must be monitored closely in the years to come.

Conclusion

The key difference between the Human Transplantation (Wales) Act 2013 and the organ procurement policies in the rest of the United Kingdom is the category of deemed consent. While families can and do override both expressed and deemed consent, the new legislation changes the starting point of this difficult conversation. The data in the NHS

Organ Donation and Transplantation Activity Report of 2016/2017 provide an excellent opportunity to assess this legislation in light of proposed concerns that the new legislation would decrease procurement rates for both living and deceased donation as well as spark an increase in family refusals. None of these concerns have materialized as Wales experiences more registered donors, fewer family refusals and more living donations. However, as the total number of actual donors has dropped slightly from a high level, the situation must be monitored closely.

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